Law360

When DOJ Seeks Dismissals Of Life Sciences FCA Cases

By **Beth Weinman, Douglas Hallward-Driemeier, Kirsten Mayer, Joshua Oyster and Deborah Cho**

December 12, 2019

Beth Weinman

Douglas Hallward-Driemeier

Kirsten Mayer

Joshua Oyster

Deborah Cho

As the real party in interest in a False Claims Act case, the government is always entitled to seek dismissal of a FCA complaint under Title 31 of U.S. Code Section 3730(c)(2)(A), even in cases in which it does not intervene. Yet the government exercises this authority rarely.

Rather, in most cases, the U.S. Department of Justice has let relators proceed on their own, at times filing statements of interest to assert particular government interests in the ongoing litigation. However, the DOJ does recognize the need to protect government interests potentially threatened by relator-driven FCA litigation.[1]

In January 2018, a DOJ memorandum, commonly referred to as the Granston memo, outlined non-exhaustive factors the government should consider in determining whether to seek dismissal in cases in which it has declined to intervene and describes the FCA's provision on dismissal as "an important tool to advance the Government's interests, preserve limited resources, and avoid adverse precedent."[2]

Recent FCA cases highlight several key considerations for U.S. Food and Drug Administration-regulated life sciences defendants navigating FCA litigation and considering a request for a government-initiated dismissal under Title 31 U.S.C. Section 3730(c)(2)(A).

Standard for Dismissal

Currently, the circuit courts of appeals are split regarding the standard that courts should apply when reviewing government-requested dismissals under the FCA. In Swift v. United States, the U.S. Court of Appeals for the District of Columbia Circuit held that the government has an unfettered right to dismiss a qui tam action under Section 3730(c)(2)(A).[3]

The U.S. Court of Appeals for the Ninth Circuit, on the other hand, adopted a different standard of review in United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., holding that a two-step analysis applies to test the government's justification for dismissal.[4]

First, the government must identify a valid government purpose for dismissal, and, second, it must show a rational relationship between the dismissal and accomplishment of the valid government purpose. In the Granston memo, the DOJ espoused its view that the appropriate standard for dismissal is the standard adopted by the D.C. Circuit in Swift providing the government an unfettered right to dismiss a qui tam action.[5]

Nonetheless, the Granston memo advises the government to argue that, even where a court applies the higher Sequoia Orange standard, its review should be highly deferential and that

the government satisfies any potential standard for dismissal.[6]

Impact of the Granston Memo on the DOJ

In late 2018, the DOJ sought dismissal of multiple cases brought by professional relators under the FCA alleging that certain patient assistance and support services provided by pharmaceutical manufacturers were unlawful kickbacks in violation of the Anti-Kickback Statute. Generally speaking, the DOJ argued that the government had investigated the relators' allegations in these cases and concluded that (1) the allegations lacked an adequate factual and legal basis; (2) ongoing litigation would impose unjustified costs and burdens on the government; and (3) the allegations would undermine the government's policy and enforcement prerogatives related to industry practices that benefit federal health care programs.

Of the 10 patient support cases in which the government sought Section 3730(c)(2)(A) dismissals, decisions have been issued in nine cases as of Nov. 15. The court has dismissed five cases;[7] the court denied dismissal in one case,[8] and the relator voluntarily dismissed in three cases.[9] A decision is pending on the government's motion to dismiss in one case.[10] These developments illustrate the government's ability and willingness to apply the principles of the Granston memo in cases involving the life sciences industry.

In November 2018, in an amicus brief before the U.S. Supreme Court in an FCA case involving allegations of current good manufacturing practice, or cGMP, violations by a drug manufacturer, the DOJ previewed that if the case were remanded to the district court, it would move to dismiss the suit in part because continued litigation would not serve the public interest.[11]

Based on the government's thorough investigation of relators' allegations, the DOJ explained that dismissal would be appropriate because the burdensome discovery process would distract from the FDA's public health responsibilities, stating that "allowing this suit to proceed to discovery (and potentially a trial) would impinge on agency decision-making and discretion and would disserve the interests of the United States."[12]

On remand, the DOJ — as promised — moved to dismiss under Section 3730(c)(2)(A), emphasizing the lack of merit to the relators' case, FDA's ongoing oversight and that "[t]he FCA was never intended to allow a relator to substitute his or her own judgment for that of the Government as to whether the Government received the benefit of its bargain."[13]

On Nov. 5, 2019, after months of supplemental briefing and hearings, the court granted the government's motion to dismiss.[14] The court found a sufficient factual basis to support the governmental purposes for dismissal asserted by the DOJ, which were (1) "to prevent [relators] from undermining the considered decisions of FDA and [the Centers for Medicare and Medicaid Services] about how to address the conduct at issue here," and (2) "to avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue."[15]

Applying the Sequoia Orange standard, the court found dismissal appropriate because there was a rational relationship between dismissal and accomplishment of the government's two purposes, especially as the FDA had taken into account the relators' claims in its regulatory oversight of the drug manufacturer and had taken the actions it deemed appropriate.[16]

Takeaways for the Life Sciences Industry

The Granston memo and recent FCA cases implicating FDA's regulatory authority have the potential to be of great significance to drug and medical device companies fighting qui tam litigation.

Courts have increasingly recognized the potential for qui tam cases, especially meritless ones, to hinder the FDA's mission to promote and protect the public health. In United States ex rel. Rostholder v. Omnicare Inc., the U.S. Court of Appeals for the Fourth Circuit affirmed the district court's grant of the defendant drug manufacturer's motion to dismiss, holding that its submission of claims to the government for payment of drugs allegedly packaged in violation of cGMP did not constitute fraud on the government under the FCA.[17]

There, the court stated that relators failed to allege that defendants made a false statement or that they acted with the necessary scienter, as compliance with cGMP was not required for payment by Medicare and Medicaid. The court highlighted the FDA's significant remedial powers, including seizure, injunction and recommending disapproval of new applications from the manufacturer, and found that allowing FCA liability based on regulatory noncompliance "could short circuit the very remedial process the Government has established to address non-compliance with those regulations."[18]

In 2016, the U.S. Court of Appeals for the First Circuit, in United States ex el. D'Agostino v. Ev3 Inc., rejected the relator's claims that the defendant device manufacturer's allegedly fraudulent representations to the FDA when seeking approval to market its medical devices caused the submission of false claims under the FCA.[19]

The First Circuit explained that qui tam actions based on claims of fraud on the FDA could undermine the FDA's public health responsibilities and lead to second-guessing of the agency's decisions by juries. Pointing to the fact that the FDA had chosen not to require a recall or relabeling of the devices at issue, and had not sought to withdraw product approval during the six-year period after the FDA became aware of the allegations, the court held: The FDA's failure actually to withdraw its approval of [the subject device] in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.[20]

Likewise, in United States ex. rel. Petratos v. Genentech Inc., the U.S. Court of Appeals for the Third Circuit affirmed the district court's grant of the defendant drug manufacturer's motion to dismiss, finding that relator had failed to allege materiality under the FCA.[21] The relator had alleged that the drug manufacturer concealed information about the health risks of its drug, but the relator did not dispute that the government would reimburse claims even with full knowledge of the alleged deficiencies.[22]

The court described that even after the drug manufacturer's alleged noncompliance had been disclosed to the government, the FDA maintained approval of the drug, approved additional indications and did not initiate proceedings to require the manufacturer to change the drug's label, thereby indicating that relators had failed to meet the high standard for alleging materiality established by the Supreme Court in Universal Health Services Inc. v. United States ex rel. Escobar.[23]

In Escobar, the Supreme Court had described the standard for materiality as demanding and rigorous, stating that "[t]he False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[24]

Since the issuance of the Granston memo in 2018, the government has increasingly recognized that meritless qui tam actions are a concern not only for defendants in such cases, but also for the government itself, and the public. These actions can be a drain on limited government resources and can interfere with agency expert determinations, priority setting and policy considerations.

They can also divert industry resources away from research and development and investment in manufacturing infrastructure, exacerbate product shortages or result in increased prices for medical products, thus also undermining important government interests and the public health generally.[25] If the facts of a case are unfavorable to the government, a ruling could lead to adverse precedent, which could ultimately make it more difficult for an agency to enforce its statutory and regulatory authority in a manner aligned with its policy and enforcement priorities.

The government's decision to seek dismissal of appropriate Federal Food, Drug and Cosmetic Act-based FCA cases reflects its understanding that these types of FCA cases could make it harder for the FDA to enforce the FDCA as the agency deems appropriate and that the government is acknowledging Congress did not intend the FCA as a tool for enforcing the FDCA.

Considerations for Discussions With the DOJ During FCA Litigation

In light of the Granston memo and the evolving FCA landscape, defendants in the life sciences industry facing FCA litigation should consider whether and how to engage in discussions with DOJ attorneys regarding the potential for the government to request Section 3730(c)(2)(A) dismissal of cases in which the government has declined to intervene.

As the cases described above illustrate, FCA litigation in the drug and medical device context has the potential to divert scarce resources to nonpriority matters. Relators may easily underestimate how onerous FCA litigation can be for the agency, even when the government has not intervened.

For example, the burden accompanying discovery of FDA documents, many of which contain privileged and confidential information, may not be fairly appreciated by relators. Coordinating discovery across multiple FDA centers and offices and ensuring that any materials produced are appropriately redacted can be a challenging task, particularly when production of such materials is not a priority for the agency. As FDA-regulated products account for about 20 cents of every dollar spent by U.S. consumers,[26] the FDA's resources are already spread thin. The agency cannot pursue every potential violation of the FDCA.

In addition to the use, or misuse, of scarce resources, there are other issues defendants should consider raising with the DOJ. FCA litigation could second-guess agency expert determinations and undermine important FDA and public health policy interests, leading to unfavorable downstream consequences for the FDA and, ultimately, for the public health.

Where FDA is aware of particular allegations and has made a determination that agency

action is not warranted, or where the agency is already engaged in regulatory compliance activities with respect to a defendant that may be undermined by an FCA action, a request for dismissal may be appropriate and well-received.

In the context of FCA cases premised on alleged violations of cGMP requirements or other quality-related allegations, the threat of enforcement and a potential treble damages award could lead manufacturers to shut down production when faced with minor issues, potentially exacerbating drug shortages and adversely impacting public health.

As drug shortages are of great concern to the FDA and the public[27], shortage implications of FCA action should be raised to the government early in a government FCA investigation or when urging the government to seek to dismiss relator-led FCA litigation. In particular, if the issues raised by qui tam relators do not impact product quality in any material respect, a potential drug shortage resulting from FCA litigation could be extremely harmful to the public health.

With respect to FCA cases premised on allegedly off-label promotion of drugs or medical devices, the FDA may not wish to pursue such action if it could potentially lead to unfavorable First Amendment precedent. The DOJ and FDA are already cautious about litigating cases raising First Amendment issues because judicial decisions may further expand on prior decisions where the courts have ruled against the government.[28] Further unfavorable precedent in this area could make it more difficult for FDA to pursue enforcement where the conduct at issue does risk patient harm.

Where safety-related labeling is at issue, if a relator continues litigation despite the government's objections, a judge or jury could determine that a defendant should have included information in labeling that FDA did not believe was required or prudent.

When the FDA reviews a potential label for a drug as part of a new drug application or a medical device as part of a premarket approval application, the agency carefully reviews the specific wording and ultimately approves a label based on its expert analysis. The agency does not require approved product labels to list every possible adverse event, as doing so could drown out the more significant risks.

Allowing these types of FCA cases to proceed would be tantamount to allowing a judge or jury to second-guess the FDA's decisions, thereby inappropriately substituting agency expertise with the opinions of untrained individuals, potentially to the detriment of public health.

The FDA, as the agency responsible for protecting the public health, requires the freedom to regulate the drug and medical device industries in accordance with its expert judgment. The DOJ is beginning to recognize the potential risks of continued relator-led qui tam litigation of declined cases, both to government priorities and the American public.

When a DOJ investigation has determined that intervention is not warranted in a qui tam case because the allegations lack merit or the FDA or other relevant federal agencies do not support the case for important policy reasons, defendants can and should marshal the evidence and arguments supporting a Section 3730(c)(2)(A) dismissal by the government.

The recent Section 3730(c)(2)(A) dismissal of a case against a drug manufacturer illustrates that even under the higher Sequoia Orange standard, dismissal may be appropriate where a relator continues to pursue litigation on its own despite the FDA's extensive oversight of the defendant and involvement in the government's decision not to intervene.[29]

Conclusion

In summary, if a drug or medical device company finds itself subject to a qui tam FCA action, it should highlight the considerations described above, and outlined in the Granston memo, in discussions with the DOJ as the government weighs whether to intervene or move to dismiss.

Meritless FCA cases in the drug and medical device fields, where the FDA has powerful regulatory tools and authority, could ultimately lead to a negative impact on the public health. The FCA was not intended to be a tool for private individuals to seek monetary damages from life sciences companies for violations of the FDCA, especially when the FDA has already decided that regulatory action under that act is not warranted or when such action has the potential to interfere with ongoing regulatory action or agency priorities.

Beth Weinman is counsel, Douglas Hallward-Driemeier and Kirsten Mayer are partners, and Joshua Oyster and Deborah Cho are associates at Ropes & Gray LLP.

[1] DOJ, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018) (hereinafter "Granston Memo"). This memorandum was authored by Michael Granston, Director of the Civil Fraud Section of the Commercial Litigation Branch.

[2] Granston Memo at 2. The principles articulated in the Granston memo are incorporated in the Justice Manual at section 4-4.111.

[3] Swift v. United States, 318 F.3d 250, 252 (D.C. Cir. 2003).

[4] United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139, 1145 (9th Cir. 1998). The Tenth Circuit has adopted the Sequoia Orange standard. Ridenour v. Kaiser-Hill Co., 397 F.3d 925, 936 (10th Cir. 2005).

[5] Granston Memo at 7.

[6] Id.

[7] Order Granting United States' Motion to Dismiss Relators' Complaint, United States ex rel. SCEF, LLC v. Astrazeneca PLC, No. 17-cv-1328 (W.D. Wash. Nov. 5, 2019); United States ex rel. SMSPF, LLC v. EMD Serono, Inc., No. 16-cv-5594, 2019 WL 1468934 (E.D. Pa. Apr. 3, 2019); Order, United States ex rel. Health Choice Group, LLC. v. Bayer Corp., No. 5:17-cv-126 (E.D. Tex. Sept. 27, 2019); Order, United States ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co., No. 5:17-cv-123 (E.D. Tex. Sept. 27, 2019); Order, United States ex rel. SMSF, LLC v. Biogen Inc., No. 1:16-cv-11379 (D. Mass. Dec. 18, 2018). In Health Choice Group and Health Choice Alliance, the relators have filed notices of appeal. See First Amended Notice of Appeal, United States ex rel. Health Choice Group, LLC. v. Bayer Corp., No. 5:17-cv-126 (E.D. Tex. Oct. 25, 2019); Second Amended Notice of Appeal, United States ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co., No. 5:17-cv-123 (E.D.

Tex. Oct. 25, 2019).

[8] United States ex. rel. CIMZNHCA, LLC v. UCB, Inc., No. 17-cv-765, 2019 WL 1598109 (S.D. Ill. Apr. 15, 2019). The Government filed a notice of interlocutory appeal on July 5, 2019. Amended Notice of Appeal, United States ex. rel. CIMZNHCA, LLC v. UCB, Inc., No. 17-cv-765 (S.D. Ill. July 5, 2019).

[9] Minute Entry, United States ex rel. Carle v. Otsuka Holdings Co., No. 17-cv-966 (N.D. Ill. Jan. 29, 2019) (granting voluntary dismissal and expressly denying Government's motion to dismiss as moot); Order, United States ex rel. SAPF, LLC v. Amgen, Inc., No. 16-cv-5203 (E.D. Pa. Feb. 11, 2019); and Order, United States ex rel. Miller, v. AbbVie, Inc., No. 3:16-cv-2111 (N.D. Tex. May 9, 2019).

[10] United States ex rel. NHCA-TEV, LLC v. Teva Pharm., No. 17-cv-2040 (E.D. Pa.).

[11] Brief for the United States as Amicus Curiae at 14-16, Gilead Sciences, Inc. v. United States ex rel. Campie, 139. S. Ct. 783 (2019).

[12] Id.

[13] United States' Motion to Dismiss Relators' Second Amended Complaint at 10, United States ex rel. Campie v. Gilead Sciences, Inc., No. C-11-0941 (N.D. Cal. Mar. 28, 2019).

[14] Order Granting United States' Motion to Dismiss, Campie, No. C-11-0941 (N.D. Cal. Nov. 5, 2019).

[15] Id. at 7, 12-13.

[16] Id. at 7, 9-11.

[17] United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 703 (4th Cir. 2014).

[18] Id. at 702 (internal citations omitted).

[19] United States ex el. D'Agostino v. Ev3, Inc., 845 F.3d 1, 8-9 (1st Cir. 2015).

[20] Id. at 8.

[21] United States ex. rel. Petratos v. Genentech Inc., 855 F.3d 481, 484 (3d Cir. 2017)

[22] Id. at 490.

[23] Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016) (holding that a "misrepresentation about compliance with a statutory, regulatory, or contractual relationship must be material to the Government's payment decision in order to be actionable under the False Claims Act").

[24] Id. at 2003 (citation and internal quotations omitted); see also Order Granting United States' Motion to Dismiss at 12, Campie, No. C-11-0941 (N.D. Cal. Nov. 5, 2019) (explaining that FDA's years-long investigation of the defendant, which did not result in "a recall or even a consumer or physician alert" for the defendant's drugs, "casts some doubt on the element of materiality").

[25] For example, as discussed above, the Government argued for dismissal of the Campie action by highlighting the resources expended on investigation and litigation, FDA's ongoing regulatory oversight of the manufacturing processes for the drugs, and lack of action by the FDA against the drug manufacturer. United States' Motion to Dismiss Relators' Second Amended Complaint at 8-10, Campie, No. C-11-0941 (N.D. Cal. Mar. 28, 2019).

[26] FDA, Fact Sheet: FDA at a Glance, https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited Nov. 15, 2019).

[27] See, e.g., FDA, Drug Shortages: Root Causes and Potential Solutions: A Report by the Drug Shortages Task Force (Oct. 2019), available at https://www.fda.gov/media/131130/download; FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's work to mitigate shortages of intravenous drugs, shorten supply disruptions and better predict vulnerabilities (May 31, 2018), available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-work-mitigate-shortages-intravenous-drugs-shorten.

[28] See, e.g., United States v. Caronia, 703 F.3d 149 (2d Cir. 2012) (holding that First Amendment bars criminal prosecution for truthful, non-misleading speech promoting the lawful, off-label use of an FDA-approved drug); and Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (holding that First Amendment protects all truthful and non-misleading off-label speech).

[29] See Order Granting United States' Motion to Dismiss at 7-14, Campie, No. C-11-0941 (N.D. Cal. Nov. 5, 2019).