Professional Perspective

Circuit Split Doesn't Slow DOJ False Claims Act Settlements Based on FDCA Allegations

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Over the past decade, a circuit split has emerged within the federal courts regarding whether alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA), including quality and manufacturing deficiencies, can—or should—give rise to violations of the False Claims Act (FCA).

This fundamental question is of key significance for pharmaceutical, biotech, and medical device companies because the FCA is a civil statute, subject to a lower burden of proof than the criminal provisions of the FDCA and provides for treble damages that may far exceed the penalties that the Food and Drug Administration (FDA) seeks in FDCA civil actions.

The Department of Justice (DOJ) recently filed a Statement of Interest in an FCA case arguing that, in certain cases, FDCA violations can give rise to FCA liability because they may be material to the government's decision as to whether to pay for a particular product. DOJ's Statement places a thumb on the scale in an area where the case law is far from settled, but where the possibility of FCA liability remains quite lucrative for DOJ and relators.

This is confirmed by the fact that, despite the lack of clarity in this area, the past five years have seen a steady drumbeat of DOJ FCA-based civil settlements related to alleged quality and manufacturing deficiencies. Each of these settlements potentially makes it more difficult for companies to challenge the fundamental legal premise that FDCA violations may give rise to false claims. The settlements also raise the stakes for promptly and thoroughly addressing quality and manufacturing issues when they arise.

Overview

- Relators have pursued a variety of FCA theories based upon alleged FDCA violations, including the so-called "fraud-on-the-FDA" theory that, where FDCA violations are so pervasive that FDA would not have approved or kept a product on the market if it had known of the violations, any claims for payment related to the product are false.
- Courts have split on whether this theory can support FCA liability, with the Biden DOJ (like the Obama DOJ before it) arguing that the theory may be valid in certain circumstances.
- Despite the legal uncertainty surrounding this theory, since 2017 DOJ has secured six DOJ FCA settlements, totaling approximately $730 million, premised on alleged quality or manufacturing deficiencies.
- Given the continued scrutiny in this area, and the high stakes for potential violations, companies should prioritize identification and remediation of quality and manufacturing issues and ensure that they receive necessary attention from senior leadership and legal counsel.

Courts Divided

Over the past decade, courts have disagreed on whether an alleged violation of the FDCA can give rise to FCA liability, with varied outcomes hinging on detailed analyses of the specific alleged violations and their connection to the FCA elements of materiality and falsity. Of note, while DOJ declined to intervene in many of the relevant cases, relators have shown a willingness to pursue FDCA-based FCA claims.

In the early 2010s, circuit courts appeared poised to reject the premise that alleged FDCA violations could give rise to FCA liability. In *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014), a former employee alleged that Omnicare submitted claims for drugs that were ineligible for reimbursement because Omnicare violated regulations requiring that penicillin and non-penicillin drugs be packaged in complete isolation from each other.

Although FDA eventually issued a warning letter relating in part to this conduct, the U.S. Court of Appeals for the Fourth Circuit affirmed the district court's dismissal, finding that the submission of a claim for an approved drug does not become a "false claim" on the sole basis of a regulatory violation, because the FCA is not a "sweeping mechanism" to promote regulatory compliance. Rather, the court found, there must be evidence of a false statement or other fraudulent misrepresentation made to the government to establish FCA liability.

Two years later, in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), a former medical device salesman alleged that a medical device company caused the submission of fraudulent claims by: (1) allegedly making fraudulent representations—regarding intended use, the nature of training the manufacturer would provide, and the device's safety profile—to FDA in seeking approval (i.e., fraud-on-the-FDA); (2) encouraging medically unnecessary and unsafe use of its device by physicians who did not attend its training programs; (3) alleged manufacturing deficiencies; and (4) alleged design deficiencies.

The U.S. Court of Appeals for the First Circuit rejected the relator's fraud-on-the-FDA claim, holding that he could not "establish a causal link" between the company's allegedly fraudulent representations to FDA and government payments because FDA did not withdraw approval of the device after becoming aware of the relator's allegations.

The court also rejected the remainder of the relator's theories, finding that FDA did not require physicians to obtain training from the manufacturer itself, that the relator failed to plausibly allege pervasive manufacturing defects, and that later design improvements did not render an earlier design inherently defective.

More recent cases, however, have found that FCA liability may arise out of quality-related FDCA violations, in at least certain circumstances. In *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017), two quality assurance/control employees alleged that a manufacturer: (1) failed to seek FDA approval when it switched active ingredient manufacturers; (2) falsified or concealed data when it eventually sought FDA approval of the change (including making false claims regarding sterility testing); and (3) in the interim, illicitly used active ingredient from the unapproved manufacturer in its finished products. The relators further alleged that FDA would not have approved the change in its active ingredient manufacturer if it had been aware of the negative sterility test results or associated quality and purity issues.

The U.S. Court of Appeals for the Ninth Circuit found that the relators sufficiently alleged that the manufacturer made explicit and implicit false representations to FDA that active ingredients had been manufactured in approved, registered facilities, which resulted in fraudulently obtaining FDA approval. The court also concluded that the fact that FDA did not withdraw approval of the drug after learning of the relators' allegations did not necessarily render the alleged falsity immaterial, finding that "[m]ere FDA approval cannot preclude False Claims Act liability, especially where, as here, the alleged false claims procured certain approvals in the first instance."

Most recently, in *Dan Abrams Co. v. Medtronic, Inc.*, 850 F. App'x 508 (9th Cir. 2021), the Ninth Circuit allowed a relator's "fraud-on-the FDA" allegations to move forward regarding a group of devices that the relator alleged could only be used for contraindicated uses but which the manufacturer allegedly falsely represented were intended for other uses in seeking 510(k) clearance.

In the intervening years, in *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), the First Circuit found that the relators pled a "theory of actionable misconduct" under the FCA where they alleged that a medical device company caused the submission of false claims by selling devices that, due to a latent manufacturing defect, materially deviated from the design specifications included in their cleared 510(k).

The Biden DOJ Supports FCA Liability

Despite the uncertainty in the relevant case law, as noted above, the Biden DOJ recently filed a Statement of Interest in an FCA case in which it asked the court not to "foreclose the possibility that, under certain circumstances, conduct giving rise to violations of the FDCA or FDA regulations could be material to the government's payment decisions and provide a basis for FCA liability assuming all necessary FCA elements are demonstrated."

DOJ argued that "deficiencies in the affected product resulting from FDCA violations may, in certain circumstances, be material to the government's decision whether to pay for the affected product, and thus relevant in an FCA case," such as "where the violations are significant, substantial, and give rise to actual discrepancies in the composition, functioning, safety, or efficacy of the affected product." United States' Statement of Interest as to Defendant's Motion to Dismiss at 6, *United States ex rel. Crocano v. Trividia Health, Inc.*, No. 0:22-cv-60160-RAR (S.D. Fla. filed June 3, 2022), ECF No. 124.

As examples, DOJ pointed to situations where:

- Manufacturing deficiencies so profoundly affect the "safety, efficacy, or performance" of the product as to render it "worthless" or result in a product's quality, safety and efficacy falling below specifications approved by FDA;
- Manufacturing defects are so pervasive that FDA "never would have approved or cleared the affected products—or allowed them to remain on the market—if it had known the truth, and claims involving those devices never would have been eligible for federal healthcare program reimbursement"; and
- "[M]aterially false or fraudulent statements [are] made to FDA regarding drugs or medical devices" including hiding material information regarding the safety or efficacy of a product during or after the FDA approval process or to avoid a recall.

DOJ's Continued Pursuit of FCA Settlements

Consistent with the arguments set forth in DOJ's recent Statement of Interest, and despite the uncertain case law discussed above, the past five years have seen six DOJ FCA settlements, totaling approximately $730 million, based upon alleged FDCA quality and manufacturing violations.

Four of the six settlements involved medical devices alleged to be defective due to material deviations from specifications or technical defects affecting device performance, all of which were associated with customer complaints, serious injury or death, or recalls. The two remaining settlements involved allegations of drug product quality issues stemming from unsanitary manufacturing conditions that, presumably due to the more egregious facts involved, resulted in both FCA and criminal FDCA violations.

- **Alere Inc. and Alere San Diego Inc. Press Release (July 2021):** Alere agreed to pay approximately $38.75 million to resolve FCA allegations that the company had billed for, or caused others to bill Medicare for, unreliable point-of-care testing devices. DOJ alleged that from 2008 to 2016, Alere knowingly sold blood coagulation devices containing an algorithm defect that returned discrepant results for certain patients. Alere allegedly failed to correct prior statements it had made to FDA that the root cause of the discrepant results was unknown, and failed to take corrective action until 2016, when it conducted a nationwide recall at FDA's request.
- **St. Jude Medical, Inc. Press Release (July 2021):** St. Jude agreed to pay $27 million to resolve FCA allegations that, from 2014 to 2016, the company knowingly sold defective defibrillators with battery depletion issues, which were implanted in patients insured by federal health care programs. St. Jude allegedly made misrepresentations to FDA in requesting approval of a design change for this issue, including that no serious injuries or deaths had been associated with the issue. St. Jude subsequently issued a medical advisory (later classified as a recall) following an uptick in medical device reports and stopped selling the device. DOJ's allegations were premised on sales of the legacy devices that were made after St. Jude received permission from FDA to sell the new design.
- **AmerisourceBergen Corporation (ABC) Press Release (October 2018):** ABC and its subsidiaries agreed to pay $625 million to resolve allegations under the FCA and the federal Anti-Kickback Statute that, from 2001 to 2014, ABC operated a program where it repackaged drug products, including overfills, into pre-filled syringes in an unsanitary environment and unregistered facility. DOJ alleged that the company submitted false claims for drugs that did not meet the quality or purity they were represented to possess and were contaminated with foreign particles. Notably, ABC also entered into a plea agreement with DOJ one year earlier to resolve criminal FDCA liability for related conduct and paid $260 million in criminal fines and forfeiture.

- **Allergan Inc. Press Release (April 2018):** Allergan agreed to pay $3.5 million to settle FCA allegations that the company knowingly caused health care providers to submit false or fraudulent claims for its surgically implanted LAP-BAND device, which aids with weight loss. DOJ alleged, among other things, that between 2008 and 2010, Allergan knowingly sold devices with defective or flawed access ports, concealed the defect/flaw, and misrepresented facts about the cause of the issue to the public, health care professionals, and FDA.

- **Alere Inc. and Alere San Diego Press Release (March 2018):** Alere agreed to pay $33.2 million to resolve FCA allegations that the company caused hospitals to submit false claims by knowingly selling materially unreliable point-of-care diagnostic testing devices from 2006 to 2012. DOJ alleged that the company received customer complaints that put it on notice that its devices produced erroneous results that had the potential to adversely affect clinical decision-making, but failed to take appropriate corrective actions until an FDA inspection in 2012 prompted a nationwide recall.

- **Baxter Healthcare Corporation Press Release (January 2017):** Baxter agreed to pay $2.158 million to resolve civil liability under the FCA, and $16 million to resolve criminal liability under the FDCA, in connection with its manufacture of sterile IV solutions in a room with moldy HEPA filters. DOJ alleged that the company's failure to follow cGMPs in manufacturing the sterile drug products resulted in the submission of false claims to the Department of Veterans Affairs.

Considerations For Life Science Manufacturers

As life science industry observers know well, because DOJ settlement agreements and press releases generally describe alleged misconduct at a high level, it can be quite difficult to discern how the alleged misconduct at issue would have fared under judicial review. Nevertheless, the recent resolutions discussed above confirm that, regardless of how they might hold up if tested in litigation, alleged FDCA violations may, as a practical matter, give rise to FCA liability. It is likely that FCA resolutions based on alleged FDCA violations will continue, as relators and the DOJ are incentivized to pursue them, and companies may have reasons to settle regardless of the strength of the allegations.

DOJ's recent settlements, combined with the recent Statement of Interest affirming that the Biden DOJ will pursue FCA liability for at least certain FDCA violations, confirm that life sciences companies should continue to direct significant resources toward design, quality, and safety issues to mitigate risk under both the FDCA and the FCA.

A close examination of the recent settlements suggests that a company with internal knowledge of product problems, coupled with an attempt to conceal or minimize quality issues that could have significant public health ramifications, is more likely to face DOJ scrutiny. Given this, any decisions not to inform FDA of identified product problems should be consistent with statutory and regulatory requirements, well-reasoned, and fully documented. Companies must work to spot issues early and identify their root causes and, where needed, enhance quality procedures to ensure prompt reporting of product quality issues to management, decision-makers and, where necessary, to regulators.

In addition, despite the fact that FDCA quality issues can create significant legal risks, personnel responsible for identifying and addressing quality issues are often siloed without significant involvement from their companies' regulatory and legal departments. Given the potential risk involved, a company's legal and regulatory groups should be directly involved in addressing quality issues, recall strategy, inspections, and responses to regulators, in order to ensure that decisions are made with a full understanding of the relevant legal requirements and attendant risk.