UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 22-CV-60160-RAR

UNITED STATES OF AMERICA,
ex rel. PATRICIA CROCANO,

Plaintiff-Relator

v.

TRIVIDIA HEALTH INC.,

Defendant.

UNITED STATES' STATEMENT OF INTEREST AS TO DEFENDANT'S MOTION TO DISMISS

The United States of America, as the real party in interest in this False Claims Act (FCA) action, submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain legal arguments in Defendant's Motion to Dismiss Relator's Amended Complaint (ECF No. 95). Because the relator has asserted claims on behalf of the United States for harms purportedly suffered by the government, the United States remains the real party in interest in this matter even where, as here, it has declined to intervene in the action. 31 U.S.C. § 3730(d); *United States ex rel. Timson v. Samson*, 518 F.3d 870, 873 (11th Cir. 2008) (citing United *States ex rel. Walker v. R&F Properties of Lack County, Inc.*, 433 F.3d 1349,1359 (11th Cir. 2005)). In addition, because the FCA, 31 U.S.C. §§ 3729-3733, is the United States' primary civil tool for prosecuting fraud against the government, the United States has a substantial interest in the development of the law in this area and in the correct application of that law in this, and similar, cases. Accordingly, the United States respectfully seeks to clarify its position on certain legal arguments in Defendant's Motion to Dismiss (MTD).

I. CONDUCT GIVING RISE TO A REGULATORY VIOLATION CAN ALSO GIVE RISE TO FCA LIABILITY

Defendant argues, in part, that Relator's claims must be dismissed because they are based on alleged Food Drug and Cosmetic Act (FDCA) violations that cannot serve as a basis for FCA liability. Without passing on the merits of relator's factual allegations here, the United States respectfully submits that deficiencies in the affected product resulting from FDCA violations may, in certain circumstances, be material to the government's decision whether to pay for the affected product, and thus relevant in an FCA case.

One of the "core objectives" of the FDCA, 21 U.S.C. § 301 *et seq.*, is to ensure that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000). Violations of the FDCA may be relevant in FCA cases where the violations are significant, substantial, and give rise to actual discrepancies in the composition, functioning, safety, or efficacy of the affected product. This may occur, for example, in situations where, as a result of the regulatory violations, the affected product's quality, safety and efficacy fell below what was specified to and cleared by the Food and Drug Administration (FDA) through its approval processes. *See* 21 U.S.C. §§ 351(b), 351(c), 351(e), 360d, 360k. In some cases, manufacturing deficiencies could affect the quality, safety, and efficacy of the affected products such that the FDA never would have approved or cleared the affected products—or allowed them to remain on the market—if it had known the truth, and claims involving those devices never would have been eligible for federal healthcare program reimbursement. For example, when a medical device manufacturer obtains FDA approval or clearance for a device and "then palm[s] off a defective version of that device both directly on the government itself and on the unsuspecting government payors," the manufacturer may be liable under the FCA if the elements of the FCA are sufficiently met. *See*

United States ex rel. Wallace v. Exactech, Inc., No. 2:18-CV-01010-LSC, 2020 WL 4500493, at *12 (N.D. Ala. Aug 5, 2020) (citing *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37 (1st Cir. 2017).

The FCA creates liability for one who "knowingly presents, *or causes to be presented*, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A) (emphasis added), as well as one who "knowingly makes, uses, *or causes to be made or used*, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B) (emphasis added). A false statement is "material" if it has a natural tendency to influence, or is capable of influencing, the government's payment decision. *See id.* § 3729(b)(4). A false statement that "is integral to a causal chain leading to payment" may prompt FCA liability, even where that statement is not included in the actual claim for government funds. *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (concluding that where such a "causal chain" exists, "it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork").

The statutory text makes clear that the defendant need not be the entity that actually submits the "false or fraudulent" claim. Rather, the False Claims Act "indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943). A claim can therefore be "false or fraudulent" for purposes of the FCA if it is submitted under a "contract or extension of government benefit [that] was originally obtained through false statements or fraudulent conduct." *United States ex rel. Hendow v. University of Phx.*, 461 F.3d 1166, 1173 (9th Cir. 2006). Under this theory, "subsequent claims are false because of an *original fraud*,"

even if the subsequent claim for payment is not false on its face and makes no false certification. *Id.*; *see also In re Baycol Prods. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013) ("[A] claim alleging fraud in the inducement of a government contract . . . focus[es] on the false or fraudulent statements which induced the government to enter into the contract at the outset."); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (explaining that there may be instances in which claims for payment are "not in and of themselves false," but FCA liability attaches "because of the fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder").

Consistent with the decisional law cited above, it is possible to articulate a viable FCA claim based on materially false or fraudulent statements made to the FDA regarding drugs or medical devices for which the government provides payment or reimbursement. In deciding whether to pay for a drug or device, federal healthcare programs often rely on the FDA's decision as to whether the drug or device is sufficiently safe and effective to be sold in the United States. The FDA is responsible for evaluating the safety and efficacy of drugs and devices. In assessing the safety and efficacy of a drug or device, the FDA relies on the information provided by the manufacturer, and therefore the manufacturer's compliance with its reporting obligations, including reporting of adverse events. Among other things, device manufacturers are required to investigate adverse events and report information to the FDA within 30 days of becoming aware of information that the marketed device "[h]as malfunctioned…and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. §§ 803.50(1) and (2). In general, FDA approval or clearance of a drug or medical device is required for Medicare coverage. *See International Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012) (explaining that FDA approval

or clearance "is *necessary*, but not *sufficient*, for Medicare coverage."); CMS, *Medicare Benefit Policy Manual*, ch. 14, § 10 (listing categories of medical devices that may be covered by Medicare). Moreover, the Secretary of the Department of Health & Human Services retains broad discretion to assess the safety and effectiveness of both the drug or device and the overall procedure in determining whether a service is "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Whereas "FDA review seeks to determine whether a device is 'safe and effective' such that it can be marketed to the general public," Medicare is charged with determining "whether the device is 'reasonable and necessary' for treatment such that the device is worth the government's money." *International Rehab. Scis.*, 688 F. 3d at 1002.; *see also* 42 U.S.C. § 1395y(a)(1)(A) (prohibiting Medicare reimbursement for "items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury"). When a manufacturer perpetrates a fraud on the FDA by hiding material information concerning the safety or efficacy of a device – either during or after the approval process or to avoid a recall – and federal healthcare programs then pay for that device, that fraud may be "integral to a causal chain leading to payment" and can be actionable under the FCA. *Univ. of Phoenix*, 461 F.3d at 1174 (quoting *Oakland City Univ.*, 426 F.3d at 916).

In circumstances in which the defendant's false statements or material omissions masked problems that, for example, would have prompted the FDA to institute or require a product recall, subsequent claims relating to the affected devices could be rendered "false or fraudulent" because the government would not have paid the claims for those affected devices but for the defendant's conduct. *See Univ. of Phoenix*, 461 F.3d at 1173 (recognizing FCA liability where "subsequent claims are false because of an original fraud") (emphasis omitted). Further, in some situations, manufacturing deficiencies violating the FDCA or FDA regulations could materially

affect the safety, efficacy, or performance of a device such that the product is essentially "worthless" and not eligible for payment by the government. Submitting claims (or causing claims to be submitted) to federal healthcare programs for products or services that are so deficient as to be essentially worthless may give rise to FCA liability. *See*, *e.g.*, *Chesbrough v. VPA,P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (stating that a test known to be of "no medical value," that is billed to the government would constitute a claim for "worthless services"); *Mikes v. Straus*, 274F.3d 687, 703 (2d Cir. 2001) ("In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."); *United States ex rel. Lee v. Smithkline Beecham, Inc.,* 245 F. 3d 1048, 1053 (9th Cir. 2001) ("In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under §3729, regardless of any false certification conduct."); *In re Genesis Health Care Ventures, Inc.,* 112 F. App'x 140, 143 (3d Cir.2001) ("Case law in the area of 'worthless services' under the FCA addresses instances in which either services are literally not provided or the service is so substandard as to be tantamount to no service at all."). That these manufacturing deficiencies might separately violate FDA regulations does not preclude FCA liability arising from the claims for payment submitted for the affected products.

The United States takes no position on whether the relator's complaint provides sufficient detail under Rule 9(b) to state a claim. However the Court rules on the present motion, the United States requests that the ruling not foreclose the possibility that, under certain circumstances, conduct giving rise to violations of the FDCA or FDA regulations could be material to the government's payment decisions and provide a basis for FCA liability assuming all necessary FCA elements are demonstrated.

II. ANY DISMISSAL SHOULD BE WITHOUT PREJUDICE TO THE UNITED STATES.

The FCA explicitly provides that the public disclosure bar does not apply to claims brought by the United States. 31 U.S.C. § 3730(e)(4). Thus, if a relator's complaint is dismissed on these grounds, the dismissal could not preclude the United States from bringing or continuing with an action involving the same or similar claims.

Pursuant to the FCA, a relator files his or her complaint on behalf of the United States, and once the United States has notified the Court that it declines to intervene, the relator is free to pursue the action. 31U.S.C. § 3730. Because the United States has no part in preparing a relator's complaint, it should not be prejudiced if a relator has failed to plead the allegations sufficiently. Such a dismissal does not constitute a ruling on the merits of the defendant's conduct, and does not mean that a better informed relator or the United States could not make out a viable claim in the future. Moreover, a broadly drafted *qui tam* complaint, if dismissed with prejudice as to the United States, could improperly be argued by a defendant to have the preclusive effect of preventing future actions by the United States for conduct that the United States did not investigate and did not know was part of the relator's action. Such a result would not be in accord with the FCA's *qui tam* provisions – which are designed to assist the United States in pursuing fraud, not to hinder it – and should not be the result of a dismissal of a relator's improperly pleaded complaint.

Accordingly, the United States respectfully submits that any dismissal of Relators' complaint in this case should be without prejudice to the United States.

Respectfully submitted,

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Dated: June 3, 2022 By: /s/ *Yolonda Y. Campbell*

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