Annual Review
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Supplementary Materials

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[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 16-13004

D.C. Docket No. 2:12-cv-00245-KOB

UNITED STATES OF AMERICA,

Plaintiff - Appellant,

versus

ASERACARE, INC.,
GGNSC ADMINISTRATIVE SERVICES,
d.b.a. Golden Living,
f.k.a. Beverly Enterprises, Inc.,
HOSPICE PREFERRED CHOICE, INC.,
HOSPICE OF EASTERN CAROLINA, INC.,

Defendants - Appellees.

Appeal from the United States District Court
for the Northern District of Alabama

(September 9, 2019)

Before ROSENBAUM and JULIE CARNES, Circuit Judges, and SCHLESINGER,* District Judge.

JULIE CARNES, Circuit Judge:

This case requires us to consider the circumstances under which a claim for hospice treatment under Medicare may be deemed "false" for purposes of the federal False Claims Act. Defendants comprise a network of hospice facilities that routinely bill Medicare for end-of-life care provided to elderly patients. In the underlying civil suit, the Government alleged that Defendants had certified patients as eligible for Medicare's hospice benefit, and billed Medicare accordingly, on the basis of erroneous clinical judgments that those patients were terminally ill. Based on the opinion of its expert witness, the Government contends that the patients at issue were not, in fact, terminally ill at the time of certification, meaning that AseraCare's claims to the contrary were false under the False Claims Act.

* The Honorable Harvey E. Schlesinger, United States District Judge for the Middle District of Florida, sitting by designation.

As the case proceeded through discovery and a partial trial on the merits, the district court confronted the following question: Can a medical provider's clinical judgment that a patient is terminally ill be deemed false based merely on the existence of a reasonable difference of opinion between experts as to the accuracy of that prognosis? The district court ultimately answered this question in the negative and therefore granted summary judgment to AseraCare on the issue of falsity.

Upon careful review of the record and the relevant law, and with the benefit of oral argument, we concur with the district court's ultimate determination that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment. We do, however, think that the Government should have been allowed to rely on the entire record, not just the trial record, in making its case that disputed issues of fact, beyond just the difference of opinion between experts, existed sufficient to warrant denial of the district court's post-verdict *sua sponte* reconsideration of summary judgment on the falsity question. We therefore affirm in part and remand in part.

I. BACKGROUND[1]

Each year, more than a million Americans make the difficult decision to forgo curative care and turn instead to end-of-life hospice care, which is designed to relieve the pain and symptoms associated with terminal illness. *See* 79 Fed. Reg. 50452, 50454–55 (Aug. 22, 2014). The federal government's Medicare program makes such care affordable for a significant number of terminally ill individuals. Defendants, collectively referred to as AseraCare, operate approximately sixty hospice facilities across nineteen states and admit around 10,000 patients each year. Most of AseraCare's patients are enrolled in Medicare. In fact, from 2007 to 2012, Medicare payments composed approximately ninety-five percent of AseraCare's revenues. As such, AseraCare routinely prepares and submits claims for reimbursement under Medicare.

This case began when three former AseraCare employees alleged that AseraCare had a practice of knowingly submitting unsubstantiated Medicare claims in violation of the federal False Claims Act. We begin by setting out the requirements hospice providers like AseraCare must meet in order to be entitled to

[1] We derive the pertinent facts from the parties' submissions, the summary judgment record, and the trial testimony presented in the proceeding below.

hospice reimbursement and identifying the tools the Government uses to police compliance with these requirements.

A. The Medicare Hospice Benefit

In order for a hospice claim to be eligible for Medicare reimbursement, the patient's attending physician, if there is one, and the medical director of the hospice provider must "each certify in writing at the beginning of [each] period, that the individual is terminally ill . . . based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." 42 U.S.C. § 1395f(7)(A). "Terminally ill" means that the individual "has a medical prognosis that the individual's life expectancy is 6 months or less." 42 U.S.C. § 1395x(dd)(3)(A). Under the statute's implementing regulations, a claim for hospice reimbursement must conform to several requirements in order to be payable. Most notably for purposes of this appeal, the certification must be accompanied by "[c]linical information and other documentation that support the medical prognosis," and such support "must be filed in the medical record with the written certification." 42 C.F.R. § 418.22(b)(2).

An initial certification conforming to these requirements is valid for a period of ninety days. 42 U.S.C. § 1395f(7)(A). The patient must be recertified in a similar manner for each additional sixty- or ninety-day period during which he or she remains in hospice. *Id.* While a life-expectancy prognosis of six months or

less is a necessary condition for reimbursement, regulators recognize that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. 70372, 70488 (Nov. 17, 2010). Accordingly, the Medicare framework does not preclude reimbursement for periods of hospice care that extend beyond six months, as long as the patient's eligibility is continually recertified. This framework also recognizes that, in some cases, patients with an initial prognosis of terminality can improve over time, and it allows such patients to exit hospice without losing their right to Medicare coverage to treat illness. *Id*. Thus, there is no statutory limit to the number of periods for which a patient may be properly certified. 42 U.S.C. § 1395d(d)(1) (establishing that hospice providers may collect reimbursement for an unlimited number of recertification periods).

The Medicare program is overseen by the Centers for Medicare and Medicaid Services ("CMS"), a division of the Department of Health and Human Services. CMS operates locally through so-called Medicare Administrative Contractors ("MACs"), which process claims from healthcare providers and make payment for eligible services. A majority of AseraCare's Medicare claims are processed by a MAC called Palmetto GBA ("Palmetto"), which operates in the southeast United States.

In preparing its claims for hospice reimbursement, AseraCare employs interdisciplinary teams of skilled staff—including physicians, nurses,

psychologists, social workers, and chaplains—that render services directly to patients and collectively make eligibility determinations. To guide this review, AseraCare professionals rely in part on documents called Local Coverage Determinations ("LCDs"), which are issued by Palmetto's medical directors. LCDs provide detailed lists of diagnostic guidance and clinical information that, if documented in a patient's medical record, suggest that the patient has a life expectancy of six months or less. LCDs are not clinical benchmarks or mandatory requirements for hospice eligibility, however. Rather, they are designed to help clinical staff understand the type of information that should be considered prior to concluding that a patient is terminally ill. The LCDs themselves explicitly state that they are non-binding.

Once AseraCare physicians reach a clinical judgment that a patient is eligible for hospice care, AseraCare may begin providing treatment. It submits claims to Palmetto for reimbursement only after care has been rendered. The trial testimony of Mary Jane Schultz, a registered nurse and former director of Palmetto's medical review team, clarified at trial the process by which Palmetto reviewed and paid claims for hospice coverage during the relevant time period of 2007 to 2012. As Ms. Schultz described, the first round of claim review was conducted by an automated claim-processing system designed to ensure that no critical information, such as a patient's Medicare identification number, was

missing or invalid. If no critical information was missing, the system would then check for any "red flags" that might require further review of the claim—such as the involvement of a particular provider, patient, or type of care that Palmetto staff believed may pose heightened eligibility risks. For instance, if Palmetto wished to conduct a targeted audit of claims submitted by a particular provider, it could program the automated system to pull all or a portion of those claims for additional review before payment.

If automated review uncovered no missing information or red flags, the system would process the claim directly for payment. As a result, Palmetto paid many claims without directly reviewing the medical documentation underpinning them. Where, on the other hand, a claim was flagged for heightened medical review, Palmetto would immediately issue a request to the provider for medical documentation substantiating the patient's terminal prognosis, such as notes from physicians, nurses, and social workers and records of medications and treatments prescribed. A trained medical review team would then review the supporting documentation before determining whether the claim should be paid in full, paid in part, or denied. Like AseraCare's medical staff, the medical review team commonly uses the LCDs as guidelines in its assessment, but it is not required to rigidly apply their criteria. Instead, the review team also looks at the "whole picture" of information submitted with the claim.

B. The False Claims Act

The False Claims Act ("FCA") serves as a mechanism by which the Government may police noncompliance with Medicare reimbursement standards after payment has been made. The Act imposes civil liability—including treble damages—on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). To prevail on an FCA claim, the plaintiff must prove that the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the Government to make a payment. *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015).

Private citizens, called *qui tam* relators, are authorized to bring FCA suits on behalf of the United States. 31 U.S.C. § 3730(b). The United States can, and frequently does, intervene in *qui tam* suits to develop the civil case itself. Thus, to the extent the Government concludes that it has reimbursed a hospice provider that knowingly submitted deficient claims, the Government can use the FCA cause of action to recoup payments and to penalize the provider.

II. PROCEDURAL HISTORY

A. Suit Against AseraCare Under the FCA

The underlying case began in 2008, when three former AseraCare employees, acting as *qui tam* relators, filed a complaint against AseraCare alleging submission of unsubstantiated hospice claims. Following a transfer of venue from the Eastern District of Wisconsin to the Northern District of Alabama, the Government intervened and filed the operative complaint. In its complaint, the Government alleged that AseraCare knowingly employed reckless business practices that enabled it to admit, and receive reimbursement for, patients who were not eligible for the Medicare hospice benefit "because it was financially lucrative," thus "misspending" millions of Medicare dollars. The Government's complaint described a corporate climate that pressured sales and clinical staff to meet aggressive monthly quotas for patient intake and, in so doing, discouraged meaningful physician involvement in eligibility determinations. More specifically, the Government alleged that AseraCare "submitted documentation that falsely represented that certain Medicare recipients were 'terminally ill'" when, in the Government's view, they were not.

In light of these allegations, the Government's case falls under the "false certification" theory of FCA liability. Under this theory, FCA liability may arise where a defendant falsely asserts or implies that it has complied with a statutory or regulatory requirement when, in actuality, it has not so complied. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016).

In developing its case, the Government began by identifying a universe of approximately 2,180 patients for whom AseraCare had billed Medicare for at least 365 continuous days of hospice care. The Government then focused its attention on a sample of 223 patients from within that universe. Through direct review of these patients' medical records and clinical histories, the Government's primary expert witness, Dr. Solomon Liao, identified 123 patients from the sample pool who were, in Dr. Liao's view, ineligible for the hospice benefit at the time AseraCare received reimbursement for their care. Should it prevail as to this group, the Government intended to extrapolate from the sample to impose further liability on AseraCare for a statistically valid set of additional claims within the broader universe of hospice patients for whom AseraCare received Medicare payments.

To supplement the testimony of Dr. Liao, the Government also sought to develop evidence that AseraCare's broader business practices fostered and promoted improper certification procedures while deemphasizing clinical training on terminal-illness prognostication. Several former AseraCare employees, including the *qui tam* relators, supported the Government's narrative by describing a process in which physicians merely rubber-stamped terminal-illness certifications without thoroughly examining the relevant medical records underlying them.

Importantly, though, the Government's false-claims allegations in this case

were narrowly circumscribed. There were no allegations that AseraCare billed for phantom patients, that certifications or medical documentation were forged, or that AseraCare employees lied to certifying physicians or withheld critical information regarding patient conditions. Indeed, there was no doubt in the proceeding below that AseraCare possessed accurate and comprehensive documentation of each patient's medical condition and that its certifications of terminal illness were signed by the appropriate medical personnel. Rather, the Government asserted that its expert testimony—contextualized by broad evidence of AseraCare's improper business practices—would demonstrate that the patients in the sample pool were not, as a medical fact, terminally ill at the time AseraCare collected reimbursement for their hospice care. The sole question related to the sufficiency of the clinical judgments on which the claims were based.

On this theory, the Government sought to recover damages under two subsections of the FCA, 31 U.S.C. § 3729(a)(1)(A)[2] and 31 U.S.C. § 3729(a)(1)(B),[3] and on claims of common-law unjust enrichment and mistaken

[2] "[A]ny person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government . . . ." 31 U.S.C. § 3729(a)(1)(A).

[3] "[A]ny person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government . . . ." 31 U.S.C. § 3729(a)(1)(B).

payment.

B. First Motion for Summary Judgment

Following extensive discovery and expert analysis of relevant patient records, AseraCare moved for summary judgment on the ground that the Government failed to adduce evidence of the falsity of any disputed claims and failed to show that AseraCare had any knowledge of the alleged falsity. Most notably for purposes of this appeal, AseraCare put squarely before the district court the question whether the Government's medical-opinion evidence was sufficient to establish the threshold element of falsity. To that point, AseraCare urged the district court to embrace a "reasonable doctor" standard for the assessment of falsity, which would state that, to avoid summary judgment in an action involving false claims for hospice reimbursement, the Government must show that a reasonable physician applying his or her clinical judgment could not have held the opinion that the patient at issue was terminally ill at the time of certification.[4]

The district court found the "reasonable doctor" standard "appealing and logical," but noted that it had not been adopted by the Eleventh Circuit and

[4] AseraCare asked the district court to adopt the standard for falsity established by the Northern District of Illinois in a case with a similar fact pattern and posture. The court in that case dismissed FCA claims against a for-profit hospice facility because relators failed to allege facts "demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care." *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012).

declined to apply it. The court ultimately denied AseraCare's motion for summary judgment, concluding that fact questions remained regarding whether clinical information and other documentation in the relevant medical records supported the certifications of terminal illness on which AseraCare's claims were based.

Following the denial of its motion for summary judgment, AseraCare moved to certify the following question for interlocutory appeal before this Court under 28 U.S.C. § 1292(b):

> In a False Claims Act case against a hospice provider relating to the eligibility of a patient for the Medicare hospice benefit, for the Government to establish the falsity element under 31 U.S.C. § 3729(a)(1), must it show that, in light of the patient's clinical information and other documentation, no reasonable physician could have believed, based on his or her clinical judgment, that the patient was eligible for the Medicare hospice benefit?

The district court certified the question for interlocutory appeal. We considered AseraCare's motion for review but declined to consider the question at that stage of the proceeding.

C. Bifurcation of Trial

Subsequent to the denial of summary judgment, AseraCare moved the district court to bifurcate trial under Federal Rule of Civil Procedure 42(b) into two phases: one phase on the falsity element of the FCA and a second phase on the FCA's remaining elements and the Government's common-law claims. The Government vehemently opposed the motion. It argued that the proposed

bifurcation was "extraordinary," requiring the Government "to jump over an arbitrary hurdle that is without precedent" because "the elements of 'falsity' and 'knowledge of falsity' are not so distinct and separable that they may be tried separately without injustice." Indeed, the Government noted, the elements of FCA liability had "never before been bifurcated by a federal district court." The Government further argued that bifurcation was unworkable because documentary and testimonial evidence that was probative in the falsity phase—"because it undermines the reliability of the [certifications of terminal illness]"—was "also probative in the 'knowledge of falsity' phase because it shows AseraCare knew or should have known that it was submitting false claims for non-terminally [*sic*] patients."

Nonetheless, the district court granted the motion in light of its concern that evidence pertinent to the knowledge element of the FCA would confuse the jury's analysis of the threshold question of whether the claims at issue were "false" in the first instance. The court noted that, while "pattern and practice" evidence showing deficiencies in AseraCare's admission and certification procedures could help establish AseraCare's *knowledge* of the alleged scheme to submit false claims—the second element of the Government's case—the *falsity* of the claims "cannot be inferred by reference to AseraCare's general corporate practices unrelated to specific patients." In the court's view, allowing the Government to present

knowledge evidence before falsity was determined would be unduly prejudicial to AseraCare, thus warranting separation of the knowledge and falsity elements.

In accordance with this rationale, the district court "drew the line of admissibility" in Phase One of trial "at anecdotal evidence about a specific, but unidentified, patient or event that would be impossible for the Defense to rebut." The court did, however, allow in Phase One anecdotal testimony regarding improper clinical or corporate practices that "had a time and place nexus with the 123 allegedly ineligible patients at issue." Such testimony, in the court's view, would have been "highly probative and admissible in Phase One." Indeed, in bifurcating trial, the court presumed—based on the Government's own representations—that the Government possessed and would present such evidence in Phase One. The court did allow in Phase One general testimony regarding AseraCare's business practices and claim-submission process during the relevant time period, but only to contextualize the falsity analysis and "afford[] the jury an opportunity to more fully understand the hospice process within AseraCare." Such evidence was not, however, admissible to prove the falsity of the claims at issue.[5]

[5] The Government continues to complain on appeal that bifurcation of the trial was "fundamentally unfair" and confused the issues, albeit it does not expressly challenge on appeal the district court's decision.

D. Phase One of Trial

The first phase of the trial lasted approximately eight weeks and proceeded to a jury verdict largely against AseraCare on the question of falsity. During its case in chief, the Government presented several days of testimony from Dr. Liao, who explained that, in his expert opinion, the medical records of the patients at issue did not support AseraCare's "terminal illness" certifications because they did not reveal a life expectancy of six months or less. Dr. Liao made clear that his testimony was a reflection of only his own clinical judgment based on his after-the-fact review of the supporting documentation he had reviewed. He conceded that he was "not in a position to discuss whether another physician [was] wrong about a particular patient's eligibility. Nor could he say that AseraCare's medical expert, who disagreed with him concerning the accuracy of the prognoses at issue, was necessarily "wrong." Notably, Dr. Liao never testified that, in his opinion, no reasonable doctor could have concluded that the identified patients were terminally ill at the time of certification. Instead, he only testified that, in his opinion, the patients were not terminally ill. Even more notable is the fact that Dr. Liao himself changed his opinion concerning the eligibility of certain patients over the course of the proceeding—deciding that some of the patients he had earlier concluded were not terminally ill were in fact terminally ill. Nevertheless, he testified at trial that both sets of contradictory opinions remained "accurate to a reasonable degree of

certainty." To explain these reversals, Dr. Liao stated that he "was not the same physician in 2013 as [he] was in 2010."

The Government also presented testimony of the relators and other AseraCare employees regarding AseraCare's certification procedures, but, as discussed *supra*, this testimony was characterized as being offered solely to show context, not falsity. In rebuttal, AseraCare offered expert testimony that directly contradicted Dr. Liao's opinions.

The parties' expert witnesses disagreed along two lines. First and foremost, they fundamentally differed as to how a doctor should analyze a patient's life expectancy for Medicare reimbursement purposes. The Government's Dr. Liao applied what might be called a "checkbox approach" to assessing terminal illness: He examined the patients' records and compared them against Palmetto's LCDs (and other, similar medical guidelines) for specific diagnoses, including Alzheimer's, heart disease, cardiopulmonary disease, and "adult failure to thrive." By contrast, AseraCare's experts considered but did not formulaically apply the LCD guidance in making their assessments. Instead, they took a "whole patient" approach, making prognoses based on the entirety of the patient's history, the confluence of ailments from which a patient may be suffering, and their own experience with end-of-life care. AseraCare's experts did not discount the LCD "criteria," but—as the latter instruct— these experts did not consider themselves

compelled to conclude that a patient was ineligible merely because the patient had failed to meet one of those indicia.

The district court correctly stated in its instructions to the jury that the LCDs are "eligibility guidelines" that are not binding and should not be considered "the exact criteria used for determining" terminal illness. As such, the jury was not permitted to conclude that Dr. Liao's testimony was more credible because he made reference to the LCD criteria, or that AseraCare's claims were false if they failed to conform to those criteria. Nonetheless, the experts' disagreement as to the proper analytical approach impacted their ultimate judgments as to each patient's terminality.

Because neither the checkbox approach nor the holistic approach to making terminal-illness prognoses is contrary to the law, the jury's sole job at trial was to review the medical records of each patient and decide which experts' testimony seemed more persuasive on the question whether a particular patient should be characterized as "terminally ill" at the time of certification. To be clear, the Government never alleged that AseraCare's doctors relied on medical documentation that was too thin, vague, or lacking in detail to reasonably substantiate their "clinical judgments" of terminal illness. Indeed, there is no dispute that each patient certification was supported by a meaningful set of medical records evidencing various serious and chronic ailments for which the patient was

entitled to some level of treatment. The question before the jury was instead which doctor's interpretation of those medical records sounded more correct. In other words, in this battle of experts, the jury was to decide which expert it thought to be more persuasive, with the less persuasive opinion being deemed to be false. To guide that assessment, the district court provided the following instruction on falsity: "A claim is 'false' if it is an assertion that is untrue when made or used. Claims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable."

Ultimately, the expert testimony in this case revealed a fundamental difference of professional opinion regarding the manner in which each patient's complete medical picture contributed to his or her life expectancy at the time he or she received hospice care. Both sets of experts looked at the same medical documentation, considered the same medical standards for the terminal-illness determination (even while differing as to the weight such standards should be given), and relied on their own experience as seasoned physicians specializing in end-of-life care. Dr. Liao testified that, in his professional opinion, the patients at issue were not likely to die within six months of the date on which they were certified for hospice care. AseraCare's experts arrived at opposite conclusions.

As an illustration of this disagreement, consider the testimony of the Government's Dr. Liao and AseraCare's Dr. Gail Cooney regarding the patient

Elsin K., who was an AseraCare hospice patient for over a year and who ultimately died in an AseraCare facility. Elsin was first admitted to hospice upon her physician's diagnosis of "debility," also called "adult failure to thrive," in which a patient experiences a general decline in health due to old age. Elsin experienced subsequent periods of improvement and decline; she left hospice care and was recertified on at least two occasions before her death.

As with each patient at issue in this case, Dr. Liao's assessment of Elsin's hospice eligibility contrasted starkly with Dr. Cooney's, even though there was no dispute as to Elsin's underlying diagnoses. Dr. Liao noted that many of Elsin's ailments, including severe infections arising from a joint replacement, were chronic and had recurred for many years. He also noted that she did not demonstrate the level of physical debility that published medical criteria typically associate with terminal patients. On the basis of his medical review, he described Elsin as struggling with chronic illness but "overall rather stable, if not improving," and thus lacking a prognosis of six months or less to live at the time of her certifications and recertifications. Dr. Cooney, the defense expert, also recognized that Elsin "had been sick for a long time," but she saw in the medical records a trend of steady physical and mental decline, decreased mobility, and increasing pain. Elsin's physical and psychological ailments, viewed in combination with one another, complicated the picture of Elsin's overall health and

contributed to Dr. Cooney's judgment that Elsin was terminally ill during each relevant time period. In the Government's view, it was properly within the purview of the jury to decide which doctor's judgment was correct and, to the extent the jury found Dr. Liao's prognosis to be more persuasive, to find that AseraCare had thereby submitted a false statement when it filed a claim based on a prognosis that differed from Dr. Liao's.

At the conclusion of the parties' cases, the court instructed the jury to answer special interrogatories regarding the prognoses of each of the 123 patients at issue. The jury ultimately found that AseraCare had submitted false claims for 104 patients of the 123 patients at issue during the relevant time periods.

E. Grant of New Trial and Second Motion for Summary Judgment

Following the partial verdict in this first phase of trial, AseraCare moved for judgment as a matter of law, arguing that the court had articulated the wrong legal standard in its instructions to the jury. The district court agreed. In the court's own words, "[a]s the court worked through AseraCare's challenges," it "became convinced that it had committed reversible error in the instructions it provided to the jury." It ultimately concluded that proper jury instructions would have advised the jury of two "key points of law" that the court had not previously acknowledged: (1) that the FCA's falsity element requires proof of an objective falsehood; and (2) that a mere difference of opinion between physicians, *without*

more, is not enough to show falsity. AseraCare had advocated for this legal standard since the start of trial, but only after hearing all the evidence had the court become "convinced" that "a difference of opinion is not enough." The court ultimately concluded that the failure to instruct the jury on these points was reversible error and that the only way to cure the prejudice caused thereby was to order a new trial.

The court then went one step further, deciding to consider summary judgment *sua sponte* under Federal Rule of Civil Procedure 56(f)(3). Specifically, it informed the parties that it intended to consider "whether the Government, under the correct legal standard, has sufficient admissible evidence of more than just a difference of opinion to show that the claims at issue are objectively false as a matter of law." The court gave the parties an opportunity to brief the issue, advising that:

> The Government's proof under the FCA for the falsity element would fail as a matter of law if all the Government has as evidence of falsity in the second trial is Dr. Liao's opinion based on his *clinical judgment* and the medical records that he contends do not support the prognoses for the 123 patients at issue in Phase One.

In its summary-judgment briefing, the Government argued that it was procedurally improper for the court to raise summary judgment *sua sponte* after already deciding to grant a new trial. The district court rejected this argument, and the Government does not revive the challenge on appeal.

Following briefing and a hearing, the court granted summary judgment in AseraCare's favor on the basis of the court's newly adopted legal standard. The court concluded, "[a]fter careful review of all [the parties'] submissions and the Phase One [trial] record, . . . that the Government has failed to point the court to any admissible evidence to prove falsity other than Dr. Liao's opinion that the medical records for the 123 patients at issue did not support the Certifications of Terminal Illness" that were submitted for Medicare reimbursement. Because "[t]he Government [ ] presented no evidence of an objective falsehood for any of the patients at issue," it could not prove the falsity element of its FCA claim as a matter of law. The court thus granted summary judgment in AseraCare's favor.

The Government appeals the district court's summary judgment order and its grant of a new trial, contending that the legal standard the court ultimately adopted reflected a "deeply flawed" understanding of the falsity element of an FCA claim. The Government thus asks this Court to reject the legal standard for falsity that the district court adopted, reverse the district court's grant of summary judgment and order of a new trial, and reinstate the jury's Phase One findings: namely, that the Government successfully proved falsity as to several of the claims at issue.

III. STANDARD OF REVIEW

This Court reviews the district court's grant of summary judgment *de novo*, viewing all the evidence and drawing all reasonable inferences in favor of the non-

moving party. *Vessels v. Atlanta Indep. Sch. Sys.*, 408 F.3d 763, 767 (11th Cir. 2005). By contrast, we review a district court's ruling on a motion for a new trial for abuse of discretion. *Hewitt v. B.F. Goodrich Co.*, 732 F.2d 1554, 1556 (11th Cir. 1984).

IV. DISCUSSION

This appeal requires us to consider how Medicare's requirements for hospice eligibility—which are centered on the subjective "clinical judgment" of a physician as to a patient's life expectancy—intersect with the FCA's falsity element. Under this Court's precedent, "Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005). There is no allegation that the hospice services AseraCare provided were not rendered as claimed. Thus, the sole question is whether the claims AseraCare submitted were reimbursable under the Medicare framework for hospice care—that is, whether AseraCare's certifications that patients were terminally ill satisfied Medicare's statutory and regulatory requirements for reimbursement. If not, the claims are capable of being "false" for FCA purposes.

Thus framed, our primary task on appeal is to clarify the scope of the hospice eligibility requirements, which are set out in the federal Medicare statute,

42 U.S.C. § 1395f, and its implementing regulation, 42 C.F.R. § 418.22. Our secondary task is to determine whether the district court's formulation of the falsity standard was consistent with the law and properly applied. Neither this Court nor any of our sister circuits has considered the standard for falsity in the context of the Medicare hospice benefit, where the controlling condition of reimbursement is a matter of clinical judgment. After careful review of the relevant law, the underlying record, and the considerations raised by the parties and the amici curiae, we agree that the instruction given to the jury was inadequate and agree with the general sense of the legal standard embraced by the district court after the verdict.

A. Legal Standard for Falsity of Hospice Claims

The Government argues that the district court's initial jury instructions—that "[a] claim is 'false' if it is an assertion that is untrue when made or used" and that "[c]laims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable"—comprised a complete and correct statement of the legal standard for falsity. As applied to this case, the Government argues that it can show falsity by producing expert testimony that a patient's medical records do not support a terminal-illness prognosis as a factual matter. Where the parties present competing expert views on a patient's prognosis, the "falsity" of the defendant's prognosis is put to a jury.

AseraCare contests the Government's characterization of the statutory and regulatory framework, arguing that the determinative inquiry in an eligibility analysis is whether the certifying physician exercised genuine clinical judgment regarding a patient's prognosis and further arguing that the accuracy of such judgment is not susceptible to being proven true or false as a factual matter.

Given the dearth of controlling case law regarding the intersection of the FCA and the Medicare hospice benefit and the parties' vigorous disagreement on the fundamental points of law, we begin by defining the contours of the hospice-eligibility framework and clarifying the circumstances under which a claim violates the requirements for reimbursement. We then consider the ways in which a hospice claim might be deemed "false" for purposes of the FCA.

1. Hospice Eligibility Framework

Our analysis begins with the language of the relevant statute and regulations. *See United States v. Aldrich*, 566 F.3d 976, 978 (11th Cir. 2009) ("[T]he 'starting point' of statutory interpretation is 'the language of the statute itself.'") (citing *Randall v. Loftsgaarden*, 478 U.S. 647, 656 (1986)). "To determine the plain meaning of a statute or regulation, we do not look at one word or term in isolation, but rather look to the entire statutory or regulatory context." *Sec. & Exch. Comm'n v. Levin*, 849 F.3d 995, 1003 (11th Cir. 2017).

In relevant part, the statute states that payment for hospice care provided to an individual may be made only if:

> (i) in the first 90-day period . . . (I) the individual's attending physician . . . and (II) the medical director (or physician member of the interdisciplinary group described in [42 U.S.C. § 1395x(dd)(2)(B)]) of the hospice program providing . . . the care, *each certify in writing at the beginning of the period, that the individual is terminally ill* (as defined in [42 U.S.C. § 1395x(dd)(3)(A)]) *based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness*, [and]
>
> (ii) in a subsequent 90- or 60-day period, the medical director or physician . . . recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment.

42 U.S.C. § 1395f(a)(7)(A) (emphasis added).[6] "Terminally ill" means that the individual "has a medical prognosis that the individual's life expectancy is 6

[6] The statute contains three additional requirements, each of which was in place during the relevant time period of 2007 through 2012:

> (B) a written plan for providing hospice care with respect to such individual has been established . . . and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in 42 U.S.C. § 1395x(dd)(2)(B)]) of the hospice program;
>
> (C) such care is being or was provided pursuant to such plan of care; [and]
>
> (D) on and after January 1, 2011 . . . a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility . . . prior to the 180th-day recertification and each subsequent recertification . . . and attests that such visit took place . . . .

42 U.S.C. § 1395f(a)(7). The Government does not allege that AseraCare failed to meet any of these additional requirements.

months or less." 42 U.S.C. § 1395x(dd)(3)(A). In any case, "no payment may be made . . . for any expenses incurred . . . which are not reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C).

The implementing regulations echo the language of the statute, reiterating that each written certification of terminal illness "will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." 42 C.F.R. § 418.22(b). *See also* 42 C.F.R. § 418.22(a)(1) (stating "general rule" that hospice provider "must obtain written certification of terminal illness" for each claimed period of care).

The regulations go on to identify several requirements for the submission of claims. First, and most significant to this appeal, "[c]linical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification." 42 C.F.R. § 418.22(b)(2). Second, the certifying physician must include with the certification "a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less." 42 C.F.R. § 418.22(b)(3). This narrative explanation "must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients." 42 C.F.R.

§ 418.22(b)(3)(iv).[7] And third, in deciding whether to certify a patient as terminally ill, a physician is obligated to consider several factors: the patient's primary terminal condition and related diagnoses; current subjective and objective medical findings; current medication and treatment orders; and information about the medical management of any conditions unrelated to the terminal illness. 42 C.F.R. § 418.102(b); 42 C.F.R. § 418.25(b) (establishing that, "[i]n reaching a decision to certify that the patient is terminally ill, the hospice medical direct must consider at least" the diagnosis of the patient, other health conditions, and "[c]urrent clinically relevant information supporting all diagnoses"). *See also* 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) ("[T]he certification of terminal illness is based in the unique clinical picture of the individual that is reflected in the comprehensive assessment and other clinical records and documentation . . . ."); 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (noting that, in deciding whether to recertify a patient who has not shown measurable decline, the physician "must assess and evaluate the full clinical picture" of the patient).

The language of the statute and implementing regulations makes plain that the clinical judgment of the patient's attending physician (or the provider's medical

[7] The requirement of a brief narrative explanation accompanying the certification was added to the regulations on October 1, 2009. *See* 74 Fed. Reg. 39384, 39398–400, 39413 (Aug. 6, 2009).

director, as the case may be) lies at the center of the eligibility inquiry. Under this language, a patient is eligible for the Medicare hospice benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as evidenced by the patient's medical records.

Importantly, none of the relevant language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact. Indeed, CMS has recognized in crafting the implementing regulations that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010). *See also* 79 Fed. Reg. at 50470 ("[W]e also have recognized the challenges in prognostication" and therefore expect "that the certifying physicians will use their best clinical judgment.").[8] Nor does this framework state or imply that the patient's medical records must unequivocally demonstrate to an unaffiliated physician, reviewing the records after the fact, that the patient was likely to die within six months of the time the certifying physician's clinical judgment was made. Rather, the framework asks a physician

[8] We have held in the context of FCA proceedings that "guidance issued by the governmental agency charged with administrating the regulatory scheme," including the Medicare regulatory scheme, "can be consulted to understand the meaning of that regulation." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1357 (11th Cir. 2005).

responsible for the patient's care to exercise his or her judgment as to the proper interpretation of the patient's medical records.

The Government seeks to elevate the significance of the regulation's supporting-documentation requirement, asserting that eligibility "turns on" whether the clinical information and other documentation accompanying a certification of terminal illness support, as a factual matter, the physician's certification. Specifically, the Government maintains that the testimony of Dr. Liao, which "was designed to assist the jury in understanding the medical records" for each patient, created "a factual dispute as to whether '[c]linical information and other documentation' in the medical record 'support[ed] the medical prognosis' of a life expectancy of six months or less." (Citing 42 C.F.R. § 418.22(b)(2).)

We conclude that the Government's framing of the eligibility inquiry is not consistent with the text or design of the law. The relevant regulation requires only that "clinical information and other documentation that support the medical prognosis . . . *accompany the certification*" and "*be filed in the medical record*." 42 C.F.R. § 418.22(b)(2) (emphases added). This "medical prognosis" is, itself, "based on the physician's . . . clinical judgment." 42 C.F.R. § 418.22(b). To conclude that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment would read more into the legal framework than its language allows. Read in the context of the statute and

regulations, the requirement that supporting documentation "accompany" the claim is designed to address CMS's mandate that "there must be a clinical basis for a certification." 79 Fed. Reg. at 50470 (noting that, although "certification is based on a clinical judgment," this "does not negate the fact that there must be a clinical basis for a certification"). That is, the physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records.

We also note that, had Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet, Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support"—instead of, for example, "demonstrate" or "prove"—does not imply the level of certitude the Government wishes to attribute to it. *Cf. Davidson v. Capital One Bank (USA), N.A.*, 797 F.3d 1309, 1316 (11th Cir. 2015) (We "presume that Congress said what it meant and meant what it said.") (quotation marks omitted).

More broadly, CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference. As noted *supra*, CMS has repeatedly emphasized that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. at 70448. *See also* 79 Fed. Reg. at 50470 (same). And in clarifying

the process for reporting a patient's "principal hospice diagnosis" on a hospice claim, CMS stated: "We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill." 78 Fed. Reg. at 48247. Furthermore, in response to public comment, CMS removed the term "criteria" from a proposed regulation defining the certification requirements, wishing "to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness." 73 Fed. Reg. 32088, 32138 (June 5, 2008). While there is no question that clinical judgments must be tethered to a patient's valid medical records, it is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.

The Government cautions that a narrow reading of the eligibility framework "would entitle hospice providers to reimbursement for services provided to *any* individual, regardless of medical condition, assuming the provider could find a physician willing to sign the certification." This point again ignores that the physician's clinical judgment, informed by the patient's medical records, is the threshold requirement for eligibility. A physician cannot, as the Government suggests, hold a clinical judgment under the eligibility framework that disregards the patient's underlying medical condition. *See, e.g.*, 42 C.F.R. § 418.102(b)

(identifying factors physicians must consider when arriving at clinical judgments regarding terminal illness, including "subjective and objective medical findings" regarding the patient's condition). Such a clinical judgment would clearly be illegitimate under the law.

The Government further warns that, under our reading of the framework, "if a physician certifies a patient as terminally ill, CMS is *required* to reimburse the hospice care provider unless it can determine that *no* other reviewer of the patient's medical records could possibly conclude the patient was terminally ill." But, as the Government elsewhere notes, CMS is statutorily prohibited from reimbursing providers for services "which are not reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C). *See also* 79 Fed Reg. 50452, 50470 (Aug. 22, 2014) (explaining that CMS retains a well-established right to review claims for hospice reimbursement and to deny claims that it does not consider to be "reasonable and necessary" under the statutory standard). The Government's argument that our reading of the eligibility framework would "tie CMS's hands" and "requir[e] improper reimbursements" is contrary to the plain design of the law.

2. Falsity in this case under the FCA

Having identified the contours of the Medicare framework, it becomes clear that there are two separate representations embedded in each claim for hospice

reimbursement: a representation by a physician to AseraCare that the patient is terminally ill in the physician's clinical judgment and a representation by AseraCare to Medicare that such clinical judgment has been obtained and that the patient is therefore eligible. As such, this case requires us to distinguish between two possible species of "falsity." The first relates to the legitimacy of a physician's clinical judgment. The second relates to the legitimacy of AseraCare's statement that a clinical judgment has been properly made.

Under the Government's false-certification theory in this case, AseraCare "submitted documentation that falsely represented that certain Medicare recipients were 'terminally ill'" when, in the Government's view, they were not. There is no allegation that AseraCare submitted claims that were not, in fact, based on a physician's properly formed clinical judgment, nor is there an allegation that AseraCare failed to abide by each component of the claim requirements.[9] The Government's allegations focus solely on the accuracy of the physician's clinical judgment regarding terminality. If, the theory goes, AseraCare represented to Medicare that a patient was "terminally ill" based on a physician's clinical

[9] We might, for instance, envision a viable FCA suit alleging that a hospice provider failed to obtain any clinical judgment at all, or obtained a clinical judgment from someone other than the patient's attending physician or the provider's medical director, or fabricated the certification itself. No such facts are alleged here.

judgment, and the Government later persuades a jury that this clinical judgment was wrong, then AseraCare's representation was, in turn, "false." This "falsity" opens the door to FCA liability. Thus, the Government's FCA case hangs entirely on the following question: When can a physician's clinical judgment regarding a patient's prognosis be deemed "false"?

In light of our foregoing discussion, we concur with the district court's post-verdict conclusion that "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [ ] be wrong." Indeed, the Government's own witness—Mary Jane Schultz, the former head of Palmetto's medical review department—conceded at trial that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." Nothing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment. Nor does the law suggest that a hospice provider has failed to comply with Medicare's requirements for hospice reimbursement if the only flaw in its claim is an absence of certitude that, in light of the relevant medical records, the patient will die within six months. The legal framework signals, and CMS itself has acknowledged, that no such certitude can be expected of physicians in the practice of treating end-of-

life illness. All the legal framework asks is that physicians exercise their best judgment in light of the facts at hand and that they document their rationale.

It follows that when a hospice provider submits a claim that certifies that a patient is terminally ill "based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness," 42 U.S.C. § 1395f(7), 42 C.F.R. § 418.22(b), the claim cannot be "false"—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood.

Objective falsehood can be shown in a variety of ways. Where, for instance, a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal, his ill-formed "clinical judgment" reflects an objective falsehood. The same is true where a plaintiff proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification. A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records. In each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts.

By contrast, a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those

judgments—or any claims based on them—are false under the FCA. A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong. *Cf. Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015) (holding that "a sincere statement of pure opinion is not an 'untrue statement of material fact'" under the Securities Act of 1933, "regardless whether an investor can ultimately prove the belief wrong").

Accordingly, in order to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law.

In so holding, we agree with the district court's conclusion that, in order to show objective falsity as to a claim for hospice benefits, the Government must show something more than the mere difference of reasonable opinion concerning the prognosis of a patient's likely longevity.[10] And although we appear to be the

[10] Several district courts within and outside the Eleventh Circuit have embraced comparable reasoning in cases alleging FCA liability on the basis of clinical judgments of terminal illness. *See, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *17 (N.D.

first circuit court to consider the precise question at issue here, a number of opinions from our sister circuits lends support to our conclusion that the Government must show an objective falsity.[11]

Tex. June 20, 2016) ("Because a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis."); *United States ex rel. Fowler v. Evercare Hospice, Inc.*, 2015 WL 5568614, at *9 (D. Colo. Sept. 21, 2015) (observing that, if Government's complaint had been "based entirely on disagreements with [the provider's] certifying physicians," the complaint "would be insufficient to state a claim"); *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012) (dismissing FCA claims because "[r]elators have not alleged facts demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care"). *But see Druding v. Care Alternatives, Inc.*, 164 F. Supp. 3d 621, 623 (D.N.J. 2016) (holding that where plaintiffs alleged that patients were ineligible for hospice because they did not meet LCD criteria, claims were "legally false . . . because the claim[s] did not include sufficient clinical facts in the patient's medical records to justify a terminal prognosis").

[11] *See United States ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) (stating that "[a] statement may be deemed 'false' for purposes of the False Claims Act only if the statement presents 'an objective falsehood'") (citing *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)); *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010), (explaining that an opinion may qualify as a false statement for purposes of the FCA where the speaker "knows facts 'which would preclude such an opinion'") (quoting *United States ex rel. Siewick v. Jamieson Science and Engineering, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000)); *Wilson*, 525 F.3d at 376–77 (holding that "[t]o satisfy [the] first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood" and "imprecise statements or differences in interpretation growing out of a disputed legal question are [ ] not false under the FCA") (quotation omitted); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("At a minimum the FCA requires proof of an objective falsehood."); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999) (noting that opinions or estimates can be "false" under the FCA if their speaker knows they are not supported by the facts); *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047–49 (9th Cir. 2012) (same). *Cf. Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1323, 1326–27 (2015) (holding in the context of securities fraud statutes that a statement of opinion can be "false" if the opinion did not reflect the speaker's actual belief at the time it was given).

The Government urges that the standard we adopt today improperly "usurp[s] the role of the jury" by precluding the jury from determining, based on expert testimony, the accuracy of the clinical judgments at issue. In support of this contention, the Government relies heavily on this Court's reasoning in *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349 (11th Cir. 2005). But *Walker* is clearly distinguishable and does not control our analysis.

In *Walker*, an FCA relator contended that her employer, a medical-clinic operator, billed Medicare for services rendered by non-physicians as if those services had been rendered "incident to the service of a physician," as the relevant statute required. *See id*. at 1353. In reality, the relator alleged, services had been provided by nurse practitioners or physician assistants without any physician involvement. *Id*. The defendant-clinic did not dispute that physicians were not present in the clinic when services were rendered. *Id*. at 1354. It argued instead that these claims could not have been false as a matter of law because the meaning of "incident to the service of a physician" was "vague and subject to reasonable interpretations other than that championed by Walker." *Id*. Specifically, the clinic argued that it interpreted "incident to the service of a physician" to cover services that were rendered by non-physicians as long as a physician was available by pager or telephone, even if not actually physically present in the office. *Id*. The district

court agreed, finding the statute ambiguous and defendant's interpretation of the statute reasonable. *Id.*

This Court reversed. *Walker*, 433 F.3d at 1356. The question presented was whether a claim based on a reasonable interpretation of an ambiguous statutory term could never be deemed "false," or whether instead the meaning of the ambiguous term—and the corresponding falsity of the claims made thereunder—could potentially pose factual questions that should be put to a factfinder. *Id.* Given the particular facts of the case before us, our Court adopted the latter approach. Specifically, the relator presented evidence from the Medicare Carrier's manual, Medicare bulletins, and seminar programs to "support a finding that, in the Medicare community, the language of the statute was understood to mean that a physician had to be physically present in the office suite" in order to justify reimbursement for the medical service provided by a non-physician. *Id.* at 1356–57. We concluded that this evidence created a jury question as to both whether the Medicare regulation required more physician involvement with a patient than the defendant clinic had provided and whether the defendant knew of this requirement. *Id.* at 1358.

In *Walker*, the eligibility criterion at issue was subject to multiple interpretations because its language was ambiguous, yet ultimately only one of the two possible interpretations could be deemed correct. By contrast, the key

eligibility criterion at issue here—"terminally ill"—presents, by design, a question of debatable clinical judgment that may not, in all circumstances, lend itself to just one determination as to the proper exercise of that judgment. As the district court noted below, asking the jury to decide whether medical records supported a finding of "terminal illness" put the jury in the position of evaluating, and second-guessing, the clinical judgment of the certifying physician. This is not the role the factfinder was playing in *Walker*; indeed, it is a role requiring medical knowledge and expertise that Congress has clearly reserved for physicians in the hospice-benefit context. *Walker* therefore does not compel the conclusion that eligibility requirements that hinge on clinical judgment present jury questions simply because they are susceptible to differing opinions, each of which could be reasonable.

The Government has also filed supplemental authority, citing to out-of-circuit appellate cases that it says establish that a mere difference of medical opinion can be sufficient to show that a statement is false. We find these cases distinguishable. In *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), the physician-defendant had been convicted of healthcare fraud based on his performance of allegedly unnecessary coronary stent procedures. In arguing for reversal of his conviction, the defendant contended that he based his decision to perform the procedures on his interpretation of angiogram tests showing a high degree of blockage in the patients' arteries, and thus his medical judgment on this

point represented merely an opinion that could neither be truthful nor false. The Government contended that, to the contrary, the defendant had lied when he said that he interpreted the angiograms as showing a level of coronary blockage that would warrant inserting a stent into the heart, and it offered substantial expert testimony disputing that the level of blockage shown on the angiogram test was at the level the defendant asserted it was.

The Sixth Circuit[12] agreed with the defendant that "[o]rdinarily, facts are the only item that fits in [the false statement] category; opinions—when given honestly—are almost never false . . . .There is no such thing as a false idea." *Id*. at 275 (citations and internal quotation marks omitted). Nevertheless, the court continued, opinions have "never been completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion." *Id.* The court then cited with apparent approval the district court opinion in the present case for the proposition that "certain good-

[12] The *Paulus* court indicated its intention to clarify the standard underlying its earlier decision in *United States v. Persaud*, 866 F.3d 371 (6th Cir. 2017), which the Government has also cited in the present case. *Paulus*, 894 F.3d at 275.

faith medical diagnoses by a doctor cannot be false." [13] *Id*. In the case before it, however, the *Paulus* court noted that "coronary artery blockage actually exists as an aspect of reality," meaning that an assertion about the degree of blockage can be objectively true or false. *Id.* at 276 (quotation marks omitted). And it concluded that the Government's expert testimony was sufficient to support an inference that the defendant had lied when he reported readings of the angiograms that the experts said were simply not true: "[W]e think it is clear that Paulus was convicted for misrepresenting facts, not giving opinions." *Id.*

Moreover, whereas in the present case the Government's expert witness declined to conclude that Asercare's physicians had lied about their clinical judgment or even that their judgments were unreasonable or wrong[14]—as opposed to just different from what the Government's expert opined—in *Paulus*, it appears clear that the Government's experts there were not so charitable. The *Paulus* court noted that the Government had claimed that "Paulus repeatedly and systematically saw one thing on the angiogram and consciously wrote down another, and then

[13] The court stated, "*see also United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016) (holding that certain good-faith medical diagnoses by a doctor cannot be false.") *Paulus*, 894 F.3d at 275.

[14] As noted *supra*, the former head of the Palmetto medical review team, called as a Government witness, also conceded at trial that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong."

used that misinformation to perform and bill unnecessary procedures," and it explained that "[h]owever difficult it might be for a cardiology expert to prove that his colleague was lying about what he saw on a scan," it was up to the jury to decide the reliability of that testimony. *Id*. at 267–77. In short, the Government's expert testimony in *Paulus* appeared to suggest that no reasonable doctor could interpret the scan as had Paulus and that Paulus was actually lying. Thus, *Paulus* is not supportive of the Government's contentions here.[15]

[15] The Government here also cites *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), an FCA case in which the district court had granted the defendant's motion to dismiss on the ground that his medical judgment about the need for cardiac PFO closure procedures to prevent future strokes in his patients was an opinion that was not subject to being deemed true or false. The Tenth Circuit reversed, found a plausible allegation of falsity, and directed that the case proceed to discovery. The circuit court noted that the Government had alleged that the applicable Medicare statute authorized reimbursement only when the he PFO procedure was reasonable and necessary for the treatment of an illness; that there is agreement in the medical community that a PFO closure is not medically necessary except where there is a confirmed diagnosis of a recurrent stroke; that the applicable guidelines allow for consideration of the procedure only when the patient has had two or more strokes and that the guidelines do not "contemplate the potential for PFO closures" if the patient has not had a prior stroke; that the defendant claimed to believe that the procedure should be performed prophylactically to cure migraine headaches or to prevent strokes even if the patient had never before had a stroke; and, knowing that Medicare would not pay on that basis, the defendant falsely represented that the procedure was being performed based on the indications set forth in the guidelines. *Id.* at 736, 737. In addition, a fellow physician alleged that he had witnessed the defendant perform an unnecessary procedure and actually *create* the problem the surgery was intended to remedy by puncturing intact septa in the patients. *Id.* at 738.

Obviously, the above facts are quite different from those alleged in this case. It is true that the Tenth Circuit opinion held that regardless of the physician's opinion to the contrary, he will be deemed to have made a false statement when claiming reimbursement if the medical procedure is determined to have not been reasonable or necessary. "We thus hold that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."

The Government expresses concern that a requirement of objective falsehood will produce a troubling under-inclusion problem: that is, by holding that an FCA claim fails as a matter of law if the plaintiff proves nothing more than a reasonable difference of opinion as to the patient's prognosis, hospice providers with sloppy or improper admission practices may evade FCA liability so long as they can argue after the fact that their physicians' clinical judgments were justifiable. That may well be. To be sure, it will likely prove more challenging for an FCA plaintiff to present evidence of an objective falsehood than to find an expert witness willing to testify to a contrasting clinical judgment regarding cold medical records.

But if this is a problem, it is one for Congress or CMS to solve. In deciding how to craft the hospice eligibility requirements, Congress and CMS could have imposed a more rigid set of criteria for eligibility determinations that would have minimized the role of clinical judgment. Instead, they were careful to place the physician's clinical judgment at the center of the inquiry. Indeed, CMS has considered and expressly declined to impose defined criteria that would govern the physician's exercise of judgment. *See* 73 Fed. Reg. 32088, 32138 (June 5, 2008).

Id. at 742. As set out in text, however, the hospice-benefit provision at issue here, by design, looks to whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion as to a patient's likely longevity.

In any event, absent a showing of an objective and knowing falsehood, the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits. For the above reasons, we agree that the district court's jury instruction concerning falsity was lacking and that a new trial was warranted to allow the giving of a more complete charge: specifically, a charge that would convey that the mere difference of reasonable opinion between physicians, without more,[16] as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood. We therefore AFFIRM the district court's grant of a new trial.

B. Grant of Summary Judgment

Deciding that the district court acted correctly in determining that a new trial was warranted—with a revised instruction to the jury concerning falsity—does not end our review of this case. Instead, as noted in the procedural discussion above, the district court went further and, after granting a new trial, it then *sua sponte* granted summary judgment to AseraCare. The court reasoned as follows. Given its new position on the standard for determining falsity—that falsity cannot be established based merely on a reasonable disagreement between experts as to

[16] Should there be another trial on this matter, we leave to the district court and the parties the task of fleshing out just what that "more" needs to include.

whether clinical records in a patient's file warranted a prognosis of a terminal illness that would likely result in the patient's death within six months—the district court indicated that it would hear from the Government whether the court record contained any other evidence sufficient to create a jury question as to whether AseraCare had made an objectively false representation when claiming reimbursement for hospice benefits it had provided. Following that response and concluding that the Government's evidence of falsity consisted only of Dr. Liao's testimony indicating his disagreement with the prognosis arrived at by AseraCare for most of the patient files he reviewed, the district court found that the Government's evidence of falsity was insufficient to allow it to proceed further. For that reason, the court granted summary judgment.

Leaving aside the question whether the substance of an opinion, by itself, can ever be deemed to constitute an objective falsity, the parties agree that an opinion can be considered objectively false if the speaker does not actually hold that opinion. *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1323, 1326–27 (2015) (holding in the context of securities fraud statutes that a statement of opinion can be "false" if the opinion did not reflect the speaker's actual belief at the time it was given). Further, in examining whether a physician's clinical judgment was truly communicated, the latter must first have actually exercised such judgment. If it can be shown that the physician

never considered the underlying records supporting the prognosis at issue, but instead rubber-stamped whatever file was put in front of him, then the physician has offered no clinical judgment. Moreover, an opinion can enter falsifiable territory when it is based on information that the physician knew, or had reason to know, was incorrect. Finally, if no reasonable physician would think that a patient had a terminal illness based on the evidence before that physician, then falsity can be inferred, as well as the existence of a knowing violation.

With the above thoughts in mind, the Government argues that the district court took too constricted a view of the evidence upon which a determination of falsity could be made by a jury when it refused to consider other evidence from the first phase of the trial that the Government asserts tended to show knowledge of the falsity of the claim, as well as evidence that the Government intended to present in the second phase of the trial to further show AseraCare's alleged awareness[17] that it was submitting claims that did not reflect a physician's good faith clinical judgment and prognosis for each patient. In its opposition to the *sua sponte* grant of summary judgment, the Government stated:

[17] For purposes of the FCA, "the terms 'knowing' and 'knowingly' (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in in reckless disregard of the truth or falsity of the information, and (B) no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

> It is indefensible for the Court to grant summary judgment on the grounds that this case is just about a good faith disagreement between experts—and that the United States failed to present evidence that AseraCare knew or recklessly disregarded that its claims were false—when the Court bifurcated the trial and expressly excluded from Phase One any evidence of AseraCare's knowledge of falsity.

We agree with the Government that before granting summary judgment, the district court should have considered all the evidence, both in the trial record and the summary judgment record, to determine whether a triable issue existed regarding falsity. Here is why we reach that conclusion.

The Government had been prepared to introduce evidence to show AseraCare's knowledge at trial, but was prevented from doing so by the district court's decision, over the Government's strong objections, to bifurcate the trial and preclude introduction of any evidence showing knowledge of falsity in Phase I. The Government did, however, introduce evidence in that first phase that seems to offer some potential basis for inferring knowledge. Specifically, nine witnesses, whose testimony was purportedly connected in time and location to the patients at issue, testified that AseraCare had a deliberate practice of not giving physicians relevant, accurate, and complete information about patients whose certifications for hospice the doctors were being asked to sign. For example, one former director of clinical services in Decatur, Alabama, testified that when she declined to admit ineligible patients to hospice, she was instructed to go back and find whatever she

needed to admit the patient. Further, she typically did not provide the certifying physician with any clinical information, but usually just gave him a stack of papers to sign. Indeed, each of the nine former-employee witnesses reiterated these themes in their testimony. In large part, because the Government had not denominated this evidence as proof of falsity during this first phase—but instead as evidence of context—the district court refused to consider it as evidence of falsity in this post-verdict summary judgment phase.

The Government also intended to offer at the second phase evidence from AseraCare's internal and external auditors criticizing the company because the certifying medical directors were not adequately involved in making initial eligibility determinations and did not consistently receive medical information prior to the initial certification. In addition to the testimony of other former employees, the Government also planned to offer testimony from a former AseraCare physician that employees did not defer to his clinical judgment that certain patients were unentitled to hospice benefits, but instead proceeded to file the claims. The district court declined to factor the above evidence into its evaluation of whether a jury question still remained concerning AseraCare's knowledge that it was submitting claims that did not warrant the reimbursement of hospice benefits.

The district court's refusal to consider any of the above-described additional evidence on the question of falsity was largely based on the Government's response to AseraCare's discovery interrogatories inquiring what evidence the Government would offer on that issue. The district court emphasized that the Government had "painted itself into a corner by failing to disclose during discovery that it would use anything other than the testimony of Dr. Liao and medical records to prove the falsity of the claims."

It is true that the Government denominated only the Liao testimony as evidence of falsity during the discovery period. But, in fairness to the Government, it disclosed all the above evidence in question during discovery, including the evidence that the district court declined to consider for post-verdict summary judgment purposes. At the time of disclosure, the Government had no idea that the district court would later order the bifurcation of trial between falsity and knowledge phases, and it clearly assumed that all of its evidence would be heard by the jury in one proceeding, with no need to so starkly pigeon-hole the category into which a given piece of evidence might fit. As the Government noted in its opposition to bifurcation, with no contradiction by AseraCare, the elements of an FCA liability claim had "never been before been bifurcated by a federal district court." Nor had the Government ever anticipated such a decision, because, according to it, such an order was "extraordinary, requiring the United States to

jump over an arbitrary hurdle that is without precedent . . . [because] [t]he elements of 'falsity' and 'knowledge of falsity' are not so distinct and separable that they may be tried separately without injustice."

Moreover, the district court had rejected AseraCare's initial motion for summary judgment based on the latter's argument that the mere disagreement of experts is insufficient to imply falsity. At the time of trial, the court had already declined to apply this "reasonable physician" standard to the falsity analysis, despite granting AseraCare's § 1292(b) motion for review. As such, the Government's failure to present its case in a manner consistent with such a standard is understandable. Moreover, the court declined to give the instructions requested by AseraCare to that effect and instead gave only the charge requested by the Government: "Claims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable. For a hospice provider's claims to Medicare to be reimbursable, the patient must be eligible for the Medicare hospice benefit."

Accordingly, the Government, which had prepared and presented its case based on all the above information, was never alerted to the possibility that the conceptual underpinnings of its case would shift so dramatically once it had won a jury verdict on that theory. We emphasize that we do not criticize the district court for its post-verdict change of mind about the appropriate standard for proving

falsity. To the contrary, this district court judge was diligent, conscientious, and thoughtful throughout the long and complex pre-trial proceedings and the eight-week trial whose verdict she ultimately vacated. Given that expenditure of time and energy, it is commendable that the district court would consider starting over once she became convinced that she had made a legal error.

Nonetheless, under all these unusual circumstances, it is only fair that the Government be allowed to have summary judgment considered based on all the evidence presented at both the summary judgment and trial stages, and we direct that this occur. When the goalpost gets moved in the final seconds of a game, the team with the ball should, at the least, have one more opportunity to punch it into the endzone.

Having given the Government the green light to once again try to persuade the district court that a triable issue exists on both falsity and knowledge, we emphasize that we do not know that this effort will succeed. For sure, to the extent that a reasonable jury might credit the Government's proffered evidence regarding AseraCare's practices, that evidence suggests that AseraCare's certification procedures were seriously flawed. As noted, a former Director of Clinical Services testified that one physician she worked with was in the habit of signing certifications before reviewing any medical documentation whatsoever; clinical staff typically "just gave him . . . a stack of papers to sign, [and] he just signed the

papers." Another former employee testified that signing certifications had become so rote for one physician that he "would nod off" while signing. This testimony certainly raises questions regarding AseraCare's certification process writ large. But crucially, on remand the Government must be able to link this evidence of improper certification practices to the specific 123 claims at issue in its case. Such linkage is necessary to demonstrate both falsehood and knowledge.[18] *See Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) ("disregard of government regulations or failure to maintain proper internal procedures" are not sufficient to demonstrate FCA violation); *Carrel v. AIDS Healthcare Foundation, Inc.*, 898 F.3d 1267, 1277–78 (11th Cir. 2018) (a relator cannot prove that an actual false claim was filed based only on a showing of general practices untethered to that claim).

[18] Alternatively, the Government could meet its burden under the falsity standard now adopted by the district court, and endorsed by this Court, if it could establish through expert testimony that no reasonable physician reviewing the medical records at issue could have concluded that a particular patient was terminally ill. The Court, however, is unaware that any such evidence exists. Indeed, as noted, Mary Jane Schultz, the former head of Palmetto's medical review department, testified that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." Also, as noted, Dr. Liao himself changed his opinion concerning the eligibility of certain patients over the course of the proceeding but testified at trial that both sets of opinions remained "accurate to a reasonable degree of certainty." To explain these reversals, Dr. Liao stated that he "was not the same physician in 2013 as [he] was in 2010." As the district court observed, if Dr. Liao can form contradictory opinions based on the same medical records and yet claim not to have been wrong on either occasion, then it is difficult to explain how his difference of opinion with AseraCare's physicians concerning other patients would demonstrate that no reasonable physician could agree with AseraCare, absent some additional evidence to warrant that inference.

For the above reasons, we VACATE the district court's post-verdict grant of summary judgment to AseraCare and REMAND for the court to reconsider that matter based on the entirety of the evidence, not just that evidence presented at trial nor just the evidence denominated as being offered to prove falsity.

V. CONCLUSION

For the reasons explained above, we **AFFIRM** the district court's grant of a new trial. We, however, **VACATE** the post-verdict grant of summary judgment to AseraCare and **REMAND** for the district court to reconsider that decision in light of all the relevant evidence proffered by the Government.

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 18-3298

_____

UNITED STATES OF AMERICA and STATE OF NEW JERSEY ex rel. VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; RONNI O'BRIEN

v.

CARE ALTERNATIVES

Victoria Druding, Barbara Bain, Linda Coleman, and Ronni O'Brien
Appellants

_____

On Appeal from the United States
District Court for the District of New Jersey
(D.C. Civ. Action No. 1-08-cv-02126)
District Judge: Honorable Jerome B. Simandle

_____

Argued September 10, 2019

_____

Before: HARDIMAN, GREENAWAY, JR. and BIBAS,
Circuit Judges.

(Opinion filed: March 4, 2020)

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OPINION

GREENAWAY, JR., *Circuit Judge*.

This case requires us to consider whether and when clinical judgments can be considered "false" in the context of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733 (2009). It is a matter of first impression in this Court.

Victoria Druding, Linda Coleman, Barbara Bain, and Ronni O'Brien (collectively, "Appellants"), each of whom is a former employee of Appellee Care Alternatives, brought this FCA action alleging that Care Alternatives admitted patients who were ineligible for hospice care and directed its employees to improperly alter those patients' Medicare certifications to reflect eligibility. In support of their position, Appellants retained an expert. The expert opined in his report that, based on the records of the forty-seven patients he examined, the patients were inappropriately certified for hospice care thirty-five percent of the time.

Care Alternatives' expert disagreed and testified that a reasonable physician would have found all of the patients reviewed by Appellants' expert hospice-eligible on each occasion that Appellants' expert had deemed certification inappropriate. In considering Care Alternatives' summary judgment motion, the District Court determined that a mere difference of opinion between experts regarding the accuracy of the prognosis was insufficient to create a triable dispute of fact as to the element of falsity. In fact, the District Court required Appellants to instead provide evidence of an objective falsehood. Upon finding Appellants had not adduced such evidence, the District Court granted summary judgment in favor of Care Alternatives.

Today, we reject the District Court's objective-falsehood requirement for FCA falsity. Since we find that Appellants' expert testimony created a genuine dispute of material fact as to falsity, we will vacate the judgment and remand to the District Court for further proceedings consistent with this opinion.

I. BACKGROUND

Care Alternatives provides hospice care to patients throughout New Jersey. It employs a team of clinicians known as "interdisciplinary teams," ("IDTs") consisting of registered nurses, chaplains, social workers, home health aides, and therapists working alongside independent physicians who serve as hospice medical directors. The IDTs meet twice a month to review patient care plans and to identify any particular needs as well as discuss patients who are up for recertification of their need for hospice care.

Appellants are former employees of Care Alternatives, many of whom were clinicians that participated in IDTs. They brought this action under the FCA alleging, among other things, that Care Alternatives admitted ineligible patients and directed its employees to alter Medicare certifications to increase the number of eligible patients.

Before reaching the essential question of whether expert testimony may suffice to generate a genuine dispute as to a Medicare claim's falsity, we will review the requirements that hospice care providers must meet to qualify for Medicare reimbursement and the circumstances leading to this appeal.

A. Medicare Hospice Benefit

In 1983, Congress established the Medicare Hospice Benefit ("MHB"). *See* 48 Fed. Reg. 56,008 (Dec. 16, 1983) (codified at 42 C.F.R. pts. 400, 405, 408, 409, 418, 420, 421, 489). This regulation expanded the Health and Human Services Secretary's statutory authority to reimburse contractors that provide hospice care to eligible persons. 42 U.S.C. §§ 1395h (2006), 1395kk-1 (2015). Hospice care is considered palliative care, meaning it is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering." 42 C.F.R. § 418.3 (2019). It aims to "mak[e a terminally ill] individual as physically and emotionally comfortable as possible." 48 Fed. Reg. at 56,008. A patient who has been certified as eligible for hospice care and elects to receive the MHB waives the right to Medicare payment for "curative" care that is designed to help improve the individual's condition. *See* 42 U.S.C. § 1395d(d)(2)(A) (2005); 42 C.F.R. § 418.24(e) (2019); 72 Fed. Reg. 50,452, 50,452 (Aug. 22, 2014).

The Medicare provisions that set forth the conditions for payment of the MHB require that an individual be certified within a ninety-day period by one or more physicians as terminally ill. 42 U.S.C. § 1395f(a)(7)(A)(i). The patient must also be recertified in a similar manner for each additional sixty- or ninety-day period during which he or she remains in hospice care.[1] *Id*. § 1395f(a)(7)(A)(ii). An individual is considered "terminally ill" when the individual has a medical prognosis

[1] In relevant part, the statute states that:

payment for services furnished an individual may be made . . . only if . . . in the case of hospice care provided an individual—

> (A)(i) in the first 90-day period—
>
> > (I) the individual's attending physician . . . , and
> >
> > (II) the medical director . . . of the hospice care program providing (or arranging for) the care, each certify in writing at the beginning of the period, that the individual is terminally ill . . . based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and
>
> (ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment . . .

§ 1395f(a)(7)(A); *see also* § 1395f(a)(7)(B)–(E) (providing the other statutory prerequisites).

that the individual's life expectancy is six months or less, if the illness runs its normal course. *Id*. § 1395x(dd)(3)(A) (2018); 42 C.F.R. § 418.3.

Regulations promulgated by the Secretary add another requirement. *See* 42 C.F.R. § 418.20. The regulations provide that, "[i]n order to be eligible to elect hospice care under Medicare, an individual must be . . . (b) Certified as being terminally ill in accordance with § 418.22." *Id*. Section 418.22, in turn, imposes certain obligations on hospices regarding the timing, content, and source of a certification, in addition to a maintenance-of-records requirement. Among these is the requirement that

> [c]linical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

§ 418.22(b)(2) (2011).

Therefore, in order for a patient to be eligible to receive the MHB and for a hospice provider to be entitled to bill for such benefits, an individual's certification of terminal illness must be signed by at least one physician, and be accompanied by "[c]linical information and other documentation that support the medical prognosis" of terminal illness in the medical record. *Id.* Indeed, while the Center for Medicare & Medicaid Services, the agency responsible for administering health benefits, has recognized that "making a prognosis is not

an exact science," it has explained that this inexactitude "does not negate the fact that there must be a clinical basis for a certification[:] [a] hospice is *required* to make certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course." 79 Fed. Reg. at 50,470 (emphasis added); *see also* 70 Fed. Reg. 70,532, 70,534–35 (Nov. 22, 2005) ("A hospice needs to be certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course. A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare.").

B. Factual and Procedural Background

Appellants brought this suit under the *qui tam* provision of the FCA, which encourages actions by private individuals, called relators, who are entitled to a portion of the amount recovered, subject to certain limitations. *See* 31 U.S.C. § 3730(b), (d). Pursuant to the *qui tam* provision, Appellants filed their complaint under seal and provided the Government with the information upon which they intended to rely so that the Government could make an informed decision as to whether it should intervene and take over the case. *Id.* § 3730(b)(2). Appellants alleged that Care Alternatives submitted false hospice-reimbursement claims to Medicare and Medicaid between 2006 and 2007, in violation of the FCA, which finds liable any person who knowingly submits to the United States a false claim for payment or approval. 31 U.S.C. §§ 3729(a)(1)(A), 3730(b)(1).

Seven years after the complaint was filed, the Government notified the District Court of its decision not to intervene in this action. Appellants opted to proceed independently and served the First Amended Qui Tam Complaint upon Care Alternatives.

During discovery, the parties produced extensive evidence addressing whether Care Alternatives admitted ineligible patients. This included dueling expert opinions. Appellants' expert, Dr. Jayes, prepared a report as to whether patient certifications were accompanied by supporting documentation. He examined the records of forty-seven patients and opined that the documents did not support a certification of need for hospice in thirty-five percent of these patients' hospice certification periods. In his view, for those periods, any reasonable physician would have reached the conclusion he reached. He also found that the medical records were incomplete for at least three patients.

Care Alternatives' expert, Dr. Hughes, disagreed. For each certification that Dr. Jayes reviewed, Dr. Hughes opined that a physician could have reasonably determined that the prognosis for each patient was six months or less.

Care Alternatives moved for summary judgment arguing that Appellants could not make out the four prima facie elements of a claim under the FCA: falsity, causation, knowledge, and materiality. [2] *See United States ex rel.*

[2] Care Alternatives had also moved to dismiss the amended complaint for failure to comply with the statutory requirements of 31 U.S.C. § 3730(b)(2), which, among other things, requires a relator to submit a "written disclosure of substantially all material evidence and information the person possesses" in

Petratos v. Genentech Inc., 855 F.3d 481, 487 (3d Cir. 2017). Most relevant to this appeal were Care Alternative's arguments that Appellants had not produced sufficient evidence of falsity. The Government submitted a statement of interest urging the District Court to reject the argument that the FCA requires evidence of an "objective falsehood."

The District Court granted summary judgment to Care Alternatives based solely on failure to show falsity. Relying on two district court decisions from Alabama and Texas, it rejected the Government's assertions and held that a "mere difference of opinion between physicians, *without more*, is not enough to show falsity." *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669, 685 (D.N.J. 2018) (emphasis in original) (internal citation omitted). In doing so, it relied on the premise that medical opinions are subjective and cannot be false. *Id.* (quoting *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (finding that "scientific judgments about which reasonable minds may differ cannot be 'false'" (internal citation omitted))).

Regarding the element of falsity, the District Court adopted a standard not previously embraced or established by this Court, which required Appellants to show evidence of "an objective falsehood," that the physician's prognosis of terminal

order for the Government to decide whether it will intervene in an action or move to dismiss the complaint. 31 U.S.C. § 3730(b)(2), (c)(2)(A). The District Court denied the motion. *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669, 683–84 (D.N.J. 2018).

illness was incorrect, in order to prevail on the element of falsity. *Id.*

Appellants appealed, and the Government submitted an amicus brief advancing substantially the same argument as it had before the District Court.

II. JURISDICTION & STANDARD OF REVIEW

The District Court had jurisdiction pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, and we have jurisdiction pursuant to 28 U.S.C. § 1291. "Our review of a district court's decision at summary judgment is plenary," so, viewing "all facts in the light most favorable to the non-moving party and draw[ing] all inferences in that party's favor," "[w]e determine whether the moving party has established that there is no genuine dispute of material fact . . . ." *Forrest v. Parry*, 930 F.3d 93, 105 (3d Cir. 2019) (citations omitted).

III. DISCUSSION

The central question on appeal is whether a hospice-care provider's claim for reimbursement can be considered "false" under the FCA on the basis of medical-expert testimony that opines that accompanying patient certifications did not support patients' prognoses of terminal illness. The answer is a straightforward yes. In coming to this conclusion, we decline to adopt the District Court's "objective" falsity standard, as the test is inconsistent with the statute and contrary to this Court's interpretations of what is required for legal falsity. The District Court also erred in its determination that clinical judgments cannot be "false" for the purposes of FCA liability. In light of this analysis, we find Appellants' medical testimony creates a genuine dispute of material fact as to the element of falsity.

A.

In analyzing the statute's text, we find the premise of the District Court's holding—that a "mere difference of opinion" is insufficient to show FCA falsity—is at odds with the meaning of "false" under the statute. *Druding*, 346 F. Supp. 3d at 685. We also conclude that the District Court's "objective" falsity standard improperly conflates the elements of falsity and scienter, inconsistent with the application of the FCA.

As with any statutory interpretation question, our analysis begins with the text. *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). The FCA provides that any person who "knowingly presents, or causes to be presented, a *false or fraudulent* claim for payment or approval" is liable to the United States for a civil penalty between $5,000 and $10,000 as well as treble damages. 31 U.S.C. § 3729(a)(1)(A) (emphasis added). It also imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a *false or fraudulent* claim." *Id*. § 3729(a)(1)(B) (emphasis added).

Since Congress did not define what makes a claim "false" or "fraudulent" under the FCA, the Supreme Court has looked to common law to fill the definitional gap. *Escobar*, 136 S. Ct. at 1999–2000 ("[A]bsent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." (citation omitted)). Under the common law, an opinion can be considered "false" for purposes of liability. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183–86 (2015) (finding that an opinion may be a "false statement" in

determining liability under the securities laws); *Herskowitz v. Nutri/Sys., Inc.*, 857 F.2d 179, 184 (3d Cir. 1988) ("An opinion or projection . . . will be deemed untrue for purposes of the federal securities laws if it is issued without reasonable genuine belief or if it has no basis."); *see also* Restatement (Second) of Torts §§ 525 cmt. c, 539 cmt. a (1977) (instructing that an opinion may be false when the speaker makes an express statement contrary to the opinion he or she actually holds). Since there are circumstances in which an opinion may be considered "false" under common law, we find that the District Court's premise—an opinion is subjective and a difference of opinion is not enough to show falsity—is inconsistent with the meaning of "false" under the FCA.

Moreover, the District Court's "objective" falsity standard conflates the elements of scienter and falsity. Although the common law cases involving false opinions are often accompanied by a finding related to scienter, the plain language of the FCA denotes scienter as an element independent of falsity. 31 U.S.C. § 3729(a)(1)(A) (requiring "knowledge" separate from a "false or fraudulent claim"); *see Petratos*, 855 F.3d at 487 (stating an FCA violation has four elements: falsity, causation, knowledge, materiality). Combining the two elements into "falsity" reads the scienter element out of the text of the statute.

That scienter serves a distinct purpose under the FCA further supports separating the falsity and scienter analyses. Scienter helps to limit the possibility that hospice providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018) (noting scienter requirements are "rigorous" and can be

used to address excessive liability concerns). Indeed, the Supreme Court has instructed as much. *Escobar*, 136 S. Ct. at 2002 ("[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA]'s materiality and scienter requirements." (internal quotations and citations omitted)).

By requiring "factual evidence that Defendant's certifying doctor was making a *knowingly* false determination," the District Court's "objective" falsity standard conflates scienter and falsity. *Druding*, 346 F. Supp. 3d at 688 (emphases added). In finding that Appellants could not prove falsity because they had not produced evidence that any physician lied and "received a kickback to certify any patient as hospice eligible" or "certif[ied] any patient whom that physician believed was not hospice eligible," the District Court incorporated a scienter element into its analysis regarding falsity that was inconsistent with the text and application of the statute. *Id.* at 687.

B.

The District Court's "objective" falsity standard is also at odds with this Court's cases that have interpreted falsity to encompass a theory of liability based on non-compliance with regulatory instructions and not just objectively verifiable facts.

As the District Court itself recognized, a claim can be proven "false" in two ways: factually, when the facts contained within the claim are untrue, and legally, "when the claimant . . . falsely certifies that it has complied with *a statute or regulation* the compliance with which is a *condition* for

Government payment." *Druding*, 346 F. Supp. 3d at 682 (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)) (emphasis added) (internal quotation marks omitted); *see also Petratos*, 855 F.3d at 487 ("[A] claim can be false if it does not comply with statutory conditions for payment . . . ."); *Polukoff*, 895 F.3d at 741 (noting legal falsity can be express, such as a false affirmative statement of compliance with a statutory, regulatory, or contractual prerequisite, or it can be implied—for instance, the absence of a material disclosure that would have prevented compliance with a statutory, regulatory, or contractual prerequisite). Although legal falsity necessarily encompasses situations of factual falsity, for instance, where a physician's lies about medical test results would render certifications for reimbursement inaccurate and non-compliant with regulations, *cf. United States v. Paulus*, 894 F.3d 267, 273 (6th Cir. 2018), the District Court nevertheless limited its analysis to factual falsity.

According to the District Court, a medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy. In other words, opinions being subjective, a differing medical conclusion regarding a patient's prognosis alone is not enough to show the certifying physician's determination of terminal illness was factually incorrect.

We disagree with the District Court's decision to circumscribe FCA falsity to findings of factual falsity. This runs contrary to the cases in this Court, which have recognized falsity to include legal falsity. *See, e.g.*, *Petratos*, 855 F.3d at 486; *Wilkins*, 659 F.3d at 305; *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 441 (3d Cir. 2004); *see also United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)

(observing that the FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government"). In other words, our cases instruct that FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government. *See Wilkins*, 659 F.3d at 305 (explaining that "[a] legally false FCA claim is based on a 'false certification' theory of liability" (citations omitted)); *see also United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005) ("Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed.").

Under legal falsity, Appellants must show that Care Alternatives failed to meet at least one of the two regulatory requirements: (1) that a physician certified the patient is terminally ill and (2) that the certification is in accordance with section 418.22, which requires that "[c]linical information and other documentation that support the medical prognosis [] accompany the certification . . . ." 42 C.F.R. §§ 418.20, 418.22(b)(2). Based on this theory, we find that disagreement between experts as to a patient's prognosis may be evidence of the latter; its relevance need not be limited to evidence of the accuracy of another physician's judgment.

This interpretation is also supported by the Tenth Circuit, which recently reversed a similar district court decision that had adopted an "objective" falsity requirement for FCA claims. *Polukoff*, 895 F.3d at 743, 745–46. In *Polukoff*, the Tenth Circuit considered whether a cardiologist falsely represented in his claims for Medicare reimbursement that the procedures he was performing were reasonable and necessary. *Id*. at 735, 738–39. In finding it "possible for a

medical judgment to be 'false or fraudulent' as proscribed by the FCA," the Tenth Circuit emphasized that liability is not premised on factual falsity alone, but a certification is false simply "if the procedure was not reasonable and necessary under the government's definition of the phrase." *Id*. at 742–43. There, the Tenth Circuit adopted the view that FCA falsity is based on legal falsity—that falsity is simply a question of whether the claim is reimbursable, that is, compliant with the Medicare reimbursement instructions. *Id*. at 742–43. In so doing, it found that the plaintiff-physician's opinion that the defendant-cardiologist's procedures were not "reasonable and necessary" was a cognizable allegation as to whether the cardiologist's reimbursement claims were "false" for failing to comply with Medicare procedures. *Id*. at 743–44.

So, based on our cases and the Tenth Circuit's rationale in *Polukoff*, we will not limit our inquiry to factual falsity and instead apply a theory of legal falsity.

C.

Moreover, we reject the District Court's bright-line rule that a doctor's clinical judgment cannot be "false." In *United States v. Paulus*, the Sixth Circuit reversed a cardiologist's acquittal for healthcare fraud based on expert testimony that he recorded severe arterial blockage in patients' medical records when the angiograms showed only mild or no blockage. 894 F.3d at 276–77, 280. In doing so, the Sixth Circuit stressed that medical "opinions are not, and have never been, completely insulated from scrutiny." *Id*. at 275. For example, "opinions may trigger liability for fraud when they are not honestly held by their maker. . . ." *Id.* Such was the case in *Paulus* where the defendant was charged with lying about the results of angiograms he conducted and billed taxpayers for

procedures conducted based on those results. *Id.* at 272–73. As the Sixth Circuit explained, a good faith medical opinion is not punishable, but a bright-line rule that medical opinions can never be false fails to hold accountable a physician who "saw one thing on the angiogram and consciously wrote down another, and then used that misinformation to perform and bill unnecessary procedures." *Id*. at 276. The court concluded that whether the defendant was acting in good faith or committing fraud by misrepresenting the angiogram results was an appropriate question for the jury. *Id*. at 276–77; *see also United States v. Rockwell*, 781 F.2d 985, 990 (3d Cir. 1986) ("The law will not countenance a usurpation by the court of the function of the jury to decide the facts and to assess the credibility of the witnesses."). In weighing that decision, the jury could consider evidence of different doctors who had interpreted the angiograms differently. *Paulus*, 894 F.3d at 276–77.

We can apply these same principles to our civil FCA case. The "reliability and believability of expert testimony . . . is exclusively for the jury to decide." *Id*. at 277 (citations omitted). Contrary to the District Court's reasoning, medical opinions may be "false" and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider on the question of falsity.

D.

In adopting and applying an "objective" falsity standard, the District Court relied on *United States v. AseraCare Inc.*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015) ("*AseraCare I*") and *United States v. AseraCare Inc.*, 176 F.

Supp. 3d 1282 (N.D. Ala. 2016) ("*AseraCare II*").[3] Since the Eleventh Circuit issued its opinion affirming both *AseraCare I* and *AseraCare II*'s adoption of the "objective" falsity standard shortly before oral argument in this case, we briefly discuss our reasons for departing from our sister circuit. *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019) ("*AseraCare III*").

In *AseraCare*, former employees of the defendant hospice provider brought a *qui tam* suit alleging that AseraCare had a practice of knowingly submitting unsubstantiated

[3] It also relied on *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016) ("*Vista Hospice*"), an unreported case from the Northern District of Texas whose relevant facts and holding are nearly identical to those in *AseraCare I* and *AseraCare II*. Like Appellants here and the plaintiffs in *AseraCare*, the plaintiff-relator in *Vista Hospice* was also a former employee of the defendants, which are hospice care providers in fourteen states. *Vista Hospice*, 2016 WL 3449833, at *1. The *qui tam* suit alleged that the defendants violated the FCA by "causing patients who were not eligible for the MHB to be certified as eligible, and then submitting claims for ineligible patients[.]" *Id*. As here, the district court granted summary judgment in favor of defendants, finding that a report by the relator's expert, a hospice physician, insufficient to create a genuine dispute of material fact regarding the element of falsity. *Id.* at *5, *17–18 (holding that "[a] testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity" (citing *AseraCare II*, 176 F. Supp. 3d at 1283)).

Medicare claims in violation of the FCA. *Id.* at 1284. The Government chose to intervene. *Id*. In deciding AseraCare's first motion for summary judgment, the district court declined to adopt a "reasonable doctor" standard for the assessment of falsity, which would have required the Government to show that a reasonable physician could not have held the opinion that the patient was certifiably ill. *Id*. at 1285–86. The case proceeded to a bifurcated trial where the falsity element was tried first, followed by the remaining elements and the other common law claims in the second phase. *Id*. at 1286. During the first phase, the parties presented dueling expert opinions from two doctors about whether, based on their own clinical judgment, the medical records of particular patients supported AseraCare's certifications that the patients were terminally ill. *Id*. at 1287. The question was then put to the jury to decide which expert's testimony was more persuasive. *Id*. at 1288–89. Following the partial verdict in which the jury found some of the medical records supported AseraCare's certifications and some did not, AseraCare moved for judgment as a matter of law, arguing that the court had articulated the wrong standard for falsity in its instructions to the jury. This time, the district court agreed that it had committed reversible error and that it should have advised the jury that the FCA's falsity element requires proof of an objective falsehood and that "a mere difference of opinion [between physicians] , *without more*, is not enough to show falsity." *AseraCare I*, 153 F. Supp. 3d at 1384.

The district court then took the extra step of considering summary judgment *sua sponte* and, after additional briefing from the parties, granted summary judgment in AseraCare's favor based on the district court's newly adopted "objective" falsity standard. *AseraCare II*, 176 F. Supp. 3d at 1284, 1286.

On appeal, the Eleventh Circuit affirmed the district court's adoption of the "objective" falsity test. *AseraCare III*, 938 F.3d at 1296–97. In setting up its discussion of FCA falsity, the Eleventh Circuit rejected the Government's framing of the falsity inquiry as a question of "whether the clinical information and other documentation accompanying a certification of terminal illness support[s] . . . the physician's certification." *Id.* at 1294. Instead, it concluded that the supporting documentation requirement is only designed to address the mandate that there be a medical basis for certification. *Id*. at 1296–97. In deciding a claim's eligibility is therefore premised on the physician's clinical judgment and decision to certify a patient as terminally ill, the Eleventh Circuit limited the relevant inquiry to whether the Government had adduced sufficient evidence of "the accuracy of the physician's clinical judgment regarding terminality." *Id.* at 1294, 1296.

We depart from this framing of FCA falsity. As previously articulated, limiting falsity to factual falsity is inconsistent with our case law, which reads FCA falsity more broadly as legal falsity, encompassing circumstances where a claim for reimbursement is non-compliant with requirements under the statute and regulations. The MHB regulations state two requirements: (1) that a physician certifies the patient as terminally ill and (2) that clinical information and documentation supporting the prognosis accompany the certification. 42 C.F.R. §§ 418.20, 418.22(b)(2). Under a legal falsity theory, a medical opinion that differs from the certifying physician's opinion is therefore relevant evidence of the latter requirement, whether there was documentation accompanying the certification that supported the medical prognosis.

The Eleventh Circuit also determined that clinical judgments cannot be untrue. *AseraCare III*, 938 F.3d at 1297. ("[A] reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments . . . are false under the FCA."). We again disagree. In reaching the opposite determination, we invoke the principles previously articulated—that the common-law definition of fraud permits a finding that subjective opinions may be considered false and that medical opinions can be false and are not shielded from scrutiny. *Paulus*, 894 F.3d at 276–77. We therefore find that a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity.

This does not mean that objectivity is never relevant for FCA liability. However, we find that objectivity speaks to the element of *scienter*, not *falsity*. As discussed above, the text and application of the FCA require that the elements of falsity and scienter be analyzed separately. In fact, *AseraCare III* supports this position. The Eleventh Circuit affirmed the adoption of the "objective" falsity test, but it reversed the District Court's *sua sponte* grant of summary judgment in favor of the defendants and remanded for further consideration of evidence the Government had intended to present to show "knowledge of the falsity of the claim." *AseraCare III*, 938 F.3d at 1302. Although the Eleventh Circuit instructions on remand were to consider all of the evidence "to determine whether a triable issue existed regarding *falsity*," *id.* at 1303 (emphasis added), we make clear that in our Court, findings of falsity and scienter must be independent from one another for

purposes of FCA liability.[4] More than a formality, we seek to avoid the precise outcome in *AseraCare II*, where the district court folded the element of scienter into its "objective" falsity test, but failed to fully consider evidence of scienter and, as a result, prematurely granted summary judgment.

For these reasons, we are persuaded that the District Court's reliance on *AseraCare II* was misplaced.

E.

Since the District Court's decision to grant summary judgment in favor of Care Alternatives was based solely on its analysis of the falsity element, our decision is limited to the same. So, regarding FCA falsity, we reject the objective falsehood standard. Instead, we hold that for purposes of FCA falsity, a claim may be "false" under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements. We also find that a physician's judgment may be scrutinized and considered "false."

We therefore find that a physician's expert testimony challenging a hospice certification creates a triable issue of fact for the jury regarding falsity. Since Dr. Jayes's expert report

[4] We acknowledge that the Seventh Circuit's view differs somewhat from our instruction to keep falsity and scienter separate. *United States ex rel. Yannocopoulos v. Gen. Dynamics*, 652 F.3d 818, 836–37 (7th Cir. 2011) (citing *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (requiring an objective falsehood based on a test that conflates an analysis of the falsity and knowledge elements)).

has done just that, we conclude the report was sufficient evidence to create a genuine dispute of material fact. Having found that Appellants adduced enough evidence to overcome summary judgment as to the element of falsity, we need not address Appellants' other arguments regarding whether the evidence they submitted met the District Court's erroneous "objective" falsity test. Nor do we opine as to Appellants' odds of surviving summary judgment on the other prima facie elements, which the District Court did not reach.

IV. CONCLUSION

We therefore reverse the District Court's grant of summary judgment in favor of Defendant and remand for consideration of the other elements of FCA liability, consistent with this opinion.

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JANE WINTER, ex rel. United States of America, *Plaintiff-Appellant,* v. GARDENS REGIONAL HOSPITAL AND MEDICAL CENTER, INC., DBA Tri-City Regional Medical Center, a California corporation; ROLLINSNELSON LTC CORP., a California corporation; VICKI ROLLINS; BILL NELSON; S&W HEALTH MANAGEMENT SERVICES, INC., a California corporation; BERYL WEINER; PRODE PASCUAL, M.D.; RAFAELITO VICTORIA, M.D.; ARNOLD LING, M.D.; CYNTHIA MILLER-DOBALIAN, M.D.; EDGARDO BINOYA, M.D.; NAMIKO NERIO, M.D.; MANUEL SACAPANO, M.D., *Defendants-Appellees.*	No. 18-55020 D.C. No. 2:14-cv-08850-JFW-E OPINION

Appeal from the United States District Court
for the Central District of California
John F. Walter, District Judge, Presiding

Argued and Submitted September 13, 2019
Pasadena, California

Filed March 23, 2020

Before: Johnnie B. Rawlinson, John B. Owens, and Mark J. Bennett, Circuit Judges.

Opinion by Judge Bennett

SUMMARY[*]

False Claims Act

The panel reversed the district court's dismissal for failure to state a claim and remanded in an action under the False Claims Act, alleging that defendants submitted, or caused to be submitted, Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary.

Plaintiff alleged that the admissions were not medically necessary and were contraindicated by the patients' medical records and the hospital's own admissions criteria. The district court held that "to prevail on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation," and so a statement that implicates a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions . . . cannot be proven to be objectively false."

[*] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that a plaintiff need not allege falsity beyond the requirements adopted by Congress in the FCA, which primarily punishes those who submit, conspire to submit, or aid in the submission of false or fraudulent claims. The panel stated that Congress imposed no requirement of objective falsity, and the panel had no authority to rewrite the statute to add such a requirement. The panel held that a doctor's clinical opinion must be judged under the same standard as any other representation. A doctor, like anyone else, can express an opinion that he knows to be false, or that he makes in reckless disregard of its truth or falsity. Agreeing with other circuits, the panel therefore held that a false certification of medical necessity can give rise to FCA liability. The panel also held that a false certification of medical necessity can be material because medical necessity is a statutory prerequisite to Medicare reimbursement.

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OPINION

BENNETT, Circuit Judge:

Appellant-Relator Jane Winter ("Winter"), the former Director of Care Management at Gardens Regional Hospital ("Gardens Regional"), brought this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–33. Winter alleges Defendants[1] submitted, or caused to be submitted, Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary. Winter alleges that the admissions were not medically necessary and were contraindicated by the patients' medical records and the hospital's own admissions criteria. The district court dismissed Winter's second amended complaint ("the complaint") for failure to state a claim. The district court held that "to prevail on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation," so a statement that implicates a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions . . . cannot be proven to be objectively false."

We have jurisdiction under 28 U.S.C. § 1291. We hold that a plaintiff need not allege falsity beyond the requirements adopted by Congress in the FCA, which primarily punishes those who submit, conspire to submit, or aid in the submission of false or fraudulent claims. Congress imposed no requirement of proving "objective falsity," and we have no authority to rewrite the statute to add such a

[1] The Defendants include Gardens Regional Hospital, the hospital management company (S&W Health Management Services) and its owners (RollinsNelson, Rollins, Nelson, and Weiner), and individual physicians who diagnosed and admitted patients.

requirement. A doctor's clinical opinion must be judged under the same standard as any other representation. A doctor, like anyone else, can express an opinion that he knows to be false, or that he makes in reckless disregard of its truth or falsity. *See* 31 U.S.C. § 3729(b)(1). We therefore hold that a false certification of medical necessity can give rise to FCA liability.[2] We also hold that a false certification of medical necessity can be material because medical necessity is a statutory prerequisite to Medicare reimbursement. Accordingly, we reverse and remand.

BACKGROUND

A. The "Medical Necessity" Requirement

The Medicare program provides basic health insurance for individuals who are 65 or older, disabled, or have end-stage renal disease. 42 U.S.C. § 1395c. "[N]o payment may be made . . . for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). Medicare reimburses providers for inpatient hospitalization only if "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose[.]" 42 U.S.C. § 1395f(a)(3).

The Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS"), administers the

[2] The FCA covers claims that are "false or fraudulent." 31 U.S.C. § 3729(a)(1). For convenience, we will generally use "false" to mean "false or fraudulent."

Medicare program and issues guidance governing reimbursement. CMS defines a "reasonable and necessary" service as one that "meets, but does not exceed, the patient's medical need," and is furnished "in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition . . . in a setting appropriate to the patient's medical needs and condition[.]" CMS, Medicare Program Integrity Manual § 13.5.4 (2019). The Medicare program tells patients that "medically necessary" means health care services that are "needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." CMS, Medicare & You 2020: The Official U.S. Government Medicare Handbook 114 (2019).

Admitting a patient to the hospital for inpatient—as opposed to outpatient—treatment requires a formal admission order from a doctor "who is knowledgeable about the patient's hospital course, medical plan of care, and current condition." 42 C.F.R. § 412.3(b). Inpatient admission "is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights," but inpatient admission can also be appropriate under other circumstances if "supported by the medical record." *Id.* § 412.3(d)(1), (3).

The Medicare program trusts doctors to use their clinical judgment based on "complex medical factors," but does not give them unfettered discretion to decide whether inpatient admission is medically necessary: "The factors that lead to a particular clinical expectation *must be documented in the medical record* in order to be granted consideration." *Id.* § 412.3(d)(1)(i) (emphasis added). And the regulations consider medical necessity a question of fact: "No

presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification . . . in determining the medical necessity of inpatient hospital services . . . . A physician's order or certification will be evaluated in the context of the evidence in the medical record." *Id.* § 412.46(b).

B. The False Claims Act

The FCA imposes significant civil liability on any person who, *inter alia*, (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or (C) "conspires to commit a violation of subparagraph (A), [or] (B)[.]" 31 U.S.C. § 3729(a)(1). The Act allows private plaintiffs to enforce its provisions by bringing a *qui tam* suit on behalf of the United States. *Id.* § 3730(b).

A plaintiff must allege: "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing, (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). Winter's allegations fall under a "false certification" theory of FCA liability.[3] *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016). Because medical necessity is a condition of payment, every Medicare claim includes an express or implied certification that treatment was medically necessary. Claims for unnecessary treatment are false claims. Defendants act with the required scienter if they know the treatment was not

[3] The complaint alleges both express and implied false certification.

medically necessary, or act in deliberate ignorance or reckless disregard of whether the treatment was medically necessary. *See* 31 U.S.C. § 3729(b)(1).

C. The Allegations in Winter's Complaint[4]

Winter, a registered nurse, became the Director of Care Management and Emergency Room at Gardens Regional in August 2014, and came to the job with thirteen years of experience as a director of case management at hospitals in Southern California and Utah.

Winter reviewed hospital admissions using the admissions criteria adopted by Gardens Regional—the InterQual Level of Care Criteria 2014 ("the InterQual criteria"). The InterQual criteria, promulgated by McKesson Health Solutions LLC and updated annually, "are reviewed and validated by a national panel of clinicians and medical experts," and represent "a synthesis of evidence-based standards of care, current practices, and consensus from licensed specialists and/or primary care physicians." Medicare uses the criteria to evaluate claims for payment. And, as the criteria require a secondary review of all care decisions, Winter's job included reviewing Garden Regional patients' medical records and applying the criteria to evaluate the medical necessity of hospital admissions.

In mid-July 2014, Defendant RollinsNelson—which owned and operated nursing facilities in the Los Angeles area—acquired a 50% ownership interest in Defendant S&W, the management company that oversaw operations at

[4] All facts are taken from Winter's second amended complaint. "We accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Outdoor Media Grp., Inc. v. City of Beaumont*, 506 F.3d 895, 900 (9th Cir. 2007).

Gardens Regional. RollinsNelson then began jointly managing the hospital with S&W. When Winter started work, she noticed that the emergency room saw an unusually high number of patients transported from RollinsNelson nursing homes, including from a facility sixty miles away. The RollinsNelson patients were not just treated on an outpatient basis or held overnight for observation—most were admitted for inpatient hospitalization. In August 2014, 83.5% of the patients transported from RollinsNelson nursing homes were admitted to Gardens Regional for inpatient treatment—an unusually high admissions rate based on Winter's experience and judgment.

Winter was concerned about this pattern and scrutinized Gardens Regional's admissions statistics, comparing July and August 2014 to prior months. She realized that the spike in admissions from RollinsNelson nursing homes corresponded with RollinsNelson's acquisition of S&W. Not only did the number of admissions increase, the number of Medicare beneficiaries admitted rose as well. The number of Medicare beneficiaries admitted in August 2014, for example, surpassed that of any month before RollinsNelson began managing the hospital. Winter alleges that RollinsNelson and S&W—including the individual owners of both entities—"exerted direct pressure on physicians to admit patients to [Gardens Regional] and cause false claims to be submitted based on false certifications of medical necessity."

Winter's complaint details sixty-five separate patient admissions—identified by the admitting physician, patient's initials, chief complaint, diagnosis, length of admission, the Medicare billing code, and the amount billed to Medicare—that Winter alleges did not meet Gardens Regional's admissions criteria and were unsupported by the patients'

medical records. She alleges that none of the admissions were medically necessary. Winter observed several trends: i) admitting patients for urinary tract infections ("UTIs") ordinarily treated on an outpatient basis with oral antibiotics; ii) admitting patients for septicemia with no evidence of sepsis in their records; and iii) admitting patients for pneumonia or bronchitis with no evidence of such diseases in their medical records. Winter estimates that in less than two months—between July 14 and September 9, 2014—Gardens Regional submitted $1,287,701.62 in false claims to the Medicare program.

Winter repeatedly tried to bring her concerns to the attention of hospital management, with no success. In her first week, she reported the high number of unnecessary admissions to the hospital's Chief Operating Officer. After receiving no response, she reached out to the hospital's Chief Executive Officer. When she still received no response, she tried confronting Dr. Sacapano directly. He told her: "You know who I'm getting pressure from." Winter understood Dr. Sacapano to mean the hospital management.

At the beginning of September 2014, Defendants Rollins, Nelson and Weiner—the owners of S&W and RollinsNelson—"called an urgent impromptu meeting," and "instructed case management not to question the admissions to [Gardens Regional.]" When Winter tried to speak up, Rollins cut her off, using profanity. Shortly after the meeting, Rollins instructed one of the hospital's case managers to "coach" physicians, explaining in an email that "[t]hese Mds will most likely increase their admits because their documentation will be 'assisted.'"

In November 2014, Gardens Regional fired Winter and replaced her with an employee who had never questioned

any inpatient admissions. Winter filed her complaint a week later.

D. Procedural History

In November 2017, after the Government had declined to intervene and Winter had filed the second amended complaint, Defendants RollinsNelson, Rollins, Nelson, S&W, Weiner and Dr. Pascual filed motions to dismiss the complaint for failure to state a claim.[5] The district court granted the motions, dismissing Winter's three FCA claims against all Defendants for the same reasons: (1) because a determination of "medical necessity" is a "subjective medical opinion[] that cannot be proven to be objectively false," and (2) because the alleged false statements, which the district court characterized as the "failure to meet InterQual criteria," were not material.[6]

STANDARD OF REVIEW

We review the grant of a motion to dismiss de novo. *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1030 (9th Cir. 2008). "In reviewing the dismissal of a complaint, we inquire whether the complaint's factual

[5] At oral argument, Winter's counsel acknowledged that Dr. Sacapano and Dr. Nerio had not yet been served with the second amended complaint when the district court, in granting the moving Defendants' motions to dismiss, sua sponte dismissed the complaint against them as well. Oral Argument at 10:58, *Winter v. Gardens Regional Hosp., et al.*, No. 18-55020 (9th Cir. Sept. 13, 2019), https://www.ca9.uscourts.gov/media/view_video.php?pk_vid=0000016196.

[6] The district court did not dismiss Winter's retaliation claim against Gardens Regional. Winter voluntarily dismissed that claim without prejudice to allow for an appeal.

allegations, together with all reasonable inferences, state a plausible claim for relief." *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 (9th Cir. 2011). As with all fraud allegations, a plaintiff must plead FCA claims "with particularity" under Federal Rule of Civil Procedure 9(b). *Id.*

DISCUSSION

A. Winter properly alleges false or fraudulent statements

We interpret the FCA broadly, in keeping with the Congress's intention "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). For that reason, the Supreme Court "has consistently refused to accept a rigid, restrictive reading" of the FCA, *id.*, and has cautioned courts against "adopting a circumscribed view of what it means for a claim to be false or fraudulent," *Escobar*, 136 S. Ct. at 2002 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)).

"[W]e start, as always, with the language of the statute." *Id.* at 1999 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 668 (2008)). The plain language of the FCA imposes liability for presenting, or causing to be presented, a "false or fraudulent claim for payment or approval," making "a false record or statement material to a false or fraudulent claim," or conspiring to do either. 31 U.S.C. § 3729(1)(A)–(C). Because Congress did not define "false or fraudulent," we presume it incorporated the common-law definitions, including the rule that a statement need not contain an "express falsehood" to be actionable. *Escobar*, 136 S. Ct. at 1999 ("[I]t is a settled principle of

interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." (quoting *Sekhar v. United States*, 570 U.S. 729, 732 (2013))). And, in at least one respect, Congress intended for the FCA to be broader than the common law: Under the FCA, "'knowingly' . . . require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B).

"[O]pinions are not, and have never been, completely insulated from scrutiny." *United States v. Paulus*, 894 F.3d 267, 275–76 (6th Cir. 2018) (upholding conviction for Medicare fraud where physician justified unnecessary procedures by exaggerating his interpretation of medical tests); *see also Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1049 (9th Cir. 2012) (holding that false estimates "can be a source of liability under the FCA"). Under the common law, a subjective opinion is fraudulent if it implies the existence of facts that do not exist, or if it is not honestly held. Restatement (Second) of Torts § 525; *id.* § 539. As the Supreme Court recognized, "the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 191 (2015) (quoting W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 109, at 760 (5th ed. 1984)).

Defendants and amici curiae American Health Care Association, National Center for Assisted Living, and California Association of Health Facilities urge this court to hold the FCA requires a plaintiff to plead an "objective falsehood." But "[n]othing in the text of the False Claims Act supports [Defendants'] proposed restriction." *Escobar*, 136 S. Ct. at 2001. Under the plain language of the statute,

the FCA imposes liability for all "false or fraudulent claims"—it does not distinguish between "objective" and "subjective" falsity or carve out an exception for clinical judgments and opinions.

Defendants are correct that if clinical judgments can be fraudulent under the FCA, doctors will be exposed to liability they would not face under Defendants' view of the law. "But policy arguments cannot supersede the clear statutory text." *Id.* at 2002. Our role is "to apply, not amend, the work of the People's representatives." *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1726 (2017). And the Supreme Court has already addressed Defendants' concern: "Instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *Escobar*, 136 S. Ct. at 2002 (quotation marks, alterations, and citation omitted).

We have similarly explained that the FCA requires "the 'knowing presentation of what is known to be false'" and that "[t]he phrase 'known to be false'. . . does not mean 'scientifically untrue'; it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors." *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (citations omitted), *overruled on other grounds by United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121 (9th Cir. 2015) (en banc). This does not mean, as the district court understood it, that only "objectively false" statements can give rise to FCA liability. It means that falsity is a necessary, but not sufficient, requirement for FCA liability—after alleging a false statement, a plaintiff must still establish scienter. *Id.* ("What is false as a matter of science is not, by that very fact, wrong as a matter of

morals."). To be clear, a "scientifically untrue" statement is "false"—even if it may not be actionable because it was not made with the requisite intent. And an opinion with no basis in fact can be fraudulent if expressed with scienter.

We are not alone in concluding that a false certification of medical necessity can give rise to FCA liability. In *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, the Fifth Circuit recognized that "claims for medically unnecessary treatment are actionable under the FCA." 355 F.3d 370, 376 (5th Cir. 2004). The plaintiff alleged the defendants filed false claims "for services that were . . . medically unnecessary," *id.* at 373, and the Fifth Circuit reversed the district court's dismissal for failure to state a claim, explaining that because the complaint alleged that the defendants ordered medical services "knowing they were unnecessary," the statements were lies, not simply errors. *Id.* at 376.

Likewise, in *United States ex rel. Polukoff v. St. Mark's Hospital*, the Tenth Circuit recognized "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA[.]" 895 F.3d 730, 742 (10th Cir. 2018). The court looked to CMS's definition of "medically necessary," and held, "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Id.* at 743. The Third Circuit reached a similar conclusion in *United States ex rel. Druding v. Care Alternatives*, No. 18-3298, 2020 WL 1038083 (3d Cir. Mar. 4, 2020), rejecting the "bright-line rule that a doctor's clinical judgment cannot be 'false.'" *Id.* at *7 (holding that, in the context of certifying terminal illness, "for purposes of FCA falsity, a claim may be 'false' under a theory of legal falsity, where it fails to

comply with statutory and regulatory requirements," and that "a physician's judgment may be scrutinized and considered 'false,'" *id.* at *9).

The Eleventh Circuit's recent decision in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), is not directly to the contrary. In *AseraCare*, the Eleventh Circuit held that "a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is *only* a reasonable disagreement between medical experts as to the accuracy of that conclusion, *with no other evidence* to prove the falsity of the assessment." *Id.* at 1281 (emphases added). We recognize that the court also said "a claim that certifies that a patient is terminally ill . . . cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood." *Id.* at 1296–97. But we conclude that our decision today does not conflict with *AseraCare* for two reasons.

First, the Eleventh Circuit was not asked whether a medical opinion could ever be false or fraudulent, but whether a reasonable disagreement between physicians, *without more*, was sufficient to prove falsity at summary judgment. *Id.* at 1297–98. Notwithstanding the Eleventh Circuit's language about "objective falsehoods," the court clearly did not consider all subjective statements—including medical opinions—to be incapable of falsity, and identified circumstances in which a medical opinion would be false.[7]

[7] For example, "if the [doctor] does not actually hold that opinion" or simply "rubber-stamp[s] whatever file was put in front of him," if the opinion is "based on information that the physician knew, or had reason to know, was incorrect," or if "no reasonable physician" would agree

Second, the Eleventh Circuit recognized that its "objective falsehood" requirement did not necessarily apply to a physician's certification of medical necessity—explicitly distinguishing *Polukoff*. *Id.* at 1300 n.15. Rather, the court explained that the "hospice-benefit provision at issue" purposefully defers to "whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion" whether a patient was terminally ill.[8] *Id.*; *see also id.* at 1295. In fact, after holding that physicians' hospice-eligibility determinations are entitled to deference, the Eleventh Circuit explained that the less-deferential medical necessity requirement remained an important safeguard: "The Government's argument that our reading of the eligibility framework would 'tie CMS's hands' and 'require improper reimbursements' is contrary to the plain design of the law" because "CMS is statutorily prohibited from reimbursing providers for services 'which are not reasonable and necessary[.]'" *Id.* at 1295 (alteration and citation omitted). Thus, for the same reason the Eleventh Circuit recognized *AseraCare* did not conflict with *Polukoff*, we believe our decision does not conflict with *AseraCare*. And to the extent that *AseraCare* can be read to graft any type of "objective falsity" requirement onto the FCA, we

with the doctor's opinion, "based on the evidence[.]" *AseraCare*, 938 F.3d at 1302.

[8] A patient must have less than six months to live to be eligible for hospice care. *AseraCare*, 938 F.3d at 1282. But, as the Eleventh Circuit explained, CMS "repeatedly emphasized that '[p]redicting life expectancy is not an exact science,' [and that] 'certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill.'" *Id.* at 1295 (quoting 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010) and 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013)). By contrast, a certification of medical necessity is not entitled to deference. 42 C.F.R. § 412.46(b).

reject that proposition. *See Druding*, 2020 WL 1038083, at *8.

In sum, we hold that the FCA does not require a plaintiff to plead an "objective falsehood." A physician's certification that inpatient hospitalization was "medically necessary" can be false or fraudulent for the same reasons any opinion can be false or fraudulent. These reasons include if the opinion is not honestly held, or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist. *See Polukoff*, 895 F.3d at 742–43.

We now turn to Winter's complaint. We accept all facts alleged as true and draw all inferences in Winter's favor, and conclude that her complaint plausibly alleges false certifications of medical necessity.

First, the complaint "alleges a 'scheme' connoting knowing misconduct." *Riley*, 355 F.3d at 376. RollinsNelson and S&W—and their individual owners Rollins, Nelson and Weiner—had a motive to falsify Medicare claims and pressure doctors to increase admissions. Gardens Regional relied on Medicare for a "significant portion" of its revenue, and the spike in admissions corresponded with an increased number of Medicare beneficiaries in its care. Moreover, the increased admissions of RollinsNelson patients began when RollinsNelson started managing Gardens Regional.

Second, not only does Winter identify suspect trends in inpatient admissions—for example, hospitalizing patients for UTIs—she also alleges statistics showing an overall increase in hospitalizations once RollinsNelson started managing the hospital. For example, the daily occupancy

rate jumped by almost 10%, the number of Medicare beneficiaries became the highest it had ever been by a significant margin, and the admissions rate from RollinsNelson nursing homes was over 80%. Plus, the large number of admissions that did not meet the criteria, and the fact that the vast majority of admissions came from a single doctor—Dr. Pascual, who had contractually agreed to use the InterQual criteria—decreases the likelihood that any given admission was an outlier.

Third, Winter's detailed allegations as to each Medicare claim support an inference of falsity. This is not a complaint that "identifies a general sort of fraudulent conduct but specifies no particular circumstances of any discrete fraudulent statement[.]" *Cafasso*, 637 F.3d at 1057. The complaint identifies sixty-five allegedly false claims in great detail, listing the date of admission, the admitting physician, the patient's chief complaint and diagnosis, and the amount billed to Medicare. The complaint alleges that each admission failed to satisfy the hospital's own admissions criteria—the InterQual criteria that Gardens Regional and Dr. Pascual had contractually agreed to use and that Winter's job as Director of Care Management required her to apply. And, as the district court recognized, the InterQual criteria represent the "consensus of medical professionals' opinions," so a failure to satisfy the criteria also means that the admission went against the medical consensus.

Finally, we note that many of the allegations supporting an inference of scienter also support an inference of falsity. *Cf. AseraCare*, 938 F.3d at 1304–05 (remanding for district court to consider evidence related to scienter in determining falsity on summary judgment). For example, when confronted, Dr. Sacapano corroborated Winter's suspicions, telling her that hospital management pressured him into

recommending patients for medically unnecessary inpatient admission. And following Winter's numerous attempts to bring her concerns to the attention of hospital management, Defendants Rollins, Nelson, and Weiner held a meeting where they instructed Winter and other staff not to question the admissions.

Defendants argue that "Winter has alleged nothing more than her competing opinion with the treating physicians who actually saw the patients at issue." The district court similarly dismissed the complaint because Winter's "contention that the medical provider's certifications were false is based on her own after-the-fact review of [Gardens Regional's] admission records." To begin with, an opinion can establish falsity. *See Paulus*, 894 F.3d at 270, 277 (affirming doctor's conviction for healthcare fraud by performing medically unnecessary procedures and holding that experts' "opinions, having been accepted into evidence, are sufficient to carry the government's burden of proof"); *cf. AseraCare*, 938 F.3d at 1300 (distinguishing *Paulus* because in *AseraCare* "the Government's expert witness declined to conclude that [the clinical judgments of] AseraCare's physicians . . . were unreasonable or wrong"). Winter alleges more than just a reasonable difference of opinion. In addition to the allegations discussed above, she alleges that a number of the hospital admissions were for diagnoses that had been disproven by laboratory tests, and that several admissions were for psychiatric treatment, even though Gardens Regional was not a psychiatric hospital—and one of those patients never even saw a psychiatrist. Even if we were to discount Winter's evaluation of the medical records, as the district court did, the other facts she alleges would be sufficient to make her allegations of fraud plausible.

But more importantly, assessing medical necessity based on an "after-the-fact review" of patients' medical records *was Winter's job*. At the motion to dismiss stage, her assessment is "entitled to the presumption of truth[.]" *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). "The standard at this stage of the litigation is not that plaintiff's explanation must be true or even probable. The factual allegations of the complaint need only 'plausibly suggest an entitlement to relief.'" *Id.* at 1216–17 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009)). Winter's complaint satisfies that standard.[9]

B. Winter properly alleges material false or fraudulent statements

The district court also held that Winter failed to allege any material false statements. We disagree.

"[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "Under any understanding of the concept, materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (quoting 26 Samuel Williston & Richard A. Lord,

[9] FCA claims must also be pleaded with particularity under Federal Rule of Civil Procedure 9(b). *Cafasso*, 637 F.3d at 1054. While a plaintiff need not "allege 'all facts supporting each and every instance' of billing submitted," she must "provide enough detail 'to give [defendants] notice of the particular misconduct which is alleged to constitute the fraud charged so that [they] can defend against the charge and not just deny that [they have] done anything wrong.'" *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010) (quoting *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051–52 (9th Cir. 2001)). Winter's detailed allegations clearly suffice to put Defendants on notice of their alleged false statements.

Williston on Contracts § 69:12 (4th ed. 2003)) (alteration omitted). No "single fact or occurrence" determines materiality—"the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2001, 2003 (citation omitted). For a false statement to be material, a plaintiff must plausibly allege that the statutory violations are "so central" to the claims that the government "would not have paid these claims had it known of these violations." *Id.* at 2004; *see also id.* at 2003 ("[P]roof of materiality can include . . . evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.").

The district court analyzed whether failure to meet the InterQual criteria was material and concluded that it was not because "[t]here is no mention of the InterQual criteria in any of the relevant statutes or regulations." This misreads the complaint. Winter does not allege that failure to satisfy the InterQual criteria made Defendants' Medicare claims per se false—although, as discussed above, she claims that the InterQual criteria support her allegations because they reflect a medical consensus. Rather, she alleges that "[Defendants'] claims for payment . . . were false in that the services claimed for (inpatient hospital admissions) were not medically necessary and economical," and that Defendants submitted "false certifications of . . . medical necessity."

We conclude that a false certification of medical necessity can be material. The medical necessity requirement is not an "insignificant regulatory or contractual violation[.]" *Escobar*, 136 S. Ct. at 2004. Congress *prohibited* payment for treatment "not reasonable and necessary for the diagnosis or treatment of illness or injury

or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). And Medicare pays for inpatient hospitalization "*only if* . . . such services are required to be given on an inpatient basis for such individual's medical treatment[.]" *Id.* § 1395f(a)(3) (emphasis added). In fact, Medicare regulations require all doctors to sign an acknowledgment that states,

> Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

42 C.F.R. § 412.46(a)(2). In addition to highlighting the above Medicare statutes and regulations, Winter's complaint alleges that the government "would not" have "paid" Defendants' false claims "if the true facts were known." In sum, Winter alleges that Defendants' false certification of the medical necessity requirement is "so central" to the Medicare program that the government "would not have paid these claims had it known" that the inpatient hospitalizations were, in fact, unnecessary. *Escobar*, 136 S. Ct. at 2004. Thus, Winter has "sufficiently ple[d] materiality at this stage of the case." *Campie*, 862 F.3d at 907.

C. Scienter

Defendants urge us to determine whether Winter adequately alleged scienter. The district court did not reach this issue but expressed doubt that Winter had. Although we may consider alternate grounds for upholding the district court's decision, *see Islamic Republic of Iran v. Boeing Co.*, 771 F.2d 1279, 1288 (9th Cir. 1985), we decline to do so here.

We remind the district court, however, that under Rule 9(b), scienter need not be pleaded with particularity, but may be alleged generally. Fed. R. Civ. P. 9(b). A complaint needs only to allege facts supporting a plausible inference of scienter. *United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011). And unlike in common law fraud claims, a plaintiff need not prove a "specific intent to defraud" under the FCA—the Act imposes liability on any person acting "knowingly," which includes acting with "actual knowledge," as well as acting "in deliberate ignorance," or "in reckless disregard of the truth or falsity of the information[.]" 31 U.S.C. § 3729(b)(1). As the Supreme Court noted in another Medicare case, "[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law[.]" *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 63 (1984).

CONCLUSION

We hold that a plaintiff need not plead an "objective falsehood" to state a claim under the FCA, and that a false certification of medical necessity can be material. Accordingly, we reverse the district court's dismissal of Winter's complaint and remand for further proceedings consistent with this opinion.

Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute

Washington, DC ~ Wednesday, December 2, 2020

Good afternoon. I want to thank the American Bar Association, as well as the co-leaders of this conference, Sara Mclean, Rick Morgan and Lisa Noller, for inviting me to speak with you.

The False Claims Act is the Government's primary tool for redressing the knowing misuse of taxpayer funds, and conferences like this one provide an important forum for interested parties to share their views about the act and how it should be interpreted and enforced.

I cannot help but recall that one of the long-time co-leaders of this conference was Jack Boese, who as many of you are probably aware, passed away on Thanksgiving Day. Jack was truly a dean of the False Claims Act bar, and through his treatise, and decades of advocacy, had a lasting impact on the act and its development. He was fond of noting that he was counsel in the ATMI case, one of the cases that prompted the 2009 False Claims Act amendments, and not surprisingly, he was one of the individuals asked to testify at the Senate Hearing on those amendments, where he could be heard using his stock introduction – "the last name's Boese, rhymes with Crazy." The False Claims Act community has lost a true legend, and Jack's boundless energy, booming voice, and generous spirit will be sorely missed.

Today, I was asked to share with you some thoughts on the future of the Department's False Claims Act enforcement efforts. As in many circumstances, however, to understand where we may be headed, it is important to remember where we have been. So let me begin with a look at what has transpired over the last four years. I think it is fair to say that during this period there were significant developments on a number of fronts.

Since fiscal year 2017, the Department has recovered approximately $11.4 billion under the False Claims Act – the third largest total for any similar period. This total was the result of 993 settlements or judgments, which is the second highest total for any similar period.

Of the $11.4 billion recovered over the last four years, approximately 80 percent, or $9 billion, was recovered in health care fraud matters. The next largest categories of recoveries involved procurement fraud and mortgage fraud.

Qui tam cases continued to serve as the predominant source of False Claims Act recoveries, accounting for approximately 80 percent of the Department's collections since 2017. And over that timeframe, qui tam relators received more than $1.54 billion as their share of these returns.

The Department's False Claims Act recoveries, however, do not capture the full breadth of the Department's enforcement efforts over the last four years. Since fiscal year 2017, the Civil Division opened a record number of new matters. These new matters were the result of the filing of 2,638 qui tam cases, and the initiation of more than 660 investigations based on other sources of potential violations.

While these cases and recoveries reflect the Department's continued commitment to broadly protect federal programs and operations, the Department also used the False Claims Act to target a number of specific enforcement priorities. Let me highlight just a few of those priorities.

In response to the opioid epidemic, which according to data from the CDC claimed nearly 50,000 lives last year, we have used the False Claims Act to pursue individuals and entities that contributed to the epidemic by facilitating the diversion and abuse of prescription opioids.

For example, Insys Therapeutics, the manufacturer of Subsys, a highly addictive sublingual fentanyl spray, agreed to pay $225 million to resolve its criminal and civil liability for paying kickbacks and engaging in other unlawful marketing practices. The kickbacks allegedly took the form of jobs for the prescribers' relatives and friends, and lavish meals and entertainment. The United States also alleged that Insys improperly encouraged physicians to prescribe Subsys for patients who did not have cancer, and lied to insurers about patients' diagnoses to obtain reimbursement for Subsys prescriptions written for Medicare and TRICARE beneficiaries.

The United States also settled separately with Reckitt Benckiser and Indivior for a total of $2 billion for their shared criminal and civil liability in connection with the marketing of the opioid addiction treatment drug Suboxone. The False Claims Act portion of the resolution encompassed allegations that the two companies promoted the sale and use of Suboxone to physicians who were writing prescriptions for uses that lacked a legitimate medical purpose and to state Medicaid agencies using false and misleading safety claims.

This historic recovery involving Suboxone was subsequently eclipsed by the settlement announced last month with Purdue, which agreed to pay more than $8.3 billion in fines, forfeiture, and damages. The $2.8 billion False Claims Act component of the settlement encompassed allegations that Purdue knowingly marketed its opioid drug Oxycontin to physicians that were prescribing the drug for medically unnecessary purposes and also engaged in various kickback schemes. Separately, the owners of Purdue, the Sackler family, agreed to pay $225 million to resolve their related False Claims Act liability, which is the largest settlement under the act with a non-corporate entity.

In addition to pursuing those directly facilitating improper opioid prescriptions, we have also used the False Claims Act against individuals and entities that have sought to exploit the opioid epidemic by improperly billing for services related to opioid prescriptions. For example, we settled for $20 million allegations that the owner of a series of pain management clinics in Kentucky and Georgia that performed medically unnecessary balance tests, nerve conduction procedures, and qualitative drug screens. And we have pursued drug testing laboratories for using bundled tests or other fraudulent schemes to induce physicians to bill for excessive drug tests.

A second area of focus over the last four years has been fraudulent schemes contributing to rising drug prices. We have used the False Claims Act in various ways to address such schemes.

We have pursued cases where pharmaceutical companies have failed to report accurate information to the Medicaid program under the Drug Rebate Statute in order to underpay rebates that they owe. For example, the drug company Mylan paid $465 million to resolve allegations that it knowingly misclassified its EpiPen product as a generic drug. The misclassification allowed the company to demand massive price increases in the private market while avoiding its corresponding obligation to pay higher rebates that would have otherwise been required. And recently, the United States filed a complaint under the False Claims Act alleging that Mallinckrodt ARD and its predecessor underpaid Medicaid rebates due as a result of large increases in the price of one of its drugs.

The Department also used the False Claims Act to pursue fraudsters who grossly inflated the price of compound medications reimbursed by TRICARE, a federally-funded health care program for military personnel and their families. In one case, a compounding pharmacy charged TRICARE at least 2,000 percent more for drugs than they charged cash-paying customers. Notably, TRICARE's costs for compounded drugs rose from $5 million in 2004 to $1.75 billion in fiscal year 2015.

Another fraudulent scheme that has undermined safeguards designed to serve as a check on drug pricing has been the practice by pharmaceutical companies of improperly using foundations as conduits for the payment of patient copays. When Congress created the Medicare drug program, it included a copayment requirement, which creates customer price sensitivity that in turn serves as a control on overutilization of unnecessary drugs. We discovered that drug companies were improperly seeking to avoid this limitation by using information from foundations that allowed the companies to improperly tailor their donations to cover just the copays of patients taking their drugs. These practices not only illegally induced prescriptions and gave the violators a competitive advantage, but they also undercut a key safeguard on rising drug costs. To date, we have resolved more than 16 separate matters involving such schemes in which we have collectively recovered more than $1 billion.

Yet another important priority for the Department has been investigating and litigating a growing number of matters related to Medicare Part C, which is Medicare's managed care program. In 2019, a third of all Medicare beneficiaries – approximately 22 million beneficiaries – were covered by Medicare Part C. And in 2018, CMS paid more than $233 billion on behalf of such beneficiaries.

Unlike Medicare Parts A and B, where Medicare pays for each patient admission or service, Medicare Part C pays a capitated amount for each patient, which is risk-adjusted based on a patient's demographic information and health status. Over the past four years, we have obtained favorable settlements in a number of Medicare Part C cases involving participating plans or physicians who manipulated the risk adjustment process by submitting unsupported diagnosis codes to make their patients appear sicker than they actually were. For example, DaVita Healthcare Partners, which contracted with participating plans to provide healthcare services to Part C beneficiaries, paid $270M in September 2018 to resolve allegations that it (among other things) failed to alert Part C plans to diagnosis codes that its auditors determined were unsupported, provided coding guidance to its physicians that resulted in unsupported diagnoses, and improperly submitted acute care diagnoses based on non-acute encounters with primary care physicians. And just last month, California based Kaiser Foundation Health Plan of Washington, formerly known as Group Health Cooperative (GHC), agreed to pay over $6 million to resolve allegations that it submitted invalid diagnoses that resulted in inflated Part C payments.

One type of scheme, in particular, that we have uncovered has been the attempt by certain participating plans to manipulate the risk-adjustment process by auditing – or hiring others to audit – patient medical records to identify additional codes that would increase their Medicare reimbursement. In the process of conducting these

audits, the plans have uncovered unsupported diagnosis codes that were improperly submitted to Medicare. Rather than deleting these diagnosis codes at the same time they submitted the additional codes, however, they simply ignored the unsupported diagnosis codes. We are currently litigating two such cases against participating plans and a third case against a medical services provider.

The final priority that I want to mention has been the use of the False Claims Act to combat schemes designed to take advantage of the elderly by providing them poor or unnecessary health care – or too often no care at all. Over the last four years the Department has reinforced its commitment to protect the health and welfare of these vulnerable members of society, who often lack the ability to advocate for themselves or others who can do so on their behalf.

This past year, for example, we resolved False Claims Act matters with various skilled nursing facility chains and rehabilitation contactors for knowingly providing and/or billing for medically unnecessary rehabilitation therapy services that were influenced by financial considerations rather than patient needs.

As another example of the Department's commitment to protect the health of our seniors, in September 2019, Avanir Pharmaceuticals agreed to pay $95.9 million to resolve allegations that it paid kickbacks and engaged in false and misleading marketing of its drug, Nuedexta, to induce providers in long term care facilities, including nursing homes, to prescribe it for behaviors commonly associated with dementia patients, which was not an approved use. Over-medicating nursing homes residents is a well-documented problem, which can lead to a host of issues, including unnecessary side effects and over-sedation of patients.

Particularly disturbing was our settlement last year with Vanguard Healthcare, its majority owner and CEO, as well as its former director of operations, who collectively agreed to pay more than $18 million in allowed claims to resolve a False Claims Act lawsuit brought by the United States and Tennessee for billing the Medicare and Medicaid programs for grossly substandard nursing home services. During our investigation, we found a number of troubling practices at certain Vanguard nursing facilities, including the failure to administer medications or to provide standard infection control, as well as the use of unnecessary physical restraints and the failure to meet basic nutrition and hygiene requirements.

In light of the continuing evidence of deficient care being provided to our nation's seniors, in March of this year, the Department launched a National Nursing Home Initiative. The Department has opened investigations across the country and is actively and aggressively pursuing those matters.

Let me turn now to another facet of the Department's approach to False Claims Act enforcement over the last four years. During this period, the Department enacted a number of policies governing both when such cases should be brought and how such cases should be settled.

The first category includes what has become known as the "Brand Memo," which announced that agency guidance should not serve as the basis for bringing enforcement actions, and that such actions should instead be based on existing statutory, regulatory or contractual requirements. The principles of the Brand Memo were subsequently incorporated into and expanded upon by the Justice Manual, which identifies various purposes for which agency guidance may be used in establishing violations of law.

The Department also added to the Justice Manual guidance on how attorneys should use the United States' authority under the False Claims Act to dismiss a qui tam action that does not advance the act's goal of redressing fraud. The guidance identifies the factors that the Department will consider, after investigating the applicable law and facts, in evaluating whether to invoke this authority, and instructs that the authority should be used judiciously.

Consistent with the guidance, the Department has filed motions to dismiss in approximately 50 qui tam actions since it was issued. While that is more than had been dismissed prior to the guidance, it is a very small fraction of the more than 2000 qui tam actions that have been filed over that same period of time.

As I mentioned, over the last four years the Department also enacted a number of policies that have impacted the settlement of False Claims Act cases. For example, the Yates memo was modified in several respects, including to make the identification by a corporate entity of responsible individuals a precondition in civil settlements for the receipt of maximum cooperation credit, rather than a precondition for any cooperation credit.

Building on the updated Yates Memo, the Civil Division announced a specific cooperation policy applicable to False Claims Act cases. Under this policy, corporate defendants can earn credit — and a reduction in penalties and damages — by voluntarily disclosing misconduct, cooperating with pending investigations, and taking remedial measures. Since the False Claims Act cooperation policy was issued, the Civil Division has extended cooperation credit consistent with its terms as part of the resolution of a number of matters.

Two other policies that apply to enforcement actions more generally are the Department's Anti-Piling on Policy and its Third Party Payment Policy. The former directs Department components to coordinate with each other, and with other governmental entities, to avoid the unnecessary imposition of duplicative fines and penalties on a settling company. The latter provides that it is generally inappropriate to include as part of any resolution a payment to non-governmental, third-party organizations who are not victims or parties to the lawsuit.

Finally, this past September, the Civil Division adopted guidelines for settling cases based on a defendants' ability to pay. The guidelines detail both the procedures that the Civil Division will follow, and the factors it will consider, in evaluating whether to settle a matter based on a consideration of the defendant's financial condition rather than the underlying merits of the case.

Against this backdrop of the priorities and policies of the last four years, let me turn now to the question of what may be in store for False Claims Act enforcement over the next four years. It is always difficult to predict what the future may hold, and new leadership often brings new ideas and priorities. Nevertheless, let me offer a few observations about what may lie ahead.

First, if the history of the False Claims Act teaches us anything, it is that protecting taxpayer funds is a nonpartisan issue and that enforcement of the False Claims Act will likely continue to be an area of emphasis for the Department. Moreover, it is a good bet not only that health care fraud will remain a top focus of the Department's enforcement efforts generally, but that the Department will continue to pursue many of the specific health care fraud priorities of the last four years, including fraud schemes involving prescription opioids, Medicare Part C, and the quality of care provided to the elderly.

Second, while many aspects of the Department's current enforcement efforts will likely remain unchanged, there are areas where you are likely to see some differences.

You should expect, for example, that going forward the False Claims Act will play a central role in the Department's pursuit of COVID-19 related fraud. The government's coronavirus response includes $2.6 trillion in loans and other economic support for individual citizens, small businesses, hospitals and other medical providers, other impacted industries, and state, local and tribal governments. By comparison, the Congressional Budget Office has estimated that total disbursements under the TARP program were about a sixth of this amount. Given the unprecedented scale of the COVID-19 relief programs, the potential for fraud is significant.

While the circumstances of the current pandemic may be novel, the inevitable fraud schemes it will produce will in many cases resemble misconduct that the False Claims Act has long been used to address. Whether the target of these schemes is the SBA's Paycheck Protection Program or HHS' Provider Relief Program, they will likely include false representations regarding eligibility, misuse of program funds, and false certifications pertaining to loan forgiveness. The Civil Division is working closely with various Inspector Generals and other agency stakeholders to identify, monitor, and investigate these potential violations, and these efforts are expected to translate into significant cases and recoveries.

Another area that is likely to be a focal point of the Department's future enforcement efforts is fraud pertaining to electronic health records. Providers increasingly rely on electronic health records to provide vital and unbiased information to improve treatment outcomes for patients. While electronic software is intended to reduce errors and improve the delivery of care, the transition to a digital format has also introduced new opportunities for fraud and abuse.

We have already successfully pursued several matters involving the misuse of electronic health records software. In its recent settlement with Purdue, for example, among other matters the United States resolved Purdue's criminal and civil liability for paying kickbacks to a health information technology developer in exchange for the latter including clinical alerts in its software that were designed to increase prescriptions for Purdue's drugs. The United States also settled the criminal and civil liability of the vendor for its role in the kickback arrangement, and has similarly pursued other electronic health records vendors for engaging in kickback schemes. And we have pursued cases where vendors misrepresented the capabilities of their software, which in turn resulted in providers falsely claiming incentive payments for using compliant computer systems. Given the critical and growing role that electronic health records play in our health care system today, and CMS' continued use of incentive payments to encourage the use of such records, we expect to see more of these cases.

On a related note, cybersecurity related fraud is another area where we could see enhanced False Claims Act activity. With the growing threat of cyberattacks, federal agencies are increasingly focused on the importance of robust cybersecurity protections. Where such protections are a material requirement of payment or participation under a government program or contract, the knowing failure to include such protections could give rise to False Claims Act liability.

In addition to these potentially new or expanded uses of the False Claims Act, we could also see changes in how the False Claims Act is applied in connection with existing areas of pursuit. For example, to date a significant focus of our opioid related False Claims Act matters have targeted unlawful activity by manufacturers. Going forward, you may see False Claims Act cases being brought against other participants in the supply chain who contributed to the opioid crisis.

Similarly, the False Claims Act has long served as an important vehicle for ensuring compliance with the Anti-Kickback Statute and Stark Law. Indeed, such cases have been at or near the top of the list of cases most frequently pursued by the Department over the last several years. With the changes that HHS enacted just two weeks ago to the Anti-Kickback Statute and Stark Law regulations, however, we may see new cases and issues arising in this area.

A third observation I wanted to share relates to the source of future False Claims Act matters. In 1995, 269 qui tam cases were filed – and for the first time such cases became the primary source of False Claims Act violations. Since then, the number of qui tam cases has continued to increase, and in recent years the number of cases filed has been between 600 and 700 per year. Undoubtedly, the Department will continue to rely heavily on whistleblowers to help root out the misuse and abuse of taxpayer funds.

At the same time, you can expect the Civil Division to expand its reliance on data analysis to identify potential fraud cases. Increasingly, the Civil Division has been undertaking sophisticated analyses of Medicare data to uncover potential fraud schemes that have not been identified by whistleblower suits, as well as to help analyze the allegations that we do receive from such suits.

Our sophisticated data analytics allow us to identify patterns across different types of health care providers to identify trends and extreme outliers. We can see where the highest fraud risk physicians are located in each state and federal district, and how much they are costing the Medicare program. The data can even allow us to demonstrate and quantify sophisticated relationships, such as a physician offering controlled substance prescriptions to a patient who is likely to divert them. Identifying these types of relationships can help combat opioid and other forms of prescription drug abuse, and the Civil Division has been actively using its data analysis for this very purposes. The benefits of data analysis extend beyond just the health care arena, however, and the Civil Division is relying on the use of such analysis to combat other types of frauds, including COVID-19 related misconduct that may give rise to False Claims Act liability.

Finally, I would be remiss if I did not note that, as the Department prepares to meet the new challenges that lie ahead, it will do so with a new management team leading the Fraud Section. As many of you already know, Jamie Yavelberg is now the Director of that office, and is ably assisted by her two Deputies, Andy Mao and Colin Huntley. The combined experience and skill of these individuals, as well as the broader group of very talented attorneys in the Civil Division and throughout the U.S. Attorneys' Offices, will ensure a smooth transition between the last four years and the next four years – and that the False Claims Act will continue to serve as an important ingredient in the Department's efforts to protect taxpayer funds from fraud.

Thank you again for the opportunity to share these thoughts with you, and I hope everyone enjoys the rest of the conference.

Speaker:
Deputy Assistant Attorney General Michael Granston (Commercial Litigation Branch)

Component(s):
Civil Division

Updated December 16, 2020

No. 19-50818
UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

United States ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health

Decided May 28, 2020

No. 19-50818

05-28-2020

UNITED STATES OF AMERICA, ex rel., INTEGRA MED ANALYTICS, L.L.C., Plaintiff-Appellant, v. BAYLOR SCOTT & WHITE HEALTH; BAYLOR UNIVERSITY MEDICAL CENTER-DALLAS; HILLCREST BAPTIST MEDICAL CENTER; SCOTT & WHITE HOSPITAL-ROUND ROCK; SCOTT & WHITE MEMORIAL HOSPITAL TEMPLE, Defendants-Appellees.

PER CURIAM

Appeal from the United States District Court for the Western District of Texas
USDC No. 5:17-CV-886 Before OWEN, Chief Judge, and HIGGINBOTHAM and WILLETT, Circuit Judges.
PER CURIAM:[*]

[*] Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

2 Integra Med Analytics, L.L.C., filed a qui tam suit[1] on behalf of the *2 United States against Baylor Scott & White Health system and its affiliates under the False Claims Act for allegedly using inflated codes to bill Medicare. The district court dismissed Integra Med's claims. We affirm.

[1] At the federal level, qui tam suits are those that are filed "for the person and for the United States Government" and "brought in the name of the Government." 31 U.S.C. § 3730(b)(1). Thus, in qui tam suits, the government is the real party in interest. *United States v. Tex. Tech Univ.*, 171 F.3d 279, 289 (5th Cir. 1999).

I

The Baylor Scott & White Health system and its affiliates (Baylor) operate a network consisting of around twenty inpatient short-term acute care hospitals in Texas. A significant number of patients served by Baylor are covered by Medicare. Thus, Baylor regularly submits reimbursement claims to Medicare. In this case, Integra Med Analytics, L.L.C. (Integra Med) alleges that Baylor submitted $61.8 million in fraudulent claims to Medicare, in violation of the False Claims Act (FCA).[2]

[2] 31 U.S.C. § 3729.

Medicare reimburses hospitals like Baylor on a per-discharge basis, which means Baylor gets paid each time a patient stays at the hospital. The exact amount that Medicare reimburses primarily depends on a hospital's diagnoses of Medicare-covered patients. Medicare classifies similar diagnoses by putting them into a diagnosis related group (DRG). Each DRG is determined by several kinds of codes, including the principal diagnosis

code and secondary diagnosis codes. The principal diagnosis code is for the "condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."[3] Secondary diagnosis codes are for "all conditions that coexist at the time of admission, that develop subsequently, or that
3 affect the treatment received and/or length of stay."[4] *3 Reimbursement can also be affected, to a lesser extent, by other hospital-specific factors, such as market conditions in the hospital's city.

[3] *See* Centers for Disease Control, *ICD-9-CM Official Guidelines for Coding and Reporting*, Oct. 1, 2011 at 88, available at https://goo.gl/DC55Wx.

[4] *See* Centers for Disease Control, *ICD-9-CM Official Guidelines for Coding and Reporting*, Oct. 1, 2011 at 91, available at https://goo.gl/DC55Wx.

Integra Med's allegations specifically concern Baylor's use of secondary diagnosis codes. The Centers for Medicare and Medicaid Services (CMS) publishes a list of secondary codes each year that can modify a claim to include a complication or comorbidity (CC) or a major complication or comorbidity (MCC). The inclusion of CCs and MCCs can add thousands of dollars to a Medicare reimbursement claim. Integra Med alleges that Baylor, led by its clinical documentation improvement (CDI) program, fraudulently used higher-value CCs and MCCs than were justified by actual medical diagnoses to increase its revenues. Integra Med contends that Baylor's scheme had three main components.

First, Integra Med contends that Baylor trained its physicians and CDI employees to "upcode" MCCs. According to Integra Med, Baylor trained its physicians to focus on key words, provided lists of high-value MCCs to physicians to reinforce that training, and emphasized that using certain terms would increase their performance pay. Integra Med also contends that Baylor had its CDI employees seek opportunities to use higher-value secondary codes.

Second, Integra Med alleges that Baylor pressured physicians to alter their original diagnoses by providing documents and asking them to "specify" or change their diagnosis if the diagnosis did not include CCs or MCCs. According to Integra Med, these clarification documents that requested physicians to "specify" their diagnoses would often "suggest either specific revenue-increasing CCs or MCCs or provide options listing several possible CCs and MCCs." Integra Med contends these clarification documents "reveal a clear intent towards influencing doctors to code higher-paying CCs and MCCs."

4 Third, Integra Med alleges that Baylor provided unnecessary treatment *4 in order to code high-value MCCs. Specifically, Integra Med contends that "Baylor purposefully placed and kept post-operative patients on ventilator support" when it was medically unnecessary. Integra Med bases this allegation on the fact "that Baylor patients undergoing major heart surgery were placed on mechanical ventilation [at rates] over twice the national average."

Integra Med analyzed inpatient claims data for the 2011-2017 period from CMS to discover that Baylor had been claiming certain MCCs significantly above the national average for other hospitals. Specifically, Integra Med found that Baylor coded for the MCCs of encephalopathy, respiratory failure, and severe malnutrition at much higher rates than other hospitals. Integra Med contends that its statistical analyses show that Baylor's higher rate of coding cannot be explained by patient characteristics, county demographic data, the patient's attending physician, or regional differences. According to Integra Med, its "analyses prove that the excessive rates of [certain] MCCs can be directly attributed to [Baylor's] fraudulent activity as opposed to external factors, indicating that the fraud was known by the system and was intentional."

Besides statistical data, Integra Med also relied on several statements from a former Baylor medical coder in concluding that Baylor had defrauded Medicare. According to Integra Med, this medical coder recalled a then-Baylor executive "telling CDIs things that were totally not true" as a part of a "deliberate effort to promote the coding of MCCs." This medical coder also allegedly received specific instructions on how to code. Integra Med claims that this medical coder quit her job with Baylor because she was unable to work where she "was continually getting directives to compromise her integrity." Integra Med also relied on certain statements about
5 increasing hospital revenues from a former Baylor executive's social media. *5

Based on these statistics and statements, Integra Med sued Baylor under the FCA in federal district court in April 2018. After Integra Med amended its complaint twice, Baylor moved under Federal Rule of Civil Procedure Rule 12(b)(6) to dismiss Integra Med's complaint. The district court granted Baylor's motion to dismiss, holding that Integra Med's complaint failed to state a particularized claim for which relief could be granted as required by Federal Rules of Civil Procedure 8(a) and 9(b). This appeal followed.

II

To survive a motion to dismiss an FCA claim, Integra Med must plead the following four elements: (1) "a false statement or fraudulent course of conduct;" (2) that was "made or carried out with the requisite scienter;" (3) "that was material;" and (4) "that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)."[5] Integra Med's case on appeal hinges on whether Integra Med sufficiently pleaded facts showing that Baylor's claims were fraudulent. Thus, we will examine each of Integra Med's bases for its claims, including its statistical data generally, the documents it has gathered from Baylor, statements by a former Baylor medical coder, and the claim that Baylor provided unnecessary medical care to boost its Medicare reimbursements.

5 *United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 324 (5th Cir. 2017) (quoting *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009)).

A

We first examine the statistical data presented by Integra Med, reviewing whether it sufficiently shows that Baylor's Medicare reimbursement claims were fraudulent. "[A] complaint filed under the False Claims Act
6 must *6 meet the heightened pleading standard of Rule of 9(b)."[6] Federal Rule of Civil Procedure 9(b) provides, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."[7] Although the particularity Rule 9(b) demands "differs with the facts of each case,"[8] it does generally require that a complaint detail "the who, what, when, and where . . . before access to the discovery process is granted."[9] Rule 9(b)'s particularity requirement supplements Rule 8(a)'s demand that "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[10] Rule 8(a) prohibits any claims that are merely conceivable rather than plausible.[11] A claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and "obvious alternative explanation."[12]

6 *See, e.g., United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (first citing *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308-09 (5th Cir. 1999), *abrogated on other grounds by United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009); and then citing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)).

7 FED. R. CIV. P. 9(b); *see also Kanneganti*, 565 F.3d at 185-86.

8 *Hart v. Bayer Corp.*, 199 F.3d 239, 247 n.6 (5th Cir. 2000) (citing *Guidry v. Bank of LaPlace*, 954 F.2d 278, 288 (5th Cir. 1992)).

9 *Id.* (alteration in original) (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997)).

10 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Kanneganti*, 565 F.3d at 185.

11 *Iqbal*, 556 U.S. at 680 (quoting *Twombly*, 550 U.S. at 570).

12 *Id.* at 682 (quoting *Twombly*, 550 U.S. at 567).

Here, Integra Med's statistical analysis is consistent with both Baylor having submitted fraudulent Medicare reimbursement claims to the government and with Baylor being ahead of most healthcare providers in following new guidelines from CMS. In 2007, CMS reduced the standardized amount paid out to hospitals for Medicare reimbursement claims but increased the number of secondary diagnoses identified as CCs and MCCs,
7 and coding *7 more CCs and MCCs can increase hospital reimbursements.[13] In response to public comments expressing concern that the new rules would lead to lower reimbursements, CMS stated that it expected reimbursements to increase under the system.[14] CMS believed it was "clear" that hospitals would "change their documentation and coding practices and increase case mix consistent with the payment incentives that are provided by the" then new coding system.[15] In fact, CMS encouraged hospitals to adopt CDI programs "in order to increase reimbursement" and highlighted an article touting the effectiveness of CDI programs at increasing Medicare reimbursement rates.[16] CMS unequivocally stated in its guidelines that, "[w]e do not believe there is anything inappropriate, unethical or otherwise wrong with hospitals taking full advantage of coding opportunities to maximize Medicare payment that is supported by documentation in the medical record."[17]

13 *See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates*, 72 Fed. Reg. 47,130, 47,135-39 (Aug. 22, 2007) (final rule).

14 *See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates*, 72 Fed. Reg. at 47,180-82.

15 *Id.* at 47,182.

16 *Id.*

17 *Id.* at 47,180.

The conclusion that Baylor was simply ahead of the healthcare industry in following CMS guidelines is supported by the data in Integra Med's own complaint. Integra Med's complaint shows that the rate at which non-Baylor hospitals were using the MCCs for encephalopathy, respiratory failure, and severe malnutrition was increasing every year. These increases were causing the MCC usage rates of both Baylor and non-Baylor hospitals to converge. Moreover, for severe malnutrition, non-Baylor hospitals were coding it at a higher rate in 2017 than Baylor was in 2015. Similarly, for respiratory failure, non-Baylor hospitals were coding it at a higher
8 rate in 2017 than Baylor was *8 in 2011. These show that the healthcare industry as a whole was following Baylor in its trajectory and by 2017, other hospitals' coding was within a few percentage points of Baylor's.

These facts strongly indicate that a legal and "obvious alternative explanation" for the statistical data presented by Integra Med is that Baylor was simply ahead of the healthcare industry at implementing the Medicare reimbursement guidelines supplied by CMS.[18] We note that this conclusion does not exclude statistical data

from being used to meet the pleading requirements of Federal Rule of Civil Procedure 8(a) and, when paired with particular details, Rule 9(b).[19] Our conclusion merely means that statistical data cannot meet those pleading requirements if, among other possible issues, it is also consistent with a legal and obvious alternative explanation.[20]

18 *See Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567 (2007)).

19 *See, e.g.*, *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 247-48, 258 (3d Cir. 2016) (concluding, in the Rule 8(a) and 9(b) context, that statistical data about the lack of markings on a company's pipe fittings was sufficient to state an FCA claim for avoiding import duties when paired with an expert's declaration analyzing the facts of that case, specific examples of unmarked pipes with photographs, a witness statement about receiving improperly marked pipes, and detailed records about the shipments at issue); *Boykin v. Georgia-Pac. Corp.*, 706 F.2d 1384, 1390-94 (5th Cir. 1983) (concluding, in the Rule 8(a) context, that plaintiff's presentation of statistical data successfully stated a prima facie case of racial discrimination).

20 *See Iqbal*, 556 U.S. at 678.

Insofar as Integra Med purports to give specific examples of fraudulent claims, it also fails to meet the pleading requirements of Rules 8(a) and 9(b). Integra Med's examples simply give some identifying patient information and pair it with a diagnosis. No example gives any indication about what makes it a false claim. The claims of
9 falsity are simply conclusory.[21] *9

21 *See Taylor v. Books A Million, Inc.*, 296 F.3d 376, 378 (5th Cir. 2002) ("[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." (quoting *S. Christian Leadership Conference v. Supreme Court of the State of La.*, 252 F.3d 781, 786 (5th Cir. 2001))).

B

1

We next examine whether Integra Med's allegations that Baylor trained and pressured its physicians and CDI employees to "upcode" MCCs are sufficient to establish that Baylor was engaging in a scheme to submit fraudulent claims to Medicare. We conclude that they are not. In publishing the new DRG coding rules, CMS explicitly expected hospitals to work with their physicians and medical coders, including through training, to "focus on understanding the impact of the revised CC list."[22] According to Integra Med, Baylor trained physicians to focus on keywords, provided tip sheets reminding physicians of how to report high-value MCCs, had CDI employees look for opportunities where high-value MCCs might be present, and would sometimes send physicians documents asking them to clarify their diagnoses. Integra Med argues that these practices show Baylor was involved in a scheme to defraud Medicare. But CMS encouraged hospitals to employ practices like these after it implemented the new DRG rules.[23] Far from a fraudulent scheme, Baylor's implementation of such practices is entirely consistent with the new DRG rules.[24]

22 *See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates*, 72 Fed. Reg. at 47,182 ("[H]ospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.").

23 *See id.*

24 *Id.*

For example, Baylor's use of tip sheets is consistent with the fact that coding and clinic terminology are often different. Tip sheets help hospitals align the two. Likewise, non-leading documents asking physicians to clarify
10 their diagnoses are also consistent with implementing the new DRG rules since *10 the new DRG rules moved hospitals away from focusing on general diagnoses and codes to frequently using more specific diagnoses and codes.[25] Physicians were likely still accustomed to the old, more general system. These clarification documents had numerous suggestions, a simple box to check to decline clarification, and a disclaimer not to take implications from the fact clarification was asked for. Additionally, some of the clarification documents provided by Integra Med in its complaint show that clarification was requested in instances in which physicians wrote down symptoms but failed to provide a diagnosis for the cause of those symptoms. These clarification documents also did not ask leading questions. Considering diagnoses are critical for Medicare reimbursements and these specific clarification documents were not leading, they are consistent with Baylor engaging in legal activity.

25 *See id*. at 47,130-82 (Aug. 22, 2007) (final rule).

Therefore, we conclude that these allegations are also consistent with a legal and "obvious alternative explanation."[26]

26 *See Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567 (2007)).

2

In its complaint, Integra Med also cites the statements of a medical coder who said that a then-Baylor executive told "CDIs things that were totally not true" as a part of a "deliberate effort to promote the coding of MCCs." According to Integra Med, this medical coder said she was given specific instructions on how to code, and that medical coders "receive[d] pressure directly from . . . leadership to code unethically." This medical coder also allegedly quit her job because she "was continually getting directives to compromise her integrity." But these allegations fail to satisfy the heightened pleading standards required by Federal Rule of Civil Procedure 9(b)
11 because they fail to state the content of these allegedly unethical and fraudulent *11 directives, trainings, and guidance.[27] Thus, the district court correctly dismissed the claim based on these conclusory allegations.

27 *See Hart v. Bayer Corp*., 199 F.3d 239, 247 n.6 (5th Cir. 2000) (concluding that to meet the pleading requirements of Rule 9(b) a complaint must state "the who, what, when, and where" of a claim. (quoting *Williams v. WMX Techs*., *Inc*., 112 F.3d 175, 178 (5th Cir. 1997))). Integra Med claims that the situation here is "strikingly similar" to the situation in *United States ex rel. Integra Med Analytics*, *LLC v. Creative Solutions in Healthcare*, *Inc*., No. SA-17-CV-1249-XR, 2019 WL 5970283 (W.D. Tex. Nov. 13, 2019). We disagree. In *Creative Solutions*, the employee witness interviews actually revealed the contents of a specific fraudulent scheme. *Id*. at *4. That opinion notes, "a physical therapist at Fairfield recalled being instructed to allot 15 minutes for evaluation, even though it required 45 minutes, with the rest of the evaluation session charged at therapy rates." *Id*. (internal quotation omitted). The interview responses given by Integra Med here, while alleging a vague scheme to "promote the coding of MCCs," do not provide the who, what, when, and where of such scheme as required by Rule 9(b). The vague allegation here contrasts with the *Creative Solutions* interview responses, which included the requisite particularity and specificity.

C

We next look at Integra Med's allegations that Baylor provided unnecessary treatment to patients in order to use higher-value MCCs. Specifically, Integra Med contends that "Baylor purposefully placed and kept post-operative patients on ventilator support" when it was medically unnecessary. The allegations here are based

solely on the fact "that Baylor patients undergoing major heart surgery were placed on mechanical ventilation over twice the national average." These allegations do not withstand the heightened pleading requirements for fraud under Rule 9(b).

Integra Med fails to plead particular details of a scheme to defraud Medicare. Even when plaintiffs in an FCA case use statistics, which can be reliable indicia of fraud, they must still plead particular details of a fraudulent
12 scheme for each claim.[28] Here, Integra Med's complaint contains a conclusory *12 allegation that Baylor was providing unnecessary treatment to its patients and supports it with a single statistic—that Baylor patients undergoing major heart surgery were put on a mechanical ventilator at a rate over twice the national average. Integra Med does not present sufficient particular details of this alleged fraud claim. The district court correctly dismissed the FCA claim based on Integra Med's allegation that Baylor provided unnecessary treatment to patients to increase its Medicare reimbursements.

28 *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) ("We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."); *see also United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 (5th Cir. 2013) ("We established that a relator could, in some circumstances, satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond mere possibility, without necessarily providing details as to each false claim. This standard nonetheless requires the relator to provide other reliable indications of fraud and to plead a level of detail that demonstrates that an alleged scheme likely resulted in bills submitted for government payment." (emphasis and citations omitted)).

In conclusion, Integra Med has failed to meet its pleading requirements under Rules 8(a) and 9(b). The district court did not, as Integra Med contends, view the complaint in the light most favorable to Baylor—it simply correctly held Integra Med to the higher pleading standard required for an FCA claim.

III

Integra Med contends that the district court improperly held its allegations to a more rigorous scienter requirement than was required by the FCA. But we need not address scienter because the district court correctly dismissed Integra Med's claims for failing to meet the pleading requirements required by Rules 8(a) and 9(b) for pleading the FCA's element that there be "a false statement or fraudulent course of conduct."[29]

29 *United States ex rel King v. Solvay Pharm., Inc.*, 871 F.3d 318, 324 (5th Cir. 2017) (quoting *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009)).

Integra Med also contends that the district court improperly applied a probability standard at the pleadings stage instead of a plausibility standard. But regardless of whether the district court mistakenly applied a
13 probability *13 standard rather than a plausibility standard, our conclusion is the same.[30] Since "[we] may affirm the district court on any grounds supported by the record and argued in the court below," any misapplication that might have occurred here would not require us to vacate or reverse the district court's judgment.[31]

30 *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of "entitlement to relief."'" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007))).

31 *Maria S. ex rel. E.H.F. v. Garza*, 912 F.3d 778, 783 (5th Cir. 2019) (citing *Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 307 (5th Cir. 1997)). --------

* * *

For these reasons, the district court's judgment is AFFIRMED.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 17-1694 PSG (SSx)	Date	July 16, 2019
Title	United States ex rel. Integra Med Analytics LLC v. Providence Health and Services, et al.		

Present: The Honorable	Philip S. Gutierrez, United States District Judge

Wendy Hernandez	Not Reported
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiff(s):	Attorneys Present for Defendant(s):
Not Present	Not Present

Proceedings (In Chambers): **Order GRANTING in part and DENYING in part Defendants' motions to dismiss**

Before the Court are a motion to dismiss filed by Defendant Providence Health & Services ("Providence" or "Providence H&S") and its affiliate hospitals[1] (collectively the "Hospital Defendants"), *see* Dkt. # 56 ("*Hosp. Mot.*"), and a motion to dismiss filed by Defendant J.A. Thomas and Associates, Inc. ("JATA"), *see* Dkt. # 57 ("*JATA Mot.*"). Relator Integra Med Analytics LLC ("Relator" or "Integra") has opposed both motions. *See* Dkts. # 61 ("*Hosp. Opp.*"), #62 ("*JATA Opp.*"). Defendants have filed replies. *See* Dkts. # 67 ("*JATA Reply*"), # 68 ("*Hosp. Reply*"). The Court held a hearing on this matter on February 13, 2019. Following the hearing, the parties submitted supplemental briefs at the Court's request. *See* Dkt. # 77 ("*Def. Supp.*"); #78 ("*Integra Supp.*"). The Court then held a second hearing on July 1, 2019. Having considered the moving papers and the arguments made at the hearings, the Court **GRANTS** the motions in part and **DENIES** them in part.

I. Background

In this case, Relator Integra alleges that Defendants conspired to submit, and did submit, false claims to Medicare in violation of the False Claims Act, 31 U.S.C. §§ 3729 et seq.

[1] The affiliate Hospital Defendants joining this motion are Providence Health System—Southern California, Providence Health & Services—Washington, Providence Health & Services—Oregon, Providence Saint John's Health Center, Providence Health & Services—Montana, Swedish Health Services, and Swedish Edmonds.

A. Factual Background

Defendant Providence H&S is "one of the nation's largest health systems, operating 34 hospitals and 600 clinics across five states." *Second Amended Complaint*, Dkt. # 39 ("*SAC*"), ¶ 2. The seven other Hospital Defendants are affiliates of Providence H&S. *Id.* Providence H&S's business relies in large part on reimbursements from Medicare. For example, of Providence H&S's $14.4 billion in revenue in 2015, approximately $6.2 billion came from Medicare reimbursements. *Id.*

Medicare pays hospitals on a "per-discharge" basis—that is, it makes a single payment for each inpatient hospital stay. *Id.* ¶ 21. This payment is "designed to cover the average cost of resources needed to treat each patient's needs." *Id.* As part of the payment calculation, Medicare assigns each hospital discharge to a "diagnosis related group" ("DRG"). *Id.* According to Relator, the DRG "is the single most impactful factor in determining the average payment for a claim." *Id.* The DRG is primarily determined by three types of codes: (1) the principal diagnosis code (defined as the "condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care"), (2) the surgical procedure code (representing any surgical procedures performed), and (3) secondary diagnosis codes (which represent "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of the stay"). *Id.* ¶ 22.

These codes produce more than 330 base DRGs. *Id.* ¶ 23. Adding another level of complexity, each DRG can have up to three severity levels: (1) "without Complication or Major Complication," (2) "with Complication," or (3) "with Major Complication." *Id.* The severity level of a DRG is determined by the secondary diagnoses present. *Id.* Each year, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicare program, publishes a list of codes that, when added to a claim, result in the claim being considered a Complication or Comorbidity (a "CC") or a Major Complication or Comorbidity ("MCC"). *Id.* Adding a CC or MCC code to a claim can increase the severity level of the DRG from the base level of "without Complication or Major Complication" to the higher levels of "with Complication" or "with Major Complication." *Id.* Importantly, increasing the severity level can increase the amount of the reimbursement that the hospital receives from Medicare. For example, Relator alleges that adding a CC secondary code can increase the value of the reimbursement by $1,000 to $10,000 and adding an MCC secondary code can increase the value by $1,000 to $25,000. *Id.*

To translate the clinical language that medical professionals use during treatment into codes that satisfy Medicare's coding standards, the Hospital Defendants, like many hospitals, have a "clinical documentation improvement" ("CDI") program. *Id.* ¶ 24. The Hospital Defendants retained Defendant JATA to assist with that program. *Id.* JATA is a company that provides CDI consulting services, purporting to help hospitals "ensure the accuracy of clinical documentation reflecting the appropriate severity of illness." *Id.*

Relator alleges that JATA and the Hospital Defendants worked together to train doctors to describe medical conditions with language that would support adding secondary CCs and MCCs, thereby allowing the Hospital Defendants to increase the severity level of the DRGs they reported to Medicare, leading to larger reimbursements. *Id.* Because the "documentation tips" that JATA provided to Providence doctors "often bore no relation to the clinical realities," Relator alleges that they resulted in "upcoding" of CCs and MCCs—in other words, adding CCs and MCCs to claims when the clinical circumstances did not merit such designations—leading to Defendants receiving more money from Medicare than they were entitled to.

Integra is not a prototypical False Claims Act relator. Parties bringing *qui tam* cases under the FCA are often insiders who claim knowledge of false claims from their previous relationships and/or interactions with the defendant. *See United States ex rel. McCready v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 114, 119 (D.D.C. 2003). Integra was not an insider of Defendants or the Government and has no first-hand knowledge of the upcoding that it alleges. Instead, it bases its claims on analysis it performed on data it received from CMS regarding inpatient claims from short term acute care hospitals as well as information it has gathered about JATA's business practices. *See SAC* ¶ 49.

Integra's analysis compared the rate at which the Hospital Defendants submitted claims with certain MCCs accompanying certain diagnoses to the rates at which those MCCs accompanied the same diagnoses in claims submitted by other hospitals. *See id.* Integra describes its methodology as follows. It first formed groupings corresponding to 312 specific principal diagnosis codes. *Id.* ¶ 50. For each of these diagnosis codes—what Integra refers to as comparative "bins"—it compared the rates at which specific MCCs were used at hospitals in the Providence system to the usage rates in other acute care inpatient hospitals. *Id.* "To ensure that only the truly fraudulent claims were analyzed," Integra excluded any diagnosis codes for which adding an MCC did not increase the value of the Medicare reimbursement.[2] *See id.* ¶ 50 and n.8.

[2] Integra also excluded claims involving patients who died during treatment as it alleges that "these claims tend to involve patients that are sicker and have higher rates of MCCs." *SAC* ¶ 50.

To account for natural variation in usage among hospitals and to "further ensure that it identified truly abnormal usage" of MCCs, Integra labeled the use of a particular MCC a false claim only when it was either (1) used at more than twice the national rate or (2) at a rate three percentage points higher than in other hospitals. *Id.* ¶ 51.

Using this methodology, Integra alleges that it "identified 271 combinations of principal diagnosis codes and Misstated MCCs in which Providence excessively upcodes." *Id.* Its claims in this case focus on three categories of secondary MCC codes that it alleges the Hospital Defendants, in consultation with JATA, used to increase the value of their claims: (1) encephalopathy[3] (including toxic encephalopathy), (2) respiratory failure (including pulmonary insufficiency), and (3) severe malnutrition. *Id.* ¶ 55. As one example of the disparity Relator alleges between Providence's claims and the claims of other hospitals, among Providence's more than 11,000 claims involving a "Fracture of the Neck of the Femur" (i.e. the hip), 12.34 percent of them were coded with a secondary MCC of encephalopathy. *Id.* ¶ 52. In contrast, of the more than 1.1 million femoral neck fracture claims submitted by other hospitals, only 4.46 percent of them were coded with a secondary MCC of encephalopathy. *Id.* In other words, Integra alleges that the Hospital Defendants coded encephalopathy in conjunction with femoral neck fracture claims at a rate 2.77 times higher than comparable hospitals and "profited nearly $7,500 each time it did so." *Id.*

Relator alleges that this upcoding was driven in part by tip sheets created by Defendant JATA, which trained Providence doctors on how to document conditions so that the medical records would support adding an MCC to the diagnosis code. *Id.* ¶ 29. For example, one tip sheet informed doctors that encephalopathy is an MCC, whereas "delirium" is not a CC unless specified as a certain type, and "altered MS [mental state] is a *symptom*—not even a CC." *Id.* The same sheet also informed doctors that "acute respiratory failure" is an MCC, whereas "respiratory distress" is "low severity." *Id.* And another tip sheet instructed doctors to "document *severe malnutrition*—it not only adds severity as an MCC, it will likely prolong the post-op course thereby aligning the illness severity with length of stay." *Id.* ¶ 30. In short, these tip sheets informed Providence doctors of the diagnoses that would support adding CCs and

[3] According to the allegations in the complaint, "[e]ncephalopathy is a term for brain disease or damage to the brain where the brain is regarded as 'altered in its structure or function.' The telltale symptom is an altered mental state, but altered mental state alone is insufficient for diagnosing encephalopathy . . . . [Encephalopathy] commonly manifests as confusion, agitation, or lethargy, but may include aphasia (altered speech), ataxia (altered gait) and memory loss." *SAC* ¶ 59.

MCCs, and therefore potentially increase the hospitals' reimbursements. Relator alleges that the physicians then went on to use the MCCs emphasized in the JATA tips sheets at a rate disproportionate to comparable hospitals. *See id.* ¶ 41.

Relator also alleges that Defendants' practice of using "leading queries" led to miscoding of these MCCs. Hospitals may only add CCs or MCCs to a claim when information supporting them is sufficiently documented in the patient's medical files. *Id.* ¶ 32. Relator alleges that Providence's CDI specialists sent "queries" to doctors that were phrased in a manner "designed to push them to change their initial assessments in ways that would justify coding of a CC or MCC." *Id.* The practice of querying doctors in a way that directs them to specific diagnoses allegedly failed to conform to industry standards. *Id.* ¶ 33 n.6. Relator also alleges that Defendants pressured doctors "to document for higher severity to the point of acquiescence." *Id.* ¶ 38. JATA's regional director allegedly taught Providence doctors that the only way to avoid being queried would be to initially document an MCC. *Id.* This sometimes led to contradictory medical records as doctors initially documented a less severe condition before "hastily adding [an MCC] to the bottom of the chart." *Id.* ¶ 38. Relator alleges that the pressure Defendants put on doctors predictably led them to code MCCs at excessive rates. *Id.* ¶ 39.

B. Procedural History

Relator brings this case under the FCA, which allows individuals having knowledge of false claims submitted to the federal government to bring suit on behalf of the government, and, if successful, to receive a percentage of the money recovered. *See* 31 U.S.C. § 3730(b). It asserts two causes of action, both against all Defendants:

> First Cause of Action: Violation of the FCA, arising from falsifying patient diagnoses, complications, and comorbidities. This also contains allegations of a "reverse" FCA claim and a claim of a conspiracy to violate the FCA. *SAC* ¶¶ 129–33.
>
> Second Cause of Action: Violation of the FCA, arising from the Defendants' violations of the Anti-Kickback Statute. *Id.* ¶¶ 134–42.

The United States declined to exercise its statutory right to intervene and prosecute the action. *See* Dkt. # 28; 31 U.S.C. § 3730(b)(4). Defendants now move to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that the allegations in the Second Amended Complaint ("SAC") fail to state a claim upon which relief can be granted. *See generally Hosp. Mot.*; *JATA Mot.*

II. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In assessing the adequacy of the complaint, the court must accept all pleaded facts as true and construe them in the light most favorable to the plaintiff. *See Turner v. City & Cty. of San Francisco*, 788 F.3d 1206, 1210 (9th Cir. 2015); *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). The court then determines whether the complaint "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. However, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. Accordingly, "for a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009) (internal quotation marks omitted).

Rule 9(b) requires a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To plead fraud with particularity, the pleader must state the time, place, and specific content of the false representations. *See Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir. 2007). The allegations "must set forth more than neutral facts necessary to identify the transaction. The plaintiff must set forth what is false or misleading about the statement, and why it is false." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (internal quotation marks omitted). In essence, the defendant must be able to prepare an adequate answer to the allegations of fraud.

III. Judicial Notice

JATA has asked the Court to take judicial notice of thirty-three exhibits it has proffered with its motion to dismiss. *JATA Request for Judicial Notice*, Dkt. # 59 ("*RJN*").

"Generally, the scope of review on a motion to dismiss . . . is limited to the contents of the complaint." *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006); *see also Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002) ("Ordinarily, a court may look only at the face of the complaint to decide a motion to dismiss."). Courts may also, however, consider "attached exhibits, documents incorporated by reference, and matters properly subject to judicial notice." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1051 (9th Cir. 2014).

Under Federal Rule of Evidence 201, the court "can take judicial notice of '[p]ublic records and government documents available from reliable sources on the Internet,' such as websites run by governmental agencies." *Gerritsen v. Warner Bros. Entm't Inc.*, 112 F. Supp. 3d 1011, 1033 (C.D. Cal. 2015) (quoting *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG (POR), 2009 WL 6598891, at *2 (S.D. Cal. Dec. 23, 2009)); *see also L'Garde, Inc. v. Raytheon Space & Airborne Sys.*, 805 F. Supp. 2d 932, 937–38 (C.D. Cal. 2011) (noting that public records from the internet are "generally considered not to be subject to reasonable dispute") (internal quotation marks omitted).

The documents for which JATA seeks judicial notice fall into three categories: (1) documents incorporated by reference into the SAC, (2) government documents available from reliable sources, and (3) other documents available on the internet for which JATA asks the Court only to take judicial notice of the fact that they are publicly available. *See RJN*, Addendum A.

The Court will discuss the online sources in the third category further below. As for the other two categories, Relator has not opposed JATA's request. In light of this non-opposition and the fact that many of the documents are not helpful in deciding the current motions, the Court does not analyze here whether each document is a proper subject for judicial notice. Rather, to the extent the Court relies on a document, it finds that judicial notice is proper and therefore **GRANTS** judicial notice as to that document.

IV. Discussion

Defendants' arguments for dismissal fall into five categories: (1) Relator's suit is barred by the FCA's "public disclosure bar"; (2) Relator has failed to adequately allege elements of its FCA claim (falsity, materiality, and scienter) under Federal Rules of Civil Procedure 9(b) and 12(b)(6); (3) Relator has not adequately pleaded a "reverse FCA" claim; (4) Relator has not adequately pleaded a conspiracy to violate the FCA; and (5) Relator has not adequately pleaded an FCA claim based on violation of the Anti-Kickback Statute. *See generally Hosp. Mot.*; *JATA Mot.*[4] The Court addresses each in turn.

[4] For sake of brevity, where both motions address the same issue, the Court cites to only one of the motions.

A. Public Disclosure Bar

As explained above, Integra is not a prototypical FCA relator in that it had no insider relationship with Defendants. This on its own, however, is not enough to bar its suit. While "[i]t is generally contemplated than an FCA relator will be an insider . . . the statute contains no such requirement." *McGready*, 251 F. Supp. at 119. Instead, "[a]ny person who can muster significant evidence of fraud, that is not publicly disclosed, and be the first to file a complaint alleging that fraud, may maintain a *qui tam* suit." *Id.*

Whether information has previously been publicly disclosed is a key factor in determining whether a relator may bring suit under the FCA. If there has been a public disclosure, the suit may be maintained only if the relator was the "original source" of the information. *See* 31 U.S.C. § 3730(e)(4)(A) ("The court shall dismiss an action or claim under this section . . . if substantially the same allegations or transactions as in the action or claim were publicly disclosed [through specified channels]."); *United States ex rel. Lee v. Corinthian Colls.*, No. CV 07-1984 PSG (MANx), 2013 WL 12114015, at *3 (C.D. Cal. Mar. 15, 2013). "This public disclosure bar is based on the proposition that, where the government is already in possession of information regarding allegations or transactions that would put it on notice that some person is obtaining government funds through fraud or false pretenses, no public benefit is derived from permitting the private party to proceed with the case unless that party was the source of the information." *Lee*, 2013 WL 12114015, at *3.

The FCA's public disclosure bar is triggered only if three conditions are met: (1) the disclosure occurred through one of the channels specified in the statute, (2) the disclosure was "public," and (3) the lawsuit is "based upon" the allegations or transactions publicly disclosed. *United States ex rel. Solis v. Millennium Pharms., Inc.*, 885 F.3d 623, 626 (9th Cir. 2018). The public disclosure bar is an affirmative defense. *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1103 (9th Cir. 2017). The Court may consider it on a motion to dismiss only when the allegations in the complaint or materials that are subject to judicial notice are sufficient to establish the defense. *See Sams v. Yahoo! Inc.*, 713 F.3d 1175, 1179 (9th Cir. 2013).

Defendants argue that Relator's claims are barred by the public disclosure bar because they are based on information gleaned from three categories of public disclosures: (1) the Medicare claims data that CMS provided to Relator, (2) information about JATA's business practices, which was available from online sources, and (3) reports issued by the Department of Health and Human Services Office of the Inspector General ("HHS OIG") relating to improper use of the diagnosis code of kwashiorkor, a form of malnutrition. *See JATA Mot.* 26:15–30:23.

The Court first addresses whether each of the three categories of information were publicly disclosed through a channel specified in the FCA before turning to the question of whether Plaintiff's complaint was based upon publicly disclosed information such that it is precluded by the public disclosure bar.

i. Public Disclosure

a. Medicare Claims Data

The public disclosure bar applies to, among other things, lawsuits based upon information publicly disclosed in a "Federal report." 31 U.S.C. § 3730(e)(4)(A)(ii). Defendants argue that the claims data Relator received from Medicare falls within this provision. *See JATA Mot.* 26:15–28:2. The Court will first analyze whether the claims data was a "Federal report" within the meaning of the statute before determining whether it was publicly disclosed.

1. Federal Report

The Court's analysis of whether the Medicare claims data was disclosed in a "Federal report" is guided by the Supreme Court's decision in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011), which construed that term in the FCA. The relator in *Schindler Elevator* alleged that the defendant submitted false claims by failing to file required reports with its claims and including false information in the reports it did file. *See id.* at 405. To support his allegations, the relator relied on information that his wife had received from the relevant government agency via Freedom of Information Act ("FOIA") requests, which had been used to obtain copies of the reports at issue as well as information about the years in which the defendant failed to file the required reports. *See id.* at 406. The case presented the question of whether the responses to the FOIA requests were "reports" within the meaning of the FCA's public disclosure bar. *Id.*

As the term "report" is not defined in the FCA, the Supreme Court first looked to its ordinary meaning, finding that a "report" is "something that gives information" or a "notification," or is "an official or formal statement of facts or proceedings." *See id.* at 407–08 (cleaned up) (quoting Webster's Third New International Dictionary (1986) and Black's Law Dictionary (6th ed. 1990)). The Court noted that this definition, which it acknowledged was "broad," was "consistent with the generally broad scope of the FCA's public disclosure bar." *Id.* at 408. Relying on this definition, the Court held that the FOIA responses were "reports,"

because "[e]ach response was an 'official or formal statement' that 'gave information' and 'notified [the requestor]' of the agency's resolution of [the] FOIA request." *Id.* at 410–11.

With *Schindler Elevator* as a guide, the Court now turns to the question of whether the Medicare data Relator received from CMS was disclosed through a federal report because it "gave information" or was "an official or formal statement of facts or proceedings." *See id.* at 407–08. There are many similarities between the relator's actions in *Schindler Elevator* and Integra's actions here. As in that case, Integra had no previous relationship with Defendants and received the information underlying its claims via a request to a government agency. In arguing that the Medicare data should not be considered a federal report, Integra focuses heavily on the fact that unlike information discovered through a FOIA request, the Medicare data was released only to researchers who intend to "improve the quality of life for Medicare beneficiaries or improve the administration of the Medicare program" and was subject to various restrictions designed to preserve the confidentiality of Medicare beneficiaries. *See Hosp. Opp.* 12:9–22 (citing Ctrs. for Medicare & Medicaid Servs., Instructions for Completing the Limited Data Set Data Use Agreement, *available at* https://goo.gl/HJMiro; *CMS Cell Size Suppression Policy*, Ctrs. for Medicare & Medicaid Servs., Research Data Assistance Ctr., https://www.resdac.org/articles/cms-cell-size-suppression-policy (last updated May 8, 2017)).[5] But this conflates two separate elements of the public disclosure bar analysis: whether the data was disclosed in a federal report and whether the disclosure was "public." *See Solis*, 885 F.3d at 626. The restrictions placed on the Medicare data will be discussed further below in the context of determining whether it was publicly disclosed, but they say nothing about whether the data was disclosed through a means that "gave information" or was "an official or formal statement of facts or proceedings." *See Schindler Elevator*, 563 U.S. at 407–08.

Relator additionally argues that "[t]he data [it] obtained from CMS was not part of any kind of report . . . [but] was simply confidential, raw data provided to researchers." *See Hosp. Opp.* 14:9–11. This argument is similar to the position taken by the dissent in *Schindler Elevator*. *See* 563 U.S. at 419 (Ginsburg, J., dissenting) (favorably citing the Court of Appeals's conclusion that the FOIA responses were not reports because they "merely assembled and duplicated records, or noted the absence of records" and did not "synthesize the documents or their contents with the aim of . . . gleaning any insight or information"). But the majority rejected this proposition, instead taking the broad view that a report is "something that gives information" or is "an official or formal statement of facts or proceedings." *Id.* at 407–08

[5] The Court takes judicial notice of these government documents, which are publicly available on the agencies' websites.

(cleaned up). Just as the FOIA responses in *Schindler Elevator* disclosed the contents of reports filed with the government, the Medicare data that CMS provided to Integra disclosed the contents of Medicare claims filed with the government. As the disclosure gave Integra information about Medicare claims and was an official statement of the claims that had been filed, the Court concludes that it constituted a federal report within the meaning of the public disclosure bar. *See id.*

2. Public Disclosure

Having concluded that the Medicare claims data was disclosed to Relator in a federal report, the Court now turns to the question of whether that disclosure was "public." *See* 31 U.S.C. § 3730(e)(4)(A); *Solis*, 885 F.3d at 626. As detailed above, Relator argues that Medicare claims data was not disclosed publicly because it was given only to researchers seeking to improve the life of Medicare beneficiaries or the administration of the Medicare system and was subject to various privacy provisions. *See Hosp. Opp.* 12:9–22

In this Circuit, "a disclosure need not be made to the public at large to qualify as 'public'" under the FCA. *Malhotra v. Steinberg*, 770 F.3d 853, 858 (9th Cir. 2014) (citing *Seal 1 v. Seal A*, 255 F.3d 1154, 1161–62 (9th Cir. 2001)). To evaluate whether information was publicly disclosed, the Ninth Circuit has looked to whether the individual receiving the disclosure was an "insider" or "outsider" with regard to the information's subject matter. *See Malhotra*, 770 F.3d at 858–60; *Seal 1*, 255 F.3d at 1161–62.

For example, in *Seal 1*, the relator developed a relationship with lawyers from the U.S. Attorney's Office who were investigating fraud committed by his former employer. *See* 255 F.3d at 1156. Over the course of this relationship, the government lawyers allowed the relator to view internal documents that revealed that one of his employer's competitors, Zenith, was likely committing the same type of fraud. *See id.* The court concluded that this sharing of information was a public disclosure because the relator "was an outsider to the Zenith investigation at the time he received the information [from] the U.S. Attorney's office." *Id.* at 1161. It rejected the relator's contention that the disclosure was not public because he had signed a declaration requiring him to keep the information confidential, finding that a determination that the disclosure was public was "consistent with Congress' intent that the FCA not be used by people attempting to 'free ride' in information obtained from the government." *Id.* at 1161–62.

The Ninth Circuit elaborated on this insider/outsider distinction in *Malhotra*. *See* 770 F.3d at 858–61. The relators in that case believed that the trustee appointed to administer their

bankruptcy, named Steinberg, was engaging in fraudulent conduct. *See id.* at 855. They began conducting their own investigation into his conduct, reviewing thousands of pages of bankruptcy court and county assessor records. *Id.* The relators shared the fruits of their investigation with the Office of the United States Trustee, which eventually decided to depose an associate of Steinberg's. *Id.* at 856. At the deposition, which the relators attended, the associate revealed information that led the relators to believe that Steinberg had engaged in fraudulent conduct with regard to several other bankruptcies. *Id.* On the basis of this information, they filed an FCA case against Steinberg. *Id.* The Ninth Circuit determined that the information the relators had received at the deposition was a public disclosure. While recognizing that the relators had conducted their own investigation into Steinberg's actions and that they might be considered insiders with regard to their *own* bankruptcy, the court held that they were outsiders with regard to the U.S. Trustee's investigation into Steinberg's conduct *in other bankruptcies* and therefore could not rely on the information as the basis for their FCA claims.[6] *Id.* at 860.

The Court believes that it is clear under *Seal 1* and *Malhotra* that Integra was an outsider for purposes of the allegations against Defendants, and therefore CMS's disclosure of Medicare claims data to Integra was a public disclosure. Integra was neither an employee of Defendants nor an employee of the government. *See id.* at 859. Nor was it in anyway deputized by the government to conduct an investigation into Medicare fraud. Integra's contention that the data would not have been released to just anyone is therefore beside the point. *See Hosp. Opp.* 12:9–14:11. The Ninth Circuit has expressly held that "[d]isclosure of information to one member of the public, when that person seeks to take advantage of that information by filing an FCA action, is public disclosure" because Congress did not intend for the FCA to be "used by people attempting to 'free ride' on information obtained from the government." *Seal 1*, 255 F.3d

[6] In *Malhotra*, the Ninth Circuit appears to have held that only employees of the target of an investigation or employees of the government can be considered "insiders," such that a disclosure of information to them is not a public disclosure. *See* 770 F.3d at 859 ("In *Seal 1*, we had no occasion to define with precision the meaning of 'outsider.' [The relator in that case] was neither an employee of the target of the investigation (Zenith) nor an employee of the government—the two categories of individuals who, even under the broadest reading of our precedents, could be considered insiders. That made it easy to conclude that [the relator] was an 'outsider' to the Zenith investigation.") It is not clear, however, whether the Ninth Circuit was contemplating situations in which there is no existing government investigation into the defendant in the FCA case. Ultimately, the Court does not need to decide if insider status is limited to employees of targets of investigations or the government because it concludes that Integra was an outsider under any definition.

at 1162. As for Integra's argument that the privacy and confidentiality restrictions render the disclosure private, the Ninth Circuit rejected an essentially identical argument in *Seal 1*. *See Seal 1*, 255 F.3d at 1162 ("[The relator] signed a 'Declaration' requiring him to keep confidential the information he obtained from the USAO, but this does not undermine our conclusion that [he] is a member of the public for purposes of his suit.").

Relator largely ignores *Seal 1* and *Malhotra*, instead arguing that the Ninth Circuit's decision in *Berg v. Honeywell Int'l, Inc.*, 502 F. App'x 674 (9th Cir. 2012), "expressly limited the holding" in *Seal 1*. *See Hosp. Opp.* 13 n.6. However, as an unpublished memorandum disposition, *Berg* cannot limit *Seal 1*, a published decision. It certainly cannot limit *Malhotra*, a published precedential decision *that postdated it*. But even taking Relator's argument at face value, the Court finds it unconvincing.

In *Berg*, the Ninth Circuit found that a government report was not publicly disclosed when it was given to a private company hired by the government to conduct an audit. 502 F. App'x at 676. The court reached this conclusion because the recipient of the report "was not an 'outsider' to the investigation, but rather was acting on behalf of the government and had an incentive to keep confidential the information learned during its audit." *Id.* In contrast, Integra was not hired by the government or otherwise acting on its behalf. Instead, it was given the information for its own purposes. And beyond complying with the confidentiality provisions designed to protect the privacy of Medicare beneficiaries, Integra had no incentive to keep the information it learned during its analysis confidential. Indeed, it turned around and used that information as the basis of this suit.

Relator relies heavily on the decision in *United States ex rel. Spey v. CVS Caremark Corp.*, 913 F. Supp. 2d 125 (E.D. Pa. 2012), *see Hosp. Opp.* 12:23–13:9, but *Spey* addressed an entirely different issue. In that case, the defendants argued that various reports should be considered publicly disclosed because the defendants themselves had submitted them to the government, at which point members of the public theoretically could have obtained them by making a request. *Spey*, 913 F. Supp. at 182–84. The court rejected this argument, finding that it would be tantamount to saying that the mere act of submitting a false claim via the reports would immunize the defendant from liability. *Id.* at 183. The argument made by the *Spey* defendants is quite different than the one Defendants make here. An analogous scenario in this case would be if Defendants were arguing that the mere act of filing (allegedly) false Medicare claims constituted a public disclosure because claim data could later be obtained by researchers like Integra. But that is not the argument before the Court. Instead, Defendants argue that the

data became publicly disclosed only when the CMS *actually* provided it to Integra, an outsider. *Spey* is simply inapposite.

For the foregoing reasons, the Court concludes that the Medicare claims data was publicly disclosed in a federal report within the meaning of the FCA.

b. HHS OIG Reports

Relator does not dispute that information in the HHS OIG reports regarding the improper coding of kwashiorkor was publicly disclosed in a federal report. Accordingly, the Court concludes that this information was publicly disclosed within the meaning of the public disclosure bar.

c. The JATA Business Practice Information

The public disclosure bar applies to information "publicly disclosed . . . from the news media." 31 U.S.C. § 3730(e)(4)(A)(iii). Defendants argue that seven categories of information regarding JATA's business practices were publicly disclosed from the news media by virtue of being available on the internet:

> **Case Mix Guarantee**—In the SAC, Relator alleges that JATA "guaranteed an increase in its clients' Case Mix Index ("CMI"), which is influenced by a hospital's CC and MCC rates." *SAC* ¶ 24. In support, it includes a screenshot of text from JATA's website that reads "**Guaranteed to increase CMI** . . . . See how we're helping hospitals achieve a 4–8% increase in their Case Mix Index through better documentation." *Id.*; *Exhibit 13 to RJN*, Dkt. # 59-14, at 202–03.
>
> **Return on Investment Sales Pitch**—Relator alleges that JATA gave a sales pitch promising "guaranteed return on investment if [the hospital] followed [JATA]'s process." *SAC* ¶ 25. This quote was taken from a case study put together by JATA and another hospital that is publicly available on the website of Becker Hospital Review, a hospital industry trade publication. *Exhibit 14 to RJN*, Dkt. # 59-15, at 227.
>
> **Documentation Tip Sheets**—The documentation tip sheets cited in the SAC—which, as explained above, informed Providence doctors about clinical language that would and would not support adding MCCs and CCs to diagnoses—are available on the website of

Providence Health & Services Southern California. *See SAC* ¶¶ 26–27, 29–30; *Exhibits 15–18 to RJN*, Dkts. # 59-16–59-19.

Newsletter—A monthly hospital newsletter that Relator alleges is evidence that "Providence gave CDI and doctors financial incentives for successful queries and . . . made clear to doctors and staff that it closely tracked their responsiveness," *SAC* ¶ 41, is available on the website of Defendant Swedish/Edmonds. *Exhibit 19 to RJN*, Dkt. # 59-20.

Training Video—A JATA training video described in the complaint is publicly available on YouTube. *See SAC* ¶ 31; *Exhibit 20 to RJN*, Dkt. # 59-21.

Message Board Posts—The complaint quotes several statements made by CDI specialists, questioning JATA's coding practices. *See SAC* ¶¶ 36–37, 45. These statements were taken verbatim from discussions on a message board that is hosted on the website of the Association of Clinical Documentation Improvement Specialists ("ACDIS"), a trade organization. *See Exhibits 21–25 to RJN*, Dkts. #59-22–59-26.

JATA Audit Presentation—The SAC references a presentation in which JATA staff "coached hospitals to avoid being audited." *SAC* ¶ 40. This presentation is available on the ACDIS website. *See Exhibit 26 to RJN*, Dkt. # 59-27, at 304–05.

See JATA Mot. 28:3–29:3.

Relator does not dispute that this information was publicly available on the internet. Instead, it argues that the websites containing this information are not "news media" within the meaning of the FCA. *See Hosp. Opp.* 14:14–15:23; *JATA Opp.* 28:10–29:17.

The public disclosure bar, read as a whole, provides context for the Court's discussion of whether the online information in this case was publicly disclosed "from the news media." The bar applies if "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report,

hearing, audit, or investigation; or

(iii) from the news media."

31 U.S.C. § 3730(e)(4)(A). This framework does not capture all information that could be described as "public" in common parlance. Instead, "[b]y its plain terms, the public disclosure bar applies to some methods of public disclosure and not to others." *Schindler Elevator*, 563 U.S. at 414.

As described above, the information about JATA's business practices comes from websites operated by industry groups, websites operated by Defendants, and an online message board. None of these would traditionally be described as "news media." But this is not necessarily dispositive. Courts have generally taken a broad view of the term "news media." For example, the Eleventh Circuit has held that a health clinic's publicly available websites qualified as news media because they were "intended to disseminate information about the clinics' programs." *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 813 (11th Cir. 2015). And applying differing but related standards, numerous other decisions cited by Defendants have held that various online sources were "news media." *See United States ex rel. Carter v. Bridgeport Educ., Inc.*, No. 10-CV-1401 JLS (WVG), 2015 WL 4892259, at *6 n.4 (S.D. Cal. Aug. 17, 2015) (holding that an online comment on the San Diego Reader website was disclosed from the news media because the site was a "well-established website designed to convey news to the public"); *United States ex rel. Green v. Serv. Contract Educ. & Training Tr. Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012) (concluding that the term includes "readily accessible websites"); *United States ex rel. Brown v. Walt Disney World Co.*, No. 6:06-cv-1943-Orl-22KRS, 2008 WL 2561975, at *4 (M.D. Fla. June 24, 2008) (finding that Wikipedia is a news media outlet); *United States ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413 PJH, 2007 WL 4557788, at *14 (N.D. Cal. Dec. 21, 2007) (holding that information about contracts between the defendant and the government was publicly disclosed because it "was available on the Internet"); *see also United States ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 43 n.6 (4th Cir. 2016) (stating in dicta that "[c]ourts have unanimously construed the term 'public disclosure' to include websites and online articles").

In particular, Defendants ask the Court to adopt the holding of a case from this District that stated, without further elaboration, that "[i]nformation publicly available on the Internet generally qualifies as 'news media.'" *United States ex rel. Hong v. Newport Sensors Inc.*, No. SACV 13-1164 JLS (JPRx), 2016 WL 8929246, at *5 (C.D. Cal. May 19, 2016) ("*Hong I*"). But in affirming *Hong* on other grounds, the Ninth Circuit explicitly noted that it was not

adopting "the district court's broad holding that most public webpages . . . generally fall within the category of 'news media.'" *United States ex rel. Hong v. Newport Sensors, Inc.*, 728 F. App'x 660, 662–63 (9th Cir. 2018) ("*Hong II*"). And the Court finds *Hong I*'s holding unpersuasive.

"News media" is not defined in the FCA. The courts that have interpreted the term to include all, or substantially all, information available online appear to have extrapolated their holdings from the Supreme Court's description of the public disclosure bar as having a "generally broad scope." *See Schindler Elevator*, 563 U.S. at 408; *see also, e.g.*, *Green*, 843 F. Supp. 2d at 32. Notably, none attempted to analyze whether the online sources at issue fell within the ordinary meaning of the term "news media." As the Court informed the parties at both hearings, it believes that an analysis of whether the information about JATA's business practices was "publicly disclosed . . . from the news media" must start with the statute's text. *See Schindler Elevator*, 563 U.S. at 407 ("Because the [FCA] does not define 'report,' we look first to the word's ordinary meaning."). After the first hearing, the Court invited the parties to submit supplemental briefs providing their views on the ordinary meaning of the term "news media," and both have done so. With the issue fully briefed, the Court now turns to the question of whether the online information about JATA's business practices was publicly disclosed from the news media.

1. Whether All *Online Information Is Disclosed From the News Media*

The Court first addresses Defendants' argument that *all* publicly available online information has been publicly disclosed "from the news media." As explained above, the analysis must begin with the statute's text. While the compound term "news media" is not commonly defined in dictionaries, its component parts give some indication of its scope. "News" is a "report of a recent event," "what is reported in a newspaper, news periodical, or news broadcast," or "matter that is interesting to newspaper readers or news broadcast audiences . . . or is suitable for news copy." Webster's Third New International Dictionary 1524 (1986). "Medium," the singular of "media," can be defined as a "channel, method, or system of communication, information, or entertainment" or "a vehicle (such as a radio or television program or a newspaper) used to carry advertising." *Id.* at 1403. Read together, these definitions suggest that "news media" includes methods of communication that are used to convey a particular type of information: information about recent events or that would otherwise commonly be found in a newspaper, news broadcast, or other news source. It follows, then, that

the term cannot refer to the internet in general, a channel that is designed to be able to convey essentially anything.

That "news media" cannot encompass *all* online information is also clear as a matter of common sense. Nobody would use the term this way in everyday speech. Information is available on the internet from innumerable sources. A person might go to a restaurant's website to look at its menu. Or the Dodgers' website to find out the ticket prices for the upcoming series. Or, closer to this case, a doctor's website to determine the next available appointment. In none of these circumstances would it be natural, or really conceivable, to say that the information had been learned by consulting the news media.

Defendants' unbounded reading of the news media provision also seems likely to swallow limitations that Congress specifically placed on the scope of the public disclosure bar. For example, the bar applies to suits based on information disclosed "in a Federal criminal, civil, or administrative hearing *in which the Government or its agent is a party*." 31 U.S.C. § 3730(e)(4)(A)(i). This provision evinces Congress's intent to exclude from the public disclosure bar information disclosed at hearings in cases in which the Government is *not* a party, conceivably in part based on a presumption that the Government is less likely to learn about events that transpire in cases it is not involved with. But transcripts of hearings in cases where the Government is not a party are commonly made available to the public for a small fee through the federal courts' PACER website. And many hearings are open to the public, such that a private citizen could attend and tweet his observations afterwards.

Under Defendants' view, the mere posting of the transcript on PACER or a tweet sent to a small handful of followers could render the information from the hearing publicly disclosed under the FCA, even though it otherwise would not be. This would run contrary to the purposes underlying the public disclosure bar, and indeed the FCA itself. *See Schindler Elevator*, 563 U.S. at 412 (describing the public disclosure bar as "narrower" than its predecessor, the Government knowledge bar, which was intended to preclude "parasitic *qui tam* actions based on evidence or information in the possession of the United States at the time such suit was brought") (cleaned up); *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740, 742 (9th Cir. 1995) ("[T]he purpose of the *qui tam* provisions of the False Claims Act is to encourage private individuals who are aware of fraud being perpetrated against the Government to bring such information forward.") (cleaned up).

In short, the Court concludes that applying the news media provision to anything ever published publicly on the internet is contrary to the ordinary meaning of the term "news media"

and has the potential to eviscerate the balance Congress struck between encouraging private parties to bring forth evidence of fraud and preventing parasitic suits. Accordingly, the Court declines to adopt Defendants' interpretation.

Defendants make several arguments to the contrary, none of which are persuasive. First, they contend that the ordinary meaning of the term "news media" must encompass all websites because "93 percent of adults get news online" and several news publishers, such as Slate.com and Vox.com, were founded on the internet. *See Def. Supp.* 10:6–23. But this fallaciously conflates the indisputable proposition that *some* websites are news media sources with a conclusion that *all* must be. Just as the fact that 93 percent of Americans may get their milk from the supermarket does not make everything in the supermarket milk, the fact that 93 percent of adults get their news online does not make everything on the internet a news media source.

Second, Defendants assert that Congress implicitly ratified previous judicial decisions holding that everything available on the internet is disclosed through the news media when it amended the public disclosure bar in 2010 but did not alter the news media provision. *See id.* 11:7–12:25. This argument invokes the so-called "prior-construction canon," under which "[i]f a statute uses words or phrases that have already received authoritative construction by the jurisdiction's court of last resort, or even uniform construction by inferior courts . . . they are to be understood according to that construction." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 322 (2012); *see also Merck & Co. v. Reynolds*, 559 U.S. at 648 (2010) ("We normally assume that, when Congress enacts statutes, it is aware of relevant judicial precedent."); *United States v. Male Juvenile*, 280 F.3d 1008, 1016 (9th Cir. 2002) (similar).

There are two problems with Defendants' argument. First, Defendants emphasize that Congress failed to alter the news media provision when amending *other* provisions of the public disclosure bar in 2010. *See Def. Supp.* 11:7–12:25. But a mere failure to *correct* previous judicial constructions of a statute is generally not viewed as "a sound basis for believing that the legislature has 'adopted' them." Scalia & Garner, *Reading Law* 326. Even viewed in the light most favorable to Defendants, that is all Congress did here.

Further, the vast majority of decisions adopting Defendants' preferred rule—including all relevant decisions from the Courts of Appeals—were not issued until *after* the 2010 amendment. As evidence that the law was settled in their favor at the time of the amendment, Defendants point only to four pre-2010 district court decisions from the Northern District of California, Middle District of Florida, Southern District of Ohio, and Western District of Virginia. *See Def.*

Supp. 12:8–16 (citing *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766, 772 (W.D. Va. 2008), *rev'd on other grounds*, 600 F.3d 319 (4th Cir. 2010); *United States ex rel. Brown v. Walt Disney World Co.*, No. 6:06-cv-1943-Orl-22KRS, 2008 WL 2561975 (M.D. Fla. Jun. 24, 2008); *United States ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413 PJH, 2007 WL 4557788 (N.D. Cal. Dec. 21, 2007); *United States ex rel. Doyle v. Diversified Collection Servs., Inc.*, No. 2:04 CV 053, 2006 WL 3834407 (S.D. Ohio Dec. 29, 2006)). Even putting aside the fact that some of these decisions did not go as far as adopting Defendants' rule that everything on the internet has been publicly disclosed through the news media—and indeed one explicitly declined to do so[7]—the central question in applying the prior-construction canon is whether the weight of authority is such that the construction of the statutory term can be considered "settled law." *See* Scalia & Garner, *Reading Law* 325. The Court does not believe that four scattered district court decisions sufficiently settled the law such that Congress should be presumed to have adopted their constructions of the term "news media" when it amended some provisions of the public disclosure bar but not others. *See United States v. Davis*, 139 S. Ct. 2319, 2331 (2019) ("[I]nterpretations of three courts of appeals 'may not have 'settled' the meaning" of a statute . . . .") (quoting *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L.P.A.*, 559 U.S. 573, 590 (2010)). Accordingly, the prior-construction canon has little to no persuasive value in this case.

Finally, Defendants point to more than thirty cases that held that various forms of online information were publicly disclosed through the news media. *See Def. Supp.* 12:27–16:25. These decisions applied differing rationales to reach their conclusions. Some looked to the extent to which the purpose of an online source was to disseminate information. *See, e.g.*, *Osheroff*, 776 F.3d at 813 (information on a clinic's websites was disclosed through the news media because the websites were "intended to disseminate information about the clinics' programs"); *United States ex rel. Oliver v. Philip Morris USA, Inc.*, 101 F. Supp. 3d 111, 125 (D.D.C. 2015) (information on the websites of two military entities was disclosed through the news media notwithstanding the fact that the websites did not contain a "news header," because the purpose of the pages "was clearly to give the public an accurate account of those entities' contracting requirements"). Others looked at the number of visitors to the website. *Green*, 843 F. Supp. 2d at 33 (information was disclosed through the news media when "thousands" of visitors would have come across it during the relevant time period). Still others have focused upon the ease with which an online source can be accessed. *See United States ex rel. Liotine v.*

[7] *See Radcliffe*, 582 F. Supp. 2d at 772 ("I am not ready to conclude that anything posted online would automatically constitute a public disclosure within the meaning of [the public disclosure bar].")

CDW Gov't, Inc., No. 05-33-DRH, 2009 WL 3156704, at *6 n.5 (S.D. Ill. Sept. 29, 2009) (information in an internal employee newsletter posted online was *not* disclosed through the news media in part because several steps needed to be taken before it could be located on the organization's website). And some have adopted the broad position that Defendants urge here, that all publicly available information on the internet has been disclosed through the news media within the meaning of the FCA. *See Hong I*, 2016 WL 8929246, at *5; *United States v. Honeywell Int'l, Inc.*, No. CV 12-2214 JAK (JCGx), 2013 WL 12122693, at *9 (C.D. Cal. Nov. 8, 2013) ("Documents that are publicly available on the internet generally qualify as 'publicly disclosed' documents under [the public disclosure bar].").

The Court does not lightly depart from what appears to be a general consensus in the federal courts that the news media provision of the public disclosure bar encompasses information from at least some types of online sources that might not traditionally be described as news media. But none of these decisions are binding on this Court. And their persuasive value is diminished by two factors.

First, most of the cases Defendants cite did not undertake their own independent analysis of the meaning and scope of the news media provision and instead simply cited to previous decisions of other courts (that themselves often contained sparse analysis) with little additional explanation. *See, e.g.*, *United States ex rel. Cherwenka v. Fastenal Co.*, Civ. No. 15-187 (PAM/BRT), 2018 WL 2069026, at *7 (D. Minn. May 6, 2018); *Hong I*, 2016 WL 8929246, at *5. Second, and more importantly, none of the decisions Defendants cite attempted to define the ordinary meaning of the term "news media" or to otherwise ground their interpretation in the statutory text. Most began their analysis with the Supreme Court's description of the news media provision as having a "broad[] sweep," *Graham Cty.*, 559 U.S. at 290, and proceeded to interpret it to encompass information from a broad swath of online sources without pausing to consider whether those sources could reasonably be defined as "news media" within any ordinary meaning of the term. *See, e.g.*, *Osheroff*, 776 F.3d at 813. Some appear to have gone so far as to suggest that information falls within the scope of the news media provision simply because it is publicly known, *see United States ex rel. Cervantes v. Deere & Co.*, No. CV-10-3034-RMP, 2011 WL 5325466, at *5 (E.D. Wash. Nov. 3, 2011), a conclusion that is at odds with the Supreme Court's description of the public disclosure bar as applying "to some methods of public disclosure and not to others," *see Schindler Elevator*, 563 U.S. at 402.

The Court believes that this approach improperly strays from the Supreme Court's instruction that interpretation of the undefined term "news media" must begin with its ordinary meaning. *See id.* at 407. While the Court in *Schindler Elevator* acknowledged the "generally

broad scope" of the public disclosure bar in giving the term "report" a broad construction, the documents in that case—written letters and emails from the Department of Labor containing information about records the agency found in response to FOIA requests—could still be considered "reports" within some ordinary meaning of the term because they were official government communications that conveyed information. *See id.* at 406–07. In contrast, as the Court illustrated above, there are many types of sources on the internet that cannot be realistically described as "news media."

A desire to carry out what may appear to the purposes of the public disclosure bar or to update the statute for the Internet Age, while perhaps understandable, does not provide the judiciary with a license to jettison the actual text that Congress enacted. Because many types of online sources clearly fall outside the ordinary meaning of the term news media, the news media provision cannot be read to encompass all publicly available online information.

Having reached this conclusion, the Court turns to the question of what the news media provision *does* encompass.

2. Scope of the News Media Provision

In a world where the line between what is and is not considered news media has become increasingly blurred, attempting to set forth a single conclusive definition of the term may be an impossible task.[8] Nevertheless, the Court believes that several factors provide useful guideposts in determining whether information from an online source has been disclosed "from the news media" within the meaning of the FCA's public disclosure bar.

First, as explained above, combining the dictionary definitions of the terms "news" and "media" suggests that the compound term "news media" describes methods of communication

[8] Citing this difficulty, Defendants suggested at the second hearing that the Court could avoid attempting to determine the ordinary meaning of the term news media and instead simply analyze the websites in this case by comparing them to online sources in other cases. But the Court believes that it is important to provide an ordinary meaning definition. As discussed above, none of the dozens of cases cited by both sides conducted an analysis that was anchored in the statutory text. While there may be room to disagree with the contours of the "news media" analysis that the Court sets forth below, perhaps this attempt to fashion an ordinary meaning definition of the term will lead others to attempt the same. *See Schindler Elevator*, 563 U.S. at 407.

that are used to convey information about recent events or other information that would commonly be found in a newspaper, news broadcast, or other news source. Accordingly, the extent to which the information typically conveyed by a source would be considered newsworthy is relevant to whether it is a news media source.

Second, the term "news media" generally carries with it a connotation of editorial independence, or at least some separation, between the original source of information and the medium that conveys it. Along these lines, Relator points to FOIA, which defines "a representative of the news media" for purposes of that statute as "any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." *See* 5 U.S.C § 552(a)(4)(A)(ii)(III); *see also Integra Supp.* 15:9–15. While the Court does not simply import this definition from FOIA into the FCA, it believes that it accurately reflects the sense in which a news media entity is ordinarily viewed as one that collects information from outside sources, exercises some editorial judgment in deciding what to publish, and then transmits the published information to an audience—put more simply, it curates information—in contrast to an entity that simply publishes information about itself.

Third, the Court believes that a source's intent to disseminate information widely, as opposed to only to a few individuals, is relevant to whether it is acting as a news media entity.

Fourth, traditional news outlets like newspapers and radio and television stations unquestionably fall within the news media provision of the public disclosure bar. Accordingly, the more that an online source functions like one of these traditional outlets, the more likely it is to be news media under the FCA. Relevant to this consideration is the extent to which the conveyance of newsworthy information is the primary purpose of entity publishing the online source or whether the dissemination of such information is merely ancillary to some other purpose.

Finally, consistent with the Supreme Court's approach in *Schindler Elevator*, the Court believes that the most important consideration is whether the source in question falls within the "broad ordinary meaning" of the term "news media"—in other words, whether it could reasonably be described as "news media" as at least some people would that term in everyday speech. *See Schindler Elevator*, 363 U.S. at 408. Accordingly, while there may be some debate in society about whether non-traditional sources, like blogs, should be considered part of the news media, the fact that at least some people would describe them as such is likely enough to bring them within the public disclosure bar's "broad scope." *See id.* In contrast, the fact that

nobody would describe a menu on a restaurant website as coming from the news media is strong evidence that it falls outside the reach of the public disclosure bar.

None these factors on their own are necessarily dispositive of whether an online source should be considered news media, and other factors may be relevant in a given case. But taken together, the Court believes that they provide guidance on how to adhere to the Supreme Court's description of the news media provision as evidencing the public disclosure bar's "broad sweep," *see id.* (cleaned up), while still ensuring that any application of the provision remains tethered to the text—"news media"—that Congress has chosen.

3. Application

Having set forth a framework for determining the contours of the public disclosure bar's news media provision as applied to online sources, the Court now turns to whether it can decide at the current stage whether the online sources containing information about JATA's business practices constitute "news media." It concludes that it cannot. The public disclosure bar is an affirmative defense, and an affirmative defense can only be adjudicated on a motion to dismiss when the allegations in the complaint or information that the court can take judicial notice of are sufficient to establish the defense. *See Sams*, 713 F.3d at 1179. The complaint does not describe the sources of the JATA business practice information.[9] Accordingly, the Court could decide

[9] Defendants argue that the websites containing the JATA business practice information have been incorporated by reference into the SAC. *See Def. Supp.* 25:8–18. In support, they cite to cases holding that a court adjudicating a motion to dismiss can take into account "documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the plaintiff's pleading." *See Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005) (cleaned up); *see also Oaktree Principal Fund V, LP v. Warburg Pincus LLC*, No. CV 15-8574 PSG (MRWx), 2016 WL 6782768, at *8 (C.D. Cal. Aug. 9, 2016). However, the incorporation by reference doctrine is most commonly applied when the allegations in the complaint clearly implicate a document but the document is not attached to the pleading, for example when claims are based on a contract or insurance policy. *See Knievel*, 393 F.3d at 1076. Here, there appears to be at least some dispute about the extent to which the information underlying the allegations in the SAC came from the websites Defendants have put forward, as opposed to interviews with former JATA employees. *See Pl. Supp.* 22:5–23:8; *SAC* ¶ 1 (alleging that information about the fraud came in part from "interviewing former employees"). In any event, even assuming for the sake of argument that the online sources were incorporated by reference, a determination of whether any source constitutes "news media"

now whether that information has been publicly disclosed from the news media only if this fact is "not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy is not in question." *See* Fed. R. Evid. 201(b)(2) (standard for judicial notice). These conditions are not present here.

Relator very much disputes the extent to which several of the online sources qualify as "news media." For example, it contends that information about JATA's "Documentation Tips" was marked "Proprietary and Confidential" and was posted only on "internal staff homepages." *See Integra Supp.* 17:11–19. Likewise, it argues that information in Providence's internal newsletters was not publicly disclosed from the news media because the newsletters were only intended for Providence's own medical staff. *See id.* 18:2–10. Additionally, it appears that at least some of the information comes from online sources that were not easily accessible. For example, according to Relator, a presentation hosted on the webpage of Becker's Hospital Review can only be accessed "by typing in a precise URL," which brings up a list of hundreds of folders, one of which contains the presentation, which is labeled only by a gibberish file name. *See id.* 19:20–20:9.

These facts, which in some instances seem to be in dispute, could be relevant to whether the sources at issue were "news media" sources within the meaning of the FCA. Further, Defendants have largely ignored them in the briefing currently before the Court, instead resting on their contention that everything on the Internet falls within the scope of public disclosure bar. Without evidence and briefing from both sides about the specific nature of each source, the Court is not able to determine which sources constitute "news media" and which do not. Accordingly, adjudication of whether the information about JATA's business practices was publicly disclosed from the news media will have to await a later stage of the case.

ii. Substantial Similarity

Defendants argue that regardless of whether the JATA business practice information was publicly disclosed through the news media, the case should *still* be dismissed because Relator's claims are based on substantially the same information contained in the Medicare claims data

within the meaning of the public disclosure bar will require more than simply looking at the screenshots Defendants have put forward. *See* Dkt. # 76. Accordingly, the issue is not ripe for adjudication.

and HHS OIG reports, which, as explained above, were publicly disclosed in federal reports within the meaning of the FCA.[10] *See Def. Supp.* 4:16–7:18.

The FCA's public disclosure bar provides that a case should be dismissed "if substantially the same allegations or transactions" were publicly disclosed through the channels listed in the statute. 31 U.S.C. § 3730(e)(4)(A). In deciding whether a case falls within the scope of the public disclosure bar, a court must determine (1) whether the publicly disclosed information contains an "'allegation or transaction' of fraud" and (2) whether the claims in the complaint are "'based upon' said 'allegation or transaction.'" *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 570 (9th Cir. 2016). An "allegation" is a "direct claim of fraud," while a transaction refers to "facts from which fraud can be inferred." *Id.* at 571.

The Court begins with the Medicare claims data. It is undisputed that this raw data does not contain an "allegation" of fraud—that is, "a direct claim of fraud." *Id.* But "the substance of the disclosure need not contain an explicit 'allegation' of fraud so long as the material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain." *Id.* (cleaned up). As the Ninth Circuit has explained:

> If X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

Id. (quoting *United States ex rel. Found. Aiding the Elderly v. Horizon W.*, 265 F.3d 1011, 1015 (9th Cir. 2001)). "[I]n a fraud case, X and Y inevitably stand for but two elements: a misrepresented state of facts and a true state of facts." *Id.* (cleaned up). Therefore, unless the

[10] Defendants had originally taken the position that Relator's claims would be precluded by the public disclosure bar as substantially similar to publicly disclosed information only if the Medicare claims data, HHS OIG reports, *and* the online information about JATA's business practices were *all* publicly disclosed. *See, e.g*, *JATA Reply*, 17:15–19. But at the February 13 hearing, they argued for the first time that public disclosure of the Medicare claims data and HHS OIG reports *alone* would be enough to trigger the public disclosure bar, regardless of whether the information about the JATA business practices was publicly disclosed. At the Court's request, the parties submitted supplemental briefs addressing this argument, *see Def. Supp.* 4:16–7:18; *Relator Supp.* 6:1–12:27, and it is now ripe for adjudication.

information at issue reveals *both* the misrepresented state of facts and the true state of facts, the fraudulent transaction has not been publicly disclosed. *See id.*

The Medicare claims data undoubtedly contains the alleged misrepresented state of facts: it reveals the extent to which Defendants submitted Medicare claims that included MCCs for encephalopathy, respiratory failure, and severe malnutrition—codes that the SAC alleges were not merited by the clinical circumstances. The question is whether the data also reveals the *true* state of facts, i.e. whether it reveals that the use of the codes was not merited.

The Court does not believe that it does. The most that can be determined from the data alone is that the Hospital Defendants submitted claims with MCCs for encephalopathy, respiratory failure, and severe malnutrition at rates that far exceeded their peers. The data itself does not provide an explanation for the high coding rates.

At other points in their motions, Defendants appear to agree. They argue strenuously that these allegations of statistical disparities in the Medicare claims data are not enough to plead fraud under the relevant pleading standards.[11] As discussed further below, the Court agrees with Defendants that the statistics alone are likely not enough to state a viable fraud claim. *See infra* IV.B.i. This does not end up being fatal to Relator's claims here, however, because the complaint contains more than just numbers. Specifically, the complaint alleges facts—taken from the JATA business practice information—that explain why the high coding rates for the three MCCs are plausibly attributable to fraud, as opposed to some other cause. The JATA business practice information is therefore key to Relator's fraud claim; without it, there likely *would be no claim*.

For this same reason, then, the Court concludes that the Medicare claims data alone does not reveal the alleged true state of facts that would allow readers to "infer . . . the conclusion that fraud has been committed." *See Mateski*, 816 F.3d at 571. Nothing in the claims data reveals JATA's role in the alleged scheme, or even JATA's existence. Accordingly, public disclosure of the Medicare claims data alone did not publicly disclose "substantially the same allegations or transactions" of fraud that are alleged in Relator's complaint. *See* 31 U.S.C. § 3730(e)(4)(A).

[11] *See, e.g.*, *Hosp. Mot.* 24:17–21 ("Relator's central allegation is that Providence had a statistically significant higher incidence of coding for three MCCs than other hospitals. From this, Relator makes the inferential leap that the claims that use those codes are fraudulent. This lack of a claim-specific analysis is fatal to its complaint.")

Nor does the public disclosure of the OIG reports regarding kwashiorkor coding change the analysis. These reports addressed industry-wide miscoding of kwashiorkor caused by a discrepancy in the ICD-9 coding guidelines[12] that created ambiguity as to whether a code that was intended only for kwashiorkor could be used to code other forms of malnutrition. *See* Dep't Health & Human Servs. OIG, *CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor* (Dec. 2017), *Exhibit 31 to RJN*, Dkt. # 59-35 ("*Dec. 2017 OIG Report*"), at 731–32. While a 2014 OIG report specifically addressed Providence Portland Medical Center's overcoding of kwashiorkor, it did not draw a conclusion about the cause of the overcoding, and the hospital attributed it to confusion about the ICD-9 guidelines. *See* Dep't Health & Human Servs. OIG, *Providence Portland Medical Center Incorrectly Billed Medicare Inpatient Claims With Kwashiorkor* (Sept. 2014), *Exhibit 10 to RJN*, Dkt. # 59-11 ("*Sept. 2014 OIG Report*"), at 188–94. The industry-wide miscoding of kwashiorkor, which was attributed to ambiguous ICD-9 guidelines, is far different than the scheme alleged by Relator: that Providence and JATA specifically instructed doctors to code kwashiorkor—even though it is "not typically found in the United States"—in order to increase reimbursements. *See SAC* ¶¶ 26–27. Accordingly, the OIG reports, even taken together with the Medicare claims data, did not publicly disclose the "substantially the same allegations or transactions" of fraud that are alleged in Relator's complaint. *See* 31 U.S.C. § 3730(e)(4)(A).

Because Relator's claims are not substantially based on the information revealed in the Medicare claims data and HHS OIG reports alone, and because the Court cannot determine on the current record and briefing whether the online information about JATA's business practices was publicly disclosed, the Court **DENIES** Defendants' motion to dismiss based on the public disclosure bar.

The Court now proceeds to address Defendants' arguments that Relator has nonetheless failed to sufficiently plead its claims.

B. Primary FCA Claims

To state a claim under the FCA, Relator must allege the following elements: "(1) a false or fraudulent claim (2) that was material to the decision-making process (3) which defendant

[12] The ICD or "International Classification of Diseases" is maintained by the World Health Organization and is the "international standard diagnostic tool for epidemiology, health management, and clinical purposes." *Dec. 2017 OIG Report* at 728. ICD-9 was the ninth revision of the ICD.

presented, or caused to be presented, to the United States for payment or approval (4) with knowledge that the claim was false or fraudulent." *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047 (9th Cir. 2012).

Because FCA claims sound in fraud, they must satisfy both the plausibility requirement of Rule 8 *and* the particularity requirement of Rule 9(b). *See United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2004 n.6 (2016). Accordingly, Relator's complaint must "set forth what is false or misleading about a statement, and why it is false"; in other words, "the who, what, when, where, and how" of the misconduct charged. *Vess*, 317 F.3d at 1106; *see also Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) ("To comply with Rule 9(b), allegations of fraud must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong.") (internal quotation marks omitted). In the context of the FCA, Rule 9(b) requires "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

Defendants argue that Relator failed to adequately plead the elements of falsity, materiality, and scienter.

i. Falsity

Relator alleges that the Hospital Defendants submitted false claims to Medicare by including unwarranted MCCs for encephalopathy, respiratory failure, and severe malnutrition. *See generally SAC*. For each of these three categories, the complaint contains a table listing specific claims that Relator alleges were false. *See id.* ¶¶ 66, 74, 81. Among other information, the tables list the claim ID number, the hospital, the principal diagnosis, the alleged MCC false claim, and the false claim amount. *See id.* While the complaint does not contain allegations about the medical conditions of specific patients—i.e. the symptoms they exhibited or their medical test results—because Relator does not have access to patient medical records, it alleges, based on its proprietary statistical analysis, that there is only a 1 in 1,000 to 1 in 100 million probability (depending on the diagnosis) that Providence's use of the encephalopathy, respiratory failure, and severe malnutrition MCCs at rates disproportionate to other hospitals is attributable to chance. *See JATA Opp.* 18:14–24. Importantly, Relator provides an explanation for this disparity, alleging that the MCCs Providence used at high rates line up with Defendant JATA's documentation tips, which instructed Providence doctors that these were MCCs that could result

in increased reimbursement. *See SAC* ¶ 29. And Relator further alleges that Defendants' use of leading queries and the incentives doctors had to code MCCs give rise to a plausible inference that false claims were submitted. *See id.* ¶¶ 32–39.

Defendants argue that this is not enough. They contend that without information about the actual medical conditions of specific patients, Relator cannot plausibly allege that any particular use of an MCC was not supported by the clinical circumstances.
Relator's attempt at identifying false Medicare claims through statistical analysis appears to be novel. Neither side has identified any cases precisely on point. But the Third Circuit has relied on similar statistical data in determining that a relator had adequately pleaded its FCA claims. *See United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 258 (3d Cir. 2016).

In *Victaulic*, the relator alleged that the defendant had failed to properly mark pipe fittings it had imported from abroad (only imported fittings had to be marked). *See id.* at 247–48. In support of its claims, it relied principally on two sources of information: (1) an analysis of shipping manifest data that showed the majority of the defendant's pipe fittings were imported from abroad and (2) a study that showed that most of the defendant's products in the marketplace did not have the proper markings. *Id.* Notably, the complaint did not identify any specific pipe fittings that were alleged to be both imported from abroad and improperly marked; instead, it alleged that the number of pipe fittings the defendant imported combined with the number of unmarked fittings on the market gave rise to an inference that at least some imported fittings did not have the proper markings. *Id.* The Third Circuit found this sufficient to allege falsity under both Rule 8 and Rule 9(b). *See id.* at 256–58. It determined at the motion to dismiss stage that it had to credit the relator's expert's conclusion that the only possible explanation for the lack of markings on products in the marketplace was that unmarked goods were being imported. *Id.* at 257. And it concluded that the relator did not need to identify specific shipments of unmarked goods under Rule 9(b) because only the defendant had "access to the documents that could prove or disprove [Relator's] well-pled allegations." *Id.* at 258.

The Court finds the Third Circuit's analysis persuasive. At this stage, it must credit Relator's allegations that the Hospital Defendants' high rates of coding for encephalopathy, respiratory failure, and severe malnutrition are highly unlikely to be caused by chance. And while the coding rates alone likely would not be enough to state a claim for fraud, Relator's allegations about the documentation tips that JATA gave to Providence's doctors, along with

JATA's promotion of leading queries[13] and its guarantee that it would increase hospitals' case mix, are enough to give rise to a plausible inference that the increased coding rates were plausibly caused by the Hospital Defendants submitting claims with MCCs that were not supported by the clinical realities.

Defendants' arguments to the contrary are unpersuasive. *See JATA Mot.* 24:14–28:14. First, they rely on three out-of-circuit cases that they contend stand for the proposition that relators cannot rely on statistical analyses to allege falsity. *See United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013); *United States ex rel. Crews v. NCA Healthcare of Ill., Inc.*, 460 F.3d 853 (7th Cir. 2006); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997). But these cases are inapposite.

In *Thompson*, the defendant alleged only that "in reasonable probability, based on statistical studies performed by the Government and others approximately 40 percent of claims submitted by defendants . . . were for services that were not medically necessary." 125 F.3d at 903. The Fifth Circuit found that this bare reference to statistical studies was not enough to allege falsity because the studies did not show that the defendants were the cause of the disparity. *Id.* In contrast, Relator here has provided detailed allegations explaining why JATA and the Hospital Defendants were responsible for the allegedly false claims reflected by the statistical analysis.

In *Nathan*, the Fourth Circuit found that the statistical inferences the relator was making to connect various data points were "implausible and unsupported by the stated facts." 707 F.3d at 460. Here, however, the Court believes the Hospital Defendants' use of certain MCC codes at rates that far exceed other hospitals, when combined with allegations about JATA's business practices, renders Relator's inferences at least plausible.

[13] Defendants argue that Relator cannot base its FCA claims on allegedly leading queries because there is no CMS or other government guidance on the use of queries. *See Hosp. Mot.* 30:16–32:13. But while the Court agrees that merely violating industry practices that are not codified in any government regulation cannot create liability, that is not what Relator alleges here. Relator instead points to Defendants' alleged non-conformance with the practices of the industry to explain *why* Defendants coded MCCs at rates that far exceeded other hospitals. If these allegations are true, they could tend to show that the queries predictably led Providence doctors to code MCCs that were not supported by a patient's condition. In other words, Relator does not ground its FCA claim in violations of industry standards; it instead points to Defendants' query practices as evidence that supports its theory that false claims were submitted.

Finally, in *Crews*, the Seventh Circuit found that a statistical analysis was not enough to show that any given claim was false. *See* 460 F.3d at 856–57. But in the Ninth Circuit, unlike in the Seventh Circuit, relators need not identify a specific false claim; instead, they may "allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid*, 616 F.3d at 998–99. Accordingly, *Crews*'s holding is simply not relevant in this circuit.

Defendants also point to the fact that while Medicare conducts similar statistical analyses of claims as part of its auditing practices, its contractors are not permitted to deny claims on the basis of statistics without first reviewing the relevant medical record. *See Hosp. Mot.* 27:9–28:10 (citing CMS, *Medicare Program Integrity Manual*, Pub. 100-08 Ch. 2—Data Analysis (rev. June 22, 2016) ("PIM")). However, Defendant cannot argue that statistical analysis of the type performed by Relator is entirely irrelevant. Medicare's manual itself specifically notes that "Data Analysis is an essential first step in determining whether patterns of claims submissions and payments indicate potential problems. Such data should include identification of statistical outliers in billing patterns within a well-defined group, or more sophisticated detection of patterns within claims or groups of claims that might suggest improper billing or payment." PIM § 2.1.C.

Defendants view this Medicare guidance as a point in their favor, arguing that that if statistical analyses "are not even enough to deny a claim, they are certainly not enough to initiate an FCA action." *Hosp. Mot.* 28:11–14. But the argument proceeds from a faulty premise. On a motion to dismiss, Relator does not need to have enough evidence to justify denying a claim—i.e. to *prove* that a claim is false—because it does not need to prove its case at this stage. Instead, it need only allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 545. Relator's statistical analysis, which Medicare itself has acknowledged can suggest improper billing, combined with its allegations about JATA's practices, take its claims out of the realm of the speculative.

Defendants also argue that Relator has failed to satisfy the particularized pleading requirements of Rule 9(b). *See JATA Reply*, 6:15–7:22. But the Court agrees with Relator that it has adequately alleged the "who, what, when, where, and how" of the alleged fraud: the "who" is JATA and the Providence hospitals, the "what" is the upcoding of three categories of MCCs (encephalopathy, respiratory failure, and severe malnutrition), the "when" is between 2011 and 2017, and the "how" is by training doctors to use language supporting the MCCs and steering them into using that language through leading queries and incentives. *See Hosp. Opp.* 30:9–20; *see also Vess*, 317 F.3d at 1106. Defendants argue that Relator has not alleged the "who"

because it has "failed to identify a single Providence affiliate who engaged in misconduct or a single physician who went against her own medical judgement to diagnose a patient with a condition she did not have." *Hosp. Mot.* 10:21. But this is not entirely correct. Relator has provided a list of 125 alleged false claims and has identified the hospital at issue for each of them. *See id.* ¶¶ 66, 74, 81. As for the names of the doctors who provided the diagnoses that led to these specified claims, their names can be easily determined by Defendants and therefore did not need to be alleged in the complaint. *See United States ex rel. Mei Ling v. City of L.A.*, No. CV 11-974 PSG (JCx), 2018 WL 3814498, at *11 (C.D. Cal. July 25, 2018) ("The individuals who signed the claims and statements can be divined by [Defendants]; the Government need not include them in its complaint when its allegations already provide Defendants with the notice required by Rule 9(b)" (cleaned up)). In short, the Court concludes that the detailed allegations in the complaint provide Defendants with sufficient notice of the allegedly fraudulent conduct, satisfying the requirements of Rule 9(b).

ii. Materiality

A falsehood is material under the False Claims Act if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

Defendants contend that Relator has not adequately alleged materiality because "coding an MCC does not necessarily change reimbursement." *Hosp. Mot.* 32:22–23. This is because while each claim can have multiple secondary diagnoses, there are only three severity levels: (1) "without Complication or Major Complication," (2) "with Complication," or (3) "with Major Complication." *SAC* ¶ 23. Defendants argue that even if some MCCs for encephalopathy, respiratory failure, and severe malnutrition were coded incorrectly, it is possible that the severity level of the claim—and consequently the reimbursement—would not have changed because it could have been adequately supported by other, legitimately coded, MCCs. *See JATA Mot.* 20:1–11. In support, it points to an audit that HHS OIG performed of Providence Portland Medical Center's claims using the diagnosis code for kwashiorkor, a type of severe malnutrition. *See id.* 20:12–25; *Sept. 2014 OIG Report*. HHS OIG identified 90 claims that improperly used the kwashiorkor code but determined that for 87 of those 90 claims, the severity level of the claim was unaffected because it was adequately supported by other diagnosis codes that had a similar or greater severity level. *Sept. 2014 OIG Report at* 189–90.

However, Relator alleges that for each of the 125 specific claims identified in the SAC, adding the MCC increased the severity level and the reimbursement amount. *See Hosp. Opp.*

26:7–12; *see SAC* ¶¶ 66, 74, 81. At the motion to dismiss stage, the Court must take these allegations as true, and they are enough to adequately plead materiality.

iii. Scienter

A defendant is liable under the FCA only if it acted "knowingly." 31 U.S.C. § 3729(b)(1). The defined term "knowingly" is somewhat of a misnomer because it includes both acting with "actual knowledge of the information" and acting with "deliberate ignorance" or "reckless disregard of the truth or falsity of the information. *See id.* § 3729(b)(1)(i)–(iii). Mere negligence, however, is insufficient to state a claim under the FCA. *See United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007) ("Congress specifically expressed its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence.") (internal quotation marks omitted). Although "knowledge must [] be pleaded sufficiently to make entitlement to relief plausible," *United States ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d 993, 1012 (C.D. Cal. 2015), it need not be pleaded with particularity. *See id.* at 1011–12; *see also United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 996 (9th Cir. 2011) ("[M]alice, intent, knowledge, and other conditions of a person['s] mind, including scienter, can be alleged generally.") (internal quotation marks omitted).

Defendants' argument for lack of scienter is essentially that Relator has not adequately alleged that Defendants knew the claims they were submitting to Medicare contained MCCs that were not justified by the clinical circumstances. *See JATA Mot.* 21:1–22:9. But the Court is not persuaded. Relator has alleged that Defendants implemented a coding program that was intended to increase Medicare revenue by leading physicians to use language that would support coding of certain MCCs. *SAC* ¶¶ 26–31. They did so by training physicians to use such language and by sending allegedly leading queries, in contravention of industry practices, that physicians responded to in a manner that supported the addition of an MCC. *Id.* ¶¶ 33–39. Further, JATA's Regional Director allegedly taught Providence physicians that the only way to avoid being harassed by queries would be to document an MCC in the first place. *Id.* ¶ 38. All of these allegations taken together are enough to give rise to a plausible inference that Defendants were primarily focused on increasing their Medicare revenue such that they at least recklessly disregarded the possibility that the tactics they used could lead to improper upcoding. Because acting with reckless disregard is enough to satisfy the FCA's "knowingly" requirement, Relator has adequately alleged scienter.

C. Conspiracy Claims

The FCA claims described above provide for liability if the defendant acts "knowingly," which is defined as having actual knowledge *or* acting in deliberate ignorance or with reckless disregard. *See* 31 U.S.C. § 3729(b)(1). However, the FCA's reference to *conspiracy* claims does *not* have this "knowingly" requirement. *See id.* § 3729(a)(1)(C). Accordingly, most courts have concluded that general civil conspiracy principles apply to the conspiracy provision of the FCA. *See United States ex rel. Rizzo v. Horizon Lines, LLC*, No. CV 10-7409 PA (AJWx), 2013 WL 12131171, at *4 (C.D. Cal. Oct. 23, 2013); *see also United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 n.3 (7th Cir. 1999). Under these principles, Relator "must show that the conspiring parties reached a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful agreement." *Gilbrook v. City of Westminster*, 177 F.3d 839, 856 (9th Cir. 1999) (cleaned up). As the alleged object of this conspiracy was to submit false claims to Medicare, Relator must show that Defendants jointly intended to do so. For conspiracy, reckless disregard is not enough.

The Court concludes that the allegations in the SAC are not sufficient to make this showing. While Relator adequately alleges that Defendants may have recklessly disregarded the possibility that their actions would lead to false claims, nothing in the SAC—beyond a conclusory allegation of conspiracy—alleges that the Hospital Defendants and JATA set out with a joint purpose to submit false claims. It instead alleges that they intended to increase the Hospital Defendants' Medicare reimbursements. That, in and of itself, is not illegal. If the Hospital Defendants were previously underbilling Medicare, then it would be legitimate to attempt to increase the billing rate. While Relator has plausibly alleged Defendants' plan was executed in a manner that predictably led to false claims, such that it was reckless for Defendants to disregard the fact that false claims were submitted, this does not necessarily mean that submitting false claims was Defendants' goal at the outset.

Because Relator has not adequately alleged an agreement between the Hospital Defendants and JATA to submit false claims, it has not adequately alleged a conspiracy. Accordingly, the Court **GRANTS** Defendants' motion to dismiss the conspiracy claims.

D. Reverse FCA Claims

In 2009, Congress expanded the scope of the FCA by making it unlawful to "knowingly conceal[] or knowingly and improperly avoid[] . . . an obligation to pay or transmit money or

property to the Government." 31 U.S.C. § 3729(a)(1)(G). These claims based on failure to pay money owed to the Government are known as "reverse FCA claims."

Relator's reverse FCA claim is predicated upon Defendants' statutory obligation to report and return Medicare overpayments. *See Hosp. Opp.*; 42 U.S.C. § 1320a-7k. Essentially, Relator alleges that after overcharging Medicare, Defendants further violated the FCA by failing to return the overpayments. However, "[i]n cases where a plaintiff alleges a reverse false claim by claiming that the defendant fraudulently overcharged the government and then failed to repay the government, courts have consistently dismissed the [reverse FCA] claim as redundant." *United States v. Kinetic Concepts, Inc.*, No. CV 08-1885 BRO (AGRx), 2017 WL 2713730, at *13 (C.D. Cal. Mar. 6, 2017).

Relator argues that its reverse FCA claim is not redundant because the Court could find that Defendants did not knowingly submit false claims but did "knowingly conceal" false claims by avoiding Medicare audits. *See Hosp. Opp.* 28:19–26. But the Court does not believe this theory is supported by the single allegation Relator cites from the SAC, which alleges that a JATA official advised hospitals at an industry event to avoid single CC or single MCC diagnoses to avoid triggering audits. *See SAC* ¶ 40. The complaint does not allege that this advice was ever given *to Defendants*, and in any event, Relator has not explained how Defendants could knowingly attempt to avoid audits by manipulating CC or MCC codes without at least recklessly disregarding whether the codes it used were accurate (which would give rise to a primary FCA claim).

Because the Court finds that Relator's reverse FCA claim is redundant of its primary claims, it **GRANTS** Defendants' motion to dismiss this claim.

E. Anti-Kickback Claims

Relator's second cause of action alleges that Defendants violated the FCA by submitting claims that were tainted by violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). *See SAC* ¶¶ 134–42. The statute prohibits paying or receiving kickbacks in exchange for "referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made . . . under a Federal health care program." 42 U.S.C. § 1320a-7b(b).

Relator's theory of liability on this claim is that JATA and the Hospital Defendants conspired to pay JATA kickbacks, in the form of increased remuneration, in exchange for a

guarantee that JATA would increase the hospitals' Medicare billing. But under the plain text of the Anti-Kickback Statute, this is not a violation. The statute applies only to kickbacks paid in exchange for "referring *an individual*" for health care services. *See id.* There are no allegations that JATA referred individuals to the Hospital Defendants for treatment; nor could there be because JATA is a coding consultant, not a physician.

As Relator has not adequately alleged a violation of the Anti-Kickback Statute, it likewise has not alleged an FCA violation based on violation of that statute. Accordingly, the Court **GRANTS** Defendants' motion to dismiss the FCA claims in the second cause of action.

F. Summary

For the foregoing reasons, the Court concludes that Relator has adequately pleaded its FCA claims against both Defendants based on the submission of false claims to Medicare but has not adequately pleaded its claims based on conspiracy or violation of the Anti-Kickback Statute. The Court further concludes that the reverse FCA claims should be dismissed as redundant. And it finds that resolution of the question of whether the public disclosure bar prohibits Relator's claims must wait for further factual development.

Accordingly, Defendants' motions to dismiss are **GRANTED** in part and **DENIED** in part. The Court **DISMISSES** the conspiracy, reverse FCA, and Anti-Kickback Statute claims. Relator may proceed on its other claims.

V. Leave to Amend

Whether to grant leave to amend rests in the sound discretion of the trial court. *See Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995). The Court considers whether leave to amend would cause undue delay or prejudice to the opposing party, and whether granting leave to amend would be futile. *See Sisseton-Wahpeton Sioux Tribe v. United States*, 90 F.3d 351, 355 (9th Cir. 1996). Generally, dismissal without leave to amend is improper "unless it is clear that the complaint could not be saved by any amendment." *Jackson v. Carey*, 353 F.3d 750, 758 (9th Cir. 2003).

The Court **GRANTS** leave to amend in part and **DENIES** it in part. As the defects in Relator's conspiracy claims could be cured by additional allegations about the nature of the agreement between JATA and the Hospital Defendants, the Court **GRANTS** leave to amend the conspiracy claims. As for the reverse FCA claims, the Court is skeptical that Relator will be

able to allege a claim that is not redundant of its primary claims, but it concludes that it should at least be given an opportunity to do so. Accordingly, the Court **GRANTS** leave to amend the reverse FCA claims. However, the Court concludes that amendment of the Anti-Kickback Statute claims would be futile and therefore **DENIES** leave to amend these claims.

Relator must amend its conspiracy and reverse FCA claims no later than **August 16, 2019** or they will be dismissed with prejudice.

VI. Conclusion

For the foregoing reasons, Defendants' motions to dismiss are **GRANTED** in part and **DENIED** in part. The Anti-Kickback Statute claims are **DISMISSED** with prejudice. The conspiracy and reverse FCA claims are **DISMISSED** without prejudice to amendment. The motions to dismiss are **DENIED** as to Relator's primary FCA claims based on Defendants' alleged knowing submission of false claims to Medicare.

Relator must amend its conspiracy and reverse FCA claims no later than **August 16, 2019** or they will be dismissed with prejudice.

IT IS SO ORDERED.

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 18-10500

D.C. Docket No. 8:11-cv-01303-SDM-TBM

ANGELA RUCKH,
Relator,

Plaintiff – Appellant,

versus

SALUS REHABILITATION, LLC,
d.b.a. La Vie Rehab,
207 MARSHALL DRIVE OPERATIONS, LLC,
d.b.a. Marshall Health and Rehabilitation Center, et al.,

Defendants – Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(June 25, 2020)

Before BRANCH and MARCUS, Circuit Judges, and UNGARO,[*] District Judge.

[*] Honorable Ursula Ungaro, United States District Judge for the Southern District of Florida, sitting by designation.

UNGARO, District Judge:

Relator Angela Ruckh, a registered nurse, brought this *qui tam* action alleging violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and the Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq*. (the "Florida FCA"), against two skilled nursing home facilities, two related entities that provided management services at those and 51 other facilities in the state, and an affiliated company that provided rehabilitation services. The relator appeals the district court's grant, after jury trial, of the defendants' renewed motion for judgment as a matter of law or, in the alternative, for a new trial.

The jury found the defendants liable for the submission of 420 fraudulent Medicare claims and 26 fraudulent Medicaid claims and awarded $115,137,095 in damages. After applying statutory trebling and penalties, the district court entered judgment in favor of the relator, the United States, and the State of Florida in the total amount of $347,864,285. After judgment was entered, the defendants timely renewed their motion for judgment as a matter of law or, in the alternative, for a new trial. The district court ultimately set aside the jury's verdict as unsupported by the evidence and granted judgment as a matter of law. In the alternative, the district court conditionally granted the defendants' request for a new trial.

After thorough consideration, and with the benefit of oral argument, we affirm in part and reverse in part. We remand with instructions for the district

court to reinstate the jury's verdict in favor of the relator, the United States, and the State of Florida and against the defendants on the Medicare claims in the amount of $85,137,095, and to enter judgment on those claims after applying trebling and statutory penalties.

I.

We begin with an overview of the Medicare and Medicaid programs in the skilled nursing home context, the relevant statutory and regulatory requirements that skilled nursing facilities, like the defendants, must satisfy to obtain Medicare and Medicaid reimbursement, and the consequences for failing to comply with these requirements.

The Medicare Program

The Social Security Amendments of 1965 established the Medicare program, which provides federally funded health insurance to eligible elderly and disabled persons. *See* 42 U.S.C. §§ 1395 *et seq.* Medicare Part A pays skilled nursing facilities, or "SNFs," a daily rate for the routine services they provide to each resident. 42 U.S.C. § 1395yy; 42 C.F.R. § 413.335. Medicare bases its payment amount in part on information provided to it by SNFs. 42 C.F.R. § 413.343. Specifically, Medicare requires SNFs to "conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity." *Id.* § 483.20; *see also* 42 U.S.C. § 1395i-

3(b)(3). The assessments must be made using the resident assessment instrument ("RAI") specified by Centers for Medicare & Medicaid Services ("CMS") and must address several factors, including each resident's cognitive patterns, psychological well-being, disease diagnoses and health conditions, medications, and special treatments or procedures. 42 C.F.R. § 483.20(b)(1).

Medicare regulations require SNFs to complete these evaluations, known as Minimum Data Set ("MDS") assessments, at regular intervals.[1] 42 U.S.C. § 1395i-3(b)(3)(C); 42 C.F.R. §§ 413.343, 483.20(b)(2). The final day of the assessment interval is referred to as the "assessment reference date," or "ARD." Medicare's assessment schedule includes 5-day, 14-day, 30-day, 60-day, and 90-day scheduled assessments. The assessment looks back over a 7-day period, and Medicare also reserves for the SNFs a grace period during which SNFs have discretion to set the precise ARD.

MDS assessments are designed to be comprehensive, accurate, standardized, and reproducible. *See* 42 U.S.C. § 1395i-3(b)(3)(A); 42 C.F.R. § 483.20(g). Each assessment must be conducted or coordinated and certified as complete by a registered professional nurse ("RN"). 42 U.S.C. § 1395i-3(b)(3)(B)(i); 42 C.F.R. § 483.20(h), (i)(1). Each individual who completes a portion of the assessment

[1] Failure to comply with the assessment schedule carries consequences: "CMS pays a default rate for the Federal rate . . . for the days of a patient's care for which the SNF is not in compliance with the assessment schedule." 42 C.F.R. § 413.343(c).

must sign and certify the accuracy of that portion. 42 U.S.C. § 1395i-3(b)(3)(B)(i); 42 C.F.R. § 483.20(h), (i)(2). RNs are guided in completing the assessments by the Resident Assessment Instrument Manual ("RAI Manual"), which is promulgated and regularly updated by CMS. The RAI Manual facilitates accurate, effective, and uniform resident assessment practices by SNFs and fosters a holistic approach to optimizing resident care, well-being, and outcomes.

The accuracy of MDS assessments is critical because under the Resource Utilization Group ("RUG") model, which governed at the time of this lawsuit, CMS tied the amount of its payments to SNFs in part to RUG codes derived from MDS assessments.[2] Medicare used SNFs' self-reported RUG codes during assessment periods to set payment rates on a forward-looking basis, and the RUG codes governed payment until the next assessment period. The RUG codes were divided among eight classification groups. The relevant RUG codes began with the letter "R," as they were classified as rehabilitation services. The RUG codes were further divided based on each resident's "activities of daily living" ("ADL") needs. Residents with more specialized nursing needs and with greater ADL dependency were assigned to higher groups in the RUG hierarchy. Because

[2] In October 2019, CMS shifted from the RUG model to a patient-driven payment model. *See* Ctrs. for Medicare & Medicaid Servs., Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual ch. 6-2 (Oct. 2019), https://downloads.cms.gov/files/mds-3.0-rai-manual-v1.17.1_october_2019.pdf. Our opinion in this appeal is limited to the RUG model, which governed at the time of this lawsuit.

providing care to these residents was more costly, CMS reimbursed SNFs for this care at a higher daily rate. *See* Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities, 63 Fed. Reg. 26252, 26261–65 (May 12, 1998). The second letter of the RUG codes reflected the number of minutes of therapy services provided to residents, and the third letter indicated the level of nursing assistance provided to the residents. Therapy codes ranged from "Low" ("L") to "Ultra High" ("U"). Nursing codes "A," "B," and "C" generally reflected increasing levels of nursing services and greater ADL dependency, with additional codes "L" and "X" reflecting more extensive services.

To receive Medicare reimbursement, SNFs must electronically transmit the MDS assessment to CMS within 14 days of completing it. 42 C.F.R. § 483.20(f)(3).

The Medicaid Program

The Social Security Amendments of 1965 established the Medicaid program. *See* 42 U.S.C. §§ 1396 *et seq.* Medicaid, which is jointly financed by the federal and state governments and administered by the states, helps states provide medical assistance to low-income persons. 42 C.F.R. § 430.0. States pay service providers directly, subject to broad federal rules, and receive partial reimbursement from the federal government for their Medicaid expenses. *Id.*; 42 U.S.C. §§ 1396b(a), 1396d(b). Unlike Medicare's fee-for-service model, Florida

Medicaid reimburses SNFs for resident care at a flat daily rate. *See* Fla. Stat. § 409.908(1)(f).

Under Florida's Medicaid program, SNFs are required to present claims that "[a]re documented by records made at the time the goods or services were provided, demonstrating the medical necessity for the goods or services rendered." Fla. Stat. § 409.913(7)(f). "Medicaid goods or services are excessive or not medically necessary unless both the medical basis and the specific need for them are fully and properly documented in the recipient's medical record." *Id.*

SNFs are required by federal law and Florida administrative law to "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care." 42 U.S.C. § 1396r(b)(2); *see also* Fla. Admin. Code Ann. r. 59A-4.109(2). The written plan of care must:

> (A) describe[] the medical, nursing, and psychosocial needs of the resident and how such needs will be met;
>
> (B) [be] initially prepared, with the participation to the extent practicable of the resident or the resident's family or legal representative, by a team which includes the resident's attending physician and a registered professional nurse with responsibility for the resident; and
>
> (C) [be] periodically reviewed and revised by such team after each assessment under paragraph (3).

42 U.S.C. § 1396r(b)(2); *see also* Fla. Admin. Code Ann. r. 59A-4.109(2) (requiring SNFs to develop a "comprehensive care plan for each resident").

The Florida Medicaid Nursing Facility Services Coverage and Limitations Handbook, with which SNFs must comply under Florida's Medicaid regulations, elaborates on this requirement. *See* Fla. Admin. Code Ann. r. 59G-4.200 (July 23, 2006). This handbook states that SNFs are "responsible for developing a comprehensive plan of care for each resident." It further states that the care plan is to be developed based on resident evaluations conducted in connection with the MDS assessment process. Additionally, the Florida Medicaid Provider General Handbook puts SNFs on notice that "Medicaid payments for services that lack required documentation or appropriate signatures will be recouped." *See also* Fla. Admin. Code Ann. r. 59G-5.020 (requiring compliance with the Florida Medicaid Provider General Handbook). It cautions that providers are responsible for presenting claims that are "true and accurate" and that are for "goods and services" that "[a]re provided in accord with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state and local law."

Florida's Medicaid regulations require SNFs to submit billing forms known as UB-04s to receive Medicaid reimbursement. *See* Fla. Admin. Code Ann. r. 59G-4.003. The back of the UB-04 contains several representations, including:

> • The submitter of this form understands that misrepresentation or falsification of essential information as requested by this form, may serve as the basis for civil monetary penalties and assessments and may upon conviction include fines and/or imprisonment under federal and/or state law(s).
>
> • Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts.
>
> • For Medicaid Purposes: The submitter understands that because payment and satisfaction of this claim will be from Federal and State funds, any false statements, documents, or concealment of a material fact are subject to prosecution under applicable Federal or State Laws.

Procedural History

The relator, Ruckh, is a registered nurse certified in preparing MDS assessments. From January 2011 until May 2011, she worked at Marshall Health and Rehabilitation Center ("Marshall") and Governor's Creek Health and Rehabilitation Center ("Governor's Creek") as an interim MDS coordinator preparing RUG assessments. She claimed that over the course of these five months, she discovered that the defendants were misrepresenting the services they provided to Medicare beneficiaries and failing to comply with certain Medicaid requirements in three ways: first, the defendants routinely engaged in "upcoding," or the artificial inflation of RUG codes; second, the defendants engaged in "ramping," or the timing of spikes in treatment to coincide with the ARD, which

exaggerated the required payment levels; and third, the defendants submitted claims for Medicaid reimbursement without creating or maintaining comprehensive care plans.

On June 10, 2011, Ruckh filed suit against five defendants: (i) Sea Crest Health Care Management, LLC, which did business under the name La Vie Management Services of Florida ("LVMSF"); (ii) CMC II, LLC, LVMSF's successor-in-interest (together with LVMSF, "La Vie Management"); (iii) Salus Rehabilitation, LLC, which provided rehabilitation therapy services at Marshall; (iv) 207 Marshall Drive Operations, LLC, which did business under the name Marshall Health and Rehabilitation Center; and (v) 803 Oak Street Operations, LLC, which did business under the name Governor's Creek Health and Rehabilitation Center. La Vie Management provided management services to a network of 53 SNFs throughout Florida, including Marshall and Governor's Creek.

In the *qui tam* complaint, Ruckh alleged that the defendants violated 31 U.S.C. § 3729(a)(1)(A), (B), and (G), along with parallel provisions of the Florida FCA. The FCA subjects to liability any person who, in relevant part:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> . . . .

> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(l)(A)–(B), (G).[3]

After both the United States and the State of Florida declined to intervene, Ruckh prosecuted the action on her own as a *qui tam* relator. On January 17, 2017, following several years of motions and discovery, the case proceeded to a month-long trial.

At the conclusion of the relator's case-in-chief, the defendants moved for judgment as a matter of law under Federal Rule of Civil Procedure 50(a), which the district court denied. The defendants raised four grounds in support of their motion: first, the relator failed to prove a corporate scheme to knowingly cause the submission of false claims; second, the relator failed to present sufficient evidence of materiality as to the allegedly fraudulent Medicaid claims; third, the relator

[3] The term "claim" includes "direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. _ _ _ _, 136 S. Ct. 1989, 1996, 195 L. Ed. 2d 348, 358 (2016) (citing § 3729(b)(2)(A)). The statute specifies that a person acts "knowingly" with respect to information when she has "actual knowledge," "acts in deliberate ignorance of the truth or falsity," or "acts in reckless disregard of the truth or falsity" of the information. 31 U.S.C. § 3729(b)(l)(A). The statute further defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

failed to present sufficient evidence of materiality and scienter as to the allegedly fraudulent Medicare claims; and fourth, the relator's use of statistical sampling and extrapolation to establish damages was impermissible.

On February 13, 2017, the case was submitted to the jury. After two days of deliberation, the jury returned its verdict finding the defendants liable under § 3729(a)(1)(A) and (B) for the submission of 420 fraudulent Medicare claims and 26 fraudulent Medicaid claims and awarded $115,137,095 in damages.[4,5] After trebling and the application of statutory penalties, the district court entered judgment in favor of the relator, the United States, and the State of Florida totaling $347,864,285.

On March 29, 2017, following entry of judgment, the defendants renewed their motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b). Defendants advanced three arguments in support of their motion: first, that

[4] The jury also found the defendants liable under § 3729(a)(1)(G) but calculated damages as $0. The jury's finding in this regard is not before this Court on appeal.

[5] The district court, in its order, did not address whether the methodology employed by the relator's expert to calculate damages was flawed either because the sample size was too small or improvidently drawn and the defendants have abandoned any argument regarding the admission of the expert testimony on appeal. "[T]he law is by now well settled in this Circuit that a legal claim or argument that has not been briefed before the court is deemed abandoned and its merits will not be addressed." *Holland v. Gee*, 677 F.3d 1047, 1066 (11th Cir. 2012) (quoting *Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004)). Accordingly, we do not address whether the sampling method and extrapolation employed by the relator's expert was reliable and otherwise admissible pursuant to Federal Rule of Evidence 701 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).

the alleged Medicaid-related fraud was unsupported by evidence of materiality; second, that the relator failed to prove the materiality of the alleged Medicare-related fraud; and third, that no evidence supported any allegation of fraud on the part of La Vie Management. In the alternative, the defendants moved the court to grant a new trial, arguing the verdict was "excessive and against the weight of the evidence." In the event the court viewed a new trial as unnecessary, the defendants alternatively sought remittitur.

On January 11, 2018, the district court granted the motion for judgment as a matter of law and set aside the jury's verdict. In the alternative, the district court conditionally granted the defendants' request for a new trial and denied the request for remittitur as moot. In granting the defendants' motion for judgment as a matter of law, the district court relied mainly on its assessment that the relator failed to introduce evidence of materiality and scienter at trial. The district court held that "the relator failed to offer competent evidence that defendants knew that the governments regarded the disputed practices as material" and would have refused to pay the claims had they known about the disputed practices. The district court concluded that the evidence was insufficient to support any theory of FCA liability against La Vie Management, as the evidence did not show that the management entity "presented" or "caused to be presented" a false claim or "produced" or "caused the production" of a "'false record or statement' material to a false claim."

As to the existence of a "corporate scheme," the district court agreed with the defendants that "the relator fail[ed] entirely to connect the testimony about 'RUG budgets,' 'LaVie meetings,' and 'corporate profits' to any particular claim 'actually submitted' to the government." In alternatively granting the defendants' motion for a new trial, the district court did not explain its reasoning except to state that it was conditionally granted "for the reasons explained above and for the reasons identified and satisfactorily explained in the defendants' motion."

The relator filed the instant appeal on February 8, 2018. Before the parties submitted their respective briefs on the merits, the defendants moved to dismiss the appeal for lack of jurisdiction. The defendants' motion to dismiss this appeal was carried with the case. We deny the motion to dismiss. We affirm as to the Medicaid claims. We reverse as to the Medicare claims and remand with instructions for the district court to reinstate the jury's verdict on those claims.

II.

"[T]he decision to grant or deny a motion to dismiss is within the discretion of the Court of Appeals." *Showtime/The Movie Channel, Inc. v. Covered Bridge Condo. Ass'n*, 895 F.2d 711, 713 (11th Cir. 1990) (quoting *Brookhaven Landscape & Grading Co. v. J. F. Barton Contracting Co.*, 681 F.2d 734, 736 (11th Cir. 1982)).

"We review de novo a district judge's granting judgment as a matter of law under Federal Rule of Civil Procedure 50(b) and apply the same standard as the trial judge. In reviewing the record evidence, we draw all inferences in favor of the nonmoving party." *Cadle v. GEICO Gen. Ins. Co.*, 838 F.3d 1113, 1121 (11th Cir. 2016) (citing *Collado v. United Parcel Serv., Co.*, 419 F.3d 1143, 1149 (11th Cir. 2005)). "In considering a Rule 50(b) motion after the jury verdict, 'only the sufficiency of the evidence matters. The jury's findings are irrelevant.'" *Id.* (quoting *Connelly v. Metro. Atlanta Rapid Transit Auth.*, 764 F.3d 1358, 1363 (11th Cir. 2014)). "Judgment as a matter of law for a defendant is appropriate, 'when there is insufficient evidence to prove an element of the claim, which means that no jury reasonably could have reached a verdict for the plaintiff on that claim.'" *Id.* (quoting *Collado*, 419 F.3d at 1149); *see also Munoz v. Oceanside Resorts, Inc.*, 223 F.3d 1340, 1344–45 (11th Cir. 2000) ("A Rule 50(b) motion should only be granted where reasonable jurors could not arrive at a contrary verdict." (citation, internal quotation marks, and alteration omitted)).

"We review the grant of a new trial pursuant to Rule 59 [of the Federal Rules of Civil Procedure] for abuse of discretion. Our review for abuse of discretion is 'more rigorous when the basis' of the grant was the weight of the evidence." *Aronowitz v. Health-Chem Corp.*, 513 F.3d 1229, 1242 (11th Cir. 2008) (internal citation omitted) (quoting *Williams v. City of Valdosta*, 689 F.2d

964, 974 (11th Cir. 1982)). We nevertheless give deference to "the trial court's first-hand experience of the witnesses, their demeanor and a context of the trial." *MacPherson v. Univ. of Montevallo*, 922 F.2d 766, 777 (11th Cir. 1991). Further, the district court is allowed wide discretion when it grants a new trial and "evidentiary weight is merely one of numerous factors cited in support" thereof. *J.A. Jones Constr. Co v. Steel Erectors, Inc.*, 901 F.2d 943, 944 (11th Cir. 1990).

III.

A.

We first consider the defendants' claim that the relator's entry into a litigation funding agreement (the "Agreement") dated October 17, 2017 with ARUS 1705-556 LLC ("ARUS") vitiates her standing to pursue this appeal.[6] The relator agreed to sell ARUS less than 4% of her share of the judgment originally entered by the district court, if the jury verdict were upheld on appeal, assuming a

[6] The relator entered into the Agreement with ARUS during the pendency of the defendants' renewed motion for judgment as a matter of law in the court below. However, the defendants discovered this financing arrangement upon reviewing the relator's Certificate of Interested Persons filed in this Court. The Certificate of Interested Persons describes ARUS as a "privately owned limited liability company focused on litigation funding."

30% share to the relator.[7] According to the relator, the Agreement is explicit that ARUS has no power to influence or control this litigation.[8]

In moving to dismiss the present appeal, the defendants argue that the relator's entry into the Agreement is a partial reassignment of her interest in the action to ARUS, which precludes her from continuing as a relator and requires this Court to dismiss her appeal. Specifically, the defendants argue that this partial reassignment violates the Constitution and the text and structure of the FCA.[9] The

[7] The relator's counsel represented that the Agreement contains a confidentiality provision that precludes its public filing but offered to provide a copy to the Court for an *in camera* review to aid in our consideration of its relevant provisions. At oral argument, the Court informed the parties that we would consider the Agreement only if the relator provided a copy to the defendants. Subsequently, the relator notified the Court that it declined to share the Agreement with the defendants. Nevertheless, at oral argument, the parties acknowledged that the Agreement assigned to ARUS less than 4% of the relator's share of the recovery. Additionally, the relator's counsel submitted a declaration attached to the response in opposition to the motion to dismiss the appeal, stating: "The Agreement is a purchase agreement for less than 4% of Relator's share of the $347 million judgment . . . , assuming Relator were to receive a 30% relator's share."

[8] The relator represents in opposition to the motion to dismiss and the relator's counsel averred in her declaration that the Agreement provides that ARUS shall not become a party to the litigation, the relator will retain sole authority over the litigation (including settlement authority), and ARUS will offer no advice, issue no instructions, and exercise no influence over the litigation. In the motion to dismiss, the defendants argue that it is unrealistic to conclude that a relator or her counsel would give no consideration to the views of a litigation funding entity, which has powerful incentives to participate in the management of the litigation. The defendants' position at oral argument was that even if this Court accepts as true the relator's contention that she assigned less than 4% of her share of the recovery and maintained complete control of the litigation, the partial assignment nonetheless violates the FCA.

[9] Defendants also argue that relator's entry into the litigation funding agreement violates Article II. We decline to address the issue because it is not jurisdictional. *See Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 778 n.8 (2000) (declining to reach the validity of *qui tam* suits under Article II because it is not "a jurisdictional issue that we must resolve here").

defendants urge this Court to conclude that because the relator has reassigned her interest in this action, she has forfeited her standing to represent the interests of the United States.

Article III Standing

The defendants contend that the relator has forfeited standing to pursue the appeal because she no longer belongs to the class of *qui tam* plaintiffs authorized to bring suit under the FCA and, therefore, the appeal must be dismissed. For the reasons discussed below, we find that the relator's standing is unaffected by the Agreement and that this case is justiciable.

Article III extends "'the judicial power of the United States' . . . only to 'Cases' and 'Controversies.'" *Spokeo, Inc. v. Robins*, 578 U.S. _ _ _ _, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635, 643 (2016) (quoting U.S. Const. art. III, §§ 1, 2). The Supreme Court has explained that the doctrine of standing to sue is "rooted in the traditional understanding of a case or controversy" and "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Id.* (citations omitted). "'The law of Article III standing serves to prevent the judicial process from being used to usurp the powers of the political branches' and confines the federal courts to a properly judicial role." *Id.* (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408, 133 S. Ct. 1138, 1146, 185 L. Ed. 2d 264, 275 (2013)) (citations, alterations and ellipsis omitted). To establish

standing, a plaintiff must show that: (i) she suffered an "injury in fact" that is "concrete and particularized" and "actual or imminent," not "conjectural or hypothetical"; (ii) the injury complained of is "fairly traceable to the challenged action of the defendant"; and (iii) it is "likely," not "merely speculative," that the injury will be "redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61, 112 S. Ct. 2130, 2136, 119 L. Ed. 2d 351, 364 (1992) (quotations omitted and alterations adopted).

In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 120 S. Ct. 1858, 146 L. Ed. 2d 836 (2000), the Supreme Court affirmed that *qui tam* relators have Article III standing to pursue actions on behalf of the federal government. The Court held that *qui tam* relators have standing as partial assignees of the United States. *Id.* at 773. In *qui tam* actions, the injury suffered by the United States "suffices to confer standing on" the relator. *Id.* at 774.

In this case, the relator sought to remedy an injury in fact suffered by the United States fairly traceable to the defendants' conduct and likely redressable by a favorable decision under the FCA. *See Lujan*, 504 U.S. at 560–61. For us to hold that relator lacks standing would require a showing that she is no longer the assignee of the United States, or that the United States in fact suffered no injury. The defendants do not assert the latter. Instead, they argue that by entering into a

litigation funding agreement, the relator disqualified herself from serving as the government's assignee.

We find the defendants' argument unavailing. The relator has given only a small interest—less than 4% of her share of the potential recovery in this case—to ARUS in exchange for immediate liquidity. *Cf. Aaron Ferer & Sons Ltd. v. Chase Manhattan Bank, N.A.*, 731 F.2d 112, 125 (2d Cir. 1984) (explaining that "[a]n unequivocal and complete assignment extinguishes the assignor's rights against the obligor and leaves the assignor without standing to sue the obligor"). And, as the relator acknowledged, the Agreement is clear that the relator retains sole authority over the litigation and ARUS has no power to control or influence it. Thus, although she has now entered into the litigation funding agreement, these facts remain essentially unchanged: the relator retains sufficient interest to meet the "irreducible constitutional minimum" of standing under Article III. *Id.* at 560. Consequently, she has constitutional standing to pursue this appeal.

FCA

The defendants' position on standing is better understood as an argument that the relator cannot pursue a claim under the FCA once she has assigned even a small portion of any possible recovery to ARUS, because the litigation funding

agreement violates the text and structure of the FCA.[10] We recognize that the statute does not expressly authorize relators to reassign their right to represent the interests of the United States in *qui tam* actions. However, we are not persuaded that the FCA proscribes such assignment.

The FCA includes a number of restrictions, including on the conduct of *qui tam* actions and who may serve as a relator. *See* 31 U.S.C. § 3730. It does not, however, prohibit the relator's entry into the litigation funding agreement. Indeed, the statute is silent as to this point. It also does not require a court to dismiss a *qui tam* action upon learning of such an agreement. The defendants nonetheless persist in arguing that the assignment is proscribed because the statute does not affirmatively authorize it.

The text of 31 U.S.C. § 3730(b)(1) provides that "[a] person" may bring a suit under the FCA. From this general grant of power, Congress specifically excludes a person from bringing suit in three situations: where a person serves in the armed forces (under certain circumstances), § 3730(e)(1); where a person seeks to sue certain government officials, § 3730(e)(2); and where the person suing was

[10] Courts have referred to this inquiry as one of "statutory standing." However, the Supreme Court has cautioned against use of the phrase, because "the absence of a valid . . . cause of action does not implicate subject-matter jurisdiction, *i.e.*, the court's statutory or constitutional *power* to adjudicate the case." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4, 134 S. Ct. 1377, 1388 n.4, 188 L. Ed. 2d 392, 404 n.4 (2014). (emphasis omitted) (quoting *Verizon Md. Inc v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 642–43, 122 S. Ct. 1753, 1758, 152 L. Ed. 2d 871, 880 (2002)).

involved in the very fraud at issue in the claim, § 3730(d)(3). Because the FCA "explicitly enumerates certain exceptions to a general grant of power, courts should be reluctant to imply additional exceptions in the absence of clear legislative intent to the contrary." *United States ex rel. Williams v. NEC Corp.*, 931 F.2d 1493, 1502 (11th Cir. 1991) (citation omitted); *see also* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW 107–11 (2012) (summarizing the "Negative-Implication Canon" as "[t]he expression of one thing implies the exclusion of others").

We decline to interfere in Congress's legislative prerogatives by engrafting any further limitations onto the statute; that task is appropriately left for Congress. *See State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 443, 196 L. Ed. 2d 340, 349 (2016) (declining to read a mandatory dismissal rule into the statute for failure to comply with the statute's seal requirement); *United States v. Florida*, 938 F.3d 1221, 1253 (11th Cir. 2019) ("It is not our function to engraft on a statute additions which we think the legislature logically might or should have made." (Branch, J., dissenting) (quoting *United States v. Cooper Corp.*, 312 U.S. 600, 605, 61 S. Ct. 742, 744, 85 L. Ed. 1071, 1075 (1941))).

Furthermore, we find no basis in the record suggesting that the relator has not complied with all requirements of the FCA to maintain the action and reject the defendants' characterization of ARUS as an unqualified relator. ARUS may fail to

meet every requirement imposed by the FCA for serving as a relator, but it is Ruckh—not ARUS—who is pursuing the claim as relator. We therefore reject the defendants' contention that the relator's relationship with ARUS disqualifies her as a relator under the FCA and that dismissal is warranted.

We conclude the relator has sufficiently demonstrated she has constitutional standing and, therefore, the case or controversy requirement is satisfied. We further conclude that the relator's entry into the litigation funding agreement does not violate the FCA. Accordingly, we deny the motion to dismiss.

B.

"The FCA is designed to protect the Government from fraud by imposing civil liability and penalties upon those who seek federal funds under false pretenses." *United States ex rel. Lesinski v. S. Fla. Water Mgmt. Dist.*, 739 F.3d 598, 600 (11th Cir. 2014). "Liability under the [FCA] arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal procedures." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005)); *see also McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) ("The [FCA] does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such

acts, the provider knowingly asks the Government to pay amounts it does not owe." (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). "Simply put, the '*sine qua non* of [an FCA] violation' is the submission of a false claim to the government." *Urquilla-Diaz*, 780 F.3d at 1045 (quoting *Corsello*, 428 F.3d at 1012).

Our circuit has expressly adopted a false certification theory of liability under the FCA. *See id.* Under this theory, a defendant may be found liable for falsely certifying its compliance with applicable laws and regulations. *Id.* To prevail, a relator must prove "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Id.* (quoting *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006)).

The Supreme Court upheld and clarified the contours of the implied false certification theory of liability in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. _ _ _ _, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016). The Court first held that "the implied false certification theory can, at least in some circumstances, provide a basis for [FCA] liability." *Escobar*, 136 S. Ct. at 1999. The Court explained that the FCA's prohibition against the submission of "false or fraudulent claims" is broad enough to "encompass[] claims that make fraudulent misrepresentations, which include certain misleading omissions." *Id.* "When . . . a

defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Id.* Accordingly, the Court held that the implied certification theory can serve as a basis for FCA liability where at least two conditions are satisfied: (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001.

The Court also addressed a second, related question: whether FCA liability attaches only if a defendant's failure to disclose noncompliance with a contractual, statutory, or regulatory provision has been expressly designated by the Government a condition of payment. *Id.* The Court declined to so cabin liability but added that only misrepresentations that are "material to the Government's payment decision" are actionable under the FCA. *Id.* at 2002. The Court further emphasized that this materiality standard is "demanding."[11] *Id.* at 2003. The concept of materiality "looks to the effect on the likely or actual behavior of the

[11] The Court declined to address whether the materiality requirement under § 3729(a)(l)(A) is governed by the definition of "materiality" in § 3729(b)(4) or by common law principles. *See Escobar*, 136 S. Ct. at 2002.

recipient of the alleged misrepresentation." *Id.* at 2002 (internal quotation and alteration omitted). Ultimately, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2003. The Court explained further that "proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* On the other hand, the Court noted:

> [I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04.

C.

Medicare Fraud

Drawing all inferences in favor of the relator, as we must when considering a Rule 50(b) motion, we conclude that the evidence at trial permitted a reasonable jury to find that the defendants committed Medicare-related fraud. In this case, the relator alleged that defendants defrauded Medicare through the use of two improper practices: upcoding and ramping. The Court addresses each in turn.

In the context of this case, upcoding involves submitting bills to Medicare with elevated RUG codes. Evidence presented at trial indicated the defendants inflated their RUG codes in two ways. First, the defendants exaggerated the second letter of the code, representing to Medicare that they provided a greater number of therapy minutes than were reflected in their residents' medical records. And second, the defendants elevated the third letter of the code, indicating they provided more extensive nursing services than reflected in their residents' medical records.

Shirley Bradley is a registered nurse who testified as an expert on the relator's behalf at trial. Bradley conducted an audit of 300 Medicare claims and 300 Medicaid claims submitted across the 53 SNFs. Bradley's audit of the Medicare claims revealed evidence of upcoding, which fit into three categories. First, Bradley found evidence that the number of therapy minutes that the defendants reported to the government for billing purposes was higher than those reflected in contemporaneous medical records. Bradley concluded that in 56 of the 300 claims she reviewed, the defendants inflated the number of therapy minutes actually provided to residents.

Second, the relator alleged that the defendants inflated the nursing services they provided to residents. Bradley found evidence that the level of nursing services that the defendants reported to Medicare was higher than those reflected in

contemporaneous medical records. Bradley testified that 45 of the 300 claims she reviewed contained higher levels of nursing services than actually provided to residents. And third, the relator alleged that the defendants billed for certain complex nursing services when contemporaneous medical records did not include any such services. As an example, Bradley testified she reviewed the file of one patient whose claim was billed at a level reflecting extensive nursing services, but a review of the patient's medical records revealed no such services had been provided. Based upon her audit, Bradley testified that 50 of the 300 claims she reviewed included this type of extensive nursing services upcoding.

Contrary to the district court's decision, these types of affirmative misrepresentations are material. At the time, Medicare reimbursement rates were tied in part to RUG codes. The district court dismissed the relator's upcoding theory as "a handful of paperwork defects." That characterization misses the mark. The defendants' theory at trial was that the RUG codes were accurate and that the entries in the corresponding patient files supporting the RUG codes were either missing or never recorded essentially due to clerical error, and that is the type of recordkeeping mistake the FCA does not punish. But the jury was not required to believe the defendants' position. Rather, a jury could reasonably find mistake to be an implausible explanation for the defendants' upcoding.

At its core, the concept of upcoding is a simple and direct theory of fraud. SNFs receive money from Medicare based on the services they provide. In this case, the SNFs indicated they had provided more services—in quantity and quality—than they, in fact, provided. Therefore, Medicare paid the SNFs higher amounts than they were truly owed. This plain and obvious materiality went to the heart of the SNFs' ability to obtain reimbursement from Medicare.

Like upcoding, ramping presents a fairly straightforward case. Ramping is the impermissible, artificial timing of services to coincide with Medicare's regularly scheduled assessment periods and thereby maximize reimbursements. Because Medicare uses the level of services provided during the assessment reference period to set reimbursement levels on a forward-looking basis, it is possible for SNFs to manipulate this system by providing more extensive services during the look-back period than medically necessary to address patients' needs. An SNF thereby causes Medicare to reimburse at a higher level than it would had the SNF reported the appropriate level of services. Like upcoding, ramping is material, as it goes to the essence of the parties' economic relationship.

We find that the relator presented sufficient evidence to permit a jury to conclude that the defendants engaged in ramping. At trial, the relator testified that she personally witnessed ramping while working at Marshall and Governor's Creek. For instance, she testified that she was transferred to Governor's Creek

because she brought up ramping at Marshall by "complaining about the grace days being used on every single assessment and that the patients weren't getting therapy after the [ARDs] or the MDS." Moreover, Bradley testified that she found 112 instances of ramping in her audit. Bradley explained the case of one patient, Jean H., in which the defendants billed Medicare for providing the Ultra High level of therapy. Bradley explained that in each week used to set the payment level, the defendants reported providing the patient with 720 minutes of therapy—the minimum amount needed to qualify for the Ultra High level. Bradley further noted that in the weeks between assessment periods, the patient routinely received far fewer than 720 minutes of therapy. In addition, La Vie Management's former chief compliance officer, Stephanie Griffin, confirmed through video testimony at trial that an SNF is not allowed to engage in the practice of ramping: "If you're asking me if you can manipulate grace days in order to maximize reimbursement, that is not allowed. But it's not allowed anywhere in the system. It's not just about grace days, it's any manipulation of a particular aspect of coding and billing that the sole purpose of, unrelated to care, is to impact reimbursement is a problem."

In sum, drawing all inferences in favor of the relator's testimony, as we must, a jury could reasonably conclude the defendants engaged in ramping. And ramping is material, as it directly affects the payments Medicare makes to SNFs.

Had the defendants provided only the necessary services to their residents during assessment windows, Medicare would have reimbursed the defendants at a lower level. Instead, the defendants artificially and impermissibly inflated the level of services they provided. Medicare, therefore, paid the defendants more for their services than it owed.

La Vie Management's Liability as to Medicare Fraud

Lastly, the Court addresses the relator's separate contention that the district court erred in concluding as a matter of law that she failed to establish liability with respect to La Vie Management, the entity that provided management services to the defendant facilities.

"To prevail on an FCA claim, the plaintiff must prove that the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the Government to make a payment." *See United States v. AseraCare, Inc.*, 938 F.3d 1278, 1284 (11th Cir. 2019) (citing *Urquilla-Diaz*, 780 F.3d at 1045). Section 3729(a)(1)(A) prohibits knowingly presenting or causing to be presented a false claim. This creates two theories of liability: (1) a presentment theory and (2) a cause to be presented theory.

At trial, the jury returned a general verdict that La Vie Management knowingly presented or caused to be presented false and fraudulent claims to Medicare. The district court disagreed, citing the absence of any evidence that La

Vie Management submitted any claims at all and insufficient evidence to establish the type of "massive, authorized, cohesive, concerted, enduring, top-down" corporate scheme necessary to show that La Vie Management caused the presentation of false Medicare claims. We understand from its words that the district court found the relator's proof lacking as to scienter and causation under either theory. Because on appeal relator argues only that the evidence was sufficient to establish that La Vie Management caused the presentment of false Medicare claims, we confine our discussion to the sufficiency of the evidence in respect of the "cause to be presented" theory.

We begin by noting that this Court has not previously addressed the appropriate standard to prove causation in FCA "cause to be presented" actions. Relator points to two persuasive precedents which use traditional proximate cause tests: *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 714–15 (10th Cir. 2006) (adopting a proximate cause test "to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA"), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 203 L. Ed. 2d 791 (2019), and *United States ex rel. Schiff v. Marder*, 208 F. Supp. 3d 1296, 1312 (S.D. Fla. 2016) (noting that "courts have applied traditional concepts of proximate causation to determine whether there is a

sufficient nexus between the Defendants' conduct and the ultimate presentation of the allegedly false claim") (internal quotation omitted).

We find that for "cause to be presented" claims, proximate causation is a useful and appropriate standard by which to determine whether there is a sufficient nexus between the defendant's conduct and the submission of a false claim. It has the advantage of familiarity and serves to cull those claims with only attenuated links between the defendant's conduct and the presentation of the false claim. "Under this analysis, a defendant's conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *Marder*, 208 F. Supp. 3d at 1312-13. (internal quotation and alteration omitted).

We find that the relator introduced sufficient evidence to permit a jury to reasonably conclude that La Vie Management caused the submission of false claims. For example, Pamela Horn, a former investigator with the State of Florida, testified to a conversation she had with Carolyn Packer, another registered nurse who worked at Governor's Creek:

> Q: And did Ms. Packer say anything about what [Lee] Juliano [La Vie Management's regional reimbursement specialist] did with the RUG rate information that she received?

A: Yes, sir.

Q: What did she say?

A: Ms. Juliano reported that to her boss at corporate.

Q: And did Ms. Packer indicate what this all came down to, this focus on the RUG levels?

A: Yes, sir.

Q: What did she say?

A: It was to have the RUG levels as high as possible so that the revenue, the reimbursement, was high.

The relator also introduced evidence that the defendants' employees were pressured routinely to elevate RUG scores irrespective of the services provided. The relator testified:

Q: What was the focus of the discussion about UH RUG groups in these meetings?

A: That we needed to get the RUGs higher. There was a lot of criticism of the rehab director. Every day he would read off the minutes that he delivered to the patient the previous day. He would have a lot of criticism from the administrator and the business office manager. And the goal was always the 720 minutes for the date of the MDS assessment, when it was due, so that the patient would be a rehab ultra.

Q: And in these -- in these daily meetings, was there any discussion about financial targets and financial goals?

A: Yes, they had a Medicare budget, a RUG budget, and so it must be met or exceeded and you were criticized if

> it wasn't and you were pretty much directed to make that happen.
>
> Q: Were these RUG budgets that were set by the company or by the patients, the residents?
>
> A: They were RUG budgets set by the company. I guess, you know -- yeah, without any clinical knowledge of the patient whatsoever.

The relator further testified that La Vie Management would reprimand employees constantly for failing to meet RUG budgets. The relator explained that the focus of weekly calls with La Vie Management, including regional coordinators for multiple facilities including Marshall and Governor's Creek, was on "[r]ehab ultra opportunities, how to get the RUGs higher, criticism if you weren't meeting or exceeding their RUG budget for the facility, criticism if you weren't, but really praising the facilities that were above budget for their region." Moreover, the relator introduced into evidence a La Vie Management presentation to SNFs that referred to its one goal as "RUG enhancement" and indicated that the employees should focus on "maximizing therapy minutes." The evidence also suggested La Vie Management had a policy of prohibiting the submission of claims at the lowest RUG code without management approval.

In light of this evidence, a jury could reasonably conclude that La Vie Management's conduct was "(l) a substantial factor in inducing providers to submit claims for reimbursement," and that (2) "the submission of claims for

reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *Id.* at 1313 (internal quotation and alteration omitted).

This same evidence supports an inference that La Vie Management acted knowingly. The scienter requirement in FCA actions is rigorous and must be strictly enforced. *See Escobar*, 136 S. Ct. at 2002. Under the rigorous standard, the evidence reasonably permitted the jury to conclude that La Vie Management acted knowingly under the FCA.

Therefore, with respect to the allegations of Medicare fraud, we conclude that the relator presented sufficient evidence to permit a reasonable jury to conclude that the defendants violated the FCA when they submitted the claims. Further, we find that the district court erred in holding that La Vie Management did not cause the submission of false claims. Accordingly, we reverse the district court's grant of judgment as a matter of law to the defendants as to the Medicare-related fraud claims.

Medicaid Fraud

For the reasons discussed below, we hold that the district court correctly granted the defendants' motion for judgment as a matter of law as to the alleged false Medicaid claims. Specifically, we conclude that based on the evidence presented at trial, no jury could have reasonably concluded that the defendants defrauded Medicaid.

At trial, the relator introduced evidence that the defendants routinely submitted claims for Medicaid reimbursement without preparing and maintaining comprehensive care plans. The relator testified that while working at Governor's Creek and Marshall, there were few, if any, care plans in the patient files. An email introduced into evidence from Juliano confirmed care plans were "a mess." And Bradley testified her audit revealed missing care plans for approximately 52 residents.

The relator's sole allegation as to Medicaid fraud consists of the defendants' failure to prepare and maintain comprehensive care plans for their residents. Even if we accept this allegation as true, we hold that the failure to do so cannot establish Medicaid fraud as a matter of law. Under *Escobar*, the relator was required to prove not only that the defendants failed to comply with this requirement, but that their failure to do so was material. Again, this materiality standard sets a "demanding" bar. *Escobar*, 136 S. Ct. at 2003.

The relator contends she met the standard, pointing to evidence at trial that indicated Florida would or could automatically deny payment if the state were to discover care plans are missing. The district court rejected this argument and granted judgment as a matter of law because the relator did not introduce evidence that the state in fact declines to pay claims when it learns SNFs have failed to prepare and maintain comprehensive care plans. We note that the relator

introduced evidence at trial of the opposite. The relator testified that when she informed her direct supervisors at La Vie Management that her patient files lacked care plans, they self-reported the deficiencies to the state. There was no evidence, however, that the state refused reimbursement or sought recoupment after this self-reporting. And there was no evidence that the state ever declines payment for, or otherwise enforces, these types of violations. As the Supreme Court stated in *Escobar*, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 2003–04.

We acknowledge that the absence of evidence that the state declines payment when an SNF fails to comply with the care plans requirement, alone, is not fatal to the relator's case. Rather, this evidence is a useful, but not necessary, indicator of materiality. *See id.* (describing evidence of materiality but noting evidence need not be limited to the examples given). However, we find in this case that the relator's scant evidence supported only the conclusion that care plans are, at most, labeled as conditions of payment under Medicaid regulations. This evidence, without more, is insufficient to establish materiality. Thus, we agree with the district court's conclusion that the relator failed to prove the materiality of the absence of care plans.

Additionally, we conclude that the lack of care plans fails to establish Medicaid fraud for an entirely separate reason under the analysis in *Escobar*. The relator relied on the implied certification theory of liability in alleging Medicaid fraud. That theory can support a jury verdict only where the relevant claim not only requests payment but also "makes specific representations about the goods or services provided." *Id.* at 2001. Here, the relator failed to connect the absence of care plans to specific representations regarding the services provided. Moreover, the relator did not allege, let alone prove, any deficiencies in the Medicaid services provided.

Without more, the failure to create and maintain care plans cannot serve as a basis for FCA liability. The FCA is not a wide-ranging tool to combat failures to comply with even important government regulations. *See Clausen*, 290 F.3d at 1311 ("[W]hile the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the [FCA]."); *see also Escobar*, 136 S. Ct. at 2003 ("The [FCA] is not an all-purpose antifraud statute . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations." (internal quotation omitted)).[12]

[12] In arguing that the district court erred in granting the defendants' renewed motion for judgment as a matter of law, the relator also contends that the district court impermissibly considered two grounds that the defendants waived by not raising them in their Rule 50(a) motion: the sufficiency of evidence as to (1) Medicare fraud and (2) the defendants' knowledge of the materiality of their claims. Rule 50 is designed to protect a plaintiff's Seventh

E.

Because we affirm the district court's judgment as a matter of law on the Medicaid claims, we need only address the district court's grant of a conditional new trial with respect to our reversal of the judgment as a matter of law on the Medicare claims. The district judge's reasoning for granting a new trial is not evident— he wrote only that "the request for a new trial is conditionally **GRANTED** for the reasons explained above and for the reasons identified and satisfactorily explained in the defendants' motion."

Amendment right to cure evidentiary deficiencies before a case is submitted to the jury. *See Ross v. Rhodes Furniture, Inc.*, 146 F.3d 1286, 1289 (11th Cir. 1998). To determine whether the district court improperly considered arguments waived by defendants, we compare the grounds originally argued in defendants' Rule 50(a) motion with those cited by the court in granting judgment as a matter of law. *See id.* (citing *Nat'l Indus., Inc. v. Sharon Steel Corp.*, 781 F.2d 1545 (11th Cir. 1986)). We do not require complete identity of issues; instead, we consider whether the Rule 50(a) and Rule 50(b) issues are "closely related." *Id.* Only if the old and new grounds "vary greatly" is the district court prohibited from relying on those new grounds in setting aside the jury's verdict. *Id.* (citing *Sulmeyer v. Coca Cola Co.*, 515 F.2d 835, 845–46 (5th Cir. 1975)). The purpose of this waiver rule is to avoid ambush; setting aside a jury's verdict cannot come as a surprise to the non-movant. *Id.* (citing *Sharon Steel*, 781 F.2d at 1549–50).

Here, in granting the defendants' Rule 50(b) motion, the district court cited the defendants' arguments as to materiality and scienter. Since these issues are closely related to the arguments the defendants made in their Rule 50(a) motion, the relator cannot argue she has been ambushed. Further, the district court criticized the sufficiency of evidence as to materiality during the proceeding. Thus, the relator cannot argue that the district court's order came as a surprise. We therefore reject the relator's procedural waiver argument.

We perceive no need for a new trial on liability.[13] Our reasons for reversing the judgment as a matter of law on the Medicare claims also support the conclusion that the jury verdict finding the defendants liable with respect to the Medicare claims was not contrary to the weight of the evidence. *Lipphardt v. Durango Steakhouse of Brandon, Inc.*, 267 F.3d 1183, 1186, 1189 (11th Cir. 2001) ("[N]ew trials should not be granted on evidentiary grounds unless, at a minimum, the verdict is against the great—not merely the greater—weight of the evidence." (quoting *Hewitt v. B.F. Goodrich Co.*, 732 F.2d 1554, 1556 (11th Cir. 1984))); *see also McGinnis v. Am. Home Mortg. Servicing, Inc.*, 817 F.3d 1241, 1257 (11th Cir. 2016) (new trial not appropriate where "the verdict was not against the clear weight of the evidence") (quotation omitted). Having held that the relator introduced sufficient evidence to permit a reasonable jury to find the defendants liable for Medicare-related fraud, and not for Medicaid-related fraud, we hold that the district court abused its discretion in conditionally granting the defendants' request for a new trial as to liability on the Medicare claims.

Defendants contend on appeal that a new trial is appropriate because the Medicare-related damages are excessive. We decline to entertain the defendants'

[13] Because the district court's order did not expressly discuss the excessiveness of the verdict, "the reasons explained above" could have referred only to the court's determination that the verdict was contrary to the weight of the evidence.

arguments because they are conclusory and were not adequately developed in the district court. "As a general principle, this court will not address an argument that has not been raised in the district court." *Stewart v. Dep't of Health & Human Servs.*, 26 F.3d 115, 115 (11th Cir. 1994) (citing *Baumann v. Savers Fed. Sav. & Loan Ass'n*, 934 F.2d 1506, 1510 (11th Cir. 1991)).[14] "The corollary of this rule is that, if a party hopes to preserve a claim, argument, theory, or defense on appeal, she must first clearly present it to the district court, that is, in such a way as to afford the district court an opportunity to recognize and rule on it." *Juris v. Inamed Corp.*, 685 F.3d 1294, 1325 (11th Cir. 2012) (quoting *Leonard v. Pan Am. World Airways, Inc. (In re Pan Am. World Airways, Inc., Maternity Leave Practices & Flight Attendant Weight Program Litig.)*, 905 F.2d 1457, 1462 (11th

[14] We have permitted issues to be raised for the first time on appeal in five limited circumstances:

> First, an appellate court will consider an issue not raised in the district court if it involves a pure question of law, and if refusal to consider it would result in a miscarriage of justice. Second, the rule may be relaxed where the appellant raises an objection to an order which he had no opportunity to raise at the district court level. Third, the rule does not bar consideration by the appellate court in the first instance where the interest of substantial justice is at stake. Fourth, a federal appellate court is justified in resolving an issue not passed on below . . . where the proper resolution is beyond any doubt. Finally, it may be appropriate to consider an issue first raised on appeal if that issue presents significant questions of general impact or of great public concern.

Cita Tr. Co. AG v. Fifth Third Bank, 879 F.3d 1151, 1156 (11th Cir. 2018) (quoting *Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1332 (11th Cir. 2004)). None of these circumstances apply to this case.

Cir. 1990)). The defendants' argument to the district court in their Rule 50(b) motion consisted of one sentence: "The jury's single damages award of over $115 million is excessive and against the weight of the evidence in light of all the deficiencies in Relator's proof discussed above." To the extent the defendants elaborated on their assertion, they pointed only to evidentiary deficiencies with respect to the Medicaid-related damages. These superficial assertions were insufficient to permit reasoned consideration by the district court and were an inadequate justification for the district court's conditional grant of a new trial.

The defendants insist in their Response Brief that their one-sentence argument to the district court was sufficient to preserve on appeal the issue of the excessiveness of the Medicare-related damages because their argument "was not limited to Medicaid, although Defendants highlighted the Medicaid verdict as the '[m]ost egregious' example of this excess." And for the first time on appeal, the defendants offer new arguments as to why the Medicare-related damages award allegedly is excessive. However, having failed to articulate the fact-based reasons for its contentions in the district court, the defendants cannot raise them for the first time on appeal for the purpose of salvaging the erroneous decision of the district court to conditionally grant a new trial. *See Stewart*, 26 F.3d 115 ("Judicial economy is served and prejudice is avoided by binding the parties to the facts

presented and the theories argued below." (quoting *Bliss v. Equitable Life Assurance Soc'y of U.S.*, 620 F.2d 65, 70 (5th Cir. 1980))).

IV.

For the foregoing reasons, the motion to dismiss is denied. We affirm in part and reverse in part the district court's grant of the defendants' renewed motion for judgment as a matter of law or, alternatively, for a new trial, and affirm in part and reverse and vacate in part the judgment. Specifically, we affirm the district court's grant of judgment notwithstanding the verdict as to the Medicaid claims. With respect to the Medicare claims, we reverse the district court's grant of judgment notwithstanding the verdict and vacate that part of its opinion. In light of our reversal on the Medicare claims, we remand with instructions for the district court to reinstate the jury's verdict in favor of the relator, the United States, and the State of Florida and against the defendants on the Medicare claims in the amount of $85,137,095, and to enter judgment on those claims after applying trebling and statutory penalties. We also reverse and vacate the district court's grant of a conditional new trial.

AFFIRMED in part, REVERSED in part and REMANDED for reinstatement of the jury's verdict consistent with this opinion.

FILED
United States Court of Appeals
Tenth Circuit

February 7, 2020

Christopher M. Wolpert
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

UNITED STATES OF AMERICA, ex rel. STACEY L. JANSSEN, as Special Administrator of the Estate of Megen Corin Duffy, Plaintiff Counter Defendant - Appellant, v. LAWRENCE MEMORIAL HOSPITAL, Defendant - Appellee.	No. 19-3011

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS
(D.C. NO. 2:14-CV-02256-SAC)

Anthony E. LaCroix, LaCroix Law Firm, LLC (Theodore J. Lickteig, Law Office of Theodore J. Lickteig, Lenexa, Kansas, Sarah A. Brown, Brown and Curry, LLC, Kansas City, Missouri, and Robert K. Collins, Collins Law Office, LLC, Olathe, Kansas, with him on the briefs), Kansas City, Missouri, for Appellant.

Andrew W. Lester (Mark A. Cole, Andrew R. Ramirez, and Kathryn G. Lee, with him on the brief), Spencer Fane LLP, Overland Park, Kansas, for Appellee.

Before **TYMKOVICH**, Chief Judge, **MURPHY**, and **CARSON**, Circuit Judges.

TYMKOVICH, Chief Judge.

In this False Claims Act case, Stacey Janssen alleges Lawrence Memorial Hospital engaged in two healthcare schemes to fraudulently receive money from the United States. Janssen first contends LMH falsified patients' arrival times in order to increase its Medicare reimbursement under certain pay-for-reporting and pay-for-performance programs the Government uses to study and improve hospitals' quality of care. Next, Janssen contends LMH falsely certified compliance with the Deficit Reduction Act in order to receive Medicare reimbursements to which it was otherwise not entitled.

LMH moved for summary judgment below, arguing Janssen failed to show her allegations satisfied the Act's materiality requirement—that the alleged falsehoods influenced the Government's payment decision as required under the FCA. The district court granted LMH summary judgment on all of Janssen's claims on this basis, and we AFFIRM.

I. Background

We first explain the fraud schemes alleged in the complaint and then discuss the procedural background relevant to the legal issues on appeal.

A. LMH's Alleged Fraud Schemes

Janssen claims LMH engaged in two fraudulent schemes. The first concerns LMH's alleged falsification of patients' arrival times. The second centers on LMH's false certification of compliance with the Deficit Reduction Act.

1. Falsification of Patients' Arrival Times

LMH contracts with the Centers for Medicare and Medicaid Services (CMS) to provide services to Medicare patients. CMS pays LMH for services based on pre-determined rates. These rates are affected by certain programs, including the Inpatient Quality Reporting (IQR) program, the Outpatient Quality Reporting (OQR) program, and the Hospital Value Based Purchasing (HVBP) program. To varying degrees, each of these programs rely on measures that incorporate patients' arrival times. The arrival time data is considered because it helps the Government analyze the timeliness of the care patients receive.

a. The IQR, OQR, and HVBP Programs

The IQR program is a pay-for-reporting program. Under this program, hospitals report certain designated quality measures regarding inpatient care. In exchange for timely and accurately reporting, hospitals receive an annual increase—what is termed a "market basket index increase"—in the rate at which they are reimbursed under Medicare. *See* 42 C.F.R. § 412.64. Those hospitals

that fail to submit accurate data on a timely basis have their market basket index increase reduced.[1] *Id.* at (d)(2).

The OQR program operates similarly to the IQR program, except it relates to outpatient, as opposed to inpatient, care. Hospitals must report certain quality measures regarding outpatient care under the program. In exchange for accurate and timely data, hospitals protect their annual market basket index increase from reduction.

For both the IQR and OQR programs, LMH understands that submitting accurate and complete data was a condition of receiving its full market basket index increase. For the IQR program, LMH also submits Data Accuracy and Completeness Acknowledgments on an annual basis certifying that the data submitted is "accurate and complete." App. at 2608.

The HVBP program is a pay-for-performance program. It operates as an incentive program based on hospitals' relative performance on a subset of IQR measures. Unlike the IQR and OQR programs—which reward the mere submission of data to CMS without regard for the substantive content of that data—the HVBP program considers how well or poorly hospitals performed

[1] For fiscal years 2007 through 2014, noncompliant hospitals' increases were reduced by 2 percent. 42 C.F.R. § 412.64(d)(2)(i)(B). For fiscal years 2015 and later, noncompliant hospitals' increases were reduced by one-fourth. 42 C.F.R. § 412.64(d)(2)(i)(C).

compared to their peers. Under this program, CMS withholds a percentage from the total annual Medicare payments due to all participating hospitals and redistributes these funds according to each hospital's performance score. A hospital's performance score is calculated based on four different domains. Each domain has a number of different measures within it. Accordingly, during the relevant time period, LMH's performance on certain IQR measures affected its overall HVBP performance score, which in turn impacted its Medicare reimbursement rate.

The healthcare measures used in the IQR, OQR, and HVBP programs change from year to year. During the relevant period some, but not all, of these measures incorporated patients' arrival times. For example, the only measures in the HVBP program that incorporated arrival times were AMI-7a (fribrinolytic therapy received within 30 minutes of hospital arrival) and AMI-8a (primary surgical intervention received within 90 minutes of hospital arrival). In fiscal year 2015, these constituted two out of twelve measures contributing to LMH's Clinical Process of Care Domain score—one of four domain scores that contributed to LMH's overall HVBP performance score. Similarly, of the measures utilized by the IQR and OQR programs, only a subset include arrival

times.[2] Moreover, for certain periods, LMH did not report any data for even those measures that incorporate arrival times.[3]

LMH reports data for the IQR and OQR programs to CMS either through automatically generated reports or by "abstracting" the data from patient charts. Abstraction is performed using Specifications Manuals promulgated by CMS. Abstractors do not, and cannot, alter data or patient records, nor do they investigate the accuracy of the data. Thus, for both forms of reporting, any inaccuracies in patients' records are simply carried over to the data reported to CMS.

b. Reporting False Patient Arrival Times

Under the IQR and OQR programs, LMH must report a patient's arrival time as the earliest time shown among a variety of documentation, including the

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[2] At oral argument, counsel for Janssen responded to a question regarding the extent each program utilized arrival times:

> Q: How many other of the metrics employ the arrival time?
> A: I don't have a dispositive number for you there, your honor. . . .
> Q: Is it like two of three employed arrival time or is it two of twenty?
> A: I think it's probably, on the inpatient side, it may be two or three of eighteen . . . and on the outpatient side there are a few more.

Oral Argument Recording, 32:02–33:00, Nov. 11, 2019.

[3] For example, for fiscal year 2015, LMH did not report any data with respect to AMI-7a because it had no relevant cases. App. at 3435.

patient's triage record or emergency department fact sheets.[4] As the district court notes in its order granting summary judgment, numerous pieces of evidence in the record support the contention that "LMH knowingly falsified patient records with the intent of causing abstracted 'arrival times' to be later than they would have been absent the falsification." App. at 3641.

For example, the former director of LMH's Emergency Department testified that LMH used "interim forms" and "triage sheets" to record patient arrival times but later discarded these forms so that the recorded arrival times did not enter the patient's hospital record. App. at 814–16. A former registration clerk in LMH's Emergency Department also declared that she was trained and instructed to delay registration of patients until after the administration of electrocardiograms (EKGs) so that the arrival time on the patient's record was synonymous with their EKG time. She also declared that LMH altered patients' arrival times to match EKG times in order to obtain Medicare compensation. *Id.* at 1369.

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[4] According to CMS Specifications Manuals, arrival time is "the earliest documented time the patient arrived" at the hospital emergency department or as an outpatient. App. at 255. This may be gleaned from a number of acceptable sources, including (1) any emergency department documentation; (2) nursing admission assessment/admitting note; (3) observation record; (4) procedure notes; and (5) vital sign graphics record. *Id.* at 265. As of July 1, 2012, CMS defined emergency department documentation to include "any documentation from the time period that the patient was an ED patient e.g., ED fact sheet, ED consent/Authorization for treatment forms, ED/Outpatient Registration/sign-in forms, ED vital sign record, triage record, ED physician orders, ECG reports, telemetry rhythm strips, laboratory reports, x-ray reports." *Id.* at 313.

Certain statistics are consistent with these assertions. Between 2010 and 2017, LMH reported a total of 17,714 records that incorporated "arrival time" as part of the IQR program. App. at 2606. For 15.89% of these records, the patient's arrival time was either the same as or later than a recorded EKG time. *Id.* During the same period, LMH reported 8,672 records to CMS that incorporated arrival time as part of the OQR program. *Id.* Of these, 4.09% contained an arrival time that was either the same as or later than a recorded EKG time. *Id.* Moreover, from the second quarter of 2008 through the last quarter of 2010, LMH frequently reported a median arrival-to-EKG time of more than eight minutes and never reported a time below three minutes. *Id.* at 948. But beginning in the first quarter of 2011, LMH began frequently reporting a median arrival-to-EKG time of zero or one minute. *Id.*

A reasonable inference from this testimonial and statistical evidence is that LMH falsified certain patient arrival times and reported some inaccuracies to CMS through the IQR and OQR programs. But the record is silent as to the extent LMH's alleged falsification of arrival times affected the accuracy of its IQR and OQR reporting or its HVBP performance score.[5]

[5] As Janssen concedes, "there is little evidence of the precise degree to which each measure is off is solely a function of LMH's scheme." Aplt. Br. at 59.

2. False Certification of Compliance with the Deficit Reduction Act

As a condition of receiving more than $5 million each year from Medicare, LMH must comply with Section 6032 of the Deficit Reduction Act. Section 6032 requires LMH to educate its employees with detailed information regarding the False Claims Act. *See* 42 U.S.C. § 1396a(a)(68). Among other things, Section 6032 requires that "any employee handbook" include "specific discussion" of "detailed information about the False Claims Act . . . administrative remedies for false claims and statements . . . any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs . . . ." *Id.*

From 2007 to 2016, LMH's New Associate Resource Handbooks lacked detailed discussion of the FCA, although these sources were supplemented with additional training and informational materials.

LMH also signed Attestations of Compliance for at least fiscal years ending September 30, 2014 through 2017. Each attestation states that "as a condition for receiving payments exceeding $5 million per federal fiscal year" the executor has "examined" LMH's policies and procedures and read Section 6032 of the Deficit Reduction Act. App. at 1707, 1714. Each further certifies that LMH is in compliance with the requirements of Section 6032.

For the fiscal years ending September 30, 2016 and 2017, the executors of LMH's attestations testified that they signed the forms without engaging in the activities to which they attested. Specifically, LMH's Chief Financial Officer executed the attestation for the fiscal year ending September 30, 2016, and testified that he did so without reviewing any educational materials distributed to employees. *Id.* at 1704. LMH's Chief Operating Officer executed the attestation for the year ending September 30, 2017, and testified that she did so without reviewing any policies or procedures. *Id.* at 1722.

B. Procedural and Investigatory History

In November 2013, the original Relator in this action, Megen Duffy,[6] called a CMS hotline to report LMH for alleged Medicare fraud. NCI AdvanceMed (NCI), a third-party investigative service for CMS, subsequently began investigating the allegations, including the claim that LMH committed fraud by "manipulating their door-to-EKG times" so as to "avoid losing money as a result of a reduced Medicare reimbursement." App. at 2534.

On May 30, 2014, Duffy filed her initial complaint. On June 16, 2015, she filed her second amended complaint. The Department of Justice received each, and sought additional time to consider intervention, stating it "assembled an investigative team and commenced an investigation." Supp. App. at 1. The DOJ

[6] On October 26, 2018, the district court ordered Stacey L. Janssen, the Special Administrator of Duffy's estate, substituted as the *qui tam* Relator.

notified the Health and Human Services Office of Inspector General, interviewed Duffy, and expressed interest in "thoroughly review[ing] and analyz[ing]" the allegations. *Id*. at 2. Ultimately, the DOJ opted not to intervene.

Around August 2014, NCI closed the investigation, noting "CMS is aware of quality issue." *Id.* at 2542. To date, CMS has not taken any action with respect to LMH. It has not ceased paying the Medicare claims that LMH continues to submit or asked LMH to adjust its reporting practices under the IQR, OQR, or HVBP programs.

After several years of litigation, LMH moved twice for summary judgment. The district court denied the first motion, which was filed before the close of discovery. The district court granted the second motion. With respect to both alleged fraud schemes, the district court held Janssen failed to raise a genuine issue of material fact with respect to the materiality of the alleged falsehoods. This appeal followed.

II. Analysis

Janssen brings the present claims under 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G).[7] To show a false claim, Janssen must establish (1) a false statement or

[7] Subsection (A) creates liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Subsection (B) creates liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* at § 3729(a)(1)(B). Subsection (G), (continued...)

fraudulent course of conduct; (2) made with the requisite scienter; (3) *that is material*; and (4) that results in a claim to the Government or conceals, decreases, or avoids an obligation to pay the Government. *See U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 734 (10th Cir. 2018). Here, the focus is on materiality, a required element under each of the provisions Janssen relies on. *See* 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G); *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).[8] Materiality is a mixed question of law and fact that can be decided as a matter of law if reasonable minds could not differ on the question. *See Long v. Ins. Co. of N. Am.*, 670 F.2d 930, 934 (10th Cir. 1982). We review the district court's grant of summary judgment de novo,

[7](...continued)
sometimes referred to as the reverse false claims section, creates liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* at § 3729(a)(1)(G).

[8] With respect to 31 U.S.C. §§ 3279(a)(1)(B) and (G), this requirement is explicitly included in the text of the statute. With respect to 31 U.S.C. § 3729(a)(1)(A), the Supreme Court has unequivocally stated a materiality requirement exists. *See Escobar*, 136 S. Ct. at 2001–02. The parties do not advance, and we do not take, any position with respect to whether any distinctions exist between the materiality requirements applicable to each subsection. For purposes of this appeal, any such distinctions are irrelevant as Janssen fails to meet any conception of materiality. *See Escobar*, 136 S. Ct. at 2002 (declining to decide whether "§ 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law" because "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'").

applying the same standard as the district court. *Smothers v. Solvay Chems.*, 740 F.3d 530, 538 (10th Cir. 2014).

A. Legal Framework

When originally enacted in 1863, the FCA aimed to stop "massive frauds perpetrated by large contractors during the Civil War." *United States v. Bornstein*, 423 U.S. 303, 309 (1976). Today, the FCA's focus "remains on those who present or directly induce the submission of false or fraudulent claims" to the Government. *Escobar*, 136 S. Ct. at 1996. But the FCA does not impose liability for any and all falsehoods. *Id.*; *see also* 31 U.S.C § 3729(a)(1)(A) *et seq*. Simply put, the FCA is not an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003 (citations omitted); *U.S. ex rel Bulbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("The FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." (quoting *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999))). Instead, FCA liability attaches only where the alleged misrepresentations are material to the Government's payment decision. *See Escobar*, 136 S. Ct. at 2001–02.

In the FCA context, materiality is a "rigorous" and "demanding" requirement. *Id.* at 2002–03; *see also U.S. ex rel. Coffman v. City of Leavenworth*, 770 F. App'x 417, 419 (10th Cir. 2019) (holding "[a]n FCA claim

must satisfy materiality . . . which [is] 'rigorous' and strictly enforced"). Assessing materiality requires analysis of the "effect on the likely or actual behavior of the recipient of the alleged misrepresentation."[9] *See Escobar*, 136 S. Ct. at 2002; *see also* 31 U.S.C. § 3729(b)(4) (defining materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"). Thus, the sine qua non of materiality is some quotient of potential influence on the decisionmaker—in this case, CMS.

Janssen dedicates much of her briefing to arguing for a "broad" interpretation of materiality. Aplt. Br. at 31. She contends the Supreme Court in *Escobar* adopted the concept of materiality familiar to contract and tort law and, under such a view, materiality may be shown through either an objective or subjective showing.[10] *Id.* at 27, 33. According to Janssen, under either an

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[9] Although the focus is on the Government's likely conduct, Janssen need not demonstrate actual reliance to survive summary judgment. *Cf. United States v. Williams*, 934 F.3d 1122, 1128–30 (10th Cir. 2019). That is, a false statement can be material even if the government's decision to pay or not pay the claim does not hinge on that statement alone. To erect such a bar—one requiring a showing of actual reliance—would impermissibly go beyond the text of the statute. *See, e.g.*, 31 U.S.C. § 3729(a)(1)(A) (attaching liability to the presentment of a false or fraudulent claim for payment rather than the actual payment of the claim); *see also U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009) ("The False Claims Act . . . lacks the elements of reliance and damages.").

[10] Janssen also cites numerous cases in support of her argument in favor of a purely objective or subjective understanding of materiality. We find these unpersuasive. *Long v. Insurance Co. of North America* involved allegations of insurance fraud between two private parties. 670 F.2d at 934. *Gilbert v. Nixon*

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objective or subjective showing, the focus need not be on the recipient of the misrepresentation. *See* Aplt. Br. at 34 (stating that "absent from both the objective and subjective tests is any requirement of proof of what the recipient of a misrepresentation actually thought or did in response to it").

But contrary to Janssen's argument, the Supreme Court in *Escobar* did not adopt the formulation of materiality contained in the Restatement (Second) of Torts § 538 and the Restatement (Second) of Contracts § 162(2). Instead, the Court cited these formulations in support of the statement that "under any understanding of the concept, materiality 'look[s] to the *effect on the likely or actual behavior of the recipient* of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (emphasis added). Thus, rather than directing courts to focus exclusively on a reasonable person—as they would under a purely objective

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involved allegations of fraud connected to investments in certain oil and gas leases executed between two private parties. 429 F.2d 348, 351–54 (10th Cir. 1970). Neither case offers an analogy to the present FCA allegations, much less a persuasive reason to distinguish and attempt to depart from the controlling directive of *Escobar*. *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), and *United States v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017), involve FCA allegations, but neither control nor support Janssen's conceptualization of materiality. First, both cases concerned the sufficiency of pleadings to withstand a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *See Brookdale*, 892 F.3d at 825–26; *Triple Canopy*, 857 F.3d at 175. Second, each explicitly considered the likely or actual effect of the alleged misrepresentations on the Government in its analysis, consistent with the approach adopted here. *Brookdale*, 892 F.3d at 832–38. *Triple Canopy*, 857 F.3d at 178–79.

analysis—or exclusively on the mindset of the misrepresenter—as they would under a purely subjective analysis—*Escobar* focuses the materiality inquiry on the likely reaction of the recipient.[11]

This inquiry is holistic. In cases such as this one, where the allegations base FCA liability on noncompliance with regulatory or contractual provisions, relevant factors include, but are not limited to (1) whether the Government consistently refuses to pay similar claims based on noncompliance with the provision at issue, or whether the Government continues to pay claims despite knowledge of the noncompliance; (2) whether the noncompliance goes to the "very essence of the bargain" or is only "minor or insubstantial;" and (3) whether the Government has expressly identified a provision as a condition of payment. *Escobar*, 136 S. Ct. at 2003 & n.5. None of these factors alone are dispositive. *See United States v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

Applying this standard of materiality, we turn first to LMH's alleged falsification of arrival times before addressing LMH's alleged false certifications of compliance with the Deficit Reduction Act.

[11] Evidence of objective or subjective materiality are not irrelevant. Such evidence may be probative in the materiality analysis. *U.S. ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). But it is relevant primarily because it casts light on the likely reaction of the recipient, not because it holds any isolated independent importance.

B. Patient Arrival Times

Assessing the factors discussed above, we conclude Janssen has failed to present sufficient evidence to raise a fact issue with respect to whether the alleged falsification of arrival times was material to the Government's payment decision.

1. Government's Prior Conduct

The Government's prior conduct weighs in favor of immateriality. Where the "Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," this demonstrates materiality. *Escobar*, 136 S. Ct. at 2003–04. Conversely, if the "Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.*

Neither party presents other cases concerning CMS reimbursement under the IQR, OQR, or HVBP programs, and we are aware of none. But the Government's actual behavior in *this* case suggests Janssen's allegations are immaterial.[12] *See U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("[W]e have the benefit of hindsight and should not ignore what

[12] We focus here on CMS's inaction despite knowledge of the allegations. Although stressed in LMH's briefing, we put little weight on the fact that the DOJ was aware of the allegations and declined intervention. To infer much, if anything, from such a declination would undermine the purposes of the FCA, which is explicitly designed to permit private persons to litigate suits in lieu of the Government. *Brookdale*, 892 F.3d at 836; *see also* 31 U.S.C. § 3730(d)(2).

actually occurred."). The record shows that in 2014 NCI conducted an investigation over several months into the central allegations presently at issue and made CMS aware of the quality issues complained of. To this day, CMS has done nothing in response and continues to pay LMH's Medicare claims. Although CMS may not have independently verified LMH's noncompliance—and thus may not have obtained "actual knowledge" of the alleged infractions—its inaction in the face of detailed allegations from a former employee suggests immateriality. *See U.S. ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 538 (9th Cir. 2018) (upholding summary judgment where the Government continued to pay claims "up to at least 2008, despite being aware of Relators' fraud allegations since 2002 [and] the results of its own audit since 2003"); *see also D'Agostino v. Ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations.").

Janssen claims that NCI did not engage in an "actual investigation." Aplt. Br. at 61. But NCI's report undermines this claim, and an affidavit from the NCI custodian of record avers that "NCI AdvanceMed investigated Megen Duffy's claim against Lawrence Memorial Hospital that is the subject of this lawsuit." App. at 2530. Janssen also contends the scope of the investigation was confined to whether or not "door-to-EKG" was, at the time, an HVBP measure. Aplt. Br.

at 61. This too is belied by the record. Although the NCI documents fail to precisely detail the scope of the investigation, they indicate that NCI was focused on the central complaint at issue here. For example, the cover sheet for the CMS hotline states that "Ms. Duffy claims that the employees of LMH are falsifying patients' charts . . . in order to get higher reimbursements." App. at 2532. The NCI closing investigative summary further describes the allegations under review as involving LMH "manipulating their door-to-EKG times . . . so that Lawrence Memorial Hospital can receive the highest reimbursement possible." App. at 2537. Although the evidence with respect to NCI's investigation is not overwhelming, the NCI summary details identification of a "quality issue" with respect to the precise allegations at issue and notes that CMS was made aware of the matter. This constitutes some evidence in favor of immateriality.[13]

[13] Janssen cites to the First Circuit's decision on remand in *Escobar*, arguing that nothing should be drawn from the CMS's continued payment of claims where it had only knowledge of allegations, as opposed to actual violations. *U.S. ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[A]wareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance.") While the distinction between allegations and actual knowledge is relevant, we find the First Circuit's decision distinguishable. In *Escobar* the court assessed the sufficiency of a complaint at the motion to dismiss stage, finding that potential knowledge of allegations was insufficient to warrant dismissal where the alleged noncompliance went to the essence of the bargain. The procedural posture here is quite different. It is not inconsistent to state that knowledge of allegations is insufficient, alone, to warrant dismissal under Rule 12(b)(6) and yet constitutes some evidence of immateriality under Rule 56(a). Moreover, in *Escobar* the allegations only noted that the Government continued to pay claims up to the filing of litigation. Here

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2. Essence of the Bargain

The minimal aspects of LMH's alleged misconduct similarly suggest immateriality. Where noncompliance with a regulatory requirement is "minor or insubstantial," it indicates immateriality. *Escobar*, 136 S. Ct. at 2003. Conversely, where noncompliance goes to the "essence of the bargain," it suggests materiality. *Id.* at 2003 n.5.

Janssen emphasizes the importance of accurate reporting to the effective operation of the IQR, OQR, and HVBP programs as justification for the importance and centrality of LMH's misconduct. Aplt. Br. at 45. The need for accurate reporting is at least arguably enshrined in the statutory and regulatory requirements for the programs, and was understood, at least at a general level, by LMH staff. But in the complex matrix of Medicare reporting and reimbursement, such broad appeals to the importance of accurate reporting cannot clear the rigorous materiality hurdle. *See U.S. ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1221 (10th Cir. 2008) (holding a hospital's failure to comply perfectly with Medicare regulations does not automatically generate FCA liability). As we noted in *Conner*, the Government has an "administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into

[13](...continued)
CMS has continued to pay claims—and has requested no changes in LMH's data reporting or Emergency Room practices—for years despite ongoing litigation.

compliance when they fall short of what the Medicare regulations and statutes require." *Id.* at 1220.

Here, that scheme envisions administrative procedures designed to address noncompliance with requirements of the IQR and OQR programs, including inaccurate reporting. *See* 42 C.F.R. §§ 412.140, 419.46. Substituting FCA liability for every failure to achieve perfect compliance with Medicare regulations would not only undermine the Government's administrative program, but would render the FCA a general antifraud statute and tool for policing minor regulatory compliance issues, contrary to the Court's directive in *Escobar*. *See Conner*, 543 F.3d at 1221; *see also Escobar*, 136 S. Ct. at 2003.

Accordingly, we must look not to simply whether Janssen has shown some inaccuracies in LMH's reporting, but to whether Janssen has demonstrated sufficiently widespread deficiencies that they would likely affect the Government's payment decision. We conclude she has failed to do so.

As Janssen concedes, there is "little evidence" demonstrating the extent to which inaccurate arrival times affected the accuracy of LMH's reporting. Aplt. Br. at 59. In the IQR and OQR programs, arrival time is only incorporated into a subset of measures for which LMH reports data. Moreover, not all the patient records relating to each affected measure were falsified. Even taking all reasonable inferences in Janssen's favor, we can at most conclude that relatively

few records reported false arrival times. *See* App. at 2606 (averring that only 15.99% of inpatient records and 4.09% of outpatient records incorporating arrival time had an EKG time identical to or earlier than the patient's arrival time). Thus, at most, LMH's alleged misconduct affected only a subset of a subset of the data reported under the IQR and OQR programs.

The effect of LMH's alleged misconduct is similarly limited with respect to the HVBP program. Only two measures in one of the four domains that affect LMH's performance score under the program incorporated arrival times. Within these measures, the degree to which LMH's alleged misconduct affected its performance is not ascertainable. At most, Janssen has shown uncertain effects on a factor of a factor of LMH's performance score. This evidence is insufficient to raise a fact issue with respect to materiality. *See Conner*, 543 F.3d at 1220–21; *Escobar*, 136 S. Ct. at 2003–04.

Nor has Jassen put forward evidence of a cover-up, which might signal materiality despite the minor effects of the alleged misconduct. *See United States v. Triple Canopy, Inc.*, 775 F.3d 628, 638 (4th Cir. 2015) *judgment vacated by Triple Canopy, Inc. v. U.S. ex rel. Badr*, 136 S. Ct. 2504 (2016), *but reaffirmed in Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017). In *Triple Canopy*, the Fourth Circuit inferred materiality, in part, from a "scheme" the defendant orchestrated to cover up the deficiencies of guards contracted to provide security services on

U.S. military bases overseas. There, after learning of the guards' deficient training, defendant's supervisors falsified scorecards so that its guards would meet the marksmanship requirements in its contract with the Government. Supervisors signed and post-dated the guards' false marksmanship scorecards despite knowing the guards could not zero their rifles or shoot straight.

Here, no analogous cover-up is evident. Janssen points to Medicare claim forms and Data Accuracy and Completeness Acknowledgments, arguing both constitute false certifications of accuracy regarding LMH's reported arrival times. But these boilerplate compliance documents are part of the complex Medicare regulatory system and fail to elevate potentially less-than-perfect compliance to FCA liability. *See Conner*, 543 F.3d at 1221 (rejecting the "sweeping" argument that Medicare certifications give rise to FCA liability with respect to minor or insubstantial regulatory noncompliance). Moreover, none of the deposition testimony Janssen cites supports the assertion that LMH's certifications were signed despite knowledge of inaccuracies similar to the guards' scorecards in *Triple Canopy*.

In light of the, at most, minimal nature of the inaccuracies in LMH's reporting under the IQR, OQR, and HVBP programs, we find Janssen's allegations do not go to the essence of the bargain between LMH and CMS and are therefore immaterial.

3. Express Condition of Payment

Finally, Janssen contends that the Government has expressly required accurate reporting as a condition of payment under the IQR, OQR, and HVBP programs. Aplt. Br. at 41, 52 (citing 42 U.S.C. §§ 1395ww(b), 1395l(t)(17), 1395ww(o); 42 U.S.C. §§ 1395ww(b)(3)(B)(viii)(I), 1395l(t), 1395ww(o)(1); and 42 C.F.R. § 482.24). Such requirements, while relevant, are not dispositive. *Escobar*, 136 S. Ct. at 2003.

Certain conditions for participating in Medicare are provided by 42 C.F.R. § 482.24. Among other things, participating hospitals such as LMH must maintain accurate medical records. While this requirement casts some light on the general importance of accurate reporting to the Government, it does not directly address the IQR, OQR, and HVBP programs. More importantly, such generic regulatory requirements fall short of establishing the materiality of perfect compliance therewith, especially when encased in a complex regulatory system with separate administrative remedies. *Conner*, 543 F.3d at 1218–22.

The remaining provisions of 42 U.S.C. §§ 1395ww(b), 1395l(t), and 1395ww(o) similarly fail to establish materiality. Even assuming these statutes require accurate reporting as an express condition under the relevant programs, that alone is insufficient to establish materiality. *Escobar*, 136 S. Ct. at 2003.

Accordingly, we find that the statutes and regulations related to the IQR, OQR, and HVBP programs do not overcome Janssen's failure to establish materiality with respect to LMH's alleged falsification of arrival times.

C. Deficit Reduction Act

Janssen's claims with respect to the Deficit Reduction Act similarly fail for lack of materiality. Although the record reveals a fact issue with respect to whether all of LMH's employee handbooks comply with Section 6032, not all potential compliance failures warrant FCA liability. *Escobar*, 136 S. Ct. at 2003 (noting the FCA is not a "vehicle for punishing garden-variety breaches of . . . regulatory violations").

Numerous New Associate Resource Handbooks distributed by LMH between 2007 and 2016 lack detailed, if any, discussion of the False Claims Act or the specific topics required to be communicated to employees under Section 6032. This may raise a jury issue with respect to whether LMH violated Section 6032. *See* 42 U.S.C. § 1396a(a)(68). Further, it is reasonable to infer from the testimony of LMH's Chief Financial Officer and Chief Operating Officer that LMH management submitted inadequate or false attestations of compliance with the DRA.

But while LMH's potential failure to educate its employees in the manner and detail required by Section 6032 and its management's certification of

compliance without sufficient knowledge, investigation, or review raise concerns with respect to LMH's regulatory compliance, these points do not translate into FCA liability. As we have previously explained, the FCA is not a tool to police everyday regulatory noncompliance. *U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("The FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."); *see also Escobar*, 136 S. Ct. at 2002. This rings especially true where complex regulatory schemes are managed by specific agencies with extensive technical experience. *See Conner*, 543 F.3d at 1221 ("It is therefore with good reason that the agencies of the federal government, rather than the courts, manage Medicare participation in the first instance . . . ."). In such scenarios, not every regulatory foot-fault will enable Relators to avail themselves of the FCA's potentially costly damages awards.

LMH's potential DRA compliance failures are precisely the type of garden-variety compliance issues that the demanding materiality standards of the FCA are meant to forestall. First, Janssen has at most demonstrated limited compliance issues, not a wholesale failure of LMH's compliance function. Outside of the new employee resource handbooks and attestations mentioned, Janssen does not dispute that LMH provides employees information regarding FCA compliance in line with the requirements of Section 6032. For example, LMH provides specific compliance training to new employees, which include discussion of the FCA,

state-based equivalents, and other fraud-related issues. Even the new employee resource handbooks assailed by Janssen include cross-references to other resources containing FCA information.

Second, Janssen fails to show any likely effect the DRA compliance issues would have on the Government's payment decision. Janssen argues DRA compliance was an "absolute prerequisite" to LMH receiving Medicare compensation. Aplt. Br. at 69. But as the Supreme Court made clear in *Escobar*, making a certain contractual or regulatory requirement an explicit condition of payment is insufficient to establish materiality. *Escobar*, 136 S. Ct. at 2003 ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.").

Recognizing this, Janssen also cites the Kansas Medical Assistance Program Fee-for-Service Provider (KMAP) manual. This manual, generated by the Kansas state government, reiterates the requirements of Section 6032 of the DRA and notes that hospitals receiving over $5 million annually in Medicare must comply therewith. Such inclusion fails to demonstrate any peculiar importance Section 6032 may have to the Government's payment decision. To the contrary, as a compliance aid, it is unsurprising the KMAP manual reiterates compliance requirements.

Accordingly, Janssen fails to raise a fact issue with respect to the materiality of LMH's alleged noncompliance with Section 6032 of the DRA.

III. Conclusion

For the foregoing reasons, we **AFFIRM** the decision of the district court.

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
February 17, 2020

Lyle W. Cayce
Clerk

No. 18-20501

UNITED STATES OF AMERICA, EX REL., RICHARD DRUMMOND,

Plaintiff-Appellee,

UNITED STATES OF AMERICA,

Intervenor-Appellee,

v.

BESTCARE LABORATORY SERVICES, L.L.C.; KARIM A. MAGHAREH,

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Texas

Before ELROD, WILLETT, and OLDHAM, Circuit Judges.

ANDREW S. OLDHAM, Circuit Judge:

BestCare Laboratory Services, L.L.C., obtained millions of dollars in reimbursements from Medicare for miles that its technicians never traveled. In this False Claims Act suit against BestCare and its CEO, the district court granted summary judgment to the United States. We affirm.

I.

Karim A. Maghareh founded BestCare in 2002 and served as its CEO. BestCare provided clinical testing services for nursing-home residents, many of whom were Medicare beneficiaries. Its main laboratory was in Webster, Texas, a suburb of Houston. BestCare grew its business; it opened labs in

Dallas and San Antonio and specimen-processing centers in Waco, Austin, and El Paso. Maghareh owned 51% of the company, and his wife owned the other 49%.

Richard Drummond was one of Maghareh's competitors. Drummond was suspicious of Maghareh's success in expanding BestCare. After all, diagnostic testing for Medicare patients isn't high-margin work. *Cf.* 42 U.S.C. § 1395*l*(h)(3)(A) (providing only a "nominal fee" for specimen collection). In 2008, Martha Shirali left her job as BestCare's billing manager, and Drummond subsequently hired her. When Shirali described BestCare's billing practices for travel reimbursements to Drummond, he realized that BestCare had been improperly billing Medicare.

In 2008, Drummond brought a *qui tam* whistleblower suit under the False Claims Act against BestCare and Maghareh on behalf of the United States. Three years passed with no activity in the district court. In 2011, the United States exercised its right to intervene, *see* 31 U.S.C. § 3730(b)(4)(A), and brought claims for fraud, unjust enrichment, payment by mistake, and violations of the False Claims Act.

The Government alleged that BestCare submitted false claims for travel reimbursements to Medicare. Specifically, BestCare sought reimbursements for miles purportedly driven by technicians to collect specimens from patients—when the samples were actually shipped one-way via airplane without any technician onboard. In addition, BestCare often failed to prorate mileage, treating a single shipment of multiple samples as though each sample had been shipped separately.

The Government filed two partial motions for summary judgment. The first sought to hold BestCare and Maghareh liable for fraud, unjust enrichment, and payment by mistake. The Government limited its damages calculation to a modest subset of BestCare's fraudulent billings: those

purporting to involve trips of 400 miles or more between August 4, 2005, and January 26, 2010. The Government did so because it is undisputed that no technician traveled 400 miles or more to collect samples. The Government's expert calculated damages by estimating the non-reimbursable portion of what Medicare paid using a sampling methodology developed by the Office of the Inspector General. He estimated that the total excess payment to BestCare during the time period in question was $10,600,000 (+/– 1.34%). The Government sought a judgment in that amount.

The second partial motion for summary judgment sought to hold BestCare and Maghareh liable for violating the False Claims Act. In this motion, the Government limited its damages calculation to an even smaller subset of fraudulent billings: those purporting to involve trips of more than 400 miles between August 4, 2005, and June 30, 2008. The Government's expert found that the total amount paid by Medicare during this time period for trips involving more than 400 miles was $10,190,545. Unlike the previous damages calculation, no sampling was used to disaggregate the reimbursable and non-reimbursable portions of what Medicare paid. Because the False Claims Act permits treble damages, *see* 31 U.S.C. § 3729(a)(1), the Government sought damages of $30,571,635.

In 2014, the district court granted partial summary judgment to the Government. It ruled only on the Government's first summary-judgment motion and held Maghareh liable for unjust enrichment and payment by mistake. The court adopted the Government's damages calculation of $10,600,000 and held BestCare and Maghareh jointly and severally liable. BestCare and Maghareh sought reconsideration. The district court refused.

The Government's second partial summary-judgment motion, involving the False Claims Act, sat undecided in the district court for four years. We issued a writ of mandamus and ordered the court to rule on the motion. *See In*

re United States ex rel. Drummond, 886 F.3d 448, 450 (5th Cir. 2018) (per curiam). The court granted summary judgment to the Government, adopting its damages calculation of $30,571,635. It entered a final judgment in that amount on the same day.

BestCare and Maghareh timely appealed. We review *de novo* a district court's grant of summary judgment. *See Morrow v. Meachum*, 917 F.3d 870, 874 (5th Cir. 2019). We ask whether the movant has shown "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

II.

The defendants do not dispute that BestCare sought and obtained round-trip, driving mileage reimbursements for the one-way shipment of samples via airplane with no technician onboard. Instead, they argue that their billing practices were lawful. Alternatively, they argue that they didn't have the requisite *mens rea* because they thought it was lawful to bill the Government for technicians' road trips—when in fact there were no road trips, and the technicians stayed at home. We review and reject both arguments in turn.

A.

The byzantine laws governing Medicare reimbursement have been aptly described as a "labyrinth." *Biloxi Reg'l Med. Ctr. v. Bowen*, 835 F.2d 345, 349 (D.C. Cir. 1987). Even the most complicated labyrinth has an outer boundary, however. And BestCare's machinations fell well outside of it.

Medicare allows laboratories to collect "a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed," "except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter." 42 U.S.C. § 1395*l*(h)(3)(A). In addition, labs may collect:

> a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital).

Id. § 1395*l*(h)(3)(B).

The statutory text clearly forbids BestCare's billing practices. It is undisputed that BestCare billed for the shipment of samples via airplane when no technician was traveling. That violates the statute's limitation of travel reimbursements to "expenses for trained personnel to travel." *Ibid.* BestCare's indisputable violation of the statute makes this an open-and-shut case.

Defendants cannot avoid that result by pointing to the "sub-regulatory guidance" of the Medicare Claims Processing Manual ("CMS Manual"). Defendants insist that they complied with that manual, which they characterize as the "principal repository of sub-regulatory guidance on specific billing issues." Blue Br. 21. But the guidance the Defendants point to in the CMS Manual is a "policy statement" that has "no binding legal effect." *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017). Its instructions cannot legally justify a clear violation of a statute. The statutory text is what matters, and BestCare violated the statute's limitations on travel reimbursements.

B.

In the alternative, the defendants argue that their good-faith reliance on the CMS Manual creates a genuine fact dispute about whether they had the requisite mental state to violate the False Claims Act. *See* 31 U.S.C. § 3729(a)–(b) (requiring a defendant to act "knowingly," which includes not only "actual knowledge" of information, but also "deliberate ignorance" or "reckless disregard" of the truth or falsity of information, even when there is no "proof of specific intent to defraud"). This argument also fails because there is no

plausible reading of the CMS Manual that could support the defendants' billing practices.

We have said that when "state of mind is an essential element," "it is less fashionable to grant summary judgment." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1265 (5th Cir. 1991). But we have also recognized that the "presence of an intent issue does not automatically preclude summary judgment; the case must be evaluated like any other to determine whether a genuine issue of material fact exists." *Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1326 (5th Cir. 1996). In *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458 (5th Cir. 2009), we affirmed a grant of summary judgment to the Government under the False Claims Act, holding that the defendants "either purposefully, or with reckless disregard to the truth or falsity of their statements, misled" the Government. *Id.* at 471; *see also United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 303–04 (6th Cir. 1998) (affirming grant of summary judgment to the Government under the False Claims Act).

The CMS Manual provides two billing codes for the collection of travel reimbursements. P9603 covers trips of twenty miles or more, and P9604 covers trips that are less than twenty miles. All of the claims at issue in this case deal with P9603. The defendants seek to justify their billing practices by pointing to two paragraphs discussing the P9603 billing code in Chapter 16, Section 60.2, of the CMS Manual:

- The minimum "per mile travel allowance" is $1.035. The per mile travel allowance is to be used in situations where the average trip to patients' homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip. - one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient;

prorated miles actually traveled (carrier allowance on per mile basis);[1] or

- The per mile allowance was computed using the Federal mileage rate plus an additional 45 cents a mile to cover the technician's time and travel costs. Contractors have the option of establishing a higher per mile rate in excess of the minimum (1.035 cents a mile in CY 2008) if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the clinical lab fee schedule as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

The defendants note that only the second paragraph contains the language: "At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician." They argue that the word "or" separating the first paragraph from the second makes it reasonable to read the two paragraphs as setting forth alternative situations in which P9603 can be used. They claim they were following the instructions in the first paragraph and ignoring the second. Therefore, the defendants say, they couldn't reasonably know it was unlawful to bill a "per mile travel allowance" for miles not traveled by anyone.

That argument borders on the absurd. Both paragraphs in the CMS Manual concern the rules governing per-mile reimbursements for technicians who're *actually* traveling somewhere. The first paragraph specifies a baseline per-mile rate for miles "actually traveled" by the technician. Alternatively, certain contractors can use a higher per-mile rate—but "[*a*]*t no time* will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician." (emphasis added). There is no way to read the Manual to suggest BestCare can bill Medicare for miles *not* actually traveled by anyone.

[1] All typographical errors in original.

This is confirmed by language preceding the two paragraphs cited by the defendants in Chapter 16, Section 60.2, of the CMS Manual. The defendants misleadingly omitted these two paragraphs from their trial-court exhibit:

> In addition to a specimen collection fee allowed under § 60.1, Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under § 1833(h)(3) of the Act and payment is made based on the clinical laboratory fee schedule. The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.
>
> The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.

It is apparent from this passage that P9603 reimbursements are permitted only for miles that technicians actually travel to collect specimens from patients who are homebound or in nursing homes. Reimbursements are not allowed for the mere transportation of samples that have already been collected, even if a technician is traveling. They are certainly not allowed when samples are shipped with no technician traveling. And no reasonable person could possibly think that *round-trip* mileage reimbursements are permissible for the *one-way* shipment of samples, when no technician is traveling.

The defendants fare no better by invoking alleged conversations between BestCare employees and the Government's third-party administrators. Defendants say those conversations show they acted in good-faith reliance on the Government's representations, without knowledge that they were submitting false claims. Defendants further say they relied on statements from Trailblazer Health Enterprises (a contractor that handled BestCare's Medicare

reimbursements) and Medigain (a billing consultant that took over BestCare's billing in late 2008). But as the Government rightly notes, those conversations took place after June 30, 2008. So they could not have affected the defendants' submission of claims between August 4, 2005, and June 30, 2008, which is all that matters for the Government's summary-judgment motion involving the False Claims Act.

The conversations that pre-date June 30, 2008, are either irrelevant or support the grant of summary judgment to the Government. For example, the defendants cite a March 2007 letter purporting to summarize guidance from a Medicare representative. But it says nothing about whether BestCare could bill for technician travel when no technician traveled anywhere; it only commented on proration. The defendants argue that an auditor named TriCenturion did not kick BestCare out of Medicare. But TriCenturion's inaction before the *qui tam* relator's suit says nothing about whether the defendants knowingly submitted false claims. Finally, the defendants point to evidence they submitted to Medicare's Comprehensive Error Rate Testing ("CERT") office. But that evidence proves rather than undermines the Government's theory. In one letter to CERT, BestCare attached a MapQuest printout as evidence of "the mileage traveled to provide service to Ms. [redacted]." Of course, the real mileage traveled by a technician was *zero* because the defendants shipped the patient's specimen one way, by air, without a technician onboard.

The district court did not err in granting the Government's motions for summary judgment.

III.

The defendants also argue that there are genuine disputes of material fact about the accuracy of the $10,600,000 damages calculation for the award involving unjust enrichment and payment by mistake. They do not clearly

challenge the calculation of the $30,571,635 False Claims Act award in their opening brief, so that argument is forfeited. *See Cantú v. Moody*, 933 F.3d 414, 418–19 (5th Cir. 2019). The defendants try to correct this forfeiture in their reply brief by asking us to construe their challenge to the first award as implicitly challenging the second award. But that is impossible because the two awards were calculated using different empirical methodologies, and they involve different legal standards. The only damages award before us is the first one, for $10.6 million.

We need not consider defendants' challenges to the $10.6 million judgment. That's because it is subsumed within the second judgment for $30.6 million under the False Claims Act. Both judgments arise from the same underlying conduct, so the Government is entitled to recover only once. *Cf. United States ex rel. Portland Constr. Co. v. Weiss Pollution Ctrl. Corp.*, 532 F.2d 1009, 1012 (5th Cir. 1976) (noting that "double recovery for a single wrong" is not permitted); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 505 F. Supp. 2d 20, 24 (D.D.C. 2007) (noting that it would be an "academic exercise" to consider liability on claims for unjust enrichment and payment by mistake after finding liability under the False Claims Act, because "any recovery under them would be duplicative"). Because we affirm the $30.6 million award under the False Claims Act, the defendants' challenge to the $10.6 million award is moot. *See Gil Ramirez Grp., L.L.C. v. Marshall*, 765 F. App'x 970, 974 (5th Cir. 2019), *cert. denied sub nom. Fort Bend Mech., Ltd. v. Gil Ramirez Grp., L.L.C.*, 140 S. Ct. 248 (2019) (mem.); *Am. Rice, Inc. v. Producers Rice Mill, Inc.*, 518 F.3d 321, 341 (5th Cir. 2008).

IV.

Maghareh argues that the district court erred in holding him personally liable for BestCare's improper billings. He first argues that the Government hasn't met the Texas-law standard for piercing the corporate veil. That

argument is plainly wrong, as state law has no relevance to the Government's federal claim under the False Claims Act, which allows Maghareh to be held personally liable. *See* 31 U.S.C. § 3729(a)(1) (holding liable "any person" who knowingly causes false claims to be presented).

Maghareh's second argument is that there are genuine disputes about whether he is personally responsible for BestCare's improper billings. We disagree. Maghareh signed the Medicare enrollment form, CMS 855B, in which he promised not to "submit claims with deliberate ignorance or reckless disregard of their truth or falsity." He signed every false P9603 claim that BestCare submitted, causing the Government to pay more than $10 million for miles that no technician traveled. And BestCare's billing manager Martha Shirali testified that Maghareh and his wife instructed her on how to bill for travel reimbursements. A supervisor's delegation of responsibility for claims submission to another person does not necessarily absolve the supervisor of liability under the False Claims Act. *See United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997).

Third, Maghareh argues he did not personally benefit from the fraud. But that would not matter even if it were true. To hold Maghareh jointly and severally liable under the False Claims Act, the Government need only prove he participated in a conspiracy to submit false claims. *See Mortgs., Inc. v. U.S. Dist. Court for the Dist. of Nev. (Las Vegas)*, 934 F.2d 209, 212 (9th Cir. 1991) (holding that where "one or more persons have committed a fraud upon the government in violation of the [False Claims Act], each is jointly and severally liable"); *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1013 (5th Cir. 1972) (imposing joint and several liability). The Government met its burden. Therefore, the district court did not err in holding Maghareh jointly and severally liable.

V.

Finally, the defendants argue that the district judge should be required to recuse under 28 U.S.C. § 455 because he is not impartial. That argument was not raised in the district court, so it is forfeited. *See Andrade v. Chojnacki*, 338 F.3d 448, 454 (5th Cir. 2003) ("Requests for recusal raised for the first time on appeal are generally rejected as untimely."). In any event, the defendants' perfunctory, two-sentence argument cites no evidence and is meritless.

* * *

BestCare and Maghareh spent years submitting false claims to the Government. Now they must pay. The district court's judgment is AFFIRMED.

UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-1241

In re: FLUOR INTERCONTINENTAL, INC., a California corporation; FLUOR FEDERAL GLOBAL PROJECTS, INC.; FLUOR FEDERAL SERVICES, LLC,

Petitioners.

On Petition for Writ of Mandamus. (1:19-cv-00289-LO-TCB)

Submitted: March 2, 2020 Decided: March 25, 2020

Before DIAZ, THACKER, and RUSHING, Circuit Judges.

Petition granted by unpublished per curiam opinion.

Mark C. Moore, Jennifer S. Cluverius, NEXSEN PRUET, LLC, Greenville, South Carolina; John P. Elwood, Craig D. Margolis, Tirzah S. Lollar, Christian D. Sheehan, Samuel M. Shapiro, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Petitioners. Eric N. Heyer, Thomas O. Mason, THOMPSON HINE LLP, Washington, D.C., for Respondent.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

On March 13, 2020, we granted a petition by Fluor Intercontinental, Inc., Fluor Federal Global Projects, Inc., and Fluor Federal Services, LLC (collectively "Fluor") for a writ of mandamus. We directed the district court to vacate portions of three orders that required Fluor to produce information over which the district court concluded Fluor had waived attorney-client privilege. We set out our reasons here.

I.

In 2017, Fluor, a government contractor, began an internal investigation of an alleged conflict of interest involving an employee, Steven Anderson, and a company (Relyant Global, LLC) to which Fluor planned to award a contract. Fluor's legal department supervised the investigation, providing advice about Fluor's potential legal exposure and the need to report any wrongdoing to the government. Following its investigation, Fluor terminated Anderson. It also sent a summary of its findings to the government pursuant to 48 C.F.R. § 52.203-13(b)(3)(i), which provides that "[t]he Contractor shall timely disclose, in writing, to the agency Office of the Inspector General . . . whenever . . . the Contractor has credible evidence" that an employee has violated certain federal criminal laws, including the False Claims Act.[1]

[1] In addition to the disclosure requirement, this regulatory regime, called the "Contractor Code of Business Ethics and Conduct," requires government contractors to have a written code of business ethics and conduct, exercise due diligence to prevent and detect criminal conduct, and establish an ongoing business ethics awareness and compliance program as well as an internal control system. *Id.* § 52.203-13(b)–(c). The

The summary of Fluor's findings includes the following statements: (1) "Anderson had a financial interest in and appears to have inappropriately assisted [a] Fluor supplier and potential subcontractor"; (2) "Fluor considers this a violation of its conflict of interest policy and Code of Business Conduct and Ethics"; (3) "Anderson used his position as the [Afghanistan] project manager to pursue Relyant concrete contracts with the German military, and Mr. Anderson used his position as the [Afghanistan] project manager to obtain and improperly disclose nonpublic information to Relyant"; and (4) "Fluor estimates there may have been a financial impact to the Government because Mr. Anderson's labor was charged to the contract task order while he engaged in improper conduct." Pet. Writ of Mandamus 13.

Anderson filed suit against Fluor, asserting claims of, among other things, wrongful termination, defamation, and negligence stemming from Fluor's internal investigation and disclosure to the government. In discovery, Anderson sought copies of Fluor's files regarding the internal investigation. Fluor objected, arguing that the files were protected by attorney-client privilege and the work-product doctrine. Anderson moved to compel production, but a magistrate judge denied the motion, agreeing with Fluor that the files were protected from disclosure.

internal control system must provide for, among other things, "[f]ull cooperation with any Government agencies responsible for audits, investigations, or corrective actions." *Id.* § 52.203-13(c)(2)(ii)(G). The disclosure requirement is meant to "emphasize the critical importance of integrity in contracting." Federal Acquisition Regulation; FAR Case 2007-006, Contractor Business Ethics Compliance Program and Disclosure Requirements, 73 Fed. Reg. 67064-02, 67071 (Nov. 12, 2008).

On November 8, 2019, the district court overruled (in part) the magistrate judge's order. As relevant here, the court concluded that the four statements described above in Fluor's disclosure to the government revealed "legal conclusions which characterize [Anderson's] conduct in a way that reveals attorney-client communications," Pet. Writ of Mandamus Ex. D, at 10, and thus that Fluor had waived attorney-client privilege as to those statements, other communications on the same subject matter, and the details underlying them, including fact work product. The district court also concluded that Fluor's description of the disclosure as "voluntary" in its answer and counterclaim was a binding judicial admission. And it asserted that 48 C.F.R. § 52.203-13(b)(3)(i) requires only "a mere notice disclosing the fact that the contractor has credible evidence," so Fluor's disclosure of information beyond that fact was voluntary. Pet. Writ of Mandamus Ex. D, at 12 n.1. Fluor moved for reconsideration of the district court's ruling, but the court denied the motion on December 20, 2019.

The magistrate judge then ordered Fluor to produce the relevant internal investigation files. But based on Fluor's representation that it would promptly seek appellate review, the magistrate judge stayed the production order. On February 26, 2020, the district court overruled the magistrate judge's order staying production and ordered Fluor to produce the relevant materials within seven days.

Fluor then sought mandamus relief in our court.

II.

"Mandamus is a 'drastic' remedy that must be reserved for 'extraordinary situations[.]'" *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 52 (4th Cir. 2016) (quoting *Kerr v. U.S. Dist. Court for the N. Dist. of Cal.*, 426 U.S. 394, 402 (1976)). We provide mandamus relief "only when (1) petitioner 'ha[s] no other adequate means to attain the relief [it] desires'; (2) petitioner has shown a 'clear and indisputable' right to the requested relief; and (3) the court deems the writ 'appropriate under the circumstances.'" *In re Murphy-Brown, LLC*, 907 F.3d 788, 795 (4th Cir. 2018) (quoting *Cheney v. U.S. Dist. Court*, 542 U.S. 367, 380–81 (2004)). As we explain, we conclude that Fluor has satisfied these exacting standards.

A.

We consider first whether Fluor has other adequate means to attain the relief it seeks. Anderson argues that Fluor has available to it three such means—(1) disobey the district court's order, be found in contempt, and appeal the contempt order; (2) seek certification of an interlocutory appeal under 28 U.S.C. § 1292(b); and (3) appeal after final judgment.

But under the circumstances of this case, we cannot agree that these means are adequate. As to appealing from a contempt order, we have previously held that "such an appellate remedy is hardly 'adequate.'" *Rowley v. McMillan*, 502 F.2d 1326, 1335 (4th Cir. 1974); *see also In re Kellogg Brown & Root, Inc.*, 756 F.3d 754, 761 (D.C. Cir. 2014) (noting that "forcing a party to go into contempt is not an 'adequate' means of relief"). As we have explained, a civil contempt sanction is not immediately appealable as an interlocutory order. *United States v. Myers*, 593 F.3d 338, 344 (4th Cir. 2010). And while

"a party to an action may immediately appeal an order of *criminal* contempt," Fluor couldn't have known in advance "whether the [d]istrict [c]ourt would punish its disobedience with an appealable criminal sanction or an 'onerously coercive civil contempt sanction with no means of review until the perhaps far distant day of final judgment.'" *See In re The City of New York*, 607 F.3d 923, 934 (2d Cir. 2010) (quoting 15B Charles Alan Wright, Arthur R. Miller & Edward C. Cooper, *Federal Practice and Procedure* § 3914.23, at 146 (2d ed. 1992)).

As to seeking certification of an interlocutory appeal under § 1292(b), we agree with Fluor that this means of relief is inadequate in light of the district court's suggestion that such an effort would be futile. When considering the magistrate judge's order staying production, the district court evaluated Fluor's likelihood of success on appeal. In doing so, it noted that, despite Fluor's "significant briefing and argument," Fluor "ha[d] not gone so far as to identify specific grounds which will satisfy the preconditions for [interlocutory appeal]." Pet. Writ of Mandamus Ex. K, at 8.

Nor are we satisfied that appealing after a final judgment is an adequate means of relief here. True, in *Mohawk Industries, Inc. v. Carpenter*, the Supreme Court concluded that post-judgment appeals are generally adequate means of relief from disclosure orders adverse to attorney-client privilege. 558 U.S. 100, 109 (2009). But it also noted that in "extraordinary circumstances," such as "when a disclosure order 'amount[s] to a judicial usurpation of power or a clear abuse of discretion,' or otherwise works a manifest injustice," a party may still "petition the court of appeals for a writ of mandamus." *Id.* at 111 (quoting *Cheney*, 542 U.S. at 390).

We conclude that such circumstances are present in this case. First, for the reasons discussed below, the district court's ruling that Fluor's disclosure waived attorney-client privilege is clearly and indisputably incorrect. Second, the ruling implicates "the important legal principles that protect attorney-client relationships," which we recently "elucidate[d]" in *In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 172–74 (4th Cir. 2019). Third, requiring Fluor to produce privileged materials is particularly injurious here, where Fluor acted pursuant to a regulatory scheme mandating disclosure of potential wrongdoing. Government contractors should not fear waiving attorney-client privilege in these circumstances. We think that together, these circumstances work a manifest injustice.

For these reasons, we conclude that Fluor has no other adequate means to attain the relief it desires.

B.

We consider next whether Fluor has shown a clear and indisputable right to relief. Fluor contends that it has done so as to three erroneous conclusions by the district court: (1) that Fluor's disclosure revealed attorney-client communications and thus waived attorney-client privilege, (2) that Fluor's disclosure was voluntary under 48 C.F.R. § 52.203-13, and (3) that Fluor's description of the disclosure as "voluntary" in its answer and counterclaim was a binding judicial admission. We agree that the district court clearly and indisputably erred as to the first conclusion, and so find it unnecessary to address the others.

The district court overruled the magistrate judge's denial of Anderson's motion to compel production of the internal investigation files because it concluded that the four

statements described above in Fluor's disclosure to the government waived attorney-client privilege. It focused on the following portions of the statements: "(i) Plaintiff 'appears to have inappropriately assisted . . .'; (ii) 'Fluor considers [that] a violation . . .'; (iii) Plaintiff 'used his position . . . to pursue [improper opportunities] and . . . to obtain and improperly disclose nonpublic information . . .'; and (iv) 'Fluor estimates there may have been a financial impact . . . [due to] improper conduct.'" Pet. Writ of Mandamus Ex. D, at 9–10.

According to the district court, because these four statements are "conclusions which only a lawyer is qualified to make," *id.* at 10 (quoting *In re Allen*, 106 F.3d 582, 605 (4th Cir. 1997)), they revealed attorney-client communications and thereby waived attorney-client privilege. Respectfully, the district court's conclusion was clearly and indisputably incorrect.

To find waiver, a court must find that there has been "disclosure of a communication or information covered by the attorney-client privilege or work-product protection." Fed. R. Evid. 502. But we will not infer a waiver merely because a party's disclosure covers "the same topic" as that on which it had sought legal advice. *Sky Angel U.S., LLC v. Discovery Commc'ns, LLC*, 885 F.3d 271, 276 (4th Cir. 2018); *see also United States v. O'Malley*, 786 F.2d 786, 794 (7th Cir. 1986) ("[A] client does not waive his attorney-client privilege 'merely by disclosing a subject which he had discussed with his attorney.' In order to waive the privilege, the client must disclose the communication with the attorney itself." (internal citation omitted)).

Relatedly, in determining whether there has been disclosure of a communication covered by the attorney-client privilege, we distinguish between disclosures based on the

advice of an attorney, on the one hand, and the underlying attorney-client communication itself, on the other. *See In re Grand Jury Subpoena*, 341 F.3d 331, 336 (4th Cir. 2003). In *In re Grand Jury Subpoena*, we considered whether the appellant waived attorney-client privilege by answering "no" to a question on a publicly filed document based on the advice of his attorney, and whether the appellant waived privilege by telling FBI agents that he answered "no" to the question "under the advice of an attorney." *Id.* at 334, 336.

We concluded that the appellant's statement—based on the advice of his attorney—on a publicly filed document did not waive privilege. *Id.* at 336. We explained that "[t]he underlying *communications* between Counsel and Appellant regarding his submission of [the publicly filed document] are privileged, regardless of the fact that those communications may have assisted him in answering questions in a public document." *Id.* Put differently, "Appellant filled out and submitted [the publicly filed document] himself; that he may have answered a question in a particular way on the advice of his attorney does not subject the underlying attorney-client communications to disclosure." *Id.* Ruling otherwise, we noted, "would lead to the untenable result that any attorney-client communications relating to the preparation of publicly filed legal documents—such as court pleadings—would be unprotected." *Id.*

But, as to the appellant's statements to the FBI agents, we concluded that he waived attorney-client privilege because he "clearly stated to a third party that his attorney had advised him to answer 'no'" to the relevant question, thereby disclosing the content of the underlying attorney-client communication itself. *Id.* at 337.

These principles reveal the clear and indisputable error in the district court's assertion that Fluor's disclosure contained "legal conclusions as to past events, as well as recommendations for future conduct, [] conclusions which only a lawyer is qualified to make." Pet. Writ of Mandamus Ex. D, at 10 (quoting *In re Allen*, 106 F.3d at 605). Setting aside whether Fluor's statements were in fact legal conclusions that only a lawyer could make, that is not the test for whether waiver of attorney-client privilege has occurred.[2] Instead, to find waiver, a court must conclude that there has been disclosure of *protected communications*.

As applied here, the fact that Fluor's disclosure covered the same topic as the internal investigation or that it was made pursuant to the advice of counsel doesn't mean that privileged communications themselves were disclosed. The district court clearly and indisputably erred in finding otherwise.

We also disagree with the district court's conclusion that this case is similar to *In re Martin Marietta Corp.*, 856 F.2d 619 (4th Cir. 1988). On the contrary, that case highlights the problem with the district court's determination that Fluor disclosed privileged communications. There, we concluded that the appellant waived privilege over protected internal audit interviews because its disclosure to the government quoted from the interviews, and it waived privilege over protected internal notes and memoranda on the

[2] As Fluor correctly notes, *In re Allen* has nothing to do with waiver. There, we held simply that because documents prepared by a lawyer contained legal conclusions that only an attorney was qualified to make, the documents were prepared in the attorney's capacity as an attorney rather than as a lay investigator. 106 F.3d at 605.

interviews because the disclosure "summariz[ed] in substance and format the interview results." *Id.* at 626 n.2. For example, the disclosure stated that "'of those consulted within the Company all will testify that any qualms they had about the arrangement had nothing to do with worries about fraud,' and 'there is no evidence, testimonial or documentary, that any company officials in the meeting [of November 17, 1983] except Mr. Pollard and his Maxim employees, understood that Maxim had departed from the strict procedures of its [] contract.'" *Id.* at 623. By directly quoting and summarizing what employees had said to counsel in the interviews, the appellant in *In re Martin Marietta Corp.* revealed privileged communications.

But here, there is no evidence to suggest that the four statements in Fluor's disclosure quoted privileged communications or summarized them in substance and format. Rather, the statements do no more than describe Fluor's general conclusions about the propriety of Anderson's conduct. We are unwilling to infer a waiver of privilege on these facts. The most that can be inferred from this record is that Fluor's statements were based on the advice of its counsel. Because that is clearly and indisputably insufficient to show waiver, Fluor has shown a clear and indisputable right to relief.

C.

Lastly, we are satisfied that a writ is appropriate under the circumstances. In addition to being manifestly incorrect, the district court's decision has potentially far-reaching consequences for companies subject to 48 C.F.R. § 52.201-13 and other similar disclosure requirements. We struggle to envision how any company could disclose credible evidence of unlawful activity without also disclosing its conclusion, often based

on the advice of its counsel, that such activity has occurred. More likely, companies would err on the side of making vague or incomplete disclosures, a result patently at odds with the policy objectives of the regulatory disclosure regime at issue in this case.

The district court's decision also introduces uncertainty and irregularity into waiver determinations. Whether a conclusion is one that only an attorney could make is a subjective determination that will likely depend on the particular legal question at issue. The Supreme Court has stated that "[a]n uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all." *Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981). We agree, and therefore find it necessary to issue the writ here.

***

For the reasons given, we grant Fluor's petition for a writ of mandamus on the terms set out in our March 13 order.

PETITION GRANTED

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

GENERAL MEDICINE, PC,	
Petitioner,	
v.	**Case No. 3:20-MC-53-NJR**
UNITED STATES OF AMERICA,	
Respondent.	

MEMORANDUM AND ORDER

ROSENSTENGEL, Chief Judge:

Pending before the Court is a Petition filed by General Medicine, PC, to set aside certain Civil Investigative Demands (CIDs) served upon nursing facilities for which General Medicine provides healthcare services (Doc. 2). The CIDs were issued by Respondent United States of America pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA), in the course of an FCA investigation (*Id.*). For the following reasons, the petition is denied.

BACKGROUND

General Medicine, a Michigan-based company, employs physicians and nurse practitioners that specialize in the near-daily monitoring and care of post-acute patients (Doc. 2 at ¶ 1; Doc. 4). These medical professionals provide care exclusively for patients in nursing homes, skilled nursing, rehabilitation, assisted living, and other long-term care facilities (*Id.*). According to General Medicine, the U.S. Attorney's Office for the Southern District of Illinois ("the Government") has been investigating General Medicine for possible violations of the False Claims Act since at least 2015 (*Id.* at ¶ 2).

The Government seeks to determine whether General Medicine submitted false claims for payment to Medicare based on excessive, inflated, and medically unnecessary services provided to nursing facility residents (Doc. 4). Specifically, the investigation seeks to determine "whether federal insurers have paid General Medicine millions of dollars for false claims arising from excessive, medically unnecessary visits to nursing home residents." (Docs. 4; 4-1). Also being investigated is whether General Medicine knowingly upcoded claims for payment to obtain higher reimbursement, performed cursory visits with residents that did not provide any benefit or meet reimbursement requirements, and unbundled related services into multiple visits to artificially generate additional claims and revenue (*Id.*). The Government has focused its inquiry on General Medicine's Care Plan Reviews (CPRs) and Monthly Medication Reconciliations/Reviews (MMRs), which General Medicine requires its clinicians to conduct every month with every Medicare patient, regardless of the patient's need for the services (*Id.*). General Medicine also apparently bills these CPRs and MMRs at the highest reimbursement code available, which should only be used for comprehensive, complex visits (*Id.*).

During its investigation, the Government learned that "certain nursing facilities had relevant concerns about General Medicine's services, including the frequency and medical necessity of some visits" (*Id.*). The Government points to a letter from one nursing facility, in which the facility noted that it terminated its contract with General Medicine because management and the Medical Director "felt that too many unnecessary orders were being written. There would be 2 people at the facility five days a week; we felt it was too excessive." (Doc. 4-2). Based on this information, the Government issued

CIDs containing the six interrogatories to select nursing facilities likely to have recent and relevant knowledge about General Medicine's services" pursuant to 31 U.S.C. § 3733 (Doc. 4).

On July 28, 2020, General Medicine initiated this action to set aside the CIDs issued by the Government to North Carolina State Veterans Home and an unknown number of other facilities as part of its investigation (Doc. 2 at ¶ 3). The CIDs consist of six interrogatories (*Id.* at ¶ 4). Specifically, the CIDs ask the facilities to indicate: (1) the General Medicine practitioners who have provided services at the facility within the last 12 months; (2) whether the facility has received any complaints about General Medicine or a General Medicine practitioner during the past 12 months and details about the complaint(s); (3) whether resident medications are regularly reviewed for dosage, discontinuation, and/or contraindication and details about that review including General Medicine's involvement; (4) whether resident care plans are regularly reviewed and details about that review, including General Medicine's involvement; (5) whether the facility has any concern regarding General Medicine or its practitioners, including the frequency of visits, quality of care, time spent with residents, or any other concerns; and (6) the name of the person who prepared the responses or is knowledgeable about the responses (Doc. 2-2).

General Medicine argues the CIDs should be set aside because they fail to comply with the specificity requirements of 31 U.S.C § 3733, do not seek information reasonably relevant to an investigation and/or seek information already in possession of the Government, are overbroad and harassing, and were issued in bad faith. General

Medicine also asserts it would be an abuse of process to enforce the CIDs.

In response, the United States argues General Medicine has no right to set aside the CIDs under the FCA, as the statute permits only the recipient of a CID to move to set it aside (Doc. 4). Further, even if General Medicine could challenge CIDs it did not receive, the CIDs were issued in good faith, serve a legitimate purpose, and request specific information that is directly relevant and material to the investigation (*Id.*).

General Medicine asserts in reply that it has standing to challenge the CIDS. And, furthermore, the CIDs could not have been issued in good faith, considering the alleged impetus for the CIDs occurred more than a year before the CIDs were issued (Doc. 12). General Medicine also contends the Government is no longer "investigating" but conducting one-sided discovery through the irrelevant CIDs (*Id*).

In essence, General Medicine seeks to compel the Government to decide either file a False Claims Act case against it—or leave it alone. General Medicine asserts that, since the investigation began in 2015, it has lost approximately 83 percent of the facilities it served and over 70 percent of its staff (Doc. 12). Prior to the investigation, General Medicine had a less than 6 percent attrition rate per year (*Id.*). Thus, the Government continues to inflict harm on General Medicine and the patients it serves, while at the same time failing to "diligently" investigate whether a violation of the False Claims Act has occurred, as required by 31 U.S.C § 3730(a).

LEGAL STANDARD

Under the False Claims Act, before commencing a civil proceeding under section 3730(a), the Attorney General or a designee may issue a CID to any person believed to be in possession, custody, or control of any documentary material or information relevant

to a false claims law investigation. 31 U.S.C. § 3733(a)(1). The purpose of the CID, which serves as an administrative subpoena, is to "enable the Government to determine whether enough evidence exist[s] to warrant the expense of filing [a civil] suit, as well as to prevent the potential Defendant from being dragged into court unnecessarily." *United States v. Witmer*, 835 F. Supp. 208, 211 (M.D. Pa. 1993), aff'd, 30 F.3d 1489 (3d Cir. 1994) (quoting H.R.Rep. 660, 99th Cong., 2d Sess. 26 (1986); *United States v. Markwood*, 48 F.3d 969, 975–76 (6th Cir. 1995). "Although Congress has chosen to call this subpoena by another name, a false claims CID is, at its essence, a subpoena issued by an administrative agency." *Markwood*, 48 F.3d at 796.

"[A] district court's role in the enforcement of an administrative subpoena is a limited one." *Id.* A court's "inquiry is appropriate only into whether the evidence sought is material and relevant to a lawful purpose of the agency." *E.E.O.C. v. Kloster Cruise Ltd.*, 939 F.2d 920, 922 (11th Cir. 1991).

DISCUSSION

I. Standing

Before addressing whether the CIDs comply with the requirements set forth by 31 U.S.C. § 3733, the Court must determine whether General Medicine has standing to bring this action to set aside the CIDs.

The False Claims Act provides that "[a]ny person who has received a civil investigative demand . . . may file, in the district court of the United States for the judicial district within which such person resides, is found, or transacts business . . . a petition for an order of the court to modify or set aside such demand." *Id.* § 3733(j)(2). The Government argues that, because General Medicine was not the recipient of the CIDs,

under the statute it has no right to bring this action to set the CIDs aside. General Medicine disagrees, arguing that the target of an investigation has standing to challenge the validity of a subpoena on the ground that it is in excess of the terms of the applicable statute. Moreover, it argues, federal courts have inherent federal question jurisdiction to grant equitable relief against actions that exceed statutory authority.

In order to have Article III standing, a "plaintiff must have suffered or be imminently threatened with a concrete and particularized 'injury in fact' that is fairly traceable to the challenged action of the defendant and likely to be redressed by a favorable judicial decision." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 125, 134 S. Ct. 1377, 1386, 188 L. Ed. 2d 392 (2014). The Supreme Court also has recognized prudential limits on the parties that may invoke the courts' powers. Prudential standing encompasses "at least three broad principles: the general prohibition on a litigant's raising another person's legal rights, the rule barring adjudication of generalized grievances more appropriately addressed in the representative branches, and the requirement that a plaintiff's complaint fall within the zone of interests protected by the law invoked." *Id.* (quotations and citations omitted).

The Government argues General Medicine is not within the zone of interests created by § 3733(j) of the FCA because it states that any person who has "received" a CID may move to have it set aside. But the statute does not *prohibit* a third party from challenging a CID, and the United States has pointed to no statute or rule that divests the Court of its authority to hear a third-party's objections to a subpoena. *See Noble Roman's, Inc. v. Hattenhauer Distrib. Co.*, 314 F.R.D. 304, 305 (S.D. Ind. 2016). Indeed, as noted in

Noble Roman's, the only Seventh Circuit case to discuss a party's "standing" to challenge a non-party subpoena found that "[a] party has standing to move to quash a subpoena addressed to another if the subpoena infringes upon the movant's legitimate interests." *Id.* (quoting *United States v. Raineri*, 670 F.2d 702, 712 (7th Cir. 1982)).

Here, General Medicine has shown that it is imminently threatened with a concrete and particularized injury in fact. It states that it has lost approximately 83 percent of the facilities it served and over 70 percent of its staff since the investigation began, and one facility terminated its business relationship with General Medicine after being served with a similar CID, citing "ongoing legal proceedings" as the reason. Additionally, General Medicine notes that much of the information requested in the CIDs will have to be obtained from General Medicine and its employees. Thus, General Medicine has shown that the CIDs infringe upon its legitimate business interests such that it has standing to raise its objection in this Court.

II. Compliance with FCA Requirements

A district court should enforce an administrative subpoena as long as (1) the inquiry is within the authority of the agency; (2) the demand is not too indefinite; and (3) the information sought is reasonably relevant. *E.E.O.C. v. Aerotek, Inc.*, 815 F.3d 328, 333 (7th Cir. 2016). "Under this familiar formulation, known as the *Morton Salt* test, disclosure may be restricted where it would impose an unreasonable or undue burden on the party from whom production is sought." *Id.*; *see United States v. Morton Salt Co.*, 338 U.S. 632, 652, 70 S.Ct. 357, 94 L.Ed. 401 (1950).

General Medicine does not assert the Government's inquiry is outside its authority, but argues the CIDs are overbroad, irrelevant, and unnecessary given that it

has provided the Government with the identity of all practitioners who perform CPRs and MMRs, numerous documents explaining the services and why they are performed, and thousands of Medicare audit and Administrative Law Judge decisions. Thus, there is no need to seek the same information from the nursing facilities. General Medicine also contends the Government, rather than narrowing its years-long investigation, is now embarking on a fishing expedition by asking the facilities if they have received "any complaints" or have "any concerns" about General Medicine. *See Blue Cross, Blue Shield of Ohio v. Klein*, 117 F.3d 1420 (6th Cir. 1997) ("[W]hile substantial deference is given to CIDs and subpoenas, the government cannot merely engage in 'arbitrary fishing expeditions."). General Medicine argues these inquiries, in addition to being overbroad, are irrelevant to the Government's investigation, which is focused on CPRs and MMRs. Finally, General Medicine asserts the CIDs were issued in bad faith, considering the Government waited a year after obtaining certain information to send the CIDs.

In response, the Government argues that General Medicine's claim that it has acted in bad faith is unsupported and nothing more than speculation. Furthermore, it has a valid purpose for issuing the CIDs: to assess whether General Medicine submitted false, inflated claims to government insurers for medically unnecessary and excessive visits to nursing home patients. The Government further asserts that each interrogatory requests specific information that is that is relevant and material to the Government's investigation.

After reviewing the interrogatories and the scope of the Government's inquiry, the Court finds that the CIDs seek information reasonably relevant to the United States'

pending FCA investigation, are not unduly burdensome or overbroad, and do not seek information already in the Government's possession.

Interrogatory No. 1 simply asks for the names of General Medicine practitioners who have provided medical services to residents in the facility in the past 12 months. This request is limited in time and is reasonably related to the Government's investigation. While the Government may already have the names of all practitioners who perform CPRs and MMRs, this interrogatory narrows the list to those providers who, in the last 12 months, may have been involved in the activity under investigation.

Interrogatory No. 2, which asks whether the facility has received any complaints about General Medicine or a General Medicine practitioner during the past 12 months, is not limited to any specific type of complaint about General Medicine or its practitioners. As the Government explains, however, there are many different types of complaints that could relate to the purpose of its investigation—*i.e.*, "instances where General Medicine was not providing the level of service that it billed to federal insurers." (Doc. 4 at p. 12). The Government further clarifies that Interrogatories 3 and 4 seek the nursing facilities' perspective on resident care plans[1] and medication reviews, which clearly is relevant to the investigation.

Finally, Interrogatory No. 5 asks for information regarding any concerns the facility has about General Medicine or any specific General Medicine practitioners,

[1] General Medicine argues this question, while seemingly relevant, is actually misleading because the "resident care plans" prepared and maintained by the facility is very different from the Care Plan Reviews conducted each month by General Medicine practitioners (Doc. 12 at p. 11). The Government, in its response, however, notes that it is requesting information "from the *nursing facility* about the *nursing facility's* procedures and experiences with General Medicine." (Doc. 4 at p. 13). Given the limited role of the Court in this action, the undersigned cannot say with certainty that the question is immaterial and irrelevant to a lawful purpose of the agency. *See Aerotek, Inc.*, 815 F.3d at 333.

including any concerns about the frequency of visits, the quality of care being provided, the time spent with residents, or any other issue. Again, the Court cannot say this information is irrelevant to the Government's investigation. And because the Government is seeking the perspective of the nursing facilities, this is not information already in the Government's possession.

The Court also cannot say the CIDs issued in bad faith or that enforcing them would be an abuse of process. "[T]he party asserting that the agency acted in bad faith bears a heavy burden of proof." *Markwood*, 48 F.3d at 978 (citing *United States v. LaSalle Nat'l Bank*, 437 U.S. 298, 98 S.Ct. 2357, 57 L.Ed.2d 221 (1978)). General Medicine has not met that burden. General Medicine claims the CIDs were issued to harass and harm it and to cause it to settle a collateral dispute. It further argues the CIDs were issued after years of its cooperation with the Government, and with the Government's knowledge that the CIDs would harm its business. But General Medicine has presented no actual evidence that the CIDs were issued with the intent to harass, cause General Medicine harm, or entice it to settle some unspecified collateral dispute. Furthermore, the questions are directed to nursing facilities that have direct knowledge of General Medicine's practices. While General Medicine is understandably frustrated by the length of the investigation and the effect it is having on its business, that does not mean the CIDs were issued in bad faith.

That being said, the Court would be remiss not to express its concern regarding the length of the Government's investigation and the purported losses General Medicine has incurred as a result. "Congress intended the false claims CID to provide the

Department of Justice with a means to assess quickly, and at the least cost to the taxpayers or to the party from whom information is requested, whether grounds exist for initiating a false claim suit under 31 U.S.C. §§ 3729–32 . . . ." *Markwood*, 48 F.3d at 979. General Medicine believes the investigation has been ongoing since 2015; the Government states that it first "disclosed" to General Medicine that it was under investigation in November 2017. An investigation spanning at least three years is hardly a quick assessment. Yet, as General Medicine concedes, this is not a *qui tam* action, and the Court, of course, has no authority to compel the United States to file a False Claims Act case against it. Because the CIDs were properly issued under 31 U.S.C. § 3733, the Court must deny General Medicine's motion to set the CIDs aside. To conclude otherwise would constitute an overstep of this Court's limited authority in this action.

CONCLUSION

For the reasons set forth above, the Petition filed by General Medicine, PC, to set aside certain Civil Investigative Demands (CIDs) (Doc. 2) is **DENIED**, and this action is **DISMISSED**. The Clerk of Court is **DIRECTED** to enter judgment and close this case.

IT IS SO ORDERED.

DATED: December 7, 2020

NANCY J. ROSENSTENGEL
Chief U.S. District Judge

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. *See* U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled "Selection of Monitors in Criminal Division Matters" issued by Assistant Attorney General Brian Benczkowski (hereafter, the "Benczkowski Memo") instructs prosecutors to consider, at the time of the resolution, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future" to determine whether a monitor is appropriate.

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three "fundamental questions" a prosecutor should ask:

1. "Is the corporation's compliance program well designed?"

2. "Is the program being applied earnestly and in good faith?" In other words, is the program adequately resourced and empowered to function effectively?

3. "Does the corporation's compliance program work" in practice?

See JM 9-28.800.

In answering each of these three "fundamental questions," prosecutors may evaluate the company's performance on various topics that the Criminal Division has frequently found relevant in evaluating a corporate compliance program both at the time of the offense and at the time of the charging decision and resolution.[1] The sample topics and questions below form neither a checklist nor a formula. In any particular case, the topics and questions set forth below may not all be relevant, and others may be more salient given the particular facts at issue and the circumstances of the company.[2] Even though we have organized the topics under these three fundamental questions, we recognize that some topics necessarily fall under more than one category.

I. Is the Corporation's Compliance Program Well Designed?

The "critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct." JM 9-28.800.

Accordingly, prosecutors should examine "the comprehensiveness of the compliance program," JM 9-28.800, ensuring that there is not only a clear message that misconduct is not tolerated, but also policies and procedures – from appropriate assignments of responsibility, to training programs, to systems of incentives and discipline – that ensure the compliance program is well-integrated into the company's operations and workforce.

A. Risk Assessment

The starting point for a prosecutor's evaluation of whether a company has a well-designed compliance program is to understand the company's business from a commercial perspective, how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks. In short, prosecutors should endeavor to understand why the company has chosen to set up the compliance program the way that it has, and why and how the company's compliance program has evolved over time.

Prosecutors should consider whether the program is appropriately "designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business" and "complex regulatory environment[]." JM 9-28.800.[3] For example, prosecutors should consider whether the company has analyzed and addressed the varying risks presented by, among other factors, the location of its operations, the industry sector, the competitiveness of the market, the regulatory landscape, potential clients and business partners, transactions with foreign governments, payments to foreign officials, use of third parties, gifts, travel, and entertainment expenses, and charitable and political donations.

Prosecutors should also consider "[t]he effectiveness of the company's risk assessment and the manner in which the company's compliance program has been tailored based on that risk assessment" and whether its criteria are "periodically updated." *See, e.g.*, JM 9-47-120(2)(c); U.S.S.G. § 8B2.1(c) ("the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement [of the compliance program] to reduce the risk of criminal conduct").

Prosecutors may credit the quality and effectiveness of a risk-based compliance program that devotes appropriate attention and resources to high-risk transactions, even if it fails to prevent an infraction. Prosecutors should therefore consider, as an indicator of risk-tailoring, "revisions to corporate compliance programs in light of lessons learned." JM 9-28.800.

- **Risk Management Process** – What methodology has the company used to identify, analyze, and address the particular risks it faces? What information or metrics has the company collected and used to help detect the type of misconduct in question? How have the information or metrics informed the company's compliance program?

- **Risk-Tailored Resource Allocation –** Does the company devote a disproportionate amount of time to policing low-risk areas instead of high-risk areas, such as questionable payments to third-party consultants, suspicious trading activity, or excessive discounts to resellers and distributors? Does the company give greater scrutiny, as warranted, to high-risk transactions (for instance, a large-dollar contract with a government agency in a high-risk country) than more modest and routine hospitality and entertainment?

- **Updates and Revisions** – Is the risk assessment current and subject to periodic review? Is the periodic review limited to a "snapshot" in time or based upon continuous access to operational data and information across functions? Has the periodic review led to updates in policies, procedures, and controls? Do these updates account for risks discovered through misconduct or other problems with the compliance program?

- **Lessons Learned** – Does the company have a process for tracking and incorporating into its periodic risk assessment lessons learned either from the company's own prior issues or from those of other companies operating in the same industry and/or geographical region?

B. Policies and Procedures

Any well-designed compliance program entails policies and procedures that give both content and effect to ethical norms and that address and aim to reduce risks identified by the company as part of its risk assessment process. As a threshold matter, prosecutors should examine whether the company has a code of conduct that sets forth, among other things, the company's commitment to full compliance with relevant Federal laws that is accessible and applicable to all company employees. As a corollary, prosecutors should also assess whether the company has established policies and procedures that incorporate the culture of compliance into its day-to-day operations.

- **Design** – What is the company's process for designing and implementing new policies and procedures and updating existing policies and procedures, and has that process changed over time? Who has been involved in the design of policies and procedures? Have business units been consulted prior to rolling them out?

- **Comprehensiveness** – What efforts has the company made to monitor and implement policies and procedures that reflect and deal with the spectrum of risks it faces, including changes to the legal and regulatory landscape?

- **Accessibility** – How has the company communicated its policies and procedures to all employees and relevant third parties? If the company has foreign subsidiaries, are there linguistic or other barriers to foreign employees' access? Have the policies and procedures been published in a searchable format for easy reference? Does the company track access to various policies and procedures to understand what policies are attracting more attention from relevant employees?

- **Responsibility for Operational Integration** – Who has been responsible for integrating policies and procedures? Have they been rolled out in a way that ensures employees' understanding of the policies? In what specific ways are compliance policies and procedures reinforced through the company's internal control systems?

- **Gatekeepers** – What, if any, guidance and training has been provided to key gatekeepers in the control processes (*e.g.*, those with approval authority or

certification responsibilities)? Do they know what misconduct to look for? Do they know when and how to escalate concerns?

C. Training and Communications

Another hallmark of a well-designed compliance program is appropriately tailored training and communications.

Prosecutors should assess the steps taken by the company to ensure that policies and procedures have been integrated into the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners. Prosecutors should also assess whether the company has relayed information in a manner tailored to the audience's size, sophistication, or subject matter expertise. Some companies, for instance, give employees practical advice or case studies to address real-life scenarios, and/or guidance on how to obtain ethics advice on a case-by-case basis as needs arise. Other companies have invested in shorter, more targeted training sessions to enable employees to timely identify and raise issues to appropriate compliance, internal audit, or other risk management functions. Prosecutors should also assess whether the training adequately covers prior compliance incidents and how the company measures the effectiveness of its training curriculum.

Prosecutors, in short, should examine whether the compliance program is being disseminated to, and understood by, employees in practice in order to decide whether the compliance program is "truly effective." JM 9-28.800.

- **Risk-Based Training** – What training have employees in relevant control functions received? Has the company provided tailored training for high-risk and control employees, including training that addresses risks in the area where the misconduct occurred? Have supervisory employees received different or supplementary training? What analysis has the company undertaken to determine who should be trained and on what subjects?

- **Form/Content/Effectiveness of Training** – Has the training been offered in the form and language appropriate for the audience? Is the training provided online or in-person (or both), and what is the company's rationale for its choice? Has the training addressed lessons learned from prior compliance incidents? Whether online or in-person, is there a process by which employees can ask questions arising out of the trainings? How has the company measured the effectiveness of the training? Have employees been tested on what they have learned? How has the company addressed

employees who fail all or a portion of the testing? Has the company evaluated the extent to which the training has an impact on employee behavior or operations?

- **Communications about Misconduct** – What has senior management done to let employees know the company's position concerning misconduct? What communications have there been generally when an employee is terminated or otherwise disciplined for failure to comply with the company's policies, procedures, and controls (*e.g.*, anonymized descriptions of the type of misconduct that leads to discipline)?

- **Availability of Guidance** – What resources have been available to employees to provide guidance relating to compliance policies? How has the company assessed whether its employees know when to seek advice and whether they would be willing to do so?

D. Confidential Reporting Structure and Investigation Process

Another hallmark of a well-designed compliance program is the existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct. Prosecutors should assess whether the company's complaint-handling process includes proactive measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers. Prosecutors should also assess the company's processes for handling investigations of such complaints, including the routing of complaints to proper personnel, timely completion of thorough investigations, and appropriate follow-up and discipline.

Confidential reporting mechanisms are highly probative of whether a company has "established corporate governance mechanisms that can effectively detect and prevent misconduct." JM 9-28.800; *see also* U.S.S.G. § 8B2.1(b)(5)(C) (an effectively working compliance program will have in place, and have publicized, "a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation").

- **Effectiveness of the Reporting Mechanism** – Does the company have an anonymous reporting mechanism and, if not, why not? How is the reporting mechanism publicized to the company's employees and other third parties? Has it been used? Does the company take measures to test whether employees are aware of the hotline and feel comfortable using it? How has the company assessed the seriousness of the

allegations it received? Has the compliance function had full access to reporting and investigative information?

- **Properly Scoped Investigations by Qualified Personnel** – How does the company determine which complaints or red flags merit further investigation? How does the company ensure that investigations are properly scoped? What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented? How does the company determine who should conduct an investigation, and who makes that determination?

- **Investigation Response** – Does the company apply timing metrics to ensure responsiveness? Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations?

- **Resources and Tracking of Results** – Are the reporting and investigating mechanisms sufficiently funded? How has the company collected, tracked, analyzed, and used information from its reporting mechanisms? Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses? Does the company periodically test the effectiveness of the hotline, for example by tracking a report from start to finish?

E. Third Party Management

A well-designed compliance program should apply risk-based due diligence to its third-party relationships. Although the need for, and degree of, appropriate due diligence may vary based on the size and nature of the company, transaction, and third party, prosecutors should assess the extent to which the company has an understanding of the qualifications and associations of third-party partners, including the agents, consultants, and distributors that are commonly used to conceal misconduct, such as the payment of bribes to foreign officials in international business transactions.

Prosecutors should also assess whether the company knows the business rationale for needing the third party in the transaction, and the risks posed by third-party partners, including the third-party partners' reputations and relationships, if any, with foreign officials. For example, a prosecutor should analyze whether the company has ensured that contract terms with third parties specifically describe the services to be performed, that the third party is actually performing the work, and that its compensation is commensurate with the work being provided in that industry and geographical region. Prosecutors should further assess whether the

company engaged in ongoing monitoring of the third-party relationships, be it through updated due diligence, training, audits, and/or annual compliance certifications by the third party.

In sum, a company's third-party management practices are a factor that prosecutors should assess to determine whether a compliance program is in fact able to "detect the particular types of misconduct most likely to occur in a particular corporation's line of business." JM 9-28.800.

- **Risk-Based and Integrated Processes** – How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company? How has this process been integrated into the relevant procurement and vendor management processes?

- **Appropriate Controls** – How does the company ensure there is an appropriate business rationale for the use of third parties? If third parties were involved in the underlying misconduct, what was the business rationale for using those third parties? What mechanisms exist to ensure that the contract terms specifically describe the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered?

- **Management of Relationships** – How has the company considered and analyzed the compensation and incentive structures for third parties against compliance risks? How does the company monitor its third parties? Does the company have audit rights to analyze the books and accounts of third parties, and has the company exercised those rights in the past? How does the company train its third party relationship managers about compliance risks and how to manage them? How does the company incentivize compliance and ethical behavior by third parties? Does the company engage in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process?

- **Real Actions and Consequences** – Does the company track red flags that are identified from due diligence of third parties and how those red flags are addressed? Does the company keep track of third parties that do not pass the company's due diligence or that are terminated, and does the company take steps to ensure that those third parties are not hired or re-hired at a later date? If third parties were involved in the misconduct at issue in the investigation, were red flags identified from the due diligence or after hiring the third party, and how were they resolved? Has a similar third party been suspended, terminated, or audited as a result of compliance issues?

F. Mergers and Acquisitions (M&A)

A well-designed compliance program should include comprehensive due diligence of any acquisition targets, as well as a process for timely and orderly integration of the acquired entity into existing compliance program structures and internal controls. Pre-M&A due diligence, where possible, enables the acquiring company to evaluate more accurately each target's value and negotiate for the costs of any corruption or misconduct to be borne by the target. Flawed or incomplete pre- or post-acquisition due diligence and integration can allow misconduct to continue at the target company, causing resulting harm to a business's profitability and reputation and risking civil and criminal liability.

The extent to which a company subjects its acquisition targets to appropriate scrutiny is indicative of whether its compliance program is, as implemented, able to effectively enforce its internal controls and remediate misconduct at all levels of the organization.

- **Due Diligence Process** – Was the company able to complete pre-acquisition due diligence and, if not, why not? Was the misconduct or the risk of misconduct identified during due diligence? Who conducted the risk review for the acquired/merged entities and how was it done? What is the M&A due diligence process generally?

- **Integration in the M&A Process** – How has the compliance function been integrated into the merger, acquisition, and integration process?

- **Process Connecting Due Diligence to Implementation** – What has been the company's process for tracking and remediating misconduct or misconduct risks identified during the due diligence process? What has been the company's process for implementing compliance policies and procedures, and conducting post-acquisition audits, at newly acquired entities?

II. Is the Corporation's Compliance Program Adequately Resourced and Empowered to Function Effectively?

Even a well-designed compliance program may be unsuccessful in practice if implementation is lax, under-resourced, or otherwise ineffective. Prosecutors are instructed to probe specifically whether a compliance program is a "paper program" or one "implemented, reviewed, and revised, as appropriate, in an effective manner." JM 9-28.800. In addition, prosecutors should determine "whether the corporation has provided for a staff sufficient to audit, document, analyze, and utilize the results of the corporation's compliance efforts." JM 9-28.800. Prosecutors should also determine "whether the corporation's employees are adequately informed about the compliance program and are convinced of the corporation's

commitment to it." JM 9-28.800; *see also* JM 9-47.120(2)(c) (criteria for an effective compliance program include "[t]he company's culture of compliance, including awareness among employees that any criminal conduct, including the conduct underlying the investigation, will not be tolerated").

A. Commitment by Senior and Middle Management

Beyond compliance structures, policies, and procedures, it is important for a company to create and foster a culture of ethics and compliance with the law at all levels of the company. The effectiveness of a compliance program requires a high-level commitment by company leadership to implement a culture of compliance from the middle and the top.

The company's top leaders – the board of directors and executives – set the tone for the rest of the company. Prosecutors should examine the extent to which senior management have clearly articulated the company's ethical standards, conveyed and disseminated them in clear and unambiguous terms, and demonstrated rigorous adherence by example. Prosecutors should also examine how middle management, in turn, have reinforced those standards and encouraged employees to abide by them. *See* U.S.S.G. § 8B2.1(b)(2)(A)-(C) (the company's "*governing authority* shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight" of it; "[*h*]*igh-level personnel* … shall ensure that the organization has an effective compliance and ethics program" (emphasis added)).

- **Conduct at the Top** – How have senior leaders, through their words and actions, encouraged or discouraged compliance, including the type of misconduct involved in the investigation? What concrete actions have they taken to demonstrate leadership in the company's compliance and remediation efforts? How have they modelled proper behavior to subordinates? Have managers tolerated greater compliance risks in pursuit of new business or greater revenues? Have managers encouraged employees to act unethically to achieve a business objective, or impeded compliance personnel from effectively implementing their duties?

- **Shared Commitment** – What actions have senior leaders and middle-management stakeholders (*e.g.*, business and operational managers, finance, procurement, legal, human resources) taken to demonstrate their commitment to compliance or compliance personnel, including their remediation efforts? Have they persisted in that commitment in the face of competing interests or business objectives?

- **Oversight** – What compliance expertise has been available on the board of directors? Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions? What types of information have

the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?

B. Autonomy and Resources

Effective implementation also requires those charged with a compliance program's day-to-day oversight to act with adequate authority and stature. As a threshold matter, prosecutors should evaluate how the compliance program is structured. Additionally, prosecutors should address the sufficiency of the personnel and resources within the compliance function, in particular, whether those responsible for compliance have: (1) sufficient seniority within the organization; (2) sufficient resources, namely, staff to effectively undertake the requisite auditing, documentation, and analysis; and (3) sufficient autonomy from management, such as direct access to the board of directors or the board's audit committee. The sufficiency of each factor, however, will depend on the size, structure, and risk profile of the particular company. "A large organization generally shall devote more formal operations and greater resources . . . than shall a small organization." Commentary to U.S.S.G. § 8B2.1 note 2(C). By contrast, "a small organization may [rely on] less formality and fewer resources." *Id.* Regardless, if a compliance program is to be truly effective, compliance personnel must be empowered within the company.

Prosecutors should evaluate whether "internal audit functions [are] conducted at a level sufficient to ensure their independence and accuracy," as an indicator of whether compliance personnel are in fact empowered and positioned to "effectively detect and prevent misconduct." JM 9-28.800. Prosecutors should also evaluate "[t]he resources the company has dedicated to compliance," "[t]he quality and experience of the personnel involved in compliance, such that they can understand and identify the transactions and activities that pose a potential risk," and "[t]he authority and independence of the compliance function and the availability of compliance expertise to the board." JM 9-47.120(2)(c); *see also* JM 9-28.800 (instructing prosecutors to evaluate whether "the directors established an information and reporting system in the organization reasonably designed to provide management and directors with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law"); U.S.S.G. § 8B2.1(b)(2)(C) (those with "day-to-day operational responsibility" shall have "adequate resources, appropriate authority and direct access to the governing authority or an appropriate subgroup of the governing authority").

- **Structure** – Where within the company is the compliance function housed (e.g., within the legal department, under a business function, or as an independent function reporting to the CEO and/or board)? To whom does the compliance function report? Is the compliance function run by a designated chief compliance officer, or another executive within the company, and does that person have other roles within the company? Are compliance personnel dedicated to compliance responsibilities, or do

they have other, non-compliance responsibilities within the company? Why has the company chosen the compliance structure it has in place? What are the reasons for the structural choices the company has made?

- **Seniority and Stature** – How does the compliance function compare with other strategic functions in the company in terms of stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers? What has been the turnover rate for compliance and relevant control function personnel? What role has compliance played in the company's strategic and operational decisions? How has the company responded to specific instances where compliance raised concerns? Have there been transactions or deals that were stopped, modified, or further scrutinized as a result of compliance concerns?

- **Experience and Qualifications** – Do compliance and control personnel have the appropriate experience and qualifications for their roles and responsibilities? Has the level of experience and qualifications in these roles changed over time? How does the company invest in further training and development of the compliance and other control personnel? Who reviews the performance of the compliance function and what is the review process?

- **Funding and Resources** – Has there been sufficient staffing for compliance personnel to effectively audit, document, analyze, and act on the results of the compliance efforts? Has the company allocated sufficient funds for the same? Have there been times when requests for resources by compliance and control functions have been denied, and if so, on what grounds?

- **Data Resources and Access** – Do compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions? Do any impediments exist that limit access to relevant sources of data and, if so, what is the company doing to address the impediments?

- **Autonomy** – Do the compliance and relevant control functions have direct reporting lines to anyone on the board of directors and/or audit committee? How often do they meet with directors? Are members of the senior management present for these meetings? How does the company ensure the independence of the compliance and control personnel?

- **Outsourced Compliance Functions** – Has the company outsourced all or parts of its compliance functions to an external firm or consultant? If so, why, and who is responsible for overseeing or liaising with the external firm or consultant? What level of access does the external firm or consultant have to company information? How has the effectiveness of the outsourced process been assessed?

C. Incentives and Disciplinary Measures

Another hallmark of effective implementation of a compliance program is the establishment of incentives for compliance and disincentives for non-compliance. Prosecutors should assess whether the company has clear disciplinary procedures in place, enforces them consistently across the organization, and ensures that the procedures are commensurate with the violations. Prosecutors should also assess the extent to which the company's communications convey to its employees that unethical conduct will not be tolerated and will bring swift consequences, regardless of the position or title of the employee who engages in the conduct. *See* U.S.S.G. § 8B2.1(b)(5)(C) ("the organization's compliance program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct").

By way of example, some companies have found that publicizing disciplinary actions internally, where appropriate and possible, can have valuable deterrent effects. At the same time, some companies have also found that providing positive incentives – personnel promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership – have driven compliance. Some companies have even made compliance a significant metric for management bonuses and/or have made working on compliance a means of career advancement.

- **Human Resources Process** – Who participates in making disciplinary decisions, including for the type of misconduct at issue? Is the same process followed for each instance of misconduct, and if not, why? Are the actual reasons for discipline communicated to employees? If not, why not? Are there legal or investigation-related reasons for restricting information, or have pre-textual reasons been provided to protect the company from whistleblowing or outside scrutiny?

- **Consistent Application** – Have disciplinary actions and incentives been fairly and consistently applied across the organization? Does the compliance function monitor its investigations and resulting discipline to ensure consistency? Are there similar instances of misconduct that were treated disparately, and if so, why?

- **Incentive System** – Has the company considered the implications of its incentives and rewards on compliance? How does the company incentivize compliance and ethical behavior? Have there been specific examples of actions taken (*e.g.*, promotions or awards denied) as a result of compliance and ethics considerations? Who determines the compensation, including bonuses, as well as discipline and promotion of compliance personnel?

III. Does the Corporation's Compliance Program Work in Practice?

The Principles of Federal Prosecution of Business Organizations require prosecutors to assess "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision." JM 9-28.300. Due to the backward-looking nature of the first inquiry, one of the most difficult questions prosecutors must answer in evaluating a compliance program following misconduct is whether the program was working effectively at the time of the offense, especially where the misconduct was not immediately detected.

In answering this question, it is important to note that the existence of misconduct does not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense. *See* U.S.S.G. § 8B2.1(a) ("[t]he failure to prevent or detect the instant offense does not mean that the program is not generally effective in preventing and deterring misconduct"). Indeed, "[t]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees." JM 9-28.800. Of course, if a compliance program did effectively identify misconduct, including allowing for timely remediation and self-reporting, a prosecutor should view the occurrence as a strong indicator that the compliance program was working effectively.

In assessing whether a company's compliance program was effective at the time of the misconduct, prosecutors should consider whether and how the misconduct was detected, what investigation resources were in place to investigate suspected misconduct, and the nature and thoroughness of the company's remedial efforts.

To determine whether a company's compliance program is working effectively at the time of a charging decision or resolution, prosecutors should consider whether the program evolved over time to address existing and changing compliance risks. Prosecutors should also consider whether the company undertook an adequate and honest root cause analysis to understand both what contributed to the misconduct and the degree of remediation needed to prevent similar events in the future.

For example, prosecutors should consider, among other factors, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future." Benczkowski Memo at 2 (observing that "[w]here a corporation's compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will not likely be necessary").

A. Continuous Improvement, Periodic Testing, and Review

One hallmark of an effective compliance program is its capacity to improve and evolve. The actual implementation of controls in practice will necessarily reveal areas of risk and potential adjustment. A company's business changes over time, as do the environments in which it operates, the nature of its customers, the laws that govern its actions, and the applicable industry standards. Accordingly, prosecutors should consider whether the company has engaged in meaningful efforts to review its compliance program and ensure that it is not stale. Some companies survey employees to gauge the compliance culture and evaluate the strength of controls, and/or conduct periodic audits to ensure that controls are functioning well, though the nature and frequency of evaluations may depend on the company's size and complexity.

Prosecutors may reward efforts to promote improvement and sustainability. In evaluating whether a particular compliance program works in practice, prosecutors should consider "revisions to corporate compliance programs in light of lessons learned." JM 9-28.800; *see also* JM 9-47-120(2)(c) (looking to "[t]he auditing of the compliance program to assure its effectiveness"). Prosecutors should likewise look to whether a company has taken "reasonable steps" to "ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct," and "evaluate periodically the effectiveness of the organization's" program. U.S.S.G. § 8B2.1(b)(5). Proactive efforts like these may not only be rewarded in connection with the form of any resolution or prosecution (such as through remediation credit or a lower applicable fine range under the Sentencing Guidelines), but more importantly, may avert problems down the line.

- **Internal Audit** – What is the process for determining where and how frequently internal audit will undertake an audit, and what is the rationale behind that process? How are audits carried out? What types of audits would have identified issues relevant to the misconduct? Did those audits occur and what were the findings? What types of relevant audit findings and remediation progress have been reported to management and the board on a regular basis? How have management and the board followed up? How often does internal audit conduct assessments in high-risk areas?

- **Control Testing** – Has the company reviewed and audited its compliance program in the area relating to the misconduct? More generally, what testing of controls, collection and analysis of compliance data, and interviews of employees and third parties does the company undertake? How are the results reported and action items tracked?

- **Evolving Updates** – How often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices? Has the company undertaken a gap analysis to determine if particular areas of risk are not sufficiently addressed in its policies, controls, or training? What steps has the company taken to determine whether policies/procedures/practices make sense for particular business segments/subsidiaries? Does the company review and adapt its compliance program based upon lessons learned from its own misconduct and/or that of other companies facing similar risks?

- **Culture of Compliance** – How often and how does the company measure its culture of compliance? Does the company seek input from all levels of employees to determine whether they perceive senior and middle management's commitment to compliance? What steps has the company taken in response to its measurement of the compliance culture?

B. <u>Investigation of Misconduct</u>

Another hallmark of a compliance program that is working effectively is the existence of a well-functioning and appropriately funded mechanism for the timely and thorough investigations of any allegations or suspicions of misconduct by the company, its employees, or agents. An effective investigations structure will also have an established means of documenting the company's response, including any disciplinary or remediation measures taken.

- **Properly Scoped Investigation by Qualified Personnel** – How has the company ensured that the investigations have been properly scoped, and were independent, objective, appropriately conducted, and properly documented?

- **Response to Investigations** – Have the company's investigations been used to identify root causes, system vulnerabilities, and accountability lapses, including among supervisory managers and senior executives? What has been the process for responding to investigative findings? How high up in the company do investigative findings go?

C. Analysis and Remediation of Any Underlying Misconduct

Finally, a hallmark of a compliance program that is working effectively in practice is the extent to which a company is able to conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes.

Prosecutors evaluating the effectiveness of a compliance program are instructed to reflect back on "the extent and pervasiveness of the criminal misconduct; the number and level of the corporate employees involved; the seriousness, duration, and frequency of the misconduct; and any remedial actions taken by the corporation, including, for example, disciplinary action against past violators uncovered by the prior compliance program, and revisions to corporate compliance programs in light of lessons learned." JM 9-28.800; *see also* JM 9-47.120(3)(c) ("to receive full credit for timely and appropriate remediation" under the FCPA Corporate Enforcement Policy, a company should demonstrate "a root cause analysis" and, where appropriate, "remediation to address the root causes").

Prosecutors should consider "any remedial actions taken by the corporation, including, for example, disciplinary action against past violators uncovered by the prior compliance program." JM 98-28.800; *see also* JM 9-47-120(2)(c) (looking to "[a]ppropriate discipline of employees, including those identified by the company as responsible for the misconduct, either through direct participation or failure in oversight, as well as those with supervisory authority over the area in which the criminal conduct occurred" and "any additional steps that demonstrate recognition of the seriousness of the misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risk").

- **Root Cause Analysis** – What is the company's root cause analysis of the misconduct at issue? Were any systemic issues identified? Who in the company was involved in making the analysis?

- **Prior Weaknesses** – What controls failed? If policies or procedures should have prohibited the misconduct, were they effectively implemented, and have functions that had ownership of these policies and procedures been held accountable?

- **Payment Systems** – How was the misconduct in question funded (*e.g.*, purchase orders, employee reimbursements, discounts, petty cash)? What processes could have prevented or detected improper access to these funds? Have those processes been improved?

- **Vendor Management** – If vendors were involved in the misconduct, what was the process for vendor selection and did the vendor undergo that process?

- **Prior Indications** – Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations? What is the company's analysis of why such opportunities were missed?

- **Remediation** – What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?

- **Accountability** – What disciplinary actions did the company take in response to the misconduct and were they timely? Were managers held accountable for misconduct that occurred under their supervision? Did the company consider disciplinary actions for failures in supervision? What is the company's record (*e.g.*, number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue? Has the company ever terminated or otherwise disciplined anyone (reduced or eliminated bonuses, issued a warning letter, etc.) for the type of misconduct at issue?

[1] Many of the topics also appear in the following resources:

- Justice Manual ("JM")
    - JM 9-28.000 Principles of Federal Prosecution of Business Organizations, Justice Manual ("JM"), *available at* https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations.
    - JM 9-47.120 FCPA Corporate Enforcement Policy, *available at* https://www.justice.gov/jm/jm-9-47000-foreign-corrupt-practices-act-1977#9-47.120.
- Chapter 8 – Sentencing of Organizations - United States Sentencing Guidelines ("U.S.S.G."), *available at* https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8#NaN.

- Memorandum entitled "Selection of Monitors in Criminal Division Matters," issued by Assistant Attorney General Brian Benczkowski on October 11, 2018, *available at* https://www.justice.gov/criminal-fraud/file/1100366/download.

- Criminal Division corporate resolution agreements, *available at* https://www.justice.gov/news (the Department of Justice's ("DOJ") Public Affairs website contains press releases for all Criminal Division corporate resolutions which contain links to charging documents and agreements).

- A Resource Guide to the U.S. Foreign Corrupt Practices Act ("FCPA Guide"), published in November 2012 by the DOJ and the Securities and Exchange Commission ("SEC"), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf.

- Good Practice Guidance on Internal Controls, Ethics, and Compliance, adopted by the Organization for Economic Co-operation and Development ("OECD") Council on February 18, 2010, *available at* https://www.oecd.org/daf/anti-bribery/44884389.pdf.

- Anti-Corruption Ethics and Compliance Handbook for Business ("OECD Handbook"), published in 2013 by OECD, United Nations Office on Drugs and Crime, and the World Bank, *available at* https://www.oecd.org/corruption/Anti-CorruptionEthicsComplianceHandbook.pdf.

- Evaluation of Corporate Compliance Programs in Criminal Antitrust Investigations, published in July 2019 by DOJ's Antitrust Division, *available at* https://www.justice.gov/atr/page/file/1182001/download.

- A Framework for OFAC Compliance Commitments, published in May 2019 by the Department of the Treasury's Office of Foreign Assets Control ("OFAC"), *available at https://www.treasury.gov/resource-center/sanctions/Documents/framework_ofac_cc.pdf.*

[2] Prosecutors should consider whether certain aspects of a compliance program may be impacted by foreign law. Where a company asserts that it has structured its compliance program in a particular way or has made a compliance decision based on requirements of foreign law, prosecutors should ask the company the basis for the company's conclusion about foreign law, and how the company has addressed the issue to maintain the integrity and effectiveness of its compliance program while still abiding by foreign law.

[3] As discussed in the Justice Manual, many companies operate in complex regulatory environments outside the normal experience of criminal prosecutors. JM 9-28.000. For example, financial institutions such as banks, subject to the Bank Secrecy Act statute and regulations,

require prosecutors to conduct specialized analyses of their compliance programs in the context of their anti-money laundering requirements. Consultation with the Money Laundering and Asset Recovery Section is recommended when reviewing AML compliance. *See* https://www.justice.gov/criminal-mlars. Prosecutors may also wish to review guidance published by relevant federal and state agencies. *See* Federal Financial Institutions Examination Council/Bank Secrecy Act/Anti-Money Laundering Examination Manual, *available at* https://www.ffiec.gov/bsa_aml_infobase/pages_manual/manual_online.htm).

FCPA

A Resource Guide to the U.S. Foreign Corrupt Practices Act
Second Edition

By the Criminal Division of the U.S. Department of Justice and
the Enforcement Division of the U.S. Securities and Exchange Commission

This guide is intended to provide information for businesses and individuals regarding the U.S. Foreign Corrupt Practices Act (FCPA). The guide has been prepared by the staff of the Criminal Division of the U.S. Department of Justice and the Enforcement Division of the U.S. Securities and Exchange Commission. This guidance reflects the views of the Division of Enforcement, but it is not a statement by the Commission and the Commission has neither approved nor disapproved its content. It is non-binding, informal, and summary in nature, and the information contained herein does not constitute rules or regulations. As such, it is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, that are enforceable at law by any party, in any criminal, civil, or administrative matter. It is not intended to substitute for the advice of legal counsel on specific issues related to the FCPA. It does not in any way limit the enforcement intentions or litigating positions of the U.S. Department of Justice, the U.S. Securities and Exchange Commission, or any other U.S. government agency.

Companies or individuals seeking an opinion concerning specific prospective conduct are encouraged to use the U.S. Department of Justice's opinion procedure discussed in Chapter 9 of this guide.

This guide is United States Government property. It is available to the public free of charge online at https://www.justice.gov/criminal-fraud/fcpa-resource-guide and https://www.sec.gov/spotlight/fcpa/fcpa-resource-guide.pdf.

A RESOURCE GUIDE TO THE

U.S. FOREIGN CORRUPT PRACTICES ACT

SECOND EDITION

By the Criminal Division of the U.S. Department of Justice and
the Enforcement Division of the U.S. Securities and Exchange Commission

FOREWORD

We are pleased to announce the publication of the Second Edition of *A Resource Guide to the U.S. Foreign Corrupt Practices Act*. The *Guide* was originally published by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) in November 2012 to provide companies, practitioners, and the public with detailed information about the statutory requirements of the Foreign Corrupt Practices Act (FCPA) while also providing insight into DOJ and SEC enforcement practices through hypotheticals, examples of enforcement actions and anonymized declinations, and summaries of applicable case law and DOJ opinion releases. Then and now, the *Guide* represents one of the most thorough compilations of information about any criminal statute, and remains relevant to this day.

Although many aspects of the *Guide* continue to hold true today, the last eight years have also brought new cases, new law, and new policies. The Second Edition of the *Guide* reflects these updates, including new case law on the definition of the term "foreign official" under the FCPA, the jurisdictional reach of the FCPA, and the FCPA's foreign written laws affirmative defense. It addresses certain legal standards, including the *mens rea* requirement and statute of limitations for criminal violations of the accounting provisions. It reflects updated data, statistics, and case examples. And it summarizes new policies applicable to the FCPA that have been announced in the DOJ's and SEC's continuing efforts to provide increased transparency, including the DOJ's FCPA Corporate Enforcement Policy, Selection of Monitors in Criminal Division Matters, Coordination of Corporate Resolution Penalties (or Anti-Piling On Policy), and the Criminal Division's Evaluation of Corporate Compliance Programs.

Foreign bribery is a scourge that must be eradicated. It undermines the rule of law, empowers authoritarian rulers, distorts free and fair markets, disadvantages honest and ethical companies, and threatens national security and sustainable development. This updated *Guide* is meant not only to summarize the product of the dedicated and hardworking individuals who combat foreign bribery as part of their work for the U.S. government, but also to help companies, practitioners, and the public—many of whom find themselves on the front lines of this fight—prevent corruption in the first instance. We hope that the *Guide* will continue to be an invaluable resource in those efforts.

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The payment of bribes to influence the acts or decisions of foreign officials, foreign political parties or candidates for foreign political office is unethical. It is counter to the moral expectations and values of the American Public. But not only is it unethical, it is bad business as well. It erodes public confidence in the integrity of the free market system. It short-circuits the marketplace by directing business to those companies too inefficient to compete in terms of price, quality or service, or too lazy to engage in honest salesmanship, or too intent upon unloading marginal products. In short, it rewards corruption instead of efficiency and puts pressure on ethical enterprises to lower their standards or risk losing business. Bribery of foreign officials by some American companies casts a shadow on all U.S. companies.[1]

- United States House of Representatives, 1977

Corporate bribery is bad business. In our free market system it is basic that the sale of products should take place on the basis of price, quality, and service. Corporate bribery is fundamentally destructive of this basic tenet. Corporate bribery of foreign officials takes place primarily to assist corporations in gaining business. Thus foreign corporate bribery affects the very stability of overseas business. Foreign corporate bribes also affect our domestic competitive climate when domestic firms engage in such practices as a substitute for healthy competition for foreign business.[2]

- United States Senate, 1977

INTRODUCTION

Congress enacted the U.S. Foreign Corrupt Practices Act (FCPA or the Act) in 1977 in response to revelations of widespread bribery of foreign officials by U.S. companies. The Act was intended to halt those corrupt practices, create a level playing field for honest businesses, and restore public confidence in the integrity of the marketplace.[3]

The FCPA contains both anti-bribery and accounting provisions. The anti-bribery provisions prohibit U.S. persons and businesses (domestic concerns), U.S. and foreign public companies listed on stock exchanges in the United States or that are required to file periodic reports with the Securities and Exchange Commission (issuers), and certain foreign persons and businesses acting while in the territory of the United States (territorial jurisdiction) from making corrupt payments to foreign officials to obtain or retain business. The accounting provisions require issuers to make and keep accurate books and records and to devise and maintain an adequate system of internal accounting controls. The accounting provisions also prohibit individuals and businesses from knowingly falsifying books and records or knowingly circumventing or failing to implement a system of internal controls.

The Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) share FCPA enforcement authority and are committed to fighting foreign bribery through robust enforcement. An important component of this effort is education, and this resource guide, prepared by DOJ and SEC staff, aims to provide businesses and individuals with information to help them abide by the law, detect and prevent FCPA violations, and implement effective compliance programs.

The Costs of Corruption

Corruption is a global problem. In the four decades since Congress enacted the FCPA, the extent of corporate bribery has become clearer and its ramifications in a transnational economy starker. Corruption impedes economic growth by diverting public resources from important priorities such as

health, education, and infrastructure. It undermines democratic values and public accountability and weakens the rule of law.[4] And it threatens stability and security by facilitating criminal activity within and across borders, such as the illegal trafficking of people, weapons, and drugs.[5] International corruption also undercuts good governance and impedes U.S. efforts to promote freedom and democracy, end poverty, and combat crime and terrorism across the globe.[6]

Corruption is also bad for business. Corruption is anti-competitive, leading to distorted prices and disadvantaging honest businesses that do not pay bribes. It increases the cost of doing business globally and inflates the cost of government contracts in developing countries.[7] Corruption also introduces significant uncertainty into business transactions: Contracts secured through bribery may be legally unenforceable, and paying bribes on one contract often results in corrupt officials making ever-increasing demands.[8] Bribery has destructive effects within a business as well, undermining employee confidence in a company's management and fostering a permissive atmosphere for other kinds of corporate misconduct, such as employee self-dealing, embezzlement,[9] financial fraud,[10] and anti-competitive behavior.[11] Bribery thus raises the risks of doing business, putting a company's bottom line and reputation in jeopardy. Companies that pay bribes to win business ultimately undermine their own long-term interests and the best interests of their investors.

Historical Background

Congress enacted the FCPA in 1977 after revelations of widespread global corruption in the wake of the Watergate political scandal. SEC discovered that more than 400 U.S. companies had paid hundreds of millions of dollars in bribes to foreign government officials to secure business overseas.[12] SEC reported that companies were using secret "slush funds" to make illegal campaign contributions in the United States and corrupt payments to foreign officials abroad and were falsifying their corporate financial records to conceal the payments.[13]

Congress viewed passage of the FCPA as critical to stopping corporate bribery, which had tarnished the image of U.S. businesses, impaired public confidence in the financial integrity of U.S. companies, and hampered the efficient functioning of the markets.[14]

> No problem does more to alienate citizens from their political leaders and institutions, and to undermine political stability and economic development, than endemic corruption among the government, political party leaders, judges, and bureaucrats.
>
> – *USAID Anti-Corruption Strategy*

As Congress recognized when it passed the FCPA, corruption imposes enormous costs both at home and abroad, leading to market inefficiencies and instability, sub-standard products, and an unfair playing field for honest businesses.[15] By enacting a strong foreign bribery statute, Congress sought to minimize these destructive effects and help companies resist corrupt demands, while addressing the destructive foreign policy ramifications of transnational bribery.[16] The Act also prohibited off-the-books accounting through provisions designed to "strengthen the accuracy of the corporate books

and records and the reliability of the audit process which constitute the foundations of our system of corporate disclosure."[17]

In 1988, Congress amended the FCPA to add two affirmative defenses: (1) the local law defense; and (2) the reasonable and bona fide promotional expense defense.[18] Congress also requested that the President negotiate an international treaty with members of the Organisation for Economic Co-operation and Development (OECD) to prohibit bribery in international business transactions by many of the United States' major trading partners.[19] Subsequent negotiations at the OECD culminated in the Convention on Combating Bribery of Foreign Officials in International Business Transactions (Anti-Bribery Convention), which, among other things, required parties to make it a crime to bribe foreign officials.[20]

In 1998, the FCPA was amended to conform to the requirements of the Anti-Bribery Convention. These amendments expanded the FCPA's scope to: (1) include payments made to secure "any improper advantage"; (2) reach certain foreign persons who commit an act in furtherance of a foreign bribe while in the United States; (3) cover public international organizations in the definition of "foreign official"; (4) add an alternative basis for jurisdiction based on nationality; and (5) apply criminal penalties to foreign nationals employed by or acting as agents of U.S. companies.[21] The Anti-Bribery Convention came into force on February 15, 1999, with the United States as a founding party.

National Landscape: Interagency Efforts

DOJ and SEC share enforcement authority for the FCPA's anti-bribery and accounting provisions.[22] They also work with many other federal agencies and law enforcement partners to investigate and prosecute FCPA violations, reduce bribery demands through good governance programs and other measures, and promote a fair playing field for U.S. companies doing business abroad.

Department of Justice

DOJ has criminal FCPA enforcement authority over "issuers" (i.e., public companies) and their officers, directors, employees, agents, or stockholders acting on the issuer's behalf. DOJ also has both criminal and civil enforcement responsibility for the FCPA's anti-bribery provisions over "domestic concerns"—which include (a) U.S. citizens, nationals, and residents and (b) U.S. businesses and their officers, directors, employees, agents, or stockholders acting on the domestic concern's behalf—and certain foreign persons and businesses that act in furtherance of an FCPA violation while in the territory of the United States. Within DOJ, the Fraud Section of the Criminal Division has primary responsibility for all FCPA matters.[23] The FCPA Unit within the Fraud Section handles all FCPA matters for DOJ, and regularly works jointly with U.S. Attorneys' Offices around the country.

DOJ maintains a website dedicated to the FCPA and its enforcement at http://www.justice.gov/criminal/fraud/fcpa/. The website provides translations of the FCPA in numerous languages, relevant legislative history, and selected documents from FCPA-related prosecutions and resolutions since 1977, including charging documents, plea agreements, deferred prosecution agreements, non-prosecution agreements, press releases, and other relevant pleadings and court decisions. The website also provides copies of opinions issued in response to requests by companies and individuals under DOJ's FCPA opinion procedure.

The procedures for submitting a request for an opinion can be found at http://www.justice.gov/criminal/fraud/fcpa/docs/frgncrpt.pdf and are discussed further in Chapter 9. Individuals and companies wishing to disclose information about potential FCPA violations are encouraged to contact the FCPA Unit at the telephone number or email address below.

DOJ Contact Information

FCPA Unit Chief, Fraud Section, Criminal Division
Bond Building
1400 New York Ave, N.W.
Washington, DC 20005

Telephone: (202) 514-2000

Facsimile: (202) 514-7021

Email: FCPA.Fraud@usdoj.gov

Securities and Exchange Commission

SEC is responsible for civil enforcement of the FCPA over issuers and their officers, directors, employees, agents, or stockholders acting on the issuer's behalf. SEC's Division of Enforcement has responsibility for investigating and prosecuting FCPA violations. In 2010, SEC's Enforcement Division created a specialized FCPA Unit, with attorneys in Washington, D.C. and in regional offices around the country, to focus specifically on FCPA enforcement.

The Unit investigates potential FCPA violations; facilitates coordination with DOJ's FCPA program and with other federal and international law enforcement partners; uses its expert knowledge of the law to promote consistent enforcement of the FCPA; analyzes tips, complaints, and referrals regarding allegations of foreign bribery; and conducts public outreach to raise awareness of anti-corruption efforts and good corporate governance programs.

The FCPA Unit maintains a "Spotlight on FCPA" section on SEC's website at http://www.sec.gov/spotlight/fcpa.shtml. The website, which is updated regularly, provides general information about the Act and links to all SEC enforcement actions involving the FCPA, including both federal court actions and administrative proceedings, and contains other useful information.

Individuals and companies with information about possible FCPA violations by issuers may report them to the Enforcement Division via SEC's online Tips, Complaints and Referral system, https://www.sec.gov/tcr. They may also submit information to SEC's Office of the Whistleblower through the same online system or by contacting the Office of the Whistleblower at (202) 551-4790. Additionally, investors with questions about the FCPA can call the Office of Investor Education and Advocacy at (800) SEC-0330. For more information about SEC's Whistleblower Program, under which certain eligible whistleblowers may be entitled to a monetary award if their information leads to certain SEC actions, see Chapter 8.

SEC Contact Information

FCPA Unit Chief, Division of Enforcement, U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Online Tips, Complaints, and Referrals website: https://www.sec.gov/tcr

Office of Investor Education and Advocacy: (800) SEC-0330

Law Enforcement Partners

DOJ's FCPA Unit regularly works with the Federal Bureau of Investigation (FBI) to investigate potential FCPA violations. The FBI's International Corruption Unit has primary responsibility for international corruption and fraud investigations and coordinates the FBI's national FCPA enforcement program. The FBI also has dedicated FCPA squads of FBI special agents that are responsible for investigating many, and providing support for all, of the FBI's FCPA investigations. In addition, Homeland Security Investigations, the Internal Revenue Service – Criminal Investigations, and the Postal Inspection Service regularly investigate potential FCPA violations. A number of other agencies are also involved in the fight against international corruption, including the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, and the Department of Treasury's Office of Foreign Assets Control and Financial Crimes Enforcement Network.

Departments of Commerce and State

Besides enforcement efforts by DOJ and SEC, the U.S. government is also working to address corruption abroad and level the playing field for U.S. businesses through the efforts of the Departments of Commerce and State. Both agencies advance anti-corruption and good governance initiatives globally and regularly assist U.S. companies doing business overseas in several important ways. Both agencies encourage U.S. businesses to seek the assistance of U.S embassies when they are confronted with bribe solicitations or other corruption-related issues overseas.[24]

The Department of Commerce offers a number of important resources for businesses, including the International Trade Administration's United States and Foreign Commercial Service (Commercial Service). The Commercial Service has export and industry specialists located in over 100 U.S. cities and 70 countries who are available to provide counseling and other assistance to U.S. businesses, particularly small and medium-sized companies, regarding exporting their products and services. The Commercial Service maintains a website with online resources to help companies perform due diligence on markets and partners, at: https://www.trade.gov/perform-due-diligence. For example, Country Commercial Guides provide market conditions, opportunities, regulations, and business customs for more than 70 major markets, prepared by ITA trade professionals at U.S. embassies worldwide.[25] Commercial Service specialists can also help a U.S. company conduct background checks when choosing business partners or agents overseas. The International Company Profile Program, for instance, can be part of a U.S. company's evaluation of potential overseas business partners.[26] U.S. companies may contact the Commercial Service through its website, https://www.trade.gov/let-our-experts-help-0 or directly at its domestic and foreign offices.[27]

Additionally, the Department of Commerce's Office of the General Counsel maintains a website, https://ogc.commerce.gov/collection/office-chief-counsel-international-commerce that contains anti-corruption resources and a list of international conventions and initiatives. The Office of Trade Agreements Negotiations and Compliance in the Department of Commerce's International Trade Administration also hosts a website with anti-bribery resources, https://tcc.export.gov/Bribery/index.asp. This website contains a link to an online form through which U.S. companies can report allegations of foreign bribery by foreign competitors in international business transactions.

More information on resolving trade barriers can be found at: https://www.trade.gov/resolve-foreign-trade-barrier.[28]

The Departments of Commerce and State also provide advocacy support, when determined to be in the national interest, for U.S. companies bidding for foreign government contracts. The Department of Commerce's Advocacy Center, for example, supports U.S. businesses competing against foreign companies for international contracts, such as by arranging for the delivery of an advocacy message by U.S. government officials or assisting with unanticipated problems such as suspected bribery by a competitor.[29]

The Department of State's Bureau of Economic and Business Affairs (specifically, its Office of Commercial and Business Affairs) similarly assists U.S. firms doing business overseas by providing advocacy on behalf of U.S. businesses and identifying risk areas for U.S. businesses; more information is available on its website, https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/bureau-of-economic-and-business-affairs/office-of-commercial-and-business-affairs/. Also, the Department of State's economic officers serving overseas provide commercial advocacy and support for U.S. companies at the many overseas diplomatic posts where the Commercial Service is not represented.

The Department of State promotes U.S. government interests in addressing corruption internationally through country-to-country diplomatic engagement; development of and follow-through on international commitments relating to corruption; promotion of high-level political engagement (e.g., the G20 Anticorruption Action Plan); public outreach in foreign countries; and support for building the capacity of foreign partners to combat corruption. In fiscal year 2019, the U.S. government provided more than $112 million for anti-corruption and related good governance assistance abroad.

The Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL) manages U.S. participation in many multilateral anti-corruption political and legal initiatives at the global and regional level. INL also funds and coordinates significant efforts to assist countries with combating corruption through legal reform, training, and other capacity-building efforts. Inquiries about the U.S. government's general anti-corruption efforts and implementation of global and regional anti-corruption initiatives may be directed to INL on its website, https://www.state.gov/combating-corruption-and-promoting-good-governance/, or by email to: anti-corruption@state.gov. In addition, the U.S. Agency for International Development (USAID) has developed several anti-corruption programs and publications, information about which can be found at https://www.usaid.gov/what-we-do/democracy-human-rights-and-governance/promoting-accountability-transparency.

International Landscape: Global Anti-Corruption Efforts

There has been a growing international consensus that corruption must be combated, and the United States and other countries are parties to a number of international anti-corruption conventions. Under these conventions, countries that are parties undertake commitments to adopt a range of preventive and criminal law measures to combat corruption. The conventions incorporate review processes that allow the United States to monitor other countries to ensure that they are meeting their international obligations. Likewise, these processes in turn permit other parties to monitor the United States' anti-corruption laws and enforcement to ensure that such enforcement

and legal frameworks are consistent with the United States' treaty obligations.[30] U.S. officials regularly address the subject of corruption with our foreign counterparts to raise awareness of the importance of fighting corruption and urge stronger enforcement of anti-corruption laws and policies. As a result of the recognition by other countries of the need to combat corruption, as well as the significant efforts by organizations such as the OECD Working Group on Bribery, a number of countries have implemented foreign bribery laws and significantly increased their enforcement efforts. For example, in December 2016, France enacted its *Sapin II* law, which significantly strengthened its existing foreign bribery legislation and enforcement regime.

OECD Working Group on Bribery and the Anti-Bribery Convention

The OECD was founded in 1961 to stimulate economic progress and world trade. As noted, the Anti-Bribery Convention requires its parties to criminalize the bribery of foreign public officials in international business transactions.[31] As of June 30, 2020, there were 44 parties to the Anti-Bribery Convention. All of these parties are also members of the OECD Working Group on Bribery (Working Group).

The Working Group is responsible for monitoring the implementation of the Anti-Bribery Convention, the 2009 Recommendation of the Council for Further Combating Bribery of Foreign Public Officials in International Business Transactions, and related instruments. Its members meet quarterly to review and monitor implementation of the Anti-Bribery Convention by member states around the world. Each party undergoes periodic peer review.[32] This peer-review monitoring system is conducted in four phases. The Phase 1 review includes an in-depth assessment of each country's domestic laws implementing the Convention. The Phase 2 review examines the effectiveness of each country's laws and anti-bribery efforts. The final phases are permanent cycles of peer review (the first cycle of which is referred to as the Phase 3 review and the next is the Phase 4 review) that evaluate a country's enforcement actions and results, as well as the country's efforts to address weaknesses identified during the prior review.[33] All of the monitoring reports for the parties to the Convention can be found on the OECD website and can be a useful resource about the foreign bribery laws of the OECD Working Group member countries.[34]

The reports and appendices for all of the phases of reviews for the United States can be found on DOJ's and SEC's websites.[35] In its Phase 3 review of the United States, which was completed in October 2010, the Working Group commended U.S. efforts to fight transnational bribery and highlighted a number of best practices developed by the United States. The report also noted areas where the United States' anti-bribery efforts could be improved, including consolidating publicly available information on the application of the FCPA and enhancing awareness among small and medium-sized companies about the prevention and detection of foreign bribery. Initial publication of this guide was, in part, a response to these Phase 3 recommendations and is intended to help businesses and individuals better understand the FCPA.[36]

U.N. Convention Against Corruption

The United States is a state party to the United Nations Convention Against Corruption (UNCAC), which was adopted by the U.N. General Assembly on October 31, 2003, and entered into force on

December 14, 2005.[37] The United States ratified the UNCAC on October 30, 2006. The UNCAC requires parties to criminalize a wide range of corrupt acts, including domestic and foreign bribery and related offenses such as money laundering and obstruction of justice. The UNCAC also establishes guidelines for the creation of anti-corruption bodies, codes of conduct for public officials, transparent and objective systems of procurement, and enhanced accounting and auditing standards for the private sector. A peer review mechanism assesses the implementation of the UNCAC by parties to the Convention, with a focus in the first round on criminalization and law enforcement as well as international legal cooperation.[38] The United States has been reviewed under the Pilot Review Programme, the report of which is available on DOJ's website. As of June 30, 2020, 187 countries were parties to the UNCAC.[39]

Other Anti-Corruption Conventions

The Inter-American Convention Against Corruption (IACAC) was the first international anti-corruption convention, adopted in March 1996 in Caracas, Venezuela, by members of the Organization of American States.[40]

The IACAC requires parties (of which the United States is one) to criminalize both foreign and domestic bribery. A body known as the Mechanism for Follow-Up on the Implementation of the Inter-American Convention Against Corruption (MESICIC) monitors parties' compliance with the IACAC. As of June 30, 2020, 33 countries were parties to MESICIC.

The Council of Europe established the Group of States Against Corruption (GRECO) in 1999 to monitor countries' compliance with the Council of Europe's anti-corruption standards, including the Council of Europe's Criminal Law Convention on Corruption.[41] These standards include prohibitions on the solicitation and receipt of bribes, as well as foreign bribery. As of June 30, 2020, GRECO member states, which need not be members of the Council of Europe, include 49 European countries and the United States.[42]

The United States has been reviewed under both MESICIC and GRECO, and the reports generated by those reviews are available on DOJ's website.

THE FCPA: ANTI-BRIBERY PROVISIONS

The FCPA addresses the problem of international corruption in two ways: (1) the anti-bribery provisions, which are discussed below, prohibit individuals and businesses from bribing foreign government officials in order to obtain or retain business; and (2) the accounting provisions, which are discussed in Chapter 3, impose certain record keeping and internal control requirements on issuers, and prohibit individuals and companies from knowingly falsifying an issuer's books and records or circumventing or failing to implement an issuer's system of internal controls. Violations of the FCPA can lead to civil and criminal penalties, sanctions, and remedies, including fines, disgorgement, and/or imprisonment.

In general, the FCPA prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.[43]

Who Is Covered by the Anti-Bribery Provisions?

The FCPA's anti-bribery provisions apply broadly to three categories of persons and entities: (1) "issuers" and their officers, directors, employees, agents, and stockholders acting on behalf of an issuer; (2) "domestic concerns" and their officers, directors, employees, agents, and stockholders acting on behalf of a domestic concern; and (3) certain persons and entities, other than issuers and domestic concerns, acting while in the territory of the United States.

Issuers—15 U.S.C. § 78dd-1

Section 30A of the Securities Exchange Act of 1934 (the Exchange Act), which can be found at 15 U.S.C. § 78dd-1, contains the anti-bribery provision governing issuers.[44] A company is an "issuer" under the FCPA if it has a class of securities registered under Section 12 of the Exchange Act[45] or is required to file periodic and other reports with SEC under Section 15(d) of the Exchange Act.[46] In practice, this means that any company with a class of securities listed on a national securities exchange in the United States, or any company with a class of securities quoted in the over-the-counter market in the United States and required to file periodic reports with SEC, is an issuer. A company thus need

not be a U.S. company to be an issuer. Foreign companies with American Depository Receipts that are listed on a U.S. exchange are also issuers.[47] As of December 31, 2015, 923 foreign companies were registered with SEC.[48] Officers, directors, employees, agents, or stockholders acting on behalf of an issuer (whether U.S. or foreign nationals) also can be prosecuted under the FCPA.[49]

How Can I Tell If My Company Is an "Issuer"?

- It is listed on a national securities exchange in the United States (either stock or American Depository Receipts); or
- Its stock trades in the over-the-counter market in the United States and the company is required to file SEC reports.
- To see if your company files SEC reports, go to SEC's website at http://www.sec.gov/edgar/searchedgar/webusers.htm.

Domestic Concerns—15 U.S.C. § 78dd-2

The FCPA also applies to "domestic concerns."[50] A domestic concern is any individual who is a citizen, national, or resident of the United States, or any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship, other than an issuer, that is organized under the laws of the United States or its states, territories, possessions, or commonwealths or that has its principal place of business in the United States.[51] Officers, directors, employees, agents, or stockholders acting on behalf of a domestic concern, including foreign nationals or companies, are also covered.[52]

Territorial Jurisdiction—15 U.S.C. § 78dd-3

The FCPA also applies to certain foreign nationals or entities that are not issuers or domestic concerns.[53] Since 1998, the FCPA's anti-bribery provisions have applied to foreign persons and foreign non-issuer entities that, either directly or through an agent, engage in any act in furtherance of a corrupt payment (or an offer, promise, or authorization to pay) while in the territory of the United States.[54] Also, officers, directors, employees, agents, or stockholders acting on behalf of such persons or entities may be subject to the FCPA's anti-bribery provisions.[55]

What Jurisdictional Conduct Triggers the Anti-Bribery Provisions?

The FCPA's anti-bribery provisions can apply to conduct both inside and outside the United States. Issuers and domestic concerns—as well as their officers, directors, employees, agents, or stockholders—may be prosecuted for using the U.S. mails or any means or instrumentality of interstate commerce in furtherance of a corrupt payment to a foreign official. The Act defines "interstate commerce" as "trade, commerce, transportation, or communication among the several States, or between any foreign country and any State or between any State and any place or ship outside thereof …."[56] The term also includes the intrastate use of any interstate means of communication, or any other interstate instrumentality.[57] Thus, placing a telephone call or sending an e-mail, text message, or fax from, to, or through the United States involves interstate commerce—as does sending a wire transfer from or to a U.S. bank or otherwise using the U.S. banking system, or traveling across state borders or internationally to or from the United States.

Those who are not issuers or domestic concerns may be prosecuted under the FCPA if they directly, or through an agent, engage in any act in furtherance of a corrupt payment while in the territory of the United States, regardless of

whether they utilize the U.S. mails or a means or instrumentality of interstate commerce.[58] Thus, for example, a foreign national who attends a meeting in the United States that furthers a foreign bribery scheme may be subject to prosecution.[59]

In addition, under the "alternative jurisdiction" provision of the FCPA enacted in 1998, U.S. companies or persons may be subject to the anti-bribery provisions even if they act outside the United States.[60] The 1998 amendments to the FCPA expanded the jurisdictional coverage of the Act by establishing an alternative basis for jurisdiction, that is, jurisdiction based on the nationality principle.[61] In particular, the 1998 amendments removed the requirement that there be a use of interstate commerce (e.g., wire, email, telephone call) for acts in furtherance of a corrupt payment to a foreign official by U.S. companies and persons occurring wholly outside of the United States.[62]

What Is Covered?

The FCPA applies only to payments, offers, or promises made for the purpose of: (i) influencing any act or decision of a foreign official in his official capacity, (ii) inducing a foreign official to do or omit to do any act in violation of the lawful duty of such official, (iii) securing any improper advantage; or (iv) inducing a foreign official to use his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality.[63] In addition, the payment, offer, or promise must be made in order to assist "in obtaining or retaining business for or with, or directing business to, any person."[64] This requirement is known as the "business purpose test" and is broadly interpreted.[65]

Not surprisingly, many enforcement actions involve bribes to obtain or retain government contracts.[66] The FCPA also prohibits bribes in connection with conducting business or to gain a business advantage.[67] For example, bribe payments made to secure favorable tax treatment, to reduce or eliminate customs duties, to obtain government action to prevent competitors from entering a market, or to circumvent a licensing or permit requirement, can all satisfy the business purpose test.[68]

Hypothetical: FCPA Jurisdiction

Company A, a Delaware company with its principal place of business in New York, is a large energy company that operates globally, including in a number of countries that have a high risk of corruption, such as Foreign Country. Company A's shares are listed on a national U.S. stock exchange. Company A enters into an agreement with a European company (EuroCo) to submit a joint bid to the Oil Ministry to build a refinery in Foreign Country. EuroCo is not an issuer.

Executives of Company A and EuroCo meet in New York to discuss how to win the bid and decide to hire a purported third-party consultant (Intermediary) and have him use part of his "commission" to bribe high-ranking officials within the Oil Ministry. Intermediary meets with executives at Company A and EuroCo in New York to finalize the scheme. Eventually, millions of dollars in bribes are funneled from the United States and Europe through Intermediary to high-ranking officials at the Oil Ministry, and Company A and EuroCo win the contract. A few years later, a front page article alleging that the contract was procured through bribery appears in Foreign Country, and DOJ and SEC begin investigating whether the FCPA was violated.

Based on these facts, which entities fall within the FCPA's jurisdiction?

All of the entities easily fall within the FCPA's jurisdiction. Company A is an "issuer" under the FCPA, and Intermediary is an "agent" of Company A. EuroCo and Intermediary are also subject to the FCPA's territorial jurisdiction provision based on their conduct while in the United States.

Examples of Actions Taken to Obtain or Retain Business

- Winning a contract
- Influencing the procurement process
- Circumventing the rules for importation of products
- Gaining access to non-public bid tender information
- Evading taxes or penalties
- Influencing the adjudication of lawsuits or enforcement actions
- Obtaining exceptions to regulations
- Avoiding contract termination

In 2004, the U.S. Court of Appeals for the Fifth Circuit addressed the business purpose test in *United States v. Kay* and held that bribes paid to obtain favorable tax treatment—which reduced a company's customs duties and sales taxes on imports—could constitute payments made to "obtain or retain" business within the meaning of the FCPA.[69]

The court explained that in enacting the FCPA, "Congress meant to prohibit a range of payments wider than only those that directly influence the acquisition or retention of government contracts or similar commercial or industrial arrangements."[70] The *Kay* court found that "[t]he congressional target was bribery paid to engender assistance in improving the business opportunities of the payor or his beneficiary, irrespective of whether that assistance be direct or indirect, and irrespective of whether it be related to administering the law, awarding, extending, or renewing a contract, or executing or preserving an agreement."[71]

Accordingly, *Kay* held that payments to obtain favorable tax treatment can, under appropriate circumstances, violate the FCPA:

> Avoiding or lowering taxes reduces operating costs and thus increases profit margins, thereby freeing up funds that the business is otherwise legally obligated to expend. And this, in turn, enables it to take any number of actions to the disadvantage of competitors. Bribing foreign officials to lower taxes and customs duties certainly can provide an unfair advantage over competitors and thereby be of assistance to the payor in obtaining or retaining business.
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> * * *
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> [W]e hold that Congress intended for the FCPA to apply broadly to payments intended to assist the payor, either directly or indirectly, in obtaining or retaining business for some person, and that bribes paid to foreign tax officials to secure illegally reduced customs and tax liability constitute a type of payment that can fall within this broad coverage.[72]

Paying Bribes to Customs Officials

In 2010, a global freight forwarding company and six of its corporate customers in the oil and gas industry resolved charges that they paid bribes to customs officials. The companies bribed customs officials in more than ten countries in exchange for such benefits as:

- evading customs duties on imported goods
- improperly expediting the importation of goods and equipment
- extending drilling contracts and lowering tax assessments
- obtaining false documentation related to temporary import permits for drilling rigs
- enabling the release of drilling rigs and other equipment from customs officials

In many instances, the improper payments at issue allowed the company to carry out its existing business, which fell within the FCPA's prohibition on corrupt payments made for the purpose of "retaining" business. The seven companies paid a total of more than $235 million in civil and criminal sanctions and disgorgement.

In short, although the FCPA does not cover every type of bribe paid around the world for every purpose, it does apply broadly to bribes paid to help obtain or retain business, which can include payments made to secure a wide variety of unfair business advantages.[73]

What Does "Corruptly" Mean?

To violate the FCPA, an offer, promise, or authorization of a payment, or a payment, to a government official must be made "corruptly."[74] As Congress noted when adopting the FCPA, the word "corruptly" means an intent or desire to wrongfully influence the recipient:

> The word "corruptly" is used in order to make clear that the offer, payment, promise, or gift, must be intended to induce the recipient to misuse his official position; for example, wrongfully to direct business to the payor or his client, to obtain preferential legislation or regulations, or to induce a foreign official to fail to perform an official function.[75]

Where corrupt intent is present, the FCPA prohibits paying, offering, or promising to pay money or anything of value (or authorizing the payment, offer, or promise).[76] By focusing on intent, the FCPA does not require that a corrupt act succeed in its purpose.[77] Nor must the foreign official actually solicit, accept, or receive the corrupt payment for the bribe payor to be liable.[78] For example, in one case, a New York-based commercial real estate broker promised a middleman that he would pay a $2.5 million dollar bribe—and in fact paid $500,000 to the middleman as an upfront payment—to a government official at the sovereign wealth fund of a Middle Eastern country in order to induce the sovereign wealth fund to buy an $800 million dollar office building complex owned by the broker's client. However, unbeknownst to the real estate broker, the middleman did not have any relationship with the foreign official, and simply kept the $500,000 payment. Even though there was no foreign official actually receiving the bribe, the defendant was convicted of violating the FCPA.[79]

Also, as long as the offer, promise, authorization, or payment is made corruptly, the actor need not know the identity of the recipient; the attempt is sufficient.[80] Thus, an executive who authorizes others to pay "whoever you need to" in a foreign government to obtain a contract has violated the FCPA—even if no bribe is ultimately offered or paid.

What Does "Willfully" Mean and When Does It Apply?

In order for an individual defendant to be criminally liable under the FCPA, he or she must act "willfully."[81] Proof of willfulness is not required to establish corporate criminal or civil liability,[82] though proof of corrupt intent is.

The term "willfully" is not defined in the FCPA, but it has generally been construed by courts to connote an act committed voluntarily and purposefully, and with a bad purpose, i.e., with "knowledge that [a defendant] was doing a 'bad' act under the general rules of law."[83] As the Supreme Court explained in *Bryan v. United States*, "[a]s a general matter, when used in the criminal context, a 'willful' act is one undertaken with a 'bad purpose.' In other words, in order to establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'"[84]

Notably, as both the Second Circuit and Fifth Circuit Courts of Appeals have found, the FCPA does not require the government to prove that a defendant was specifically aware of the FCPA or

knew that his conduct violated the FCPA.[85] To be guilty, a defendant must act with a bad purpose, i.e., know generally that his conduct is unlawful.

What Does "Anything of Value" Mean?

In enacting the FCPA, Congress recognized that bribes can come in many shapes and sizes—a broad range of unfair benefits[86]—and so the statute prohibits the corrupt "offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift promise to give, or authorization of the giving of *anything of value* to" a foreign official.[87]

An improper benefit can take many forms. While cases often involve payments of cash (sometimes in the guise of "consulting fees" or "commissions" given through intermediaries), others have involved travel expenses and expensive gifts. Like the domestic bribery statute, the FCPA does not contain a minimum threshold amount for corrupt gifts or payments.[88] Indeed, what might be considered a modest payment in the United States could be a larger and much more significant amount in a foreign country.

Regardless of size, for a gift or other payment to violate the statute, the payor must have corrupt intent—that is, the intent to improperly influence the government official. The corrupt intent requirement protects companies that engage in the ordinary and legitimate promotion of their businesses while targeting conduct that seeks to improperly induce officials into misusing their positions. Thus, it is difficult to envision any scenario in which the provision of cups of coffee, taxi fare, or company promotional items of nominal value would ever evidence corrupt intent, and neither DOJ nor SEC has ever pursued an investigation on the basis of such conduct. Moreover, as in all areas of federal law enforcement, DOJ and SEC exercise discretion in deciding which cases promote law enforcement priorities and justify investigation. Certain patterns, however, have emerged: DOJ's and SEC's anti-bribery enforcement actions have focused on small payments and gifts only when they comprise part of a systemic or long-standing course of conduct that evidences a scheme to corruptly pay foreign officials to obtain or retain business. These assessments are necessarily fact specific.

Cash

The most obvious form of corrupt payment is large amounts of cash. In some instances, companies have maintained cash funds specifically earmarked for use as bribes. One Brazilian company that was a stockholder of a U.S. issuer developed and operated a secret financial structure that operated to make and account for corrupt payments to foreign officials. Among other methods the company used, it would transfer funds to Brazilian moneychangers (*doleiros*) who would withdraw the amounts in cash and deliver them to the officials.[89] In another instance, a four-company joint venture used its agent to pay $5 million in bribes to a Nigerian political party.[90] The payments were made to the agent in suitcases of cash (typically in $1 million installments), and, in one instance, the trunk of a car when the cash did not fit into a suitcase.[91]

Gifts, Travel, Entertainment, and Other Things of Value

A small gift or token of esteem or gratitude is often an appropriate way for business people to display respect for each other. Some hallmarks of appropriate gift-giving are when the gift is given openly and transparently, properly recorded in the giver's books and records, provided only to reflect esteem or gratitude, and permitted under local law.

Items of nominal value, such as cab fare, reasonable meals and entertainment expenses, or company promotional items, are unlikely to improperly influence an official, and, as a result, are not, without more, items that have resulted in enforcement action by DOJ or SEC. The larger or more extravagant the gift, however, the more likely it was given with an improper purpose. DOJ and SEC enforcement cases thus have involved single instances of large, extravagant gift-giving (such as sports cars, fur coats, and other luxury items) as well as widespread gifts of smaller items as part of a pattern of bribes.[92] For example, in a recent case, a publicly traded energy company in the Netherlands resolved with DOJ over bribes it paid that included extravagant gifts such as paying for foreign officials to travel to sporting events and providing them with "spending money," paying for school tuition for the children of foreign officials, and shipping luxury vehicles to foreign officials.[93]

In another case brought by DOJ and SEC, a defendant gave a government official a country club membership fee and a generator, as well as household maintenance expenses, payment of cell phone bills, an automobile worth $20,000, and limousine services. The same official also received $250,000 through a third-party agent.[94]

In addition, a number of FCPA enforcement actions have involved the corrupt payment of travel and entertainment expenses. Both DOJ and SEC have brought cases where these types of expenditures occurred in conjunction with other conduct reflecting systemic bribery or other clear indicia of corrupt intent.

A case involving a Sweden-based telecommunications company "issuer" illustrates the types of improper travel and entertainment expenses that may violate the FCPA. Beginning in the 1990s and continuing until at least 2013, the company paid millions of dollars to various third parties, a portion of which was used to pay for gifts, travel, and entertainment, including overseas trips, for Chinese government officials in order to win business with state-owned telecommunications companies. Although a portion of the trips were purportedly for the individuals to participate in training at the company's facilities, in reality, no training occurred on many of these trips and the company had no facilities at those locations. Such trips included, among others, a luxury cruise through the Caribbean and trips to Las Vegas and London. The company also mischaracterized payments for these trips in its internal books and records.[95]

Likewise, a New Jersey-based telecommunications company spent millions of dollars on approximately 315 trips for Chinese government officials, ostensibly to inspect factories and train the officials in using the company's equipment.[96] In reality, during many of these trips, the officials spent little or no time visiting the company's facilities, but instead visited tourist destinations such as Hawaii, Las Vegas, the Grand Canyon, Niagara Falls, Disney World, Universal Studios, and New York City.[97] Some of the trips were characterized as "factory inspections" or "training" with government customers, but consisted primarily or entirely of sightseeing at locations chosen by the officials, typically lasting two weeks and costing between $25,000 and $55,000 per trip. In some instances, the company gave the government officials $500 to $1,000 per day in spending money and paid all lodging, transportation, food, and entertainment expenses. The company either failed to record these expenses or improperly recorded them as "consulting fees" in its corporate books and records. The company also failed to implement appropriate internal controls to monitor the provision of travel and other things of value to Chinese government officials.[98]

Companies also may violate the FCPA if they give payments or gifts to third parties, such as an official's family members, as an indirect way of corruptly influencing a foreign official. For example, one defendant paid personal bills and provided airline tickets to a cousin and close friend of the foreign official whose influence the defendant sought in obtaining contracts.[99] The defendant was convicted at trial and received a prison sentence.[100] In another example, a Hong Kong subsidiary of a Switzerland-based bank engaged in a systematic scheme to hire, promote, and retain the children of Chinese officials in order to win business with those officials.[101] The company ultimately disgorged approximately $30 million and paid a $47 million criminal fine for its FCPA violations.

Examples of Improper Travel and Entertainment

- a $12,000 birthday trip for a government decision maker from Mexico that included visits to wineries and dinners
- $10,000 spent on dinners, drinks, and entertainment for a government official
- a trip to Italy for eight Iraqi government officials that consisted primarily of sightseeing and included $1,000 in "pocket money" for each official
- a trip to Paris for a government official and his wife that consisted primarily of touring activities via a chauffeur-driven vehicle

As part of an effective compliance program, a company should have clear and easily accessible guidelines and processes in place for gift-giving by the company's directors, officers, employees, and agents. Though not necessarily appropriate for every business, many larger companies have automated gift-giving clearance processes and have set clear monetary thresholds for gifts along with annual limitations, with limited exceptions for gifts approved by appropriate management. Clear guidelines and processes can be effective and efficient means for controlling gift-giving, deterring improper gifts, and protecting corporate assets.

The FCPA does not prohibit gift-giving. Rather, just like its domestic bribery counterparts, the FCPA prohibits the payments of bribes, including those disguised as gifts.

Charitable Contributions

Companies often engage in charitable giving as part of legitimate local outreach. The FCPA does not prohibit charitable contributions or prevent corporations from acting as good corporate citizens.

Companies, however, cannot use the pretense of charitable contributions as a way to funnel bribes to government officials.

For example, a pharmaceutical company used charitable donations to a small local castle restoration charity headed by a foreign government official to induce the official to direct business to the company. Although the charity was a bona fide charitable organization, internal documents at the pharmaceutical company's subsidiary established that the payments were not viewed as charitable contributions but rather as "dues" the subsidiary was required to pay for assistance from the government official. The payments constituted a significant portion of the subsidiary's total promotional donations budget and were structured to allow the subsidiary to exceed its authorized limits. The payments also were not in compliance with the company's internal policies, which provided that charitable donations generally should be made to healthcare institutions and relate to the practice of medicine.[102]

Hypothetical: Gifts, Travel, and Entertainment

Company A is a large U.S. engineering company with global operations in more than 50 countries, including a number that have a high risk of corruption, such as Foreign Country. Company A's stock is listed on a national U.S. stock exchange. In conducting its business internationally, Company A's officers and employees come into regular contact with foreign officials, including officials in various ministries and state-owned entities. At a trade show, Company A has a booth at which it offers free pens, hats, t-shirts, and other similar promotional items with Company A's logo. Company A also serves free coffee, other beverages, and snacks at the booth. Some of the visitors to the booth are foreign officials.

Is Company A in violation of the FCPA?

No. These are legitimate, bona fide expenditures made in connection with the promotion, demonstration, or explanation of Company A's products or services. There is nothing to suggest corrupt intent here. The FCPA does not prevent companies from promoting their businesses in this way or providing legitimate hospitality, including to foreign officials. Providing promotional items with company logos or free snacks as set forth above is an appropriate means of providing hospitality and promoting business. Such conduct has never formed the basis for an FCPA enforcement action.

At the trade show, Company A invites a dozen current and prospective customers out for drinks, and pays the moderate bar tab. Some of the current and prospective customers are foreign officials under the FCPA. Is Company A in violation of the FCPA?

No. Again, the FCPA was not designed to prohibit all forms of hospitality to foreign officials. While the cost here may be more substantial than the beverages, snacks, and promotional items provided at the booth, and the invitees specifically selected, there is still nothing to suggest corrupt intent.

Two years ago, Company A won a long-term contract to supply goods and services to the state-owned Electricity Commission in Foreign Country. The Electricity Commission is 100% owned, controlled, and operated by the government of Foreign Country, and employees of the Electricity Commission are subject to Foreign Country's domestic bribery laws. Some Company A executives are in Foreign Country for meetings with officials of the Electricity Commission. The General Manager of the Electricity Commission was recently married, and during the trip Company A executives present a moderately priced crystal vase to the General Manager as a wedding gift and token of esteem. Is Company A in violation of the FCPA?

No. It is appropriate to provide reasonable gifts to foreign officials as tokens of esteem or gratitude. It is important that such gifts be made openly and transparently, properly recorded in a company's books and records, and given only where appropriate under local law, customary where given, and reasonable for the occasion.

During the course of the contract described above, Company A periodically provides training to Electricity Commission employees at its facilities in Michigan. The training is paid for by the Electricity Commission as part of the contract. Senior officials of the Electricity Commission inform Company A that they want to inspect the facilities and ensure that the training is working well. Company A pays for the airfare, hotel, and transportation for the Electricity Commission senior officials to travel to Michigan to inspect Company A's facilities. Because it is a lengthy international flight, Company A agrees to pay for business class airfare, to which its own employees are entitled for lengthy flights. The foreign officials visit Michigan for several days, during which the senior officials perform an appropriate inspection. Company A executives take the officials to a moderately priced dinner, a baseball game, and a play. Do any of these actions violate the FCPA?

(cont'd)

No. Neither the costs associated with training the employees nor the trip for the senior officials to the Company's facilities in order to inspect them violates the FCPA. Reasonable and bona fide promotional expenditures do not violate the FCPA. Here, Company A is providing training to the Electricity Commission's employees and is hosting the Electricity Commission senior officials. Their review of the execution and performance of the contract is a legitimate business purpose. Even the provision of business class airfare is reasonable under the circumstances, as are the meals and entertainment, which are only a small component of the business trip.

Would this analysis be different if Company A instead paid for the senior officials to travel first-class with their spouses for an all-expenses-paid, week-long trip to Las Vegas, where Company A has no facilities?

Yes. This conduct almost certainly violates the FCPA because it evinces a corrupt intent. Here, the trip does not appear to be designed for any legitimate business purpose, is extravagant, includes expenses for the officials' spouses, and therefore appears to be designed to corruptly curry favor with the foreign government officials. Moreover, if the trip were booked as a legitimate business expense—such as the provision of training at its facilities—Company A would also be in violation of the FCPA's accounting provisions. Furthermore, this conduct suggests deficiencies in Company A's internal controls.

Company A's contract with the Electricity Commission is going to expire, and the Electricity Commission is offering the next contract through its tender process. An employee of the Electricity Commission contacts Company A and offers to provide Company A with confidential, non-public bid information from Company A's competitors if Company A will pay for a vacation to Paris for him and his girlfriend. Employees of Company A accede to the official's request, pay for the vacation, receive the confidential bid information, and yet still do not win the contract. Has Company A violated the FCPA?

Yes. Company A has provided things of value to a foreign official for the purpose of inducing the official to misuse his office and to gain an improper advantage. It does not matter that it was the foreign official who first suggested the illegal conduct or that Company A ultimately was not successful in winning the contract. This conduct would also violate the FCPA's accounting provisions if the trip were booked as a legitimate business expense and suggests deficiencies in Company A's internal controls.

Proper due diligence and controls are critical for charitable giving. In general, the adequacy of measures taken to prevent misuse of charitable donations will depend on a risk-based analysis and the specific facts at hand. In Opinion Procedure Release No. 10-02, DOJ described the due diligence and controls that can minimize the likelihood of an FCPA violation. In that matter, a Eurasian-based subsidiary of a U.S. non-governmental organization was asked by an agency of a foreign government to make a grant to a local microfinance institution (MFI) as a prerequisite to the subsidiary's transformation to bank status. The subsidiary proposed contributing $1.42 million to a local MFI to satisfy the request. The subsidiary undertook an extensive, three-stage due diligence process to select the proposed grantee and imposed significant controls on the proposed grant, including ongoing monitoring and auditing, earmarking funds for capacity building, prohibiting compensation of board members, and implementing anti-corruption compliance provisions. DOJ explained that it would not take any enforcement action because the company's due diligence and the controls it planned to put in place sufficed to prevent an FCPA violation.

Other opinion releases also address charitable-type grants or donations. Under the facts presented in those releases, DOJ approved the proposed grant or donation,[103] based on due diligence measures and controls such as:

- certifications by the recipient regarding compliance with the FCPA;[104]
- due diligence to confirm that none of the recipient's officers was affiliated with the foreign government at issue;[105]
- a requirement that the recipient provide audited financial statements;[106]
- a written agreement with the recipient restricting the use of funds;[107]
- steps to ensure that the funds were transferred to a valid bank account;[108]
- confirmation that the charity's commitments were met before funds were disbursed;[109] and
- ongoing monitoring of the efficacy of the program.[110]

Legitimate charitable giving does not violate the FCPA. Compliance with the FCPA merely requires that charitable giving not be used as a vehicle to conceal payments made to corruptly influence foreign officials.

Five Questions to Consider When Making Charitable Payments in a Foreign Country:

1. What is the purpose of the payment?
2. Is the payment consistent with the company's internal guidelines on charitable giving?
3. Is the payment at the request of a foreign official?
4. Is a foreign official associated with the charity and, if so, can the foreign official make decisions regarding your business in that country?
5. Is the payment conditioned upon receiving business or other benefits?

Who Is a Foreign Official?

The FCPA's anti-bribery provisions apply to corrupt payments made to (1) "any foreign official"; (2) "any foreign political party or official thereof"; (3) "any candidate for foreign political office"; or (4) any person, while knowing that all or a portion of the payment will be offered, given, or promised to an individual falling within one of these three categories.[111] Although the statute distinguishes between a "foreign official," "foreign political party or official thereof," and "candidate for foreign political office," the term "foreign official" in this guide generally refers to an individual falling within any of these three categories.

The FCPA defines "foreign official" to include: any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.[112]

As this language makes clear, the FCPA broadly applies to corrupt payments to "any" officer or employee of a foreign government and to those acting on the foreign government's behalf.[113] The FCPA thus covers corrupt payments to low-ranking employees and high-level officials alike.[114]

The FCPA prohibits payments to foreign *officials*, not to foreign *governments*.[115] That said, companies contemplating contributions or donations to foreign governments should take steps to ensure that no monies are used for corrupt purposes, such as the personal benefit of individual foreign officials.

Department, Agency, or Instrumentality of a Foreign Government

Foreign officials under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. When a foreign government is organized in a fashion similar to the U.S. system, what constitutes a government department or agency is typically clear (e.g., a ministry of energy, national security agency, or transportation authority).[116] However, governments can be organized in very different ways.[117] Many operate through state-owned and state-controlled entities, particularly in such areas as aerospace and defense manufacturing, banking and finance, healthcare and life sciences, energy and extractive industries, telecommunications, and transportation.[118] By including officers or employees of agencies and instrumentalities within the definition of "foreign official," the FCPA accounts for this variability.

The term "instrumentality" is broad and can include state-owned or state-controlled entities. Whether a particular entity constitutes an "instrumentality" under the FCPA requires a fact-specific analysis of an entity's ownership, control, status, and function.[119] The Eleventh Circuit addressed the definition of "instrumentality" in *United States v. Esquenazi*, a case involving the state-owned and controlled telecommunications company of Haiti.[120] The Eleventh Circuit concluded that an "instrumentality" under the FCPA is "an entity controlled by the government of a foreign country that performs a function the controlling government treats as its own."[121] Although the court noted that this test is a fact-bound inquiry, it provided the following non-exhaustive list of factors to determine whether the government "controls" an entity:

- the foreign government's formal designation of that entity;
- whether the government has a majority interest in the entity;
- the government's ability to hire and fire the entity's principals;
- the extent to which the entity's profits, if any, go directly into the governmental fiscal accounts, and, by the same token, the extent to which the government funds the entity if it fails to break even; and
- the length of time these indicia have existed.[122]

To determine whether the entity performs a function that the government treats as its own, the Eleventh Circuit listed the following non-exhaustive factors:

- whether the entity has a monopoly over the function it exists to carry out;
- whether the government subsidizes the costs associated with the entity providing services;
- whether the entity provides services to the public at large in the foreign country; and
- whether the public and the government of that foreign country generally perceive the entity to be performing a governmental function.[123]

In addition, a number of courts in other circuits have approved final jury instructions providing a similar non-exclusive list of factors to be considered.[124]

Companies should consider these factors when evaluating the risk of FCPA violations and designing compliance programs.

DOJ and SEC have pursued cases involving instrumentalities since the time of the FCPA's enactment and have long used an analysis of ownership, control, status, and function to determine whether a particular entity is an agency or instrumentality of a foreign government. For example, the second-ever FCPA case charged by DOJ involved a California company that paid bribes through a Mexican corporation to two executives of a state-owned Mexican national oil company.[125] And in the early 1980s, DOJ and SEC brought cases

involving a $1 million bribe to the chairman of Trinidad and Tobago's racing authority.[126]

DOJ and SEC continue to regularly bring FCPA cases involving bribes paid to employees of agencies and instrumentalities of foreign governments. In one such case, the subsidiary of a Swiss engineering company paid bribes to officials of a state-owned and controlled electricity commission. The commission was created by, owned by, and controlled by the Mexican government, and it had a monopoly on the transmission and distribution of electricity in Mexico. Many of the commission's board members were cabinet-level government officials, and the director was appointed by Mexico's president.[127] Similarly, in the case involving Haiti's state-owned and controlled telecommunications company, Miami telecommunications executives were charged with paying bribes to the telecommunications company's employees. The telecommunications company was 97% owned and 100% controlled by the Haitian government, Haiti granted the company a monopoly over telecommunications service and gave it various tax advantages, the company's Director General was chosen by the Haitian President with the consent of the Haitian Prime Minister and the ministers of public works and economic finance, and the Haitian President appointed all of the telecommunications company's board members.[128]

While no one factor is dispositive or necessarily more important than another, as a practical matter, an entity is unlikely to qualify as an instrumentality if a government does not own or control a majority of its shares. However, there are circumstances in which an entity would qualify as an instrumentality absent 50% or greater foreign government ownership, which are reflected in a limited number of DOJ or SEC enforcement actions brought in such situations. For example, in addition to being convicted of funneling millions of dollars in bribes to two sitting presidents in two different countries, a French issuer's three subsidiaries were convicted of paying bribes to employees of a Malaysian telecommunications company that was 43% owned by Malaysia's Ministry of Finance. There, notwithstanding its minority ownership stake in the company, the Ministry held the status of a "special shareholder," had veto power over all major expenditures, and controlled important operational decisions.[129] In addition, most senior company officers were political appointees, including the Chairman and Director, the Chairman of the Board of the Tender Committee, and the Executive Director.[130] Thus, despite the Malaysian government having a minority shareholder position, the company was an instrumentality of the Malaysian government as the government had substantial control over the company.

Companies and individuals should also remember that, whether an entity is an instrumentality of a foreign government or a private entity, commercial (i.e., private-to-private) bribery may still violate the FCPA's accounting provisions, the Travel Act, anti-money laundering laws, and other federal or foreign laws. Any type of corrupt payment thus carries a risk of prosecution.

Public International Organizations

In 1998, the FCPA was amended to expand the definition of "foreign official" to include employees and representatives of public international organizations.[131] A "public international organization" is any organization designated as such by Executive order under the International Organizations Immunities Act, 22 U.S.C. § 288, or any other organization that the President so designates.[132] Currently, public international organizations include entities such as the United Nations, the World

Bank, the International Monetary Fund, the World Intellectual Property Organization, the World Trade Organization, the OECD, the Organization of American States, and numerous others. A comprehensive list of organizations designated as "public international organizations" is contained in 22 U.S.C. § 288 and can also be found on the U.S. Government Publishing Office website at https://www.govinfo.gov/content/pkg/USCODE-2018-title22/html/USCODE-2018-title22-chap7-subchapXVIII-sec288.htm. DOJ has brought charges against persons who pay bribes to such employees and representatives of such "public international organizations."[133]

How Are Payments to Third Parties Treated?

The FCPA expressly prohibits corrupt payments made through third parties or intermediaries.[134] Specifically, it covers payments made to "any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly,"[135] to a foreign official. Many companies doing business in a foreign country retain a local individual or company to help them conduct business. Although these foreign agents may provide entirely legitimate advice regarding local customs and procedures and may help facilitate business transactions, companies should be aware of the risks involved in engaging third-party agents or intermediaries. The fact that a bribe is paid by a third party does not eliminate the potential for criminal or civil FCPA liability.[136]

For example, a French global financial services institution and a U.S.-based investment management firm retained a third-party sales agent to win business in Libya. The financial institutions repeatedly engaged the third-party sales agent to win business with Libyan state-owned financial institutions, ultimately paying the sales agent over $90 million in commissions. In fact, the sales agent used portions of the commission payments to bribe high-level Libyan government officials in order to secure the placement of approximately $3.66 billion in assets with the financial institutions. As a consequence, the French global financial services institution and the U.S. investment management firm paid a combined approximately $600 million in penalties; the French financial institution entered into a deferred prosecution agreement with DOJ, and a wholly owned subsidiary pleaded guilty; while the U.S. financial institution entered into a non-prosecution agreement with DOJ, and disgorged $34.5 million as part of its resolution with SEC.[137]

In another case, between 1996 and 2012, a publicly traded energy company in the Netherlands engaged in the regular practice of retaining third-party sales agents to pay bribes to foreign officials in at least five countries: Brazil, Angola, Equatorial Guinea, Kazakhstan, and Iraq. Over the course of the conspiracy, the company paid at least $180 million in "commission" payments to its agents, earning profits of at least $2.8 billion. The company and its U.S. subsidiary admitted to violating the FCPA, as did its former CEO and a sales and marketing executive.[138]

Because Congress anticipated the use of third-party agents in bribery schemes—for example, to avoid actual knowledge of a bribe—it defined the term "knowing" in a way that prevents individuals and businesses from avoiding liability by putting "any person" between themselves and the foreign officials.[139] Under the FCPA, a person's state of mind is "knowing" with respect to conduct, a circumstance, or a result if the person:

- is aware that [he] is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or
- has a firm belief that such circumstance exists or that such result is substantially certain to occur.[140]

Thus, a person has the requisite knowledge when he is aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist.[141] As Congress made clear, it meant to impose liability not only on those with actual knowledge of wrongdoing, but also on those who purposefully avoid actual knowledge:

> [T]he so-called "head-in-the-sand" problem—variously described in the pertinent authorities as "conscious disregard," "willful blindness" or "deliberate ignorance"—should be covered so that management officials could not take refuge from the Act's prohibitions by their unwarranted obliviousness to any action (or inaction), language or other "signaling device" that should reasonably alert them of the "high probability" of an FCPA violation.[142]

Common red flags associated with third parties include:

- excessive commissions to third-party agents or consultants;
- unreasonably large discounts to third-party distributors;
- third-party "consulting agreements" that include only vaguely described services;
- the third-party consultant is in a different line of business than that for which it has been engaged;
- the third party is related to or closely associated with the foreign official;
- the third party became part of the transaction at the express request or insistence of the foreign official;
- the third party is merely a shell company incorporated in an offshore jurisdiction; and
- the third party requests payment to offshore bank accounts.

Businesses may reduce the FCPA risks associated with third-party agents by implementing an effective compliance program, which includes due diligence of any prospective agents.

United States v. Kozeny, et al.

In December 2011, the U.S. Court of Appeals for the Second Circuit upheld a conscious avoidance instruction given during the 2009 trial of a businessman who was convicted of conspiring to violate the FCPA's anti-bribery provisions by agreeing to make payments to Azeri officials in a scheme to encourage the privatization of the Republic of Azerbaijan's state oil company. The court of appeals found that the instruction did not lack a factual predicate, citing evidence and testimony at trial demonstrating that the defendant knew corruption was pervasive in Azerbaijan; that he was aware of his business partner's reputation for misconduct; that he had created two U.S. companies in order to shield himself and other investors from potential liability for payments made in violation of the FCPA; and that the defendant expressed concerns during a conference call about whether his business partner and company were bribing officials.

The court of appeals also rejected the defendant's contention that the conscious avoidance charge had improperly permitted the jury to convict him based on negligence, explaining that ample evidence in the record showed that the defendant had "serious concerns" about the legality of his partner's business practices "and worked to avoid learning exactly what [he] was doing," and noting that the district court had specifically instructed the jury not to convict based on negligence.

What Affirmative Defenses Are Available?

The FCPA's anti-bribery provisions contain two affirmative defenses: (1) that the payment was lawful under the written laws of the foreign country (the "local law" defense), and (2) that the money was spent as part of demonstrating a product or performing a contractual obligation (the "reasonable and bona fide business expenditure" defense). Because these are affirmative defenses, the defendant bears the burden of proving them.

The Local Law Defense

For the local law defense to apply, a defendant must establish that "the payment, gift, offer, or promise of anything of value that was made, was lawful under the written laws and regulations of the foreign official's, political party's, party official's, or candidate's country."[143] The defendant must establish that the payment was lawful under the foreign country's written laws and regulations at the time of the offense. In creating the local law defense in 1988, Congress sought "to make clear that the absence of written laws in a foreign official's country would not by itself be sufficient to satisfy this defense."[144] Thus, the fact that bribes may not be prosecuted under local law is insufficient to establish the defense. In practice, the local law defense arises infrequently, as the written laws and regulations of countries rarely, if ever, permit corrupt payments. Nevertheless, if a defendant can establish that conduct that otherwise falls within the scope of the FCPA's anti-bribery provisions was lawful under written, local law, he or she would have a defense to prosecution.

In *United States v. Kozeny*, the defendant unsuccessfully sought to assert the local law defense regarding the law of Azerbaijan. The parties disputed the contents and applicability of Azeri law, and each presented expert reports and testimony on behalf of their conflicting interpretations. The court ruled that the defendant could not invoke the FCPA's affirmative defense because Azeri law did not actually legalize the bribe payment. The court concluded that an exception under Azeri law relieving of criminal liability bribe payors who voluntarily disclose bribe payments to the authorities did not make the bribes legal.[145]

In *United States v. Ng Lap Seng*, the district court rejected the defendant's request to instruct the jury with respect to the local law affirmative defense.[146] In that case, the defendant was convicted of conspiracy, violating the FCPA, bribery, and money laundering, in connection with a scheme to bribe two ambassadors to the United Nations. In arguing in favor of a jury instruction for the local law affirmative defense, the defendant maintained that a finding by the jury that the payments at issue were not unlawful under the written laws and regulations of Antigua and the Dominican Republic would require acquittal on the FCPA-related counts. The court denied the defendant's request for the affirmative defense instruction, finding that the proposed instruction was "inconsistent with the plain meaning of the language of the written laws and regulations affirmative defense contained in the FCPA."[147] The court further explained that the defendant's request was not directly supported by the majority of sources that had addressed the issue and, if applied, "would lead to impractical results."[148]

Reasonable and Bona Fide Expenditures

The FCPA allows companies to provide reasonable and bona fide travel and lodging expenses to a foreign official, and it is an affirmative defense where expenses are directly related to the promotion, demonstration, or explanation of a company's products or services, or are related to a company's execution or performance of a contract with a foreign government or agency.[149] Trips that are primarily for personal entertainment purposes, however, are not bona fide business expenses and may violate the FCPA's anti-bribery provisions.[150] Moreover, when expenditures, bona fide or not, are mischaracterized in a company's books and records, or where unauthorized or improper expenditures occur due to a failure to implement adequate internal controls, they may also violate the FCPA's accounting provisions. Purposeful

mischaracterization of expenditures may also, of course, indicate a corrupt intent.

DOJ and SEC have consistently recognized that businesses, both foreign and domestic, are permitted to pay for reasonable expenses associated with the promotion of their products and services or the execution of existing contracts. In addition, DOJ has frequently provided guidance about legitimate promotional and contract-related expenses—addressing travel and lodging expenses in particular—through several opinion procedure releases. Under the circumstances presented in those releases,[151] DOJ opined that the following types of expenditures on behalf of foreign officials did not warrant FCPA enforcement action:

- travel and expenses to visit company facilities or operations;
- travel and expenses for training; and
- product demonstration or promotional activities, including travel and expenses for meetings.

Whether any particular payment is a bona fide expenditure necessarily requires a fact-specific analysis. But the following non-exhaustive list of safeguards, compiled from several releases, may be helpful to businesses in evaluating whether a particular expenditure is appropriate or may risk violating the FCPA:

- Do not select the particular officials who will participate in the party's proposed trip or program[152] or else select them based on predetermined, merit-based criteria.[153]
- Pay all costs directly to travel and lodging vendors and/or reimburse costs only upon presentation of a receipt.[154]
- Do not advance funds or pay for reimbursements in cash.[155]
- Ensure that any stipends are reasonable approximations of costs likely to be incurred[156] and/or that expenses are limited to those that are necessary and reasonable.[157]
- Ensure the expenditures are transparent, both within the company and to the foreign government.[158]
- Do not condition payment of expenses on any action by the foreign official.[159]
- Obtain written confirmation that payment of the expenses is not contrary to local law.[160]
- Provide no additional compensation, stipends, or spending money beyond what is necessary to pay for actual expenses incurred.[161]
- Ensure that costs and expenses on behalf of the foreign officials will be accurately recorded in the company's books and records.[162]

In sum, while certain expenditures are more likely to raise red flags, they will not give rise to prosecution if they are: (1) reasonable, (2) bona fide and (3) directly related to (4) the promotion, demonstration, or explanation of products or services or the execution or performance of a contract.[163]

What Are Facilitating or Expediting Payments?

The FCPA's bribery prohibition contains a narrow exception for "facilitating or expediting payments" made in furtherance of routine governmental action.[164] The facilitating payments exception applies only when a payment is made to further "routine governmental action" that involves non-discretionary acts.[165] Examples of "routine governmental action" include processing visas, providing police protection or mail service, and supplying utilities like phone service, power, and water. Routine government action does not include a decision to award new business or to continue business with a particular party.[166] Nor does it include acts that are within an official's discretion or that would constitute misuse of an official's office.[167] Thus, paying an official a small amount to have the power turned on at a factory might be a facilitating payment; paying an inspector to ignore the fact that the company does not have a valid permit to operate the factory would not be a facilitating payment.

Examples of "Routine Governmental Action"

An action that is ordinarily and commonly performed by a foreign official in:

- obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country;
- processing governmental papers, such as visas and work orders;
- providing police protection, mail pickup and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country;
- providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or
- actions of a similar nature.

Whether a payment falls within the exception is not dependent on the size of the payment, though size can be telling, as a large payment is more suggestive of corrupt intent to influence a non-routine governmental action. But, like the FCPA's anti-bribery provisions more generally, the facilitating payments exception focuses on the *purpose* of the payment rather than its value. For instance, an Oklahoma-based corporation violated the FCPA when its subsidiary paid Argentine customs officials approximately $166,000 to secure customs clearance for equipment and materials that lacked required certifications or could not be imported under local law and to pay a lower-than-applicable duty rate. The company's Venezuelan subsidiary had also paid Venezuelan customs officials approximately $7,000 to permit the importation and exportation of equipment and materials not in compliance with local regulations and to avoid a full inspection of the imported goods.[168] In another case, three subsidiaries of a global supplier of oil drilling products and services were criminally charged with authorizing an agent to make at least 378 corrupt payments (totaling approximately $2.1 million) to Nigerian Customs Service officials for preferential treatment during the customs process, including the reduction or elimination of customs duties.[169]

Labeling a bribe as a "facilitating payment" in a company's books and records does not make it one. A Swiss offshore drilling company, for example, recorded payments to its customs agent in the subsidiary's "facilitating payment" account, even though company personnel believed the payments were, in fact, bribes. The company was charged with violating both the FCPA's anti-bribery and accounting provisions.[170]

Although true facilitating payments are not illegal under the FCPA, they may still violate local law in the countries where the company is operating, and the OECD's Working Group on Bribery recommends that all countries encourage companies to prohibit or discourage facilitating payments, which the United States has done regularly.[171] In addition, other countries' foreign bribery laws, such as the United Kingdom's, may not contain an exception for facilitating payments.[172] Individuals and companies should therefore be aware that although true facilitating payments are permissible under the FCPA, they may still subject a company or individual to sanctions. As with any expenditure, facilitating payments may violate the FCPA if they are not properly recorded in an issuer's books and records.[173]

Hypothetical: Facilitating Payments

Company A is a large multinational mining company with operations in Foreign Country, where it recently identified a significant new ore deposit. It has ready buyers for the new ore but has limited capacity to get it to market. In order to increase the size and speed of its ore export, Company A will need to build a new road from its facility to the port that can accommodate larger trucks. Company A retains an agent in Foreign Country to assist it in obtaining the required permits, including an environmental permit, to build the road. The agent informs Company A's vice president for international operations that he plans to make a one-time small cash payment to a clerk in the relevant government office to ensure that the clerk files and stamps the permit applications expeditiously, as the agent has experienced delays of three months when he has not made this "grease" payment. The clerk has no discretion about whether to file and stamp the permit applications once the requisite filing fee has been paid. The vice president authorizes the payment.

A few months later, the agent tells the vice president that he has run into a problem obtaining a necessary environmental permit. It turns out that the planned road construction would adversely impact an environmentally sensitive and protected local wetland. While the problem could be overcome by rerouting the road, such rerouting would cost Company A $1 million more and would slow down construction by six months. It would also increase the transit time for the ore and reduce the number of monthly shipments. The agent tells the vice president that he is good friends with the director of Foreign Country's Department of Natural Resources and that it would only take a modest cash payment to the director and the "problem would go away." The vice president authorizes the payment, and the agent makes it. After receiving the payment, the director issues the permit, and Company A constructs its new road through the wetlands.

Was the payment to the clerk a violation of the FCPA?

No. Under these circumstances, the payment to the clerk would qualify as a facilitating payment, since it is a one-time, small payment to obtain a routine, non-discretionary governmental service that Company A is entitled to receive (i.e., the stamping and filing of the permit application). However, while the payment may qualify as an exception to the FCPA's anti-bribery provisions, it may violate other laws, both in Foreign Country and elsewhere. In addition, if the payment is not accurately recorded, it could violate the FCPA's books and records provision.

Was the payment to the director a violation of the FCPA?

Yes. The payment to the director of the Department of Natural Resources was in clear violation of the FCPA, since it was designed to corruptly influence a foreign official into improperly approving a permit. The issuance of the environmental permit was a discretionary act, and indeed, Company A should not have received it. Company A, its vice president, and the local agent may all be prosecuted for authorizing and paying the bribe.

Does the FCPA Apply to Cases of Extortion or Duress?

Situations involving extortion or duress will not give rise to FCPA liability because a payment made in response to true extortionate demands under imminent threat of physical harm cannot be said to have been made with corrupt intent or for the purpose of obtaining or retaining business.[174] In enacting the FCPA, Congress recognized that real-world situations might arise in which a business is compelled to pay an official in order to avoid threats to health and safety. As Congress explained, "a payment to an official to keep an oil rig from being dynamited should not be held to be made with the requisite corrupt purpose."[175]

Mere economic coercion, however, does not amount to extortion. As Congress noted when it enacted the FCPA: "The defense that the payment

was demanded on the part of a government official as a price for gaining entry into a market or to obtain a contract would not suffice since at some point the U.S. company would make a conscious decision whether or not to pay a bribe."[176] The fact that the payment was "first proposed by the recipient … does not alter the corrupt purpose on the part of the person paying the bribe."[177]

This distinction between extortion and economic coercion was recognized by the court in *United States v. Kozeny*. There, the court concluded that although an individual who makes a payment under duress (i.e., upon threat of physical harm) will not be criminally liable under the FCPA,[178] a bribe payor who claims payment was demanded as a price for gaining market entry or obtaining a contract "cannot argue that he lacked the intent to bribe the official because he made the 'conscious decision' to pay the official."[179] While the bribe payor in this situation "could have turned his back and walked away," in the oil rig example, "he could not."[180]

Businesses operating in high-risk environments may face real threats of violence or harm to their employees, and payments made in response to imminent threats to health or safety do not violate the FCPA.[181] If such a situation arises, and to ensure the safety of its employees, companies should immediately contact the appropriate U.S. embassy for assistance.

Principles of Corporate Liability for Anti-Bribery Violations

General principles of corporate liability apply to the FCPA. Thus, a company is liable when its directors, officers, employees, or agents, acting within the scope of their employment, commit FCPA violations intended, at least in part, to benefit the company.[182] Similarly, just as with any other statute, DOJ and SEC look to principles of parent-subsidiary and successor liability in evaluating corporate liability. As described more fully below, unlike with most other statutes, DOJ has instituted an FCPA Corporate Enforcement Policy that applies to corporate resolutions in the FCPA context.

Parent-Subsidiary Liability

There are two ways in which a parent company may be liable for bribes paid by its subsidiary.

First, a parent may have participated sufficiently in the activity to be directly liable for the conduct—as, for example, when it directed its subsidiary's misconduct or otherwise directly participated in the bribe scheme.

Second, a parent may be liable for its subsidiary's conduct under traditional agency principles. The fundamental characteristic of agency is control.[183] Accordingly, DOJ and SEC evaluate the parent's control—including the parent's knowledge and direction of the subsidiary's actions, both generally and in the context of the specific transaction—when evaluating whether a subsidiary is an agent of the parent. Although the formal relationship between the parent and subsidiary is important in this analysis, so are the practical realities of how the parent and subsidiary actually interact.

If an agency relationship exists and the subsidiary is acting within the scope of authority conferred by the parent, a subsidiary's actions and knowledge are imputed to its parent.[184] Moreover, under traditional principles of *respondeat superior*, a company is liable for the acts of its agents, including its employees, undertaken within the scope of their employment and intended, at least in part, to benefit the company.[185] Thus, if an agency relationship exists between a parent and a subsidiary, the parent is liable for bribery committed by the subsidiary's employees. For example, SEC brought an administrative action against a parent for bribes paid by the president of its indirect, wholly owned

subsidiary. In that matter, the subsidiary's president reported directly to the CEO of the parent issuer, and the issuer routinely identified the president as a member of its senior management in its annual filing with SEC and in annual reports. Additionally, the parent's legal department approved the retention of the third-party agent through whom the bribes were arranged despite a lack of documented due diligence and an agency agreement that violated corporate policy; also, an officer of the parent approved one of the payments to the third-party agent.[186] Under these circumstances, the parent company had sufficient knowledge and control of its subsidiary's actions to be liable under the FCPA.

Successor Liability

Companies acquire a host of liabilities when they merge with or acquire another company, including those arising out of contracts, torts, regulations, and statutes. As a general legal matter, when a company merges with or acquires another company, the successor company assumes the predecessor company's liabilities.[187] Successor liability is an integral component of corporate law and, among other things, prevents companies from avoiding liability by reorganizing.[188] At the same time, DOJ and SEC recognize the potential benefits of corporate mergers and acquisitions, particularly when the acquiring entity has a robust compliance program in place and implements that program as quickly as practicable at the merged or acquired entity. Successor liability applies to all kinds of civil and criminal liabilities,[189] and FCPA violations are no exception. Whether successor liability applies to a particular corporate transaction depends on the facts and the applicable state, federal, and foreign law. Successor liability does not, however, create liability where none existed before. For example, if an issuer were to acquire a foreign company that was not previously subject to the FCPA's jurisdiction, the mere acquisition of that foreign company would not retroactively create FCPA liability for the acquiring issuer.

DOJ and SEC encourage companies to conduct pre-acquisition due diligence and improve compliance programs and internal controls after acquisition for a variety of reasons.

First, due diligence helps an acquiring company to accurately value the target company. Contracts obtained through bribes may be legally unenforceable, business obtained illegally may be lost when bribe payments are stopped, there may be liability for prior illegal conduct, and the prior corrupt acts may harm the acquiring company's reputation and future business prospects. Identifying these issues before an acquisition allows companies to better evaluate any potential post-acquisition liability and thus properly assess the target's value.[190] *Second*, due diligence reduces the risk that the acquired company will continue to pay bribes. Proper pre-acquisition due diligence can identify business and regional risks and can also lay the foundation for a swift and successful post-acquisition integration into the acquiring company's corporate control and compliance environment. *Third*, the consequences of potential violations uncovered through due diligence can be handled by the parties in an orderly and efficient manner through negotiation of the costs and responsibilities for the investigation and remediation. *Finally*, comprehensive due diligence demonstrates a genuine commitment to uncovering and preventing FCPA violations.

DOJ and SEC also recognize that, in certain instances, robust pre-acquisition due diligence may not be possible. In such instances, DOJ and SEC will look to the timeliness and thoroughness of the acquiring company's post-acquisition due diligence and compliance integration efforts.

In a significant number of instances, DOJ and SEC have declined to take action against companies that voluntarily disclosed and remediated conduct and cooperated with DOJ and SEC in the merger and acquisition context.[191] And DOJ and SEC have taken action against successor companies only in limited circumstances, generally in cases involving egregious and sustained violations or where the successor company directly participated in the violations or failed to stop the misconduct from continuing after the acquisition. In one case, a U.S.-based issuer was charged with books and records and internal controls violations for continuing a kickback scheme originated by its predecessor.[192] Another recent case involved a merger between two oil and gas companies, where prior to the merger both predecessor companies committed FCPA violations over the course of many years. The two companies, one of which was an issuer and the other a former issuer operating through a U.S.-based subsidiary, merged to form a new publicly traded company. Under these circumstances—the merger of two companies that had each engaged in bribery—both the new entity and the foreign subsidiaries were liable under the FCPA. The new parent entered into a deferred prosecution agreement with DOJ and settled a civil action with SEC, while the company's U.S.-based subsidiary pleaded guilty.[193]

More often, DOJ and SEC have pursued enforcement actions against the predecessor company (rather than the acquiring company), particularly when the acquiring company uncovered and timely remedied the violations or when the government's investigation of the predecessor company preceded the acquisition. In one such case, a U.S.-based multinational conglomerate acquired the power business of a French power and transportation company, which had paid bribes to obtain contracts prior to the acquisition. In that case the matter was resolved with a guilty plea for the French power and transportation company, and deferred prosecution agreements for two of the newly acquired subsidiaries; no successor liability was sought against the acquiring entity.[194]

Practical Tips to Reduce FCPA Risk in Mergers and Acquisitions

Companies pursuing mergers or acquisitions can take certain steps to identify and potentially reduce FCPA risks:

M&A Opinion Procedure Release Requests:

One option is to seek an opinion from DOJ in anticipation of a potential acquisition, such as occurred with Opinion Release 08-02. That case involved special circumstances, namely, severely limited pre-acquisition due diligence available to the potential acquiring company, and, because it was an opinion release (i.e., providing certain assurances by DOJ concerning prospective conduct), it necessarily imposed demanding standards and prescriptive timeframes in return for specific assurances from DOJ, which SEC, as a matter of discretion, also honors. Thus, obtaining an opinion from DOJ can be a good way to address specific due diligence challenges, but, because of the nature of such an opinion, it will likely contain more stringent requirements than may be necessary in all circumstances.

M&A Risk-Based FCPA Due Diligence and Disclosure:

As a practical matter, most acquisitions will typically not require the type of prospective assurances contained in an opinion from DOJ. DOJ and SEC encourage companies engaging in mergers and acquisitions to: (1) conduct thorough risk-based FCPA and anti-corruption due diligence on potential new business acquisitions;

(cont'd)

(2) ensure that the acquiring company's code of conduct and compliance policies and procedures regarding the FCPA and other anti-corruption laws apply as quickly as is practicable to newly acquired businesses or merged entities; (3) train the directors, officers and employees of newly acquired businesses or merged entities, and when appropriate, train agents and business partners, on the FCPA and other relevant anti-corruption laws and the company's code of conduct and compliance policies and procedures; (4) conduct an FCPA-specific audit of all newly acquired or merged businesses as quickly as practicable; and (5) disclose any corrupt payments discovered as part of its due diligence of newly acquired entities or merged entities. DOJ and SEC will give meaningful credit to companies who undertake these actions, and, in appropriate circumstances, DOJ and SEC may consequently decline to bring enforcement actions.

In another case, a Pennsylvania-based issuer that supplied heating and air conditioning products and services was subject to an ongoing investigation by DOJ and SEC at the time that it was acquired; DOJ and SEC resolved enforcement actions only against the predecessor company, which had by that time become a wholly owned subsidiary of the successor company.[195]

In another example, when a Florida-based U.S. company discovered in post-acquisition due diligence that the telecommunications company (a domestic concern) it had acquired had engaged in foreign bribery, the successor company disclosed the FCPA violations to DOJ. It then conducted an internal investigation, cooperated fully with DOJ, and took appropriate remedial action—including terminating senior management at the acquired company. No enforcement action was taken against the successor, but the predecessor company pleaded guilty to one count of violating the FCPA and agreed to pay a $2 million fine.[196] Later, four executives from the predecessor company were convicted of FCPA violations, three of whom received terms of imprisonment.[197]

On occasion, when an enforcement action has been taken against a predecessor company, the successor seeks assurances that it will not be subject to a future enforcement action. In one such case, a Dutch predecessor resolved FCPA charges with DOJ through a deferred prosecution agreement.[198] While both the predecessor and successor signed the agreement, which included a commitment to ongoing cooperation and an improved compliance program, only the predecessor company was charged; in signing the agreement, the successor company gained the certainty of conditional release from criminal liability, even though it was not being pursued for FCPA violations.[199] In another case, after a Connecticut-based company uncovered FCPA violations by a California company it sought to acquire, both companies voluntarily disclosed the conduct to DOJ and SEC.[200] The predecessor company resolved its criminal liability through a non-prosecution agreement with DOJ that included an $800,000 monetary penalty and also settled with SEC, paying a total of $1.1 million in disgorgement, pre-judgment interest, and civil penalties. The successor company proceeded with the acquisition and separately entered into a non-prosecution agreement with DOJ in which it agreed, among other things, to ensure full performance of the predecessor company's non-prosecution agreement. This agreement provided certainty to the successor concerning its FCPA liability.[201]

Importantly, a successor company's voluntary disclosure, appropriate due diligence, and implementation of an effective compliance program

may also decrease the likelihood of an enforcement action regarding an acquired company's post-acquisition conduct when pre-acquisition due diligence is not possible.[202] In fact, under the DOJ FCPA Corporate Enforcement Policy, in appropriate cases, an acquiring company that voluntarily discloses misconduct may be eligible for a declination, even if aggravating circumstances existed as to the acquired entity.

Hypothetical: Successor Liability Where Acquired Company Was Not Previously Subject to the FCPA

Company A is a Delaware corporation with its principal offices in the United States and whose shares are listed on a national U.S. exchange. Company A is considering acquiring Foreign Company, which is not an issuer or a domestic concern. Foreign Company takes no actions within the United States that would make it subject to territorial jurisdiction. Company A's proposed acquisition would make Foreign Company a subsidiary of Company A.

Scenario 1:

Prior to acquiring Foreign Company, Company A engages in extensive due diligence of Foreign Company, including: (1) having its legal, accounting, and compliance departments review Foreign Company's sales and financial data, its customer contracts, and its third-party and distributor agreements; (2) performing a risk-based analysis of Foreign Company's customer base; (3) performing an audit of selected transactions engaged in by Foreign Company; and (4) engaging in discussions with Foreign Company's general counsel, vice president of sales, and head of internal audit regarding all corruption risks, compliance efforts, and any other corruption-related issues that have surfaced at Foreign Company over the past ten years. This due diligence aims to determine whether Foreign Company has appropriate anti-corruption and compliance policies in place, whether Foreign Company's employees have been adequately trained regarding those policies, how Foreign Company ensures that those policies are followed, and what remedial actions are taken if the policies are violated.

During the course of its due diligence, Company A learns that Foreign Company has made several potentially improper payments in the form of an inflated commission to a third-party agent in connection with a government contract with Foreign Country. Immediately after the acquisition, Company A discloses the conduct to DOJ and SEC, suspends and terminates those employees and the third-party agent responsible for the payments, and makes certain that the illegal payments have stopped. It also quickly integrates Foreign Company into Company A's own robust internal controls, including its anti-corruption and compliance policies, which it communicates to its new employees through required online and in-person training in the local language. Company A also requires Foreign Company's third-party distributors and other agents to sign anti-corruption certifications, complete training, and sign new contracts that incorporate FCPA and anti-corruption representations and warranties and audit rights.

Based on these facts, could DOJ or SEC prosecute Company A?

No. Although DOJ and SEC have jurisdiction over Company A because it is an issuer, neither could pursue Company A for conduct that occurred prior to its acquisition of Foreign Company. As Foreign Company was neither an issuer nor a domestic concern and was not subject to U.S. territorial jurisdiction, DOJ and SEC have no jurisdiction over its pre-acquisition misconduct. The acquisition of a company does not create jurisdiction where none existed before.

Importantly, Company A's extensive pre-acquisition due diligence allowed it to identify and halt the corruption. As there was no continuing misconduct post-acquisition, the FCPA was not violated.

(cont'd)

Scenario 2:

Company A performs only minimal and pro forma pre-acquisition due diligence. It does not conduct a risk-based analysis, and its review of Foreign Company's data, contracts, and third-party and distributor agreements is cursory. Company A acquires Foreign Company and makes it a wholly owned subsidiary. Although Company A circulates its compliance policies to all new personnel after the acquisition, it does not translate the compliance policies into the local language or train its new personnel or third-party agents on anti-corruption issues.

A few months after the acquisition, an employee in Company A's international sales office (Sales Employee) learns from a legacy Foreign Company employee that for years the government contract that generated most of Foreign Company's revenues depended on inflated commissions to a third-party agent "to make the right person happy at Foreign Government Agency." Sales Employee is told that unless the payments continue the business will likely be lost, which would mean that Company A's new acquisition would quickly become a financial failure. The payments continue for two years after the acquisition. After another employee of Company A reports the long-running bribe scheme to a director at Foreign Government Agency, Company A stops the payments and DOJ and SEC investigate.

Based on these facts, would DOJ or SEC charge Company A?

Yes. DOJ and SEC have prosecuted companies like Company A in similar circumstances. Any charges would not, however, be premised upon successor liability, but rather on Company A's post-acquisition bribe payments, which themselves created criminal and civil liability for Company A.

Scenario 3:

Under local law, Company A's ability to conduct pre-acquisition due diligence on Foreign Company is limited. In the due diligence it does conduct, Company A determines that Foreign Company is doing business in high-risk countries and in high-risk industries but finds no red flags specific to Foreign Company's operations. Post-acquisition, Company A conducts extensive due diligence and determines that Foreign Company had paid bribes to officials with Foreign Government Agency Company A takes prompt action to remediate the problem, including following the measures set forth in Opinion Procedure Release No. 08-02. Among other actions, it voluntarily discloses the misconduct to DOJ and SEC, ensures all bribes are immediately stopped, takes remedial action against all parties involved in the corruption, and quickly integrates Foreign Company into a robust compliance program and Company A's other internal controls.

Based on these facts, would DOJ or SEC prosecute Company A?

DOJ and SEC have declined to prosecute companies like Company A in similar circumstances. Companies can follow the measures set forth in Opinion Procedure Release No. 08-02, or seek their own opinions, where adequate pre-acquisition due diligence is not possible.

Hypothetical: Successor Liability Where Acquired Company Was Already Subject to the FCPA

Both Company A and Company B are Delaware corporations with their principal offices in the United States. Both companies' shares listed on a national U.S. exchange.

Scenario 1:

Company A is considering acquiring several of Company B's business lines. Prior to the acquisition, Company A engages in extensive due diligence, including: (1) having its legal, accounting, and compliance departments review Company B's sales and financial data, its customer contracts, and its third-party and distributor agreements; (2) performing a risk-based analysis of Company B's customer base; (3) performing an audit of selected transactions engaged in by Company B; and (4) engaging in discussions with Company B's general counsel, vice president of sales, and head of internal audit regarding all corruption risks, compliance efforts, and any other major corruption-related issues that have surfaced at Company B over the past ten years. This due diligence aims to determine whether Company B has appropriate anti-corruption and compliance policies in place, whether Company B's employees have been adequately trained regarding those policies, how Company B ensures that those policies are followed, and what remedial actions are taken if the policies are violated. During the course of its due diligence, Company A learns that Company B has made several potentially improper payments in connection with a government contract with Foreign Country. As a condition of the acquisition, Company A requires Company B to disclose the misconduct to the government. Company A makes certain that the illegal payments have stopped and quickly integrates Company B's business lines into Company A's own robust internal controls, including its anti-corruption and compliance policies, which it communicates to its new employees through required online and in-person training in the local language. Company A also requires Company B's third-party distributors and other agents to sign anti-corruption certifications, complete training, and sign new contracts that incorporate FCPA and anti-corruption representations and warranties and audit rights.

Based on these facts, would DOJ or SEC prosecute?

DOJ and SEC have declined to prosecute companies like Company A in similar circumstances. DOJ and SEC encourage companies like Company A to conduct extensive FCPA due diligence. By uncovering the corruption, Company A put itself in a favorable position, and, because the corrupt payments have stopped, Company A has no continuing liability. Whether DOJ and SEC might charge Company B depends on facts and circumstances beyond the scope of this hypothetical. DOJ would consider its Principles of Federal Prosecution of Business Organizations and SEC would consider the factors contained in the Seaboard Report, both of which are discussed in Chapter 5. In general, the more egregious and long-standing the corruption, the more likely it is that DOJ and SEC would prosecute Company B. In certain limited circumstances, DOJ and SEC have in the past declined to bring charges against acquired companies, recognizing that acquiring companies may bear much of the reputational damage and costs associated with such charges.

Scenario 2:

Company A plans to acquire Company B. Although, as in Scenario 1, Company A conducts extensive due diligence, it does not uncover the bribery until after the acquisition. Company A then makes certain that the illegal payments stop and voluntarily discloses the misconduct to DOJ and SEC. It quickly integrates Company B into Company A's own robust internal controls, including its anti-corruption and compliance policies, which it communicates to its new employees through required online and in-person training in the local language. Company A also requires Company B's third-party distributors and other agents to sign anti-corruption certifications, complete training, and sign new contracts that incorporate FCPA and anti-corruption representations and warranties and audit rights.

(cont'd)

Based on these facts, would DOJ or SEC prosecute?

Absent unusual circumstances not contemplated by this hypothetical, DOJ and SEC are unlikely to prosecute Company A for the pre-acquisition misconduct of Company B, provided that Company B still exists in a form that would allow it to be prosecuted separately (e.g., Company B is a subsidiary of Company A). DOJ and SEC understand that no due diligence is perfect and that society benefits when companies with strong compliance programs acquire and improve companies with weak ones. At the same time, however, neither the liability for corruption—nor the harms caused by it—are eliminated when one company acquires another. Whether DOJ and SEC will pursue a case against Company B (or, in unusual circumstances, Company A) will depend on consideration of all the factors in the Principles of Federal Prosecution of Business Organizations and the Seaboard Report, respectively.

Scenario 3:

Company A merges with Company B, which is in the same line of business and interacts with the same Foreign Government customers, and forms Company C. Due diligence before the merger reveals that both Company A and Company B have been engaging in similar bribery. In both cases, the bribery was extensive and known by high-level management within the companies.

Based on these facts, would DOJ or SEC prosecute?

Yes. DOJ and SEC have prosecuted companies like Company C on the basis of successor liability. Company C is a combination of two companies that both violated the FCPA, and their merger does not eliminate their liability. In addition, since Company C is an ongoing concern, DOJ and SEC may impose a monitorship to ensure that the bribery has ceased and a compliance program is developed to prevent future misconduct.

Additional Principles of Criminal Liability for Anti-Bribery Violations: Aiding and Abetting and Conspiracy

Under federal law, individuals or companies that aid or abet a crime, including an FCPA violation, are as guilty as if they had directly committed the offense themselves. The aiding and abetting statute provides that whoever "commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission," or "willfully causes an act to be done which if directly performed by him or another would be an offense against the United States," is punishable as a principal.[203] Aiding and abetting is not an independent crime, and the government must prove that an underlying FCPA violation was committed.[204]

Under normal principles of conspiracy liability, individuals and companies, including foreign nationals and companies, may also be liable for conspiring to violate the FCPA—i.e., for agreeing to commit an FCPA violation—even if they are not, or could not be, independently charged with a substantive FCPA violation. For instance, a foreign, non-issuer company could be convicted of conspiring with a domestic concern to violate the FCPA. Under certain circumstances, it could also be held liable for the domestic concern's substantive FCPA violations under *Pinkerton v. United States*, which imposes liability on a defendant for reasonably foreseeable crimes committed by a co-conspirator in furtherance of a conspiracy that the defendant joined.[205]

A foreign company or individual may be held liable for aiding and abetting an FCPA violation or for conspiring to violate the FCPA, even if the foreign company or individual did not take any act in furtherance of the corrupt payment while in the territory of the United States. In conspiracy cases, the United States generally has jurisdiction over all the conspirators where at least one conspirator is an issuer, domestic concern, or commits a reasonably foreseeable overt act within the United States.[206] For example, if a foreign company or individual conspires to violate the FCPA with someone who commits an overt act within the United States, the United States can prosecute the foreign company or individual for the conspiracy. The same principle applies to aiding and abetting violations. For instance, even though they took no action in the United States, Japanese and European companies were charged with conspiring with and aiding and abetting a domestic concern's FCPA violations.[207]

However, in *United States v. Hoskins*, the Second Circuit addressed the question of whether individuals not directly covered by the FCPA anti-bribery provisions could nevertheless be guilty of conspiring to violate, or aiding and abetting the violation of, the FCPA anti-bribery provisions, and concluded they could not.[208] Therefore, at least in the Second Circuit, an individual can be criminally prosecuted for conspiracy to violate the FCPA anti-bribery provisions or aiding and abetting an FCPA anti-bribery violation only if that individual's conduct and role fall into one of the specifically enumerated categories expressly listed in the FCPA's anti-bribery provisions.

At least one district court from another circuit has rejected the reasoning in the *Hoskins* decision, and concluded that the defendants could be criminally liable for conspiracy to violate the FCPA anti-bribery provisions, and aiding and abetting a violation, even though they do not "belong to the class of individuals capable of committing a substantive FCPA violation."[209]

Additional Principles of Civil Liability for Anti-Bribery Violations: Aiding and Abetting and Causing

Both companies and individuals can be held civilly liable for aiding and abetting FCPA anti-bribery violations if they knowingly or recklessly provide substantial assistance to a violator.[210] Similarly, in the administrative proceeding context, companies and individuals may be held liable for causing FCPA violations.[211] This liability extends to the subsidiaries and agents of U.S. issuers.

In one case, the U.S. subsidiary of a Swiss freight forwarding company was held civilly liable for paying bribes on behalf of its customers in several countries.[212] Although the U.S. subsidiary was not an issuer for purposes of the FCPA, it was an "agent" of several U.S. issuers. By paying bribes on behalf of its issuers' customers, the subsidiary both directly violated the FCPA and aided and abetted the issuers' FCPA violations.

What Is the Applicable Statute of Limitations?

Statute of Limitations in Criminal Cases

The FCPA's anti-bribery and accounting provisions do not specify a statute of limitations for criminal actions. Accordingly, the general statutes of limitations periods apply. For substantive violations of the FCPA anti-bribery provisions, the five-year limitations period set forth in 18 U.S.C. § 3282 applies.[213] For violations of the FCPA accounting provisions, which are defined as "securities fraud offense[s]" under 18 U.S.C. § 3301, there is a limitations period of six years.[214]

In cases involving FCPA conspiracies, the government may be able to reach conduct occurring before the general limitations period applicable to conspiracies under 18 U.S.C. § 371. For conspiracy offenses, the government generally need prove only that one act in furtherance of the conspiracy occurred during the limitations period, thus enabling the government to prosecute bribes paid or accounting violations occurring more than five or six years, respectively, prior to the filing of formal charges.[215]

There are at least two ways in which the applicable limitations period is commonly extended. First, companies or individuals cooperating with DOJ may enter into a tolling agreement that voluntarily extends the limitations period. Companies and individuals may choose to do this so that they may have additional time to do their own investigation of the conduct, as well as to give them an opportunity to meet with the government to discuss the case and attempt to reach a negotiated resolution. Second, under 18 U.S.C. § 3292, the government may seek a court order suspending the statute of limitations period in a criminal case for up to three years in order to obtain evidence from foreign countries. Generally, the suspension period begins when the official request is made by the U.S. government to the foreign authority and ends on the earlier of the date on which the foreign authority takes final action on the request, or three years.[216]

Statute of Limitations in Civil Actions

In civil cases brought by SEC, the statute of limitations is set by 28 U.S.C. § 2462, which provides for a five-year limitation on any "suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture." The five-year period begins to run "when the claim first accrued." The five-year limitations period applies to SEC actions seeking civil penalties, but it does not prevent SEC from seeking equitable remedies, such as an injunction, for conduct pre-dating the five-year period. In *Kokesh v. SEC*, the Supreme Court ruled that, because the disgorgement remedy constitutes a "penalty," it is therefore subject to the five-year statute of limitations in 28 U.S.C. § 2462.[217]

In cases against individuals who are not residents of the United States, the statute is tolled for any period when the defendants are not "found within the United States in order that proper service may be made thereon."[218] Furthermore, companies or individuals may enter into tolling agreements that voluntarily extend the limitations period.

THE FCPA: ACCOUNTING PROVISIONS

In addition to the anti-bribery provisions, the FCPA contains accounting provisions applicable to public companies. The FCPA's accounting provisions operate in tandem with the anti-bribery provisions[219] and prohibit off-the-books accounting. Company management and investors rely on a company's financial statements and internal accounting controls to ensure transparency in the financial health of the business, the risks undertaken, and the transactions between the company and its customers and business partners. The accounting provisions are designed to "strengthen the accuracy of the corporate books and records and the reliability of the audit process which constitute the foundations of our system of corporate disclosure."[220]

The accounting provisions consist of two primary components. First, under the "books and records" provision, issuers must make and keep books, records, and accounts that, in reasonable detail, accurately and fairly reflect an issuer's transactions and dispositions of an issuer's assets.[221] Second, under the "internal controls" provision, issuers must devise and maintain a system of internal accounting controls sufficient to assure management's control, authority, and responsibility over the firm's assets.[222] These components, and other aspects of the accounting provisions, are discussed in greater detail below.

Although the accounting provisions were originally enacted as part of the FCPA, they do not apply only to bribery-related violations. Rather, the accounting provisions require that all public companies account for all of their assets and liabilities accurately and in reasonable detail, and they form the backbone for most accounting fraud and issuer disclosure cases brought by DOJ and SEC.[223]

> In the past, "corporate bribery has been concealed by the falsification of corporate books and records" and the accounting provisions "remove[] this avenue of coverup."
>
> *Senate Report No. 95-114, at 3 (1977)*

What Is Covered by the Accounting Provisions?

Books and Records Provision

Bribes, both foreign and domestic, are often mischaracterized in companies' books and records. Section 13(b)(2)(A) of the Exchange Act (15 U.S.C. § 78m(b)(2)(A)), commonly called the "books and records" provision, requires issuers to "make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer."[224] The "in reasonable detail" qualification was adopted by Congress "in light of the concern that such a standard, if unqualified, might connote a degree of exactitude and precision which is unrealistic."[225] The addition of this phrase was intended to make clear "that the issuer's records should reflect transactions in conformity with accepted methods of recording economic events and effectively prevent off-the-books slush funds and payments of bribes."[226]

The term "reasonable detail" is defined in the statute as the level of detail that would "satisfy prudent officials in the conduct of their own affairs."[227] Thus, as Congress noted when it adopted this definition, "[t]he concept of reasonableness of necessity contemplates the weighing of a number of relevant factors, including the costs of compliance."[228]

Although the standard is one of reasonable detail, it is never appropriate to mischaracterize transactions in a company's books and records.[229] Bribes are often concealed under the guise of legitimate payments, such as commissions or consulting fees.

In instances where all the elements of a violation of the anti-bribery provisions are not met—where, for example, there was no use of interstate commerce—companies nonetheless may be liable if the improper payments are inaccurately recorded. Consistent with the FCPA's approach to prohibiting payments of any value that are made with a corrupt purpose, there is no materiality threshold under the books and records provision. In combination with the internal controls provision, the requirement that issuers maintain books and records that accurately and fairly reflect the corporation's transactions "assure[s], among other things, that the assets of the issuer are used for proper corporate purpose[s]."[230] As with the anti-bribery provisions, DOJ's and SEC's enforcement of the books and records provision has typically involved misreporting of either large bribe payments or widespread inaccurate recording of smaller payments made as part of a systematic pattern of bribery, and both DOJ and SEC look to the nature and seriousness of the conduct in determining whether to pursue an enforcement action.

Bribes Have Been Mischaracterized As:

- Commissions or Royalties
- Consulting Fees
- Sales and Marketing Expenses
- Scientific Incentives or Studies
- Travel and Entertainment Expenses
- Rebates or Discounts
- After Sales Service Fees
- Miscellaneous Expenses
- Petty Cash Withdrawals
- Free Goods
- Intercompany Accounts
- Supplier / Vendor Payments
- Write-offs
- "Customs Intervention" Payments

Internal Accounting Controls Provision

The payment of bribes often occurs in companies that have weak internal accounting control environments. Internal controls over financial reporting are the processes used by companies to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. They include various components, such as: a control environment that covers the tone set by the organization regarding integrity and ethics; risk assessments; control activities that cover policies and procedures designed to ensure that management directives are carried out (e.g., approvals, authorizations, reconciliations, and segregation of duties); information and communication; and monitoring. Section 13(b)(2)(B) of the Exchange Act (15 U.S.C. § 78m(b)(2)(B)), commonly called the "internal controls" provision, requires issuers to:

devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that—

- (i) transactions are executed in accordance with management's general or specific authorization;
- (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets;
- (iii) access to assets is permitted only in accordance with management's general or specific authorization; and
- (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences ....[231]

Like the "reasonable detail" requirement in the books and records provision, the Act defines "reasonable assurances" as "such level of detail and degree of assurance as would satisfy prudent officials in the conduct of their own affairs."[232]

The Act does not specify a particular set of controls that companies are required to implement. Rather, the internal accounting controls provision gives companies the flexibility to develop and maintain a system of controls that is appropriate to their particular needs and circumstances.

Although a company's internal accounting controls are not synonymous with a company's compliance program, an effective compliance program contains a number of components that may overlap with a critical component of an issuer's internal accounting controls. Fundamentally, the design of a company's internal controls must take into account the operational realities and risks attendant to the company's business, such as: the nature of its products or services; how the products or services get to market; the nature of its work

force; the degree of regulation; the extent of its government interaction; and the degree to which it has operations in countries with a high risk of corruption. Just as a company's internal accounting controls are tailored to its operations, its compliance program needs to be tailored to the risks specific to its operations. Businesses whose operations expose them to a high risk of corruption will necessarily devise and employ different compliance programs than businesses that have a lesser exposure to corruption, just as a financial services company would be expected to devise and employ different internal accounting controls than a manufacturer.

Companies with ineffective internal controls often face risks of embezzlement and self-dealing by employees, commercial bribery, export control problems, and violations of other U.S. and local laws.

A 2008 case against a German manufacturer of industrial and consumer products illustrates a systemic internal controls problem involving bribery that was unprecedented in scale and geographic reach.

From 2001 to 2007, the company created elaborate payment schemes—including slush funds, off the-books accounts, and systematic payments to business consultants and other intermediaries—to facilitate bribery. Payments were made in ways that obscured their purpose and the ultimate recipients of the money. In some cases, employees obtained large amounts of cash from cash desks and then transported the cash in suitcases across international borders. Authorizations for some payments were placed on sticky notes and later removed to avoid any permanent record. The company made payments totaling approximately $1.36 billion through various mechanisms, including $805.5 million as bribes and $554.5 million for unknown purposes.[233] The company was charged with internal controls and books and records violations, along with anti-bribery violations, and paid over $1.6 billion to resolve the case with authorities in the United States and Germany.[234]

The types of internal control failures identified in the above example exist in many other cases where companies were charged with internal controls violations.[235] A 2010 case against a multinational automobile manufacturer involved bribery that occurred over a long period of time in multiple countries.[236] In that case, the company used dozens of ledger accounts, known internally as "internal third party accounts," to maintain credit balances for the benefit of government officials.[237] The accounts were funded through several bogus pricing mechanisms, such as "price surcharges," "price inclusions," or excessive commissions.[238] The company also used artificial discounts or rebates on sales contracts to generate the money to pay the bribes.[239] The bribes also were made through phony sales intermediaries and corrupt business partners, as well as through the use of cash desks.[240] Sales executives would obtain cash from the company in amounts as high as hundreds of thousands of dollars, enabling the company to obscure the purpose and recipients of the money paid to government officials.[241] In addition to bribery charges, the company was charged with internal controls and books and records violations.

Good internal accounting controls can prevent not only FCPA violations, but also other illegal or unethical conduct by the company, its subsidiaries, and its employees. DOJ and SEC have repeatedly brought FCPA cases that also involved other types of misconduct, such as financial fraud,[242]

commercial bribery,[243] export controls violations,[244] and embezzlement or self-dealing by company employees.[245]

Potential Reporting and Anti-Fraud Violations

Issuers have reporting obligations under Section 13(a) of the Exchange Act, which requires issuers to file an annual report that contains comprehensive information about the issuer. Failure to properly disclose material information about the issuer's business, including material revenue, expenses, profits, assets, or liabilities related to bribery of foreign government officials, may give rise to anti-fraud and reporting violations under Sections 10(b) and 13(a) of the Exchange Act.

For example, a California-based technology company was charged with reporting violations, in addition to violations of the FCPA's anti-bribery and accounting provisions, when its bribery scheme led to material misstatements in its SEC filings.[246] The company was awarded contracts procured through bribery of Chinese officials that generated material revenue and profits. The revenue and profits helped the company offset losses incurred to develop new products expected to become the company's future source of revenue growth. The company improperly recorded the bribe payments as sales commission expenses in its books and records.

Companies engaged in bribery may also be involved in activity that violates the anti-fraud and reporting provisions. For example, an oil and gas pipeline company and its employees perpetrated a long-running scheme to use the company's petty cash accounts in Nigeria to make a variety of corrupt payments to Nigerian tax and court officials using false invoices.[247] The company and its employees also engaged in a fraudulent scheme to minimize the company's tax obligations in Bolivia by using false invoices to claim false offsets to its value-added tax obligations. The scheme resulted in material overstatements of the company's net income in the company's financial statements, which violated the Exchange Act's anti-fraud and reporting provisions. Both schemes also violated the books and records and internal controls provisions.

What Are Management's Other Obligations?

Sarbanes-Oxley Act of 2002

In 2002, in response to a series of accounting scandals involving U.S. companies, Congress enacted the Sarbanes-Oxley Act (Sarbanes-Oxley or SOX),[248] which strengthened the accounting requirements for issuers. All issuers must comply with Sarbanes-Oxley's requirements, several of which have FCPA implications.

SOX Section 302 (15 U.S.C. § 7241)—Responsibility of Corporate Officers for the Accuracy and Validity of Corporate Financial Reports

Section 302 of Sarbanes-Oxley requires that a company's "principal officers" (typically the Chief Executive Officer (CEO) and Chief Financial Officer (CFO)) take responsibility for and certify the integrity of their company's financial reports on a quarterly basis. Under Exchange Act Rule 13a-14, which is commonly called the "SOX certification" rule, each periodic report filed by an issuer must include a certification signed by the issuer's principal executive officer and principal financial officer stating, among other things, that: (i) based on the officer's knowledge, the report contains no material misstatements or omissions; (ii) based on the officer's knowledge, the relevant financial statements are accurate in all material respects; (iii) internal controls are properly designed; and

(iv) the certifying officers have disclosed to the issuer's audit committee and auditors all significant internal control deficiencies.

SOX Section 404 (15 U.S.C. § 7262)—Reporting on the State of a Company's Internal Controls over Financial Reporting

Sarbanes-Oxley also strengthened a company's required disclosures concerning the state of its internal controls over financial reporting. Under Section 404, issuers are required to present in their annual reports management's conclusion regarding the effectiveness of the company's internal controls over financial reporting. This statement must also assess the effectiveness of such internal controls and procedures. In addition, the company's independent auditor must attest to and report on its assessment of the effectiveness of the company's internal controls over financial reporting.

As directed by Section 404, SEC has adopted rules requiring issuers and their independent auditors to report to the public on the effectiveness of the company's internal controls over financial reporting.[249] These internal controls include those related to illegal acts and fraud—including acts of bribery—that could result in a material misstatement of the company's financial statements.[250] In 2007, SEC issued guidance on controls over financial reporting.[251]

SOX Section 802 (18 U.S.C. §§ 1519 and 1520)—Criminal Penalties for Altering Documents

Section 802 of Sarbanes-Oxley prohibits altering, destroying, mutilating, concealing, or falsifying records, documents, or tangible objects with the intent to obstruct, impede, or influence a potential or actual federal investigation. This section also prohibits any accountant from knowingly and willfully violating the requirement that all audit or review papers be maintained for a period of five years.

Who Is Covered by the Accounting Provisions?

Civil Liability for Issuers, Subsidiaries, and Affiliates

The FCPA's accounting provisions apply to every issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act or that is required to file annual or other periodic reports pursuant to Section 15(d) of the Exchange Act.[252] These provisions apply to any issuer whose securities trade on a national securities exchange in the United States, including foreign issuers with exchange-traded American Depository Receipts.[253] They also apply to companies whose stock trades in the over-the-counter market in the United States and which file periodic reports with the Commission, such as annual and quarterly reports. Unlike the FCPA's anti-bribery provisions, the accounting provisions do not apply to private companies.[254]

Although the FCPA's accounting provisions are directed at "issuers," an issuer's books and records include those of its consolidated subsidiaries and affiliates. An issuer's responsibility thus extends to ensuring that subsidiaries or affiliates under its control, including foreign subsidiaries and joint ventures, comply with the accounting provisions. For instance, DOJ and SEC brought enforcement actions against a California company for violating the FCPA's accounting provisions when two Chinese joint ventures in which it was a partner paid more than $400,000 in bribes over a four-year period to obtain business in China.[255] Sales personnel in China made the illicit payments by obtaining cash advances from accounting personnel, who recorded the payments on the books as "business fees" or "travel and entertainment" expenses. Although the payments were made exclusively in China by Chinese employees of the joint venture, the California company failed to have adequate internal

controls and failed to act on red flags indicating that its affiliates were engaged in bribery. The California company paid $1.15 million in civil disgorgement and a criminal monetary penalty of $1.7 million.

Companies may not be able to exercise the same level of control over a minority-owned subsidiary or affiliate as they do over a majority or wholly owned entity. Therefore, if a parent company owns 50% or less of a subsidiary or affiliate, the parent is only required to use good faith efforts to cause the minority-owned subsidiary or affiliate to devise and maintain a system of internal accounting controls consistent with the issuer's own obligations under the FCPA.[256] In evaluating an issuer's good faith efforts, all the circumstances—including "the relative degree of the issuer's ownership of the domestic or foreign firm and the laws and practices governing the business operations of the country in which such firm is located"—are taken into account.[257]

Civil Liability for Individuals and Other Entities

Companies (including subsidiaries of issuers) and individuals may also face civil liability for aiding and abetting or causing an issuer's violation of the accounting provisions.[258] For example, in April 2010, SEC charged four individuals—a Country Manager, a Senior Vice President of Sales, a Regional Financial Director, and an International Controller of a U.S. issuer—for their roles in schemes to bribe Kyrgyz and Thai government officials to purchase tobacco from their employer. The complaint alleged that, among other things, the individuals aided and abetted the issuer company's violations of the books and records and internal controls provisions by "knowingly provid[ing] substantial assistance to" the parent company.[259] All four executives settled the charges against them, consenting to the entry of final judgments permanently enjoining them from violating the accounting and anti-bribery provisions, with two executives paying civil penalties.[260] As in other areas of federal securities law, corporate officers also can be held liable as control persons.[261]

Similarly, in October 2011, SEC instituted a proceeding against a U.S. water valve manufacturer and a former employee of the company's Chinese subsidiary for violations of the FCPA's accounting provisions.[262] The Chinese subsidiary had made improper payments to employees of certain design institutes to create design specifications that favored the company's valve products. The payments were disguised as sales commissions in the subsidiary's books and records, thereby causing the U.S. issuer's books and records to be inaccurate. The general manager of the subsidiary, who approved the payments and knew or should have known that they were improperly recorded, was ordered to cease-and-desist from committing or causing violations of the accounting provisions, among other charges.[263]

Additionally, individuals and entities can be held directly civilly liable for falsifying an issuer's books and records or for circumventing internal controls. Exchange Act Rule 13b2-1 provides: "No person shall, directly or indirectly, falsify or cause to be falsified, any book, record or account subject to [the books and records provision] of the Securities Exchange Act."[264] And Section 13(b)(5) of the Exchange Act (15 U.S.C. § 78m(b)(5)) provides that "[n]o person shall knowingly circumvent or knowingly fail to implement a system of internal accounting controls or knowingly falsify any book, record, or account …."[265] The Exchange Act defines "person" to include a "natural person, company, government, or political subdivision, agency, or instrumentality of a government."[266]

An issuer's officers and directors may also be held civilly liable for making false statements to a company's auditor. Exchange Act Rule 13b2-2 prohibits officers and directors from making (or causing to be made) materially false or misleading statements, including an omission of material facts, to an accountant. This liability arises in connection with any audit, review, or examination of a company's financial statements or in connection with the filing of any document with SEC.[267]

Finally, the principal executive and principal financial officer, or persons performing similar functions, can be held liable for violating Exchange Act Rule 13a-14 by signing false personal certifications required by SOX. Thus, for example, in January 2011, SEC charged the former CEO of a U.S. issuer for his role in schemes to bribe Iraqi government officials in connection with the United Nations Oil-For-Food Programme and to bribe Iraqi and Indonesian officials to purchase the company's fuel additives. There, the company used false invoices and sham consulting contracts to support large bribes that were passed on to foreign officials through an agent, and the bribes were mischaracterized as legitimate commissions and travel fees in the company's books and records. The officer directed and authorized the bribe payments and their false recording in the books and records. He also signed annual and quarterly SOX certifications in which he falsely represented that the company's financial statements were fairly presented and the company's internal controls sufficiently designed, as well as annual representations to the company's external auditors where he falsely stated that he complied with the company's code of ethics and was unaware of any violations of the code of ethics by anyone else. The officer was charged with aiding and abetting violations of the books and records and internal controls provisions, circumventing internal controls, falsifying books and records, making false statements to accountants, and signing false certifications.[268] He consented to the entry of an injunction and paid disgorgement and a civil penalty.[269] He also later pleaded guilty in the United Kingdom to conspiring to corrupt Iraqi and Indonesian officials.[270]

Criminal Liability for Accounting Violations

Criminal liability can be imposed on companies and individuals for knowingly and willfully failing to comply with the FCPA's books and records or internal controls provisions.[271]

For example, a U.S.-based hedge fund was criminally charged with violating the books and records and the internal accounting controls provisions of the FCPA, among other things. As part of its deferred prosecution agreement, the company admitted to falsifying its books and records by falsifying records related to the retention and nature of services of, and payments to, an intermediary it used in Libya in order to conceal the true nature of the payments. Also, the hedge fund admitted that it failed to implement a system of internal controls relating to due diligence for the retention of third-party intermediaries, pre-clearance and approval of agreements with third parties and agents, notification to clients and prospective clients of arrangements with third parties having an impact on the client arrangements, documentation and proof of services provided by the third parties, auditing assets and operations in areas that posed a high risk of corruption, ensuring appropriate justification for the use of and payment to nominee entities, and oversight of payment processes to ensure that payments were made pursuant to appropriate controls.[272] Similarly, a U.S.-based electronics company entered into a deferred prosecution agreement to resolve charges that it

knowingly and willfully caused its Japanese-parent issuer to falsify its books and records concerning the improper retention of consultants and concealment of payments to third-party sales agents. As part of its agreement, the company admitted that it retained certain so-called consultants, who did little or no actual consulting work, through a third-party service provider and paid for those services out of a budget over which a senior executive had complete control and discretion, without meaningful oversight by anyone at the company or the parent. By mischaracterizing these payments as "consultant payments" on its general ledger, the company caused its issuer-parent to incorrectly designate those payments as "selling and general administrative expenses" on its books, records, and accounts. In addition, the company admitted that its senior executives provided false or incomplete representations about the effectiveness of the company's internal controls to the parent on their Sarbanes-Oxley certifications.[273]

Individuals can be held criminally liable for accounting violations. For example, a former managing director of a U.S. bank's real estate business in China pleaded guilty to conspiring to evade internal accounting controls in order to transfer a multi-million dollar ownership interest in a Shanghai building to himself and a Chinese public official with whom he had a personal friendship. The former managing director repeatedly made false representations to his employer about the transaction and the ownership interests involved.[274]

Conspiracy and Aiding and Abetting Liability

Companies (including subsidiaries of issuers) and individuals may face criminal liability for conspiring to commit or for aiding and abetting violations of the accounting provisions.

For example, the subsidiary of a Houston-based company pleaded guilty both to conspiring to commit and to aiding and abetting the company's books and records and anti-bribery violations.[275] The subsidiary paid bribes of over $4 million and falsely characterized the payments as "commissions," "fees," or "legal services," consequently causing the company's books and records to be inaccurate. Although the subsidiary was not an issuer and therefore could not be charged directly with an accounting violation, it was criminally liable for its involvement in the parent company's accounting violation.

Similarly, a U.S. subsidiary of a Swiss freight forwarding company that was not an issuer was charged with conspiring to commit and with aiding and abetting the books and records violations of its customers, who were issuers and therefore subject to the FCPA's accounting provisions.[276] The U.S. subsidiary substantially assisted the issuer-customers in violating the FCPA's books and records provision by masking the true nature of the bribe payments in the invoices it submitted to the issuer-customers.[277] The subsidiary thus faced criminal liability for its involvement in the issuer-customers' FCPA violations even though it was not itself subject to the FCPA's accounting provisions.

Unlike the FCPA anti-bribery provisions, the accounting provisions apply to "any person," and thus are not subject to the reasoning in the Second Circuit's decision in *United States v. Hoskins* limiting conspiracy and aiding and abetting liability under the FCPA anti-bribery provisions.[278]

Auditor Obligations

All public companies in the United States must file annual financial statements that have been prepared in conformity with U.S. Generally Accepted

Accounting Principles (U.S. GAAP). These accounting principles are among the most comprehensive in the world. U.S. GAAP requires an accounting of all assets, liabilities, revenue, and expenses as well as extensive disclosures concerning the company's operations and financial condition. A company's financial statements should be complete and fairly represent the company's financial condition.[279] Thus, under U.S. GAAP, any payments to foreign government officials must be properly accounted for in a company's books, records, and financial statements.

U.S. laws, including SEC Rules, require issuers to undergo an annual external audit of their financial statements and to make those audited financial statements available to the public by filing them with SEC. SEC Rules and the rules and standards issued by the Public Company Accounting Oversight Board (PCAOB) under SEC oversight, require external auditors to be independent of the companies that they audit. Independent auditors must comply with the rules and standards set forth by the PCAOB when they perform an audit of a public company. The audit standards govern, for example, the auditor's responsibility concerning material errors, irregularities, or illegal acts by a client and its officers, directors, and employees. Additionally, the auditor has a responsibility to obtain an understanding of an entity's internal controls over financial reporting as part of its audit and must communicate all significant deficiencies and material weaknesses identified during the audit to management and the audit committee.[280]

Under Section 10A of the Exchange Act, independent auditors who discover an illegal act, such as the payment of bribes to domestic or foreign government officials, have certain obligations in connection with their audits of public companies.[281] Generally, Section 10A requires auditors who become aware of illegal acts to report such acts to appropriate levels within the company and, if the company fails to take appropriate action, to notify SEC.

OTHER RELATED U.S. LAWS

Businesses and individuals should be aware that conduct that violates the FCPA's anti-bribery or accounting provisions may also violate other statutes or regulations. Moreover, payments to foreign government officials and intermediaries may violate these laws even if all of the elements of an FCPA violation are not present.

Travel Act

The Travel Act, 18 U.S.C. § 1952, prohibits travel in interstate or foreign commerce or using the mail or any facility in interstate or foreign commerce, with the intent to distribute the proceeds of any unlawful activity or to promote, manage, establish, or carry on any unlawful activity.[282] "Unlawful activity" includes violations of not only the FCPA, but also state commercial bribery laws. Thus, bribery between private commercial enterprises may, in some circumstances, be covered by the Travel Act. Said differently, if a company pays kickbacks to an employee of a private company who is not a foreign official, such private-to-private bribery could possibly be charged under the Travel Act.

DOJ has previously charged both individual and corporate defendants in FCPA cases with violations of the Travel Act.[283] For instance, an individual investor was convicted of conspiracy to violate the FCPA and the Travel Act in 2009 where the relevant "unlawful activity" under the Travel Act was an FCPA violation involving a bribery scheme in Azerbaijan.[284] Also in 2009, a California company that engaged in both bribery of foreign officials in violation of the FCPA and commercial bribery in violation of California state law pleaded guilty to conspiracy to violate the FCPA and the Travel Act, among other charges.[285]

Money Laundering

Many FCPA cases also involve violations of anti-money laundering statutes.[286] For example, two Florida executives of a Miami-based telecommunications company were convicted of

FCPA and money laundering conduct where they conducted financial transactions involving the proceeds of specified unlawful activities—violations of the FCPA, the criminal bribery laws of Haiti, and wire fraud—in order to conceal and disguise these proceeds.

Notably, although foreign officials cannot be prosecuted for FCPA violations,[287] they can be prosecuted for money laundering violations where the specified unlawful activity is a violation of the FCPA.[288]

Mail and Wire Fraud

The mail and wire fraud statutes may also apply. In 2006, for example, a wholly owned foreign subsidiary of a U.S. issuer pleaded guilty to both FCPA and wire fraud counts where the scheme included overbilling the subsidiary's customers—both government and private—and using part of the overcharged money to pay kickbacks to the customers' employees. The wire fraud charges alleged that the subsidiary had funds wired from its parent's Oregon bank account to off-the-books bank accounts in South Korea that were controlled by the subsidiary. The funds, amounting to almost $2 million, were then paid to managers of state-owned and private steel production companies in China and South Korea as illegal commission payments and kickbacks that were disguised as refunds, commissions, and other seemingly legitimate expenses.[289]

Certification and Reporting Violations

Certain other licensing, certification, and reporting requirements imposed by the U.S. government can also be implicated in the foreign bribery context. For example, as a condition of its facilitation of direct loans and loan guarantees to a foreign purchaser of U.S. goods and services, the Export-Import Bank of the United States requires the U.S. supplier to make certifications concerning commissions, fees, or other payments paid in connection with the financial assistance and that it has not and will not violate the FCPA.[290] A false certification may give rise to criminal liability for false statements.[291]

Similarly, manufacturers, exporters, and brokers of certain defense articles and services are subject to registration, licensing, and reporting requirements under the Arms Export Control Act (AECA), 22 U.S.C. § 2751, *et seq.*, and its implementing regulations, the International Traffic in Arms Regulations (ITAR), 22 C.F.R. § 120, *et seq.* For example, under AECA and ITAR, all manufacturers and exporters of defense articles and services must register with the Directorate of Defense Trade Controls. The sale of defense articles and services valued at $500,000 or more triggers disclosure requirements concerning fees and commissions, including bribes, in an aggregate amount of $100,000 or more.[292] Violations of AECA and ITAR can result in civil and criminal penalties.[293]

Tax Violations

Individuals and companies who violate the FCPA may also violate U.S. tax law, which explicitly prohibits tax deductions for bribes, such as false sales "commissions" deductions intended to conceal corrupt payments.[294] Internal Revenue Service – Criminal Investigation has been involved in a number of FCPA investigations involving tax violations, as well as other financial crimes like money laundering.

GUIDING PRINCIPLES OF ENFORCEMENT

What Does DOJ Consider When Deciding Whether to Open an Investigation or Bring Charges?

Whether and how DOJ will commence, decline, or otherwise resolve an FCPA matter is guided by the *Principles of Federal Prosecution* in the case of individuals, and the *Principles of Federal Prosecution of Business Organizations* and *FCPA Corporate Enforcement Policy* in the case of companies.

DOJ Principles of Federal Prosecution

The *Principles of Federal Prosecution*, set forth in Chapter 9-27.000 of the Justice Manual,[295] provide guidance for DOJ prosecutors regarding initiating or declining prosecution, selecting charges, and plea-bargaining. The *Principles of Federal Prosecution* provide that prosecutors should recommend or commence federal prosecution if the putative defendant's conduct constitutes a federal offense and the admissible evidence will probably be sufficient to obtain and sustain a conviction unless: (1) no substantial federal interest would be served by prosecution; (2) the person is subject to effective prosecution in another jurisdiction; or (3) an adequate non-criminal alternative to prosecution exists. In assessing the existence of a substantial federal interest, the prosecutor is advised to "weigh all relevant considerations," including the nature and seriousness of the offense; the deterrent effect of prosecution; the person's culpability in connection with the offense; the person's history with respect to criminal activity; the person's willingness to cooperate in the investigation or prosecution of others; and the probable sentence or other consequences if the person is convicted. The *Principles of Federal Prosecution* also set out the considerations to be weighed when deciding whether to enter into a plea agreement with an individual defendant, including the nature and seriousness of the offense and the person's willingness to cooperate, as well as the desirability of prompt and certain disposition of the case and the expense of trial and appeal.[296]

DOJ Principles of Federal Prosecution of Business Organizations

The *Principles of Federal Prosecution of Business Organizations*, set forth in Chapter 9-28.000 of the

Justice Manual,[297] provide guidance regarding the resolution of cases involving corporate wrongdoing. The Principles of Federal Prosecution of Business Organizations recognize that resolution of corporate criminal cases by means other than indictment, including non-prosecution and deferred prosecution agreements, may be appropriate in certain circumstances. Ten factors are considered in conducting an investigation, determining whether to charge a corporation, and negotiating plea or other agreements:

- the nature and seriousness of the offense, including the risk of harm to the public;
- the pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management;
- the corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it;
- the corporation's willingness to cooperate with the government's investigation, including as to potential wrongdoing by the corporation's agents;
- the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging or resolution decision;
- the corporation's timely and voluntary disclosure of wrongdoing;
- the corporation's remedial actions, including any efforts to implement an adequate and effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, or to pay restitution;
- collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution;
- the adequacy of remedies such as civil or regulatory enforcement actions, including remedies resulting from the corporation's cooperation with relevant government agencies; and
- the adequacy of the prosecution of individuals responsible for the corporation's malfeasance.

As these factors illustrate, in many investigations it will be appropriate for a prosecutor to consider a corporation's pre-indictment conduct, including voluntary disclosure, cooperation, and remediation, in determining whether to seek an indictment. In assessing a corporation's cooperation, prosecutors are prohibited from requesting attorney-client privileged materials with two exceptions—when a corporation or its employee asserts an advice-of-counsel defense and when the attorney-client communications were in furtherance of a crime or fraud. Otherwise, an organization's cooperation may only be assessed on the basis of whether it disclosed the relevant facts underlying an investigation—and not on the basis of whether it has waived its attorney-client privilege or work product protection.[298]

DOJ FCPA Corporate Enforcement Policy

The *FCPA Corporate Enforcement Policy* (CEP), contained in the Justice Manual, provides that, where a company voluntarily self-discloses misconduct, fully cooperates, and timely and appropriately remediates, there will be a presumption that DOJ will decline prosecution of the company absent aggravating circumstances.[299] CEP declinations are public and available on the Fraud Section's website at https://www.justice.gov/criminal-fraud/corporate-enforcement-policy/declinations. Aggravating circumstances that may warrant a criminal resolution instead of a declination include, but are not limited to: involvement by executive management of the company in the misconduct; a significant profit to the company from the misconduct; pervasiveness of the misconduct within the company; and criminal recidivism.[300] Even where aggravating circumstances exist, DOJ may still

decline prosecution, as it did in several cases in which senior management engaged in the bribery scheme.[301]

If a criminal resolution is appropriate, where a company that voluntarily self-discloses, fully cooperates, and timely and appropriately remediates, DOJ will accord, or recommend to a sentencing court, a 50% reduction off of the low end of the U.S. Sentencing Guidelines (Guidelines) fine range, except in the case of a criminal recidivist; and generally will not require appointment of a monitor if a company has, at the time of resolution, implemented an effective compliance program.[302]

The CEP also recognizes the potential benefits of corporate mergers and acquisitions, particularly when the acquiring entity has a robust compliance program in place and implements that program as quickly as practicable at the merged or acquired entity. Accordingly, where a company undertakes a merger or acquisition, uncovers misconduct by the merged or acquired entity through thorough and timely due diligence or, in appropriate instances, through post-acquisition audits or compliance integration efforts, and voluntarily self-discloses the misconduct and otherwise takes action consistent with the CEP, there will be a presumption of a declination in accordance with and subject to the other requirements of the CEP. In appropriate cases, an acquiring company that discloses misconduct may be eligible for a declination, even if aggravating circumstances existed as to the acquired entity.

Where a company does not voluntarily self-disclose the misconduct, but nevertheless fully cooperates, and timely and appropriately remediates, the company will receive, or the Department will recommend to a sentencing court, up to a 25% reduction off of the low end of the Guidelines fine range.[303]

To be eligible for the benefits of the CEP, including a declination, the company is required to pay all disgorgement, forfeiture, and/or restitution resulting from the misconduct at issue.[304]

The CEP also provides definitions of the terms "voluntary self-disclosure," "full cooperation," and "timely and appropriate remediation." By outlining in the Justice Manual how DOJ defines these terms and the benefits that will accrue to a company that engages in such behavior, companies can make an informed decision as to whether they believe such behavior is in their best interest. Of course, if a company chooses not to engage in such behavior, and DOJ learns of the misconduct and establishes sufficient proof for prosecution, the company should not expect to receive any benefits outlined in the CEP or to otherwise receive leniency.[305]

The CEP applies only to DOJ, and does not bind or apply to SEC.[306] The CEP and the declinations that have been announced pursuant to it are posted on DOJ's website.[307] Three such cases are as follows:

CEP Declination Example 1

In 2018, DOJ declined prosecution of a privately held company based in the United Kingdom that manufactures and sells equipment used to detect earthquakes and other seismic events. The company had voluntarily self-disclosed to DOJ that it had made numerous payments amounting to nearly $1 million to the director of a Korean government-funded research center. Following the disclosure of these payments, DOJ indicted the director and in July 2017 tried and convicted him in the Central District of California of one count of money laundering in violation of 18 U.S.C. § 1957. The director was subsequently sentenced to 14 months in prison in October 2017.

The company received a declination under

the CEP because it voluntarily self-disclosed, fully cooperated, and timely and appropriately remediated pursuant to the CEP. In addition, the company was the subject of a parallel investigation by the United Kingdom's Serious Fraud Office (SFO) for legal violations relating to the same conduct and committed to accepting responsibility with the SFO (the company subsequently entered into a deferred prosecution with the SFO and agreed to pay approximately £2.07M of gross profits arising from the payments to the director).

CEP Declination Example 2

In 2018, DOJ declined prosecution of an insurance company incorporated and headquartered in Barbados. DOJ's investigation found that the company, through its employees and agents, paid approximately $36,000 in bribes to a Barbadian government official in exchange for insurance contracts resulting in approximately $686,827 in total premiums for the contracts and approximately $93,940 in net profits. Specifically, in or around August 2015 and April 2016, high-level employees of the company took part in a scheme to pay approximately $36,000 in bribes to the Minister of Industry in Barbados, and to launder the bribe payments into the United States.

Despite the high-level involvement of corporate officers in the misconduct, DOJ declined prosecution based on a number of factors, including but not limited to: (1) the company's timely, voluntary self-disclosure of the conduct; (2) the company's thorough and comprehensive investigation; (3) the company's cooperation (including its provision of all known relevant facts about the misconduct) and its agreement to continue to cooperate in DOJ's ongoing investigations and/or prosecutions; (4) the company's agreement to disgorge to DOJ all profits it made from the illegal conduct, which equaled $93,940; (5) the steps the company had taken to enhance its compliance program and its internal accounting controls; (6) the company's remediation, including but not limited to terminating all of the executives and employees who were involved in the misconduct; and (7) the fact that DOJ had been able to identify and charge the culpable individuals.

CEP Declination Example 3

In 2019, DOJ declined prosecution of a publicly traded technology services company. DOJ's investigation found that the company, through its employees, authorized its agents to pay an approximately $2 million bribe to one or more government officials in India in exchange for securing and obtaining a statutorily required planning permit in connection with the development of an office park, as well as other improper payments in connection with other projects in India. Despite the fact that certain members of senior management participated in and directed the criminal conduct at issue, DOJ declined prosecution of the company based on an assessment of the factors set forth in the CEP and the Principles of Federal Prosecution of Business Organizations, including but not limited to: (1) the company's voluntary self-disclosure within two weeks of the Board learning of the criminal conduct; (2) the company's thorough and comprehensive investigation; (3) the company's full and proactive cooperation in the matter (including its provision of all known relevant facts about the misconduct) and its agreement to continue to cooperate in DOJ's ongoing investigations and any prosecutions that might result; (4) the nature and seriousness of the offense; (5) the company's lack of prior criminal history; (6) the existence and effectiveness of the company's pre-existing compliance program, as well as steps that it had taken to enhance its

compliance program and internal accounting controls; (7) the company's full remediation, including but not limited to terminating the employment of, and disciplining, employees and contractors involved in misconduct; (8) the adequacy of remedies such as civil or regulatory enforcement actions, including the company's resolution with SEC and agreement to pay a civil penalty of $6 million and disgorgement; (9) the company's agreement to disgorge the full amount of its cost savings from the bribery; and (10) the fact that, as a result of the company's timely voluntary disclosure, DOJ was able to conduct an independent investigation and identify individuals with culpability for the corporation's malfeasance.

What Does SEC Staff Consider When Deciding Whether to Open an Investigation or Recommend Charges?

SEC's *Enforcement Manual*, published by SEC's Enforcement Division and available on SEC's website,[308] sets forth information about how SEC conducts investigations, as well as the guiding principles that SEC staff considers when determining whether to open or close an investigation and whether civil charges are merited. There are various ways that potential FCPA violations come to the attention of SEC staff, including: tips from informants or whistleblowers; information developed in other investigations; self-reports or public disclosures by companies; referrals from other offices or agencies; public sources, such as media reports and trade publications; and proactive investigative techniques, including risk-based initiatives. Investigations can be formal, such as where SEC has issued a formal order of investigation that authorizes its staff to issue investigative subpoenas for testimony and documents, or informal, such as where the staff proceeds with the investigation without the use of investigative subpoenas.

In determining whether to open an investigation and, if so, whether an enforcement action is warranted, SEC staff considers a number of factors, including: the statutes or rules potentially violated; the egregiousness of the potential violation; the potential magnitude of the violation; whether the potentially harmed group is particularly vulnerable or at risk; whether the conduct is ongoing; whether the conduct can be investigated efficiently and within the statute of limitations period; and whether other authorities, including federal or state agencies or regulators, might be better suited to investigate the conduct. SEC staff also may consider whether the case involves a possibly widespread industry practice that should be addressed, whether the case involves a recidivist, and whether the matter gives SEC an opportunity to be visible in a community that might not otherwise be familiar with SEC or the protections afforded by the securities laws.

For more information about the Enforcement Division's procedures concerning investigations, enforcement actions, and cooperation with other regulators, see the *Enforcement Manual* at https://www.sec.gov/divisions/enforce/enforcementmanual.pdf.

Self-Reporting, Cooperation, and Remedial Efforts

While the conduct underlying any FCPA investigation is obviously a fundamental and threshold consideration in deciding what, if any, action to take, both DOJ and SEC place a high premium on self-reporting, along with cooperation and remedial efforts, in determining the appropriate resolution of FCPA matters.

Criminal Cases

Under DOJ's *Principles of Federal Prosecution of Business Organizations* and the *CEP*, federal prosecutors consider whether the company made a voluntary and timely disclosure as well as the company's willingness to provide relevant information and evidence and identify relevant actors inside and outside the company, including senior executives.

In addition, prosecutors may consider a company's remedial actions, including efforts to improve an existing compliance program or appropriate disciplining of wrongdoers.[309] A company's remedial measures should be meaningful and illustrate its recognition of the seriousness of the misconduct, for example, by taking steps to implement the personnel, operational, and organizational changes necessary to establish an awareness among employees that criminal conduct will not be tolerated.[310]

The *Principles of Federal Prosecution* similarly provide that prosecutors may consider an individual's willingness to cooperate in deciding whether a prosecution should be undertaken and how it should be resolved. Although a willingness to cooperate will not, by itself, generally relieve a person of criminal liability, it may be given "serious consideration" in evaluating whether to enter into a plea agreement with a defendant, depending on the nature and value of the cooperation offered.[311]

The U.S. Sentencing Guidelines similarly take into account an individual defendant's cooperation and voluntary disclosure. Under § 5K1.1, a defendant's cooperation, if sufficiently substantial, may justify the government filing a motion for a reduced sentence. And under § 5K2.16, a defendant's voluntary disclosure of an offense prior to its discovery—if the offense was unlikely to have been discovered otherwise—may warrant a downward departure in certain circumstances. Chapter 8 of the Sentencing Guidelines, which governs the sentencing of organizations, takes into account an organization's remediation as part of an "effective compliance and ethics program." One of the seven elements of such a program provides that after the detection of criminal conduct, "the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program."[312] Having an effective compliance and ethics program may lead to a three-point reduction in an organization's culpability score under § 8C2.5, which affects the fine calculation under the Guidelines. Similarly, an organization's self-reporting, cooperation, and acceptance of responsibility may lead to fine reductions under § 8C2.5(g) by decreasing the culpability score. Conversely, an organization will not qualify for the compliance program reduction when it unreasonably delayed reporting the offense.[313] Similar to § 5K1.1 for individuals, organizations can qualify for departures pursuant to § 8C4.1 of the Guidelines for cooperating in the prosecution of others.

Civil Cases

SEC's Framework for Evaluating Cooperation by Companies

SEC's framework for evaluating cooperation by companies is set forth in its 2001 Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions, which is commonly known as the Seaboard Report.[314] The report, which explained the Commission's decision not to take enforcement action against a public company

for certain accounting violations caused by its subsidiary, details the many factors SEC considers in determining whether, and to what extent, it grants leniency to companies for cooperating in its investigations and for related good corporate citizenship. Specifically, the report identifies four broad measures of a company's cooperation:

- self-policing prior to the discovery of the misconduct, including establishing effective compliance procedures and an appropriate tone at the top;
- self-reporting of misconduct when it is discovered, including conducting a thorough review of the nature, extent, origins, and consequences of the misconduct, and promptly, completely, and effectively disclosing the misconduct to the public, to regulatory agencies, and to self-regulatory organizations;
- remediation, including dismissing or appropriately disciplining wrongdoers, modifying and improving internal controls and procedures to prevent recurrence of the misconduct, and appropriately compensating those adversely affected; and
- cooperation with law enforcement authorities, including providing SEC staff with all information relevant to the underlying violations and the company's remedial efforts.

Since every enforcement matter is different, this analytical framework sets forth general principles but does not limit SEC's broad discretion to evaluate every case individually on its own unique facts and circumstances. Similar to SEC's treatment of cooperating individuals, credit for cooperation by companies may range from taking no enforcement action to pursuing reduced sanctions in connection with enforcement actions.

SEC's Framework for Evaluating Cooperation by Individuals

In 2010, SEC announced a new cooperation program for individuals.[315] SEC staff has a wide range of tools to facilitate and reward cooperation by individuals, from taking no enforcement action to pursuing reduced sanctions in connection with enforcement actions. Although the evaluation of cooperation depends on the specific circumstances, SEC generally evaluates four factors to determine whether, to what extent, and in what manner to credit cooperation by individuals:

- the assistance provided by the cooperating individual in SEC's investigation or related enforcement actions, including, among other things: the value and timeliness of the cooperation, including whether the individual was the first to report the misconduct to SEC or to offer his or her cooperation; whether the investigation was initiated based upon the information or other cooperation by the individual; the quality of the cooperation, including whether the individual was truthful and the cooperation was complete; the time and resources conserved as a result of the individual's cooperation; and the nature of the cooperation, such as the type of assistance provided;
- the importance of the matter in which the individual provided cooperation;
- the societal interest in ensuring that the cooperating individual is held accountable for his or her misconduct, including the severity of the individual's misconduct, the culpability of the individual, and the efforts undertaken by the individual to remediate the harm; and
- the appropriateness of a cooperation credit in light of the profile of the cooperating individual.

Corporate Compliance Program

In a global marketplace, an effective compliance program reinforces a company's internal controls and is essential to detecting and preventing FCPA violations.[316] Effective compliance programs are tailored to the company's specific business and to the risks associated with that business. They are dynamic and evolve as the business and the markets change.

An effective compliance program promotes "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[317] Such a program protects a company's

reputation, ensures investor value and confidence, reduces uncertainty in business transactions, and secures a company's assets.[318] A company's compliance and ethics program can help prevent, detect, remediate, and report misconduct, including FCPA violations, where it is well-constructed, effectively implemented, appropriately resourced, and consistently enforced.

In addition to considering whether a company has self-reported, cooperated, and taken appropriate remedial actions, DOJ and SEC also consider the adequacy and effectiveness of a company's compliance program at the time of the misconduct and at the time of the resolution when deciding what, if any, action to take. In criminal resolutions, the compliance program factors into three key areas of decision: (1) the form of resolution or prosecution, if any; (2) the monetary penalty, if any; and (3) the compliance obligations to be included in any corporate criminal resolution (e.g., whether a compliance monitor is appropriate and the length and nature of any reporting obligations).[319] For example, compliance program adequacy may influence whether or not charges should be resolved through a guilty plea, deferred prosecution agreement (DPA) or non-prosecution agreement (NPA), as well as the appropriate length of any DPA or NPA, or the term of corporate probation.[320] As discussed above, SEC's Seaboard Report focuses, among other things, on a company's self-policing prior to the discovery of the misconduct, including whether it had established effective compliance procedures.[321] Likewise, three of the ten factors set forth in DOJ's Principles of Federal Prosecution of Business Organizations relate, either directly or indirectly, to a compliance program's design, implementation, and effectiveness, including the pervasiveness of wrongdoing within the company, the adequacy and effectiveness of the company's compliance program, and the nature of the company's remedial actions.[322] DOJ also considers the U.S. Sentencing Guidelines' elements of an effective compliance program, as set forth in § 8B2.1 of the Guidelines.

These considerations reflect the recognition that a company's failure to prevent every single violation does not necessarily mean that a particular company's compliance program was not generally effective. DOJ and SEC understand that "no compliance program can ever prevent all criminal activity by a corporation's employees,"[323] and they do not hold companies to a standard of perfection. An assessment of a company's compliance program, including its design and good faith implementation and enforcement, is an important part of the government's assessment of whether a violation occurred, and if so, what action should be taken. In appropriate circumstances, DOJ and SEC may decline to pursue charges against a company based on the company's effective compliance program, or may otherwise seek to reward a company for its program, even when that program did not prevent the particular underlying FCPA violation that gave rise to the investigation.[324]

DOJ and SEC have no formulaic requirements regarding compliance programs. Rather, they employ a common-sense and pragmatic approach to evaluating compliance programs, making inquiries related to three basic questions:

- Is the company's compliance program well designed?
- Is it being applied in good faith? In other words, is the program adequately resourced and empowered to function effectively?
- Does it work in practice?[325]

This guide contains information regarding some of the basic elements DOJ and SEC consider when evaluating compliance programs. Although

the focus is on compliance with the FCPA, given the existence of anti-corruption laws in many other countries, businesses should consider designing programs focused on anti-corruption compliance more broadly.[326]

Hallmarks of Effective Compliance Programs

Individual companies may have different compliance needs depending on their size and the particular risks associated with their businesses, among other factors. When it comes to compliance, there is no one-size-fits-all program. Thus, the discussion below is meant to provide insight into the aspects of compliance programs that DOJ and SEC assess, recognizing that companies may consider a variety of factors when making their own determination of what is appropriate for their specific business needs.[327] Indeed, small and medium-size enterprises likely will have different compliance programs from large multinational corporations, a fact DOJ and SEC take into account when evaluating companies' compliance programs.

Compliance programs that employ a "check-the-box" approach may be inefficient and, more importantly, ineffective. Because each compliance program should be tailored to an organization's specific needs, risks, and challenges, the information provided below should not be considered a substitute for a company's own assessment of the corporate compliance program most appropriate for that particular business organization. In the end, if designed carefully, implemented earnestly, and enforced fairly, a company's compliance program—no matter how large or small the organization—will allow the company generally to prevent violations, detect those that do occur, and remediate them promptly and appropriately.

Commitment from Senior Management and a Clearly Articulated Policy Against Corruption

Within a business organization, compliance begins with the board of directors and senior executives setting the proper tone for the rest of the company. Managers and employees take their cues from these corporate leaders. Thus, DOJ and SEC consider the commitment of corporate leaders to a "culture of compliance"[328] and look to see if this high-level commitment is also reinforced and implemented by middle managers and employees at all levels of a business. A well-designed compliance program that is not enforced in good faith, such as when corporate management explicitly or implicitly encourages employees to engage in misconduct to achieve business objectives, will be ineffective. DOJ and SEC have often encountered companies with compliance programs that are strong on paper but that nevertheless have significant FCPA violations because management has failed to effectively implement the program even in the face of obvious signs of corruption. This may be the result of aggressive sales staff preventing compliance personnel from doing their jobs effectively and of senior management, more concerned with securing a valuable business opportunity than enforcing a culture of compliance, siding with the sales team. The higher the financial stakes of the transaction, the greater the temptation for management to choose profit over compliance.

A strong ethical culture directly supports a strong compliance program. By adhering to ethical standards, senior managers will inspire middle managers to reinforce those standards. Compliant middle managers, in turn, will encourage employees to strive to attain those standards throughout the organizational structure.[329]

In short, compliance with the FCPA and ethical rules must start at the top. DOJ and SEC thus

evaluate whether senior management has clearly articulated company standards, communicated them in unambiguous terms, adhered to them scrupulously, and disseminated them throughout the organization.

Code of Conduct and Compliance Policies and Procedures

A company's code of conduct is often the foundation upon which an effective compliance program is built. As DOJ has repeatedly noted in its charging documents, the most effective codes are clear, concise, and accessible to all employees and to those conducting business on the company's behalf. Indeed, it would be difficult to effectively implement a compliance program if it was not available in the local language so that employees in foreign subsidiaries can access and understand it. When assessing a compliance program, DOJ and SEC will review whether the company has taken steps to make certain that the code of conduct remains current and effective and whether a company has periodically reviewed and updated its code.

Whether a company has policies and procedures that outline responsibilities for compliance within the company, detail proper internal controls, auditing practices, and documentation policies, and set forth disciplinary procedures will also be considered by DOJ and SEC. These types of policies and procedures will depend on the size and nature of the business and the risks associated with the business. Effective policies and procedures require an in-depth understanding of the company's business model, including its products and services, third-party agents, customers, government interactions, and industry and geographic risks. The risks that a company may need to address include the nature and extent of transactions with foreign governments, including payments to foreign officials; use of third parties; gifts, travel, and entertainment expenses; charitable and political donations; and facilitating and expediting payments. For example, some companies with global operations have created web-based approval processes to review and approve routine gifts, travel, and entertainment involving foreign officials and private customers with clear monetary limits and annual limitations. Many of these systems have built-in flexibility so that senior management, or in-house legal counsel, can be apprised of and, in appropriate circumstances, approve unique requests. These types of systems can be a good way to conserve corporate resources while, if properly implemented, preventing and detecting potential FCPA violations.

Regardless of the specific policies and procedures implemented, these standards should apply to personnel at all levels of the company.

Oversight, Autonomy, and Resources

In appraising a compliance program, DOJ and SEC also consider whether a company has assigned responsibility for the oversight and implementation of a company's compliance program to one or more specific senior executives within an organization.[330] Those individuals must have appropriate authority within the organization, adequate autonomy from management, and sufficient resources to ensure that the company's compliance program is implemented effectively.[331] Adequate autonomy generally includes direct access to an organization's governing authority, such as the board of directors and committees of the board of directors (e.g., the audit committee).[332] Depending on the size and structure of an organization, it may be appropriate for day-to-day operational responsibility to be

delegated to other specific individuals within a company.[333] DOJ and SEC recognize that the reporting structure will depend on the size and complexity of an organization. Moreover, the amount of resources devoted to compliance will depend on the company's size, complexity, industry, geographical reach, and risks associated with the business. In assessing whether a company has reasonable internal controls, DOJ and SEC typically consider whether the company devoted adequate staffing and resources to the compliance program given the size, structure, and risk profile of the business.

Risk Assessment

Assessment of risk is fundamental to developing a strong compliance program, and is another factor DOJ and SEC evaluate when assessing a company's compliance program.[334] One-size-fits-all compliance programs are generally ill-conceived and ineffective because resources inevitably are spread too thin, with too much focus on low-risk markets and transactions to the detriment of high-risk areas. Devoting a disproportionate amount of time policing modest entertainment and gift-giving instead of focusing on large government bids, questionable payments to third-party consultants, or excessive discounts to resellers and distributors may indicate that a company's compliance program is ineffective. A $50 million contract with a government agency in a high-risk country warrants greater scrutiny than modest and routine gifts and entertainment. Similarly, performing identical due diligence on all third-party agents, irrespective of risk factors, is often counterproductive, diverting attention and resources away from those third parties that pose the most significant risks. DOJ and SEC will give meaningful credit to a company that implements in good faith a comprehensive, risk-based compliance program, even if that program does not prevent an infraction in a low risk area because greater attention and resources had been devoted to a higher risk area. Conversely, a company that fails to prevent an FCPA violation on an economically significant, high-risk transaction because it failed to perform a level of due diligence commensurate with the size and risk of the transaction is likely to receive reduced credit based on the quality and effectiveness of its compliance program.

As a company's risk for FCPA violations increases, that business should consider increasing its compliance procedures, including due diligence and periodic internal audits. The degree of appropriate due diligence is fact-specific and should vary based on industry, country, size, and nature of the transaction, and the method and amount of third-party compensation. Factors to consider, for instance, include risks presented by: the country and industry sector, the business opportunity, potential business partners, level of involvement with governments, amount of government regulation and oversight, and exposure to customs and immigration in conducting business affairs. When assessing a company's compliance program, DOJ and SEC take into account whether and to what degree a company analyzes and addresses the particular risks it faces.

Training and Continuing Advice

Compliance policies cannot work unless effectively communicated throughout a company. Accordingly, DOJ and SEC will evaluate whether a company has taken steps to ensure that relevant policies and procedures have been communicated throughout the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where

appropriate, agents and business partners.[335] For example, many larger companies have implemented a mix of web-based and in-person training conducted at varying intervals. Such training typically covers company policies and procedures, instruction on applicable laws, practical advice to address real-life scenarios, and case studies. Regardless of how a company chooses to conduct its training, however, the information should be presented in a manner appropriate for the targeted audience, including providing training and training materials in the local language. For example, companies may want to consider providing different types of training to their sales personnel and accounting personnel with hypotheticals or sample situations that are similar to the situations they might encounter. In addition to the existence and scope of a company's training program, a company should develop appropriate measures, depending on the size and sophistication of the particular company, to provide guidance and advice on complying with the company's ethics and compliance program, including when such advice is needed urgently. Such measures will help ensure that the compliance program is understood and followed appropriately at all levels of the company.

Incentives and Disciplinary Measures

In addition to evaluating the design and implementation of a compliance program throughout an organization, enforcement of that program is fundamental to its effectiveness.[336] A compliance program should apply from the board room to the supply room—no one should be beyond its reach. DOJ and SEC will thus consider whether, when enforcing a compliance program, a company has appropriate and clear disciplinary procedures, whether those procedures are applied reliably and promptly, and whether they are commensurate with the violation. Many companies have found that publicizing disciplinary actions internally, where appropriate under local law, can have an important deterrent effect, demonstrating that unethical and unlawful actions have swift and sure consequences.

DOJ and SEC recognize that positive incentives can also drive compliant behavior. The incentives can take many forms such as personnel evaluations and promotions, rewards for improving and developing a company's compliance program, and rewards for ethics and compliance leadership.[337] Some organizations, for example, have made adherence to compliance a significant metric for management's bonuses so that compliance becomes an integral part of management's everyday concern. Beyond financial incentives, some companies have highlighted compliance within their organizations by recognizing compliance professionals and internal audit staff. Others have made working in the company's compliance organization a way to advance an employee's career.

SEC, for instance, has encouraged companies to embrace methods to incentivize ethical and lawful behavior:

> [M]ake integrity, ethics and compliance part of the promotion, compensation and evaluation processes as well. For at the end of the day, the most effective way to communicate that "doing the right thing" is a priority, is to reward it. Conversely, if employees are led to believe that, when it comes to compensation and career advancement, all that counts is short-term profitability, and that cutting ethical corners is an acceptable way of getting there, they'll perform to that measure. To cite an example from a different walk of life: a college football coach can be told that the graduation rates of his players are what matters, but he'll know differently if the sole focus of his contract extension talks or the decision to fire him is his win-loss record.[338]

No matter what the disciplinary scheme or potential incentives a company decides to adopt, DOJ and SEC will consider whether they are fairly and consistently applied across the organization. No executive should be above compliance, no employee below compliance, and no person within an organization deemed too valuable to be disciplined, if warranted. Rewarding good behavior and sanctioning bad behavior reinforces a culture of compliance and ethics throughout an organization.

Third-Party Due Diligence and Payments

DOJ's and SEC's FCPA enforcement actions demonstrate that third parties, including agents, consultants, and distributors, are commonly used to conceal the payment of bribes to foreign officials in international business transactions. Risk-based due diligence is particularly important with third parties and will also be considered by DOJ and SEC in assessing the effectiveness of a company's compliance program.

Although the degree of appropriate due diligence may vary based on industry, country, size and nature of the transaction, and historical relationship with the third party, some guiding principles always apply.

First, as part of risk-based due diligence, companies should understand the qualifications and associations of its third-party partners, including its business reputation, and relationship, if any, with foreign officials. The degree of scrutiny should increase as red flags surface.

Second, companies should have an understanding of the business rationale for including the third party in the transaction. Among other things, the company should understand the role of and need for the third party and ensure that the contract terms specifically describe the services to be performed. Additional considerations include payment terms and how those payment terms compare to typical terms in that industry and country, as well as the timing of the third party's introduction to the business. Moreover, companies may want to confirm and document that the third party is actually performing the work for which it is being paid and that its compensation is commensurate with the work being provided.

Third, companies should undertake some form of ongoing monitoring of third-party relationships.[339] Where appropriate, this may include updating due diligence periodically, exercising audit rights, providing periodic training, and requesting annual compliance certifications by the third party.

In addition to considering a company's due diligence on third parties, DOJ and SEC also assess whether the company has informed third parties of the company's compliance program and commitment to ethical and lawful business practices and, where appropriate, whether it has sought assurances from third parties, through certifications and otherwise, of reciprocal commitments. These can be meaningful ways to mitigate third-party risk.

Hypothetical: Third-Party Vetting

Part 1: Consultants

Company A, a U.S. issuer headquartered in Delaware, wants to start doing business in a country that poses high risks of corruption. Company A learns about a potential $50 million contract with the country's Ministry of Immigration. This is a very attractive opportunity to Company A, both for its profitability and to open the door to future projects with the government. At the suggestion of the company's senior vice president of international sales (Sales Executive), Company A hires a local businessman who assures them that he has strong ties to political and government leaders in the country and can help them win the contract. Company A enters into a consulting contract with the local businessman (Consultant). The agreement requires Consultant to use his best efforts to help the company win the business and provides for Consultant to receive a significant monthly retainer as well as a success fee of 3% of the value of any contract the company wins.

What steps should Company A consider taking before hiring Consultant?

There are several factors here that might lead Company A to perform heightened FCPA-related due diligence prior to retaining Consultant: (1) the market (high-risk country); (2) the size and significance of the deal to the company; (3) the company's first time use of this particular consultant; (4) the consultant's strong ties to political and government leaders; (5) the success fee structure of the contract; and (6) the vaguely defined services to be provided. In order to minimize the likelihood of incurring FCPA liability, Company A should carefully vet Consultant and his role in the transaction, including close scrutiny of the relationship between Consultant and any Ministry of Immigration officials or other government officials. Although there is nothing inherently illegal about contracting with a third party that has close connections to politicians and government officials to perform legitimate services on a transaction, this type of relationship can be susceptible to corruption. Among other things, Company A may consider conducting due diligence on Consultant, including background and reference checks; ensuring that the contract spells out exactly what services and deliverables (such as written status reports or other documentation) Consultant is providing; training Consultant on the FCPA and other anti-corruption laws; requiring Consultant to represent that he will abide by the FCPA and other anti-corruption laws; including audit rights in the contract (and exercising those rights); and ensuring that payments requested by Consultant have the proper supporting documentation before they are approved for payment.

Part 2: Distributors and Local Partners

Assume the following alternative facts:

Instead of hiring Consultant, Company A retains an often-used local distributor (Distributor) to sell Company A's products to the Ministry of Immigration. In negotiating the pricing structure, Distributor, which had introduced the project to Company A, claims that the standard discount price to Distributor creates insufficient margin for Distributor to cover warehousing, distribution, installation, marketing, and training costs and requests an additional discount or rebate, or, in the alternative, a contribution to its marketing efforts, either in the form of a lump sum or as a percentage of the total contract. The requested discount/allowance is significantly larger than usual, although there is precedent at Company A for granting this level of discount in unique circumstances. Distributor further advises Company A that the Ministry's procurement officials responsible for awarding the contract have expressed a strong preference for including a particular local company (Local Partner) in the transaction as a subcontractor of Company A

(cont'd)

to perform installation, training, and other services that would normally have been performed by Distributor of Company A. According to Distributor, the Ministry has a solid working relationship with Local Partner, and it would cause less disruption for Local Partner to perform most of the on-site work at the Ministry. One of the principals (Principal 1) of the Local Partner is an official in another government ministry.

What additional compliance considerations do these alternative facts raise?

As with Consultant in the first scenario above, Company A should carefully vet Distributor and Local Partner and their roles in the transaction in order to minimize the likelihood of incurring FCPA liability. While Company A has an established relationship with Distributor, the fact that Distributor has requested an additional discount warrants further inquiry into the economic justification for the change, particularly where, as here, the proposed transaction structure contemplates paying Local Partner to provide many of the same services that Distributor would otherwise provide. In many cases, it may be appropriate for distributors to receive larger discounts to account for unique circumstances in particular transactions. That said, a common mechanism to create additional margin for bribe payments is through excessive discounts or rebates to distributors. Accordingly, when a company has pre-existing relationships with distributors and other third parties, transaction-specific due diligence—including an analysis of payment terms to confirm that the payment is commensurate with the work being performed—can be critical even in circumstances where due diligence of the distributor or other third party raises no initial red flags.

Company A should carefully scrutinize the relationship among Local Partner, Distributor, and Ministry of Immigration officials. While there is nothing inherently illegal about contracting with a third party that is recommended by the end-user, or even hiring a government official to perform legitimate services on a transaction unrelated to his or her government job, these facts raise additional red flags that warrant significant scrutiny. Among other things, Company A would be well-advised to require Principal 1 to verify that he will have no role in the Ministry of Immigration's decision to award the contract to Company A, notify the Ministry of Immigration and his own ministry of his proposed involvement in the transaction, and certify that he will abide by the FCPA and other anti-corruption laws and that his involvement in the transaction is permitted under local law.

Assume the following additional facts:

Under its company policy for a government transaction of this size, Company A requires both finance and compliance approval. The finance officer is concerned that the discounts to Distributor are significantly larger than what they have approved for similar work and will cut too deeply into Company A's profit margin. The finance officer is also skeptical about including Local Partner to perform some of the same services that Company A is paying Distributor to perform. Unsatisfied with Sales Executive's explanation, she requests a meeting with Distributor and Principal 1. At the meeting, Distributor and Principal 1 offer vague and inconsistent justifications for the payments and fail to provide any supporting analysis, and Principal 1 seems to have no real expertise in the industry. During a coffee break, Distributor comments to Sales Executive that the finance officer is naïve about "how business is done in my country." Following the meeting, Sales Executive dismisses the finance officer's concerns, assuring her that the proposed transaction structure is reasonable and legitimate. Sales Executive also reminds the finance officer that "the deal is key to their growth in the industry."

The compliance officer focuses his due diligence on vetting Distributor and Local Partner and hires a business investigative firm to conduct a background check. Distributor appears reputable, capable, and financially stable and is willing to take on real risk in the project, financial and otherwise. However, the compliance officer learns that Distributor has established an offshore bank account for the transaction.

(cont'd)

The compliance officer further learns that Local Partner's business was organized two years ago and appears financially stable but has no expertise in the industry and has established an offshore shell company and bank account to conduct this transaction. The background check also reveals that Principal 1 is a former college roommate of a senior official of the Ministry of Immigration. The Sales Executive dismisses the compliance officer's concerns, commenting that what Local Partner does with its payments "isn't our problem." Sales Executive also strongly objects to the compliance officer's request to meet with Principal 1 to discuss the offshore company and account, assuring him that it was done for legitimate tax purposes and complaining that if Company A continues to "harass" Local Partner and Distributor, they would partner with Company A's chief competitor. The compliance officer and the finance officer discuss their concerns with each other but ultimately sign off on the deal even though their questions had not been answered. Their decision is motivated in large part by their conversation with Sales Executive, who told them that this was the region's most important contract and that the detailed FCPA questionnaires and robust anti-corruption representations in the contracts placed the burden on Distributor and Local Partner to act ethically.

Company A goes forward with the Distributor and Local Partner agreements and wins the contract after six months. The finance officer approves Company A's payments to Local Partner via the offshore account, even though Local Partner's invoices did not contain supporting detail or documentation of any services provided. Company A recorded the payments as legitimate operational expenses on its books and records. Sales Executive received a large year-end bonus due to the award of the contract. In fact, Local Partner and Distributor used part of the payments and discount margin, respectively, to funnel bribe payments to several Ministry of Immigration officials, including Principal 1's former college roommate, in exchange for awarding the contract to Company A. Thousands of dollars are also wired to the personal offshore bank account of Sales Executive.

How would DOJ and SEC evaluate the potential FCPA liability of Company A and its employees?

This is not the case of a single "rogue employee" circumventing an otherwise robust compliance program. Although Company A's finance and compliance officers had the correct instincts to scrutinize the structure and economics of the transaction and the role of the third parties, their due diligence was incomplete. When the initial inquiry identified significant red flags, they approved the transaction despite knowing that their concerns were unanswered or the answers they received raised additional concerns and red flags. Relying on due diligence questionnaires and anti-corruption representations is insufficient, particularly when the risks are readily apparent. Nor can Company A or its employees shield themselves from liability because it was Distributor and Local Partner—rather than Company A directly—that made the payments.

The facts suggest that Sales Executive had actual knowledge of or was willfully blind to the consultant's payment of the bribes. He also personally profited from the scheme (both from the kickback and from the bonus he received from the company) and intentionally discouraged the finance and compliance officers from learning the full story. Sales Executive is therefore subject to liability under the anti-bribery, books and records, and internal controls provisions of the FCPA, and others may be as well. Company A may also be liable for violations of the anti-bribery, books and records, and internal controls provisions of the FCPA given the number and significance of red flags that established a high probability of bribery and the role of employees and agents acting on the company's behalf.

Confidential Reporting and Internal Investigation

An effective compliance program should include a mechanism for an organization's employees and others to report suspected or actual misconduct or violations of the company's policies on a confidential basis and without fear of retaliation.[340] Companies may employ, for example, anonymous hotlines or ombudsmen. Moreover, once an allegation is made, companies should have in place an efficient, reliable, and properly funded process for investigating the allegation and documenting the company's response, including any disciplinary or remediation measures taken. Companies will want to consider taking "lessons learned" from any reported violations and the outcome of any resulting investigation to update their internal controls and compliance program and focus future training on such issues, as appropriate.

Continuous Improvement: Periodic Testing and Review

Finally, a good compliance program should constantly evolve. A company's business changes over time, as do the environments in which it operates, the nature of its customers, the laws that govern its actions, and the standards of its industry. In addition, compliance programs that do not just exist on paper but are followed in practice will inevitably uncover compliance weaknesses and require enhancements. Consequently, DOJ and SEC evaluate whether companies regularly review and improve their compliance programs and do not allow them to become stale.

An organization should take the time to review and test its controls, and it should think critically about its potential weaknesses and risk areas. For example, some companies have undertaken employee surveys to measure their compliance culture and strength of internal controls, identify best practices, and detect new risk areas. Other companies periodically test their internal controls with targeted audits to make certain that controls on paper are working in practice. DOJ and SEC will give meaningful credit to thoughtful efforts to create a sustainable compliance program if a problem is later discovered. Similarly, undertaking proactive evaluations before a problem strikes can lower the applicable penalty range under the U.S. Sentencing Guidelines.[341] Although the nature and the frequency of proactive evaluations may vary depending on the size and complexity of an organization, the idea behind such efforts is the same: continuous improvement and sustainability.[342]

Mergers and Acquisitions: Pre-Acquisition Due Diligence and Post-Acquisition Integration

In the context of the FCPA, mergers and acquisitions present both risks and opportunities. A company that does not perform adequate FCPA due diligence prior to a merger or acquisition may face both legal and business risks.[343] Perhaps most commonly, inadequate due diligence can allow a course of bribery to continue—with all the attendant harms to a business' profitability and reputation, as well as potential civil and criminal liability.

In contrast, companies that conduct effective FCPA due diligence on their acquisition targets are able to evaluate more accurately each target's value and negotiate for the costs of the bribery to be borne by the target. In addition, such actions demonstrate to DOJ and SEC a company's commitment to compliance and are taken into account when evaluating any potential enforcement action. For example, DOJ and SEC declined to take enforcement action against an acquiring issuer when the issuer, among other things, uncovered the corruption at the company being acquired as part of due diligence, ensured that the corruption was voluntarily disclosed to the government,

cooperated with the investigation, and incorporated the acquired company into its compliance program and internal controls. On the other hand, SEC took action against the acquired company, and DOJ took action against a subsidiary of the acquired company.[344] When pre-acquisition due diligence is not possible, DOJ has described procedures, contained in Opinion Procedure Release No. 08-02, pursuant to which companies can nevertheless be rewarded if they choose to conduct thorough post-acquisition FCPA due diligence.[345]

FCPA due diligence, however, is normally only a portion of the compliance process for mergers and acquisitions. DOJ and SEC evaluate whether the acquiring company promptly incorporated the acquired company into all of its internal controls, including its compliance program. Companies should consider training new employees, reevaluating third parties under company standards, and, where appropriate, conducting audits on new business units.

For example, as a result of due diligence conducted by a California-based issuer before acquiring the majority interest in a joint venture, the issuer learned of corrupt payments to obtain business. However, the issuer only implemented its internal controls "halfway" so as not to "choke the sales engine and cause a distraction for the sales guys." As a result, the improper payments continued, and the issuer was held liable for violating the FCPA's internal controls and books and records provisions.[346]

Investigation, Analysis, and Remediation of Misconduct

The truest measure of an effective compliance program is how it responds to misconduct. Accordingly, for a compliance program to be truly effective, it should have a well-functioning and appropriately funded mechanism for the timely and thorough investigations of any allegations or suspicions of misconduct by the company, its employees, or agents. An effective investigations structure will also have an established means of documenting the company's response, including any disciplinary or remediation measures taken.

In addition to having a mechanism for responding to the specific incident of misconduct, the company's program should also integrate lessons learned from any misconduct into the company's policies, training, and controls. To do so, a company will need to analyze the root causes of the misconduct to timely and appropriately remediate those causes to prevent future compliance breaches.

Other Guidance on Compliance and International Best Practices

In addition to this guide, DOJ has published guidance concerning the Evaluation of Corporate Compliance Programs.[347] The Evaluation of Corporate Compliance Programs is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate: (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations). The DOJ compliance guidance provides companies insight into the types of questions that prosecutors ask to evaluate and assess a company's compliance program.

In addition, the U.S. Departments of Commerce and State have both issued publications that contain guidance regarding compliance programs. The Department of Commerce's International Trade Administration

has published *Business Ethics: A Manual for Managing a Responsible Business Enterprise in Emerging Market Economies*,[348] and the Department of State has published *Fighting Global Corruption: Business Risk Management*.[349]

There is also a developing international consensus on compliance best practices, and a number of inter-governmental and non-governmental organizations have issued guidance regarding best practices for compliance.[350] Most notably, the OECD's 2009 Anti-Bribery Recommendation and its Annex II, *Good Practice Guidance on Internal Controls, Ethics, and Compliance*,[351] published in February 2010, were drafted based on consultations with the private sector and civil society and set forth specific good practices for ensuring effective compliance programs and measures for preventing and detecting foreign bribery. In addition, businesses may wish to refer to the following resources:

- Asia-Pacific Economic Cooperation—*Anti-Corruption Code of Conduct for Business*[352]
- International Chamber of Commerce—*ICC Rules on Combating Corruption*[353]
- Transparency International—*Business Principles for Countering Bribery*[354]
- United Nations Global Compact—*The Ten Principles*[355]
- World Bank—*Integrity Compliance Guidelines*[356]
- World Economic Forum—*Partnering Against Corruption–Principles for Countering Bribery*[357]

Compliance Program Case Study

DOJ and SEC actions relating to a financial institution's real estate transactions with a government agency in China illustrate the benefits of implementing and enforcing a comprehensive risk-based compliance program. The case involved a joint venture real estate investment in the Luwan District of Shanghai, China, between a U.S.-based financial institution and a state-owned entity that functioned as the District's real estate arm. The government entity conducted the transactions through two special purpose vehicles ("SPVs"), with the second SPV purchasing a 12% stake in a real estate project.

The financial institution, through a robust compliance program, frequently trained its employees, imposed a comprehensive payment-approval process designed to prevent bribery, and staffed a compliance department with a direct reporting line to the board of directors. As appropriate given the industry, market, and size and structure of the transactions, the financial institution (1) provided extensive FCPA training to the senior executive responsible for the transactions and (2) conducted extensive due diligence on the transactions, the local government entity, and the SPVs. Due diligence on the entity included reviewing Chinese government records; speaking with sources familiar with the Shanghai real estate market; checking the government entity's payment records and credit references; conducting an on-site visit and placing a pretextual telephone call to the entity's offices; searching media sources; and conducting background checks on the entity's principals. The financial institution vetted the SPVs by obtaining a letter with designated bank account information from a Chinese official associated with the government entity (the "Chinese Official"); using an international law firm to request and review 50 documents from the SPVs' Canadian attorney; interviewing the attorney; and interviewing the SPVs' management.

Notwithstanding the financial institution's robust compliance program and good faith enforcement of it, the company failed to learn that the Chinese Official personally owned nearly 50% of the second SPV (and therefore a nearly 6% stake in the joint venture) and that the SPV was used as a vehicle for corrupt payments. This failure was due, in large part, to misrepresentations by the Chinese Official, the financial institution's executive in charge of the project, and the SPV's attorney that the SPV was 100% owned and controlled by the government entity. DOJ and SEC declined to take enforcement action against the financial institution, and its executive pleaded guilty to conspiracy to violate the FCPA's internal control provisions and also settled with SEC.

FCPA PENALTIES, SANCTIONS, AND REMEDIES

What Are the Potential Consequences for Violations of the FCPA?

The FCPA provides for different criminal and civil penalties for companies and individuals.

Criminal Penalties

For each violation of the anti-bribery provisions, the FCPA provides that corporations and other business entities are subject to a fine of up to $2 million.[358] Individuals, including officers, directors, stockholders, and agents of companies, are subject to a fine of up to $250,000 and imprisonment for up to five years.[359]

For each violation of the accounting provisions, the FCPA provides that corporations and other business entities are subject to a fine of up to $25 million.[360] Individuals are subject to a fine of up to $5 million and imprisonment for up to 20 years.[361]

Under the Alternative Fines Act, 18 U.S.C. § 3571(d), courts may impose significantly higher fines than those provided by the FCPA—up to twice the benefit that the defendant obtained by making the corrupt payment, as long as the facts supporting the increased fines are included in the indictment and either proved to the jury beyond a reasonable doubt or admitted in a guilty plea proceeding.[362] Fines imposed on individuals may not be paid by their employer or principal.[363]

U.S. Sentencing Guidelines

When calculating penalties for violations of the FCPA, DOJ focuses its analysis on the U.S. Sentencing Guidelines[364] in all of its resolutions, including guilty pleas, DPAs, and NPAs. The Guidelines provide a very detailed and predictable structure for calculating penalties for all federal crimes, including violations of the FCPA. To determine the appropriate penalty, the "offense level" is first calculated by examining both the severity of the crime and facts specific to the crime, with appropriate reductions for cooperation and acceptance of responsibility, and, for business entities, additional factors such as voluntary disclosure, pre-existing compliance programs, and remediation.

The Guidelines provide different penalties for the different provisions of the FCPA. The initial offense level for violations of the anti-bribery provisions is determined under § 2C1.1, while violations of the accounting provisions are assessed under § 2B1.1. For individuals, the initial offense level is modified by factors set forth in Chapters 3, 4, and 5 of the Guidelines[365] to identify a final offense level. This final offense level, combined with other factors, is used to determine whether the Guidelines would recommend that incarceration is appropriate, the length of any term of incarceration, and the appropriate amount of any fine. For corporations, the offense level is modified by factors particular to organizations as described in Chapter 8 to determine the applicable organizational penalty.

For example, violations of the anti-bribery provisions are calculated pursuant to § 2C1.1. The offense level is determined by first identifying the base offense level;[366] adding additional levels based on specific offense characteristics, including whether the offense involved more than one bribe, the value of the bribe or the benefit that was conferred, and the level of the public official;[367] adjusting the offense level based on the defendant's role in the offense;[368] and using the total offense level as well as the defendant's criminal history category to determine the advisory guideline range.[369] For violations of the accounting provisions assessed under § 2B1.1, the procedure is generally the same, except that the specific offense characteristics differ. For instance, for violations of the FCPA's accounting provisions, the offense level may be increased if a substantial part of the scheme occurred outside the United States or if the defendant was an officer or director of a publicly traded company at the time of the offense.[370]

For companies, the offense level is calculated pursuant to §§ 2C1.1 or 2B1.1 in the same way as for an individual—by starting with the base offense level and increasing it as warranted by any applicable specific offense characteristics. The organizational guidelines found in Chapter 8, however, provide the structure for determining the final advisory guideline fine range for organizations. The base fine consists of the greater of the amount corresponding to the total offense level, calculated pursuant to the Guidelines, or the pecuniary gain or loss from the offense.[371] This base fine is then multiplied by a culpability score that can either reduce the fine to as little as five percent of the base fine or increase the recommended fine to up to four times the amount of the base fine.[372] As described in § 8C2.5, this culpability score is calculated by taking into account numerous factors such as the size of the organization committing the criminal acts; the involvement in or tolerance of criminal activity by high-level personnel within the organization; and prior misconduct or obstructive behavior. The culpability score is reduced if the organization had an effective pre-existing compliance program to prevent violations and if the organization voluntarily disclosed the offense, cooperated in the investigation, and accepted responsibility for the criminal conduct.[373]

Civil Penalties

Although only DOJ has the authority to pursue criminal actions, both DOJ and SEC have civil enforcement authority under the FCPA. DOJ may pursue civil actions for anti-bribery violations by domestic concerns (and their officers, directors, employees, agents, or stockholders) and foreign nationals and companies for violations while in the United States, while SEC may pursue civil actions against issuers and their officers, directors,

employees, agents, or stockholders for violations of the anti-bribery and the accounting provisions.[374]

For violations of the anti-bribery provisions, corporations and other business entities are subject to a civil penalty of up to $21,410 per violation.[375] Individuals, including officers, directors, stockholders, and agents of companies, are similarly subject to a civil penalty of up to $21,410 per violation,[376] which may not be paid by their employer or principal.[377]

For violations of the accounting provisions in district court actions, SEC may obtain a civil penalty not to exceed the greater of (a) the gross amount of the pecuniary gain to the defendant as a result of the violations or (b) a specified dollar limitation. The specified dollar limitations are based on the nature of the violation and potential risk to investors, ranging from $9,639 to $192,768 for an individual and $96,384 to $963,837 for a company.[378] SEC may obtain civil penalties both in actions filed in federal court and in administrative proceedings.[379]

Forfeiture and Disgorgement

In addition to criminal and civil penalties, companies may also be required to forfeit the proceeds of their crimes, or disgorge the profits generated from the crimes. While the purpose of a penalty or fine is to punish and deter misconduct, the purpose of forfeiture and disgorgement is primarily to return the perpetrator to the same position as before the crime, ensuring that the perpetrator does not profit from the misconduct. However, in *Kokesh v. SEC*, the Supreme Court ruled that the civil disgorgement remedy is subject to the same five-year statute of limitations as a penalty under 28 U.S.C. § 2462. Following *Kokesh*, in *SEC v. Liu*, the court again addressed the disgorgement remedy stating, "[e]quity courts have routinely deprived wrongdoers of their net profits from unlawful activity," and holding that disgorgement is permissible equitable relief when it does not exceed a wrongdoer's net profits and is awarded for victims.[380]

Coordinated Resolutions and Avoiding "Piling On"

In resolving cases against companies, DOJ and SEC strive to avoid imposing duplicative penalties, forfeiture, and disgorgement for the same conduct. DOJ and SEC attempt to similarly credit fines, penalties, forfeiture, and disgorgement of foreign authorities resolving with the same company for the same conduct. In a case involving a publicly-traded Brazilian petrochemical company, DOJ, SEC, Brazilian authorities, and Swiss authorities credited one another in imposing fines and disgorgement.[381]

DOJ has coordinated resolutions with foreign authorities in more than 10 cases, and SEC has coordinated resolutions with foreign authorities in at least five.[382] DOJ has memorialized this practice of coordinating resolutions to avoid "piling on" in the Justice Manual, which instructs prosecutors to "endeavor, as appropriate, to coordinate with and consider the amount of fines, penalties, and/or forfeiture paid to other federal, state, local, or foreign enforcement authorities that are seeking to resolve a case with a company for the same misconduct."[383] In determining whether and how much to credit another authority, prosecutors are to consider, among other factors, "the egregiousness of a company's misconduct; statutory mandates regarding penalties, fines, and/or forfeitures; the risk of unwarranted delay in achieving a final resolution; and the adequacy and timeliness of a company's disclosures and its cooperation with the Department, separate from any such disclosures and cooperation with other relevant enforcement authorities."[384]

Collateral Consequences

In addition to the criminal and civil penalties described above, individuals and companies who violate the FCPA may face significant collateral consequences, including suspension or debarment from contracting with the federal government, cross-debarment by multilateral development banks, and the suspension or revocation of certain export privileges.

Debarment

Under federal guidelines governing procurement, an individual or company that violates the FCPA or other criminal statutes may be barred from doing business with the federal government. The Federal Acquisition Regulations (FAR) provide for the potential suspension or debarment of companies that contract with the government upon conviction of or civil judgment for bribery, falsification or destruction of records, the making of false statements, or "[c]ommission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a Government contractor or subcontractor."[385] These measures are not intended to be punitive and may be imposed only if "in the public's interest for the Government's protection."[386]

Under the FAR, a decision to debar or suspend is discretionary. The decision is not made by DOJ prosecutors or SEC staff, but instead by independent debarment authorities within each agency, such as the Department of Defense or the General Services Administration, which analyze a number of factors to determine whether a company should be suspended, debarred, or otherwise determined to be ineligible for government contracting. Such factors include whether the contractor has effective internal control systems in place, self-reported the misconduct in a timely manner, and has taken remedial measures.[387] If a cause for debarment exists, the contractor has the burden of demonstrating to the satisfaction of the debarring official that it is presently responsible and that debarment is not necessary.[388] Each federal department and agency determines the eligibility of contractors with whom it deals. However, if one department or agency debars or suspends a contractor, the debarment or suspension applies to the entire executive branch of the federal government, unless a department or agency shows compelling reasons not to debar or suspend the contractor.[389]

Although guilty pleas, DPAs, and NPAs do not result in automatic debarment from U.S. government contracting, committing a federal crime and the factual admissions underlying a resolution are factors that the independent debarment authorities may consider. Moreover, indictment alone can lead to suspension of the right to do business with the government.[390] The Justice Manual also provides that when a company engages in fraud against the government, a prosecutor may not negotiate away an agency's right to debar or delist the company as part of the plea bargaining process.[391] In making debarment determinations, contracting agencies, including at the state and local level, may consult with DOJ in advance of awarding a contract. Depending on the circumstances, DOJ may provide information to contracting authorities in the context of the corporate settlement about the facts and circumstances underlying the criminal conduct and remediation measures undertaken by the company, if any. This information sharing is not advocacy, and the ultimate debarment decisions are squarely within the purview of the independent

debarment authorities. In some situations, the contracting agency may impose its own oversight requirements in order for a company that has admitted to violations of federal law to be awarded federal contracts, such as the Corporate Integrity Agreements often required by the Department of Health and Human Services.

Cross-Debarment by Multilateral Development Banks

Multilateral Development Banks (MDBs), like the World Bank, also have the ability to debar companies and individuals for corrupt practices.[392] Each MDB has its own process for evaluating alleged corruption in connection with MDB-funded projects. When appropriate, DOJ and SEC work with MDBs to share evidence and refer cases. On April 9, 2010, the African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, the Inter-American Development Bank Group, and the World Bank Group entered into an agreement under which entities debarred by one MDB will be sanctioned for the same misconduct by other signatory MDBs.[393] This cross-debarment agreement means that if a company is debarred by one MDB, it is debarred by all.[394]

Loss of Export Privileges

Companies and individuals who violate the FCPA may face consequences under other regulatory regimes, such as the Arms Export Control Act (AECA), 22 U.S.C. § 2751, *et seq.*, and its implementing regulations, the International Traffic in Arms Regulations (ITAR), 22 C.F.R. § 120, *et seq.* AECA and ITAR together provide for the suspension, revocation, amendment, or denial of an arms export license if an applicant has been indicted or convicted for violating the FCPA.[395] They also set forth certain factors for the Department of State's Directorate of Defense Trade Controls (DDTC)[396] to consider when determining whether to grant, deny, or return without action license applications for certain types of defense materials. One of those factors is whether there is reasonable cause to believe that an applicant for a license has violated (or conspired to violate) the FCPA; if so, the Department of State "may disapprove the application."[397] In addition, it is the policy of the Department of State not to consider applications for licenses involving any persons who have been convicted of violating the AECA or convicted of conspiracy to violate the AECA.[398] In an action related to the criminal resolution of a U.K. military products manufacturer, the DDTC imposed a "policy of denial" for export licenses on three of the company's subsidiaries that were involved in violations of AECA and ITAR.[399]

When Is a Compliance Monitor or Independent Consultant Appropriate?

One of the primary goals of both criminal prosecutions and civil enforcement actions against companies that violate the FCPA is ensuring that such conduct does not occur again. As a consequence, enhanced compliance and reporting requirements may be part of criminal and civil resolutions of FCPA matters. The amount of enhanced compliance and kind of reporting required varies according to the facts and circumstances of individual cases.

In criminal cases, a company's sentence, or a DPA or NPA with a company, may require the appointment of an independent corporate monitor. Whether a monitor is appropriate depends on the specific facts and circumstances of the case. In 2008, DOJ issued internal guidance regarding the selection and use of corporate monitors in DPAs and NPAs with companies.[400] Additional guidance has since been issued.[401] A monitor is an independent third

party who assesses and monitors a company's adherence to the compliance requirements of an agreement that was designed to reduce the risk of recurrence of the company's misconduct. Appointment of a monitor is not appropriate in all circumstances, and a monitor should never be imposed for punitive purposes, but it may be appropriate, for example, where a company does not already have an effective internal compliance program or needs to establish necessary internal controls. DOJ's guidance provides that, in determining whether to impose a monitor as part of a corporate resolution, prosecutors should assess (1) the potential benefits that employing a monitor may have for the corporation and the public, and (2) the cost of a monitor and its impact on the operations of a corporation.[402] In evaluating the potential benefits of a monitor, prosecutors consider, among other factors: (a) whether the underlying misconduct involved the manipulation of corporate books and records or the exploitation of an inadequate compliance program or internal control systems; (b) whether the misconduct at issue was pervasive across the business organization or approved or facilitated by senior management; (c) whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal control systems; and (d) whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future.[403] "Where a corporation's compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will likely not be necessary."[404]

In civil cases, a company may similarly be required to retain an independent compliance consultant or monitor to provide an independent, third-party review of the company's internal controls. The consultant recommends improvements, to the extent necessary, which the company must adopt. When both DOJ and SEC require a company to retain a monitor, the two agencies have been able to coordinate their requirements so that the company can retain one monitor to fulfill both sets of requirements.

The most successful monitoring relationships are those in which the company embraces the monitor or consultant. If the company takes the recommendations and suggestions seriously and uses the monitoring period as a time to find and fix any outstanding compliance issues, the company can emerge from the monitorship with a stronger, long-lasting compliance program.

Factors DOJ and SEC Consider When Determining Whether a Compliance Monitor Is Appropriate Include:

- Nature and seriousness of the offense
- Duration of the misconduct
- Pervasiveness of the misconduct, including whether the conduct cuts across geographic and/or product lines
- The risk profile of the company, including its nature, size, geographical reach, and business model
- Quality of the company's compliance program at the time of the misconduct
- Subsequent remediation efforts and quality of the company's compliance program at the time of resolution
- Whether the company's current compliance program has been fully implemented and tested

RESOLUTIONS

What Are the Different Types of Resolutions with DOJ?

Criminal Complaints, Informations, and Indictments

Charges against individuals and companies are brought in three different ways under the Federal Rules of Criminal Procedure: criminal complaints, criminal informations, and indictments.

DOJ may agree to resolve criminal FCPA matters against companies either through a declination or, in appropriate cases, a negotiated resolution resulting in a plea agreement, deferred prosecution agreement, or non-prosecution agreement. For individuals, a negotiated resolution will generally take the form of a plea agreement, which may include language regarding cooperation, or a non-prosecution cooperation agreement. When negotiated resolutions cannot be reached with companies or individuals, the matter may proceed to trial.

Plea Agreements

Plea agreements—whether with companies or individuals—are governed by Rule 11 of the Federal Rules of Criminal Procedure. The defendant generally admits to the facts supporting the charges, admits guilt, and is convicted of the charged crimes when the plea agreement is presented to and accepted by a court.

The plea agreement may jointly recommend a sentence or fine, jointly recommend an analysis under the U.S. Sentencing Guidelines, or leave such items open for argument at the time of sentencing.

Deferred Prosecution Agreements

Under a deferred prosecution agreement, or a DPA as it is commonly known, DOJ files a charging document with the court,[405] but it simultaneously requests that the prosecution be deferred, that is, postponed for the purpose of allowing the company to demonstrate its good conduct. DPAs generally require a defendant to agree to pay a monetary penalty, waive the statute of limitations, cooperate with the government, admit the relevant facts, and enter into certain compliance and remediation commitments, potentially including a corporate compliance monitor. DPAs describe the company's conduct, cooperation, and remediation, if any, and provide a calculation of the penalty pursuant

to the U.S. Sentencing Guidelines. In addition to being publicly filed, DOJ places all of its DPAs on its website. If the company successfully completes its obligations during the term of the agreement (typically three years), DOJ will then move to dismiss the filed charges. A company's successful completion of a DPA is not treated as a criminal conviction. Other countries, such as the United Kingdom and France, have also instituted DPA-like frameworks to resolve corporate matters whereby a company can avoid prosecution if it adheres to conditions imposed upon it for a set period of time.

Non-Prosecution Agreements

Under a non-prosecution agreement, or an NPA as it is commonly known, DOJ maintains the right to file charges but refrains from doing so to allow the company to demonstrate its good conduct during the term of the NPA. Unlike a DPA, an NPA is not filed with a court but is instead maintained by the parties. In circumstances where an NPA is with a company for FCPA-related offenses, it is made available to the public through DOJ's website. The requirements of an NPA are similar to those of a DPA, and generally require a waiver of the statute of limitations, ongoing cooperation, admission of the material facts, and compliance and remediation commitments, in addition to payment of a monetary penalty. If the company complies with the agreement throughout its term, DOJ does not file criminal charges. If an individual complies with the terms of his or her NPA, namely, truthful and complete cooperation and continued law-abiding conduct, DOJ will not pursue criminal charges.

Declinations

As discussed above, DOJ's decision to bring or decline to bring an enforcement action under the FCPA is made pursuant to the *Principles of Federal Prosecution*, in the case of individuals, and the *Principles of Federal Prosecution of Business Organizations* and the CEP, in the case of companies. As described, in the case of individuals, the *Principles of Federal Prosecution* advise prosecutors to weigh all relevant considerations, including:

- federal law enforcement priorities;
- the nature and seriousness of the offense;
- the deterrent effect of prosecution;
- the person's culpability in connection with the offense;
- the person's history of criminal activity;
- the person's willingness to cooperate in the investigation or prosecution of others; and
- the probable sentence or other consequences if the person is convicted.[406]

The *Principles of Federal Prosecution* provide additional commentary about each of these factors. For instance, they explain that prosecutors should take into account federal law enforcement priorities because federal law enforcement and judicial resources are not sufficient to permit prosecution of every alleged offense over which federal jurisdiction exists. The deterrent effect of prosecution should also be kept in mind because some offenses, "although seemingly not of great importance by themselves, if commonly committed would have a substantial cumulative impact on the community."[407]

As discussed above, the *Principles of Federal Prosecution of Business Organizations* require prosecutors to consider ten factors when determining whether to prosecute a corporate entity for an FCPA violation, including the nature and seriousness of the offense; the pervasiveness of wrongdoing within the company; the company's history of similar conduct; the existence and effectiveness of the company's pre-existing compliance program; whether the company voluntarily self-disclosed the misconduct; the extent of the company's cooperation with the

government's investigation; the company's remediation; the collateral consequences that would flow from the resolution; the adequacy of prosecutions against individuals; and the adequacy of remedies, such as civil or regulatory enforcement actions.

Pursuant to these guidelines, DOJ has declined to prosecute both individuals and corporate entities in numerous cases based on the particular facts and circumstances presented in those matters, taking into account the available evidence.[408] To protect the privacy rights and other interests of the uncharged and other potentially interested parties, DOJ has a long-standing policy not to provide, without the party's consent, non-public information on matters it has declined to prosecute. To put DOJ's declinations in context, however, DOJ has recently declined several dozen cases against companies where potential FCPA violations were alleged.

In addition to the *Principles of Federal Prosecution of Business Organizations*, as discussed above, DOJ has implemented the *CEP* to provide additional incentives and benefits to companies that voluntarily self-disclose misconduct, fully cooperate, and fully remediate, including a presumption of a declination (with the disgorgement of ill-gotten profits), absent aggravating circumstances. A declination pursuant to the CEP is a case that would have been prosecuted or criminally resolved except for the company's voluntary disclosure, full cooperation, remediation, and payment of disgorgement, forfeiture, and/or restitution. If a case would have been declined in the absence of such circumstances, it is not considered as a declination pursuant to the CEP. Declinations awarded under the CEP are made public on the DOJ/FCPA website.

What Are the Different Types of Resolutions with SEC?

Civil Injunctive Actions and Remedies

In a civil injunctive action, SEC seeks a court order enjoining the defendant from future violations of the laws charged in the action. Civil contempt sanctions, brought by SEC, are remedial rather than punitive in nature and serve one of two purposes: to compensate the party injured as a result of the violation of the injunction or force compliance with the terms of the injunction.

Where a defendant has profited from a violation of law, SEC can obtain the equitable relief of disgorgement of ill-gotten gains and pre-judgment interest and can also obtain civil money penalties pursuant to Sections 21(d)(3) and 32(c) of the Exchange Act. SEC may also seek ancillary relief (such as an accounting from a defendant). Pursuant to Section 21(d)(5), SEC also may seek, and any federal court may grant, any other equitable relief that may be appropriate or necessary for the benefit of investors, such as enhanced remedial measures or the retention of an independent compliance consultant or monitor.

Civil Administrative Actions and Remedies

SEC has the ability to institute various types of administrative proceedings against a person or an entity that it believes has violated the law. This type of enforcement action is brought by SEC's Enforcement Division and is litigated before an SEC administrative law judge (ALJ). The ALJ's decision is subject to appeal directly to the Securities and Exchange Commission itself, and the Commission's decision is in turn subject to review by a U.S. Court of Appeals.

Administrative proceedings provide for a variety of relief. For regulated persons and entities, such as broker-dealers and investment advisers and persons associated with them, sanctions include censure, limitation on activities, suspension of up to twelve months, and bar from association or revocation of registration. For professionals such as attorneys and accountants, SEC can order in Rule 102(e) proceedings that the professional be censured, suspended, or barred from appearing or practicing before SEC.[409] SEC staff can seek an order from an administrative law judge requiring the respondent to cease and desist from any current or future violations of the securities laws. In addition, SEC can obtain disgorgement, pre-judgment interest, and civil money penalties in administrative proceedings under Section 21B of the Exchange Act, and also can order other relief to effect compliance with the federal securities laws, such as enhanced remedial measures or the retention of an independent compliance consultant or monitor.

Deferred Prosecution Agreements

A deferred prosecution agreement is a written agreement between SEC and a potential cooperating individual or company in which SEC agrees to forego an enforcement action against the individual or company if the individual or company agrees to, among other things: (1) cooperate truthfully and fully in SEC's investigation and related enforcement actions; (2) enter into a long-term tolling agreement; (3) comply with express prohibitions and/or undertakings during a period of deferred prosecution; and (4) under certain circumstances, agree either to admit or not to contest underlying facts that SEC could assert to establish a violation of the federal securities laws. If the agreement is violated during the period of deferred prosecution, SEC staff may recommend an enforcement action to the Commission against the individual or company for the original misconduct as well as any additional misconduct. Furthermore, if the Commission authorizes the enforcement action, SEC staff may use any factual admissions made by the cooperating individual or company in support of a motion for summary judgment, while maintaining the ability to bring an enforcement action for any additional misconduct at a later date.

In May of 2011, SEC entered into its first deferred prosecution agreement against a company for violating the FCPA.[410] In that case, a global manufacturer of steel pipe products violated the FCPA by bribing Uzbekistan government officials during a bidding process to supply pipelines for transporting oil and natural gas. The company made almost $5 million in profits when it was subsequently awarded several contracts by the Uzbekistan government. The company discovered the misconduct during a worldwide review of its operations and brought it to the government's attention. In addition to self-reporting, the company conducted a thorough internal investigation; provided complete, real-time cooperation with SEC and DOJ staff; and undertook extensive remediation, including enhanced anti-corruption procedures and training. Under the terms of the DPA, the company paid $5.4 million in disgorgement and prejudgment interest. The company also paid a $3.5 million monetary penalty to resolve a criminal investigation by DOJ through an NPA.[411]

For further information about deferred prosecution agreements, see SEC's *Enforcement Manual*.[412]

Non-Prosecution Agreements

A non-prosecution agreement is a written agreement between SEC and a potential cooperating individual or company, entered into in limited and appropriate circumstances, that provides that SEC will not pursue an enforcement action against the individual or company if the individual or company agrees to, among other things: (1) cooperate truthfully and fully in SEC's investigation and related enforcement actions; and (2) comply, under certain circumstances, with express undertakings. If the agreement is violated, SEC staff retains its ability to recommend an enforcement action to the Commission against the individual or company.

For further information about non-prosecution agreements, see SEC's *Enforcement Manual*.[413]

Termination Letters and Declinations

As discussed above, SEC's decision to bring or decline to bring an enforcement action under the FCPA is made pursuant to the guiding principles set forth in SEC's *Enforcement Manual*. The same factors that apply to SEC staff 's determination of whether to recommend an enforcement action against an individual or entity apply to the decision to close an investigation without recommending enforcement action.[414] Generally, SEC staff considers, among other things:

- the seriousness of the conduct and potential violations;
- the resources available to SEC staff to pursue the investigation;
- the sufficiency and strength of the evidence;
- the extent of potential investor harm if an action is not commenced; and
- the age of the conduct underlying the potential violations.

SEC has declined to take enforcement action against both individuals and companies based on the facts and circumstances present in those matters, where, for example, the conduct was not egregious, the company fully cooperated, and the company identified and remediated the misconduct quickly. SEC Enforcement Division policy is to notify individuals and entities at the earliest opportunity when the staff has determined not to recommend an enforcement action against them to the Commission. This notification takes the form of a termination letter.

In order to protect the privacy rights and other interests of the uncharged and other potentially interested parties, SEC does not provide non-public information related to closed investigations unless required by law.

What Are Some Examples of Past Declinations by DOJ and SEC?

As discussed above, under the CEP, DOJ has announced declinations of companies that voluntarily self-disclosed, fully cooperated and timely and appropriately remediated. Other than those pursuant to the CEP, neither DOJ or SEC typically publicizes declinations but, to provide some insight into the process, the following are anonymized examples of matters DOJ and SEC have declined to pursue:

Example 1: Public Company Declination

DOJ and SEC declined to take enforcement action against a public U.S. company. Factors taken into consideration included:

- **The company discovered that its employees had received competitor bid information from a third-party with connections to the foreign government.**

(cont'd)

- The company began an internal investigation, withdrew its contract bid, terminated the employees involved, severed ties to the third-party agent, and voluntarily disclosed the conduct to DOJ's Antitrust Division, which also declined prosecution.
- During the internal investigation, the company uncovered various FCPA red flags, including prior concerns about the third-party agent, all of which the company voluntarily disclosed to DOJ and SEC.
- The company immediately took substantial steps to improve its compliance program.

Example 2: Public Company Declination

DOJ and SEC declined to take enforcement action against a public U.S. company. Factors taken into consideration included:

- With knowledge of employees of the company's subsidiary, a retained construction company paid relatively small bribes, which were wrongly approved by the company's local law firm, to foreign building code inspectors.
- When the company's compliance department learned of the bribes, it immediately ended the conduct, terminated its relationship with the construction company and law firm, and terminated or disciplined the employees involved.
- The company completed a thorough internal investigation and voluntarily disclosed to DOJ and SEC.
- The company reorganized its compliance department, appointed a new compliance officer dedicated to anti-corruption, improved the training and compliance program, and undertook a review of all of the company's international third-party relationships.

Example 3: Public Company Declination

DOJ and SEC declined to take enforcement action against a U.S. publicly held industrial services company for bribes paid by a small foreign subsidiary. Factors taken into consideration included:

- The company self-reported the conduct to DOJ and SEC.
- The total amount of the improper payments was relatively small, and the activity appeared to be an isolated incident by a single employee at the subsidiary.
- The profits potentially obtained from the improper payments were very small.
- The payments were detected by the company's existing internal controls. The company's audit committee conducted a thorough independent internal investigation. The results of the investigation were provided to the government.
- The company cooperated fully with investigations by DOJ and SEC.
- The company implemented significant remedial actions and enhanced its internal control structure.

Example 4: Public Company Declination

DOJ and SEC declined to take enforcement action against a U.S. publicly held oil-and-gas services company for small bribes paid by a foreign subsidiary's customs agent. Factors taken into consideration included:

- The company's internal controls timely detected a potential bribe before a payment was made.
- When company management learned of the potential bribe, management immediately reported the issue to the company's General Counsel and Audit Committee and prevented the payment from occurring.

(cont'd)

- Within weeks of learning of the attempted bribe, the company provided in-person FCPA training to employees of the subsidiary and undertook an extensive internal investigation to determine whether any of the company's subsidiaries in the same region had engaged in misconduct.
- The company self-reported the misconduct and the results of its internal investigation to DOJ and SEC.
- The company cooperated fully with investigations by DOJ and SEC.
- In addition to the immediate training at the relevant subsidiary, the company provided comprehensive FCPA training to all of its employees and conducted an extensive review of its anti-corruption compliance program.
- The company enhanced its internal controls and record-keeping policies and procedures, including requiring periodic internal audits of customs payments.
- As part of its remediation, the company directed that local lawyers rather than customs agents be used to handle its permits, with instructions that "no matter what, we don't pay bribes"—a policy that resulted in a longer and costlier permit procedure.

Example 5: Public Company Declination

DOJ and SEC declined to take enforcement action against a U.S. publicly held consumer products company in connection with its acquisition of a foreign company. Factors taken into consideration included:

- The company identified the potential improper payments to local government officials as part of its pre-acquisition due diligence.
- The company promptly developed a comprehensive plan to investigate, correct, and remediate any FCPA issues after acquisition.
- The company promptly self-reported the issues prior to acquisition and provided the results of its investigation to the government on a real-time basis.
- The acquiring company's existing internal controls and compliance program were robust.
- After the acquisition closed, the company implemented a comprehensive remedial plan, ensured that all improper payments stopped, provided extensive FCPA training to employees of the new subsidiary, and promptly incorporated the new subsidiary into the company's existing internal controls and compliance environment.

Example 6: Private Company Declination

In 2011, DOJ declined to take prosecutorial action against a privately held U.S. company and its foreign subsidiary. Factors taken into consideration included:

- The company voluntarily disclosed bribes paid to social security officials in a foreign country. The total amount of the bribes was small.
- When discovered, the corrupt practices were immediately terminated.
- The conduct was thoroughly investigated, and the results of the investigation were promptly provided to DOJ.
- All individuals involved were either terminated or disciplined. The company also terminated its relationship with its foreign law firm.
- The company instituted improved training and compliance programs commensurate with its size and risk exposure.

WHISTLEBLOWER PROVISIONS AND PROTECTIONS

Assistance and information from a whistleblower who knows of possible securities law violations can be among the most powerful weapons in the law enforcement arsenal. Through their knowledge of the circumstances and individuals involved, whistleblowers can help SEC and DOJ identify potential violations much earlier than might otherwise have been possible, thus allowing SEC and DOJ to minimize the harm to investors, better preserve the integrity of the U.S. capital markets, and more swiftly hold accountable those responsible for unlawful conduct.

The Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010 both contain provisions affecting whistleblowers who report FCPA violations. Sarbanes-Oxley prohibits issuers from retaliating against whistleblowers and provides that employees who are retaliated against for reporting possible securities law violations may file a complaint with the Department of Labor, for which they would be eligible to receive reinstatement, back pay, and other compensation.[415] Sarbanes-Oxley also prohibits retaliation against employee whistleblowers under the obstruction of justice statute.[416]

In 2010, the Dodd-Frank Act added Section 21F to the Exchange Act, addressing whistleblower incentives and protections. Section 21F authorizes SEC to provide monetary awards to eligible individuals who voluntarily come forward with high quality, original information that leads to enforcement actions in which over $1,000,000 in sanctions is ordered.[417] The Commission issues awards in an aggregate amount equal to not less than 10 percent, and not more than 30 percent, of monetary sanctions that have been collected in the actions. The Dodd-Frank Act also prohibits employers from retaliating against whistleblowers and creates a private right of action for employees who are retaliated against.[418]

Furthermore, businesses should be aware that retaliation against a whistleblower may also violate state, local, and foreign laws that provide protection of whistleblowers.

On August 12, 2011, the final rules for SEC's Whistleblower Program became effective. These rules set forth the requirements for a whistleblower to be eligible for an award, factors that SEC will use to determine the amount of the award, the categories of individuals who are excluded from award consideration, and the categories of individuals who are subject to limitations in award considerations.[419] The final rules strengthen incentives for employees to report the suspected violations internally through internal compliance programs when appropriate, although they do not require an employee to do so in order to qualify for an award.[420]

Individuals with information about a possible violation of the federal securities laws, including FCPA violations, should submit that information to SEC either online through SEC's Tips, Complaints, and Referrals (TCR) system and complaint form (available at https://www.sec.gov/tcr) or by mailing or faxing a completed Form TCR to the Commission's Office of the Whistleblower.

Whistleblowers can submit information anonymously. To be considered under SEC's whistleblower program as eligible for an award, however, the information must be submitted on an anonymous whistleblower's behalf by an attorney.[421] Whether or not a whistleblower reports anonymously, SEC is committed to protecting the identity of a whistleblower to the fullest extent possible under the statute.[422] SEC's Office of the Whistleblower administers SEC's Whistleblower Program and answers questions from the public regarding the program. Additional information regarding SEC's Whistleblower Program, including answers to frequently asked questions, is available online at http://www.sec.gov/whistleblower.

SEC Office of the Whistleblower

100 F Street NE, Mail Stop 5971
Washington, DC 20549

Facsimile: (703) 813-9322

Online Report Form:
http://www.sec.gov/whistleblower

DOJ OPINION PROCEDURE

DOJ's opinion procedure remains a valuable mechanism for companies and individuals to determine whether proposed conduct would be prosecuted by DOJ under the FCPA.[423] Generally speaking, under the opinion procedure process, parties submit information to DOJ, after which DOJ issues an opinion about whether the proposed conduct falls within its enforcement policy. All of DOJ's prior opinions are available online.[424] Parties interested in obtaining such an opinion should follow these steps:[425]

First, those seeking an opinion should evaluate whether their question relates to actual, prospective conduct.[426] The opinion procedure cannot be used to obtain opinions on purely historical conduct or on hypothetical questions. DOJ will not consider a request unless that portion of the transaction for which an opinion is sought involves only prospective conduct, although the transaction as a whole may have components that already have occurred. An executed contract is not a prerequisite and, in most—if not all—instances, an opinion request should be made before the requestor commits to proceed with a transaction.[427] Those seeking requests should be aware that FCPA opinions relate only to the FCPA's anti-bribery provisions.[428]

Second, before making the request, the company or individual should check that they are either an issuer or a domestic concern, as only those categories of parties can receive an opinion.[429] If the transaction involves more than one issuer or domestic concern, consider making a request for an opinion jointly, as opinions apply only to the parties that request them.[430]

Third, those seeking an opinion must put their request in writing. The request must be specific and accompanied by all relevant and material information bearing on the conduct and

circumstances for which an opinion is requested. Material information includes background information, complete copies of all operative documents, and detailed statements of all collateral or oral understandings, if any. Those seeking opinions are under an affirmative obligation to make full and true disclosures.[431] Materials disclosed to DOJ will not be made public without the consent of the party submitting them.[432]

Fourth, the request must be signed. For corporate requestors, the signatory should be an appropriate senior officer with operational responsibility for the conduct that is the subject of the request and who has been designated by the corporation's chief executive officer. In appropriate cases, DOJ also may require the chief executive officer to sign the request. Those signing the request must certify that it contains a true, correct, and complete disclosure with respect to the proposed conduct and the circumstances of the conduct.[433]

Fifth, an original and five copies of the request should be addressed to the Assistant Attorney General in charge of the Criminal Division, Attention: FCPA Opinion Group.[434] The mailing address is P.O. Box 28188 Central Station, Washington, D.C. 20038. DOJ also asks that you send an electronic courtesy copy to FCPA.Fraud@usdoj.gov.

DOJ will evaluate the request for an FCPA opinion.[435] A party may withdraw a request for an opinion at any time prior to the release of an opinion.[436] If the request is complete and all the relevant information has been submitted, DOJ will respond to the request by issuing an opinion within 30 days.[437] If the request is incomplete, DOJ will identify for the requestor what additional information or documents are required for DOJ to review the request. Such information must be provided to DOJ promptly. Once the additional information has been received, DOJ will issue an opinion within 30 days of receipt of that additional information.[438] DOJ's FCPA opinions state whether, for purposes of DOJ's present enforcement policy, the prospective conduct would violate either the issuer or domestic concern anti-bribery provisions of the FCPA.[439] DOJ also may take other positions in the opinion as it considers appropriate.[440] To the extent that the opinion concludes that the proposed conduct would not violate the FCPA, a rebuttable presumption is created that the requestor's conduct that was the basis of the opinion is in compliance with the FCPA.[441] In order to provide non-binding guidance to the business community, DOJ makes versions of its opinions publicly available on its website.[442]

If, after receiving an opinion, a party is concerned about prospective conduct that is beyond the scope of conduct specified in a previous request, the party may submit an additional request for an opinion using the procedures outlined above.[443]

CONCLUSION

The FCPA was designed to prevent corrupt practices, protect investors, and provide a fair playing field for those honest companies trying to win business based on quality and price rather than bribes. Following Congress' leadership in enacting the FCPA 43 years ago, and through determined international diplomatic and law enforcement efforts in the time since, laws like the FCPA prohibiting foreign bribery have been enacted by most of the United States' major trading partners.

This guide is designed to provide practical advice about, and useful insights into, our enforcement considerations. For businesses desiring to compete fairly in foreign markets, it is our goal to maximize those businesses' ability to comply with the FCPA in the most effective and efficient way suitable to their business and the markets in which they operate. Through our ongoing efforts with the U.S. and international business and legal communities and non-governmental organizations, DOJ and SEC can continue effectively to protect the integrity of our markets and reduce corruption around the world.

THE FOREIGN CORRUPT PRACTICES ACT

15 U.S.C. §§ 78dd-1, 78dd-2, 78dd-3, 78m, 78ff

15 U.S.C. § 78dd-1 Prohibited foreign trade practices by issuers [Section 30A of the Securities Exchange Act of 1934]

(a) Prohibition

It shall be unlawful for any issuer which has a class of securities registered pursuant to section 78*l* of this title or which is required to file reports under section 78*o*(d) of this title, or for any officer, director, employee, or agent of such issuer or any stockholder thereof acting on behalf of such issuer, to make use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to—

(1) any foreign official for purposes of—

(A) (i) influencing any act or decision of such foreign official in his official capacity, (ii) inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or (iii) securing any improper advantage; or

(B) inducing such foreign official to use his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such issuer in obtaining or retaining business for or with, or directing business to, any person;

(2) any foreign political party or official thereof or any candidate for foreign political office for purposes of—

(A) (i) influencing any act or decision of such party, official, or candidate in its or his official capacity, (ii) inducing such party, official, or candidate to do or omit to do an act in violation of the lawful duty of such party, official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such party, official, or candidate to use its or his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such issuer in obtaining or retaining business for or with, or directing business to, any person; or

(3) any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official, to any foreign political party or official thereof, or to any candidate for foreign political office, for purposes of—

(A) (i) influencing any act or decision of such foreign official, political party, party official, or candidate in his or its official capacity, (ii) inducing such foreign official, political party, party official, or candidate to do or omit to do any act in violation of the lawful duty of such foreign official, political party, party official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such foreign official, political party, party official, or candidate to use his or its influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist such issuer in obtaining or retaining business for or with, or directing business to, any person.

(b) Exception for routine governmental action

Subsections (a) and (g) shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.

(c) Affirmative defenses

It shall be an affirmative defense to actions under subsection (a) or (g) that—

(1) the payment, gift, offer, or promise of anything of value that was made, was lawful under the written laws and regulations of the foreign official's, political party's, party official's, or candidate's country; or

(2) the payment, gift, offer, or promise of anything of value that was made, was a reasonable and bona fide expenditure, such as travel and lodging expenses, incurred by or on behalf of a foreign official, party, party official, or candidate and was directly related to—

(A) the promotion, demonstration, or explanation of products or services; or

(B) the execution or performance of a contract with a foreign government or agency thereof.

(d) Guidelines by Attorney General

Not later than one year after August 23, 1988, the Attorney General, after consultation with the Commission, the Secretary of Commerce, the United States Trade Representative, the Secretary of State, and the Secretary of the Treasury, and after obtaining the views of all interested persons through public notice and comment procedures, shall determine to what extent compliance with this section would be enhanced and the business community would be assisted by further clarification of the preceding provisions of this section and may, based on such determination and to the extent necessary and appropriate, issue—

(1) guidelines describing specific types of conduct, associated with common types of export sales arrangements and business contracts, which for purposes of the Department of Justice's present enforcement policy, the Attorney General determines would be in conformance with the preceding provisions of this section; and

(2) general precautionary procedures which issuers may use on a voluntary basis to conform their conduct to the Department of Justice's present enforcement policy regarding the preceding provisions of this section. The Attorney General shall issue the guidelines and procedures referred to in the preceding sentence in accordance with the provisions of subchapter II of chapter 5 of title 5 and those guidelines and procedures shall be subject to the provisions of chapter 7 of that title.

(e) Opinions of Attorney General

(1) The Attorney General, after consultation with appropriate departments and agencies of the United States and after obtaining the views of all interested persons through public notice and comment procedures, shall establish a procedure to provide responses to specific inquiries by issuers concerning conformance of their conduct with the Department of Justice's present enforcement policy regarding the preceding provisions of this section. The Attorney General shall, within 30 days after receiving such a request, issue an opinion in response to that request. The opinion shall state

whether or not certain specified prospective conduct would, for purposes of the Department of Justice's present enforcement policy, violate the preceding provisions of this section. Additional requests for opinions may be filed with the Attorney General regarding other specified prospective conduct that is beyond the scope of conduct specified in previous requests. In any action brought under the applicable provisions of this section, there shall be a rebuttable presumption that conduct, which is specified in a request by an issuer and for which the Attorney General has issued an opinion that such conduct is in conformity with the Department of Justice's present enforcement policy, is in compliance with the preceding provisions of this section. Such a presumption may be rebutted by a preponderance of the evidence. In considering the presumption for purposes of this paragraph, a court shall weigh all relevant factors, including but not limited to whether the information submitted to the Attorney General was accurate and complete and whether it was within the scope of the conduct specified in any request received by the Attorney General. The Attorney General shall establish the procedure required by this paragraph in accordance with the provisions of subchapter II of chapter 5 of Title 5 and that procedure shall be subject to the provisions of chapter 7 of that title.

(2) Any document or other material which is provided to, received by, or prepared in the Department of Justice or any other department or agency of the United States in connection with a request by an issuer under the procedure established under paragraph (1), shall be exempt from disclosure under section 552 of title 5 and shall not, except with the consent of the issuer, be made publicly available, regardless of whether the Attorney General responds to such a request or the issuer withdraws such request before receiving a response.

(3) Any issuer who has made a request to the Attorney General under paragraph (1) may withdraw such request prior to the time the Attorney General issues an opinion in response to such request. Any request so withdrawn shall have no force or effect.

(4) The Attorney General shall, to the maximum extent practicable, provide timely guidance concerning the Department of Justice's present enforcement policy with respect to the preceding provisions of this section to potential exporters and small businesses that are unable to obtain specialized counsel on issues pertaining to such provisions. Such guidance shall be limited to responses to requests under paragraph (1) concerning conformity of specified prospective conduct with the Department of Justice's present enforcement policy regarding the preceding provisions of this section and general explanations of compliance responsibilities and of potential liabilities under the preceding provisions of this section.

(f) Definitions

For purposes of this section:

(1)(A) The term "foreign official" means any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

(B) For purposes of subparagraph (A), the term "public international organization" means—

(i) an organization that is designated by Executive order pursuant to section 288 of title 22; or

(ii) any other international organization that is designated by the President by Executive order for the purposes of this section, effective as of the date of publication of such order in the Federal Register.

(2) (A) A person's state of mind is "knowing" with respect to conduct, a circumstance, or a result if—

(i) such person is aware that such person is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or

(ii) such person has a firm belief that such circumstance exists or that such result is substantially certain to occur.

(B) When knowledge of the existence of a particular circumstance is required for an offense, such knowledge is established if a person is aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist.

(3)(A) The term "routine governmental action" means only an action which is ordinarily and commonly performed by a foreign official in—

(i) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country;

(ii) processing governmental papers, such as visas and work orders;

(iii) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country;

(iv) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or

(v) actions of a similar nature.

(B) The term "routine governmental action" does not include any decision by a foreign official whether, or on what terms, to award new business to or to continue business with a particular party, or any action taken by a foreign official involved in the decision making process to encourage a decision to award new business to or continue business with a particular party.

(g) Alternative Jurisdiction

(1) It shall also be unlawful for any issuer organized under the laws of the United States, or a State, territory, possession, or commonwealth of the United States or a political subdivision thereof and which has a class of securities registered pursuant to section 78l of this title or which is required to file reports under section 78o(d)) of this title, or for any United States person that is an officer, director, employee, or agent of such issuer or a stockholder thereof acting on behalf of such issuer, to corruptly do any act outside the United States in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to any of the persons or entities set forth in paragraphs (1), (2), and (3) of this subsection (a) of this section for the purposes set forth therein, irrespective of whether such issuer or such officer, director, employee, agent, or stockholder makes use of the mails or any means or instrumentality of interstate commerce in furtherance of such offer, gift, payment, promise, or authorization.

(2) As used in this subsection, the term "United States person" means a national of the United States (as defined in section 1101 of title 8) or any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship organized under the laws of the United States or any State, territory, possession, or commonwealth of the United States, or any political subdivision thereof.

* * *

15 U.S.C. § 78dd-2 Prohibited foreign trade practices by domestic concerns

(a) Prohibition

It shall be unlawful for any domestic concern, other than an issuer which is subject to section 78dd-1 of this title, or for any officer, director, employee, or agent of such domestic concern or any stockholder thereof acting on behalf of such domestic concern, to make use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to—

(1) any foreign official for purposes of—

(A) (i) influencing any act or decision of such foreign official in his official capacity, (ii) inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or (iii) securing any improper advantage; or

(B) inducing such foreign official to use his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such domestic concern in obtaining or retaining business for or with, or directing business to, any person;

(2) any foreign political party or official thereof or any candidate for foreign political office for purposes of—

(A) (i) influencing any act or decision of such party, official, or candidate in its or his official capacity, (ii) inducing such party, official, or candidate to do or omit to do an act in violation of the lawful duty of such party, official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such party, official, or candidate to use its or his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such domestic concern in obtaining or retaining business for or with, or directing business to, any person;

(3) any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official, to any foreign political party or official thereof, or to any candidate for foreign political office, for purposes of—

(A) (i) influencing any act or decision of such foreign official, political party, party official, or candidate in his or its official capacity, (ii) inducing such foreign official, political party, party official, or candidate to do or omit to do any act in violation of the lawful duty of such foreign official, political party, party official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such foreign official, political party, party official, or candidate to use his or its influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such domestic concern in obtaining or retaining business for or with, or directing business to, any person.

(b) Exception for routine governmental action

Subsections (a) and (i) of this section shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.

(c) Affirmative defenses

It shall be an affirmative defense to actions under subsection (a) or (i) of this section that—

(1) the payment, gift, offer, or promise of anything of value that was made, was lawful under the written laws and regulations of the foreign official's, political party's, party official's, or candidate's country; or

(2) the payment, gift, offer, or promise of anything of value that was made, was a reasonable and bona fide expenditure, such as travel and lodging expenses, incurred by or on behalf of a foreign official, party, party official, or candidate and was directly related to—

(A) the promotion, demonstration, or explanation of products or services; or

(B) the execution or performance of a contract with a foreign government or agency thereof.

(d) Injunctive relief

(1) When it appears to the Attorney General that any domestic concern to which this section applies, or officer, director, employee, agent, or stockholder thereof, is engaged, or about to engage, in any act or practice constituting a violation of subsection (a) or (i) of this section, the Attorney General may, in his discretion, bring a civil action in an appropriate district court of the United States to enjoin such act or practice, and upon a proper showing, a permanent injunction or a temporary restraining order shall be granted without bond.

(2) For the purpose of any civil investigation which, in the opinion of the Attorney General, is necessary and proper to enforce this section, the Attorney General or his designee are empowered to administer oaths and affirmations, subpoena witnesses, take evidence, and require the production of any books, papers, or other documents which the Attorney General deems relevant or material to such investigation. The attendance of witnesses and the production of documentary evidence may be required from any place in the United States, or any territory, possession, or commonwealth of the United States, at any designated place of hearing.

(3) In case of contumacy by, or refusal to obey a subpoena issued to, any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which such investigation or proceeding is carried on, or where such person resides or carries on business, in requiring the attendance and testimony of witnesses and the production of books, papers, or other documents. Any such court may issue an order requiring such person to appear before the Attorney General or his designee, there to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey such order of the court may be punished by such court as a contempt thereof. All process in any such case may be served in the judicial district in which such person resides or may be found. The Attorney General may make such rules relating to civil investigations as may be necessary or appropriate to implement the provisions of this subsection.

(e) Guidelines by Attorney General

Not later than 6 months after August 23, 1988, the Attorney General, after consultation with the Securities and Exchange Commission, the Secretary of Commerce, the United States Trade Representative, the Secretary of State, and the Secretary of the Treasury, and after obtaining the views of all interested persons through public notice and comment procedures, shall determine to what extent compliance with this section would be enhanced and the business community would be assisted by further clarification of the preceding provisions of this section and may, based on such determination and to the extent necessary and appropriate, issue—

(1) guidelines describing specific types of conduct, associated with common types of export sales arrangements and business contracts, which for purposes of the Department of Justice's present enforcement policy, the Attorney General determines would be in conformance with the preceding provisions of this section; and

(2) general precautionary procedures which domestic concerns may use on a voluntary basis to conform their conduct to the Department of Justice's present enforcement policy regarding the preceding provisions of this section.

The Attorney General shall issue the guidelines and procedures referred to in the preceding sentence in accordance with the provisions of subchapter II of chapter 5 of title 5 and those guidelines and procedures shall be subject to the provisions of chapter 7 of that title.

(f) Opinions of Attorney General

(1) The Attorney General, after consultation with appropriate departments and agencies of the United States and after obtaining the views of all interested persons through public notice and comment procedures, shall establish a procedure to provide responses to specific inquiries by domestic concerns concerning conformance of their conduct with the Department of Justice's present enforcement policy regarding the preceding provisions of this section. The Attorney General shall, within 30 days after receiving such a request, issue an opinion in response to that request. The opinion shall state whether or not certain specified prospective conduct would, for purposes of the Department of Justice's present enforcement policy, violate the preceding provisions of this section. Additional requests for opinions may be filed with the Attorney General regarding other specified prospective conduct that is beyond the scope of conduct specified in previous requests. In any action brought under the applicable provisions of this section, there shall be a rebuttable presumption that conduct, which is specified in a request by a domestic concern and for which the Attorney General has issued an opinion that such conduct is in conformity with the Department of Justice's present enforcement policy, is in compliance with the preceding provisions of this section. Such a presumption may be rebutted by a preponderance of the evidence. In considering the presumption for purposes of this paragraph, a court shall weigh all relevant factors, including but not limited to whether the information submitted to the Attorney General was accurate and complete and whether it was within the scope of the conduct specified in any request received by the Attorney General. The Attorney General shall establish the procedure required by this paragraph in accordance with the provisions of subchapter II of chapter 5 of title 5 and that procedure shall be subject to the provisions of chapter 7 of that title.

(2) Any document or other material which is provided to, received by, or prepared in the Department of Justice or any other department or agency of the United States in connection with a request by a domestic concern under the procedure established under paragraph (1), shall be exempt from disclosure under section 552 of title 5 and shall not, except with the consent of the domestic concern, be made publicly available, regardless of whether the Attorney General response to such a request or the domestic concern withdraws such request before receiving a response.

(3) Any domestic concern who has made a request to the Attorney General under paragraph (1) may withdraw such request prior to the time the Attorney General issues an opinion in response to such request. Any request so withdrawn shall have no force or effect.

(4) The Attorney General shall, to the maximum extent practicable, provide timely guidance concerning the Department of Justice's present enforcement policy with respect to the preceding provisions of this section to potential exporters and small businesses that are unable to obtain specialized counsel on issues pertaining to such provisions. Such guidance shall be limited to responses to requests under paragraph (1) concerning conformity of specified prospective conduct with the Department of Justice's present enforcement policy regarding the preceding provisions of this section and general explanations of compliance responsibilities and of potential liabilities under the preceding provisions of this section.

(g) Penalties

(1)(A) Any domestic concern that is not a natural person and that violates subsection (a) or (i) of this section shall be fined not more than $2,000,000.

(B) Any domestic concern that is not a natural person and that violates subsection (a) or (i) of this section shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Attorney General.

(2)(A) Any natural person that is an officer, director, employee, or agent of a domestic concern, or stockholder acting on behalf of such domestic concern, who willfully violates subsection (a) or (i) of this section shall be fined not more than $100,000 or imprisoned not more than 5 years, or both.

(B) Any natural person that is an officer, director, employee, or agent of a domestic concern, or stockholder acting on behalf of such domestic concern, who violates subsection (a) or (i) of this section shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Attorney General.

(3) Whenever a fine is imposed under paragraph (2) upon any officer, director, employee, agent, or stockholder of a domestic concern, such fine may not be paid, directly or indirectly, by such domestic concern.

(h) Definitions

For purposes of this section:

(1) The term "domestic concern" means—

(A) any individual who is a citizen, national, or resident of the United States; and

(B) any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship which has its principal place of business in the United States, or which is organized under the laws of a State of the United States or a territory, possession, or commonwealth of the United States.

(2)(A) The term "foreign official" means any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

(B) For purposes of subparagraph (A), the term "public international organization" means—

(i) an organization that has been designated by Executive order pursuant to section 288 of title 22; or

(ii) any other international organization that is designated by the President by Executive order for the purposes of this section, effective as of the date of publication of such order in the Federal Register.

(3)(A) A person's state of mind is "knowing" with respect to conduct, a circumstance, or a result if—

(i) such person is aware that such person is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or

(ii) such person has a firm belief that such circumstance exists or that such result is substantially certain to occur.

(B) When knowledge of the existence of a particular circumstance is required for an offense, such knowledge is established if a person is aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist.

(4)(A) The term "routine governmental action" means only an action which is ordinarily and commonly performed by a foreign official in—

(i) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country;

(ii) processing governmental papers, such as visas and work orders;

(iii) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country;

(iv) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or

(v) actions of a similar nature.

(B) The term "routine governmental action" does not include any decision by a foreign official whether, or on what terms, to award new business to or to continue business with a particular party, or any action taken by a foreign official involved in the decision-making process to encourage a decision to award new business to or continue business with a particular party.

(5) The term "interstate commerce" means trade, commerce, transportation, or communication among the several States, or between any foreign country and any State or between any State and any place or ship outside thereof, and such term includes the intrastate use of—

(A) a telephone or other interstate means of communication, or

(B) any other interstate instrumentality.

(i) Alternative Jurisdiction

(1) It shall also be unlawful for any United States person to corruptly do any act outside the United States in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to any of the persons or entities set forth in paragraphs (1), (2), and (3) of subsection (a), for the purposes set forth therein, irrespective of whether such United States person makes use of the mails or any means or instrumentality of interstate commerce in furtherance of such offer, gift, payment, promise, or authorization.

(2) As used in this subsection, a "United States person" means a national of the United States (as defined in section 1101 of title 8) or any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship organized under the laws of the United States or any State, territory, possession, or commonwealth of the United States, or any political subdivision thereof.

* * *

15 U.S.C. § 78dd-3 Prohibited foreign trade practices by persons other than issuers or domestic concerns

(a) Prohibition

It shall be unlawful for any person other than an issuer that is subject to section 78dd-1 [Section 30A of the Exchange Act] of this title or a domestic concern (as defined in section 78dd-2 of this title), or for any officer, director, employee, or agent of such person or any stockholder thereof acting on behalf of such person, while in the territory of the United States, corruptly to make use of the mails or any means or instrumentality of interstate commerce or to do any other act in furtherance of

an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to—

(1) any foreign official for purposes of—

(A) (i) influencing any act or decision of such foreign official in his official capacity, (ii) inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or (iii) securing any improper advantage; or

(B) inducing such foreign official to use his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such person in obtaining or retaining business for or with, or directing business to, any person;

(2) any foreign political party or official thereof or any candidate for foreign political office for purposes of—

(A) (i) influencing any act or decision of such party, official, or candidate in its or his official capacity, (ii) inducing such party, official, or candidate to do or omit to do an act in violation of the lawful duty of such party, official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such party, official, or candidate to use its or his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such person in obtaining or retaining business for or with, or directing business to, any person; or

(3) any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official, to any foreign political party or official thereof, or to any candidate for foreign political office, for purposes of—

(A) (i) influencing any act or decision of such foreign official, political party, party official, or candidate in his or its official capacity, (ii) inducing such foreign official, political party, party official, or candidate to do or omit to do any act in violation of the lawful duty of such foreign official, political party, party official, or candidate, or (iii) securing any improper advantage; or

(B) inducing such foreign official, political party, party official, or candidate to use his or its influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,

in order to assist such person in obtaining or retaining business for or with, or directing business to, any person.

(b) Exception for routine governmental action

Subsection (a) of this section shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.

(c) Affirmative defenses

It shall be an affirmative defense to actions under subsection (a) of this section that—

(1) the payment, gift, offer, or promise of anything of value that was made, was lawful under the written laws and regulations of the foreign official's, political party's, party official's, or candidate's country; or

(2) the payment, gift, offer, or promise of anything of value that was made, was a reasonable and bona fide expenditure, such as travel and lodging expenses, incurred by or on behalf of a foreign official, party, party official, or candidate and was directly related to—

(A) the promotion, demonstration, or explanation of products or services; or

(B) the execution or performance of a contract with a foreign government or agency thereof.

(d) Injunctive relief

(1) When it appears to the Attorney General

that any person to which this section applies, or officer, director, employee, agent, or stockholder thereof, is engaged, or about to engage, in any act or practice constituting a violation of subsection (a) of this section, the Attorney General may, in his discretion, bring a civil action in an appropriate district court of the United States to enjoin such act or practice, and upon a proper showing, a permanent injunction or a temporary restraining order shall be granted without bond.

(2) For the purpose of any civil investigation which, in the opinion of the Attorney General, is necessary and proper to enforce this section, the Attorney General or his designee are empowered to administer oaths and affirmations, subpoena witnesses, take evidence, and require the production of any books, papers, or other documents which the Attorney General deems relevant or material to such investigation. The attendance of witnesses and the production of documentary evidence may be required from any place in the United States, or any territory, possession, or commonwealth of the United States, at any designated place of hearing.

(3) In case of contumacy by, or refusal to obey a subpoena issued to, any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which such investigation or proceeding is carried on, or where such person resides or carries on business, in requiring the attendance and testimony of witnesses and the production of books, papers, or other documents. Any such court may issue an order requiring such person to appear before the Attorney General or his designee, there to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey such order of the court may be punished by such court as a contempt thereof.

(4) All process in any such case may be served in the judicial district in which such person resides or may be found. The Attorney General may make such rules relating to civil investigations as may be necessary or appropriate to implement the provisions of this subsection.

(e) Penalties

(1)(A) Any juridical person that violates subsection (a) of this section shall be fined not more than $2,000,000.

(B) Any juridical person that violates subsection (a) of this section shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Attorney General.

(2)(A) Any natural person who willfully violates subsection (a) of this section shall be fined not more than $100,000 or imprisoned not more than 5 years, or both.

(B) Any natural person who violates subsection (a) of this section shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Attorney General.

(3) Whenever a fine is imposed under paragraph (2) upon any officer, director, employee, agent, or stockholder of a person, such fine may not be paid, directly or indirectly, by such person.

(f) Definitions

For purposes of this section:

(1) The term "person," when referring to an offender, means any natural person other than a national of the United States (as defined in section 1101 of title 8) or any corporation, partnership, association, joint-stock company, business trust, unincorporated organization, or sole proprietorship organized under the law of a foreign nation or a political subdivision thereof.

(2)(A) The term "foreign official" means any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

For purposes of subparagraph (A), the term "public international organization" means—

(i) an organization that has been designated by Executive order pursuant to section 288 of title 22; or

(ii) any other international organization that is designated by the President by Executive order for the purposes of this section, effective as of the date of publication of such order in the Federal Register.

(3)(A) A person's state of mind is knowing with respect to conduct, a circumstance, or a result if—

(i) such person is aware that such person is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or

(ii) such person has a firm belief that such circumstance exists or that such result is substantially certain to occur.

(B) When knowledge of the existence of a particular circumstance is required for an offense, such knowledge is established if a person is aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist.

(4)(A) The term "routine governmental action" means only an action which is ordinarily and commonly performed by a foreign official in—

(i) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country;

(ii) processing governmental papers, such as visas and work orders;

(iii) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country;

(iv) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or

(v) actions of a similar nature.

(B) The term "routine governmental action" does not include any decision by a foreign official whether, or on what terms, to award new business to or to continue business with a particular party, or any action taken by a foreign official involved in the decision-making process to encourage a decision to award new business to or continue business with a particular party.

(5) The term "interstate commerce" means trade, commerce, transportation, or communication among the several States, or between any foreign country and any State or between any State and any place or ship outside thereof, and such term includes the intrastate use of—

(A) a telephone or other interstate means of communication, or

(B) any other interstate instrumentality.

* * *

15 U.S.C. § 78m Periodical and other reports [Section 13 of the Securities Exchange Act of 1934]

(a) Reports by issuer of security; contents

Every issuer of a security registered pursuant to section 78*l* of this title shall file with the Commission, in accordance with such rules and regulations as the Commission may prescribe as necessary or appropriate for the proper protection of investors and to insure fair dealing in the security—

(1) such information and documents (and such copies thereof) as the Commission shall require to keep reasonably current the information and documents required to be included in or filed with an application or registration statement filed pursuant to section 78*l* of this title, except that the Commission may not require the filing of any material contract wholly executed before July 1, 1962.

(2) such annual reports (and such copies thereof), certified if required by the rules and regulations of the Commission by independent public accountants, and such quarterly reports (and such copies thereof), as the Commission may prescribe.

Every issuer of a security registered on a national securities exchange shall also file a duplicate original of such information, documents, and reports with the exchange. In any registration statement, periodic report, or other reports to be filed with the Commission, an emerging growth company need not present selected financial data in accordance with section 229.301 of title 17, Code of Federal Regulations, for any period prior to the earliest audited period presented in connection with its first registration statement that became effective under this chapter or the Securities Act of 1933 [15 U.S.C. §§ 77a, *et seq.*] and, with respect

to any such statement or reports, an emerging growth company may not be required to comply with any new or revised financial accounting standard until such date that a company that is not an issuer (as defined under section 7201 of this title) is required to comply with such new or revised accounting standard, if such standard applies to companies that are not issuers.

(b) Form of report; books, records, and internal accounting; directives

(1) The Commission may prescribe, in regard to reports made pursuant to this chapter, the form or forms in which the required information shall be set forth, the items or details to be shown in the balance sheet and the earnings statement, and the methods to be followed in the preparation of reports, in the appraisal or valuation of assets and liabilities, in the determination of depreciation and depletion, in the differentiation of recurring and nonrecurring income, in the differentiation of investment and operating income, and in the preparation, where the Commission deems it necessary or desirable, of separate and/or consolidated balance sheets or income accounts of any person directly or indirectly controlling or controlled by the issuer, or any person under direct or indirect common control with the issuer; but in the case of the reports of any person whose methods of accounting are prescribed under the provisions of any law of the United States, or any rule or regulation thereunder, the rules and regulations of the Commission with respect to reports shall not be inconsistent with the requirements imposed by such law or rule or regulation in respect of the same subject matter (except that such rules and regulations of the Commission may be inconsistent with such requirements to the extent that the Commission determines that the public interest or the protection of investors so requires).

(2) Every issuer which has a class of securities registered pursuant to section 78*l* of this title and every issuer which is required to file reports pursuant to section 78*o*(d) of this title shall—

(A) make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer;

(B) devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that—

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and

(C) notwithstanding any other provision of law, pay the allocable share of such issuer of a reasonable annual accounting support fee or fees, determined in accordance with section 7219 of this title.

(3)(A) With respect to matters concerning the national security of the United States, no duty or liability under paragraph (2) of this subsection shall be imposed upon any person acting in cooperation with the head of any Federal department or agency responsible for such matters if such act in cooperation with such head of a department or agency was done upon the specific, written directive of the head of such department or agency pursuant to Presidential authority to issue such directives. Each directive issued under this paragraph shall set forth the specific facts and circumstances with respect to which the provisions of this paragraph are to be invoked. Each such directive shall, unless renewed in writing, expire one year after the date of issuance.

(B) Each head of a Federal department or agency of the United States who issues such a directive pursuant to this paragraph shall maintain a complete file of all such directives and shall, on October 1 of each year, transmit a summary of matters covered by such directives in force at any time during the previous year to the Permanent Select Committee on Intelligence of the House

of Representatives and the Select Committee on Intelligence of the Senate.

(4) No criminal liability shall be imposed for failing to comply with the requirements of paragraph (2) of this subsection except as provided in paragraph (5) of this subsection.

(5) No person shall knowingly circumvent or knowingly fail to implement a system of internal accounting controls or knowingly falsify any book, record, or account described in paragraph (2).

(6) Where an issuer which has a class of securities registered pursuant to section 78*l* of this title or an issuer which is required to file reports pursuant to section 78*o*(d) of this title holds 50 per centum or less of the voting power with respect to a domestic or foreign firm, the provisions of paragraph (2) require only that the issuer proceed in good faith to use its influence, to the extent reasonable under the issuer's circumstances, to cause such domestic or foreign firm to devise and maintain a system of internal accounting controls consistent with paragraph (2). Such circumstances include the relative degree of the issuer's ownership of the domestic or foreign firm and the laws and practices governing the business operations of the country in which such firm is located. An issuer which demonstrates good faith efforts to use such influence shall be conclusively presumed to have complied with the requirements of paragraph (2).

(7) For the purpose of paragraph (2) of this subsection, the terms "reasonable assurances" and "reasonable detail" mean such level of detail and degree of assurance as would satisfy prudent officials in the conduct of their own affairs.

[Reminder of the statute omitted]

* * *

15 U.S.C. § 78ff Penalties [Section 32 of the Securities Exchange Act of 1934]

(a) Willful violations; false and misleading statements

Any person who willfully violates any provision of this chapter (other than section 78dd-1 of this title [Section 30A of the Exchange Act]), or any rule or regulation thereunder the violation of which is made unlawful or the observance of which is required under the terms of this chapter, or any person who willfully and knowingly makes, or causes to be made, any statement in any application, report, or document required to be filed under this chapter or any rule or regulation thereunder or any undertaking contained in a registration statement as provided in subsection (d) of section 78o of this title, or by any self-regulatory organization in connection with an application for membership or participation therein or to become associated with a member thereof which statement was false or misleading with respect to any material fact, shall upon conviction be fined not more than $5,000,000, or imprisoned not more than 20 years, or both, except that when such person is a person other than a natural person, a fine not exceeding $25,000,000 may be imposed; but no person shall be subject to imprisonment under this section for the violation of any rule or regulation if he proves that he had no knowledge of such rule or regulation.

(b) Failure to file information, documents, or reports

Any issuer which fails to file information, documents, or reports required to be filed under subsection (d) of section 78o of this title or any rule or regulation thereunder shall forfeit to the United States the sum of $100 for each and every day such failure to file shall continue. Such forfeiture, which shall be in lieu of any criminal penalty for such failure to file which might be deemed to arise under subsection (a) of this section, shall be payable into the Treasury of the United States and shall be recoverable in a civil suit in the name of the United States.

(c) Violations by issuers, officers, directors, stockholders, employees, or agents of issuers

(1)(A) Any issuer that violates subsection (a) or (g) of section 78dd-1 [Section 30A of the Exchange Act] of this title shall be fined not more than $2,000,000.

(B) Any issuer that violates subsection (a) or (g) of section 78dd-1 [Section 30A of the Exchange Act]

of this title shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Commission.

(2)(A) Any officer, director, employee, or agent of an issuer, or stockholder acting on behalf of such issuer, who willfully violates subsection (a) or (g) of section 78dd-1 [Section 30A of the Exchange Act] of this title shall be fined not more than $100,000, or imprisoned not more than 5 years, or both.

(B) Any officer, director, employee, or agent of an issuer, or stockholder acting on behalf of such issuer, who violates subsection (a) or (g) of section 78dd-1 [Section 30A of the Exchange Act] of this title shall be subject to a civil penalty of not more than $10,000 imposed in an action brought by the Commission.

(3) Whenever a fine is imposed under paragraph (2) upon any officer, director, employee, agent, or stockholder of an issuer, such fine may not be paid, directly or indirectly, by such issuer.

ENDNOTES

1 H. R. Rep. No. 95-640, at 4-5 (1977) [hereinafter H.R. Rep. No. 95-640], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/houseprt-95-640.pdf.

2 S. Rep. No. 95-114, at 4 (1977) [hereinafter S. Rep. No. 95-114], *available at* http://www.justice.gov/criminal/fraud/fcpa/history/1977/senaterpt-95-114.pdf.

3 *Id*.; H.R. Rep. No. 95-640, at 4-5. The House Report made clear Congress' concerns: "The payment of bribes to influence the acts or decisions of foreign officials, foreign political parties or candidates for foreign political office is unethical. It is counter to the moral expectations and values of the American public. But not only is it unethical, it is bad business as well. It erodes public confidence in the integrity of the free market system. It short-circuits the marketplace by directing business to those companies too inefficient to compete in terms of price, quality or service, or too lazy to engage in honest salesmanship, or too intent upon unloading marginal products. In short, it rewards corruption instead of efficiency and puts pressure on ethical enterprises to lower their standards or risk losing business." *Id*.

4 *See, e.g.*, U.S. Agency for Int'l Dev., USAID Anticorruption Strategy 5-6 (2005), *available at* https://www.usaid.gov/sites/default/files/documents/1868/200mbo.pdf. The growing recognition that corruption poses a severe threat to domestic and international security has galvanized efforts to combat it in the United States and abroad. *See, e.g.*, Int'l Anti-Corruption and Good Governance Act of 2000, Pub. L. No. 106-309, § 202, 114 Stat. 1090 (codified as amended at 22 U.S.C. §§ 2151-2152 (2000)) (noting that "[w]idespread corruption endangers the stability and security of societies, undermines democracy, and jeopardizes the social, political, and economic development of a society. . . . [and that] [c]orruption facilitates criminal activities, such as money laundering, hinders economic development, inflates the costs of doing business, and undermines the legitimacy of the government and public trust").

5 *See* Maryse Tremblay & Camille Karbassi, *Corruption and Human Trafficking* 4 (Transparency Int'l, Working Paper No. 3, 2011), *available at* https://issuu.com/transparencyinternational/docs/ti-working_paper_human_trafficking_28_jun_2011?mode=window&backgroundColor=%23222222; U.S. Agency for Int'l Dev., Foreign Aid in the National Interest 40 (2002), *available at* http://pdf.usaid.gov/pdf_docs/PDABW900.pdf ("No problem does more to alienate citizens from their political leaders and institutions, and to undermine political stability and economic development, than endemic corruption among the government, political party leaders, judges, and bureaucrats. The more endemic the corruption is, the more likely it is to be accompanied by other serious deficiencies in the rule of law: smuggling, drug trafficking, criminal violence, human rights abuses, and personalization of power.").

6 President George W. Bush observed in 2006 that "the culture of corruption has undercut development and good governance and . . . impedes our efforts to promote freedom and democracy, end poverty, and combat international crime and terrorism." President's Statement on Kleptocracy, 2 Pub. Papers 1504 (Aug. 10, 2006), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2006/08/20060810.html. The administrations of former President George W. Bush and former President Barack Obama both recognized the threats posed to security and stability by corruption. For instance, in issuing a proclamation restricting the entry of certain corrupt foreign public officials, former President George W. Bush recognized "the serious negative effects that corruption of public institutions has on the United States' efforts to promote security and to strengthen democratic institutions and free market systems. . ." Proclamation No. 7750, 69 Fed. Reg. 2287 (Jan. 14, 2004). Similarly, former President Barack Obama's National Security Strategy paper, released in May 2010, expressed the administration's efforts and commitment to promote the recognition that "pervasive corruption is a violation of basic human rights and a severe impediment to development and global security." The White

House, National Security Strategy 38 (2010), *available at* https://obamawhitehouse.archives.gov/sites/default/files/rss_viewer/national_security_strategy.pdf.

7 *See, e.g.*, Int'l Chamber of Commerce, et al., Clean Business Is Good Business: The Business Case Against Corruption (2008), *available at* https://d306pr3pise04h.cloudfront.net/docs/news_events%2F8.1%2Fclean_business_is_good_business.pdf; World Health Org., *Reinforcing the Focus on Anti-corruption, Transparency and Accountability in National Health Policies, Strategies and Plans* (2019), *available at* https://apps.who.int/iris/bitstream/handle/10665/326229/9789241515689-eng.pdf?ua=1.

8 *See, e.g.*, *The Corruption Eruption*, Economist (Apr. 29, 2010), *available at* http://www.economist.com/node/16005114 ("The hidden costs of corruption are almost always much higher than companies imagine. Corruption inevitably begets ever more corruption: bribe-takers keep returning to the trough and bribe-givers open themselves up to blackmail."); Daniel Kaufmann and Shang-Jin Wei, *Does "Grease Money" Speed Up the Wheels of Commerce?* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 7093, 1999), *available at* http://www.nber.org/papers/w7093.pdf ("Contrary to the 'efficient grease' theory, we find that firms that pay more bribes are also likely to spend more, not less, management time with bureaucrats negotiating regulations, and face higher, not lower, cost of capital.").

9 For example, in a number of recent enforcement actions, the same employees who were directing or controlling the bribe payments were also enriching themselves at the expense of the company. *See, e.g.*, Criminal Information, *United States v. Cyrus Allen Ahsani, et al.*, No. 19-cr-147 (S.D. Tex. Mar. 4, 2019), ECF No. 1 [hereinafter *United States v. Ahsani*] (paying kickbacks to executives who were involved in bribe payments), *available at* https://www.justice.gov/criminal-fraud/case/file/1266861/download; Criminal Information, *United States v. Colin Steven*, No. 17-cr-788 (S.D.N.Y. Dec. 21, 2017), ECF No. 2 [hereinafter *United States v. Steven*] (receiving kickbacks related to certain corrupt payments made by Embraer, S.A.), *available at* https://www.justice.gov/criminal-fraud/file/1021856/download; Criminal Information, *United States v. Robert Zubiate*, No. 17-cr-591 (S.D. Tex. Oct. 6, 2017), ECF No. 1 [hereinafter *United States v. Zubiate*] (receiving kickbacks related to certain corrupt payments made by SBM Offshore, N.V. in Brazil), *available at* https://www.justice.gov/criminal-fraud/file/1017281/download; Complaint, *SEC v. Peterson*, No. 12-cv-2033 (E.D.N.Y. 2012), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2012/comp-pr2012-78.pdf; Criminal Information, *United States v. Peterson*, No. 12-cr-224 (E.D.N.Y. 2012), ECF No. 7 [hereinafter *United States v. Peterson*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/04/26/petersong-information.pdf; Plea Agreement, *United States v. Stanley*, No. 08-cr-597 (S.D. Tex. 2008), ECF No. 9 [hereinafter *United States v. Stanley*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/03/19/09-03-08stanley-plea-agree.pdf; Plea Agreement, *United States v. Sapsizian*, No. 06-cr-20797 (S.D. Fla. 2007), ECF No. 42 [hereinafter *United States v. Sapsizian*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/06-06-07sapsizian-plea.pdf.

10 *See, e.g.*, Criminal Information, *United States v. Société Générale S.A.*, No. 18-cr-253 (E.D.N.Y. May 18, 2018), ECF No. 4 [hereinafter *United States v. Société Générale*], *available at* https://www.justice.gov/criminal-fraud/file/1072456/download; Complaint, *SEC v. Tyco Int'l Ltd.*, 06-cv-2942 (S.D.N.Y. 2006), ECF No. 1 [hereinafter *SEC v. Tyco Int'l*], *available at* http://www.sec.gov/litigation/complaints/2006/comp19657.pdf; Complaint, *SEC v. Willbros Group, Inc.*, No. 08-cv-1494 (S.D. Tex. 2008), ECF No. 1 [hereinafter *SEC v. Willbros*], *available at* http://www.sec.gov/litigation/complaints/2008/comp20571.pdf.

11 *See United States v. Ahsani*, *supra* note 9 (engaging in bid-rigging); Plea Agreement, *United States v. Bridgestone Corp.*, No. 11-cr-651 (S.D. Tex. 2011), ECF No. 21, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/10/18/10-05-11bridgestone-plea.pdf.

12 *See* S. Rep. No. 95-114, at 6; H.R. Rep. No. 95-640, at 4; *see also* A. Carl Kotchian, *The Payoff: Lockheed's 70-Day Mission to Tokyo*, Saturday Rev., Jul. 9, 1977, at 7.

13 U.S. Sec. and Exchange Comm., Report of the Securities and Exchange Commission on Questionable and Illegal Corporate Payments and Practices 2-3 (1976).

14 *See* H.R. Rep. No. 95-640, at 4-5; S. Rep. No. 95-114, at 3-4.

15 H.R. Rep. No. 95-640, at 4-5; S. Rep. No. 95-114, at 4. The Senate Report observed, for instance, that "[m]anagements which resort to corporate bribery and the falsification of records to enhance their business reveal a lack of confidence about themselves," while citing the Secretary of the Treasury's testimony that "'[p]aying bribes—apart from being morally repugnant and illegal in most countries—is simply not necessary for the successful conduct of business here or overseas.'" *Id*.

16 *See* S. Rep. No. 100-85, at 46 (1987) (recounting FCPA's historical background and explaining that "a strong antibribery statute could help U.S. corporations resist corrupt demands . . . .") [hereinafter S. Rep. No. 100-85].

17 S. Rep. No. 95-114, at 7.

18 Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100- 418, § 5003, 102 Stat. 1107, 1415-25 (1988); *see also* H.R. Rep. No. 100-576, at 916-24 (1988) (discussing FCPA amendments, including changes to standard of liability for acts of third parties) [hereinafter H.R. Rep. No. 100-576].

19 *See* Omnibus Trade and Competitiveness Act of 1988, § 5003(d). The amended statute included the following directive: "It is the sense of the Congress that the President should pursue the negotiation of an international agreement, among the members of the Organization of Economic Cooperation and Development, to govern persons from those countries concerning acts prohibited with respect to issuers and domestic concerns by the amendments made by this section. Such international agreement should include a process by which problems and conflicts associated with such acts could be resolved." *Id*.; *see also* S. Rep. No. 105-277, at 2 (1998) (describing efforts by Executive Branch to encourage U.S. trading partners to enact legislation similar to FCPA following 1988 amendments) [hereinafter S. Rep. No. 105-277].

20 Convention on Combating Bribery of Foreign Public Officials in International Business Transactions art. 1.1, Dec.

18, 1997, 37 I.L.M. 1 [hereinafter Anti-Bribery Convention]. The Anti-Bribery Convention requires member countries to make it a criminal offense "for any person intentionally to offer, promise or give any undue pecuniary or other advantage, whether directly or through intermediaries, to a foreign public official, for that official or for a third party, in order that the official act or refrain from acting in relation to the performance of official duties, in order to obtain or retain business or other improper advantage in the conduct of international business." The Convention and its commentaries also call on all parties (a) to ensure that aiding and abetting and authorization of an act of bribery are criminal offenses, (b) to assert territorial jurisdiction "broadly so that an extensive physical connection to the bribery act is not required," and (c) to assert nationality jurisdiction consistent with the general principles and conditions of each party's legal system. *Id*. at art. 1.2, cmts. 25, 26.

21 *See* International Anti-Bribery and Fair Competition Act of 1998, Pub. L. 105-366, 112 Stat. 3302 (1998); *see also* S. Rep. No. 105-277, at 2-3 (describing amendments to "the FCPA to conform it to the requirements of and to implement the OECD Convention").

22 There is no private right of action under the FCPA. *See, e.g.*, *Lamb v. Phillip Morris, Inc.*, 915 F.2d 1024, 1028-29 (6th Cir. 1990); *McLean v. Int'l Harvester Co.*, 817 F.2d 1214, 1219 (5th Cir. 1987).

23 U.S. Dept. of Justice, Justice Manual § 9-47.110 (2008) [hereinafter JM], *available at* https://www.justice.gov/jm/justice-manual.

24 Go to https://www.trade.gov/virtual-services and https://2016.export.gov/worldwide_us/index.asp for more information.

25 *See* International Trade Administration, Country Commercial Guides, *available at*: https://www.trade.gov/ccg-landing-page.

26 The International Company Profile reports include a listing of the potential partner's key officers and senior management; banking relationships and other financial information about the company; and market information, including sales and profit figures and potential liabilities. They are not, however, intended to substitute for a company's own due diligence, and the Commercial Service does not offer ICP in countries where Dun & Bradstreet or other private sector vendors are already performing this service. *See* International Trade Administration, International Company Profile, *available at* https://www.trade.gov/international-company-profile-0.

27 *See* International Trade Administration, The U.S. Commercial Service – Virtual Services, *available at* https://www.trade.gov/virtual-services.

28 *See* https://tcc.export.gov/Report_a_Barrier/index.asp.

29 Information about the Advocacy Center services can be found at https://www.trade.gov/advocacy-center-services.

30 Reports on U.S. compliance with these treaties can be found at http://www.justice.gov/criminal/fraud/fcpa/intlagree/.

31 *See* Statement on Signing the International Anti-Bribery and Fair Competition Act of 1998, 34 Weekly Comp. Pres. Doc. 2290, 2291 (Nov. 10, 1998) ("U.S. companies have had to compete on an uneven playing field . . . . The OECD Convention . . . is designed to change all that. Under the Convention, our major competitors will be obligated to criminalize the bribery of foreign public officials in international business transactions.").

32 OECD, *Country Monitoring of the OECD Anti-Bribery Convention, available at* http://www.oecd.org/document/12/0,3746,en_2649_34859_35692940_1_1_1_1,00.html.

33 OECD, *Phase 3 Country Monitoring of the OECD Anti-Bribery Convention, available at* http://www.oecd.org/document/31/0,3746,en_2649_34859_44684959_1_1_1_1,00.html.

34 OECD, *Country Reports on the Implementation of the OECD Anti-Bribery Convention, available at* http://www.oecd.org/document/24/0,3746,en_2649_34859_1933144_1_1_1_1,00.html.

35 The OECD Phase 1, 2, and 3 reports on the United States, as well as the U.S. responses to questionnaires, are *available at* http://www.justice.gov/criminal/fraud/fcpa/intlagree.

36 *See* OECD Working Group on Bribery, *United States: Phase 3, Report on the Application of the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions and the 2009 Revised Recommendation on Combating Bribery in International Business Transactions*, Oct. 2010, at 61-62 (recommending that the United States "[c]onsolidate and summarise publicly available information on the application of the FCPA in relevant sources"), *available at* https://www.oecd.org/unitedstates/UnitedStatesphase3reportEN.pdf.

37 United Nations Convention Against Corruption, Oct. 31, 2003, S. Treaty Doc. No. 109-6, 2349 U.N.T.S. 41, *available at* https://www.unodc.org/documents/brussels/UN_Convention_Against_Corruption.pdf [hereinafter UNCAC].

38 For more information about the UNCAC review mechanism, *see Mechanism for the Review of Implementation of the United Nations Convention Against Corruption*, United Nations Office on Drugs and Crime, *available at* http://www.unodc.org/documents/treaties/UNCAC/Publications/ReviewMechanism-BasicDocuments/Mechanism_for_the_Review_of_Implementation_-_Basic_Documents_-_E.pdf.

39 For information about the status of UNCAC, *see* United Nations Office on Drugs and Crime, *UNCAC Signature and Ratification Status as of 6 February 2020, available at* http://www.unodc.org/unodc/en/treaties/CAC/signatories.html.

40 Organization of American States, Inter-American Convention Against Corruption, Mar. 29, 1996, 35 I.L.M. 724, *available at* http://www.oas.org/juridico/english/treaties/b-58.html. For additional information about the status of the IACAC, *see* Organization of American States, Signatories and Ratifications, *available at* http://www.oas.org/juridico/english/Sigs/b-58.html.

41 Council of Europe, Criminal Law Convention on Corruption, Jan. 27, 1999, 38 I.L.M. 505, *available at* http://conventions.coe.int/Treaty/en/Treaties/html/173.html.

42 For additional information about GRECO, *see* Council of Europe, *Group of States Against Corruption, available at* http://www.coe.int/t/dghl/monitoring/greco/default_EN.asp. The United States has not yet ratified the GRECO convention.

43 The text of the FCPA statute is set forth in the appendix. *See also* Jury Instructions at 52-64, *United States v. Mark Lambert*, No. 18-cr-012 (D. Md. Nov. 14, 2019), ECF No. 152 [hereinafter *United States v. Lambert*] (FCPA jury instructions); Jury Instructions at 1259-66, *United States v. Lawrence Hoskins,* No. 12-cr-238 (D. Conn. Nov. 6, 2019), ECF No. 601 [hereinafter *United States v. Hoskins*] (same); Jury Instructions at 33-37, *United States v. Joseph Baptiste*, No. 17-cr-10305 (D. Mass. June 19, 2019), ECF No. 195 [hereinafter *United States v. Baptiste*] (same); Jury Instructions at 1081-89, *United States v. Chi Ping Patrick Ho*, No. 17-cr-779 (S.D.N.Y. Dec. 4, 2018), ECF No. 214 [hereinafter *United States v. Ho*] (same); Jury Instructions at 4249-62, *United States v. Ng Lap Seng*, No. 15-cr-706 (S.D.N.Y. July 26, 2017), ECF No. 609 [hereinafter *United States v. Ng*] (same); Jury Instructions at 21-27, *United States v. Esquenazi*, No. 09-cr-21010 (S.D. Fla. Aug. 5, 2011), ECF No. 520 [hereinafter *United States v. Esquenazi*] (same); Jury Instructions at 14-25, *United States v. Kay*, No. 01-cr-914 (S.D. Tex. Oct. 6, 2004), ECF No. 142 (same), *aff'd*, 513 F.3d 432, 446-52 (5th Cir. 2007), *reh'g denied*, 513 F.3d 461 (5th Cir. 2008) [hereinafter *United States v. Kay*]; Jury Instructions at 76-87, *United States v. Jefferson*, No. 07-cr-209 (E.D. Va. July 30, 2009), ECF No. 684 [hereinafter *United States v. Jefferson*] (same); Jury Instructions at 8-10, *United States v. Green*, No. 08-cr-59 (C.D. Cal. Sept. 11, 2009), ECF No. 288 [hereinafter *United States v. Green*] (same); Jury Instructions at 23-29, *United States v. Bourke*, No. 05-cr-518 (S.D.N.Y. July 2009) [hereinafter *United States v. Bourke*] (same, not docketed); Jury Instructions at 2-8, *United States v. Mead*, No. 98-cr-240 (D.N.J. Oct. 1998) [hereinafter *United States v. Mead*] (same).

44 The provisions of the FCPA applying to issuers are part of the Securities Exchange Act of 1934 [hereinafter Exchange Act]. The anti-bribery provisions can be found at Section 30A of the Exchange Act, 15 U.S.C. § 78dd-1.

45 15 U.S.C. § 78l.

46 15 U.S.C. § 78o(d).

47 SEC enforcement actions have involved a number of foreign issuers. *See, e.g.*, Complaint, *SEC v. Magyar Telekom Plc., et al.*, No. 11-cv-9646 (S.D.N.Y. Dec. 29, 2011), ECF No. 1 (German and Hungarian companies), *available at* http://www.sec.gov/litigation/complaints/2011/comp22213-co.pdf; Complaint, *SEC v. Alcatel-Lucent, S.A.*, No. 10-cv-24620 (S.D. Fla. Dec. 27, 2010), ECF No.1 [hereinafter *SEC v. Alcatel-Lucent*] (French company), *available at* http://www.sec.gov/litigation/complaints/2010/comp21795.pdf; Complaint, *SEC v. ABB, Ltd.*, No. 10-cv-1648 (D.D.C. Sept. 29, 2010), ECF No. 1 [hereinafter *SEC v. ABB*] (Swiss company), *available at* http://www.sec.gov/litigation/complaints/2010/comp-pr2010-175.pdf; Complaint, *SEC v. Daimler AG*, No. 10-cv-473 (D.D.C. Apr. 1, 2010), ECF No. 1 [hereinafter *SEC v. Daimler AG*] (German company), *available at* http://sec.gov/litigation/complaints/2010/comp-pr2010-51.pdf; Complaint, *SEC v. Siemens Aktiengesellschaft*, No. 08- cv-2167 (D.D.C. Dec. 12, 2008), ECF No. 1 [hereinafter *SEC v. Siemens AG*] (German company), *available at* http://www.sec.gov/litigation/complaints/2008/comp20829.pdf. Certain DOJ enforcement actions have likewise involved foreign issuers. *See, e.g.*, Criminal Information, *United States v. Telefonaktiebolaget LM Ericsson*, No. 19-cr-884 (S.D.N.Y. Dec. 6, 2019), ECF No. 3 [hereinafter *United States v. Ericsson*], *available at* https://justice.gov/criminal-fraud/file/1226526/download; Non-Pros. Agreement, *In re Petróleo Brasileiro S.A.* (Sept. 26, 2018), *available at* https://www.justice.gov/criminal-fraud/file/1097256/download; Criminal Information, *United States v. Teva LLC*, No. 16-cr-20967 (S.D. Fla. Dec. 22, 2016), ECF No. 1, *available at* https://www.justice.gov/criminal-fraud/file/920421/download; Criminal Information, *United States v. Braskem S.A.*, No. 16-cr-709 (E.D.N.Y. Dec. 21, 2016), ECF No. 6, *available at* https://www.justice.gov/criminal-fraud/file/920086/download.

48 *See* http://www.sec.gov/divisions/corpfin/internatl/companies.html.

49 *See, e.g.*, Criminal Information, *United States v. Ericsson*, *supra* note 47 (charging issuer company with violating FCPA for paying bribes to foreign officials in Djibouti, China, Vietnam, Indonesia, and Kuwait); Criminal Information, *United States v. Tim Leissner*, No. 18-cr-439 (E.D.N.Y. Aug. 28, 2018), ECF No. 16 (charging an employee and agent of U.S. publicly traded company with violating FCPA for bribery of official in Malaysia), *available at* https://www.justice.gov/criminal-fraud/file/1231346/download; *United States v. Steven*, *supra* note 9 (charging a UK employee of U.S. publicly traded company with violating FCPA for bribery of officials in Saudi Arabia).

50 15 U.S.C. § 78dd-2.

51 15 U.S.C. § 78dd-2(h)(1).

52 *See, e.g.*, Indictment, *United States v. Lambert*, *supra* note 43, ECF No. 1 (employee of domestic concern charged with violating FCPA for bribes paid to a Russian government official), *available at* https://www.justice.gov/criminal-fraud/file/1044676/download; Criminal Information, *United States v. James Finley*, No. 17-cr-160 (S.D. Ohio July 21, 2017), ECF No. 3 (executive of foreign parent company charged as an agent of a domestic concern in directing bribes to Kazakh official on behalf of U.S.-based subsidiary), *available at* https://www.justice.gov/criminal-fraud/file/1009596/download; Superseding Indictment, *United States v. Dmitrij Harder*, No. 15-cr-001 (E.D. Pa. Dec. 15, 2015), ECF No. 62 [hereinafter *United States v. Harder*] (owner of U.S. corporation charged for bribes paid to an official at the European Bank for Reconstruction and Development), *available at* https://www.justice.gov/criminal-fraud/file/843621/download.

53 15 U.S.C. § 78dd-3(a). As discussed above, foreign companies that have securities registered in the United States or that are required to file periodic reports with SEC, including certain foreign companies with American Depository Receipts, are covered by the FCPA's anti-bribery provisions governing "issuers" under 15 U.S.C. § 78dd-1.

54 *See* International Anti-Bribery and Fair Competition Act of 1998, Pub. L. 105-366, 112 Stat. 3302 (1998); 15 U.S.C. § 78dd-3(a); *see also* U.S. Dept. of Justice, Criminal Resource

Manual § 9-1018 (Nov. 2000) (the Department "interprets [Section 78dd-3(a)] as conferring jurisdiction whenever a foreign company or national *causes* an act to be done within the territory of the United States by any person acting as that company's or national's agent."). This interpretation is consistent with U.S. treaty obligations. *See* S. Rep. No. 105-2177 (1998) (expressing Congress' intention that the 1998 amendments to the FCPA "conform it to the requirements of and to implement the OECD Convention"); Anti-Bribery Convention at art. 4.1, *supra* note 20 ("Each Party shall take such measures as may be necessary to establish its jurisdiction over the bribery of a foreign public official when the offence is committed in whole or in part in its territory.").

55 *See, e.g.*, Criminal Information, *United States v. Airbus SE*, No. 20-cr-021 (D.D.C. Jan. 28, 2020), ECF No. 1 (Netherlands-headquartered company with main offices in France convicted of FCPA violations for paying bribes to Chinese officials in order to obtain contracts to sell aircraft) [hereinafter *United States v. Airbus*], *available at* https://www.justice.gov/criminal-fraud/file/1242046/download; Superseding Indictment, *United States v. Ng*, *supra* note 43, ECF No. 322 (Chinese businessman convicted of paying bribes to former United Nations (U.N.) Ambassador from the Dominican Republic and former Permanent Representative of Antigua and Barbuda to the U.N. in exchange for corrupt assistance in obtaining formal U.N. support for defendant's conference center in Macau), *available at* https://www.justice.gov/criminal-fraud/file/913286/download; Criminal Information, *United States v. Samuel Mebiame*, No.16-cr-627 (E.D.N.Y. Dec. 9, 2016), ECF No. 19 (Gabonese consultant who worked on behalf of a British Virgin Islands company and a joint venture between a U.S. company and a Turks and Caicos company convicted of FCPA violations for paying bribes to officials in Niger, Chad, and Guinea), *available at* https://www.justice.gov/criminal-fraud/file/943121/download.

56 *See* 15 U.S.C. §§ 78dd-2(h)(5) (defining "interstate commerce"), 78dd-3(f)(5) (same); *see also* 15 U.S.C. § 78c(a)(17).

57 15 U.S.C. §§ 78dd-2(h)(5), 78dd-3(f)(5).

58 *See* 15 U.S.C. § 78dd-3.

59 *See, e.g.*, Superseding Indictment, *United States v. Nervis G. Villalobos-Cardenas, et al.*, No. 17-cr-514 (S.D. Tex. Apr. 24, 2019) (establishing jurisdiction under 15 U.S.C. § 78dd-3 based on meetings in the U.S.), *available at* https://www.justice.gov/criminal-fraud/file/1267066/download; Criminal Information, *United States v. Steven Hunter*, No. 18-cr-415 (S.D. Tex. Sept. 17, 2018) (same), *available at* https://www.justice.gov/criminal-fraud/file/1266876/download; *United States v. Ramiro Andres Luque Flores*, No. 17-cr-537 (E.D.N.Y. Oct. 6, 2017) (same); *see also United States v. Société Générale*, *supra* note 10 (establishing corporate jurisdiction under 15 U.S.C. § 78dd-3 based on, among other things, meetings in the U.S.).

60 *See* 15 U.S.C. §§ 78dd-1(g) ("irrespective of whether such issuer or such officer, director, employee, agent, or stockholder makes use of the mails or any means or instrumentality of interstate commerce in furtherance of such offer, gift, payment, promise, or authorization"), 78dd-2(i)(1) ("irrespective of whether such United States person makes use of the mails or any means or instrumentality of interstate commerce in furtherance of such offer, gift, payment, promise, or authorization").

61 S. Rep. No. 105-277 at 2 ("[T]he OECD Convention calls on parties to assert nationality jurisdiction when consistent with national legal and constitutional principles. Accordingly, the Act amends the FCPA to provide for jurisdiction over the acts of U.S. businesses and nationals in furtherance of unlawful payments that take place wholly outside the United States. This exercise of jurisdiction over U.S. businesses and nationals for unlawful conduct abroad is consistent with U.S. legal and constitutional principles and is essential to protect U.S. interests abroad.").

62 *Id.* at 2-3.

63 15 U.S.C. § 78dd-1(a), 78dd-2(a), 78dd-3(a).

64 *Id.*

65 *See* H.R. Rep. No. 95-831 at 12 (referring to "business purpose" test).

66 *See, e.g.*, Complaint, *SEC v. Telefonaktiebolaget LM Ericsson*, No. 19-cv-11214 (S.D.N.Y. Dec. 6, 2019), ECF No. 1 [hereinafter *SEC v. Ericsson*], *available at* https://www.sec.gov/litigation/complaints/2019/comp-pr2019-254.pdf; Criminal Information, *United States v. Ericsson*, *supra* note 47; *SEC v. Ericsson*, https://www.sec.gov/news/press-release/2019-254.

67 In amending the FCPA in 1988, Congress made clear that the business purpose element, and specifically the "retaining business" prong, was meant to be interpreted broadly: "The Conferees wish to make clear that the reference to corrupt payments for 'retaining business' in present law is not limited to the renewal of contracts or other business, but also includes a prohibition against corrupt payments related to the execution or performance of contracts or the carrying out of existing business, such as a payment to a foreign official for the purpose of obtaining more favorable tax treatment. The term should not, however, be construed so broadly as to include lobbying or other normal representations to government officials." H.R. Rep. No. 100-576, at 1951-52 (internal citations omitted).

68 *See, e.g.*, Non-Pros. Agreement, *In re: Wal-Mart, Inc.* (June 20, 2019) (holding company liable for internal controls failures resulting in corrupt payments related to obtaining permits and licenses), *available at* https://www.justice.gov/criminal-fraud/page/file/1177596/download; Non-Pros. Agreement, *In re: Archer Daniels Midland Company* (Dec. 20, 2013) (favorable tax treatment), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2014/01/03/adm-npa.pdf; Non-Pros. Agreement, *In re Ralph Lauren Corporation* (Apr. 22, 2013) (customs clearance), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2013/04/23/Ralph-Lauren.-NPA-Executed.pdf.

69 *United States v. Kay*, 359 F.3d 738, 755-56 (5th Cir. 2004).

70 *Id.* at 749. Indeed, the *Kay* court found that Congress' explicit exclusion of facilitation payments from the scope of the FCPA was evidence that "Congress intended for the FCPA to prohibit *all other* illicit payments that are intended to influence non-trivial official foreign action in an effort to aid in obtaining or retaining business for some person." *Id.* at 749-50 (emphasis added).

71 *Id.* at 750.

72 *Id.* at 749-55.

73 *Id.* at 756 ("It still must be shown that the bribery was intended to produce an effect—here, through tax savings—that would 'assist in obtaining or retaining business.'").

74 The FCPA does not explicitly define "corruptly," but in drafting the statute Congress adopted the meaning ascribed to the same term in the domestic bribery statute, 18 U.S.C. § 201(b). *See* H.R. Rep. No. 95-640 at 7.

75 The House Report states in full: "The word 'corruptly' is used in order to make clear that the offer, payment, promise, or gift, must be intended to induce the recipient to misuse his official position; for example, wrongfully to direct business to the payor or his client, to obtain preferential legislation or regulations, or to induce a foreign official to fail to perform an official function. The word 'corruptly' connotes an evil motive or purpose such as that required under 18 U.S.C. 201(b) which prohibits domestic bribery. As in 18 U.S.C. 201(b), the word 'corruptly' indicates an intent or desire wrongfully to influence the recipient. It does not require that the act [be] fully consummated or succeed in producing the desired outcome." *Id.* The Senate Report provides a nearly identical explanation of the meaning of the term: "The word 'corruptly' is used in order to make clear that the offer, payment, promise, or gift, must be intended to induce the recipient to misuse his official position in order to wrongfully direct business to the payor or his client, or to obtain preferential legislation or a favorable regulation. The word 'corruptly' connotes an evil motive or purpose, an intent to wrongfully influence the recipient." S. Rep. No. 95-114, at 10.

76 *See* 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-3(a).

77 *See, e.g.*, Complaint, *SEC v. Monsanto Co.*, No. 05-cv-14 (D.D.C. Jan. 6, 2005) (among other things, the company paid a $50,000 bribe to influence an Indonesian official to repeal an unfavorable law, which was not repealed despite the bribe), *available at* http://www.sec.gov/litigation/complaints/comp19023.pdf; Criminal Information, *United States v. Monsanto Co.*, No. 05-cr-8 (D.D.C. Jan. 6, 2005), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/monsanto-co/01-06-05monsanto-info.pdf.

78 Jury instructions in FCPA cases have defined "corruptly" consistent with the definition found in the legislative history. *See, e.g.*, Jury Instructions at 56, *United States v. Lambert*, *supra* note 43; Jury Instructions at 34, *United States v. Baptiste*, *supra* note 43; Jury Instructions at 1261, *United States v. Hoskins*, *supra* note 43; Jury Instructions at 1084-85, *United States v. Ho*, *supra* note 43; Jury Instructions at 4242, *United States v. Ng*, *supra* note 43; Jury Instructions at 22-23, *United States v. Esquenazi*, *supra* note 43; Jury Instructions at 10, *United States v. Green*, *supra* note 43; Jury Instructions at 35, *United States v. Jefferson*, *supra* note 43; Jury Instructions at 25, *United States v. Bourke*, *supra* note 43; Jury Instructions at 17, *United States v. Kay*, *supra* note 43; Jury Instructions at 5, *United States v. Mead*, *supra* note 43.

79 *See* Indictment, *United States v. Joo Hyun Bahn, et al.*, No. 16-cr-831 (S.D.N.Y. Dec. 15, 2016), ECF No. 1, *available at* https://www.justice.gov/criminal-fraud/case/file/942226/download; *see also*, *In the Matter of JooHyun Bahn, available at* https://www.sec.gov/news/press-release/2018-181.

80 *See* Complaint, *SEC v. Innospec, Inc.*, No. 10-cv-448 (D.D.C. Mar. 18, 2010), ECF No. 1 [hereinafter *SEC v. Innospec*], *available at* http://www.sec.gov/litigation/complaints/2010/comp21454.pdf; Criminal Information at 8, *United States v. Innospec Inc.*, No. 10-cr-61 (D.D.C. Mar. 17, 2010), ECF No. 1 [hereinafter *United States v. Innospec*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/03-17-10innospec-info.pdf.

81 *See* 15 U.S.C. §§ 78dd-2(g)(2)(A), 78dd-3(e)(2)(A), 78ff(c)(2)(A).

82 *Compare* 15 U.S.C. § 78ff(c)(1)(A) (corporate criminal liability under issuer provision) with § 78ff(c)(2)(A) (individual criminal liability under issuer provision); *compare* 15 U.S.C. § 78dd-2(g)(1)(A) (corporate criminal liability under domestic concern provision) *with* § 78dd-2(g)(2)(A) (individual criminal liability under issuer provision); *compare* 15 U.S.C. § 78dd-3(e)(1)(A) (corporate criminal liability under territorial provision) with § 78dd-3(e)(2)(A) (individual criminal liability under territorial provision). However, companies still must act corruptly. *See* Section 30A(a), 15 U.S.C. § 78dd-1(a); 15 U.S.C. §§ 78dd-2(a), 78dd-3(a).

83 *United States v. Kay*, 513 F.3d 432, 448 (5th Cir. 2007); *see also* Jury Instructions at 56-57, *United States v. Lambert*, *supra* note 43; Jury Instructions at 34-35, *United States v. Baptiste*, *supra* note 43; Jury Instructions at 1261, *United States v. Hoskins*, *supra* note 43; Jury Instructions at 1084-85, *United States v. Ho*, *supra* note 43; Jury Instructions at 4242, *United States v. Ng*, *supra* note 43; Jury Instructions at 38, *United States v. Esquenazi*, *supra* note 43; Jury Instructions at 10, *United States v. Green*, *supra* note 43; Jury Instructions at 35, *United States v. Jefferson*, *supra* note 43; Jury Instructions at 25, *United States v. Bourke*, *supra* note 43; Jury Instructions at 5, *United States v. Mead*, *supra* note 43.

84 *Bryan v. United States*, 524 U.S. 184, 191-92 (1998) (construing "willfully" in the context of 18 U.S.C. § 924(a)(1)(A)) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137 (1994)); *see also Kay*, 513 F.3d at 446-51 (discussing *Bryan* and term "willfully" under the FCPA).

85 *Kay*, 513 F.3d at 447-48; *Stichting Ter Behartiging Van de Belangen Van Oudaandeelhouders In Het Kapitaal Van Saybolt Int'l B.V. v. Schreiber*, 327 F.3d 173, 181 (2d Cir. 2003).

86 The phrase "anything of value" is not defined in the FCPA, but the identical phrase under the domestic bribery statute has been broadly construed to include both *tangible* and *intangible* benefits. *See, e.g.*, *United States v. Moore,* 525 F.3d 1033, 1048 (11th Cir. 2008) (rejecting defendant's objection to instruction defining sex as a "thing of value," which "unambiguously covers intangible considerations"); *United States v. Gorman*, 807 F.2d 1299, 1304-05 (6th Cir. 1986) (holding that loans and promises of future employment are "things of value"); *United States v. Williams*, 705 F.2d 603, 622-23 (2d Cir. 1983) (approving jury instruction that stock could be a "thing of value" if defendant believed it had value, even though the shares had no commercial value, and noting that "[t]he phrase 'anything of value' in bribery and related statutes has consistently been given a broad meaning").

87 Section 30A(a), 15 U.S.C. § 78dd-1(a); 15 U.S.C. §§ 78dd-2(a), 78dd- 3(a) (emphasis added).

88 Like the FCPA, the domestic bribery statute, 18 U.S.C. § 201, prohibits giving, offering, or promising "anything of

value." Numerous domestic bribery cases under Section 201 have involved "small" dollar bribes. *See, e.g.*, *United States v. Franco*, 632 F.3d 880, 882-84 (5th Cir. 2011) (affirming bribery convictions of inmate for paying correctional officer $325 to obtain cell phone, food, and marijuana, and noting that 18 U.S.C. § 201 does not contain minimum monetary threshold); *United States v. Williams*, 216 F.3d 1099, 1103 (D.C. Cir. 2000) (affirming bribery conviction for $70 bribe to vehicle inspector); *United States v. Traitz*, 871 F.2d 368, 396 (3rd Cir. 1989) (affirming bribery conviction for $100 bribe paid to official of Occupational Health and Safety Administration); *United States v. Hsieh Hui Mei Chen*, 754 F.2d 817, 822 (9th Cir. 1985) (affirming bribery convictions including $100 bribe to immigration official); *United States v. Bishton*, 463 F.2d 887, 889 (D.C. Cir. 1972) (affirming bribery conviction for $100 bribe to division chief of District of Columbia Sewer Operations Division).

89 *See* Criminal Information, *United States v. Odebrecht S.A.*, No. 16-CR-643 (E.D.N.Y. Dec. 21, 2016), ECF No. 8, *available at* https://www.justice.gov/criminal-fraud/file/920096/download.

90 Complaint, *SEC v. Halliburton Company and KBR, Inc.*, No. 09-cv-399 (S.D. Tex. Feb. 11, 2009), ECF No 1 [hereinafter *SEC v. Halliburton and KBR*], *available at* http://www.sec.gov/litigation/complaints/2009/comp20897.pdf; Criminal Information, *United States v. Kellogg Brown & Root LLC*, No. 09-cr-71, ECF No. 1 (S.D. Tex. Feb. 6, 2009) [hereinafter *United States v. KBR*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/02-06-09kbr-info.pdf.

91 Complaint, *SEC v. Halliburton and KBR*, *supra* note 90; Criminal Information, *United States v. KBR, supra* note 90.

92 *See, e.g.*, Complaint, *SEC v. RAE Sys. Inc.*, No. 10-cv-2093 (D.D.C. Dec. 10, 2010), ECF No. 1 [hereinafter *SEC v. RAE Sys., Inc.*] (fur coat, among other extravagant gifts), *available at* http://www.sec.gov/litigation/complaints/2010/comp21770.pdf; Non-Pros. Agreement, *In re RAE Sys. Inc.* (Dec. 10, 2010) [hereinafter *In re RAE Sys. Inc.*] (same), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/12-10-10rae-systems.pdf; Complaint, *SEC v. Daimler AG, supra* note 47 (armored Mercedes Benz worth €300,000); Criminal Information, *United States v. Daimler AG, supra* note 47 (same).

93 *See* Criminal Information, *United States v. SBM Offshore, N.V.*, No. 17-cr-686 (S.D. Tex. Nov. 21, 2017), ECF No. 1 [hereinafter *United States v. SBM*], *available at* https://www.justice.gov/criminal-fraud/file/1017351/download.

94 *See* Complaint, *SEC v. ABB Ltd*, No. 04-cv-1141 (D.D.C. July 6, 2004), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/comp18775.pdf; Criminal Information, *United States v. ABB Vetco Gray Inc., et al.*, No. 04-cr-279 (S.D. Tex. June 22, 2004), ECF No. 1 [hereinafter *United States v. ABB Vetco Gray*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2014/11/07/06-22-04abbvetco-info.pdf.

95 Criminal Information, *United States v. Ericsson, supra* note 47.

96 Complaint, *SEC v. Lucent Technologies Inc.*, No. 07-cv-2301 (D.D.C. Dec. 21, 2007), ECF No.1 [hereinafter *SEC v. Lucent*], *available at* http://www.sec.gov/litigation/complaints/2007/comp20414.pdf; Non-Pros. Agreement, *In re Lucent Technologies* (Nov. 14, 2007) [hereinafter *In re Lucent*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/11-14-07lucent-agree.pdf.

97 Complaint, *SEC v. Lucent*, *supra* note 96; Non-Pros. Agreement, *In re Lucent, supra* note 96.

98 The company consented to the entry of a final judgment permanently enjoining it from future violations of the books and records and internal controls provisions and paid a civil penalty of $1,500,000. Complaint, *SEC v. Lucent*, *supra* note 96. Additionally, the company entered into a non-prosecution agreement with DOJ and paid a $1,000,000 monetary penalty. Non-Pros. Agreement, *In re Lucent, supra* note 96.

99 *United States v. Liebo*, 923 F.2d 1308, 1311 (8th Cir. 1991).

100 Judgment, *United States v. Liebo*, No. 89-cr-76 (D. Minn. Jan. 31, 1992), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/liebor/1992-01-31-liebor-judgment.pdf.

101 Non-Pros. Agreement, *In re Credit Suisse* (May 30, 2018), *available at* https://www.justice.gov/criminal-fraud/file/1079596/download; *In the Matter of Credit Suisse Group AG*, *available at* https://www.sec.gov/news/press-release/2018-128.

102 Complaint, *SEC v. Schering-Plough Corp.*, No. 04-cv-945 (D.D.C. June 9, 2004), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/comp18740.pdf; Admin. Proc. Order, *In the Matter of Schering-Plough Corp.*, Exchange Act Release No. 49838 (June 9, 2004) (finding that company violated FCPA accounting provisions and imposing $500,000 civil monetary penalty), *available at* http://www.sec.gov/litigation/admin/34-49838.htm.

103 FCPA opinion procedure releases can be found at https://www.justice.gov/criminal-fraud/opinion-procedure-releases. In the case of the company seeking to contribute the $1.42 million grant to a local MFI, DOJ noted that it had undertaken each of these due diligence steps and controls, in addition to others, that would minimize the likelihood that anything of value would be given to any officials of the Eurasian country. U.S. Dept. of Justice, FCPA Op. Release 10-02 (July 16, 2010), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/2010/1002.pdf.

104 U.S. Dept. of Justice, FCPA Op. Release 95-01 (Jan. 11, 1995), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/1995/9501.pdf.

105 *Id.*

106 *Id*.

107 U.S. Dept. of Justice, FCPA Op. Release 97-02 (Nov. 5, 1997), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/1997/9702.pdf; U.S. Dept. of Justice, FCPA Op. Release 06-01 (Oct. 16, 2006), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0601.pdf.

108 U.S. Dept. of Justice, FCPA Op. Release 06-01 (Oct. 16, 2006), *supra* note 107.

109 *Id.*

110 *Id.*

111 *See* Section 30A(a)(1)-(3) of the Exchange Act, 15 U.S.C. § 78dd-1(a)(1)-(3); 15 U.S.C. §§ 78dd-2(a)(1)-(3), 78dd-3(a)(1)-(3).

112 Section 30A(f)(1)(A) of the Exchange Act, 15 U.S.C. § 78dd-1(f)(1)(A); 15 U.S.C. §§ 78dd-2(h)(2)(A), 78dd-3(f)(2)(A).

113 Under the FCPA, any person "acting in an official capacity for or on behalf of" a foreign government, a department, agency, or instrumentality thereof, or a public international organization, is a foreign official. Section 30A(f)(1)(A), 15 U.S.C. § 78dd-1(f)(1)(A); 15 U.S.C. §§ 78dd-2(h)(2)(A), 78dd-2(f)(2)(A). *See also* U.S. Dept. of Justice, FCPA Op. Release No. 10-03, at 2 (Sept. 1, 2010), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/2010/1003.pdf (listing safeguards to ensure that consultant was not acting on behalf of foreign government).

114 *But see* Sections 30A(b) and f(3)(A) of the Exchange Act, 15 U.S.C. § 78dd-1(b) & (f)(3); 15 U.S.C. §§ 78dd-2(b) & (h)(4), 78dd-3(b) & (f)(4) (facilitating payments exception). Even though payments to a foreign government may not violate the anti-bribery provisions of the FCPA, such payments may violate other U.S. laws, including wire fraud, money laundering, and the FCPA's accounting provisions. This was the case in a series of matters brought by DOJ and SEC involving kickbacks to the Iraqi government through the United Nations Oil-for-Food Programme. *See, e.g.*, Complaint, *SEC v. Innospec, supra* note 80; Complaint, *SEC v. Novo Nordisk A/S*, No. 09-cv-862 (D.D.C. May 11, 2009), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2009/comp21033.pdf; Criminal Information, *United States v. Novo Nordisk A/S*, No. 09-cr-126 (D.D.C. May 11, 2009), ECF No. 1, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/nordiskn/05-11-09novo-info.pdf; Complaint, *SEC v. Ingersoll-Rand Company Ltd.*, No. 07-cv-1955 (D.D.C. Oct. 31, 2007), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2007/comp20353.pdf; Criminal Information, *United States v. Ingersoll-Rand Italiana SpA*, No. 07-cr-294 (D.D.C. Oct. 31, 2007), ECF No. 1, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/ingerand-italiana/10-31-07ingersollrand-info.pdf; Complaint, *SEC v. York Int'l Corp.*, No. 07-cv-1750 (D.D.C. Oct. 1, 2007), ECF No. 1 [hereinafter *SEC v. York Int'l Corp.*], *available at* https://www.sec.gov/litigation/complaints/2007/comp20319.pdf; Criminal Information, *United States v. York Int'l Corp.,* No. 07-cr-253 (D.D.C. Oct. 1, 2007), ECF No. 1 [hereinafter *United States v. York Int'l Corp.*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/03/19/10-01-07york-info.pdf; Complaint, *SEC v. Textron Inc.*, No. 07-cv-1505 (D.D.C. Aug. 23, 2007), ECF No. 1 [hereinafter *SEC v. Textron*], *available at* https://www.sec.gov/litigation/complaints/2007/comp20251.pdf; Non-Pros. Agreement, *In re Textron Inc.* (Aug. 22, 2007), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/08-21-07textron-agree.pdf. DOJ has issued opinion procedure releases concerning payments (that were, in essence, donations) to government agencies or departments. *See* U.S. Dept. of Justice, FCPA Op. Release 09-01 (Aug. 3, 2009) (involving donation of 100 medical devices to foreign government), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/2009/0901.pdf; U.S. Dept. of Justice, FCPA Op. Release 06-01 (Oct. 16, 2006) (involving contribution of $25,000 to regional customs department to pay incentive rewards to improve local enforcement of anti-counterfeiting laws), *available at* http://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0601.pdf.

115 Exhibit I, *United States v. Carson, infra* note 118, ECF No. 335 (list of examples of enforcement actions based on foreign officials of state-owned entities).

116 The United States has some state-owned entities, like the Tennessee Valley Authority, that are instrumentalities of the government. *McCarthy v. Middle Tenn. Elec. Membership Corp.*, 466 F.3d 399, 411 n.18 (6th Cir. 2006) ("[T]here is no question that TVA is an agency and instrumentality of the United States.") (internal quotes omitted).

117 During the period surrounding the FCPA's adoption, state-owned entities held virtual monopolies and operated under state-controlled price-setting in many national industries around the world. *See generally* World Bank, Bureaucrats in Business: The Economics 1997), and Politics of Government Ownership, World Bank Policy Research Report at 78 (1995); Sunita Kikeri and Aishetu Kolo, State Enterprises, The World Bank Group (Feb. 2006), *available at* http://documents.worldbank.org/curated/en/169041468768316446/pdf/353300PAPER0VP0304Kikeri1Kolo.pdf.

118 *Id.* at 1 ("[A]fter more than two decades of privatization, government ownership and control remains widespread in many regions—and in many parts of the world still dominates certain sectors.").

119 To date, consistent with the approach taken by DOJ and SEC, all district courts that have considered this issue have concluded that this is an issue of fact for a jury to decide. *See* Order, *United States v. Carson*, 2011 WL 5101701, No. 09-cr-77 (C.D. Cal. May 18, 2011), ECF No. 373 [hereinafter *United States v. Carson*]; *United States v. Aguilar*, 783 F. Supp. 2d 1108 (C.D. Cal. 2011); Order, *United States v. Esquenazi, supra* note 43, ECF No. 309; *see also* Order, *United States v. O'Shea*, No. 09-cr-629 (S.D. Tex. Jan. 3, 2012), ECF No. 142; Order, *United States v. Nguyen*, No. 08-cr-522 (E.D. Pa. Dec. 30, 2009), ECF No. 144. These district court decisions are consistent with the acceptance by district courts around the country of over 35 guilty pleas by individuals who admitted to violating the FCPA by bribing officials of state-owned or state-controlled entities. *See* Government's Opposition to Defendants' Amended Motion to Dismiss Counts One Through Ten of the Indictment at 18, *United States v. Carson,* ECF No. 332.

120 *United States v. Esquenazi*, 752 F.3d 912, 920-33 (11th Cir. 2014).

121 *Id.* at 925.

122 *Id.*

123 *Id.* at 926.

124 *See* Jury Instructions at 60-61, *United States v. Lambert, supra* note 43; Jury Instructions at 1264, *United States v. Hoskins, supra* note 43; Order at 5 and Jury Instructions, *United States v. Carson, supra* note 119, ECF No. 373 and ECF No. 549; *Aguilar*, 783 F. Supp. 2d at 1115.

125 Criminal Information, *United States v. C.E. Miller Corp., et al.,* No. 82-cr-788 (C.D. Cal. Sept. 17, 1982), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/06/22/1982-09-17-ce-miller-information.pdf.

126 *See* Complaint, *SEC v. Sam P. Wallace Co., Inc., et al.,* No. 81-cv-1915 (D.D.C. Aug. 31, 1982); Criminal Information, *United States v. Sam P. Wallace Co., Inc.*, No. 83-cr-34 (D.P.R. Feb. 23, 1983), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/sam-wallace-company/1983-02-23-sam-wallace-company-information.pdf; *see also* Criminal Information, *United States v. Goodyear Int'l Corp.,* No. 89-cr-156 (D.D.C. May 11, 1989) (Iraqi Trading Company identified as "instrumentality of the Government of the Republic of Iraq"), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/goodyear/1989-05-11-goodyear-information.pdf.

127 *See* Complaint, *SEC v. ABB, supra* note 47; Criminal Information at 3, *United States v. ABB Inc.,* No. 10-cr-664 (S.D. Tex. Sept. 29, 2010), ECF No. 1 [hereinafter *United States v. ABB*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2014/11/07/09-20-10abbinc-info.pdf; Constitución Política de los Estados Unidos Mexicanos [C.P.], as amended, art. 27, Diario Oficial de la Federación [DO], 5 de Febrero de 1917 (Mex.); Ley Del Servicio Publico de Energia Electrica, as amended, art. 1-3, 10, Diario Oficial de la Federación [DO], 22 de Diciembre de 1975 (Mex.).

128 *See Esquenazi*, 752 F.3d at 928-29, *supra* note 120; Indictment at 2, *United States v. Esquenazi, supra* note 43, ECF No. 3; Affidavit of Mr. Louis Gary Lissade at 1-9, *id.*, ECF No. 417-2.

129 Criminal Information at 30-31, *United States v. Alcatel-Lucent France, S.A.,* No. 10-cr-20906 (S.D. Fla. Dec. 27, 2010), ECF No. 1 [hereinafter *United States v. Alcatel-Lucent France*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/07/29/12-27-10alcatel-et-al-info.pdf.

130 *Id*.

131 *See* International Anti-Bribery and Fair Competition Act of 1998, Pub. L. 105-366 § 2, 112 Stat. 3302, 3303, 3305, 3308 (1998).

132 Section 30A(F)(1)(B) of the Exchange Act, 15 U.S.C. § 78dd-1(f)(1)(B); 15 U.S.C. §§ 78dd-2(h)(2)(B), 78dd-3(f)(2)(B).

133 *See, e.g.*, Superseding Indictment, *United States v. Ng, supra* note 43 (charging violations of the FCPA for payment of bribes to ambassadors to the United Nations); Superseding Indictment, *United States v. Harder, supra* note 52 (charging FCPA violations for bribes paid to an official at the European Bank for Reconstruction and Development).

134 Third parties and intermediaries themselves are also liable for FCPA violations. Section 30A(a) of the Exchange Act, 15 U.S.C. § 78dd-1(a); 15 U.S.C. §§ 78dd-2(a), and 78dd-3(a).

135 Section 30A(a)(3) of the Exchange Act, 15 U.S.C. § 78dd-1(a)(3); 15 U.S.C. §§ 78dd-2(a)(3), 78dd-3(a)(3).

136 *See, e.g.*, Complaint, *SEC v. Johnson & Johnson*, No. 11-cv-686 (D.D.C. Apr. 8, 2011) [hereinafter *SEC v. Johnson & Johnson*] (bribes paid through Greek and Romanian agents), *available at* https://www.sec.gov/litigation/complaints/2011/comp21922.pdf; Criminal Information, *United States v. DePuy, Inc.*, No. 11-cr-99 (D.D.C. Apr. 8, 2011), ECF No. 1 [hereinafter *United States v. DePuy*] (bribes paid through Greek agents), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/04/27/04-08-11depuy-info.pdf; Complaint, *SEC v. ABB, supra* note 47 (bribes paid through Mexican agents); Criminal Information, *United States v. ABB, supra* note 127 (same); Criminal Information, *United States v. Int'l Harvester Co.*, No. 82-cr-244 (S.D. Tex. Nov. 17, 1982) (bribes paid through Mexican agent), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/06/22/1982-11-17-international-harvester-information.pdf.

137 *See United States v. Société Générale*; Information, *United States v. SGA Société Générale Acceptance, N.V.*, No. 18-cr-274 (E.D.N.Y. May 30, 2018), ECF No. 4, *available at* https://www.justice.gov/criminal-fraud/file/1072436/download; Non-Pros. Agreement, *In re Legg Mason* (June 4, 2018), *available at* https://www.justice.gov/criminal-fraud/file/1072461/download; *In the Matter of Legg Mason, Inc.*, https://www.sec.gov/news/press-release/2018-168.

138 *See United States v. SBM, supra* note 93; Criminal Information, *United States v. SBM Offshore USA, Inc.,* No. 17-cr-685 (S.D. Tex. Nov. 21, 2017), ECF No. 1, *available at* https://www.justice.gov/criminal-fraud/file/1017336/download; Criminal Information, *United States v. Anthony Mace*, No. 17-cr-618 (S.D. Tex. Oct. 19, 2017), ECF No. 1 [hereinafter *United States v. Mace*], *available at* https://www.justice.gov/criminal-fraud/file/1017326/download; *United States v. Zubiate, supra* note 9.

139 Section 30A(a)(3) of the Exchange Act, 15 U.S.C. § 78dd-1(a)(3); 15 U.S.C. §§ 78dd-2(a)(3), 78dd-3(a)(3).

140 *See* Section 30A(f)(2)(A) of the Exchange Act, 15 U.S.C. § 78dd-1(f)(2)(A); 15 U.S.C. §§ 78dd-2(h)(3)(A), 78dd-3(f)(3)(A).

141 *See* Section 30A(f)(2)(B) of the Exchange Act, 15 U.S.C. § 78dd-1(f)(2)(B); 15 U.S.C. §§ 78dd-2(h)(3)(B), 78dd-3(f)(3)(B). The "knowing" standard was intended to cover "both prohibited actions that are taken with 'actual knowledge' of intended results as well as other actions that, while falling short of what the law terms 'positive knowledge,' nevertheless evidence a conscious disregard or deliberate ignorance of known circumstances that should reasonably alert one to the high probability of violations of the Act." H.R. Rep. No. 100-576, at 920; *see also* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100- 418, § 5003, 102 Stat. 1107, 1423-24 (1988). *Cf.* Plea Agreement, *United States v. Mace, supra* note 138, ECF No. 18, *available at* https://www.justice.gov/criminal-fraud/file/1017331/download (former CEO admitting he was guilty of FCPA violation by "continuing to make payments that furthered [a] bribery scheme and deliberately avoiding learning that certain payments, including payments Defendant authorized and approved, were in fact bribes paid to foreign officials").

142 H.R. Rep. No. 100-576, at 920 (1988).

143 Section 30A(c)(1) of the Exchange Act, 15 U.S.C. § 78dd-1(c)(1); 15 U.S.C. §§ 78dd-2(c)(1), 78dd-3(c)(1).

144 H.R. Rep. No. 100-576, at 922. The conferees also noted that "[i]n interpreting what is 'lawful under the written laws and regulations' . . . the normal rules of legal construction would apply." *Id.*

145 *See United States v. Kozeny*, 582 F. Supp. 2d 535, 537-40 (S.D.N.Y. 2008). Likewise, the court found that a provision under Azeri law that relieved bribe payors of criminal liability if they were extorted did not make the bribe payments legal. Azeri extortion law precludes the prosecution of the payor of the bribes for the illegal payments, but it does not make the payments legal. *Id.* at 540-41.

146 *See* Trial Transcript 715-18, *United States v. Ng, supra* note 43.

147 *Id.*

148 *Id.*

149 Section 30A(c)(2)(A), (B) of the Exchange Act, 15 U.S.C. § 78dd-1(c)(2); 15 U.S.C. §§ 78dd-2(c)(2), 78dd-3(c)(2).

150 For example, the Eighth Circuit Court of Appeals found that providing airline tickets to a government official in order to corruptly influence that official may form the basis for a violation of the FCPA's anti-bribery provisions. *See Liebo*, 923 F. 2d at 1311-12.

151 *See generally*, U.S. Dept. of Justice, FCPA Op. Release 11-01 (June 30, 2011) (travel, lodging, and meal expenses of two foreign officials for two-day trip to United States to learn about services of U.S. adoption service provider), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/2011/11-01.pdf; U.S. Dept. of Justice, FCPA Op. Release 08-03 (July 11, 2008) (stipends to reimburse minimal travel expenses of local, government-affiliated journalists attending press conference in foreign country), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0803.pdf; U.S. Dept. of Justice, FCPA Op. Release 07-02 (Sept. 11, 2007) (domestic travel, lodging, and meal expenses of six foreign officials for six-week educational program), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0702.pdf; U.S. Dept. of Justice, FCPA Op. Release 07-01 (July 24, 2007) (domestic travel, lodging, and meal expenses of six foreign officials for four-day educational and promotional tour of U.S. company's operations sites), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0701.pdf; U.S. Dept. of Justice, FCPA Op. Release 04-04 (Sept. 3, 2004) (travel, lodging, and modest per diem expenses of five foreign officials to participate in nine-day study tour of mutual insurance companies), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0404.pdf; U.S. Dept. of Justice, FCPA Op. Release 04-03 (June 14, 2004) (travel, lodging, meal, and insurance expenses for twelve foreign officials and one translator on ten-day trip to three U.S. cities to meet with U.S. public sector officials), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0403.pdf; U.S. Dept. of Justice, FCPA Op. Release 04-01 (Jan. 6, 2004) (seminar expenses, including receptions, meals, transportation and lodging costs, for one-and-a-half day comparative law seminar on labor and employment law in foreign country), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/0401.pdf; U.S. Dept. of Justice, FCPA Op. Release 96-01 (Nov. 25, 1996) (travel, lodging, and meal expenses of regional government representatives to attend training courses in United States), *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion/1996/9601.pdf; U.S. Dept. of Justice, FCPA Op. Release 92-01 (Feb. 1992) (training expenses so that foreign officials could effectively perform duties related to execution and performance of joint-venture agreement, including seminar fees, airfare, lodging, meals, and ground transportation), *available at* http://www.justice.gov/criminal/fraud/fcpa/review/1992/r9201.pdf.

152 U.S. Dept. of Justice, FCPA Op. Release 11-01 (June 30, 2011); U.S. Dept. of Justice, FCPA Op. Release 07-02 (Sept. 11, 2007); U.S. Dept. of Justice, FCPA Op. Release 07-01 (July 24, 2007); U.S. Dept. of Justice, FCPA Op. Release 04-04 (Sept. 3, 2004); U.S. Dept. of Justice, FCPA Op. Release 04-03 (June 14, 2004); U.S. Dept of Justice, FCPA Op. Release 04-01 (Jan. 6, 2004).

153 U.S. Dept. of Justice, FCPA Op. Release 96-01 (Nov. 25, 1996).

154 U.S. Dept. of Justice, FCPA Op. Release 11-01 (June 30, 2011); U.S. Dept. of Justice, FCPA Op. Release 07-02 (Sept. 11, 2007); U.S. Dept. of Justice, FCPA Op. Release 07-01 (July 24, 2007); U.S. Dept. of Justice, FCPA Op. Release 04-04 (Sept. 3, 2004); U.S. Dept. of Justice, FCPA Op. Release 04-01 (Jan. 6, 2004).

155 U.S. Dept. of Justice, FCPA Op. Release 04-01 (Jan. 6, 2004).

156 U.S. Dept. of Justice, FCPA Op. Release 08-03 (July 11, 2008).

157 U.S. Dept. of Justice, FCPA Op. Release 11-01 (June 30, 2011); U.S. Dept. of Justice, FCPA Op. Release 92-01 (Feb. 1992).

158 U.S. Dept. of Justice, FCPA Op. Release 08-03 (July 11, 2008).

159 *Id.*

160 *Id.*; U.S. Dept. of Justice, FCPA Op. Release 04-03 (June 14, 2004); U.S. Dept. of Justice, FCPA Op. Release 04-01 (Jan. 6, 2004); U.S. Dept. of Justice, FCPA Op. Release 07-01 (July 24, 2007).

161 U.S. Dept. of Justice, FCPA Op. Release 11-01 (June 30, 2011); Admin. Proc. Order, *In the Matter of Helmerich & Payne, Inc.*, Exchange Act Release No. 60400 (July 30, 2009) [hereinafter *In the Matter of Helmerich & Payne*], *available at* http://www.sec.gov/litigation/admin/2009/34-60400.pdf.

162 U.S. Dept. of Justice, FCPA Op. Release 07-01 (July 24, 2007); U.S. Dept. of Justice, FCPA Op. Release 08-03 (July 11, 2008).

163 For example, DOJ has previously approved expenditures on behalf of family members or for entertainment purposes under certain, limited circumstances. *See, e.g.*, U.S. Dept. of Justice, FCPA Rev. P. Release 83-02 (July 26, 1983) (declining to take enforcement action against company seeking to provide promotional tour for foreign official and wife, where both had already planned a trip to the United States at their own expense and company proposed to pay only for all reasonable and necessary actual domestic expenses for the extension of their travel to allow the promotional tour, which would not exceed $5,000), *available at* http://www.justice.gov/criminal/fraud/fcpa/review/1983/r8302.pdf.

164 Unlike the local law and bona fide expenditures defenses, the facilitating payments exception is not an affirmative defense to the FCPA. Rather, payments of this kind fall outside the scope of the FCPA's bribery prohibition. Prior to 1988, the "facilitating payments" exception was incorporated into the definition of "foreign official," which excluded from the statute's purview officials whose duties were primarily ministerial or clerical. *See* Foreign Corrupt Practices Act of 1977, Pub. L. No. 95-213, § 104(d)(2), 91 Stat. 1494, 1498 (1977) (providing that the term foreign official "does not include any employee of a foreign government or any department, agency, or instrumentality thereof whose duties are essentially ministerial or clerical"). The original exception thus focused on the duties of the recipient, rather than the purpose of the payment. In practice, however, it proved difficult to determine whether a foreign official's duties were "ministerial or clerical." S. Rep. No. 100-85, at 53. Responding to criticism that the statutory language "does not clearly reflect Congressional intent and the boundaries of the prohibited conduct," Congress revised the FCPA to define the exception in terms of the purpose of the payment. H. Rep. No. 100-40, pt. 2, at 77. In doing so, Congress reiterated that while its policy to exclude facilitating payments reflected practical considerations of enforcement, "such payments should not be condoned." *Id.* The enacted language reflects this narrow purpose.

165 In exempting facilitating payments, Congress sought to distinguish them as "payments which merely move a particular matter toward an eventual act or decision or which do not involve any discretionary action," giving the examples of "a gratuity paid to a customs official to speed the processing of a customs document" or "payments made to secure permits, licenses, or the expeditious performance of similar duties of an essentially ministerial or clerical nature which must of necessity be performed in any event." H.R. Rep. No. 95-640, at 8.

166 Section 30A(f)(3)(B) of the Exchange Act, 15 U.S.C. § 78dd-1(f)(3)(B); 15 U.S.C. §§ 78dd-2(h)(4)(B), 78dd-3(f)(4)(B).

167 In a 2004 decision, the Fifth Circuit emphasized this precise point, commenting on the limited nature of the facilitating payments exception:

> A brief review of the types of routine governmental actions enumerated by Congress shows how limited Congress wanted to make the grease exceptions. Routine governmental action, for instance, includes "obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country," and "scheduling inspections associated with contract performance or inspections related to transit of goods across country." Therefore, routine governmental action does not include the issuance of *every* official document or *every* inspection, but only (1) documentation that qualifies a party to do business and (2) scheduling an inspection—very narrow categories of largely non-discretionary, ministerial activities performed by mid- or low-level foreign functionaries.

United States v. Kay, 359 F.3d 738, 750-51 (5th Cir. 2004) (internal footnote omitted) (emphasis in original).

168 Non-Pros. Agreement, *In re Helmerich & Payne, Inc.* (July 29, 2009) [hereinafter *In re Helmerich & Payne*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/06-29-09helmerich-agree.pdf.

169 Criminal Information, *Vetco Gray Controls Inc., et al.*, No. 07-cr-4 No. (S.D. Tex. Jan. 5, 2007), ECF Nos. 1-2, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/vetco-controls/02-06-07vetcogray-info.pdf.

170 Complaint, *SEC v. Noble Corp.*, No. 10-cv-4336 (S.D. Tex. Nov. 4, 2010), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2010/comp21728.pdf; Non-Pros. Agreement, *In re Noble Corp*. (Nov. 4, 2010), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/11-04-10noble-corp-npa.pdf; *see also* sources cited *supra* note 68.

171 Working Group on Bribery, *2009 Recommendation of the Council for Further Combating Bribery of Foreign Public Officials in International Business Transactions*, at § VI (recommending countries should periodically review their policies and approach to facilitation payments and should encourage companies to prohibit or discourage facilitation payments "in view of the corrosive effect of small facilitation payments, particularly on sustainable economic development and the rule of law"); Working Group on Bribery, *United States: Phase 3*, at 24 (Oct. 15, 2010), *available at* https://www.oecd.org/daf/anti-bribery/44176910.pdf (commending United States for steps taken in line with 2009 recommendation to encourage companies to prohibit or discourage facilitation payments).

172 Facilitating payments are illegal under the U.K. Bribery Act 2010, which came into force on July 1, 2011, and were also illegal under prior U.K. legislation. *See* Bribery Act 2010, c.23 (Eng.), *available at* http://www.legislation.gov.uk/ukpga/2010/23/contents; *see also* U.K. Ministry of Justice, *The Bribery Act 2010: Guidance About Procedures Which Relevant Commercial Organisations Can Put into Place to Prevent Persons Associated with Them from Bribing (Section 9 of the Bribery Act 2010)*, at 18 (2011), *available at* http://www.justice.gov.uk/guidance/docs/bribery-act-2010-guidance.pdf.

173 *See, e.g.*, Non-Pros. Agreement, *In re Helmerich & Payne, supra* note 168; Admin. Proc. Order, *In the Matter of Helmerich & Payne, supra* note 161.

174 In order to establish duress or coercion, a defendant must demonstrate that the defendant was under unlawful, present, immediate, and impending threat of death or serious bodily injury; that the defendant did not negligently or recklessly create a situation where he would be forced to engage in criminal conduct (*e.g.*, had been making payments as part of an ongoing bribery scheme); that the defendant had no reasonable legal alternative to violating the law; and that there was a direct causal relationship between the criminal action and the avoidance of the threatened harm. *See* Eleventh Circuit Pattern Jury Instr., Special Instr. No. 16 (2020); *see also* Fifth Circuit Pattern Jury Instr. No. 1.38 (2019); Sixth Circuit Pattern Jury Instr. No. 6.05 (2019); Seventh Circuit Pattern Jury Instr. No. 6.08 (2012); Ninth Circuit Pattern Jury Instr. No. 6.5 (2010); 1A Kevin F. O'Malley, Jay E. Grenig, Hon. William C. Lee, *Federal Jury Practice and Instructions* § 19.02 (6th ed. 2008 & Supp. 2012).

175 S. Rep. No. 95-114, at 11.

176 *Id.* at 10.

177 *Id.* at 11.

178 *United States v. Kozeny*, 582 F. Supp. 2d 535, 540 n.31 (S.D.N.Y. 2008).

179 *Id.* at 540 (citing S. Rep. No. 95-114, at 10-11).

180 *Id.*

181 These payments, however, must be accurately reflected in the company's books and records so that the company and its management are aware of the payments and can assure that the payments were properly made under the circumstances. For example, in one instance, a Kazakh immigration prosecutor threatened to fine, jail, or deport employees of a U.S. company's subsidiary. Believing the threats to be genuine, the employees in Kazahkstan sought guidance from senior management of the U.S. subsidiary and were authorized to make the payments. The employees then paid the government official a total of $45,000 using personal funds. The subsidiary reimbursed the employees, but it falsely recorded the reimbursements as "salary advances" or "visa fines." The parent company, which eventually discovered these payments, as well as other improperly booked cash payments made to a Kazakh consultant to obtain visas, was charged with civil violations of the accounting provisions. Admin. Proc. Order, *In the Matter of NATCO Group Inc.*, Exchange Act Release No. 61325 (Jan. 11, 2010), *available at* http://www.sec.gov/litigation/admin/2010/34-61325.pdf (imposing cease-and-desist order and $65,000 civil monetary penalty).

182 *See* Jury Instructions at 21, *United States v. Aguilar*, No. 10-cr-1031 (C.D. Cal. May 16, 2011), ECF No. 511.

183 *See, e.g.*, *Pacific Can Co. v. Hewes*, 95 F.2d 42, 46 (9th Cir. 1938) ("Where one corporation is controlled by another, the former acts not for itself but as directed by the latter, the same as an agent, and the principal is liable for the acts of its agent within the scope of the agent's authority."); *United States v. NYNEX Corp*., 788 F. Supp. 16, 18 n.3 (D.D.C. 1992) (holding that "[a] corporation can of course be held criminally liable for the acts of its agents," including "the conduct of its subsidiaries").

184 *Pacific Can Co.*, 95 F.2d at 46; *NYNEX Corp.*, 788 F. Supp. at 18 n.3.

185 *See, e.g.*, *Standard Oil Co. v. United States*, 307 F.2d 120, 127 (5th Cir. 1962).

186 Admin. Proc. Order, *In the Matter of United Industrial Corp.*, Exchange Act Release No. 60005 (May 29, 2009), *available at* http://www.sec.gov/litigation/admin/2009/34-60005.pdf; *see also* Lit. Release No. 21063, *SEC v. Wurzel* (May 29, 2009), *available at* http://www.sec.gov/litigation/litreleases/2009/lr21063.htm.

187 *See, e.g.*, Philip Urofksy, *What You Don't Know Can Hurt You: Successor Liability Resulting From Inadequate FCPA Due Diligence in M&A Transactions*, 1763 PLI/Corp. 631, 637 (2009) ("As a legal matter, when one corporation acquires another, it assumes any existing liabilities of that corporation, including liability for unlawful payments, regardless of whether it knows of them."). Whether or not successor liability applies to a particular corporate transaction depends on the facts involved and state, federal, and, potentially, foreign law.

188 *See, e.g.*, Carolyn Lindsey, *More Than You Bargained for: Successor Liability Under the U.S. Foreign Corrupt Practices Act*, 35 Ohio N.U.L. Rev. 959, 966 (2009) ("Allowing a company to escape its debts and liabilities by merging with another entity is considered to lead to an unjust result.").

189 *See, e.g.*, *Melrose Distillers, Inc. v. United States*, 359 U.S. 271, 274 (1959) (affirming criminal successor liability for antitrust violations); *United States v. Alamo Bank of Texas*, 880 F.2d 828, 830 (5th Cir. 1989) (affirming criminal successor liability for Bank Secrecy Act violations); *United States v. Polizzi*, 500 F.2d 856, 907 (9th Cir. 1974) (affirming criminal successor liability for conspiracy and Travel Act violations); *United States v. Shields Rubber Corp.,* 732 F. Supp. 569, 571-72 (W.D. Pa. 1989) (permitting criminal successor liability for customs violations); *see also United States v. Mobile Materials, Inc.,* 776 F.2d 1476, 1477 (10th Cir. 1985) (allowing criminal post-dissolution liability for antitrust, mail fraud, and false statement violations).

190 Complaint, *SEC v. The Titan Corp.*, No. 05-cv-411 (D.D.C. Mar. 1, 2005) (discovery of FCPA violations during pre-acquisition due diligence protected potential acquiring company and led to termination of merger agreement), *available at* https://www.sec.gov/litigation/complaints/comp19107.pdf; Criminal Information, *United States v. Titan Corp.*, No. 05-cr-314 (S.D. Cal. Mar. 1, 2005) (same) [hereinafter *United States v. Titan Corp.*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/03-01-05titan-info.pdf.

191 For a discussion of declinations, see Chapter 7.

192 *See* Complaint, *SEC v. El Paso Corp.*, No. 07-cv-899 (S.D.N.Y. Feb. 7, 2007), ECF No. 1 [hereinafter *SEC v. El Paso Corp.*] (charging company with books and records and internal controls charges for improper payments to Iraq under U.N. Oil-for-Food Program), *available at* https://www.sec.gov/litigation/complaints/2007/comp19991.pdf.

193 Criminal Information, *United States v. TechnipFMC plc*, No. 19-cr-278 (E.D.N.Y. June 25, 2019), ECF No. 5 [hereinafter *United States v. TechnipFMC*], *available at* https://www.justice.gov/criminal-fraud/file/1225056/download; *United States v. Technip Offshore USA, Inc.*, No. 19-cr-279 (E.D.N.Y. June 25, 2019), ECF No. 5, *available at* https://www.justice.gov/criminal-fraud/file/1225066/download; Cease-and-Desist Order, *In the Matter of TechnipFMC plc*, Admin. Proc. 3-19493 (Sept. 23, 2019), *available at* https://www.sec.gov/litigation/admin/2019/34-87055.pdf.

194 *See* Plea Agreement, *United States v. Alstom S.A.,* No. 14-cr-246 (D. Conn. Dec. 22, 2014), ECF No. 1 [hereinafter *United States v. Alstom*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/09/DE-5-Plea-Agreement-for-SA.pdf; Deferred Pros. Agreement, *United States v. Alstom Grid, Inc.,* No. 14-cr-247 (D. Conn. Dec. 22, 2014), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/09/DE-4-DPA-Grid.pdf; Deferred Pros. Agreement, *United States v. Alstom Power, Inc.*, No. 14-cr-248 (D. Conn. Dec. 22, 2014), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/09/DE-4-DPA-Power.pdf.

195 *See* Complaint, *SEC v. York Int'l Corp., supra* note 114; Criminal Information, *United States v. York Int'l Corp., supra* note 114.

196 *See* Criminal Information, *United States v. Latin Node, Inc.,* No. 09-cr-20239 (S.D. Fla. Mar. 23, 2009), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/03-23-09latinnode-info.pdf; eLandia Int'l Inc., Annual Report (Form 10-K), at 20 (Apr. 2, 2009), *available at* https://www.sec.gov/Archives/edgar/data/1352819/000119312509070961/d10k.htm.

197 *See* Criminal Information, *United States v. Salvoch,* No. 10-cr-20893 (S.D. Fla. Dec. 17, 2010), ECF No. 3, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2013/09/05/12-17-10salvoch-info.pdf; Criminal Information, *United States v. Vasquez*, No. 10-cr-20894 (S.D. Fla. Dec. 17, 2010), ECF No. 3, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2013/09/05/12-17-10vasquez-juan-info.pdf; Indictment, *United States v. Granados, et al.*, No. 10-cr-20881, (S.D. Fla. Dec. 14, 2010), ECF No. 3, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/10/18/12-21-10granados-indict.pdf.

198 *See* Deferred Pros. Agreement, *United States v. Snamprogetti Netherlands B.V.*, No. 4:10-cr-00460 (S.D. Tex. July 7, 2010), ECF No. 3 [hereinafter *United States v. Snamprogetti*], *available at* https://www.justice.gov/criminal/fraud/fcpa/cases/snamprogetti/07-07-10snamprogetti-dpa.pdf.

199 *Compare* Criminal Information, *United States v. Snamprogetti*, No. 4:10-cr-00460 (S.D. Tex. July 7, 2010), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/07-07-10snamprogetti-info.pdf, *with* Deferred Pros. Agreement, *United States v. Snamprogetti, supra* note 198.

200 *See* Press Release, General Electric Co., General Electric Agrees to Acquire InVision (Mar. 15, 2004), *available at* https://www.ge.com/files/usa/company/investor/downloads/sharpeye_press_release.pdf; Press Release, U.S. Dept. of Justice, InVision Technologies, Inc. Enters into Agreement with the United States (Dec. 6, 2004), *available at* https://www.justice.gov/opa/pr/2004/December/04_crm_780.htm; Company News; G.E. Gets InVision, a Maker of Bomb Detectors, N.Y. Times, Dec. 7, 2004, at C4.

201 Non-Pros. Agreement, *In re InVision* (Dec. 3, 2004), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/12-03-04invisiontech-agree.pdf; Non-Pros. Agreement, *In re General Elec. Co.*, (Dec. 3, 2004), *available at* https://www.justice.gov/criminal/fraud/fcpa/cases/invision-tech/12-03-04invisiontech-agree-ge.pdf; Complaint, *SEC v. GE InVision, Inc., f/k/a InVision Technologies, Inc.*, No. 05-cv-660 (N.D. Cal. Feb. 14, 2005), ECF No. 1, *available at* https://www.sec.gov/litigation/complaints/comp19078.pdf.

202 *See* U.S. Dept. of Justice, FCPA Op. Release 08-02 (June 13, 2008), *available at* https://www.justice.gov/criminal/fraud/fcpa/opinion/2008/0802.pdf; *see also* Press Release, U.S. Dept. of Justice, Pfizer H.C.P. Corp. Agrees to Pay $15 Million Penalty to Resolve Foreign Bribery Investigation (Aug. 7, 2012) ("In the 18 months following its acquisition of Wyeth, Pfizer Inc., in consultation with the department, conducted a due diligence and investigative review of the Wyeth business operations and integrated Pfizer Inc.'s internal controls system into the former Wyeth business entities. The department considered these extensive efforts and SEC resolution in its determination not to pursue a criminal resolution for the pre-acquisition improper conduct of Wyeth subsidiaries."), *available at* https://www.justice.gov/opa/pr/2012/August/12-crm-980.html.

203 18 U.S.C. § 2.

204 In enacting the FCPA in 1977, Congress explicitly noted that "[t]he concepts of aiding and abetting and joint participation would apply to a violation under this bill in the same manner in which those concepts have always applied in both SEC civil actions and in implied private actions brought under the securities laws generally." H.R. Rep. No. 95-640, at 8.

205 *Pinkerton* held that a conspirator may be found guilty of a substantive offense committed by a co-conspirator in furtherance of the conspiracy if the co-conspirator's acts were reasonably foreseeable. *See Pinkerton v. United States*, 328 U.S. 640, 647-48 (1946).

206 *See United States v. MacAllister*, 160 F.3d 1304, 1307 (11th Cir. 1998); *United States v. Winter*, 509 F.2d 975, 982 (5th Cir. 1975).

207 *See* Criminal Information, *United States v. Marubeni Corp.*, No. 12- cr-22 (S.D. Tex. Jan. 17, 2012), ECF No. 1 [hereinafter *United States v. Marubeni*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/01/24/2012-01-17-marubeni-information.pdf; Criminal Information, *United States v. JGC Corp., supra* note 60; Criminal Information, *United States v. Snamprogetti, supra* note 199; *see also* Criminal Information, *United States v. Technip, supra* note 193.

208 *United State v. Hoskins*, 902 F.3d 69, 76-97 (2d Cir. 2018).

209 *United States v. Firtash*, 392 F. Supp. 3d 872, 889 (N.D. Ill. 2019).

210 Section 20(e) of the Exchange Act, "Prosecution of Persons Who Aid and Abet Violations," explicitly provides that, for purposes of a civil action seeking injunctive relief or a civil penalty, "any person that knowingly or recklessly provides substantial assistance to another person in violation of a provision of this chapter, or of any rule or regulation issued under this chapter, shall be deemed to be in violation of such provision to the same extent as the person to whom such assistance is provided." Section 20(e) of the Exchange Act, 15 U.S.C. § 78t(e).

211 Under Section 21C(a) of the Exchange Act, SEC may impose a cease-and-desist order through SEC's administrative proceedings upon any person who is violating, has violated, or is about to violate any provision of the Exchange Act or any rule or regulation thereunder, and upon any other person that is, was, or would be a cause of the violation, due to an act or omission the person knew or should have known would contribute to such violation. Section 21C(a) of the Exchange Act, 15 U.S.C. § 78u-3(a).

212 *See* Complaint, *SEC v. Panalpina, Inc.*, No. 10-cv-4334 (S.D. Tex. Nov. 4, 2010), ECF No. 1, *available at* https://www.sec.gov/litigation/complaints/2010/comp21727.pdf.

213 18 U.S.C. § 3282(a) provides: "Except as otherwise expressly provided by law, no person shall be prosecuted, tried, or punished for any offense, not capital, unless the indictment is found or the information is instituted within five years next after such offense shall have been committed."

214 *See* 18 U.S.C. § 3301(a) ("[T]he term 'securities fraud offense' means a violation of, or a conspiracy or an attempt to violate . . . section 32(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78ff(a))"; 18 U.S.C. § 3301(b) ("No person shall be prosecuted, tried, or punished for a securities fraud offense,

unless the indictment is found or the information is instituted within 6 years after the commission of the offense.").

215 *See Grunewald v. United States*, 353 U.S. 391, 396-97 (1957) (holding government must prove conspiracy still existed and at least one overt act was committed within the statute of limitations); *Fiswick v. United States*, 329 U.S. 211, 216 (1946) ("The statute of limitations, unless suspended, runs from the last overt act during the existence of the conspiracy. The overt acts averred and proved may thus mark the duration, as well as the scope, of the conspiracy.") (citation omitted); *see generally* Julie N. Sarnoff, Federal Criminal Conspiracy, 48 Am. Crim. L. Rev. 663, 676 (Spring 2011); *see also United States v. SBM, supra* note 93 (charging a single conspiracy to violate the FCPA spanning conduct from in or around 1996 until in or around 2012).

216 18 U.S.C. § 3292.

217 *Kokesh v. SEC*, 137 S. Ct. 1635 (2017).

218 28 U.S.C. § 2462.

219 S. Rep. No. 95-114, at 3 (noting that, in the past, "corporate bribery has been concealed by the falsification of corporate books and records," that the accounting provisions "remove [] this avenue of coverup," and that "[t]aken together, the accounting requirements and criminal [anti-bribery] prohibitions . . . should effectively deter corporate bribery of foreign government officials").

220 S. Rep. No. 95-114, at 7.

221 Section 13(b)(2)(A) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(A).

222 Section 13(b)(2)(B) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(B).

223 The accounting provisions contain a narrow exemption related to national security and the protection of classified information. Under this "national security" provision, "no duty or liability [under Section 13(b)(2) of the Exchange Act] shall be imposed upon any person acting in cooperation with the head of any federal department or agency responsible for such matters if such act in cooperation with such head of a department or agency was done upon the specific, written directive of the head of such department or agency pursuant to Presidential authority to issue such directives." Section 13(b)(3) of the Exchange Act, 15 U.S.C. § 78m(b)(3). As Congress made clear, however, the exception is narrowly tailored and intended to prevent the disclosure of classified information. H.R. Rep. 94-831, at 11 (1977), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/corruptrpt-94-831.pdf.

224 Section 13(b)(2)(A) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(A).

225 H.R. Rep. No. 94-831, at 10.

226 *Id.*

227 Section 13(b)(7) of the Exchange Act, 15 U.S.C. § 78m(b)(7).

228 H.R. Rep. No. 100-576, at 917 (1988), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/tradeact-100-418.pdf. Congress rejected the addition of proposed cost-benefit language to the definition "in response to concerns that such a statutory provision might be abused and weaken the accounting provisions at a time of increasing concern about audit failures and financial fraud and resultant recommendations by experts for stronger accounting practices and audit standards." *Id.*

229 *See, e.g.*, Complaint, *SEC v. Biomet, Inc.*, No. 12-cv-454 (D.D.C. Mar. 26, 2012), ECF No. 1 [hereinafter *SEC v. Biomet*], *available at* https://www.sec.gov/litigation/complaints/2012/comp22306.pdf; Criminal Information, *United States v. Biomet, Inc.*, No. 12-cr-80 (D.D.C. Mar. 26, 2012) [hereinafter *United States v. Biomet*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/03/30/2012-03-26-biomet-information.pdf; Complaint, *SEC v. Smith & Nephew plc*, No. 12-cv-187 (D.D.C. Feb. 6, 2012), ECF No. 1, *available at* https://www.sec.gov/litigation/complaints/2012/comp22252.pdf; Criminal Information, *United States v. Smith & Nephew, Inc.*, No. 12-cr-30 (D.D.C. Feb. 6, 2012), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/02/08/2012-02-06-s-n-information.pdf; Complaint, *SEC v. Johnson & Johnson, supra* note 136; Criminal Information, *United States v. DePuy, supra* note 136; Complaint, *SEC v. Maxwell Techs. Inc.*, No. 11-cv-258 (D.D.C. Jan. 31, 2011), ECF No. 1 [hereinafter *SEC v. Maxwell Technologies*], *available at* https://www.sec.gov/litigation/complaints/2011/comp21832.pdf; Criminal Information, *United States v. Maxwell Techs. Inc.*, No. 11-cr-329 (S.D. Cal. Jan. 31, 2011), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/04/27/01-31-11maxwell-tech-info.pdf; Complaint, *SEC v. Transocean, Inc.*, No. 10-cv-1891 (D.D.C. Nov. 4, 2010), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2010/comp21725.pdf; Criminal Information, *United States v. Transocean, Inc.*, No. 10-cr-768 (S.D. Tex. Nov. 4, 2010), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/11-04-10transocean-info.pdf.

230 S. Rep. No. 95-114, at 7.

231 Section 13(b)(2)(B) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(B).

232 Section 13(b)(7) of the Exchange Act, 15 U.S.C. § 78m(b)(7).

233 *See* Complaint, *SEC v. Siemens AG, supra* note 47; Criminal Information, *United States v. Siemens Aktiengesellschaft*, No. 08-cr-367 (D.D.C. Dec. 12, 2008), ECF. No. 1 [hereinafter *United States v. Siemens AG*], *available at* https://www.justice.gov/archive/opa/pr/2008/December/08-crm-1105.html.

234 Complaint, *SEC v. Siemens AG, supra* note 47; Criminal Information, *United States v. Siemens AG, supra* note 233; Press Release, U.S. Dept. of Justice, Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay $450 Million in Combined Criminal Fines (Dec. 15, 2008), *available at* https://www.justice.gov/archive/opa/pr/2008/December/08-crm-1105.html.

235 *ee, e.g.*, Complaint, *SEC v. Biomet, supra* note 229 (bribes paid to government healthcare providers in which phony invoices were used to justify payments and bribes were falsely recorded as "consulting fees" or "commissions" in company's books and records); Criminal Information, *United States v. Biomet, supra* note 229 (same); *SEC v. Alcatel-Lucent, supra* note 47 (bribes paid to foreign officials to secure telecommunications contracts where company lacked proper internal controls and permitted books and records to falsified); *United States v. Alcatel-Lucent France, supra* note 129 (same).

236 Complaint, *SEC v. Daimler AG, supra* note 47; Criminal Information, *United States v. Daimler AG, supra* note 47.

237 *Id.*

238 *Id.*

239 *Id.*

240 *Id.*

241 *Id.*

242 *See supra* note 10.

243 *See, e.g.*, Complaint, *SEC v. Siemens AG, supra* note 47; Complaint, *SEC v. York Int'l Corp., supra* note 116; Complaint, *SEC v. Textron, supra* note 116; Criminal Information, *United States v. Control Components, Inc.*, No. 09-cr-162 (C.D. Cal. July 22, 2009), ECF No. 1 [hereinafter *United States v. Control Components*], *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/07-22-09cci-info.pdf; Criminal Information, *United States v. SSI Int'l Far East, Ltd.*, No. 06-cr-398, ECF No. 1 [hereinafter *United States v. SSI Int'l*] (D. Or. Oct. 10, 2006), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/10-10-06ssi-information.pdf.

244 *See, e.g.*, Complaint, *SEC v. El Paso Corp., supra* note 188; Complaint, *SEC v. Innospec, supra* note 80; Complaint, *SEC v. Chevron Corp.*, 07- cv-10299 (S.D.N.Y. Nov. 14, 2007), ECF No. 1, *available at* https://www.sec.gov/litigation/complaints/2007/comp20363.pdf.

245 *See supra* note 9.

246 *See* Complaint, *SEC v. Maxwell Technologies, supra* note 229.

247 *See* Complaint, *SEC v. Willbros Group, supra* note 10.

248 15 U.S.C. § 7201 *et seq.*

249 Exchange Act Rule 13a-15, 17 C.F.R. § 240.13a-15; Exchange Act Rule 15d-15, 17 C.F.R. § 240.15d-15; Item 308 of Regulation S-K, 17 C.F.R. § 229.308; Item 15, Form 20-F, *available at* https://www.sec.gov/about/forms/form20-f.pdf; General Instruction (B), Form 40-F (for foreign private issuers), *available at* https://www.sec.gov/about/forms/form40-f.pdf.

250 *See* U.S. Sec. and Exchange Comm'n, Commission Guidance Regarding Management's Report on Internal Control over Financial Reporting Under Section 13(a) or 15(d) of the Securities Exchange Act of 1934, Release No. 33-8810 (June 27, 2007), *available at* https://www.sec.gov/rules/interp/2007/33-8810.pdf.

251 *Id*.

252 Foreign Corrupt Practices Act of 1977, Pub. L. No. 95-213, § 102, 91 Stat. 1494 (1977).

253 *See supra* note 47; *In the Matter of TechnipFMC plc, supra* note 193, (French company); *United States v. Technip, supra* note 193, (same); *see also* Admin. Proc. Order, *In the Matter of Diageo plc*, Exchange Act Release No. 64978 (SEC July 27, 2011) (UK company), *available at* https://www.sec.gov/litigation/admin/2011/34-64978.pdf; Admin. Proc. Order, *In the Matter of Statoil, ASA*, Exchange Act Release No. 54599 (SEC May 29, 2009) (Norwegian company), *available at* https://www.sec.gov/litigation/admin/2006/34-54599.pdf; Criminal Information, *United States v. Statoil, ASA*, No. 06-cr-960 (S.D.N.Y. Oct. 13, 2006) (same), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/10-13-09statoil-information.pdf.

254 Although private companies are not covered by the books and records and internal controls provisions of the FCPA and do not fall within SEC's jurisdiction, such companies generally are required by federal and state tax laws and state corporation laws to maintain accurate books and records sufficient to properly calculate taxes owed. Further, most large private companies maintain their books and records to facilitate the preparation of financial statements in conformity with GAAP to comply with financial institutions' lending requirements.

255 *See SEC v. RAE Sys. Inc., supra* note 92; *In re RAE Sys. Inc., supra* note 92.

256 *See* Section 13(b)(6) of the Exchange Act, 15 U.S.C. § 78m(b)(6), which provides that where an issuer "holds 50 per centum or less of the voting power with respect to a domestic or foreign firm," the issuer must "proceed in good faith to use its influence, to the extent reasonable under the issuer's circumstances, to cause such domestic or foreign firm to devise and maintain a system of internal accounting controls consistent with [Section 13(b)(2)]."

257 *See* 15 U.S.C. § 78m(b)(6). Congress added the language in sub-section 78m(b)(6) to the FCPA in 1988, recognizing that "it is unrealistic to expect a minority owner to exert a disproportionate degree of influence over the accounting practices of a subsidiary." H.R. Rep. No. 100-576, at 917. The Conference Report noted that, with respect to minority owners, "the amount of influence which an issuer may exercise necessarily varies from case to case. While the relative degree of ownership is obviously one factor, other factors may also be important in determining whether an issuer has demonstrated good-faith efforts to use its influence." *Id.*; *see also* S. Rep. No. 100-85, at 50.

258 Section 20(e) of the Exchange Act, titled "Prosecution of Persons Who Aid and Abet Violations," explicitly provides that for purposes of a civil action seeking injunctive relief or a civil penalty, "any person that knowingly or recklessly provides substantial assistance to another person in violation of a provision of this title, or of any rule or regulation issued under this title, shall be deemed to be in violation of such provision to the same extent as the person to whom such assistance is provided." *See* Section 20(e) of the Exchange Act, 15 U.S.C. § 78t(e).

259 *See* Complaint at 11-12, *SEC v. Elkin*, No. 10-cv-661 (D.D.C. Apr. 28, 2010), ECF No. 1, *available at* https://www.sec.gov/litigation/complaints/2010/comp21509.pdf.

260 *Id.*, ECF Nos. 6-9 (final judgments).

261 *See, e.g.*, Complaint, *SEC v. Nature's Sunshine Prod., Inc.*, No. 09-cv-672 (D. Utah, July 31, 2009), ECF No. 2, *available at* https://www.sec.gov/litigation/complaints/2009/comp21162.pdf.

262 *See* Admin. Proc. Order, *In re Watts Water Tech., Inc. and Leesen Chang*, Exchange Act Release No. 65555 (SEC Oct. 13, 2011), *available at* https://www.sec.gov/litigation/admin/2011/34-65555.pdf.

263 *Id.* at 2, 4, 6-7.

264 Exchange Act Rule 13b2-1, 17 C.F.R. § 240.13b2-1.

265 15 U.S.C. § 78m(b)(5).

266 Section 3(a)(9) of the Exchange Act, 15 U.S.C. § 78c(a)(9).

267 Exchange Act Rule 13b2-2, 17 C.F.R. § 240.13b2-2.

268 Complaint, *SEC v. Jennings*, No. 11-cv-144 (D.D.C. Jan. 24, 2011), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/2011/comp21822.pdf.

269 *Id.*, ECF Nos. 1, 3 (Complaint and Final Judgment).

270 Serious Fraud Office, Innospec Ltd: Former CEO admits bribery to falsify product tests (July 30, 2012), *available at* https://www.sfo.gov.uk/2012/07/30/innospec-ltd-former-ceo-admits-bribery-falsify-product-tests/.

271 15 U.S.C. § 78ff(a).

272 *See* Deferred Pros. Agreement, *United States v. Och-Ziff Capital Mgmt. Group LLC*, No. 16-cr-516 (E.D.N.Y. Sept. 29, 2016), *available at* https://www.justice.gov/criminal-fraud/file/900261/download.

273 *See* Deferred Pros. Agreement, *United States v. Panasonic Avionics Corp.*, No. 18-cr-118 (D.D.C. Apr. 30, 2018), *available at* https://www.justice.gov/opa/press-release/file/1058466/download.

274 *See* Minute Entry of Guilty Plea, *United States v. Peterson, supra* note 9, ECF No. 13; *see also* Press Release, U.S. Dept. of Justice, Former Morgan Stanley Managing Director Pleads Guilty for Role in Evading Internal Controls Required by FCPA (Apr. 25, 2012), *available at* http://www.justice.gov/opa/pr/2012/April/12-crm-534.html.

275 *See* Criminal Information, *United States v. Baker Hughes Svcs. Int'l, Inc.*, No. 07-cr-129 (S.D. Tex. Apr. 11, 2007), ECF No. 1, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/04-11-07bakerhughesintl-info.pdf.

276 *See* Criminal Information, *United States v. Panalpina, Inc.*, No. 10-cr-765 (S.D. Tex. Nov. 4, 2010), ECF No. 1, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/panalpina-inc/11-04-10panalpina-info.pdf.

277 *Id.*

278 *See* 15 U.S.C. § 78ff(a).

279 *See* FASB Statement of Financial Accounting Concepts No. 2, ¶¶ 63-80.

280 PCAOB Auditing Standard No. 12 and PCAOB AU Section 325.

281 *See* Section 10A of the Exchange Act, 15 U.S.C. § 78j-1.

282 18 U.S.C. § 1952.

283 *See, e.g.*, *United States v. Baptiste, supra* note 43; Criminal Information, *United States v. Ernesto Lujan*, No. 13-cr-671 (S.D.N.Y. Aug. 29, 2013), ECF No. 11, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2013/08/30/lujan-filed-information.pdf; Criminal Information, *United States v. Robert Richard King*, No. 01-cr-190 (W.D. Mo. June 27, 2001), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/05-03-02king-robert-indict.pdf; Superseding Indictment, *United States v. Mead, supra* note 43, ECF No. 22; Criminal Information, *United States v. Saybolt North America Inc.*, No. 98-cr-10266 (D. Mass. Aug. 18, 1998), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/08-10-98saybolt-info.pdf.

284 *See* Second Superseding Indictment, *United States v. Kozeny*, No. 05-cr-518 (S.D.N.Y. May 26, 2009), ECF No. 203, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/kozenyv/05-26-09bourke2nd-supersed-indict.pdf; Judgment, *United States v. Bourke*, No. 05-cr-518 (S.D.N.Y. Nov. 12, 2009), ECF No. 253, *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/kozenyv/11-12-09bourke-judgment.pdf.

285 Plea Agreement, *United States v. Control Components, supra* note 243, ECF No. 7, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/07-24-09cci-plea-agree.pdf; *see also* Order, *United States v. Carson, supra* note 119, ECF No. 440 (denying motion to dismiss counts alleging Travel Act violations), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/carsons/2011-09-20-carson-minutes-denying-motion-to-dismiss.pdf.

286 *See, e.g.*, *United States v. Ahsani, supra* note 9; Criminal Information, *United States v. Matthias Krull*, No. 18-cr-20682 (S.D. Fla. Aug. 16, 2018), ECF. No. 23, *available at* https://www.justice.gov/criminal-fraud/file/1119951/download; *United States v. Ng, supra* note 43; Criminal Information, *United States v. Darwin Enrique Padron-Acosta*, No. 16-cr-437 (S.D. Tex. Sept. 30, 2016), ECF No. 1, *available at* https://www.justice.gov/criminal-fraud/file/1226941/download; Criminal Information, *United States v. Esquenazi, supra* note 43; Criminal Information, *United States v. Green, supra* note 43; Criminal Information, *United States v. General Elec. Co.*, No. 92-cr-87 (S.D. Ohio July 22, 1992), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/general-electric/1992-07-22-general-electric-information.pdf.

287 Foreign officials may "not be charged with violating the FCPA itself, since the [FCPA] does not criminalize the receipt of a bribe by a foreign official." *United States v. Blondek,* 741 F. Supp. 116, 117 (N.D. Tex. 1990), *aff 'd United States v. Castle*, 925 F.2d 831 (5th Cir. 1991) ("We hold that

foreign officials may not be prosecuted under 18 U.S.C. § 371 for conspiring to violate the FCPA."). Foreign officials, however, can be charged with violating the FCPA when the foreign official acts as an intermediary of a bribe payment. *See, e.g.*, Information, *United States v. Basu*, No. 02-cr-475 (D.D.C. Nov. 26, 2002) (World Bank employee charged with wire fraud and FCPA violations for facilitating bribe payments to another World Bank official and Kenyan government official), *available at* http://www.justice.gov/criminal/fraud/fcpa/cases/basu/11-26-02basu-info.pdf; Information, *United States v. Sengupta*, No. 02-cr-40 (D.D.C. Jan. 30, 2002), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/01-30-02sengupta-info.pdf.

288 *See, e.g.*, Judgments, *United States v. Esquenazi, supra* note 43, ECF Nos. 182, 816, 824 (judgments against foreign official defendants).

289 Criminal Information, *United States v. SSI Int'l, supra* note 243 (alleging violations of 18 U.S.C. §§ 1343, 1346); Plea Agreement, *United States v. SSI Int'l, supra* note 243, (Oct. 10, 2006), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/10-10-06ssi-fareast-plea.pdf.

290 *See* Ex-Im Bank, Form of Exporter's Certificate, EIB 15-04 (May 2019), *available at* https://www.exim.gov/sites/default/files/forms/eib15-04_0.pdf.

291 *See* 18 U.S.C. § 1001.

292 22 C.F.R. §§ 130.2, 130.9.

293 For example, in *United States v. BAE Systems plc*, BAE pleaded guilty to conspiring to defraud the United States by impairing and impeding its lawful functions, to making false statements about its FCPA compliance program, and to violating the AECA and ITAR. BAE paid a $400 million fine and agreed to an independent corporate monitor to ensure compliance with applicable anti-corruption and export control laws. Criminal Information and Plea Agreement, *United States v. BAE Sys. plc*, No. 10-cr-35 (D.D.C. Mar. 1, 2010), ECF Nos. 1, 8, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/02-01-10baesystems-info.pdf and https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/03-01-10baesystems-plea-agree.pdf. In an action based on the same underlying facts as the criminal guilty plea, BAE entered a civil settlement with the Directorate of Defense Trade Controls for violations of AECA and ITAR, including over 2500 ITAR violations that included a failure to report the payment of fees or commissions associated with defense transactions and failure to maintain records involving ITAR-controlled transactions. BAE paid $79 million in penalties, and the State Department imposed a "policy of denial" for export licenses on three BAE subsidiaries involved in the wrongful conduct. Press Release, BAE Systems plc Enters Civil Settlement of Alleged Violations of the AECA and ITAR and Agrees to Civil Penalty of $79 Million (May 17, 2011), *available at* https://2009-2017.state.gov/r/pa/prs/ps/2011/05/163530.htm.

294 26 U.S.C. § 162(c)(1); *see also, e.g.*, Criminal Superseding Information, *United States v. Julia Vivi Wang*, No. 16-cr-495 (S.D.N.Y. Apr. 4, 2018), ECF. No. 55, *available at* https://www.justice.gov/criminal-fraud/file/1061041/download; Criminal Information, *United States v. Roberto Enrique Rincon-Fernandez*, No. 15-cr-654 (S.D. Tex. June 15, 2016), ECF No. 61, *available at* https://www.justice.gov/criminal-fraud/file/878951/download; Plea Agreement, *United States v. Leo Winston Smith*, No. 07-cr-69 (C.D. Cal. Sept. 3, 2009), ECF No. 89, *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/02/16/09-03-09smithl-plea-agree.pdf; Criminal Information, *United States v. Titan Corp., supra* note 190.

295 *See* JM § 9-27.000.

296 *See* JM § 9-27.420 (setting forth considerations to be weighed when determining whether it would be appropriate to enter into plea agreement).

297 *See* JM § 9-28.000 *et seq.*

298 *See* JM § 9-28.710 (discussing attorney-client and work product protections).

299 FCPA Corporate Enforcement Policy, *available at* https://www.justice.gov/criminal-fraud/file/838416/download.

300 *Id.*

301 *See, e.g.*, DOJ Declination Letter, Cognizant Technology Solutions Corporation (Feb. 13, 2019), *available at* https://www.justice.gov/criminal-fraud/file/1132666/download; DOJ Declination Letter, Insurance Corporation of Barbados Limited (Aug. 23, 2018), *available at* https://www.justice.gov/criminal-fraud/page/file/1089626/download; DOJ Declination Letter, Guralp Systems Limited (Aug. 20, 2018), *available at* https://www.justice.gov/criminal-fraud/page/file/1088621/download.

302 *See* FCPA Corporate Enforcement Policy, *supra* note 299.

303 *Id.*

304 *Id.*

305 *See* Plea Agreement, *United States v. Alstom S.A., supra* note 194; Criminal Information, *United States v. Marubeni Corp.*, Press Release, U.S. Dept. of Justice, Marubeni Corporation Agrees to Plead Guilty to Foreign Bribery Charges and to Pay an $88 Million Fine, *available at* https://www.justice.gov/opa/pr/marubeni-corporation-agrees-plead-guilty-foreign-bribery-charges-and-pay-88-million-fine.

306 *See, e.g.*, DOJ Declination Letter, Dun & Bradstreet Corp. (Apr. 23, 2018), *available at* https://www.justice.gov/criminal-fraud/file/1055401/download; Cease-and-Desist Order, *In the Matter of The Dun & Bradstreet Corp.*, Admin. Proc. 3-18446 (Apr. 23, 2018), *available at* https://www.sec.gov/litigation/admin/2018/34-83088.pdf; DOJ Declination Letter, Nortek Inc. (June 3, 2016), *available at* https://www.justice.gov/criminal-fraud/file/865406/download; Nortek Inc., SEC Non-Prosecution Agreement (June 7, 2016), *available at* https://www.sec.gov/news/press/2016/2016-109-npa-nortek.pdf.

307 DOJ Declination Letters, *available at* https://www.justice.gov/criminal-fraud/corporate-enforcement-policy/declinations.

308 *See* SEC Enforcement Manual, *available at* https://www.sec.gov/divisions/enforce/enforcementmanual.pdf.

309 *See* JM § 9-28.300.A; *see also* JM § 9-28.700.B (explaining benefits of cooperation for both government and corporation).

310 *See* JM § 9-28.1000 (discussing restitution and remediation). The commentary further provides that prosecutors should consider and weigh whether the corporation appropriately disciplined wrongdoers and a corporation's efforts to reform, including its quick recognition of the flaws in the program and its efforts to improve the program. *Id.*

311 *See* JM §§ 9-27.230, 9-27.420.

312 U.S. Sentencing Guidelines § 8B2.1(b)(7) (2018).

313 *Id.* § 8C2.5(f)(2) (2011).

314 U.S. Sec. and Exchange Comm., Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions, SEC Rel. Nos. 34-44969 and AAER-1470 (Oct. 23, 2001) [hereinafter *Seaboard* Report] *available at* http://www.sec.gov/litigation/investreport/34-44969.htm.

315 U.S. Sec. and Exchange Comm., Policy Statement Concerning Cooperation by Individuals in its Investigations and Related Enforcements Actions, 17 C.F.R. § 202.12 (Jan. 10, 2010), *available at* http://www.sec.gov/rules/policy/2010/34-61340.pdf.

316 *See* U.S. Sentencing Guidelines § 8B2.1(a)(2).

317 U.S. Sentencing Guidelines § 8B2.1(b).

318 *See generally* Debbie Troklus, *et al.*, Compliance 101: How to build and maintain an effective compliance and ethics program, Society of Corp. Compliance and Ethics (2008) 3-9 [hereinafter Compliance 101] (listing reasons to implement compliance program, including protecting company's reputation, creating trust between management and employees, preventing false statements to customers, creating efficiencies and streamlining processes, detecting employee and contractor fraud and abuse, ensuring high-quality products and services, and providing "early warning" system of inappropriate actions); Transparency Int'l, Business Principles for Countering Bribery: Small and Medium Enterprise (SME) Edition 5 (2008) (citing benefits of anti-bribery program like protecting reputation, creating record of integrity enhances opportunities to acquire government business, protecting company assets otherwise squandered on bribes); Mark Pieth, Harmonising Anti-Corruption Compliance: The OECD Good Practice Guidance 45-46 (2011) [hereinafter Harmonising Anti-Corruption Compliance] (citing need for compliance program to prevent and detect in-house risks, such as workplace security or conflicts of interest, and external risks, like anti-trust violations, embargo circumvention, environmental hazards, and money laundering).

319 U.S. Dep't. of Justice, Crim. Div., Evaluation of Corporate Compliance Programs, at 1 (June 2020) [hereinafter Evaluation of Corporate Compliance Programs], *available at* https://www.justice.gov/criminal-fraud/page/file/937501/download.

320 Debarment authorities, such as the Department of Defense or the General Services Administration, may also consider a company's compliance program when deciding whether to debar or suspend a contractor. Specifically, the relevant regulations provide that the debarment authority should consider "[w]hether the contractor had effective standards of conduct and internal control systems in place at the time of the activity which constitutes cause for debarment or had adopted such procedures prior to any Government investigation of the activity cited as a cause for debarment," and "[w]hether the contractor has instituted or agreed to institute new or revised review and control procedures and ethics training programs." 48 C.F.R. § 9.406-1(a).

321 *Seaboard* Report, *supra* note 314; U.S. Sec. and Exchange Comm., Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions, SEC Release No. 44969 (Oct. 23, 2001), *available at* http://www.sec.gov/litigation/investreport/34-44969.htm.

322 JM § 9-28.300. When evaluating the pervasiveness of wrongdoing within the corporation, prosecutors are advised that while it may be appropriate to charge a corporation for minor misconduct where the wrongdoing was pervasive, "it may not be appropriate to impose liability upon a corporation, *particularly one with a robust compliance program in place*, under a strict *respondeat superior* theory for the single isolated act of a rogue employee." *Id.* § 9-28.500.A (emphasis added). Prosecutors should also consider a company's compliance program when examining any remedial actions taken, including efforts to implement an effective compliance program or to improve an existing one. As the commentary explains, "although the inadequacy of a corporate compliance program is a factor to consider when deciding whether to charge a corporation, that corporation's quick recognition of the flaws in the program and its efforts to improve the program are also factors to consider as to appropriate disposition of a case." *Id.* § 9-28.1000.B. Finally, the Principles of Federal Prosecution of Business Organizations provides that prosecutors should consider the existence and effectiveness of the corporation's pre-existing compliance program in determining how to treat a corporate target. *Id.* § 9-28.800.

323 *See* JM § 9-28.800.B; *see also* U.S. Sentencing Guidelines § 8B2.1(a) (2018) ("The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.").

324 *See* Press Release, U.S. Dept. of Justice, Former Morgan Stanley Managing Director Pleads Guilty for Role in Evading Internal Controls Required by FCPA (Apr. 25, 2012) (declining to bring criminal case against corporate employer that had "constructed and maintained a system of internal controls, which provided reasonable assurances that its employees were not bribing government officials"), *available at* http://www.justice.gov/opa/pr/2012/April/12-crm-534.html; Press Release, U.S. Sec. and Exchange Comm., SEC Charges Former Morgan Stanley Executive with FCPA Violations and Investment Adviser Fraud, No. 2012-78 (Apr. 25, 2012) (indicating corporate employer was not

charged in the matter and had "cooperated with the SEC's inquiry and conducted a thorough internal investigation to determine the scope of the improper payments and other misconduct involved"), *available at* http://www.sec.gov/news/press/2012/2012-78.htm.

325 *See* JM § 9-28.800.B.

326 *See, e.g.*, Int'l Chamber of Commerce, ICC Rules on Combating Corruption (2011) [hereinafter ICC Rules on Combating Corruption], *available at* https://cdn.iccwbo.org/content/uploads/sites/3/2011/10/ICC-Rules-on-Combating-Corruption-2011.pdf; Transparency Int'l, Business Principles for Countering Bribery (3rd ed. 2013) [hereinafter Business Principles for Countering Bribery], *available at* https://issuu.com/transparencyinternational/docs/business_principles_web_final; United Kingdom Ministry of Justice, The Bribery Act of 2010, Guidance about procedures which relevant commercial organisations can put into place to prevent persons associated with them from bribing (2010), *available at* http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf; World Bank Group, Integrity Compliance Guidelines (2017) [hereinafter Integrity Compliance Guidelines], *available at* https://wallensteinlawgroup.com/wp-content/uploads/2017/12/WBG-Integrity-Compliance-Guidelines-full.pdf; Asia-Pacific Economic Cooperation, APEC Anti-corruption Code of Conduct for Business (2007) [hereinafter APEC Anti-corruption Code], *available at* http://www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Task-Groups/~/media/Files/Groups/ACT/07_act_codebrochure.ashx; Int'l Chamber of Commerce, et al., Resisting Extortion and Solicitation in International Transactions: A Company Tool for Employee Training (2011), *available at* https://iccwbo.org/content/uploads/sites/3/2016/11/RESIST-English.pdf; Int'l Chamber of Commerce, et al., Clean Business Is Good Business: The Business Case against Corruption (2008), *available at* https://www.unglobalcompact.org/library/158; World Economic Forum, Partnering Against Corruption Initiative: Global Principles for Countering Corruption (May 2016) [hereinafter Partnering Against Corruption], *available at* http://www3.weforum.org/docs/WEF_PACI_Global_Principles_for_Countering_Corruption.pdf; Working Group on Bribery, OECD, Good Practice Guidance on Internal Controls, Ethics, and Compliance (Feb. 2010) [hereinafter OECD Good Practice Guidance], *available at* http://www.oecd.org/daf/anti-bribery/44884389.pdf; U.N. Global Compact, The Ten Principles of the UN Global Compact [hereinafter The Ten Principles], *available at* https://www.unglobalcompact.org/what-is-gc/mission/principles.

327 This is also reflected in the *Sentencing Guidelines*, which recognizes that no single, formulaic set of requirements should be imposed, but instead focuses on a number of factors like "applicable industry practice or the standards called for by any applicable governmental regulation," the size of the organization, and whether the organization has engaged in similar misconduct in the past. *See* U.S. Sentencing Guidelines § 8B2.1 & app. note 2 (2018).

328 This was underscored by then-SEC Commissioner Cynthia Glassman in 2003 in a speech on SEC's implementation of the Sarbanes-Oxley Act: "[T]he ultimate effectiveness of the new corporate governance rules will be determined by the 'tone at the top.' Adopting a code of ethics means little if the company's chief executive officer or its directors make clear, by conduct or otherwise, that the code's provisions do not apply to them. . . . Corporate officers and directors hold the ultimate power and responsibility for restoring public trust by conducting themselves in a manner that is worthy of the trust that is placed in them." Cynthia Glassman, SEC Implementation of Sarbanes-Oxley: The New Corporate Governance, Remarks at National Economists Club (Apr. 7, 2003), *available at* http://www.sec.gov/news/speech/spch040703cag.htm.

329 Indeed, research has found that "[e]thical culture is the single biggest factor determining the amount of misconduct that will take place in a business." Ethics Resource Center, 2009 National Business Ethics Survey: Ethics in the Recession (2009), at 41. Metrics of ethical culture include ethical leadership (tone at the top), supervisor reinforcement of ethical behavior (middle management reinforcement), and peer commitment (supporting one another in doing the right thing). Ethics Resource Center, 2013 National Business Ethics Survey: Workplace Ethics in Transition (2014) at 19. Strong ethical cultures and strong ethics and compliance programs are related, as data show that a well-implemented program helps lead to a strong ethical culture. *Id.* at 17. "Understanding the nature of any gap between the desired culture and the actual culture is a critical first step in determining the nature of any ethics-based risks inside the organization." David Gebler, *The Role of Culture* at 1.7, *in* Society of Corporate Compliance and Ethics, The Complete Compliance and Manual (2011). To create an ethical culture, attention must be paid to norms at all levels of an organization, including the "tone at the top," "mood in the middle," and "buzz at the bottom." *Id.* 1.9-1.10.

330 *See, e.g.*, U.S. Sentencing Guidelines § 8B2.1(b)(2)(B)-(C) (2018).

331 *Id.*

332 *Id.*

333 *Id.*

334 *See, e.g.*, Ethics and Compliance Officer Association Foundation, The Ethics and Compliance Handbook: A Practical Guide From Leading Organizations (2008) at 13-26 [hereinafter The Ethics and Compliance Handbook].

335 *See, e.g.*, U.S. Sentencing Guidelines § 8B2.1(b)(4) (2018).

336 *See* U.S. Sentencing Guidelines § 8B2.1(b)(6) (2018) ("The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.").

337 *See, e.g.*, Joseph E. Murphy, Society of Corp. Compliance and Ethics, Using Incentives in Your Compliance and Ethics Program (2011) at 4; The Ethics and Compliance Handbook, *supra* note 334, at 111-23.

338 Stephen M. Cutler, Director, Division of Enforcement, SEC, *Tone at the Top: Getting It Right*, Second Annual General Counsel Roundtable (Dec. 3, 2004), *available at* http://www.sec.gov/news/speech/spch120304smc.htm.

339 *See, e.g.*, ICC Rules on Combating Corruption, *supra* note 326, at 7.

340 *See, e.g.*, U.S. Sentencing Guidelines § 8B2.1(b)(5)(C) (2018); Compliance 101, *supra* note 318, at 30-33.

341 *See* U.S. Sentencing Guidelines § 8B2.1(b)(5)(B) (2018) ("The organization shall take reasonable steps . . . to evaluate periodically the effectiveness of the organization's compliance and ethics program.").

342 *See, e.g.*, Compliance 101, *supra* note 318, at 60-61; The Ethics and Compliance Handbook, *supra* note 334, at 155-60; Business Principles for Countering Bribery, *supra* note 326, at 14.

343 *See, e.g.*, Michael M. Mannix and David S. Black., *Compliance Issues in M&A: Performing Diligence on the Target's Ethics and Compliance Program* at 5.71-5.81, *in* Society of Corporate Compliance and Ethics, The Complete Compliance and Ethics Manual (2011).

344 Complaint, *SEC v. Syncor International Corp.*, No. 02-cv-2421 (D.D.C. Dec. 10, 2002), ECF No. 1, *available at* http://www.sec.gov/litigation/complaints/comp17887.htm; Criminal Information, *United States v. Syncor Taiwan, Inc.*, No. 02-cr-1244 (C.D. Cal. Dec. 5, 2002), ECF No. 1, *available at* https://www.justice.gov/criminal-fraud/case/united-states-v-syncor-taiwan-inc-court-docket-number-02-cr-1244-svw.

345 U.S. Dept. of Justice, FCPA Op. Release 08-02 (June 13, 2008), *available at* http://justice.gov/criminal/fraud/fcpa/opinion/2008/0802.pdf.

346 Complaint, *SEC v. Rae Sys., Inc., supra* note 92; Non-Pros. Agreement, *In re Rae Sys. Inc., supra* note 92.

347 *See* Evaluation of Corporate Compliance Programs, *supra* note 319.

348 U.S. Dept. of Commerce, Business Ethics: A Manual for Managing a Responsible Business Enterprise in Emerging Market Economies (2004), *available at* https://legacy.trade.gov/goodgovernance/adobe/bem_manual.pdf.

349 U.S. Dept. of State, Fighting Global Corruption: Business Risk Management (2d ed. 2001), *available at* http://wgfacml.asa.gov.eg/en/anticorrupcion/USA/EU%20fighting%20against%20corruption.usa%202001-2003.pdf.

350 *See* Harmonising Anti-Corruption Compliance, *supra* note 318, at 46 ("Anti-corruption compliance is becoming more and more harmonised worldwide.").

351 OECD Good Practice Guidance, *supra* note 326.

352 APEC Anti-corruption Code, *supra* note 326.

353 ICC Rules on Combating Corruption, *supra* note 326.

354 Business Principles for Countering Bribery, *supra* note 326.

355 The Ten Principles, *supra* note 326.

356 Integrity Compliance Guidelines, *supra* note 326.

357 Partnering Against Corruption, *supra* note 326.

358 15 U.S.C. §§ 78dd-2(g)(1)(A), 78dd-3(e)(1)(A), 78ff(c)(1)(A).

359 15 U.S.C. §§ 78dd-2(g)(2)(A), 78dd-3(e)(2)(A), 78ff(c)(2)(A); 18 U.S.C. § 3571(b)(3), (e) (fine provision that supersedes FCPA-specific fine provisions).

360 15 U.S.C. § 78ff(a).

361 *Id.*

362 18 U.S.C. § 3571(d); *see Southern Union v. United States*, 132 S. Ct. 2344, 2350-51 & n.4 (2012).

363 15 U.S.C. §§ 78dd-2(g)(3), 78dd-3(e)(3), 78ff(c)(3).

364 The U.S. Sentencing Guidelines are promulgated by the U.S. Sentencing Commission:

> The United States Sentencing Commission ("Commission") is an independent agency in the judicial branch composed of seven voting and two non-voting *ex-officio* members. Its principal purpose is to establish sentencing policies and practices for the federal criminal justice system that will assure the ends of justice by promulgating detailed guidelines prescribing the appropriate sentences for offenders convicted of federal crimes. The guidelines and policy statements promulgated by the Commission are issued pursuant to Section 994(a) of Title 28, United States Code.

U.S. Sentencing Guidelines § 1A1.1 (2018).

365 *Id.* at ch. 3-5.

366 *Id.* § 2C1.1.

367 *Id.* § 2C1.1(b).

368 *Id.* § 3B1.1.

369 *Id.* at ch. 4, § 5A.

370 *Id.* § 2B1.1(b)(10)(B), 2B1.1(b)(18)(A).

371 *Id.* § 8C2.4 (a).

372 *Id.* § 8C2.5.

373 *Id.* § 8C2.5(f), 8C2.5(g).

374 DOJ has exercised this civil authority in limited circumstances in the last thirty years. *See, e.g.*, *United States & SEC v. KPMG Siddharta Siddharta & Harsono, et al.*, No. 01-cv-3105 (S.D. Tex. 2001) (entry of injunction barring company from future FCPA violations based on allegations that company paid bribes to Indonesian tax official in order to reduce the company's tax assessment); *United States v. Metcalf & Eddy, Inc.*, No. 99-cv-12566 (D. Mass. 1999) (entry of injunction barring company from future FCPA violations and requiring maintenance of compliance program based on allegations that it paid excessive marketing and promotional expenses such as airfare, travel expenses, and per diem to an Egyptian official and his family); *United States v. American Totalisator Co. Inc.*, No. 93-cv-161 (D. Md. 1993) (entry of injunction barring company from future FCPA violations

based on allegations that it paid money to its Greek agent with knowledge that all or some of the money paid would be offered, given, or promised to Greek foreign officials in connection with sale of company's system and spare parts); *United States v. Eagle Bus Manufacturing, Inc.*, No. 91-cv-171 (S.D. Tex. 1991) (entry of injunction barring company from future FCPA violations based on allegations that employees of the company participated in bribery scheme to pay foreign officials of Saskatchewan's state-owned transportation company $50,000 CAD in connection with sale of buses); *United States v. Carver, et al.*, No. 79-cv-1768 (S.D. Fla. 1979) (entry of injunction barring company from future FCPA violations based on allegations that Carver and Holley, officers and shareholders of Holcar Oil Corp., paid $1.5 million to Qatar foreign official to secure an oil drilling concession agreement); *United States v. Kenny, et al.*, No. 79-cv-2038 (D.D.C. 1979) (in conjunction with criminal proceeding, entry of injunction barring company from future FCPA violations for providing illegal financial assistance to political party to secure renewal of stamp distribution agreement).

375 15 U.S.C. §§ 78dd-2(g)(1)(B), 78dd-3(e)(1)(B), 78ff(c)(1)(B); *see also* 17 C.F.R. § 201.1004 (providing adjustments for inflation).

376 15 U.S.C. §§ 78dd-2(g)(2)(B), 78dd-3(e)(2)(B), 78ff(c)(2)(B); *see also* 17 C.F.R. § 201.1004 (providing adjustments for inflation).

377 15 U.S.C. §§ 78dd-2(g)(3), 78dd-3(e)(3), 78ff(c)(3); *see also* 17 C.F.R. § 201.1004 (providing adjustments for inflation).

378 Section 21(B)(b) of the Exchange Act, 15 U.S.C. § 78u(d)(3); *see also* 17 C.F.R. § 201.1004 (providing adjustments for inflation), *available at* https://www.sec.gov/enforce/civil-penalties-inflation-adjustments.htm.

379 *See* Securities Enforcement Remedies and Penny Stock Reform Act of 1990, Pub. L. No. 101-429, 104 Stat. 931 §§ 202, 301, 401, and 402 (codified in scattered sections of Title 15 of the United States Code).

380 591 U.S. __ (2020).

381 Press Release, *United States v. Braskem* S.A., No. 16-cr-644 (E.D.N.Y. Dec. 21, 2016), *available at* https://www.justice.gov/opa/pr/odebrecht-and-braskem-plead-guilty-and-agree-pay-least-35-billion-global-penalties-resolve.

382 *See, e.g.*, Press Release, *United States v. Airbus* (DOJ coordinating with France and United Kingdom), *available at* https://www.justice.gov/opa/pr/airbus-agrees-pay-over-39-billion-global-penalties-resolve-foreign-bribery-and-itar-case; Press Release, *United States v. TechnipFMC* (DOJ coordinating with Brazil), *available at* https://www.justice.gov/opa/pr/technipfmc-plc-and-us-based-subsidiary-agree-pay-over-296-million-global-penalties-resolve; Press Release, *United States v. Société Générale* (DOJ coordinating with France), *available at* https://www.justice.gov/opa/pr/soci-t-g-n-rale-sa-agrees-pay-860-million-criminal-penalties-bribing-gaddafi-era-libyan; Press Release, *United States v. Keppel Offshore & Marine Ltd.*, No 17-cr-697 (E.D.N.Y. Dec. 22, 2017) (DOJ coordinating with Brazil and Singapore), *available at* https://www.justice.gov/opa/pr/keppel-offshore-marine-ltd-and-us-based-subsidiary-agree-pay-422-million-global-penalties; Press Release, *United States v. SBM Offshore* (S.D. Tex. Nov. 29, 2017). (DOJ coordinating with the Netherlands and Brazil), *available at* https://www.justice.gov/opa/pr/sbm-offshore-nv-and-united-states-based-subsidiary-resolve-foreign-corrupt-practices-act-case; Press Release, *United States v. Telia Company AB*, No. 17-cr-581 (S.D.N.Y. Sept. 21, 2017) (DOJ and SEC coordinating with the Netherlands), *available at* https://www.justice.gov/opa/pr/telia-company-ab-and-its-uzbek-subsidiary-enter-global-foreign-bribery-resolution-more-965; Press Release, *United States v. Rolls-Royce plc*, No. 16-cr-247 (S.D. Ohio Jan. 17, 2017) (DOJ coordinating with United Kingdom and Brazil), *available at* https://www.justice.gov/opa/pr/rolls-royce-plc-agrees-pay-170-million-criminal-penalty-resolve-foreign-corrupt-practices-act; Press Release, *United States v. Odebrecht S.A.*, No. 16-cr-643 (E.D.N.Y. Dec. 21, 2016) (DOJ coordinating with Brazil and Switzerland), *available at* https://www.justice.gov/opa/pr/odebrecht-and-braskem-plead-guilty-and-agree-pay-least-35-billion-global-penalties-resolve; Press Release, *United States v. Braskem S.A.*, No. 16-cr-644 (E.D.N.Y. Dec. 21, 2016) (DOJ and SEC coordinating with Brazil and Switzerland), *available at* https://www.justice.gov/opa/pr/odebrecht-and-braskem-plead-guilty-and-agree-pay-least-35-billion-global-penalties-resolve; Press Release, *United States v. VimpelCom Ltd.*, No. 16-cr-137 (S.D.N.Y. Feb. 18, 2016) (DOJ and SEC coordinating with the Netherlands), *available at* https://www.justice.gov/opa/pr/vimpelcom-limited-and-unitel-llc-enter-global-foreign-bribery-resolution-more-795-million; Press Release, *United States v. Siemens AG, supra* note 233 (DOJ and SEC coordinating with Germany), *available at* https://www.justice.gov/archive/opa/pr/2008/December/08-crm-1105.html.

383 *See* Rod J. Rosenstein, Deputy Attorney General, U.S. Department of Justice, Letter to Heads of Department Components on Policy on Coordination of Corporate Resolution Penalties (May 9, 2018), *available at* https://www.justice.gov/opa/speech/file/1061186/download.

384 *Id.* at 1.

385 48 C.F.R. §§ 9.406-2, 9.407-2.

386 48 C.F.R. § 9.402(b).

387 *See* 48 C.F.R. §§ 9.406-1, 9.407-1(b)(2). Section 9.406-1 sets forth the following non-exhaustive list of factors: (1)Whether the contractor had effective standards of conduct and internal control systems in place at the time of the activity which constitutes cause for debarment or had adopted such procedures prior to any Government investigation of the activity cited as a cause for debarment.

(2) Whether the contractor brought the activity cited as a cause for debarment to the attention of the appropriate Government agency in a timely manner.

(3) Whether the contractor has fully investigated the circumstances surrounding the cause for debarment and, if so, made the result of the investigation available to the debarring official.

(4) Whether the contractor cooperated fully with Government agencies during the investigation and any court or administrative action.

(5) Whether the contractor has paid or has agreed to pay all criminal, civil, and administrative liability for the improper activity, including any investigative or administrative costs incurred by the Government, and has made or agreed to make full restitution.

(6) Whether the contractor has taken appropriate disciplinary action against the individuals responsible for the activity which constitutes cause for debarment.

(7) Whether the contractor has implemented or agreed to implement remedial measures, including any identified by the Government.

(8) Whether the contractor has instituted or agreed to institute new or revised review and control procedures and ethics training programs.

(9) Whether the contractor has had adequate time to eliminate the circumstances within the contractor's organization that led to the cause for debarment.

(10) Whether the contractor's management recognizes and understands the seriousness of the misconduct giving rise to the cause for debarment and has implemented programs to prevent recurrence.

388 48 C.F.R. § 9.406-1(a).

389 Exec. Order No. 12,549, 51 Fed. Reg. 6,370 (Feb. 18, 1986); Exec. Order No. 12,689, 54 Fed. Reg. 34131 (Aug. 18, 1989).

390 48 C.F.R. § 9.407-2(b).

391 JM § 9-28.1500.B.

392 *See, e.g.*, African Development Bank Group, Integrity and Anti-Corruption Progress Report 2009-2010 7, 14 ("As the premier financial development institution in Africa, the AfDB is determined to root out misconduct, fraud and corruption within its own ranks as well as in the implementation of the projects it finances. In order to do so, the Bank created an anti-corruption and fraud investigation division in November 2005 as its sole investigative body. The unit became operational in June 2006 and commenced investigations in January 2007. . . . Investigations conducted by the IACD [Integrity and Anti-Corruption Department] are not criminal proceedings; they are administrative in nature. Sanctions range from personnel disciplinary actions, such as separation, to loan cancellation and debarment for contractors, which can be temporary or permanent."), *available at* https://www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/Integrity%20and%20Anti-Corruption.pdf; World Bank Report Concerning the Debarment Process of the World Bank, *available at* https://www.worldbank.org/content/dam/documents/sanctions/other-documents/osd/ThornburghReport.pdf. The World Bank's debarment process was first formulated in July 1996, and the Sanctions Committee was established in November 1998 to review allegations and recommend sanctions to the President. Written procedures were issued in August 2001 and are posted on the Bank's website, along with the sanction actions, and are posted at https://www.worldbank.org/en/about/unit/sanctions-system/sanctions-board.

393 *See* African Development Bank Group, Asian Development Bank, European Bank for Reconstruction and Development, Inter-American Development Bank Group and World Bank Group, *Agreement for Mutual Enforcement of Debarment Decisions* (Apr. 9, 2010), *available at* https://www.adb.org/documents/agreement-mutual-enforcement-debarment-decisions.

394 *Id.*; *see also* The World Bank Group, *Multilateral Development Banks Step Up Their Fight Against Corruption with Joint Sanction Accord* (Apr. 9, 2010) ("'With today's cross-debarment agreement among development banks, a clear message on anticorruption is being delivered: Steal and cheat from one, get punished by all,' said World Bank Group President Robert B. Zoellick."), *available at* https://www.worldbank.org/en/news/press-release/2010/04/09/multilateral-development-banks-step-up-fight-against-corruption-joint-sanction-accord.

395 22 C.F.R. §§ 126.7(a)(3)-(4), 120.27(a)(6).

396 Authority under the AECA is delegated to the DDTC. *See* 22 C.F.R. § 120.1(a).

397 22 U.S.C. § 2778(g)(1)(A)(vi), (g)(3)(B).

398 22 C.F.R. § 127.7(c).

399 *See supra* note 293.

400 *See* Gary G. Grindler, Acting Dep. Att'y Gen., U.S. Dept. of Justice, Mem. to the Heads of Department Components and United States Attorneys on Additional Guidance on the Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution (May 25, 2010), *available at* http://www.justice.gov/dag/dag-memo-guidance-monitors.pdf; Lanny A. Breuer, Assist. Att'y Gen., Dep't of Justice, Mem. to All Criminal Division Personnel on Selection of Monitors in Criminal Division Matters (June 24, 2009), *available at* http://www.justice.gov/criminal/fraud/fcpa/docs/response3-supp-appx-3.pdf; *see also* Craig S. Morford, Acting Dep. Att'y Gen., U.S. Dept. of Justice, Mem. to the Heads of Department Components and United States Attorneys on Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations (Mar. 7, 2008), *available at* https://www.justice.gov/sites/default/files/dag/legacy/2008/03/20/morford-useofmonitorsmemo-03072008.pdf.

401 *See* Brian A. Benczkowski, Assistant Att'y General, U.S. Department of Justice, Memo to All Criminal Division Personnel on Selection of Monitors in Criminal Division Matters (Oct. 11, 2018), *available at* https://www.justice.gov/opa/speech/file/1100531/download.

402 *Id.* at 2.

403 *Id.*

404 *Id.*

405 Historically, DOJ had, on occasion, agreed to DPAs with companies that were not filed with the court. That is no longer the practice of DOJ.

406 JM § 9-27.230.

407 *Id*.

408 DOJ has declined matters where some or all of the following circumstances were present: (1) a corporation voluntarily and fully disclosed the potential misconduct; (2) corporate principles voluntarily engaged in interviews with DOJ and provided truthful and complete information about their conduct; (3) a parent company conducted

extensive pre-acquisition due diligence of potentially liable subsidiaries and engaged in significant remediation efforts post-acquisition; (4) a company provided information about its extensive compliance policies, procedures, and internal controls; (5) a company agreed to a civil resolution with the Securities and Exchange Commission while also demonstrating that criminal declination was appropriate; (6) only a single employee was involved in the improper payments; and (7) the improper payments involved minimal funds compared to overall business revenues.

409 SEC Rules of Practice, 17 C.F.R. § 201.102(e).

410 Deferred Pros. Agreement, *In the Matter of Tenaris, S.A.* (May 17, 2011), *available at* http://www.sec.gov/news/press/2011/2011-112-dpa.pdf; *see also* Press Release, U.S. Sec. and Exchange Comm., Tenaris to Pay $5.4 Million in SEC's First-Ever Deferred Prosecution Agreement (May 17, 2011), *available at* http://www.sec.gov/news/press/2011/2011-112.htm.

411 *See* Non-Pros. Agreement, *In re Tenaris, S.A.* (May 17, 2011), *available at* https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2011/12/08/2011-03-14-tenaris.pdf.

412 *See* U.S. Sec. and Exchange Comm., Enforcement Manual § 6.2.3. (Mar. 9, 2012), *available at* https://www.sec.gov/divisions/enforce/enforcementmanual.pdf.

413 *See id*. § 6.2.4.

414 *See id*. § 2.6.

415 18 U.S.C. § 1514A(c).

416 18 U.S.C. § 1513(e).

417 15 U.S.C. § 78u-6(a)(3). The new provision defines "original information" to mean information that:

> (A) is derived from the independent knowledge or analysis of a whistleblower; (B) is not known to the Commission from any other source, unless the whistleblower is the original source of the information; and (C) is not exclusively derived from an allegation made in a judicial or administrative or investigation, or from the news media, unless the whistleblower is a source of the information.

418 15 U.S.C. § 78u-6; *see also* Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 922, 124 Stat. 1376, 1841-49 (2010).

419 For detailed information about the program, including eligibility requirements and certain limitations that apply, *see* Section 922 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, *available at* https://www.sec.gov/files/dodd-frank-sec-922.pdf, and the final rules on eligibility, Exchange Act Rule 21F-8, 17 C.F.R. § 240.21F-8, *available at* https://www.sec.gov/about/offices/owb/reg-21f.pdf.

420 For example, the rules: (1) make a whistleblower eligible for an award if the whistleblower reports original information internally, and the company informs SEC about the violations; (2) give whistleblowers 120 days to report information to SEC after first reporting internally and still be treated as if he or she had reported to SEC at the earlier reporting date, thus preserving their "place in line" for a possible whistleblower award from SEC; and (3) provide that a whistleblower's voluntary participation in an entity's internal compliance and reporting systems is a factor that can increase the amount of an award, and that a whistleblower's interference with internal compliance and reporting system is a factor that can decrease the amount of an award. *See* Exchange Act Rule 21F, 17 C.F.R. § 240.21F.

421 *See* Exchange Act Rule 21F-7(b), 17 C.F.R. § 240.21F-7(b).

422 For example, SEC staff will not disclose a whistleblower's identity in response to requests under the Freedom of Information Act. However, there are limits on SEC's ability to shield a whistleblower's identity, and in certain circumstances SEC must disclose it to outside entities. For example, in an administrative or court proceeding, SEC may be required to produce documents or other information that would reveal the whistleblower's identity. In addition, as part of ongoing SEC investigatory responsibilities, SEC staff may use information provided by a whistleblower during the course of the investigation. In appropriate circumstances, SEC may also provide information, subject to confidentiality requirements, to other governmental or regulatory entities. *See* Exchange Act Rule 21F-7(a), 17 C.F.R. 240.21F-7(a).

423 Although SEC does not have an opinion procedure release process, it has declared its decision to follow the guidance announced through DOJ's FCPA Opinion Release Procedure. U.S. Sec. and Exchange Comm., SEC Release No. 34-17099 (Aug. 29, 1980), *available at* http://www.sec.gov/news/digest/1980/dig082980.pdf. SEC Release No. 34-17099 stated that, to encourage issuers to take advantage of DOJ's FCPA Review Procedure, as a matter of prosecutorial discretion, SEC would "not take enforcement action alleging violations of Section 30A in any case where an issuer has sought and obtained an FCPA Review Procedure letter from the Department, prior to May 31, 1981, stating that the Department will not take enforcement action under Section 30A with 385 respect to the transaction involved." *Id.* The release further noted that it would revisit this policy once DOJ had evaluated the results of the FCPA Review Procedure after its first year of operation. A second release stated that SEC would continue to adhere to the policy announced in Release No. 34-17099. U.S. Sec. and Exchange Comm., SEC Release. No. 34-18255 (Nov. 13, 1981), *available at* http://www.sec.gov/news/digest/1981/dig111381.pdf.

424 Both DOJ's opinion procedure releases (from 1993 to present) and 03-review procedure releases (from 1980-1992) are *available at* http://www.justice.gov/criminal/fraud/fcpa/opinion.

425 The full regulations relating to DOJ's opinion procedure are *available at* http://www.justice.gov/criminal/fraud/fcpa/docs/frgncrpt.pdf.

426 28 C.F.R. § 80.1.

427 28 C.F.R. § 80.3.

428 28 C.F.R. § 80.12 ("Neither the submission of a request for an FCPA Opinion, its pendency, nor the issuance of an FCPA Opinion, shall in any way alter the responsibility of an issuer to comply with the accounting requirements of 15 U.S.C. 78m(b)(2) and (3).").

429 28 C.F.R. § 80.4.

430 28 C.F.R. § 80.5.

431 28 C.F.R. § 80.6.

432 28 C.F.R. § 80.14(a). This non-disclosure policy applies regardless of whether DOJ responds to the request or the party withdraws the request before receiving a response. *Id.*

433 28 C.F.R. § 80.6.

434 28 C.F.R. § 80.2.

435 In connection with any request for an FCPA opinion, DOJ may conduct whatever independent investigation it believes appropriate. 28 C.F.R. § 80.7.

436 28 C.F.R. § 80.15. Once a request is withdrawn, it has no effect. However, DOJ reserves the right to retain a copy of any FCPA opinion request, documents, and information submitted during the opinion release procedure for any governmental purpose, subject to the restrictions on disclosures in 28 C.F.R. § 80.14.

437 28 C.F.R. § 80.8.

438 28 C.F.R. § 80.7. "Such additional information, if furnished orally, must be confirmed in writing promptly. The same person who signed the initial request must sign the written, supplemental information and must again certify it to be a true, correct and complete disclosure of the requested information." *Id.*

439 28 C.F.R. § 80.9 ("No oral clearance, release or other statement purporting to limit the enforcement discretion of the Department of Justice may be given. The requesting issuer or domestic concern may rely only upon a written FCPA opinion letter signed by the Attorney General or his designee.").

440 28 C.F.R. § 80.8. FCPA opinions do not bind or obligate any agency other than DOJ. They also do not affect the requesting party's obligations to any other agency or under any statutory or regulatory provision other than those specifically cited in the particular FCPA opinion. 28 C.F.R. § 80.11. If the conduct for which an FCPA opinion is requested is subject to approval by any other agency, such FCPA opinion may not be taken to indicate DOJ's views on any legal or factual issues before that other agency. 28 C.F.R. § 80.13.

441 28 C.F.R. § 80.10. DOJ can rebut this presumption by a preponderance of the evidence. A court determining whether the presumption has been rebutted weighs all relevant factors, including whether the submitted information was accurate and complete and the activity was within the scope of conduct specified in the request. *Id.* As of September 2012, DOJ has never pursued an enforcement action against a party for conduct that formed the basis of an FCPA opinion stating that the prospective conduct would violate DOJ's present enforcement policy.

442 As a general matter, DOJ normally anonymizes much of the information in its publicly released opinions and includes the general nature and circumstances of the proposed conduct. DOJ does not release the identity of any foreign sales agents or other types of identifying information. 28 C.F.R. § 80.14(b). However, DOJ may release the identity of the requesting party, the foreign country in which the proposed conduct is to take place, and any actions DOJ took in response to the FCPA opinion request. *Id.* If a party believes that an opinion contains proprietary information, it may request that DOJ remove or anonymize those portions of the opinion before it is publicly released. 28 C.F.R. § 80.14(c).

443 28 C.F.R. § 80.16.

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U.S. Department of Justice

Civil Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

September 4, 2020

MEMORANDUM FOR ALL CIVIL DIVISION EMPLOYEES

FROM: ETHAN P. DAVIS
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

SUBJECT: Assessing an Entity's Assertion of an Inability to Pay

The Civil Division brings civil claims on behalf of the United States that provide for the recovery of money or property, including damages and penalties. Although the Division may litigate these claims to final judgment, the Division also may agree to resolve them, either before or after judgment is entered, through settlement. In seeking to resolve a claim for money, a party may assert that it is unable to satisfy the payment sought by the Division. This memorandum provides guidance and an analytical framework for the Division to assess an assertion of an inability to pay an otherwise appropriate amount to resolve potential civil liability.[1]

I. General Policy Regarding Inability to Pay

The Assistant Attorney General is authorized to compromise claims for money when any entity, including an individual, corporation, limited liability company, partnership, sole proprietorship, or estate, offers the maximum it has the ability to pay. *See* 28 C.F.R. § 0.160(a)(2). The Division may, therefore, consider an entity's assertion that it is unable to pay an otherwise appropriate amount to resolve an alleged claim or violation of the law because it lacks sufficient assets required to pay the government and meet its ordinary and necessary business and/or living expenses. *See* Justice Manual § 4-3.200. The entity bears the burden of establishing its inability to pay, and why a higher payment amount would constitute an undue financial hardship, including by providing all information requested by the Division. The entity should complete the Division's certified Financial Disclosure Form, and provide, as requested, tax returns, audited financial statements, and access to appropriate personnel. The entity must certify under penalty of perjury that the information it provides is complete, accurate, and current. Until a final settlement is reached, the Division may request periodic updates to

[1] This memorandum provides internal guidance to the Division on legal and policy issues. It does not create any substantive or procedural rights, privileges, or benefits enforceable in any administrative, civil, or criminal matter, nor does it limit the Attorney General's discretion to determine whether to compromise claims in litigation on behalf of the United States. This memorandum also does not apply to claims that are referred to the Division for approval of authority to compromise pursuant to 31 C.F.R. Part 902.

previously requested materials, and notification is required of any material changes to the financial condition that likely will affect an entity's ability to pay.

As described below, in evaluating such an assertion, the Division will analyze numerous factors, typically with the assistance of a qualified financial expert. The Division's analysis and ultimate decision, however, are determined by the specific facts and circumstances present in a particular matter. The factors identified in this memorandum are not exhaustive and do not preclude the consideration of other relevant information.

II. Relevant Factors for Assessing Inability to Pay

The Division evaluates an entity's assertion of an inability to pay consistent with the factors set forth in the Justice Manual. *See, e.g.*, § 4-3.200. The Division also reviews and analyzes responses to the Division's certified Financial Disclosure Form, which identifies assets and liabilities, current and anticipated income and expenses, cash flow, projections, working capital, and other relevant information. The Division considers additional factors as appropriate, including the following:

- **Background on Current Financial Condition.** The review considers the entity's current financial condition, what gave rise to it, and projected financial earnings and expenses. For example, the Division considers whether the entity: (1) engaged in related party transactions; (2) removed capital, such as in the form of dividends, distributions, or loans, or invested in facilities expansion, capital improvements, or acquisitions of real or personal property or other types of assets; and/or (3) may reduce discretionary expenses, such as decreasing or eliminating executive bonuses.

- **Alternative Sources of Capital.** The review considers an entity's ability to borrow funds (e.g., by obtaining a mortgage on real property), or to raise capital (e.g., through existing or new credit facilities or via a sale of assets or equity). The review also evaluates the existence of booked reserves, plans for the acquisition or divestment of assets, and an entity's forecasts. The Division also considers whether an entity has any claim under an insurance or indemnification agreement, or has any other type of enforceable monetary claim against a third party.

- **Timing of Payments.** The review considers the amount that an entity can afford to pay immediately and over time, typically for a period not to exceed three to five years. While immediate payment is preferable, *cf.* 31 C.F.R. §§ 901.8, 902.2(f), the Division may agree to accept payments over time if it determines that doing so would enhance its recovery and is administratively feasible. In such a case, any payments over time will reflect interest to maintain the present value of a resolution and the agreement will contain provisions to protect the government's recovery in the event of default or a future bankruptcy filing by the entity. The entity typically will need to provide appropriate security. In some cases, a solvent entity may provide guarantees from a third party.

- **Tax Deductibility.** The review takes into account the tax deductibility of any monetary payments.

- **Contingency Arrangements.** The review considers, in certain circumstances, acceleration or escalation contingency arrangements. Such circumstances include but are not limited to forecasts of a future sale of significant assets, a new product launch or contract, other new earnings, or growth opportunity.

- **Collateral Consequences.** The review considers any significant adverse collateral consequences of a monetary resolution that exceeds an entity's financial capacity. For example, the Division evaluates potential disproportionate impacts on an entity's ability to provide support to other family members, or an entity's operations and obligations. The Division also considers the adverse impact of a monetary resolution on an entity's ability to maintain the amount of capital, maintenance, or equipment required by law or regulation. Collateral consequences that generally are not relevant include adverse impacts on growth, future opportunities, planned or future product lines, future dividends, unvested or future executive compensation or bonuses, and planned or future hiring or retention.

- **Third Party Liability.** In appropriate cases, the Division considers whether additional entities, including family members or related parties, may be liable for the debt as a result of a fraudulent transfer, successor liability, or the Federal Priority Statute.

III. Approval Required for Compromise Based Upon Inability to Pay

Before entering into a resolution that reduces the amount recovered based upon an entity's inability to pay, Division attorneys must secure the appropriate level of authority consistent with 28 C.F.R. § 0.160 and Civil Division Directive 1-15.