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MEDICAL DEVICE REPORTING

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Medical Device Reporting through the MAUDE system

In the past, consumer advocates and Congress alike have cited two primary problems in the Medical Device Reporting (MDR) system:

- (1) Inability of the MDR system to obtain meaningful information (either because manufacturers will not, or cannot, provide performance data, and/or the agency has not successfully captured or organized the data in a meaningful way once obtained.
- (2) FDA's ability to operate the management information system and conduct meaningful analysis to obtain data regarding device performance.

The effectiveness of the MDR system in producing meaningful information is limited to the extent that manufacturers and user facilities accurately report adverse events. The regulation as stated in the SMDA of 1990, created a check in the system by requiring user facilities to report adverse events not only to the manufacturer but also to FDA directly. It was believed that the Center for Devices and Radiological Health could thereby track manufacturers who did not in turn notify FDA of device problems (as they were required to do under law) or who inaccurately reported adverse events. However, because of the backlog of MDRs and difficulty enforcing "mandatory user facility" reporting, the Agency's checks-and-balance system has not proven effective.

For example, we have discovered serious discrepancies in MDR reporting for several manufacturers of breast implant medical devices.

Since July of 1996, 167 MDRs have been filed by McGhan Medical for their silicone-gel filled breast implants under the 510(k) identifier K881046. This identifier is not a McGhan 510(k) number, it belongs to a 510(k) assigned to U.S. Dental Corporation's Super Pik Massaging Pick for Oral Hygiene, submitted to FDA in March of 1988 and cleared in May of 1988.

As part of the conditions of approval and post-market surveillance of saline breast implants, Mentor Corporation and McGhan Medical (now Inamed Corporation) were required to report

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MDRs using the PMA identifiers included in their 2000 saline breast implant PMA clearance letters.

The majority of Mentor Corporation's MDRs associated with their saline breast implant products have been filed under the identifier PMA#940039. Yet this identifier does not exist in FDA's approved PMA database. Therefore, it appears to be an "incorrect" PMA number used in Mentor's MDRs filed with FDA, particularly when used alone and without any other correct baseline identifier.

Both Mentor Corporation and McGhan Medical have filed MDRs using PMA numbers not in FDA's system. Mentor has filed MDRs under the identifier P940039 and McGhan has filed under the identifier P940038. PMA numbers are assigned chronologically, based on the date submitted to FDA. Therefore, we can determine that PMAs with these numbers would have been filed sometime between November 23, 1994 and December 22, 1994. This "coincidence" would suggest that McGhan and Mentor may have been seeking approval for breast products in 1994 that were either not filed, denied approval, or perhaps still under review. Yet, there were no Federal Register notices regarding a PMA application or agency action submitted during this time period.

These examples serve to illustrate the inherent flaws in the FDA's MDR system. We have to question the usefulness of a system that would accommodate such blatant errors. The MDR system is intended to provide FDA with an "early warning system" for medical devices that have malfunctioned or may cause or contribute to death or serious injury. Yet, if false or incorrect reporting by manufacturers is commonplace, how valuable is this system in evaluating the safety of medical devices on the market.

Alternative Summary Reporting (ASR)

Manufacturers of saline and silicone breast implants were given an exemption to report under the new Alternative Summary Reporting system in 1999. Yet, according to FDA's own statements, Alternative Summary Reporting is not to be used for PMA reporting for Class III devices approved less than two (2) years.

Under the authority of 21 CFR Part 803.19, the FDA is required to ensure that manufacturers investigate and evaluate complaints as specified in 21 CFR 803.18(e) and 803.50 and to establish and maintain MDR event files as specified in 21 CFR 803.18 for events covered by this exemption.

We have learned that the majority of adverse events filed for Mentor Corporation and McGhan Medical have been filed with FDA as Alternative Summary Reporting (ASR) for the years 1999-2001. During this time approximately 34,356 adverse event reports were filed with the FDA through the ASR system for these manufacturers. Of those, 30,290 are for saline breast implants alone.

In order to find usefulness in this data and identify trends and anomalies associated with the occurrence of these medical devices, there has to be a level of scrutiny around the specific generation of the device. The adverse event reports for all saline and silicone breast implants are

generically lumped together in a manner that is incapable of producing meaningful information regarding the safety and effectiveness, and conversely failures and malfunctions, of these devices by generation. Therefore, if a specific generation of breast implant devices were culpable in a significant number of these reports, it would be impossible for FDA to identify provided the current system of reporting and recording of adverse events.

Recommendations

In order to enhance the quality, utility, and clarity of the information collected, we recommend the following changes at a minimum:

- The collection and analysis of adverse event reports should be aggregated by generation of device in order to assure accurate evaluation of the failures and complications associated with each particular model or generation.
- Quality assurance measures should be established to ensure that manufacturers and user facility report adverse events to the MDR system in an accurate and timely manner. Furthermore, the false or inaccurate reporting (including the use of incorrect identifiers) should result in swift regulatory action by the Agency. Ensuring accuracy around MDR reporting is critical since the public at large and officers with FDA rely on the information obtained through the MAUDE system, via the identifiers associated with a particular manufacturer, in order to evaluate the safety and effectiveness, and conversely the failures, of medical devices.