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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

THE DAN ABRAMS COMPANY LLC, Relator, Plaintiff-Appellant, and UNITED STATES OF AMERICA, ex rel.; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VIRGINIA;	No. 19-56377 D.C. No. 2:15-cv-01212-JAK-AS MEMORANDUM*

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

STATE OF WASHINGTON; STATE OF WISCONSIN,

Plaintiffs,

v.

MEDTRONIC INC.; MEDTRONIC PLC; MEDTRONIC SOFAMOR DANEK USA, INC.; WARSAW ORTHOPEDIC, INC.; MEDTRONIC SOFAMOR DANEK DEGGENDORF GMBH; MEDTRONIC PUERTO RICO OPERATIONS CO.; HUMACAO,

Defendants-Appellees.

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

Argued and Submitted February 10, 2021
Pasadena, California

Before: TALLMAN, CALLAHAN, and LEE, Circuit Judges.

The Dan Abrams Company LLC (Relator) appeals the dismissal of its False Claims Act (FCA) lawsuit. 31 U.S.C. §§ 3729-3733. Relator alleges that Medtronic Inc. and various related entities fraudulently obtained Food and Drug Administration clearance for several devices used in spinal fusion surgeries (Subject Devices), unlawfully marketed them for an off-label and contraindicated use, and illegally compensated physicians to use them. According to Relator, these fraudulent and unlawful practices caused physicians to submit false claims to Medicare. We affirm

in part and reverse in part.

The False Claims Act makes liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "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). The essential elements of an FCA claim are "(1) a false statement or fraudulent course of conduct, (2) made with the [requisite] scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)).

1. Off-label/contraindicated-use theory: Relator alleges that Medtronic marketed the Subject Devices without FDA approval or clearance for use in the cervical spine—an "off-label" and indeed contraindicated use. Relator thus alleges that Medtronic engaged in misbranding, mislabeling, and adulterating in violation of the Food, Drug, and Cosmetics Act (FDCA).

The fundamental problem with this theory is that Relator incorrectly assumes that the federal government will not reimburse for an off-label use of a medical device. To the contrary, the federal government has recognized that doctors may use medical devices for off-label purposes as long as it is medically necessary and reasonable. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350

(2001) ("'[O]ff label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); U.S. Dep't of Health & Hum. Serv. (HHS), *Medicare Benefit Policy Manual*, ch. 14 § 10, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf (noting that Medicare reimburses for "[*d*]*evices* cleared by the FDA through the 510(k) process"—not cleared *uses* of a device) (emphasis added).

Thus, the federal government does not distinguish between on-label and off-label uses in determining whether to pay for medical devices. Rather, to be reimbursable, a device must (1) have FDA approval/clearance, (2) be "reasonable and necessary," *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 997, 1002 (9th Cir. 2012), and (3) meet any other pertinent regulations, HHS, *Medicare Benefit Policy Manual*, ch. 14 § 10. Relator's argument must thus be considered through the prism of these three requirements.

First, the FDA cleared the Subject Devices through the 510(k) process (though, as discussed later, Relator claims Medtronic defrauded FDA in the clearance process).

Second, the Relator has not plausibly alleged that the Subject Devices are not "reasonable and necessary." This court has cited Centers for Medicare & Medicaid

(CMS) guidance in explaining that "a device is not 'reasonable and necessary' — and thus is not eligible for Medicare coverage—if it is (a) "not 'safe' and 'effective," (b) "experimental," (c) "not appropriate for the individual beneficiary's needs," or (d) "substantially more costly than a medically appropriate and realistically feasible alternative pattern of care." *Int'l Rehab. Sci., Inc.*, 688 F.3d at 997 (cleaned up). CMS guidance makes clear that safety and efficacy determinations are based on "authoritative evidence" or "general[] accept[ance] in the medical community." *Id*.

Relator makes no allegations about published studies demonstrating that cervical use of vertebral body replacement (VBR) is medically unsafe or ineffective. Nor does Relator allege that VBR use in the cervical spine is contrary to accepted standards of medical practice. Instead, Relator points to a few anecdotal examples of harm caused by the Subject Devices. The problem is that *any* surgery carries the potential risk of harm. Merely showing that harm *can* occur is insufficient. Relator also argues that the Subject Devices were not reasonable and necessary because cheaper and equally effective options existed. Yet, as the district court correctly observed, Relator does not connect any "alleged false statements and the pricing criterion of Medicare coverage."

Relator argues that this is not a case of merely off-label use, but contraindicated use of the Subject Devices. But neither the federal government nor the judiciary appears to carve out an exception for contraindicated use in discussing

off-label uses. Indeed, the FDCA specifically contemplates that devices may be cleared even if contraindicated uses are expected: if the FDA suspects that a potential Class II device may be used for contraindicated purposes, the FDA "may require a statement" on the product's label disclosing that use. 21 U.S.C. §360c(i)(1)(E)(i). As long as a doctor finds an off-label use to be medically reasonable and necessary, then the off-label use is permitted, even if the particular use is contraindicated on the label.

Third, Relator points to no statute, regulation, or administrative manual that specifically states that a contraindicated use of a device is categorically not reasonable and necessary.

Relator cites this court's *Campie* decision for the proposition that "misbranded and adulterated devices are not eligible for Medicare reimbursement." But in *Campie*, one of the relator's claims was that the drug was "misbranded" or "adulterated" because the drug company had substituted an unapproved ingredient for an approved ingredient. 862 F.3d at 902. In contrast here, Relator alleges that the Subject Devices were misbranded because they were sold for a contraindicated purpose. But the federal government acknowledges that doctors may use medical devices for off-label and even contraindicated uses if they believe that such use is medically necessary and reasonable. So contraindicated use of the Subject Devices is not material to the government's decision to pay.

We thus affirm the district court's dismissal of Relator's claim based on off-label/contraindicated labels.

2. Fraud-on-the-FDA theory: Relator also alleges that Medtronic defrauded the FDA into granting the Subject Devices Class II clearance. According to this theory, since Medicare reimbursement requires FDA clearance, the Subject Devices would have been ineligible for reimbursement but for Medtronic's fraud.

Relator appears to divide the Subject Devices into two distinct groups. The first group of Subject Devices consists of those that allegedly cannot be used for their labeled intended use and can *only* be used for their contraindicated use in the cervical spine. For these "Contraindicated-only Devices,"[1] Relator alleges that Medtronic falsely represented in its clearance application that they were intended for use in the thoracolumbar spine (the part of the spine below the neck) when in fact they could *not* be used there and could *only* be used in the cervical (neck-area) of the spine.

The second group of Subject Devices—"Extra-use Devices"[2]—includes those that *could be* used for their stated intended use (i.e., use in the thoracolumbar spine) but which were contraindicated for use in the cervical spine. Relator alleges that

[1] This label was not used by the parties but is included here for the sake of clarity.

[2] Again, this is not a term that the parties use and is included here only for the sake of clarity.

Medtronic secretly intended to sell these Extra-use Devices for their contraindicated use.

The district court dismissed Relator's fraud-on-the-FDA theory for failure to state a claim, finding that its allegations were offered "solely as a predicate for the claim that the Subject Devices were intended for off-label use."

The district court is correct that the materiality element cannot be met for the Extra-use Devices because the federal government allows reimbursement for off-label and even contraindicated uses. Put another way, Medtronic's alleged omission about its intent to market the devices for a contraindicated use was immaterial to the FDA's clearance for Extra-use Devices.

But the Contraindicated-only Devices present a different story. For those devices, Relator does not allege mere off-label use. Rather, Relator alleges that the Contraindicated-only Devices were not properly cleared for any use: they cannot be used for their labeled intended use (and are thus not substantially similar to the predicate device), and they can *only* be used for their contraindicated use. Relator claims that Medtronic knew that cervical VBRs posed different questions of safety to its previously approved devices, and if Medtronic disclosed that the devices were intended for use in the cervical spine, then the FDA may have required Class III approval. These considerations—intended use, similarity to a predicate device, and different questions about safety—are precisely those that the FDA considers in

granting Class II certification. 21 U.S.C. § 360c(i)(1)(A). Put differently, Medtronic's alleged fraud went "to the very essence of the bargain." *United Health Serv., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 n.5 (2016) (cleaned up).

Medtronic argues that the FCA is not the proper vehicle to bring a fraud-on-the-FDA claim. In *Buckman*, the Supreme Court held that the FDCA bars a private party from asserting state law claims that the device manufacturer defrauded the FDA during the 510(k)-clearance process concerning a device's intended use. 531 U.S. at 348. And the First Circuit has extended *Buckman*'s holding to the FCA context. *United States ex rel. D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7-9 (1st Cir. 2016). Medtronic invites us to follow suit. But this court's decision in *Campie* forecloses that path. In *Campie*, we noted that other jurisdictions had "cautioned against allowing claims under the False Claims Act to wade into the FDA's regulatory regime." 862 F.3d. at 905 (citing, amongst others, *D'Agostino*, 845 F.3d at 9). Yet we nevertheless allowed the relator's fraud-on-the-FDA theory to go forward. *Id.* at 905-06.

We thus affirm the district court for claims based on the Extra-use Devices, but we reverse for claims based on Contraindicated-only Devices.

3. Anti-Kickback Statute (AKS): The AKS prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . to any person to induce such

person . . . to purchase . . . [any] item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B).

Relator first alleges that Medtronic entered into improper rebate agreements with hospitals to buy the Subject Devices. But the AKS exempts from its scope discounts offered to providers if properly disclosed to and reflected in charges to the federal program. 42 U.S.C. § 1320a-7b(b)(3)(A). Similarly, Medicaid allows rebate agreements so long as the state Medicaid programs are offered the same pricing. 42 U.S.C. § 1396r-8(a)(1). Relator does not explain how Medtronic's rebate agreement violated the AKS. Therefore, in relation to the rebate agreements, Relator fails to state a claim.

Relator next alleges that Medtronic remunerated physicians by paying the costs, including food, travel, and promotional expenses, in connection with certain business development events. But as the district court observed, these "general allegations do not identify any physicians, or categories of them, who actually received payment in connection with decisions — in which they participated — to purchase or use of any of the Subject Devices." We thus affirm the district court's dismissal of Relator's AKS claim.

AFFIRMED IN PART; REVERSED IN PART. Each party shall bear its own costs.