

Hypothetical problem situations involving Medical Device Reporting

The following problems were posed in Jeffrey Shapiro's article in the Summer 2003 issue of the Regulatory Compliance Newsletter. Here are Jeffrey Shapiro's answers.

Disclaimer

These hypotheticals and responses do not constitute, and are not intended as, legal advice. They are intended as a teaching tool to help companies better understand the issues involved in complying with FDA's Medical Device Reporting regulation (21 C.F.R. Part 803). Companies facing an MDR issue, no matter how seemingly similar to the hypotheticals, should take into account their own circumstances when formulating a course of action. Companies should consult their legal counsel as appropriate.

1. Hypothetical

You have just started as Complaint Coordinator at a large medical device company. You inherit some open complaint files. On your first day, you review the files and find that one of the complaints appears to be MDR reportable and the report is at least 30 days overdue.

You notice, however, that this type of complaint is not reportable under the company's internal MDR reporting guideline for this product. It turns out that the company's internal guideline does not properly conform to the requirements of FDA's MDR regulation. Upon investigation, you learn that there may be as many as 300 to 400 similar complaints in the past three years that the company did not report to FDA, because of the inaccurate MDR reporting guideline.

What should you do?

Response

This hypothetical raises difficult issues that will likely require assistance from legal counsel at the earliest possible moment. Any action or inaction could have significant legal consequences. We can only scratch the surface in this response.

As a first step, the company needs to determine the scope of the problem. To do so, the guideline should be corrected and past complaints reviewed to determine how many are potentially reportable under the new guideline that were not reported under the old guideline. If it is true that the company potentially failed to report 300 to 400 complaints to FDA as MDRs, the company must make a difficult judgment. On the one hand, although these MDRs would obviously be late, it may be better for the company to file them retrospectively than to wait for FDA to discover the apparent violations. On the other hand, even if the company volunteers the information, FDA could still pursue a criminal and/or civil enforcement action with significant penalties. The company should consult legal counsel and make a considered judgment about how to proceed in light of all of the relevant circumstances.

If the company decides to file retrospectively, the company should consult FDA in advance so that they know what to expect. The company should consider asking FDA to accept a summary report if there are numerous individual MDRs; this approach would save time and effort for both FDA and the company. If FDA agrees, then the company should create a summary report for FDA. If not, then the company should prepare and file individual MDRs. The company should remember to train all relevant employees to follow the newly revised MDR guidelines.

Again, this situation—the discovery of possible past violations—can potentially expose the company to significant criminal and civil liability. Legal counsel should be consulted at the earliest possible moment.

2. Hypothetical

You are the Director of RA at a medium size company that sells a cardiovascular surgical device. A physician's office staffer calls to say that a patient being treated with the device died in surgery.

The physician (and the office staff) are otherwise uncooperative and refuse to provide any more information or to return the device.

What should you do?

Response

FDA requires a "good faith" effort to get information, including at least one request in writing. The number of follow ups with the physician's office that constitute "good faith" cannot be set mechanically but is related to the nature and severity of the event.

The company should keep a file reflecting all requests made (telephone and in writing) and responses received (or lack of a response). In the final analysis, the most prudent course from a regulatory standpoint would be to report the complaint to FDA as an MDR and note the lack of cooperation from the physician office as reason for the lack of information about the event and the connection between the device and the event.

3. Hypothetical

Your small company is dependent upon sale of one product. One day, the company receives a complaint that is probably MDR reportable. There is an argument against reporting, but FDA would likely disagree with it. As Director of RA, you recommend filing an MDR report.

The VP of Marketing vehemently objects, stating that your fiercest competitor receives such complaints all the time and never files MDR reports. The VP of Marketing states that if your small company begins to report this type of complaint, the competitor will use it as a talking point and your company will lose sales.

What should the company do and why?

Response

If an event is clearly reportable, a company must report when required regardless of what its competitors do, because it is not a legal defense to point to a competitor's violations. This hypothetical, however, muddies the waters by characterizing the event as “probably” reportable. In the face of this uncertainty, the company must decide how conservative it wishes to be. On the one hand, there may be a competitive disadvantage that arises from reporting. On the other hand, there are potentially very significant sanctions for failing to report a complaint that should have been reported, which can include civil penalties, criminal fines and imprisonment, depending upon factors such as intent, magnitude and duration of the violations. In recent years, the FDA has been increasingly willing to pursue criminal cases based upon MDR violations.

In this particular hypothetical there are insufficient facts to determine whether the event is reportable. In close call cases, if the decision is not to report, the company should maintain thorough documentation explaining why it is reasonable not to do so. The company should also consider attempting to take advantage of the provision in the MDR regulation indicating that an MDR report is not required if there is information that would cause a person who is qualified to make a medical judgment to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury or that a malfunction would not be likely to do so if it were to recur. 21 C.F.R. 803.20(c)(2). The best approach would be to obtain a written statement from a physician, nurse, engineer or other appropriate professional.

Another consideration is that the company needs to be consistent in determining whether close call events are reportable. Often, companies implement internal guidelines that set forth examples of events that the company believes are (or are not) reportable. This approach can be helpful in training employees and ensuring consistent reporting practices and in demonstrating to FDA the company's decision making process. Such guidelines should be carefully reviewed for accuracy and completeness by qualified regulatory personnel and/or legal counsel.

4. Hypothetical

The manufacturer of digital thermometers receives a complaint that the digital display of the Model 1000 frequently displays garbled symbols that do not resemble a temperature reading.

The complaint coordinator immediately dismisses the complaint because the company does not manufacture or distribute a thermometer called the Model 1000.

Did the complaint coordinator act appropriately in this situation?

Response

The complaint coordinator needs to be cautious about reaching the conclusion that the device is not manufactured by the company. Some companies have many different product models—the complaint coordinator should make certain that the consumer has not misreported the model number and that the device truly is not manufactured by the company.

If the complaint truly does not involve any of the company's devices, but appears to be MDR reportable, the company is supposed to forward it to FDA and indicate as much. If the complaint is not MDR reportable, then the company is not required to forward it to FDA. Most companies, however, would simply forward the complaint to FDA as a matter of prudence.