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QUI TAM QUARTERLY

THE DEPARTMENT OF JUSTICE FALSE CLAIMS ACT POLICY ISSUE

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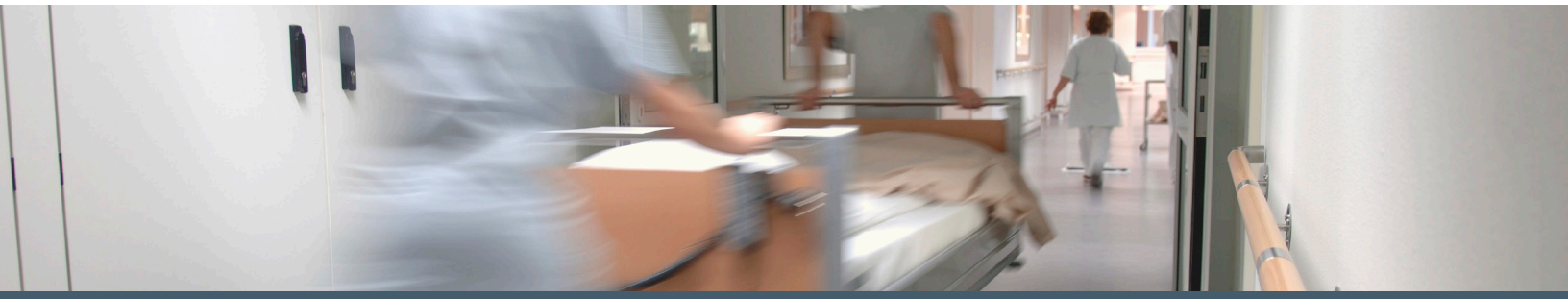

Qui Tam Quarterly is a quarterly publication authored by members of the K&L Gates Health Care Fraud & Abuse team highlighting emerging and pressing issues in health care fraud and abuse, including litigation and governmental investigations involving the False Claims Act, the Stark Law, the Anti-Kickback Statute, and other health care fraud related statutes.

In this issue of Qui Tam Quarterly, K&L Gates breaks down two policy statements by the U.S. Department of Justice (DOJ)—the 2018 "Granston Memo," and the recent policy guidance on awarding credit for self-disclosures and cooperation with DOJ in False Claims Act cases. We go beyond the press releases and sound bites and address what this guidance means for practitioners.

THE "GRANSTON MEMO" 18 MONTHS LATER: PRACTICAL CONSIDERATIONS AND JUDICIAL RESPONSES

In January 2018, a memo by Michael Granston, Director of the Civil Fraud Section of the U.S. Department of Justice (DOJ) Commercial Litigation Branch, was leaked to the public. In the memo Mr. Granston directed the attorneys under his supervision to consider whether the government's interests would be served by affirmatively dismissing qui tam actions filed under the False Claims Act (FCA) when evaluating recommendations to decline intervention in such cases. In the memo Mr. Granston stated, "The Department of Justice plays an important gatekeeper role in protecting the False Claims Act, because in qui tam cases where we decline to intervene, the relators largely stand in the shoes of the Attorney General. That is why the FCA provides us with the authority to dismiss cases." Since the leak of the "Granston Memo" there has been much hopeful speculation among the FCA defense bar that the DOJ would more aggressively and more frequently dismiss frivolous or marginal qui tam cases brought by relators seeking large windfalls.[1] The government apparently has dismissed at least 30 such cases since the guidance was adopted, but according to Mr. Granston himself those were "just a fraction of the cases that were filed in the same period of time."[2] Does this recent moderate uptick in affirmative dismissals really signal a significant shift toward more aggressive affirmative dismissal of qui tam cases by the government? Many attorneys, including us, speculated that it might.[3] However, a survey of recent court rulings, and consideration of practical realities facing U.S. Attorneys Offices, now suggests that this might not be the case. Indeed, Mr. Granston recently stated that while the DOJ is still going to judiciously exercise its authority to dismiss cases, he expects that will be the exception, not the rule, as to whether cases ultimately get dismissed.[4]

Granston Guidance on Affirmative Qui Tam Dismissals

Section 4-4.111 of the DOJ's Justice Manual codifies the guidance found in the Granston Memo, and lists seven government interests that could weigh in favor of affirmative dismissal:

1. Curbing meritless qui tam actions that facially lack merit (either because the relator's legal theory is inherently defective, or the relator's factual allegations are frivolous).
2. Preventing parasitic or opportunistic qui tam actions that duplicate a pre-existing government investigation and add no useful information to the investigation.
3. Preventing interference with an agency's policies or the administration of its programs.
4. Controlling litigation brought on behalf of the United States, in order to protect the DOJ's litigation prerogatives.

5. Safeguarding classified information and national security interests.
6. Preserving government resources, particularly where the government's costs (including the opportunity costs of expending resources on other matters) are likely to exceed any expected gain.
7. Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation.[5]

Distilling these considerations, factors 1, 2, and 7 suggest that the government should affirmatively dismiss cases that are unlikely to survive dispositive motions because the relator's legal theory is deficient, because the relator's factual allegations are frivolous, or because the government is already aware of and investigating the matter.[6] The remaining four factors, however, suggest that some cases that might survive dispositive motions and result in a favorable judgment for the government should nevertheless be dismissed because the prosecution of the case might interfere with other government interests such as agency policy interests or prerogatives, protection of national security interests, and the conservation of DOJ resources. How likely is the government to deny the relator her day in court, or a court to allow such outcome, if the relator has actually articulated a viable legal theory and is likely to make a substantial (sometimes enormous) recovery on behalf of herself or the government?

Pragmatic Considerations: Limited Investigative Resources Naturally Limit Affirmative Dismissals

As a practical matter, there is tension between the Granston Memo's guidance on affirmative dismissals and the reasonable reluctance of U.S. Attorneys Offices to spend substantial resources to fully investigate a marginal *qui tam* case. As any attorney with FCA experience knows, it is often not a simple matter to determine whether a relator's claims lack merit. Especially in false certification cases in the wake of the United States Supreme Court's decision in *Escobar,*[7] the merit of a particular FCA case can rise or fall on the degree to which the government agency had knowledge of the alleged false certification, the extent of that knowledge, and the extent to which the agency continued to pay the defendant's claims despite knowledge of the false certification. Investigating these issues can require an enormous investment of time by both the investigating U.S. Attorneys Office and the investigating agency.

Also time-consuming is making a convincing determination about whether the relator had the requisite degree of knowledge or intent required by 31 U.S.C. § 3729(b) to state an FCA claim or whether a putative defendant made an innocent administrative mistake or genuinely misinterpreted a regulatory requirement, as these evaluations can require extensive investigation and analysis of documents and electronic data, such as emails, concerning the prospective defendant's conduct. In light of the complex burden involved in reaching a conclusive determination concerning the merit of a particular case, the government has a clear incentive to allow a relator to pursue a claim and determine for herself whether the case has merit. In many cases, actually determining whether a case should be affirmatively dismissed requires the DOJ to expend just as many resources as would a recommendation that the government should intervene under 31 U.S.C. § 3730(b)(2).

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Recent Cases Scrutinizing and Even Denying DOJ Motions to Dismiss

Adding additional roadblocks to potential future dismissals, recent district court decisions demonstrate the likelihood that district courts in at least some circuits will deny the government's motion to dismiss unless the government can **prove** that its investigation was sufficient to determine that the relator's claim genuinely lacks merit. Alternatively, to the extent that affirmative dismissal is based on policy considerations or government priorities beyond the simple merits of the case, the government risks the court rejecting such justification out of hand.

Scrutiny of DOJ motion to dismiss. In *United States ex rel. Harris v. EMD Serono Inc.,*[8] though the U.S. District Court for the Eastern District of Pennsylvania recently granted the government's motion to dismiss a qui tam action that alleged Anti-Kickback Statute violations against pharmaceutical companies, it set a higher bar for the outcome. In making its ruling, the court observed a circuit split on the standard for dismissal over a relator's objection and adopted the more stringent "rational relationship" test from the Ninth and Tenth Circuits, which requires the government to show that dismissal is related to a valid governmental purpose, rather than the D.C. Circuit's more lenient view that the government's right to dismiss is unfettered.[9] To satisfy this test and defeat a relator's objection that the motion to dismiss is arbitrary and capricious,

the **government must show** that it properly investigated the case or otherwise demonstrated sufficient due diligence.[10] As applied to this matter, the court found that the government, after 18 months of investigation, had reasonably concluded the case was unlikely to yield recovery justifying the costs and burdens of monitoring the case if it were to proceed and, therefore, had a valid interest in avoiding those costs in a case it deemed, after reasonable inquiry, lacked sufficient factual and legal support.[11] The government achieved its objective of getting the case dismissed, but it had to work for it.

Denial of DOJ motion to dismiss. In *United States ex rel. Cimznhca, LLC v. UCB, Inc.,* the court similarly observed that 31 USC § 3730(c)(2)(A) does not create a particular standard for dismissal and that courts are split as to the appropriate standard to be applied.[12] The U.S. District Court for the Southern District of Illinois further articulated two parts of the "rational relationship" standard: (1) identification of a valid governmental purpose; and (2) a rational relationship between dismissal and accomplishment of the purpose.[13] Here the relator asserted that the pharmaceutical company defendants had violated the Anti-Kickback Statute by giving free nursing and reimbursement support services to providers. In addition to arguing that it would be a waste of government resources to monitor a case it believed to be without merit, the government argued the case was contrary to important policy prerogatives of federal health care programs, presumably to allow companies to provide educational and beneficial information support to providers. The court denied the government's motion to dismiss, finding the policy arguments to be spurious and a pretext for animus toward the relator.[14] Interestingly, the court also found the government had not made the requisite showing of adequate investigation, which, if it is to urge dismissal based on litigation costs, the court believed must include a meaningful cost-benefit analysis.[15] This court recently doubled down on its rejection of the government's dismissal arguments by denying the government's motion to alter judgment. The court stated that the asserted "manifest error" of law or fact required to prevail on such a motion "is not demonstrated merely by the disappointment of the losing party" and then issued a resounding rejection of the D.C. Circuit's Swift standard deferring to DOJ prosecutorial discretion.[16]

Recent Government Motions to Dismiss Suggest That the Government Is Likely to Dismiss Only a Small Percentage of Qui Tam Actions Going Forward

A closer look at the government's stated reasons for recent affirmative dismissal motions supports the notion that it is only likely to exercise its dismissal authority in exceptional cases. The cases that the government has dismissed so

far generally exhibit unique factors or characteristics that are unlikely to be shared by a large number of FCA claims, such as claims contrary to clear agency decision-making or policy decisions, or duplicative claims brought by shell companies funded by speculative investors seeking FCA windfalls. Notably, 10 of the dismissals sought in 2018 were of cases brought by the same entity, National Health Care Analysis Group (NHCAG), a venture capital-funded plaintiff group that asserted almost identical claims in 10 different jurisdictions against 38 different defendants through corporate shell relators.

As of April 2019, NHCAG, through various subsidiaries, is the relator in 11 *qui tam* complaints filed across the country that raise common Anti-Kickback Statute allegations against pharmaceutical industry defendants for engaging in "white coat marketing" and for providing free nursing and reimbursement support services to providers as an inducement to prescribe their drugs. In seeking dismissal, the government argues that allowing the cases to continue would result in an improper use of government resources to monitor actions that lack merit and that subvert federal health care program policy interests. As discussed in reference to the Cimznhca case above, the government's success in obtaining dismissal will depend in part on the court's view of whether the DOJ has adequately investigated the case or whether it is simply acting out of disdain for relator's business model. In pending motions and relator responses, the arguments continue to focus on the varying standards for dismissal and, where a court may apply a heightened test, whether the government has met its burden of demonstrating that it performed sufficient investigation to articulate a legitimate governmental interest that would be served by dismissal.[17]

A noteworthy DOJ motion for dismissal is pending in a closely watched case in California.[18] In 2015, two former employees of Gilead Sciences, Inc. (Gilead) initiated a *qui tam* action under the FCA alleging that Gilead made false statements about its compliance with FDA regulations with respect to certain of its HIV drugs, which false statements

resulted in billions of dollars in reimbursement from the government. The government originally had declined to intervene in the case after what it claims was extensive investigation and later argued under the rational relationship standard that it has a valid governmental purpose in dismissing the case—"to avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue"[19] —and that dismissal would accomplish this purpose. The government further urged the court to protect, and not allow relator to supplant, the FDA's interest in continued regulatory oversight, noting the agency already made multiple inspections of Gilead facilities both before and after relators' complaint.[20] The government argued that the relevant standard is intended to be largely deferential to the government's prosecutorial discretion, but also addressed the court's prior and more restrictive evidentiary requirements by specifically stating that it had conducted a cost-benefit analysis.[21] According to the government, the burden should then shift to relators to show that DOJ's decision to seek dismissal is unreasonable, not a result of full investigation, or based on arbitrary and improper considerations, a showing that DOJ claims relator cannot make.[22] Relator countered that the government's "abrupt, about-face" from its prior support of relators' legal arguments is arbitrary and does not satisfy the rational relationship test since its cost-benefit analysis considered only monitoring costs, not expected gains in potentially millions of dollars of recovery (citing the $500 million recovery in the FCA settlement with Schering Plough related to alleged knowing distribution of adulterated drugs).[23] Interestingly, relator seeks to turn the Granston Memo itself on the government, citing the sixth factor as suggesting consideration of both sides of the cost-benefit equation is required.

The U.S. District Court for the Northern District of California granted Gilead's motion to dismiss, accepting the argument that relators did not state a valid FCA case since the alleged fraudulent conduct related to FDA regulatory violations and not to fraudulent activity in submitting false claims for payment.[24] The Ninth Circuit reversed the district court and remanded, noting that the District Court decision was made prior to the U.S. Supreme Court decision in *Escobar*.[25] On August 1, 2019, a hearing is scheduled to be held on the government's motion to dismiss relator's second amended complaint, and relator's opposition to the same.[26]

The Government Continues to Obtain Substantial Recoveries in Non-Intervened Cases

Perhaps the most important reason for the government not to seek dismissal of qui tam cases is that dismissals would cost the government money. Even in cases where the government does not intervene, it continues to enjoy substantial recoveries. According to the DOJ, qui tam settlements and judgments in non-intervened health care fraud cases over the past five years were as follows:[27]

Year	Settlements and Judgments	Relator Share of Settlements and Judgments
2014	$66,322,326	$10,877,186
2015	$474,408,065	$132,579,390
2016	$75,145,688	$20,481,847
2017	$445,241,304	$123,462,284
2018	$80,834,205	$22,259,606
Total	**$1,141,951,588**	**$309,660,313**

Conclusion

Given some courts' apparent hostility to DOJ motions to dismiss qui tam FCA cases, and the fact that doing so would adversely affect the DOJ's bottom line, we do not believe that the Granston Memo is likely to have the impact practitioners initially believed it might have. On January 28, 2019, Deputy Associate Attorney General Stephen Cox (Michael Granston's boss) gave a speech on the subject of FCA and qui tam enforcement.[28] He stated, "The Granston Memo is not really a change in the Department's historical position… It is true that this authority has been used sparingly… Our exercise of this authority will remain judicious, but we will use this tool more consistently to preserve our resources for cases that are in the United States' interests."[29] As previously noted, Mr. Granston himself stated on June 24, 2019, that the DOJ would "judiciously" exercise its authority to dismiss cases and that dismissal would be the exception and not the rule.[30] We could not have said it any better ourselves.

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BENEFITS AND UNCERTAINTIES OF SELF-DISCLOSURE IN FALSE CLAIMS ACT CASES

On May 7, 2019, the DOJ released formal guidance for civil DOJ prosecutors to use in determining how to assess cooperation by entities and individuals in FCA cases.[31] The guidance, found in the DOJ Justice Manual Chapter 4-4.112,[32] identifies factors that the DOJ will consider and the credit that may be provided to entities or individuals who voluntarily self-disclosed misconduct that could serve as the basis for FCA liability or administrative remedies. It also defines voluntary disclosure, provides examples of forms of cooperation other than disclosure for which cooperation credit may be given, and provides a non-exhaustive list of the types of remedial measures that may qualify cooperating individuals or entities for credit. Finally, the guidance addresses how the DOJ will respond to entities or individuals who take other steps to cooperate with FCA investigations and settlements, and it clarifies that DOJ attorneys retain discretion in terms of how cooperation credit will be awarded.

Cooperation Credit

The purpose of the guidance is to specify the ways in which a defendant in an FCA case may receive cooperation credit, which generally may be achieved through one or a combination of the following means: (1) a voluntary disclosure; (2) an action that meets the definition of "other forms of cooperation;" or (3) remedial measures. Recent public statements by DOJ officials have noted that a voluntary disclosure of misconduct previously unknown to the government is the most valuable form of cooperation.[33] However, even if the government has already initiated an investigation, actions constituting other forms of cooperation and remedial measures may qualify an entity or individual for cooperation credit.[34] For example, a company may receive credit for making a voluntary self-disclosure of misconduct outside the scope of the government's existing investigation that is unknown to the government.

Voluntary Self-Disclosure

The guidance defines "voluntary disclosure" as "proactive, timely, and voluntary self-disclosure" to the DOJ about misconduct that benefits the government by revealing, and enabling the government to make itself whole from, previously unknown false claims and fraud.[35] Disclosures that enable the government to preserve and gather evidence that would otherwise be lost may also be treated as voluntary disclosures for purposes of cooperation credit. Disclosures occurring both before a federal investigation has begun as well as during the course of an internal investigation into the government's concerns may also qualify for cooperation credit.

Other Forms of Cooperation

In addition to voluntarily self-disclosing misconduct, an individual or entity can earn credit by assisting and cooperating with an ongoing government investigation. The guidance provides a list of "other forms of cooperation" that are illustrative of the types of activities that may qualify for some cooperation credit. These include:

- Identifying individuals substantially involved in or responsible for the misconduct.
- Disclosing relevant facts and identifying opportunities for the government to obtain evidence relevant to the government's investigation that is not in the possession of the entity or individual or not otherwise known to the government.
- Preserving, collecting, and disclosing relevant documents and information relating to their provenance beyond existing business practices or legal requirements.
- Identifying individuals who are aware of relevant information or conduct, including an entity's operations, policies, and procedures.
- Making available for meetings, interviews, examinations, or depositions an entity's officers and employees who possess relevant information.
- Disclosing facts relevant to the government's investigation gathered during the entity's independent investigation (not to include information subject to attorney-client privilege or work product protection), including attribution of facts to specific sources rather than a general narrative of facts, and providing timely updates on the organization's internal investigation into the government's concerns, including rolling disclosures of relevant information.[36]
- Providing facts relevant to potential misconduct by third-parties.
- Providing information in native format, and facilitating review and evaluation of that information if it requires special or proprietary technologies so that the information can be evaluated.
- Admitting liability or accepting responsibility for the wrongdoing or relevant conduct.
- Assisting in the determination or recovery of the losses caused by the misconduct.[37]

Determination of Disclosure Value

In determining the value of a voluntary disclosure or additional cooperation, the DOJ will consider four factors:

- Timeliness and voluntariness of the assistance.
- Truthfulness, completeness, and reliability of any information or testimony provided.
- Nature and extent of the assistance.
- Significance and usefulness of the cooperation to the government.[38]

Remedial Measures

Where an FCA violation has occurred, the guidance instructs DOJ attorneys to consider whether an entity has taken appropriate remedial actions in response to the violation. The guidance explains that such remedial actions may include:

- Demonstrating a thorough analysis of the cause of the underlying conduct and, where appropriate, remediation to address the root cause.
- Implementing or improving an effective compliance program designed to ensure the misconduct or similar problem does not occur again.
- Appropriately disciplining or replacing those identified by the entity as responsible for the misconduct either through direct participation or failure in oversight, as well as those with supervisory authority over the area where the misconduct occurred.
- Any additional steps demonstrating recognition of the seriousness of the entity's misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risks.[39]

Maximum Available Credit and DOJ Discretion

Although the guidance states that an entity or individual that makes a "proactive, timely, and voluntary self-disclosure to the [DOJ] about misconduct will receive credit during the resolution of an FCA case,"[40] the DOJ has discretion to determine the type and amount of credit awarded. The guidance specifies that most often the discretion will be used to reduce penalties or damages sought by the government in the FCA case.

The guidance specifies the steps an entity or individual would need to take in order to earn "maximum credit" in an FCA matter, which would include the following:

- Making a timely self-disclosure that includes identifying all individuals substantially involved in or responsible for the misconduct.
- Providing full cooperation with the government's investigation.
- Taking remedial steps designed to prevent and detect similar wrongdoing in the future.

Significantly for would-be cooperators, the term "maximum credit" is not defined as it will depend on the specifics of the case. The guidance notes that any cooperation credit granted to a defendant "may not exceed an amount that would result in the government receiving less than full compensation for the losses caused by the defendant's misconduct (including the government's damages, lost interest, costs of investigation, and relator share)."[41] Where maximum credit is not earned, an entity or individual that cooperates may still receive partial credit if they have meaningfully assisted the government's investigation.[42]Notably, the DOJ "will not award any credit to an entity or individual that conceals involvement in the misconduct by members of senior management or the board of directors, or to an entity or individual that otherwise demonstrates a lack of good faith to the government during the course of its investigation."[43]

On May 20, 2019, Principal Deputy Associate Attorney General Claire McCusker Murray gave a speech at the Compliance Week Annual Conference.[44] During the speech she provided an example of cooperation credit that the DOJ had given to a durable medical equipment manufacturer in connection with a $17.4 million settlement of kickback allegations. She stated that "during the settlement process, the manufacturer shared the results of its extensive internal investigation and also helped the government assess its losses by developing a damages model. As a result of the cooperation, the manufacturer received a discounted damages multiple of 1.7 times the government's single damages."[45] She pointed out that the new guidance permits the DOJ "to provide a substantial discount down to the government's single (as opposed to treble) damages, plus lost interest, costs of investigation, and, in a qui tam case, the share going to the whistleblower" in cases where an organization's cooperation has been robust and complete.[46] Finally, Ms. McCusker Murray stated that other "valuable incentives for companies to

self-police and self-disclose misconduct" could include the DOJ's notification to the relevant regulatory agency that the company had been cooperative and the DOJ's assistance in resolving qui tam litigation with the relator.[47]

A Remarkable Degree of Symmetry

On May 9, 2019, Deputy Assistant Attorney General Matthew S. Miner gave a speech at the American Bar Association's 29th Annual National Institute on Health Care Fraud.[48] Referring to the new FCA cooperation guidance, he stated:

> For those tracking the Department's approach to voluntary self-disclosure in the civil and criminal health care fraud arenas, there is a remarkable degree of symmetry. And that is no accident. Although our criminal and civil enforcement tools are separate and often run along different tracks with different investigative teams, the reality is that a company facing a self-disclosure dilemma does not have multiple tracks. It must factor different risks, legal considerations, and potential outcomes into its analysis and reach a decision in the best interest of the company and its shareholders. At the Department, we understand that we need to be as clear as reasonably possible about our approach to those who voluntarily self-disclose, if we hope to influence the rational decision-makers when they face self-disclosure dilemmas.[49]

Traditional Cooperation Guidance in the Criminal Context

Given Mr. Miner's comments, we consider and compare the recent civil cooperation guidance to traditional DOJ cooperation guidance historically provided in the criminal context. Though there is symmetry between the civil and criminal guidance, we believe the criminal guidance historically has been more transparent. It is important that the public perceive these prosecutorial decisions as being made fairly and in recognition of this the DOJ Justice Manual states:

> Prosecutors should also be mindful that confidence in the Department is affected both by the results we achieve and by the real and perceived ways in which we achieve them. Thus, the manner in which we do our job as prosecutors—including the professionalism and civility we demonstrate, our willingness to secure the facts in a manner that encourages corporate compliance and self-regulation, and also our appreciation that corporate prosecutions can harm blameless investors, employees, and others—affects public perception of our mission. Federal prosecutors must maintain public confidence in the way in which we exercise our charging discretion.[50]

Though the practice of "plea bargaining," i.e., where a defendant pleads guilty to an offense in exchange for a concession from the prosecution, has been around a very long time, we look to the June 1984 version of the Justice Manual's predecessor resource, then called the U.S. Attorney's Manual (USAM), as an early concrete example of the federal government's consideration of cooperation when deciding whether to decline prosecution. USAM Chapter 9-27.620 directed DOJ lawyers to consider the following three factors when determining whether a person's cooperation was sufficient to reward them with a non-prosecution agreement:

- The importance of the investigation or prosecution to an effective program of law enforcement.
- The value of the person's cooperation to the investigation or prosecution.
- The person's relative culpability in connection with the offense or offenses being investigated or prosecuted and his/her history with respect to criminal activity.[51]

The policy made clear that the reward for cooperation could be non-prosecution.

In November 1991, the U.S. Sentencing Commission added to its Guidelines Manual a new Chapter Eight called "Sentencing of Organizations." Section 8C2.5 offered instructions on how to determine a business organization's "culpability score," and subsection (g), titled "Self-Reporting, Cooperation, and Acceptance of Responsibility," read as follows:

> (1) if the organization (A) prior to an imminent threat of disclosure or government investigation; and (B) within a reasonably prompt time after becoming aware of the offense, reported the offense to appropriate governmental authorities, fully cooperated in the investigation, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract 5 points.[52]

In contrast to the relatively vague credit a self-disclosing entity might receive under the recent guidance in the civil

context, this criminal sentencing guideline expressly stated the offense level reduction the cooperator would receive in exchange for its cooperation.

In years subsequent to the addition of Chapter Eight to the Guidelines Manual, the DOJ continued to increase transparency about what it would offer in exchange for cooperation in criminal cases. For example, in our experience it is the practice of the U.S. Attorneys Offices around the country to offer a defendant who pleads guilty to a federal crime a discount of one-third off the low end of the sentencing guideline range in exchange for cooperating in his or her own case, or one-half off the low end in exchange for cooperating in a new case about which the government was not already aware. These benefits are offered in writing in advance of the guilty plea. Likewise, the DOJ Antitrust Division has had a public leniency policy for corporations since 1993, and for individuals since 1994.[53] Under those policies, companies and people who self-report and cooperate with the government, and satisfy other specified requirements, will receive an explicit benefit—non-prosecution. In June 1999, then Deputy Attorney General Eric A. Holder issued a memorandum to senior DOJ officials called "Bringing Criminal Charges Against Corporations." Section VI of the memo, called "Charging the Corporation: Cooperation and Voluntary Disclosure," described the factors the DOJ would consider when deciding whether to charge the corporation at all. Today these considerations of cooperation and voluntary disclosure are codified in Justice Manual sections 9-28.720 and 9-28.900.[54] Perhaps with the passage of time, the new cooperation credit guidance in the civil FCA context will similarly mature in its transparency and specificity.

Conclusion

The decision of whether to self-report misconduct of which the government may not already be aware is an extremely difficult one. If the government does not already know of the misconduct, and would never have discovered it, a company or individual will have "served themselves up" to the government by self-reporting, resulting in investigative and other costs, business disruption, anxiety and fear, and perhaps even fines and imprisonment. Companies, individuals, and their advisors need clear guidance from the DOJ concerning the "reward" component of the "risk/reward" calculation. Though the DOJ has been providing detailed guidance in criminal cases for decades, the recent guidance in FCA cases is welcome but too new to be yet proven or fully understood. Until further settlements and their underlying facts and circumstances are publicly reported, self-reporting in FCA cases will to some degree require participants in the health care industry to make a leap of faith.

SEEING AROUND THE CORNER

In the March 2019 issue of Qui Tam Quarterly we characterized the intersection of telemedicine and ancillary services, such as durable medical equipment (DME), as "health care's new wilderness." We wrote that the potential for a significant increase in enforcement activity surrounding arrangements at that intersection was largely due to the high level of scrutiny the DME industry had independently and historically experienced. We observed that the relatively recent overlay of telehealth services onto heavily scrutinized DME sales activities naturally heightened the possibility that the government would investigate these arrangements and that it would not be surprising if the telehealth-DME intersection proved to be fertile ground for health care fraud allegations in 2019. Our predictions were correct. On April 9, 2019, the DOJ announced a nationwide enforcement effort involving the filing of indictments and the execution of search warrants in a matter now known as "Operation Brace Yourself." According to the DOJ, the various cases involved an alleged scheme concerning the payment of illegal kickbacks and bribes by DME companies in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies for back, shoulder, wrist, and knee braces that were medically unnecessary. According to the DOJ, the defendants paid doctors to prescribe DME either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. The proceeds of the fraudulent scheme were allegedly laundered through international shell corporations and used to purchase luxury goods in the United States and abroad. Though we believe that the government is mistaken in its belief that certain arrangements are unlawful, the intersection of telemedicine and DME is fraught with risk. The April 9, 2019 press release is found here: https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

[1] U.S. DEPARTMENT OF JUSTICE, FACTORS FOR EVALUATING DISMISSAL PURSUANT TO 31 U.S.C. § 3730(c)(2)(A) (January 10, 2018), *available at* https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.

[2] See Lydia Wheeler, *Government Tosses Out More Whistleblower Cases After 2018 Memo,* BLOOMBERG LAW (June 24, 2019, 3:57 PM) (summarizing Michael Granston's remarks during a luncheon at the American Health Lawyers Association Annual Meeting in Boston).

[3] M. Rush, et al., *Granston Guidance: Leaked Memorandum Encourages DOJ Attorneys to Seek Dismissal of Meritless FCA Qui Tam Suits* (Feb. 27, 2018), http://www.klgates.com/granston-guidance-leaked-memorandum-encourages-doj-attorneys-to-seek-dismissal-of-meritless-fca-qui-tam-suits-02-27-2018/.

[4] *See supra note* 2.

[5] U.S. DEPARTMENT OF JUSTICE, JUSTICE MANUAL § 4-4.111 (Sept. 2018), *available at* https://www.justice.gov/jm/jm-4-4000-commercial-litigation.

[6] These latter cases would be subject to dismissal under the FCA's "original source" requirement. See 31 U.S.C. § 3730(e)(4)(A)(iii).

[7] *Universal Health Services, Inc. v. United States ex rel. Escobar,* 136 S. Ct. 1989 (2016).

[8] *United States v. EMD Serono, Inc.,* 370 F. Supp. 3d 483 (E.D. Pa. 2019).

[9] *Id.* at 487. *See United States ex rel., Sequoia Orange Co. v. Baird-Neece Packing Corp.,* 151 F.3d 1139, 1145-47 (9th Cir. 1998); *Swift v. United States,* 318 F.3d 250, 252 (D.C. Cir. 2003).

[10] *EMD Serono,* 370 F. Supp. at 487.

[11] *Id.* at 490.

[12] *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.,* No. 17-CV-765-SMY-MAB (S. D. Ill. April 15, 2019).

[13] *Id.* at *2.

[14] *Id.* at *4.

[15] *Id.* at *3. *See also United States v. Acad. Mortg. Corp.,* No. 16-CV-02120-EMC, at *1 (N.D. Cal. June 29, 2018) (denying the government's motion to dismiss because relator's evidence showed that the government performed only limited investigation of the original complaint and did not perform a full investigation of the amended complaint).

[16] *CIMZNHCA,* No. 17-CV-765-SMY-MAB (S.D. Ill. June 7, 2019).

[17] *See, e.g.,* United States Motion to Dismiss Relator's Second Amended Complaint, United States Reply Memorandum in Support of Motion to Dismiss Relator's Second Amended Complaint, and Relator's Sur-Reply in Response to United States Motion to Dismiss the Second Amended Complaint, filed in *United States ex rel. Health Choice Group, LLC v. Bayer Corporation,* No.5:17-CV-126-RWS-CMC (E.D. Tex. July 31, 2018)

[18] United States' Motion to Dismiss Relators' Second Amended Complaint, *United States ex. rel. Campie v. Gilead Sciences, Inc.,* No. C-11-0941 EMC (N.D. Cal. June 20, 2019).

[19] *Id.* at 8.

[20] *Id.* at 10.

[21] *Id.* at 9, acknowledging this was a requirement the court articulated in *Academy Mortgage; see supra* note 15.

[22] *Id.* at 7.

[23] Relator's Opposition to the United States' Motion to Dismiss, *Gilead,* No. C-11-0941 EMC (N.D. Cal. May 31, 2019) (redacted) at 3, and 9–10.

[24] *See* Order Granting Defendant's Motion to Dismiss, Gilead, No. C-11-0941 EMC (June 12, 2015). Relators asserted a nexus between the FDA non-compliance and FCA liability by arguing that had the FDA known the truth about Gilead's manufacturing practices, it would have denied or revoked the relevant drugs' approval, which in turn would have affected the drugs' eligibility for payment under federal health care programs.

[25] *Gilead,* No. 15-16380 (9th Cir. July 7, 2017).

[26] United States' Motion to Dismiss Relator's Second Amended Complaint, *Gilead,* No. C-11-0941 EM (March 28, 2019).

[27] U.S. Department of Justice, Civil Division Fraud Statistics (broken out by Department of Health and Human Services as the "primary client agency") *available at* https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

[28] U.S. Department of Justice, "Remarks of Deputy Associate Attorney General Stephen Cox at the American Conference Institute 2019 Advanced Forum on False Claims and Qui Tam Enforcement" (January 28, 2019), *available at* https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-delivers-remarks-2019-advanced-forum-false.

[29] *Id.*.

[30] *See supra* note 2.

[31] Press Release, U.S. Department of Justice, "Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual" (May 7, 2019), *available at* https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.

[32] U.S. DEPARTMENT OF JUSTICE, JUSTICE MANUAL, § 4-4.112 (May 2019).

[33] U.S. Department of Justice, "Remarks of Principal Deputy Associate Attorney General Claire McCusker Murray at the Compliance Week Annual Conference" (May 20, 2019), *available at* https://www.justice.gov/opa/speech/remarks-principal-deputy-associate-attorney-general-claire-mccusker-murray-compliance.

[34] *Id.*

[35] U.S. DEPARTMENT OF JUSTICE, JUSTICE MANUAL § 4-4.112.

[36] Practitioners should take care when involving the government in their internal investigations. A recent decision from the U.S. District Court for the Southern District of New York in *U.S. v. Connolly,* No. 16 CR. 370 (CM) (May 2, 2019) identified several areas of concern that could result from the government too closely directing the internal investigation and from private practitioners following that direction, including the direction to regularly report to the government. Though a complete analysis of that decision is beyond the scope of this article, the court stated it was "deeply troubled by the issue" of the government "routinely outsourcing its investigations in complex financial matters to the targets of those investigations, who are in a uniquely coercive position vis-à-vis potential targets of criminal activity." *Id.* at 2.

[37] U.S. DEPARTMENT OF JUSTICE, JUSTICE MANUAL, § 4-4.112.

[38] *Id.*

[39] *Id.*

[40] *Id.* (emphasis added).

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *See supra* note 33.

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] U.S. Department of Justice, "Deputy Assistant Attorney General Matthew S. Miner Gives Remarks at the 29th Annual National Institute on Health Care Fraud" (May 9, 2019), *available at* https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-matthew-s-miner-gives-remarks-29th-annual-national.

[49] *Id.*

[50] DEPARTMENT OF JUSTICE, U.S. ATTORNEY'S MANUAL (1984), *available at* https://www.justice.gov/archive/usao/usam/1984/1984.pdf.

[51] Later versions of this USAM chapter contained a fourth factor; the interest of victims. See DEPARTMENT OF JUSTICE, JUSTICE MANUAL § 9-27.620 (Feb. 2018), *available at* https://www.justice.gov/jm/jm-9-27000-principles-federal-prosecution#9-27.620.

[52] U.S. SENTENCING COMMISSION, GUIDELINES MANUAL, § 8C2.5(g) (1991), *available at* https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/1991/manual-pdf/1991_Guidelines_Manual_Full.pdf (emphasis added).

[53] An overview of the DOJ Antitrust Division's Leniency Program is *available at* https://www.justice.gov/atr/leniency-program.

[54] *See also* U.S. DEPARTMENT OF JUSTICE, THE FRAUD SECTION'S FOREIGN CORRUPT PRACTICES ACT ENFORCEMENT PLAN AND GUIDANCE (April 5, 2016), *available at* https://www.justice.gov/archives/opa/blog-entry/file/838386/download (explaining that the rewards that it would give in exchange for timely self-reporting and full cooperation in Foreign Corrupt Practices Act matters; a reduction of up to 50% off the low end of the Sentencing Guidelines fine range and the potential to avoid the appointment of a corporate monitor). The DOJ Civil Fraud Section continues to update and refine this guidance. Similarly, the DOJ's National Security Division issued a memo in which it expressly stated that reduced penalties, including a non-prosecution agreement, are available under its program. *See* U.S. DEPARTMENT OF JUSTICE, GUIDANCE REGARDING VOLUNTARY SELF-DISCLOSURES, COOPERATION, AND REMEDIATION IN EXPORT CONTROL AND SANCTIONS INVESTIGATIONS INVOLVING BUSINESS ORGANIZATIONS (Oct. 2, 2016), *available at* https://www.justice.gov/nsd/file/902491/download.

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