UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

UNITED STATES OF AMERICA, *ex rel.* JOHN R BORZILLERI, M.D. et al., *Plaintiffs*, vs. ABBVIE, INC., et al., *Defendants*.	Case No. 19-2947

BRIEF IN SUPPORT OF
RELATOR'S APPEAL OF DISTRICT COURT'S GRANTING OF UNITED STATES' MOTION TO DISMISS PURSUANT TO 31 U.S.C. § 3730(c)(2)(A)

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The Relator, John R. Borzilleri, M.D., respectfully submits this brief in support of his request that the Second Circuit Court of Appeals vacate the District Court's Order granting the Government's 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss this *qui tam* action. In the public interest, the Relator respectfully requests that the Second Circuit Court of Appeals promptly remand the Government's motion to dismiss back to the District Court for discovery and an evidentiary hearing regarding the Government's dismissal effort and the adequacy of its *qui tam* investigation. The Relator respectfully requests oral argument before the Court of Appeals regarding this matter.

SUBJECT MATTER AND JURISDICTION

On July 16, 2019, the District Court in the Southern District of New York (SDNY) issued an Order granting the Government's 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss this *qui tam* action. Memorandum Opinion and Order, Case: 1:15-cv-07881 (JMF), SDNY, July 16, 2019. See Special Appendix, Document 1. Upon granting the Government's motion, the District Court then dismissed the Relator's False Claims Act (FCA) claims against all defendants, with prejudice. With this disposition, the District Court denied the Defendants' motions to dismiss (Docket Nos. 258 & 260) as moot. The District Court Clerk was directed to terminate all motions and close the case. See the manufacturer defendants' and PBM defendants' Motions to Dismiss (filed October 1, 2018), respectively, in Special Appendix, Documents 2 & 3.

The Second Circuit Court of Appeals has jurisdiction over Relator's appeal of the District Court decision. In compliance with Second Circuit rules, Relator filed a Notice of Appeal on September 13, 2019.

PRELIMINARY STATEMENT

It is not hyperbole to say that this *qui tam* case alleges the largest ongoing healthcare fraud in the history of this nation. Relator's Second Amended Complaint (SAC), filed August 3, 2018, SAC ¶¶ 22-23. See Special Appendix, Document 4. Through a secretive, long-standing series of illicit agreements, drug manufacturers and the four dominant health insurer/pharmacy benefit managers (PBMs, UnitedHealth Group, CVS Health, Cigna/Express Scripts and Humana) have "partnered" together to cause fraudulent, massive, systemic and uniform brand drug price inflation across this nation. SAC ¶¶ 178, 731, 745. While garnering egregious profits from the scheme, the senior executives from both industries have deceitfully and publicly claimed to be "enemies" battling each other for the "public good." SAC ¶¶ 601-22.

This centralized and covert scheme is remarkably straightforward. With virtually no public or financial disclosure, via national contracts, the defendant drug manufacturers have been paying these dominant health insurer/PBMs a "percentage" of virtually each and every massive "sticker" price increase on a wide array of major U.S. brand drugs which have increased five-to-ten-fold or more in cost over the past decade-plus. SAC ¶¶ 35.

Notable examples include the life-sustaining blockbuster cancer, insulin, autoimmune and other widely used therapies targeted in this *qui tam* case. In clear violation of the law, for most of the U.S. brand drugs in this *qui tam* case, the large increase in illicit "fee" payments from drug manufacturers to the dominant PBMs, driven only by fast-rising "list" or "sticker" prices, has occurred while clinical use by physicians and patients (and legitimate PBM defendant "support service" needs) have been plummeting due to escalating competition.

As widely discussed in the media, these vast price increases on life-sustaining drugs have caused unimaginable health and financial harm to vulnerable patients and families across this country. Among a myriad of examples, many U.S. diabetics have lost their lives without access to now

unaffordable insulin, with numerous people now resorting to trips to Mexico in desperation where this life-saving drug can be obtained at a fraction of the cost on the black market. "We either buy insulin or we die", *New York Times*, June 13, 2019.

The drugs in this *qui tam* case include many of the top-selling brands in the U.S. and in the Medicare Part D program, including: AbbVie's Humira and Amgen's Enbrel (rheumatoid arthritis/autoimmune disorders), Sanofi's Lantus and Eli Lilly's Humulin (insulins for diabetes), Novartis' Gleevec (leukemia, cancer), Pfizer's Lyrica (seizures, diabetic neuropathy) and Pfizer's Premarin (hormone replacement/osteoporosis). SAC ¶¶ 47-8.

The estimated taxpayer harm, driven by massive U.S. price increases, just for the fourteen blockbuster U.S. drugs in this *qui tam* case is now more than $114 billion over the past decade-plus (with 30-40% in the Medicare Part D program) and continues to rise with this ongoing straightforward, clandestine arrangement. SAC ¶¶ 23, 92.

The simple conspiracy now fueling a national crisis began with the Medicare Part D program, which provided essential outpatient drug coverage to American senior citizens for the first time. The four dominant health insurer/PBMs were given the privilege of managing this program. Rather than negotiating lower drug prices on behalf of Americans, the dominant health insurer/PBMs (which now administer 80-90% of drug plans in this country, including Medicare Part D) entered into an illicit covert scheme with certain drug manufacturers to increase U.S. brand drug prices egregiously, driving massive profits for both parties at the expense of the American public. SAC ¶¶ 15, 27-8. While the scheme originated in the Medicare Part D program, it has expanded across the entire U.S. health insurance market, leading to higher healthcare costs, decreased access and medical harm for all Americans. SAC ¶¶ 23-4. The ongoing scheme threatens the long-term viability of the Medicare Part D program itself. SAC ¶ 24.

This secretive pharmaceutical/insurance/PBM scheme has caused a uniquely American drug

pricing crisis. After a decade-plus of egregious price increases occurring only in the US, many major U.S. brand drugs now cost 7-8 times more in the U.S. compared to Europe. Before Medicare Part D began, the U.S. and European costs for most of these long-marketed brand drugs were the same. SAC ¶¶ 17-8.

SUMMARY

The Relator, John R. Borzilleri, M.D., respectfully submits this brief in support of his request that the Second Circuit Court of Appeals vacate the District Court's granting of the Government's 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss this *qui tam* action. In the public interest, the Relator respectfully requests that the Court of Appeals promptly remand the government's motion to dismiss back to the District Court for discovery and an evidentiary hearing regarding the Government's dismissal motion and the adequacy of its *qui tam* investigation. The relator requests oral argument regarding this matter before the Court of Appeals.

As set forth in the Senate Report to the False Claims Amendments Act of 1986, a hearing is appropriate "if the Relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations (emphasis added), or that the Government's decision was based on arbitrary or improper considerations." S. Rep No. 99-345, at 26(1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5291. as referenced in *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998)

In the instant case, the District Court inaccurately claimed that the Relator is not entitled to discovery or an evidentiary hearing because he fails to even "present a colorable claim". *Ridenour*, 397 F. 3d at 931. Rather, counter to the District Court's conclusion, the experienced investigator Relator has provided, under oath and penalty of perjury[1], sufficient evidence of a capricious, inadequate FCA

[1] The Relator provided the District Court a 12-page declaration under oath, which described, in detail, evidence of DOJ investigative fraud in this *qui tam* action from the government's voluntary update conference call. Apparently atypical of *qui tam* cases, the Relator and counsel participated together in virtually all investigative update calls with the consent of

investigation, which warranted a thorough inquiry by the Court in its assessment of the Government's eleventh hour dismissal motion. See Revised Declaration of John R. Borzilleri, M.D. in Support of Relator's Opposition to the Government's Motion to Dismiss Pursuant to 31 U.S.C. § 3730 (c)(2)(A) (Dr. Borzilleri's Affidavit), provided as Document 10 in the Special Appendix.

Dr. Borzilleri's evidence, provided under oath in his Declaration, was garnered from non-privileged conversations (recorded by him in contemporaneous notes) between the Department of Justice (DOJ), the Relator and his counsel during voluntary investigative update conference calls. In its reply to Relator's opposition to its motion to dismiss, the Government tellingly did not refute the Relator's key allegations of investigative inadequacy, either in its brief or more importantly via affidavit. The Relator's allegations could have been efficiently investigated by the District Court via targeted discovery and depositions of the Relator, his counsel and a small number of DOJ staff.

Instead, the District Court dismissively described the Relator's allegations of investigative inadequacy, submitted under oath, as a "hodgepodge of theories" and lacking coherence. The District Court further inaccurately stated that it had "no basis to doubt" the Government investigative claims in apparently relying solely upon DOJ's memoranda in its dismissal ruling. Counter to the legislative intent of the FCA and the clear language of the statute, the District Court did not even hold a hearing with Relator and counsel prior to dismissal of this *qui tam* case alleging unprecedented patient and taxpayer harm.

Further, in Relator's view the District Court had considerable reasons to doubt the legitimacy of the Government's investigation in this *qui tam* case. In early 2017, in the public interest, the Relator, who is an experienced financial analyst and physician, began opposing DOJ investigative extension

DOJ. At no point during the investigation of this case, did DOJ indicate these investigative update calls were privileged in any manner. Given the government's clear investigative failure in this *qui tam* matter and its efforts to dismiss this case counter to Relator's wishes and the public interest , DOJ's claims regarding common interest privilege pertaining to these investigative update calls have no merit. Under federal law, perjury carries risk of a prison sentence of five years.

requests in the District Court. In support of these efforts, the Relator filed a motion under seal with the SDNY District Court in September 2017 highlighting the same long-standing investigative concerns that were subsequently provided via affidavit in opposition to the Government's 31 U.S.C. § 3730 (c)(2)(A) motion. Memorandum of Law Opposing Extension of Time to Consider Election of Intervention and Seeking Unsealing of *Qui Tam* Documents, Under Seal, Civ Act. No. 15 CV 7881 (JMF), September 5, 2017.

To their disappointment, Relator and counsel have had no hearing before the District Court throughout the Government investigation and Court review of this *qui tam* matter, despite repeated requests and despite the requirement set forth in 31 U.S.C. Section 3730(c)(2)(A) that a hearing take place when the DOJ moves to dismiss Relator's case.

As will be discussed in more detail, the Relator's District Court case filings include additional new factual evidence, especially Defendants' public admissions and new particular Medicare Part D data, which Relator avers irrefutably verify the fraudulent defendant scheme in this case. See SAC ¶¶, especially at 177-213 and 448-51. See Memorandum of Law in Support of Relator's Opposition Defendants' Motions to Dismiss, provided as Document 5 in Special Appendix (Rel. Opp. Def. MD), especially pgs. 44-50. See Memorandum of Law in Support of Relator's Opposition to Motion to Dismiss Pursuant to 31 U.S.C. § 3730 (c)(2)(A), provided as Document 9 in Special Appendix (Rel. Opp. Gov't MD), especially pgs. 8, 21-6.

As communicated to the District Court in the opposition to the Government's dismissal motion, this extensive new factual evidence was never discussed with DOJ following its March 2018 non-intervention decision, nor prior to (or during) its 31 U.S.C. § 3730 (c)(2)(A) dismissal efforts. In Relator's view, this significant failure to investigate provides further verification of the Government's pretextual, arbitrary and inadequate investigative and late-date dismissal efforts pertaining to this case. Surprisingly, the District Court made no mention of investigative deficiency in its Order granting the

Government's motion to dismiss.

In admittedly failing to investigate the central allegations, in failing to depose firsthand and directly involved defendant witnesses, and in failing to consider substantive new factual evidence, the Government violated the clear legal and legislative requirements of the False Claims Act (FCA) to properly and fully investigate Relator's claims. See *Sequoia Orange*.

The Relator's substantive and unrefuted evidence of Government investigative inadequacies exceed the legal requirements of a colorable claim warranting discovery and an evidentiary hearing in this matter. Relator's claim is certainly strong enough to have a reasonable chance of being valid; the legal basis is correct and, with sufficient investigation, the facts can be proven in court. With verification by the District Court of any of the Relator's numerous claims of investigative insufficiency via targeted discovery and investigation, the Government's motion to dismiss should be rescinded based upon either the *Swift* or *Sequoia Orange* standards of review. With extensive first-hand and verifiable evidence of investigative inadequacy, given under oath, the Relator has clearly shown "a substantial and particularized need for a hearing", especially given the massive scale of alleged financial fraud and public health harm from this long-standing, remarkably straightforward, but secretive scheme. *Ridenour*, 397 F. 3d at 931; *Sequoia Orange*, 151 F.3d at 1145.

However, in granting the Government's motion, the District Court demurred from taking "a side in the dispute" regarding the *Swift* or *Sequoia Orange* standard for 31 U.S.C. § 3730 (c)(2)(A) motions to dismiss. Rather, the District Court "concludes that the Government may dismiss the case even under the more stringent standard articulated in *Sequoia Orange."* However, in dismissing this case, the District Court ignored the "stringent standard" outlined and applied carefully in *Sequoia Orange* and related cases.

As stated in *Sequoia*, "The district court acted reasonably in adopting the following standard: "A two-step analysis applies here to test the justification for dismissal: (1) identification of a valid

government purpose; and (2) a rational relation between dismissal and accomplishment of that purpose." 912 F. Supp. As per *Sequoia*, the "rational relationship" test "held that dismissal of a *qui tam* action pursuant to 31 U.S.C. § 3730 (c)(2)(A) is appropriate only (emphasis added) if the government has a valid government purpose, and (emphasis added) dismissal is rationally related to accomplishing that legitimate government interest." *Sequoia*, 151 F. 3d at 1145-47.

In sharp contrast to the extensive Court involvement in *Sequoia* (which included a four-day evidentiary hearing), in this case the District Court has provided no evidence of due diligence pertaining to the essential "rational relations standard" portion of the *Sequoia* two step requirement. The District Court held no hearing and ignored the massive financial harm alleged in detail and with specificity in this *qui tam* case; totaling more than $115 billion for the fourteen defendant drugs, with 30-40% attributed to Medicare Part D based on CMS' own recently released public data for defendant drug products in the program. SAC ¶¶ 23, 92.

The District Court's abdication from any inquiry regarding a "rational" basis for the Government's "resource" claims is wholly inadequate. In agreeing with the Government's contention that "that is was better to use these resources pursuing other claims", the District Court references a recent 31 U.S.C. § 3730 (c)(2)(A) case in which no taxpayer harm occurred. *United States, ex rel. Toomer v. TerraPower, LLC*, No. 4: 16-CV-00226 (DCN), 2018 WL 4934070 (D. Idaho, Oct. 10, 2018).

The *Sequoia* standard requires that the "rational relation" indicate "plausible, or arguable, reasons supporting the agency decision." *Ridenour*, 397, referencing *Sequoia*. Given the vast scale of alleged public financial harm in this *qui tam* action, the Government's resource preservation arguments are not remotely plausible. The potential financial rewards for the Government and taxpayers from the meritorious pursuit of even a small portion of this vast systemic scheme far exceed the potential costs of any unverified "resource" claims by the Government for assisting the Relator's efficient legal

efforts.

A recent letter request from the Chairman of the Senate Finance Committee to the Department of Justice indicates rising Congressional concern regarding the marked acceleration of Government 31 U.S.C. § 3730 (c)(2)(A) motions to dismiss *qui tam* cases, particularly pertaining to "vague" claims regarding "preserving government resources", as with this *qui tam* matter. See Letter from Senator Grassley to Attorney General William Barr, provided as Document 14 in the Special Appendix.

In the September 4, 2019 letter to Attorney General William Barr, Senator Charles E. Grassley (an architect of the 1986 FCA Amendments), noted the repeated lack of "cost-benefit analyses" (as has occurred this case) to support the Government dismissal decisions based upon resource claims.

Even "more troubling" to Senator Grassley was the DOJ claim that "cases where it declines to intervene lack merit or face little chances of success." As per Senator Grassley, "History has shown that the opposite is true. Since 1986, Relators have recovered over $2.4 billion for the federal government via claims in which DOJ chose not to intervene", including nearly $600 million in "*qui tam* cases in 2017 alone." A review of *qui tam* actions recently targeted for dismissal by DOJ indicate that the potential Government and taxpayer financial benefit from the Relator's two well-supported cases likely dwarfs, by a wide margin, the combined impact of all other cases.

With the District Court's acceptance of the "resource" argument, with minimal inquiry, the Court admitted that it did not address the other two Government claimed justifications for dismissal, especially its extensive factually supported merits[2], which includes substantive factual evidence not investigated by DOJ.

In the public interest, the Relator respectfully requests that the Court of Appeals remand the

[2] As per the District Court's July 16, 2019 Order: "Because the burden of further litigation is a valid and sufficient justification for the Government's dismissal, the Court need not and does not reach the Government's other proffered justifications. See Gov't Mem. 16-18.

Government's motion back to the District Court for discovery and an evidentiary hearing to include a thorough assessment of the Government's non-specific lack of merit arguments for dismissal.

The District Court also did not address the Government's basis for dismissal predicated on inappropriate and inaccurate disparagement of the Relator, claiming "serious doubts as to whether the Relator' interests and priorities align with those of the United States." The Government's unsubstantiated claims are solely based upon documents filed by the Relator's former employer in the Relator's False Claims Act/SEC whistleblower retaliation and wrongful termination lawsuit now pending in Massachusetts Superior Court.[3]

Relator's well-documented interactions with the Government and his actions during the District Court proceedings clearly indicate that the public interest has been and remains his priority pertaining to this *qui tam* action.

To preserve the sanctity of his and other citizen's whistleblower rights, the Relator respectfully asks the Court of Appeals to request the District Court to allow Relator to address in a hearing these serious and unsubstantiated Government allegations against the Relator.

BACKGROUND AND CASE HISTORY

In this *qui tam* action, the Relator, John R. Borzilleri, M.D., a 30-year experienced healthcare professional investment analyst, has alleged, in detail and specificity, that the Manufacturer and PBM

[3] After 15-years of unblemished and excellent performance as a professional healthcare analyst and portfolio manager, the Relator was terminated by his former employer, Shepherd Kaplan Krochuk (SKK), without a stated cause, on April 20, 2018, just two days after providing his firm with notice of the unsealing of this *qui tam* action. The Relator's termination is now part of an ongoing *qui tam*/ SEC whistleblower retaliation and wrongful termination lawsuit in Massachusetts Superior Court. The case is scheduled for pre-trial conference on March 19, 2020. In its case filings, SKK has alleged that Dr. Borzilleri's trading activities "risked" violating federal securities laws. Both the *qui tam* defendants and DOJ incorporated these unsubstantiated allegations in court filings for this action. Dr. Borzilleri has refuted these former employer allegations. Dr. Borzilleri has also repeatedly requested of both SKK and DOJ that any concerns should be referred to the Securities and Exchange Commission (SEC) for investigation, while pledging his full cooperation. Dr. Borzilleri is unaware of any such referral and has never been contacted by the SEC pertaining to his professional trading activities on behalf of his prior investment fund. Dr. Borzilleri did no personal trading in any securities during his employment by SKK.

Defendants have and continue to cause severe patient and taxpayer harm through brand drug price inflation, driven by a straightforward, fraudulent "service fee" scheme in the Medicare Part D program. SAC ¶¶ 12-13. For the Defendant parties, massive Part D profits related to the specific Defendant products have been driven almost entirely by four-to-seven-fold price increases over the past decade, even though clinical use of the drugs by Part D beneficiaries has plummeted, eroded or stagnated. SAC ¶¶ 2, 31. The egregious "service fee" arrangements are standardly calculated, by contract, as a percent of "list" or "sticker" prices that have had astronomical price increases; and the "service fees" bear no relation to services being provided or legitimate fair market value (FMV) compensation as required by law. SAC ¶ 26.

This "service fee" conspiracy between drug manufacturers and the dominant PBMs is the "Rosetta stone" behind massive US brand drug prices over the past 15 years. SAC ¶ 123.

The Relator originally filed this SDNY *qui tam* action on October 6, 2015, targeting major insulin, cancer, rheumatoid arthritis and other therapies. In the public interest, Dr. Borzilleri filed this in a separate jurisdiction from his initial *qui tam* filing, due to already serious concerns about inadequate Government investigations. See Rel. Opp. Gov't MD, p. 17 and Dr. Borzilleri's Affidavit. Dr. Borzilleri had previously filed a *qui tam* case in the District of Rhode Island (D-RI) in early 2014, targeting severe pricing and "fee" abuse in the U.S. multiple sclerosis (MS) market. At the time of the D-RI filing, numerous long-marketed blockbuster defendant MS drugs had already increased five-fold in cost (to the $50,000/patient/year range), despite sharply eroding clinical use (down 50-70% over the past decade-plus) with a corresponding decrease in legitimate PBM "support" needs. *U.S. ex rel. Borzilleri v. Bayer et al*., 14-CV-031-WES-LDA, D-RI, (2014). As per the Amended D-RI Complaint filed in August 2018, the defendant "sticker" U.S. drug costs had increased to approximately $100,000/patient/year, leading to a tripling of the estimated taxpayer harm to the $60 billion range (30-40% in Medicare Part D) due to the straightforward conspiracy. Rel. Opp. Gov't MD, p. 1.

The District Court in Rhode Island granted the Government's motion to dismiss, which was virtually identical to the SDNY 31 U.S.C. § 3730 (c)(2)(A) filing, via a text order the day after a brief hearing on September 26, 2019. The D-RI Court's memorandum, issued on October 21, 2019, fully agreed with the SDNY rationale for dismissal.

There is nothing subtle or complicated about the vast kickbacks paid by the manufacturer defendants to the PBM defendants directly caused by these severe illicit price increases, nor the tremendous patient and taxpayer harm that has resulted from this now nearly 15-year, ongoing conspiracy. Over the past decade, as indicated in District Court filings, the media is rife with stories of patient and family harm directly caused by scheme-related massive price increases for the defendant drugs in this case, especially essential insulins, cancer and rheumatoid arthritis drugs.

For most of the drug products in the case, after more than a decade of extreme price inflation (while clinical use and legitimate support needs have been in sharp decline), the manufacturer defendants are now routinely paying the dominant PBM defendants "service fees" that are approximately five-fold greater, for doing half or less as much legitimate "support work" for far fewer patients, relative to a decade ago. SAC ¶ 104. These fraudulent payments exceed the clear regulatory and legal requirements for fair market value (FMV) and fair compensation by a wide margin. SAC ¶ 26.

These excessive "service fee" payments from the manufacturer defendants now account for most and in many cases virtually all PBM defendant profits for the specific defendant brand drugs, especially extreme-priced "specialty" therapies whose massive U.S. price inflation has caused harm to patients and families across this nation. SAC ¶¶ 59-60.

The scheme is verified by extensive factual evidence and firsthand commentary from insider witnesses (including from Defendants' employees) provided in the Complaint and subsequent court filings, none of which have been refuted factually by either the government or the defendants. In fact,

the primary reason the non-insider Relator filed this action, in the public interest, was his attendance (with a colleague) at a one-of-a-kind industry conference specifically regarding this "service fee" price-inflation kickback scheme in October 2013. At the conference, the Relator obtained shocking firsthand commentary from an array of industry insiders centrally involved in the scheme, verifying all aspects of the intentional conspiracy in detail.

Directly involved insider statements, provided to the government in Relator's Complaint, include stunning admissions such as: 1) "fees were the key to government pricing"; 2) the majority of compensation has "shifted from rebates to fees"; 3) "service fee agreements" were a "substantial pool of money" and were the "main source of income" in government drug programs; 4) "percent of revenue" deals, inclusive of all price increases, remain the standard; 5) I "hope the conference is not being recorded"; and 6) when is the "government going to be dangerous enough to know how industry works." Simply put, it is hard to imagine how Dr. Borzilleri's firsthand evidence of this harmful systemic conspiracy could have been any clearer. SAC ¶¶ 452-89.

In the initial and Amended Complaint filed in SDNY on October 9, 2015, the Relator provided DOJ and the Court an Exhibit List (see SAC, Exhibit 14) of 40-45 firsthand insider witnesses from the conference, including executives from Defendants Pfizer, AbbVie, Amgen and Express Scripts. Unfortunately, as per Relator's affidavit, DOJ investigative staff in both SDNY and the D-RI repeatedly admitted in update conference calls with Relator and counsel that no witnesses from this conference were ever deposed during the Government's four-plus year investigation. In fact, DOJ repeatedly admitted to Relator and counsel that only a single witness (an unidentified person from Express Scripts), among eleven major pharmaceutical and six dominant health insurer/PBMs in the two vast *qui tam* cases, was deposed in the entire Government investigation. These glaring investigative failures should have been of great concern to the District Court but were disregarded.

In contrast to most *qui tam* actions, in the SDNY complaint the Relator provided detailed

quantification of the financial fraud for each of the 14 defendant pharmaceutical products in the case. Overall, the Relator avers that massive price increases directly caused by the ongoing scheme, just for the 14 specific Defendant drugs in the SDNY action, have already caused more than $114 billion in public harm, with 30-40% directly attributable to the Medicare Part D. SAC ¶¶ 23, 92.

Furthermore, the patient and taxpayer harm greatly accelerated during the government's two-and-a-half year arbitrary and inadequate investigation of the case. As irrefutable evidence of the "fee" conspiracy mounted, U.S. prices of the all the Defendant brand drugs doubled again (as their U.S. prescription volume largely continued to erode), leading to accelerating patient and taxpayer harm from the conspiracy. SAC ¶¶ 93-5, 388.

Due to escalating public harm, the amount of time the investigation was taking, and the apparent lack of meaningful progress in the investigation, the Relator reluctantly began opposing DOJ requests for investigative extensions in the SDNY Court in early 2017 when the arbitrary and inadequate nature of the government investigation became apparent.

Following the Government's non-intervention decisions in March 2018, the Relator promptly began pursuing the cases in the public interest in both SDNY and D-RI. Under a highly efficient District Court schedule in both SDNY and the D-RI, multiple defendants in the systemic scheme were grouped into two main parties, the Manufacturer and PBM Defendants. With new definitive evidence of the scheme, including Defendant public admissions and highly particular Medicare Part D data, the Relator completed service of the Defendants in the SDNY case, and his separate D-RI action in August 2018. The SDNY Defendant parties filed their motions to dismiss the case on October 1, 2018.

To the Relator's surprise, just three days before his reply to the defendants' motions to dismiss were due for SDNY Court filing, the combined SDNY and D-RI Justice Department requested and had a conference call with Relator's counsel on November 16, 2018. On the brief phone call, DOJ informed Relator's counsel for the first time that it was considering seeking a 31 U.S.C. §

3730(c)(2)(A) dismissal of both Relator's SDNY and D-RI *qui tam* cases. On the call, DOJ cited "government resource" concerns, as well as behavior of the Relator as potential reasons for seeking unilateral dismissal. Prior to this November 16, 2018 conference call, Relator and counsel had virtually no contact with DOJ since its simultaneous March 2018 non-intervention decisions for the SDNY and D-RI *qui tam* actions.

In August 2018, the Relator completed service of Amended Complaints to all the defendants in both his SDNY and D-RI *qui tam* actions. The Amended Complaint in both jurisdictions included extensive additional evidence, which was never discussed by the Relator with DOJ.

Following the November 16, 2018 call, at the request of DOJ, the Relator promptly responded to concerns regarding his trading activities as a professional healthcare investment analyst and portfolio manager. In the written communication, to allay any concerns, the Relator requested a DOJ referral to the Securities and Exchange Commission (SEC) for investigation and pledged full cooperation. DOJ did not respond to Relator's request. Rel. Opp. Gov't MD, pgs. 13-4.

After 15-years of unblemished and top-performing employment, the Relator was terminated by his former long-term employer, Shepherd Kaplan Krochuk, without a stated cause, on April 20, 2018, just two days after providing the firm notice of the unsealing of the SDNY *qui tam* case**.** *id.* The Relator's termination is now part of an ongoing *qui tam*/SEC whistleblower retaliation and wrongful termination lawsuit in Massachusetts Superior Court, with a pre-trial conference scheduled for March 19, 2020.

Dr. Borzilleri has never been contacted by the SEC pertaining to his professional trading activities but would welcome the opportunity and again pledges full cooperation. While employed at Shepherd Kaplan Krochuk, the Relator never traded any equities in any personal accounts.

As per the District Court schedule, the Relator filed his opposition to the SDNY Defendants' motion to dismiss on November 19, 2018. The opposition included extensive new factual evidence

highly supportive of the conspiracy, including (Rel. Opp. Def. MD, especially pgs. 3, 25-6) (1) first time admissions by PBM Defendants CVS Health and Cigna/Express Scripts in August 2018 that "manufacturer brand drug rebates" account for less than 10% of overall corporate profits. As noted repeatedly in the Complaint, other than the retention of potential manufacturer rebates, "service fees" linked to massive "sticker" price increases from the manufacturer defendants are the only other major potential source of profits for the PBM Defendants in either Medicare Part D or the private health insurance market, SAC ¶¶ 59-60, 102; and (2) first time CMS data released in May 2018, providing particular data for the defendant brand drugs targeted in the *qui tam* cases. SAC ¶¶ 44-50.

Relator and counsel never discussed this new substantive evidence with DOJ, further indicating the pretextual, capricious, and arbitrary nature of the Government's investigative and dismissal efforts.

As per DOJ's letter sent to the District Courts on November 16, 2018, the government simultaneously filed 31 U.S.C. § 3730(c)(2)(A) motions to dismiss both Relator *qui tam* actions on December 21, 2018. In the filings, relative to the November 16, 2018 conference call with DOJ, the government added a third "lack of merit" argument as justification for dismissal.

On January 11, 2019, Relator filed his opposition to the Government's SDNY 31 U.S.C. § 3730(c)(2)(A) motion to dismiss. Based upon contemporaneous notes, the Relator simultaneously filed a 12-page affidavit under oath detailing extensive interactions between Relator, his counsel and DOJ during voluntary investigative update conference calls.

On February 6, 2019, the Government filed its reply memorandum further in support of its motion to dismiss. DOJ did not file an affidavit refuting any of the Relator's claims under oath of investigative inadequacy by the Government.

The Relator and counsel had no subsequent interaction with DOJ or the SDNY District Court prior to the Court Memorandum Opinion and Order issued on July 16, 2019. In the Order, the District Court granted the Government's motion to dismiss, based on the DOJ's "government resource"

argument. The District Court found no basis for Relator's arguments regarding a capricious, unlawful or inadequate investigation. The District dismissed the Relator's federal FCA claims against all the defendants. The defendants' motions to dismiss were denied as moot and the Clerk of the Court was directed to terminate all motions and close the case.

The Relator filed a Notice of Appeal regarding the Government's 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss with the SDNY District Court on September 13, 2019.

ARGUMENT

A. The District Court Disregarded Extensive Firsthand Evidence, from Senior DOJ Investigative Staff, of a Fraudulent Government Investigation in this *Qui Tam* Case Alleging Unprecedented Patient and Taxpayer Harm.

Throughout the four-plus years of Government investigation of this *qui tam* cases alleging unprecedented public harm (including two-and-half years for this SDNY action), the Relator and counsel sought to voluntary assist DOJ in any manner possible. As indicated and provided in the opposition to the Government's motion to dismiss, the Relator voluntarily provided numerous extended analyses to DOJ and a wide array of other email communications, all of which supported the systemic "service fee" scheme fueling massive U.S brand drug price inflation. Rel. Opp. Gov't MTD, pgs. 14-17.

As part of this process, the Relator and counsel participated in an array of voluntary update phone conference calls with DOJ, primarily when the Government was requesting additional investigative time. Unfortunately, as time passed and the public harm from the systemic US brand "service fee" drug price inflation scheme accelerated, it became increasingly apparent from repeated firsthand DOJ phone interactions that the Government was failing to properly and fully investigate the Relator's central *qui tam* allegations and definitive firsthand witnesses provided in the Complaint. The Relator kept contemporaneous notes during these DOJ investigative update conference calls.

With accelerating public harm driven by defendant price increases, the physician Relator reluctantly began opposing DOJ investigative extension requests, in the public interest, starting in early 2017. In the SDNY case, on September 5, 2017, Relator filed a motion with the District Court, detailing DOJ's investigative failures, contesting DOJ's request for additional investigative time and requesting that the case be unsealed. Memorandum of Law Opposing Extension of Time to Consider Election of Intervention and Seeking Unsealing of *Qui Tam* Documents, under seal, Civ Act. No. 15 CV 7881 (JMF), September 5, 2017. As patient and public harm escalated from widespread brand drug price increases, the experienced financial professional and physician Relator reluctantly concluded that the public interest would be better served by his own more efficient discovery of the straightforward scheme in the Courts. Ultimately, the Relator did file both *qui tam* cases and serve all defendants following the Government's simultaneous non-intervention decisions in the SDNY and D-RI cases in March 2018.

In response to the Government's unexpected motions to dismiss in December 2018, Dr. Borzilleri provided a 12-page affidavit to both *qui tam* District Courts, providing extensive first-hand evidence of a pretextual, capricious, and thoroughly inadequate investigation. See Dr. Borzilleri's Affidavit**.** In its reply to Relator's opposition and Affidavit, the Government did not refute most of these investigative fraud allegations, either in its brief nor more importantly under oath. Most of the same investigative fraud concerns were provided under seal to the SDNY District Court in the Relator's prior September 2017 motion.

Despite extensive firsthand evidence of long-standing investigative inadequacy, the District Court cursorily dismissed Relator's allegations in its July 2019 Order granting the Government' Motion to Dismiss.

First, consistent with the Government's claims, the District Court inaccurately described the Relator's substantive investigative fraud evidence as a "subjective disagreement with the

Government's investigative strategy…which does not provide the Court with a basis to second-guess the Government's decision to dismiss the case." The Relator's disagreement with the Government's investigation was not based upon beliefs, attitude and opinions; but rather, upon verifiable evidence. The District Court was provided, under oath, with Relator's Declaration which detailed extensive and objective facts showing an insufficient Government investigation, based on firsthand admissions by DOJ staff during numerous voluntary investigative calls with Relator and counsel over several years.

Contrary to the District Court's ruling, the physician Relator's public interest concerns are far more specific than the Government's assertion that he illegitimately seeks to "second guess the Government's investigative choices." Rather, via extensive firsthand evidence from DOJ itself, the Relator asserts that the Government failed to investigate the central *qui tam* allegations and to pursue specifically identified witnesses provided in the Complaint. By doing so, the Government abrogated the legal and legislative investigative requirements of the False Claim Act, thereby enabling accelerating patient and taxpayer harm as the defendant brand drug prices doubled again following the *qui tam* filing.

Second, the District Court cursorily described Dr. Borzilleri's detailed firsthand fraud concerns provided via affidavit as a "hodgepodge of theories" lacking coherence. In sharp contrast to this inaccurate characterization, Dr. Borzilleri's unrefuted affidavit, sworn under oath under penalty of perjury, describes major investigative fraud concerns in clear and precise detail, including: 1) the Government failed to investigate the central kickback and Part D catastrophic cost-sharing allegations; 2) the Government quickly shifted away from investigating the pharmaceutical defendants despite their central legal liability; 3) the Government failed to pursue a wide array of directly involved insider witnesses provided by the Relator in the Complaint; 4) the Government deposed only one defendant witness in 4+ years of a claimed extensive investigation (and not a single pharmaceutical defendant employee); 5) the Government ignored definitive new evidence since its non-intervention decision;

and (6) the SDNY lead DOJ investigator provided a clearly false rationale, namely protection by the Group Purchasing Organization (GPO) anti-kickback safe harbor) as the basis for non-intervention. See Dr. Borzilleri's Affidavit.

Most importantly, the central kickback and Part D catastrophic cost-sharing fraud allegations were the primary focus of the initial and Amended Complaints in both Relator *qui tam* cases. The "kickback" allegations are set forth in SAC ¶¶ 28, 44, 79, 85, 87, 95, 169-70, 176. Part D catastrophic cost-sharing allegations are specified in SAC ¶¶ 32-33, 395-444. DOJ staffs' repeated admissions to Dr. Borzilleri and counsel regarding their failure to investigate these central *qui tam* allegations is of major public concern and consequence.

Given the vast alleged public harm in this case, all these severe investigative inadequacy allegations warranted careful consideration by the District Court. Instead, the District Court simply described these serious allegations with grave public implications as a "hodgepodge of theories" and "investigative choices", while only listing them in a footnote[4] with no further consideration.

Despite its prior awareness of Dr. Borzilleri's consistent investigative fraud concerns, the District Court stated that it had "no basis to doubt" the Government and apparently relied solely upon DOJ's memoranda in granting the dismissal.

Further, the District Court disregarded DOJ's repeated admissions of CMS (Centers for Medicare and Medicaid Services) interference and lack of support in this *qui tam* investigation, also provided via affidavit and easily verifiable. See Dr. Borzilleri's Affidavit, pgs. 4-5, 8-9. DOJ's staff admitted to Relator and counsel that: 1) DOJ would not intervene primarily because CMS was not supportive; 2) Subpoenas were put on hold, pending further discussions with CMS; and, 3) the lead SDNY DOJ investigator admitted that CMS was not supportive and failed to provide data in the *qui tam* investigation.

[4] See the footnote at the bottom of page 4 of the District Court's Memorandum Opinion and Order, dated July 16, 2019.

As reiterated in the opposition to the Government's motion to dismiss, the Relator's initial and Amended Complaint clearly state that CMS oversight failure has been a central factor enabling this long-standing conspiracy. SAC ¶¶ 66, 163, 281. Given these direct admissions from DOJ investigative staff and the clear concerns in Relator's Complaints, potential CMS interference warranted careful consideration. Instead, the District Court simply stated that Relator's concerns of "stonewalling by CMS and conflicts of interest …do not rise above the level of speculation", with no further inquiry. Further, in its Order, the District Court was supportive of DOJ's primary dismissal argument of preserving CMS "time and resources to respond to discovery requests" from the Relator following potential advancement of his case.

While not mentioned by the District Court in its Order granting dismissal, the eleventh-hour Government filing of its motion to dismiss, just prior to the Court's start of review of the case's substantive merits following efficient Relator pursuit, should have been cause for alarm. DOJ filed its motion on December 21, 2018, more than nine months after its non-intervention decision in early March 2018, with no subsequent investigative interaction with Relator and counsel.

As outlined in Relator's opposition, between the government's non-intervention decision and its late-dated motion to dismiss, the following occurred: (1) in August 2018, Relator completed service of the defendants with Amended Complaints, including extensive additional factual evidence which was never discussed with the government; (2) On October 1, 2018 the defendants filed motions to dismiss Relator's Amended Complaint, with virtually no factual support refuting Relators' well-pleaded allegations; and (3) on November 19, 2018, Relator filed his opposition to the defendants' motions to dismiss, including more substantive new factual evidence verifying the straightforward conspiracy (including defendant public admissions and particular Medicare Part D data for the defendant brand drugs), which was not discussed with the Government. These glaring Government deficiencies provide further clear evidence of the Government's inadequate investigation and

pretextual, capricious dismissal efforts.

Given extensive evidence of inadequate Government investigation and the well-supported vast public harm, the Relator avers that the Government's motion to dismiss should have been denied by the District Court based upon either the *Swift* or the *Sequoia Orange* standard of review.

B. The District Court Failed to Properly Assess the Government "Resource" Rationale Based Upon the *Sequoia Orange* Two Step Test.

In granting the Government's motion, the District Court demurred from taking "a side in the dispute" regarding the *Swift* or *Sequoia Orange* standard for 31 U.S.C. § 3730 (c)(2)(A) motions to dismiss. Rather, in a perfunctory manner, the District Court "concludes that the Government may dismiss the case even under the more stringent standard articulated in *Sequoia Orange"*.

However, in mentioning *Sequoia Orange*, the District Court ignored the "stringent standard" outlined and applied carefully in *Sequoia Orange* and related cases. As per *Sequoia* itself, "The district court acted reasonably in adopting the following standard: "A two-step analysis applies here to test the justification for dismissal: (1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of that purpose." 912 F. Supp.

As per *Sequoia*, the "rational relationship" test "held that dismissal of a *qui tam* action pursuant to 31 U.S.C. § 3730 (c)(2)(A) is appropriate only (emphasis added) if the government has a valid government purpose, and (emphasis added) dismissal is rationally related to accomplishing that legitimate government interest." *Sequoia*, 151 F. 3d at 1145-47. In *Sequoia*, preservation of government resources was just one of six reasons provided by the government for dismissal under 31 U.S.C. § 3730 (c)(2)(A), all of which were addressed by the District Court in *Sequoia* during a four-day evidentiary hearing.

In sharp contrast, in this case, the District Court has provided no evidence of due diligence pertaining to the essential "rational relations standard" portion of the *Sequoia* two step requirement.

The District Court held no hearing and ignored the massive financial harm alleged in unprecedented detail and specificity in this *qui tam* case.

The *Sequoia* standard requires that the "rational relation" indicate "plausible, or arguable, reasons supporting the agency decision." *Ridenour*, 397, referencing *Sequoia*. Given the vast scale of public harm in this *qui tam* case, the Government's "resource preservation" basis for dismissal is not remotely plausible. The potential financial returns for the government and taxpayers, from the meritorious pursuit of even just one of the fourteen major brands in this case, would clearly outstrip any potential resource utilization to "monitor" or "assist" the Relator's efforts. Given the systemic nature of this scheme, the potential for government and taxpayer financial benefits in this case are unprecedented, not to mention the patient and societal gains from derailing this ongoing, well-supported conspiracy fueling a national crisis.

In its discussion of government resources, this District Court referenced another recent 31 U.S.C. § 3730 (c)(2)(A) Court ruling, *EMD Serono, Inc.*, 370 F. Supp. 3d 483, (E.D. Pa 2019). In *Serono*, the District Court highlighted the essential role of the "rational relation standard" and the Courts in its executive branch oversight. "We find that the reasoning of the Ninth and Tenth Circuits is more persuasive than that of the District of Columbia Circuit. The rational relationship standard accords with statutory interpretation and fosters transparency. It is consistent with the constitutional scheme of checks and balances." "The rational relationship test strikes a balance among the branches of government. It does not give unlimited power to the Executive to dismiss legitimate action the Legislature created".

With the District Court's acceptance of the "resource" argument, with minimal inquiry, it admittedly did not address the other two Government claimed justifications for dismissal, especially the extensive factually supported merits of the Relator's case. In the public interest, the Relator respectfully requests that the Court of Appeals also remand the Government's motion back to the

District Court for discovery and an evidential hearing to include a thorough assessment of the Government's lack of merit dismissal argument.

With its unjustified granting of the Government's 31 U.S.C. § 3730 (c)(2)(A) motion to dismiss, the District Court also dismissed the Relator's *qui tam* case in its entirety without any indication that it considered the vast public harm and the factually-supported merit detailed in the Relator's extensive *qui tam* filings.

C. Escalating Congressional Concern Regarding Accelerating Government 31 U.S.C. § 3730 (c)(2)(A) Motions to Dismiss Q*ui Tam* Cases Warrants Acute Judicial Concern.

In mid-January 2018, less than two months before the Government's pretextual non-intervention decisions regarding Relator's two vast *qui tam* cases, a DOJ memo, called the "Granston Memo," was publicly "leaked." See Special Appendix, Document 12. In the "Granston Memo," the DOJ announced its new directive to increasingly seek unilateral dismissal of *qui tam* cases, thereby preventing Relators from pursuing them on their own as has been a central component of the FCA for decades.

Without Congressional or public input, DOJ added the new directive to its policy in April 2018 (See Special Appendix, Document 13), the same month that the Relator's two *qui tam* cases, which allege unprecedented and ongoing public harm, were unsealed. With concern regarding the coincident timing of the new DOJ policy and the Government's non-intervention decisions, Relator and counsel discussed the issue with DOJ in an early 2018 phone conference call. On the call, DOJ informed Relator and counsel that the Government had no plans to pursue dismissal of his *qui tam* cases via the 31 U.S.C. § 3730 (c)(2)(A) process.

Following unsealing, Relator and counsel promptly pursued both his SDNY and D-RI *qui tam* cases privately, based upon efficient briefing schedules in both District Courts. Due to the systemic nature of the scheme, the Courts placed the defendants into only two major groups for briefing, namely

the manufacturer and PBM defendants.

As per the Amended Complaints served on the defendants in both actions in the summer of 2018, the carefully documented cumulative financial harm in the two cases has doubled and tripled to $114 billion and $60 billion (with 30-40% in Part D) in the SDNY and D-RI cases, respectively, as the defendant U.S. brand drug prices doubled again since the initial Complaint filings. SAC ¶¶ 93, 95, 116, 388.

Despite efficient Court progress in both *qui tam* cases, in a brief conference call with DOJ staff from both jurisdictions on November 16, 2018, Relator's counsel was notified for the first time that the Government was considering seeking 31 U.S.C. § 3730 (c)(2)(A) dismissal for Relator *qui tam* cases. On the phone call, DOJ cited concerns about the preservation of government resources, as well as surprising claims attacking Dr. Borzilleri's fitness based upon unsubstantiated claims in his ongoing *qui tam*/SEC whistleblower retaliation and wrongful termination employment lawsuits. The defendants had inappropriately highlighted these same ad hominem and unsubstantiated claims against Dr. Borzilleri in their motions to dismiss in both jurisdictions.

Relator and counsel were surprised and concerned by this sudden and unexpected DOJ announcement due to: 1) no prior indication of any such concerns from DOJ in four-plus years of frequent interaction; 2) clear and repeated DOJ feedback indicating only a cursory investigation on the part of the DOJ, without inquiry regarding the main components of the fraud; 3) no investigative contact with the Government since its March 2018 non-intervention decisions; 4) extensive new factual evidence supporting the scheme that was never discussed with the Government, both in the Amended Complaints and in Relator's reply to the SDNY defendants' motions to dismiss; and 5) DOJ's extensive awareness of the physician Relator's consistent public interest focus and his considerable voluntary efforts to assist the Government investigations. See Rel. Opp. Gov't MD, generally.

Despite promptly addressing the Government's concerns in writing, the Relator and counsel

had no subsequent interaction with DOJ prior its filing of its 31 U.S.C. § 3730 (c)(2)(A) motions to dismiss simultaneously in both jurisdictions on December 21, 2018. Rel. Opp Gov't MD, pgs. 13-14. In the filed motions, relative to the November 16, 2018 conference call, DOJ added conclusory claims that the cases lack merit as a basis for dismissal.

Relator avers that this eleventh hour dismissal effort is consistent with the Government's pre-textual, capricious, and inadequate handling of these vast *qui tam* cases over several years. Reluctantly and with great public concern, Relator and counsel concluded that DOJ was filing these late-dated motions to dismiss primarily to derail Court review of the accelerating merit of these two unprecedented *qui tam* cases.

A recent Congressional request to DOJ indicates rising legislative concern regarding a sudden acceleration of Government 31 U.S.C. § 3730 (c)(2)(A) motions to dismiss *qui tam* cases. Special Appendix, Document 14. In a September 4, 2019 letter to Attorney General William Barr, Senator Charles E. Grassley, Chairman of the Senate Finance Committee and an architect of the 1996 FCA Amendments, specifically noted with grave concern DOJ's escalating efforts to unilaterally dismiss *qui tam* cases, particularly with "vague" claims regarding "preserving government resources". As in this instant case, in reviewing other targeted *qui tam* cases, Senator Grassley noted the repeated lack of "cost-benefit analyses" to support the Government dismissal decisions.

Even "more troubling" to Senator Grassley was the DOJ claim that "cases where it declines to intervene lack merit or face little chances of success." As per Senator Grassley, "History has shown that the opposite is true. Since 1986, relators have recovered over $2.4 billion for the federal government via claims in which the DOJ chose *not* to intervene." (emphasis added.) Senator Grassley noted that the marked increase in dismissals initiated by the DOJ may be "undermining the purpose of the False Claims Act by discouraging whistleblowers and dismissing potentially serious fraud on the taxpayer."

Senator Grassley continued, "Denying Relators the right to pursue False Claims Act cases if the government does not intervene is counter to the basic, essential purpose of the Act, which is to empower private citizens to help the government fight fraud. DOJ's actions in these cases will send a clear message that bad actors can get away with fraud as long as they make litigating painful and sufficiently burdensome for the government. By opting to save resources without first conducting a sufficient cost-benefit analysis, DOJ is circumventing Congress and taking a shortsighted position that may end up costing taxpayers much more money in the future."

In this case, Congressional concerns regarding DOJ's recent change in policy appear particularly warranted and acute given: 1) unprecedented, well documented, and ongoing patient and public financial harm; 2) extensive factual support for Defendants' fraudulent scheme; 3) the DOJ's filing of the motion to dismiss just as the relator's investigation was to begin; and, most importantly, 4) significant evidence of DOJ investigative inadequacy. In Senator Grassley's words, "Congress gave whistleblowers the ability to proceed with claims on their own *precisely* for situations in which DOJ either would not or could not pursue the case. We know from experience that without whistleblowers, fraudsters multiply and bad behavior balloons." (emphasis in original.)

It is public knowledge that since the "Granston Memo" was issued, the DOJ has filed motions to dismiss close to 100 qui tam cases, and virtually all of its motions have been granted. The DOJ is not required to disclose details about what or who it investigated, or the documents it obtained; nor is it required to provide specific evidence showing why its monitoring of relators' lawyers' work on the cases will be burdensome. Therefore, there is little that relators can do to contest these motions.

If any industry has sufficient resources to challenge a whistleblower's claims, it is the pharmaceutical and pharmacy benefit manager industry. Should the Relator be allowed to pursue this case on his own, if his allegations could be considered inadequate to state a claim, that would be apparent soon enough. Instead, here, the Department of Justice, which is pledged to ensure justice on

behalf of the people, is expending its limited resources effectively assisting pharmaceutical companies that have cost U.S. taxpayers billions of dollars.

CONCLUSION

For the reasons above, Relator respectfully requests that the Court of Appeals rescind the District Court's Order granting the Government's 31 U.S.C. § 3730(c)(2)(A) motion to dismiss. In the public interest, the Relator respectfully requests that the case be remanded back to the District Court for discovery and an evidentiary hearing regarding the Government's motion to dismiss and the adequacy of its investigation of this *qui tam* matter. The Relator respectfully requests oral argument with the Court of Appeals regarding this matter.

Dated: New York, New York
December 23, 2019

Respectfully submitted,
s/s Mary Ann H. Smith
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CERTIFICATE OF COMPLIANCE

In compliance with Second Circuit Court of Appeals requirements, this document has less than 9,700 words, which is below the 14,000-word briefing limit.

CERTIFICATE OF SERVICE

I, Mary Ann H. Smith, hereby certify that, on December 23, 2019, I caused a copy of the foregoing notice of motion, along with the supporting papers, in *U.S.* et al. ex rel. *Borzilleri v. AbbVie, Inc. et al.*, Second Circuit Court of Appeals Case No. 19-2947 to be served, by ECF.

Dated: December 23, 2019

ss/ *Mary Ann H. Smith*
Mary Ann H. Smith