
**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT**

JEFFREY D'AGOSTINO,

Plaintiff-Appellant,

STATE OF CALIFORNIA; STATE OF CONNECTICUT; DISTRICT OF
COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF
HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF
LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF
MASSACHUSETTS; STATE OF MICHIGAN; 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; COMMONWEALTH OF VIRGINIA;
STATE OF WISCONSIN; JOHN DOE; UNITED STATES; STATE OF
DELAWARE; STATE OF MINNESOTA,

Plaintiffs,

v.

EV3, INC.; JOHN HARDIN; MICROTHERAPEUTICS, INC.; BRETT WALL,

Defendants-Appellees,

JOHN CUBELIC; VITAS J. SIPELIS,

Defendants.

On Appeal from the United States for the District of Massachusetts

**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE
SUPPORTING NEITHER PARTY**

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INTEREST OF THE UNITED STATES

The False Claims Act, 31 U.S.C. § 3729 *et seq.* (FCA), is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA. The United States submits this amicus brief pursuant to Fed. R. App. P. 29(a) to provide this Court with the government's views as to the proper interpretation and application of the FCA.

The district court concluded that relator failed to state a claim under the FCA because the allegations implicate decisions made by the Food and Drug Administration (FDA) and because alternative administrative remedies are available. This erroneous reasoning, if adopted, would categorically foreclose claims that involve federal agency oversight of a defendant's conduct. The United States submits this amicus brief to address the district court's reasoning and to clarify, in particular, that "fraud in the inducement" is a potentially viable theory of FCA liability. The government takes no position on whether relator's allegations actually state a claim for relief or whether dismissal was warranted on any other basis.

STATEMENT OF THE ISSUE

Whether federal agency oversight of a defendant's conduct forecloses liability under the False Claims Act, including for claims alleging "fraud in the inducement."

STATEMENT OF THE CASE

A. Statutory Background

1. The False Claims Act

The False Claims Act is “the Government’s primary litigative tool” for combatting fraud, and was intended “to reach all fraudulent attempts to cause the Government to pay out sums of money.” S. Rep. No. 99-345, at 2, 9 (1986). Congress therefore drafted the statute “expansively . . . to reach all types of fraud, without qualification, that might result in financial loss to the Government.” *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003).

An FCA violation occurs when a person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A). A violation also occurs when a person “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).

The FCA authorizes suits to collect statutory damages and penalties either by the Attorney General or by a private person (known as a *qui tam* relator) in the name of the United States. 31 U.S.C. § 3730(a), (b)(1); *see also Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769-78 (2000). If a relator files a *qui tam* action, the government may intervene and take over the case “within 60 days after it receives both the complaint and the material evidence and information,” 31 U.S.C. § 3730(b)(2), or “at a later date upon a showing of good cause,” *id.* § 3730(c)(3). If the

government declines to intervene, the relator conducts the litigation. *Id.* Monetary proceeds from a *qui tam* suit are divided between the government and the relator. *Id.* § 3730(d).

2. FDA Regulation of Medical Devices

One of the “core objectives” of the Federal Food, Drug, and Cosmetic Act (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). FDA categorizes medical devices into one of three classes according to the risk posed by the devices: Classes I, II, and III. 21 U.S.C. § 360c(a)(1). Class III devices, which involve the greatest risk, must be approved by FDA through the pre-market approval process before they can be sold in the United States. *Id.* § 360c(a)(1)(C). Class I and II devices must be cleared by FDA through the premarket notification process under section 510(k) of the FDCA, unless they qualify for an exemption. *See id.* § 360(k). FDA also has authority to withdraw approval of, or recall, medical devices. *See id.* §§ 360e(e)(1), 360h(e).

3. Medicare Payment and Reimbursement Decisions

The Medicare program is established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, to pay for medical care for the elderly and disabled. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS). Medicare Part A reimburses treating facilities (such as hospitals) for inpatient

treatment, *see id.* §§ 1395c through 1395i-5, while Medicare Part B reimburses health care providers (such as doctors) for outpatient treatment, *see id.* §§ 1395j through 1395w-6.

Under the Medicare program, “no payment may be made under part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 U.S.C. § 1395y(a)(1)(A). If CMS determines that a medical device is not covered because it is “not ‘reasonable’ and ‘necessary,’” then “Medicare payment is not made for medical and hospital services that are related to the use of [the] device,” regardless of whether the device has been approved or cleared by FDA. 42 C.F.R. § 405.207(a). In general, FDA approval or clearance “is *necessary*, but not *sufficient*, for Medicare coverage.” *International Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012); *see also* CMS, *Medicare Benefit Policy Manual*, ch. 14, § 10 (listing categories of medical devices that may be covered by Medicare).¹

B. Factual Background²

Relator is a former sales representative for defendant ev3, Inc. (ev3), a medical device manufacturer. Addendum (“Add.”) 7-8; Appendix (“App.”) 149-50. Relator alleges that ev3 and other defendants caused false claims to be submitted to federal

¹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf>.

² Since the case was resolved on a motion to dismiss, we accept as true the allegations of the proposed Fourth Amended Complaint for purposes of this appeal.

health care programs as a result of their marketing of two medical devices: the Onyx embolization system (Onyx) and Axium coils (Axium). Add. 7; App. 144, 147. Onyx and Axium are embolization devices approved or cleared by FDA for the treatment of certain vascular conditions. Add. 8, 15; App. 144.

Relator asserts numerous claims, which generally fall within two categories. *First*, relator's primary theory, known as "fraud in the inducement," alleges that defendants made a series of misrepresentations to FDA concerning Onyx and Axium. For example, relator claims that defendants misled FDA by proposing an overly narrow indication for Onyx, while concealing their robust marketing strategy for unapproved uses. Add. 8-13; App. 155-66, 171-205, 212. Because defendants' fraud allegedly induced FDA to approve Onyx, relator asserts that reimbursement claims for procedures involving Onyx for unapproved uses were fraudulent. Add. 14-15, 39; App. 210-18. Relator also alleges that defendants failed to submit accurate adverse event reports for Onyx and Axium, and that FDA would have recalled the devices or restricted their use if FDA had known the truth. Add. 18-19; App. 245-48.

Second, relator makes claims that are not expressly premised on FDA's decision to approve or clear a device, or to allow a device to stay on the market. Relator alleges that Axium devices on the market were defective and improperly manufactured. Add. 15-18, 39; App. 223-42. Relator further alleges that defendants' conduct caused physicians to perform procedures using Axium, and that such procedures were not "reasonable and necessary for the diagnosis or treatment of

illness or injury,” and thus not reimbursable by Medicare. App. 242 (quoting 42 C.F.R. § 405.207).

C. Prior Proceedings

This is the second appeal in this case, which dates back to relator’s original under-seal filing in 2010. *United States ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 190 (1st Cir. 2015). Relator amended the complaint several times, and defendants filed a motion to dismiss the Third Amended Complaint. *Id.* at 190-91. Although the United States did not intervene in the case, *id.* at 190, the government filed a statement of interest in response to defendants’ motion. Dkt. No. 105.

The first appeal arose when relator—instead of responding to defendants’ motion to dismiss the Third Amended Complaint—filed another amended complaint without requesting leave of the court. *D’Agostino*, 802 F.3d at 191. The district court denied leave to amend, granted defendants’ motion to strike, and dismissed the case with prejudice. *Id.* On appeal, this Court vacated and remanded because the district court applied the wrong legal standard when it denied leave to amend. *Id.* at 194-95. On remand, relator filed a motion for leave to file a Fourth Amended Complaint, which defendants opposed. Dkt. Nos. 128, 131-133. Applying the standard directed by this Court, the district court again denied leave and dismissed the case with prejudice. Add. 44.

The district court’s renewed order of dismissal is the subject of the present appeal. The district court held that amendment would be futile for several reasons.

As to two theories, the district court held that the public disclosure bar applies. Add. 23-25. The remaining theories include relator's "fraud-in-the-inducement" claims based on marketing for an unapproved use and failing to accurately report adverse events, as well as relator's defective-device claims. Add. 25-39. As to these remaining theories, the district court held that amendment would be futile for two independent reasons: (1) the allegations were not sufficiently specific as required by Rule 9(b), *see* Add. 26-38, and (2) the allegations failed to state a claim under Rule 12(b)(6), *see* Add. 38-41.

The district court's Rule 12(b)(6) ruling is the focus of this brief. The district court broadly rejected relator's "fraud-in-the-inducement" and defective-device theories. In the district court's view, relator's claims ask the court to "usurp the FDA's prerogative" and to "reevaluate years of FDA decisions concerning the approval or recall" of the devices. Add. 39. The court explained that "[t]he FCA . . . is not a substitute for the certiorari review of discretionary decisions taken by the FDA," and that "an FCA action is not the appropriate vehicle for this court to exercise its judgment in second-guessing decisions taken by the FDA." Add. 40-41. The court further suggested that the availability of alternative legal and administrative remedies warn against recognizing an FCA action. Add. 40 ("There are . . . well-established legal, regulatory, and administrative mechanisms for managing the risks and benefits of the device . . ."); Add. 40-41 (describing the FDA's "significant

administrative sanction and enforcement powers” and its ability to refer cases for criminal prosecution).

SUMMARY OF ARGUMENT

In concluding that relator failed to state a claim for relief, the district court held that FCA liability is improper because relator’s claims implicate decisions made by FDA and because alternative administrative remedies are available. That reasoning is erroneous and, if adopted, would seriously impair FCA enforcement in any case involving conduct subject to federal agency oversight. FCA cases routinely implicate decisions within the authority and expertise of an agency. Moreover, the availability of alternative legal and administrative remedies does not foreclose FCA liability; rather, “Congress intended to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud.” *United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410, 415 (8th Cir. 2012). If this Court reaches the Rule 12(b)(6) issue, it should correct the district court’s erroneous reasoning, which it invoked to dismiss relator’s claims based on both the “fraud-in-the-inducement” theory and the defective-device theory.

Although the district court rejected both theories of liability, its reasoning appears to target the “fraud-in-the-inducement” theory, which necessarily asks whether FDA would have made a different decision absent the fraud. There is no reason to categorically foreclose the “fraud-in-the-inducement” theory in cases involving fraud on FDA. In appropriate circumstances, it is possible to state a claim

for FCA liability when a defendant uses deceit to gain or maintain FDA approval or clearance of a medical device, resulting in subsequent reimbursement or payment by the government.

The United States takes no position on whether relator has stated a claim for relief under any theory of liability for purposes of Rule 12(b)(6), and it similarly takes no position on whether relator's allegations satisfy the pleading requirements of Rule 9(b).

ARGUMENT

FEDERAL AGENCY OVERSIGHT OF A DEFENDANT'S CONDUCT DOES NOT PREVENT CLAIMS FOR "FRAUD IN THE INDUCEMENT," NOR DOES IT FORECLOSE FALSE CLAIMS ACT LIABILITY MORE GENERALLY

The district court held that relator failed to state a claim under Rule 12(b)(6) because the allegations involve matters subject to FDA oversight. Under the court's flawed reasoning, FCA actions are barred if they implicate "discretionary decisions taken by the FDA in the area of competence delegated to it by Congress." Add. 40. This reasoning is incorrect, and it would have far-reaching implications if adopted by this Court; it would substantially undermine FCA enforcement by foreclosing virtually all FCA claims involving conduct that falls within an agency's regulatory authority. Indeed, the district court appears to have applied this reasoning to reject relator's defective-device theory of liability, a straightforward theory of liability that does not directly implicate FDA decisions.

The district court’s statements directly target relator’s claims for “fraud in the inducement,” which assert that claims relating to Onyx and Axium were “false or fraudulent” because defendants used deceit to obtain or maintain FDA approval or clearance of those devices. Add. 39. Relator alleges that FDA never would have approved or cleared the medical devices—or allowed them to remain on the market—if it had known the truth, and therefore claims involving those devices never would have been eligible for reimbursement. App. 210-18, 245-48. In the district court’s view, this theory improperly asks “[the] court to exercise its judgment in second-guessing decisions taken by the FDA in approving the use of medical devices.” Add. 41. Contrary to the district court’s reasoning, it is possible to state a claim for FCA liability when a defendant uses deceit to gain or maintain FDA approval or clearance of a medical device, resulting in subsequent reimbursement or payment by the government.

The United States takes no position on whether relator’s allegations state a claim for relief under the FCA, or on the district court’s dismissal of claims under the public disclosure bar and Rule 9(b). If this Court reaches the Rule 12(b)(6) issue, however, it should reject the district court’s erroneous reasoning regarding the impact of federal agency oversight on FCA liability.

A. FEDERAL AGENCY OVERSIGHT OF A MATTER DOES NOT FORECLOSE FCA LIABILITY

In the district court’s view, allowing FCA liability in this case would infringe on FDA’s regulatory authority and interfere with FDA’s “significant administrative sanction and enforcement powers.” Add. 39-41. This reasoning is erroneous, and it would foreclose FCA claims in virtually any case involving conduct subject to agency oversight. This Court should clarify that the FCA permits actions that implicate decisions within the authority and expertise of an agency, as well as claims involving conduct for which alternative administrative remedies may be available.

1. FCA Liability May Be Premised On Claims That Implicate Agency Decisions

The district court reasoned that relator failed to state a claim because the case implicates “discretionary decisions taken by the FDA in the area of competence delegated to it by Congress.” Add. 40. This Court should reject the district court’s rationale, because the authority and expertise of an agency to make decisions is not a categorical bar to FCA liability. If accepted, this reasoning would impact a wide variety of agency decisions and significantly undermine FCA enforcement.

The district court invoked this flawed reasoning to reject relator’s “fraud-in-the-inducement” and defective-device theories, but it did not explain how the reasoning applies to each theory. Relator’s “fraud-in-the-inducement” theory, which is discussed further below, alleges that FDA would not have approved or cleared the devices, or would not have allowed them to stay on the market, if it had known the

truth. This theory thus considers the impact of the fraud on FDA's regulatory decisions. Relator's defective-device theory does not allege that FDA would have made a different regulatory decision absent the fraud, but simply alleges that CMS would not have allowed reimbursement for procedures involving defective devices if it had known of the defect. *See* App. 242 (alleging that Axium was defective and that CMS would not have allowed reimbursement if it had known of the defect, because surgeries involving Axium would not have been "reasonable and necessary" for the treatment of illness or injury) (quoting 42 C.F.R. § 405.207).³ This theory thus implicates CMS's decision to pay a claim.

The district court's reasoning is erroneous and would have far-reaching implications. The authority and expertise of an agency to make decisions is not a

³ In support of their motion to dismiss the defective-device theory, defendants argued that because Medicare reimburses for services as a whole, rather than for the medical device itself, there can be no FCA liability unless the service was rendered worthless. Dkt. No. 131, at 15-16. But "bureaucratic [payment] mechanism[s]," including "the fact that the . . . claims [seek] payment for services rather than devices," do not insulate a defendant from FCA liability. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 394-95 (1st Cir. 2011) (holding that kickbacks relating to medical devices may be material to Medicare's decision to pay for a procedure). Indeed, fraud relating to a medical device may affect payment for related services; Medicare regulations expressly provide that "Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not 'reasonable' and 'necessary.'" 42 C.F.R. § 405.207(a). Moreover, the Secretary retains broad discretion to assess the safety and effectiveness of both the device and the overall procedure in determining whether a service is "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Defendants are thus incorrect to suggest that reimbursement may be withheld only if the procedure is wholly without any value. *See* Dkt. No. 131, at 15-16.

categorical bar to FCA liability. Fraud can influence a wide range of agency decisions, and there is nothing improper about a fact-finder in an FCA case hearing evidence about whether an agency would have acted differently had it known the truth. Indeed, courts routinely consider the impact of fraud on agency decisions. *See United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 307 (1st Cir. 2010) (concluding that a statement is material if it “had a natural tendency to influence or was capable of influencing the [agency’s] decision”). If accepted, the district court’s broad reasoning could foreclose FCA liability in countless cases involving agency decisions, including the decision to pay a claim. Moreover, liability would be foreclosed even when the government intervenes in a *qui tam* suit or files a complaint alleging that it was misled and that it would have made a different decision had it known the truth. The district court’s reasoning would dramatically undermine FCA enforcement. The United States takes no position on whether relator properly stated a claim under any theory of liability, but argues that the district court’s reasoning should be rejected.

2. Alternative Administrative Remedies Do Not Bar FCA Liability

The court’s suggestion that FCA liability is not appropriate when there are alternative legal and administrative remedies is also mistaken. *See* Add. 40 (“There are . . . well-established legal, regulatory, and administrative mechanisms for managing the risks and benefits of the device”); Add. 40-41 (describing FDA’s “significant administrative sanction and enforcement powers” and its ability to refer cases for

criminal prosecution). The text of the FCA provides no exemption from liability simply because there may be a parallel, agency-specific mechanism for uncovering or addressing fraud. *See* 31 U.S.C. § 3729(a)(1) (imposing liability on “any person” who commits various forms of fraudulent activity). Indeed, the existence of certain narrow exceptions to FCA liability confirms that Congress knows how to limit FCA liability when it so desires, and that Congress did not intend the broad exception suggested by the district court. For example, Congress created an “[e]xclusion” for “claims, records, or statements made under the Internal Revenue Code of 1986,” *id.* § 3729(d), and barred actions by relators “based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party,” *id.* § 3730(e)(3). As this Court has explained, “when Congress has provided limited exceptions within the same statute, courts will not read in additional exceptions.” *United States v. Roberson*, 752 F.3d 517, 523 (1st Cir. 2014). Creating a broad exception for actions in which an alternative agency remedy exists would conflict with the plain text of the statute and dramatically undermine FCA enforcement. *See Commissioner v. Clark*, 489 U.S. 726, 739-40 (1989) (“In construing [statutory] provisions . . . in which a general statement of policy is qualified by an exception, we usually read the exception narrowly in order to preserve the primary operation of the provision.”); *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (highlighting the broad reach of the FCA).

The Eighth Circuit has correctly concluded that alternative administrative remedies do not preclude FCA liability. *United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410 (8th Cir. 2012). In *Onnen*, the district court granted summary judgment for defendants, ruling that FCA liability was precluded by a comprehensive scheme of administrative remedies and sanctions governing defendants' conduct. *Id.* at 412-15. The Eighth Circuit reversed, explaining that "a complex regime of regulatory sanctions" does not foreclose FCA liability. *Id.* at 415. The court "agree[d] with the government that 'Congress intended to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud.'" *Id.*

Moreover, allowing "a variety of remedies," *Onnen*, 688 F.3d at 415, is particularly appropriate when the remedies serve different functions. As the Ninth Circuit has explained, "FDA review and Medicare coverage review have different purposes." *See International Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012). 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." *Id.*; *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 determining Medicare coverage, FDA approval or clearance "is *necessary*, but not

sufficient.” *International Rehab. Scis.*, 688 F.3d at 1002; *see also* 42 C.F.R. § 405.201(a)(1) (“CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions.”). While the district court identified various remedies available to FDA to regulate drugs and devices in the marketplace, these remedies do not supplant the FCA’s role in addressing the impact of fraud on Medicare coverage decisions and the payment of government funds. The district court thus erred in dismissing relator’s “fraud-in-the-inducement” and defective-device claims simply because alternative legal and administrative remedies may be available.

B. “FRAUD IN THE INDUCEMENT” IN CONNECTION WITH FDA-REGULATED MEDICAL DEVICES MAY RESULT IN FCA LIABILITY

The district court’s broad reasoning targeted relator’s claims for “fraud-in-the-inducement,” foreclosing this theory at the motion-to-dismiss stage.⁴ Relator’s theory asserts that claims relating to Onyx and Axium are “false or fraudulent” because defendants used deceit to obtain or maintain FDA approval or clearance of those devices, making them eligible for reimbursement. In the district court’s view, this theory improperly asks “[the] court to exercise its judgment in second-guessing decisions taken by the FDA in approving the use of medical devices.” Add. 41. As discussed above, the district court’s reasoning is erroneous. Moreover, there is no

⁴ As discussed above, the district court also dismissed relator’s defective-device theory, which is a straightforward theory of FCA liability. Because the district court’s reasoning appears to target the “fraud-in-the-inducement” claims, however, the government provides an extended discussion of this theory.

reason to categorically bar the “fraud-in-the-inducement” theory as a matter of law. While the United States takes no position on whether relator has stated a claim under this theory with sufficient particularity for purposes of Rule 9(b), it is important to clarify that, in appropriate circumstances, it is possible to state a claim for FCA liability when a defendant uses deceit to gain or maintain FDA approval or clearance of a medical device, resulting in subsequent reimbursement or payment by the government.

1. 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). 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). As this Court has explained, “the ‘causes’ clauses” of the FCA mean that “unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party.” *Hutcherson*, 647 F.3d at 390.

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). This theory, known as the “fraud-in-the-inducement” theory, provides that “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 in “fraud-in-the-inducement” cases, the 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”).

This theory is consistent with Congress’s intention “to reach all types of fraud, without qualification, that might result in financial loss to the Government.” *Neifert-White*, 390 U.S. at 232. The FCA’s legislative history explains, for example, that “each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct . . . constitutes a false claim.” S. Rep. No. 99-345, at 9. Similarly, “claims

may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program” providing payment. *Id.*

2. Consistent with this theory, it is possible to articulate a viable FCA claim based on materially false or fraudulent statements made to FDA regarding medical devices for which the government provides payment or reimbursement. In general, FDA approval or clearance of a medical device is required for Medicare coverage. *See International Rehab. Scis.*, 688 F.3d at 1002; CMS, *Medicare Benefit Policy Manual*, ch. 14, § 10.⁵ Accordingly, FCA liability is possible if a manufacturer’s false statements to FDA about a medical device actually caused FDA to approve or clear the device, or to allow the device to stay on the market, such that FDA would have made a different decision had it known the truth. Stated differently, there is potential for liability if a defendant’s fraud actually induced FDA to approve or clear a device, or to allow the device to stay on the market, rendering it eligible for subsequent reimbursement or payment by the government. *See Hendow*, 461 F.3d at 1173 (recognizing FCA liability where “subsequent claims are false because of an original fraud”) (emphasis omitted).

As a general matter, merely demonstrating lack of compliance with FDA procedures, or with the Federal Food, Drug, and Cosmetic Act, is insufficient to establish FCA liability. But in the (likely rare) circumstances in which the defendant’s

⁵ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf>.

false statements masked problems that are so serious that FDA would have (for example) withheld or withdrawn its approval of the medical device had it known the truth, subsequent claims relating to that device could be rendered “false or fraudulent” because the government would not have paid the claims but for the defendant’s fraud.⁶

The United States does not contend that a claim is necessarily “fraudulent” simply because some antecedent fraud was a “but for” cause of the claim being submitted. Rather, at some point the causal chain can become so attenuated that the subsequent claim for payment no longer retains the “taint,” *Hess*, 317 U.S. at 543, of the defendant’s initial fraud. *Accord Hendon*, 461 F.3d at 1174 (discussing situations where the false statement is “integral to a causal chain leading to payment”); *cf. Paroline v. United States*, 134 S. Ct. 1710, 1720 (2014) (explaining that “[p]roximate cause is a standard aspect of causation in . . . the law of torts”). The necessary connection between the fraud and the later claim would certainly exist, however, when the effect of the fraud on FDA—enabling the defendant’s device to qualify or remain qualified for (among other things) government payment—was a natural, foreseeable, and intended reason for the defendant’s conduct.

⁶ There may also be other circumstances in which a defendant’s fraud causes FDA to take actions that make various claims eligible for reimbursement when they would otherwise have been ineligible. This brief does not attempt to provide an exhaustive catalog of viable theories of FCA liability.

The United States takes no position on whether the relator's complaint provides sufficient detail under Rule 9(b) to state a claim under the "fraud-in-the-inducement" theory. If this Court reaches the district court's 12(b)(6) ruling, however, it should make clear that the district court erred in concluding that the theory could never be viable.

CONCLUSION

For the foregoing reasons, this Court should reject the district court's conclusion that federal agency oversight of a matter forecloses liability under the False Claims Act.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a). This brief contains 5,113 words.

s/ Tara S. Morrissey

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CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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