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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA, NORTHEASTERN DIVISION

SIGMATECH, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF DEFENSE, et al., Defendants.

Case No.: 5:19-cv-0089-LCB

February 4, 2019, Filed February 4, 2019, Decided

For Sigmatech Inc, Plaintiff: J Andrew Watson, III, Michael Wade Rich, W Brad English, LEAD ATTORNEYS MAYNARD COOPER & GALE PC, Huntsville, AL; Jon Davidson Levin, LEAD ATTORNEY, Robert G Jones, MAYNARD, COOPER & GALE, Huntsville, AL.

For United States Department of Defense, Patrick Shanahan, in his official capacity as Acting Secretary of the United States Department of Defense, United States Army, Mark Esper, in his capacity as Secretary of the United States Army, United States Army Material Command, Defendants: Jay E Town, US Attorney, LEAD ATTORNEY, US ATTORNEY'S OFFICE, Birmingham, AL; Don B Long, III, United States Attorney's Office - NDAL, Birmingham, AL.

For DigiFlight, Inc., Intervenor: Christopher Lea Lockwood, Jerome S Gabig, Jr, LEAD ATTORNEYS, Richard R Raleigh, Jr, WILMER & LEE PA, Huntsville, AL.

LILES C. BURKE, UNITED STATES DISTRICT JUDGE.

LILES C. BURKE

[*1203] ***MEMORANDUM OPINION***

On January 15, 2019, plaintiff Sigmatech, Inc., filed a Verified Petition for Review of Agency Action ("Petition")(doc. 1) against defendants the United States Department of Defense; Patrick Shanahan, Acting Secretary of Defense; the United States Army; and Mark Esper, Secretary of the Army (collectively, the "Agency"). Sigmatech seeks review of the Agency's actions allegedly designed to prevent (1) Sigmatech from competing for the award of government contracts; and/or (2) award of government contracts to Sigmatech. According to Sigmatech, the Agency's actions constitute a *de facto* debarment.

Background

In its petition, Sigmatech explained that it holds a Blanket Purchase Agreement ("BPA") with the Agency that allows it to compete for various "task orders" among other BPA holders. While the BPA itself is not a contract, the task orders issued under the BPA have the force of contract because they obligate both parties. Sigmatech asserted that it has provided excellent services to the Agency since being awarded the BPA, and that its success in performing various task orders led the Agency to increase Sigmatech's work.

However, Sigmatech claims that its relationship with the Agency began to deteriorate in 2015. Since that time, it says, the Agency has taken actions to prevent Sigmatech from competing for and/or obtaining new task orders. According to Sigmatech, the Agency began to classify task orders for "small businesses," despite the increased size of the task orders, in order to prevent Sigmatech, which is not classified as a small business, from being eligible to compete.[1] For example, Sigmatech asserts that it was the incumbent contractor on "Task Order 15" when the Agency issued a re-compete solicitation for further work on the project. According to Sigmatech, the Agency issued that re-compete as a small business set aside, thus preventing Sigmatech from competing for it.

Sigmatech also points to its work on "Task Order 22," which is set to expire on April 26, 2019. According to Sigmatech, the Agency initially tried to set aside the re-compete on that work for small businesses but was unable to find enough small businesses to compete for the job. Then, Sigmatech says, the Agency attempted to prevent it from competing for the work by using a different contracting vehicle in order to circumvent the BPA procurement process but was again unable to find enough contractors to compete for the work. Finally, Sigmatech says, the Agency delayed the project until it was able to bring new small businesses onto the BPA to bid for the work. Sigmatech claims that it will lose this additional work because it will not have the opportunity to compete for it. Sigmatech asserts that other similarly-situated contractors have been treated differently by the Agency.

The focal point of Sigmatech's petition, however, appears to be "Task Order 18," on which it is the incumbent contractor. Sigmatech alleges that the Agency used the same tactics that it used in relation to the re-compete process on Task Order 22 **[*1204]** in order to prevent it from competing for the follow-on work to Task Order 18. Specifically, Sigmatech alleges that the Agency improperly attempted to set aside the work for small businesses and attempted to use a different contracting vehicle. When those tactics failed, Sigmatech says, the Agency unlawfully awarded the procurement to a single small business. Sigmatech claims that after it protested this action, the Agency reissued the re-compete for "full and open" competition, thus allowing Sigmatech to compete for the work. However, the Agency ultimately awarded the follow on to Task Order 18 to DigiFlight, Inc. According to Sigmatech, the Agency's decision to award the contract to DigiFlight turned on DigiFlight's proposal to use a subcontractor that owned proprietary financial-management software. However, Sigmatech says, it recently learned that DigiFlight did not renew the license for the financial-management software and did not actually plan to use it. Therefore, Sigmatech argues that the Agency's decision to award the contract to DigiFlight was based on a "sham discriminator," i.e., its use of the financial-management software. According to Sigmatech, the decision was arbitrary, capricious, and otherwise contrary to law.

Procedural History

Sigmatech challenged the Agency's award of Task Order 18 to DigiFlight by first filing a protest with the U.S. Government Accountability Office ("GAO"), which was ultimately unsuccessful. (Doc. 8-1). Then, on September 18, 2018, Sigmatech filed a bid-protest complaint in the United States Court of Federal Claims ("CFC"), in which it challenged the Agency's decision to award Task Order 18 to DigiFlight as being irrational, arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law. (Doc. 8-2). The CFC made extensive factual findings regarding the particulars of the Agency's decision and ultimately held that Sigmatech was not entitled to relief. *Sigmatech v. United States*, **141 Fed. Cl. 284** , [**2018 BL 483922**], 2018 U.S. Claims LEXIS 1777 (November 30, 2018), [**2018 BL 483922**], 2018 WL 6920166 . Sigmatech appealed the CFC' s decision to the United States Court of Appeals for the Federal Circuit but moved to dismiss the appeal shortly after filing the instant petition in this Court.

The Present Petition

Sigmatech filed the present petition on January 15, 2019. On January 16, 2019, Sigmatech filed an "Application to Stay Administrative Action Pending Judicial Review" in which it asked this Court to stay the expiration of Task Order 18 along with "any other actions constituting a *de facto* debarment of Sigmatech." (Doc. 4, p. 1). On January 18, 2019, DigFlight filed a motion to intervene, which this Court granted. On January 23, 2019, DigiFlight filed a motion to dismiss pursuant to **Rules 12(b)(1)** and **12 (b)(6)** , Fed. R. Civ. P., based on its assertion that this Court lacked subject-matter jurisdiction over Sigmatech's claim and that the present action was precluded by principles of *res judicata* and collateral estoppel. This Court conducted a hearing over two days in which it heard arguments from the parties regarding the jurisdictional issue. For the reasons set forth below, this Court finds that it lacks subject-matter jurisdiction over Sigmatech's petition.

Discussion

When "a Rule 12(b)(1) motion is filed in conjunction with other Rule 12 motions, the court should consider the Rule 12(b)(1) jurisdictional attack before addressing any attack on the merits." *Ramming v. United States*, **281 F.3d 158** , **161** (5th Cir. 2001) (citing *Hitt v. City of Pasadena*, **561 F.2d 606** , **608** (5th Cir. 1977));[2] *Harris v. Bd. of Trustees Univ. of* **[*1205]** *Ala.*, **846 F.Supp.2d 1223** , **1230** (N.D.Ala.2012). A motion under **Federal Rule of Civil Procedure 12(b)(1)** allows a party to assert a defense of lack of subject-matter jurisdiction. A Rule 12(b)(1) motion to dismiss should be granted "only if it appears certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle plaintiff to relief." *Harris*, **846 F.Supp. 2d at 1232** (quoting *Ramming*, **281 F.3d at 161**). The burden of proof on a motion to dismiss for lack of subject-matter jurisdiction is on the party asserting jurisdiction (i.e., Plaintiff). ***Id*** . "A federal district court is under a mandatory duty to dismiss a suit over which it has no jurisdiction." *Southeast Bank, N.A. v. Gold Coast Graphics Grp. Partners*, **149 F.R.D. 681** , **683** (S.D. Fla.1993) (citing *Stanley v. Central Intelligence Agency*, **639 F.2d 1146** , **1157** (5th Cir. 1991)*; Marshall v. Gibson's Prods., Inc. of Plano*, **584 F. 2d 668** , **671-72** (5th Cir. 1978)).

In its motion to dismiss, DigiFlight argues, among other things, that this Court lacks subject-matter jurisdiction to decide Sigmatech's petition. According to DigiFlight, the Court of Federal Claims ("CFC") has exclusive jurisdiction over the present matter and is the only forum in which Sigmatech can bring such a claim. DigiFlight argues that the Administrative Disputes Resolution Act ("ADRA"), **Pub. L. No. 104-320** , **110 Stat. 3870** (1996), vests jurisdiction of this case solely in the CFC. In *Vero Technical Support, Inc. v. U.S. Dept. of Defense*, **437 Fed. Appx. 766** , **768-69** (11th Cir. 2011), the Eleventh Circuit explained:

> The Administrative Dispute Resolution Act ("ADRA"), which amended the Tucker Act, "was enacted in 1996 in part to reorganize the jurisdiction of the federal courts over bid protests cases and other challenges to government contracts. Prior to the ADRA, the [COFC] and the federal district courts had enjoyed overlapping jurisdiction to hear these claims." *Labat-Anderson, Inc. v. United States*, **346 F.Supp.2d 145** , **149** (D.D.C.2004). The ADRA streamlined this jurisdictional framework by creating "a transitional period during which the federal district courts and the [COFC] would enjoy concurrent jurisdiction over government contract cases." **Id. at 150** . Specifically, the ADRA amendment to the Tucker Act provides:
>
> > Both the Unite[d] States Court of Federal Claims and the district courts of the United States shall have jurisdiction to render judgment on an action by an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement. Both the United States Court of Federal Claims and the district courts of the United States shall have jurisdiction to entertain such an action without regard to whether suit is instituted before or after the contract is awarded.
>
> **28 U.S.C. § 1491(b)(1)** .
>
> The ADRA amendment also contains a sunset provision stating that the jurisdiction of the federal district courts over actions described in **§ 1491(b)(1)** would expire on January 1, 2001, unless otherwise extended by Congress. Congress did not extend the deadline. As the Federal Circuit has explained, "[i]t is clear that Congress's intent in enacting the ADRA with the sunset provision was to vest a single judicial tribunal with exclusive jurisdiction to review government contract protest actions." *Emery Worldwide Airlines, Inc. v. United States*, **264 F.3d 1071** , **1079** **[*1206]** (Fed. Cir. 2001). Accordingly, the COFC now enjoys exclusive jurisdiction over Tucker Act claims.

Thus, the CFC has exclusive jurisdiction to "render judgment on an action by an interested party objecting to a solicitation by a federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement." **28 U.S.C. 1491(b)(1)** .

Sigmatech argues that its claim does not fall into the category of claims for which the CFC has exclusive jurisdiction. Sigmatech asserts that their claim before this Court is not a bid protest, which would be proper only in the CFC, but rather a *de facto* debarment claim that this Court can review under the Administrative Procedures Act ("APA"). Sigmatech contends that the Agency's actions in allegedly preventing it from competing for or receiving contracts, i.e., improperly setting aside jobs for small businesses, using different contract vehicles, and reducing its existing work, were not protestable actions. Therefore, Sigmatech says, it could not have brought those claims in the CFC. Rather, this Court was the only venue in which it could obtain relief from the Agency's alleged *de facto* debarment.

However, the ADRA's scope is much wider than Sigmatech argues. In *Vero Tech.*, **437 F. App'x at 768** , the Eleventh Circuit held:

> The Administrative Procedure Act ("APA") waives the sovereign immunity of the United States to the extent that it permits "[a] person suffering legal wrong because of agency action" to "seek[ ] relief other than money damages" in federal court. **5 U.S.C. § 702** . The Act provides that a reviewing court shall, among other things, "hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." **Id. § 706(2)(A)** . However, the Act also provides:

> Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.
>
> **Id. § 702** . Because both the Tucker Act and the [Contract Disputes Act ("CDC")] vest jurisdiction over certain disputes exclusively with the COFC, these statutes forbid relief that would otherwise be available under the APA, mainly the ability to resolve an APA claim that falls within the scope of the Tucker Act or the CDA in a federal district court.

The Eleventh Circuit then proceeded to determine whether the claim in *Vero Tech* . fell within the scope of the ADRA amendment to the Tucker Act. This Court must do the same with Sigmatech's claim. As noted, the ADRA amendment to the Tucker Act, read along with the sunset provision contained in the legislation, provides that the CFC has exclusive jurisdiction to "render judgment on an action by an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement." **28 U.S.C. § 1491(b)(1)** (emphasis added). In the present case, there is no question that Sigmatech is challenging "a proposed award or the award of a contract," i.e., the follow on to Task Order 18, to DigiFlight. Even viewing this case solely as a *de facto* debarment **[*1207]** claim, it follows that Sigmatech believes it was prevented from competing for work on other contracts and is challenging the award of those contracts to other entities. Therefore, Sigmatech's claim in the present case falls within ambit of the ADRA.

In its response to DigiFlight's motion to dismiss, Sigmatech attempts to distinguish the present claim by stating that, although it has challenged the award of Task Order 18 to DigiFlight in the past, i.e., in the proceedings before the CFC, the issues raised in that case are not the same as the issues raised in the present case. However, the fact that the issues raised in the present case may be somewhat different from the issues raised before the CFC does not mean that the issues raised in this case do not still constitute a challenge to "a proposed award or the award of a contract." Even in the instances where Sigmatech points to other alleged conduct by the Agency unrelated to DigiFlight and Task Order 18, that action still involved the Agency's award of a contract to another entity or the Agency's decision not to award the contract to Sigmatech. The *de facto* debarment that Sigmatech alleges in the present case involves conduct that is related to the award of or the proposed award of a procurement contract. Thus, the Agency's alleged actions fall within **28 U.S.C. § 1491(b)(1)** , and are therefore exclusively within the jurisdiction of the CFC.

Additionally, in *Res. Conservation Grp., LLC v. United States*, **597 F.3d 1238** , **1246** (Fed. Cir. 2010), the Federal Circuit quoted the Conference Report to the ADRA, which provides: "It is the intention of the Managers to give the Court of Federal Claims exclusive jurisdiction over the full range of procurement protest cases previously subject to review in the federal district courts and the Court of Federal Claims." In *Vero Tech, **supra*** , the Eleventh Circuit held:

> While the Tucker Act itself does not define the terms "procurement" or "proposed procurement," the Federal Circuit has adopted the definition of procurement provided in **41 U.S.C. § 403(2)** . *Distributed Solutions, Inc. v. United States*, **539 F.3d 1340** , **1345** (Fed. Cir. 2008). **Section 403(2)** provides that "'procurement' includes all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout." **41 U.S.C. § 403(2)** .

Vero Tech .**437 F. App'x at 769** . Based on that definition of "procurement," it is clear that all of the Agency's alleged improper activity regarding the various task orders fell within the procurement process. Even the Agency's decision to award the contract to DigiFlight based on its use of certain financial-management software - even if the decision was a sham - was nonetheless an action taken within the procurement process. Thus, any challenge to those actions must be brought in the CFC.

To be sure, not every claim related to a government contract must be brought in the CFC. For example, in *Eco Tour Adventures, Inc. v. Jewell*, **174 F. Supp. 3d 319** , **327-28** (D.D.C. 2016), the plaintiff brought an APA challenge in district court to the government's decision to grant a concessions contract to one of its competitors. The district court denied the defendant's motion to dismiss for lack of subject-matter jurisdiction and held that the plaintiff's claim was proper in the district court because it was not a procurement-related claim.

As noted above, Sigmatech repeatedly attempts to distinguish the present claim from the claim it raised in the CFC by arguing that the present claim is a *de facto* **[*1208]** debarment claim, not a bid protest. Implicit in that assertion appears to be an argument that only bid protest claims are allowed to be brought in the CFC or that *de facto* debarment claims cannot be brought in the CFC. However, as explained above, the ADRA is much more expansive. *See Labat-Anderson, Inc. v. United States*, **346 F. Supp. 2d 145** , **153** (D.D.C. 2004)("When Congress elected to overrule the *Scanwell* doctrine and vest jurisdiction over *Scanwell*-type cases in the Court of Federal Claims as well, there is no reason to believe that it intended to leave in the federal district courts the small subset of challenges to the procurement process where there was no 'bid protest.' ... Instead, the more persuasive result is the one apparent on the face of the statute: All challenges to the award or proposed award of government contracts, including challenges in connection with government procurements, were to be consolidated in the Court of Federal Claims."). Nothing prohibits *de facto* debarment claims like Sigmatech's from being brought in the CFC as long as they fit within **28 U.S.C. § 1491(b)(1)** .

Sigmatech also highlights the fact that it only recently learned about DigiFlight's decision not to use the proprietary financial-management software that the Agency cited as a reason it chose to award the contract to DigiFlight.[3] Therefore, it says, it could not have included that information in its case before the CFC. While that may be true, this Court is not aware of anything that would have prevented Sigmatech from filing a new petition or a post-trial motion in the CFC raising that issue and its implications. However, this Court expresses no opinion on the proper method for doing so. The bottom line is that the ADRA removed jurisdiction to hear such claims from this Court and vested it exclusively in the CFC.

Based on the foregoing, this Court finds that it does not have subject-matter jurisdiction over the claims brought by Sigmatech in its Petition for Review of Agency Action. Accordingly, DigiFlight's motion to dismiss pursuant to **Rule 12 (b)(1), Fed. R. Civ. P** ., is due to be GRANTED, and Sigmatech's petition DISMISSED WITHOUT PREJUDICE. Because this Court finds that it lacks subject-matter jurisdiction over this case, discussion of the *res judicata* and collateral estoppel issues is pretermitted.

DONEand **ORDERED**February 4, 2019.

/s/ Liles C. Burke

LILES C. BURKE

UNITED STATES DISTRICT JUDGE

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fn 1

Sigmatech explains that it began performing work for the Agency as a small business and won its initial task orders under that classification. However, once the Agency increased Sigmatech's workload, the company expanded such that it was no longer considered a "small business."

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

JBL SYSTEM SOLUTIONS, LLC, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:19-cv-226 (AJT/TCB)
	)	
U.S. DEFENSE LOGISTICS AGENCY, *et al.*,	)	
	)	
Defendants.	)	
	)	

ORDER

In this action, Plaintiffs JBL System Solutions, LLC ("JBL"), Joseph Lazzari, Brenda Lazzari, Potomac Military Manufacturing, LLC ("Potomac"), Judith Gordon, and Lisa Miller challenge their suspensions and/or proposed debarments as government contractors or affiliated persons by the Defense Logistics Agency ("DLA"). *See* [Doc. 22]. Plaintiffs have moved for a preliminary injunction prohibiting Defendants from (1) "maintaining the historical record of JBL, Mr. Lazzari, and Ms. Lazzari's 30 day 'suspensions' from government contracting listed publicly in the System for Award Management ('SAM')" and (2) "maintaining the 'proposed debarment' actions initiated on March 1, 2019, listed in SAM as 'Ineligible (Proceedings Pending),' while this lawsuit is pending." *See* Plaintiffs' Emergency Amended Motion for Preliminary Injunction [Doc. 30] ("the Motion"). The Court held a hearing on the Motion on March 15, 2019, at which the Court took the Motion under advisement. For the foregoing reasons, the Motion is DENIED.

I. BACKGROUND

Plaintiff JBL System Solutions, LLC is a service-disabled veteran-owned small

business headquartered in Maryland. [Doc. 22 at 5]. According to Plaintiff, Joseph Lazzari is, and has always been, the sole owner of JBL Systems Solutions, LLC ("JBL"). *Id.* Plaintiff Brenda Lazzari is Mr. Lazzari's wife. *Id.* Plaintiff alleges that she does not own any stake in JBL, but she does own another company, Potomac Military Manufacturing LLC ("Potomac"). *Id.* Plaintiff Judith Gordon is an employee of JBL, and Plaintiff Lisa Miller is the sole employee of Potomac. *Id.* at 8, 9. Defendants are all officials with the United States Defense Logistics Agency ("DLA"). *Id.* at 5–6.

On January 30, 2019, DLA issued a Notice of Suspension notifying JBL, Mr. Lazzari, and Mrs. Lazzari that it was suspending them as government contractors and placing their names into SAM as "Ineligible (Proceedings Pending)" for new contracts or bids. *Id.* at 11–12. It explained that it was doing so on the ground that Mr. Lazzari, while vacationing abroad in Jamaica, Colombia, and Spain, "downloaded technical data identified as export-controlled from DLA's servers in the United States. [Doc. 22-4 at 3]. According to DLA, on one occasion, Mr. Lazzari downloaded technical data marked "Distribution Statement F" and "NOFORN," "which under Department of Defense Policy is the most restrictive designation for unclassified material possible and is typically reserved for classified documents." *Id.* DLA further stated that after detecting these downloads and before taking action, it had initiated an administrative review and emailed Mr. Lazzari to learn more about these downloads. *Id.* at 3. According to DLA, these downloads constituted "illegal exports," in violation of the International Traffic in Arms Regulations ("ITAR") and the Export Administration Regulations ("EAR"), 22 C.F.R. § 120.17(a). [Doc. 22-4 at 3]. When asked about the downloads, Mr. Lazzari dd not contest that he did in fact engage in the conduct alleged.[1]

[1] According to DLA, when asked about the downloads, Mr. Lazzari stated, "I can't confirm what I downloaded or if I downloaded any [technical documents] from cFolders [the online program from which contractors download

Based on Mr. Lazzari's conduct, DLA also suspended JBL and Mrs. Lazzari on the grounds that they were "affiliates" of Mr. Lazzari as defined in 48 C.F.R. §§ 9.406-5(a) and 9.407-2(c). [Doc. 22-4 at 5]. In that regard, DLA referenced that (1) Mrs. Lazzari was JBL's owner and President, as reflected in a LexisNexis open source report on JBL in the Administrative Record; (2) Mrs. Lazzari is married to Mr. Lazzari; (3) the Lazzaris and JBL all share the same address; and (4) Mrs. Lazzari had engaged in communications with DLA personnel regarding JBL. *Id. at* 6.

On February 5, 2019, JBL, Mr. Lazzari, and Mrs. Lazzari, through counsel, delivered an interim response to their suspension in which they argued, supported by Mrs. Lazzari's declaration, that the LexisNexis report was incorrect in that Mrs. Lazzari was not, and has never been, JBL's owner and requested an immediate termination of Mrs. Lazzari's suspension. [Doc. 22 at 15–16]. On February 12, 2019, JBL, Mr. Lazzari, and Mrs. Lazzari also filed a response to the proposed debarment in which they argued that Mr. Lazzari did not violate export control laws because he was eligible for an exemption which permitted a person travelling abroad to "export" technical data for their own use, so long as they took "[s]ufficient security precautions" to protect the data from disclosure to others. *Id.* at 16–17. Mr. Lazzari submitted a sworn declaration averring that he was eligible for the exemption because he (1) used a password-protected internet connection, (2) accessed cFolders, which is a password-protected website, (3) left any downloaded data on his personal laptop, (4) kept the laptop in his possession at all times, (5) used a password on his laptop to secure it, (6) did not release the information to any foreign

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technical data to bid on open contracts]; and I won't argue that your findings say that JBL's credentials show that there was a download—that is possible. I can confirm that I was out of the country on vacation and I'm sure I worked those days and it's possible that I logged in to cFolders." *Id.* at 3–4. However, he also responded that he took steps to secure the data—namely, he used a password-protected personal laptop and turned off the laptop prior to leaving it unattended—and he did not give anyone else access to the data. [Doc. 22-5 at 58].

person, and (7) "even if someone were to turn on Mr. Lazzari's laptop outside of his presence, the laptop computer is password protected and the individual would not be able to access the data within it." *Id.* at 18. JBL and the Lazzaris sent another follow-up letter to DLA's counsel on February 13, 2019. *Id.*

Following its suspension action, DLA cancelled a number of JBL's current contracts with DLA, including many that were categorized as "delinquent" but which DLA had routinely allowed JBL to deliver under. *Id.* at 19. When asked about these cancellations, DLA took the position that these cancellations were "required by" 48 C.F.R. § 9.405 as a necessary consequence of DLA's suspension action, although, according to Plaintiffs, there is no such requirement. *Id.* Thus far, DLA has terminated contracts valued at $1,404,729 and JBL has $2 million more in so-called "delinquent" but soon-to-be-delivered status. *Id.* at 20. According to Plaintiffs, "[t]hese financial losses are becoming dire and threaten the viability of Mr. Lazzari's service-disabled veteran-owned small business," caused permanent damage to JBL's reputation, and forced Mrs. Lazzari to inform a customer of her unrelated business that she is excluded from government contracting, "which reduces her likelihood of winning new work and causes economic harm." *Id.*

On February 25, 2019, JBL and the Lazzaris filed this action, in which they seek declaratory and injunctive relief from DLA's suspension action. [Doc. 1]. On the same day, they moved for a preliminary injunction prohibiting the publication of the suspension in SAM. [Doc. 3].

On March 1, 2019, DLA notified all Plaintiffs that it was initiating debarment proceedings against them and also BJL Solutions, LLC ("BJL"), a company which Mrs. Lazzari

owns and which shares an address with JBL and the Lazzaris.[2] [Doc. 22 at 21]. At the same time, DLA lifted its suspensions of JBL and the Lazzaris without prejudice. [Doc. 31-14 at 3 n.23].

In a memorandum in support of the debarment proceedings, DLA stated that it was pursuing debarment on four grounds, three of which involved JBL's purported failures to perform under various contracts with DLA and the last of which concerned Mr. Lazzari's purported export violations while travelling abroad, which according to DLA was a "separate and independent ground" for Plaintiffs' debarment. *Id.* at 4–5. The memorandum also stated that DLA was suspending Mrs. Lazzari, Gordon, Miller, and Potomac under the doctrines of imputation and affiliation. With regard to Mrs. Lazzari, DLA again stated that JBL's deficient conduct could be imputed to her because "she is the owner of JBL, is located at the same address as JBL, and until December 12, 2016, was listed as Government POC for JBL. Therefore, she knew of, or had reason to know of, the seriously improper conduct of JBL." [Doc. 22-12 at 14]. The memorandum further stated that the Administrative Record showed that Mrs. Lazzari "is Joseph Lazzari's wife and has access to JBL's credentials to access export-controlled and NOFORN technical data," was "BJL's owner and registered POC," was "Potomac's owner, registered agent, and FLA Internet Board Bid System (DIBBS) POC," and "is located at the same address as JBL, BJL, and Joseph Lazzari." *Id.* at 3.

With regard to BJL, DLA stated that BJL "is affiliated with JBL and Joseph Lazzari because, as described above, BJL and JBL share the same residential address that is owned by Brenda Lazzari and Joseph Lazzari, who are a married couple, and because Brenda Lazzari is BJL's owner and registered POC." *Id.* at 14. With regard to Gordon, DLA stated that she was affiliated with JBL and Mr. Lazzari because she "is an employee of both JBL and BJL," "holds

[2] Plaintiffs Potomac, Miller, and Gordon had not been earlier suspended.

cFolders credentials on behalf of JBL, and because she is the Government Sales POC for BJL." *Id.* at 14, 15. With regard to Potomac, DLA stated that "Potomac Military Manufacturing LLC is affiliated with Brenda Lazzari because she is Potomac's owner, registered agent, and DLA Internet Board Bid System (DIBBS) POC," thus making Potomac an affiliate of Mrs. Lazzari. *Id.* at 15. Finally, with regard to Miller, DLA stated that she "is affiliated with Potomac . . . because she is the manager and registered POC of Potomac." *Id.* at 15.

On March 4, 2019, following receiving notice of DLA's proposed debarment proceedings, Plaintiffs filed their Amended Complaint. [Doc. 22]. The Amended Complaint contains thirteen counts and seeks declaratory judgments that the suspension action was unlawful as to JBL, Mr. Lazzari, and Mrs. Lazzari; that the ongoing proposed debarment action is unlawful as to all Plaintiffs; and therefore that these actions are void *ab initio* as to all Plaintiffs. *Id.* at 29–43. The Amended Complaint also seeks various forms of injunctive relief related to the suspension and debarment and public notice thereof in SAM. *See id.* at 43–45.

Briefly summarized, the Amended Complaint alleges in support of Plaintiffs' claims that suspensions and debarments may only be imposed for the Government's protection and not to punish contractors and that "[t]he timing of the Notices of Debarment, only one day after Defendants were formally served with the Complaint . . . evinces the improperly punitive nature of the proposed debarment actions." *Id.* at 28–29. Plaintiffs further allege that DLA's suspension and debarment actions violate the APA because the Administrative Record contains no "adequate evidence" that Mr. Lazzari violated export controls or to warrant imputing his conduct or affiliating him with the other Plaintiffs; that the suspension of JBL and the Lazzaris was unlawful because it was handed down without an "investigation" having been performed, as

required by applicable regulations; and therefore that the decisions are "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law." *See id.* at 29–39.

Plaintiffs filed the Motion with their Amended Complaint. [Doc. 30]. In the Motion, they seek a preliminary injunction prohibiting DLA (1) "from maintaining the historical record of JBL, Mr. Lazzari, and Ms. Lazzari's 30 day 'suspensions' from government contracting listed publicly in the System for Award Management ('SAM')," and (2) "from maintaining the 'proposed debarment' actions initiated on March 1, 2019, listed in SAM as 'Ineligible (Proceedings Pending),' while this lawsuit is pending." *Id.* at 1–2. Nevertheless, Plaintiffs do not challenge DLA's proposed debarment proceeding as to Mr. Lazzari, JBL, or BJL, or the cancellation of any JBL contracts, as they concede that DLA has reasonable grounds to support these actions and therefore will contest the proposed debarments in the applicable administrative forum. [Doc. 22 at 22–23]. Rather, they are only seeking to enjoin the continued listing of their now withdrawn suspensions in SAM, and also any debarment proceedings against Mrs. Lazzari, Potomac, Miller, and Gordon on the grounds that they have been improperly labelled "affiliates" of JBL and Mr. Lazzari.

II. LEGAL STANDARD

A. Preliminary Injunction

Federal Rule of Civil Procedure 65 authorizes a federal court to issue temporary restraining orders and preliminary injunctions. In order to receive a preliminary injunction, the moving party must make a clear showing that (1) it is likely to succeed on the merits of its case; (2) it is likely to suffer irreparable harm in the absence of injunctive relief; (3) the balance of the equities tips in its favor; and (4) an injunction would be in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008); *Manning v. Hunt*, 119 F.3d 254, 263 (4th Cir.

1997); *see also Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013). The movant must satisfy all four factors. *The Real Truth About Obama, Inc. v. Fed. Elec. Comm'n*, 575 F.3d 342, 351 (4th Cir. 2009) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 19–20 (2008)).

B. Review of Agency Action

Where no other statute provides a private right of action, federal courts have jurisdiction to review only "agency action" that is "final." *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 61 (2004). The court must set aside a final agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

III. ANALYSIS

As a threshold matter, the Court lacks jurisdiction to enjoin the historical recording of the suspension contained in SAM. Even assuming that such a listing constitutes final agency action, Plaintiffs have not sufficiently alleged an injury in fact that is capable of being redressed by the relief sought. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). Although Plaintiffs allege in conclusory fashion that they will suffer reputational harm from the historical fact of their now withdrawn suspensions, they have not identified any concrete harm resulting from this historical fact or cited any regulations, procedures, or other evidence that indicates that contracting officials consider inactive suspensions negatively when awarding contracts. Nor have they identified any concrete reputational harm they have suffered or will suffer with their non-government customers as a result of their now-inactive suspension. And with regard to the contracts that Plaintiffs allege DLA canceled in the wake of the suspensions, Plaintiffs do not request any relief in that regard, as it appears that the cancellations have continued, not as a result of the now-withdrawn suspensions, but because of the pending debarment proceedings.

With respect to Plaintiffs' request that the debarment proceedings against Mrs. Lazzari, Potomac, Miller, and Gordon be enjoined, there also is a substantial question whether the Court has jurisdiction at this point to enjoin ongoing debarment proceedings that have not resulted in a final agency decision.

To be final, the challenged decision must constitute the "'consummation' of the agency's decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 178 (1997). This finality rule is designed to give the agency "an opportunity to correct its own mistakes and to apply its expertise" and avoid "piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary." *FTC v. Std. Oil Co.*, 449 U.S. 232, 242 (1980). Here, Plaintiffs challenge the propriety of their proposed debarments as affiliates of JBL and Mr. Lazzari on multiple grounds; however, they still retain the ability to contest that debarment in ongoing administrative proceedings before DLA finally decides whether to debar any of the Plaintiffs. *See* [Doc. 31-13 at 3].

Plaintiffs contend that DLA's decision to initiate debarment proceedings against them constitute *de facto* debarments that are ripe for federal court review even in the absence of a final decision by DLA in the forthcoming debarment proceedings. [Doc. 44 at 6]. Federal courts may review *de facto* debarments in the absence of a formal agency decision because they are still "final" for purposes of APA review. *See Peter Kiewit Sons' Co. v. U.S. Army Corps of Eng'rs*, 714 F.2d 163, 168 (D.C. Cir. 1983). A *de facto* debarment occurs when an agency effectively "suspend[s] or blacklist[s]" a contractor "without due process, namely, adequate notice and a meaningful hearing." *Phillips v. Mabus*, 894 F. Supp. 2d 71, 81 (D.D.C. 2012). To demonstrate a *de facto* debarment, "plaintiffs must show a systematic effort by the procuring agency to reject all of the bidder's contract bids. Two options exist to establish a *de facto* debarment claim: 1) by

an agency's statement that it will not award the contractor future contracts; or 2) by an agency's conduct demonstrating that it will not award the contractor future contracts." *Phillips*, 894 F. Supp. 2d at 81 (quotation omitted).

Plaintiffs argue that DLA has instituted a *de facto* debarment based on its cancellation of JBL's contracts.[3] But unlike in the *de facto* debarment cases they cite, Plaintiffs have the opportunity to participate in a formal debarment process. *See, e.g.*, *Kiewit*, 714 F.2d at 168 (reviewing an "illegal suspension *without notice*" as a *de facto* debarment (emphasis added)); *Leslie & Elliott Co. v. Garrett*, 732 F. Supp. 191, 196 (D.D.C. 1990) (reviewing, as a *de facto* debarment, the Navy's informal decision to avoid contracts with a contractor based on statements by Navy personnel that they no longer wanted to do business with the contractor because "fair play and due process dictates that the Navy follow its debarment procedures, put the plaintiff on notice and conduct the necessary hearings before making a determination"); *Art-Metal-USA, Inc. v. Solomon*, 473 F. Supp. 1, 5 (D.D.C. 1978) (reviewing, as a *de facto* debarment, an agency's decision to cancel a contract and summarily categorize four other bids by the same contractor as "status quo or suspended animation for a point in time which has not been set" without notice for as long as the company was "being investigated" (alterations omitted)).

Nevertheless, there is no doubt that the proposed debarments have impacted Mrs. Lazzari, Potomac, Miller and Gordon, as they are no longer eligible to bid on or receive government contracts. *See* 48 C.F.R. § 9.405(a) ("Contractors debarred, suspended, *or proposed for debarment* are excluded from receiving contracts . . . ." (emphasis added)). The Court therefore concludes that DLA's proposed debarments, with the collateral consequences that flow from that action, is sufficiently "final" to confer jurisdiction on the Court to consider the Motion.

[3] At the hearing on the Motion, Plaintiffs also proffered that Potomac was the low bidder on a government contract but has not been awarded that contract because of the pending debarment proceedings.

The first and most central inquiry with respect to Plaintiffs' request for injunctive relief is whether they have made a clear showing of a likelihood of success on the merits of their claim. It is therefore important to frame precisely what that showing must be.

Although Plaintiffs Mrs. Lazzari, Potomac, Miller, and Gordon claim they are not affiliates of JBL, Mr. Lazzari or BJL, the issue for the purposes of the Motion is not whether they are in fact "affiliates" or will ultimately succeed on that claim that they are not "affiliates"during the debarment proceedings, but whether DLA had adequate grounds upon which to subject them to the debarment proceedings instituted against Mr. Lazzari, JBL, and BJL.

An agency may extend a debarment "to include any affiliates of the contractor if they are (1) specifically named and (2) given written notice of the proposed debarment and an opportunity to respond." 48 C.F.R. § 9.406-1(b). An "affiliate" is defined as follows:

> Affiliates. Business concerns, organizations, or individuals are affiliates of each other if, directly or indirectly, (1) either one controls or has the power to control the other, or (2) a third party controls or has the power to control both. Indicia of control include, but are not limited to, interlocking management or ownership, identity of interests among family members, shared facilities and equipment, common use of employees, or a business entity organized following the debarment, suspension, or proposed debarment of a contractor which has the same or similar management, ownership, or principal employees as the contractor that was debarred, suspended, or proposed for debarment.

48 C.F.R. § 9.403.

The standard for debarring an affiliate is broad and does not require any showing that the debarred affiliate committed or had knowledge of the contractor's wrongdoing. *See* 48 C.F.R. § 9.406-1(b) ("The debarring official may extend the debarment decision to include any affiliates of the contractor if they are (1) specifically named and (2) given written notice of the proposed debarment and an opportunity to respond." (citation omitted)); *Agility Def. & Gov't Servs. v.*

U.S. Dep't of Def., 739 F.3d 586, 590 (11th Cir. 2013) ("The agency may also debar an affiliate of that contractor based solely on its affiliate status. Like suspensions, an agency can debar an affiliate even if the affiliate has not engaged in wrongdoing." (citation omitted)).

In citing Mrs. Lazzari as an affiliate of Mr. Lazzari and JBL, her debarment notice references a LexisNexis report which stated that Mrs. Lazarri was the owner of JBL and Mr. Lazzari was its president, and that the Lazzaris and JBL shared the same address. *See* [Doc. 31-6 at 12]. The Debarment Notice also references other information that ties Mrs. Lazzari to JBL, Mr. Lazzari, and other affiliated companies:

> Brenda Lazzari (aka Brenda Riva) is Joseph Lazzari's wife and has access to JBL's credentials to access export-controlled and NOFORN technical data. Brenda Lazzari is listed in LexisNexis as the owner of JBL. Moreover, Brenda Lazzari is BJL's owner and registered POC. Additionally, Brenda Lazzari is Potomac's owner, registered agent, and DLA Internet Bid System (DIBBS) POC. Ms. Lazzari is located at the same address as JBL, BJL, and Joseph Lazzari.

[Doc. 31-14 at 3 (footnotes omitted)]. In support of its actions, DLA further states that Mrs. Lazzari "was also listed as JBL's registered POC for Government Business in the past." *Id.* at n.15. Additionally, DLA states the following concerning Mrs. Lazzari's connection with BJL, another company owned by Mr. Lazzari and affiliated with JBL:

> Note that on the date her suspension went into effect, January 30, 2019, Brenda Lazzari updated SAM to change BJL's business type from a Woman Owned Business to Veteran Owned Business and removing herself as the listed owner and POC of BJL. This change in business type indicates BJL either (1) now represents itself as a Veteran Owned Business as of January 30, 2019, but no longer lists its owner, and/or (2) Joseph Lazzari now owns BJL, a fact that would further demonstrate his control over BJL for purposes of concluding that BJL is an affiliate of JBL and Mr. Lazzari. Additionally, as of February 1, 2019, Brenda Lazzari was still listed as BJL's DTBBS POC and was still submitting quotations after her suspension, representing BJL as a service disabled veteran owned small business.

Id. at n.17 (citations omitted).

The Report clearly references "indicia of control," including Mrs. Lazzari's purported status as JBL's owner. Although Plaintiffs contend this report is inaccurate, they do not contest the accuracy of the other information that supports a finding that Mrs. Lazzari is an affiliate of either Mr. Lazzari or JBL, or both, including that there is "identity of interests among family members" or "shared facilities and equipment." Moreover, at the time it issued the suspension and initiated the debarment proceedings, DLA had no reason to suspect that the report was incorrect. Even now, Plaintiffs have not proffered any corporate documents reflecting JBL's ownership, placing in the record only a set of declarations by Mr. and Mrs. Lazzari. *See* [Doc. 22-7]. Given her extensive connections with Mr. Lazzari and the various organizations subject to the debarment action, only one of which is JBL, DLA clearly had adequate grounds to proceed against Mrs. Lazzari as an affiliate and its decision to do so was not arbitrary, capricious, an abuse of discretion, or otherwise unlawful under the broad definition of "affiliate" in 48 C.F.R. § 9.403.

DLA likewise had adequate grounds to proceed with debarment proceedings against Potomac, Miller, and Gordon. Gordon is an employee of both JBL and BJL and "is affiliated with JBL because she holds cFolders credentials on behalf of JBL, and because she is the Government Sales POC for BJL." [Doc. 31-14 at 15]. As to Potomac, Mrs. Lazzari is Potomac's "owner, registered agent, and DLA Internet Board Bid System (DIBBS) POC." [Doc. 31-14 at 15]. Miller "is affiliated with Potomac Military Manufacturing because she is the manager and registered POC of Potomac." *Id.* Based on these Plaintiffs' various connections to the Lazzaris and their various companies and the FAR's broad inclusion standard, DLA had adequate grounds upon which to proceed against them in debarment proceedings as affiliates;

and Plaintiffs have failed to clearly establish that DLA's decision to do so was arbitrary, capricious, an abuse of discretion, or contrary to law.

In summary, Plaintiffs have not made the necessary showing of likelihood of success on the merits of their claim. The Court also finds that while Plaintiffs have sufficiently established that they have suffered or will suffer irreparable harm to some degree, they have failed to sufficiently establish that the balance of equities weigh in their favor or that enjoining the on-going debarment proceedings is in the public interest.

IV. CONCLUSION

Accordingly, it is hereby

ORDERED that Plaintiffs' Emergency Amended Motion for Preliminary Injunction [Doc. 30] be, and the same hereby is, DENIED.

The Clerk is directed to forward copies of this Order to all counsel of record.

/s/
Anthony J. Trenga
United States District Judge

Alexandria, Virginia
March 22, 2019

fn 2

The Eleventh Circuit recognizes all of the Fifth Circuit decisions rendered prior to the close of business on September 30, 1981, as binding precedent. *Bonner v. City of Prichard*, Ala., **661 F.2d 1206** (11th Cir. 1981)(en banc).

fn 3

In its petition, Sigmatech asserts that it learned this information approximately one week before it filed the present petition. (Doc. 1, p. 9).

[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.

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* 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

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[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

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[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

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[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]

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[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:

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[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).

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[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.

Cybersecurity as an Insecurity in the FCA Space

By Andy Liu, Robert Nichols & Jason C. Lynch

In April 2014, Robert Nichols co-authored a Briefing Paper entitled *Cybersecurity for Government Contractors*, which is available on our website.[1] The paper discussed the growing regulatory requirements that government agencies had been imposing on contractors to protect government data. It also warned that failure to abide by these new

cybersecurity requirements could lead to potential False Claims Act (FCA) liability. This prediction has now come true, as described below. But first, a little more background.

The USIS Incident

Just four months after the Briefing Paper was published, on August 6, 2014, US Investigative Services LLC (USIS), the largest commercial provider of background investigations to the federal government, issued a media statement:

"Our internal IT security team recently identified an apparent external cyber-attack on USIS' corporate network. We immediately informed federal law enforcement, the Office of Personnel Management (OPM) and other relevant federal agencies. We are working closely with federal law enforcement authorities and have retained an independent computer forensics investigations firm to determine the precise nature and extent of any unlawful entry into our network. Experts who have reviewed the facts gathered to-date believe it has all the markings of a state-sponsored attack."

Yet within a matter of months, USIS was in bankruptcy, thousands of its employees were laid off, and its assets and remaining government contracts were transferred to another contractor. Why? USIS had committed no crime. The company had self-identified and reported the cyber breach to federal authorities and by all accounts cooperated with their investigation. And it had early detection systems that the government had approved and reviewed on a regular basis. At bottom, though, federal officials had lost confidence in the company.

The USIS incident demonstrated that contractors – because they hold

valuable government information – are targets for cyber criminals and state actors. Just last year, *The Washington Post* reported that "China hacked a Navy contractor and secured a trove of highly sensitive data on submarine warfare." This has been precisely the government's concern – and why new regulatory standards keep finding their way into contract clauses that govern the cyber activities of contractors. As a result of such clauses, contractors are now required to undertake cyber measures that they may not even have considered just a few years ago, and the number of such requirements is growing at a rapid pace.

And now the consequences of non-compliance have just gone up.

Applying the FCA to Cyber

Just last month, a federal judge denied a contractor's motion to dismiss an FCA case premised on noncompliance with federal cybersecurity requirements. The case undoubtedly portends more cyber-based FCA suits.

In *United States ex rel. Markus v. Aerojet Rocketdyne Holdings, Incorporated*, No. 2:15-cv-2245, slip op. (E.D. Cal. May 8, 2019), defendants' former senior director of Cyber Security, Compliance and Controls alleged that defendants fraudulently misrepresented their compliance with DoD's and NASA's minimum security requirements for safeguarding unclassified controlled technical information. The relator alleged that, as a result, the government was fraudulently induced to award contracts to the defendants.

The government declined to intervene in the case, and the defendants moved to dismiss the complaint for failure to plead materiality. The court disagreed, holding that the relator's allegations that defendants did

not “fully” disclose the extent of their noncompliance with relevant regulations was sufficient to survive a Rule 12(b)(6) motion. While the court did not find that compliance with cyber requirements is, in fact, material, the *Markus* decision is significant because of the ease by which a relator can plausibly plead a cybersecurity-based FCA case.

One of Aerojet’s more interesting arguments was that the defense industry’s general non-compliance with these regulations weighed against a finding of materiality. As an aside, and as recently reported on, for example, a survey of small and medium-sized defense contractors surveyed by the National Defense Industrial Association found that less than 60% of respondents had even read the DFARS requirement documentation, and over 45% had not read the NIST publication that forms the foundation for the DFARS requirements.[2] Without conceding the point, the court held that “[e]ven if the government never expected full technical compliance, relator properly pleads that the extent to which a company was technically compliant still mattered to the government’s decision to enter into a contract.” If this reasoning takes hold, relators would need only allege that some misrepresentation or omission was made in describing one’s cybersecurity safeguards in order to survive a motion to dismiss.[3]

It is challenging enough to keep up with the ever-evolving federal regulatory landscape on cyber. The prospect of having to face *qui tam* suits based on any perceived misrepresentations regarding compliance only raises the stakes. But the task is made harder still by the differing degrees to which agencies demand protection. This is exemplified in *Markus*, where DoD’s regulations define “adequate security” as “protective measures that are commensurate with the consequences and probability of loss, misuse, or unauthorized access to, or modification of

information" (48 C.F.R. 252.204-7012(a)), but NASA's regulations rigidly required contractors "to protect the confidentiality, integrity, and availability of NASA [information] and protect [it] from unauthorized disclosure" (48 C.F.R. 1852.204-76(a)). On top of these technical and legal challenges, Ellen Lord, DoD Undersecretary for Acquisition and Sustainment, stated in January that DoD will begin auditing the cybersecurity procedures of companies that seek to do business with the government.

Unfortunately, we are likely to see many more cases like *Markus* in the coming years.

How We Can Help

Nichols Liu advises on both cybersecurity requirements for government contractors, and the fallout from breaches and lapses in compliance related to these requirements.

[1] https://nicholsliu.com/cybersecurity-for-government-contractors/

[2] http://www.ndia.org/-/media/sites/ndia/divisions/manufacturing/documents/cybersecurity-in-dod-supply-chains.ashx?la=en

[3] The court also rejected other, more traditional arguments in the wake of *Escobar*: that the government had been told of Aerojet's non-compliance, if any; that the government continued to contract with Aerojet thereafter; that DOJ had declined the case; and that cybersecurity was not the "central purpose" of the missile-defense contract.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

COCHISE CONSULTANCY, INC., ET AL. *v.* UNITED STATES EX REL. HUNT

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 18–315. Argued March 19, 2019—Decided May 13, 2019

The False Claims Act permits a private person, known as a relator, to bring a *qui tam* civil action "in the name of the [Federal] Government," 31 U. S. C. §3730(b), against "any person" who "knowingly presents . . . a false or fraudulent claim for payment" to the Government or to certain third parties acting on the Government's behalf, §§3729(a), (b)(2). The Government may choose to intervene in the action. See §§3730(b)(2), (4). Two limitations periods apply to a "civil action under section 3730." §3731(b). An action must be brought within either 6 years after the statutory violation occurred, §3731(b)(1), or 3 years after the "the official of the United States charged with responsibility to act in the circumstances" knew or should have known the relevant facts, but not more than 10 years after the violation, §3731(b)(2). The period providing the later date serves as the limitations period.

In November 2013, respondent Hunt filed a complaint alleging that petitioners—two defense contractors (collectively, Cochise)—defrauded the Government by submitting false payment claims for providing security services in Iraq up until early 2007. Hunt claims that he revealed Cochise's allegedly fraudulent scheme during a November 30, 2010, interview with federal officials about his role in an unrelated contracting fraud in Iraq. The United States declined to intervene in the action, and Cochise moved to dismiss the complaint as barred by the statute of limitations. Hunt countered that his complaint was timely under §3731(b)(2). In dismissing the action, the District Court considered three potential interpretations: that §3731(b)(2) does not apply to a relator-initiated action in which the Government elects not to intervene; that §3731(b)(2) applies in non-

intervened actions, and the limitations period begins when the relator knew or should have known the relevant facts; or that §3731(b)(2) applies in nonintervened actions, and the limitations period begins when the Government official responsible for acting knew or should have known the relevant facts. The court rejected the third interpretation and found that Hunt's complaint would be untimely under either of the first two. The Eleventh Circuit reversed and remanded, adopting the third interpretation.

Held:

1. The limitations period in §3731(b)(2) applies in a relator-initiated suit in which the Government has declined to intervene. Both Government-initiated suits under §3730(a) and relator-initiated suits under §3730(b) are "civil action[s] under section 3730." Thus, the plain text of the statute makes the two limitations periods applicable in both types of suits. Cochise claims that starting a limitations period when the party entitled to bring a claim learns the relevant facts is a default rule of tolling provisions, so subsection (b)(2) should apply only when the Government is a party. But treating a relator-initiated, nonintervened suit as a "civil action under section 3730" for purposes of subsection (b)(1) but not subsection (b)(2) is at odds with fundamental rules of statutory interpretation. Because a single use of a statutory phrase generally must have a fixed meaning, see *Ratzlaf* v. *United States*, 510 U. S. 135, 143, interpretations that would "attribute different meanings to the same phrase" should be avoided, *Reno* v. *Bossier Parish School Bd.*, 528 U. S. 320, 329. Here, the clear text of the statute controls. Cochise's reliance on *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 545 U. S. 409, is misplaced. Nothing in *Graham County* supports giving the phrase "civil action under section 3730" in §3731(b) two different meanings depending on whether the Government intervenes. While the *Graham County* Court sought "a construction that avoids . . . counterintuitive results," there the text "admit[ted] of two plausible interpretations." *Id.,* at 421, 419, n. 2. Here, Cochise points to no other plausible interpretation of the text, so the "'judicial inquiry is complete.'" *Barnhart* v. *Sigmon Coal Co.,* 534 U. S. 438, 462. Pp. 4–8.

2. The relator in a nonintervened suit is not "the official of the United States" whose knowledge triggers §3731(b)(2)'s 3-year limitations period. The statute provides no support for such a reading. First, a private relator is neither appointed as an officer of the United States nor employed by the United States. Second, the provision authorizing *qui tam* suits is entitled "Actions by Private Persons." §3730(b). Third, the statute refers to "the" official "charged with responsibility to act in the circumstances." Regardless of precisely

Syllabus

which official or officials the statute is referring to, §3731(b)(2)'s use of the definite article "the" suggests that Congress did not intend for private relators to be considered "the official of the United States." See *Rumsfeld* v. *Padilla*, 542 U. S. 426, 434. Nor are private relators "charged with responsibility to act" in the sense contemplated by §3731(b), as they are not required to investigate or prosecute a False Claims Act action. Pp. 8–9.

887 F. 3d 1081, affirmed.

THOMAS, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 18–315

COCHISE CONSULTANCY, INC., ET AL., PETITIONERS *v.* UNITED STATES, EX REL. BILLY JOE HUNT

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

[May 13, 2019]

JUSTICE THOMAS delivered the opinion of the Court.

The False Claims Act contains two limitations periods that apply to a "civil action under section 3730"—that is, an action asserting that a person presented false claims to the United States Government. 31 U. S. C. §3731(b). The first period requires that the action be brought within 6 years after the statutory violation occurred. The second period requires that the action be brought within 3 years after the United States official charged with the responsibility to act knew or should have known the relevant facts, but not more than 10 years after the violation. Whichever period provides the later date serves as the limitations period.

This case requires us to decide how to calculate the limitations period for *qui tam* suits in which the United States does not intervene. The Court of Appeals held that these suits are "civil action[s] under section 3730" and that the limitations periods in §3731(b) apply in accordance with their terms, regardless of whether the United States intervenes. It further held that, for purposes of the second period, the private person who initiates the *qui tam* suit

cannot be deemed the official of the United States. We agree, and therefore affirm.

I

As relevant, the False Claims Act imposes civil liability on "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the Government or to certain third parties acting on the Government's behalf. 31 U. S. C. §§3729(a), (b)(2). Section 3730 authorizes two types of actions: First, the Attorney General, who "diligently shall investigate a violation under section 3729," may bring a civil action against the alleged false claimant. §3730(a). Second, a private person, known as a relator, may bring a *qui tam* civil action "for the person and for the United States Government" against the alleged false claimant, "in the name of the Government." §3730(b).

If a relator initiates the action, he must deliver a copy of the complaint and supporting evidence to the Government, which then has 60 days to intervene in the action. §§3730(b)(2), (4). During this time, the complaint remains sealed. §3730(b)(2). If the Government intervenes, it assumes primary responsibility for prosecuting the action, though the relator may continue to participate. §3730(c). Otherwise, the relator has the right to pursue the action. §§3730(b)(4), (c)(3). Even if it does not intervene, the Government is entitled to be served with all pleadings upon request and may intervene at any time with good cause. §3730(c)(3). The relator receives a share of any proceeds from the action—generally 15 to 25 percent if the Government intervenes, and 25 to 30 percent if it does not—plus attorney's fees and costs. §§3730(d)(1)–(2). See *Vermont Agency of Natural Resources* v. *United States ex rel. Stevens*, 529 U. S. 765, 769–770 (2000).

At issue here is the Act's statute of limitations, which provides:

"(b) A civil action under section 3730 may not be brought—

"(1) more than 6 years after the date on which the violation of section 3729 is committed, or

"(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

"whichever occurs last." §3731(b).

On November 27, 2013, respondent Billy Joe Hunt filed a complaint alleging that petitioners—two defense contractors (collectively, Cochise)—defrauded the Government by submitting false claims for payment under a subcontract to provide security services in Iraq "from some time prior to January 2006 until early 2007." App. 43a. A little less than three years before bringing his complaint, Hunt was interviewed by federal agents about his role in an unrelated contracting fraud in Iraq. Hunt claims to have revealed Cochise's allegedly fraudulent scheme during this November 30, 2010, interview.

The United States declined to intervene in Hunt's action, and Cochise moved to dismiss the complaint as barred by the statute of limitations. Hunt conceded that the 6-year limitations period in §3731(b)(1) had elapsed before he filed suit on November 27, 2013. But Hunt argued that his complaint was timely under §3731(b)(2) because it was filed within 3 years of the interview in which he informed federal agents about the alleged fraud (and within 10 years after the violation occurred).

The District Court dismissed the action. It considered three potential interpretations of §3731(b). Under the first interpretation, §3731(b)(2) does not apply to a relator-initiated action in which the Government elects not to

intervene, so any such action must be filed within six years after the violation. Under the second interpretation, §3731(b)(2) applies in nonintervened actions, and the limitations period begins when the relator knew or should have known the relevant facts. Under the third interpretation, §3731(b)(2) applies in nonintervened actions, and the limitations period begins when "the official of the United States charged with responsibility to act in the circumstances" knew or should have known the relevant facts. The District Court rejected the third interpretation and declined to choose between the first two because it found that Hunt's complaint would be untimely under either. The Court of Appeals reversed and remanded, adopting the third interpretation. 887 F. 3d 1081 (CA11 2018).

Given a conflict between the Courts of Appeals,* we granted certiorari. 586 U. S. ___ (2018).

II

The first question before us is whether the limitations period in §3731(b)(2) is available in a relator-initiated suit in which the Government has declined to intervene. If so, the second question is whether the relator in such a case should be considered "the official of the United States" whose knowledge triggers §3731(b)(2)'s 3-year limitations period.

A

Section 3731(b) sets forth two limitations periods that apply to "civil action[s] under section 3730." Both

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*Compare 887 F. 3d 1081, 1089–1097 (CA11 2018) (adopting the third interpretation), with *United States ex rel. Hyatt* v. *Northrop Corp.*, 91 F. 3d 1211, 1216–1218 (CA9 1996) (adopting the second interpretation); *United States ex rel. Sanders* v. *North Am. Bus Industries, Inc.*, 546 F. 3d 288, 293–294 (CA4 2008) (adopting the first interpretation); and *United States ex rel. Sikkenga* v. *Regence Bluecross Blueshield of Utah*, 472 F. 3d 702, 725–726 (CA10 2006) (same).

Government-initiated suits under §3730(a) and relator-initiated suits under §3730(b) are "civil action[s] under section 3730." Thus, the plain text of the statute makes the two limitations periods applicable in both types of suits.

Cochise agrees with that view as to the limitations period in §3731(b)(1), but argues that the period in §3731(b)(2) is available in a relator-initiated suit only if the Government intervenes. According to Cochise, starting a limitations period when the party entitled to bring a claim learns the relevant facts is a default rule of tolling provisions, so subsection (b)(2) should be read to apply only when the Government is a party. In short, under Cochise's reading, a relator-initiated, nonintervened suit is a "civil action under section 3730" for purposes of subsection (b)(1) but not subsection (b)(2).

This reading is at odds with fundamental rules of statutory interpretation. In all but the most unusual situations, a single use of a statutory phrase must have a fixed meaning. See *Ratzlaf* v. *United States*, 510 U. S. 135, 143 (1994). We therefore avoid interpretations that would "attribute different meanings to the same phrase." *Reno* v. *Bossier Parish School Bd.*, 528 U. S. 320, 329 (2000). Here, either a relator-initiated, nonintervened suit is a "civil action under section 3730"—and thus subject to the limitations periods in subsections (b)(1) and (b)(2)—or it is not. It is such an action. Whatever the default tolling rule might be, the clear text of the statute controls this case.

Under Cochise's reading, a relator-initiated civil action would convert to "[a] civil action under section 3730" for purposes of subsection (b)(2) if and when the Government intervenes. That reading cannot be correct. If the Government intervenes, the civil action remains the same—it simply has one additional party. There is no textual basis to base the meaning of "[a] civil action under section 3730" on whether the Government has intervened.

Cochise relies on our decision in *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 545 U. S. 409 (2005), which addressed the question whether §3731(b)(1) or federal common law provided the limitations period for §3730(h) retaliation actions. Section 3730(h) creates a cause of action for an employee who suffers retaliation for, among other things, assisting with the prosecution of a False Claims Act action. At the time, §3730(h) did not specify a time limit for bringing a retaliation action, so the question before us was whether the phrase "civil action under section 3730" in §3731(b) encompassed actions under §3730(h). We considered the statute "ambiguous because its text, literally read, admits of two plausible interpretations." *Id.*, at 419, n. 2. One reading was that a "civil action under section 3730" includes §3730(h) actions because such actions arise under §3730. *Id.*, at 415. "Another reasonable reading" was that a "civil action under section 3730" "applies only to actions arising under §§3730(a) and (b)" because "§3731(b)(1) t[ies] the start of the time limit to 'the date on which the violation of section 3729 is committed.'" *Ibid.* That reading had force because retaliation claims need not involve an actual violation of §3729. *Ibid.* Looking to statutory context, we explained that the phrase "'civil action under section 3730' means only those civil actions under §3730 that have as an element a 'violation of section 3729,' that is, §§3730(a) and (b) actions"—not §3730(h) retaliation actions. *Id.*, at 421–422.

A relator-initiated, nonintervened suit arises under §3730(b) and has as an element a violation of §3729. *Graham County* supports our reading. Nonetheless, Cochise points out that in considering the statutory context, we discussed a similar phrase contained in §3731(c) (now §3731(d)), which stated: "In *any action brought under section 3730*, the United States shall be required to prove all essential elements of the cause of action, including

damages, by a preponderance of the evidence." (Emphasis added.) We explained that §3731(c) "use[d] the similarly unqualified phrase 'action brought under section 3730' to refer only to §§3730(a) and (b) actions." *Id.*, at 417–418. We then stated: "As [respondent] and the United States concede, the context of this provision implies that the phrase 'any action brought under section 3730' is limited to §3730(a) actions brought by the United States and §3730(b) actions in which the United States intervenes as a party, as those are the types of §3730 actions in which the United States necessarily participates." *Id.*, at 418.

Cochise contends that we should adopt a similar construction of the phrase "civil action under section 3730" in §3731(b). We disagree. Our discussion of §3731(c) was focused on "the context of th[at] provision" and on whether it could be read to impose the burden of proof on the Government even in cases where the Government did not participate. *Id.*, at 418. Those considerations do not apply here; there is nothing illogical about reading §3731(b) to apply in accordance with its plain terms. Moreover, if a "civil action under section 3730" included only an action in which the Government participates for purposes of §3731(b)(2), then we would be obligated to give it a like meaning for purposes of §3731(b)(1). This would mean that a relator-initiated, nonintervened suit would be subject to neither §3731(b)(1) nor §3731(b)(2)—a reading Cochise expressly disclaims. See Brief for Petitioners 20, n. 3. Nothing in *Graham County* supports giving the same phrase in §3731(b) two different meanings depending on whether the Government intervenes.

Again pointing to *Graham County*, Cochise next contends that our reading would lead to "'counterintuitive results.'" Brief for Petitioners 26. For instance, if the Government discovers the fraud on the day it occurred, it would have 6 years to bring suit, but if a relator instead discovers the fraud on the day it occurred and the Gov-

ernment does not discover it, the relator could have as many as 10 years to bring suit. That discrepancy arises because §3731(b)(2) begins its limitations period on the date that "the official of the United States charged with responsibility to act" obtained knowledge of the relevant facts. But we see nothing unusual about extending the limitations period when the Government official did not know and should not reasonably have known the relevant facts, given that the Government is the party harmed by the false claim and will receive the bulk of any recovery. See §3730(d). In any event, a result that "may seem odd . . . is not absurd." *Exxon Mobil Corp.* v. *Allapattah Services*, *Inc.*, 545 U. S. 546, 565 (2005). Although in *Graham County* we sought "a construction that avoids . . . counterintuitive results," there the text "admit[ted] of two plausible interpretations." 545 U. S., at 421, 419, n. 2. Here, Cochise points to no other plausible interpretation of the text, so the "'judicial inquiry is complete.'" *Barnhart* v. *Sigmon Coal Co.*, 534 U. S. 438, 462 (2002).

B

Cochise's fallback argument is that the relator in a nonintervened suit should be considered "the official of the United States charged with responsibility to act in the circumstances," meaning that §3731(b)(2)'s 3-year limitations period would start when the relator knew or should have known about the fraud. But the statute provides no support for reading "the official of the United States" to encompass a private relator.

First, a private relator is not an "official of the United States" in the ordinary sense of that phrase. A relator is neither appointed as an officer of the United States, see U. S. Const., Art. II, §2, cl. 2, nor employed by the United States. Indeed, the provision that authorizes *qui tam* suits is entitled "Actions by Private Persons." §3730(b). Although that provision explains that the action is

brought "for the person and for the United States Government" and "in the name of the Government," *ibid.*, it does not make the relator anything other than a private person, much less "the official of the United States" referenced by the statute. Cf. *Stevens*, 529 U. S., at 773, n. 4 ("[A] *qui tam* relator is, in effect, suing as a partial assignee of the United States" (emphasis deleted)).

Second, the statute refers to "the" official "charged with responsibility to act in the circumstances." The Government argues that, in context, "the" official refers to the Attorney General (or his delegate), who by statute "shall investigate a violation under section 3729." §3730(a). Regardless of precisely which official or officials the statute is referring to, §3731(b)(2)'s use of the definite article "the" suggests that Congress did not intend for any and all private relators to be considered "the official of the United States." See *Rumsfeld* v. *Padilla*, 542 U. S. 426, 434 (2004) (explaining that the "use of the definite article . . . indicates that there is generally only one" person covered). More fundamentally, private relators are not "charged with responsibility to act" in the sense contemplated by §3731(b), as they are not required to investigate or prosecute a False Claims Act action.

* * *

For the foregoing reasons, the judgment of the Court of Appeals is

Affirmed.

[redacted]

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, May 7, 2019

Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual

The Civil Division today announced the release of formal guidance to the Department of Justice's False Claims Act litigators. The False Claims Act provides important remedies for fraud committed against the United States. The guidance announced today explains the manner in which the Department of Justice awards credit to defendants who cooperate with the Department during a False Claims Act investigation. The formal policy, included as of today in the Justice Manual Section 4-4.112, identifies the type of cooperation eligible for credit.

"The Department of Justice has taken important steps to incentivize companies to voluntarily disclose misconduct and cooperate with our investigations; enforcement of the False Claims Act is no exception," Assistant Attorney General Jody Hunt said. "False Claims Act defendants may merit a more favorable resolution by providing meaningful assistance to the Department of Justice – from voluntary disclosure, which is the most valuable form of cooperation, to various other efforts, including the sharing of information gleaned from an internal investigation and taking remedial steps through new or improved compliance programs."

Under the policy, cooperation credit in False Claims Act cases may be earned by voluntarily disclosing misconduct unknown to the government, cooperating in an ongoing investigation, or undertaking remedial measures in response to a violation. Even if the government already has initiated an investigation, for example, a company may receive credit for making a voluntary self-disclosure of other misconduct outside the scope of the government's existing investigation that is unknown to the government. Similarly, a company may earn credit by preserving relevant documents and information beyond existing business practices or legal requirements, identifying individuals who are aware of relevant information or conduct, and facilitating review and evaluation of data or information that requires access to special or proprietary technologies.

Under the policy, the Department of Justice will take into account corrective action that a company has taken in response to a False Claims Act violation. Such remedial measures may include undertaking a thorough analysis of the root cause of the misconduct, appropriately disciplining or replacing those responsible for the misconduct, accepting responsibility for the violation and implementing or improving compliance programs to prevent a recurrence.

Most frequently, cooperation credit will take the form of a reduction in the damages multiplier and civil penalties. If appropriate, the Department may also notify a relevant agency about the company's voluntary disclosure, cooperation, or remediation so that the agency can take those actions into account in deciding how to apply administrative remedies. And the Department may publicly acknowledge the company's cooperation.

For the full policy, click here.

Topic(s):
False Claims Act

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

September 4, 2019

VIA ELECTRONIC TRANSMISSION

The Honorable William Barr
Attorney General
U.S. Department of Justice
Washington D.C., 20220

Dear Attorney General Barr:

I write today with concerns about the Department of Justice's (DOJ) implementation of the Granston Memorandum and its efforts to dismiss greater numbers of *qui tam* cases for reasons that appear primarily unrelated to the merits of individual cases.[1] Those efforts rely at least in part on vague and at times questionable concerns over prerogatives or limited government resources to handle the cases. Such actions could undermine the purpose of the False Claims Act by discouraging whistleblowers and dismissing potentially serious fraud on the taxpayers.

Originally enacted in 1863, the False Claims Act allows the government to recover triple damages and impose fines against those who knowingly defraud the government.[2] This is a powerful tool in the U.S. government's toolbox to prevent and deter fraud and has resulted in the recovery of more than $59 billion since 1986.[3] The key feature of the False Claims Act is the *qui tam* provision, which allows whistleblowers privy to inside information about fraudulent conduct to sue on the government's behalf.[4] For their efforts, successful whistleblowers may receive a reward of up to 30% of funds recouped by the government.[5] The statute requires that the relator file a claim under seal, and then DOJ has 60 days to investigate the allegations raised in the complaint.[6] After the 60 day investigatory period, DOJ may prosecute the case themselves in a process often referred to as "intervening" in a case.[7] In such intervening cases, the whistleblowers

[1] *See* Motion to Dismiss, United States *ex rel.* Campie v. Gilead Scis., Inc., No. C-11-0941 EMC (N.D. Cal. Mar. 28, 2019).
[2] 31 U.S.C. §§ 3729 -3733 (2012); *See* U.S. Dep't of Justice, *The False Claims Act: A Primer* (Apr. 22, 2011), *available at* https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[3] Civil Div., U.S. Dep't. of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018*, (Dec. 21, 2018), *available at* https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.
[4] 31 U.S.C. § 3730(c).
[5] 31 U.S.C. § 3730(c).
[6] 31 U.S.C. § 3730(b).
[7] *Id*.

who alerted the government of the fraud through their *qui tam* claim remain eligible for a reward regardless of DOJ involvement.[8]

On January 10, 2018, Michael D. Granston, Director of the Commercial Litigation Branch at DOJ, issued new guidance on when to seek dismissals of *qui tam* claims.[9] Prior to the memo, motions to dismiss by the government were extremely rare.[10] I raised concerns about this new guidance with you during your confirmation hearing.[11] You assured me that you would review the Granston memo and work with me to address any concerns.[12] As I have noted, the guidance includes several vague criteria for DOJ attorneys to consider.[13] For example, listed as one of the possible reasons to seek dismissals was "preserving government resources."[14] Seemingly in response to the Granston memo, DOJ has moved to dismiss or threaten to dismiss several cases at least in part because of litigation costs, even though its arguments were vague, pretextual and could not demonstrate cost was prohibitive. Some examples follow:

In *United States, ex rel. Cimznhca, LLC v. UCB, Inc.*, relators alleged violations of the Anti-Kickback Statute by several pharmaceutical companies.[15] DOJ moved to dismiss the claim arguing that the case lacked merit, but also because continued litigation would be costly and contrary to governmental prerogatives.[16] DOJ further asserted that substantial costs would be incurred responding to discovery requests and monitoring the litigation.[17]

However, during an evidentiary hearing on the motion, DOJ admitted that it did not thoroughly investigate the specific claims made by the relators.[18] The court noted, "[DOJ] did not review any additional materials from the relator relevant to this case…nor did the Government effort a cost-benefit analysis; it did not assess or analyze the costs it would likely incur versus the potential recovery that would flow to the Government if this case were to proceed."[19] The court also found fault with DOJ's expressed policy interest, highlighting that even the government acknowledges that the allegations made by the relators "assert a classic violation" of the Anti-Kickback Statute.[20] The court ultimately denied DOJ's motion to dismiss finding that its decision

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[8] 31 U.S.C. § 3730(c).; *see also* Paden M. Hanson, *True Damages for False Claims: Why Gross Trebling Should Be Adopted*, 104 IOWA L. REV. 2093, 2099 (2019).
[9] Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, to Atty.'s in the Commercial Litig. Branch, Fraud Section (January 10, 2018), *available at* https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.
[10] Schooner, Steven L., *FALSE CLAIMS ACT: Greater DOJ Scrutiny of Frivolous Qui Tam Actions?* (April 2018) 32 NASH & CIBINIC REP. ¶ 20 at 60 (2018) (only a single reported instance between 1986 to 1996 in which the DOJ has sought to dismiss a qui tam suit on the ground that the suit lacked substantive merit or otherwise contradicted the interests of the United States), *available at* https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=2593&context=faculty_publications.
[11] *Nomination of the Honorable William Pelham Barr to be Attorney General of the United States*, 116th Cong. (2019) (statement of Sen. Charles E. Grassley, Member, S. Comm. on the Judiciary).
[12] *Id*.
[13] *Id*.
[14] Memorandum from Michael D. Granston, *supra*, note 9.
[15] *See* United States *ex rel.* Cimznhca, LLC. v. UBC Inc., No. 17-CV-765 –SMY-MAB (S.D. Ill. April 15, 2019) (order denying government's motion to dismiss); *see also* 42 U.S.C. § 1320a-7b(b).
[16] UBC Inc., No. 17-CV-765 –SMY-MAB at 6.
[17] *Id*. at 5.
[18] *Id*. at 6.
[19] *Id*. at 6.
[20] *Id*. at 6.

was arbitrary and capricious, and likely motivated by animus towards the relator.[21] To summarize, DOJ did not thoroughly investigate a case it argued lacked merit; argued for dismissal on policy grounds while admitting the claims present a classic violation of law; and finally, failed to do a cost-benefit analysis while arguing that litigation would be too costly.

In *United States*, *ex rel. Campie v. Gilead Scis. Inc.*, DOJ made similar cost-based arguments.[22] The relators in *Campie* alleged that Gilead Sciences Inc. manufactured certain drugs using illicit and potentially dangerous ingredients from unregistered facilities in China.[23] In the mid-2000's Gilead received approval from the Food and Drug Administration (FDA) for several drugs which contained the active ingredient emtricitabine (commonly known as FTC).[24] Gilead represented to the FDA that it would source its FTC from FDA-approved facilities in Canada, Germany, South Korea, and the U.S.[25] However, for a period of sixteen months beginning in December 2007, Gilead allegedly used illicit FTC purchased from a facility in China in order to cut costs and trigger price reduction clauses in contracts with other FTC suppliers.[26] In an effort to hide its actions, Gilead allegedly falsified labels so that their origins were disguised, and claimed that the FTC had come from an FDA-approved facility in South Korea.[27] On October 2008, Gilead sought FDA approval for the use of FTC purchased in the Chinese facility.[28] However, the relators further alleged that Gilead concealed or falsified quality control issues in the Chinese facility in order to receive FDA approval.[29] Based upon these alleged facts, the relators brought a *qui tam* action in October 2010.[30] DOJ then investigated the allegations for two years before declining to intervene in January 2013.[31] Nonetheless, the relators elected to proceed without the government, and filed an amended complaint to that effect.[32] Years later, the government moved to unilaterally dismiss the relators' claim in 2019.[33]

DOJ's main rationale for seeking to dismiss the *qui tam* claim in *Campie* was that it would "avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue."[34] Here, once again, DOJ has attempted to dismiss a claim by citing litigation costs. Similar to the court in *Cimznhca, LLC v. UCB*, the Judge in the *Campie* case asked DOJ if a cost-benefit analysis had been performed, noting that "some meaningful cost-benefit

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[21] *Id*. at 7.
[22] *See* Gilead Scis., Inc., No. C-11-0941 EMC (2019).
[23] *Id*. at 1-2.
[24] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 895-96 (9th Cir. 2017).
[25] *Id*. at 896.
[26] *Id*.
[27] *Id*.
[28] *Id*.
[29] *Id*.
[30] *See* Gilead Scis., Inc., No. C-11-0941 EMC at 8 (2019).
[31] *Id*. at 8.
[32] *Id*. at 8.
[33] *Id*. at 8; *see also* United States, ex. rel. Campie *et al.* v. Gilead Scis., Inc,, 2015 WL 3659765 (N.D. Cal. 2015), United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 895-96 (9th Cir. 2017), Gilead Scis., Inc. v. United States, *ex. rel.* Campie, 139 S.Ct. 783 (2019) (District court dismissed relators claim in 2015, under the theory that fraud was directed at the FDA and not the payer agency, that payment was not conditioned on compliance with FDA regulations but merely FDA approval, and that FCA was not meant to intrude on FDA's regulatory regime. The 9th Circuit Court of Appeals reversed and remanded stating that relators adequately pled theories of factual false certification, implied false certification, and promissory fraud. The Supreme Court denied writ on defendant's appeal of the 9th Circuit's ruling. The case is now pending before the District court).
[34] *See supra*, note 30.

analysis" could be necessary.[35] The court subsequently allowed the government more time to file supplemental briefs to support their claims.[36]

In a similar pattern, I was recently informed that DOJ moved to dismiss *United States ex rel. Polansky v. Exec. Health Res., Inc*, citing the growing cost of discovery as the main rationale.[37] Since litigation began in 2012, the government has produced approximately 42,000 pages of documents for this case.[38] However, the court recently granted Defendant's requests for the production of documents previously withheld and new email discovery limited to three new custodians using previously approved targeted search terms.[39] In response to this court order, DOJ has moved to dismiss this *qui tam* claim on the basis that continued production and litigation would be burdensome and costly.[40] Yet, similar to the aforementioned cases, no cost-benefit analyses have been produced.

More troubling, DOJ has implied that cases where it declines to intervene lack merit or face little chances of success. History has shown that the opposite is true. Since 1986, relators have recovered over $2.4 billion for the federal government via claims in which DOJ chose to not intervene.[41] For example, that's $599,038,273 in *qui tam* cases in 2017 alone.[42] Furthermore, DOJ has repeatedly asserted that a decision to not intervene in a case is based on several factors including resource constraints. For example, during oral arguments before the Supreme Court in 2016, Deputy Solicitor General Malcolm Stewart stated:

> "[W]e don't typically give public explanations of why we don't intervene. Sometimes it's because the dollar amount is small. Sometimes it's because … we think that the relator is capable of handling the case himself, or the relator's counsel. Sometimes we do decline to intervene, because we're skeptical of the merits of a case. But even in those situations, it could be that we agree with the relator's theory and simply don't know whether the facts could be proved."[43]

Not only is DOJ's argument contradicted by its own admissions, it also ignores the statutory intent of the *qui tam* provision. Congress gave whistleblowers the ability to proceed with claims on their own *precisely* for situations in which DOJ either would not or could not pursue the case. We know from experience that without whistleblowers, fraudsters multiply and bad behavior balloons. In 1943, Congress bowed to pressure to undo the Act's crucial *qui tam* provisions and

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[35] Hannah Albarazi, *DOJ's Bid to Toss Whistleblowers' Gilead FCA Suit Hits Snag*, Law360, Aug. 1, 2019, *available at* https://www.law360.com/articles/1184571/doj-s-bid-to-toss-whistleblowers-gilead-fca-suit-hits-snag.
[36] *Id*.
[37] *See* Motion to Dismiss, United States *ex rel.* Polansky v. Exec. Health Res., Inc., No. 12-CV-4239-MMB (E.D. Pa. Aug. 20, 2019).
[38] Id. at 8.
[39] Id.
[40] *Id.*
[41] Civil Div., U.S. Dep't. of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018*, (Dec. 21, 2018), *available at* https://www.justice.gov/civil/page/file/1080696/download.
[42] *Id*.
[43] Transcript of Oral Argument at 48, Universal Health Servs. Inc. v. United States *ex rel.* Escobar, 136 S.Ct. 1986 (2016) (No. 15-7), *available at* https://www.supremecourt.gov/oral_arguments/argument_transcripts/2015/15-7_6537.pdf.

essentially block private actions.[44] Congress assumed that the DOJ could do a good job prosecuting fraud without whistleblowers. They were wrong. In the words of a 1981 report by the Government Accountability Office, "For those who are caught committing fraud, the chances of being prosecuted and eventually going to jail are slim . . . . The sad truth is that crime against the Government often does pay."[45] By 1986, taxpayer dollars became easier and easier to scam, and fraud on the government had skyrocketed.[46] The DOJ estimated at that time that fraud was a drain on 1 to 10 percent of the entire Federal budget.[47] In 1985, that meant fraudulent activity cost taxpayers $10 billion to $100 billion every year.[48]

In 1986, I spearheaded the effort to empower whistleblowers to help the government combat fraud by bringing back the *qui tam* provisions Congress had undone in the 1940s.[49] Denying relators the right to pursue False Claims Act cases if the government does not intervene is counter to the basic, essential purpose of the Act, which is to empower private citizens to help the government fight fraud. DOJ's actions in these cases will send a clear message that bad actors can get away with fraud as long as they make litigating painful and sufficiently burdensome for the government. By opting to save resources without first conducting a sufficient cost-benefit analysis, DOJ is circumventing Congress and taking a shortsighted position that may end up costing taxpayers much more money in the future.

The facts show that the False Claim Act is working. The *qui tam* provisions have reinvigorated an Act which had been mostly left for dead after the 1940s. In order for the law to continue working, DOJ must let the *qui tam* provision work the way it was intended and allow relators to proceed with litigation on their own. In order to better understand DOJ's plans with respect to future *qui tam* cases, please answer the following questions no later than September 18, 2019.

1. Did FDA request that DOJ dismiss the *qui tam* claim in *Campie*? If so, what reasoning did FDA give?

    a. How much deference does DOJ give to regulatory agencies in deciding whether to petition a court to dismiss a *qui tam* claim?

    b. In the past 10 years, has DOJ ever moved to dismiss a claim in order to shield an agency's decision-making process? If so, please list each case.

2. Is DOJ concerned that by moving to dismiss *Campie* and similar cases, such a precedent will lead other defendants to seek to make litigation as costly as possible in order to incentivize DOJ to dismiss future claims? If not, why not?

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[44] *Oversight of the False Claims Act: Hearing Before the Subcomm. on the Constitution and Civil Justice of the H. Comm. on the Judiciary*, 114th Cong. 11 (2016) (statement of Sen. Grassley, Chairman, S. Comm. on the Judiciary).
[45] *Id*.
[46] *Id*.
[47] *Id*. at 12.
[48] *Id*.
[49] False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986).

3. What role did the Granston memo play in DOJ's decision to move to dismiss in *Campie*? Is the decision to dismiss in line with the Granston memo? Would DOJ have moved to dismiss the case absent the Granston memo?

4. Please explain the cost-benefit analysis process DOJ uses in determining which cases warrant dismissal at least in part due to litigation costs. Please provide examples of any previously used cost-benefit analysis documents. Who in DOJ ultimately makes these decisions?

5. How many cases has DOJ moved to dismiss since the publication of the Granston memo? Please describe the reasons for moving to dismiss each case and note the point of litigation at which DOJ moved to dismiss the case.

    a. In how many of the above cases did the relator(s) survive a motion to dismiss prior to DOJ filing its motion to dismiss?

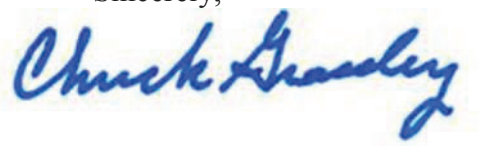
    b. How much time had passed since the relator(s) filed the case under seal?

    c. How many discovery obligations remain outstanding?

6. Since the Granston memo, what resources have been devoted to dismissing *qui tam* claims? Are there staff specifically devoted to working on dismissals? If so, please provide the number of staff, to include full time and part time, devoted to determining whether a claim should be dismissed.

Should you have any questions, please contact Dario Camacho of my Committee staff at (202) 224-4515. Thank you for your attention on this important matter.

Sincerely,



Charles E. Grassley
Chairman
Senate Committee on Finance

October 30, 2019

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and
Governmental Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Interagency Suspension and Debarment Committee (ISDC) reports to Congress annually on the status of the Federal suspension and debarment system, pursuant to Section 873 of Public Law 110-417.[1] As required by Section 873, this report describes Governmentwide progress in improving the suspension and debarment process and provides a summary of each agency's suspension and debarment activities for Fiscal Year (FY) 2018. This is the ISDC's tenth year of reporting.

The ISDC's mission is to help agencies build and maintain the expertise necessary to manage effective suspension and debarment programs. Suspension and debarment are remedies designed to protect the Government's business interests from potential harm posed by individuals or entities whose conduct indicates either serious poor performance or a lack of business honesty or integrity. Agencies consider suspension and debarment action against both business entities and individuals.[2]

Agencies exclude individuals who engage in serious past misconduct and fail to demonstrate an appropriately altered attitude as to business honesty, integrity, and performance. This ensures that this individual does not pose a current risk to the Government and cannot serve as an agent or representative of another entity in Government transactions or create a new entity to evade award ineligibility. This approach helps to reduce business risk to taxpayer funds or interests in accordance with the purpose of suspension and debarment: to protect the Government; not to punish wrongdoers. The suspension and debarment remedy gives agencies an array of tools (including alternate resolution through administrative agreement), which allow business entities and individuals to demonstrate that, past problematic conduct notwithstanding, a present risk does not exist.

[1] The ISDC is an interagency body created by Executive Order 12549, consisting chiefly of representatives from Executive-branch organizations that work together to provide support for suspension and debarment programs throughout the Government. The 24 agencies covered by the Chief Financial Officers Act (CFO Act) are standing members of the ISDC. Over 18 additional independent Federal agencies and corporations participate in the ISDC. Together, ISDC member agencies are responsible for virtually all Federal procurement and discretionary assistance, loan, and benefit (non-procurement) transactions. For additional general background on the ISDC, see its homepage at https://www.acquisition.gov/isdc-home.

[2] Suspension and debarment of individuals may be appropriate whether that misconduct is committed on behalf of a business, or for the individual's interest. A significant portion of those who are subject to a debarment action generally are convicted. Individuals are routinely, and appropriately, subject to actions because the only way a business entity engages in misconduct is through the individuals who act on the business's behalf.

Strategic Objectives and Activities

The ISDC's work focuses around four strategic objectives:

- promoting the fundamental fairness of the suspension and debarment process;
- increasing transparency and consistency through training, engagement, and outreach;
- enhancing Federal suspension and debarment practices, and alternatives to them, by developing resources available to the ISDC community; and
- encouraging the development of more effective compliance and ethics programs by Government contractors and nonprocurement participants to address business risks.

To further these objectives, the ISDC pursued the following activities in FY 2018:

- Provided member program training with a particular emphasis on current legal developments affecting suspension and debarment programs and identifying best practices to promote programmatic integrity, greater procedural consistency, transparency, and fairness in suspension and debarment programs across the Federal Government.
- Strengthened understanding and awareness of suspension and debarment activities within the Federal acquisition and financial assistance communities by --
    - inviting stakeholders to make presentations at monthly ISDC meetings on perceived remedy process issues and evaluation of corporate compliance programs; and
    - ensuring continuation of the ISDC's public website to promote transparency.
- Improved the effectiveness of ISDC operations by:
    - formalizing new subcommittees to address specific needs within the ISDC and within the Government as a whole, including a subcommittee for tracking and reporting to the membership on cybersecurity contractor compliance issues and developments;
    - collaborating with the Council of the Inspectors General on Integrity and Efficiency and the Federal Law Enforcement Training Center to provide additional training opportunities;
    - advancing its proposal to modernize and streamline the lead agency coordination process in collaboration with the Office of Management and Budget through development of an internal, online lead agency coordination portal; and
    - disseminating regular updates on items of interest to the ISDC community, such as relevant case law and regulatory and legislative developments.

Outreach

The ISDC engaged in outreach with public and private sector stakeholders to discuss ISDC initiatives and exchange ideas and perspectives from members of the broader suspension and debarment community including, but not limited to, the Government Accountability Office and various external stakeholders.

Improving Consistency Between Procurement and Nonprocurement Suspension and Debarment Procedures

The ISDC continued to explore the development of a consistent set of procedures for both procurement and nonprocurement suspensions and debarments, including the use of pre-notice tools in the FAR and enhancing the discussion of decision factors at FAR 9.406-1(a) by adopting the mitigating and aggravating circumstances at 2 C.F.R. § 180.860. The Committee believes the use of consistent practices between the procurement and nonprocurement communities may help to reduce procedural inconsistency and is considering the benefits and drawbacks of utilizing the nonprocurement approach.

Based on input from 29 agencies (*see* Appendices 2 and 6), 20 agencies, or approximately 69% of Federal agencies, use both procurement and nonprocurement debarment regulations. Eight agencies, or approximately 29% of Federal agencies, use only the procurement debarment regulation. The ISDC is exploring with the FAR Council how to bring the procurement and nonprocurement suspension and debarment processes into closer procedural alignment.

Fiscal Year Metrics

Suspensions and debarments fluctuate from year to year as such actions are considered and used when necessary to protect the Government's business interests. To that end, the ISDC's efforts have continued to focus on refining the suspension and debarment process and promoting Governmentwide agencies' awareness, understanding, and effective implementation of the remedial tool.[3] Overall, agencies reported receipt of 2,444 total referrals with 114 declinations in FY 2018. Agencies also reported issuing 480 suspensions, 1,542 proposed debarments, and 1,334 debarments. As set forth in Appendix 4, the total number of suspensions, proposed debarments, and debarments in FY 2018 represents nearly double the activity level reported in FY 2009,[4] when the ISDC formally commenced data tracking and at a time when

[3] The ISDC is responsible for the discretionary procurement and nonprocurement suspension and debarment system governed, respectively, by the Federal Acquisition Regulation (FAR) at 48 C.F.R. Subpart 9.4 and the Nonprocurement Common Rule (NCR) at 2 C.F.R. Part 180. Accordingly, data collected for this report reflects activity levels related only to use of the discretionary Governmentwide suspension and debarment remedy. However, the System for Award Management (SAM) also includes additional types of exclusions distinct in scope and/or extent of application. In addition to those business risk-focused exclusions with Governmentwide reciprocal effect imposed under Subpart 9.4 and Part 180, there are also narrower prohibitions and restrictions including those mandated by, or as an automatic collateral consequence of, violations of various statutes and/or regulatory compliance regimes, agency-specific prohibitions and restrictions, voluntary exclusions, etc.

[4] In FY 2009, agencies reported 417 suspensions, 750 proposed debarments, and 669 debarments. FY 2009 represents the baseline and the first year ISDC tracked such information Governmentwide. Please note that the number of debarments originally reported in FY 2009 was subsequently corrected to conform with current reporting and counting criteria.

some Agency suspension and debarment programs either did not exist or were still developing. Compared to FY 2009 results, agencies reported greater reliance on the administrative remedies identified below as alternatives to immediate and/or continued imposition of suspension and debarment during FY 2018.[5]

Proactive engagements by entities and individuals: As a result of ISDC outreach efforts, individuals and entities continued to reach out to Suspending and Debarring Officials (SDOs) proactively to provide information relating to their present responsibility, particularly, when a company has identified possible misconduct within its operations. This activity makes possible even earlier consideration of present responsibility factors by agency SDOs; it allows both sides to focus on corrective measures taken by the company to address the misconduct, along with efforts by the company to improve internal controls, enhance compliance programs, and to promote a culture of ethics. For those agencies that track such information, eight (8) member-agencies reported 40 instances of proactive engagement initiated by potential respondents during FY 2018.[6]

Agency Pre-notice Letters: Pre-notice letters, which include show cause letters, requests for information, and similar types of letters, are used to inform an individual or entity that the agency debarment program is reviewing matters for potential SDO action, identify the assertion of misconduct, and give the recipient an opportunity to respond prior to formal SDO action.[7] Use of these letters helps agencies better assess the risk to Government programs and determine what measures are necessary to protect the Government's interest without immediately imposing an exclusion action. For FY 2018, agencies reported issuing 197 pre-notice letters to potential respondents, approximately tripling the total of 70 first reported in FY 2009. (*See* Appendix 5.) The number of agencies reporting the use of such letters also more than doubled, increasing from seven in FY 2009 to 16 in FY 2018.

Administrative Agreements: Administrative agreements are used as an alternative to suspension and debarment and typically mandate the implementation of several provisions to improve the ethical culture and corporate governance processes of a respondent, often with the use of independent third-party monitors. Agreements may be entered with any respondent, whether an individual or an organization with appropriate provisions, where such resolution is in the best business interest of the Government. The viability of an administrative agreement as the appropriate outcome of a matter will always be case-specific to the circumstances of the action. This tool can be effective in situations where award eligibility would further the Government's interests such as, for example, in increasing competition for procurement opportunities. Administrative agreements provide that certain verifiable actions are taken in a prescribed timeframe, such as implementation of enhanced internal corporate governance practices and procedures and/or use of independent third-party monitors.

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[5] See Appendixes 4 and 5.

[6] The number of proactive engagements is based on voluntary agency submissions as the information is not readily available from all agencies and is not currently a standard reporting element.

[7] Show cause letters issued by SDOs under FAR 9.4 and 2 C.F.R. Part 180 are distinct from and unrelated to the show cause letters issued by contracting officers.

Agreement terms are tailored to the nature of the issues giving rise to the action agency's concerns. The ISDC also understands that, as to appropriate provisions, "one size does not fit all." Terms of an agreement for an individual or a small business may look very different from those appropriate to a large organization. Agreements may arise at different points in the process: either out of proactive pre-notice engagement or in resolution of an issued action notice.

Fourteen (14) agencies reported entering into 61 administrative agreements in FY 2018. In contrast, in FY 2009, only 35 administrative agreements were utilized by five agencies to resolve suspension or debarment concerns. Of the 14 agencies entering into administrative agreements in FY 2018, six reported entering into agreements with individuals to resolve suspension or debarment concerns. Where appropriate as a resolution of Government debarment concerns, the administrative agreement tool, while ensuring protection for the Government, can provide a resolution beneficial to all parties.

Additional data regarding the FY 2018 actions is available in the enclosed appendices. Among these is a chart displaying the results of all ten ISDC reporting years to date. The ISDC looks forward to its continued work with agencies to better protect taxpayer programs and operations from fraud, waste, and abuse through effective suspension and debarment programs.

Sincerely,

/s/

David M. Sims, Chair
ISDC

/s/

Lori Y. Vassar, Vice Chair
ISDC

/s/

Monica Aquino-Thieman, Vice Chair
ISDC

Enclosures

Identical Letter Sent to:
The Honorable Ron Johnson
The Honorable Gary C. Peters
The Honorable Carolyn B. Maloney
The Honorable Jim Jordan

Appendix 1
Glossary and Counting Conventions

For consistency and clarity, the ISDC used the following in preparing the Appendices to this report.

Glossary

"Administrative agreement" - also known as an administrative compliance agreement, refers to a document that is ordinarily negotiated after the recipient has responded to a notice of suspension or proposed debarment. The election to enter into an administrative agreement is solely within the discretion of the SDO and will only be used if the administrative agreement appropriately furthers the Government's interest. Agreements may potentially be entered into with any respondent, whether an individual person or organization where it is appropriate to do so. While administrative agreements vary according to the SDO's concerns regarding each respondent, these agreements typically mandate the implementation of several provisions to improve the ethical culture and corporate governance processes of a respondent in a suspension or debarment proceeding. Agreements may also call for the use of independent third-party monitors or the removal of individuals associated with a violation from positions of responsibility within a company. Administrative agreements are made publicly available online in the Federal Awardee Performance and Integrity Information System (FAPIIS).

"Declination" - a SDO's determination after receiving a referral that issuing a suspension or debarment notice is inappropriate. Placing a referral on hold in anticipation of additional evidence for future action is not a declination.
"Referral" - a written request prepared in accordance with agency procedures and guidelines, supported by documentary evidence, presented to the SDO for issuance of a notice of suspension or notice of proposed debarment as appropriate under FAR Subpart 9.4 and 2 C.F.R. Part 180.

Note: This definition is designed to eliminate potential variations due to differences in agency tracking practices and organizational structures. For example, agency programs organized as fraud remedies divisions (responsible for the coordination of the full spectrum of fraud remedies: criminal, civil, contractual and administrative) may not have a common starting point for tracking case referrals as agency programs exclusively performing suspension and debarment functions.

"Agency Pre-notice Letters"- includes show cause letters, requests for information and similar types of letters used to inform the recipient that the agency debarment program is reviewing matters for potential SDO action, identify the assertion of misconduct, and give the recipient an opportunity to respond prior to formal SDO action. This is a discretionary tool employed where appropriate to the circumstances of the matter under consideration.

"Voluntary Exclusion" - a term expressly used only under 2 C.F.R. Part 180 referring to the authority for an agency to enter into a voluntary exclusion with a respondent in lieu of suspension or debarment. A voluntary exclusion, like a debarment, carries the same Government-wide reciprocal effect and bars the respondent from participating in procurement and non-procurement transactions with the Government. Agencies must enter all voluntary exclusions in the General Services Administration's System for Award Management (SAM).

Counting Conventions

Consistent with previous years' Section 873 reports, the number of suspensions, proposed debarments, and debarment actions are broken out as separate exclusion actions even if they relate to the same respondents. With each of these exclusion actions, both FAR Subpart 9.4 and 2 C.F.R. Part 180 require an analysis performed by program personnel involving separate procedural and evidentiary considerations. Furthermore, a suspension may resolve without proceeding to a notice of proposed debarment, a notice of proposed debarment may commence without a prior suspension action, and a proposed debarment may resolve without an agency SDO necessarily imposing a debarment. Moreover, separate "referrals" are typically generated for suspensions and proposed debarments. Finally, suspension and debarment actions trigger separate notice and other due process requirements by the agency.

Agencies were instructed to count individuals as one action regardless of the number of associated pseudonyms and AKAs ("also known as"). Businesses operating under different names or that have multiple DBAs ("doing business as") are counted separately as separate business entities or units for counting suspensions debarments.

The data in the appendices focus on the suspension and debarment activities of the 24 agencies and departments subject to the CFO Act. These are the agencies and departments with the highest activity levels in procurement and non-procurement awards.

The report addresses the discretionary suspension and debarment actions taken under the Governmentwide regulations at FAR Subpart 9.4 and 2 C.F.R. Part 180. The Report does not track statutory or other nondiscretionary debarments outside of the scope of these regulations.

Appendix 2
Suspension and Debarment Actions in FY 2018

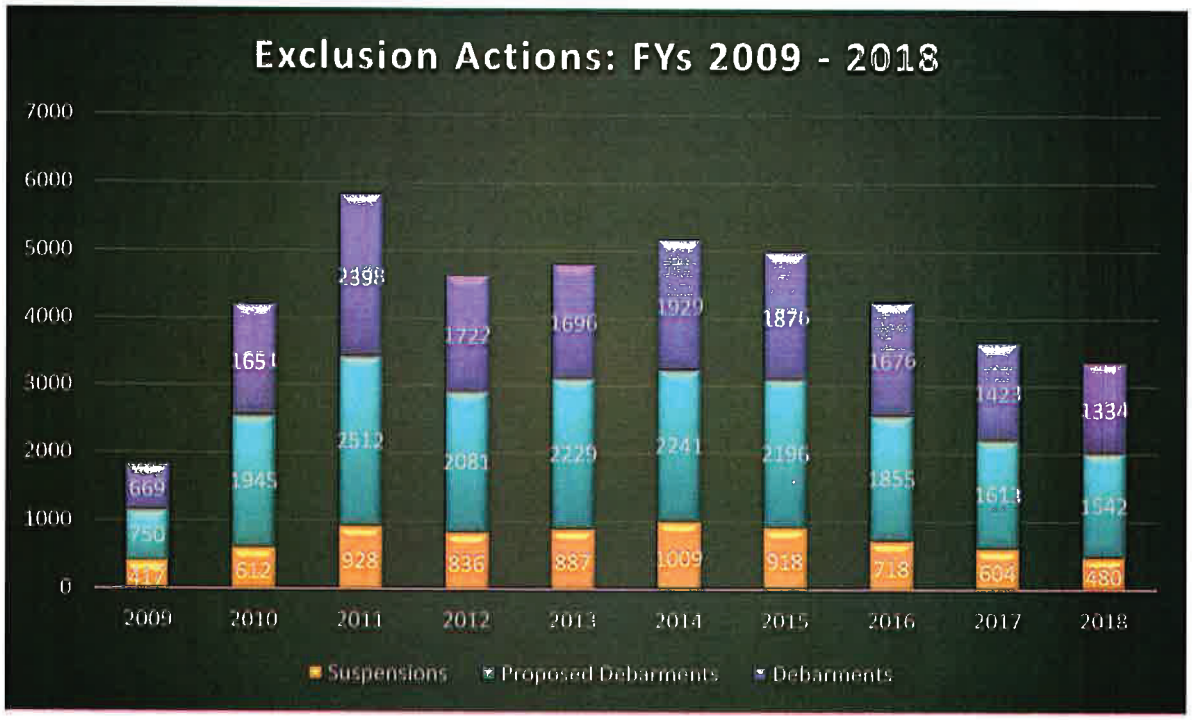
Agency/Department	Suspensions	Proposed Debarments	Debarments*
Agency for International Development	1	43	32
Department of Agriculture	11	59	43
Department of Commerce	0	6	1
Department of Defense			
(U.S. Air Force)	19	60	67
(U.S. Army)	32	197	174
(Defense Logistics Agency)	6	111	46
(U.S. Navy)	64	166	149
Department of Education	6	11	9
Department of Energy	25	25	25
Department of Health and Human Services	13	40	24
Department of Homeland Security	16	177	129
Department of Housing and Urban Development	74	201	218
Department of the Interior	1	23	22
Department of Justice	5	6	7
Department of Labor	21	5	15
Department of State	9	27	39
Department of Transportation	67	72	64
Department of the Treasury	2	4	4
Department of Veterans Affairs	8	16	2
Environmental Protection Agency	34	75	112
Export-Import Bank	13	13	8
General Services Administration	20	134	96
National Aeronautics and Space Administration	3	7	4
National Nuclear Security Administration	0	5	5
National Science Foundation	9	10	8
Nuclear Regulatory Commission	0	0	0
Office of Personnel Management	0	4	2
Small Business Administration	21	45	29
Social Security Administration	0	0	0
Total Actions	**480**	**1542**	**1334**

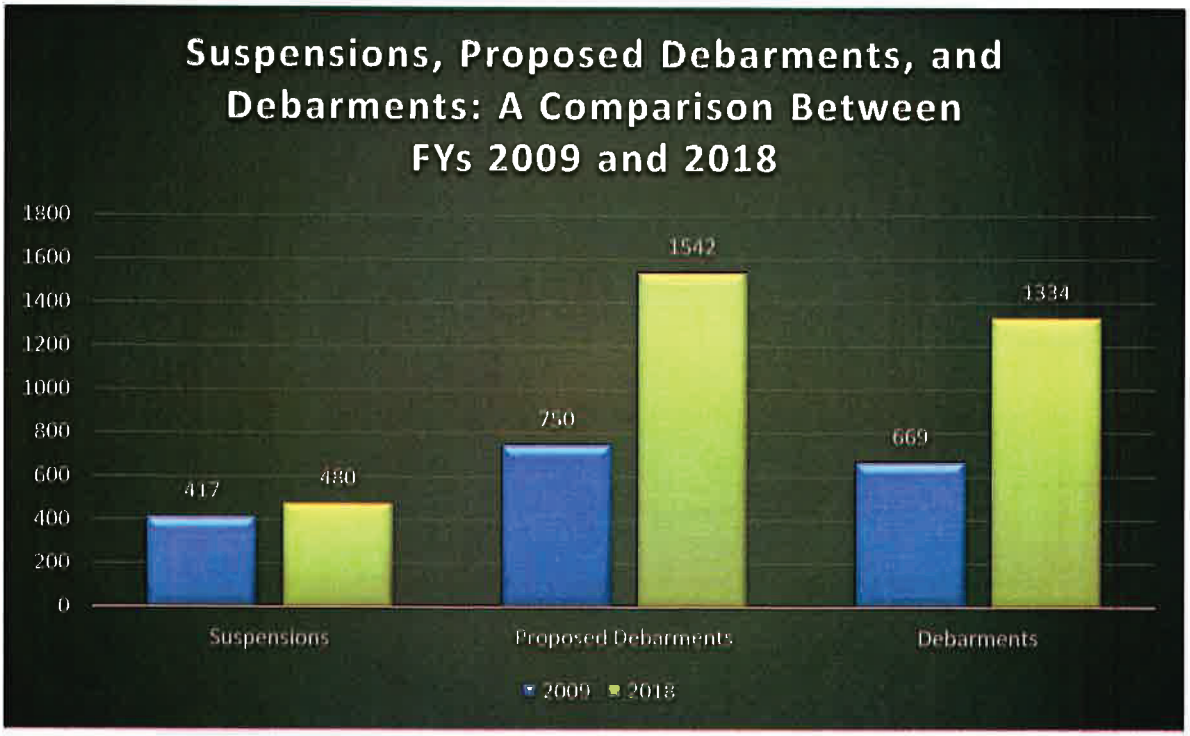
*The number of debarments does not include voluntary exclusion actions, which are reported in Appendix 3. As noted in the text above, voluntary exclusions appear only under 2 C.F.R. Part 180, but have the same Governmentwide reciprocal effect as a debarment and are entered in SAM.

Appendix 3
Other Actions Related to Suspension and Debarment in FY 2018

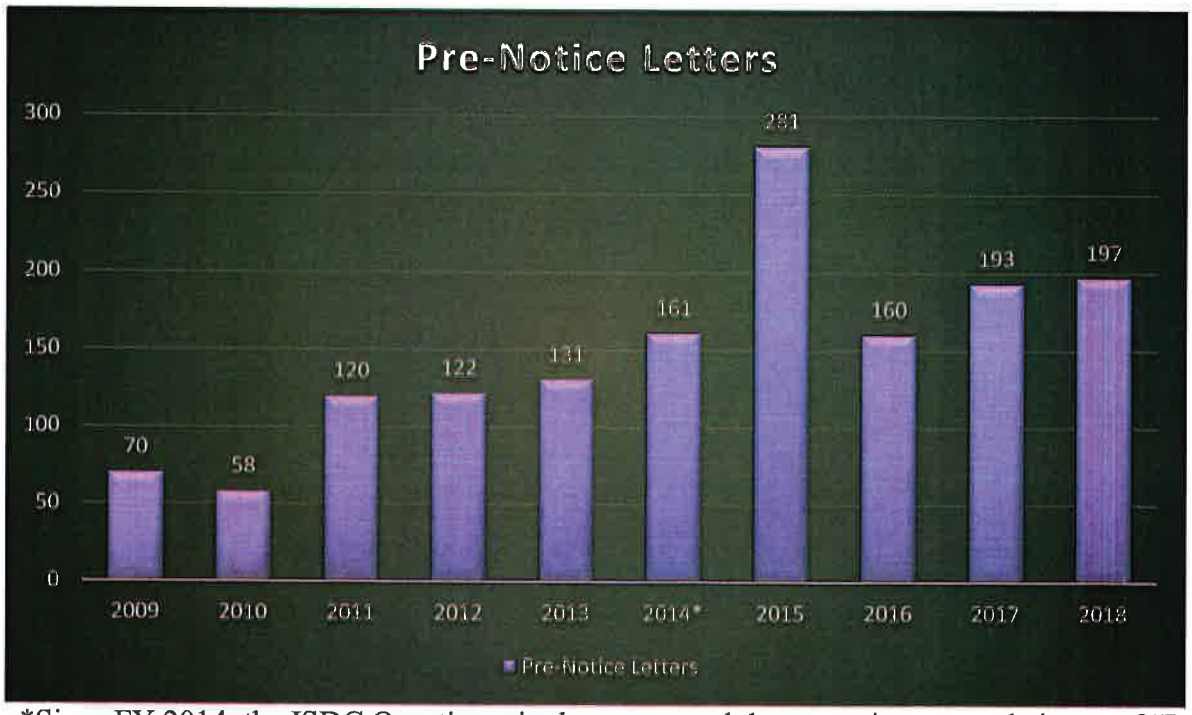
Agency/Department	Show Cause Notices	Referrals	Declinations	Administrative Agreements	Voluntary Exclusions
Agency for International Development	3	43	0	0	0
Department of Agriculture	3	70	27	0	0
Department of Commerce	0	6	0	0	0
Department of Defense					
(U.S. Air Force)	6	79	0	2	0
(U.S. Army)	17	410	7	3	0
(Defense Logistics Agency)	1	31	1	1	0
(U.S. Navy)	32	398	0	4	0
Department of Education	0	21	0	0	0
Department of Energy	0	10	1	0	0
Department of Health and Human Services	0	23	0	0	4
Department of Homeland Security	41	215	0	1	0
Department of Housing and Urban Development	0	154	0	5	0
Department of the Interior	0	24	0	1	0
Department of Justice	1	15	0	3	0
Department of Labor	0	43	2	0	0
Department of State	0	36	0	0	0
Department of Transportation	5	170	22	14	3
Department of the Treasury	0	0	4	0	0
Department of Veterans Affairs	1	24	0	3	0
Environmental Protection Agency	17	140	41	10	6
Export-Import Bank	1	17	9	0	0
General Services Administration	39	392	0	5	0
National Aeronautics and Space Administration	5	10	0	2	0
National Nuclear Security Administration	0	7	0	0	0
National Science Foundation	0	19	0	0	0
Nuclear Regulatory Commission	0	0	0	0	0
Office of Personnel Management	0	0	0	0	0
Small Business Administration	9	84	0	7	0
Social Security Administration	16	0	0	0	0
Total Actions	**197**	**2441**	**114**	**61**	**13**

Appendix 4
Governmentwide Suspensions, Proposed Debarments, & Debarments

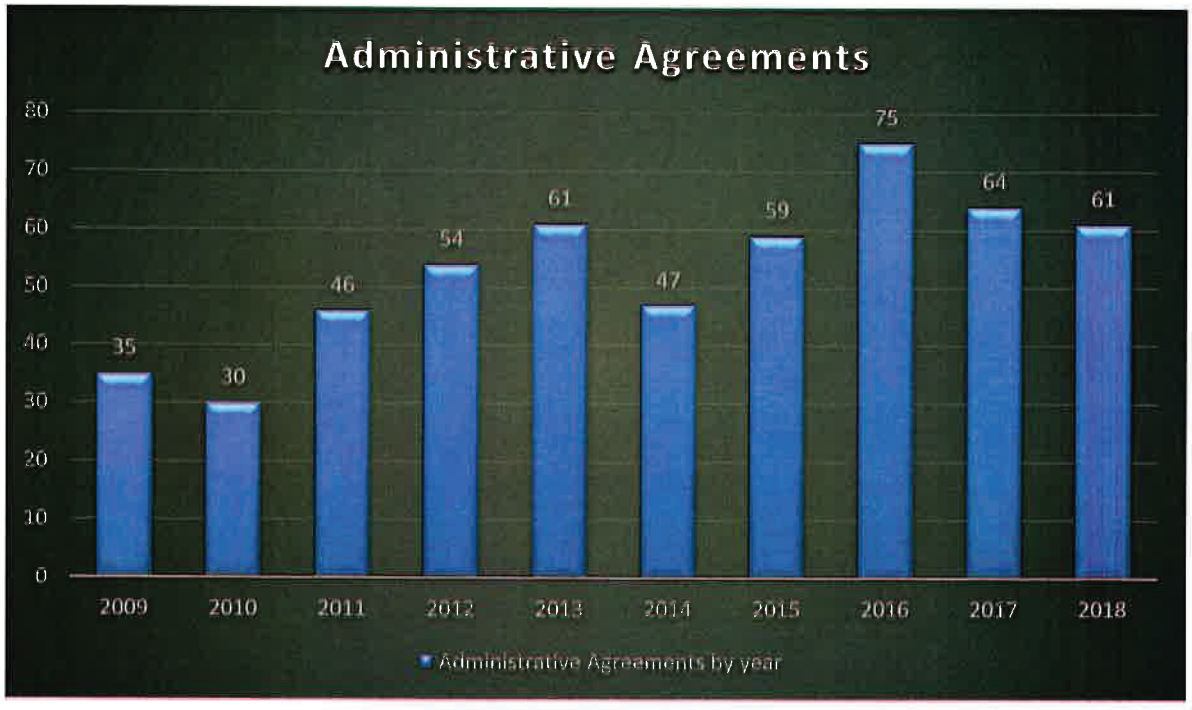




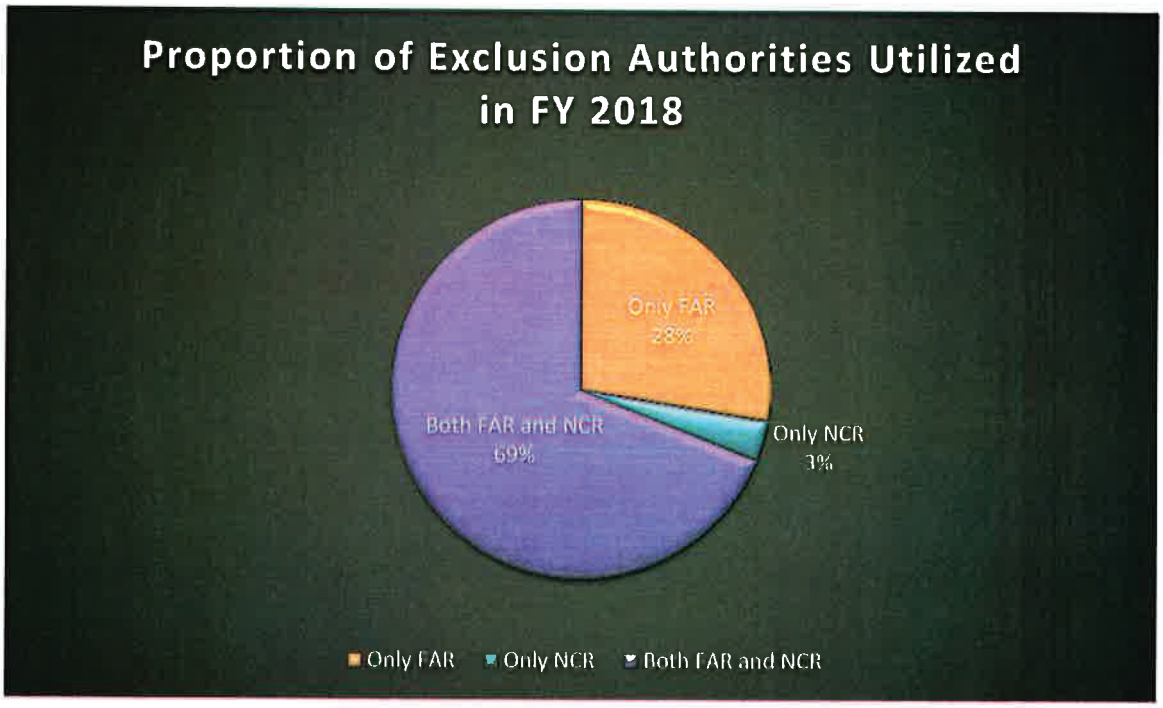
Appendix 5
Agency Pre-Notice Letters and Administrative Agreements During FYs 2009 - 2018

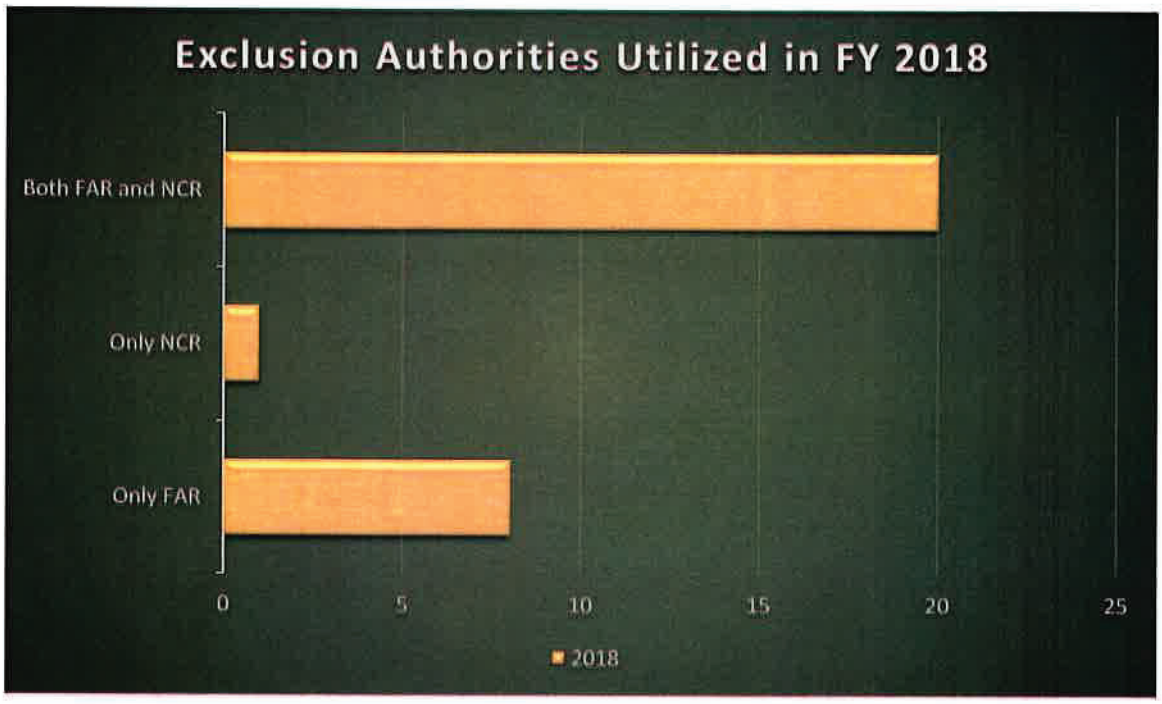


*Since FY 2014, the ISDC Questionnaire has requested that agencies report their use of "Pre-Notice Letters" defined as letter requests for information including, but not limited to, show cause letters. Prior to FY 2014, the ISDC Questionnaire asked about only show cause letters.

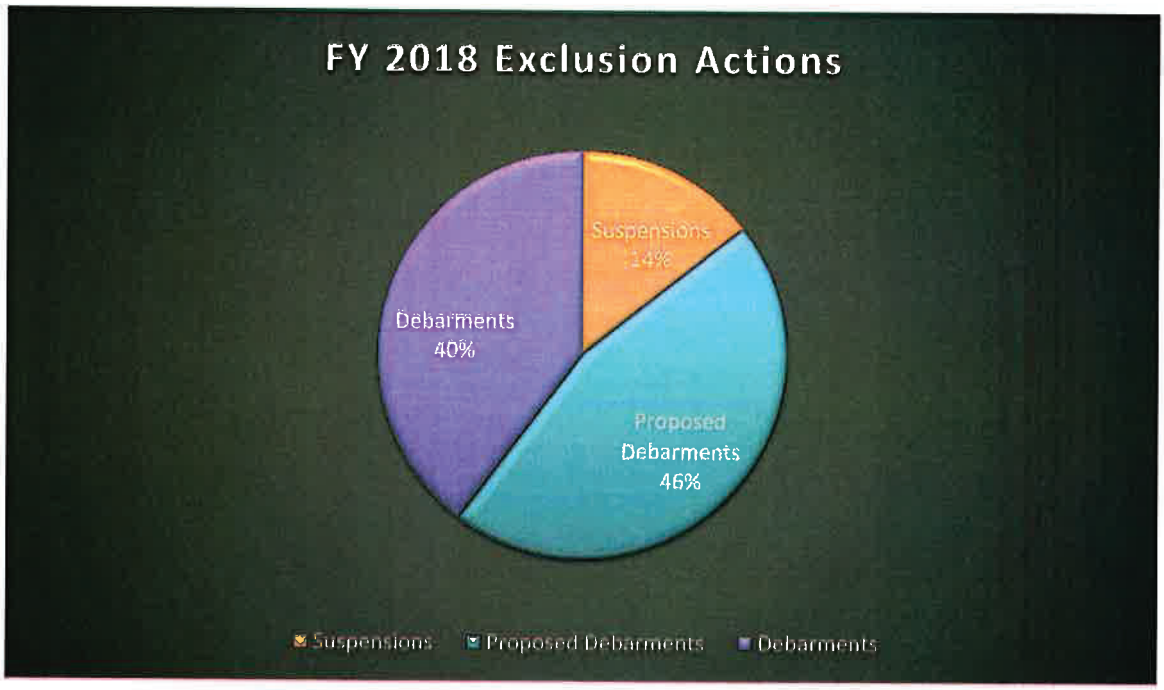


Appendix 6
Use of Agency Exclusion Authority by FAR, NCR, or Both





Appendix 7
Agency Exclusion Actions by Type



U.S. DEPARTMENT OF LABOR

News Release

U.S. DEPARTMENT OF LABOR ANNOUNCES NEW PILOT PROGRAM FOR DISCRETIONARY SUSPENSIONS AND DEBARMENTS TO ENSURE ACCOUNTABILITY

WASHINGTON, DC - Today, the U.S. Department of Labor announced a new pilot program for discretionary suspensions and debarments to ensure accountability and protect the federal government from doing business with those who engage in inappropriate or illegal conduct.

Discretionary suspensions and debarments make individuals or organizations ineligible for federal contracting and transactions with the federal government typically for up to 12 months for a suspension and up to three years for a debarment.

The pilot program's goal is to reduce the processing time on discretionary suspension and debarment actions from months to days through increased efficiency and sharing of information based on indictments or convictions. The pilot program involves the Department's Office of Inspector General (OIG) including additional information in its referrals to the Office of the Assistant Secretary for Administration and Management (OASAM) that will allow decisions to be made faster than ever before.

This pilot program builds on recent steps taken by the Department to enhance its discretionary suspension and debarment efforts in the last few years, including increased coordination and collaboration with the OIG. Under these efforts, discretionary suspensions increased from a total of two during the seven years of Fiscal Year (FY) 2010 through FY2016 to 29 during FY2017-FY2018. Discretionary debarments spiked from one during FY2010-FY2016 to 32 during FY2017-FY2018. In FY2018, the OIG referred a record number of 156 individuals and organizations to

OASAM for review. In just the first quarter of FY2019, the Department has issued 32 discretionary suspensions and five discretionary debarments. The pilot program preserves the due process and fairness protections for the entities involved.

“Launching this pilot program will help to protect resources from fraud, waste, and abuse - faster than ever before,” said U.S. Secretary of Labor Alexander Acosta. “Taxpayer resources will be better protected by streamlining the process and improving the use of information from indictments and convictions that result from the work of the Office of Inspector General. Given the Department of Labor’s commitment and duty to be a good steward of taxpayer resources, this pilot program is a clear reminder that the Department requires those conducting business with the federal government to be responsible and act with honesty and integrity.”

The pilot program will be in effect from April 2019 to April 2020.

The pilot program does not affect mandatory suspensions and debarments that are set by law and result in an automatic removal from being able to participate in transactions.

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