ONE YEAR LATER: THE EFFECT OF THE GRANSTON MEMO ON *QUI TAM* ACTIONS

Serra J. Schlanger, Esq.
Hyman, Phelps & McNamara, PC
Washington, DC

On January 10, 2018, the Department of Justice ("DOJ") issued a memo to all attorneys in the Commercial Litigation Branch, Fraud Section, and all Assistant U.S. Attorneys handling False Claims Act ("FCA") cases, directing those attorneys to seek dismissal of FCA *qui tam* actions under certain circumstances.[1] When the so-called "Granston Memo" was issued, it remained to be seen what effect the directive would have and when the DOJ would seek to dismiss an FCA *qui tam* case. One year later, the DOJ has taken certain actions that are presumably, at least in part, related to the principles set forth in the Granston Memo.

The Granston Memo

Under the FCA, a relator may bring a *qui tam* lawsuit on behalf of the government.[2] The government can choose to take over the litigation by intervening in the case. If the government declines to intervene in the case, the relator can proceed with the action on behalf of the government,[3] but the government has statutory authority pursuant to 31 U.S.C. § 3730(c)(2)(A) to outright dismiss a *qui tam* action, even over the objection of the relator.

According to the Granston Memo, the DOJ has seen "record increases" in the number of *qui tam* actions filed, but the rate of intervention has remained relatively static and the DOJ has sparingly utilized its statutory authority to dismiss *qui tam* complaints.[4] The Granston Memo notes that the DOJ expends significant resources on non-intervened cases and suggests that government attorneys should consider whether the public interest would be better served by seeking dismissal of certain *qui tam* complaints.[5]

The Granston Memo instructs DOJ attorneys to seek dismissal of a *qui tam* action if any of the following seven factors are present:

1. The complaint is "facially lacking in merit" either because the legal theory is inherently defective or the factual allegations are frivolous.[6]
2. The *qui tam* action duplicates a pre-existing government investigation without adding any useful information to the investigation (*i.e.*, parasitic or opportunistic actions).[7]
3. The *qui tam* action threatens to interfere with a government agency's "policies or the administration of its programs" and the agency "has recommended dismissal to avoid these effects." Examples of such interference include diverting agency personnel and resources away from an ongoing related project or risk of "significant economic harm" that could cause a "critical supplier" to exit the government program or industry.[8]
4. Dismissal is necessary to protect the DOJ's "litigation prerogatives."[9]
5. Dismissal is necessary to safeguard classified information, such as in cases involving intelligence agencies or military procurement contracts.[10]
6. The government's expected costs are likely to exceed any expected gain. Costs to the government include the need to monitor or participate in ongoing litigation, responding to discovery requests, and internal staff costs.[11]
7. Problems with the relator's action, including noncompliance with FCA procedures, are frustrating the government's efforts to conduct a proper investigation.[12]

The Granston Memo notes that this list of factors is not an exhaustive list and that the factors are not mutually exclusive.[13] The Granston Memo reminds DOJ attorneys that there may be alternative grounds to § 3730(c)(2)(A) to use in seeking dismissal of a *qui tam* complaint (*e.g.*, first to file bar, public disclosure bar, Federal Rule of Civil Procedure 9(b)) and that it may be appropriate to dismiss only certain claims or defendants.[14] The Granston Memo also instructs DOJ attorneys to "consult closely" with the affected agency to determine whether dismissal is warranted.[15]

United States ex rel. Campie v. Gilead Sciences

The first impactful effect of the Granston Memo may be seen in the U.S. Supreme Court's decision to deny Gilead Sciences Inc.'s petition for certiorari in a closely watched FCA case.[16] In this case, two former employees filed a *qui tam* complaint alleging that Gilead made false statements to the U.S. Food and Drug Administration ("FDA") about the company's anti-HIV drugs.[17] The relators alleged that Gilead concealed its use of unapproved ingredients in its drugs, failed to report manufacturing problems to the FDA, and falsified or covered up data in statements to the FDA. According to the relators, if the FDA had been aware of these regulatory violations it would not have permitted Gilead to market the drug products. Because the drugs were reimbursed by federal healthcare programs, the relators contended that Gilead's actions resulted in the submission of false claims in violation of the FCA.

After the DOJ declined to intervene in the case, the relators proceeded with the litigation. The district court dismissed the relators' complaint twice for failure to state a claim under the FCA.[18] However, in July 2017 the

continued on page 10

continued from page 9

Ninth Circuit Court of Appeals reversed the district court and found that the relators had alleged sufficient facts to state a claim for relief under three separate theories.[19] Gilead's petition for rehearing or rehearing *en banc* before the Ninth Circuit was denied, so the company filed a petition for certiorari with the Supreme Court in December 2017.[20] Even though the DOJ had previously declined to intervene in the case, in April 2018 the Supreme Court invited the U.S. Solicitor General to file a brief expressing the views of the United States on Gilead's petition.

The DOJ filed a Statement of Interest on November 30, 2018, disclosing that the government would affirmatively seek dismissal of the case should it be remanded to the district court.[21] Although the Statement did not cite the Granston Memo directly, the government cited its authority to dismiss a case under 31 U.S.C. § 3730(c)(2)(A) and claimed that allowing the case to continue could result in burdensome discovery that would distract from the FDA's public health responsibilities. The government concluded that continuing with the case would "impinge on agency decisionmaking and discretion and would disserve the interests of the United States."[22] Although it is unknown how influential the government's Statement of Interest was, the Supreme Court denied Gilead's petition for certiorari on January 7, 2019.

The case now returns to the Ninth Circuit, but it is widely expected that the DOJ will seek to dismiss the case as it pledged in its Statement of Interest. The relators may challenge the DOJ's decision to dismiss the case, but it is likely that the government will prevail, as the standard for dismissal only requires the government to identify a basis for dismissing the case that is rationally related to a legitimate government interest.[23]

The *United States ex rel. Health Choice Group, LLC* Cases

The government also recently filed Motions to Dismiss in several pending *qui tam* actions brought by a "professional relator" after "finding the allegations to lack sufficient merit to justify the cost of investigation and prosecution and otherwise [] contrary to the public interest."[24] In these cases, the relators allege that pharmaceutical companies and commercial outsourcing vendors violated the federal Anti-Kickback Statute by engaging in "white coat marketing" and by providing free nurse services to patients and free reimbursement support services to physicians.[25] According to the DOJ, the relators accuse 38 different defendants of actions that implicate more than 73 million prescriptions written by "hundreds of thousands of different physicians for millions of different Medicare beneficiaries" in 11 separate actions.[26]

The DOJ set forth arguments supporting dismissal under either of the two standards adopted by the courts – one which grants the DOJ "an unfettered right to dismiss" a *qui tam* action (called the *Swift* standard), and the other that requires a "rational relationship" between the government's decision to dismiss and a legitimate government interest.[27] The *Swift* standard is based on the general principles of separation of powers, which indicate that the Executive Branch, not courts, should decide whether to pursue litigation on behalf of the government. The "rational relationship" standard requires the DOJ to identify a "valid government purpose" for dismissing the case and then to show a "rational relationship between dismissal and accomplishment of the purpose."[28]

The DOJ identified substantial litigation burden on the government as the reason to affirmatively dismiss these cases. The DOJ explained that dismissal is necessary to preserve scarce government resources and protect important policy prerogatives.[29] Similar to the examples set forth in the Granston Memo,[30] the DOJ identified multiple costs that would exceed any expected gain, including expenses for: monitoring the litigation; collecting, reviewing, processing and producing documents; screening and redacting patient health information; preparing agency witnesses for depositions; filing statements of interest; and addressing the relator's interpretation of laws.[31] In addition, aligned with the third factor in the Granston Memo, the DOJ stated that the case conflicts with the policy and enforcement prerogatives of the federal government's healthcare programs.[32] In particular, the DOJ argued that the relators should not be allowed to advance claims that would "undermine common industry practices" the government has deemed appropriate and beneficial to the federal healthcare programs and their beneficiaries.[33] The relators recently filed responses to the DOJ's Motions to Dismiss, arguing that the government has not demonstrated that dismissal is appropriate.[34]

Conclusion

In the year since its issuance, the DOJ has invoked the principles set forth in the Granston Memo in two different contexts. Based on the government's actions in the *Gilead* and *Health Choice Group* cases, it appears that factor three (preventing interference with agency policies and programs) and factor six (preserving government resources) have the most traction. This may be because the DOJ can deal with *qui tam* cases that raise issues addressed by other factors using other legal methods (*e.g.*, the DOJ could seek to dismiss a parasitic or opportunistic *qui tam* action (factor

two) under the first to file or public disclosure bars).

Regardless of which Granston Memo factors have already been put into play, the DOJ has clearly indicated that it is less likely to allow relators to pursue certain FCA claims when the government has declined to intervene in a *qui tam* case.

Serra J. Schlanger is a senior associate at Hyman, Phelps & McNamara, P.C. where she advises clients on FDA regulatory strategy as well as compliance and enforcement issues. She counsels clients on federal and state healthcare fraud and abuse matters, and defends clients in connection with government investigations, *qui tam* actions, and other enforcement inquiries. She also advises clients on legal and regulatory issues associated with the privacy of health information (HIPAA), state licensure, and the Clinical Laboratory Improvement Amendments ("CLIA"). Before beginning her legal career, Ms. Schlanger worked in clinical administration as a liaison between physicians, patients, researchers, and administrators at Memorial Sloan-Kettering Cancer Center. She graduated *cum laude* with a certification in Health Care Law from the University of Maryland School of Law. As a law student, Ms. Schlanger interned at the U.S. Department of Health and Human Services, Office of the General Counsel, Public Health Division, and the Office of the General Counsel at the University of Maryland Medical System. She is a contributor to the FDA Law Blog (http://www.fdalawblog.net) and may be reached at *sschlanger@hpm.com*.

Endnotes

1 Memorandum from Michael D. Granston, Director, Commercial Litigation Branch, Fraud Section, to Attorneys, Commercial Litigation Branch, Fraud Section and Assistant U.S. Attorneys Handling False Claims Act Cases, Offices of the U.S. Attorneys, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* (Jan. 10, 2018) [hereinafter "Granston Memo"], *available at* https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.

2 31 U.S.C. § 3730(b).

3 *Id.* at § 3730(b)(4).

4 Granston Memo, *supra* note 1, at 1.

5 *Id.*

6 *Id.* at 3.

7 *Id.* at 4.

8 *Id.* The Granston Memo identifies a highway guardrail manufacturer as an example of a critical supplier. *Id.* at 5.

9 *Id.* at 5. The DOJ's litigation prerogatives are not specifically defined, but the Granston Memo cites cases that were dismissed to avoid interference with other ongoing litigation and cases that were dismissed to avoid unfavorable precedent. *Id.*

10 *Id.* at 6.

11 *Id.*

12 *Id.* at 7. For example, the Granston Memo cites a case where the relator ignored repeated requests to serve the complaint and disclose material facts.

13 *Id.*

14 *Id.* The first to file bar prevents repetitive cases from being filed by barring individuals from bringing related actions based on the same facts that underly a current action. 31 U.S.C. § 3730(b)(5). The public disclosure bar allows the court to dismiss a *qui tam* action if the action is based on allegations that were already publicly disclosed, unless the relator is an "original source" of the information. 31 U.S.C. § 3730(e)(4). Federal Rule of Civil Procedure 9(b) requires that allegations of fraud be pled with particularity, e.g., the who, what, where, when, and how of the alleged fraudulent conduct.

15 *Id.* at 8.

16 *Gilead Scis., Inc. v. U.S. ex rel. Campie*, No. 17-936, *cert. denied*, 586 U.S. __ (Jan. 7, 2019).

17 *U.S. ex rel. Campie v. Gilead Scis., Inc.*, No. C-11-0941 (N.D. Cal.) (date of original complaint under seal).

18 *See* Order Granting Defendant's Motion to Dismiss, *U.S. ex rel. Campie v. Gilead Scis., Inc.*, No. C-11-0941, 2015 U.S. Dist. LEXIS 77261 (N.D. Cal. June 12, 2015).

19 *U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). For a summary of the three theories, *see* Anne K. Walsh, Ninth Circuit Revives False Claims Act Case Applying Escobar Materiality Standard, The FDA Law Blog (July 17, 2017), http://fdalawblog.net/2017/07/ninth-circuit-revives-false-claims-act-case-applying-escobar-materiality-standard.

20 Petition for Certiorari, *Gilead Scis., Inc. v. U.S. ex rel. Campie*, No. 17-936 (Dec. 26, 2017).

21 Brief for the United States as Amicus Curiae, *Gilead Scis., Inc. v. U.S. ex rel. Campie*, No. 17-936, 15 (Nov. 30, 2018).

22 *Id.* at 16.

23 *See U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998) (setting forth a "rational relationship test" for the dismissal of *qui tam* cases).

24 *See, e.g.*, The United States' Motion to Dismiss Relator's Second Amended Complaint, *U.S. ex rel. Health Choice Group, LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC (E.D. Tex.) (Dec. 17, 2018) [hereinafter "Motion to Dismiss"].

25 *Id.* at 3. The federal Anti-Kickback Statute ("AKS") makes it a crime to knowingly and willingly offer, pay, solicit, or receive any remuneration (e.g., a kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a person to (1) refer an individual for the furnishing of an item or service; or (2) purchase, lease or order, or arrange for or recommend the purchase, lease, or order of, an item or service, if the item or service is reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b). For the purposes of the AKS, "remuneration" includes the transfer of "anything of value in any form or manner whatsoever." 56 Fed. Reg. 35,952, 35,958 (July 29, 1991); *see, e.g.*, *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

26 Motion to Dismiss, *supra* note 24, at 6.

27 *Id.* at 9-16. The *Swift* standard is based on *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003). The "rational relationship test" was set forth in *U.S. ex rel. Sequoia Orange Co.*, *supra* note 23.

28 Motion to Dismiss, *supra* note 24, at 12.

29 *Id.* at 14.

30 Granston Memo, *supra* note 1, at 6.

31 Motion to Dismiss, *supra* note 24, at 15.

32 *Id.* at 16.

33 *Id.* The DOJ explained that, although the relators alleged that providing educational information and instruction to patients constitutes an illegal kickback to physicians, the "federal healthcare programs have a strong interest in ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medication." *Id.* The DOJ also pointed to guidance from the Department of Health and Human Services' Office of Inspector General indicating that, without more, the provision of educational materials or information programs to patients does not constitute unlawful remuneration. *Id.*; *see also* 81 Fed. Reg. 88368, 88396 (Dec. 7, 2016).

34 *See, e.g.*, Relator's Response to the United States' Motion to Dismiss the Second Amended Complaint, *U.S. ex rel. Health Choice Group, LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC (E.D. Tex.) (Jan. 22, 2019).