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STATEMENT OF

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BEFORE THE

HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

ON THE

FEDERAL REGULATION OF MEDICAL DEVICES

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Mr. Chairman, we are pleased to be here today to discuss our September 30, 1983, report to the Congress on the federal regulation of medical devices which range, as you know, from simple instruments, such as tongue depressors, to complex ones, such as kidney dialysis machines and artifical organs.

In 1976, the Congress added the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. These amendments required FDA to

- --classify devices, according to three different degrees of risk
- --review the safety and effectiveness of certain devices on the market before passage of the amendments (preenactment devices)
- --determine as a condition for market entry whether new devices are substantially equivalent to preenactment devices
- --review the safety and effectiveness of certain new devices before marketing
- --develop performance standards for some devices and
- --require manufacturers to develop and adhere to good manufacturing practices.

Our objective was to review the focus and extent of federal regulation of medical devices. During the early phase of our work we became aware that FDA did not have a comprehensive system to collect and analyze data on medical device problems and their causes and severity. Therefore, to obtain an indication of the nature and extent of device problems and the

manner in which devices were being regulated, we interviewed 68 persons having considerable knowledge about devices, including:

--hospital based physicians,

--biomedical engineers and researchers,

--consumer and trade group representatives,

--manufacturers,

--attorneys specializing in device law, and

--former Department of Health and Human Services officials.

The names and affiliations of the persons interviewed are included in Appendix I to our report. We also reviewed a number of articles and studies on medical device problems and methods of regulation along with data collected by FDA on the nature, extent and severity of medical device problems. In addition, we determined FDA's progress in implementing the various provisions of the 1976 amendments.

SUMMARY OF OUR OBSERVATIONS

We reported that:

--FDA needs to develop a comprehensive medical device information system and develop the capability to analyze trends associated with particular groups of devices as well as the seriousness and causes of device problems.

--While FDA has not yet completed the final classification process, it appears that more than 1,000 devices will be placed in a category requiring the development of performance standards. Such standards will be both time

consuming and expensive to develop and may do little to assure that devices are safe and effective.

--FDA has not reviewed the safety and effectiveness of any class III preenactment devices as required by the law and may not be able to do so for many years.

--The provision of the amendments allowing FDA to approve new devices for marketing, if they are substantially equivalent to preenactment devices needs to be reexamined. FDA's review of risky new devices on the basis that they are substantially equivalent to preenactment devices has not been effective because FDA has not reviewed preenactment devices for safety and effectiveness. Moreover, FDA does not require safety and effectiveness data to be part of the process for determining substantial equivalency.

--Lastly, most of the experts we interviewed believed that while the amendments focused control on medical device performance and manufacture, the leading cause of device failure involved user and maintenance problems.

I would now like to discuss each of these areas in a little more depth.

FDA NEEDS COMPREHENSIVE MEDICAL DEVICE INFORMATION SYSTEM

The effectiveness of FDA's regulation of medical devices depends largely on its information system. FDA's current

system has major deficiencies that hinder the development of a useful medical device data base. For example, the system focuses on problems with individual devices and has rarely been used to analyze trends with particular groups of devices, is not well publicized, and fails to provide meaningful feedback to those who report problems. In addition, device manufacturers and distributors are not required to notify FDA when they become aware of a death, injury, or hazard caused by a medical device.

We recommended in our report that FDA improve its data collection and analysis efforts by:

--Expanding its present system to include available medical device literature and studies.

--Encouraging more complete and continued reporting of medical device incidents by developing an effective means of providing feedback to reporters on the use made of the information furnished and the results achieved.

--Developing and promulgating a mandatory experience reporting requirement for manufacturers.

--Developing capabilities to permit greater use of the information collected to identify trends and generic problems.

In commenting on our report, HHS agreed that FDA should develop a more complete and useful device information system and that such a system would enable FDA and others to reduce public exposure to device risks.

As to promulgating a mandatory experience reporting requirement for manufacturers, HHS stated that FDA has developed a proposed regulation that would require manufacturers and importers to report all deaths or serious injuries associated with the use of their products. As proposed, the regulation would require manufacturers and importers to report device malfunctions which, if they recurred, are likely to cause or contribute to death or serious injury.

DEVELOPMENT OF PERFORMANCE STANDARDS FOR OVER 1,000 DEVICES WILL BE TIME CONSUMING AND EXPENSIVE

The Medical Device Amendments of 1976 require FDA to classify and regulate devices according to degrees of risk. The amendments create a three-tiered classification system. Class I devices, involving minimum risk, are to be regulated under general controls, such as good manufacturing practices. Those placed in Class II, which involve a greater risk and for which general controls are not sufficient to ensure safety and effectiveness, require performance standards. Those placed in Class III are subject to the most stringent level of control and require premarket approval by FDA before marketing.

FDA--assisted by panels of nongovernment medical, scientific, and industry experts and consumer representatives--identified about 1,700 types of devices, of which 1,093 were placed or proposed to be placed in class II, thereby requiring the development of performance standards.

To date, FDA has not promulgated any standards. Because of the time and resources required to develop standards, FDA believes that developing over 1,000 of them will be a very time consuming, expensive and perhaps unnecessary task that cannot be accomplished in less than several decades.

Many device experts we interviewed questioned the feasibility and utility of developing standards for so many devices and told us that:

--standards may stifle innovation and not assure the safety and effectiveness of devices, and

--standards may be obsolete by the time they are developed.

We believe that, while standards may be needed for some devices, there is a sufficient basis for the Congress to review the existing statutory requirement that standards be developed for all Class II devices. If the Congress shares these concerns, it could revise the law and give FDA the flexibility to determine on a case-by-case basis when standards are needed.

HHS advised us that FDA is undertaking a variety of initiatives that are in concert with our report and is considering (1) a legislative proposal to give FDA flexibility to develop standards on an as-needed basis, and (2) streamlining the current standards setting process.

REVIEW OF OLDER DEVICES WILL TAKE YEARS AND MAY NOT BE NECESSARY IN ALL CASES

The Medical Device Amendments of 1976 permitted devices that were on the market before the enactment of the legislation--termed preenactment devices--to continue in use

subject to eventual approval by FDA. FDA estimates that about 1,000 preenactment devices must undergo premarket approval or be reclassified. At the time of our review FDA had not reviewed any preenactment devices for safety or effectiveness.

Several experts we interviewed expressed the view that since many preenactment devices had been used safely for years, there was no need for a full premarket approval review. One suggested that FDA concentrate its review on those devices with a history of adverse incidents.

In our report we proposed that, should the Congress decide that a review of all class III preenactment devices was not feasible or necessary, it could consider giving FDA the flexibility to decide which ones needed to be reviewed. At the time of our review HHS stated it would study the matter to see if any changes should be made.

PROOF OF SAFETY AND EFFECTIVENESS SHOULD BE REQUIRED FOR ALL NEW RISKY DEVICES

The 1976 amendments permit FDA to approve new devices for marketing if they are substantially equivalent to preenactment devices. Many of the experts we interviewed believed that FDA's substantial equivalence review process for new devices should be changed or abolished. The most serious problem cited was that the review process does not provide assurance of device safety and effectiveness.

The amendments do not specifically define the term "substantially equivalent" and FDA does not require a determination of safety and effectiveness in making substantial equivalence determinations. FDA does occasionally obtain some safety data for a few devices, such as pacemakers, to see if the device works "as well as" something already on the market, but has not developed guidelines for determining which devices should undergo such a review.

In commenting on the substantial equivalence process, experts advised us that (1) the process is too superficial, (2) the process is not effective since FDA has not reviewed the safety and effectiveness of the preenactment devices to which new ones are being compared and (3) there is no guarantee that new devices will perform the same way as older ones because variations in design and differences in manufacturing processes may affect performance.

Because Class III devices have inherent potential for harm, we suggested that the Congress consider eliminating the provision of the Act that permits FDA to approve new Class III devices on the basis of substantial equivalence and revise the law to require that all new Class III devices be subject to premarket approval. We also recommended that FDA's process for determining the substantial equivalence of certain risky Class II devices include consideration of safety and effectiveness data.

At the time of our report FDA had no comment on our proposal relating to Class III devices. On risky Class II devices FDA said initiating our recommendation would significantly alter classification and marketing procedures in a way not intended by the Congress.

EXPERTS ATTRIBUTE MOST DEVICE FAILURES TO USER AND MAINTENANCE PROBLEMS

Although the amendments focus control on medical device performance and manufacture, many experts expressed the opinion that user and maintenance problems are the leading causes of device failure. Research at one hospital showed that in certain fields, such as anesthesiology, operator errors account for over 70 percent of the failures analyzed. Operator errors range from mistakes in the operation or application of a device to serious errors in judgment affecting the use of a device on a particular patient. Although some operator errors can be prevented by increased training, many are committed under conditions of stress, haste, fatigue, carelessness or inattention.

According to the experts we interviewed, inadequate maintenance and repair is also a leading cause of device failure. According to some experts, maintenance problems are caused not by a lack of concern or knowledge, but by a lack of funds. One told us that many hospitals simply cannot afford to pay an engineering staff to pretest and properly maintain

equipment. This is especially true for many small community hospitals. Lack of funds not only prevents some hospitals from hiring in-house biomedical engineers, but also prevents poorer hospitals from replacing obsolete equipment.

All parties involved in the manufacture and use of medical devices share the responsibility for solving user and maintenance problems. Some experts believe manufacturers and medical community organizations are beginning to address these problems, and that progress is being made. Some FDA involvement in the user and maintenance problem areas, however, is also warranted. FDA could play a useful role by developing an effective device experience reporting system and by providing information on the nature and extent of improper use and maintenance problems. This could be done through an expanded FDA information role. We recommended that FDA undertake such a role. FDA concurs in this recommendation.

This concludes our testimony Mr. Chairman. We would be glad to answer any questions you or other members of the subcommittee might have.