

January 1997

# MEDICAL DEVICE REPORTING

## Improvements Needed in FDA's System for Monitoring Problems With Approved Devices



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**Health, Education, and  
Human Services Division**

B-266228

January 29, 1997

The Honorable James M. Jeffords  
Chairman  
The Honorable Edward M. Kennedy  
Ranking Minority Member  
Committee on Labor and Human Resources  
United States Senate

The Honorable Thomas J. Bliley, Jr.  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Commerce  
House of Representatives

The Food and Drug Administration (FDA) is responsible for protecting the American public from unsafe and ineffective medical devices, which range from simple household items, such as thermometers, to implanted heart valves. More than 100,000 medical device products are currently in use in the United States, including a substantial number that health care professionals use every day to diagnose, treat, or prevent illness; improve the quality of patients' lives; and support and sustain life. Over the past 15 years, the U.S. medical device industry has grown from 5,900 to 16,900 firms. More than \$40 billion was spent on such devices in the United States in 1994.<sup>1</sup>

FDA's adverse event reporting system gathers information about problems associated with marketed medical devices, which enables FDA and the medical device industry to work together to take corrective action on device problems and, when appropriate, to alert the public to potentially hazardous devices to prevent injury or death. Although medical device manufacturers have been required to report malfunctions and device-related injuries and deaths to FDA since 1984, hospitals and other facilities that use devices were not required to report these matters and, consequently, rarely did so.

Recognizing this problem, the Congress enacted the Safe Medical Devices Act of 1990 (SMDA 90), which expanded the reporting requirements to include user facilities, such as hospitals and nursing homes, and medical

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<sup>1</sup>Medical Device Regulation: Too Early to Assess European System's Value as Model for FDA (GAO/HEHS-96-65, Mar. 6, 1996).

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device distributors.<sup>2</sup> SMDA 90 required user facilities to report device-related adverse events to FDA and manufacturers of devices. SMDA 90 also required us to report on user facilities' compliance with the act's reporting requirements. To carry out this responsibility, we sought answers to five questions: (1) Has the enactment of SMDA 90 led to an increase in reporting of device-related adverse events to FDA? (2) Have the amount and quality of information from user facilities enhanced FDA's ability to quickly identify and take action on device problems? (3) How have manufacturers and FDA responded to device problems identified in user facility reports? (4) How well does FDA communicate device problem trends and corrective actions taken to user facilities and the public? (5) What changes, if any, need to be made to the user facility reporting requirements and FDA's adverse event reporting system to improve medical device problem reporting?

To address these questions, we met with officials from FDA's Center for Devices and Radiological Health (CDRH) to discuss the agency's efforts to implement the user facility reporting requirements of the act and procedures used to process, review, and take action on adverse event reports. We analyzed data from FDA's adverse event reporting system on device-related incidents that occurred during fiscal years 1987 through 1995. We also contacted representatives of the medical device community (manufacturers, user facilities, and nonprofit organizations with health care-related objectives) to discuss their views on the user facility reporting requirements and on whether or not changes to the law and FDA's adverse event reporting system are needed. Appendix I provides a more detailed description of our scope and methodology. We did our work between April 1995 and January 1997 in accordance with generally accepted government auditing standards.

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## Results in Brief

Although the amount of information reported to FDA about medical device problems has increased dramatically since SMDA 90 was enacted, FDA does not systematically act to ensure that the reported problems receive prompt attention and appropriate resolution. As a result, FDA's adverse event reporting system is not providing an early warning about problem medical devices as SMDA 90 intended.

During fiscal years 1991 through 1994, FDA received almost four times as many adverse event reports from device manufacturers as it did during fiscal years 1987 through 1990. However, the extent to which user facility

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<sup>2</sup>P.L. 101-629, Nov. 28, 1990.

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reporting under SMDA 90 directly accounted for the increased volume of reports is unclear because, until recently, FDA did not require manufacturers to disclose whether serious injury reports originated from user facilities or from some other source. This increased volume made it difficult for FDA to process and review reports in a timely manner. To address this problem, FDA chose to give priority to death and serious injury reports, which resulted in its delaying for nearly 2 years processing and reviewing almost 50,000 malfunction reports. Malfunction reports are essential in alerting FDA to potentially serious device problems before they result in death or serious injury. To better manage the reporting workload in the future, FDA has initiated several changes to the adverse event reporting system, such as consolidating reporting system components and using electronic reporting.

FDA has received significantly fewer adverse event reports from user facilities than it expected. Moreover, much of the information that user facilities did provide was of poor quality and incomplete, in part because FDA did not issue the final medical device reporting regulation in a timely manner or periodically educate user facilities about their responsibilities under SMDA 90. For example, our comparison of death reports submitted by manufacturers and user facilities found that user facilities did not report about 5,000 device-related deaths to FDA between fiscal years 1992 and 1995, which may have been required by law. FDA learned about these deaths because they were reported by manufacturers.

Although FDA contends that it notifies manufacturers and user facilities about imminent hazards and industrywide safety concerns, it does not routinely document the corrective actions it takes—or those taken by manufacturers—to address reported medical device problems. As a result, it is unclear how manufacturers and FDA have responded to device problems reported by user facilities. Further, FDA does not keep track of the length of time it takes to process, review, and initiate action on serious device-related problems or the time that elapses before manufacturers resolve the problems.

Manufacturer and user facility representatives told us they do not know how FDA uses adverse event reports to protect the public health. Although feedback to medical device users could increase knowledge about the performance of medical devices, improve patient safety awareness, and assist users in making device purchase decisions, FDA does not routinely communicate the results of analyses of medical device problems and corrective actions to the medical device user facility community.

FDA and representatives of both medical device users and manufacturers believe that the reporting system is overburdened with reports and data that may not be necessary to detect and resolve device problems. FDA is studying the feasibility of using a statistical sample of user facilities to reduce the volume of reports it has to review. However, concerns exist about whether a sample of users can provide FDA with the information that it needs to protect the public health. Further, while FDA's initiatives may improve the adverse event reporting system, they do not ensure timely resolution of device problems, user facility compliance with SMDA 90, or systematic dissemination of adverse event-related information to the medical device community.

## Background

To protect the public from harmful medical devices, the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act expanded FDA's responsibility for regulating medical devices in the United States. FDA uses three primary mechanisms to ensure that all medical devices are safe and effective for their intended use:

- Premarket review is a system of checks, reviews, and controls intended to be applied before new devices are approved and made available to the public.
- On-site inspections of device manufacturers' facilities are intended to ensure compliance with FDA laws and regulations, including good manufacturing practices (GMP), and prevent the production and marketing of defective devices.
- The adverse event reporting system is intended to provide FDA with early warning of problems associated with devices after they become available for public use. This monitoring system gathers information about device problems that could necessitate withdrawing a device from the market or taking other corrective actions.

Among other things, the act authorized FDA to establish a reporting system for adverse events associated with the use of medical devices. As a result, FDA established the Mandatory Medical Device Reporting (MDR) system. Under this system, since 1984, manufacturers of medical devices have been required to report to FDA—and maintain records on—device-related deaths, serious injuries, and malfunctions<sup>3</sup> that, should they recur, would be likely to result in death or serious injury. A system called the Medical Device and Laboratory Problem Reporting Program (PRP) was

<sup>3</sup>"Malfunction" refers to the failure of a device to meet one of its performance specifications or to otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

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established to receive voluntary reports from health care professionals. FDA's responsibility is to audit manufacturers' performance to identify systemic problems and trends associated with an individual firm, a specific device, or the entire device industry, issuing guidance as necessary.

The Office of Surveillance and Biometrics (OSB) within CDRH operates the adverse event reporting system. OSB reviews adverse event reports on medical devices to identify, manage, and resolve public health issues; prepares safety alerts and public health advisories;<sup>4</sup> and provides regulatory guidance on adverse event reporting issues. CDRH estimates that it spent approximately \$8 million<sup>5</sup> and used about 80 full-time-equivalent (FTE) positions<sup>6</sup> in support of the medical device reporting program in fiscal year 1996. This represents an increase of about \$606,000 and three FTEs over medical device reporting program expenditures in fiscal year 1995.

When FDA receives an adverse event report, OSB health care analysts evaluate and compare the report with other information contained in FDA databases. A decision is then made about whether or not the device problem poses a potential risk to the public health. If so, depending on the nature and severity of the risk, an analyst may initiate a follow-up investigation, which generally involves a written request for additional information or an inspection of the manufacturer or user facility. (App. II provides a detailed description of FDA's report evaluation process.)

For years, FDA's implementation and enforcement of the medical device reporting regulation have concerned the Congress. Studies issued by our office, the former Office of Technology Assessment, and the Office of Inspector General of the Department of Health and Human Services (HHS) have found significant weaknesses in FDA's ability to gather information about medical devices in use. For example, in 1986, we found that less

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<sup>4</sup>A safety alert is issued by FDA in response to an identified problem that has resulted in a death, a serious injury, or both and that requires immediate action. A public health advisory is issued in response to a potential death, serious injury, or both.

<sup>5</sup>This estimate includes all of the CDRH and field office dollars expended for the medical device reporting program. It includes computer support, contract costs for data entry of the adverse event report information, operating expenses, and salary costs (excluding benefits) associated with CDRH and field personnel.

<sup>6</sup>This estimate reflects resources expended by CDRH as well as by FDA's field force for the medical device reporting program. In addition to the actual program FTEs for OSB, the estimate includes (1) CDRH FTEs for support services for the program, such as computer and administrative/management assistance, and (2) field FTEs used to follow up on manufacturer and user facility reports.

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than 1 percent of the device problems occurring in hospitals were reported to FDA and that, the more serious the problem with the device, the less likely it was to be reported to FDA.<sup>7</sup> In a follow-up study, we concluded that the problem still existed despite full-scale implementation of the medical device reporting regulation.<sup>8</sup>

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## SMDA 90 and Related Regulations

To improve the flow of information about medical device problems to FDA's adverse event reporting system, the Congress passed SMDA 90, which requires user facilities and device distributors to report device-related serious illnesses, serious injuries, and deaths. User facilities are a vital link in the network of reporters because they can provide accurate and complete information on adverse events, patient outcomes, and device interactions, all of which are critical to manufacturers and FDA in identifying serious problems with devices and taking action to protect lives.

SMDA 90 requires the establishment of a network of communication about device-related events among user facilities, distributors, manufacturers, and FDA. The act requires that user facilities report to FDA—and to device manufacturers, if known—when they become aware of information that reasonably suggests that a device caused or contributed to a death. User facilities are also required to report to manufacturers when they become aware of information that reasonably suggests that a device caused or contributed to a serious injury or serious illness.<sup>9</sup> In the event that the manufacturer of the device is unknown, the facility is required to report a serious injury or illness directly to FDA. User facilities are required to submit reports within 10 work days of becoming aware of such situations. The act also requires that user facilities submit to FDA semiannual summaries of all the adverse event reports they submitted to manufacturers and FDA during the previous 6 months. Table 1 summarizes the medical device reporting requirements for user facilities, distributors, and manufacturers.

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<sup>7</sup>Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting (GAO/PEMD-87-1, Dec. 19, 1986).

<sup>8</sup>Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation (GAO/PEMD-89-10, Feb. 17, 1989).

<sup>9</sup>SMDA 90 defines a "serious injury or serious illness" as one that is life threatening, results in permanent impairment of a body function or permanent damage to the body, or necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. However, the 1992 amendments to the Federal Food, Drug, and Cosmetic Act deleted the requirement that an injury require immediate intervention to preclude permanent impairment or damage in order to qualify as a reportable adverse event.



**Table 1: Summary of Medical Device Reporting Requirements, 1996**

<b>Reason for report</b>	<b>Recipient</b>	<b>Deadline</b>
<b>User facility</b>		
Deaths	FDA and manufacturer, if known	Within 10 work days
Serious injuries <sup>a</sup>	Manufacturer; FDA only if manufacturer unknown	Within 10 work days
Semiannual report of deaths and serious injuries	FDA	January 1 and July 1
<b>Distributor</b>		
Deaths and serious injuries and illnesses	FDA and manufacturer	Within 10 work days
Malfunctions	FDA and manufacturer	Within 10 work days
<b>Manufacturer</b>		
Deaths, serious injuries, and malfunctions	FDA	Within 30 calendar days
Basic baseline data on each device that is the subject of a report	FDA	At same time report is submitted (within 30 calendar days)
Events that require remedial action and certain other types of events designated by FDA	FDA	Within 5 work days

<sup>a</sup>For purposes of the reporting requirements, serious illnesses are considered "serious injuries."

In addition, SMDA 90 required the Secretary of HHS to promulgate regulations implementing the reporting requirements for user facilities by November 28, 1991, and for distributors, by May 28, 1992. In November 1991, FDA issued what it called a "tentative medical device reporting regulation," which provided user facilities and distributors with nonbinding interim operating guidance on complying with SMDA 90 reporting requirements.<sup>10</sup> In addition to the statutory requirement that user facilities and distributors report serious medical device-related events to FDA and manufacturers, the tentative medical device reporting regulation provided nonmandatory guidance. This guidance instructed user facilities to establish and maintain written procedures that include (1) training and educational programs to inform employees about how to identify and report reportable events,

<sup>10</sup>SMDA 90 provided that the proposed regulation affecting distributors would become effective if FDA did not issue its final regulation within 18 months of the act. Because FDA took more than 18 months to issue its final regulation, the proposed regulation became final by operation of law. FDA did not issue its final regulation affecting distributors until September 1993. FDA told us it will propose revoking its final regulation and replacing it with a regulation that is consistent with the final medical device reporting regulation for manufacturers and user facilities.

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- (2) internal systems for documenting and reporting adverse events, and
  - (3) documentation and recordkeeping guidelines.

In December 1995, 4 years after the tentative medical device reporting regulation was issued, FDA published the final regulation for user facilities and manufacturers. As of July 31, 1996, they are both required to report device-related events under a uniform system of reporting.<sup>11</sup> Also under the final medical device reporting regulation, manufacturers are required to submit baseline reports<sup>12</sup> and annual certifications<sup>13</sup> to FDA. FDA can issue various types of written notification to inform a user facility that it has not complied with the medical device reporting regulation, which could result in civil monetary penalties or warning letters.

Finally, SMDA 90 required the Secretary of HHS to report to the Congress no later than November 1993 on such matters as the safety benefits of the user facility reporting requirements, the burdens placed on FDA and device user facilities by the reporting requirements, and the cost-effectiveness of the user facility reporting requirements. As of December 1996, FDA had not issued its report.

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## The New Reporting System

In 1992, in response to the broadened reporting requirements of SMDA 90, CDRH established the Manufacturer and User Device Experience (MAUDE) system to replace the PRP and MDR systems. From 1992 to 1996, voluntary reports from user facilities, distributors, and health professionals were input into the MAUDE system; as of April 1996, the MAUDE system contained approximately 20,000 such reports.

During this same period, FDA continued to enter manufacturer reports into the MDR system. FDA plans to begin entering into the MAUDE system manufacturers' reports that give July 31, 1996, or later as the date the

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<sup>11</sup>The final medical device reporting regulation requires user facilities and manufacturers to develop and maintain written procedures for reporting medical device-related events. Included must be (1) procedures for timely and effective identification and evaluation of events, (2) a standardized review process and procedure for determining whether or not events are reportable, (3) procedures to ensure the timely submission of complete reports, and (4) procedures to ensure adequate documentation and recordkeeping.

<sup>12</sup>A baseline report provides basic device identification information (such as the brand name, device family designation, and model number) and marketing and distribution information.

<sup>13</sup>The final medical device reporting regulation requires chief executive officers or firm representatives to annually certify that they have filed reports for all their firms' reportable events. However, FDA has stated that it will revise the certification requirement and issue a subsequent regulation to address concerns from the industry that the certification requirement "may raise liability concerns and may exceed the intent of Congress."

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manufacturer learned of an adverse event. FDA expects to have moved all the data from the PRP and MDR systems into the MAUDE system by January 1997.

Finally, in 1993, FDA established the Medical Products Reporting Program—called “MedWatch”—to encourage health professionals to report adverse events and product problems to FDA, simplify reporting, and improve the postmarket product information in FDA’s adverse event reporting system. MedWatch consists of two forms used to elicit the information needed to monitor the safety of marketed devices: the form 3500 is completed by health professionals for voluntary reporting, and the form 3500A is completed by user facilities, distributors, and manufacturers for required reporting. Using the 3500A was voluntary until the final medical device reporting regulation became effective in July 1996.

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## Growth in Reporting Results in Significant Backlogs

Although the flow of information to FDA about medical device problems increased dramatically after SMDA 90 became effective in late 1991, the extent to which SMDA 90 is directly responsible for this growth is unclear because the majority of reports were provided by manufacturers rather than by user facilities. The increased volume posed problems for CDRH’s adverse event reporting system, and CDRH experienced significant delays in processing and reviewing reports of potentially hazardous device problems. These delays could hinder the timely identification and resolution of device problems. Moreover, the annual volume of reporting is expected to rise significantly in fiscal year 1997 due, in part, to increased reporting requirements under the final medical device reporting regulation. To speed processing and analysis of reports, FDA has initiated several changes to its adverse event reporting system.

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## Manufacturer Reports Have Increased Significantly

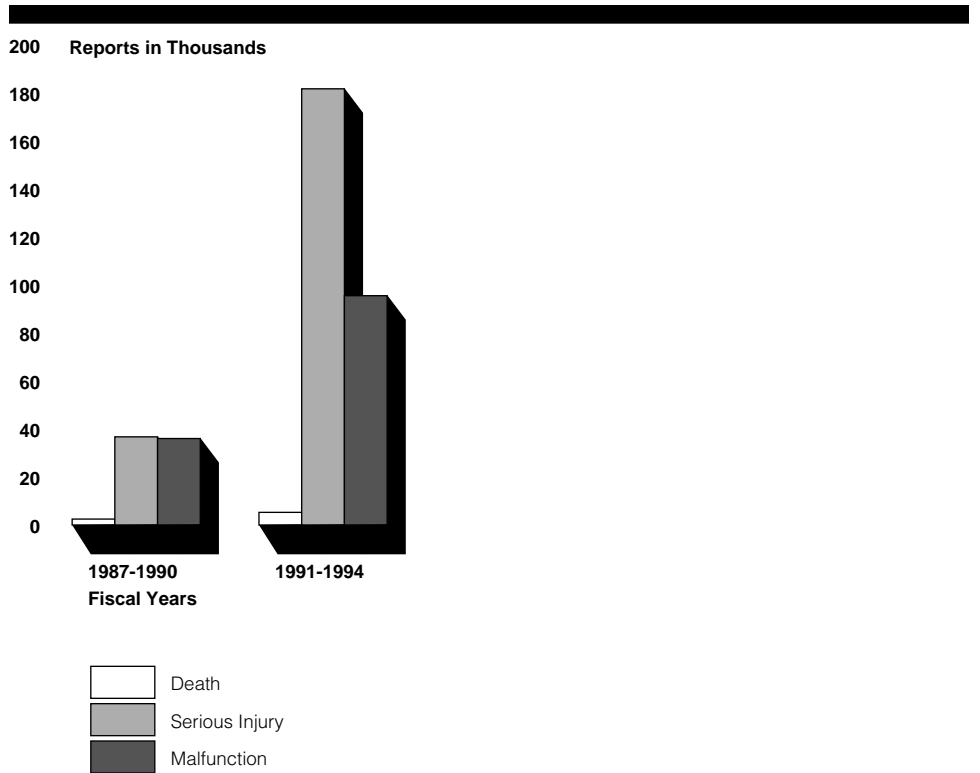
Manufacturer reports of medical device problems increased dramatically after SMDA 90 went into effect in 1991. It is unclear whether user facilities reporting under SMDA 90 directly accounted for the increased volume of reports because, until recently, FDA did not systematically collect information on the source of complaints.<sup>14</sup> Device manufacturers submitted over 370,400 of the approximately 407,700 (91 percent) adverse event reports that FDA received from all sources during fiscal years 1991 through 1995. A comparison of two 4-year periods, fiscal years 1987 through 1990 and 1991 through 1994, illustrates the rapid growth of

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<sup>14</sup>The final medical device reporting regulation requires manufacturers to indicate on the form 3500A the source of the complaint.

manufacturer reporting since SMDA 90 enactment. CDRH data show that during fiscal years 1987 through 1990, manufacturers submitted about 75,200 death, serious injury, and malfunction reports in response to the 1984 medical device reporting regulation—an average of about 19,000 reports per year. But, during fiscal years 1991 through 1994, the number of adverse event reports submitted by manufacturers soared to 282,700—an average of more than 70,600 reports per year. (See fig. 1.)

**Figure 1: Adverse Event Reports Filed by Manufacturers, Fiscal Years 1987-90 and 1991-94**



Note: Excludes 95 reports categorized as “other” that were filed during fiscal years 1991 through 1994.

FDA officials believe the upward trend in reporting is due to (1) the unanticipated, large volume of problems associated with silicone gel-filled breast implants, which accounted for nearly one-third of all of the manufacturer event reports submitted to FDA during fiscal years 1992

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through 1994, and (2) increased compliance by manufacturers with the 1984 medical device reporting regulation and SMDA 90.

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## System Could Not Handle Volume of Reports

CDRH has had considerable difficulty processing and reviewing the heavy volume of adverse event reports in a timely manner. Between March 1994 and April 1995, a backlog of about 48,900 malfunction reports from manufacturers accumulated at CDRH. Many of the malfunction reports were not entered into the adverse event reporting system and available for complete review and assessment until 1996. Although FDA assigns malfunction reports a lower priority than reports of death and serious injury, processing malfunction reports quickly is critical because of their potential to alert FDA to device problems that could cause or contribute to a death or serious injury if the malfunction were to recur. Entering all adverse event reports into the system promptly allows FDA analysts to perform more complete reviews and assessments on device problems. Further, entering event reports expeditiously is important because an event report, regardless of whether it requires immediate action, can become part of a group of reports that ultimately stimulates corrective action on a device problem.

Two factors contributed to the backlog, according to FDA. First, FDA received an unanticipated, heavy volume of breast implant adverse event reports. Second, FDA lacked funds to increase hiring for the former medical device reporting contractor (United States Pharmacopeial Convention, Inc.) that performed data processing functions related to the reports. FDA told us that it recognized the potential impact of the increasing backlog and decided to enter death and serious injury reports immediately, leaving less serious injury and malfunction reports to be entered when resources permitted. FDA also emphasized that it screened the malfunction reports for hazards that required immediate attention and that it believes the public health was not compromised by the backlog.

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## Volume Expected to Continue to Increase

In addition, the volume of reporting from all sources is projected to rise in fiscal year 1997 due, in part, to increased reporting requirements under the final medical device reporting regulation. Additional reports that are required include imminent hazard reports<sup>15</sup> and baseline reports for manufacturers. FDA estimates that its fiscal year 1997 reporting workload

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<sup>15</sup>Manufacturers are required to file a report within 5 work days after becoming aware of events that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

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will exceed 152,000 reports, up 52 percent from the approximately 100,000 reports received in 1995.<sup>16</sup>

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## FDA Is Acting to Speed Processing and Improve Analysis

CDRH is taking steps to minimize backlogs and speed report reviews through changes it made to the final medical device reporting regulation and through computer innovations. To minimize the effects of potential backlogs caused by large increases in reporting, a CDRH official told us, FDA wrote the final medical device reporting regulation with the flexibility for FDA to modify the timing and content of adverse event reports. FDA may, upon written request or at its own discretion, grant to user facilities or manufacturers an exemption or variance from any of the reporting requirements or change the frequency of reporting.

Also, CDRH is in the process of developing an electronic data interchange (EDI) system to allow firms to submit their adverse event reports electronically. Currently, most of the reports are manually transmitted and then entered into FDA computers. The EDI system will function as a single system that receives device reports and distributes them for automated data entry into FDA computers. CDRH believes the EDI system, once embraced by the device industry, will reduce the likelihood of a significant backlog in coding and data entry of reports. EDI requirements and standards are currently being developed and will be piloted in fiscal year 1997.

In addition, CDRH is developing alternative methods of analyzing event reports through enhancements to the computerized MAUDE system. For many years, CDRH has used several adverse event databases that are not integrated for analysis of reports. As a result, gaps have existed in the information available to analysts, and this information has also been redundant.

CDRH's goal, according to officials, is to reduce its dependency on the individual review of reports and move toward aggregate analysis and other methods of statistical review. The MAUDE system is expected to enable analysts to identify generic product problems and problem-reporting trends across industries and product lines, thereby helping analysts to more efficiently determine appropriate courses of action on device problems. MAUDE will also include a trend and statistical analysis subsystem that will allow analysts to compute statistical trends, such as

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<sup>16</sup>The total number of reports projected for fiscal year 1997 excludes estimates for manufacturer and distributor annual certification reports because FDA is revising the medical device reporting certification requirement and, thus, is not enforcing the regulation as currently written.

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increases in frequency or severity of reported events for a particular model, family, or type of device.

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## User Facilities Have Not Adequately Reported Adverse Events

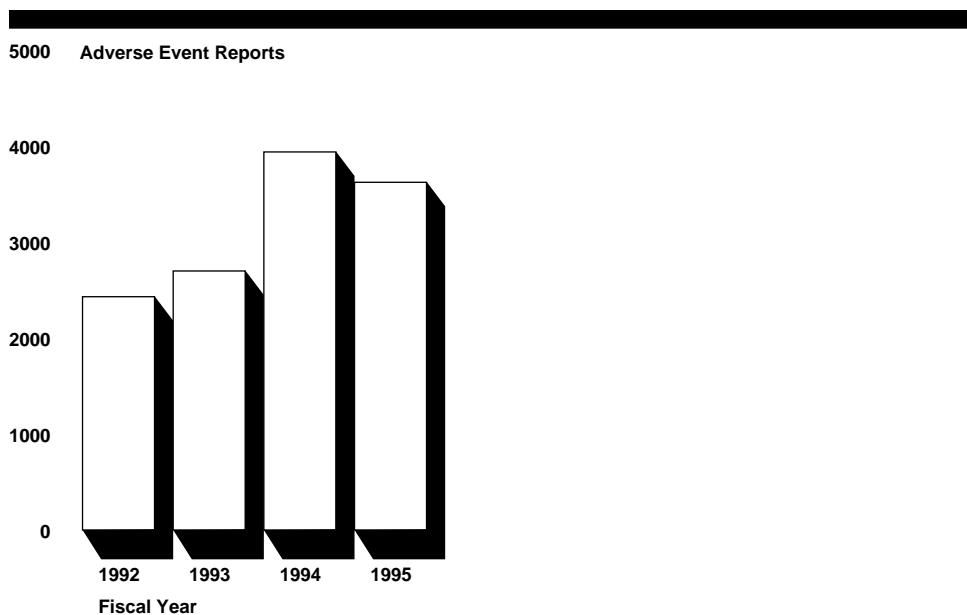
Despite the surge in reporting by manufacturers, user facilities' participation in reporting device-related events to FDA has been significantly lower than expected. Moreover, the quality of the medical device reports that have been received from user facilities has frequently been poor. Our analysis of CDRH data shows, for example, that many user facilities may be underreporting deaths to FDA and that some facilities are reporting events they are not required to report. Further, user facilities' reports are often late, inaccurate, or incomplete. User facility reports of device problems are important to manufacturers and FDA because only the user facility's physicians and staff have direct access to the patient and the device, as well as the clinical skills necessary to detect any adverse effects. Thus, the user facility is in the best position to obtain information that manufacturers and FDA need to determine whether a device presents a public health risk. Without sufficient high-quality reports from user facilities, therefore, FDA's ability to analyze device problems and assess the public health risk is hampered. Finally, FDA attributed user facilities' inadequate reporting to FDA's delay in issuing a final medical device reporting regulation to fully enforce the law, a low level of awareness about SMDA 90 among user facilities caused by turnover of user facility staff, limited educational and compliance efforts by FDA, and concerns among user facility staff that reporting adverse events could raise liability issues.

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## User Facilities Have Reported Much Less Frequently Than Anticipated

In 1990, the Congressional Budget Office estimated that the user facility reporting regulation would result in an increase of about 40,000 adverse event reports per year for FDA. Nevertheless, during fiscal years 1992 through 1995, FDA received a total of only about 12,700 event reports from user facilities, or an average of about 3,200 reports per year (see fig. 2).

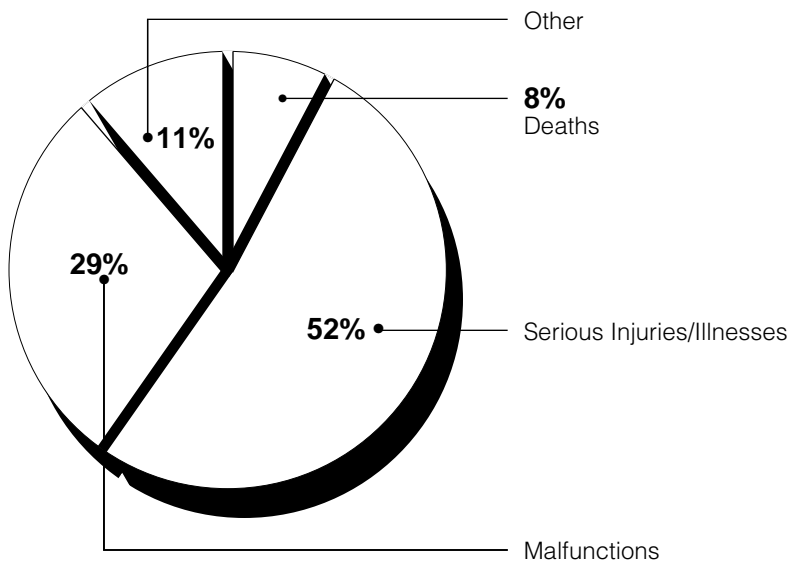
**Figure 2: Adverse Event Reports Received by FDA From User Facilities, Fiscal Years 1992-95**



During the 4-year period, more than 80 percent of the user facility event reports were for serious injuries and illnesses (52 percent) and malfunctions (29 percent). Death reports accounted for less than 10 percent of the device-related incidents reported. (See fig. 3.)



**Figure 3: Percentage of User Facility Reports Submitted by Event Type, Fiscal Years 1992-95**



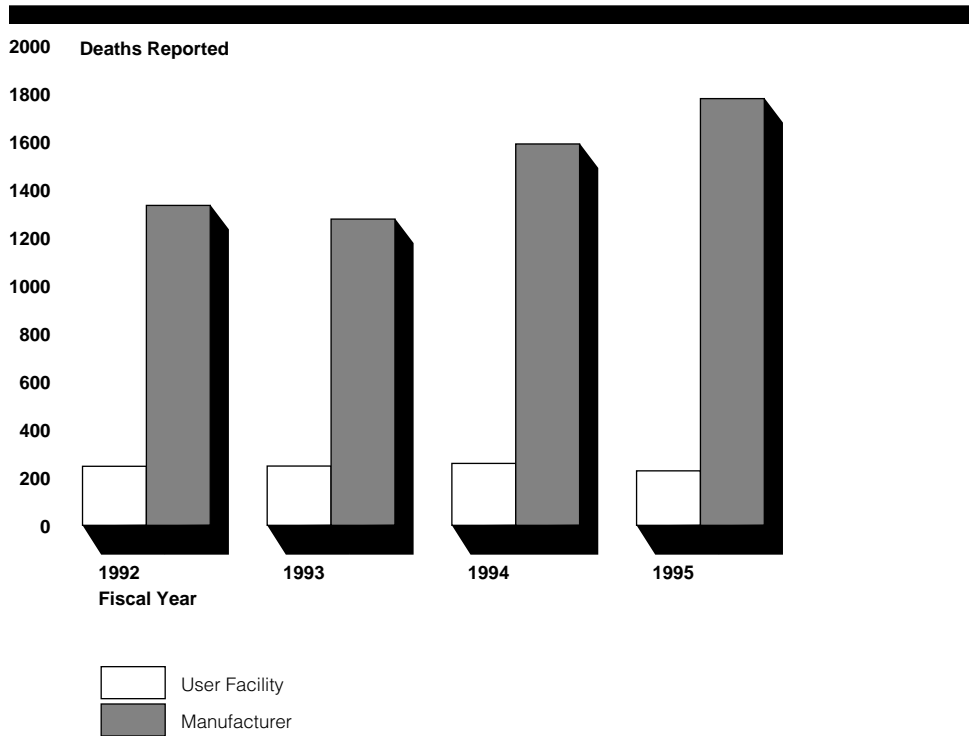
Note: The 1992 Medical Device Amendments authorized FDA to issue regulations requiring user facilities to report other significant adverse events to FDA. FDA is drafting regulations, which will be proposed through notice and comment procedures.

### User Facilities May Be Underreporting Deaths to FDA

Before SMDA 90's reporting requirements became effective in late 1991, user facilities were not required to submit device-related adverse event reports to manufacturers and FDA. Consequently, FDA's knowledge about unsafe devices involved in adverse events, such as deaths, was generally confined to reports from manufacturers, which were themselves sometimes limited by the degree of their compliance with the 1984 medical device reporting regulation. In contrast, user facility reporting under SMDA 90 is intended to provide FDA with more complete information on devices that pose hazards to the public health. In cases of death, SMDA 90 requires user facilities to submit a report to FDA and manufacturers, if known, within 10 work days of receiving information that reasonably suggests that a device has caused or contributed to a patient death. However, our analysis of CDRH data revealed that user facilities may have underreported thousands of patient deaths to FDA. Without the user facilities' perspective on these events, FDA's adverse event reporting system has significantly less information about medical device problems to use in identifying problems and assessing the public health risk.

We found that during fiscal years 1992 through 1995, manufacturers reported 5,976 deaths to FDA, while user facilities reported only 978 deaths—a difference of 4,998 death reports (see fig. 4). According to CDRH officials, FDA has taken no action to determine the extent to which the discrepancy in reporting is due to underreporting by user facilities to FDA. Nevertheless, a CDRH official told us that the difference in the number of death reports received is a gross estimate of possible underreporting. Accurately determining the number of facilities that actually did not report deaths would require CDRH to use manufacturers' reports to identify the user facilities that may not have reported a death and then determine if the death was required to be reported—a task the official said would be very time consuming.

**Figure 4: Comparison of Death Reports Filed by User Facilities and Manufacturers, Fiscal Years 1992-95**



The official also stated that the difference in the number of deaths reported could be due, in part, to the different criteria that manufacturers and user facilities were required to use in deciding whether to report an

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event. For example, under the 1984 medical device reporting regulation, manufacturers were required to submit all event reports from health care professionals, even if the firm believed or knew that the event was not related to its device.<sup>17</sup> In contrast, SMDA 90 only requires user facilities to report deaths they believe were caused or contributed to by medical devices. The official also pointed to subjective factors that may account for differences in reporting. For example, facilities have immediate access to a physician's assessment of the relationship between a device, event, and patient and, thus, may decide that an event was unrelated to a device. Device firms, on the other hand, do not have direct access to this information.

Although these factors may, in part, explain the discrepancy in reporting, they appear to conflict with the results of an analysis of user facility reports conducted by FDA. In 1993, FDA reported receiving 2,834 event reports from user facilities, of which only 664 should have been submitted. However, during the same period, 47,605 reports of death and serious injury were received from manufacturers. FDA concluded that since most event reports are sent to manufacturers by health care facilities, there was "obviously gross underreporting or misunderstanding" by user facilities.<sup>18</sup>

Once fully operational, the MAUDE system will be able to match and cross-reference all reports from manufacturers, distributors, user facilities, and health professionals so that an analyst will have a complete picture of the event. Thus, the analyst will be better able to determine, for example, whether or not a death report was submitted by a user facility, as required by law. If a death occurred and the user facility did not report it, the analyst can notify the district offices within the Office of Regional Operations, which is responsible for monitoring compliance with SMDA 90 reporting.

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## Late and Incomplete Reports Hamper Identification and Assessment of Device Problems

The submission of timely and accurate reports of device problems is important for FDA's early warning system to operate effectively. Generally, when FDA receives complete reports, they can be reviewed and assessed for public health risks without additional follow-up to obtain information on aspects of the reported incident. However, our review of CDRH statistics shows that many user facility reports are not submitted to FDA in a timely

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<sup>17</sup>Under the final medical device reporting regulation, manufacturers have the responsibility for determining the cause of each event and whether it must be reported to FDA.

<sup>18</sup>CDRH, Food and Drug Administration User Facility Reporting Quarterly Bulletin (Washington, D.C.: FDA, spring 1993).

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manner and that they frequently lack essential information on the device problem. Untimely and poor quality reports limit FDA's ability to identify device problems and assess the risk to the public health. Several examples of such problems with reports follow.

First, SMDA 90 requires user facilities to submit reports of deaths to FDA and the manufacturer, if known, within 10 work days of becoming aware of the event. User facilities are also required to forward reports of serious injuries to manufacturers—or FDA, if the manufacturer is unknown—within 10 work days of becoming aware of the event. However, CDRH data show that as of August 1995, 40 percent, or 746, of 1,875 required death and serious injury reports took longer than 10 days to be submitted to FDA. We could not determine how late the reports were submitted to FDA because CDRH could not provide the information from its MAUDE system.

In addition, many user facilities are not providing FDA a semiannual summary of all adverse event reports they submitted to manufacturers and FDA during the previous 6 months, as required. CDRH data indicate that 34 percent, or 713, of the 2,075 user facilities that filed individual event reports did not submit corresponding semiannual reports. Semiannual reports can be used by CDRH as a check to determine whether manufacturers have submitted all device-related events that have occurred during the period to FDA. Without semiannual reports, CDRH's ability to detect underreporting by manufacturers is limited.

Third, many of the user facility event reports lacked information critical to identifying and acting on device problems. A December 1995 analysis of user facility event reports received during fiscal years 1992 through 1995 disclosed that 1,367 reports omitted the device type; 1,033 did not identify the event category (such as death or serious injury); and 5,865 did not include information on patient outcome. The submission of device reports with incomplete or erroneous information requires analysts to contact the user facility to request additional information on the event and ultimately slows review and action on reported health hazards.

Fourth, manufacturers are also receiving poor quality reports from user facilities. Medical device reports from user facilities have generally been incomplete and untimely, according to representatives of the National Electrical Manufacturers Association (NEMA). Health Industry Manufacturers Association officials said they have also received some

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incomplete reports and that many of the user facility reports go directly to FDA instead of to the manufacturer.

Finally, most of the adverse event reports that FDA has received from user facilities are not even required by SMDA 90. By increasing the agency's workload, extraneous reports can slow CDRH's review of adverse events that truly merit the agency's attention. For example, the act requires user facilities to submit event reports to manufacturers when they receive information that suggests a device may have caused or contributed to a serious injury or illness. Only in instances in which the manufacturer of the device is unknown is a serious injury or illness to be reported to FDA. However, of the 5,199 serious injury and illness reports FDA had received from user facilities as of June 1995, 3,588 (69 percent) did not need to have been sent to FDA because the user facility knew the manufacturer and identified it in the report. Moreover, during fiscal years 1992 through 1995, user facilities submitted 3,678 malfunction reports that were not required by SMDA 90. FDA encourages facilities to submit reports of device malfunctions to manufacturers. Thus, at least 57 percent (7,266 out of 12,688) of the reports user facilities submitted to FDA during the 4-year period were not required by the act.

CDRH officials told us they hope that requiring user facilities to use the form 3500A for reporting device-related events to manufacturers and FDA, along with more complete guidance and instructions, will minimize the submission of incorrect, insufficient, and unnecessary information and improve the quality of reporting.

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## User Facilities Need Additional Training to Improve Reporting

We found that user facilities need additional training on the medical device reporting requirements. In 1992, FDA conducted an extensive outreach campaign to educate user facilities about medical device reporting. FDA mailed the tentative final regulation to over 150,000 facilities and individuals and participated in numerous conferences and training sessions. Yet, in 1993, a three-state study conducted by the departments of health in Colorado, Texas, and Massachusetts for FDA determined that only 46 percent of the 468 user facilities surveyed knew about the reporting requirements. Thus, despite FDA's efforts, the studies indicated that many user facilities in the three states were unaware of or unclear about their reporting responsibilities.

Moreover, CDRH learned through reviews of 119 user facilities' written medical device reporting procedures that only 9 facilities had procedures

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consistent with those in the tentative final regulation (that is, they provided definitions of event terminology, descriptions of educational programs to teach employees how to identify and report device-related events, internal systems for documenting and reporting device-related events, and separate medical device reporting incident files). CDRH concluded that many facilities would benefit from additional educational efforts.

FDA attributed user facilities' lack of adherence to FDA's tentative final regulation to several additional factors. First, a CDRH official told us that before the final medical device reporting regulation became effective in July 1996, the only requirements that were legally enforceable were the requirements of SMDA 90, which do not provide sufficient detail on medical device reporting. As a result, user facilities had to rely on guidance in the tentative final medical device reporting regulation to establish the program's requirements. This guidance was not enforceable, and, as the official pointed out, user facilities did not have to follow it because doing so was voluntary.

In addition, FDA officials said that planning and performing compliance inspections are difficult because FDA has a limited number of investigators available to conduct the inspections that are required at over 70,000 regulated facilities. However, FDA believes that, by working closely with the Joint Commission on Accreditation of Healthcare Organizations and the Health Care Financing Administration, it will be better able to monitor user facility compliance with SMDA 90.

The CDRH official cited above also believes that CDRH's educational efforts during the early 1990s may have been ineffective because facilities may have lost, misrouted, or simply discarded the guidance on medical device reporting. He added that, given the reportedly high mobility of health care facility personnel, replacement staff may not have received the guidance and, consequently, may have been unaware of the law. Finally, both FDA officials and representatives of the medical community told us that another deterrent to user facility reporting is the concern user facility staff have with the institutional and professional liability that may result from reporting device problems, particularly if the problem is related to user error.

Efforts to educate user facilities about medical device reporting include distributing material through various health care organizations and FDA's electronic bulletin board, which can be accessed from a personal

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computer. In addition, CDRH plans to continue to publish a quarterly User Facility Reporting Bulletin that provides information to user facilities on various medical device reporting issues. Finally, CDRH held a teleconference with user facilities in May 1996 to discuss matters concerning the final medical device reporting regulation.

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## FDA Does Not Document Corrective Actions Adequately

For its early warning system to be effective, FDA must be able to rapidly process, review, and assess the potential risk of device problems to the public health. These assessments must result in an appropriate course of action to resolve device problems. Our review of a sample of adverse event reports and discussions with CDRH officials revealed that for many years FDA has not routinely documented the final corrective actions taken by manufacturers and FDA to resolve the problems identified in these reports. As a result, we were not able to determine how manufacturers and FDA have responded to user facility adverse event reports. In cases in which resolutions of problems are undocumented, FDA has little assurance that problems with devices are being corrected. FDA also has limited information both to share with other reporters who have encountered difficulties with similar devices about preventing potentially hazardous situations and for its own use in analyzing subsequent problems with similar devices. Moreover, without adequate documentation, FDA has little assurance that the many reports received are, in fact, useful and result in better protection of the public health.

CDRH attributed its lack of documentation to the large volume of adverse event reports and limited staff resources. In spite of not having systematically documented the actions taken in response to reports received, CDRH did provide us with several examples of corrective actions it has taken. In addition, FDA said it plans to maintain more complete data on corrective actions that are taken in response to event reports submitted after July 31, 1996. Finally, FDA cannot assess its performance as an early warning system for device problems because it does not keep track of the length of time that it takes to review and resolve serious device problems.

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## FDA Does Not Routinely Document Resolutions of Reported Problems

In previous work, we found that over two-thirds of the adverse event reports received by FDA from 1985 through 1987 lacked a clear-cut determination, such as a recall, a voluntary action by the manufacturer, or even an indication that the information submitted by the manufacturer was insufficient to process the case.<sup>19</sup> To encourage greater use of medical

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<sup>19</sup>GAO/PEMD-89-10, Feb. 17, 1989.

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device reporting data, we recommended that FDA fully document its use of these data in acting to correct device problems, especially by ensuring that such actions were recorded in the database. FDA agreed with our recommendation and reported that changes were under way to improve its handling of event reports. However, we found during our recent analysis of adverse event reports and discussions with CDRH officials that CDRH has not begun routinely documenting the final dispositions of device problems in individual event reports.

To determine how manufacturers and FDA have responded to user facility reports, we reviewed 30 reports of events that manufacturers became aware of through user facility reports from 1992 through 1995. The reports documented 1 death, 20 injuries, and 9 malfunctions. Our initial review showed that 29 of the 30 reports contained neither the final determination of the cause of the device problem reported nor a description of the corrective action taken by the manufacturer or FDA. The remaining report described a serious injury that was allegedly caused by a faulty ventilator. FDA later found the injury to have been unrelated to the device.

We reviewed the 30 reports with an FDA analyst to obtain an update on each adverse event. In 16 out of 30 cases, the cause of the event had not yet been identified, and FDA planned to continue to monitor the devices.<sup>20</sup> Twelve reports were reviewed by analysts upon initial receipt, but no further action was documented. Two malfunction reports were assigned to ad hoc groups to determine whether the devices posed an immediate health risk to the public; the groups determined that no additional action was needed.

A CDRH official explained that, under FDA's medical device reporting system, the decisions that analysts make on adverse event reports are not routinely documented, and statistics are not maintained on the types of corrective actions taken by FDA and manufacturers.<sup>21</sup> The official recalled that during the early 1980s, CDRH closed each case with a conclusion about the probable cause and effect of the event but that this was too resource intensive. When the number of reports increased significantly, CDRH chose to focus on reviewing the reports rather than on documenting how they were resolved.

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<sup>20</sup>Upon receipt of additional information on the serious injury report involving a ventilator, FDA designated the report for further monitoring.

<sup>21</sup>See app. II for a description of the process used by analysts to evaluate device reports.



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The official also emphasized that documenting problem resolutions is only an issue with regard to reports that can be or are investigated, which is a relatively small subset of all reports received. Moreover, complete documentation of the resolution of a problem is dependent upon a number of factors that FDA cannot control. According to the official, in some cases FDA has great difficulty obtaining required information from user facilities on device-related events so that it can assess the public health risks. As an example, he cited the following scenario: A manufacturer receives a report that one of its disposable devices has failed. However, the device in question has been discarded by the user facility before the manufacturer can examine it and perform tests on it. Consequently, the manufacturer is unable to adequately report pertinent information, and FDA's ability to ascertain the problem, its causes, and any resolutions is hampered.

Despite the problems associated with receiving complete information on device problems, the official acknowledged that providing a close-out record for each report could, among other things, provide reporters with feedback to encourage reporting and provide FDA with a pool of information that could be used to ascertain the impact or probable outcome of any subsequent reports on similar problems with the device.

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## FDA Has Documented Some Corrective Actions

Although CDRH does not routinely link corrective actions to reported medical device problems, it provided us examples of how it has nevertheless identified and acted on serious problems with devices in several instances. The following examples show that well documented events, analysis, and corrective actions are invaluable in responding to reported problems.

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## Hospital Bed Side Rails

Between January 1990 and June 1995, FDA received 102 reports of head and body entrapment incidents involving hospital bed side rails. These reports indicated that 68 deaths, 22 injuries, and 12 entrapments without injury had occurred in hospitals, long-term care facilities, and private homes. FDA's analysis of the reports showed that the entrapments actually involved side rails, headboards, footboards, and mattresses. The majority of these adverse events involved elderly patients who were suffering from confusion, restlessness, lack of muscle control, or a combination of these conditions.

In July 1995, a CDRH ad hoc group decided that a safety alert should be issued to apprise health care professionals of the entrapment hazards

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associated with hospital beds and of ways to prevent them.<sup>22</sup> CDRH consulted with the Consumer Product Safety Commission and the Canadian government, as well as with numerous professional organizations and manufacturers, to obtain their comments as it developed the alert. CDRH reported that 94,000 copies of the alert were distributed to the user facility community.

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### Dialysate Solution Storage Containers

A dialysis nurse reported an incident involving eight patients who exhibited several symptoms, including severe hypotension, during dialysis. Three of these patients died. A top priority inspection revealed the patients had high serum aluminum levels. After further investigation, it was found that the dialysis solution was being stored in a pump containing aluminum, metered to the patients through such a pump, or both, and that the aluminum had leached into the dialysate concentrate. A safety alert that discussed the potential hazard created when patients are exposed to dialysate with excessive aluminum levels was issued in May 1992.<sup>23</sup>

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### Apnea Monitor

In February 1985, an infant was disconnected from its apnea monitor but the electrodes with the lead wires were left attached to the infant. A sibling plugged the lead into the power cord, electrocuting the infant. CDRH assembled a committee of experts to investigate the hazard. At that time, about 50,000 apnea monitors—of 20 different models—were on the market. The committee decided that a voluntary plan of action would be most effective because of the speed with which it could be implemented.

In June 1985, CDRH issued a safety alert summarizing the reported events and outlining steps to guard against future incidents.<sup>24</sup> CDRH also sent letters to 31 manufacturers of breathing frequency monitors and heart monitors for home use requesting that each firm evaluate its device for the electrode problem and, when necessary, consider design changes to prevent insertion of the lead connectors into AC power cords or outlets. All 31 device firms either changed their lead designs or explained to CDRH why their device did not present a hazard.

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<sup>22</sup>FDA, "Entrapment Hazards With Hospital Bed Side Rails," a safety alert (Washington, D.C.: FDA, Aug. 23, 1995).

<sup>23</sup>FDA, "Aluminum and Other Trace Contaminations in Dialysis Facilities," a safety alert (Washington, D.C.: FDA, May 20, 1992).

<sup>24</sup>FDA, "Electrocution of an Infant," a safety alert (Washington, D.C.: FDA, June 1985).

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An FDA analysis also shows that many other adverse event reports were used to resolve device problems. For example, FDA reported that from 1985 through 1995, 1,099 of its 4,365 classified recalls (25 percent) were associated with event reports. FDA also reports using information in adverse event reports for other health-related purposes, including identifying areas in which user education can be improved, analyzing premarket approval applications, developing medical device standards, and monitoring device problems in foreign countries.

In the near future, CDRH expects to have better data on corrective actions taken by manufacturers in response to user facility reports. The final medical device reporting regulation requires manufacturers to list on the form 3500A a corrective action taken—such as a recall, repair, relabeling, or other modification—for each device associated with an adverse event report. According to a CDRH official, manufacturers are now also required to refer to the user facility's unique reporting number when submitting an adverse event report.

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### FDA Does Not Record How Long It Takes to Respond to Reported Device Problems

Maintaining reliable productivity indicators on the length of time FDA takes to process, review, and initiate action on device problems and on the time that passes before manufacturers correct the problems would better ensure that serious device problems are receiving prompt attention. It would also allow FDA to better measure its adverse event reporting system's performance as an early warning system. However, CDRH does not have statistics available on these areas of performance. Thus, FDA has no reliable way of knowing how long it takes to respond to reported device problems.

According to FDA, once the enhancements to the MAUDE system are fully operational, it will be able to provide FDA with better information on the time FDA takes to process and review reports. However, FDA officials told us that the MAUDE system will not be able to provide meaningful statistics on the time FDA and manufacturers require to take action on reports. According to FDA, given the complexity of the issues involved and the volume of reports received, any performance indicator based on the length of time needed to correct reported problems would not provide statistics that are reliable. FDA contends that this is an inherent attribute of any system that builds on reports accumulated over many years.

While FDA may not be able to develop reliable measures of performance based on the time taken to correct device problems, it can track the time

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needed by FDA analysts to initiate action on reports. As a result of report reviews, FDA analysts may request additional information from manufacturers and user facilities about the severity of the event and any corrective action taken, request an inspection of the manufacturer's facility, request ad hoc meetings to discuss issues pertaining to a problem device, or determine that a report requires no further action and archive the report for future research and monitoring. Once one of these initial courses of action is taken by an analyst, FDA can document the date the action was taken in the adverse event reporting system, thereby providing FDA with a more complete measure of its response time.

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## FDA Provides Limited Feedback on Adverse Event Trends and Corrective Actions

Another important facet of the adverse event reporting system is the communication of trends in device-related problems and corrective actions taken to ensure the safety and efficacy of medical device products. Feedback to the medical device community on reported problems and corrective actions could increase the knowledge of user facilities and manufacturers about the performance of devices, assist users in making device purchase decisions, and improve awareness of patient safety. However, CDRH does not have a system for routinely communicating adverse event reporting trends and remedial actions taken on device problems to specific reporters of device problems and the medical device community at large. Although FDA occasionally issues safety alerts and public health advisories, which inform the medical device community about health risks associated with devices, it does not provide user facilities and other medical device reporters with direct feedback on the status and outcomes of individual device investigations. Nor does it publish composite statistics on event trends and problem resolutions. Consequently, many adverse event reporters are unaware of the dispositions of their complaints and have little assurance that the agency is taking action on the device problems reported. Both user facilities and the industry have suggested that FDA provide more feedback on how it uses adverse event reports.

A CDRH official told us that FDA does not have a notification system for advising individual user facilities and other reporters about the status and outcomes of reports because significant staff time would be required to provide feedback to reporters on the more than 100,000 event reports received annually. The official said further that often no feedback is available because FDA does not follow up on each event that is reported. Voluntary reporters receive an acknowledgment letter, but it does not provide specific feedback about their report. FDA does, however,

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disseminate safety alerts and public health advisories regarding medical device problems to user facilities; it also periodically features alerts in its User Facility Reporting Bulletin. From the beginning of fiscal year 1994 through June 1996, FDA issued three safety alerts and seven public health advisories.

User facility and industry officials believe that FDA could better protect the public health by publishing statistics on adverse event trends and corrective actions that result from medical device reports. For example, a senior official at a teaching hospital in Baltimore, Maryland, told us that although the adverse event reporting system has received an increased quantity of data, he has seen no analysis of this information that would provide device users with suggestions on courses of action that could be taken to prevent incidents from recurring. Similarly, representatives of the Medical Device Manufacturers Association (MDMA) told us that since the early phases of medical device reporting, their members have derived little benefit from the hundreds of thousands of reports stored within the agency's databases. MDMA representatives believe the public should know what benefits have been derived from reporting. In addition, a senior executive of a New Jersey hospital said he was disappointed that a database has not been developed that can be searched for information about problem medical devices to help his hospital learn more about the performance of devices and assist in device purchase decisions. Similar views were repeatedly expressed in responses to a 1994 FDA questionnaire sent to user facilities: Over 642 of the 4,419 participating user facility officials—or 15 percent—indicated that they wanted more feedback from FDA on adverse event reports.

According to FDA, the MAUDE system will be used to work closely with the device community to identify safety problems; explore the most effective strategies for resolving problems; and provide feedback to user facilities, manufacturers, and the public.

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## Medical Device Community Suggests Ways to Improve Reporting

Some representatives of the medical device community believe that reducing the volume of adverse event reports could help FDA more effectively manage the reporting system. Suggestions for improving reporting include (1) requiring a statistical sample of user facilities, rather than all user facilities, to report device-related events to FDA and manufacturers and (2) eliminating malfunction reporting by manufacturers to FDA.

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## Require Only a Statistical Sample of User Facilities to Report

According to the President of the Emergency Care Research Institute (ECRI), a nonprofit research agency that operates a worldwide medical device reporting system, FDA's adverse event reporting system is hampered by prolific and duplicative data that divert resources away from analysis to data entry. ECRI contends that the adverse event reporting system, as currently configured, makes it difficult for FDA to effectively recognize, track, cross reference, investigate, and follow up on significant medical device problems.

ECRI believes that FDA should free all user facilities but hospitals from the reporting requirement and employ statistical sampling techniques to limit even the number of hospitals required to report device-related problems to manufacturers and FDA. Sampling, according to ECRI, would reduce duplication, speed processing and analysis, and free up resources to devote to analysis and educating hospitals about medical device reporting.

NEMA members, however, believe that developing a user facility reporting program predicated on reports from only a small number of entities would pose at least two implementation problems. First, NEMA members believe, in general, that statistical sampling is beneficial only when it pertains to identical devices from one manufacturer. If statistical sampling is used in the device industry, they contend, the possibility exists that problems identified with a given type of device could be incorrectly generalized to apply to devices that do not possess the same attributes. Such a generalization could impose additional costs on the manufacturer if it had to repeatedly spend resources on investigating incident reports that turned out to be groundless.

Second, statistical sampling is also problematic from the perspective of the user facility, in that not all user facilities are alike. In the opinion of NEMA members, the only useful approach to a statistical sampling program would be to confine the sample size to a small number of user facilities that share similar patient populations and operating characteristics, such as Public Health System facilities or Veterans Administration facilities.

According to the safety coordinator at a hospital in Boston, Massachusetts, statistical sampling would not be a good idea because, given the demands on the user facility community to provide quality health care, if reporting were not required, facilities would not report medical device-related problems. He believes that medical device reporting is an important prerequisite for good patient care and that user facilities must be required

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by law to report medical device-related incidents in order for them to consistently do so.

CDRH's director told us that CDRH frequently receives adverse event reports from user facilities that are not very helpful in identifying and resolving device problems. He went on to say that CDRH would prefer to receive fewer, but more helpful reports. As a result, CDRH is planning a pilot study to determine the feasibility of adopting the statistical sampling approach to medical device reporting. Under this approach, FDA would educate a smaller population of user facilities in reporting device problems, which might improve the quality of reporting and increase manufacturers' and FDA's knowledge about device problems.

CDRH recently issued a "Request for Proposals for a Sentinel System" that asked prospective bidders to develop a design for a pilot study involving about 10 to 20 user facilities. Bidders are required to recruit and negotiate with user facilities interested in participating in the pilot study. Staff of the user facilities that are chosen to participate will be trained in the medical device reporting requirements and user facility responsibilities. Participating facilities will be monitored, and the adverse events reported will be qualitatively evaluated for 12 months. User facilities will receive feedback and refresher training as needed. Depending on the results of the pilot study, CDRH envisions that a representative sample of user facilities could be used either to supplement the existing system or as a replacement for the universe of user facilities, if approved by the Congress.

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### Eliminate the Requirement That Manufacturers Report Malfunctions

Another industry suggestion for improving FDA's adverse event reporting system is to eliminate malfunction reporting. Currently, manufacturers are required to report to FDA malfunctions that are likely to cause or contribute to a death or serious injury should they recur. During fiscal years 1991 through 1995, reports of device malfunctions accounted for about one-third of all reports submitted by manufacturers. Industry officials contend that the medical device reporting system is so overburdened that FDA does not have an opportunity to evaluate the reports of device malfunction and that such reporting is costly and burdensome. Thus, these officials believe malfunctions should no longer be considered reportable events. They contend that manufacturers have systems in place to review and evaluate product malfunctions and that these evaluations are available to FDA during the routine inspections that FDA makes of their facilities.

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The purpose of the 1984 medical device regulation was to provide FDA with more information about device problems, such as malfunctions, so that the agency could learn about potential device problems before they endangered the lives of people. A CDRH official told us that deciding whether to eliminate malfunction reporting is the choice between having an adverse event reporting system that is proactive and one that is reactive. Further, he stated that if the objective of medical device reporting is to find out that a device is dangerous after it has caused or contributed to a death or serious injury, then malfunction reporting can be eliminated. However, if the objective is to become aware of problems before they have caused a death or serious injury, then malfunction reporting should not be eliminated. CDRH, he said, would prefer to retain malfunction reporting so that FDA can continue to learn of potential public health problems and resolve them before a serious injury or a death occurs.

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## Conclusions

The quantity of information reported to FDA about medical device problems has increased dramatically since SMDA 90's reporting requirements became effective in 1991. Because FDA has not ensured that reported device problems receive prompt attention and appropriate resolution, however, its adverse event reporting system is not providing an early warning about device problems. Without reliable statistics that measure the length of time that FDA takes to review and initiate action on device problems and systematic documentation of how all reported problems are resolved, FDA cannot ensure that the system is serving as an early warning system for unsafe and ineffective devices. Moreover, because FDA has not identified and followed up with user facilities that may have underreported thousands of patient deaths, its ability to analyze device problems and assess the public health risk may be significantly hampered. Finally, without feedback from FDA to user facilities about device problem trends and corrective actions taken, user facilities do not receive information that could help them determine which devices to purchase, and they have little assurance that FDA is taking action on their adverse event reports.

FDA's new MAUDE system is now providing opportunities for FDA to correct weaknesses in its adverse event reporting system. In July 1996, FDA began requiring manufacturers to list on the form 3500A corrective actions that are initiated to resolve medical device adverse events. This improvement will provide the MAUDE system with the information that FDA needs to systematically document solutions to device problems and help it



communicate more effectively with user facilities. In addition, once the MAUDE system is fully operational, it will be able to generate productivity data on the time FDA takes to process and review adverse event reports. If FDA expands this capability to include the time it requires to initiate action on reports, it will be able to more easily measure its performance as an early warning system. The MAUDE system will also enable FDA to identify and follow up with user facilities that do not submit reports of device-related deaths to FDA. If FDA uses the MAUDE system in this way, FDA will be able to ensure that user facilities are complying with the law and also obtain the user facilities' perspectives on these events.

Limiting the number of user facilities required to report medical device problems could improve the quality of data FDA receives without jeopardizing its ability to identify device problems. On the other hand, fewer reporters could mean that problems would be less likely to be identified and resolved, especially for devices with relatively low usage rates. An evaluation of whether the identification and correction of device problems would better be accomplished through the current system or through a smaller user facility reporting program may help FDA decide which approach is better for protecting the public health. Furthermore, although FDA's initiatives may improve its reporting system, they do not address its difficulty in ensuring prompt resolution of device problems, compliance with SMDA 90, and dissemination of trend analysis and corrective actions taken to the medical device community.

## Recommendations to the Commissioner of the Food and Drug Administration

To improve FDA's adverse event reporting system's ability to serve as an early warning system about medical device problems as intended by SMDA 90, we recommend that the Commissioner of FDA

- collect and maintain reliable statistics on the time it takes to process, review, and initiate action on adverse event reports;
- use reports of death provided by manufacturers and others to identify user facilities that may not be reporting to manufacturers, FDA, or both in violation of SMDA 90;
- document corrective actions on adverse event reports that result from analysis and investigations of device problems; and
- collect and disseminate adverse event trend analysis and corrective actions taken by manufacturers and FDA to the medical device community.

Finally, we recommend that FDA's study of an adverse event reporting system based on a representative sample of user facilities focus on

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whether this approach can provide manufacturers and FDA with the quantity and quality of information needed to rapidly identify and correct problems with devices that have varying usage rates.

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## Agency Comments and Our Response

FDA agreed with our recommendations for improving its adverse event reporting system. However, FDA believes that the three components of its postmarket surveillance system together provide an adequate early warning system for device problems and help to ensure that the public is protected. Specifically, FDA believes that (1) medical device reports are supplemental in nature and that its entire postmarket surveillance system, its GMP regulations, and other related activities combined constitute the most comprehensive source of information regarding marketed medical devices; (2) the deficiencies in the adverse event reporting system cited in our report are being corrected; and (3) adverse event reports from all sources are promptly and thoroughly reviewed, and appropriate actions are taken to protect the public health.

While we agree that FDA uses several sources of information to monitor marketed devices, we disagree with their suggestion that the adverse event reporting system serves mainly as a supplement to other components of the postmarket surveillance system. This suggestion conflicts with FDA's response to a recent congressional inquiry in which FDA characterized the adverse event reporting system as "critically" important to its postmarket surveillance system because it provides a balance with its premarket evaluation of new medical devices. FDA also characterized the adverse event reporting system as a "safety net" that allows the agency to move new technologies into the marketplace more rapidly because problems with devices that were not detected at the premarketing stage can be identified and corrected through the adverse event reporting system. Moreover, FDA's implication that it relies more heavily on its GMP compliance program than on the medical device reporting system to help protect the public health is worrisome. The GMP program is intended to assess the safety and effectiveness of devices before, rather than after, they reach users. Yet in an earlier study of the program, we documented that FDA did not inspect many manufacturers of medium- and high-risk devices at least once every 2 years, as required by law; the quality of the inspections that were performed was frequently poor; and the inspections did not detect quality assurance problems.<sup>25</sup>

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<sup>25</sup>Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority (GAO/PEMD-92-10, Feb. 13, 1992).

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While we acknowledge that FDA has recognized weaknesses in the adverse event reporting system and has instituted improvements to correct them, none of these improvements has been tested and proven effective. For example, although the form 3500A may provide FDA with the information it needs to better protect the public health, voluntary use of the form by user facilities since 1992 has shown that many data quality problems exist. Further, it is too early to tell if mandatory use of the form 3500A will result in improved reporting.

Although FDA has provided some information that associates medical device reports with recalls and other administrative and regulatory activities, the adverse event reporting system does not routinely identify the actions that were initiated to correct the problems detailed in event reports. Nor does the system provide data on how long it takes the agency to respond to serious device problems. In our view, an effective adverse event reporting system should permit FDA to readily determine how each event report was handled and that all problems reported received prompt attention and resolution.

FDA's written comments on a draft of this report are reproduced in appendix III. FDA also provided technical comments clarifying aspects of its adverse event reporting system, which we have incorporated in this report where appropriate.

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We are sending copies of this report to other congressional committees and Members with an interest in this matter, and we will make this report available to others upon request. If you or your staff have any questions about this report, please call me on (202) 512-7119 or John C. Hansen,

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Assistant Director, on (202) 512-7105. Others who contributed to this report are Darryl Joyce, Lynn Filla-Clark, Barbara Mulliken, and Joan Vogel.

A handwritten signature in black ink that reads "Bernice Steinhardt". The signature is written in a cursive style with a large initial 'B'.

Bernice Steinhardt  
Director, Health Services Quality  
and Public Health

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**Abbreviations**

CDRH	Center for Devices and Radiological Health
ECRI	Emergency Care Research Institute
EDI	electronic data interchange
FDA	Food and Drug Administration
FTE	full-time-equivalent
GMP	good manufacturing practices
HHS	Department of Health and Human Services
MAUDE	Manufacturer and User Device Experience
MDMA	Medical Device Manufacturers Association
MDR	mandatory medical device reporting
NEMA	National Electrical Manufacturers Association
OSB	Office of Surveillance and Biometrics
PRP	Medical Device and Laboratory Problem Reporting Program
SMDA 90	Safe Medical Devices Act of 1990

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# Scope and Methodology

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We conducted our review of the Food and Drug Administration's (FDA) implementation of the Safe Medical Devices Act of 1990 (SMDA 90) at FDA's Office of Surveillance and Biometrics (OSB), Center for Devices and Radiological Health (CDRH). We reviewed prior GAO reports related to FDA's medical device adverse event reporting system as well as studies conducted by the Emergency Care Research Institute and device manufacturer associations. We also interviewed CDRH officials about policies and procedures used to process, review, and act on adverse event reports. With these officials, we also discussed FDA's efforts to implement the user facility reporting requirements of SMDA 90 and to publish the final medical device reporting regulation required by the act.

We analyzed computerized data from FDA's adverse event reporting system on trends in device-related events from fiscal years 1987 through 1995 to determine whether the volume of reporting of device problems had changed since the user facility reporting requirement became effective in 1991. We also reviewed statistics compiled by CDRH on the extent to which user facilities had filed adverse event reports with FDA during fiscal years 1992 through 1995 in accordance with the act. Specifically, we examined whether user facilities had done the following:

- reported deaths to FDA and manufacturers,
- reported serious injuries and serious illnesses to FDA only when the manufacturer's name was unknown,
- reported these deaths and serious injuries and illnesses to FDA within 10 work days of becoming aware of them, and
- submitted a semiannual report to FDA summarizing device-related events that took place during the previous 6 months.

In addition, we reviewed FDA field office inspections of user facilities' compliance with the SMDA 90 reporting requirements. We were unable to obtain statistics from CDRH on corrective actions that have been initiated by manufacturers and FDA because CDRH does not routinely document the final resolutions (such as recalls, seizures, and warning letters) in individual adverse event reports. However, to illustrate how manufacturers and FDA have handled user facility reports, we reviewed 30 event reports that were submitted to FDA by manufacturers in response to user facility reports of problems with devices during fiscal years 1992 through 1995 and discussed the status of each report with a CDRH analyst.

Finally, we interviewed representatives of organizations within the medical device community (four hospitals, two parent corporations of



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health care providers, two nonprofit organizations, one nursing home association, and three device manufacturer associations). We discussed with them their experiences with user facility reporting and whether changes to SMDA 90 and FDA's adverse event reporting system were needed to improve reporting. We identified these organizations through a review of the literature and through a list of contacts obtained from FDA. Table I.1 provides the name, location, and a brief description of each organization interviewed.

**Appendix I  
Scope and Methodology**

**Table I.1: Organizations Interviewed Regarding SMDA 90 and FDA's Adverse Event Reporting System**

<b>Organization</b>	<b>Description</b>
Beth Israel Hospital, Boston, Mass.	A 408-bed tertiary care hospital affiliated with Harvard University
Columbia/HCA, Health Care Corporation, Nashville, Tenn.	Parent corporation of 340 hospitals and 130 ambulatory surgery centers throughout the United States
Johns Hopkins University Hospital, Baltimore, Md.	A 1,000-bed tertiary care hospital that provides a variety of treatments and patient care and serves as a referral center
Rahway Hospital, Rahway, N.J.	A 300-bed acute care, full service hospital
New Britain General Hospital, New Britain, Conn.	A 330-bed teaching hospital
American Health Care Association, Washington, D.C.	A federation of 50 state and District of Columbia nursing home affiliates
Mayo Foundation, Rochester, Minn.	A not-for-profit corporation composed of health care facilities in several states
Public Citizen, Washington, D.C.	A nonprofit public interest organization with objectives related to health care that monitors government agencies charged with health care functions
Emergency Care Research Institute, Plymouth Meeting, Penn.	A nonprofit health services research agency whose mission is to improve patient care, ECRI operates a Consumer Reports-like medical product evaluation program and a broader health care technology assessment program that encompasses devices, drugs, biotechnologies, and medical and surgical procedures.
Medical Device Manufacturers Association, Washington, D.C.	A national trade association representing 100 independent manufacturers of medical devices, diagnostic products, and health care information systems
Health Industry Manufacturers Association, Washington, D.C.	A national trade association representing more than 700 manufacturers of medical devices, diagnostic products, and health information systems
National Electrical Manufacturers Association, Rosslyn, Va.	A national trade association representing manufacturers of diagnostic X-ray, computed tomography, magnetic resonance imaging, ultrasound imaging, and radiation therapy equipment

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# FDA's Adverse Event Report Evaluation Process

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FDA receives adverse event and product problem reports from user facilities, manufacturers, distributors, and health care professionals. User facilities, manufacturers, and distributors use a standard form 3500A for reporting device-related events. User facilities and distributors must report patient information, the type of adverse event, a description of the event, relevant laboratory data and patient history, the name of the manufacturer, and certain other information about the device. Manufacturers must report such information as the source of reported information; the type of event reported to them; whether the device was returned to the manufacturer for evaluation; methods of evaluation and results of manufacturer review; and, if applicable, the type of remedial action taken (recall, repair, relabeling, or inspection). Health professionals report adverse events and product problems voluntarily on a form 3500.

Event reports are entered into an adverse event database, with the appropriate quality control checks, by FDA's data entry contractor, Logistics Applications, Inc. Thereafter, OSB evaluation teams consisting of 15 specialized health care professionals (14 nurses and 1 nuclear medicine technologist) retrieve the reports from the database via the computer for review. Analysts may each have responsibility for all products associated with an assigned medical specialty area, such as radiology, ophthalmology, or orthopedics, or they may be responsible for specific types of products associated with larger clinical areas, such as general hospital, general surgery, and cardiology. Analysts' reviews focus on identifying the device problems that pose the greatest risk to the public health. Deaths are given first priority, but serious injuries and illnesses are also important concerns, unless they are not considered life threatening.

To assess the nature and magnitude of a problem, the analysts use their clinical expertise to evaluate the data submitted in the adverse event report, as well as other information, such as premarket submissions on similar devices, recall information, and literature reviews on adverse events or reported problems. Known complications and problems associated with a particular device are screened by a computer and a sample of these reports is assigned to the appropriate analyst for review. Reports of particular importance, such as pediatric deaths, are routinely sent to the appropriate analyst either prior to or concurrent with the data entry process. This provides the analyst an opportunity to commence an investigation while the actual report is undergoing data entry.

On the basis of their evaluation of reported events, the analysts determine if any follow-up investigation is needed. These investigations generally

involve written requests for additional information from a manufacturer, user facility, or voluntary reporter on aspects of a reported incident or an inspection of either the manufacturer or the user facility.

Written requests may ask for such patient data as an evaluation of the reported incident by a health care practitioner; a patient history, underlying diagnosis, or both; and autopsy results relevant to the reported event. Similarly, requests for device data may include product identifiers such as model, lot, and catalog numbers of a device; the length of time a device has been in use; the disposition of a device involved in a reported event; results of any manufacturer failure testing; and copies of device labeling and instructions for use. This information enables the analyst to better assess the cause of a reported problem. In addition, information may be requested on the number of devices manufactured, distributed, and in use, which assists in determining the exposure of the population at risk. The analyst may also request that a manufacturer provide information on the frequency and severity of a reported event, as well as any corrective action taken by a manufacturer to address a reported problem.

In addition, the analyst may request an inspection of the manufacturer's facility when immediate follow-up on a reported event is necessary or when the reported event suggests the need for an FDA investigation. Upon receipt of the results of the investigation, the analyst evaluates the data and assesses whether or not further FDA action is needed. If warranted, the adverse event report and any related information are forwarded to the appropriate group within FDA for consideration of regulatory action, such as recall or device user notification through safety alerts, public health advisories, a press release warning the public of potential hazards associated with the device in use, or all three. If the analyst determines that no further action is needed, the adverse event report is archived for future research and monitoring.

# Comments From the Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

## Memorandum

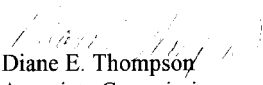
Date . OCT 28 1996

From Associate Commissioner for Legislative Affairs, FDA

Subject Comments on the GAO Draft Report entitled, **Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Approved Devices** (GAO/HAS-96-167)

To Sarah F. Jaggar  
Director, Health Services Quality and Public Health Issues  
U.S. General Accounting Office

Attached are our comments on the subject GAO draft report.

  
Diane E. Thompson  
Associate Commissioner  
for Legislative Affairs

Attachment

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COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE (GAO) DRAFT REPORT ENTITLED, "MEDICAL DEVICE REPORTING: Improvements Needed in FDA's System for Monitoring Approved Devices" (GAO/HAS-96-167)

GENERAL COMMENTS

The Department of Health and Human Services appreciates the opportunity to review the draft report and offer comments.

The GAO draft report addresses the Food and Drug Administration's (FDA or the Agency) implementation of the Safe Medical Devices Act of 1990 (SMDA) and its predecessor medical device reporting systems. It points to a number of opportunities for improvement to the current system with which we agree and which FDA has been implementing for several years. We believe it is misleading to characterize the adverse event reporting program as being fraught with weaknesses and very few, if any, strengths.

Context of Adverse Event Reporting

One significant flaw in the draft report is that it does not discuss medical devices reporting in the proper context. It gives the impression that adverse event reports operate alone in giving FDA post-market information about devices. FDA's postmarket surveillance system for medical devices includes site inspections, mandatory reports for devices approved under the premarket approval provisions of the Federal Food, Drug and Cosmetics Act (FFDCA), the Government-wide Quality Assurance Program, voluntary reporting from health care professionals and patients as well as the mandatory user facility reporting discussed in the draft report. FDA's Good Manufacturing Practices (GMP) regulations and related activities constitute the most comprehensive program FDA has for gathering intelligence regarding marketed medical devices. FDA also receives information through voluntary reports from users and manufacturers, other U.S. government agencies, foreign governments, physicians in private practice, scientific articles and from the press. The medical device reports supplement, in a systematic, deliberate way, the information gathered through inspection activities and give valuable information about the safety and effectiveness of devices when they are in use under ordinary circumstances. The draft report should clearly set forth the context in which the MDR is used and was evaluated by GAO.

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Design and process Flow of the System

The draft report does not credit FDA with recognizing and correcting deficiencies in the adverse event reporting system. The report gives the impression that problems that no longer exist still remain and remain unaddressed. To correct the problems that GAO cited, FDA has developed a new automated data system, Manufacturer and User Device Experience (MAUDE), and a new reporting form that incorporate most, if not all, the elements GAO considers necessary. The new form, the 3500A, was developed and distributed in 1992-93 and became mandatory with the effective date of the final regulations for Medical Device Reporting (MDR), July 31, 1996. Prior to that date, it was used voluntarily by many reporters. The 3500A reporting form was designed specifically to elicit from manufacturers and user facilities the information that they and FDA need to monitor the safety of marketed devices and track corrective actions. The form replaced several different individual reporting forms which were confusing to reporters.

The new form also was designed for use with the MAUDE. Input to the new system begins with the user facility providing information about a device-related incident to the manufacturer, who is responsible for determining the cause of the incident, its effect on the patient, making any required corrections, and submitting the user facility reports to FDA using the same form. FDA reviews the reports to ensure that immediate public health problems have been identified and resolved, and to identify emerging trends associated with the device, the firm, the industry or the user community. With use of the new system, FDA will receive data and have analytical capabilities that were unavailable prior to July 1996. The draft report mischaracterizes the process by assigning the manufacturers' role to FDA. This should be corrected.

Public Health Protection

The draft report states that FDA lacks evidence that adverse event reporting is currently protecting the public health or serving as an early warning system for defective medical devices because some data have not been entered into the computerized database and the system has not been completed. We believe this conclusion is much too general because it is based upon an evaluation of only one element of FDA's postmarket surveillance system. From this limited evaluation, the report indicts FDA's ability to take action against problem devices and thus protect the public. This conclusion is not supported by the facts, which are:

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1. FDA has a number of sources of information regarding medical device problems. The adverse event reporting system is only one of those.
2. FDA has available for its use a variety of regulatory actions, including civil and criminal penalties, that are utilized to protect the public.
3. FDA initiates recalls and provides training/education to user facilities and manufacturers to help ensure that the public is protected.
4. FDA's premarket approval activities and post-market surveillance are integrated into a comprehensive system that provides a network of protection for the public.

Therefore, the agency does not rely on the adverse event reporting system alone to effect corrective actions and protect the public health. Furthermore, the FDCA clearly places the responsibility for producing safe and effective devices on the manufacturers, not the FDA. The draft report offers no convincing substantiation for its very broad conclusion that the public may not be adequately protected from harmful devices.

Early Warning Use and Historical Use

While we acknowledge that better documentation of report review and data entry activities would be useful, FDA's total postmarket surveillance system does provide an adequate early warning system for device problems and helps to ensure that the public is protected. Contrary to the conclusions reached in the draft report, adverse event reports from all sources are promptly and thoroughly reviewed and appropriate actions are taken. Incoming incident reports (from both manufacturers and user facilities) are recorded in FDA's new computerized database that enables the agency to ascertain their significance to public health. The data in the system are used to protect the public health through recalls, investigations, safety alerts, public health advisories, and regulatory action when needed, as documentation provided to the GAO evaluators clearly demonstrates. FDA demonstrated MAUDE to the GAO evaluators, clearly showing that procedures are in place to ensure prompt and effective review of individual reports and to retrieve the data in a number of different configurations such as device by device, specific manufacturers, and by industry-wide segments. This system, although not yet fully operational, allows FDA to identify and analyze actual or potential device hazards in conjunction with the other components of postmarket surveillance.



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Contrary to implications in the draft report, the adverse event reporting system provides more than a one-time look at the data. FDA uses the data repeatedly for making decisions and conducting evaluations. User Facility Reports are evaluated by FDA health care professionals with clinical and scientific expertise to determine the significance of each report and decide the course of action the Agency should take. The health care professionals also must determine whether a problem is part of a trend, evaluate potential device problems, direct research and educational efforts, and issue/prioritize field investigations. When no immediate action is required by receipt of an individual report, the data is archived and may be reviewed any number of times in researching device problems.

Documenting Corrective Actions

GAO also concludes that FDA "has little assurance that the actions taken to correct device deficiencies are adequate to protect the public health without routinely documenting the corrective actions taken by manufacturers on problems identified in device reports." Although FDA currently does not annotate each individual report file with the corrective action, there is sufficient documentation of both administrative and regulatory actions required of manufacturers to correct problems that FDA is confident that the public health is being protected. Each recall, warning letter, seizure, or other formal enforcement action requires the agency to identify the risk to the public health and document it. Furthermore, FDA routinely follows up to ensure that prescribed corrective actions have been implemented and to check the effectiveness of the action. Also, when the manufacturer is next inspected, FDA investigators review the documentation of corrective actions taken independently by manufacturers. If there is no documentation, the manufacturer can be found out of compliance with FDA's regulations and subject to sanctions.

The draft report suggests that failure to link final disposition of a problem to the original report prevents FDA from notifying user facilities of the results of their reports. FDA acknowledges that the system designed in 1984 did not allow ready linkage of individual adverse device incident reports with their resolutions, although for several years the Agency made every effort to do so. In fact, before FDA eliminated this step, analysts were spending 20 percent of their time tracing corrective actions back to individual reports and recording outcomes in the file. Such linkage was complicated by the number of different sources of reports on related problems and the many possible courses of action available for resolving problems. It became very difficult and time-consuming to relate solutions to

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individual reports, particularly as the number of reports increased. The agency lacked sufficient resources to continue linking corrective action outcomes with the initiating report and also carry out higher priority activities that were more directly linked to public health. FDA, therefore, made a conscious decision to discontinue documenting problem resolutions on each individual report. Nevertheless, the MAUDE system will provide the capability to re-establish the linkage.

FDA has taken numerous actions, however, to keep the device user community informed of the requirements and current events relative to SMDA. In 1990, FDA held a public meeting of the user community to solicit input into drafting the user facility requirements. In 1992, FDA began publishing a quarterly bulletin, which is sent to over 75,000 user facilities and health care professionals. The bulletins are a significant means of reaching the user community with feedback about reports received by the agency and with educational information such as how to set up a reporting system, how to make decisions on what is reportable, devices that have not been used properly, and design problems they may encounter.

SMDA Implementation

The report also states that the user facility reporting requirements of the SMDA have not been fully implemented. The draft report would be more accurate to state that FDA issued a tentative final regulation as guidance to the user facilities in 1991, within the statutorily mandated 12-month timeframe. While the tentative final regulation was not, strictly speaking, enforceable, some user facilities began reporting in accordance with it and continued to do so until the final regulation for the SMDA, which was published in December 1995, became effective on July 31, 1996.

Confusing Use of Terminology

Throughout the draft report the terms, "Adverse Event Reporting Program," "Medical Device Reporting (MDR)," "User Facility Reporting" and "Safe Medical Devices Act (SMDA)" have been used interchangeably. Each of these terms refer to different aspects of the entire system. Using them interchangeably is confusing. For clarity, the terms should be used only to denote the specific programs defined below:

Adverse Event Reporting Program - a generic term which includes mandatory (manufacturer, user facility and distributor) and voluntary reporting.

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Medical Device Reporting - a generic term that includes all mandatory reporting obligations required by the MDR regulations, i.e., manufacturer, user facility reporting, and distributor reporting. This term does not include voluntary reporting.

User Facility Reporting - refers only to MDR reporting from device user facilities as defined in 21 CFR part 803.

Safe Medical Devices Act - refers to the SMDA of 1990 which includes user facility reporting as well as many other provisions for regulation of medical devices.

Recalls Resulting From MDR Reports

The draft report questions whether FDA can make use of the MDR reports to take appropriate corrective action. In response to the GAO draft report, FDA reviewed its database for the years 1984 through 1995 to determine how MDR reports were used to resolve medical device problems. The following table shows that of the 4365 recalls classified by FDA, 1099 (25.2 percent) have been associated with MDR reports. The table also shows that over half of all Class I recalls (those involving risk of death or serious injury) have been associated with MDR reports.

**Percentage of Recalls Associated with MDR Reports:  
Fiscal Year by Recall Classification**

	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	Avg
<b>Class I</b>	25.0	33.0	60.0	67.0	80.0	53.8	60.9	60.0	30.0	50.0	75.0	54.1
<b>Class II</b>	17.3	28.7	31.5	33.9	38.9	28.9	28.1	31.0	31.7	35.4	31.1	30.6
<b>Class III</b>	2.2	11.7	9.0	8.9	12.8	13.8	10.8	12.9	11.6	7.6	11.8	10.3

The new MDR system will make linkage of event and solution easier and may help FDA communicate better with the user facilities.

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Delays Resulting From the Volume of Adverse Event Reports

The draft report indicates that SMDA resulted in a dramatic increase in adverse event reports which created a backlog of unentered reports. At least three factors contributed to the backlog, which has since been eliminated. Enactment of the SMDA, receipt of over 90,000 breast implant reports between 1991 and 1995, and increased manufacturer compliance with the 1984 regulation all contributed to the large volume of reports that FDA had to evaluate and enter into its database between 1991 and 1995. Although some breast implant adverse events were reported under the SMDA provisions, most came from the manufacturers and would have been reported under the mandatory reporting requirements of the 1984 Act. It should be noted that the total backlog (about 48,000 reports) was less than half the total number of breast implant reports received. Although the SMDA contributed a large volume of reports, clearly, without the surge of breast implant reports, there would not have been a backlog. Even with the surge, FDA was able to address all the significant reports and has eliminated the backlog. It further should be noted that while FDA did not have adequate resources to implement the SMDA when it was enacted, today reports are all entered on the day of receipt. The draft report implies that a previously corrected problem still exists.

The GAO draft report also states that CDRH "experienced significant delays in processing and reviewing reports of potentially hazardous device problems." In fact, there was no delay in reviewing reports regarding real or potentially hazardous devices. Reports were screened immediately upon receipt to assess the severity of the incident. The FDA realized the potential impact of the increasing backlog and made a public health decision to enter death and serious injury reports immediately and to deal with less serious injury or malfunction reports when resources permitted. FDA expeditiously entered all significant reports into the database, analyzed the data as appropriate, and took action as required. The draft report should clearly state that the backlog did not compromise FDA's ability to identify serious problems or take appropriate action.

User Facility Compliance

The draft report cites a number of factors that may be affecting compliance by the user facility community and incorrectly suggests that one factor is the requirement that all user facility reports must be submitted to FDA within 10 days of the event. To the contrary, only death reports and reports of serious injuries for which the manufacturer is unknown are

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required to be submitted to FDA within the 10-day timeframe. All other user facility reports go first to the manufacturer and then are included in the user facilities' semi-annual report to FDA. Of the reports received through August 31, 1995, only the 1,863 death and serious injury reports (with no manufacturer identification) were required to be submitted to FDA within the 10-day time frame.

A particularly significant factor affecting possible under reporting that GAO did not address is the grave concern of user facility staff regarding possible institutional and/or professional liability as a result of reporting device problems, especially if the problem is related to user error. It is our impression that this is a major deterrent to user reporting.

GAO RECOMMENDATION

To improve FDA's ability to serve as an early warning system about medical device problems as intended by the Safe Medical Devices Act of 1990, we recommend that the Secretary of HHS direct FDA to ensure timeliness and accuracy of information in its medical device postmarketing surveillance system by including:

1. reliable statistics on response times for processing and reviewing, and taking action on medical device reports;

HHS COMMENT

We agree that FDA needs reliable statistics on the time taken to review and process reports and FDA has made considerable progress toward that goal. In fact, three years ago FDA began developing a new system, MAUDE, to implement the SMDA. One of the primary objectives of the new system is to produce reliable information regarding review and processing time. New capabilities in the adverse event reporting database will allow FDA to generate statistics on initial processing and review of MDR reports. It is not possible, however, to develop meaningful statistics on the time required to take action on a report. A given report may play a role in triggering action the day it is received, or at any future time because of the complex interplay of data received in multiple reports over time. This is an inherent attribute of any system that builds on reports accumulated over many years.

GAO RECOMMENDATION

2. using of medical device reports of death events provided by manufacturers and other reporters to

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identify user facilities suspected of under reporting device-related events to FDA and/or manufacturers in violation of SMDA 90;

HHS COMMENT

We concur. The draft report observes an apparent under reporting from user facilities, based on projections of the number of reports likely to be generated by the SMDA before it was enacted. It should be noted that with no previous experience with user facility reporting, projections were guesses at best. While we expect that some facilities are not reporting all reportable events, the volume of reports received to date is not insignificant and suggests that the majority of reportable events are, in fact, reported. Nevertheless, FDA already is developing methods to identify under reporting user facilities by using the User Facility Semi-annual Reports and Medical Device Reports from manufacturers. In addition, FDA's educational programs and expanded collaboration with the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the Health Care Financing Administration (HCFA) will help educate user facilities which we expect to improve compliance. FDA also will inspect user facilities to ascertain their compliance with mandatory reporting requirements.

FDA does not expect to continuously receive increasingly large numbers of previously unknown problems because the focus of FDA's regulatory activities is on prevention of adverse events. FDA's premarket approval program and enforcement of its extensive Good Manufacturing Practices (GMP) regulations are designed to prevent device problems before a product is marketed. We believe that prevention of problems is a more effective way of protecting public health than any system for identifying and correcting problems would be after the products are in use by the public.

GAO RECOMMENDATION

3. documenting of corrective actions on medical device reports that result from analysis and investigations of device problems; and

HHS COMMENT

We concur. FDA already is working to improve documentation of corrective actions associated with MDR reports. The 3500A form discussed above includes a field for recording corrective actions undertaken by manufacturers. New MDR reports will allow FDA to develop, over time, a useful database on such corrective actions. Many corrective actions, however, are not temporally associated

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with individual reports, especially corrective actions undertaken by FDA, and cannot be linked directly to the user facility reports. The resources required to do so would be prohibitive in light of the many demands placed on FDA to address situations that directly impact public health.

GAO RECOMMENDATION

4. collecting and disseminating MDR trend analysis and corrective actions taken by manufacturers and FDA to the medical device community.

HHS COMMENT

FDA agrees that communication with users, user facilities, and manufacturers concerning the value of adverse event data is necessary. To that end, FDA communicates its actions to the device user facility community through various means such as publications and public announcements, safety alerts, public health advisories, FDA newsletters and bulletins, and up-to-date information on the CDRH Internet Home Page. FDA also publishes articles in scientific and professional journals, and issues press releases and talk papers with the specific intent of informing both health care professionals and the general public about medical devices issues. While these measures are not direct communications with the user facility reporters, they do inform all interested parties about FDA actions regarding devices in general as well as specific problem devices. They also have a multiplier effect in that many more users and manufacturers are made aware of potential problems than would be possible through direct communication.

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# Related GAO Products

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Medical Device Regulation: Too Early to Assess European System's Value as Model for FDA (GAO/HEHS-96-65, Mar. 6, 1996).

Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority (GAO/PEMD-92-10, Feb. 13, 1992).

Medical Device Problem Reporting: A Case Study of a Home Apnea Monitor (GAO/T-PEMD-90-10, July 17, 1990).

Medical Devices: Underreporting of Serious Problems With a Home Apnea Monitor (GAO/PEMD-90-17, May 31, 1990).

Medical Devices: Underreporting of Problems, Backlogged Systems, and Weak Statutory Support (GAO/T-PEMD-90-2, Nov. 6, 1989).

Medical Devices: The Public Health at Risk (GAO/T-PEMD-90-2, Nov. 6, 1989).

Medical Device Recalls: Examination of Selected Cases (GAO/PEMD-90-6, Oct. 19, 1989).

Medical Device Recalls: An Overview and Analysis 1983-88 (GAO/PEMD-89-15BR, Aug. 30, 1989).

Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation (GAO/PEMD-89-10, Feb. 17, 1989).

Medical Devices: FDA's 510(k) Operations Could Be Improved (GAO/PEMD-88-30, July 11, 1988).

Medical Devices: FDA's Forecasts of Problem Reports and FTES Under H.R. 4640 (GAO/PEMD-88-30, July 11, 1988).

Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting (GAO/T-PEMD-87-4, May 4, 1987).

Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting (GAO/PEMD-87-1, Dec. 19, 1986).

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