Appendix 5.5.1
More Information About Medical Device Reporting

Medical Device Reporting (MDR) is the vehicle through which the Food and Drug Administration receives information about significant medical device adverse events from manufacturers, importers, and user facilities, so they can be detected and corrected quickly.[1] Voluntary reports can also be made by consumers and healthcare professionals through the MEDWATCH program. The FDA has yet to enable online reporting for device manufacturers and importers (although this is expected in the near future), but consumers can submit reports through the FDA website.[2]

Manufacturers and importers of medical devices have been required since 1984 to report all device-related deaths, serious injuries, and certain malfunctions to the FDA. Under the Safe Medical Devices Act of 1990 (SMDA), device user facilities also were mandated to report device-related deaths and serious injuries to the FDA and the manufacturer, if known. User facilities also must submit to the FDA a semiannual summary of all reports made during the time period. Despite these requirements, reports have shown there is widespread underreporting of such device-related incidents. One 1986 report showed that less than 1 percent of device problems encountered in hospitals were properly reported, with more serious problems increasingly less likely to be reported. A follow-up study in 1989 confirmed that serious shortcomings existed in the MDR system, despite its full implementation.[3]

To manage MDR-related issues and other customer/user concerns, most companies establish a complaint system to help ensure that all complaints are received and processed consistently and appropriately. A company must be vigilant in managing each complaint, especially if it could potentially be considered a report of an adverse event (or an event that *could cause* an adverse outcome, even if it does not). As a company grows, it is important to recognize that the maintenance of complaint and MDR reporting systems will require dedicated resources.

The MDR reporting process is prescriptive and straightforward. Occasionally, a company will receive a request for a follow-up report on an MDR. Or, if a pattern begins to emerge that gets the attention of FDA, it could trigger a "for cause" audit. However, companies are generally advised to over-report when it comes to actual or potential adverse events. Typically, there are far worse risks and penalties associated with under-reporting than over-reporting. It is also preferable for a manufacturer to voluntarily report issues, rather than having consumers or healthcare professionals report issues, since this typically results in more swift and severe attention from the FDA. All company employees must understand that reporting any issues into the complaint system is essential in order to avoid under-reporting. Furthermore, the complaint system can serve as yet another source for continuous improvement, cost savings, and preventive opportunities if issues and problems are identified early.

MDRs are reviewed, coded, and tracked on the MAUDE system—a searchable database.[4] This system includes voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.[5] Reports generally lag about a month or more behind the date of the event. Because it is publicly accessible, this system can be useful in looking up competitive technologies and understanding patterns of adverse events or device failures.

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[1] "Medical Device Reporting," U.S. Food and Drug Administration, http://www.fda.gov/medicaldevices/safety/reportaproblem/default.htm (March 21, 2014).

[2] See "MedWatch Online Voluntary Reporting Form," U.S. Food and Drug Administration, https://www.accessdata.fda.gov/scripts/medwatch/ (March 21, 2014).

[3] "Medical Device Reporting," op. cit.

[4] See "Manufacturer and User Facility Device Experience Database - (MAUDE)," U.S. Food and Drug Administration, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (March 21, 2014).

[5] "Search MAUDE Database," U.S. Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm (March 21, 2014).