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Client Alert

FDA & Life Sciences Practice Group

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Senate HELP Committee Minority Staff Report Places Blame on Manufacturers, Hospitals, and FDA Regarding Duodenoscope-Linked Antibiotic-Resistant Infections

On January 13, 2016, Senator Patty Murray (D-WA), Ranking Member of the United States Senate Health, Education, Labor, and Pensions ("HELP") Committee, released a Minority Staff Report detailing the results of a year-long investigation into deaths related to antibiotic-resistant infections from contaminated duodenoscopes. The report, ***Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients***, attributes the infections to non-compliance with regulatory obligations by the duodenoscope manufacturers and hospitals using the scopes, as well as system failures by the Food and Drug Administration ("FDA" or the "Agency").

Ranking Member Murray initiated the investigation in January 2015, after several outbreaks of antibiotic-resistant infections became public. According to the report, duodenoscopes can harbor bacteria and spread it to patients, even after they have been cleaned pursuant to manufacturer instructions. Multiple hospitals established the link between antibiotic-resistant infections and patients undergoing procedures with closed-channel duodenoscopes. The report alleges that the duodenoscope manufacturers and FDA were aware of the risk posed by the devices for 17 months before alerting hospitals, doctors, and the public.

Below, we briefly discuss: (1) the report's findings regarding the actions of three primary parties involved with the products (*i.e.*, the manufacturers, the hospitals, and FDA), (2) the report's recommendations, and (3) the implications of the report for industry.

I. Report Findings

As detailed below, the report spreads the blame for the duodenoscope-linked outbreaks broadly, to the duodenoscope manufacturers, the hospitals that use them, and FDA.

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A. Duodenoscope Manufacturers

The duodenoscopes in the United States are manufactured by three companies. The report alleges that by early 2013, one company knew of two independent lab report findings indicating that despite being cleaned according to the manufacturer's instructions, the closed-channel duodenoscopes could still contain and spread bacteria. According to the report, that company did not share this knowledge with FDA until February 2015.

The report also alleges that all three manufacturers failed to meet significant regulatory requirements. For example, the report provides that two of the companies failed to submit the required 510(k) application for significant design modifications to the company's duodenoscopes. These modifications included moving from an open channel to a closed channel, a change that the report states impacted the ability to properly sterilize the products.

Furthermore, the report alleges that all three manufacturers failed to sufficiently test their cleaning instructions to ensure that the instructions resulted in a sterilized product. Yet, according to the report, the manufacturers attested to FDA that the cleaning procedures were tested and reliable.

In addition, the report alleges that all three manufacturers failed to meet their medical device report ("MDR") obligations. For example, the report alleges that one company submitted incomplete and misleading MDRs that made "it nearly impossible for [FDA] to accurately assess the scope and severity of the infections linked to duodenoscopes." Similarly, the report alleges that the other two companies failed to submit timely and complete MDRs and that neither company filed an MDR until the Fall of 2015, despite their duodenoscopes being linked to six antibiotic-resistant infections in the United States earlier in the year.

Finally, the report notes that FDA issued a mandatory recall in November 2015 of certain automated endoscope reprocessors ("AERs"), which are used to clean duodenoscopes. This recall was in response to the Agency finding that many of the U.S. hospitals experiencing duodenoscope-linked outbreaks used an AER manufactured by the same company. The report also alleges that this AER manufacturer failed to file appropriate applications with FDA, test its products to ensure they were cleaned properly, and file complete and accurate adverse event reports.

B. Hospitals

The report also alleges hospital misconduct. Specifically, the report notes that although at least 16 U.S. hospitals traced the antibiotic-resistant infections to duodenoscopes, the hospitals largely did not report the infections to manufacturers, FDA, or the Centers for Disease Control and Prevention. In fact, the report indicates that none of the hospitals that experienced duodenoscope-linked infection outbreaks filed the required adverse event form with the device manufacturers. The report further alleges that when hospitals sent adverse event reports to the manufactures, they were often late, incomplete, or made informally over the phone or through e-mail.

C. Food and Drug Administration

Finally, the report finds fault with FDA's current post-market surveillance system for tracking and monitoring the safety of medical devices on the market. According to the report, because the system is reliant on self-reporting by hospitals and manufacturers, it often contains delayed and incomplete reports.

The report also takes FDA to task for waiting 17 months, after it became aware of the issues associated with the closed-channel duodenoscopes, to issue a safety communication. According to the report, at least 68 patients in the U.S. were infected with duodenoscope-linked antibiotic-resistant bacteria during this period. The report attributes part of the 17-month delay to FDA's ineffective post-market surveillance system and to the Agency's failure to fully understand the extent of the outbreaks.

II. Report Recommendations

To prevent future similar outbreaks, the report recommends that:

- Congress require unique device identifiers to be included in insurance claims;
- Congress authorize full funding for a National Medical Device Evaluation System to ensure that FDA is able to effectively monitor the safety of marketed medical devices;
- Congress clarify that FDA has authority to deem a 510(k) application incomplete if the application does not provide sufficient evidence that a device can be safely cleaned and reused;
- FDA evaluate the design of closed-channel duodenoscopes and implement a phased recall to ensure that necessary fixes or modifications are made;
- FDA update its guidance regarding when 510(k) clearance is required for modifications (*FDA has listed this guidance on its agenda as a top priority for 2016*);
- FDA implement new draft guidance to more quickly disseminate information to health care providers regarding potential patient safety issues related to a medical device (*This recommendation refers to draft guidance issued by FDA in December 2015, which has largely been criticized by industry. Comments are due on the draft guidance on February 29, 2016, but given the recommendations in this report, there may be an opportunity to seek extension*); and
- Compliance by hospitals with adverse event reporting related to medical devices be made a Condition of Participation in Medicare.

III. Implications

Ranking Member Murray's Minority Staff Report will likely trigger inspections, enforcement actions, investigations, and lawsuits by government agencies, including FDA, the Department of Justice, and the Department of Health and Human Service's Office of Inspector General, as well as by Congress and the plaintiffs' bar. FDA, in particular, having been censured by Congress for its failure to respond adequately to the duodenoscope-linked outbreaks, has a powerful incentive to take actions that set examples.

FDA already provided a signal with regard to how it is likely to proceed in a **news release** issued on January 15, 2016. In March 2014, the Agency required one of the duodensoscope manufacturers to submit a 510(k) for modifying the device by moving from an open to a closed-channel. FDA cleared the closed-channel device, with modifications to make it easier to clean, on January 15, 2016. The company is voluntarily recalling the original model to make necessary repairs, and it plans to conduct annual inspections in user facilities to ensure that the duodenoscopes are appropriately maintained.

Manufacturers of all devices, especially those that manufacturer duodenoscopes, or similar products, or other products that are reused and reprocessed, are likely to be scrutinized. FDA is likely to focus on ensuring that device manufacturers are submitting 510(k)s for appropriate modifications. Device manufacturers should examine their 510(k) histories and processes, to ensure that significant design, component, and manufacturing modifications, as well as major modifications to intended use, have appropriate clearances. FDA also is likely to scrutinize MDR processes to ensure that mandatory reports are filed and that reports are consistent, complete, and timely. Device manufacturers should re-examine their current MDR processes and their processes for interacting with customers, especially hospitals, to ensure compliance with FDA regulations.

In addition, FDA was already looking for ways to revise its policies on 510(k) modifications, and capture and disseminate information about safety signals more quickly. The report recommendations put significant pressure on FDA to do so more quickly, and they identify issues for continued Congressional involvement. Finally, assuming that the report recommendations are implemented, they could increase product liability issues by providing mechanisms that can better link products and injuries.

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In addition, our team a calls upon the expertise of lawyers in several related areas within the firm, including the civil and criminal litigation group and the government advocacy and public policy group, which have effectively represented clients who are the targets of government initiated lawsuits and investigations, respectively. Please let us know if you have any questions.

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