Recent Enforcement Settlements Highlight Continued Scrutiny of Quality and Manufacturing Issues

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Three recent settlements demonstrate the U.S. Department of Justice's (DOJ's) continued scrutiny of product quality and manufacturing issues in the medical device industry. Using the civil False Claims Act (FCA) and the threat of criminal prosecution via a deferred prosecution agreement (DPA), DOJ prosecutors continued their efforts to hold companies accountable for conduct that poses a risk to patient health and safety.[1] FDA-regulated companies should review these settlements to gain a better understanding of what conduct is likely to trigger enforcement scrutiny, and companies should take steps to enhance internal quality and compliance controls to prevent problems in the first instance and to promptly identify and remediate quality and manufacturing problems when they do occur.

Key Takeaways

- DOJ continues to use False Claims Act cases commenced by whistleblowers as a vehicle to investigate quality and manufacturing issues that pose a threat to patient health and safety.
- A company's 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 result in criminal investigation by DOJ.
- A company's conduct during an FDA inspection can itself be an area of risk, just as a company's response to the receipt of a subpoena can be. Companies should train and prepare employees for inspections by regulators to ensure that these interactions are conducted appropriately.
- Companies should review and, where needed, enhance their quality procedures to ensure that they clearly and conspicuously require prompt reporting of product quality issues to management decision-makers and, where necessary, to regulators.

Avanos Medical, Inc. — DPA Resolves Felony FDCA Misbranding Charges Where the Company Delayed Implementing Corrective Action and Lied to FDA Investigators

In July 2021, Avanos Medical, Inc. (Avanos) agreed to pay $22.2 million as part of a DPA to resolve one felony count of introducing misbranded devices into interstate commerce with the intent to defraud and mislead.[2] Avanos admitted to selling hundreds of thousands of misbranded surgical gowns from November 2014 to January 2015. The company represented that the gowns met rigorous quality standards established by an industry classification system, despite knowing that a manufacturing issue was causing the gowns to fail viral-penetration tests and that internal efforts were underway to change the manufacturing method used to seal the gowns.

[1] While this client alert focuses on the enforcement risks associated with quality and manufacturing problems, device companies face many other enforcement risks, particularly with respect to financial relationships with physicians and other customers. On September 7, 2021, prosecutors in the U.S. Attorney's Office in Boston announced indictments of a spinal device manufacturer and the company's CEO and CFO for offering disingenuous consulting payments to physicians in order to induce their use of the company's products. (See the DOJ press release "CEO, CFO and Boston-Area Spinal Device Company Charged in Bribery and Money Laundering Scheme" (Sept. 7, 2021).) The full range of enforcement risks for device makers was addressed in our April 28, 2020, client alert "Enforcement Spotlight: US Prosecutors Continue To Target Medical Technology Companies."

[2] See DOJ press release "Avanos Medical Inc. To Pay $22 Million To Resolve Criminal Charge Related to the Fraudulent Misbranding of Its MicroCool Surgical Gowns" (July 8, 2021).

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According to the Agreed Statement of Facts, an employee who led the company's efforts to address these test failures simultaneously helped create marketing materials that promoted the surgical gowns' misleading classification and also made misrepresentations about the quality of the gowns during meetings with hospital customers. Although the Information filed against the company was based on conduct that occurred from late 2014 to early 2015, the Agreed Statement of Facts indicates that Avanos determined as early as September 2013 that a change in machinery would likely address the quality issue, and nevertheless continued to use the existing equipment to manufacture misbranded gowns until January 2015.

In July 2016, the Food and Drug Administration (FDA) conducted a for-cause inspection of Avanos's surgical gown business. According to the settlement papers, a company employee falsified entries in company documents that summarized the results of stability tests conducted on the surgical gowns, and explained to a co-worker that the purpose of falsifying them was to avoid alerting FDA investigators to the failures of the tests performed on the surgical gowns. These falsified documents were submitted to FDA investigators during the inspection.

Under the terms of the DPA, Avanos agreed to pay victim compensation claims and a monetary penalty and to disgorge certain profits. In negotiating the settlement, DOJ considered the actions Avanos took before, during and after the investigation, including the nature and seriousness of Avanos's offense. As reflected in the DPA, DOJ declined to give Avanos disclosure credit because the company did not timely and voluntarily self-disclose the offense, but gave Avanos cooperation credit for conducting a thorough internal investigation, making factual presentations to the government, providing information about individuals involved in the conduct and voluntarily making available foreign-based employees and documents. DOJ also credited the extensive efforts made by the company to address significant gaps in its compliance programs that included:

- creating a stand-alone Compliance Committee of the Board of Directors;
- restructuring its quality and regulatory departments to report directly to the CEO;
- creating a stand-alone compliance department with a full-time chief compliance officer;
- "substantially" increasing the budget and head count for its compliance and quality departments; and
- implementing enhanced compliance training and procedures.

These efforts resulted in a discount to the criminal penalty of 25% below the low end of the range in the otherwise applicable Sentencing Guidelines.

Notably, Avanos was required to enter the DPA and agree to additional compliance enhancements, notwithstanding that three years prior to the resolution Avanos had sold its surgical gown unit, including all associated assets and employees. In addition, Avanos agreed to report to prosecutors "any evidence or allegation" of a violation of the Federal Food, Drug and Cosmetic Act (FDCA) or U.S. obstruction or fraud laws committed by the company's employees against any domestic agency, regulator or customer.

Alere Inc. and Alere San Diego — DOJ Secures Civil FCA Settlement for Alleged Fraudulent Medicare Billing of Defective Products and Misrepresentations to FDA

A second settlement announced in July 2021 similarly involved allegations regarding the sale of defective products by a medical device company, despite its alleged knowledge of product quality issues.[3] Alere Inc. and Alere San Diego, Inc. (collectively, Alere) agreed to pay approximately $38 million in a civil settlement to resolve allegations that the companies violated the FCA by billing for, or causing others to bill Medicare for, unreliable point-of-care testing devices. DOJ alleged that from 2008 to 2016, Alere knowingly sold blood coagulation devices that contained an algorithm defect that returned discrepant results for certain patients. DOJ alleged Alere was aware from various internal research and external complaints and warnings that the software algorithm used in these devices contained a material defect. Although Alere allegedly attempted to fix the algorithm, no acceptable solutions were identified that meaningfully reduced the discrepancies.

DOJ claimed that because Alere closed its internal investigation without fixing the algorithm defect, the company concealed the defect, while simultaneously submitting claims to Medicare for the devices. In particular, DOJ alleged that following the company's internal investigation, Alere represented to FDA in medical device reports that it had "investigat[ed]" the devices reported to have returned discrepant results but "did not uncover any deficiencies" in the devices. Alere also allegedly failed to correct prior statements it had made to FDA that the root cause of the discrepant results was unknown. According to the civil settlement, Alere failed to take corrective action until 2016, when it conducted a nationwide recall at FDA's urging. Alere denied DOJ's allegations and did not admit liability. Abbott

[3] See DOJ press release "Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay $38.75 Million to Settle False Claims Act Allegations" (July 8, 2021).

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Laboratories (Abbott) purchased Alere in 2017, after the alleged conduct had occurred. The settlement papers do not expressly impose any obligations on Abbott.

St. Jude Medical Inc. — DOJ Targets the Knowing Sale of Defective Products After Company Allegedly Downplayed Safety Concerns

Additionally in July 2021, St. Jude Medical, Inc. agreed to pay $27 million in a civil settlement to resolve allegations that it violated the FCA by knowingly selling defective defibrillators that were implanted in patients insured by federal health care programs.[4] Notably, the investigation was prompted by a *qui tam* suit filed by a patient who had received one of the defibrillators that was subject to St. Jude's subsequent recall of the devices.

DOJ alleged that in 2014, St. Jude submitted to FDA a Real Time Review (RTR) request for a design change to prevent a defect that caused premature depletion of the battery in certain defibrillators. An RTR request is a process used by manufacturers to obtain expedited consideration from FDA for minor changes to already approved devices. At the time it made the 2014 request, St. Jude allegedly informed FDA that no serious injuries or deaths had been associated with this issue; however, DOJ claimed that St. Jude in fact was aware of two reported serious injuries and one death associated with the battery depletion when the company made the submission. Based on the information St. Jude provided in connection with the RTR request, FDA approved the design change in 2014. DOJ claimed that had St. Jude been truthful with FDA about the injuries and death associated with the defibrillators, the agency would have requested that St. Jude initiate a voluntary recall of the defibrillators manufactured prior to the design change. Additionally, DOJ alleged that St. Jude continued to distribute defibrillators with the defective design even after FDA approved the design change and that the old design continued to be implanted until October 2016.

In August 2016, St. Jude informed FDA that the number of adverse events associated with the legacy device had increased to 729, including two deaths. In October 2016, St. Jude issued a medical advisory regarding the battery depletion issue, which FDA classified as a Class I recall. St. Jude thereafter stopped selling the legacy device. The government's false claims allegations were premised on sales of the legacy devices that were made after St. Jude received permission from FDA to sell the new design. St. Jude denied DOJ's allegations and did not admit liability. St. Jude was also purchased by Abbott in 2017, after the alleged conduct had occurred; however, unlike in the Alere settlement, Abbott is identified in this civil settlement as the guarantor of St. Jude's settlement payment obligations.

Implications for Medical Device and Other Manufacturers

These recent settlements underscore DOJ's scrutiny of inadequate product quality systems and corrective actions that threaten patient health and safety, including for those companies that manufacture personal protective equipment (PPE) in the pandemic era.

Whistleblower suits remain a frequent source of litigation exposure. As the St. Jude settlement demonstrates, companies may face increased exposure from selling products that threaten patient health or safety, as customers themselves may bring claims through whistleblower suits. Additionally, the St. Jude settlement shows how recall of the defective devices provided the patient whistleblower with critical information not only about the product defect itself but that the defect was potentially widespread, impacting more than just the whistleblower.

Where quality or manufacturing issues are discovered, companies should act promptly to identify the extent of the problem, remedy the deficiencies and thoroughly consider whether disclosure to FDA is appropriate. Companies should ensure that their complaint handling procedures clearly and conspicuously require reporting of product quality issues to management decision-makers and, where required, to regulators. Decisions not to inform FDA of product problems should be consistent with statutory and regulatory requirements, well-reasoned and fully documented. Full and prompt disclosure to FDA can often mitigate costly enforcement actions and reputational harm.

In addition, companies should maintain robust, multilevel checks and balances to affirm investigative steps and resulting corrective actions taken to address complex, systemic quality issues, and any decision to continue distributing versions of a medical device that do not reflect the company's corrective action should be carefully considered and well-documented. Companies also should be mindful that product quality issues caused by systemic failings in a company's quality and compliance processes, as well as attempts to obstruct FDA's investigative efforts, increase the likelihood of criminal prosecution.

[4] See DOJ press release "St. Jude Agrees to Pay $27 Million for Allegedly Selling Defective Heart Devices" (July 8, 2021).

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Finally, companies should be vigilant in creating and affirming a culture of compliance, including implementing controls that deter and hold accountable employees or supervisors who interfere in the review or investigation of quality issues. For example, this could include scheduling regular compliance training for employees and management, ensuring that managers and executives visibly support the company's compliance policies, establishing an effective system of confidential reporting of suspected problems and protection for employees who come forward to report problems, incentivizing compliance through positive reinforcement and disciplining those who violate the company's compliance policies. Such measures could be persuasive in showing FDA and DOJ that an alleged product defect is not indicative of a larger management or systemic failure.

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