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**MEDICAL DEVICES: EARLY WARNING OF PROBLEMS
IS HAMPERED BY SEVERE UNDERREPORTING**

Statement of
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Before the
Subcommittee on Health and the Environment
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 share with the Subcommittee some of the information we have developed regarding the postmarketing surveillance of medical devices. The results I present here come from GAO's recently released study of how the Food and Drug Administration (FDA) monitors the safety of medical devices that have been approved for use by the general public.¹ Our study dealt essentially with the structure and operation of the communications network and other related activities that make up what is known as FDA's postmarketing surveillance system, a system intended to produce early warnings or alerts to problems with medical devices.

Our review had two principal objectives. The first was to describe the communications network and the flow of information for problems associated with medical devices as it existed before the implementation of the medical-devices reporting rule.² Our second objective was to determine the degree to which the existing

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

²Our fieldwork was conducted from March 1985 through January 1986 and requested information about problems that had occurred in calendar year 1984. The medical-device reporting rule that went into effect on December 13, 1984, requires manufacturers to report to FDA when they receive or otherwise become aware of information that reasonably suggests that one of their marketed devices has caused or contributed to serious injury or death or has malfunctioned and is likely to cause or contribute to serious injury if the malfunction recurs.

communications network functions as an early warning signal for both FDA and device manufacturers, so that timely action can be taken to protect the public from harm.

Because of information developed as the result of several congressional hearings held in 1982-83 and GAO's 1983 report that suggested that the information flow from FDA's postmarketing surveillance of devices was not informing either FDA or the public about the potential danger of some medical devices, we thought it was important to examine exactly how information about medical-device problems originating in hospitals was being communicated outside the hospitals and how device manufacturers and FDA were responding to these problems.³

Our focus was thus the communications network rather than individual devices, and we were looking at the likelihood of getting timely information on problems rather than at the problems themselves.

We surveyed hospital personnel working in a nationally representative sample of community hospitals.⁴ We asked

³GAO, Federal Regulation of Medical Devices -- Problems Still To Be Overcome, GAO/HRD-83-53 (Washington, D.C.: September 1983).

⁴Community hospitals include all nonfederal, short-term, general and other special hospitals. They represent 65 percent of all hospitals in the United States and 76 percent of all acute-care community facilities. We excluded long-term-care facilities and hospitals with fewer than 50 beds because of the limited number of devices routinely used in these facilities. Eighty-one percent

respondents about their experience of safety with 1 of 10 devices in a sample we selected and about the actions they had taken with regard to specific problems they had had.⁵ And if one of the actions they had reported was to notify an organization outside the hospital (device manufacturer, device distributor, FDA, or some other), we then contacted the organizations that had been notified. We repeated this procedure with each organization until we found that the report of the problem had reached FDA or until an organization indicated that it had not received or had not forwarded the message about the problem. Generalizing from the sample, we identified 1,175 separate problems.⁶

(1,651) of the 2,038 that received our initial screening questionnaires returned at least one questionnaire. Seventy-eight percent of the individuals who identified a problem on the screening questionnaire and received our second, more detailed questionnaire returned it.

⁵We used what is known as an "extreme case strategy" to select the sample of 10 devices. Since thousands of devices are in use and our resources were limited, we focused on devices that a panel of experts believed were sufficiently problematic to have led to problems and continuing information transmissions within the postmarketing surveillance system. This strategy allowed us to maximize our chances of obtaining reports of problems and of following their communications through the system. The devices selected were replacement heart valve, intraocular lens, hemodialysis system and accessories, tracheal tube and inflatable tracheal tube cuff, infusion pump and controller, anesthesia gas machine, infant radiant warmer, electrosurgical cutting and coagulation device and accessories, pneumatic tourniquet, and arrhythmia detector and alarm.

⁶The 1,175 problems that are discussed in this testimony represent the number of problems that we would have obtained if we had sent questionnaires to the universe of all hospitals asking for one significant problem from each hospital. The sampling error is 115. This means that with repeated samples of this size, one could expect 95 of 100 times that the total number of problems would range from 1,060 to 1,290.

My remarks today will focus, first, on the nature and extent of the information associated with medical-device problems that flowed from hospitals to device manufacturers and from device manufacturers to FDA and, second, on the impact that this information flow has on FDA's ability to ensure the safety of marketed medical devices.

THE PROBLEMS IDENTIFIED BY HOSPITAL PERSONNEL

In our survey, hospital personnel indicated awareness of medical-device problems with each device in our sample of 10 devices. These problems ranged from relatively minor incidents, with no adverse effects on patients, to an incident associated with the death of a patient. For the 10 devices we studied, actual injuries to patients were associated with 9 percent of the problems identified. The potential for serious injury or death was reported in 37 percent of the cases.

Patients' burns were the most frequent type of injury, at 35 percent, but no other single type of injury (e.g., shock or lacerations) accounted for more than 7 percent of the reported injuries.

The largest proportion of the problems associated with our sample of medical devices, 28 percent, occurred in the operating room of a hospital. This was followed by intensive care units,

21 percent, and 18 percent on the general care floors of the hospitals.

The hospital personnel cited wear and deterioration of the devices as the sole or major cause of the problem in about one third of the cases. Other frequently cited causes were defective components, design flaws, and improper use.

FDA's Communications Network

The four main channels through which FDA can receive information about problems with devices are (1) directly from hospitals; (2) through FDA's problem reporting program, operated by the United States Pharmacopeia Convention (USPC); (3) through third-party monitoring organizations; and (4) through device manufacturers and independent distributors.

We found a severe reduction or "funneling" effect in the nature and amount of information as it moved from the point at which the problems occurred in the hospitals to the point at which messages were transmitted or received by device manufacturers, FDA, and others. Overall, of the 1,175 problems associated with devices that were identified in our survey, only 593, or about 51 percent, were reported to any organization outside the hospitals.

Specifically, in the first channel we found that no information flowed into the network for at least 41 percent of the

incidents hospital personnel identified (perhaps more, if the "don't knows" are accounted for). The second channel, from the hospitals directly to FDA or through USPC, was very seldom used. The third channel, through third-party organizations, provided no information to FDA, even though slightly more than 8 percent of the hospital reports were sent into this channel. Finally, only the fourth channel, through the manufacturers and independent distributors, accounted for many reports. Although our hospital respondents indicated that they sent 46 percent of their external reports into this channel, a closer analysis of the data showed that the information flow was not quite so direct. One or more intermediaries, such as sales representatives, often come between a hospital and a manufacturer's headquarters; blockages and breakdowns in the flow of information could and did occur.⁷ When we went to the manufacturers, we found that only 12 percent of the incidents were recorded in their central files.

The sparse records of problems with devices in the manufacturers' files may be partially explained by how messages are diffused after they leave the hospitals. For example, 54 percent of the reports in the manufacturers' channel went only to regional

⁷FDA distinguishes between two categories of medical-device distributor. Manufacturers are referred to as "distributors" and are subject to the medical-device reporting rule. Companies that are not wholly owned are referred to as "independent distributors" and are not subject to the rule. About 80 percent of the surveys returned to us were identified as transmittals to a manufacturer or distributor that was a wholly owned subsidiary of the device manufacturer, and about 12 percent were transmitted to independent distributors.

offices, and they may not have been forwarded to a main office. In another example, we found that 12 percent of the hospital reports intended for manufacturers really went to independent distributors, and some of these messages may not have been passed along to the manufacturers. While other examples could be given, the point is that there are a number of places in the communications network where a message might stop.

The net result is that from all four main channels through which FDA receives information, less than 1 percent of the problems in our sample were ultimately recorded in FDA's files.

Selective Reporting of Types of Problems

We found what appears to be a certain amount of selective reporting in the 51 percent of problems that were reported outside the hospitals. For example, when a problem involved an injury to a patient, an outside report was less likely to be made than if no injury to a patient were involved. Among the unreported incidents uncovered in our study was the one that involved the death of a patient.

We also discovered that how the cause of a problem was cited was related to whether or not the problem was reported outside the hospital. For example, we found that problems that were believed to have been caused by wear or deterioration were the least likely to be reported. This suggests that problems associated with older

devices may not be reported outside the hospitals. Another factor exerting a powerful influence on reporting was the existence of a manufacturer's warranty, service contract, or exchange agreement. The reporting rate of devices that were covered by these agreements was almost twice that of devices that were not covered.

We also sought to look at the means by which reports of incidents with devices were transmitted, and we found that some 83 percent of the reports from hospitals to outside organizations were transmitted orally. Since no standard reporting procedures, forms, or formats are required, we can only speculate on the quality of the information, and the possible distortion in the oral information, that was passed along. In sum, our study shows that reporting on device-associated problems that the hospitals themselves voluntarily selected as significant was cut in half at the source -- and most of what did emerge was not formally documented.

CONCLUSIONS

FDA can receive early warning of problems with medical devices only if information flows effectively from the hospitals along the various channels of the communications network. Most importantly, FDA learns of less than 1 percent of the medical-device problems in hospitals. About 9 percent of these problems are associated with injuries, and 37 percent are associated with potential serious injury or death. Taking these findings together, we conclude that

important problems with medical devices are unknown to FDA because the communications network between the hospitals and FDA does not work very well.

We realize that 100-percent reporting is not necessary to enable the agency to make appropriate postmarketing regulatory decisions and that it is the agency's role to determine the level of reporting that is required in order to establish the nature and scope of problems related to medical devices. However, we believe that the reporting of serious events, such as those described in the medical-device reporting rule, are the most important for the agency to hear about, and we found in our study that those serious events were the least likely to be reported outside the hospitals. Indeed, whether one considers serious or nonserious events, it is clear that if less than 1 percent of the reports of problems are reaching FDA, the early warning system is in need of improvement. Further, these gaps in the flow of information raise important questions about the nature and scope of problems that can be identified by the regulation.

In response to the comments HHS made on our report, we agreed that the medical-device reporting rule may be a necessary first step in improving the severe underreporting of medical-device problems and in increasing the overall effectiveness of FDA's postmarketing surveillance system. However, we believe this rule is not sufficient. We indicated to HHS that it is reasonable to

expect the implementation of the medical-device reporting rule to augment the number of reports that are sent to FDA, but since our study did not include a specific evaluation of the rule, we could not empirically assess its effect. We also pointed out that the medical-device reporting rule does not currently require reporting by independent distributors of medical devices, yet our findings show that the distributors are an important link in communications, that they are notified of the occurrence of problems, and that often they do not transmit this information to manufacturers or FDA. This finding supports the need to include the independent distributors in the mandatory reporting scheme.

Solutions to rectify weaknesses in the network should consider the network as a whole rather than trying to repair or strengthen a single link within it. For a first step toward strengthening the whole network, we have recommended to HHS that independent distributors of medical devices be required to report information about problems to manufacturers, just as manufacturers are required to report to FDA under the medical-device reporting rule. Since our study found that more than 50 percent of the hospital personnel did not know they could report problems directly to FDA or to FDA through USPC, we also recommended the establishment of a more effective cooperative relationship with professional health organizations, in order to develop and distribute educational materials for hospital personnel on FDA's need for early warning information and on how to report medical-device problems.

In addition, we recommended that FDA explore the possibility of establishing a voluntary, postmarketing surveillance system involving a representative sample of hospitals that would report directly to device manufacturers. We made this recommendation because of the void we found in the information on problems with medical devices, the potential harm to the public that could ensue, recent initiatives taken by the Joint Commission on Accreditation of Hospitals, and the extremely cooperative attitude hospitals expressed to us while we were conducting this study.

This concludes my prepared statement. I will be happy to answer any questions you or other members of the Subcommittee have.