DOJ's Fraud-On-The-FDA Liability Theory Is Problematic

By **Jaime Jones, Brenna Jenny and Krystalyn Weaver** (August 2, 2022)

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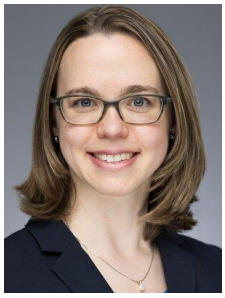

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Over the past decade, whistleblowers filing suit under the False Claims Act have attempted to expand the long-established fraudulent inducement theory of FCA liability into a novel fraud-on-the-U.S. Food and Drug Administration theory of FCA liability.

Relators have led the charge in developing and litigating this theory, arguing that supposed omissions or misstatements before the FDA can cause claims for payment presented to a different government agency to be false.

During the Obama administration, the U.S. Department of Justice filed several statements of interest expressing support for the viability of this theory. However, during the Trump administration, the DOJ's enthusiasm became muted. In 2019, the DOJ even moved to dismiss a fraud-on-the-FDA case over the relator's objections.[1]

The DOJ now appears to be revisiting its position. In June, the DOJ again filed a statement of interest encouraging a court to embrace the fraud-on-the-FDA theory.[2] The DOJ's renewed interest in supporting the viability of this theory may further encourage relators to advance these arguments in court, and may even preview the DOJ's willingness to intervene and litigate such a case.

Life sciences companies dealing with internal complaints or FDA administrative actions relating to compliance with the Federal Food, Drug and Cosmetic Act should understand the attendant FCA risk that can arise and how best to position themselves to respond to follow-on FCA investigations.

Courts have been divided as to the viability of the fraud-on-the-FDA theory, and for good reason. The fraudulent inducement theory, which has been recognized by a number of courts, posits that when a defendant's fraudulent conduct induces a government entity to enter into a contract with the defendant, the claims for payment submitted under that contract are false.[3]

However, the fraud-on-the-FDA theory stretches this causal chain beyond its theoretical underpinnings, by contending that fraudulent conduct or false statements directed at the FDA can render false the claims for payment submitted to an entirely different government entity, such as the Centers for Medicare and Medicaid Services.

Late last year, in U.S. v. Grifols USA, the U.S. District Court for the Southern District of New York refused to extend the fraudulent inducement theory to a relator's fraud-on-the-FDA theory, explaining that "there is no support for Relator's theory [that] the fraudulent inducement theory is applicable to cases where the parties did not enter into a contract."[4]

The court noted that the FCA imposes liability for a false or fraudulent claim for payment, and because a claim is defined as a request or demand for money or property, the plain language of the FCA "requires that the defendant request some form of tangible payment

from the government."[5]

Because FDA approval processes are divorced from payment processes, the court determined that a "fraudulent inducement theory based on FDA approval lies on a shaky legal foundation."[6]

Even if the fraud-on-the-FDA theory could be viable outside of circumstances involving direct contractual relationships — and the better argument suggests it is not — then at a minimum a relator or the government would need to show that the supposed false statement or fraudulent conduct actually affected the government's decision to pay, as the U.S. Court of Appeals for the First Circuit explained in U.S. v. Ev3 Inc. in 2016.[7]

But where the FDA failed "actually to withdraw its approval of [a device] in the face of [the relator's] allegations," this "precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained."[8]

In its most recent statement of interest on this topic, the DOJ has marked out a much broader position on when this theory is viable.

The relator in the underlying case, U.S. ex rel. Crocano v. Trividia, alleged that a blood glucose test manufacturer knowingly distributed defective test strips after discovering and concealing manufacturing deficiencies, and that these test strips were accordingly rendered adulterated or misbranded in violation of the FDCA.[9] The defendant rightly argued that the relator failed adequately to allege how the supposed misconduct caused the government to pay a claim.

In contrast, the DOJ encouraged the U.S. District Court for the Southern District of Florida to conclude that where

> 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.[10]

This statement of interest mirrors the position the DOJ advanced in earlier statements of interest. In a 2015 statement in U.S. ex rel. Sullivan v. Atrium Medical Corp., the DOJ stated:

> When a manufacturer's fraud allows a medical device to either gain FDA approval or to avoid a recall and federal healthcare programs then pay for the medical device, that fraud can be "integral to a causal chain leading to payment" and can be actionable under the FCA…. Fraud on the FDA that was material to the agency's determination about whether a medical device could be sold may, therefore, bear a sufficient nexus to the government's payment decision for that device to give rise to liability under the FCA.[11]

And in its statement in the Ev3 case, the DOJ stated:

> [I]n the (likely rare) circumstances in which the defendant's 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.[12]

A critical difference between the position advanced by the DOJ and the approach adopted by the First Circuit is the conception of what it means to show that FDA would have acted differently had it been aware of the supposed fraud.

The First Circuit aptly noted that to allow a jury to impose FCA liability under the fraud-on-the-FDA theory, when the FDA itself had been aware of the alleged misconduct for six years but never withdrew approval
would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so…. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments.[13]

In contrast, the version of fraud-on-the-FDA advanced by the DOJ would do just that.

In our experience, the FDA is made aware of the allegations in FCA cases that are premised on supposed violations of the FDCA. The DOJ relies on the FDA's expertise when investigating such cases, even if the FDA's views on whether the matter should proceed under the FCA are not always determinative.

Accordingly, practical challenges abound with the DOJ's approach. How is a judge or jury to conclude that the FDA would have exercised one or more of its administrative tools to take corrective action when first faced with an alleged false statement, but contemporaneous facts contradict this inference, because the FDA has been briefed on the allegations — and likely participated in the DOJ's investigation — but nonetheless has not taken corrective action?

Courts should not allow, and the DOJ should not endorse, whistleblowers to stretch the FCA to this breaking point and pursue treble damages on claims paid by the federal health care programs for approved products when the FDA has been aware of the alleged fraud and has not taken any action to withhold or withdraw its approval.

Indeed, in the Crocano case in 2017, the court was apparently unpersuaded by the DOJ's statement of interest and reached exactly this conclusion.[14] The court explained that the defendant's alleged misconduct is "proscribed by other statutes subject to their own enforcement regimes," and the court declined to "expand the scope of the False Claims Act into the realm of regulatory enforcement."[15]

Nonetheless, the DOJ and whistleblowers appear poised to continue to press this theory of liability, and some courts appear receptive. For example, in Dan Abrams Co. LLC v. Medtronic Inc. last year, the U.S. Court of Appeals for the Ninth Circuit reversed a district court's dismissal of a fraud-on-the-FDA case, with no meaningful analysis as to how the FCA's elements of falsity or causation were satisfied.[16]

Until courts more consistently reject or place clear constraints around its viability, life sciences companies faced with complex or novel questions under the FDCA could find themselves the subject of a follow-on FCA suit under the fraud-on-the-FDA theory.

While each situation is unique, the reasoning of courts that have been more hesitant to

accept the DOJ's broad fraud-on-the-FDA theory suggests that to mitigate risk, transparency with the FDA — before and during a DOJ investigation — is paramount.

Life sciences companies should transparently engage with the FDA in a manner that permits the agency to make an informed decision about whether to exercise its administrative authorities. Companies should carefully document all such communications and be prepared to produce these materials to the DOJ as appropriate.

Relevant public statements, whether issued by the company, the FDA or third parties such as news outlets, can play an important role in building defensive legal arguments, both at the investigation stage and in litigation, as applicable.

Such statements can reinforce the company's good faith efforts to disclose relevant information, as well as the FDA's knowledge of pertinent facts, which can be helpful to materiality, causation and public disclosure-based defenses.

Nonpublic communications, particularly within the FDA and CMS, are also important to consider. Given the critical importance of demonstrating the FDA's knowledge and informed decision-making process, discovery of the FDA, in addition to CMS, will be necessary for a vigorous defense.

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[1] United States' Mot. to Dismiss Relators' Second Am. Compl., United States v. Gilead Scis., Inc., No. 11-CV-00941-EMC, 2019 WL 5722618 (N.D. Cal. Mar. 28, 2019).

[2] United States' Statement of Interest as to Def.'s Mot. to Dismiss, United States ex rel. Crocano v. Trividia Health Inc., No. 22-CV-60160-RAR, 2022 WL 612632 (S.D. Fla. Jun. 3, 2022).

[3] United States ex rel. Cimino v. Int'l Bus. Machines Corp., 3 F.4th 412, 417 (D.C. Cir. 2021); but see id. at 424 (Rao, J., concurring) (questioning whether the FCA creates a cause of action for fraudulent inducement and encouraging the Supreme Court to reconsider the theory of liability).

[4] United States ex rel. Yu v. Grifols USA, LLC, No. 1:17-CV-2226-GHW, 2021 WL 5827047, *10 (S.D.N.Y. Dec. 8, 2021).

[5] Id. at *11.

[6] Id.

[7] See United States ex rel. D'Agostino v. ev3, Inc., 845 F.3d 1, 7–8 (1st Cir. 2016).

[8] Id. at 8.

[9] Compl., United States ex rel. Crocano v. Trividia Health Inc., No. 22-CV-60160-RAR, 2022 WL 612632 (S.D. Fla. Feb. 3, 2017).

[10] United States' Statement of Interest as to Def.'s Mot. to Dismiss at 5, United States ex rel. Crocano v. Trividia Health Inc., No. 22-CV-60160-RAR, 2022 WL 612632 (S.D. Fla. Jun. 3, 2022).

[11] United States of America's Statement of Interest on Def.'s Mot. to J. on the Pleadings at 9, United States ex rel. Sullivan v. Atrium Med. Corp., No. CV SA-13-CA-244-OG, 2015 WL 13799885 (W.D. Tex. June 1, 2015).

[12] Br. for the United States as Amicus Curiae Supporting Neither Party at 19–20, United States ex rel. D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. June 13, 2016); see also United States Statement of Interest at 8, United States ex rel. Higgins v. Bos. Sci. Corp., No. 11-CV-2453 (JNE/TNL), 2020 WL 968218 (D. Minn. Feb. 13, 2017) (same).

[13] D'Agostino, 845 F.3d at 7–8.

[14] Order Granting Motion to Dismiss, 22-CV-60160-RAR (S.D. Fla. July 18, 2022).

[15] Id. at 19–20.

[16] See Dan Abrams Co. LLC v. Medtronic Inc., 850 F. App'x 508, 510–11 (9th Cir. 2021).