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MEDICAL DEVICES

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

January 10, 1996

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20850

Re: Docket No. 91N-0295

To Whom It May Concern:

On behalf of Public Citizen's Health Research Group, we offer the following comments on the Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and Registration regulation, Docket No. 91N-0295. Although we support the FDA for finally publishing its long-awaited regulations, we object to several provisions of the final rule. These objections are summarized below.

1) Reporting Schedule for Manufacturers.

We oppose changing the existing 15-day schedule of reporting adverse events to the proposed 30-day schedule. Under existing regulations, manufacturers must report deaths or serious injuries resulting from the use of their products to the FDA by telephone within five calendar days and in writing within 15 working days of initially receiving the information. Reports of malfunctions must be made both by telephone and in writing within 15 days.

The new regulations would extend the time for manufacturers to submit medical device reports of adverse events to 30 days. Five-day reports would be required only if the manufacturer or the FDA believed that remedial action was necessary to prevent an unreasonable risk of substantial harm to the public health.

The new regulations require user facilities to submit reports to the FDA and the manufacturer within 10 days of becoming aware of device-related deaths. While this information will be received by the FDA relatively quickly, reports of serious injuries or malfunctions will take considerably longer. We are thus concerned that problematic devices will not become known to the FDA for up to 40 days after adverse events occur (10 days for user facility reports plus 30 days for manufacturer reports). At this point, follow-up investigations will be difficult to accomplish. Since most device failure occur within a few months after the introduction of the device, a 40-day delay could result in a large number of injuries to patients before the FDA has even become aware of the problem.

Furthermore, manufacturers may not have the objectivity to recognize trends in adverse events occurring with their own products. Thus, they may not recognize or admit problems in five-day reports.

Finally, there is particular irony in requiring user facilities, who are encountering medical device reporting requirements for the first time, to follow a strict 10-day reporting deadline--while at the same time extending the reporting deadline for manufacturers, who have been subject to reporting requirements for over 10 years.

We urge the FDA to reconsider the 30-day time frame for reporting adverse events and reduce the length of time to a more reasonable 10-15 days.

2) Expanded Definition of Physician's Office

The Safe Medical Devices Act mandates that physicians' offices are excluded from the definition of user facilities and are thereby excluded from adverse event reporting requirements. The FDA has proposed that groups performing functions similar to physicians' offices such as dental offices and offices of other health care practitioners (including chiropractors, optometrists, nurse practitioners, school nurse offices, employee health clinics, and free-standing care units) fall within the definition of physicians' offices and therefore should also be excluded from reporting.

We oppose the inclusion of dental offices and health care practitioner offices (as described above) within the definition of physician's offices (thereby excluding them from the requirement of reporting adverse events). While we recognize that the financial burden of reporting adverse events could be significant for both physicians and health care practitioners in private practices, we also believe that these personnel are, in many cases, the individuals most likely to observe and treat adverse reactions.

We thus request that the physician's-office exemption for submitting medical device reports be defined as narrowly as permitted by statute. In particular, facilities such as dental offices, chiropractic offices, and optometrist offices, that often distribute medical devices, should <u>not</u> be exempted from reporting requirements. Furthermore, physicians' offices that operate as clinics with radiology facilities and laboratories, should be considered outpatient diagnostic and treatment facilities and should be required to submit reports.

3) Definition of User Facility

The FDA has defined a user facility as "a hospital, ambulatory surgical facility, nursing home, or an outpatient diagnostic or treatment facility which is not a physician's office." The FDA raised the question of whether blood banks that operate in hospitals or as outpatient diagnostic centers fall within the definition of user facility.

We believe that the purpose of these regulations is to increase public safety by ensuring that unsafe devices are recognized and adverse reactions are prevented in as many cases as possible

through changes in labeling, warnings letters, safety alerts, or product recalls. We see no reason to exclude devices associated with blood banks or any other specialty area from these requirements.

The definition of user facility should be sufficiently broad as to include all facilities (other than physician offices) that either a) use unique medical devices in diagnosis or treatment (for example blood banks or dialysis centers), or b) have the unique ability to recognize problems with medical devices (such as imaging centers or primary care facilities).

Summary

Public Citizen is fully supportive of the FDA's efforts to increase the quantity and quality of medical device reports of adverse events. However, we oppose the weakening of existing manufacturer reporting requirements and we disagree with the FDA's exclusion of certain facilities from reporting requirements. We are concerned that the delays and restrictions written into the proposed regulations will subject medical device users to unnecessary risks that the FDA will be unable to address in a timely fashion.

Sincerely,

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