Nos. 20-16176, 20-16256

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ZACHARY SILBERSHER, RELATOR, *PLAINTIFF-APPELLANT*,
AND
UNITED STATES OF AMERICA ET AL., EX REL., *PLAINTIFFS*,
V.
VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS
INTERNATIONAL; SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.;
DR. FALK PHARMA GMBH, *DEFENDANTS-APPELLEES*.

ZACHARY SILBERSHER, RELATOR, *PLAINTIFF-APPELLEE*,
AND
UNITED STATES OF AMERICA ET AL., EX REL., *PLAINTIFFS*,
V.
VALEANT PHARMACEUTICALS INTERNATIONAL, INC., VALEANT PHARMACEUTICALS
INTERNATIONAL, SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC.,
DEFENDANTS,
AND
DR. FALK PHARMA GMBH, *DEFENDANT-APPELLANT*.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA CIVIL CASE NO. 3:18-CV-01496-JD (HONORABLE JAMES DONATO)

AMICUS CURIAE BRIEF OF TAXPAYERS AGAINST FRAUD EDUCATION FUND SUPPORTING APPELLANT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Taxpayers Against Fraud Education Fund ("TAFEF") states that it is a corporation organized under Section 501(c)(3) of the Internal Revenue Code. It has no parent corporation and no stock owned by a publicly owned company. TAFEF represents no parties in this matter and has no pecuniary interest in its outcome. However, TAFEF has an institutional interest in the effectiveness and correct interpretation of the federal False Claims Act.

Pursuant to Federal Rule of Appellate Procedure 29, Taxpayers Against Fraud Education Fund ("TAFEF") submits this brief in support of plaintiff-appellant, Zachary Silbersher. Counsel for the plaintiff-appellant has given consent to file. All parties have consented to the filing of this brief.[1]

INTEREST OF *AMICUS CURIAE*

TAFEF is a non-profit public interest organization dedicated to combating fraud against the Government and protecting public resources through public-private partnerships. TAFEF is committed to preserving effective anti-fraud legislation at the federal and state levels. The organization has worked to educate the public and the legal community about the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and provided testimony to Congress about ways to improve the FCA. It regularly participates in litigation as *amicus curiae*. TAFEF is supported by *qui tam* relators and their counsel, by membership dues and fees, and by private donations. TAFEF is the 501(c)(3) arm of Taxpayers Against Fraud, which was founded in 1986.

[1] No party's counsel authored this brief in whole or in part. No person other than *amicus* and its counsel contributed any money intended to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

Since its inception in 1863, the architects of the FCA have sought to balance the goals of encouraging anyone with knowledge of fraud on the government to come forward with those allegations and help the government uncover fraud that otherwise would have gone undetected, while also working to prevent opportunistic or parasitic relators from capitalizing on information about fraud that is clearly in the public domain for personal gain. The FCA has been amended several times to further those goals, and the current version of the public disclosure bar, if correctly interpreted, does just that.

Congress has made clear that it welcomes anyone, whether a corporate insider or outsider, to step forward with allegations of fraud. In fact, outside whistleblowers have been extremely valuable to the government and have succeeded in recovering billions of dollars for the taxpayers. Any suggestion that the *qui tam* provisions of the FCA are designed solely to encourage corporate insiders to step forward is simply incorrect. In fact, in some cases outside whistleblowers bring important perspective and expertise to the table that an insider may not possess.

Further, contrary to the defendants' claims, nothing in the case law, legislative history, or text of the FCA prevents lawyers from bringing *qui tam* actions. Courts have made clear that there while there are several carve outs in the FCA delineating who may *not* serve as a relator, none exist with respect to lawyer-relators.

Finally, it is imperative that these types of cases are allowed to proceed. Drug prices are at an all-time high in this country, and whistleblowers who put in the hard work to undercover fraud and formulate theories of liability to hold pharmaceutical companies who intentionally and artificially inflate prices responsible for their fraudulent actions are integral to reversing this trend.

ARGUMENT

I. Congress Intended that Anyone with Knowledge of Fraud Assist in Stopping Fraud on the Government.

Nothing in the text or legislative history of the FCA suggests that relators are required to be insiders in order to bring claims against corporate fraudsters on behalf of the government. In fact, many cases involving outsider whistleblowers have succeeded in returning millions of dollars to the government fisc, and outsider whistleblowers can be preferable to insiders in some cases.

A. The Text and Legislative History of the FCA Encourage Outsiders to Bring *Qui Tam* Actions.

The False Claims Act, 31 U.S.C. §§ 3729-3731, was enacted in 1863 to combat procurement fraud during the Civil War. S. Rep. No. 99-345 at 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266. Since that time, Congress has amended the Act several times in an attempt to find the right balance between encouraging people with knowledge of fraud against the United States (or, increasingly, a state, county, or city) to come forward in order to fight that fraud on the government's behalf,

while precluding "opportunistic" litigants who seek to profit from the knowledge and effort of others, or the public reporting of misconduct.

The text of the FCA explains that any "person" can file a *qui tam* action. 31 U.S.C. § 3730(b)(1). Nothing in the text of the statute limits relators to those who are insiders. Rather, since the FCA was enacted, Congress has consistently passed amendments to expand the pool of potential relators, acknowledging that the government cannot root out a large percentage of fraud on its own, and that the insight of whistleblowers – both inside and outside corporations – is integral to preventing and remedying fraud.

In 1986, Congress amended the FCA in order to encourage *qui tam* suits precisely by removing a barrier erected by the public disclosure bar. In *United States ex rel. State of Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984), the court held that the State of Wisconsin was not a proper relator where it investigated Medicaid fraud and provided its evidence to the federal government because "government knowledge" was a jurisdictional bar to a *qui tam* case under former 31 U.S.C. § 232(C), which provided that a *qui tam* case could not be "based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time the complaint was filed." *Id.* at 1103 (citation omitted). Many meritorious claims were dismissed as a result of the Seventh Circuit's holding in *Dean*, and the volume of cases filed was substantially reduced due to the

likelihood that they would be dismissed. In an attempt to fix the problem created by *Dean*, Congress amended the FCA in 1986, stating that "[t]he Committee's overall intent in amending the *qui tam* section of the False Claims Act is to encourage more private enforcement suits." S. Rep. No. 99-345 at 23-24. Congress recognized that non-parasitic relators, whether corporate insiders or outsiders, who were aware of important information about fraud schemes should be allowed to bring and proceed with their claims. *Id*. at 12-13. The resulting 1986 statute stated:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4) (1986).

However, the law as written in 1986 did not go far enough in encouraging relators to come forward. So, in 2010, Congress tried again. The revision it passed then is the current version of the public disclosure and original source provisions:

> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either
> (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. 3730(e)(4) (2010).

This time, Congress specifically removed any reference to "direct" knowledge, further opening the door for outsider relators to bring claims under the FCA. The current public disclosure provision requires only that the relator's knowledge "materially add" to the publicly disclosed information. The amendment is intended to ensure that whistleblowers who are not traditional insiders can bring claims when they use their knowledge and skill to reveal fraud that the Government otherwise would not have discovered. In addition to removing the requirement for direct knowledge to qualify as an original source, the amendments added a provision

that allows the government to veto dismissal on public disclosure grounds and limited the bar to only information disclosed in federal sources or the news media, allowing claims based on information disclosed in state and local sources to go forward. 31 U.S.C. 3730(e)(4) (2010). These changes also advance the goal of encouraging more cases to be filed and proceed.

The clear intent of Congress in amending the public disclosure provisions of the FCA was to encourage anyone with credible allegations of fraud to step forward. Congress, in attempting to combat the "growing pervasiveness of fraud," has consistently amended the statute to encourage more whistleblowers to bring *qui tam* actions and more claims to proceed. S. Rep. No. 99-345, at 1 (1986) (recognizing that "only a coordinated effort of both the Government and the citizenry" could prevent rampant fraud on the government). Congress has never limited the class of potential relators to insiders, rather, the amendments were designed to "encourage any individual knowing of Government fraud to bring that information forward." *Ibid*.

B. Many Cases Involving Outsider Relators Have Returned Funds to the Government.

There is a long history of successful FCA cases involving outsider relators – including lawyers – who relied on their expertise, experience, and analysis of data or other available documentation to uncover and formulate their theories of fraud. These cases have resulted in billions of dollars being returned to the federal fisc, and

have sometimes involved information that the government may have had access to, but which required the specialized knowledge of the whistleblower to understand the fraudulent nature of the conduct. The FCA specifically contemplates suits by outsider whistleblowers, and according to Senator Charles Grassley and Representative Howard Berman, the sponsors of the 1986 FCA amendments, a relator "who uses their education, training, experience, or talent to uncover a fraudulent scheme from publicly available documents, should be allowed to file a *qui tam* action." 145 Cong. Rec. E1546-01 (daily ed. July 14, 1999), 1999 WL 495861, at *E1547.

In many cases, the government would not have had an inkling that it was being defrauded without the outsider relator's insight. For instance, in *United States ex rel. Shea v. Verizon Communications, Inc.*, 844 F. Supp. 2d 78, 80 (D.D.C. 2012), the relator was a telecommunications consultant who sued wireless carriers for overcharging the government. In the course of his work, which involved investigation of the defendant's billing practices, he discovered the false and fraudulent claims that formed the basis of his allegations. *Id*. The court noted that, "[n]ot only did [the relator] save the Government a great deal of time and resources and contribute to obtaining a substantial settlement, it is certainly more than likely that without this lawsuit, [the defendant] would have continued to overcharge the United States indefinitely, i.e., as long as it could get away with it." *Id.* at 82. In

addition, through analysis of the defendant's arguments, the relator was able to explain to the government that an entirely separate fraud scheme was being perpetrated by the defendant and meaningfully increased the government's recovery in the case. *Id*. at 83, 87. The court recognized that the government had "no recognition" of the fraud schemes prior to the relator filing his case. *Id*. ("While it is true that the General Services Administration ("GSA") had a team of auditors who routinely reviewed the invoices under the FTS 2001 Contract, in almost a decade of auditing that contract, GSA had not previously identified the particular overcharges Shea identified, nor even audited that section of the invoice or contract."). Like the relator here, the relator in *Shea* relied on information and documents uncovered during the course of his employment and his own investigation from outside of the company to develop his allegations. *Id.* at 85. The Government eventually recovered $93.5 million. *Id.* at 80.

While the government and the taxpayers were harmed in *Shea*, there are also many cases in which outsider relators not only assist in returning funds to government, but also in stopping egregious patient harm. An outside health care reimbursement consultant and a cardiac nurse together identified a widespread scheme to install medically unnecessary implantable cardioverter defibrillators — an electronic device that is implanted near and connected to the heart, costs approximately $25,000 to install, and is potentially very dangerous if implanted

improperly – involving 457 hospitals. The relators' investigation and lawsuit allowed the government to recover over $250 million. *See* U.S. Dep't of Justice, *Nearly 500 Hospitals Pay United States More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices* (Oct. 30, 2015), https://www.justice.gov/opa/pr/nearly-500-hospitals-pay-united-states-more-250-million-resolve-false-claims-act-allegations. Many other such cases abound.[2]

Outsider relators have successfully brought cases outside of the healthcare industry as well, resulting in tangible changes to those industries, if not huge monetary recoveries. In *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co*., the relator was a company formed by a former investigator and

[2] *See* Phillips & Cohen, *Businessman Exposed Problems with Quest Subsidiary's Blood Test Kids; Led to $302 Million Settlement* (Apr. 15, 2009), https://www.phillipsandcohen.com/businessman-exposed-problems-quest-subsidiarys-blood-test-kits-led-302-million-settlement/ (outsider businessman who alleged the defendant was supplying faulty lab tests to the government and the case settled for $302 million); *United States ex rel. Anti-Discrimination Center of Metro New York, Inc. v. Westchester County*, No. 06-cv-2860-DLC (S.D.N.Y.) (a public interest organization brought allegations that a county had violated its fair housing obligations, resulting in a $62.5 million settlement); *See also*, TAFEF, *Whistleblower Stories*, https://www.taf.org/whistleblower-stories (last visited October 23, 2020) (A Medicare beneficiary brought allegations the government was being billed for care that was not provided and the Government recover $325 million; a competitor lab testing company brought allegations that other companies were defrauding California's Medicaid program and the government recovered at least $300 million; the four partners of Florida infusion company Ven-A-Care discovered kickback schemes by their competitors and recovered $486 million for the government).

assistant to the commissioner of the U.S. International Trade Commission and senior compliance specialist for the U.S. Department of Commerce, who used her knowledge of the import/export process and the pipe fitting industry, along with public shipping records, to identify a fraud scheme whereby the defendant allegedly mislabeled imports in order to evade customs duties. *See* The Morning Call, *Victaulic settles whistleblower claim over imports for $600k, ending nearly six years of litigation* (May 9, 2019), https://www.mcall.com/news/police/mc-nws-victaulic-customs-whistleblower-settlement-20190509-f4wszaykb5hnzmvyfkqwyg2uu4-story.html (noting that "[t]he Victaulic case altered the landscape of whistleblower litigation under the False Claims Act when *Customs Fraud Investigations* won an appeals court ruling that extended the reach of the act and revived its case after a lower court dismissed it.). Jonathan Tycko, who represented *Customs Fraud Investigations* in the case, noted that "[b]etter enforcement of labeling regulations benefits consumers in general by helping to ensure those who prefer to buy American-made products can rely on country of origin markings." *Id.*

Outside of the FCA context, the government has benefited substantially from outside whistleblowers in other federal whistleblower programs. Harry Markopolos, who discovered and first reported Bernie Madoff's Ponzi scheme to the Securities and Exchange Commission ("SEC"), was dismissed by SEC enforcement staff because he was not an insider or investor. SEC, Office of Investigations,

Investigation of Failure of the SEC to Uncover Bernard Madoff's Ponzi Scheme, Public Version 36 (2009), https://www.sec.gov/files/oig-509.pdf. Once the truth was exposed, the Director of the SEC's Enforcement Division commented that "[t]he voluntary submission of high-quality analysis by industry experts can be every bit as valuable as first-hand knowledge of wrongdoing by company insiders." SEC, *SEC Awards Whistleblower More than $700,000 for Detailed Analysis* (Jan. 15, 2016), https://www.sec.gov/news/pressrelease/2016-10.html.[3]

C. Outsider Whistleblowers May Be Preferable to Insiders in Some Circumstances.

Not only are outside whistleblowers expected and allowed under the FCA, there are several reasons that outside whistleblowers can be preferable. Insiders may not have the benefit of being able to see all of the individual parts of the fraud and put them together to understand the full fraud scheme, or possess the legal or technical expertise to understand the implications of actions taken by their employer.

Further, insider relators often face retaliation by their employers for coming forward with allegations of fraud and subsequent blacklisting in their respective industries. Congress has recognized the financial and personal risks associated with

[3] The Director of the Commodity Futures Trading Commission ("CFTC") Whistleblower Office also stated that "an individual doesn't have to be an insider to receive a whistleblower award," and that an "expert analysis" is valuable. CFTC, *CFTC Announces Whistleblower Award Totaling More Than $2 Million* (Mar. 4, 2019), https://www.cftc.gov/PressRoom/PressReleases/7882-19.

coming forward with allegations of fraud. See e.g., S. Rep. No. 345 at 28 (acknowledging the "risks and sacrifices of the private relator"); Testimony of Tina M. Gonter, Hearing on the False Claims Act Correction Act (S. 2041): Strengthening the Government's Most Effective Tool Against Fraud for the 21st Century, Before the Comm. of the Judiciary, 110th Cong. 167-85 (2008) (detailing risks to career, income, savings, family, friendship, and personal safety.). Further, an insider that is in a position to understand the details of the fraud scheme has often participated in the fraud, whether by choice or not, and may be reluctant to come forward and implicate herself. Even if she has not participated in the fraud, she may be concerned that it will appear that way and she will be implicated regardless. Those concerns are not present for an outsider whistleblower.

The relator here was a patent attorney who learned of the alleged fraud during the course of his representation of clients in a *inter partes* review (IPR) of the defendants' patent. The IPR resulted in the Patent and Trademark Appeals Board cancelling the relevant claims of that patent. *See GeneriCo, LLC v. Dr. Falk Pharma GmbH*, 2017 WL 2211672 (P.T.A.B. May 19, 2017). In order to recover the federal dollars lost to the defendants during the years that government healthcare programs were paying for the defendants' expensive branded drug rather than a generic drug introduced by a competitor, the relator brought this action under the FCA. In doing so, he acted exactly as the FCA contemplated, using his "education, training,

experience, [and] talent to uncover a fraudulent scheme" that the government did not, and likely would not, discover on its own. 145 Cong. Rec. E1546-01, at *E1547. These types of relators are allowed and encouraged under the FCA.

Even if the information that the relator relied on in formulating his theory of fraud were publicly available, part of the purpose of the FCA is to allow relators to supplement the government's scarce resources aimed at detecting and prosecuting fraud. Particularly in a case such as this, where the fraud may lie buried in hundreds of pages, scattered across numerous sources, the government cannot be expected to uncover every fraudulent scheme involving the theft of government funds. *See, e.g.*, S. Rep. No. 99-345, at 7 ("[T]he most serious problem plaguing effective enforcement is a lack of resources on the part of Federal enforcement agencies."). That is why the *qui tam* provisions of the FCA exist, and nothing in the public disclosure bar prevents outside whistleblowers who develop unique theories of liability that may not be readily apparent to the government, based on publicly available information, to proceed with their claims.

II. Nothing Prevents Lawyers from Bringing *Qui Tam* Actions Under the FCA.

The district court perseverates on the fact that the relator was a lawyer who was tipped off regarding the fraud through his representation of clients in the IPR. This apparent distaste for lawyer relators who learn of the alleged fraud while

representing clients in unrelated prior cases appears to have influenced the district court's decision that the relator could not be an original source of his claims. However, attorneys, like other outsiders, have and continue to make important contributions to fraud detection and enforcement.

Courts have made clear that nothing in the FCA prevents lawyers who learned of the information underlying their claims while engaged in the representation of clients in a separate action from proceeding with their claims. For instance, in *United States ex rel. Moore & Co. P.A. v. Majestic Blue Fisheries, et. al*., 812 F.3d 294, 304 (3rd Cir. 2016), the relator learned of the information on which it based its claims through discovery in a wrongful death action that it litigated in federal court against two of the defendants in the FCA case. The court held that the information obtained in the wrongful death action was independent of and materially added to the information that was publicly disclosed and that the relator qualified as an original source. *Id.* at 304-308; *See also, United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, (D.C. Cir. 1997) (allowing allegations based on information obtained during an earlier litigation, noting that the earlier litigation did not involve allegations of fraud, the documents relied on did not mention fraud, and that the corporate relator "had to have bridged the gap by its own efforts and experience…").

In *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v.*

Provident Life & Acc. Ins. Co., 721 F. Supp. 1247 (S.D. Fla. 1989), the relator was a law firm that represented a plaintiff in a previous personal injury litigation against the defendant. The court found that the relator was an original source, even under the previous iteration of the public disclosure bar which required "direct" knowledge, explaining that the relator did "not seem to be a disinterested outsider and did not 'simply stumble across an interesting court file,'" rather, the relator had knowledge of the relevant information contained in the documents relied upon from the prior litigation "by virtue of its direct relationship to, and interest in," the previous litigation. *Id.* at 1258.

In *United States ex rel. Doe v. X Corp.,* 862 F. Supp. 1502 (E.D. Va. 1994) the court denied the defendant's motion to dismiss based on the relator's status as its former attorney. The court explained in analyzing the FCA as worded in 1994, that the FCA enumerated certain categories of relators that were not permitted to bring *qui tam* actions, including members of the armed forces against other members of the armed forces and certain government officials when the allegations are already known to the government. *Id.* at 1506. The court posited that "[s]ignificantly, none of the enumerated exceptions to the universe of eligible relators includes lawyers, or lawyers suing their clients. This fact points persuasively to the conclusion that lawyers are not *per se* barred from serving as *qui tam* relators against former clients." *Id.* at 1507 (explaining that "in choosing not to exclude lawyers, Congress

made clear that lawyers are included in the universe of eligible *qui tam* relators.").

Further, the district court's holding that lawyer relators cannot make a "voluntary" disclosure for the purposes of the public disclosure bar when disclosing claims based partially on information uncovered during litigation of a separate case is fatally flawed. A disclosure is voluntary in connection with the public disclosure bar so long as it is not compelled by employment responsibilities to the government or by a subpoena. In some circumstances, courts have considered whether reports of fraud were made in the course of a plaintiff's job duties when determining whether that plaintiff was engaged in "protected activity" for the purposes of the retaliation provisions of the FCA. *See e.g., United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 908 (9th Cir. 2017) (explaining that when the activities outlined by a plaintiff as protected activity in a retaliation action are the types of activities the plaintiff was required to undertake as part of his job, courts have held that it takes more than an employer's knowledge of that activity to show that an employer was on notice of a potential *qui tam* suit.) However, that analysis does not apply when determining voluntariness under the public disclosure bar.

An attorney in the private sector has no duty to disclose fraud to the government, thus any disclosure she makes will be "voluntary." Analyzing whether a disclosure is "voluntary" is a fact-specific determination to be decided on a case by case basis. The district court relied on *United States ex rel. Fine v. Chevron*

U.S.A., Inc., 72 F.3d 740 (9th Cir. 1995) and *United States ex rel. Prather v. AT&T, Inc*., 847 F.3d 1097 (9th Cir. 2019) in determining that lawyers could not voluntarily disclose to the government. However, those cases involved relators who were government employees, performing their job duties at the time they made the alleged disclosures. That is completely different from a private attorney, who does not represent the government's interests in his everyday work. *See also, United States v. Kiewit Pacific Company*, 41 F. Supp.3d 796, 809 (N.D. Cal. 2014) (finding that outside contractors hired by the defendant to investigate a government construction project had no obligation to report the findings to the government and their disclosures were voluntary for original source purposes).[4]

III. Fraud on Government Health Care Programs is Pervasive and the FCA is One of the Only Tools to Prevent It.

[4] The district court's focus on ethical issues involved when an attorney brings FCA claims based on information gleaned during a previous litigation is misplaced. Whether an ethical issue exists has no bearing on whether the relator's claims are meritorious or whether they are precluded by the public disclosure bar, rather, those are matters for attorneys to resolve with their clients—or at most issues for bar associations and other bodies that regulate attorney conduct to take up. Those potential concerns certainly do not warrant dismissing a meritorious FCA claim and allowing a fraud on the government to go without redress. *See e.g. United States ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp.2d 522, 531 (M.D. Pa. 2008) (denying a motion to dismiss allegations of a former general counsel for the defendant, finding that the information in the complaint was not necessarily confidential or subject to attorney-client privilege and that even if it was, the state's Rules of Professional Conduct allowed a lawyer to reveal confidential information to rectify the consequences of a fraudulent act.).

Exorbitant prescription drug prices are widely recognized as a major problem in the United States. *See* NBC News, *High drug prices driven by profits, House committee reports find*, https://www.nbcnews.com/health/health-news/high-drug-prices-driven-profits-house-panel-report-finds-n1241589 (detailing two reports by the United States House of Representatives Oversight Committee that detailed the soaring prices of prescription drugs in the United States, driven by pharmaceutical company profits.). Whether the costs are borne by private insurance companies, individuals without insurance, or government healthcare programs, ultimately high drug prices are detrimental to the entire population (except for the pharmaceutical companies inflating the prices). When the government pays more than it should for drugs, it means that taxpayer dollars are being diverted from other government programs, and is a drain on the economy and government resources.

That is why allowing cases like this one to move forward is so critical to redressing fraud on the PTO. Cancelling the relevant claims of the defendants' patent may have prevented the defendants from continuing to bilk the American people out of millions of excess dollars in the future, but did not claw back the millions of dollars already paid while the patent was in force. The FCA is the perfect mechanism to do just that, and with the potential for triple damages, perhaps deter drug companies from engaging in such fraud in the future. As the State of California recently recognized in a statement of interest in a similar action, the relator's theory

of liability, if successful, "may set an important precedent that would discourage drug companies from taking advantage of the *ex parte* nature of patent proceedings by withholding or misrepresenting material information relating to patentability—and thereby significantly reduce the amount governments and insurers pay for important medicines." *See United States ex rel. Silbersher v. Allergan PLC, et. al.*, Case No. 18-cv-03018, N.D. Cal., Dkt. 133. Given the high stakes in this and similar cases, and the huge potential benefit in recouping millions if not billions of dollars fraudulently paid out by Medicare and Medicaid, it is more important than ever that courts correctly interpret the public disclosure bar and do not improperly dismiss meritorious claims.

The district court's decision would result in the unintended consequence of effectively insulating patent fraud—along with most fraud that involves making misrepresentations to government agencies— from liability under the FCA. If the district court's holding stands, anything disclosed to those agencies that is put on an electronic docket sheet would then trigger the public disclosure bar under 3730(e)(4)(A)(ii), even if the government is not a party under (i). This would create a loophole protecting fraudsters, contrary to Congress's clear intent when it amended the FCA to require the federal government to be a party to a proceeding where information is disclosed that potentially raises the public disclosure bar.

CONCLUSION

For the reasons stated above, the Court should reverse the district court's erroneous findings with respect to the FCA's public disclosure bar.

Respectfully submitted,

s/ Justin T. Berger

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CERTIFICATE OF COMPLIANCE

The undersigned, counsel for Taxpayers Against Fraud Education Fund, *Amicus Curiae*, hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and Cir. R. 32-1(a) because it contains 4947 words as reported by the word count function of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman font, 14-point type for both text and footnotes.

Dated: October 28, 2020 */s Justin T. Berger*