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September 4, 2019

VIA ELECTRONIC TRANSMISSION

The Honorable William Barr
Attorney General
U.S. Department of Justice
Washington D.C., 20220

Dear Attorney General Barr:

I write today with concerns about the Department of Justice's (DOJ) implementation of the Granston Memorandum and its efforts to dismiss greater numbers of *qui tam* cases for reasons that appear primarily unrelated to the merits of individual cases.¹ Those efforts rely at least in part on vague and at times questionable concerns over prerogatives or limited government resources to handle the cases. Such actions could undermine the purpose of the False Claims Act by discouraging whistleblowers and dismissing potentially serious fraud on the taxpayers.

Originally enacted in 1863, the False Claims Act allows the government to recover triple damages and impose fines against those who knowingly defraud the government.² This is a powerful tool in the U.S. government's toolbox to prevent and deter fraud and has resulted in the recovery of more than \$59 billion since 1986.³ The key feature of the False Claims Act is the *qui tam* provision, which allows whistleblowers privy to inside information about fraudulent conduct to sue on the government's behalf.⁴ For their efforts, successful whistleblowers may receive a reward of up to 30% of funds recouped by the government.⁵ The statute requires that the relator file a claim under seal, and then DOJ has 60 days to investigate the allegations raised in the complaint.⁶ After the 60 day investigatory period, DOJ may prosecute the case themselves in a process often referred to as "intervening" in a case.⁷ In such intervening cases, the whistleblowers

¹ See Motion to Dismiss, United States *ex rel.* Campie v. Gilead Scis., Inc., No. C-11-0941 EMC (N.D. Cal. Mar. 28, 2019).

² 31 U.S.C. §§ 3729 -3733 (2012); See U.S. Dep't of Justice, *The False Claims Act: A Primer* (Apr. 22, 2011), available at https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

³ Civil Div., U.S. Dep't. of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018*, (Dec. 21, 2018), available at https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

⁴ 31 U.S.C. § 3730(c).

⁵ 31 U.S.C. § 3730(c).

⁶ 31 U.S.C. § 3730(b).

⁷ *Id.*

who alerted the government of the fraud through their *qui tam* claim remain eligible for a reward regardless of DOJ involvement.⁸

On January 10, 2018, Michael D. Granston, Director of the Commercial Litigation Branch at DOJ, issued new guidance on when to seek dismissals of *qui tam* claims.⁹ Prior to the memo, motions to dismiss by the government were extremely rare.¹⁰ I raised concerns about this new guidance with you during your confirmation hearing.¹¹ You assured me that you would review the Granston memo and work with me to address any concerns.¹² As I have noted, the guidance includes several vague criteria for DOJ attorneys to consider.¹³ For example, listed as one of the possible reasons to seek dismissals was “preserving government resources.”¹⁴ Seemingly in response to the Granston memo, DOJ has moved to dismiss or threaten to dismiss several cases at least in part because of litigation costs, even though its arguments were vague, pretextual and could not demonstrate cost was prohibitive. Some examples follow:

In *United States, ex rel. Cimznhca, LLC v. UCB, Inc.*, relators alleged violations of the Anti-Kickback Statute by several pharmaceutical companies.¹⁵ DOJ moved to dismiss the claim arguing that the case lacked merit, but also because continued litigation would be costly and contrary to governmental prerogatives.¹⁶ DOJ further asserted that substantial costs would be incurred responding to discovery requests and monitoring the litigation.¹⁷

However, during an evidentiary hearing on the motion, DOJ admitted that it did not thoroughly investigate the specific claims made by the relators.¹⁸ The court noted, “[DOJ] did not review any additional materials from the relator relevant to this case...nor did the Government effort a cost-benefit analysis; it did not assess or analyze the costs it would likely incur versus the potential recovery that would flow to the Government if this case were to proceed.”¹⁹ The court also found fault with DOJ’s expressed policy interest, highlighting that even the government acknowledges that the allegations made by the relators “assert a classic violation” of the Anti-Kickback Statute.²⁰ The court ultimately denied DOJ’s motion to dismiss finding that its decision

⁸ 31 U.S.C. § 3730(c); see also Paden M. Hanson, *True Damages for False Claims: Why Gross Trebling Should Be Adopted*, 104 IOWA L. REV. 2093, 2099 (2019).

⁹ Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, to Atty.’s in the Commercial Litig. Branch, Fraud Section (January 10, 2018), available at <https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf>.

¹⁰ Schooner, Steven L., *FALSE CLAIMS ACT: Greater DOJ Scrutiny of Frivolous Qui Tam Actions?* (April 2018) 32 NASH & CIBINIC REP. ¶ 20 at 60 (2018) (only a single reported instance between 1986 to 1996 in which the DOJ has sought to dismiss a *qui tam* suit on the ground that the suit lacked substantive merit or otherwise contradicted the interests of the United States), available at https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=2593&context=faculty_publications.

¹¹ *Nomination of the Honorable William Pelham Barr to be Attorney General of the United States*, 116th Cong. (2019) (statement of Sen. Charles E. Grassley, Member, S. Comm. on the Judiciary).

¹² *Id.*

¹³ *Id.*

¹⁴ Memorandum from Michael D. Granston, *supra*, note 9.

¹⁵ See *United States ex rel. Cimznhca, LLC v. UCB Inc.*, No. 17-CV-765 –SMY-MAB (S.D. Ill. April 15, 2019) (order denying government’s motion to dismiss); see also 42 U.S.C. § 1320a-7b(b).

¹⁶ *UCB Inc.*, No. 17-CV-765 –SMY-MAB at 6.

¹⁷ *Id.* at 5.

¹⁸ *Id.* at 6.

¹⁹ *Id.* at 6.

²⁰ *Id.* at 6.

was arbitrary and capricious, and likely motivated by animus towards the relator.²¹ To summarize, DOJ did not thoroughly investigate a case it argued lacked merit; argued for dismissal on policy grounds while admitting the claims present a classic violation of law; and finally, failed to do a cost-benefit analysis while arguing that litigation would be too costly.

In *United States, ex rel. Campie v. Gilead Scis. Inc.*, DOJ made similar cost-based arguments.²² The relators in *Campie* alleged that Gilead Sciences Inc. manufactured certain drugs using illicit and potentially dangerous ingredients from unregistered facilities in China.²³ In the mid-2000's Gilead received approval from the Food and Drug Administration (FDA) for several drugs which contained the active ingredient emtricitabine (commonly known as FTC).²⁴ Gilead represented to the FDA that it would source its FTC from FDA-approved facilities in Canada, Germany, South Korea, and the U.S.²⁵ However, for a period of sixteen months beginning in December 2007, Gilead allegedly used illicit FTC purchased from a facility in China in order to cut costs and trigger price reduction clauses in contracts with other FTC suppliers.²⁶ In an effort to hide its actions, Gilead allegedly falsified labels so that their origins were disguised, and claimed that the FTC had come from an FDA-approved facility in South Korea.²⁷ On October 2008, Gilead sought FDA approval for the use of FTC purchased in the Chinese facility.²⁸ However, the relators further alleged that Gilead concealed or falsified quality control issues in the Chinese facility in order to receive FDA approval.²⁹ Based upon these alleged facts, the relators brought a *qui tam* action in October 2010.³⁰ DOJ then investigated the allegations for two years before declining to intervene in January 2013.³¹ Nonetheless, the relators elected to proceed without the government, and filed an amended complaint to that effect.³² Years later, the government moved to unilaterally dismiss the relators' claim in 2019.³³

DOJ's main rationale for seeking to dismiss the *qui tam* claim in *Campie* was that it would "avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue."³⁴ Here, once again, DOJ has attempted to dismiss a claim by citing litigation costs. Similar to the court in *Cimznhca, LLC v. UCB*, the Judge in the *Campie* case asked DOJ if a cost-benefit analysis had been performed, noting that "some meaningful cost-benefit

²¹ *Id.* at 7.

²² See *Gilead Scis., Inc.*, No. C-11-0941 EMC (2019).

²³ *Id.* at 1-2.

²⁴ *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 895-96 (9th Cir. 2017).

²⁵ *Id.* at 896.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ See *Gilead Scis., Inc.*, No. C-11-0941 EMC at 8 (2019).

³¹ *Id.* at 8.

³² *Id.* at 8.

³³ *Id.* at 8; see also *United States, ex. rel. Campie et al. v. Gilead Scis., Inc.*, 2015 WL 3659765 (N.D. Cal. 2015), *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 895-96 (9th Cir. 2017), *Gilead Scis., Inc. v. United States, ex. rel. Campie*, 139 S.Ct. 783 (2019) (District court dismissed relators claim in 2015, under the theory that fraud was directed at the FDA and not the payer agency, that payment was not conditioned on compliance with FDA regulations but merely FDA approval, and that FCA was not meant to intrude on FDA's regulatory regime. The 9th Circuit Court of Appeals reversed and remanded stating that relators adequately pled theories of factual false certification, implied false certification, and promissory fraud. The Supreme Court denied writ on defendant's appeal of the 9th Circuit's ruling. The case is now pending before the District court).

³⁴ See *supra*, note 30.

analysis” could be necessary.³⁵ The court subsequently allowed the government more time to file supplemental briefs to support their claims.³⁶

In a similar pattern, I was recently informed that DOJ moved to dismiss *United States ex rel. Polansky v. Exec. Health Res., Inc.*, citing the growing cost of discovery as the main rationale.³⁷ Since litigation began in 2012, the government has produced approximately 42,000 pages of documents for this case.³⁸ However, the court recently granted Defendant’s requests for the production of documents previously withheld and new email discovery limited to three new custodians using previously approved targeted search terms.³⁹ In response to this court order, DOJ has moved to dismiss this *qui tam* claim on the basis that continued production and litigation would be burdensome and costly.⁴⁰ Yet, similar to the aforementioned cases, no cost-benefit analyses have been produced.

More troubling, DOJ has implied that cases where it declines to intervene lack merit or face little chances of success. 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 to not intervene.⁴¹ For example, that’s \$599,038,273 in *qui tam* cases in 2017 alone.⁴² Furthermore, DOJ has repeatedly asserted that a decision to not intervene in a case is based on several factors including resource constraints. For example, during oral arguments before the Supreme Court in 2016, Deputy Solicitor General Malcolm Stewart stated:

“[W]e don’t typically give public explanations of why we don’t intervene. Sometimes it’s because the dollar amount is small. Sometimes it’s because ... we think that the relator is capable of handling the case himself, or the relator’s counsel. Sometimes we do decline to intervene, because we’re skeptical of the merits of a case. But even in those situations, it could be that we agree with the relator’s theory and simply don’t know whether the facts could be proved.”⁴³

Not only is DOJ’s argument contradicted by its own admissions, it also ignores the statutory intent of the *qui tam* provision. 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. In 1943, Congress bowed to pressure to undo the Act’s crucial *qui tam* provisions and

³⁵ Hannah Albarazi, *DOJ’s Bid to Toss Whistleblowers’ Gilead FCA Suit Hits Snag*, Law360, Aug. 1, 2019, available at <https://www.law360.com/articles/1184571/doj-s-bid-to-toss-whistleblowers-gilead-fca-suit-hits-snog>.

³⁶ *Id.*

³⁷ See Motion to Dismiss, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, No. 12-CV-4239-MMB (E.D. Pa. Aug. 20, 2019).

³⁸ *Id.* at 8.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Civil Div., U.S. Dep’t. of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018*, (Dec. 21, 2018), available at <https://www.justice.gov/civil/page/file/1080696/download>.

⁴² *Id.*

⁴³ Transcript of Oral Argument at 48, *Universal Health Servs. Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1986 (2016) (No. 15-7), available at https://www.supremecourt.gov/oral_arguments/argument_transcripts/2015/15-7_6537.pdf.

essentially block private actions.⁴⁴ Congress assumed that the DOJ could do a good job prosecuting fraud without whistleblowers. They were wrong. In the words of a 1981 report by the Government Accountability Office, “For those who are caught committing fraud, the chances of being prosecuted and eventually going to jail are slim The sad truth is that crime against the Government often does pay.”⁴⁵ By 1986, taxpayer dollars became easier and easier to scam, and fraud on the government had skyrocketed.⁴⁶ The DOJ estimated at that time that fraud was a drain on 1 to 10 percent of the entire Federal budget.⁴⁷ In 1985, that meant fraudulent activity cost taxpayers \$10 billion to \$100 billion every year.⁴⁸

In 1986, I spearheaded the effort to empower whistleblowers to help the government combat fraud by bringing back the *qui tam* provisions Congress had undone in the 1940s.⁴⁹ 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.

The facts show that the False Claim Act is working. The *qui tam* provisions have reinvigorated an Act which had been mostly left for dead after the 1940s. In order for the law to continue working, DOJ must let the *qui tam* provision work the way it was intended and allow relators to proceed with litigation on their own. In order to better understand DOJ’s plans with respect to future *qui tam* cases, please answer the following questions no later than September 18, 2019.

1. Did FDA request that DOJ dismiss the *qui tam* claim in *Campie*? If so, what reasoning did FDA give?
 - a. How much deference does DOJ give to regulatory agencies in deciding whether to petition a court to dismiss a *qui tam* claim?
 - b. In the past 10 years, has DOJ ever moved to dismiss a claim in order to shield an agency’s decision-making process? If so, please list each case.
2. Is DOJ concerned that by moving to dismiss *Campie* and similar cases, such a precedent will lead other defendants to seek to make litigation as costly as possible in order to incentivize DOJ to dismiss future claims? If not, why not?

⁴⁴ *Oversight of the False Claims Act: Hearing Before the Subcomm. on the Constitution and Civil Justice of the H. Comm. on the Judiciary*, 114th Cong. 11 (2016) (statement of Sen. Grassley, Chairman, S. Comm. on the Judiciary).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.* at 12.

⁴⁸ *Id.*

⁴⁹ False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986).

3. What role did the Granston memo play in DOJ's decision to move to dismiss in *Campie*? Is the decision to dismiss in line with the Granston memo? Would DOJ have moved to dismiss the case absent the Granston memo?
4. Please explain the cost-benefit analysis process DOJ uses in determining which cases warrant dismissal at least in part due to litigation costs. Please provide examples of any previously used cost-benefit analysis documents. Who in DOJ ultimately makes these decisions?
5. How many cases has DOJ moved to dismiss since the publication of the Granston memo? Please describe the reasons for moving to dismiss each case and note the point of litigation at which DOJ moved to dismiss the case.
 - a. In how many of the above cases did the relator(s) survive a motion to dismiss prior to DOJ filing its motion to dismiss?
 - b. How much time had passed since the relator(s) filed the case under seal?
 - c. How many discovery obligations remain outstanding?
6. Since the Granston memo, what resources have been devoted to dismissing *qui tam* claims? Are there staff specifically devoted to working on dismissals? If so, please provide the number of staff, to include full time and part time, devoted to determining whether a claim should be dismissed.

Should you have any questions, please contact Dario Camacho of my Committee staff at (202) 224-4515. Thank you for your attention on this important matter.

Sincerely,



Charles E. Grassley
Chairman
Senate Committee on Finance