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by Adam S. Lurie and Jodi L. Avergun

DOJ seeks reversal of decision that could significantly impair False Claims Act enforcement

» The First Circuit Court of Appeals is set to issue an important FCA decision.
» The decision could be especially important for FDA-regulated companies.
» The Department of Justice is concerned that the decision could significantly impair FCA enforcement.
» Compliance officials should monitor the decision and related developments closely.
» Regardless of the outcome, compliance officials should remain as vigilant as ever.

Adam S. Lurie *(adam.lurie@cwt.com) and* ***Jodi L. Avergun*** *(jodi.avergun@cwt.com) are Partners in the Washington DC office of Cadwalader, Wickersham & Taft LLP.*

On August 1, 2013, the Department of Justice (DOJ) submitted an *amicus curiae* brief asking the First Circuit to reverse a significant False Claims Act (FCA) decision issued in *United States ex rel. Helen Ge, MD v. Takeda Pharmaceutical Company Limited, et al.*[1] The district court dismissed the relator's complaint, concluding (among other things) that: (a) the existence of the Food and Drug Administration's (FDA) enforcement authority, and the right of citizens to petition the FDA to exercise such authority, could preclude FCA liability; and (b) FCA liability could never be premised on a failure to comply with the FDA's adverse event reporting requirements. In its *amicus curiae* brief, the DOJ argued that these conclusions were erroneous, and explained that, if allowed to stand, "the government's enforcement of the FCA could be significantly impaired."[2]

The DOJ's concern is well placed. If the First Circuit affirms the above conclusions, FCA liability may be precluded in the First Circuit in new ways, including whenever an entity is subject to alternative administrative remedies or mechanisms to report fraud. Given the significance of this matter, companies and their compliance professionals should pay attention to the First Circuit's decision and any related developments.

Lurie

Avergun

Takeda Pharmaceutical: Legal and factual background

Under the Federal Food, Drug, and Cosmetic Act, the FDA must approve a new drug as safe and effective for its intended use before a manufacturer can market the drug in the United States. Companies that market approved drugs must report adverse events associated with such drugs to the FDA. If a company fails to comply with these reporting requirements, the FDA may initiate proceedings to withdraw approval of the drug, seek an injunction, or pursue criminal prosecution. Further, FDA approval is relevant to reimbursement for drugs under government reimbursement programs, including Medicare and Medicaid.[3]

In *Takeda Pharmaceutical*, Dr. Helen Ge filed a *qui tam* action against Takeda in federal court in Massachusetts alleging that Takeda

failed to report adverse events associated with several drugs that Takeda manufactured, in violation of the FDA requirements cited above. Ge further claimed that, had Takeda properly reported these events, the FDA: (a) might have taken action, resulting in fewer claims for Medicare or Medicaid reimbursement; (b) might never have approved, or might have withdrawn approval, for the drugs.

Takeda moved to dismiss, and the district court granted the motion finding (among other things) that Ge failed to state an FCA claim, because Ge failed to allege that "compliance with the reporting requirements was a material precondition of reimbursement." The district court reasoned that the FDA "has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements" including "withdrawal of drug approval."[4]

The district court further explained that the "FDA exercises discretion in its enforcement procedures for such types of violations, and does not always prosecute them, let alone enforce the harshest penalty available," and that "[t]hese enforcement procedures have for many years allowed for citizens to petition FDA to bring action against specific violators." Accordingly, the district court concluded that it "is through [this petition] mechanism, rather than an FCA lawsuit, that relator should have brought the reported issues" to the attention of the FDA. [5]

The DOJ's *Amicus Curiae* Brief

The relator appealed the dismissal, and the DOJ filed an *amicus curiae* brief, primarily to contest to the above findings. In doing so, the DOJ argued that the district court erred because "the key question is not whether, in light of the defendant's false statement about its compliance, the agency did or had to deny payment, but rather whether the agency was *permitted* to deny payment" (emphasis added).[6] If so, then the defendant's false statements were material and can give rise to FCA liability.

Accordingly, the DOJ first argued that "the existence of alternative administrative remedies or mechanisms to report fraud does not affect, let alone preclude, the availability of False Claims Act liability."[6] In support of this argument, the DOJ asserted that the FCA text does not contain an exemption from liability where there is a "parallel, agency-specific mechanism for uncovering or addressing fraud."[7]

In addition, the DOJ pointed to the FCA's legislative history, as well as the legislative history of other statutes making administrative remedies available, to argue that "there is no evidence of congressional intent to make the availability of an action under the FCA turn on whether the alleged conduct might also be addressed through regulatory schemes."[8]

> …the DOJ asserted that the FCA text does not contain an exemption from liability where there is a "parallel, agency-specific mechanism for uncovering or addressing fraud."

The DOJ also argued that the district court erred when it suggested that a drug manufacturer's failure to report adverse events to the FDA could never form the basis of FCA liability. The DOJ explained that "[a]lthough rare, there are circumstances where such failures could trigger liability under the Act. For example, if the unreported adverse events are so serious that the FDA would have withdrawn a drug's approval…" In that situation,

"the failure to report would be material to the government's payment decisions concerning claims under the Medicare and Medicaid programs" since such claims would be ineligible under these programs.[9]

Potential impact of *Takeda Pharmaceutical*

The DOJ correctly sounded an alarm that affirmance of the district court's decision could significantly impair FCA enforcement. Indeed, a broad reading of the district court's decision could mean that FCA liability may be precluded—at least in the First Circuit—in any case involving the failure to report adverse events to the FDA, and whenever an entity is subject to alternative administrative remedies or mechanisms to report fraud.

Such remedies and mechanisms often exist for entities subject to federal regulatory schemes, including many companies that receive money from the federal government. Thus, if the First Circuit affirms a broad reading of the district court's decision, then many companies that receive money from the federal government could avoid FCA liability because of such schemes.

That the case has arisen in the First Circuit is also significant. Historically, many FCA cases have been filed in the First Circuit, especially against life science companies. Consequently, a favorite circuit for relators and the DOJ could become much less friendly to FCA suits, and relators and the DOJ may have to overcome this persuasive authority in other circuits.

Although it is impossible to predict what the First Circuit will do if it affirms the district court, it would not be surprising if the First Circuit limited any such decision to the facts of the case or affirmed on grounds other than those discussed above. For example, the district court also dismissed the relator's complaint for failure to plead fraud with particularity under Rule 9(b) for reasons unrelated to those discussed above. Accordingly, the First Circuit may very well avoid the issues that the DOJ has raised in its *amicus curiae* brief by affirming dismissal pursuant to Rule 9(b).

> Nevertheless, companies that could be subject to FCA liability …should pay attention to this case…

Nevertheless, companies that could be subject to FCA liability—an ever expanding class—and their compliance officials, should pay attention to this case, given its potential effects on FCA enforcement. For instance, the First Circuit may affirm the district court in a narrow manner, but in a way that still limits FCA liability for the reporting of adverse events to the FDA. It will be especially important for companies and their compliance officials to appreciate, however, that any decision affirming the district court only applies in the First Circuit, and not to take their compliance obligations less seriously. Thus, companies must remain as vigilant as ever in their compliance efforts as they closely monitor developments related to this matter in the courts, by regulators, and the Department of Justice.

1. *United States ex rel. Helen Ge, MD v. Takeda Pharmaceutical Company Limited, et al. U.S. District Court District of Massachusetts, Civil Actions* 10-11043-FDS and 11-10343-FDS. Available at http://1.usa.gov/1fNJLjY
2. *Amicus curiae brief of the DOJ, Takeda Pharmaceutical*, Nos. 13-1088, 13-1089 (1st Cir. August 1, 2013), at 1. Available at http://bit.ly/GCtCgT
3. *See* 21 U.S.C. § 355; 21 C.F.R. §§ 314.80, 314.98(a); *see also* 21 U.S.C. §§ 355(k), 331(e).
4. *Takeda Pharmaceutical*, 11-cv-10343 (D. Mass. November 1, 2012), at 11. Available at http://bit.ly/GAshro
5. *Id.*
6. *Amicus curiae brief of the DOJ, Takeda Pharmaceutical*, Nos. 13-1088, 13-1089 (1st Cir. August 1, 2013), at 15.
7. *Id.*
8. *Id.* at 18
9. *Id.* at 11