No. 21-15420

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ZACHARY SILBERSHER, RELATOR; UNITED STATES OF AMERICA; STATES OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; STATE OF WASHINGTON; COMMONWEALTH OF MASSACHUSETTS; COMMONWEALTH OF VIRGINIA; DISTRICT OF COLUMBIA, EX REL.,
PLAINTIFFS-APPELLEES,
v.
ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; FOREST LABORATORIES HOLDINGS, LTD.; ADAMAS PHARMA LLC; ADAMAS PHARMACEUTICALS, INC.,
DEFENDANTS-APPELLANTS.

Appeals from the United States District Court for the Northern District of California
Civil Case No. 3:18-cv-03018-JCS (Honorable Joseph C. Spero)

AMICUS CURIAE BRIEF OF TAXPAYERS AGAINST FRAUD EDUCATION FUND SUPPORTING APPELLEE

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Other Authorities

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 the Appellee, Zachary Silbersher. 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, 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.

The parties have extensively discussed the facts of this case and the addressed arguments relating to the specific statutory interpretation questions present before the Court. This brief will discuss the history and intent of the FCA and the public disclosure bar and will focus in large part on responding to misleading and inaccurate assertions and arguments made in the *amicus curiae* brief filed by the Chamber of Commerce and PhRMA in support of the Appellant.

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; or that allowing outside whistleblowers, who devote their life's work to uncovering fraud

against the government, will somehow lead to a flood of new, meritless *qui tam* actions, is simply incorrect. Outside whistleblowers bring important perspective and expertise to the table that an insider may not possess.

It is imperative that well-informed outside whistleblowers who are aiming to fight fraud in the pharmaceutical industry, are allowed to and encouraged to proceed, whether or not the government intervenes in their case. Drug prices are at an all-time high in this country, and whistleblowers who put in the hard work to uncover fraud and pursue actions to hold pharmaceutical companies that intentionally and artificially inflate prices responsible for their fraudulent actions are critical to preserving public healthcare funds.

ARGUMENT

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

Despite Appellants' arguments, and those of their supporting *amici*, to the contrary, nothing in the caselaw, 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.

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

The FCA, 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 to come forward in order to fight that fraud on the government's behalf, while precluding opportunistic or parasitic litigants who seek to profit from the knowledge and effort of others, or the public reporting of misconduct.

The text of the FCA provides that any "person" can file a *qui tam* action. 31 U.S.C. § 3730(b)(1). Nothing in the text of the statute limits the term "person" to 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 by removing a barrier erected by the public disclosure bar's predecessor, the "government knowledge bar." This 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." *United States ex rel. State of Wisconsin v. Dean*, 729 F.2d 1100, 1103 (7th Cir. 1984) (citation omitted). This provision led to many meritorious claims being dismissed, and Congress attempted to fix this problem with the 1986 amendments. The Senate Committee Report on the proposed amendment explained 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 narrowed the reach of the public disclosure bar by carving out any criminal, civil, or administrative hearing in which the federal government or its agent is not a party and mandated that the bar only apply to information disclosed in hearings in which the federal government was a party, reports and audits issued by the federal government, and the news media. 31 U.S.C. 3730(e)(4) (2010).

Additionally, 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 insiders can bring claims when they use their knowledge and skill to reveal fraud that the government would not likely have discovered on its own.

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*.

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B. Allowing Cases Brought by Knowledgeable Outsiders with Expertise in the Industry to Move Forward Will Further the Purposes of the FCA and Will Not Place Unnecessary Burdens on Defendants or the Government.

Qui tam actions, and indeed, all FCA matters, account for only a tiny fraction of the civil litigation ongoing in any given year in U.S. courts. Despite *amici* for the Appellants' assertion that there has been a recent "explosion in *qui tam* litigation," FCA filings represent only about 0.25% of the civil litigation filed in the U.S. each year. *See* Brief of the Chamber of Commerce of the United States and Pharmaceutical Research and Manufacturer of America as Amicus Curiae in support of Defendants-Appellants at 20 ("Brief of the Chamber of Commerce"). *Amici* lament the 672 *qui tam* actions filed in 2020 and the purported "burden" these cases place on "defendants, the courts, and the government itself." *See ibid*. However, not only is the number of 2020 *qui tam* filings significantly down from a high of 757 cases filed in 2013, the number of *qui tam* filings in any given year is dwarfed by the massive amount of other types of ongoing civil litigation. *See id.*; *see also* U.S. Dep't of Justice, Fraud Statistics – Overview (Oct. 1986– Sept. 2020), *available at*, https://www.justice.gov/opa/press-release/file/1354316/download ("DOJ Fraud Statistics"). For instance, in 2019, there were 286,289 civil cases filed in U.S. courts, which was an increase of 3% over the previous year, but only 638 *qui tam* actions were filed that year, a decrease from the year before. *See* Federal

Judicial Caseload Statistics 2019, *available at*, https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2019. Civil cases involving the U.S. government as a plaintiff dropped by 9% in that same time, with cases involving government contracts and involving the recovery of overpayments and enforcement of judgments each declining by 24%. *Id*.

Further, *amici's* own numbers undermine their argument that meritless *qui tam* actions are clogging up the court system and draining vital resources. Though their brief states that 672 *qui tam* actions were filed in 2020, there is no indication of how many of those cases lacked merit but were nevertheless litigated long enough to burden the courts. Without such information, the number of cases filed is meaningless, particularly because many of the cases were likely voluntarily dismissed after declination. *See* Michael D. Granston, Director, Commercial Litigation Branch, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. §3730(c)(2)(A) (January 10, 2018) ("Granston Memo") at fn. 5 (noting that since 2012 "more than 700 *qui tam* actions have been dismissed by relators after the government elected not to intervene.")[2]. *Amici* also bemoan the 2,086 *qui tam* actions that were declined and led to no recovery between 2004-2013, complaining

[2] The numbers of declined cases included in the DOJ fraud statistics do not account for the 700 cases that were voluntarily dismissed between 2012 and 2018, a number that has only increased in the three years since the Granston Memo was released.

that 278 dragged on for more than 3 years before being dismissed. Brief of the Chamber of Commerce at 23. However, those numbers do not support their argument that non-intervened cases are a massive drain on resources, as during that same time 5,022 total *qui tam* actions were filed, meaning that of the over 5,000 cases filed, only 278 – or about 5% - of them were declined and led to litigation that lasted more than 3 years. Regardless of the numbers, however, this case does not lack merit and is attempting to address an enormous fraud on the government. It is simply not part of the purported problem that the *amici* have invented.

Further, despite the steady increase in federal spending, recoveries under the FCA have remained relatively constant, and as a result, fraud recoveries as a percentage of federal spending has been, on average, continuously decreasing. *See* Fraud in America, *Fraud by the Numbers: Billions Are Lost to Fraud, available at*, https://www.fraudinamerica.com/post/fraud-by-the-numbers-september-2.

Fraud recoveries as a portion of federal spending have consistently been very low, "between .03% and .18% of total spending," accounting for only a tiny portion of the total fraud on the government. *Id.* The federal budget was $4.45 trillion in 2019, up to a whopping $6.55 trillion in 2020, due in large part to spending to combat the COVID-19 pandemic.[3] Compared to the projected levels

[3] *See* Congressional Budget Office, The Budget and Economic Outlook: 2021-2031, *available at*, https://www.cbo.gov/system/files/2021-02/51134-2021-02-11-historicalbudgetdata.xlsx

of fraud, waste, and abuse on federal programs, which could conservatively be estimated at 5% of the budget, or $327.5 billion in 2020 and $222.5 billion in 2019, FCA enforcement actions only recover approximately $2-3 billion per year on average. *See* Angie Petty, "Federal government continues to lose billions to waste, fraud and abuse," *Wall Street Journal*, March 10, 2013, *available at*, https://www.washingtonpost.com/business/capitalbusiness/federal-government-continues-to-lose-billions-to-waste-fraud-and-abuse/2013/03/08/a3fb7736-82b5-11e2-b99e-6baf4ebe42df_story.html (estimating the amount of federal dollars lost to fraud, waste, and abuse at 7% of the budget per year). Fewer than 700 *qui tam* actions involving those funds are filed per year. If anything, the number of *qui tam* actions filed is too low given the amount of fraud on the government. It is in the public interest to encourage more *qui tam* actions to recover these stolen funds, and that is the purpose of the FCA.

Actions brought by outsider whistleblowers account for only a very tiny fraction of the relatively few *qui tam* actions filed. There is no indication that allowing outside relators with particular expertise in an industry to use their knowledge, research, and skills to uncover frauds the government would not have learned about on its own would significantly increase the burden on the courts, defendants, or the government. Neither the defendants nor *amici* maintain serious arguments that this case is without merit, and cases such as this one are crucial to

recovering the hundreds of billions of dollars lost to healthcare fraud each year. If fraud can be proven with respect to a drug patent that defendants knowingly used to exclude generic competitors, and the fraudulent scheme has resulted in the government overpaying billions of dollars for a critical drug, more such cases should be encouraged, not discouraged.

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

There is a long history of successful FCA cases involving outsider relators 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.

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In many cases, the government would not have known 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"). The

government eventually recovered $93.5 million. *Id.* at 80.

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 healthcare 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 outside 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), *available at*, 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.[4]

[4] *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

Outsider relators have successfully brought cases in areas other than healthcare as well, resulting in tangible changes, 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 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 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), *available at*, 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*

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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).

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.*

Beyond the FCA context, outsider whistleblowers in other federal whistleblower programs have benefited the government substantially. Harry Markopolos, who discovered and first reported Bernie Madoff's Ponzi scheme to the Securities and Exchange Commission ("SEC"), was ignored 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), *available at*, 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), *available at*, https://www.sec.gov/news/pressrelease/2016-10.html.[5]

[5] 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.

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

There are several reasons that outside whistleblowers have advantages that can make them useful in exposing fraud that would otherwise go undetected. For example, 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. Insiders may also lack the legal or technical expertise to understand the implications of actions taken by their employer.

While there is always personal, career, and financial risk associated with whistleblowing, outside relators can be insulated from some of the risks that insiders face and that deter insiders from reporting. Insider relators often face direct 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 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). In addition, an insider that is in a position to understand the details of the fraud scheme may have 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 may be implicated regardless. Those concerns are not present for an outsider whistleblower, which can make them more effective or reliable relators in some cases.

The relator here had in-depth knowledge of the patent prosecution and approval process and the expertise to piece together a fraudulent scheme by doing a deep dive into patent histories and drug pricing. 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. The FCA not only allows these types of relators but also encourages them.

Even if the information that the relator relied on in formulating his theory of fraud was theoretically publicly available, the threshold to trigger the public disclosure bar is higher than that. Congress did not provide that all information in the public domain triggers the bar, rather, it laid down specific, enumerated channels for what qualifies as a public disclosure, and it narrowed those channels in 2010

because courts previously interpreted them too broadly. As the relator's brief explains, in keeping with congressional intent, the disclosures in this case did not fall within the enumerated channels. Particularly in a case such as this, where the fraud may lie buried in hundreds of thousands 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 to proceed with their claims.

II. Fraud on Government Healthcare Programs is Pervasive, and the FCA is One of the Only Tools to Prevent It.

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 discussed 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 it is a drain on the economy and government resources. Because the government spends so much taxpayer money on healthcare costs, it makes sense that a large majority of FCA cases involve healthcare and pharmaceutical fraud. *See* DOJ Fraud Statistics (showing that over $43 billion of the approximately $64 billion recovered under the FCA involves healthcare fraud). While there are some unique aspects to this case, using the FCA to attempt to recoup the hundreds of billions of dollars lost to fraud in the healthcare industry is not unique.

Using the FCA to redress fraud on the PTO and claw back the millions of dollars the government overpaid for Namenda XR and Namzaric because the defendants fraudulently obtained patents that excluded generic competitors, and falsely represented that it had valid patents for those drugs, is contemplated by the statute. The alleged conduct at issue in this case, the so called "evergreening" of patents, is a major driver of high drug prices. When it is accomplished by fraud, the FCA is the only real mechanism to recover money that the government overpaid for the drugs. Other existing remedies, including suing to have the patent invalidated or challenging the patent in an administrative proceeding, may stop the manufacturer from continuing to profit from the patent, but do not redress the financial harm that

has already occurred during the period of time when the pharmaceutical company had an unlawful monopoly. The FCA is the ideal mechanism to do 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 filed in this case, 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 government healthcare programs, 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 was sound in its finding that the public disclosure bar was not triggered in this case. To hold otherwise 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. Anything disclosed to those agencies that is put on an electronic docket

sheet would then trigger the public disclosure bar, even if the government is not a party. 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.

III. Allowing Non-Intervened Cases to Move Forward Is Crucial to Fighting Fraud Against the Government.

When a relator reports an alleged fraud to the government and files their complaint under seal, the government then decides whether it will intervene and take over primary responsibility for the litigation, or decline to intervene, in which case "the person who initiated the action shall have the right to conduct the action." 31 U.S.C §3730(c)(3). The government is authorized to intervene at a later date for good cause shown. *Id*.

If the government declines to intervene, the relator is entitled to an enhanced relator's share in order to incentivize relators to continue to pursue meritorious cases when the government cannot or chooses not to intervene. 31 U.S.C. §3730(d)(2). In including a larger relator's share for declined cases, Congress clearly showed that relators who move forward with meritorious cases that the government does not or cannot intervene in should be encouraged, not disfavored.

The purpose of the FCA's *qui tam* provisions is to support the Act's broad remedial purpose of combating fraud against the government by empowering private

citizens with knowledge of fraud to come forward with that information and to proceed with the case on the government's behalf if the government is unable or unwilling to do so. *See* S. Rep. No. 99-345 at 23-24 ("The Committee's overall intent in amending the *qui tam* section of the False Claims Act is to encourage more private enforcement suits."). Congress has continuously reinforced the value it places on relator driven cases since the 1986 amendments to the FCA, which were designed to revitalize the act. 145 Cong. Rec. E1546 (daily ed. July 14, 1999) (statement of Rep. Howard Berman, D-Calif.) (with the 1986 amendments, "Congress wanted to encourage those with knowledge of fraud to come forward … [and] we wanted relators and their counsel to contribute additional resources to the government's battle against fraud"). The *qui tam* provisions explicitly contemplate the relator moving forward with the case when the government declines to intervene, and the 1986 amendments were enacted after Congress determined that "only a coordinated effort of both the Government and the citizenry will decrease this wave of defrauding public funds." S. Rep. No. 99-345, at 2.

Amici in support of the Appellant attempt to dismiss the importance of cases such as this one by emphasizing its non-intervened status and pushing the familiar false narrative that non-intervened cases are meritless. *See* Brief of the Chamber of Commerce at 21 (noting that the government "tellingly declined to intervene."); *see id.* at 25 (describing "most declined *qui tam* actions" as "meritless."). However,

non-intervened cases have succeeded in recovering billions of dollars for the federal government. *See* DOJ Fraud Statistics (showing that non-intervened *qui tam* actions were responsible for returning approximately $3 billion to the federal fisc). As the DOJ has repeatedly echoed, there are myriad reasons that the DOJ may initially decline to intervene, including resource issues, that have nothing to do with the merits of the case. *See, e.g.,* Granston Memo at 1 ("Moreover, a decision not to intervene in a particular case may be based on factors other than merit, particularly in light of the government's limited resources."). Indeed, the district court in this case denied the defendants' motion to dismiss on the merits, so regardless of the merits of declined cases generally, this case has substance.

Further the numbers underlying the *amici's* assertion that the "vast majority of the over $64 billion obtained under the False Claims Act since 1986 has come from that small subset of intervened cases," are misleading. *See* Brief of the Chamber of Commerce at 25-26. The brief cites to the Department of Justice's annual fraud statistics report as the basis for this claim, which shows that the majority of the funds recovered under the FCA are the result of intervened actions. *See id*. at fn. 11. However, as noted above, the government can decide to intervene after initially declining, and the actual numbers of cases that were declined and then subsequently intervened and successfully settled are unverifiable based on the

statistics released by the DOJ, because the statistics do not delineate which types of cases account for which numbers.

Further, the government may rely on sophisticated whistleblowers, such as the relator in this case, to pursue cases involving novel theories of fraud, particularly in the technical or scientific fields, simply because DOJ enforcement lawyers are not necessarily experts in those fields. No one expects a DOJ enforcement attorney to know the ins-and-outs of patent law, just as no one would expect a patent attorney to understand how to prosecute a racketeering charge. DOJ can rely on experts in the particular field, such as the relator here, who understand the complex intricacies of the patent prosecution process and the regulatory landscape to use their knowledge and extensive research to take a risk pursuing a theory of fraud that may not already be established.

Amici also paint declined cases as a drain on the resources of defendants, the courts, and the government. *See* Brief of the Chamber of Commerce at 23-34. However, as noted above, *qui tam* actions account for only about 0.25% of the civil cases filed in the U.S. each year, and while surely all types of litigation are costly, non-intervened FCA matters do not impose a particularly outsized drain on resources.[6]

[6] Even if that were true, the *amici's* argument is irrelevant, as Congress has authorized these actions after evaluating the benefits not only of the resources *qui tam* cases generate for the government, but the additional value from deterring

Indeed, the number of declined cases that move into active litigation is even smaller still. As mentioned above, many *qui tam* actions are voluntarily dismissed after declination, either because the government has explained flaws in their cases or they do not have the resources to proceed without the government, leaving only those cases that the relator and their counsel are convinced can be successful and are worth expending their own resources to pursue. *See* Granston Memo at fn. 5 (noting that since 2012 "more than 700 *qui tam* actions have been dismissed by relators after the government elected not to intervene.").[7] Relator's counsel almost exclusively work on a contingency fee basis, so that if the case is not successful, the relator does not obtain a share of the government's recovery and their attorney does not get paid. This is a compelling reason not to move forward with a case after the government declines, and relators and their counsel have no incentive to move forward with cases that are meritless.

Additionally, relators in declined cases do not place any special burden on the government. The government, which is treated as a nonparty for discovery purposes

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fraud in the first place, which also enhances the government's resources. *See* S.Rep. No. 99-345, at 3 (explaining the cost of fraud on the government both in dollars, integrity of government programs, and public confidence in government as well as need for better deterrence).

[7] The numbers of declined cases included in the DOJ fraud statistics do not account for the 700 cases that were voluntarily dismissed between 2012 and 2018, a number that has only increased in the three years since the Granston Memo was released.

in declined cases, monitors the case and in some instances may be served with discovery. *See United States ex rel. Eisenstein v. City of N.Y.*, 556 U.S. 928 (2009). Discovery requests must be relevant, proportional and not unduly burdensome. Fed. R. Civ. P. 26(b)(1). Moreover, the cause of any resource drains on the government from *qui tam* litigation is not as obvious as *amici* for the Appellant imply. For example, under the guise of disproving materiality, FCA defense counsel are increasingly inundating government agencies with irrelevant discovery requests in order to induce the government to seek to dismiss cases on burdensomeness grounds. In a recent case in the U.S. District Court for the Eastern District of New York, *United States v. McKesson Corp*., involving the improper repackaging and sale of a McKesson drug, the government filed a motion to quash a subpoena for hundreds of thousands of what it deemed nonresponsive documents, noting that "[i]t appears that McKesson is misusing discovery as a cudgel to extract from the government a dismissal of Relator's FCA claims pursuant to 31 U.S.C. § 3730(c)(2)(A)." Motion to Quash, *U.S. et al. ex rel. Omni Healthcare Inc. v. McKesson Corp. et al*., 1:12-cv-06440 (E.D.N.Y., July 14, 2021).

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CONCLUSION

For the reasons stated above, the district court's decision should be affirmed.

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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 6,443 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: September 3, 2021 */s Justin T. Berger*