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Medical Devices: The Public Health at Risk

Statement of
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Committee on Energy and Commerce
House of Representatives



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Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here this morning to discuss our evaluations of the Food and Drug Administration's (FDA) systems of premarket review and postmarket surveillance of medical devices sold in the United States.

Medical devices run the gamut from the very simple to the extremely complex, from common household items such as thermometers and bandages to kidney dialysis machines and implanted heart valves. Devices such as artificial hips, intraocular lenses, and hearing aids increase the independence and improve the quality of life of many. Diagnostic devices such as the magnetic resonance imaging machine have increased the speed and accuracy of diagnosis and, in some cases, have replaced more dangerous procedures. More than 1,700 different types of medical devices are available in the United States today, millions of Americans come into contact with them, and these devices represent an industry of more than \$14 billion annually.

Since passage of the Food and Drugs Act in 1906, the Congress has shown concern for the protection of the public from the harmful effects of contaminated food and unsafe or ineffective drugs. In 1938, coverage was extended to the regulation of cosmetics and medical devices in the Federal Food, Drug, and Cosmetic Act, legislation which is still the basis for FDA's operations.

During the late 1960's and early 1970's, public concern about the safety and effectiveness of medical devices continued to increase. A study group, which became known as the Cooper Committee, was formed by the Department of Health, Education, and Welfare to examine the issues and make legislative recommendations. Many of the committee's recommendations are reflected in the Medical Device Amendments of 1976, which currently provide the basis for FDA's pre- and postmarket systems for regulating devices. The amendments call for the classification of medical devices according to three degrees of potential risk--low, medium, and high--and each device was to be classified and regulated according to what was needed to reasonably ensure its safety and effectiveness.¹

Since 1986, the General Accounting Office (GAO) has examined the major components of both these systems (including selected regulations developed to implement the amendments), issued seven separate reports, and testified before this Subcommittee about our

¹These terms, which we have adopted for the sake of clarity, correspond to the three FDA-defined device classes in the following ways: low-risk devices are class 1 devices, those subject to minimum FDA regulation such as registration, premarket notification, and adherence to good manufacturing practices; medium-risk devices are class 2, those where performance standards are believed necessary to assure safety and effectiveness; and high-risk devices are class 3, those viewed as potentially very hazardous and that usually require FDA approval before marketing. Finally, in addition to the requirements for their respective classes, all devices are subject to the requirements for class 1 devices.

findings.² Today I present an overview of our work to date, including the major recommendations we have made for improving the effectiveness of FDA systems and the underlying regulations.³ In the testimony that follows, Eleanor Chelimsky, Assistant Comptroller General for Program Evaluation and Methodology, will discuss some of our findings in greater detail and, in particular, will share with you the results of ongoing work that examines some issues related to the resolution of identified medical device problems.

In brief, our work reveals several shortcomings in both the premarket review and postmarket surveillance systems for medical devices and raises serious questions about the ability of these systems and related regulations to protect the American people from unsafe and ineffective medical devices.

With regard to the premarket review system, we (as well as the Subcommittee) are concerned about the large number of devices that reach the market after only a relatively cursory review. And within the FDA's postmarket surveillance system, we also discovered two major problem areas. First, there was a severe shortage of

²The seven reports and the testimony are listed in appendix I.

³Much of the information in this testimony is derived from our previous reports and thus represents the state of medical device regulation at the time the studies were completed. Although we have continued to monitor FDA's progress, we have not conducted a complete and formal follow-up review of the agency's actions on topics covered in our earlier reports.

information about the nature and scope of problems associated with the devices once they had become available in the marketplace and began to be used. Second, when information about problems encountered in using devices was available, FDA's ability to deal with that information and take efficient and effective remedial action was questionable.

Now that I have broadly stated our concerns with FDA's premarket review and postmarket surveillance systems, I would like to turn to a more detailed description of our work in these areas, with a special emphasis on the evidence that supports our conclusions and our recommendations to this Subcommittee. Let me begin with the premarket review system and then turn to the system of postmarket surveillance.

THE PREMARKET REVIEW SYSTEM

Since passage of the Medical Device Amendments of 1976, roughly 36,000 devices and device modifications have been allowed to enter the market. All followed one of two routes. One group of devices was approved if valid scientific procedures showed evidence of their safety and effectiveness. This route is known as premarket approval. In practice, this usually meant that the manufacturer had to conduct clinical trials of the device. However, only six percent of all medical devices entering the market between 1976 and 1986 were required to pass these rigorous

scientific tests. Another group of devices, 94 percent of the total, was reviewed and allowed to enter the market after FDA judged them to be substantially equivalent to devices already on the market before 1976. For almost all of these devices, no direct evidence of safety or effectiveness was required, just support for the manufacturer's claim of equivalence.

This Subcommittee has expressed concern about the large number of devices that reach the market based on their substantial equivalence to older devices already available to the public, rather than on direct evidence of their own safety and effectiveness. This is a concern we share. At the current time, the manufacturers of most devices, regardless of the device's level of risk, can market their products 90 days after notifying FDA that their devices are substantially equivalent to a product that was available prior to 1976. If FDA decides that the proposed device is substantially equivalent to one marketed before 1976, the new device can be marketed immediately. Therefore, the concept of substantial equivalence and the way it has been applied by FDA are very crucial elements in the decision process.

We see four principal issues that need to be addressed in the current premarket review system: (1) the fact that the pre-1976 devices to which new ones are found substantially equivalent may never themselves have been tested at all; (2) the use of an old and often outdated comparison base (of pre-1976 devices) for

determining substantial equivalence; (3) the lack of a definition of substantial equivalence; and (4) FDA's failure both to develop the mandated performance standards for medium-risk devices and to implement premarket approval requirements for pre-1976 high-risk devices.

The first issue is the apparent working assumption that most pre-1976 medical devices are safe and effective and thus an appropriate basis for substantial equivalency determinations. But a number of empirical studies conducted prior to 1976, including the Cooper Committee's work, found that marketed medical devices had been associated with hundreds of deaths and 10,000 injuries over a 10-year period. Thus, it is not valid to assume that simply because a device has been on the market for a long time, there is no need to prove its safety and effectiveness. This is especially the case for those pre-1976 devices that panels of experts classified as high-risk because they felt the devices should go through premarket approval to prove their safety and effectiveness.

Second, the statutory requirement that a device be compared to a pre-1976 counterpart ignores the possibility that there may be a newer similar device currently on the market that, because of the technological advances it represents, is safer or more effective than the pre-1976 comparison device. As the comparison base recedes into the more and more distant past, the current process for substantial equivalence determinations could lead to the

approval of devices that are increasingly out-of-date technologically. Further, and even more importantly, the requirement for comparison with pre-1976 devices provides little incentive for manufacturers to emphasize leading-edge technology.

Third, the statute does not define the term "substantial equivalence" and the legislative history is open to at least two different interpretations. One interpretation is that when a device about to be marketed varies from pre-1976 devices in its materials, design, or energy source, the product should be found not substantially equivalent. A second interpretation is that only when a device varies from pre-1976 devices in ways that can materially affect safety or effectiveness should it be labeled not substantially equivalent. This second interpretation, the one usually followed by FDA, allows the agency to declare that devices with apparently major differences (in materials, design, or energy source) from pre-1976 devices are substantially equivalent to those devices. Conversely, a literal application of the first interpretation would result in considerably fewer devices being found substantially equivalent.

As a result of our review of these issues, we have suggested that if the Congress is concerned about the way in which FDA interprets the term substantial equivalence, it may want to consider providing a statutory definition of that term. In addition, we have recommended that the Congress amend the Federal

Food, Drug, and Cosmetic Act to shift the comparison base from devices introduced prior to 1976 to currently marketed devices.

The fourth issue in the current premarket review system that needs to be addressed is FDA's failure to develop performance standards for medium-risk devices and to implement premarket approval for high-risk devices. The act mandates that FDA develop and apply performance standards for all medium-risk devices and that the agency approve the safety and effectiveness of all high-risk devices before they reach the market. To date, FDA has not developed any formal performance standards for medium-risk devices and, since 1976, has required premarket approvals for only 9 of 150 types of high-risk devices.

The result of this failure to implement the statutory requirements is that while a few high-risk devices are subjected to full scrutiny, the majority of high- and all medium-risk devices are treated as if they were low-risk. The agency simply declares them to be substantially equivalent to pre-1976 devices, which may themselves never have been approved, and allows them to go immediately to market. The result is that 141 types of high-risk devices may be put into use with no premarket approval. And for 854 types of medium-risk devices there is, in the absence of performance standards, no middle ground in how they are reviewed. Almost all are declared to be substantially equivalent to pre-1976 devices and are put into use with no evidence of having met

performance or safety standards. Although the 13-year-old statute set no timetable for full implementation of differential treatment of medium-risk and high-risk devices, we believe FDA's progress has been clearly inadequate.

The FDA staff time needed to implement these requirements would be considerable, and thus we recommended in our report that the Congress should consider alternatives to the full-scale approaches currently called for in the statute. For example, it may be appropriate to reclassify some types of medium-risk devices as low-risk and to adopt voluntary industry standards for others rather than have FDA develop them. FDA could then concentrate on developing performance standards only for the riskiest of medium-risk devices.

POSTMARKET SURVEILLANCE SYSTEM

Now I would like to discuss our findings with regard to the existing postmarket surveillance system. But first let me point out that no premarket review system, even the most thorough imaginable, can guarantee that there will be no problems when medical devices are put into widespread use. Thus, the purpose of FDA's postmarket surveillance system is to provide "early warning" of problems associated with devices in use. The intent is to identify serious incidents rapidly and then to act upon recurring problem-causes such as manufacturing defects, unanticipated user

errors, poorly written instruction manuals, and latent device-design problems.

The postmarket surveillance system has four main components: (1) voluntary reporting of problems by the users to FDA, to the manufacturer, or to various intermediaries; (2) mandatory reporting of known problems by manufacturers to FDA; (3) monitoring and analysis of problems by FDA; and (4) a recall process that may result in either corrective action or removal of the device from the market.

For postmarket surveillance to work, information about device problems must be promptly and accurately transmitted to FDA, the agency must be able to analyze the data and identify the problems, and there must be a systematic process by which FDA decides upon the appropriate level of action. In our review of FDA's system, we found several weaknesses in these three areas.

First, with regard to the transmission of information, in a study of 10 medical devices used in hospitals, we found reason for serious concern.⁴ Our analysis revealed that FDA knew about fewer than 1 percent of the device problems that had occurred in the hospitals. And one of the more disturbing aspects of this situation was that hospital personnel reported to us that they were

⁴See Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1 (Washington, D.C.: December 1986).

more likely not to report a problem that involved a patient injury than they were one that did not.

We concluded that FDA's lack of information about problems with medical devices had three specific sources:

- problems were not always reported; only 51 percent of the device problems known to hospital personnel were reported to any outside organization;
- of the information about problem devices that was reported, almost all (92 percent) went to manufacturers or intermediaries (for example, distributors and service centers), but almost none was passed on to the FDA; and finally,
- of the reports actually made on device problems, 83 percent were transmitted exclusively in oral fashion.

Although hospitals took action locally to avoid a recurrence in 85 percent of the problem cases, the FDA was severely limited in its ability either to understand the scope of device problems or to implement systemic solutions such as the recalling of defective devices.

As a result of our findings, we recommended that FDA attempt to increase the quantity and quality of information available for monitoring device problems by requiring the distributor of medical devices to report problem information to manufacturers. We also recommended that FDA increase its efforts to inform health care professionals as to how to report problem information. In addition, to address the problem of severe underreporting from the hospitals, we recommended that FDA explore the possibility of establishing a voluntary problem-reporting network consisting of a representative sample of hospitals that would report to manufacturers. We have since pointed out that to ensure that the postmarket surveillance system achieves its "early warning" goal, it would be necessary to include virtually all hospitals in a mandatory problem-reporting program.

FDA generally agreed with the aims of our recommendations but expected that new reporting requirements being implemented by the agency at the end of 1984 would solve many of the problems we had identified. To learn whether this turned out to be the case, we did a follow-up review of this issue, which was published earlier this year.⁵

FDA began implementing the new Medical Device Reporting regulation in the latter part of 1984. Manufacturers of medical

⁵See Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989).

devices were then required to report to FDA whenever they became aware that a device was associated with the serious injury or death of a patient, or that the device malfunctioned in such a way that a recurrence of the malfunction could result in a serious injury or death. To handle the information produced by the new regulation, FDA established a system to process and analyze the data.

We found that the new regulation did greatly improve the flow of information to FDA. Indeed, the amount of information received by FDA about problems associated with medical devices increased more than seven-fold after the implementation of the Medical Device Reporting regulation. Prior to the regulation's implementation, FDA had received only about 2,500 problem reports annually through its voluntary reporting program. During the first three calendar years after implementation of the mandatory system, FDA received approximately 18,000 problem reports annually, and there was a significant increase in the proportion of reported device problems associated with the death or serious injury of patients.

However, we found a number of problems with the new system, including the following:

- First, even though the flow of information was improved, the real size of the problem was still unclear, and the degree of compliance with the Medical Device Reporting regulation's requirements could not be established. By

FDA's count, only a quarter of the manufacturers who were expected to file reports did so during any given year. However, under the present system, FDA has no way of distinguishing between manufacturers who truly have no reportable problems, those who are negligent in reporting, and those who are not aware that they need to file reports. (FDA's first check of a non-random sample of manufacturers showed that one-third of the establishments inspected for compliance with the Medical Device Reporting regulation did not even know there was a reporting requirement.)

- Second, FDA's data processing system was not adequate to handle the volume of reports generated by the new reporting requirement. Although we found the information in the automated data base to be generally accurate, major delays were being experienced in getting reports into the system and analyzing them. For example, some portion of the processing or analysis was incomplete on more than 10,000 malfunction reports. Department of Health and Human Services (HHS) officials have stated that steps are being taken to correct these problems.

- Finally, FDA's analysis of the data generated by the Medical Device Reporting regulation often did not produce definitive results. Specifically, over two-thirds of the

reports received from 1985 through 1987 lacked a clear-cut determination (for example, a recall, a voluntary action by the manufacturer, or even an indication that the information submitted by the manufacturer was insufficient to process the case). This situation may have resulted in part from the limited capacity of the FDA data processing facility to identify trends and anomalies associated with the occurrence of device problems. Again, HHS officials have reported that changes either under way or planned will improve the handling of device reports.

To address the problem of uncertain compliance with the reporting regulation, we made two recommendations to the secretary of HHS. First, we recommended a modification of the Medical Device Reporting regulation to require each firm that manufactures a medical device to submit an annual statement in one of two forms: (1) a declaration that no problem reports were filed because there were no reportable events, as defined by the regulation; or (2) a summary of how many reports were submitted for each type of event and a declaration that the manufacturer was aware of no other reportable events. FDA chose not to accept this recommendation on the grounds that it would provide no benefits while creating a burden for both the reporters and FDA. However, we believe that an annual statement would at least ensure that all manufacturers are aware of their obligations under the Medical Device Reporting regulation. This awareness on the part of medical device

manufacturers is an indispensable first step toward achieving complete reporting.

Second, we recommended that FDA establish a program of Medical Device Reporting regulation compliance inspections that would permit generalization of the inspection results to the universe of device manufacturers--that is, the selection of establishments for inspections on a sound statistical basis. To encourage greater use of the Medical Device Reporting regulation data base, we also recommended that FDA fully document their use of data in engaging in actions to correct device problems, especially by ensuring that such actions are recorded in the data base.

The last GAO reports I want to discuss today involve our examination of some of FDA's systems, procedures, and operations for engaging in remedial action once problems with medical devices have been identified.

When postmarket surveillance discloses problems with medical devices, several remedial actions are possible. However, the most far-reaching remedy is to take the device completely out of use--that is, recall it. In our current examination of device problems, we are looking at how the device recall process works and its results over the period 1983 through 1988.

Based on our reviews to date, we have been especially struck by the constraints under which FDA must operate. The agency has no authority under the Federal Food, Drug, and Cosmetic Act to order a manufacturer to recall a product. Thus, FDA may request a recall, but it has no statutory authority, without employing a court order, to impose or seek sanctions if its request is refused. The result of this situation is that the overwhelming majority of recalls are manufacturer-initiated with FDA oversight:

- FDA did not initiate any of the 1,635 product recalls that occurred during the period of our study. This means that manufacturers took the action when they believed recalls were warranted.

- In almost half of the most serious kinds of recalls, FDA learned of the recall from a source other than the manufacturer. However, this finding reveals no impropriety on anyone's part because there is no legal requirement for device manufacturers to notify the agency.

Although FDA has surely made some progress since 1984, the overall impression created by its postmarket surveillance of medical devices remains one of inadequate information concerning the extent of existing device problems, and weaker analysis and use

of the available information than the American public could reasonably expect of a national monitoring system.

CONCLUSION

In sum, the statutes that govern medical devices need some adjustment and the existing FDA systems for premarket review and postmarket surveillance both need improvement. The evidence is that the nation does not presently have a fully functioning process for ensuring the safety and effectiveness of medical devices. We are gratified that most of the problems we have pointed out and the recommendations we have made are being addressed in these hearings, as well as in H.R. 3095, as introduced by you, Mr. Chairman, and Mr. John Dingell, Chairman of the House Committee on Energy and Commerce, in the current session of this Congress.

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

SELECTED LIST OF U.S. GENERAL ACCOUNTING OFFICE REPORTS 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 of Eleanor Chelimsky, GAO/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.