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Client Alert

FDA & Life Sciences Practice Group

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FDA Launches Form for Reporting Allegations of Misconduct by Device Manufacturers

Program Has Broad Reach

On October 21, 2016, the Food and Drug Administration launched a webpage that contains an Allegations of Regulatory Misconduct Form to enable whistleblowers, competitors, and others to report allegations of regulatory misconduct involving medical devices quickly, easily, and anonymously. The webpage provides detailed information explaining how the form should be filled out and how FDA will use the information.

Allegations of Regulatory Misconduct

As FDA states on its webpage, the Allegations of Regulatory Misconduct Form can be used to report any claim that a device manufacturer, or an individual marketing a device, is manufacturing or marketing a device in a manner that violates the law. This broad application means that whistleblowers can report alleged design, manufacturing, or other quality systems violations, or alleged violations of device reporting or marketing requirements (e.g., alleged off-label promotional activities), to FDA. It also means that competitors can report on one another.

CDRH provides a list of examples of allegations that it expects to be reported against device manufacturers, including:

- Off-label promotion activities
- Failure to submit medical device reports (MDRs) or to conduct follow-up investigations in accordance with regulatory requirements
- Non-compliance with design or manufacturing responsibilities
- Marketing devices without proper 510(k) clearance or PMA approval (including marketing devices with uncleared or unapproved modifications to design or labeling made after initial clearance or approval)
- Importing violative devices (or otherwise violating import/export requirements)
- Failure to register establishments and list medical devices

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- Knowingly deceiving FDA

Submission Process

The Allegations of Regulatory Misconduct Form is accessible online and contains a series of free-text prompts to help users input relevant information, such as the identity of the company allegedly violating the law, a description of the device at issue, and a description of the alleged legal violation(s). The submitter does not have to complete all sections of the form, and the form can be submitted anonymously. FDA notes on its webpage, however, that if the form is submitted anonymously, it will be unable to follow up with the submitter to request additional information. FDA, therefore, encourages submitters to include their contact information. FDA states further that the contact information for submitters will not be shared outside of FDA except when the Agency is required to do so by law, regulation, or court order. It should be assumed, therefore, that FDA will share any reports deemed credible for potential follow-up with law enforcement agencies and the U.S. Department of Justice.

Agency Use of the Allegations

According to FDA's webpage regarding this new reporting program, all allegations of regulatory misconduct will be reviewed by the Center for Devices and Radiological Health (CDRH or the Center). FDA states that it will prioritize its reviews based on the patient risk posed by the alleged misconduct. CDRH will take further action in response to the allegations as it sees fit. Those actions may include issuing a warning letter, initiating an investigation of the manufacturing facility, or requesting a recall. In the alternative, if no immediate action is warranted, CDRH may monitor the allegation by keeping watch for additional complaints of misconduct and/or scrutinizing information obtained from facility inspections. CDRH also may contact the manufacturer to request additional information about the alleged misconduct.

Potential Users of the Program

This new reporting program is likely to be an attractive option for potential whistleblowers within a company who feel that the company has not adequately responded to internal reports of misconduct. Thus, the new program gives leadership at medical device companies one more reason to ensure that the company has a strong internal compliance process for receiving and investigating internal complaints of potential regulatory violations or deficiencies.

In addition, the new reporting program is likely to be used by companies to complain about perceived violations by their competitors. Of course, other mechanisms already exist to address these situations. For example, companies can use the trade complaint process as an avenue for submitting allegations to FDA regarding competitors' marketing practices or other potentially violative activities. However, the new Reporting Allegation of Regulatory Misconduct Form provides a simpler and easier avenue for alerting FDA to such activities. Moreover, it allows companies to report competitors anonymously and in a manner that is non-confrontational. This is often important to companies that share clients or interact with the same key opinion leaders as their competitors.

Key Differences from the Bad Ad Program

FDA's Center for Drug Evaluation and Research (CDER) launched a similar reporting program in 2010, known as the Bad Ad Program. The Bad Ad Program, however, as its name suggests, has a narrower focus. The Bad Ad Program, unlike CDRH's new program, does not provide a mechanism for reporting all alleged regulatory violations. Rather, it facilitates the reporting of allegedly untruthful or misleading marketing practices for prescription drugs. The Bad Ad Program has resulted in the issuance of untitled letters and warning letters regarding marketing practices.

FDA indicated that its objective in creating the Bad Ad Program was to raise awareness among healthcare professionals (HCPs) about misleading prescription drug promotion, though the program of course also provides a mechanism for HCPs to report such promotion to FDA. Interestingly, FDA does not mention raising awareness among HCPs as an objective of the Allegations of Regulatory Misconduct Program. Instead, it appears that the objective of the CDRH program is to further encourage direct reporting to trigger greater CDRH and law enforcement scrutiny of medical device company activities.

Key Impacts on FDA Actions Against Device Companies Moving Forward

Although the Allegations of Regulatory Misconduct Program facilitates the reporting of allegations related to all types of regulatory violations, it will be interesting to watch whether the reports submitted are disproportionately related to alleged off-label promotional activities, given: (1) the recent high-profile decisions related to the alleged off-label promotion of devices, including the acquittal of Vascular Solutions, Inc. and its CEO, *see U.S. v. Vascular Solutions, Inc.*, No. 5:14-CR-00926 (W.D. Tex. 2016), and the misdemeanor convictions of two former device company executives in *U.S. v. Facteau, et al*, No. 1:15-CR-10076 (D. Mass. 2016), (2) FDA's public meeting on November 9-10, 2016 on manufacturer communications regarding unapproved uses of approved or cleared medical products, and (3) FDA's recent issuance of draft guidance entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device," which, among other things, provides examples of the types of changes to device labeling, including their indications for use, that FDA considers to require the submission of a new 510(k).

In addition, it will be interesting to watch how CDRH implements the Allegations of Regulatory Misconduct Program moving forward and whether it leads to an immediate uptick in inspections, untitled letters, warning letters, or enforcement actions. In the first year of the Bad Ad Program, CDER received approximately 328 reports, a significant increase over the 104 similar reports that were made the previous year. Not all of those reports, however, were actionable or even appropriate for a more comprehensive review.

What remains unknown is how CDRH is preparing to react to complaints made under this program. Presumably, it will have to create and implement a process to identify reports that warrant follow-up and facilitate timely and comprehensive review of those reports. Regardless, this new program should remind medical device companies to re-evaluate their internal compliance processes to protect themselves from allegations of misconduct.

King & Spalding will continue to follow CDRH's Reporting Allegations of Regulatory Misconduct Program, the manner in which it is implemented, and how it affects FDA compliance and enforcement actions. If you have any questions about the program, the Allegations of Regulatory Misconduct Form, or guarding against allegations made thereunder, we would be pleased to assist.

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

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