

FCA V. FDA: THE CASE AGAINST THE PRESUMPTION OF IMMATERIALITY FROM AGENCY INACTION

ALEXANDER KRISTOFCAK*

The False Claims Act is a powerful statutory vehicle for the federal government to deter fraud on its purse, a significant public policy concern. Under the Act, government contractors can be liable for violating material legal requirements of federal programs. In assessing materiality, the courts are asked to evaluate the natural tendency of a violation to influence payment. One question that has been raised in a series of cases in the health product domain is whether government’s payment, despite knowledge of a violation, necessarily means that the violation was immaterial for the purposes of FCA enforcement. The industry is asking the courts to adopt that defense—what this Note terms the “immateriality presumption from agency inaction”—at the pleading stage. To justify the presumption, the defendants argue that the nuanced judgments of the agency vested with the authority and the requisite expertise to regulate—here, the Food and Drug Administration—must prevail over both the private parties who bring actions under the statute’s qui tam provisions, as well as anyone else within the government. Using the Act’s evolution, structure, legislative history, and empirical data, this Note argues against the presumption. First, it shows that the Act’s design strikes a deliberate balance between encouraging private actors and their meaningful oversight by the government. As such, the presumption is not needed to combat unmeritorious private claims. Second, the Note argues that potential overlap between enforcement under the Act and agency oversight is valuable in several ways. The Note’s most significant contribution is in explaining why the immateriality presumption, by tethering fraud enforcement to judgments of the agencies, could be harmful to the agencies themselves and public interest writ large. In doing that, the Note challenges the claim that the presumption honors the expertise and facilitates the discretion of agencies.

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* Copyright © 2020 by Alexander Kristofcak. J.D. Candidate, 2020, New York University School of Law; B.S., 2003, University of Pennsylvania. I am grateful to Professors Catherine Sharkey, Troy McKenzie, and Rachel Barkow for their advice on this Note and much else, the editors at the *New York University Law Review*, especially Adrienne Spoto, for their careful review and helpful comments, and the lawyers who litigate FCA cases, especially Christopher B. Harwood, whose accomplishments at the U.S. Attorney’s Office at S.D.N.Y. inspired my curiosity in the FCA and public service.

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INTRODUCTION

Michael Mullen was concerned.¹ In 2009, after almost seven years at AmerisourceBergen (ABC), one of the major pharmaceutical distributors and the twelfth largest company in America by revenue,² he became the Chief Operating Officer of one of its divisions. As his first project, he conducted a strategic review to take stock of the division he was now tasked with overseeing. During that process, he became concerned that certain practices of the company could be considered kickbacks to healthcare providers in violation of federal law. Soon after raising his concerns with the leadership of the company, he was unceremoniously terminated.

The violations identified by Mr. Mullen—problematic in their own right—also put the company at risk of liability under government anti-fraud laws, since a significant portion of the drugs distributed by the company were purchased under various government healthcare schemes like Medicare and Medicaid. And indeed, the complaint that Mr. Mullen eventually filed under the False Claims Act (FCA),³ the

¹ This description of events in the *AmerisourceBergen* case is based on the complaint filed by Mullen. See generally Complaint at 34–37, United States *ex rel.* Mullen v. AmerisourceBergen Corp., No. 10-cv-4856-ng-MDG (E.D.N.Y. Oct. 21, 2010).

² See *AmerisourceBergen*, FORTUNE, <http://fortune.com/fortune500/amerisourcebergen> (last visited Nov. 9, 2019) (showing that AmerisourceBergen was previously ranked the twelfth largest company in America, although it is currently the tenth largest).

³ 31 U.S.C. §§ 3729–3733 (2018).

federal anti-fraud statute, formed the basis for an investigation that resulted in a \$625 million settlement with ABC.⁴

In a capitalist country like the United States, it may surprise some that over a fifth of the gross domestic product comes from federal government spending.⁵ Combined with the fact that a significant portion of this spending is done through private contractors,⁶ this means that misuse of government funds by those contractors is not an esoteric concern.⁷ Cases brought under the FCA, like *AmerisourceBergen*, have become a potent avenue for the government to recover any fraudulently obtained funds⁸ and deter fraud.⁹ The Act derives its potency from two key sources. First, its whistleblower provisions allow private parties like Mr. Mullen, also known as “relators,” to bring a claim on behalf of the United States in exchange for participating in the recovery,¹⁰ an arrangement known as *qui tam*.¹¹ Second, the statute targets a wide variety of fraud. Most crucially for the purposes of this Note, violations of material legal requirements of government programs can expose contractors under

⁴ Press Release, U.S. Attorney’s Office, E. Dist. of N.Y., Dept. of Justice, *AmerisourceBergen Corp. to Pay \$625 Million to Settle Civil Fraud Allegations Resulting from Its Repackaging and Sale of Adulterated Drugs and Unapproved New Drugs, Double Billing and Providing Kickbacks* (Oct. 1, 2018), <https://www.justice.gov/usao-edny/pr/amerisourcebergen-corp-pay-625-million-settle-civil-fraud-allegations-resulting-its>.

⁵ See *Federal Net Outlays as Percent of Gross Domestic Product*, FRED ECON. DATA, <https://fred.stlouisfed.org/series/FYONGDA188S> (last visited Nov. 11, 2019).

⁶ For example, Medicare “helps cover” medical care for people age sixty-five or older, but the actual provision of services is done by private practitioners who file claims for reimbursement. See generally *Medicare Program – General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html> (last visited Nov. 10, 2019); *How Do I File a Claim?*, MEDICARE, <https://www.medicare.gov/claims-appeals/how-do-i-file-a-claim> (last visited Nov. 11, 2019).

⁷ By some estimates, fraud, waste, and abuse of government funds represents a multibillion dollar problem. See, e.g., *The \$272 Billion Swindle*, ECONOMIST (May 31, 2014), <https://www.economist.com/united-states/2014/05/31/the-272-billion-swindle> (reporting on a study that estimated that fraud added \$98,000,000,000 to annual Medicare and Medicaid spending).

⁸ See *Fact Sheet: Significant False Claims Act Settlements & Judgments, Fiscal Years 2009-2016*, DEPT. JUST., <https://www.justice.gov/opa/press-release/file/918366/download> (last visited Jan. 17, 2020).

⁹ See 31 U.S.C. § 3729(a)(1)(G) (2018) (providing for treble damages plus an inflation-adjusted per-claim penalty). The maximum per-claim penalty was set at \$22,363 as of January 2018. 28 C.F.R. § 85.5 (2018).

¹⁰ See 31 U.S.C. § 3730(b) (providing for actions by private persons).

¹¹ The expression comes from Latin “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,” meaning one “who as well for the king as for himself sues in this matter.” *Qui Tam Action*, BLACK’S LAW DICTIONARY (11th ed. 2019).

those programs to FCA liability, even if they deliver the goods or services for which they billed the government.¹²

The legal requirements that can trigger this type of FCA liability are not listed in the statute; instead, the statute effectively incorporates by reference the *material* requirements of the respective government programs.¹³ This derivative nature of FCA liability necessarily means that, in addition to the Department of Justice, which is tasked with prosecuting FCA cases as well as overseeing those cases brought by private parties like Mr. Mullen,¹⁴ another government agency will typically have statutory authority over the realm in which the fraud occurred. In the *AmerisourceBergen* case, for example, the predicate infractions included violations of various drug safety regulations under the Food, Drug, and Cosmetic Act overseen by the Food and Drug Administration (FDA).¹⁵

This shared regulatory space presents an interesting puzzle: When a relator brings an FCA action on the basis of a violation within the purview of an agency, what bearing does the agency's inaction—despite knowledge of the infraction—have on the violation's materiality for the purposes of the suit? In a series of cases involving manufacturers of health products regulated by the FDA, the industry has argued that, when the agency does not act—for example, by continuing payment or not recalling a product—despite knowledge of a legal violation, this renders that violation immaterial and not actionable for the purposes of the FCA.¹⁶ Their argument is that permitting an FCA action, especially by a private party, when the regulating

¹² See *infra* Section I.B (explaining the evolution of theories of liability under the FCA and distinguishing factually false and legally false claims).

¹³ See 31 U.S.C. § 3729(a)(1)(B) (imposing liability for knowingly making “a false record or statement material to a false or fraudulent claim”). The statute defines “materiality” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

¹⁴ See 31 U.S.C. § 3730(c)(1) (providing that if the government proceeds with an action under the FCA, it shall have primary responsibility for prosecuting the action); 31 U.S.C. § 3730(c)(3) (providing some continued rights to the government to oversee the action even if it opts not to intervene).

¹⁵ Settlement Agreement at 57, *United States ex rel. Mullen v. AmerisourceBergen Corp.*, No. 1:12-cv-01178-NG-ST (E.D.N.Y. Nov. 15, 2018).

¹⁶ See, e.g., *Coyne v. Amgen, Inc.*, 717 F. App'x 26 (2d Cir. 2017) (finding that allegations must show misrepresentation caused the government to actually act); *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (finding that there was no allegation “that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations”); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (showing that Gilead argued violations were immaterial since the government continued to pay for the medications); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (finding that allegations do not meet the materiality standard); *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016) (finding that the FDA's failure to withdraw its approval precludes a claim of fraud).

agency chooses not to respond to a violation would impermissibly interfere with the expertise and discretion of the agency tasked with oversight. The “presumption of immateriality from agency inaction” thus wrests any independent control away from the FCA litigants and transfers it back to the experts at the agency.

Litigation on this question has culminated in a circuit split and a petition for certiorari to the Supreme Court in *Gilead Sciences v. United States ex rel. Campie*.¹⁷ This Note utilizes the extensive briefing in this case as a springboard for its analysis of the immateriality presumption from agency inaction at the pleading stage. It analyzes the concerns raised by the industry in *Campie* and related cases in defense of the presumption and concludes that these concerns are either illusory, already accounted for in the statute, or, in fact, valuable attributes of the FCA framework. As such, there is no need for courts to address them by tightening the materiality standard and adopting the presumption when considering a motion to dismiss.

The Note is predicated on the assumption that a tighter pleading burden would be detrimental to FCA enforcement for a mix of reasons that apply to litigation generally and FCA qui tam actions specifically.¹⁸ It also bears clarifying why the presumption has the potential to wreak havoc in FCA litigation if it is adopted broadly: When a qui tam litigant brings a claim, they put the government on notice about the alleged infraction. Arguably, the government—certainly the DOJ at first, but eventually also someone at the regulating agency—has knowledge of the alleged infraction, and the presumption of immateri-

¹⁷ Petition for Writ of Certiorari, *Gilead Scis., Inc. v. United States ex rel. Campie* at i, No. 17-936 (S. Ct. Dec. 26, 2017) [hereinafter *Campie* Petition] (stating the question presented as “[w]hether an FCA allegation fails when the Government continued to approve and pay for products after learning of alleged regulatory infractions and the pleadings offer no basis for overcoming the strong inference of immateriality that arises from the Government’s response”).

¹⁸ First, that any specific or greater burdens for pleading would make it harder to survive a motion to dismiss *generally* is hardly novel. See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (requiring a more specific pleading than parallel conduct for a violation of the Sherman Act). Second, in the FCA context specifically, pleading burdens arguably have a more pronounced impact because the claimant is typically bringing a claim on a contingency arrangement with counsel. See David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 COLUM. L. REV. 1244, 1281–82 (2012) (describing most relator-side practice as reliant on contingency fees). The counsel, in turn, screen out cases they see as higher risk. *Id.* at 1258 n.46. The relators themselves are less likely to bring a case due to the dramatic personal consequences of doing so. See *infra* note 152 and accompanying text (describing the personal burdens on whistleblowers). Third, the specific information that would be needed to rebut the presumption—whether the government knew about the infraction, whether it considered it a material breach, and why it continued to approve and pay for the product/service despite the infraction—is typically beyond the reach of the relator at the pleading stage.

ality from agency inaction *could be* activated if the government continues to pay for the purportedly fraudulent claims. As a result, a skillful defendant would, almost by definition, be able to invoke the presumption in their response to an FCA complaint.

The novel contribution of the Note is twofold. It is the first to isolate the presumption as an emerging but potent defense in FCA litigation in light of *Campie* and associated lower court cases. Second, it challenges the misconception that the FCA interferes with the expertise and discretion of the regulators, an oft-invoked mantra justifying the presumption of immateriality. Instead, it attempts to articulate why FCA enforcement untethered from agency action benefits the agencies themselves.

The Note proceeds in three parts. Part I provides a background on the FCA: a brief history of the statute with a focus on the features most relevant to the issues analyzed here, the evolution of theories of liability under the statute, and the emergence of the immateriality presumption defense. It then describes the justifications for the presumption articulated in *Campie* and disaggregates them into two distinct concerns: first, that qui tam actions under the FCA function as virtual private rights of action where no such rights exists in the organic statutes that are the source of the alleged violations, raising floodgates concerns; and second, that FCA enforcement interferes with the expertise and discretion of agencies.

Parts II and III address these two concerns, respectively. Part II addresses the argument that qui tam actions create a virtual private right of action by explaining how the statutory constraints of the Act limit the universe of claims and claimants and how the active gatekeeping role of the government¹⁹ further distinguishes qui tam actions from genuine private rights. Part III addresses the concerns stemming from the regulatory overlap between the FCA and agencies. It argues that this overlap is benign and often desirable because it adds unique tools and expertise to the regulatory toolkit, enhances agency discretion, and mitigates agency capture. As such, these concerns should not be persuasive when courts are assessing materiality in light of agency inaction.

¹⁹ To address any potential confusion, “the government” in this Note refers to the Department of Justice, as this is consistent with the language used by the FCA. *See, e.g., infra* notes 111 and 112. This is distinct from the “agency,” like, for example, the FDA in the health care context.

I BACKGROUND

This Part provides some essential background on the False Claims Act. Section I.A starts the section off with an abbreviated history of the statute. Section I.B explains the evolution of the theories of liability, especially the implied certification theory and the Supreme Court’s latest word on the FCA in *Universal Health Services v. United States ex rel. Escobar*.²⁰ Section I.C tracks the post-*Escobar* landscape which led to the development of the presumption of immateriality from agency inaction. Finally, Section I.D sets up the doctrinal and policy justifications for this presumption.

A. *Bad Mules, Parasites, and \$600 Toilet Seats: A Brief History of the FCA*

The story of fraud whistleblowers like Mr. Mullen begins, improbably, during the Civil War. Inspired by pervasive fraud against the federal government, such as the delivery of bad mules to the Union Army,²¹ Congress passed the original False Claims Act in 1863.²² The Act provided that “any person, as well for himself as for the United States”²³ may bring an action against “any person . . . who . . . present[s] . . . for payment . . . [a] claim upon or against the Government of the United States [she knows] to be false.”²⁴ In order to incentivize these sorts of claims, the Act provided a payoff to the relator of one half of the amount recovered.²⁵

The basic arc of the Act’s history is that, following an initial period of enforcement, it was stripped of some essential provisions in 1943²⁶ and thereafter lay dormant until it was resuscitated in 1986.²⁷

²⁰ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

²¹ See CONG. GLOBE, 37th Cong., 3d Sess. 952 (1863) (statement of Sen. Howard) (“The country . . . has been full of complaints respecting the frauds and corruption practiced in obtaining pay from the Government during the present war[, and] . . . further legislation is pressingly necessary to prevent this great evil”); David L. Haron et al., *Bad Mules: A Primer on the Federal and Michigan False Claims Acts*, MICH. B.J., Nov. 2009, at 22, 22 (“The federal False Claims Act (FCA) was enacted in part because of bad mules.”).

²² An Act to Prevent and Punish Frauds upon the Government of the United States, Ch. 67, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. §§ 3729–3733 (2018)).

²³ § 4, 12 Stat. at 698.

²⁴ § 1, 12 Stat. at 696.

²⁵ See § 6, 12 Stat. at 698 (setting the reward at one half of the forfeiture and damages).

²⁶ See An Act to Limit Private Suits for Penalties and Damages Arising out of Frauds Against the United States, Pub. L. No. 78-213, 57 Stat. 608, 609 (1943) (replacing sections of the 1863 statute).

²⁷ False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153.

The first set of amendments occurred in the midst of the Second World War. Congress had become concerned about *qui tam* actions filed on the basis of nothing more than information from criminal indictments of military contractors, rather than on the basis of new information not previously known to the government—what came to be termed derogatorily as “parasitic” claims.²⁸ The 1943 amendments responded by slashing the share of the awards to the *qui tam* relator²⁹ and barring actions based on facts known to *any* government agency or employee.³⁰

On the occasion of another military effort—the defense build-up undertaken during the Cold War³¹—Congress rediscovered its appreciation of the False Claims Act after reports of alarming fraud, waste, and abuse, including the famous example of a \$600 toilet seat purchased by the Navy.³² Recognizing that the 1943 amendments and subsequent “restrictive court interpretations . . . tend[ed] to thwart the effectiveness of the statute[.]”³³ the 1986 amendments made several critical changes to the law. These changes were designed to “encourage any individual knowing of Government fraud to bring that information forward” because “only a coordinated effort of both the Government and the citizenry will decrease [the] . . . defrauding [of] public funds.”³⁴ First, the whistleblower award was increased and made mandatory.³⁵ Second, the revised law altered the impact of government knowledge about the infraction: Unlike the 1943 Act, which

²⁸ See James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1267–68 (2013) (describing various instances of and concern about parasitic claims). In one case, a criminal indictment yielded a \$54,000 fine, while the *qui tam* case brought on the basis of the information revealed in the indictment resulted in a jury verdict of \$315,000. *Id.* at 1268.

²⁹ Compare § 6, 12 Stat. at 698 (1863) (setting the reward at one half of the forfeiture and damages), with § 1(E), 57 Stat. at 609 (1943) (making the award discretionary and no more than ten percent when the suit is carried by the government and no more than twenty-five percent when the suit is carried by the relator).

³⁰ See § 1(C), 57 Stat. at 609 (“[A] court shall have no jurisdiction [under this Act when] such suit was based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought.”).

³¹ See Helmer, *supra* note 28, at 1267–74 (documenting the backdrop of the 1943 and 1986 amendments).

³² See Fred Hiatt, *Now, the \$600 Toilet Seat*, WASH. POST (Feb. 5, 1985), <https://www.washingtonpost.com/archive/politics/1985/02/05/now-the-600-toilet-seat/917c98b4-c2fc-40a5-808b-87ff4e5884c8> (“Sen. William S. Cohen (R-Maine) charged yesterday that the Navy has been paying more than \$600 each for toilet seats . . .”).

³³ S. REP. NO. 99-345, at 4 (1986).

³⁴ *Id.* at 2.

³⁵ False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 3, 100 Stat. 3153, 3156–57 (setting the relator awards at fifteen to twenty-five percent if the government proceeds with the action and twenty-five to thirty percent if the government does not proceed with the action).

included a complete bar based on government knowledge,³⁶ the 1986 amendment allowed the action to proceed if the relator had direct and independent knowledge of the conduct that formed the basis of their action.³⁷ Under this compromise, someone bringing a claim on the basis of a newspaper report would be barred, whereas someone coming forward with information they obtained directly—for example, in the course of their employment—could proceed, even if the government had previously become aware of that misconduct.

The changes in the qui tam provisions succeeded in reviving enforcement under the FCA. Not only has the total number of new matters brought under the Act increased—rising from 373 in 1987 to 799 in 2017—but also the percentage of new cases initiated by relators under the qui tam provisions has grown significantly: In the ten years following the 1986 amendments, the share of relator actions rose steadily from eight percent to eighty percent, and it has remained within a ten-percent range of the latter level ever since.³⁸

B. *New Theories of Liability and Escobar*

The rise of whistleblower actions after 1986 occurred parallel with—and some argue was closely related to³⁹—an expansion in theories of liability litigated under the FCA, including the false certification theory. While paradigmatic FCA actions target factual misrepresentations of the type that gave rise to the original Act and the 1986 amendments—delivery of defective equipment and overcharging for products—the FCA has always authorized actions against a wide variety of false claims.⁴⁰ For example, in its report on the 1986 amendments, the Senate Committee on the Judiciary observed that “a false claim may take many forms, the most common

³⁶ See *supra* note 30 and accompanying text.

³⁷ § 4(A), 100 Stat. at 3157 (creating an exception to the public information bar introduced in the 1943 Act for a litigant who is the “original source of the information” and defining such person as one that has direct and independent knowledge of the information).

³⁸ Calculations are based on data from U.S. Department of Justice’s website. *Fraud Statistics – Overview*, DEP’T JUST. (Dec. 19, 2017), <https://www.justice.gov/opa/press-release/file/1020126/download>.

³⁹ See Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1014 (1998) (“[D]evelopment [of new theories of liability] was a somewhat predictable by-product of the new incentives Congress provided for use of the False Claims Act.”).

⁴⁰ The 1863 Act covered submissions of “false bill, receipt, voucher, entry, roll, account, claim, statement, certificate, affidavit, or deposition . . . or knowingly advis[ing] the making of any false oath . . . for the purpose of obtaining, or of aiding[,] . . . any approval or payment of any claim against the United States” An Act to Prevent and Punish Frauds upon the Government of the United States, Ch. 67, § 1, 12 Stat. 696, 696–97 (1863).

being a claim for goods or services not provided, or provided in *violation of contract terms, specification, statute, or regulation.*⁴¹ And yet, the false certification theory was not commonly utilized until the 1990s.⁴²

The false certification theory of liability centers on fraudulent certification of compliance with laws, rules, or regulations that are necessary for the contractor to be eligible for payment.⁴³ The falsity stems from violation of one of these legal conditions, rather than a factual misrepresentation such as the quality or quantity of the products or services delivered. This theory has been applied in a wide variety of contexts, sometimes reaching unexpected quarters.⁴⁴ In the healthcare industry, false certification cases are typically predicated on violations of the laws governing delivery of care⁴⁵ and the

⁴¹ S. REP. NO. 99-345, at 9 (1986) (emphasis added). The Committee report also documented a wide variety of conduct to which the Act had been successfully applied, including situations where claims were “submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or *in violation of any statute or applicable regulation . . .*” *Id.* at 9–10 (emphasis added) (first citing *Murray & Sorenson, Inc. v. United States*, 207 F.2d 119 (1st Cir. 1953) (finding conduct was close enough to collusion to violate the act); then citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (finding that collusive bidding violated the act)).

⁴² Of the 1162 federal False Claims Act opinions that contain any mention of “false certification” or “legally false” (another term for these types of claims), only ten were published before 1986, as many as were published in 1999 alone. By 2010, the annual rate shot up to fifty-five, and, in 2017, it was 120. *See Results for: “False Certification” OR “Legally False” AND “False Claims Act,”* LEXIS ADVANCE RES., <https://www.lexisnexis.com/en-us/gateway.page> (search for “‘false certification’ OR ‘legally false’ AND ‘false claims act,’” filter to federal courts, sort by date, and analyze by year) (last visited Feb. 3, 2020).

⁴³ *See United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (explaining that, in false certification cases, “parties avail themselves of benefits of some type, such as loan guarantees or agricultural supports, through false statements which create eligibility that otherwise would not exist”) (quoting JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS §§ 1-29 to 1-30 (1995)).

⁴⁴ For example, in 2018, the DOJ settled a claim against a Norwegian not-for-profit organization which had received funding from the U.S. Agency for International Development while certifying that it had not provided material support to terrorist organizations. Press Release, U.S. Attorney’s Office, S. Dist. of N.Y., Dep’t of Just., Manhattan U.S. Attorney Announces Settlement with Norwegian Not-for-Profit, Resolving Claims that It Provided Material Support to Iran, Hamas, and Other Prohibited Parties Under U.S. Law (Apr. 3, 2018), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-settlement-norwegian-not-profit-resolving-claims-it>.

⁴⁵ *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (finding a false claim based on violations of the Anti-Kickback Statute); *United States v. Mackby*, 339 F.3d 1013, 1019 (9th Cir. 2003) (affirming a false claim action in which the defendant was falsely certifying compliance with the provider qualification requirements provided by the Medicare program).

development and marketing of health products.⁴⁶

The false certification theory derives further strength from the development of “implied certification” as an extension of the false certification theory. Under this variant, the claimants’ certification of compliance with the relevant laws need not be expressly stated in their claim for payment; instead, it may be implied from the submittal of the claim.⁴⁷ Although it is difficult to tell with precision what percentage of false certification actions are of the implied variety, it is reasonable to say that it is substantial.⁴⁸

All of this history brings us to the Supreme Court’s most recent consideration of the FCA in *Universal Health Services v. United States ex rel. Escobar*.⁴⁹ The petitioner there asked the Court to consider “whether the ‘implied certification’ theory of legal falsity under the FCA . . . is viable.”⁵⁰ In a unanimous opinion by Justice Thomas, the Court rebuffed the effort: Not only did it embrace the implied false certification theory,⁵¹ but it also rejected the alternative argument advanced by the petitioner that the requirements not adhered to must be expressly designated as conditions of payment in order to trigger liability, so as to provide notice to the contractor and cabin liability.⁵² While rejecting the alternative argument, the Court answered the petitioner’s plea for fair notice and cabining of liability under the implied certification theory by offering another pathway: “strict enforcement of the Act’s materiality . . . requirement[.]”⁵³ As a result, numerous FCA cases have focused on materiality since *Escobar*.

⁴⁶ See, e.g., *United States ex rel. Higgins v. Bos. Sci. Corp.*, No. 11-cv-2453, 2017 U.S. Dist. LEXIS 138767, at *21 (D. Minn. Aug. 29, 2017) (finding a cognizable FCA claim under the false certification theory in the FDA approval context); *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 370 (E.D. Pa. 2014) (accepting a false certification claim grounded in violation of the FDA off-label marketing regulations).

⁴⁷ See *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (“An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.”).

⁴⁸ Implied false certifications represent approximately forty-three percent of the dataset of 1162 federal False Claims Act opinions that contain any mention of “false certification” or “legally false.” See *supra* note 42.

⁴⁹ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

⁵⁰ Petition for Writ of Certiorari at ii, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (No. 15-7).

⁵¹ *Escobar*, 136 S. Ct. at 1995.

⁵² *Id.* at 1996.

⁵³ *Id.* at 2002 (quoting *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)). Notably, the opinion was much more specific about what materiality is not than what it is: First, materiality does not automatically follow from the government’s decision to designate a rule a condition of payment; second, materiality does not flow from the government’s ability to deny payment upon finding noncompliance; third, materiality cannot be found where noncompliance is minor or insubstantial. But materiality can be found where “the defendant knows that the Government consistently

C. *The Aftermath of Escobar, the FDA Context, and Campie*

Judging from the sheer number of opinions citing *Escobar*, the impact of the case is undeniable,⁵⁴ even if the exact nature of the impact is difficult to pin down. After it was announced, some advocates celebrated *Escobar* as “justice for whistleblowers,”⁵⁵ while members of the defense bar highlighted the Court’s emphasis on the rigorous materiality requirement.⁵⁶ More recent scholarship assessing *Escobar* remains similarly ambivalent about its precise impact in the lower courts.⁵⁷

refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” *Id.* at 2003. If, on the other hand, “the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” *Id.* This last sentence is the doctrinal hook for the presumption addressed in this Note. *See infra* Section I.D (discussing the doctrinal and policy justifications for the presumption of immateriality from agency inaction).

⁵⁴ In the two and a half years since its publication, *Escobar* has been cited over five hundred times, including nearly one hundred times at the court of appeals level. *See Shepard’s Report: Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, *Citing Decisions*, LEXIS ADVANCE RES., <https://www.lexisnexis.com/en-us/gateway.page> (search for “139 S. Ct. 1989,” then follow “Shepardize” hyperlink) (last visited Nov. 13, 2019).

⁵⁵ *Universal Health Services v. U.S. ex rel. Escobar: Supreme Court Unanimously Supports Whistleblower Under False Claims Act*, NAT. WHISTLEBLOWER CTR., <https://www.whistleblowers.org/amicus-curiae-briefs/universal-health-services-v-u-s-ex-rel-escobar-supreme-court-victory-for-whistleblowers> (last visited Nov. 10, 2019).

⁵⁶ *See Rich Samp, The Supreme Court’s ‘Universal Health’ Ruling: A Net Win for Federal Government Contractors*, FORBES (June 17, 2016), <https://www.forbes.com/sites/wlf/2016/06/17/the-supreme-courts-universal-health-ruling-a-net-win-for-federal-government-contractors>; *Universal Health Services, Inc. v. Escobar*, SIDLEY, <https://www.sidley.com/en/insights/publications/2017/05/universal-health-services-inc-v-escobar> (last visited Nov. 10, 2019).

⁵⁷ *See, e.g.,* Deborah R. Farringer, *From Guns That Do Not Shoot to Foreign Staplers: Has the Supreme Court’s Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 BROOK. L. REV. 1227, 1232 (2018) (arguing that, while the lower courts are applying a “rigorous and demanding” materiality standard after *Escobar*, they have done so with little consistency); Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud That “Counts” Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1844 (2017) (arguing that, while the materiality standard after *Escobar* is more demanding, its formulation of materiality cannot be determined “solely by looking to the wording of the statute or regulations alone,” thus “potentially leading courts to conclude that factual development beyond that available at the motion to dismiss or summary judgment stage is necessary”); Latoya C. Dawkins, Note, *Not So Fast: Proving Implied False Certification Theory Post-Escobar*, 42 SETON HALL LEGIS. J. 163, 167 (2017) (observing that because materiality must be tested on a case-by-case basis, “the post-*Escobar* landscape has already splintered in different directions in the definition of ‘specific misrepresentation’ and as to which factors carry the most weight in determining whether the half-truth affected the government’s decision-making process”); Doan Phan, Comment, *Redefining Lincoln’s Law: How to Shape the Theory of Implied Certifications Post-Escobar*, 13 J.L. ECON. & POL’Y 113, 114 (2017)

The presumption of immateriality from agency inaction emerged in this uncertain, post-*Escobar* landscape, arising in a line of cases alleging false claims in the realm regulated by the FDA. In the first case, *D'Agostino v. ev3, Inc.*, the First Circuit rejected a claim from a relator alleging that the defendant made fraudulent representations to the FDA while seeking approval to market a medical device.⁵⁸ In assessing the materiality of these falsehoods, the court observed that “[t]he fact that [the government] has not denied reimbursement for [the device] in the wake of [the relator’s] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges.”⁵⁹ Similarly, in *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, the same court evaluated an action predicated on alleged misrepresentations made during the FDA approval process. Once again, the court found that the agency’s choice not to “withdraw or even suspend its approval” of the product “render[ed] a claim of materiality implausible.”⁶⁰

Similar arguments have been deployed in the context of product labeling regulated by the FDA. In *United States ex rel. Petratos v. Genentech Inc.*, the Third Circuit rejected a claim which alleged that the defendant concealed drug risk information, which would have required the company to file adverse-event reports and could have resulted in changes to the drug’s label.⁶¹ In doing so, the court emphasized the government’s continued approval of the drug and the absence of any enforcement proceedings since the agency was put on notice about the relator’s allegations.⁶²

The presumption of immateriality has been exported to other contexts. For example, in *United States ex rel. Harman v. Trinity Industries*, the Fifth Circuit rejected a claim from a relator alleging that the defendant company defrauded the Federal Highway Administration to obtain reimbursement for a highway safety product. Citing the reasoning in *D'Agostino* and *Petratos*, the court concluded that “continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality.”⁶³

(“[T]he Supreme Court’s lack of guidelines in how to find materiality has the potential of leading to a circuit split on what claims would be material.”).

⁵⁸ See *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016).

⁵⁹ *Id.*

⁶⁰ *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017).

⁶¹ See *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017).

⁶² See *id.*

⁶³ *United States ex rel. Harman v. Trinity Indus.*, 872 F.3d 645, 663 (5th Cir. 2017).

Courts around the country seemed to be coalescing around this potent immateriality presumption until the Ninth Circuit, in *United States ex rel. Campie v. Gilead Sciences*, rejected the claim that the government's continued approval and payment are determinative or even persuasive in the materiality inquiry.⁶⁴ Instead, the court said that "to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake."⁶⁵ Among the reasons offered by the court were that, first, the parties disputed what the government knew and when, thus calling into question its actual knowledge, and, second, even had the government known, there may have been many reasons behind why the agency chose not to withdraw the drug's approval.⁶⁶ In any event, the court concluded that the issues raised by the parties are "matters of proof, not legal grounds to dismiss relators' complaint."⁶⁷

The *Campie* defendants filed a petition for certiorari at the Supreme Court,⁶⁸ and the Court invited the Solicitor General to file a brief, indicating some interest in the case. Ultimately, perhaps because of diverging views about the exact nature of the split among the lower courts,⁶⁹ the Court denied certiorari in *Campie*.⁷⁰ However, the denial of review in this case means that the disagreement among the courts about the emphasis placed on agency inaction will persist. In fact, the Supreme Court has already seen at least one new petition on a very similar question, this time from the Sixth Circuit.⁷¹

⁶⁴ See *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017).

⁶⁵ *Id.*

⁶⁶ See *id.* at 906–07.

⁶⁷ *Id.* at 907. Notably, the fact-intensive nature of *Escobar*'s materiality inquiry making dismissal grants at the pleading stage less likely is precisely the effect of *Escobar* that some observers have predicted. See, e.g., Krause, *supra* note 57, at 1844.

⁶⁸ *Campie* Petition, *supra* note 17.

⁶⁹ The defendants in *Campie*, in their brief in opposition, argued that there is no actual split among the circuits and that the courts are, instead, undertaking a "holistic materiality review" in each case. See Brief in Opposition at 21, *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936 (U.S. Mar. 5, 2018). Similarly, the government in its brief took the position that the Ninth Circuit's decision does not conflict with decisions from the other courts of appeals. Instead, the Solicitor General said that materiality has been applied consistently as a "holistic inquiry . . . [in which] continued payment by the government, despite actual knowledge of violations, can constitute important but not necessarily dispositive evidence" of immateriality. Brief for the United States as Amicus Curiae at 17, *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936 (U.S. Nov. 30, 2018) [hereinafter *Campie* U.S. Brief].

⁷⁰ *Gilead Scis., Inc. v. United States ex rel. Campie*, 139 S. Ct. 783 (2019).

⁷¹ Petition for Writ of Certiorari, *Brookdale Senior Living Cmtys., Inc. v. United States ex rel. Prather*, No. 18-699 (U.S. Nov. 20, 2018); see also Amy L. O'Neill, *U.S. Supreme Court Asked to Review Escobar Circuit Splits Related to Materiality and Scier in False Claims Act (FCA) Cases*, KING & SPALDING: HEALTH HEADLINES (Nov. 26, 2018), <https://>

D. *The Underpinnings of the Presumption of Immateriality from Agency Inaction*

Before turning to a critical evaluation of the immateriality presumption, this subsection lays out the policy justifications for the presumption. In Section I.D.1, I describe the policy concerns that stem from FCA's qui tam provisions. In Section I.D.2, I explain the policy justification based on the "conflict" between the FCA and the regulating agencies.

This Note focuses on and evaluates the policy justification for the presumption of immateriality, because the Court's decision in *Escobar* alone does not *require* that lower courts apply such a presumption. That said, it derives doctrinal plausibility from several pieces of dicta from *Escobar*. First, the Supreme Court there stated that the materiality standard for false certification claims is "rigorous"⁷² and that it is the proper vehicle for cabining the scope of the FCA.⁷³ Then, warning that the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations," the Court signaled a concern about frivolous claims.⁷⁴ As part of its totality-of-the-circumstances inquiry, the Court stated that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."⁷⁵ Finally, the Court pronounced that it is appropriate to resolve materiality in a motion to dismiss.⁷⁶ The presumption of immateriality from agency inaction at the pleading stage is, effectively, a blend of all these doctrinal strands.⁷⁷

www.kslaw.com/news-and-insights/health-headlines-november-26-2018 ("As it stands now, the Sixth Circuit is on the side of a five-two split regarding its stance on what it takes to show materiality in implied false certification theory cases . . ."); Scott Stein & Naomi Igra, *Sixth Circuit's Split Decision in Prather Highlights Persistent Questions About the Pleading Standard for Materiality After Escobar*, SIDLEY: ORIGINAL SOURCE (June 20, 2018), <https://fcablog.sidley.com/sixth-circuits-split-decision-in-prather-highlights-persistent-questions-about-the-pleading-standard-for-materiality-after-escobar> ("Cert petitions have already been filed raising questions about the standard for pleading materiality in the face of government inaction. . . . Until the Supreme Court weighs in, the fundamental debate in *Prather* will likely continue in cases percolating up through the lower courts.").

⁷² *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016).

⁷³ *See id.*

⁷⁴ *Id.* at 2003.

⁷⁵ *Id.*

⁷⁶ *See id.* at 2004 n.6.

⁷⁷ To be clear, there remains plenty of daylight between the dicta of *Escobar* and the presumption of immateriality from agency inaction at the pleading stage. First, the Court in *Escobar* emphasized that its materiality factors are "not automatically dispositive." *Id.* at 2003. Second, it is unclear how "actual knowledge" might be established in the pleadings

1. Policy Appeal: Private Actions & Floodgates

The glue that holds the doctrinal ingredients of the immateriality presumption together is its policy appeal. The first family of policy concerns supporting the presumption relates to the role of private litigants under the FCA. Characterizing the qui tam relators as “motivated primarily by prospects of monetary reward rather than the public good,”⁷⁸ the defendant in *Campie* charges in its petition for certiorari that “[t]he Ninth Circuit’s decision dangerously transfers regulatory authority from expert agencies to private litigants.”⁷⁹ The pharmaceutical and biotechnology lobbying groups are even more blunt in their brief: The Ninth Circuit’s decision “effectively grants plaintiffs an end run around the FDCA’s explicit prohibition on private lawsuits seeking to enforce its provisions”⁸⁰ and makes “the FCA into an effective means for private litigants to sue companies for alleged violations of the FDCA and FDA regulations.”⁸¹ The litigants and their amici often draw support from the Court’s opinion in *Buckman Co. v. Plaintiffs’ Legal Committee* which prohibited state tort actions under a “fraud-on-the-FDA” theory on the basis of implied federal preemption.⁸² In it, the Supreme Court emphasized the potential burden of complying with the FDA’s regulatory regime in the shadow of fifty states’ tort regimes.⁸³

In their characterization of the private litigants initiating FCA actions on the basis of regulatory violations, the defendants in *Campie* invoke a floodgates concern: “The Government spent over \$117 bil-

by the relator who has no insight into what the government knew and when. This was the reasoning advanced by the First Circuit on remand in *Escobar*. See *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (refusing to require relators to allege the government’s payment practices in order to establish the government’s views on the materiality of the violation and questioning whether, in light of the privacy regulations in the healthcare industry, relators could ever access such information). Because of this reason and also the holistic nature of materiality, it is likely to be a determination reserved for a jury. See *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906–07 (9th Cir. 2017) (calling this inquiry a “matter[] of proof, not legal grounds to dismiss relators’ complaint”).

⁷⁸ *Campie* Petition, *supra* note 17, at 23 (quoting *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997)).

⁷⁹ *Id.*

⁸⁰ Brief of Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization as Amici Curiae Supporting Petitioner at 3, *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936 (U.S. Feb. 2, 2018) [hereinafter *PhRMA-BIO Brief*].

⁸¹ *Id.* at 6.

⁸² See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001).

⁸³ See *id.* at 350. For a more detailed discussion of principles underlying *Buckman*, see *infra* Section I.D.2 and Part III. Although *Buckman* is grounded in federal preemption, the policy rationales expressed in the opinion include agency expertise, which is relevant to the claims made by the petitioner in *Campie*.

lion on prescription drugs in 2016 . . . alone. . . . That is 117 billion reasons to scour the Code of Federal Regulations and scrutinize pharmaceutical companies' every move, looking for any hint of a violation that might lead to a reward."⁸⁴ In their telling, such infractions are impossible to avoid, "given the scope and complexity of FDA regulations."⁸⁵ The emphasis on the role of the private parties bringing claims under the FCA thus feeds into the widespread angst over rising litigation caseloads.⁸⁶

The concern about *qui tam* actions generally and specifically as a *de facto* private right of action is not new.⁸⁷ After all, the outcry about "parasitic" *qui tam* claims is what led to the 1943 amendments that nearly buried the Act.⁸⁸ While both the constitutionality of the *qui tam* actions⁸⁹ and the propriety of such claims on the basis of regulatory violations have since been firmly established,⁹⁰ there continues to be a clear undercurrent of discomfort with the entire statutory scheme that exposes these defendants to potentially "crushing liability."⁹¹

2. Policy Appeal: Agency Expertise

Separately from the concerns about the private litigants pursuing cases under the FCA, the petitioners and their amici in *Campie* object to the duplicative regulation regime created by the FCA that sits outside the agency with proper expertise and authority to regulate and

⁸⁴ *Campie* Petition, *supra* note 17, at 26.

⁸⁵ *Id.* at 25.

⁸⁶ See Arthur R. Miller, *The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Clichés Eroding Our Day in Court and Jury Trial Commitments?*, 78 N.Y.U. L. REV. 982, 985–86 (2003) (describing the concern about volume of litigation in American courts).

⁸⁷ See, e.g., Evan Caminker, *The Constitutionality of Qui Tam Actions*, 99 YALE L.J. 341, 348 (1989) (discussing the constitutionality of *qui tam* actions); Phelps, *supra* note 39, at 1028–29 (expressing bewilderment over FCA actions being brought by private individuals on the basis of violations of the Anti-Kickback Statute, which itself does not contain a private right of action).

⁸⁸ The government knowledge defense that emerged as a result of the 1943 amendments, see *supra* notes 28–30 and accompanying text, has some conceptual overlap with the presumption of immateriality from agency inaction.

⁸⁹ The Court has upheld the *qui tam* provisions against several challenges over the years. Prior to the 1943 amendments, the Court rejected a challenge based on the notion that "effective law enforcement requires that control of litigation be left to the Attorney General." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547 (1943). The Court simply responded that "the trouble with these arguments is that they are addressed to the wrong forum." *Id.* More recently, in *Vermont Agency of National Resources v. United States ex rel. Stevens*, the Court found adequate basis for Article III standing for the relator to assert the injury in fact suffered by the assignor of his claim, the United States government. 529 U.S. 765, 773–74 (2000).

⁹⁰ See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

⁹¹ *Campie* Petition, *supra* note 17, at 2.

enforce the law and regulations it has promulgated. The common claim is that the FDA, “the expert agency charged with regulating highly complex, research-and-development-intensive products that can be distributed globally,”⁹² is “best equipped to decide how to respond to alleged infractions.”⁹³

In addition to expertise, the petitioner in *Campie* argues that the FDA has the tools necessary to combat fraud during the approval process, rendering enforcement under the FCA not just disruptive but also unnecessary.⁹⁴ These arguments echo the Court’s opinion in *Buckman*, which the *Campie* defendants and their amici cite with zeal. There, the Court emphasized the “somewhat delicate balance of statutory objectives”⁹⁵ that the FDA is tasked with achieving, which could be skewed by allowing fraud claims. The Court found implied conflict, and thus preemption, in the fact that the FDCA contains ample powers for the FDA to punish and deter fraud against the agency.⁹⁶

The position advanced by the industry is simple: The agency knows best, so, if the agency does nothing, there cannot be a valid fraud claim. The dispositive presumption of immateriality from agency inaction is not merely a tool to keep private litigants out, but also to privilege the agency’s judgment above all others’.

Concerns about conflicts between FCA enforcement and the administrative agencies are familiar. Some practitioners have gone so far as to describe the relationship as “incongruous” and locate the disconnect at the anachronistic origins of the Act that predate the evolution of the modern administrative state.⁹⁷ This longstanding criticism stems from the duplicative oversight created by the FCA in contexts where an agency or department is vested with the power to regulate a

⁹² *Id.* at 23.

⁹³ *Id.* at 24.

⁹⁴ *See id.* at 23–24.

⁹⁵ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001).

⁹⁶ *See id.* at 348–49 (outlining several enforcement tools that are available to the FDA and concluding that these allow the agency to “make a measured response to suspected fraud upon the Administration”).

⁹⁷ *See* Malcolm J. Harkins, III, *The Ubiquitous False Claims Act: The Incongruous Relationship Between a Civil War Era Fraud Statute and the Modern Administrative State*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 131, 134 (2007) (outlining the difficulty in reconciling the Civil War era FCA with the modern administrative state); *see also* Richard Hughes IV, *With a Worthless Services Hammer, Everything Looks Like a Nail: Litigating Quality of Care Under the False Claims Act*, 37 J. LEGAL MED. 65, 65 (2017) (criticizing the application of the FCA to quality of care claims in the healthcare setting); Christopher L. Martin, Jr., Comment, *Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CALIF. L. REV. 227, 232 (2013) (advocating for the less aggressive formulation of the implied certification theory of liability articulated in *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001)).

field,⁹⁸ resembling concerns that we have seen in *Campie* and *Buckman*. These criticisms frequently emphasize that the regulating agencies often have not only the power to sanction lack of compliance with program requirements but also the express permission to continue payments even when the program participant is non-compliant in order to give them an opportunity to remedy the violations.⁹⁹ Repeatedly, these sorts of finely designed regulatory, compliance, and enforcement structures are juxtaposed with the “blunt instrument”¹⁰⁰ of the FCA. In these narratives, enforcement under the FCA necessarily mucks up the regulatory infrastructure and judgments of the agencies.

II

QUI TAM AS VIRTUAL PRIVATE RIGHT OF ACTION

This Part explores why the concern about qui tam actions as de facto private rights of action articulated in Section I.D.1 is unfounded. Section II.A covers the FCA’s statutory limits, which narrow the reach of its qui tam provisions. Section II.B explains the government’s gatekeeping role under the FCA and its impact on qui tam litigants. Section II.C reviews some empirical research about the scope of litigation by private parties under the FCA to further cement the point that the qui tam provisions cannot rightly be regarded a mechanism that creates an open season on regulatory violations.

A. *Statutory Constraints Narrow the Universe of Qui Tam Actions and Claimants*

The FCA’s qui tam provisions are distinguishable from bona fide private rights of action due to two critical features of the Act—the first-to-file bar and the public disclosure bar—which significantly limit who can bring a qui tam suit and under what circumstances.

The first-to-file provision of the FCA states that “[w]hen a person brings an action under this subsection, no person . . . may . . . bring a related action based on the facts underlying the pending action.”¹⁰¹ Legislative history shows that, by including this bar, the drafters wanted to make clear that “private enforcement under the civil False

⁹⁸ See Harkins, *supra* note 97, at 134–35 (describing the relationship between the FCA and Medicare as a “[t]ug of [w]ar” and asking “Who’s in Charge Here?” of the relationship between the FCA and the Department of Education).

⁹⁹ See *id.* at 161 (“Even if the nursing home is not in substantial compliance at the time of the survey, in most cases, the nursing home will be given an opportunity to correct any problems and federal payment may continue for months while it does so.”).

¹⁰⁰ *Mikes*, 274 F.3d at 699.

¹⁰¹ 31 U.S.C. § 3730(b)(5) (2018).

Claims Act is not meant to produce class actions or multiple separate suits based on identical facts and circumstances.”¹⁰² Additionally, the public disclosure bar instructs courts to “dismiss an action or claim under this section . . . if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed [previously] . . . unless . . . the person bringing the action is an original source of the information.”¹⁰³ The public disclosure bar, combined with the original source exception, was part of the 1986 amendments discussed in Section I.A, in which the lawmakers sought to strike a balance between encouraging reporting and preventing parasitic claims.¹⁰⁴

The combined effect of these provisions is twofold. First, they render the *qui tam* action a one-time ticket for a valid fraud claim. When fraud occurs in an organization, generally only one relator can bring a successful claim on the basis of that fraudulent conduct. Second, the provisions naturally limit who has access to the kind of information that would provide sufficient basis for an FCA action in the first place. Because one cannot sue on the basis of information that has been publicly disclosed, this makes it very likely that suits will be brought by corporate insiders, like Mr. Mullen from *AmerisourceBergen*, who are often the only ones with access to such information.¹⁰⁵

Both of these effects are in stark contrast with a typical action in tort where, for example, a product defect exposes a corporation to liability to *all* consumers who can establish that they suffered harm caused by that defect. The success of one claim makes subsequent claims more likely. In an FCA *qui tam* action, in contrast, a corporate insider is typically the source of a valid claim, and, once they initiate it, the claim vitiates all subsequent claims based on the same conduct. Thus, rather than offering a “bonanza” for the resourceful individual who “scour[s] the Code of Federal Regulations and scrutinize[s] phar-

¹⁰² S. REP. NO. 99-345, at 25 (1986).

¹⁰³ 31 U.S.C. § 3730(e)(4)(A).

¹⁰⁴ See *supra* note 37 and accompanying text.

¹⁰⁵ See *Typical Healthcare Fraud Whistleblowers*, NOLAN AUERBACH & WHITE, <https://www.whistleblowerfirm.com/qui-tamfalse-claims-act/typical-healthcare-fraud-whistleblowers> (last visited Nov. 10, 2019) (“A[n] . . . employee who blows the whistle on his or her employer is one of the most common types of *qui tam* plaintiffs. Detecting [and proving] fraud is usually very difficult, absent the cooperation of an insider close to the fraudulent activity.”); *Who Are Whistleblowers?*, BERG & ANDROPHY, <https://www.bafirm.com/practice-areas/qui-tam-litigation/qui-tam-frequently-asked-questions/who-are-whistleblowers> (last visited Nov. 10, 2019) (listing the typical whistleblowers and saying that they are “often current or former employees who have attempted to report or correct fraud to the government”).

maceutical companies' every move,"¹⁰⁶ the FCA offers a narrow avenue to bring a viable claim. And although defining the exact contours of the first-to-file and public disclosure bars has been subject to some interpretative disputes,¹⁰⁷ courts have not been shy about relying on these provisions to dismiss duplicative claims.¹⁰⁸

B. Government's Gatekeeping Limits on Qui Tam Actions

In addition to the limits imposed by the statutory and practical considerations discussed in Section II.A, FCA qui tams can be further distinguished from proper private actions because of the meaningful gatekeeping role that the government plays at every step of the suit. This role is important to explain, since much of the criticism of qui tam in the context of the false certification theory rests on the assumption that private parties are effectively enforcing rules that the agencies are tasked with overseeing.¹⁰⁹ Allowing private parties to proceed with a suit when an agency has chosen not to act, the argument goes, would "turn the FCA into a tool with which a jury of six people could

¹⁰⁶ *Campie* Petition, *supra* note 17, at 2, 26.

¹⁰⁷ The litigation of the first-to-file provision, for example, led to a conflict about whether the bar applies to actions that have been dismissed. The Court, in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, said no. 135 S. Ct. 1970, 1979 (2015). On remand, the litigation immediately led to another appeal, this time on the question of whether the application of the dismissal of a related action automatically cures the bar of an action filed during the pendency of the eventually dismissed suit. In *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 207 (4th Cir. 2017), the court said the action must be filed anew. This was in contrast to the First Circuit's answer on the same question, which allowed an amended pleading to cure the defect and thus remain within the statute of limitations. *See United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 (1st Cir. 2015). The public disclosure bar, on the other hand, presents complications due to the inherent difficulty of discerning of when disclosure is deemed public, as it relates, for example, to the source of information, *see, e.g., United States ex rel. May v. Purdue Pharma L.P.*, 811 F.3d 636, 641–42 (4th Cir. 2016) (considering whether relators can use facts learned by their attorney in a previous case), or the extent of similarity of the information provided, *see, e.g., United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 567 (9th Cir. 2016) (holding that the relator's information was different in kind and in degree and therefore must be allowed to proceed forward).

¹⁰⁸ *See, e.g., United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 531 (3d Cir. 2007) (finding lack of jurisdiction because all the allegations and transactions in the complaint were publicly disclosed); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001) (affirming dismissal based on the first-to-file bar and stating that "an exception-free, first-to-file bar conforms with the dual purposes of the 1986 amendments: to promote incentives for whistle-blowing insiders and prevent opportunistic successive plaintiffs"); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 238 (3d Cir. 1998) (affirming dismissal of several claims under the first-to-file bar); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 54 (D.D.C. 2007) (dismissing a claim because the relator did not have direct and independent knowledge of the information underlying the claims asserted).

¹⁰⁹ *See, e.g., Campie* Petition, *supra* note 17, at 23 ("The Ninth Circuit's decision dangerously transfers regulatory authority from expert agencies to private litigants.").

retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so.”¹¹⁰

The government exercises oversight over qui tam actions in several ways. First, upon the initial filing of the suit, it can choose to intervene in an action,¹¹¹ and it retains that right for the remainder of the life of the action.¹¹² When it intervenes, it assumes primary responsibility for prosecuting the action, and, in that capacity, it can dismiss or settle the action with limited involvement of the whistleblower.¹¹³

The intervention power serves two important functions: First, it can separate the wheat from the chaff. Even when the government does not formally oppose a qui tam action, empirical studies have shown that lack of intervention alone can be fatal to the litigation.¹¹⁴ There are a number of potential explanations for this phenomenon. It could be that the government excels at recognizing meritorious claims, or that the government has tools at its disposal that the relators do not.¹¹⁵ Commentators have also observed that some courts treat the government’s intervention as a signal of the merits of the case, leading to a self-fulfilling effect of the intervention.¹¹⁶ Regardless of the causal chain, it is clear that relators are generally not likely to proceed far on their own.

Second, involving the DOJ reduces concerns about private actors litigating in the wild, untethered from the oversight and expertise of

¹¹⁰ *D’Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016). The court further added that “[t]he FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies’ judgments about whether to rescind regulatory rulings.” *Id.*

¹¹¹ *See* 31 U.S.C. § 3730(b)(2) (2018) (giving the government the right to intervene within sixty days of initial filing).

¹¹² *See* 31 U.S.C. § 3730(c)(3) (giving the court the authority to permit the government to intervene at a later date upon showing of good cause).

¹¹³ *See* 31 U.S.C. § 3730(c)(1) (granting the government nearly exclusive control of the case); 31 U.S.C. §§ 3730(c)(2)(A)–(B) (granting the government the power to settle or dismiss the action after a fairness hearing).

¹¹⁴ *See* David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 *Nw. L. Rev.* 1689, 1693 (2013) (“[M]ost qui tam recoveries come where DOJ has intervened while most cases in which DOJ declines to intervene end in dismissal.”). Since the 1987 fiscal year, an average of ninety-five percent of recoveries in settlements and judgments in qui tam actions came from cases in which the DOJ intervened or otherwise pursued the case. *See Fraud Statistics – Overview*, *supra* note 38.

¹¹⁵ Chief among the tools at the government’s disposal is the Civil Investigative Demand (CID) authorized under the FCA. 31 U.S.C. § 3733(a). *See infra* notes 154–56 and accompanying text (discussing CID authority in more detail).

¹¹⁶ *See* Engstrom, *supra* note 114, at 1694 n.17 (listing examples of cases in which courts have explicitly relied on a DOJ decision not to intervene as a signal of lack of merit of the underlying claim, and other examples in which courts have refused to draw that inference).

the government. Indeed, as part of its oversight, the DOJ aims to, and often does, coordinate with the regulating agency. According to the DOJ manual on handling qui tam suits under the FCA, upon receipt of the complaint, the U.S. Attorneys must forward the complaint to the Civil Division of the DOJ; the Civil Division, in turn, “will contact the agency involved, the Criminal Division, and, frequently, the Inspector General of the agency, to determine if the allegations are known to them and to obtain an assessment of the material evidence furnished by the relator.”¹¹⁷

AmerisourceBergen, referenced in the Introduction, is a case in point: The investigation involved coordinated efforts from the U.S. Attorney’s Office; the DOJ; the Office of Criminal Investigation at the FDA; the Offices of the Inspector General at HHS, the Department of Defense, and the Office of Personnel Management; the Department of Veterans Affairs; and the New York State Medicaid Fraud Control Unit.¹¹⁸ While other cases may not involve an equally extensive roster of agencies and departments, this case illustrates the expansive scope that investigations and litigation can and do take under the FCA. Given the involvement of the government at multiple levels, it is difficult to argue that the original relators in *AmerisourceBergen* were enforcing public laws without any input from the agencies vested with the power to regulate.

At the same time, the government’s actions, important though they may be, can also provide confusing signals: Due to simple resource constraints, the DOJ and other agencies may elect not to intervene or otherwise become involved *at first*, allowing the relator to develop the case, only to intervene later.¹¹⁹ This is precisely what seems to have happened in *AmerisourceBergen*: The government did not formally intervene in the qui tam cases until August 31, 2017, whereas the first relator action was filed in 2010.¹²⁰ Notably, the conduct brought to the government’s attention in the 2010 complaint continued until early 2014,¹²¹ and the government apparently continued to reimburse for the products in question despite its knowledge of the

¹¹⁷ 932. *Provisions for the Handling of Qui Tam Suits Filed Under the False Claims Act*, DEPT. JUST., <https://www.justice.gov/jm/criminal-resource-manual-932-provisions-handling-qui-tam-suits-filed-under-false-claims-act> (last visited Jan. 17, 2020) (describing provisions for the handling of qui tam suits filed under the False Claims Act).

¹¹⁸ See Press Release, U.S. Attorney’s Office, *supra* note 4.

¹¹⁹ See S. REP. NO. 99-345, at 7 (1986) (stating that the government is often forced to make screening decisions due to a lack of resources).

¹²⁰ Settlement Agreement at 2, *United States v. AmerisourceBergen Corp.*, No. 1:12-cv-01178-NG-ST (E.D.N.Y. Nov. 15, 2018).

¹²¹ *Id.* at 4–6 (identifying the period in which the relevant conduct occurred as October 2001 to January 2014 or as June 2005 to January 2014).

purported scheme. This example illustrates two points. First, it is difficult to draw meaningful inferences about the materiality of a violation from what the government does when it first becomes aware of false claims; second, despite initial inaction and lack of involvement by the government, the eventual resolution of a case may ultimately include many layers of official input and oversight. If a court were to adopt the logic articulated by the *Campie* petitioner, cases like *AmerisourceBergen* would have had to be dismissed for lack of materiality due to the government's lack of initial response and continued reimbursement after it became aware of the violations. The eventual resolution in *AmerisourceBergen* demonstrates why this would be against public interest.

In addition to its power to intervene and manage the litigation, the government can move to dismiss a qui tam action over a relator's objection.¹²² In the government's brief opposing certiorari in *Campie*, the Solicitor General invoked these powers when disputing the notion that the action would allow a jury to interfere with the work of the FDA. And the brief does not stop at merely articulating an abstract authority to dismiss suits when the government concludes "that continued prosecution of the suit is not in the public interest."¹²³ As if to prove its seriousness, the Department of Justice committed to the position that if *Campie* were to be remanded by the Court, the government would invoke this power and move to dismiss the case.¹²⁴

To be clear, there remains some daylight between the power of the government to utilize its intervention and dismissal powers and it actually doing so. It has been a long-standing criticism that the government has not exercised this authority enough.¹²⁵ More recently, however, the Director of the Fraud Section of the Commercial Branch at the DOJ issued a confidential—yet promptly leaked—memorandum, encouraging DOJ line attorneys to consider whether the government's interests would be served by seeking dismissal.¹²⁶ The memo acknowledged that the Department had utilized the authority to dismiss sparingly in the past, largely to avoid precluding relators

¹²² See 31 U.S.C. § 3730(c)(2)(A) (2018).

¹²³ *Campie* U.S. Brief, *supra* note 69, at 15.

¹²⁴ *Id.*

¹²⁵ See Engstrom, *supra* note 114, at 1712 n.69 (citing examples of such critics and the very few cases that involved the government's affirmative exercise of the dismissal authority).

¹²⁶ Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, U.S. Dep't of Justice to Assistant U.S. Attorneys Handling False Claims Act Cases 1 (Jan. 10, 2018), <https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf>.

from pursuing potentially worthwhile matters.¹²⁷ However, emphasizing the Department's important gatekeeper role in protecting the Act, it provided a framework for deploying the dismissal power. Among the seven factors outlined, the memo included potential interference with agency policies and programs.¹²⁸ The director encouraged the attorneys to consult with the affected agency to determine whether a dismissal is warranted and noted that, if the agency views the alleged falsity as immaterial, the government can provide a declaration to that effect.¹²⁹

In addition to the Solicitor General's actions in *Campie*, the Department has recently exercised the dismissal power in at least one other high-profile set of cases, suggesting a more aggressive stance.¹³⁰ In the motion, the U.S. Attorney on the case explained that "the government has concluded that the specific allegations in this case conflict with important policy and enforcement prerogatives of the federal government's healthcare programs."¹³¹ The government's ability and increased willingness to control qui tam cases through the dismissal power, combined with the meaningful role of its intervention power, provide a significant barrier to frivolous suits.

C. Empirical Research on "Floodgates"

As articulated in Section I.D.1, businesses often invoke a concern about a flood of litigation created by the FCA generally and the false certification theory specifically. In their telling, the materiality requirement "exists to push back against this financial pressure for an ever-expanding FCA."¹³² This pressure is so significant, they claim, that it "could affect the availability of drugs and other valued products and services."¹³³ An amici group led by the Chamber of Commerce warns that "highly complex and attenuated implied false certification theories" require costly discovery and failing to strictly enforce mate-

¹²⁷ See *id.* at 1–2.

¹²⁸ See *id.* at 4.

¹²⁹ See *id.* at 8.

¹³⁰ See The United States' Motion to Dismiss Relator's Second Amended Complaint, *United States ex rel. Health Choice Group, LLC v. Bayer Corp.*, No. 5:17-cv-00126-RWS-CMC (E.D. Tex. Dec. 17, 2018) [hereinafter *Health Choice Motion*] (moving to dismiss a qui tam action by a professional relator who had filed several similar actions); see also Scott Stein & Neil Nandi, *Flexing Its Granston Muscle, DOJ Seeks Dismissal of Patient Support Services FCA Litigation*, SIDLEY: ORIGINAL SOURCE (Dec. 18, 2018), <https://fcablog.sidley.com/flexing-its-granston-muscle-doj-seeks-dismissal-of-patient-support-services-fca-litigation> (discussing the government's motion to dismiss in *Health Choice* and related actions).

¹³¹ *Health Choice Motion*, *supra* note 130, at 16.

¹³² *Campie* Petition, *supra* note 17, at 26.

¹³³ *Id.* at 23.

riality at the pleading stage leads to “enormous deadweight loss to the economy.”¹³⁴ Given the high stakes articulated by industry groups, it is useful to see if there is empirical support for the notion that the FCA’s growth is a cause for concern.

Although FCA litigation is trending up over the last few decades, its volume has stabilized in the last couple of years. After an initial period of steady climb following the 1986 amendments—rising from thirty *qui tam* cases in 1987 to 547 in 1997—the amount of litigation declined for a number of years and, between 2001 and 2008, remained in the range of 300–450 new cases filed per year. 2009 was another inflection point,¹³⁵ with new cases eventually reaching 756 in 2013. Since then, new case filings have declined again slightly, reaching a new equilibrium in the 600–720 range.¹³⁶ To put the numbers into perspective, federal district courts saw roughly 277,000 new civil suits in 2018, of which approximately 148,000 were filed on the basis of federal question jurisdiction.¹³⁷ By any measure, in addition to no longer growing, FCA litigation is merely a drop in the bucket of federal civil litigation.

Furthermore, in his amicus brief on behalf of the respondents in *Escobar*, Professor Engstrom makes three enlightening observations about the trends in FCA litigation: First, the period when the implied certification theory was developed by the courts saw a flattening or *decline* in the number of cases, calling into question how much that theory alone can explain the rise in FCA litigation; second, both periods of expansion (after 1986 and 2009) followed statutory amendments intended to expand the reach and strength of the FCA, suggesting that this growth occurred by design; third, health and military spending—the two most active FCA areas—more than doubled since 1986 and saw rapid growth in the 2000s due to the expansion of Medicare through the Prescription Drug Program.¹³⁸ In other words, even the growth that we have observed can be adequately accounted for by various factors that further undermine the notion that the litiga-

¹³⁴ Brief for the Chamber of Commerce of the United States et al. as Amici Curiae Supporting Petitioner at 13, *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936 (U.S. Feb. 1, 2018).

¹³⁵ 2009 was when the Fraud Enforcement and Recovery Act was passed. Pub. L. No. 111-21, 123 Stat. 1617 (2009).

¹³⁶ See *Fraud Statistics – Overview*, *supra* note 38.

¹³⁷ *Federal Judicial Caseload Statistics 2018*, U.S. COURTS, <https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2018> (last visited Nov. 6, 2019).

¹³⁸ Brief of Professor David Freeman Engstrom as Amicus Curiae Supporting Respondents at 5–7, *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (No. 15-7).

tion is an uncontrolled deluge of frivolous claims that threatens the viability of private enterprise and innovation.

In summary, the concerns about qui tam actions that industry groups are attempting to address through the strict heightened materiality requirement sought in *Campie* are unwarranted. As shown in Sections II.A and II.B, the qui tam regime of the FCA differs meaningfully from private rights of action. Additionally, as shown in Section II.C, the volume of litigation under the qui tam provisions does not warrant a concern about a flood of litigation. This, however, is not to diminish the importance of the relators in fraud enforcement. As we have seen, the vast majority of recoveries under the Act occur in actions brought by private relators.¹³⁹ It is therefore understandable why industry groups are deeply uncomfortable with these actors. However, the value—or danger, depending on your perspective—of the qui tam is not that it functions like a private right of action but rather that the whistleblower provides vital information which, in concert with an intervention of the government, has the potential to be the powerful enforcement instrument that it has been. In that sense, it is more properly characterized and understood as an information-gathering tool, rather than as a distinct species of private civil action. These characteristics are, in part, what justify the existence of the FCA as an independent enforcement authority, a topic I turn to in the next Section.

III

TENSION BETWEEN THE FCA AND REGULATING AGENCIES AND THE BENEFITS OF PARALLEL REGULATION

This Part responds to the policy justification for the immateriality presumption that stems from the alleged conflict between the FCA and the regulating agencies, as articulated in Section I.D.2. My central claim is that the conventional characterization of the relationship between the FCA and the administrative state as problematic, and the prescription consequently advocated for in *Campie*, are backwards: Rather than interfering with the judgment of the regulators, a strong, independent enforcement authority under the FCA gives the agencies *more* discretion to exercise the regulatory authority within their own toolkits. In contrast, fully tethering fraud enforcement to the actions of the agencies through the immateriality presumption constrains agencies and pushes them towards more dramatic actions than they would normally prefer. In other words, retaining a decoupled—and

¹³⁹ In the last five years, nearly eighty percent of recoveries came from qui tam actions. *Fraud Statistics – Overview*, *supra* note 38.

yes, occasionally conflicting—FCA enforcement regime allows both the regulator and the fraud enforcers (private or public) to achieve optimal outcomes. Section III.A highlights the unique tools and expertise that enforcement under the FCA offers, which exist nowhere else in the agencies. Section III.B shows that, even where there is theoretically a regulatory overlap between the agency and the FCA, this overlap can enhance rather than impede the discretion of the agency. Section III.C highlights the potential for an independent FCA to mitigate agency capture.

Before presenting my argument, it is worth articulating a few related concepts that are *not* core to my argument here. First, Section II.B already demonstrated that the conflict claim advanced by the industry underestimates the coordination that routinely exists between the DOJ and the affected agencies. This coordination enables easy resolutions for situations where the conflict becomes counter-productive.¹⁴⁰

Second, others have focused on the timing and the extent of the government's knowledge as a chief objection to the immateriality presumption. The Ninth Circuit in *Campie* rested its denial of the motion to dismiss, in part, on the idea that “the parties dispute exactly what the government knew and when, calling into question its ‘actual knowledge.’”¹⁴¹ The Solicitor General, in his brief opposing certiorari, argues that the petitioner's argument conflates knowledge of allegations of misconduct with knowledge that the violations actually occurred.¹⁴² Similarly, in a statement responding to *Escobar*, Senator Charles Grassley, one of the architects of the 1986 amendments, asked: “What does it mean for the government to have actual knowledge? Would it include one bureaucrat who suspected a violation but looked the other way? Would that prove the requirement was material?”¹⁴³ These arguments illustrate the inherent difficulty of administering the immateriality presumption: Even if such a presumption were to be adopted, one could expect meaningful litigation both around the question of what constitutes government's knowledge as a matter of law and the complex factual determinations surrounding that inquiry. For the sake of my argument, however, I assume that the

¹⁴⁰ The government's promise to seek dismissal in *Campie* because the litigation would interfere with the administration of the FDA is a case in point. *See supra* notes 122–29 and accompanying text (explaining the government's position regarding dismissals); *see also Health Choice Motion, supra* note 130 (discussing another instance of the government moving to dismiss on public policy grounds).

¹⁴¹ *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906–07 (9th Cir. 2017).

¹⁴² *Campie* U.S. Brief, *supra* note 69, at 12.

¹⁴³ 164 CONG. REC. S892–93 (daily ed. Feb. 13, 2018) (statement of Sen. Grassley).

government has the requisite knowledge of the infractions, even if it is far from clear what that knowledge needs to be or how it would be assessed.¹⁴⁴

Finally, one easy response to the arguments in favor of the presumption of immateriality predicated on conflict preemption under *Buckman*¹⁴⁵ is that supremacy of federal law which justifies preemption does not apply here because the FCA is a federal statute. Instead of simply disposing of *Buckman* as inapplicable here on those grounds, this Note engages with the claims of agency expertise and authority that also undergird the preemption argument. Nevertheless, it is necessary to point out that, without the federalism considerations that provide the constitutional hook for preemption in *Buckman*,¹⁴⁶ it would not be imperative to avoid conflict at all costs.

A. *The FCA Provides Access to Unique Expertise and Tools*

The basic claim of expertise resident within the FDA and other agencies whose sole purpose is to administer and oversee complex federal programs is facially compelling. The attorneys at the DOJ, let alone the private litigants bringing FCA claims, cannot claim to understand the various objectives and procedures that the Agency navigates in the ordinary course of business.¹⁴⁷ Further, given the panoply of anti-fraud tools available to the FDA, it also seems extreme to say that “it is not the FDA’s purpose to prevent fraud on the government’s fisc,”¹⁴⁸ as the Ninth Circuit did in *Campie*.

And yet, there is a kind of expertise that, by definition, necessarily resides outside the agency: insider knowledge of the companies that are regulated by the agency. Without the FCA, it would be difficult, if not impossible, for the government to access this information. This was the explicit motivation behind strengthening the *qui tam* pro-

¹⁴⁴ See Krause, *supra* note 57, at 1839–42 (discussing the temporal issues of assessing materiality, the government’s knowledge, and the analytical overlap between scienter and materiality as it relates to knowledge).

¹⁴⁵ See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (describing the conflict between the state law claims in that case and federal law as stemming from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a “somewhat delicate balance of statutory objectives”); see also *supra* Section I.D.2 (discussing agency expertise and *Buckman*).

¹⁴⁶ *Buckman*, 531 U.S. at 348.

¹⁴⁷ See, e.g., PhRMA-BIO Brief, *supra* note 80, at 17–23 (reviewing FDA’s interactive oversight of drug manufacturing).

¹⁴⁸ *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 905 (9th Cir. 2017).

visions in the 1986 amendments.¹⁴⁹ And although FDA regulations allow “citizens . . . [to] report wrongdoing and petition the agency to take action,”¹⁵⁰ empirical studies show that these agency processes are not typically used for the sort of information-gathering which the FCA has been particularly effective at, such as corporate misconduct.¹⁵¹ Given the extreme tradeoffs that someone acting against their employer must consider—including potential retaliation, loss of employability, and uncertainty whether their reporting will result in any action¹⁵²—the agency reporting mechanisms are insufficient for genuine whistleblowing due to the absence of monetary incentives that have been critical to the effectiveness of FCA’s *qui tam* provisions.¹⁵³

Aside from unique expertise in the form of insider information, the FCA contains tools to which the FDA and most other agencies do not otherwise have access. The most significant one is the Civil Investigative Demand (CID), which authorizes the DOJ to request documents, responses to interrogatories, and depositions “[w]henever [the government] has *reason to believe* that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation.”¹⁵⁴ The CID is a prelitigation discovery mechanism and as such cannot be avoided through a successful motion to dismiss. Not only is the statutory authority for the CID extremely broad, but there are also few judicially imposed limits on the issuance of CIDs.¹⁵⁵ However, the power to issue CIDs is

¹⁴⁹ S. REP. NO. 99-345, at 4 (1986) (“Detecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity.”).

¹⁵⁰ *Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30 (2000)).

¹⁵¹ See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 270–71 (2012) (showing that the vast majority of petitions are filed by other manufacturers and are typically designed to slow down the entry of generics on the market).

¹⁵² See S. REP. NO. 99-345, at 4–6 (1986) (describing the difficulties faced by potential whistleblowers and the resulting “conspiracy of silence” that has allowed fraud against the government to grow (quoting *Hearing on S. 1562, The False Claims Reform Act, Before the Subcomm. on Admin. Practice & Procedure of the S. Comm. on the Judiciary*, 99th Cong. (1985))).

¹⁵³ See Helmer, *supra* note 28, at 1281–82 (concluding that the underlying premise of the FCA of enlisting the public to combat fraud has proven successful).

¹⁵⁴ 31 U.S.C. § 3733(a) (2018) (emphasis added); see also *id.* § 3733(f)–(h) (specifying the authority of investigators to require the forms of evidence in question).

¹⁵⁵ See, e.g., *United States v. Picetti*, No. 2:19-cv-00049 KJM AC, 2019 U.S. Dist. LEXIS 71944, at *4 (E.D. Cal. Apr. 26, 2019) (finding that civil investigative demands are enforced as administrative subpoenas and that the scope of judicial review for administrative subpoenas is quite narrow); *United States v. Kernan Hosp.*, No. RDB-11-2961, slip op. at 7, 11 (D. Md. Nov. 20, 2012) (observing the paucity of case law construing the metes and bounds of the False Claims Act’s civil investigative demand); see also James P. Holloway,

significantly weaker without the information from the relator, since the statute requires some “reason to believe” there are grounds for a false claims investigation for the government to be able to issue the demand.¹⁵⁶ In other words, by combining tips from relators with the ability to issue CIDs, the FCA offers hard-to-get information, which turns on a potent discovery engine, which generates further information still.

Another consideration, besides expertise and tools, is limited resources. The knowledge and authority within the FDA are simply not useful if the agency does not have enough resources to capitalize on them. In response to this concern, the *Campie* amici supporting the petitioner point to the FDA’s Office of Regulatory Affairs which employs close to 5000 expert staff¹⁵⁷ and conducted 16,100 inspections, leading to 257 arrests, 274 convictions, and recovery of \$375 million in fines, restitutions, asset seizures, and forfeitures in fiscal year 2016.¹⁵⁸ While these numbers seem impressive at first glance, the heft of this force must be evaluated in context. First, the global pharmaceutical industry generated over \$1.135 trillion in revenues in 2017;¹⁵⁹ second, under the FCA, the DOJ collected close to \$4 billion in judgments and settlements in the same year.¹⁶⁰ The FDA’s own enforcement statistics offer another indication that the FDA staff is insufficient to police the industry: Of the astonishing 5854 drug, biotech, and medical device product recalls that occurred in 2018, 99.4% were voluntarily initiated by the manufacturer.¹⁶¹ Given the vast size of the industry and the patient safety issues at issue in regulation of drugs, the agency should welcome all the help it can get from whistleblowers.

Recent Court Decision Shows Best Way to Handle Civil Investigative Demands, BAKER DONELSON (May 22, 2019), <https://www.bakerdonelson.com/recent-court-decision-shows-best-way-to-handle-civil-investigative-demands> (writing that *United States v. Picetti* “highlights the difficulty of resisting a CID” and that “it is usually difficult to avoid a CID altogether”).

¹⁵⁶ 31 U.S.C. § 3733(a)(1).

¹⁵⁷ See PhRMA-BIO Brief, *supra* note 80, at 22.

¹⁵⁸ *Office of Global Regulatory Operations and Policy (GO)*, U.S. FOOD & DRUG ADMIN., <https://web.archive.org/web/20190208151212/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ucm20025998.htm> (last visited Nov. 11, 2019).

¹⁵⁹ *Revenue of the Worldwide Pharmaceutical Market from 2001 to 2018 (in Billion U.S. Dollars)*, STATISTICA, <https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001> (last visited Nov. 11, 2019).

¹⁶⁰ *Fraud Statistics – Overview*, *supra* note 38.

¹⁶¹ *Enforcement Report*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/ires/index.cfm#tabNav_advancedSearch (search all recall reports between January 1, 2018, and December 31, 2018, in the “Biologics,” “Devices,” and “Drugs” product types) (last visited Jan. 11, 2019) (spreadsheet on file with author).

Concerns about bandwidth are also apparent in the FCA's legislative history. The 1986 amendments, which gave qui tam plaintiffs a more direct role in the litigation,¹⁶² were designed "as a check that the Government does not neglect evidence, cause unduly [sic] delay, or drop the false claims case without legitimate reason."¹⁶³ In doing this, Congress was concerned about reports that the most frequently cited reason for failure to report fraud was "the belief that nothing would be done to correct the activity even if reported"¹⁶⁴ and "lack of confidence in the Government's ability to remedy the problem."¹⁶⁵ The root cause Congress identified was that enforcement employees were "forced to make screening decisions" due to "a lack of resources on the part of Federal enforcement agencies."¹⁶⁶ Congress was clearly acknowledging the inherent limitations of the government to police fraud against the public purse. Whether Congress struck the correct balance can be debated, but the portrayal of FCA actions as usurping authority that Congress intended to reside exclusively in the regulating agencies is contradicted by the design and history of the Act.

B. *The FCA Enhances Agency Discretion*

This Section discusses how, in addition to providing additional expertise, tools, and bandwidth, the FCA can also enhance agency discretion. Although I called the Ninth Circuit's characterization that "it is not the FDA's purpose to prevent fraud on the government's fisc"¹⁶⁷ extreme, it is accurate in one respect: Fraud prevention is not the FDA's *primary* purpose. Rather, it is one of the Agency's many competing objectives. Reflecting this reality, arguments against fraud actions in the FDA realm are often premised on the notion that such actions interfere with the functioning of the Agency because they privilege fraud enforcement over the FDA's other concerns and thus limit the Agency's discretion to accomplish its goals.¹⁶⁸ To support this proposition, advocates and scholars invoke the fact that the agencies

¹⁶² Specifically, the Act provides that the relator "shall have the right to continue as a party to the action." 31 U.S.C. § 3730(c)(1). Additionally, the relator is entitled to a hearing if the government moves to dismiss or settle the action. 31 U.S.C. § 3730(c)(2)(A)-(B).

¹⁶³ S. REP. NO. 99-345, at 26 (1986).

¹⁶⁴ *Id.* at 5.

¹⁶⁵ *Id.* at 25.

¹⁶⁶ *Id.* at 7 (quoting *Hearings on Defense Procurement Law Enforcement Before the Subcomm. on Admin. Practice & Procedure of the S. Comm. on the Judiciary*, 99th Cong. (1985)).

¹⁶⁷ *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 905 (9th Cir. 2017).

¹⁶⁸ *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration. This flexibility is a critical

often opt *not* to enforce laws and regulations due to the importance of some other objective. In the pharmaceutical realm, this other objective could be the desire to keep a life-saving medication on the market, as arguably might have been the case with the drugs at issue in *Campie*, the HIV anti-retroviral medications Atripla, Truvada, and Emtriva. The Agency may choose to keep the drug on the market while allowing the manufacturer to come into compliance with a manufacturing violation out of concern about the impact of a supply disruption on the patient population.¹⁶⁹ Similarly, in the health provider space, a nursing home may remain open and be allowed to correct clear violations of the law out of concern for disrupting critical care for elderly patients.¹⁷⁰

The problem with using the immateriality presumption in service of giving the agency unfettered discretion to maximize its goals is that it could easily have the exact opposite impact. To understand this counter-intuitive proposition, assume that a year after a drug has been introduced on the market, the FDA finds out that fraud occurred in the approval process. The immateriality presumption would direct the courts to infer that when the government does not withdraw a product from the market and continues to pay for it, the fraud was immaterial. At the same time, *Escobar*'s secondary holding—that materiality does not turn on agency designations¹⁷¹—makes it impossible for the Agency to simply provide a declaration that, while the violation was material, it is keeping the product on the market to avoid potential harm to patients who are relying on it. This puts an impossible choice in front of the Agency: either stop payment and withdraw the product immediately—and preserve the right to recoup the fraudulently obtained funds under the FCA—or, alternatively, continue payment in service of some other objective (like patient safety)—and risk forfeiting the ability to recover altogether.

component of the statutory and regulatory framework under which the *FDA pursues difficult (and often competing) objectives.*" (emphasis added) (footnote omitted)).

¹⁶⁹ Cf. PhRMA-BIO Brief, *supra* note 80, at 23 ("Because interrupting the manufacturing and supply of a drug can lead to drug shortages, and removing a drug from the market altogether renders it unavailable to patients, FDA must carefully balance competing considerations when determining the public health significance of . . . violations for a specific drug.").

¹⁷⁰ See *supra* note 99 and accompanying text.

¹⁷¹ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) ("Defendants can be liable for violating requirements even if they were not expressly designated as conditions of payment. Conversely, even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability.").

Fully tethering fraud enforcement under the FCA to the agency's decisions thus forces the agency to act in extreme ways—i.e., withdraw the product or stop payment—when it might normally prefer to enforce in some lesser fashion, like issuing a warning letter or allowing a health facility to come into compliance. In contrast, keeping FCA enforcement independent of the agency's actions gives the agency the freedom to deploy its own regulatory toolkit in an optimal manner without worrying about the downstream impact on the DOJ's ability to punish fraud under the FCA. If the immateriality presumption were sustained, the absurd outcome in many cases could be that as long as the manufacturer can get the product approved and distributed, it would most likely be immunized from fraud, since the government will be loath to take the dramatic step of taking the product off the market once patients are relying on it.

Another way to think about the problem is that enforcement under the FCA is backward-looking, while the FDA's enforcement strategies generally look forward. The Agency cares about fraud in the context of the broader mission to make safe and effective products available to the public. This evaluation is prospective, and the fact that the product or service is *already* on the market enters the cost-benefit calculus.¹⁷² In that context, the decision to not rescind approval and continue payment may be driven by many factors that are unrelated to materiality of the original misrepresentation—even if the Agency would never have approved the product had it known about the fraud during the approval process. The FCA, on the other hand, exists to recover fraudulently obtained government funds, regardless of the product's overall utility. These two assessments, while related, are analytically distinct. Payment obtained through fraud *in the past* is within the ambit of the FCA; the safety and effectiveness of a given product *today and going forward* are within the FDA's realm.

C. *An Untethered FCA Can Mitigate Capture*

Separately from enabling the positive aspects of agency discretion outlined in Section III.B, fraud enforcement mechanisms that are autonomous from agencies can be instrumental in counteracting a less savory aspect of agency discretion: the possibility of capture. The pre-occupation with capture—the phenomenon of regulatory agencies being dominated by the interests they regulate—is a common theme

¹⁷² See 164 CONG. REC. S892–93 (daily ed. Feb. 13, 2018) (statement of Sen. Grassley) (“Paying the claims in that case does not mean that the fraud is unimportant; it means that in that moment, the government wants to ensure access to critical care.”).

in scholarship about the administrative state.¹⁷³ Without issuing any judgments on the current state of affairs at the FDA, the fear that the Agency would underenforce for illegitimate reasons is understandable, given the revolving door between government agencies and industry.¹⁷⁴ In light of this concern, drawing strong inferences from the Agency's inaction could lead to inaccurate conclusions about the materiality of the violations in question.

The FCA has the potential to alleviate this concern because it provides an independent check on agency capture by unmooring fraud enforcement from agency decisions. In the event that the agency chooses not to enforce for illegitimate reasons—whether due to an explicit desire to please the regulated entities or because of subtler cognitive effects that conflicting interests can have on subjective human judgments—fraud enforcement that is independent of the agency provides an additional layer of protection. The presumption of immateriality, in contrast, privileges agency decisions and instructs the courts to dismiss FCA cases when the agency failed to act. In doing so, it neuters the capture-mitigating function of enforcement under the FCA. This concern provides an independent reason for rejecting the presumption.

CONCLUSION

Two contradictory clichés are commonly invoked in FCA litigation. On the one hand, “men must turn square corners when they deal with the Government”;¹⁷⁵ on the other hand, the FCA is not an

¹⁷³ See, e.g., George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971) (arguing that “regulation is acquired by the industry and is designed and operated primarily for its benefit”); Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1343–44 (2013) (explaining how special interest groups exert influence through a mutually beneficial alliance with lawmakers and agencies, in which interest groups provide members of Congress with contributions, Congress gives agencies authority and budgets in exchange for responsiveness, and agencies provide interest groups favorable treatment in exchange for political support and perks like postgovernment jobs).

¹⁷⁴ For example, one study tracked a group of FDA reviewers over a ten-year period and found that fifty-seven percent of those who left the agency later worked for or consulted for the biopharmaceutical industry. Jeffrey Bien & Vinay Prasad, *The Revolving Door at the FDA*, THEBMJ, Oct. 1, 2016, at 28, https://www.bmj.com/bmj/section-pdf/931160?path=/Bmj/355/8075/This_Week.full.pdf.

¹⁷⁵ The phrase was first used by Justice Holmes in *Rock Island, Ark. & La. R.R. Co. v. United States*, 254 U.S. 141, 143 (1920), a case dealing with tax procedure. The principle has been adopted with gusto in false claims litigation, with over four hundred briefs, motions, and court documents relating to the FCA and thirty-five opinions quoting “square corners.” See *Results for: “Square Corners” AND “False Claims Act,”* LEXIS ADVANCE RES., <https://advance.lexis.com/api/permalink/a444f4bb-148f-44ff-8700-9f9cfa55247c> (last visited Nov. 11, 2019).

“all-purpose antifraud statute”¹⁷⁶ for “punishing garden-variety breaches”¹⁷⁷ of legal requirements. Where one comes out on many specific interpretative questions often comes back to which vision of the statute one subscribes to. Unsurprisingly, the *Campie* defendants and their amici are more sympathetic to the latter vision: The Act should not be used to police every violation, particularly in the context of sophisticated judgments made by the FDA. The presumption of immateriality from agency inaction is an attempt to bolster that approach.

By examining the FCA’s structure and history, the legislative intent behind its current form, and empirical experience with enforcement, this Note has demonstrated a lack of support for the immateriality presumption and the harm it could do by attaching fraud enforcement completely to the judgments of the agencies. Based on insights from over a century and a half of experience, the current Act strikes a delicate balance between effectively encouraging reporting by relators while retaining sufficient control for the government to advance important public policy objectives. Specifically, Part II showed that the qui tam provisions are effectively cabined by their own terms and by the concurrent authority of the DOJ. The presumption of immateriality from agency inaction is therefore unnecessary to keep the private relators in check.

Additionally, in Part III, this Note evaluated why tethering fraud enforcement to the judgment of regulators—the necessary outcome of the immateriality presumption—is undesirable for the agencies themselves. First, the FCA gives the government access to expertise, tools, and resources that do not exist elsewhere in the administrative state. Second, the separation allows regulators to act more subtly within their toolkits to maximize their own objectives without jeopardizing the government’s ability to recover fraudulently obtained funds. Finally, the overlap and healthy competition between the FCA and regulators can be beneficial, given the risk of capture.

Considering the lack of support for the immateriality presumption from government inaction, courts considering FCA actions under the false certification theory should not treat evidence of government inaction as dispositive for the purposes of assessing liability under the Act at the pleading stage. Adopting the presumption would be inconsistent with FCA’s design, harmful to the agencies, and against the public interest.

¹⁷⁶ *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008).

¹⁷⁷ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016).