Failure to Report Adverse Events Results in Criminal Misbranding Settlement and Individual Liability

12 / 14 / 18

Skadden

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

John T. Bentivoglio
Partner / Washington, D.C.
202.371.7560
john.bentivoglio@skadden.com

Jennifer L. Bragg
Partner / Washington, D.C.
202.371.7980
jennifer.bragg@skadden.com

Maya P. Florence
Partner / Boston
617.573.4805
maya.florence@skadden.com

Amanda H. Chan
Law Clerk / Washington, D.C.
202.371.7305
amanda.chan@skadden.com

Four Times Square
New York, NY 10036
212.735.3000

On December 10, 2018, Olympus Medical Systems Corporation and a former quality manager at the company pleaded guilty to introducing misbranded medical devices into interstate commerce in violation of the Federal Food, Drug and Cosmetic Act (FDCA). The government charged that Olympus' Q180V duodenoscopes were misbranded because the company failed to file and supplement Medical Device Reports (MDRs) involving serious infections associated with the product.[1] Under the plea agreement, Olympus will pay $80 million in fines and $5 million in criminal forfeiture and will enact extensive compliance reforms. Hisao Yabe, who faces a $100,000 fine and up to one year in prison, will be sentenced on March 27, 2019.

Top-Line Summary

- FDA and DOJ take adverse event reporting obligations seriously and do not view them as technical regulatory requirements;
- When patient safety is implicated, FDA and DOJ are more likely to pursue a criminal resolution, even where the adverse events occurred outside of the United States;
- FDA regulatory lapses can create meaningful risk for a company and having input from the legal department in early stages can better position the company to remediate regulatory lapses; and
- When a company transfers business functions internally, it is important to ensure that those to whom the transfer has been made have knowledge and awareness of their responsibilities.

Duodenoscopes

The Olympus Q180V duodenoscope is a flexible, lighted tube with a light, camera and forceps elevator at one end. Because the device is reusable, it must be processed (cleaned) in accordance with manufacturer guidelines to remove infectious materials after use. In Fall 2013, the Centers for Disease Control and Prevention (CDC) alerted the Food and Drug Administration (FDA) to a potential association between multidrug resistant bacteria and duodenoscopes. FDA eventually determined that the infections were occurring despite confirmation that the users were following proper manufacturer cleaning and disinfection or sterilization instructions.[2] Thus, the ensuing investigation by the Department of Justice (DOJ) occurred against the backdrop of years of FDA focus on the association between duodenoscopes and infections. Olympus is one of three manufacturers of duodenoscopes in the United States and allegedly had approximately 85 percent of the market share during the time period in question. According to the charging documents, Olympus failed to file:

- Supplemental MDRs for infections of 22 patients at the Erasmus Medical Center in the Netherlands after receiving an expert report regarding issues with cleaning the device and the inadequacy of Olympus' processing instructions;

[1] A device is deemed "misbranded" under 21 U.S.C. § 352(t)(2) if a manufacturer fails to furnish material or information, such as initial and supplemental MDRs, regarding the device. FDA requires manufacturers to submit MDRs even if the adverse event takes place outside of the United States if the device is also sold in the United States. Under 21 U.S.C. § 331(a), the introduction of a misbranded medical device to interstate commerce is prohibited. DOJ charged that Olympus continued to ship its Q180V duodenoscopes into the U.S., despite failing to file the MDRs.

[2] https://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingofreusablemedicaldevices/ucm454630.htm.

Failure to Report Adverse Events Results in Criminal Misbranding Settlement and Individual Liability

- Supplemental MDRs for infections of three patients at Clinique de Bercy in France after receiving a lab report regarding contamination on the device and the inadequacy of the company's processing instructions; and
- Initial MDRs for infections of five patients at Kremlin Bicetre in France.

According to the government's charges, Yabe was involved in the response to the expert report regarding infections in the Netherlands and the subsequent failure to submit supplemental MDRs.

Compliance Terms in Plea Agreement

In addition to requiring Olympus to pay $85 million in fines and forfeiture, Olympus' plea agreement contains other compliance, reporting and certification obligations. These requirements include:

- Providing notice of the settlement to relevant U.S. customers and Olympus employees;
- Retaining an independent MDR expert to inspect and review the company's policies and procedures for compliance with MDR obligations and the correction of any deviations from compliance;
- Reviewing and auditing the classification and regulatory status of all endoscope devices manufactured by Olympus;
- Periodically reviewing and reporting of the company's continued compliance efforts; and
- Providing certifications and reviews by the president and board of directors regarding Olympus' MDR compliance program.

FDA and DOJ Have Focused Enforcement Resources on Patient Safety

Notwithstanding the relative rarity of criminal resolutions relating to failures to file adverse event reports, Olympus' settlement is consistent with FDA's and DOJ's policy of taking aggressive enforcement actions to protect patient safety. Prior to the Olympus settlement, the last company to face criminal charges for failure to file adverse event reports was Endovascular Technologies (EVT), in 2003. A government investigation revealed that EVT, a Guidant subsidiary, failed to file 2,628 adverse event reports relating to its Ancure endograft system, which is a surgically implantable device used to treat abdominal aortic aneurysms. Out of the adverse events that were not reported, 12 involved patient deaths and 57 involved emergency procedures where a physician converted an operation into a more invasive procedure. As a result of its failures, EVT pleaded guilty to 10 felonies, including nine counts of introducing misbranded devices into interstate commerce and one count of making false statements to the FDA. The company paid $92.4 million in criminal and civil fines.

DOJ's enforcement philosophy was well-explained in remarks from Ethan Davis, then deputy assistant attorney general for the Consumer Protection Branch, at the 2017 Food and Drug Law Institute Enforcement, Litigation and Compliance Conference. Davis explained that actual consumer harm, threat of harm and fraud are the most important factors considered by DOJ when deciding whether to start an investigation or bring an indictment. He added that DOJ is not interested in using enforcement resources for "one-off technical regulatory violations" where no harm or fraud occurs. This focus is apparent in other examples of DOJ and FDA enforcement activity involving failure to report information affecting patient safety:

- A 2015 Warning Letter to Galena Biopharma for failure to develop adequate written procedures to ensure compliance with Postmarketing Adverse Drug Experience reporting requirements relating to Abstral (fentanyl) sublingual tablets;
- GlaxoKlineSmith's 2012 plea agreement to pay $3 billion to resolve criminal and civil liability arising from activities that included failure to report Avandia safety data that was acquired from post-marketing studies and studies conducted in response to European regulator concerns about cardiovascular safety of the diabetes drug;
- Guidant's 2011 conviction and sentence to pay $296 million in criminal fines and forfeiture for failure to report safety issues related to implantable cardioverter defibrillators, which are used to detect and treat abnormal heart rhythms that can lead to sudden cardiac death; and
- The imposition of $340,000 in civil money penalties against TMJ Implants for failure to file MDRs relating to injuries associated with temporo-manidbular joint implants in 2007.

Failure to Report Adverse Events Results in Criminal Misbranding Settlement and Individual Liability

Key Takeaways

The Olympus settlement continues a trend that has been underway for some time toward FDA and DOJ focusing on cases involving quality and safety, and away from cases involving advertising and promotion. In this case, considerable public attention was trained on the duodenoscope cleaning issues because of investigations by FDA and CDC. Given that environment, it is perhaps not surprising that the government insisted on a criminal resolution and individual liability when it observed a failure to report adverse events. The government possesses a broad range of enforcement tools, from administrative to criminal, and widespread public attention to a public health issue may elevate the risk of criminal liability.

The Olympus settlement also is a stark reminder that FDA regulatory lapses can create meaningful risk for a company. Often, companies relegate responsibility for 483 and Warning Letter responses to the quality or regulatory parts of their organizations and the legal department is not meaningfully involved. Having input from the legal department or outside counsel to work through regulatory observations can position a company to better remediate mistakes and contain risk.

Additionally, the charges in this case yield an important lesson about the need to be vigilant about gaps in knowledge that may result from changes within a company. In early 2012, Olympus allegedly transferred the responsibility for filing MDRs for adverse events occurring outside the Americas from personnel in the United States to personnel in Japan. According to the Information, newly responsible personnel received "minimal training" that left them uncertain about what to include in MDRs and when supplemental MDRs were required. Some employees allegedly informed supervisors of their need for additional training and resources about their MDR compliance duties, but their requests were allegedly denied by Olympus management.

As FDA Commissioner Scott Gottlieb noted at the 2018 Food and Drug Law Institute Enforcement, Litigation and Compliance Conference, "Those who make and sell medical products are participating in a noble health care enterprise. Patients and providers should be able to trust assurances that products meet the gold standard of quality to which they're held, and that they're marketed truthfully and responsibly." The Olympus case is a reminder that companies are wise to focus on continuously improving their regulatory compliance controls, which can be key drivers of risk.