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Medical Devices: Underreporting of Problems, Backlogged Systems, and Weak Statutory Support

Statement of
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Before the
Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives

Mr. Chairman and Members of the Subcommittee:

INTRODUCTION

It is a pleasure to be here today along with the Comptroller General of the United States to discuss GAO's studies on medical devices. The Comptroller General has given you an overview of all our work. I will concentrate on the Medical Device Reporting regulation and on medical device recalls. The Medical Device Reporting regulation is the principal means available for alerting the Food and Drug Administration (FDA) about problems associated with the use of medical devices. The recall is a way of taking action against these problem devices--by correcting them or removing them from the marketplace. The testimony I present today is based on the results of GAO's evaluations of FDA's first 3 years of implementing the Medical Device Reporting regulation (1985-1988), our overview and analysis of medical device recalls (1983 through 1988), and our examination of selected recall cases (also 1983 through 1988).[1]

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[1]See Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989); Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR (Washington, D.C.: August 1989); and Medical Device Recalls: An Examination of Selected Cases, GAO/PEMD-90-6 (Washington, D.C.: October 1989).

BACKGROUND

Perhaps we can all agree that the introduction of beneficial but potentially dangerous technologies for health care involves a balancing of risks. An extreme approach on one side of the spectrum would be to introduce a technology only after all possible problems were identified and, in so doing, deny it to persons who might benefit from it. At the other extreme, a technology might be introduced as soon as minimal standards of safety and effectiveness had been satisfied but while doubts about the technology still existed. FDA reasonably aims at a middle ground between these extremes and attempts to use its premarket review and postmarket surveillance systems to balance the potential benefits of new health technologies against the associated public health risks.

As the Comptroller General stated this morning in his overview of our work on FDA's premarket review system for medical devices, our evaluations have revealed some serious flaws in that system.[2] More than a decade has passed since the 1976 amendments to the Federal Food, Drug, and Cosmetic Act were promulgated with the goal of establishing a system that could provide reasonable assurances that devices introduced into the market place were safe and effective. But we found that many provisions of the amendments

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[2]See "Medical Devices: The Public Health at Risk," GAO/T-PEMD-90-2 (Washington, D.C.: November 1989).

had only been partially implemented or not implemented at all. Among the effects of these implementation problems were the facts that FDA's premarket review process lacked some important risk-balancing components and that it did not function as well as it might to reduce the potential threat to the public health of unsafe and ineffective devices.

Perhaps these weaknesses in the premarket review system would not be viewed as such a threat if the public could be confident that FDA operated a high-quality and efficient postmarket surveillance system for medical devices. Such a system would logically include four activities: (1) gathering data about problems experienced with devices, (2) analyzing the data, (3) developing and implementing solutions to the problems, and (4) evaluating the successes of those solutions. These activities are needed to provide FDA with two critically important capabilities: to know which devices are creating what degree of risk to the public health, and to deal with those risks effectively.

OVERVIEW

Our most recent reviews of FDA's postmarket surveillance system examined mandatory problem-reporting by manufacturers and

device recalls.[3] The findings from these evaluations continue to document serious vulnerabilities in that system.[4]

With regard to the Medical Device Reporting regulation, which generates data on device problems for FDA to analyze, we found that the implementation of the regulation produced a substantial increase in FDA's knowledge of device-related problems. The number of problems reported jumped from around 2,500 to some 18,000 annually. However, because only about one quarter of device manufacturers may in fact be reporting in any given year, this source still gives no indication of the real universe of device problems known to manufacturers, and supplies only part of the data FDA needs to estimate the size and status of device problems, assess their seriousness, search for new ones, or determine priorities for solution. Also, despite the increase in device-problem reports, the information supplied by manufacturers is still often lacking in the data needed to establish the cause of the problems reported. Moreover, we found that organizational and data processing problems further inhibit FDA's ability to analyze the information it receives.

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[3]See appendix II for a discussion of the methodology used in these studies.

[4]Much of the information in this testimony is derived from our previous reports and thus represents the state of medical device regulation in 1988, at the time the studies were completed. In response to our reports, FDA has described a number of initiatives addressing many of the issues raised by our findings that were either undertaken after we had completed our data collection or were planned for the near future. However, we have not conducted a complete and formal follow-up review of the agency's actions on the issues covered in our reports.

With respect to device recalls, which are actions that can be taken to address serious device problems, we found critical deficiencies in both FDA's statutory authority and its own regulations and operating procedures. The major problem here is that the agency's ability to take problem-solving action is heavily dependent on the cooperation and goodwill of the manufacturers it is charged with regulating. Thus, the nation's principal guardian of the public health is, in many critical areas, reactive when it should be proactive.

Let me now turn to a more detailed description of these components of the postmarket surveillance system. I will begin with the Medical Device Reporting regulation and then will discuss medical device recalls.

THE MEDICAL DEVICE REPORTING REGULATION

Problems of Underreporting

This regulation was promulgated on December 13, 1984. It required device manufacturers to report to FDA whenever they became aware that one of their devices had been associated with the serious injury or death of a patient, or had malfunctioned in such a way that a recurrence of the malfunction could result in a serious injury or death. To implement the regulation, FDA

established a system to process and analyze the device-problem reports, and procedures to monitor manufacturers' compliance with the provisions of the regulation. Our evaluation dealt essentially with the implementation of the regulation, and with the characteristics and usefulness of the information received by FDA.

Nearly 53,000 problems, involving 1,059 separate devices, were reported to FDA during the first 3 years of the regulation's operation, and overall, these problems were more serious than those reported to FDA through the prior voluntary problem-reporting program. Nearly 90 percent of the voluntary problem reports had been related to device malfunctions, and only about 1 percent to the death of a patient. Under the new regulation, slightly more than half the reported problems were associated with patient injury, and about 1,550 problem reports, or 3 percent, were associated with patient death.

Problems were concentrated in relatively few medical specialties, and in relatively few devices within those specialties. For example, over 75 percent of all reported deaths were related to devices in the anesthesiology and cardiovascular medical specialties. And within the 19 FDA-designated medical specialties, 10 devices accounted for 63 percent of the problem-reports. Cardiac pacemakers and pacemaker electrodes accounted for over one-third.

With regard to the scope of the information potentially available to FDA from the Medical Device Reporting regulation, it is important to remember that the regulation addresses only one link in the chain of information associated with device problems--the link connecting device manufacturers to FDA.[5] It was not the intent of the regulation to address the other major links in the chain--those connecting hospitals to manufacturers, hospitals to independent distributors, independent distributors to manufacturers, and hospitals to FDA. What this means is that the information contained in the Medical Device Reporting data base will not reflect the problems experienced by users in hospitals and elsewhere, unless those problems have been reported to the manufacturer, who then in turn reports them to FDA. So the information potentially available to FDA through the regulation is, at best, limited to those problems manufacturers are aware of.

But even this information that flows from manufacturers to FDA is itself limited by the degree of their compliance with the regulation. We reviewed the evidence on such compliance and found, first, that problem-reporting was concentrated among a relatively small number of firms. At most, only about one-quarter of the number of device manufacturers originally expected by FDA to report, have in fact reported during any year. When we compared the number of manufacturers who have actually reported a device

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[5]See Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1 (Washington, D.C.: December 1986).

problem to the number of potential reporting manufacturers (a number suggested by the most conservative of several estimates), at least some degree of underreporting or noncompliance on their part seemed clear; how much, we cannot specify. That is, because FDA could not provide us with the total number of manufacturers subject to the problem-reporting requirements of the regulation, we could not estimate the degree of their compliance.

We also found some instances of "overreporting" by manufacturers, which were apparently caused by too much zeal or a lack of understanding of the reporting requirements. In one case, a manufacturer was reporting all routine service requests made by device users. Unfortunately, such overreporting tends to clog the information system and use up scarce resources without bringing with it any potential for significant risk reduction.

But if overreporting is wasteful and unhelpful, it is underreporting which constitutes the greater threat to FDA's ability to find out about device problems, analyze them, and act on them. We found one case in which a device manufacturer accumulated information--but did not report it to FDA--concerning a large number of incidents in which one model of the product was associated with patient deaths as well as injuries and malfunctions. Because of this manufacturer's interpretation of what the requirements of the Medical Device Reporting regulation are, no reports had been submitted to FDA on the majority of these

complaints, including 51 involving the deaths of patients, most of whom were infants.[6]

It was only through a routine FDA compliance inspection of the manufacturer's records, including a review of the previous 14 months of the files, that FDA inspectors found 10 unreported complaints that they judged should have been reported under the regulation requirements. FDA and the manufacturer then engaged in a 13-month-long negotiation to distinguish what was reportable under the regulation from what was not. The agreement finally reached between FDA and the manufacturer resulted in the manufacturer's conceding that 6 of the 10 complaints should have been reported. This failure on the part of the manufacturer to report these 6 complaints constituted noncompliance with the reporting regulation. Most important of all perhaps, in terms of what this case illustrates about manufacturers' potential underreporting, is that these events took place more than 3 years after the regulation had been promulgated and FDA had carried out

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[6]Problems to be reported under the mandatory Medical Device Reporting requirement are not limited to events in which there was a confirmed causal connection between a device and an adverse experience. They include many events in which there is an association between a device and the death or serious injury of a patient. For example, defibrillation is successful in only a small percentage of patients who experience ventricular fibrillation, even when the defibrillator works properly. Therefore, even when it does not malfunction, if a manufacturer receives information that "reasonably suggests" that the use of a defibrillator may have caused or contributed to a death or serious injury through, for example, a failure to follow instructions, the manufacturer is obligated to report the incident in a Medical Device Reporting regulation death or serious injury report.

an educational program on the reporting requirements for manufacturers. But until the agreement was reached, at least with respect to this single manufacturer, it is clear that FDA was not receiving the information expected under the regulation.

We cannot estimate the scope of this type of problem (in part, because FDA has not given us a list of the manufacturers covered by the regulation). But some findings suggest that the compliance problem just described may not be an isolated incident. FDA has tried to assess the degree to which manufacturers are conforming to the requirements of the Medical Device Reporting regulation through a series of record inspections. FDA's judgmental sample was composed of manufacturers the agency believed would be most likely not to be in compliance. These compliance inspections

-- showed that about one third of the manufacturers visited were unaware of the existence of the reporting requirements, and

-- uncovered records of a number of deaths and serious injuries--associated with pacemaker leads, intra-aortic balloon catheters, and other devices--that had not been reported to FDA.

Again, because we have no universe of manufacturers covered under the regulation and hence cannot draw a scientific sample to

analyze the representativeness of what FDA has found, these FDA results cannot be validly generalized to the industry's state of compliance as a whole.

We told FDA officials that they should not continue to use a judgmental sample selection process for scheduling Medical Device Reporting regulation compliance inspections, even if this process eventually were to lead--every 4 years or so--to a full census of manufacturers, as the agency claimed it would. Such a process might have been justified at the beginning of the program--when the primary goal of compliance inspections was to educate manufacturers--in order to induce compliance with reporting requirements. But when it becomes necessary, as it is now, to develop unbiased estimates of just how extensive the problems of noncompliance may be and how many device problems may have gone unreported, then to use a judgmental sample is to defeat the goal, because data from such a sample cannot be validly generalized to the population of device manufacturers.

We also recommended that FDA address the compliance question by requiring manufacturers to submit a single annual letter--which, for the majority of firms, would merely assert that they had nothing to report and, for the remainder, only that the stated number of reports submitted covered all reportable problems of which the manufacturer had become aware. We believe such an annual

letter would do five things to reinforce FDA's capabilities in this situation:

-- ensure manufacturers' awareness of the regulation and their responsibilities under it;

-- establish a better basis for estimating the real incidence of device problems known to manufacturers;

-- provide an annual data base for accurately gauging the number of manufacturers who have reported during the year (at present, non-reporters who have not received information about reportable events cannot be distinguished from those who don't know about or understand their reporting requirements or are otherwise in noncompliance);

-- provide data that could confirm or alter FDA's conclusion that it is normal for only a limited number of manufacturers to report problems under the regulation; and

-- allow FDA to check the number of each type of reportable event a manufacturer claims to have submitted during a year against the reports actually in its data base, and to investigate discrepancies that suggest that some reports may have been "lost" or delayed in the processing system.

Now let me turn to the organizational structures and procedures FDA established to process and analyze the reports generated by the Medical Device Reporting regulation.[7]

Backlogged, Fragmented Systems

Although FDA first proposed a mandatory adverse-experience reporting system in 1980, we found little evidence of effective overall system development and planning when we conducted our review 8 years later. Instead, we saw a system ill-equipped to handle the increase in the volume and types of reports expected to be generated by the Medical Device Reporting regulation. And indeed, when the expected problem-reports were submitted, the size of the increase and the complex nature of FDA's work flow contributed to a constant report processing backlog. In addition, we found some inefficiencies in analyzing and taking action on problem reports. For example,

-- for nearly one-third of the reports that FDA received, dispositions had not been made and cases were not closed,

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[7]FDA contracted with U.S. Pharmacopeia (USP) to receive and enter problem reports of deaths and serious injuries into an automated data base. Under this contract, reports of device malfunctions are reported directly to FDA, then analyzed and subsequently forwarded to USP for computer entry. The analysis and disposition of problem reports are primarily carried out by a team of 12 analysts in FDA's Center for Devices and Radiological Health's (CDRH) office of compliance.

even though many of these reports had been submitted more than 2 years earlier;

-- some critical information had not been entered into the problem-reports data base in a timely fashion, including reports both of deaths and serious injuries, and records of actions that FDA had taken in response to problem reports; and finally,

-- formal written procedures for report analysis were lacking, and there was a reliance on informal training for report analysts in the use of the available automated data processing equipment and software.

Thus, final dispositions were not made in about one third of all the mandatory problem reports received by FDA between 1985 and 1987, and this also means that they were not given causal evaluations. Further, for the two thirds of the reports that were evaluated, the cause of the device problem was tentatively identified in only half. This situation arises because FDA primarily relies on the manufacturer's determination of cause, as indicated on the submitted problem report. If the manufacturer has not indicated a cause--which is the case more often than not--there is generally not enough information in the problem report for FDA alone to determine the cause.

In addition, we identified several internal problems with the automated data processing facilities that severely limited their capacity to support FDA's risk assessment activities. The potentially most troublesome problem was that although there were several data bases at FDA that related to postmarket surveillance, they were not integrated into a single functional system that was easily accessible or complete enough for adequate problem-report analysis. In consequence, there were gaps in the information available to analysts and redundancy among the several different data bases used.

In sum, with the procedures we found in place, FDA can record and retrieve information about individual problem reports. But because of the reporting, analytical and efficiency problems discussed above, the agency cannot yet easily identify generic issues or provide systematic, quantitative analysis of problem-reporting patterns based on statistical trends over time.

The last aspects of the postmarket surveillance system I would like to discuss today are the use of problem-report data in solving device problems and, especially, the use of medical device recalls as postmarket surveillance tools.

USE OF PROBLEM-REPORT DATA AND MEDICAL DEVICE RECALLS

Linkage Between Problem Reports and FDA Actions

The purpose of the medical device risk assessment activities that I have just described--data gathering, processing, and analysis--is to provide an empirical basis for the development and implementation of problem solutions. For medical devices, this activity includes using the report data as a source of "early warning" about device problems and acting on that information via recalls and other regulatory actions.

Although other information supplied by FDA indicated that report data may have helped FDA in dealing with device problems in some instances (including a few device recalls initiated by manufacturers, changes in the design of one type of device, and an educational program for hemodialysis users), the automated data base we reviewed documented very little use of the report data by FDA.

The data we analyzed showed only three instances of traditional FDA regulatory actions--such as device seizures and Notice of Adverse Findings letters to manufacturers--that could be linked directly to the problem-report data.

Nature and Characteristics of the Recall Mechanism

Over the last year, we have begun to study recalls as the principal mechanism available to FDA and device manufacturers to correct problems that occur after a device is marketed. Our first two studies of medical device recalls focused on the nature and scope of recalls, while our ongoing work focuses more specifically on evaluating the effectiveness of recalls as a problem-solving tool. In a future report, we plan to examine how the recall process actually operates with respect to specific devices and, if necessary, to suggest ways to improve the overall process.

A medical device "recall" is more than the removal from the market of a particular product. It can also include the correction of labeling or of promotional materials that FDA considers to be in violation of the laws it administers. FDA divides recalls into three classes based on its evaluation of the relative degree of health hazard the products present.[8] In the most-serious class (class I), there is a strong likelihood that the

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[8]It is important to note that the potential degree of health risk associated with recall classes is designated, by FDA, in a descending order from class I to class III (that is, a class I recall involves the most serious risk), and the potential risk associated with device classes is designated in an ascending order from class 1 to class 3 (that is, a class 1 device is low risk). Therefore, classes I and 1 have opposite meanings for devices and recall classes. To avoid confusion in this testimony, we refer to class I, II, and III recalls as "most serious," "medium serious," and "least serious," respectively.

use of or exposure to the product will cause serious adverse health consequences or death. In the medium-serious class (class II), the use of or exposure to the product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse health consequences is considered remote. In the least-serious class (class III), the use of or exposure to the product is not likely to cause adverse health consequences.

Our analysis of medical device recalls was based on a total of 1,635 recalls. Medium-serious recalls were the most frequent at 1,026, or 63 percent; these were followed by 561, or 34 percent, least-serious recalls; and 48, or 3 percent, most-serious recalls.

The devices that were recalled ranged from high-risk, implantable, life-supporting devices (such as replacement heart valves) through medium-risk devices (such as tanning booths) to low-risk devices (such as dental irrigation syringes).

Devices from every medical practice specialty area were subjected to at least one recall. However, recalls in 42 percent (8 of 19) of the medical practice specialties accounted for 80 percent of all recalls. Devices from two specialties--cardiovascular and anesthesiology devices--accounted for slightly more than one-quarter of all the recalls.

FDA assigns causes of problems leading to recalls to one of nine classes by relying on narrative statements provided by the manufacturer.[9] According to this categorization of device problems, design and production problems were identified as the causes of nearly three-fourths of all recalls. We found that the most frequent cause of recall was some element of product design, which accounted for 715, or 44 percent of all recalls. Problems with production controls accounted for 460, or 28 percent, of the recalls.

We also found that 74 percent, a disproportionate share of all recalls and the majority of the most serious recalls, were related to medium-risk devices for which mandated performance standards have not been developed by FDA. (The Comptroller General has discussed the importance we attach to this omission.)[10]

Our analysis confirmed the anticipated relationship between a device's risk classification and its recall classification. High-risk devices were more likely to be among the most serious recalls, while low-risk devices were more likely to be among the least serious recalls.

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[9]FDA's categories of the causes of device problems that lead to recalls are as follows: (1) design, (2) production control, (3) component control, (4) expiration dating and Radiation Control for Health and Safety Action violation, (5) change control, (6) training, (7) misbranding, (8) no premarket approval, and (9) other.

[10]See "Medical Devices: The Public Health at Risk," GAO-T/PEMD-90-2 (Washington, D.C.: November 1989).

The Relationship of Problem-Reports to Recalls

FDA and the Congress envisioned that one of the principal benefits of the reporting requirements of the Medical Device Reporting regulation would be their function as an "early warning" of device problems. And, since the regulation has been in effect, 274 medical device recalls, or 22 percent of all recalls, have had a problem report associated with them.[11] There also was a positive relationship between the recall class and the existence of a problem report--that is, the more serious the level of the recall, the more likely it is that a report was associated with the device problem. Nonetheless, we found that only 16, or 52 percent, of the most-serious recalls had reports associated with them at the time FDA conducted a risk assessment in connection with the recall. Thus, FDA became aware of the great majority of device problems associated with a recall in some other way than through mandatory problem reports. This suggests that the reports have not served as an effective early warning of device problems serious enough to warrant a recall.

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[11]Our analysis accounts for the 1,245 recalls made between fiscal year 1985 and fiscal year 1988, the years in which the Medical Device Reporting regulation was in effect.

FDA's Statutory Authority Regarding Recalls

This suggestion is consistent with our finding that although FDA did become aware of the majority of most-serious recalls before they were completed, in 44 percent of those cases the agency learned of the recall only after it had been initiated by the manufacturer.[12] Some corrective actions by manufacturers--serious enough to be labelled most-serious recalls--did remain unknown to FDA until it learned of them during an inspection or was informed by a device user or one of the manufacturer's competitors. But since there is no statutory requirement that device manufacturers notify FDA of recalls, it is not surprising that FDA's awareness of them should be incomplete.

Our analysis showed that manufacturers notified FDA of class I recalls (that is, the most serious ones) in 58 percent of the cases; in 43 percent of the cases FDA found out about the existence of the recall from some other source (including, in 25 percent of the cases, its own inspection).

Recalls and Premarket-Approved Devices

We also looked specifically at the incidence of recalls for devices that had gone through the premarket approval route to

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[12]Information on the time of FDA's notification was missing in 7, or 15 percent, of the cases. These percentages are based on 41 cases for which the data were available.

market. These recalls are particularly noteworthy because the most stringent statutory requirements to ensure safety and effectiveness--including the performance of well-controlled studies or the production of other scientific evidence--are reserved for devices that require premarket approval. However, we found 56 recalls of premarket-approved devices over a period of 6 years, which is equivalent to 4 percent of total recalls. This roughly approximates the proportion of devices that had entered the market in the first place through the premarket-approval route (6 percent). Premarket-approved devices were also more likely to be associated with the most-serious class of recall than either of the other two classes of recalls. These findings underscore the critical nature of FDA's postmarket surveillance of all devices, even those subject to the most thorough effort to identify and solve their potential safety problems before they are marketed.

CONCLUSIONS

We believe that, at a minimum, FDA's postmarket surveillance system should be able to rapidly and completely identify serious problems experienced with medical devices (such as those described in the Medical Device Reporting regulations). We also believe the agency should have the capability to act quickly to resolve problems once they have been identified. Neither of these capabilities currently exists in adequate form at FDA.

The evidence we gathered in our evaluation of FDA's implementation of the Medical Device Reporting regulation and medical device recalls shows that both of these elements of the postmarket surveillance system are vulnerable in ways that inhibit the system's capacity to either provide early warning about device problems or allow the agency to act expeditiously on those problems.

Instead, we found that

-- the system FDA has established to process and analyze the problem reports is not adequate to handle the volume and types of reports received;

-- the degree of manufacturers' compliance with the regulation cannot be accurately determined;

-- the reporting requirement is not serving its expected purpose of providing the agency with early warning of device problems; and

-- because of the existing statutes, FDA is limited in its ability to find out about manufacturers' recalls or initiate its own corrective actions for device problems.

We recognize that during the 1980's added demands have been placed on FDA as a result of its having to deal with such problems

as the AIDS epidemic, cases of product tampering, and other issues. However, we believe that at least some of the vulnerabilities we have identified with regard to FDA's postmarket surveillance system are not resource-dependent. Much can be accomplished through improved monitoring and enforcement actions in conjunction with mandatory reporting and changes in the Federal Food, Drug, and Cosmetic Act to increase FDA's recall authority. The requirement for an annual form letter submitted by device manufacturers, certifying their compliance with the reporting regulation and documenting the use of problem-report data, is neither costly nor burdensome for either FDA or manufacturers. The statistical sampling strategy we have recommended would produce generalizable results sooner, more often, and at lower cost than the FDA proposed census. And finally, changes in the Federal Food, Drug, and Cosmetic Act would allow FDA to take prompt action against medical devices that pose unreasonable risk of substantial harm to the public health. The changes should include the requirement that manufacturers report to FDA all recalls and repairs done to eliminate health risks or violations of the law. We expect to make additional recommendations after we complete our evaluation of the effectiveness of the recall mechanism.

That concludes my statement Mr. Chairman. I will be happy to respond to any question that you or Members of the Subcommittee may have.

SELECTED LIST OF U.S. GENERAL ACCOUNTING OFFICE PRODUCTS RELATED TO MEDICAL DEVICES

1. Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1. Washington, D.C.: December 1986.
2. "Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting," Statement by Eleanor Chelimsky, GAO/T-PEMD-87-4. Washington, D.C.: May 1987.
3. Medical Devices: FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640, GAO/PEMD-88-30. Washington, D.C.: July 1988.
4. Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14. Washington, D.C.: August 1988.
5. Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10. Washington, D.C.: February 1989.
6. Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR. Washington, D.C.: August 1989.
7. FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, GAO/HRD-89-142. Washington, D.C.: September 1989.
8. Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6. Washington, D.C.: October 1989.

METHODOLOGY

Our fieldwork was conducted from October 1987 through June 1988 in accordance with generally accepted government auditing standards. Our review of the implementation of the Medical Device Reporting regulation and of medical device recalls required different kinds of information from many sources. To understand the congressional intent and historical background of each element, we reviewed the legislative histories, prior studies of the implementation of the regulation, FDA policy and guideline statements, FDA procedure manuals, and other published articles related to mandatory adverse experience reporting and device recalls. We also obtained an official chart of the problem reports processing and analysis work flow and recall processes, and used this information as a basis for structured interviews focused on the day-to-day operations of these systems. We interviewed FDA officials, program managers, inspectors, and other staff in order to clarify, supplement, and confirm the documentary evidence.

FDA provided a computer tape containing the problem reports data base for the period January 1985 through December 1987 and another tape of the recall data base for fiscal years 1983 through 1988. We used these tapes to review the accuracy and completeness of the data bases, to tabulate summary statistics, to analyze

patterns and characteristics, and to evaluate FDA's actions in response to medical device problems.

We also assembled a distinguished panel of medical device experts affiliated with academic, consumer research, industry, health care provider, and other institutions for advice and consultation. (See appendix III for a list of our panel members.)

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