HEALTH FRAUD FROM FDA APPROVAL TO CMS PAYMENTS: WHY FRAUD-ON-THE-FDA SHOULD BE A VIABLE FORM OF LIABILITY UNDER THE FALSE CLAIMS ACT

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INTRODUCTION

From 2008 to 2009, the United States government spent over $5 billion on three anti-HIV drugs, Atripla, Truvada, and Emtriva, to treat the nearly 1.2 million people living in the country with HIV.[1] While all three drugs contained the same active ingredient, emtricitabine, and were produced by the same biopharmaceutical company, Gilead Sciences, Inc.,[2] each provided unique benefits to patients with HIV. Emtriva, which must be combined with other antiretroviral medications for proper HIV management, reduced the number of pills HIV-positive patients take by only requiring a single daily dose.[3] Atripla, the first medication approved for a "one-pill-daily" regime for HIV-1 infections,[4] further reduced the overall pill burden. Truvada eventually became the first biopharmaceutical agent approved for HIV prevention.[5] With approximately 50,000 new infections annually,[6] these three drugs helped the United States respond to the relentless AIDS epidemic.[7]

Gilead, while enjoying the success that came from supplying three crucial drugs to a multi-billion-dollar market, was deceiving the Food and Drug Administration (FDA or the agency) with false and misleading

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[1] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 895 (9th Cir. 2017); Ctr. for Disease Control & Prevention, *HIV Surveillance—United States, 1981–2008,* 60 MORBIDITY & MORTALITY WKLY. REP. 689, 689 (2011).

[2] *Campie*, 862 F.3d at 895.

[3] Press Release, Gilead, U.S. FDA Approves Gilead Sciences' Emtriva, a One-Capsule, Once-Daily Medication for the Treatment of HIV (July 2, 2003), https://www.gilead.com/news-and-press/press-room/press-releases/2003/7/us-fda-approves-gilead-sciences-emtriva-a-onecapsule-oncedaily-medication-for-the-treatment-of-hiv#:~:text=Gilead%20Sciences%20(Nasdaq%3AGILD),adults%20in%20combination%20with%20other

[4] Boris Julg & Johannes R. Bogner, *Atripla™ –HIV Therapy in One Pill*, 4 THERAPY CLINICAL RISK MGMT. 573, 576 (2008).

[5] *In Brief: Truvada for HIV Prevention*, 54 MED. LETTER ON DRUGS & THERAPEUTICS 63, 63–64 (2012).

[6] *CDC Fact Sheet: New HIV Infections in the United States*, CTR. FOR DISEASE CONTROL & PREVENTION (Feb. 2016), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/new-hiv-infections-508.pdf.

[7] *See The Global HIV/AIDS Epidemic*, KAISER FAM. FOUND. (July 27, 2022), https://www.kff.org/global-health-policy/fact-sheet/the-global-hivaids-epidemic/.

submissions.[8] According to two former Gilead employees, the company began sourcing emtricitabine from an unapproved facility in 2007 but continued to report to the FDA that it only sourced ingredients from approved facilities.[9] Moreover, when Gilead requested FDA approval of this unapproved facility a year later, the company concealed data that batches from the facility contained excess levels of impurities as well as heavy metal contamination.[10]

Holding pharmaceutical companies like Gilead accountable for false and misleading FDA submissions is increasingly important as healthcare costs in the United States continue to skyrocket. In 2022, healthcare spending in the United States reached $4.5 trillion, accounting for 17.3% of the nation's Gross Domestic Product.[11] In fact, the United States spends more on healthcare than any other country but continues to have worse health outcomes than similarly situated nations.[12] Pharmaceutical products significantly contribute to growing healthcare costs: spending on prescription drugs has been one of the fastest growing areas of healthcare expenditures since the 1990s.[13] This growth is primarily driven not by per capita consumption but by prices for newly developed drugs.[14] Pharmaceutical and medical device companies, such as Gilead Sciences, benefit from the high prices as the United States' population is forced to grapple with ever-increasing healthcare spending.[15]

Currently, there is no effective way to hold pharmaceutical and

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[8] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 895 (9th Cir. 2017)..

[9] *Id*. at 895–96.

[10] *Id*.

[11] *National Health Expenditures Data: Historical*, CTR. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical (last modified Dec. 13, 2023).

[12] Munira Z. Gunja et al., *U.S. Health Care from a Global Perspective, 2020: Accelerating Spending, Worsening Outcomes*, THE COMMONWEALTH FUND (Jan. 31, 2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022. Compared to other high-income nations, the United States has the lowest life expectancy and highest maternal and infant mortality rates. *Id. See* Irene Papanicolas et al., *Health Care Spending in the United States and Other High-Income Countries*, 319 J. AM. MED. ASS'N 1024,1025 (2018).

[13] Anna Kaltenboeck, *Pharmaceutical Products and Their Value: Lessons Learned and the Path Ahead*, 23 VALUE HEALTH 421, 421 (2020).

[14] CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 5 (2022), www.cbo.gov/publication/57050*; see also* Lisa D. Ellis, *The Need to Treat the Ailing U.S. Pharmaceutical Pricing System*, HARV. T.H. CHAN SCH. PUB. HEALTH (Mar. 14, 2009), https://www.hsph.harvard.edu/ecpe/united-states-pharmaceutical-pricing/.

[15] In the first quarter of 2009, Gilead announced a record revenue of $1.53 billion with a twenty-seven percent increase in antiviral product sales compared to the first quarter of 2008. *Gilead Sciences Announces Record First Quarter 2009 Financial Results*, GILEAD (Apr. 21, 2009), https://www.gilead.com/news-and-press/press-room/press-releases/2009/4/gilead-sciences-announces-record-first-quarter-2009-financial-results. In 2008, name brand drugs cost four times as much as generic drugs; the next year, prescription drug prices in general increased by just over three percent. Janet Lundy, *Prescription Drug Trends*, KAISER FAM. FOUND. 1, 3 (May 2010), https://www.kff.org/wp-content/uploads/2013/01/3057-08.pdf.

medical device companies accountable for deceptive practices such as the ones Gilead engaged in. The FDA, which is the governmental agency responsible for approving pharmaceutical products and medical devices and then regulating them after approval, can withdraw problematic products from the market.[16] However, withdrawal does not always make sense: in the situation described above, by the time the FDA was alerted to the Gilead's use of and false submissions related to the unapproved facility, Gilead no longer sourced emtricitabine from that facility.[17] Moreover, withdrawing Gilead's three anti-HIV drugs from the market would leave people living with HIV without crucial medications.[18] Though the FDA is also authorized to police fraud on the agency,[19] scholars have drawn attention to the discrepancy between the FDA's formal policing powers and the agency's actual enforcement activity.[20] Namely, the agency may not have the resources or centralized focus to fully address fraud, especially when it is complex and attached to a billion-dollar industry.[21]

The False Claims Act (FCA) could provide an avenue to hold pharmaceutical and medical device companies accountable for false and misleading statements made to the FDA with a form of FCA liability called fraud-on-the-FDA. The FCA is a federal statute that penalizes actors who cause financial loss to the United States government through fraud or false statements.[22] For healthcare companies, FCA liability is often related to reimbursement claims submitted to federal healthcare programs, such as Medicare or Medicaid, because false statements in such claims directly cause

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[16] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351–399, 355(e).

[17] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 895–96 (9th Cir. 2017).

[18] From June 2017 to May 2018, around the time *Campie* was decided, 92% of roughly 1.1 million people living in the United States with an HIV diagnosis were medicating with antiretroviral therapy. CTR. FOR DISEASE CONTROL & PREVENTION, BEHAVIORAL AND CLINICAL CHARACTERISTICS OF PERSONS WITH DIAGNOSED HIV INFECTION—MEDICAL MONITORING PROJECT, UNITED STATES, 2017 CYCLE 4, 5 (2019), https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-23.pdf. Antiretroviral therapy, which involves taking a combination of HIV medicines every day, would include the three drugs developed by Gilead. *HIV Treatment: The Basics*, NAT'L INST. HEALTH'S OFF. AIDS RES., https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-treatment-basics#:~:text=treatment%20for%20HIV%3F-,The%20treatment%20for%20HIV%20is%20called%20antiretroviral%20therapy%20(ART).,HIV%20live%20longer%2C%20healthier%20lives (last reviewed Aug. 16, 2021). Because there was lack of manufacturer competition and minimal availability of generic substitutes within the United States at that time, pulling Gilead's products from the market would cause a significant shortage, leading to devastating public health outcomes. *See* Jennifer Kates, Lindsey Dawson & Juliette Cubanski, *Quick Look: Antiretroviral Price Increases in Medicare Part D*, KAISER FAM. FOUND. (Dec. 17, 2019), https://www.kff.org/hivaids/issue-brief/quick-look-antiretroviral-price-increases-in-medicare-part-d/.

[19] 21 U.S.C. § 331(y)-(y)(1).

[20] Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841, 860 (2008).

[21] *See* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J. L. REFORM 461, 476 (1997); *see also infra* notes 104–05 and accompanying text.

[22] 31 U.S.C. § 3729(a)(1)(A)–(B).

governmental payment.[23] Because these federal healthcare programs generally require that a drug or device has been approved by the FDA for reimbursement coverage, the theory of fraud-on-the-FDA attempts to extend liability for fraudulently obtained government payment back to the FDA approval process.[24] In other words, pharmaceutical and medical device companies that obtain FDA approval through fraud would be liable under the FCA because the fraudulently obtained approval causes healthcare companies to submit reimbursement claims to the government for payment.[25]

Claimants in federal courts of the First, Ninth, and Eleventh Circuits have asserted fraud-on-the-FDA as a form of FCA liability.[26] While the Ninth Circuit upheld the new theory of liability,[27] the First Circuit rejected it, arguing the causal link between fraud and governmental payment is too tenuous.[28] The Department of Justice (DOJ) sided with the Ninth Circuit when it submitted a Statement of Interest to a district court in the Eleventh Circuit suggesting it adopt the fraud-on-the-FDA theory of liability.[29]

Adopting fraud-on-the-FDA as a viable form of liability under the FCA forwards the FDA's policy of ensuring the safety and efficacy of products on the market, aligns with the FCA's purpose of prosecuting fraud that causes financial loss to the government, and has the potential to help curb healthcare expenditures in the United States. Fraud-on-the-FDA will also hold pharmaceutical and medical device companies accountable for fraudulent submissions when withdrawal of FDA approval would not make sense, as with Gilead's anti-HIV drugs.

Part I of this Note will discuss the background of the FCA; the relationship between the FCA and federal healthcare programs; the approval process and enforcement authority of the FDA; and the current circuit split on fraud-on-the-FDA, which combines the FCA, federal healthcare

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

[24] *Id.*; U.S. DEP'T HEALTH & HUM. SERVS., MEDICARE BENEFIT POLICY MANUAL, ch. 14, § 10.

[25] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 899 (9th Cir. 2017); *D'Agostino*, 845 F.3d at 7.

[26] Although the United States Supreme Court has not been asked to resolve the issue of fraud-on-the-FDA, it recently resolved a related circuit split on the scienter element of an FCA claim, which requires a showing that the defendant knowingly submitted the false or fraudulent claim. United States *ex rel.* Schutte v. SuperValu, Inc., 143 S. Ct. 1391, 1404 (2023); 31 U.S.C. § 3729(a)(1). In a unanimous opinion, the Court stated the correct test for scienter is subjective: "The FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed." *SuperValu*, 143 S. Ct. at 1399. However, scienter is not an issue for fraud-on-the-FDA claims specifically. This Note, although not directly applicable to the scienter question presented to the Court, will outline the relevant aims of the FCA and how those aims apply when proof of one or more elements is not clear.

[27] *Campie*, 862 F.3d at 905–06.

[28] *Id.; D'Agostino*, 845 F.3d at 10.

[29] United States' Statement of Interest as to Defendant's Motion to Dismiss, United States *ex rel.* Crocano v. Trividia Health, Inc., 615 F.Supp, 3d 1296 (S.D. Fla. 2022) (No. 22-CV-60160-RAR) [hereinafter *Statement of Interest Trividia Health*].

programs, and the FDA.[30] Part II will discuss the viability of fraud-on-the-FDA in terms of the causation and materiality requirements of the FCA.[31] Part III will demonstrate why policing fraud related to the FDA approval process with the FCA is a better option than leaving enforcement to the FDA.[32] Part III will also discuss the limitations of fraud-on-the-FDA as a theory of liability and introduce the possible implications of accepting fraud-on-the-FDA.[33] Part IV will propose a resolution to the issue: Congress should clarify that the DOJ can prosecute fraud-on-the-FDA claims under the FCA.[34]

I. BACKGROUND

To analyze the legal viability and practical benefits of fraud-the-FDA as a form of FCA liability, it is necessary to understand the history of the FCA, specifically as it relates to federal healthcare programs and FDA regulation, as well as the current disagreement between the First and Ninth Circuits over applying the FCA elements of causation and materiality to the fraud-on-the-FDA theory.

A. The False Claims Act

Congress enacted the FCA in 1863 in response to concerns that Union Army suppliers were defrauding the government during the Civil War.[35] The Act created liability for any person or entity who knowingly submitted false claims to the government.[36] FCA violators were liable for double the government's damages plus a $2,000 penalty for each false claim.[37] The FCA has been amended several times since 1863, most notably in 1986 when Congress imposed treble damages and increased the penalty for each false claim to a range of $5,000 to $10,000.[38] The most recent version of the FCA assigns liability when a person or entity "knowingly presents, or causes to be presented, a false or fraudulent claim for payment

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[30] *See* discussion *infra* Sections I.A–I.D.
[31] *See* discussion *infra* Sections II.A–II.C.
[32] *See* discussion *infra* Sections III.A–III.B.
[33] *See* discussion *infra* Section III.C.–III.D.
[34] *See* discussion *infra* Section IV.
[35] U.S. DEP'T JUST., THE FALSE CLAIMS ACT: A PRIMER 1, 1 (2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[36] *Id.*
[37] *Id.*
[38] *Id.*

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."[39] Courts may reduce damages if the violating party cooperates with the government and provides all relevant information.[40]

An FCA action requires proof of four elements: "(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')."[41] A false claim is "any request or demand . . . for money or property . . . presented to an officer, employee, or agent of the United States or . . . made to a contractor, grantee, or other recipient, if the money is to be spent or used on the Government's behalf or to advance a Government program or interest"[42] that contains express falsehoods or makes fraudulent misrepresentations, which can include misleading omissions.[43] A party is charged with knowledge of the false or fraudulent statement under the FCA if the party had actual knowledge or if the party deliberately ignored or recklessly disregarded the truth or falsity of the information.[44] A material statement is one that "has a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[45] Finally, the fourth element of an FCA claim requires that the defendant's conduct caused the government to make a payment or forfeit money owed.[46] In other words, there must be a causal relationship between the fraud and payment; the government must be induced by or rely on the fraudulent statement or omission. [47]

In addition to authorizing the DOJ to prosecute entities for FCA violations, the FCA also includes a *qui tam* provision, which allows a private person, called a relator, to file an FCA suit on behalf of the government.[48] *Qui tam* actions are advantageous to the government because the private plaintiffs do the preliminary work, decreasing the burden on government agents.[49] When a relator files a complaint, the DOJ investigates the

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[39] 31 U.S.C. § 3729(a)(1)(A)–(B).

[40] § 3729(a)(2).

[41] Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 788 (4th Cir. 1999); s*ee* United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 899 (9th Cir. 2017) (quoting United States v. Univ. of Phx., 461 F.3d 1166, 1174 (9th Cir. 2006)).

[42] 31 U.S.C. § 3729(b)(2)(A).

[43] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 187 (2016).

[44] § 3729(b)(1)

[45] § 3729(b)(4).

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

[47] *Id*.

[48] 31 U.S.C. § 3730(b).

[49] Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx*, 12 J. HEALTH CARE L. & POL'Y 119, 139 (2009).

allegations, during which time the complaint is kept under seal.[50] The DOJ can either intervene or decline to take over the action.[51] If the government declines to take over the action but the court does not dismiss it, the relator can continue with the action.[52]

Congress has incentivized *qui tam* actions by allowing relators to share a percentage of the government's recovery.[53] If the government intervenes in the action, the relator can receive 15 to 25% of the total recovery.[54] If the government declines to take over the action, the relator will receive 25 to 30% of the recovery.[55] The "extent to which the [relator] substantially contributed to the prosecution of the action" determines the actual percentage of recovery.[56]

According to Principal Deputy Assistant Attorney General Brian Boynton, "[p]rotecting taxpayer dollars from fraud and abuse is of paramount importance to the Department of Justice."[57] The FCA is crucial to fulfilling that priority; Boynton believes it is "one of [the] . . . most important tools" available to the department to deter fraud and hold fraudsters accountable.[58] The DOJ has demonstrated its robust use of the FCA: in the 2023 fiscal year, the DOJ obtained more than $2.68 billion in FCA settlements and judgments.[59]

B. The False Claims Act and Federal Healthcare Programs

Due to the federal government's high expenditures on health care,[60]

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[50] § 3730(b)(2)–(4).
[51] § 3730(b)(4).
[52] § 3730(b)(4)(B).
[53] § 3730(d).
[54] § 3730(d)(1).
[55] § 3730(d)(2).
[56] § 3730(d)(1)–(2).
[57] *False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023*, U.S. DEP'T JUST. (Feb. 22, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023 [hereinafter *FCA Settlements and Judgments 2023*].
[58] *Id.*,
[59] *Id.* This number, while large and nearly $500,000 than the 2022 recovery amount, is less than half of the recovery from 2021. *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022*, U.S. DEP'T JUST. (Feb. 7, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022. *Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021* (*FCA Settlements and Judgments 2021*), U.S. DEP'T JUST. (Feb. 1, 2022), https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.
[60] The federal government spent nearly $1.5 trillion on healthcare in 2022. *National Health Expenditures Data: Table 05-3 Federal Government Sponsor Expenditures*, CTR. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData (last modified Dec. 13, 2023) (follow "NHE Fact Sheet" hyperlink; then download "NHE Tables (ZIP)"; then open "Table 05-3"). The two largest sources of federal government healthcare spending are Medicare, the federal healthcare program that covers people aged 65 and over, people under the age

there is a significant risk of healthcare-related false claims.[61] In fact, healthcare fraud is a leading source of settlements and judgments under the FCA: of the total $2.68 billion recovered through the FCA in 2023, over $1.8 billion came from the healthcare industry.[62] Violators falling into this category include managed care providers, hospitals, pharmacies, and physicians.[63] FCA judgments and settlements against these entities help the DOJ restore funds to federal healthcare programs.[64]

FCA violations in the healthcare context carry the potential for punishment beyond the typical treble damages and penalties of up to $10,000.[65] The Secretary of Health and Human Services (HHS) has the authority to exclude individuals and entities convicted of fraud from participation in federal healthcare programs.[66] If the fraud conviction is a felony, exclusion from federal healthcare programs is mandatory.[67] The possibility of losing access to these programs prompts many healthcare providers to settle rather than risk litigation in the face of FCA allegations.[68]

Many healthcare-related FCA matters implicate the conditions of payment established by federal healthcare programs.[69] To reimburse a provider for a pharmaceutical product or medical device, federal healthcare programs require the drug or device to be FDA approved or cleared and otherwise reasonable and necessary for the medical care of the patient in

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of 65 with certain disabilities, and people of all ages with end-stage renal disease, and Medicaid, the joint state and federal health insurance program for low-income individuals and families who fit eligibility requirements. U.S. DEP'T OF HEALTH AND HUMAN SERVS., NAT'L HEALTH EXPENDITURE ACCTS.: METHODOLOGY PAPER, 2022, 1, 35 (2022), https://www.cms.gov/files/document/definitions-sources-and-methods.pdf. In 2021, the federal government spent $689 billion on Medicare and $518 billion on Medicaid. Juliette Cubanski & Tricia Neuman, *What to Know about Medicare Spending and Financing*, KAISER FAM. FOUND. (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/; CONG. RES. SERV., MEDICAID: AN OVERVIEW, 1, 18 (Feb. 8, 2023), https://crsreports.congress.gov/product/pdf/R/R43357.

[61] *See FCA Settlements and Judgments 2023*, *supra* note 57.

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] 31 U.S.C. § 3729(a)(1).

[66] 42 U.S.C. § 1320a-7(b)(1).

[67] § 1320a-7(a)(3).

[68] Joan Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that "Counts" Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1815–16 (2017); *see* Girard, *supra* note 49, at 128.

[69] *FCA Settlements and Judgments 2023*, *supra* note 57. The Centers for Medicare & Medicaid Services (CMS), a subagency of HHS, runs two of the largest federal healthcare programs, Medicare and Medicaid, in addition to the State Children's Health Insurance Program, the Health Insurance Portability and Accountability Act, and other health-related programs. *Centers for Medicare & Medicaid Services*, FED. REG., https://www.federalregister.gov/agencies/centers-for-medicare-medicaid-services (last visited Feb. 26, 2023); *see* sources cited *supra* note 60. In this Note, I will often reference CMS as if it is the only federal agency receiving reimbursement claims for healthcare. However, similar issues could arise with other healthcare agencies under the HHS, such as the Indian Health Service or the Substance Abuse and Mental Health Services Administration. See *Health and Human Services Agencies and Offices*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (last reviewed Nov. 28, 2023), for more information about these agencies.

question.[70] The DOJ regularly investigates and prosecutes matters involving providers billing federal healthcare programs for medically unnecessary services or services not performed as billed.[71] For example, the DOJ settled with SavaSeniorCare LLC and related entities for $11.2 million for allegations that rehabilitation therapy services were provided without regard for patients' actual clinical needs, resulting in medically unnecessary therapy sessions.[72]

While many health-related FCA claims are similar to the SavaSeniorCare situation, involving providers billing for products or services that were unnecessary or never used, some FCA claims involve less obvious connections between falsity and reimbursement.[73] In fact, the Supreme Court affirmed the implied certification theory of liability, which expands the use of the FCA to include some of these less obvious falsity-reimbursement connections.[74] The implied certification theory creates liability under the FCA for an individual or entity that "makes specific representation about the goods or services provided, but knowingly fails to disclose . . . noncompliance with a statutory, regulatory, or contractual requirement . . . if the omission renders those representation misleading" and is material to the government's decision to pay.[75] According to the Supreme Court, this form of liability is not dependent on whether the requirement the individual or entity violated is a condition of payment.[76] Implied certification arises in the healthcare context each time a party submits a claim to a federal healthcare program because it "implicitly communicate[s] that it . . . conformed to the relevant program requirements, such that it was entitled to payment."[77] For example, when a medical provider submits a claim to Medicaid for mental health services for a teenage patient with a National Provider Identification number corresponding to a social worker, the medical provider impliedly

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[70] U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 24, § 30. Federal healthcare programs use the phrase "safe and effective" rather than "FDA-approved" or "FDA-cleared" for the first condition of payment. *Id.* However, programs consider drug or biologicals approved for marketing by the FDA as safe and effective and generally will not cover drugs or biologicals that have not been approved by the FDA. *Id.* The Centers for Medicare & Medicaid Services has the authority to instruct programs otherwise, but such an action is uncommon. *Id.* For example, according to the Office of Inspector General, only one percent of drugs reimbursed through Medicaid in 2016 were not FDA-approved and some of those reimbursements may have been by mistake. SUZANNE MURRIN, OFF. INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS., ONE PERCENT OF DRUGS WITH MEDICAID REIMBURSEMENT WERE NOT FDA-APPROVED 1, 7, 10 (May 2019), https://oig.hhs.gov/oei/reports/oei-03-17-00120.pdf. FDA-approved drugs can be covered by federal healthcare programs for indications other than those listed on the label if those indications are generally accepted medical practices within the community. U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 24.

[71] *FCA Settlements and Judgments 2023*, *supra* note 57.

[72] *Id.*

[73] *See id.*

[74] Universal Health Servs. v. United States *ex rel.* Escobar, 579 U.S. 176, 181 (2016).

[75] *Id.* at 190.

[76] *Id.* at 181.

[77] *Id.* at 185.

certifies that the services were provided to the patient and the social worker providing the services complied with Medicaid requirements, such as the counselor treating teenagers having specialized training and experience with children.[78] According to the Supreme Court, if the individual providing mental health services does not have specialized training or experience, it is presenting a misleading half-truth that gives rise to FCA liability through the implied certification theory.[79]

The Supreme Court has also recognized another, broader approach to finding FCA liability called promissory fraud or fraud-in-the-inducement.[80] Promissory fraud, rather than requiring a false statement of compliance with government regulations, attaches liability "to each claim submitted to the government under a contract, when the contractor extension of government benefit was originally obtained through false statements or fraudulent conduct."[81] In other words, the fraud does not end with the execution of a government contract: the taint of fraud enters every subsequent claim that follows from the fraudulently obtained contract.[82]

As mentioned above, another condition of payment from federal healthcare programs is FDA approval.[83] Neither the implied certification theory of liability nor the theory of promissory fraud has been expanded to include issues related to FDA approval.[84] However, under the theory of implied certification, it is possible that a defendant who falsely or fraudulently obtained FDA approval and then submitted or caused another to submit a reimbursement claim using that approval could be seen as impliedly communicating that it conformed to program requirements and was entitled to payment.[85] Similarly, under the theory of promissory fraud, it seems plausible that a court could find that fraudulently obtained FDA approval taints subsequent claims involving the FDA-approved device submitted to the government for payment.[86]

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[78] *Id.* at 189–90.

[79] *Id.* at 190.

[80] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 902 (9th Cir. 2017).

[81] United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1166, 1173 (9th Cir. 2006); *see* United States *ex rel.* Marcus v. Hess, 317 U.S. 537, 543–45 (1943) (a separate holding of *Hess*, that relators could bring *qui tam* suits even if the government was in possession of the relevant information, was subsequently overturned by the1943 *qui tam* amendment to the FCA); *see* United States *ex rel.* Doe v. John Doe Corp., 960 F.2d 318, 321 (2nd Cir. 1992). The holding relevant here is still good law and has been cited by the U.S. Supreme Court as recently as 2016. *See Escobar*, 579 U.S. at 194.

[82] *Marcus*, 371 U.S. at 543.

[83] U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 24; *see supra* note 70 and accompanying text.

[84] *See Escobar*, 579 U.S. at 181.

[85] *See id.*

[86] *See Hendow*, 461 F.3d at 1173; *Marcus*, 317 U.S. at 537.

C. The False Claims Act and the Food and Drug Administration

Given the FCA's success in policing other forms of health-related fraud,[87] the DOJ could supplement the FDA with enforcement efforts through the fraud-on-the-FDA theory. The FDA has its own criminal investigations unit[88] and the authority to police fraud on the agency,[89] but FDA policing has been questioned.[90] Fraud-on-the-FDA could close the gap on FDA-related healthcare fraud.

Pursuant to the Federal Food Drug and Cosmetics Act (FDCA), the FDA regulates the safety, efficacy, and security of drugs, biological products, and medical devices.[91] Unless an exception or exemption applies, pharmaceutical drugs, biological products, and medical devices must obtain FDA approval or clearance before being marketed and sold.[92] The FDA grants or denies applications for approval or clearance based on a risk-benefit assessment that considers the target condition, available treatments for that condition, benefit and risk information submitted by the developer, and strategies for managing risks.[93] Depending on the nature of the proposed product and public health requirements, the FDA can alter the typical review process.[94]

The FDA continues regulating pharmaceutical products and medical devices after they hit the market: the FDCA authorizes the Secretary of the

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[87] *FCA Settlements and Judgments 2023*, *supra* note 57.

[88] *About OCI*, FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/about-oci (last updated Mar. 12, 2018).

[89] *See infra* note 95 and related text.

[90] *See infra* notes 103–08 and related text.

[91] 21 U.S.C. § 301–399; *Federal Food, Drug, and Cosmetics Act*, FOOD & DRUG ADMIN. (Mar. 29, 2018), https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.

[92] *Development & Approval Process | Drugs*, FOOD & DRUG ADMIN. (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs; *Investigational New Drug Applications for CBER-Regulated Products*, FOOD & DRUG ADMIN. (Oct. 14, 2022), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-drug-applications-inds-cber-regulated-products.

[93] *Development & Approval Process*, *supra* note 92.

[94] *Id*. The FDA would not bypass the review process entirely; the agency can give pharmaceutical drugs and biological products certain designations, such as Fast Track, Breakthrough Therapy, or Priority Review, to certain submissions that either speed up or shorten the approval process. *Id.* The approval or clearance process for medical devices also varies depending on device classification and other factors. *Products and Medical Procedures*, FOOD & DRUG ADMIN. (Sept. 14, 2021), https://www.fda.gov/medical-devices/products-and-medical-procedures. Certain devices are subjected to Premark Approval, the FDA's most stringent approval process for devices, which requires "sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses." *Device Approvals, Denials and Clearances*, FOOD & DRUG ADMIN. (Mar. 26, 2018), https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances. The FDA can also grant devices that are shown to have low to moderate risk a de novo classification, which allows clearance through a less stringent process than Premarket Approval. *Id.* Devices that are substantially equivalent to a legally marketed device can similarly bypass Premarket Approval with premarket notification, or 510(k), to the FDA. *Id.*

FDA "to conduct examinations and investigations for the purposes of this Act"[95] and authorizes the agency to recall products, withdraw approval, impose fines, and assign criminal penalties.[96] Because the FDCA prohibits "the submission of a report or recommendation . . . that is false or misleading in any material respect" in the "case of a drug, device, or food," the FDA can investigate and penalize actors for fraudulent conduct against the agency.[97] The FDCA also has provisions "aimed at detecting, deterring, and punishing false statements made during . . . [the] approval process."[98]

Much of the FDA's policing of fraud involves fraudulent labeling or false reports on compliance.[99] For example, following a seizure of a package containing what officers suspected to be human growth hormone, the FDA investigated Shontay Dessart, the intended recipient of the package.[100] The investigation revealed that Dessart was selling products with active chemical ingredients online and avoiding FDA oversight by attaching a "for research only" label to each product.[101] Dessart was convicted under the FDCA with intent to defraud or mislead the agency.[102]

Scholars have called the efficacy of the FDA's policing activities into question.[103] There is, however, considerable disagreement over the cause of the discrepancy between the agency's policing authority and its actual enforcement: some scholars point to a lack of adequate resources,[104] while others blame mismanagement of the Office of Criminal Investigations (OCI),[105] which is the team responsible for investigating violations of the FDCA and other criminal statutes under the purview of the FDA.[106] The political party in control of the White House may also play a role in the level

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[95] 21 U.S.C. § 372(a)(1)(A).

[96] Sharkey, *supra* note 20, at 860.

[97] § 331(y)(1).

[98] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).

[99] FOOD & DRUG ADMIN., *supra* note 88.

[100] United States v. Dessart, 823 F.3d 395, 398 (7th Cir. 2016).

[101] *Id.*

[102] *Id.*

[103] *See* Sharkey, *supra* note 20, at 860; Daniel G. Dauner et al., *FDA's Unimproved Enforcement of Postmarketing Requirements and Commitments: Implications for Providers and Patients*, 16 RES. IN SOC. & ADM. PHARMACY 844 (2020) (observing that the FDA routinely fails to enforce compliance with its prescription drug postmarketing-study requirements).

[104] Green, *supra* note 21. *Contra* Sarah N. Lynch, *Special Report- 'Botox Police': FDA Crime Unit Draws Fire over Import Crackdown*, REUTERS (Sept. 8, 2016), https://www.reuters.com/article/usa-fda-cases/special-report-botox-police-fda-crime-unit-draws-fire-over-import-crackdown-idUSL1N1BJ1DQ.

[105] Brad Estes, *Prosecuting Over Peanuts: How the PCA Scandal Can Inform More Effective Federal Criminal Enforcement of Food Safety Laws*, 33 REV. LITIG. 145, 155 (2014); *see also* Andrew C. Baird, *The New Park Doctrine: Missing the Mark*, 91 N.C.L. REV. 949, 949–50 (2013); *see* Rob Garver, *FDA Let Drugs Approved on Fraudulent Research Stay on the Market*, PROPUBLICA (Apr. 15, 2013), https://www.propublica.org/article/fda-let-drugs-approved-on-fraudulent-research-stay-on-the-market.

[106] FOOD & DRUG ADMIN., *supra* note 88.

of FDA enforcement.[107] Regardless of the reason, even with enforcement authority, the FDA may not be fully regulating the market.[108]

Given the DOJ's success in policing healthcare fraud through the FCA,[109] the DOJ may be able to assist the FDA by prosecuting fraud on the agency under a fraud-on-the-FDA theory of liability. FDA approval or clearance of pharmaceutical products and medical devices is generally required for reimbursement from federal healthcare programs.[110] By borrowing concepts from other theories of liability that extend the reach of the FCA, such as the implied certification theory, it seems that FDA-related violations could lead to FCA liability if FDA violations were material to the government's decision to pay.[111] Fraud-on-the-FDA combines the history and analysis of both FCA claims in the healthcare industry and FCA claims involving the FDA.

D. Fraud on the FDA and the Current Circuit Split

The current split between the First and Ninth Circuits over the viability of fraud-on-the-FDA as a form of FCA liability illuminates issues the theory has in meeting two FCA elements: causation and materiality.[112] The First Circuit rejected the fraud-on-the-FDA theory because of an insufficient causal link between the misleading statements submitted to the FDA and reimbursement from the Centers for Medicare & Medicaid Services (CMS).[113] The Ninth Circuit, in contrast, upheld fraud-on-the-FDA, barely mentioning causation, and allowed the case to proceed past the pleading stage.[114] Both the First and Ninth Circuits, however, noted that the relator had an uphill battle to prove materiality.[115] The issues identified by the First and Ninth Circuits reveal an underlying disagreement over the relationship between the FDA and the FCA.[116] Clearly defining this relationship within the context of accepted forms of FCA liability, particularly implied certification theory and promissory fraud, can help resolve the circuit split

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[107] Charles Piller, *Exclusive: FDA Enforcement Actions Plummet Under Trump*, SCIENCE (July 2, 2019), https://www.science.org/content/article/exclusive-fda-enforcement-actions-plummet-under-trump.

[108] *See* Sharkey, *supra* note 20; Dauner, *supra* note 103.

[109] *FCA Settlements and Judgments 2023*, *supra* note 57.

[110] *See* DEP'T HEALTH & HUM. SERVS., *supra* note 24.

[111] *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190 (2016); *Escobar*, 579 U.S. at 190.

[112] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 3,10 (1st Cir. 2016); United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 909 (9th Cir. 2017).

[113] *D'Agostino*, 845 F.3d at 3,10.

[114] *Campie*, 862 F.3d at 909.

[115] *Id.* at 905.

[116] *D'Agostino*, 845 F.3d at 8; *Campie*, 862 F.3d at 905.

and affirm fraud-on-the-FDA as a viable form of FCA liability.[117]

1. Fraud-on-the-FDA's failure in the First Circuit

In the First Circuit, a relator alleged that the medical device company ev3 and its subsidiary Micro Therapeutics, Inc. (MTI) were liable under the FCA based on the theory of fraud-on-the-FDA.[118] D'Agostino, the relator and a former ev3 sales representative, alleged that ev3 and MTI made false submissions to the FDA for Onyx Liquid Embolic System, a medical device developed to facilitate neurosurgery.[119] During the FDA approval process for Onyx, MTI's Vice President told the advisory panel that Onyx had a narrow indication and that physicians using Onyx would receive rigorous training as well as assistance during their first uses of the system.[120] The panel ultimately recommended approval but noted that the assurances of the narrow indication and training were critically important to that decision.[121] According to D'Agostino, MTI never intended to honor those claims: physicians with little or no training used Onyx, and Onyx was used for off-label procedures.[122] Physicians and hospitals using Onyx submitted reimbursement claims to CMS. [123] Because FDA approval is a precondition to CMS reimbursement for use of a medical device,[124] D'Agostino alleged ev3 and MTI caused physicians to submit false claims by securing FDA approval through fraudulent statements.[125]

The First Circuit Court of Appeals rejected the fraud-on-the-FDA theory, affirming the lower court's ruling that D'Agostino's complaint did not allege claims upon which the court could grant relief because it failed to establish a causal link.[126] According to the First Circuit, D'Agostino's complaint could not survive a motion to dismiss because it only alleged the statements made by MTI *could have* influenced the FDA's decision to approve Onyx.[127] The use of "could have" in the complaint was too weak; the FDA also could have approved Onyx notwithstanding the alleged fraudulent representations, which unraveled the connection between the false statements

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[117] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190 (2016) (discussing implied certification theory); United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1160, 1173 (9th Cir. 2006) (discussing promissory fraud); *D'Agostino*, 845 F.3d at 3,10; *Campie*, 862 F.3d at 909.

[118] *D'Agostino*, 845 F.3d at 5.

[119] *Id.* at 3, 5, 7.

[120] *Id.* at 4.

[121] *Id.*

[122] *Id.*

[123] *Id.* at 5.

[124] *Id.* at 7.

[125] *Id.*

[126] *Id.* at 3, 10.

[127] *Id.* at 7.

and a payment by CMS.[128] If the statements did not *actually cause* FDA approval of Onyx, they could not have caused hospitals and physicians to submit false claims because Onyx would still meet the FDA-approval requirement for CMS reimbursement.[129]

In fact, the First Circuit suggested that a relator could only meet the burden of causation by demonstrating the FDA withdrew the pharmaceutical product or medical device in question.[130] The FDA did not withdraw approval of Onyx even after the agency knew ev3 and MTI made false statements during the approval process.[131] Continued FDA approval, according to the First Circuit, fatally undercut D'Agostino's allegation that MTI's false statements led to approval and, subsequently, false claims.[132] Thus, fraud-on-the-FDA is not a viable theory of liability, according to the First Circuit, because the chain of causation from a false statement to government payment is broken without FDA withdrawal of the pharmaceutical product or medical device in question.[133]

2. Fraud-on-the-FDA's success in the Ninth Circuit

The Ninth Circuit, in contrast, upheld fraud-on-the-FDA as a form of liability under the FCA.[134] As mentioned in the introduction, the Ninth Circuit suit was filed against Gilead Sciences for using Synthetics China, a facility not approved by the FDA, to source the active ingredients while reporting to the FDA that only approved facilities were used.[135] The relators filing the suit also alleged Gilead concealed and falsified data concerning contaminated batches when it sought, and ultimately obtained, FDA registration of Synthetics China as an approved facility.[136] Like the relator in *D'Agostino*, the relators in the suit against Gilead alleged the falsified claims influenced the FDA's approval decision.[137] The FDA approval, obtained through false and concealed data, caused healthcare providers to submit false claims for reimbursement to the government through Medicare, Medicaid, and other federal programs.[138] Thus, as with *D'Agostino*, the Ninth Circuit claim alleged Gilead submitted false or fraudulent claims to the FDA to

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[128] *Id.*
[129] *Id.*
[130] *Id.* at 8.
[131] *Id.*
[132] *Id.*
[133] *Id.* at 7, 8.
[134] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 909 (9th Cir. 2017).
[135] *Id.* at 895–96.
[136] *Id.* at 896.
[137] *D'Agostino*, 845 F.3d at 7; *Campie*, 862 F.3d at 896.
[138] *Campie*, 862 F.3d at 897.

obtain approval, which caused healthcare providers to submit false claims to the government for reimbursement.[139]

The Ninth Circuit held that the Gilead relators pled sufficient factual allegations to state a claim under the False Claims Act.[140] Unlike the First Circuit, the Ninth Circuit did not find an issue with the element of causation.[141] In fact, the Ninth Circuit viewed fraud-on-the-FDA as a form of promissory fraud.[142] Under this theory, because Gilead obtained FDA approval with false statements, FCA liability attached to each reimbursement claim for the three anti-HIV drugs.[143]

The court noted, however, that although the case could pass the pleading stage, the relator would likely have difficulty proving the element of materiality: "[A]t all times relevant, the drugs at issue were FDA-approved, and . . . the government continues to make direct payments and provide reimbursement."[144] This seems to raise the same issue with continued FDA approval that the First Circuit raised with respect to causation.[145] However, the Ninth Circuit raised it as an issue with materiality: is a false statement submitted to the FDA material to CMS's decision to pay if a condition of payment is FDA approval not submission of truthful statements to the FDA?[146] The Ninth Circuit did not answer this question and noted that conditions of payment, or FDA approval in this case, is only one factor in considering materiality.[147] Nonetheless, the court noted that the relator will have trouble overcoming this factor in convincing a court of the false statement's materiality.[148]

Thus, for the Ninth Circuit, fraud-on-the-FDA is a viable form of liability under the FCA, although the arguments for successfully prosecuting an FCA claim under the theory are unclear with respect to the element of materiality.[149]

3. Resolving the circuit split in favor of fraud-on-the-FDA

Underlying the split between the First and Ninth Circuits on fraud-on-the-FDA is a disagreement over the intended relationship between the

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[139] *D'Agostino*, 845 F.3d at 7; *Campie*, 862 F.3d 895–96.
[140] *Campie*, 862 F.3d at 909.
[141] *Id.* at 903.
[142] *Id.; see supra* notes 81–82and accompanying text.
[143] *Campie*, 862 F.3d at 903.
[144] *Id.*
[145] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016).
[146] *Campie*, 862 F.3d at 905.
[147] *Id.*
[148] *Id.* at 905–07.
[149] *Id.*

FCA and the FDA.[150] Defining this relationship in the context of the circuit split and the accepted forms of FCA liability, namely implied certification and promissory fraud, can resolve the issues with fraud-on-the-FDA identified by the First and Ninth Circuits and pave the way for acceptance of fraud-on-the-FDA as a legally viable and practical form of FCA liability.[151]

The First Circuit argued that allowing fraud-on-the-FDA claims under the FCA would be using the FCA to encroach on the FDA's territory.[152] As mentioned above, the FDA can withdraw approval of a drug or device when it concludes it has been misled;[153] thus, according to the First Circuit, "allowing juries in *qui tam* actions to find causation by determining the judgment of the FDA when the FDA itself has not spoken" would undercut the Administration's responsibility to police fraud consistently with its objectives.[154] Essentially, the First Circuit argued that allowing fraud-on-the-FDA claims to move forward would make the FCA a tool to overrule the FDA.[155]

The Ninth Circuit disagreed that fraud-on-the-FDA claims would encroach on the FDA's regulatory regime.[156] According to the Ninth Circuit, "just as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the [government]."[157] Moreover, the Ninth Circuit argued that the First Circuit's focus on the FDA's continued approval is misplaced in a FCA suit: not only are there reasons unrelated to governmental payments that the FDA may consider when choosing to not withdraw a drug, but requiring FDA withdrawal for FCA liability would also allow companies to use "allegedly fraudulently-obtained FDA approval as a shield against liability for fraud."[158] Thus, according to the Ninth Circuit, the fraud-on-the FDA theory does not encroach on the FDA's purpose or objectives and serves as a means for policing fraud that would otherwise be unavailable.[159]

In a separate case in the Southern District of Florida, the DOJ submitted a Statement of Interest hinting that a better understanding of the FDA-FCA relationship could resolve the issues with fraud-on-the-FDA as a

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[150] *D'Agostino*, 845 F.3d at 3, 10; *Campie*, 862 F.3d at 909.

[151] *D'Agostino*, 845 F.3d at 7; *Campie*, 862 F.3d at 905; *see* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190 (2016) (discussing implied certification theory); United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1160, 1173 (9th Cir. 2006) (discussing promissory fraud).

[152] *D'Agostino*, 845 F.3d at 8.

[153] *See supra* notes 96–98and accompanying text.

[154] *D'Agostino*, 845 F.3d at 8–9.

[155] *Id.* at 8.

[156] *Campie*, 862 F.3d at 905.

[157] *Id.*

[158] *Id.* at 906.

[159] *Id.*

theory of liability.[160] Siding with the Ninth Circuit's affirmation of the fraud-on-the-FDA theory, the DOJ argued "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."[161] The DOJ's argument on how fraud-on-the-FDA can satisfy both the materiality and causal element of an FCA claim depends on an understanding of the FDA-FCA relationship not as antagonistic but as symbiotic.[162]

The DOJ's discussion of materiality suggests the FDA and the DOJ, as the policing agent of the FCA, work in tandem to police fraud involving both the FDA and federal healthcare programs.[163] According to the DOJ, "[i]n 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."[164] While this reliance is formally recognized in CMS's general requirement of FDA approval for payment, the DOJ's presentation clarifies that what is material to an FDA decision for approval is also material to a CMS decision for repayment.[165] Moreover, the DOJ does not view overlapping materiality as an issue: "that . . . deficiencies might separately violate FDA regulations does not preclude FCA liability arising from the claims for payment submitted for the affected products."[166] In other words, the DOJ can act even if FDA interests are implicated.

Similarly, the DOJ's explanation of how the causation element of the FCA is met in fraud-on-the-FDA claims further suggests cooperation between the DOJ and the FDA.[167] According to the DOJ, fraud-on-the-FDA can meet the causal requirement of an FCA claim because "[a] false statement that 'is integral to a causal chain leading to payment' may prompt FCA liability, even when the statement is not included in the actual claim for government funds."[168] Unlike the First Circuit, the DOJ does not view the extended connection between a false statement and ultimate government payment as a problem with causation or as encroachment on the FDA's territory precisely because the FCA is intended to reach "any person who knowingly assisted in causing the government to pay claims which were

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[160] *Statement of Interest Trividia Health*, *supra* note 29, at *4.
[161] *Id.*; *Campie*, 862 F.3d at 909.
[162] *Statement of Interest Trividia Health*, *supra* note 29, at *2–5.
[163] *Id.*
[164] *Id.* at *4.
[165] *Id.*; DEP'T HEALTH & HUM. SERVS., *supra* note 24.
[166] *Statement of Interest Trividia Health*, *supra* note 29, at *2–5.
[167] *Id.* at *3.
[168] *Id.* (citing United States *ex rel*. Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005)).

grounded in fraud."[169] Thus, according to the DOJ, the FCA cannot overreach its territory if it is being used to police fraud that caused governmental payments.[170]

The DOJ's understanding of the relationship between the FDA and the FCA draws from both implied certification theory and promissory fraud.[171] The DOJ's argument that that fraudulently obtaining FDA approval is material to the government's decision to pay when it involves issues with safety and efficacy can be understood in the context of implied certification theory: in fraudulently obtaining FDA approval, a drug or device manufacturer causes a healthcare provider who submits a claim for that drug or device to impliedly certify that the drug or device is safe and effective.[172] In addition, the DOJ's argument that a false statement used to obtain FDA approval can serve as the basis of an FCA claim because it is part of the causal chain leading to governmental payment can be understood in the context of promissory fraud: the initial fraud of obtaining FDA approval attaches to all subsequent claims based on that fraudulently obtained approval.[173] Concepts from the theories of promissory fraud and implied certification are crucial to the legal viability of fraud-on-the-FDA.[174]

Based on an understanding of the relationship between the FDA and the FCA as cooperative and on the concepts introduced through the theories of promissory fraud and implied certification, the Ninth Circuit and the DOJ are correct: fraud-on-the-FDA is a viable theory of liability under the FCA and does not encroach on the FDA's enforcement territory.

II. VIABILITY OF FRAUD-ON-THE-FDA AS A LEGAL THEORY OF LIABILITY

The First and Ninth Circuits identify issues with two FCA elements in fraud-on-the-FDA claims: causation and materiality.[175] Although the First Circuit argues that the causation element cannot be met in fraud-on-the-FDA claims without FDA withdrawal of the drug or device in question, this view

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[169] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 8 (1st Cir. 2016); *Statement of Interest Trividia Health*, *supra* note 29, at *3 (citing United States *ex rel.* Marcus v. Hess, 317 U.S. 537, 544–45 (1943),).

[170] *Statement of Interest Trividia Health*, *supra* note 29, at *3.

[171] *Id.* at *2–5; *see* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190 (2016); United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1160, 1173 (9th Cir. 2006).

[172] *Statement of Interest Trividia Health*, *supra* note 29, at *4; s*ee Escobar*, 579 U.S. at 190.

[173] *Statement of Interest Trividia Health*, *supra* note 29, at *3; *see Hendow*, 461 F.3d at 1173.

[174] *Statement of Interest Trividia Health*, *supra* note 29, at *3–4; *Hendow*, 461 F.3d at 1173; *Escobar*, 579 U.S. at 190.

[175] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 3, 10 (1st Cir. 2016); United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 909 (9th Cir. 2017)..

conflates the purposes of the FDA and the FCA.[176] Claims using the theory of fraud-on-the-FDA can satisfy the element of causation by borrowing the concept of tracing fraud from an originally fraudulent submission from the theory of promissory fraud or the concept of ongoing fraud through continual noncompliance from implied certification theory.[177] To satisfy the element of materiality, the relator cannot depend on CMS's requirement of FDA approval for reimbursement.[178] While this condition of payment will help a fraud-on-the-FDA claim survive the pleading stage, to prove the element of materiality, the relator must have additional evidence showing that false statements made to the FDA were material to CMS's decision to pay.[179] Thus, although proving materiality may be difficult depending on the factual information available, fraud-on-the-FDA is a legally viable form of liability under the FCA.

A. The Problem of Causation

The theory of fraud-on-the-FDA can satisfy the FCA element of causation by using the concept of fraud tracing from the theory of promissory fraud or the concept of ongoing fraud from the implied certification theory. Causation, the fourth element of an FCA claim, requires the relator or government to show that the fraudulent statement or omission caused the government to pay out money or forfeit money due.[180] Although the First Circuit rejected the theory of fraud-on-the-FDA based on this element, identifying continued approval by the FDA as a break in the chain of causation,[181] the Ninth Circuit does not recognize causation as a barrier to FCA liability regardless of the FDA's action.[182] A fraud-on-the-FDA claim, therefore, should not invariably fail on the element of causation without FDA action against the drug or device in question because the FDA's continued approval does not negate fraud or the chain of causation, which ultimately leads to CMS payment.[183]

The First Circuit rejected fraud-on-the-FDA because the causal link was too tenuous.[184] According to the court, the complaint could not survive a

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[176] *D'Agostino*, 845 F.3d at 7–8; *see* 31 U.S.C. § 3729(a)(1); U.S. DEP'T JUST., *supra* note 35 (explaining the purpose of the FCA); *see supra* note 9198 and accompanying text (explaining the purpose of the FDA).

[177] *See Escobar*, 579 U.S. at 190 (discussing implied certification theory); *Hendow*, 461 F.3d at 1173 (discussing promissory fraud).

[178] *See infra* notes 228–231and accompanying text.

[179] *See infra* notes 228–231and accompanying text.

[180] Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 788 (4th Cir. 1999); *Campie*, 862 F.3d at 899.

[181] *D'Agostino*, 845 F.3d at 8, 10.

[182] *Campie*, 862 F.3d at 902.

[183] *See infra* notes 199–204and accompanying text.

[184] *D'Agostino*, 845 F.3d at 8, 10.

motion to dismiss because it did not allege that the fraudulent submissions to the FDA caused the FDA to grant approval.[185] Even if a fraudulent statement or omission actually caused the FDA to grant approval, the causal link between a fraudulent submission to the FDA and a CMS payment is broken, according to the First Circuit, if the FDA does not withdraw approval.[186] The FDA's failure to recall or relabel the medical devices in question, despite the agency's "option to impose postapproval requirements[,] . . . clear prerogative to suspend approval temporarily[,] . . . [and] broad authority to withdraw approval," is evidence to the First Circuit that the false or misleading application information did not actually cause the FDA to approve the medical devices.[187] The First Circuit did not decide whether the causation problem would be sufficiently cured by an official FDA statement confirming the approval was procured by the alleged fraudulent representations.[188] Thus, under this reasoning, fraud-on-the-FDA cannot be viable as a theory of liability unless the FDA withdraws approval or makes an official statement concerning the approval of the drug or device in question.[189]

Unlike the First Circuit, the Ninth Circuit thought it a mistake to rely on the FDA's continued approval as evidence that the relator has failed to state a claim.[190] Such reliance not only would allow pharmaceutical and medical device companies to use fraudulently-obtained FDA approval as a shield from fraud liability but would also incorrectly assume that the FDA's decision to withdraw a drug or device is intertwined with a concern about the government's ultimate payment for the drug or device.[191]

The Ninth Circuit's hesitance to rely on the FDA's lack of withdrawal or official statement as a death knell for the causation element of an FCA claim seems to be a prudent choice given that the FDA is more

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[185] *Id.* at 7.
[186] *Id.* at 8.
[187] *Id.*
[188] *Id.* at 9.
[189] *Id.* at 8–9.
[190] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 906 (9th Cir. 2017). Interestingly, the Ninth Circuit does not directly discuss causation in its fraud on the FDA case. *Id.* at 902. The court does, however, discuss the effect of the FDA's continued approval of pharmaceutical products in question on the survival of the relator's complaint, but this discussion is in relation to the FCA element of materiality. *Id.* at 906. The difference in classification may reflect the Ninth Circuit's labeling of the FCA elements: the third element for the Ninth Circuit is the statement "was material, causing," which lumps materiality and causation together. *Id.* at 902. However, it is unlikely that the Ninth Circuit overlooked causation altogether, as it is required under the federal statute. 31 U.S.C. § 3729(a)(1). FDA approval is also relevant to a claim's materiality, as will be discussed in the following section, but the Ninth Circuit's argument about continued FDA approval is addressed here, as it aligns with the First Circuit's causation argument. *Campie*, 862 F.3d at 906; United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 7–8 (1st Cir. 2016).
[191] *Campie*, 862 F.3d at 906.

focused on corrective action to ensure compliance and promote public health than on punishment.[192] In some situations, the FDA may choose not to withdraw a drug or device because the fraudulent or misleading statement has been corrected or is no longer relevant.[193] For example, although Gilead misled the FDA into thinking it was using approved manufacturing facilities when it was using the unapproved Synthetics China facility from 2007 to 2010 and then submitted false statements to have Synthetics China approved by the FDA in 2010, Gilead stopped using Synthetics China as a supplier in 2011.[194] In fact, the FDA has a built-in safety valve for pharmaceutical and medical device companies to develop a corrective action operating plan upon an FDA finding of fraud.[195] In other situations, FDA withdrawal may cause public health crises that the agency would consider more harmful than government overpayment.[196] For example, if the FDA were to withdraw Gilead's anti-HIV drug therapies at the first sign of fraud, the agency may cause a supply shortage for HIV-positive patients given the large market share of Gilead's antiretrovirals.[197] Thus, the First Circuit's focus on continued FDA approval in judging the causation element of an FCA claim is misplaced because it overlooks the agency's regulatory goals.[198]

Moreover, the Ninth Circuit's discussion of a fraud-on-the-FDA claim in the context of implied false certification suggests that the causal link between a fraudulent FDA application submission and CMS payment is much tighter than the First Circuit understands it to be.[199] As noted by the Ninth Circuit, the HHS Secretary oversees both the FDA and CMS; therefore, in the context of a fraud-on-the-FDA claim, "the fraud was, at all times, committed against the Department of Health and Human Services."[200] In addition, the FCA does not distinguish between governmental agencies in its concern with the connection between regulatory omissions and claims for payment.[201] As long as the false statement "is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has

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[192] Girard, *supra* note 49, at 128–29.

[193] *See generally Campie*, 862 F.3d at 896.

[194] *Id.*

[195] CTR. DRUG EVALUATION & RSCH., OFF. REG. POL'Y, CPG § 120.100, FRAUD, UNTRUE STATEMENTS OF MATERIAL FACTS, BRIBERY, AND ILLEGAL GRATUITIES (1991).

[196] *See* Girard, *supra* note 49, at 128–29.

[197] *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 18.

[198] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 8, 10 (1st Cir. 2016).

[199] *Campie*, 862 F.3d at 903; *D'Agostino*, 845 F.3d at 8, 10.

[200] *Campie*, 862 F.3d at 903. The FDA and CMS also agreed to work together in 2010 to promote initiatives related to the review and use of FDA-regulated drugs, biologics, and medical devices. U.S. FOOD & DRUG ADMIN., DOMESTIC MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD & DRUG ADMIN. AND THE CTR. FOR MEDICARE & MEDICAID SERVS. TO PROMOTE INITIATIVES RELATED TO THE REVIEW AND USE OF FDA-REGULATED DRUGS, BIOLOGICS, MEDICAL DEVICES, AND FOODS, INCLUDING DIETARY SUPPLEMENTS, AS DEFINED BY THE FED. FOOD, DRUG & COSMETIC ACT AND THE PUBLIC HEALTH SERV. ACT (June 25, 2010).

[201] *Campie*, 862 F.3d at 903.

apportioned the statements among layers of paperwork."[202]

The causation element could be cured by the Ninth Circuit's connection between fraud-on-the-FDA and promissory fraud.[203] Under promissory fraud, liability attaches "to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct."[204] Subsequent claims are false because the contract or extension of the government benefit they fall under was originally obtained through fraud.[205] In other words, the original fraud taints subsequent related claims.[206]

Although the Ninth Circuit's classification of fraud-on-the-FDA under the umbrella of promissory fraud may help cure the theory's problem satisfying causation, courts who view CMS and the FDA as two separate agencies rather than two related subagencies of HHS may not be convinced.[207] In fact, promissory fraud typically involves continual submissions of claims under one governmental contract obtained through fraud.[208] The government agreement obtained through fraud in fraud-on-the-FDA concerns FDA approval, not CMS payment for the drug or device submitted for FDA approval.[209] While CMS reimbursement does implicate FDA approval through the conditions of payment, CMS claims are not claims submitted under the original "contract" of FDA approval.[210]

However, even if courts refuse to transfer the concept of fraud tracing from the theory of promissory fraud to fraud-on-the-FDA, they may be willing to borrow the idea of ongoing fraud from the implied certification theory.[211] The implied certification theory implicates parties who make or cause others to make specific representation to the government for payment while knowingly failing to disclose noncompliance with statutory,

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[202] United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1160, 1174 (9th Cir. 2006); *see* United States *ex rel.* Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005).

[203] *Campie*, 862 F.3d at 902, 904.

[204] *Hendow*, 461 F.3d at 1173; *see* United States *ex rel.* Marcus v. Hess, 317 U.S. 537 (1943) (for an explanation of subsequent treatment of *Hess*, see *supra* note 81).

[205] *Hendow*, 461 F.3d at 1173.

[206] *See id.*

[207] Some scholars have raised concerns about collaboration between the FDA and CMS. *See* Stanley S. Wang & John J. Smith, *Potential Legal Barriers to Increasing CMS/FDA Collaboration: The Law of Trade Secrets and Related Considerations*, 58 FOOD & DRUG L. J. 613, 613–14 (2003). The 2010 Domestic Memorandum of Understanding between the FDA and CMS also recognizes that either agency can decide not to share information or expertise in response to a particular request, which suggests the agencies understand and value their separate identities and domains. U.S. FOOD & DRUG ADMIN., *supra* note 200.

[208] *Hendow*, 461 F.3d at 1173–74.

[209] *See* United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 904 (9th Cir. 2017); United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016) (noting that the FDA made none of the payments at issue in the lawsuit).

[210] *See supra* note 70 and accompanying text.

[211] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190 (2016).

regulatory, or contractual requirements.[212] Each time a provider submits a reimbursement claim to CMS for a drug or device, the provider impliedly certifies the drug or device is FDA approved, as that is a condition of payment.[213] However, because FDA approval for a drug or device was obtained with a false or fraudulent statement, the drug or device to be reimbursed did not comply with the FDA approval process.[214] Thus, it is possible to say the drug or device is in noncompliance with a regulatory requirement and that the original pharmaceutical or medical device company is causing claims for noncompliant drugs or devices.[215]

Therefore, as suggested by the Ninth Circuit, the concept of tracing fraud from an original fraudulent submission recognized in promissory fraud and the concept of impliedly certifying compliance could be applicable to the theory of fraud and fraud-on-the-FDA.[216] Borrowing from promissory fraud, the causal chain in fraud-on-the-FDA claims would start with the original false or fraudulent submission to the FDA and continue through all claims for government reimbursement involving the approved drug or device.[217] If the fraud is present in the original approval process, it would attach to each claim made for the drug or device with fraudulently-obtained FDA approval.[218] Similarly, as with implied certification theory, the causal chain would follow noncompliance.[219] If the original FDA approval submission was false or fraudulent, it does not comply with FDA regulations.[220] Thus, the drug or device with the resulting FDA approval would continually be in noncompliance.[221] By its false or fraudulent actions, therefore, the drug or device company would knowingly cause providers to submit claims for reimbursement that impliedly certify compliance.[222]

The First Circuit's issue with causation is misplaced, as it overlooks the FDA's regulatory goals, ignores the connection between the FDA and CMS under HHS, and eschews attempting to trace fraud from an originally fraudulent submission or characterizing noncompliance with FDA approval processes as ongoing fraud.

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[212] *Id.*
[213] *See id.*; *supra* note 70 and accompanying text.
[214] *See Escobar*, 579 U.S. at 190.
[215] *See id.*
[216] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 902 (9th Cir. 2017).
[217] *See supra* text accompanying notes 207–210.
[218] *See supra* text accompanying notes 207–210.
[219] *See Escobar*, 579 U.S. at 190.
[220] 21 U.S.C. § 331(y)(1).
[221] *See id.*; *Escobar*, 579 U.S. at 190.
[222] *See Escobar*, 579 U.S. at 190.

B. The Problem of Materiality

Although both the First and Ninth Circuits mention that fraud-on-the-FDA claims may have trouble meeting the FCA element of materiality,[223] a relator or the DOJ can satisfy the element by demonstrating two concepts. First, that federal healthcare programs require the FDA to reimburse claims for pharmaceutical drugs or medical devices. Second, that the false or fraudulent statement in question was critical to either the FDA's decision to approve or CMS's decision to reimburse subsequent claims.

According to the FCA, a material statement is one that "has a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[224] To prove materiality, the government or relator must demonstrate that the false or fraudulent statement is more than a garden-variety breach and is not minor nor insubstantial.[225] Federal healthcare programs, including Medicare and Medicaid, will reimburse providers for pharmaceutical products and medical devices that have FDA approval or clearance, are reasonable and necessary for medical care, and meet any other pertinent regulations.[226] Although this suggests any false or fraudulent statements related to these payment requirements would be material to the government's decision to pay, the Supreme Court has determined such statements are relevant but not dispositive of materiality.[227]

To prove materiality, the government or relator must have something beyond a problem with the payment requirements, such as "evidence that the defendant knows that the government consistently refuses to pay [similar] claims."[228] Evidence against materiality could include the government paying a particular claim in full despite knowledge that payment requirements were violated or the government regularly paying such claims in the same situation.[229] Therefore, proving materiality in the context of a fraud-on-the-FDA claim requires more than just pointing to CMS's reimbursement requirement of FDA approval.[230] According to the Supreme Court in *Escobar*, "[t]he materiality standard is demanding."[231]

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[223] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016); United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 905 (9th Cir. 2017).
[224] 31 U.S.C. § 3729(b)(4).
[225] *Escobar*, 579 U.S. at 194.
[226] U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 24.
[227] *Escobar*, 579 U.S. at 194.
[228] *Id.*
[229] *Id.*
[230] *See id.*
[231] *Escobar*, 579 U.S. at 194.

Both the First and Ninth Circuits mention the problems relators bringing fraud-on-the-FDA cases will face in proving materiality.[232] According to the First Circuit, "the fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations D'Agostino alleges."[233] The Ninth Circuit expresses similar skepticism that the relator will be able to meet the materiality standard.[234] The three Gilead drugs in question were FDA-approved and the government continued to make direct payment and provide reimbursements for the sale of the drugs.[235] Such information is evidence against the materiality of the false or fraudulent statements to the government's decision to pay.[236]

Nonetheless, although difficult to prove, the element of materiality can be met with a fraud-on-the-FDA claim. Neither the First nor the Ninth Circuit dismissed the relators' claims because of materiality; they merely suggested the relators may have trouble proving materiality.[237] In all fraud-on-the-FDA claims, the government or relator already begins with information tending to show materiality because FDA approval is required for reimbursement through governmental health programs.[238] However, to satisfy materiality, the government or relator must demonstrate something more, such as CMS denying claims for similar drugs due to lack of compliance with an FDA regulation or due to loss of FDA approval.[239]

The government or relator can also include evidence from the FDA approval process to satisfy materiality.[240] Although critics of fraud-on-the-FDA may argue materiality to the FDA in the approval process and materiality to federal healthcare programs in payment decisions are separate, the concepts of fraud tracing and ongoing fraud from the affirmed theories of promissory fraud and implied certification suggest that the FCA does not consider the temporal or agential separation important.[241] Under promissory fraud, if a contract or extension of the government benefit was originally obtained through false or fraudulent statements, that fraud attaches to

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[232] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016); United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 905 (9th Cir. 2017).

[233] *D'Agostino*, 845 F.3d at 7.

[234] *Campie*, 862 F.3 at 905.

[235] *Id.*

[236] *Id.*

[237] *D'Agostino*, 845 F.3d at 7; *Campie*, 862 F.3d at 905.

[238] U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 24; Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 194 (2016).

[239] *See Escobar*, 579 U.S. at 194.

[240] *See generally id.* (providing examples of how to satisfy the element of materiality beyond the requirements for payment).

[241] *See* United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1160, 1173 (9th Cir. 2006); *Escobar*, 579 U.S. at 190.

subsequent claims; the materiality is measured at the original fraud, not the subsequent payment.[242] Although fraud-on-the-FDA is a different theory of liability than promissory fraud, there is no reason why materiality cannot also draw evidence from the original fraud, which occurs during the FDA approval process.[243] Using the concept of ongoing fraud from the implied certification theory and the Ninth Circuit's application of it to a fraud-on-the-FDA claim, the fraud is considered, at all times, to be committed against HHS, which includes both CMS and the FDA.[244] Separating the agencies out to argue that something material to the FDA's approval decision is not material to a CMS decision that depends on the FDA's decision does not make sense.[245]

Details from the DOJ's settlement with AngioDynamics provides an example of how the element of materiality may be satisfied with information from the FDA approval process.[246] According to the DOJ's 2018 press release announcing AngioDynamics's settlement payment of $12.5 million, AngioDynamics requested FDA approval for PVAK for use in perforator veins.[247] Although PVAK was already cleared by the FDA for use in treating superficial veins, the safety and efficacy for the newly requested indication were unknown.[248] The FDA refused the request for lack of data.[249] However, AngioDynamics instructed sales personnel to market PVAK to treat perforator veins.[250] Although the interaction between AngioDynamics and the FDA directly relates to materiality in FDA approval, information showing the FDA's response to a particular submission could provide circumstantial evidence that the information submitted to or withheld from the FDA was material to the federal healthcare programs' decisions to pay.[251]

Thus, for the government or a relator to succeed on a fraud-on-the-FDA claim, the FCA materiality element needs support beyond the federal healthcare program payment requirement that pharmaceutical products and medical devices be FDA approved.[252] Although gathering additional support may be difficult, especially if a federal healthcare program continues to pay

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[242] *Hendow*, 461 F.3d at 1173.

[243] *See id.*

[244] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 903 (9th Cir. 2017).

[245] *See generally id.* (discussing fraud as against HHS, not the FDA and CMS separately).

[246] *Medical Device Maker AngioDynamics Agrees to Pay $12.5 Million to Resolve False Claims Act Allegations*, U.S. DEP'T JUST. (July 18, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/july-18-2018-medical-device-maker-angiodynamics-agrees-pay-125-million-resolve-false-claims-act.

[247] *Id.*

[248] *Id.*

[249] *Id.*

[250] *Id.*

[251] *See id.*

[252] *See supra* text accompanying note 239.

for the product or device in question, courts should not use such difficulty to preclude fraud-on-the-FDA claims.[253]

Although fraud-on-the-FDA may be legally viable with respect to both the causation and materiality elements of the FCA, the government or relator must have enough information for the complaint to successfully survive the pleading stage.[254] Courts apply heightened pleading standards for fraud claims, which applies to any claims under the FCA.[255] Because of these standards and their variable applications, claiming fraud-on-the-FDA under the FCA faces challenges at the pleading stage.

C. Can Fraud-on-the-FDA Survive FCA Pleading Standards?

Claims using the theory of fraud-on-the-FDA can survive the heightened pleading standards applied to FCA claims if they are plausible and pled with particularity.[256] The question of whether fraud-on-the-FDA is a viable form of liability under the FCA is also a question of whether fraud-on-the-FDA can survive the pleading standards for an FCA claim. In fact, both the First Circuit and the Ninth Circuit cases were appeals from the district courts' dismissals of the relators' complaints for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).[257] FCA claims, because they involve allegations of fraud, are governed by Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure.[258] Even with the heightened pleading standards applied to FCA claims, however, complaints alleging FCA violations under the theory of fraud-on-the-FDA can survive 12(b)(6) motions.

The general pleading standard, set forth in Federal Rule of Civil Procedure 8(a), requires "a short and plain statement showing that the pleader is entitled to relief."[259] The complaint must "state a claim to relief that is plausible on its face," meaning the claim is supported by sufficient factual allegations that give rise to a reasonable inference of liability when taken as true.[260] In other words, the complaint must "give enough details about the

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[253] *See* United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 905 (9th Cir. 2017); Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 194 (2016).

[254] *See* discussion *infra* Section II.C.

[255] *See infra* text accompanying notes 262–266.

[256] *See* Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

[257] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 3 (1st Cir. 2016); *Campie*, 862 F.3d at 895. The Ninth Circuit did not address whether the relator's complaint met the Rule 9(b) standards because the district court based its dismissal on Rule 12(b)(6) without considering Rule 9(b). *Campie*, 862 F.3d at 989.

[258] FED. R. CIV. P. 8(a), 9(b); *see Campie*, 862 F.3d at 898; *D'Agostino*, 845 F.3d at 10.

[259] FED. R. CIV. P. 8(a)(2).

[260] *Ashcroft*, 556 U.S. at 678.

subject-matter of the case to present a story that holds together."[261]

Claims concerning fraud, however, are also subject to a heightened pleading standard.[262] Federal Rule of Civil Procedure 9(b) requires the complainant to plead the circumstances constituting fraud with "particularity."[263] Pleading the who, what, when, where, and how of the fraud meets this standard.[264] Rule 9(b)'s particularity requirement is relaxed, however, for "malice, intent, knowledge, and other conditions of a person's mind."[265] These elements can be "alleged generally," meaning they follow the Rule 8(a) standard.[266]

The First Circuit, in requiring a showing at the pleading stage that the FDA actually withdrew approval, asked for a higher standard than even the 9(b) heightened standard.[267] The complainant need only to plead each element with particularity, not prove that a fraudulent action led to a specific result.[268] The complainant must, however, avoid the issue of *Twombly*: the

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[261] Swanson v. Citibank, N.A., 614 F.3d 400, 404 (7th Cir. 2010).

[262] FED. R. CIV. P. 9(b). Two circuit splits exist regarding how the 9(b) pleading standards should be applied to the FCA. *See* United States *ex rel.* Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 228 (1st Cir. 2004); United States *ex rel.* Prather v. Brookdale Senior Living Communities, Inc., 838 F.3d 750, 769 (6th Cir. 2016); United States *ex rel.* Polansky v. Exec. Health Res., Inc., 196 F.Supp.3d 477, 494 (E.D. Penn. 2016). One circuit split concerns whether the 9(b) rules should be relaxed for information within the possession and control of the other party that is not already considered a condition of the person's mind. *Karvelas*, 360 F.3d at 228. While some circuits allow such information to be pled on information and belief, others either do not relax the standard or allow the complainant to plead the information generally at the outset and then later amend the complaint after discovery. *Id.; see* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir.1997); United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1314 (11th Cir. 2002). The second circuit split concerns the level of detail required for false claims allegedly submitted to the government for payment. *Prather*, 838 F.3d at 769; *Polansky*, 196 F.Supp.3d at 494. Although the circuits do not exactly fall into two camps, one group allows a complainant to plead either specific false claims or specific facts that lead to a strong inference that the claim was submitted. *Prather*, 838 F.3d at 769. Another group of circuits requires a complainant to plead particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted. *Polansky*, 196 F.Supp.3d at 494. In October 2022, the Supreme Court denied certiorari to clarify the pleading standard to resolve the second circuit split. Johnson v. Bethany Hospice & Palliative Care LLC, 853 Fed. Appx. 496 (11th Cir. 2021), *cert. denied*, 143 S. Ct. 351 (2022); United States *ex rel.* Owsley v. Fazzi Assocs., 16 4th 192 (6th Cir. 2021), *cert. denied*, 143 S. Ct. 362 (2022); United States v. Molina Healthcare of Ill., Inc., 17 F.4th 733 (7th Cir. 2021), *cert. denied*, 143 S. Ct. 352 (2022).

Neither circuit split would cause a claim using the theory of fraud-on-the-FDA to fail based on the theory of liability itself. Although the circuits that relax the 9(b) standards for information within the possession and control of an opposing party may also relax the standards if the information were in the possession and control of the FDA, there is no indication that the relaxed standards would apply to a third party. *See Thompson*, 125 F.3d at 903; *Clausen*, 290 F.3d at 1314. Moreover, the second split, although related to causation, is more concerned with whether the false claims were actually submitted for payment. *See Prather*, 838 F.3d at 796; *Polansky*, 196 F.Supp.3d at 484. While that element may be an issue for a fraud-on-the-FDA claim, it has nothing to do with the theory of liability, which has unique issues with causation and materiality, and thus will not be addressed in this Note. *See Prather*, 838 F.3d at 796; *Polansky*, 196 F.Supp.3d at 484.

[263] FED. R. CIV. P. 9(b).

[264] DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 2009).

[265] FED. R. CIV. P. 9(b).

[266] *Id.*; Ashcroft v. Iqbal, 556 U.S. 662, 688 (2009).

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

[268] *Id.*; FED. R. CIV. P. 9(b).

details pled must be such that, taken as true, it is plausible that the elements of the FCA could be met.[269] In other words, the complaint cannot just be particular, as required by 9(b),[270] and plausible, as required by 8(a),[271] it must place facts in a context that raises a suggestion that the details of the complaint are true.[272] The First Circuit's request for a showing of FDA withdrawal may indicate the court saw a *Twombly* problem, but requiring a specific fact to prove causation goes beyond the *Twombly* requirement that the complaint suggest the alleged causation is true.[273]

Although the First and Ninth Circuits noted that claims using the theory of fraud-on-the-FDA would have issues proving materiality, neither circuit suggested such claims would have issues passing the pleading stage due to lack of information on materiality.[274] Pleading that FDA approval is a condition of payment for federal healthcare programs may meet the pleading requirement on its own, as it is relevant, although not dispositive of, materiality.[275] In fact, in *Escobar*, the respondents did not have information beyond conditions of payment to prove materiality, but the Supreme Court stated that they "may well have adequately pleaded a violation" of the FCA.[276] However, because the relator or government will need evidence beyond the federal healthcare programs' payment requirements to prove materiality, it would be best practice to include details showing something beyond conditions of payment.[277]

Thus, while not all fraud-on-the-FDA claims will survive the pleading stage, the theory of liability itself should not bar the claim if the claimant pleads facts with particularity that make it plausible the elements of the FCA can be met.[278]

Legally, the fraud-on-the-FDA theory is viable as an FCA claim because the theory can meet the heightened Rule 9(b) pleading standards[279] and satisfy the FCA elements of causation[280] and materiality.[281]

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[269] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007).
[270] *Id.* at 556–57.
[271] *Id.*
[272] *Id.* at 557.
[273] *D'Agostino*, 845 F.3d at 8. *Twombly*, 550 U.S. at 556.
[274] *D'Agostino*, 845 F.3d at 7; United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 905 (9th Cir. 2017).
[275] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 194 (2016).
[276] *Id.* at 196.
[277] *See id.* at 194.
[278] FED. R. CIV. P. 8(a), 9(b); *Twombly*, 550 U.S. at 556; Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).
[279] *See* discussion *supra* Section II.C.
[280] *See* discussion *supra* Section II.A.
[281] *See* discussion *supra* Section II.B.

II. FRAUD ON THE FDA IN CONTEXT

Although deferring to the FDA to police fraudulent statements made during the FDA approval process has the benefit of flexibility and would potentially avoid a chilling effect on disclosures made to the FDA, affirming fraud-on-the-FDA would give the government a wider reach in policing healthcare fraud and potentially in lowering the nation's healthcare costs. While the previous section considered whether the theory of fraud-on-the-FDA *could* survive given the legal constraints,[282] this section will consider whether it *should* survive in the context of external factors.[283] Subsection A will discuss the problems of using the FDA for enforcement activity, including the agency's enforcement underperformance and overuse of warning letters in place of stricter penalties.[284] Subsection B will discuss the benefits of allowing the DOJ and private individuals to police FDA-related fraud through the FCA.[285] Subsection C will discuss the limitations of the theory of fraud-on-the-FDA,[286] while subsection D will introduce possible implications of the theory's adoption.[287]

A. The Problems of Deferring to the FDA for Enforcement of Fraud

Although deferring to the FDA for enforcement of fraud on the agency allows for greater flexibility and more cooperation with pharmaceutical and medical device companies, the FDA's enforcement activities are chronically underactive and fall short of holding fraudulent conduct accountable.

As mentioned above, the FDA has the power to investigate and penalize fraudulent behavior.[288] The FDCA grants the agency authority to investigate misleading or fraudulent submissions to the agency, with a specific provision aimed at "detecting, deterring, and punishing false statements made during . . . [the] approval process."[289] Private citizens can report wrongdoing to the FDA to facilitate the investigative process.[290] When

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[282] *See* discussion *supra* Section II.
[283] *See* discussion *infra* Section III.
[284] *See* discussion *infra* Section III.A.
[285] *See* discussion *infra* Section III.B.
[286] *See* discussion *infra* Section III.C.
[287] *See* discussion *infra* Section III.D.
[288] *See supra* text accompanying notes 94–98.
[289] 21 USCS § 337(a)(1)(A), § 331 (y)(1); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).
[290] *Reporting Allegations of Regulatory Misconduct*, FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct (last updated Sept. 14, 2021); *see*

the agency is notified of or suspects a wrongful act, its investigative unit, called the Office of Criminal Investigations (OCI), conducts inspections to verify the allegations and then submits recommendations for further action.[291] If certain criteria are met, such as evidence suggesting a company or individual engaged in a pattern or practice of wrongful conduct, the OCI can "initiate and monitor administrative and legal action(s)."[292] These administrative and legal actions are broad, ranging from sending warning letters[293] to imposing the more severe punishments of recalling products, withdrawing approval, imposing fines, or assigning criminal penalties.[294]

The FDA often eschews imposing harsh punishments in favor of working with medical device and pharmaceutical companies to correct any discovered violations.[295] According to the FDA's Regulatory Procedures Manual, "[w]hen it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the [FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates enforcement action."[296] The primary way the FDA encourages such voluntary corrective action is by sending warning letters.[297] While it may seem warning letters are only used for minor violations, especially with the backdrop of treble damages under the FCA, the agency issues warning letters only for violations of regulatory significance.[298] In fact, according to the most recently published report on FDA enforcement activity, the FDA heavily depends on warning letters and voluntary corrective action in enforcement.[299]

Warning letters can be successful in reversing violations. For example, when notified by a former employee that Omnicare, Inc. was violating FDA safety regulations requiring complete separation of packaging

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Sharkey, *supra* note 20, at 861; *Buckman*, 531 U.S. at 349. Unlike the FCA, the FDCA does not create a private right of action. *See* 21 U.S.C. § 337(a); Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., 48 F.4th 1040, 1050–51 (9th Cir. 2022).

[291] FOOD & DRUG ADMIN., APPLICATION INTEGRITY POLICY (1991).

[292] *Id.*

[293] FOOD & DRUG ADMIN., REGUL. PROCS. MANUAL, Ch. 4, § 4-1-1, 1, 3 (2022).

[294] 21 U.S.C. § 337(a); Sharkey, *supra* note 20, at 860.

[295] *See* United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014).

[296] FOOD & DRUG ADMIN., *supra* note 293.

[297] *Id.*

[298] *Id.*

[299] FOOD & DRUG ADMIN., FDA ENFORCEMENT STATISTICS SUMMARY FISCAL YEAR 2017 (2018), https://www.fda.gov/media/110196/download; *see Enforcement Activity*, FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/enforcement-activity (last updated Jan. 17, 2018) (listing available reports by year). The number of total warning letters is slightly misleading: of the 15,318 sent out in 2017, 14,875 were from the Center for Tobacco Products. FOOD & DRUG ADMIN., FDA ENFORCEMENT, *supra*. Two hundred ten were from the Center for Biologics Evaluation & Research, the Center for Devices & Radiological Health, and the Center for Drug Evaluation & Research, which are the organizations involved in approving medical devices, biologicals, and pharmaceutical products. *Id.*

of penicillin and non-penicillin productions, FDA agents inspected the Omnicare's facility twice and then issued a warning alerting Omnicare that it was failing to adhere to the Current Good Manufacturing Practice regulation.[300] Omnicare corrected the problem by disposing of $19 million worth of inventory.[301]

However, especially in the case of fraud, enforcement letters lack teeth. If an individual or firm is unable or unwilling to correct a violation, the agency can consider whether to take further action, meaning it need not take any action at all.[302] According to a report conducted by the Office of Inspector General on warning letters, the effectiveness of these letters depends on the agency's conscientious follow-up.[303] If the agency does decide to act, its options are broad, ranging from issuing a second warning letter to ensure notice has been given to requesting or mandating a recall.[304]

While such corrective action forwards the FDA's policy of regulating the safety, efficacy, and security of drugs, biological products, and medical devices,[305] it fails to hold pharmaceutical and medical device companies accountable for violations even when the issues are intentional. The FDA's focus on safety, efficacy, and security rather than accountability is reflected in the main topics of warning letters: between 2010 and 2020 the most common reasons for warning letters sent to pharmaceutical companies were misbranding and compliance with the FDA's Current Good Manufacturing Practice regulations.[306] While ensuring drug and device safety, efficacy, and security is essential,[307] if the FDA is the only agency able to police fraud, the current enforcement activity seems woefully inept at holding an industry that makes trillions of dollars in profits accountable for serious violations.[308]

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[300] United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694, 697–98.

[301] *Id.* at 698.

[302] OFF. INSPECTOR GEN., DEP'T HEALTH & HUM. SERVS., FDA WARNING LETTERS TIMELINESS AND EFFECTIVENESS, OEI-09-97-00381 1, 12 (Feb. 1999), https://oig.hhs.gov/oei/reports/oei-09-97-00381.pdf.

[303] *Id.* at 8.

[304] *Id.*

[305] *See Federal Food, Drug, and Cosmetics Act*, *supra* note 91.

[306] Anurag S. Rathore et al., *FDA Warning Letters: A Retrospective Analysis of Letters Issues to Pharmaceutical Companies from 2010-2020*, J. PHARM. INNOVATIONS 1, 8 (2022).

[307] *See* Carrie Scrufari James, *FDA's Homeopathic Risk-Based Enforcement: Compromised Consumer Protection or Stepped-Up Scrutiny?*, 70 SYRACUSE L. REV. 1115, 1120–21 (2020) (discussing problems with medications outside the regulatory authority of the FDA). *See generally Part I: The 1906 Food and Drugs Act and Its Enforcement*, FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement (last updated Apr. 24, 2019) (discussing the 1906 Food and Drugs Act, a precursor to the statutes that created the FDA); UPTON SINCLAIR, THE JUNGLE (Oxford Univ. Press 2010) (1906) (describing the health and safety situation at a meat packing plant before the FDA-like regulations in gruesome detail).

[308] *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 J. AM. MED. ASS'N. 834, 837 (2020) (finding that, from 2000 to 2018, 35 large pharmaceutical companies made $8.6 trillion in gross profit).

Moreover, in addition to enforcing in ways that rarely hold companies accountable for violations, research suggests the FDA is underperforming overall as a policing agency.[309] According to Catherine Sharkey, "a wide discretionary berth separates the FDA's formal powers and actual enforcement activity."[310] The FDA's enforcement of required postapproval studies provides an example of this discrepancy.[311] In 2007, the FDA gained the authority to require companies to complete studies or commitments after gaining approval for a drug or device.[312] However, of the 614 postapproval studies and commitments assigned to companies in 2009 and 2010, only 54% had been completed.[313] Twenty percent had not been started, and 25% were delayed or ongoing.[314] Although many of the drugs and devices subject to postapproval studies were only conditionally approved and needed further assessment to determine benefits, the FDA had not implemented mechanisms, such as fines or penalties, to ensure companies met deadlines.[315] While following up on postapproval studies is not the same as policing fraud, this performance indicates that enforcement may not be a top priority for the FDA.[316]

Scholars disagree over the reasons for this discrepancy. In the late-1990s, less than a decade after the creation of OCI, the FCA likely did not have adequate resources for enforcement.[317] By 2016, however, OCI's annual budget reached $77.3 million,[318] which suggests, even with increasing globalization of crime and new cybersecurity challenges,[319] resources are not the cause of the enforcement problems. Some scholars believe mismanagement is the culprit, with managers prioritizing cases that lack merit.[320] Politics may also play a role: the average number of FDA warning letters sent per year varies with the presidency.[321] From former President Obama's last year in office to the first year of former President Trump's term,

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[309] *See* Sharkey, *supra* note 20.
[310] *Id.* at 860.
[311] Steven Woloshin et al., *The Fate of FDA Postapproval Studies*, 377 NEW ENG. J. MED. 1114, 1114 (2017).
[312] *Id.*
[313] *Id.*
[314] *Id.*
[315] *Id.* at 1116.
[316] *Id.*; *see* Sharkey, *supra* note 20.
[317] Green, *supra* note 21, at 476.
[318] Lynch, *supra* note 104.
[319] *See* FOOD & DRUG ADMIN., *supra* note 88; FOOD & DRUG ADMIN. OFF. CRIM. INVESTIGATIONS PUB. AFF., *FDA Office of Criminal Investigations*, FED. L. ENFORCEMENT TRAINING CTR. (Feb. 22, 2019), https://www.fletc.gov/press-release/fda-office-criminal-investigations.
[320] Garver, *supra* note 105. *See generally* Estes, *supra* note 105.
[321] Diane Nguyen et al., *Changes in FDA Enforcement Activities Following Changes in Federal Administration: The Case of Regulatory Letters Released to Pharmaceutical Companies*, 13 BMC HEALTH SERV. RES. 1 (2013) (finding the average number of regulatory letters per year was 242.8 during the Clinton administration, 120.4 during the Bush administration, and 177.7 during the first three years of the Obama administration).

the number of sent letters decreased by one-third.[322] Regardless of the reason, even with policing authority, the FDA's enforcement activity is lackluster and variable.[323]

Thus, although enforcement by the FDA allows for flexibility and cooperation with pharmaceutical and medical device companies,[324] the agency's enforcement activities do not live up to its enforcement power and are unlikely to fully police fraudulent and false submissions during the approval process.[325] The DOJ and private individuals can close the gap by bringing claims under the FCA using the theory of fraud-on-the-FDA.[326]

B. Benefits of Using the FCA to Police FDA Fraud

While FDA-led regulation may allow for flexibility, affirming fraud-on-the-FDA would invite investigative actions from the DOJ and reports from relators, leading to wider fraud enforcement.[327] Moreover, although courts and scholars have cautioned that affirming fraud-on-the-FDA would allow the DOJ to wade into the FDA's regulatory regime, the DOJ has already demonstrated it can successfully work with CMS, another regulatory agency, and flexibly respond to FCA violations.[328]

The Supreme Court has alternatively stated that the FCA is "not designed to reach every kind of fraud practiced on the Government,"[329] and that the FCA reaches "all fraudulent attempts to cause the Government to pay out sums of money."[330] As demonstrated by the history of the FCA, the Act has evolved from a tool to curb fraud from Union Army suppliers in the Civil War to a weapon against fraud in a wide array of industries.[331] Instead of viewing the FCA as an overbroad law compared to the more nuanced enforcement regimes of other government programs, it is possible to view the FCA as one of the DOJ's most important tools available to deter fraud and recover government money lost to fraud.[332]

Unlike the FDCA, which can be enforced by the United States alone, the FCA can be enforced by relators, giving it a wider reach.[333] The FCA's

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[322] Piller, *supra* note 107.
[323] *See supra* text accompanying notes 301–316.
[324] *See supra* text accompanying notes 295–301.
[325] *See supra* text accompanying notes 301–316.
[326] *See* discussion *infra* Section III.B.
[327] *See supra* text accompanying notes 295–297; *infra* text accompanying notes 334–342.
[328] *See infra* text accompanying notes 351–358.
[329] United States v. McNinch, 356 U.S. 595, 599 (1958).
[330] United States v. Neifert-White Co., 390 U.S. 228, 233 (1968).
[331] U.S. DEP'T JUST., *supra* note 35, at 1.
[332] *Id.*
[333] 21 U.S.C. § 337(a); 31 U.S.C. § 3730(b); *see* Kyle Faget, *CGMP Violations Should Not Be Used as a Basis for FCA Actions Absent Fraud*, 38 SEATTLE U. L. REV. 37, 53 (2014) (discussing how the FDA's flexibility in

qui tam provision allows a private person, called a relator, to file an FCA suit on behalf of the government.[334] Although the FDCA allows relators to report violations potentially involving fraud to the FDA, it does not include a provision allowing the relator to instigate a suit or even conduct the investigation without the agency's help.[335] Actions by relators provide an advantage in prosecuting fraud claims because the private plaintiffs do the preliminary work, which decreases the government's burden.[336] Moreover, *qui tam* actions are far from insignificant: of the $2.68 billion recovered by the government in FCA settlements and judgments in 2022, $2.3 billion originated from suits filed under the *qui tam* provision.[337]

The FCA also has a wider reach because it is not tied to a particular government agency. This particular benefit is demonstrated in a FCA claim against DePuy Orthopaedics for allegedly manufacturing defective versions of a metal-on-metal hip replacement approved through the 510(k) process.[338] The FDA does not independently assess the safety and effectiveness of a medical device that qualifies for 510(k) approval because qualifying devices are substantially equivalent to devices already approved by the FDA.[339] Thus, the court notes that it is possible that the hip replacements were safe and effective enough to secure FDA approval but not sufficiently "reasonable and necessary" for patient care to warrant Medicaid reimbursement.[340] If DePuy Orthopaedics were to falsely state that the hip replacement was reasonable and necessary for patient care, there would be a situation in which a false claim was material to the government's decision to pay but not dependent on the FDA's continued approval or withdrawal of the device.[341] Because such a case would require an investigation into the FDA process as well as the CMS payment, a statute untethered to either agency would be necessary to freely move between both.[342] The FDA's investigatory reach would presumably stop once CMS requirements are involved.[343] The DOJ, in contrast is not circumscribed by agency boundaries when using the FCA; it can investigate wherever the causal chain leads.[344]

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deciding whether and how to enforce the FDCA reflects a regulatory framework with difficult and competing objectives).

[334] 31 U.S.C. § 3730(b).

[335] *See* FOOD & DRUG ADMIN., *supra* note 290.

[336] Girard, *supra* note 49, at 139.

[337] *FCA Settlements and Judgments 2023*, *supra* note 57.

[338] United States *ex rel.* Nargol v. DePuy Oarthopaedics, Inc., 865 F.3d 29, 32 (1st Cir. 2017).

[339] *Id.*

[340] *Id.* at 35.

[341] *Id.*

[342] *See id.*

[343] *See Nargol*, 865 F.3d at 35.

[344] *See id.*

Perhaps due to its wider reach, the DOJ has demonstrated that it is more successful in policing health-related fraud than the FDA is at policing its own agency.[345] As mentioned above, the DOJ recovered over $1.8 billion from FCA actions involving healthcare fraud in 2023 alone.[346] The FDA, in contrast, has been criticized for its lack of enforcement activity.[347] Whether this failure to police is due to the agency's lack of resources for enforcement,[348] the political party in power,[349] or a misguided perception based on the FDA's primary goal of inducing parties to correct their own actions,[350] the FDA's enforcement activity is far less than that of the DOJ with respect to fraudulent claims.

Although the FCA is thought of as a draconian tool due to treble damages, and therefore inflexible in the face of the FDA's regulatory guidance, the DOJ can reduce damages and penalties due to cooperation.[351] The FCA allows for reduced damages if the court finds "the person committing the violations . . . furnished officials . . . with all information known" within thirty days of obtaining the information, such person "fully cooperated with any Government investigation of such violation," no action had commenced at the time the information was furnished, and the person did not have actual knowledge of an investigation.[352] While this is far from the FDA's enforcement flexibility, it does offer somewhat of a pressure valve.[353]

Additionally, the DOJ and private individuals bringing claims under the FCA are able to operate successfully with other governmental agencies that have active fraud policing arms. CMS, like the FDA, has a fraud policing unit.[354] CMS's Center for Program Integrity includes a Fraud Investigations Group.[355] The Fraud Investigations Group has various divisions, including the Division of Fraud Prevention Partnerships and the Division of Investigative Support.[356] However, scholars seem unconcerned about the DOJ using the FCA to wade into CMS's regulatory regime despite most healthcare fraud cases involving CMS payments.[357] If the DOJ can

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[345] *See FCA Settlements and Judgments 2023*, *supra* note 57; *see supra* text accompanying notes 309–316.
[346] *See FCA Settlements and Judgments 2023*, *supra* note 57.
[347] *See* Sharkey, *supra* note 20, at 862.
[348] Green, *supra* note 21, at 476.
[349] Piller, *supra* note 107.
[350] FOOD & DRUG ADMIN., *supra* note 291.
[351] 31 U.S.C. § 3729(a)(2).
[352] *Id.*
[353] *Id.*
[354] U.S. DEP'T HEALTH & HUM. SERVS., CMS ORGANIZATIONAL CHART, 1, 48 (2024), https://www.cms.gov/about-cms/agency-information/cmsleadership/downloads/cms_organizational_chart.pdf.
[355] *Id.* at 51.
[356] *Id.*
[357] *See* The Dan Abrams Co. LLC v. Medtronic, Inc., 850 F. App'x 508, 511 (9th Cir. 2021).

successfully police fraud perpetrated on CMS without unraveling the agency's internal system of fraud regulation,[358] it is likely the DOJ can police fraud involving both CMS and the FDA without impeding on the FDA's regulation of fraud.

The FCA provides a better option than FDA-led enforcement for fraud committed during the FDA process. Not only is the FCA intentionally broad to help the government recover money it lost due to false statements or fraudulent conduct,[359] but the Act can also handle claims that cross multiple governmental agencies.[360] Additionally, the FCA's *qui tam* provision allows investigations to move forward without the DOJ shouldering the entire burden,[361] which is not an option for FDA-led enforcement.[362] Although critics insist allowing FCA actions through the theory of fraud-on-the-FDA would replace the flexible enforcement system of the FDA with a rigid tool, penalties under the FCA can be decreased if the person or organization that committed violations cooperates with the governmental investigation.[363] Moreover, the FCA has a history of success in the healthcare field, and the DOJ has demonstrated it can work with other federal agencies that have fraud policing subgroups when investigating and prosecuting FCA claims.[364]

C. Limitations of Fraud-on-the-FDA

While affirming fraud-on-the-FDA as a viable form of liability under the FCA will extend the current reach of the FCA, it would be subject to certain limitations. Fraud-on-the-FDA can only be used for FDA-related violations involving fraudulent conduct or false statements.[365] The FDA would retain control over and flexibility with compliance or regulatory activities.[366] Thus, accepting fraud-on-the-FDA would maintain a boundary between FDA-led enforcement and prosecution under the FDA.

Fraud-on-the-FDA would not cover compliance or regulatory activities absent fraud.[367] The language of the FCA clearly requires a false statement or fraudulent course of conduct.[368] Any compliance or regulatory violations not including fraud would not fall under the FCA and, therefore,

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[358] *See id.*; U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 354.
[359] *See supra* text accompanying notes 330–332.
[360] *See supra* text accompanying notes 338–343.
[361] *See supra* text accompanying notes 333–**Error! Bookmark not defined.**.
[362] *See* FOOD & DRUG ADMIN., *supra* note 291.
[363] *See supra* text accompanying notes 351–353.
[364] *See supra* text accompanying notes 354–358.
[365] *See infra* text accompanying notes 367–375.
[366] *See infra* text accompanying notes 376–382.
[367] *See* 31 U.S.C. § 3729(a)(1).
[368] 31 U.S.C. § 3729(a)(1).

could not be prosecuted under a theory of fraud-on-the-FDA.[369]

Both the Fourth Circuit and a district court in California have demonstrated that the language of the FCA already prevents the Act from being used to police FDA compliance absent fraud.[370] For example, in a *qui tam* action under the FCA in the Fourth Circuit, a relator alleged that Omnicare, Inc. violated safety regulations of the FDA that require separate processing of penicillin and non-penicillin products.[371] The Fourth Circuit dismissed the complaint for failure to state a claim, however, because, although payments for covered outpatient drugs under Medicare and Medicaid require FDA approval, they do not require compliance with FDA safety regulations.[372] According to the court, the claim failed to allege Omnicare made false statements or acted with the requisite scienter.[373] The failed claim in this case, along with the remedial actions available to the FDA, demonstrated to the court that Congress "did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct."[374] Similarly, a district court in California, when faced with a *qui tam* suit against Masimo Corporation under the FCA, held that regulatory violations alone do not give rise to FCA liability.[375]

The FDA is in a better position than the DOJ to police compliance with FDA standards and regulations.[376] As discussed above, the FDA has flexibility in how to respond to regulatory violations.[377] The graduated response, which typically begins with warning letters, is designed to incentivize voluntary corrective action.[378] When violations concern compliance with standards or regulations rather than fraudulent statements made during the approval process, a graduated response may be better suited to both instigate corrections and avoid market disruptions.[379]

By refraining from prosecuting compliance and regulatory violations that do not include fraudulent or misleading statements, the FCA will avoid encroaching on the FDA's territory.[380] The First Circuit expressed concern that affirming fraud-on-the-FDA would give juries the ability to use the FCA

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[369] *Id.*

[370] United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694, 697; United States *ex rel.* Ruhe v. Masimo Corp., 977 F.Supp. 2d 981, 991 (C.D. Cal. 2013).

[371] *Rostholder*, 745 F.3d at 697.

[372] *Id.* at 697, 701.

[373] *Id.* at 697.

[374] *Id.* at 701–03.

[375] *Ruhe*, 977 F.Supp. 2d at 991.

[376] *See supra* text accompanying notes 295–301.

[377] FOOD & DRUG ADMIN., *supra* note 293, at 3.

[378] *Id.*

[379] *Id.*; *see Rostholder*, 745 F.3d 694.

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

to overrule FDA decisions.[381] However, because the FCA requires a showing of fraud, the FCA cannot be used to specifically police or revisit FDA decisions.[382] Thus, although affirming fraud-on-the-FDA would involve an analysis of actions and decisions by the FDA, it would not open the gates to overruling FDA decisions.

Affirming fraud-on-the-FDA as a viable form of liability would also not exclude the FDA from continuing to police fraud.[383] The FDCA authorizes the FDA to take enforcement action concerning fraud.[384] Moreover, the FDA can continue to use its insight and expertise to recognize and investigate fraud in the application process, which the agency has been acutely aware of for many years, as demonstrated by a 1991 notice by the FDA on its final policy for fraud, untrue statements of material facts, bribery, and illegal gratuities.[385] The 1991 notice states that the FDA developed the fraud policy after uncovering "broader patterns of fraud and discrepancies in applications to the agency that raise serious questions as to the reliability of all data submissions" for safety and efficacy.[386] Not only would affirming fraud-on-the-FDA not prevent the FDA from actualizing the goals in the 1991 notice, but it would also help identify and prosecute the very problems that led the FDA to develop a fraud policy in the first place.[387]

Thus, prosecutions under the FCA for fraudulent conduct and false statements submitted during the FDA approval process would still limit the FCA to conduct and statements involving fraud, as the FDA would still regulate compliance and regulations under the FDCA.

D. Implications and Effects of Adopting Fraud-on-the-FDA

Allowing claims under the FDA using the theory of fraud-on-the-FDA to move forward can help reduce healthcare expenditures in the United States,[388] may lead to more FDA-related tort claims in state courts,[389] and can help the FDA's own investigations into fraudulent activity.[390] It is unlikely that acceptance of fraud-on-the-FDA claims would lead to a chilling effect

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[381] *D'Agostino*, 845 F.3d at 8.
[382] 31 U.S.C. § 3729(a)(1).
[383] *See* 21 U.S.C. § 337(a)(1)(A), § 331 (y)(1).
[384] 21 U.S.C. § 337(a)(1)(A), § 331 (y)(1); *see* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).
[385] 56 Fed. Reg. 46191 (July 1, 1991).
[386] *Id.*
[387] *Id.*
[388] *See infra* text accompanying notes 392–398.
[389] *See infra* text accompanying notes 399–406.
[390] *See infra* text accompanying notes 407–409.

on disclosures made to the FDA during the approval process.[391]

Allowing the DOJ and relators to bring FCA claims based on the fraud-on-the-FDA theory may help curb healthcare expenditures. As mentioned in the introduction, healthcare spending in the United States reached $4.5 trillion in 2022[392] with prices for pharmaceutical products playing a major role in driving up costs.[393] Amid these skyrocketing expenditures, pharmaceutical and medical device companies are pulling in record profits: from 2006 to 2015, the annual profit margin for the 25 largest drug companies fluctuated between 15 and 20%.[394] This is two to three times the annual profit margins for the largest non-drug companies.[395] By collecting damages and penalties through the FCA for fraudulent conduct of and false statements made by pharmaceutical and medical device companies, the government would recuperate costs at the expense of the most profitable companies in the health sector.[396] While this may seem idealistic, research has indicated that pharmaceutical fraud may be widespread.[397] Alleged FCA violations can also lead to settlements that include additional forms of oversight, potentially avoiding unjustified price increases.[398] While not a panacea to healthcare spending, fraud-on-the-FDA may help curb the government's costs.

In addition, accepting fraud-on-the-FDA as a viable form of liability may allow state court violations to move forward.[399] Following *Buckman*, which held that state law fraud-on-the-agency claims are preempted by the FDCA, Catherine Sharkey argues for a fraud caveat to preemption as a regulatory mechanism to police fraud on federal agencies.[400] In *Buckman*, the court stated that state fraud-on-the-agency claims as well as state-based tort claims relying on evidence of fraud against the FDA conflict with the FDA's responsibility to police fraud.[401] However, according to Sharkey, while the

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[391] *See infra* text accompanying notes 410–415.

[392] CTR. FOR MEDICARE & MEDICAID SERVS., *supra* note 11.

[393] Kaltenboeck, *supra* note 13; CONG. BUDGET OFF., *supra* note 14.

[394] U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (Nov. 17, 2017); *see* Rathore et al., *supra* note 306.

[395] U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 394.

[396] *See* 31 U.S.C. § 3729(a)(1) (discussing damages under the FCA).

[397] Yuriy Timofeyev et al., *Predictors of Loss due to Pharmaceutical Fraud: Evidence from the U.S.*, 20 COST EFFECTIVENESS & RES. ALLOCATION 1, 2 (2022) (citing JOHN BRAITHWAITE, CORP. CRIME IN THE PHARM. INDUS. (1984); GRAHAM DUKES ET AL., PHARMS., CORP. CRIME AND PUB. HEALTH (2014)).

[398] *See* Press Release, Off. of Pub. Aff., Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability (each company involved in the settlement agreed to enter a five-year corporate integrity agreement with the OIG, which includes internal monitoring and price transparency provisions).

[399] Sharkey, *supra* note 20, at 841.

[400] *Id.*; Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001).

[401] *Buckman*, 531 U.S. at 351.

FDA has the authority and responsibility to police fraud on the agency, it has inadequate resources to do so.[402] Not only does that mean fraud goes uninvestigated, but also, following the *Buckman* decision, many state claims could never be brought.[403] Sharkey argues for a fraud exception to preemption that would allow state claims to be brought once the FDA finds fraudulent activity occurred.[404] If the theory of fraud-on-the-FDA were affirmed, state tort claims would still be preempted by the FDCA.[405] However, by expanding the FCA's reach to false statements submitted during the FDA application process, fraud-on-the-FDA could uncover fraudulent actions that could qualify state claims for the fraud exception Sharkey proposed.[406]

Alternatively, fraud-on-the-FDA claims may accelerate the FDA's own finding of fraudulent activity. Although private individuals can report fraud to the FDA, they currently have no external incentive to do so.[407] With fraud-on-the-FDA, however, private individuals would be incentivized by the *qui tam* provision in the FCA, which allows relators to receive up to 30% of the total recovery.[408] Even if the suit is dismissed or the relator drops the claim, OCI can investigate the allegations.[409] In other words, allowing for fraud-on-the-FDA claims would incentivize private individuals to bring forward information that would be helpful to OCI's investigative activity.

Although the Supreme Court suggested that state fraud-on-the-FDA claims would have a chilling effect on disclosures made to the FDA,[410] it is unlikely that federal fraud-on-the-FDA claims would chill disclosures because companies seeking approval must comply with FDA requests for information if they want to move forward with the approval process.[411] According to the Supreme Court in *Buckman*, if an entity other than the FDA polices fraud on the FDA, would-be applicants may be discouraged from seeking certain forms of FDA approval, particularly approval related to off-label uses.[412] Policing by another agency may also cause applicants to "submit a deluge of information that the Agency neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."[413] The plausibility of either scenario is dubious given the purpose of the FDA

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[402] Sharkey, *supra* note 20, at 862.
[403] *Id.*
[404] *Id.* at 850.
[405] *See Buckman*, 531 U.S. at 351.
[406] *Sharkey*, *supra* note 20, at 848–49.
[407] *See supra* note 290 and accompanying text.
[408] 31 U.S.C. § 3730(d).
[409] *See* FOOD & DRUG ADMIN., *supra* note 291.
[410] *Buckman*, 531 U.S. at 351.
[411] FOOD & DRUG ADMIN., *supra* note 92.
[412] *Buckman*, 531 U.S. at 350.
[413] *Id.* at 351.

approval process: to secure approval of a pharmaceutical product or medical device.[414] During the application process, applicants are at the mercy of the FDA and must comply with the agency's requests.[415] Any chilling or flooding effect from a judicial opinion is likely to stagnate in the face of the approval process.

Thus, accepting the fraud-on-the-FDA theory as a form of FCA liability is unlikely to have a chilling effect on disclosures to the FDA, but could help reduce the government's overall healthcare costs and help the FDA's own fraud investigation activity. Fraud-on-the-FDA may also open the door to state court fraud-on-the-FDA claims that were rendered impossible by *Buckman*.[416]

IV. RESOLUTION: CONGRESSIONAL ACTION

While other federal courts can follow the Ninth Circuit's lead in accepting fraud-on-the-FDA claims, it is unlikely that the United States Supreme Court would resolve the split in favor of the new form of liability. Congress can support adoption of fraud-on-the-FDA by revising the FCA to state that rescission of payment or approval by the government is not necessary for liability.

Because fraud-on-the-FDA is a legally viable form of liability,[417] federal courts can follow the Ninth Circuit's approach by allowing sufficiently pled fraud-on-the-FDA claims under the FCA to survive a 12(b)(6) motion. In following the Ninth Circuit, other federal courts can ignore whether the FDA has withdrawn approval for the device or drug in question when determining whether the relator or DOJ has properly pled causation.[418] Moreover, other circuits can judge the causation element in fraud-on-the-FDA complaints using the theories of promissory fraud or implied certification.[419]

Even if other circuits adopt the Ninth Circuit's approach, it is unlikely the Supreme Court will resolve the issue in favor of the new form of liability. As mentioned above, the First Circuit court argued that fraud-on-the-FDA claims would condone using the FCA to encroach on the FDA's regulatory territory.[420] The Ninth Circuit court and the DOJ disagreed, arguing that fraud-on-the-FDA claims allow the DOJ and the FDA to work

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[414] FOOD & DRUG ADMIN., *supra* note 92.
[415] *Id.*
[416] *See* discussion *supra* Section III.D.
[417] *See* discussion *supra* Section II.
[418] *See supra* text accompanying notes 190–198.
[419] *See supra* text accompanying notes 207–222.
[420] *See supra* notes 152–155 and accompanying text.

symbiotically to police a type of fraud that would otherwise be unavailable for prosecution.[421] Given the recent rulings in *West Virginia v. EPA* and *Biden v. Nebraska*, the Supreme Court may be hesitant to resolve the circuit split in favor of adopting fraud-on-the-FDA because of the encroachment argument raised by the First Circuit.[422] In both *West Virginia* and *Biden*, the Supreme Court used the major questions doctrine to strike down an executive agency's exercise of an administrative power that the Court determined was not clearly authorized by Congress.[423] The Court was particularly concerned in both cases with the unprecedented nature of the agencies' actions as well as the significant impact the actions would have on the American economy.[424] Thus, in two recent cases, the Supreme Court struck down what it viewed as unprecedented and economically significant actions taken by executive agencies because the statutes supporting the actions did not clearly confer authority to take such an actions.[425]

Following *West Virginia* and *Biden*, the Supreme Court seems likely to hold that Congress did not clearly give the DOJ authority to prosecute fraud-on-the-FDA claims through the FCA. Under the FCA, the DOJ can prosecute a "false or fraudulent claim for [government] payment or approval" or an action that "makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[426] While this seems to authorize any prosecution related to false or fraudulent claims made to the government, the language, according to the opinions in *West Virginia* and *Biden*, may not be tight enough for the court to determine that Congress intended the FCA to authorize the DOJ to police fraud on the FDA when such fraud only later leads to claims submitted to the government for payment.[427] Moreover, like the actions taken by the Environmental Protection Agency in *West Virginia* and the Department of Education in *Biden*, the DOJ's action could be construed by the Supreme Court as unprecedented, as fraud-on-the-FDA is a new form of liability.[428] In addition, based on the historical amounts recovered from the healthcare industry in FCA actions, the Court could view liability under fraud-on-the-FDA as significant to the American economy.[429]

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[421] *See supra* notes 156–166 and accompanying text.

[422] *See generally* West Virginia v. EPA, 142 S. Ct. 2587; Biden v. Nebraska, 143 S. Ct. 2355.

[423] *West Virginia*, 142 S. Ct. at 2615–16 (ruling that the Environmental Protection Agency did not have the authority under the Clean Air Act to adopt a generation shifting approach for carbon emission caps); *Biden*, 143 S. Ct. at 2372–73 (ruling that Congress did not clearly give the Secretary of Education the authority to forgive $430 billion in student loans through the HEROES Act).

[424] *West Virginia*, 142 S. Ct. at 2610, 2612. *Biden*; 143 S. Ct. at 2372.

[425] *See supra* notes 423–424and accompanying text.

[426] 31 U.S.C. § 3729(a)(1).

[427] *See supra* notes 423–424and accompanying text.

[428] *See West Virginia*, 142 S. Ct. at 2610; *Biden*, 143 S. Ct. at 2372.

[429] *See FCA Settlements and Judgments 2023*, *supra* note 57; *West Virginia*, 142 S. Ct. at 2612; *Biden*, 143 S. Ct. at 2372. It is important to note, however, that FCA recovery actions differ significantly in magnitude from the

Thus, it is not unlikely that the Supreme Court would rely on the major questions doctrine to strike down fraud-on-the-FDA.

To circumvent any issues with a Supreme Court decision on fraud-on-the-FDA, Congress can revise the FCA to ensure this form of liability is adopted. The revision should be based on the First Circuit's suggestion that a relator can only meet the burden of causation by demonstrating the FDA withdrew the pharmaceutical product or medical device in question.[430] To the First Circuit, the issue of FDA withdrawal reveals that fraud-on-the-FDA turns the FCA into a tool to encroach on the FDA's regulatory territory.[431] Congress can resolve this problem and avoid a Supreme Court decision striking down fraud-on-the-FDA with a small change to the FCA. The current version of the FCA assigns liability when a person or entity "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."[432] Congress can make one of two changes. First, it can add "regardless of whether the government rescinds payment or approval" to the end of § 3729(a)(1)(A) so that liability attaches to a person or entity who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" regardless of whether the government rescinds payment or approval.[433] Second, Congress can add a section under § 3729(a)(1)(B) clarifying that "payment or approval" does not require that the government rescinds payment or withdraws approval.[434] These changes would directly address the First Circuit argument that fraud-on-the-FDA claims fail on the element of causation if the FDA has not withdrawn approval for the drug or device in question.[435] The revision may also add the clarity necessary for fraud-on-the-FDA to survive a major questions doctrine challenge before the Supreme Court.[436]

Thus, while other circuits should follow the Ninth Circuit's lead in adopting fraud-on-the-FDA, long-term adoption of the new form of liability may only be possible with a Congressional revision to the FCA.

$430 billion in student loans at issue in *Biden* and are unlikely to threaten an entire industry like the EPA's generation shifting plan in *West Virginia*. *Biden*, 143 S. Ct. 2368; *West Virginia*, 142 S. Ct. at 2604.

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

[431] *Id.*

[432] 31 U.S.C. § 3729(a)(1).

[433] § 3729(a)(1)(A).

[434] § 3729(a)(1)(B).

[435] *D'Agostino*, 845 F.3d at 8.

[436] It is unclear the degree of clarity the Supreme Court would need to defeat a major questions doctrine challenge. In *West Virigina*, the Court stated Congress typically does not "use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme.'" 142 S. Ct. at 2609 (*citing* MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218, 229 (1994)).

CONCLUSION

The FCA has evolved from a Civil War necessity to a tool capable of holding sophisticated healthcare organizations accountable for fraudulent conduct and false statements.[437] In an increasingly complex landscape in which the FDA, pharmaceutical and medical device companies, and federal healthcare programs are challenged with new public health crises at alarming rates, the government's ability to effectively investigate and prosecute healthcare fraud is essential.[438] The theory of fraud-on-the-FDA allows the government to further modernize the FCA and use it adeptly in this interconnected and dynamic world.

The Ninth Circuit is correct: the fraud-on-the-FDA theory should be affirmed as a form of liability under the FCA.[439] The theory is legally viable, satisfying both the causation and materiality elements of the FCA.[440] Causation is satisfied by borrowing concepts from the implied certification theory and the theory of promissory fraud, which are both accepted forms of FCA liability.[441] Materiality can be satisfied with a fraud-on-the-FDA claim as long as the government or relator has evidence in addition to CMS's conditions of payment.[442] The pleading stage does not pose an insurmountable obstacle to claims using the theory fraud-on-the-FDA, as such claims can be pled with particularity and in such a way that plausibly meets the FCA elements.[443]

Despite the First Circuit's misgivings about the DOJ encroaching on the FDA's territory if fraud-on-the-FDA were affirmed, the theory would allow the federal government to close an enforcement gap.[444] The FDA, despite its authority to investigate and police fraud, rightfully prioritizes safety, efficacy, and security of pharmaceutical products, biologicals, and medical devices over fraud policing.[445] The DOJ, in contrast, would be able to deploy its expertise in policing fraud across the healthcare field and enlist the help of relators through the FCA if fraud-on-the-FDA were affirmed.[446]

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[437] U.S. DEP'T OF JUST., *supra* note 35; *see FCA Settlements and Judgments 2023*, *supra* note 57.

[438] *See Health Emergencies List*, WORLD HEALTH ORG., https://www.who.int/emergencies/situations (last visited Mar. 1, 2023); Michael Adelberg & Melissa Garrido, *The COVID-19 Epidemic as a Catalyst for Health Care Fraud*, HEALTH AFFAIRS (May 7, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200504.459546.

[439] United States *ex rel.* Campie v. Gilead Scis., 862 F.3d 890, 909 (9th Cir. 2017).

[440] *See* discussion *supra* Sections II.A, II.B.

[441] *See* discussion *supra* Section II.A.

[442] *See* discussion *supra* Section II.B.

[443] *See* discussion *supra* Section II.C.

[444] United States *ex rel.* D'Agostino v. ev3, Inc., 845 F.3d 1, 8 (1st Cir. 2016); *see* discussion *supra* Sections III.A, III.B.

[445] *See* discussion *supra* Section III.A.

[446] *See* discussion *supra* Section III.B.

The DOJ would step in when fraud enters the equation, thus allowing the FDA to focus on compliance and regulatory issues.[447]

With trillions of dollars spent on healthcare, the nation cannot afford to overlook any subsets of health-related fraud.[448] The theory of fraud-on-the-FDA would allow courts to close a gap shielding some of the most profitable companies from liability. Congress should revise the FCA to ensure fraud-on-the-FDA is adopted as a form of liability by all federal courts.

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[447] *See* discussion *supra* Section III.C.
[448] CTR. FOR MEDICARE & MEDICAID SERVS., *supra* note 11.