Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

ADVERSE EVENT REPORTING
FOR MEDICAL DEVICES

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OBJECTIVES

1. To determine the extent of adverse event reporting from 2003 to 2007 by manufacturers and facilities that use medical devices.

2. To determine the extent to which manufacturers and facilities that use medical devices comply with adverse event reporting requirements for medical devices.

3. To assess how the Food and Drug Administration (FDA) uses medical device adverse event data to identify and address safety concerns.

BACKGROUND

Adverse event reporting enables FDA to take corrective action on problem devices and to prevent injury and death by alerting the public when potentially hazardous devices are discovered. Within FDA, the Center for Devices and Radiological Health (CDRH) is responsible for regulating medical devices.

Regulations require device manufacturers to report to FDA (1) within 30 calendar days of acquiring information that reasonably suggests one of their devices may have caused or contributed to a death, serious injury, or malfunction and (2) within 5 working days if an event requires action other than routine maintenance or service to prevent a public health issue. Regulations also require user facilities, such as hospitals and nursing homes, to report deaths to both the manufacturer, if known, and FDA within 10 working days. User facilities must report serious injuries to the manufacturers (or FDA if the manufacturer is unknown) within 10 working days. User facilities must also submit annual reports to FDA of all adverse event reports sent to manufacturers or FDA in the past year.

We used six data sources for this study: the Manufacturer and User Facility Device Experience (MAUDE) database, the alternative summary reports database, annual user facility reports, CDRH files on regulatory actions, structured interviews with CDRH analysts, and interviews with CDRH senior officials.

FINDINGS

Overall, FDA received twice as many adverse event reports for medical devices in 2007 than in 2003; however, some types of reports decreased. Manufacturers, user facilities, and other reporters submitted 72,866 medical device adverse event reports in 2003, which doubled to 150,210 reports in 2007. Manufacturers submitted the vast majority of these reports. Thirty-day reports of death, serious injury, and malfunction accounted for almost all manufacturer reports and drove the overall increase in adverse event reports.

Five-day reports made up less than 1 percent of manufacturer reports. Although the total number of manufacturer reports increased substantially, 5-day reports fell from 432 to 54 reports per year over the 5-year period.

Manufacturers submitted most adverse event reports on time, but many 5-day manufacturer and user facility reports were late. In 2007, manufacturers submitted 89 percent of all 30-day reports on time. This percentage has remained relatively unchanged since 2003. Although manufacturers submitted only 54 5-day reports in 2007, 31 percent of them were late. This was a decrease from a high of 64 percent in 2003 but an increase from 7 percent in 2005.

In 2007, user facilities submitted 39 percent of both death and injury adverse event reports late to FDA. From 2003, the percentage late ranged from 30 percent to 45 percent. Likewise, user facilities submitted at least 42 percent of adverse event reports late to manufacturers in each year from 2003 to 2007.

CDRH does not use adverse event reports in a systematic manner to detect and address safety concerns about medical devices. Analysts have documented little of their reviews, which can make it difficult to trace the response to an individual event. Outcomes of adverse events can result in a variety of postmarket surveillance activities; however, at this time CDRH cannot link these activities to particular adverse events. CDRH also lacks an established system to document when adverse event reports result in onsite inspections. CDRH's Office of Compliance does not document which reports resulted in inspections when analysts refer the reports. CDRH also does not document onsite inspections in its adverse event database (MAUDE).

CDRH does not consistently read adverse event reports for the first time in a timely manner. Analysts read fewer than one-third of adverse

event reports for the first time within 30 days and less than half within 60 days in every year from 2003 to 2007. CDRH's procedures require that high-priority adverse event reports be in MAUDE and ready for analysts to review within 96 hours of receipt; however, we were unable to verify CDRH's compliance with these procedures through its documents.

CDRH rarely acts when manufacturers and user facilities submit reports late. Analysts told us they generally forward concerns about timeliness only when they notice pervasive problems, and they usually handle concerns informally by calling the manufacturers.

The inability to obtain complete and usable information in adverse event reports hinders analysts' review of reports. Analysts also pointed to MAUDE as an impediment because they cannot easily conduct trend analysis and MAUDE does not connect with other CDRH databases.

CDRH makes limited use of annual reports. We identified at least 526 user facilities that should have submitted annual reports for 2006, but CDRH could provide only 220 annual reports for that year. We could not determine whether facilities did not submit reports or whether CDRH was unable to supply copies.

RECOMMENDATIONS

To improve how FDA uses adverse event reports to identify and address safety concerns, FDA should:

Develop a protocol for reviewing adverse event reports that specifically addresses the following needs:

Document followup on adverse events. CDRH should develop systems that reference the actions it takes on particular adverse event reports. In addition, CDRH should consider developing a tracking system to follow the outcome of referrals sent to the Office of Compliance.

Ensure and document that CDRH is meeting its guidelines for reviewing all 5-day and Code Blue adverse event reports. CDRH established 5-day and Code Blue reports (reports of pediatric deaths, multiple deaths, exsanguinations, explosions, fires, burns, electrocutions, and anaphylaxis) as the highest priority reports. Following its own procedures, which require that contractors enter all high-priority reports in MAUDE within 24 hours and analysts first read them within 96 hours, would ensure that CDRH knew whether manufacturers took the appropriate steps.

Follow up with manufacturers that routinely submit reports late or with incomplete information. CDRH should identify and target manufacturers and user facilities with a history of noncompliance with adverse event submission requirements.

Enhance outreach strategies to reduce underreporting by user facilities. CDRH should consider implementing strategies such as the type of additional training and outreach that the MedSun program has used to work effectively with its participants to increase reporting.

Seek legislative authority to eliminate the requirement for user facilities to submit annual reports. Eliminating this requirement (21 U.S.C. § 360i(b)(c)) would decrease the regulatory burden on user facilities, as well as CDRH. Other than a count of total adverse event reports, all of the information in the annual reports is redundant to the originally submitted reports.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA agreed with both of our recommendations. In response to our first recommendation, FDA said that CDRH will develop a clear review protocol that addresses the needs our report identified. To achieve this, FDA stated that its new FDA Adverse Event database will allow for more extensive documentation of followup on adverse events and permit FDA to more readily identify late and incomplete reports. FDA also stated that CDRH has developed a tracking system that facilitates referrals to the Office of Compliance and follows up on them. Finally, FDA will identify steps it will take to stimulate user facility reporting.

Because FDA stated that a change in statutory authority would be needed to eliminate the requirement to submit annual reports, we revised our second recommendation accordingly.

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BACKGROUND

FDA is responsible for ensuring the safety and effectiveness of medical devices in this country. These devices range from bandages and tongue depressors to pacemakers and implantable infusion pumps. FDA's Center for Devices and Radiological Health (CDRH) has approved more than 20,000 firms to produce nearly 100,000 medical devices.[1] [2] Within FDA, CDRH is responsible for regulating medical devices as well as regulating unnecessary radiation exposure from medical, occupational, and consumer products.[3]

Adverse event reporting represents a critical component of FDA's information-gathering process after it has approved or cleared a medical device for marketing. Adverse event reporting enables FDA to take corrective action on problem devices and to prevent injury and death by alerting the public when potentially hazardous devices are discovered. Analyzing adverse event reporting also enables FDA to detect unanticipated events and user errors, monitor and classify recalls, update medical device labels, and develop educational outreach. Adverse event reports supply FDA with the most comprehensive source

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[1] FDA, CDRH. "Better Health Care With Quality Medical Devices: FDA on the Cutting Edge of Device Technology," February 2002. Available online at http://download.journals.elsevierhealth.com/pdfs/journals/1075-4210/PIIS107542100200007X.pdf. Last accessed on June 23, 2009.

[2] FDA, CDRH. "CDRH FY 2006 Annual Report," 2006. Available online at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf. Last accessed on June 23, 2009.

[3] FDA, CDRH. "About the Center for Devices and Radiological Health," June 4, 2009. Available online at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/default.htm. Last accessed on June 11, 2009.

of information about the safety and effectiveness of the device as it is used in everyday circumstances. Using adverse event report data, FDA can detect problems previously unknown to the manufacturer as well as problems with similar devices or device categories.

Adverse Event Reporting for Medical Devices

FDA, through its MedWatch program, collects information about injuries and adverse events that occur when using medical devices. MedWatch is FDA's program for reporting serious reactions; product quality problems; therapeutic inequivalence or failure; and product use errors with human medical products, such as drugs and medical devices.[4] Mandatory adverse event reporting began in 1984 when FDA set forth regulations requiring manufacturers and importers to notify CDRH when they become aware of a death or serious injury that may be associated with one of their devices or a device malfunction that would likely cause or contribute to a death or serious injury if that malfunction were to recur.[5] The Safe Medical Devices Act of 1990 extended these reporting requirements to facilities that use medical devices (hereinafter referred to as user facilities), which include hospitals, ambulatory surgical facilities, nursing homes, and outpatient treatment facilities that are not physicians' offices.[6] The final regulations governing these reporting requirements took effect in 1996.[7]

The Medical Device Amendments of 1992 mandated changes to the adverse event regulations for manufacturers and user facilities by requiring a single reporting standard and defining the types of injuries that must be reported.[8] [9] The regulations mandate that manufacturers and user facilities provide information about the patient, adverse event, and suspect device.[10] Manufacturers must also provide the device

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[4] FDA. "MedWatch—Reporting by Consumers," June 8, 2009. Available online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm.   Last accessed on June 11, 2009.

[5] 49 Fed. Reg. 36326, 36348 (Sep. 14, 1984).

[6] Safe Medical Devices Act of 1990. P.L. No. 101-629 § 2, Federal Food, Drug, and Cosmetic Act, § 519(b), 42 U.S.C. § 360i(b).

[7] 60 Fed. Reg. 63578 (Dec. 11, 1995); 61 Fed. Reg. 16043 (Apr. 11, 1996).

[8] Medical Device Amendments of 1992, P.L. No. 102-300 § 5, Federal Food, Drug, and Cosmetic Act, § 519(a), 42 U.S.C. § 360i(a).

[9] The regulations define serious injury as any illness or injury that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or requires medical or surgical intervention to prevent such permanent effects. 21 CFR § 803.3.

[10] 21 CFR §§ 803.23, 803.52.

specifications and details about any evaluation of the device.[11] User facilities must submit information about the specific event or problem, including how the device was involved and where the event or problem occurred.[12]

Federal regulations require manufacturers to report to FDA within 30 calendar days of acquiring information that reasonably suggests one of their devices may have malfunctioned or caused or contributed to a death or serious injury.[13] Manufacturers must report within 5 working days if an event requires action other than routine maintenance or service to prevent a public health issue or if FDA has made a request for 5-day reports.[14] If a manufacturer lacks the required information at the time of the report or obtains additional information after submitting the initial report, it must provide supplemental adverse event reports to FDA.[15]

Regulations also require user facilities to report device-related deaths to both the manufacturer, if known, and FDA within 10 working days.[16] User facilities must also report device-related serious injuries to the manufacturers (or FDA if the manufacturer is unknown) within 10 working days.[17] In addition, user facilities must submit annual reports to FDA that include either summaries or copies of all adverse event reports sent to manufacturers or FDA in the past year.[18] Table 1 summarizes the reporting requirements for manufacturers and user facilities.

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[11] 21 CFR 803.52.

[12] 21 CFR §§ 803.11, 803.32; MedWatch Form FDA 3500A. Available online at http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm08272. pdf. Last accessed on March 12, 2009.

[13] 21 CFR §§ 803.3 and 803.10(c)(1).

[14] 21 CFR §§ 803.3 and 803.10(c)(2).

[15] 21 CFR § 803.10(c)(3).

[16] 21 CFR § 803.10(a)(1)(i).

[17] 21 CFR § 803.10(a)(1)(ii).

[18] 21 CFR §§ 803.10(a)(2) and 803.33.

Table 1: Adverse Event Reporting Requirements

Who Is Reporting	What To Report	To Whom To Report	When To Report
Medical Device Manufacturer	Events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated in writing by FDA	FDA	Within 5 working days of becoming aware of the event
	Deaths, serious injuries, and malfunctions	FDA	Within 30 calendar days of becoming aware of the event
User Facility	Deaths	Manufacturer (if known) and FDA	Within 10 working days of the event
	Serious injuries	Manufacturer (if known) or FDA	Within 10 working days of the event
	Annual reports of all adverse events the facility reported during the past year	FDA	Annually (by January 1st)

Source: 21 CFR § 803.

Consumers and health care professionals may voluntarily submit adverse event reports.[19] In fiscal year (FY) 2006, FDA received 114,291 mandatory reports and 5,265 voluntary reports.[20]

Alternative Summary Reports
On October 1, 1999, CDRH began accepting requests to participate in the alternative summary report (ASR) program, which allows manufacturers to submit abbreviated and aggregated adverse event reports.[21] Manufacturers must apply for permission from FDA to submit quarterly ASRs for individual medical devices.[22] For all other devices, manufacturers continue to submit full adverse event reports. Manufacturers must submit ASRs within 1 month following the

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[19] FDA. "How to Report a Medical Device Problem." Available online at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm. Last accessed on June 16, 2009.

[20] FDA, CDRH. "FY 2006 Annual Report," September 2007. Available online at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129324.htm. Last accessed on June 16, 2009.

[21] FDA, CDRH. "Medical Device Reporting—Alternative Summary Reporting Program," October 2000. Available online at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072029.htm. Last accessed on June 16, 2009.

[22] Ibid.

reporting quarter. FDA stores ASRs in a different database than other manufacturer reports.

Rather than individually reviewing ASRs, CDRH conducts trend analyses on them, such as calculating occurrence rate changes for specific events. CDRH may request a manufacturer to submit a full report if it needs additional information about a specific event. In FY 2006, CDRH received information about 104,641 adverse events submitted through ASRs.[23]

MedSun Program

In 2002, CDRH launched the Medical Product Safety Network (MedSun) pilot project to increase user facility reporting rates and improve the quality of reports. About 350 user facilities, primarily hospitals, participate voluntarily. This represents a small fraction of the thousands of hospitals, nursing homes, ambulatory surgical centers, and outpatient treatment facilities that use devices. MedSun participants submit additional information that could help improve the safe and effective use of medical devices.[24]

MedSun analysts work closely with participating user facilities to assist them in determining the appropriate response to adverse events. User facilities receive additional training on reporting events and feedback regarding the reports that they submitted. In addition to mandating reporting of deaths and serious injuries, CDRH encourages MedSun participants to report close calls and user errors voluntarily.

Manufacturer and User Facility Device Experience Database

Since 1996, the Manufacturer and User Facility Device Experience (MAUDE) database has housed all voluntary and mandatory adverse event reports, including reports submitted through MedSun. CDRH analysts use MAUDE to review the adverse event reports and examine specific devices' adverse event histories as well as those of similar devices. FDA is in the process of replacing MAUDE with the FDA Adverse Event Reporting System, which will house adverse event

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[23] FDA, CDRH. "FY 2006 Annual Report," September 2007. Available online at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129324.htm. Last accessed on March 12, 2009.

[24] FDA, CDRH. "MedSun: About MedSun," May 21, 2009. Available online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm. Last accessed on March 12, 2009.

information from all five FDA centers.[25] CDRH will implement the new system at the end of 2010.[26]

CDRH Review of Adverse Events

Each night, MAUDE forwards new reports to CDRH analysts based on their specialties, which range from nursing to engineering. CDRH prioritizes the review of adverse event reports moving from the most to the least serious:

- 5-day reports (those required to be reported within 5 days of an adverse event);

- Code Blue reports (reports of pediatric deaths, multiple deaths, exsanguinations, explosions, fires, burns, electrocutions, and anaphylaxis);

- individual death and serious injury reports (those required to be reported within 30 days of an adverse event); and

- malfunction reports (MAUDE randomly chooses 1 of every 10 malfunction reports for review).

Analysts review the device's label, research its history, and analyze trends to ensure that the device's warning reflects the adverse event and occurs at no greater than the expected rate. If analysts need more information, they may request additional details from the manufacturer.[27]   If a type of event mentioned in the warning occurred and the manufacturer took the appropriate response, analysts stop researching the adverse event and save the report in the database for trending and further use.

When appropriate, analysts may recommend specific actions based on their reviews. These actions include warning physicians and the public about potential health concerns, requiring manufacturers to conduct postmarket studies, increasing education and outreach to manufacturers and user facilities, and consulting with other CDRH offices to arrange field investigations. Analysts also may exchange

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[25] The five FDA centers are CDRH, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine.

[26] FDA, CDRH. "MedWatch Plus/FAERS." Available online at http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/SpotlightonCPIProjects/ucm083295.htm. Last accessed on March 12, 2009.

[27] 21 CFR § 803.15.

information with premarket reviewers about problems noticed during a device's approval, which might assist them in determining whether further action is necessary. In the most serious situations, CDRH may request for-cause inspections of the manufacturers.[28]

CDRH, through the Office of Compliance, sends all requests for manufacturer inspections to FDA's Office of Regulatory Affairs, which conducts inspections and recommends classifications.[29] However, CDRH makes the final decisions regarding classification after reviewing the inspection reports. FDA has several means to protect the public from unsafe and ineffective devices, including:[30]

- recalling a medical device from the marketplace,[31]

- withdrawing and temporarily suspending an approved application,[32]

- requiring a manufacturer to conduct postmarket surveillance,[33]

- levying a civil monetary penalty not to exceed $150,000 per event and $1 million per proceeding,[34]

- issuing a warning of FDA's intent to seek criminal prosecution,[35]

- filing a proceeding to seize a specified device,[36]

- seeking an injunction,[37] or

- referring the matter to the appropriate United States Attorney for prosecution.[38]

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[28] A for-cause inspection is based on a previous problem or complaint.

[29] Inspections can result in one of three classifications: no action indicated, voluntary action indicated, or official action indicated.

[30] FDA. "Regulatory Procedures Manual," March 2008. Available online at http://www.fda.gov/ora/compliance_ref/rpm/.   Last accessed on March 12, 2009.

[31] 21 U.S.C. § 360h(e).

[32] 21 U.S.C. § 360e(e).

[33] 21 U.S.C. § 360l(a).

[34] 21 U.S.C. § 333(f)(1).

[35] 21 U.S.C. § 335.

[36] 21 U.S.C. § 334(a).

[37] 21 U.S.C. § 332(a).

[38] 21 U.S.C. § 333(a).

METHODOLOGY

Scope

This study focused on the universe of reported medical device adverse events contained in the MAUDE and ASR databases from 2003 to 2007.

Data Collection and Analysis

We used six data sources for this evaluation:

(1) MAUDE: the FDA database containing manufacturer, user facility, distributor, and voluntary reports;

(2) ASR database: the FDA database containing reports that manufacturers submitted quarterly to FDA;

(3) annual user facility reports;

(4) CDRH files on compliance and enforcement actions from the Office of Compliance about manufacturer inspections and information about regulatory actions taken;

(5) structured interviews with all 16 CDRH analysts who review individual adverse event reports; and

(6) interviews with CDRH senior officials.

Appendix A contains a full description of the methods.

Limitations

We did not verify information in the adverse event reports from the user facilities or manufacturers. We also did not calculate the magnitude of underreporting from either user facilities or manufacturers. Finally, this report does not make determinations about the appropriateness of the analysts' decisions or the actions that CDRH took pertaining to any adverse event report.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

Overall, FDA received twice as many adverse event reports for medical devices in 2007 than in 2003; however, some types of reports decreased

Manufacturers, user facilities, distributors, and other voluntary reporters, such as consumers and physicians, submitted 72,866 medical device adverse event reports in 2003. By 2007, that number more than doubled to 150,210 reports. Medical device manufacturers submitted the vast majority of these reports. Between 2003 and 2007, manufacturer reports increased from 90 to 94 percent of all reports. Reports from user facilities and those from distributors and voluntary reporters made up the few remaining reports. (See Appendix B for details.)

The increase in 30-day manufacturer reports drove the overall increase
Thirty-day reports of death, serious injury, and malfunction accounted for almost 100 percent of manufacturer reports and drove the overall increase in adverse event reports. The remaining manufacturer reports were mostly 5-day reports, but also included FDA special requests and reports without a classification. (See Table 2 for details.)

Five-day reports, resulting from an adverse event that necessitates remedial action to prevent a public health risk, made up less than 1 percent of manufacturer reports. Although the total number of manufacturer reports substantially increased, 5-day reports decreased from 432 to 54 reports per year over the 5-year period. It is unclear why the number of reports decreased; however, the decrease might be explained by reporters misclassifying the reports, an actual decrease in 5-day reports, or a combination of the two.

Table 2: Manufacturer Adverse Event Reports 2003–2007

Type of Manufacturer Reports	2003	2004	2005	2006	2007
Thirty-day manufacturer reports	64,784	70,505	89,983	109,527	140,698
Percentage of total manufacturer reports	100%	100%	100%	100%	100%
Five-day manufacturer reports	432	203	160	134	54
Percentage of total manufacturer reports	1%	0%	0%	0%	0%
Other manufacturer reports*	1	10	14	15	313
Percentage of total manufacturer reports	0%	0%	0%	0%	0%
Total manufacturer reports	65,217	70,718	90,157	109,676	141,065

Source: Office of Inspector General (OIG) analysis of MAUDE adverse event data, 2009.
Percentages do not add to 100 because of rounding.

* Other manufacturer reports include FDA-requested reports and reports that are missing a classification.

In addition to submitting individual adverse event reports, manufacturers submitted 233 quarterly ASRs in 2007, a slight increase from the 209 ASRs they submitted in 2003. Each ASR may include thousands of adverse events that occurred in the preceding quarter. In 2003, ASRs contained 91,192 adverse events. This number increased steadily until 2006, when it increased more than fourfold to 443,066 events, and then stayed relatively flat with 449,978 events in 2007. The vast majority of that fourfold increase can be attributed to one particular manufacturer's device. That manufacturer started reporting adverse events involving this device using ASRs in 2006. This device accounted for 312,625 events in 2006 and 309,918 in 2007.

MedSun user facilities submitted more reports than all other user facilities
Through their submission of both mandatory and voluntary reports, the MedSun facilities accounted for 78 percent of all user facility adverse event reports in 2007. User facilities include hospitals, ambulatory surgical facilities, nursing homes, and outpatient treatment facilities that are not physicians' offices. In fact, the large increase in MedSun reports caused the total number of user facility reports to increase 12 percent over the 5 years. (See Table 3.)

Table 3: Non-MedSun and MedSun User Facility Reports

Type of Report	2003	2004	2005	2006	2007
Total non-MedSun reports	2,029	1,592	1,273	879	697
Mandatory reports	1,275	1,035	79	596	532
Voluntary reports	754	557	494	283	165
Total MedSun reports	861	1,664	2,479	2,169	2,537
Mandatory reports	100	308	330	210	251
Voluntary reports	761	1,356	2,149	1,959	2,286
Total user facility reports	**2,890**	**3,256**	**3,752**	**3,048**	**3,234**

Source: OIG analysis of MAUDE adverse event data, 2009.

The decrease in and low numbers of reports from non-MedSun facilities highlight a potential reporting problem. Of the roughly 350 MedSun facilities, 252 submitted at least one adverse event report in 2007, up from 104 facilities in 2003. (See Table 4.) Conversely, only 267 non-MedSun user facilities out of the thousands of potential user facilities submitted reports in 2007, down from 719 in 2003. Certainly some of the discrepancy results from the special attention and training MedSun facilities receive, but the low rate of reporting from other

facilities raises concerns about potential underreporting of adverse events.

Table 4: User Facilities That Reported Adverse Events

Number of User Facilities Reporting	2003	2004	2005	2006	2007
Total non-MedSun facilities	719	519	458	306	267
Total MedSun facilities	104	192	246	220	252
Total user facilities reporting	**823**	**711**	**704**	**526**	**519**

Source: OIG analysis of MAUDE adverse event data, 2009.

Despite the sharp drop in non-MedSun user facility reporting, CDRH has offered little outreach to these user facilities. CDRH staff are available during business hours to answer user facilities' reporting questions, and the agency posts guidance documents online. However, outreach has been limited to a few conferences in the last 5 years.

Manufacturers submitted most adverse event reports on time, but many 5-day manufacturer and user facility reports were late

In 2007, manufacturers submitted 89 percent of all 30-day reports on time. This percentage has remained relatively unchanged since 2003, when manufacturers submitted 88 percent on time.

Most 30-day reports were on time, but an increasing number of 5-day reports and ASRs were late

Although manufacturers submitted only 54 5-day reports in 2007, 31 percent of them were late. This was down from a high of 64 percent in 2003 but up from 7 percent in 2005. (See Table 5.) Manufacturers also submitted an increasing percentage of ASRs late. In 2003, 6 percent of ASRs were late, but by 2007, 53 percent were late.

Table 5: Timeliness of Manufacturer Reports 2003–2007

	2003	2004	2005	2006	2007
Thirty-day manufacturer reports	64,784	70,505	89,983	109,527	140,698
Percentage of reports on time	88%	89%	92%	91%	89%
Percentage of reports late	8%	7%	5%	7%	8%
Percentage of unable to determine	4%	4%	3%	3%	3%
Emergency 5-day manufacturer reports	432	203	160	134	54
Percentage of reports on time	28%	77%	88%	84%	65%
Percentage of reports late	64%	21%	7%	14%	31%
Percentage of unable to determine	8%	2%	5%	2%	4%
Other manufacturer reports *	1	10	14	15	313
Total manufacturer reports	**65,217**	**70,718**	**90,157**	**109,676**	**141,065**

Source: OIG analysis of MAUDE adverse event data, 2009.
Percentages do not add to 100 because of rounding.

* Other manufacturer reports include FDA-requested reports and reports that are missing classifications.

User facilities submitted at least 30 percent of adverse event reports late

In 2007, user facilities submitted 39 percent of both death and injury adverse event reports late to FDA. The percentage late ranged from 30 percent in 2005 to 45 percent in 2006. (See Table 6.)

Table 6: Late User Facility Reports to FDA 2003–2007

Report Types to FDA	2003	2004	2005	2006	2007
Total death reports in MAUDE to FDA	151	142	99	69	66
Number late	74	55	37	26	32
Percentage late	49%	39%	37%	38%	48%
Total injury reports in MAUDE to FDA	627	516	402	305	301
Number late	239	206	115	141	110
Percentage late	38%	40%	29%	46%	37%
Total death and injury reports in MAUDE to FDA	778	658	501	374	367
Number late	313	261	152	167	142
Percentage late	40%	40%	30%	45%	39%

Source: OIG analysis of MAUDE adverse event data, 2009.

Likewise, user facilities submitted at least 42 percent of adverse event reports late to manufacturers in each year from 2003 to 2007. Although the number of adverse event reports submitted to manufacturers

declined from 2003 to 2007, the percentage late stayed relatively flat. (See Table 7.)

Table 7: Late User Facility Reports to Manufacturers 2003–2007

Report Types to Manufacturers	2003	2004	2005	2006	2007
Total death reports in MAUDE to manufacturers	151	119	95	67	55
Number late	74	51	39	24	29
Percentage late	49%	43%	41%	36%	53%
Total injury reports in MAUDE to manufacturers	813	675	475	346	335
Number late	345	305	201	170	141
Percentage late	42%	45%	42%	49%	42%
Total death and injury reports in MAUDE to manufacturers	964	794	570	413	390
Number late	419	356	240	194	170
Percentage late	43%	45%	42%	47%	44%

Source: OIG analysis of MAUDE adverse event data, 2009.

CDRH does not use adverse event reports in a systematic manner to detect and address safety concerns about medical devices

The adverse event reporting system enables CDRH to gather information about potentially hazardous devices that could cause either injury or death. It is not clear, however, the extent to which CDRH uses this information to identify and address problems with medical devices.

CDRH has not documented followup on adverse event reports

MAUDE enables analysts to document when they send out additional information requests, place a telephone call, recommend an inspection, or take other actions during the review of an adverse event report. In practice, however, analysts document little of their reviews, which can make it difficult to trace the response to an individual event. For example, analysts reported that they often send requests for additional information to manufacturers that omitted pertinent information or specific details about the event, yet the analysts documented sending requests for only 5 percent of reports in 2007.

Outcomes of adverse events can result in a variety of postmarket surveillance activities, such as public health notifications, warning letters, and education of manufacturers and user facilities. At this time, CDRH cannot link these responses to particular adverse events through documentation.

CDRH also lacks an established system to document when adverse event reports result in onsite inspections. Although analysts refer adverse event reports to CDRH's Office of Compliance to pursue regulatory action, the office does not document which reports resulted in inspections. Between 2003 and 2007, 7 of 130 onsite inspections (5 percent) specifically referenced adverse event numbers in their files. (See Table 8.) According to CDRH staff, a single adverse event report would not generally prompt an onsite inspection, and the Office of Compliance's records do not indicate whether the adverse event report was the primary reason for the inspection.

Table 8: For-Cause Inspections Related to Adverse Event Reports

	2003	2004	2005	2006	2007	Total '03 - '07
Suspect products or devices	2	12	13	11	4	42
Inspection sites	2	19	37	62	10	130
CDRH establishment inspection reports not received	2	11	16	25	4	58
Percentage of inspection sites	100%	58%	43%	40%	40%	45%
Adverse event report numbers identified in files	0	3	3	1	0	7

Source: OIG analysis of Office of Compliance files, 2009.

The limited documentation extends to inspection results. In the Office of Compliance's files, 58 of 130 inspection files for 2003 to 2007 (45 percent) did not contain the Establishment Inspection Reports. (See Table 8.) That report includes observations from the onsite inspection and the recommended classification of the inspection. CDRH was able to determine the outcomes of 37 of those 58 inspections by looking in a separate database; however, CDRH was unable to provide information about the outcomes of the remaining 21 inspections. CDRH's files also indicated that regulatory action resulting from inspections associated with adverse events was limited to eight warning letters during that time.

CDRH also does not document onsite inspections in the MAUDE database. Our analysis found that analysts recommended inspections for 39 reports. However, we were unable to match any of those adverse event report numbers with onsite inspection files from the Office of Compliance.

The analysts we interviewed reported a need for information about the inspections or other corrective actions. Most analysts (12 of 16) reported that the lack of feedback from the Office of Compliance is a barrier for them to effectively do their jobs. They reported that the lack of information about the outcomes of their referrals makes it difficult to follow up with user facilities and manufacturers. It also affects how analysts might respond to additional adverse event reports from the same reporter.

CDRH does not consistently read adverse event reports for the first time in a timely manner

Of the adverse event reports in MAUDE that were read, analysts read fewer than one-third of them for the first time within 30 days and less than half within 60 days in every year from 2003 through 2007. (See Table 9.) The vast majority of the unread reports were malfunction reports, and MAUDE assigns only 10 percent of those reports to analysts for review. Failure to review reports in a timely manner may result in harm to other consumers if the manufacturer misclassified the adverse event (e.g., submitting a 30-day report rather than a 5-day report).

CDRH has procedures for reviewing Code Blue and 5-day reports; however, we are unable to verify through CDRH's documents whether it met the deadlines laid out in those procedures. The procedures call for a contractor to review and identify these reports. The contractor then notifies by email the appropriate personnel of all Code Blue or 5-day reports. The contractor initially enters these reports into MAUDE within 24 hours of receiving them, and they should be ready for the analysts to review within 96 hours of their receipt. Our review of MAUDE indicates that analysts first read only 6 percent of 5-day reports within 5 days of when the reports were entered in 2007. From 2003 to 2006 analysts read less than 1 percent of these reports within 5 days. For more detailed information on how soon analysts read 5-day reports, see Appendix D.

Table 9: Timeliness of FDA Review of Adverse Event Reports 2003–2007

How Soon the Report Is Read	2003	2004	2005	2006	2007
All read reports in MAUDE	48,093	52,294	61,617	86,566	122,469
Within 0 to 5 days	0%	0%	0%	0%	0%
Within 6 to 10 days	3%	3%	4%	3%	2%
Within 11 to 30 days	29%	23%	30%	27%	21%
Within 31 to 60 days	14%	12%	8%	12%	18%
After 60 days	54%	61%	58%	58%	59%

Source: OIG analysis of MAUDE adverse event data, 2009.
Percentages do not add to 100 because of rounding.

CDRH rarely acts when manufacturers and user facilities submit reports late

Analysts told us that they generally forward concerns about timeliness to CDRH's Division of Surveillance Systems, which manages reporting requirements, only when they notice pervasive problems. In interviews, many analysts told us that they handle concerns about timeliness informally by calling the manufacturer. CDRH senior officials told us that they rely on analysts to forward information on lack of timely reporting to that division. When it receives concerns, CDRH may schedule a conference with the manufacturer. If the problems persist, CDRH may forward the information to the appropriate district office to include in the manufacturer's next onsite inspection.

Inability to obtain complete and usable information in adverse event reports and in MAUDE hinders analysts' review of reports

Analysts reported that they are unable to make determinations about adverse events as quickly as they would like because of data quality and data management obstacles. Although manufacturers and user facilities generally submit the required event description on the report form, analysts told us that the description is often too vague to be of use in their evaluation. Almost all adverse event reports from 2003 to 2007 included an event description, although in 2007 the number of reports missing descriptions increased. We did not evaluate the quality of the event descriptions. Missing or vague information can force analysts to spend time tracking down additional information, potentially adding weeks or months to the process. (See Appendix C for details.)

Analysts also pointed to MAUDE as an impediment to making swift decisions. They told us that they are unable to easily conduct trend analysis of adverse events using MAUDE. Additionally, MAUDE does not connect with other CDRH databases, which would facilitate

researching information such as the current device label. FDA is in the
process of migrating to a new system, the FDA Adverse Event Reporting
System, which may address some of the current MAUDE deficiencies.

CDRH makes limited use of annual reports
We identified at least 526 user facilities that should have submitted
annual reports for 2006, but CDRH could provide only 220 annual
reports for that year. We could not determine whether facilities did not
submit reports or CDRH was unable to supply copies. Either reason
suggests that these reports have limited utility for the agency.

CDRH makes limited use of the annual reports that are submitted.
Staff use them only to verify that corresponding death reports are in
MAUDE. Our analysis confirmed that all 24 deaths from the
2006 annual reports were in MAUDE. CDRH officials told us that they
enter missing death reports from the user facilities into MAUDE but
generally do not contact the user facilities. Except for a cover sheet
with a count of reports, the event information in the annual report
should be redundant to previously submitted information.

► RECOMMENDATIONS

The adverse event reporting system provides both CDRH and manufacturers with a means to identify and monitor significant adverse events involving medical devices. Our evaluation found that although many manufacturers submitted 30-day adverse events on a timely basis, compliance rates for 5-day and user facility reports could be improved. This evaluation highlights CDRH's vulnerabilities in its ability to identify and address safety concerns for medical devices.

CDRH has taken steps to improve its data systems and how it communicates. FDA is in the process of replacing MAUDE with the FDA Adverse Event Reporting System, which will store adverse events for all five of FDA's centers. CDRH also recently formed committees made up of representatives from across CDRH to discuss how to proceed with analyzing adverse events that require followup. The goals of these committees are to improve communication and share information.

As the number of adverse event reports continues to increase, we recognize the challenges of processing a growing workload in a limited time while staffing levels remain the same. Given this challenge, it is essential that the review process be as transparent as possible and the information about specific adverse events be formally documented in a searchable and easily retrieved format.

In light of our findings, CDRH should:

Develop a protocol for reviewing adverse event reports that specifically addresses the following needs:
Document followup on adverse events. CDRH should develop systems that reference the actions it takes on particular adverse event reports. Communication with manufacturers and user facilities, recommended actions, and onsite inspections should be clearly documented in records linked by a unique adverse event number.

In addition, CDRH should consider developing a tracking system to follow the outcome of referrals that analysts send to the Office of Compliance. This could enhance the communication between the Office of Compliance and the analysts.

Ensure and document that CDRH is meeting its guidelines for reviewing all 5-day and Code Blue adverse event reports. Considerable time can pass from the date of the actual event until an analyst reads the report for the first time. Although CDRH cannot control when manufacturers submit reports, it can influence how quickly analysts first assess the

events and the actions the manufacturers are pursuing. Following its own procedures, which require that contractors initially enter all priority reports in MAUDE within 24 hours and analysts read them within 96 hours would ensure that CDRH knows whether manufacturers took the appropriate steps.

Follow up with manufacturers that routinely submit reports late or with incomplete information. CDRH should identify and target manufacturers and user facilities with a history of noncompliance with adverse event submission requirements.

Enhance outreach strategies to reduce underreporting by user facilities. To increase reporting among non-MedSun user facilities, CDRH should consider implementing strategies such as the type of additional training and outreach that the MedSun program has used to work effectively with its participants to increase reporting.

Seek legislative authority to eliminate the requirement for user facilities to submit annual reports

Other than a count of total adverse event reports, all of the information in the annual reports is redundant to the originally submitted reports. Eliminating this requirement (21 U.S.C. § 360i(b)(c)) would decrease the regulatory burden on user facilities, as well as the review burden on CDRH. Instead, CDRH should emphasize the importance of timely and appropriate reporting of all injuries and deaths by user facilities.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA agreed with both of our recommendations. In response to our first recommendation, FDA said that CDRH will develop a clear review protocol that addresses the needs our report identified. To achieve this, FDA stated that its new FDA Adverse Event database will allow for more extensive documentation of followup on adverse events and permit FDA to more readily identify late and incomplete reports. FDA also stated that CDRH has developed a tracking system that facilitates referrals to the Office of Compliance and follows up on them. Finally, FDA will identify steps it will take to stimulate user facility reporting.

Because FDA stated that a change in statutory authority would be needed to eliminate the requirement to submit annual reports, we revised our second recommendation accordingly.

The complete text of FDA comments appears in Appendix E.

Detailed Methodology

Scope

This study focused on the universe of reported adverse events in the Manufacturer and User Facility Device Experience (MAUDE) and alternative summary report (ASR) databases from 2003 to 2007. We assessed compliance with reporting requirements for manufacturers and user facilities, as well as the timeliness of the review by the Center for Device and Radiological Health (CDRH). We also assessed CDRH's use of regulatory actions in instances in which analysts determined that the manufacturers did not adequately address the adverse events.

Data Collection and Analysis

We used six data sources for this evaluation: (1) MAUDE, (2) ASR database, (3) annual user facility reports, (4) CDRH files on regulatory actions, (5) structured interviews with CDRH analysts, and (6) interviews with CDRH senior officials.

MAUDE

We analyzed all adverse event reports from January 2003 through December 2007 that CDRH stores in MAUDE. MAUDE contains manufacturer, user facility, distributor, and voluntary reports. An adverse event may have multiple follow-up reports in addition to an initial report, and each report is referred to as a document. MAUDE contained a total of 563,670 documents for 2003 through 2007. These documents include 518,422 initial reports. The Food and Drug Administration (FDA) sent the data in Access files, which we imported and analyzed using SAS.

Our analysis included all initial reports in MAUDE. We analyzed them to determine when they were read for the first time. We assessed the review status of the reports to identify completed reviews, as well how many reports were still unread. We examined 5-day manufacturer reports to compare how soon analysts read these reports for the first time versus other reports.

We used the initial adverse event reports to analyze the timeliness and completeness of manufacturer and user facility reports. We did not analyze initial voluntary or distributor reports other than to obtain a total number. We used the report dates to determine timeliness based on whether they were 5- or 30-day manufacturer reports or 10-day user facility reports. We further divided our analysis of user facility reports

based on whether they were death or serious injury reports. We did not analyze the timeliness of reports that did not fall under those categories.

We analyzed how frequently data were missing from manufacturer and user facility reports for information that analysts and CDRH staff told us was critical to assessing report completeness. Finally, we identified any documented review activity to determine how many additional information request letters CDRH sent out and to provide more information on follow-up actions recommended by analysts.

About 350 user facilities submit reports through the Medical Product Safety Network (MedSun). Certain dates in MedSun, such as dates when CDRH receives the report and when an analyst first reviews it, are reset when reports are transferred to MAUDE. To obtain correct user facility report dates, we requested all MedSun records from January 2003 through December 2007. We identified which user facility reports came through the MedSun system and performed our analysis using the MedSun dates.

ASRs

We analyzed ASRs that manufacturers submitted to FDA each quarter from April 2003 through March 2008 (to account for late reports) covering January 2003 through December 2007. FDA sent us the data in Access files, which we imported and analyzed using SAS. We compared the dates when manufacturers submitted the reports to the dates of the end of each quarter to evaluate the timeliness of manufacturers that chose to submit ASRs. We also calculated the total number of events submitted through ASRs each year. We performed comparisons to determine when CDRH received and reviewed ASRs to assess how long it takes CDRH to analyze ASR data.

Annual Reports

We requested all annual user facility reports for 2006. We reviewed the report dates user facilities provided to determine the timeliness of the reports. We identified all deaths in the annual reports and attempted to find individual death reports in MAUDE. We also compared the number of annual reports with the number of user facilities that submitted adverse event reports to MAUDE in 2006 to calculate the minimum number of missing annual reports.

CDRH Regulatory Information

We requested information from CDRH's Office of Compliance about all inspections that were associated with adverse event reports from

January 2003 through December 2007. We also requested any information about regulatory actions, such as warning letters, recalls, product seizures, and injunctions that FDA had taken relating to adverse events. We reviewed 140 cases in which FDA had initiated regulatory action associated with adverse event reports.

Structured interviews with CDRH analysts

We conducted structured interviews with all 16 CDRH analysts who reviewed adverse event reports from December 2008 through January 2009. We conducted 10 of these interviews in person and 6 by phone. Six of these analysts work in the Patient Safety branch and review adverse event reports from MedSun facilities. The remaining 10 analysts work in the Product Safety branch and review adverse event reports from all other sources.

We asked analysts how they identify adverse event reports that required followup and develop a plan of action to manage them. We also asked them about the strengths of CDRH's current procedures as well as opportunities for improvement.

Interviews with CDRH senior officials

We interviewed senior CDRH officials both by telephone and in person. The interviews covered topics ranging from MAUDE data to CDRH's communication with different divisions within the center.

Limitations

We did not verify information in the adverse event reports from the user facilities or manufacturers. In addition, we limited our analysis to those reports that user facilities and manufacturers submitted to FDA. We did not attempt to calculate the magnitude of underreporting from either user facilities or manufacturers. Finally, we did not make determinations about the appropriateness of the analysts' decisions or the actions that CDRH took pertaining to any adverse event report.

Trends in Adverse Event Reports: 2003–2007

Table B-1: Medical Device Adverse Event Reports 2003–2007

Type of Adverse Event Report	2003	2004	2005	2006	2007
Manufacturer reports	65,217	70,718	90,157	109,676	141,065
Percentage of total reports	90%	90%	92%	93%	94%
User facility reports	2,890	3,256	3,752	3,048	3,234
Percentage of total reports	4%	4%	4%	3%	2%
Other reports*	4,759	4,610	4,552	5,571	5,911
Percentage of total reports	7%	6%	4%	5%	4%
Report total	**72,866**	**78,584**	**98,461****	**118,295****	**150,210**

Source: Office of Inspector General analysis of Manufacturer and User Facility Device Experience database adverse event data, 2009.
Percentages do not add to 100 because of rounding.

* Other reports include FDA voluntary and distributor reports.

** Totals for 2005 and 2006 do not include one report and five reports, respectively, because information in the reports needed for our analysis was missing.

Adverse Event Reports Missing Critical Information

For our analysis, we included the manufacturer name; device brand name; device generic name; device product code; and, when necessary, the device identification numbers. In situations when more than one device may have been involved in the adverse event, we considered a report as missing information if any associated device field was missing information. We considered the device information missing when the field was blank; specified "do not know," "no information," or "unknown;" or contained what the Center for Device and Radiological Health called invalid data. We did not consider information missing when the field contained "not applicable."

Table C-1: Adverse Event Reports Missing Critical Information

	2003	2004	2005	2006	2007
Initial manufacturer reports	65,127	70,718	90,162	109,676	141,065
Percentage missing event description	3%	5%	2%	2%	11%
Percentage missing manufacturer name and device brand name	2%	1%	1%	1%	1%
Percentage missing device brand name and generic name	2%	1%	1%	1%	1%
Percentage missing any device identification number *	30%	36%	37%	45%	50%
Initial user facility reports	2,890	3,256	3,752	3,048	3,234
Percentage missing event description	0%	0%	0%	0%	1%
Percentage missing manufacturer name and device brand name	9%	8%	6%	5%	3%
Percentage missing device brand name and generic name	3%	3%	2%	2%	2%
Percentage missing any device identification number *	97%	97%	98%	98%	98%

* Device identification numbers include the model number, lot number, serial number, catalog number, and any other identification number.

Timeliness of FDA Review of Adverse Event Reports

Table D-1: Food and Drug Administration Review of 5-Day Reports 2003–2007

How Soon the Report Is Read	2003	2004	2005	2006	2007
Read 5-day reports	350	55	31	125	51
Within 0 to 5 days	0%	0%	0%	0%	6%
Within 6 to 10 days	23%	15%	6%	8%	6%
Within 11 to 30 days	61%	69%	13%	70%	59%
Within 31 to 60 days	16%	4%	6%	2%	10%
After 60 days	1%	13%	74%	20%	20%

Source: Office of Inspector General analysis of Manufacturer and User Facility Device Experience database adverse event data, 2009.
Percentages do not add to 100 because of rounding.

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: September 16, 2009

TO: Inspector General

FROM: Principal Deputy Commissioner of Food and Drugs

SUBJECT: FDA's General Comments to OIG's draft report titled, *Adverse Event Reporting for Medical Devices (OEI-01-08-0010)*

FDA is providing the attached general comments to the Office of Inspector General's draft report titled: *Adverse Event Reporting for Medical Devices (OEI-01-08-0010)*.

FDA appreciates the opportunity to review and comment on this draft report before it is published.

/S/

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs

Attachment

FDA's General Comments to OIG Draft Report, *Adverse Event Reporting for Medical Devices (OEI-01-08-00110)*

FDA is responsible for ensuring the continued safety and effectiveness of medical devices after they have reached the marketplace, and adverse event reporting represents a critical component of the postmarket information gathering process. These reports are used by the Agency to ensure that mandatory reporters fulfill applicable responsibilities to follow up on complaint reports and that any public health issues identified by user facilities are adequately addressed.

FDA appreciates that OIG conducted this important and valuable review of the adverse event reporting process. Such studies are extremely helpful to FDA and embolden the Agency's commitment to use adverse event reports to detect and address safety concerns for medical devices. FDA's responses to OIG's recommendations are as follows:

OIG Recommendation

FDA should develop a clear protocol for reviewing medical device adverse event reports that specifically addresses the following needs:

- *Document follow-up on adverse events by documenting actions taken on particular adverse event reports and developing a tracking system to follow outcome referrals sent to the Office of Compliance;*
- *Ensure and document that Center for Devices and Radiological Health (CDRH) is meeting its guidelines for reviewing all 5-day and Code Blue adverse event reports;*
- *Follow up with manufacturers who routinely submit reports late or with incomplete information, and*
- *Enhance outreach strategies to reduce underreporting by user facilities.*

FDA Response

FDA agrees with these recommendations.

CDRH will develop a clear protocol for reviewing medical device adverse event reports that specifically addresses the needs identified in the OIG report. One step FDA is taking that will help implement the OIG's recommendations is the development of the new FDA Adverse Event database (FAERS). It will allow for more extensive documentation of follow-up on adverse events within the body of an individual medical device report than is possible with the current Manufacturer and User Facility Device Experience (MAUDE) system. This database is scheduled to be implemented in CDRH at the end of calendar year 2010.

This new state-of-the-art database, FAERS, will also permit FDA to more readily identify late reports as well as patterns of incomplete reporting. Manufacturers who submit reports that are late or incomplete will be identified and notified of the problems. CDRH will offer educational assistance and supply access to available materials to aid reporters.

1

If the reporting problems are severe or recurring, the case will be referred to CDRH's Office of Compliance for a possible field inspection.

CDRH has also completed the development of a tracking system that facilitates referrals to the Office of Compliance, and follows up on compliance actions to these referrals.

Review metrics for 5-day and Code Blue reports will continue to be monitored weekly in a standard report. Supervisory staff who monitor these reports will investigate when a Medical Device Reporting Analyst falls behind in the review of these reports and will remedy the situation.

Finally, FDA will continue to improve outreach to user facilities in the MedSun system to stimulate user facility reporting. Strategies that have proven successful such as robust feedback of safety information, development of focused subnetworks, and regional meetings, will be enhanced. CDRH has also begun to reach out to appropriate professional organizations to investigate barriers to reporting and encourage members of these organizations to either submit voluntary individual reports or report through their clinical facility.

OIG Recommendation

FDA should consider eliminating the regulation requiring user facilities to submit annual reports.

FDA Response

FDA agrees with this recommendation, but notes the change in statutory authority necessary to achieve this goal.

2

► ACKNOWLEDGEMENTS