

The 1976 amendments to the Federal Food, Drug, and Cosmetic Act require the Food and Drug Administration (FDA) to regulate medical devices and ensure their safety and effectiveness. Medical devices range from simple instruments, such as tongue depressors, to complex ones, such as kidney dialysis machines and artificial organs. The amendments require FDA to (1) protect the public against unsafe or ineffective new devices gaining entry to the market, (2) review devices on the market before passage of the amendments, and (3) classify all devices according to risk and regulate them through a series of mechanisms, including premarket approval and the development of performance standards.

FDA has not completed many of the tasks required in the law. For example, it has not completed the process of classifying devices, begun a review of preenactment devices, or promulgated performance standards. FDA also has not developed a comprehensive system to collect and analyze data concerning medical devices. In the absence of such a system, GAO interviewed 68 experts to obtain their views on medical device regulation.

Many of the experts questioned the usefulness of having FDA develop performance standards for a large number of devices, and some questioned the usefulness of having FDA review all preenactment devices. Their views on these and other matters suggest that the Congress may wish to consider modifying several provisions of the act.



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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the Food and Drug Administration's (FDA's) efforts to regulate the medical device industry under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. The amendments require FDA to (1) protect the public against unsafe or ineffective new devices gaining entry to the market, (2) review devices on the market before passage of the amendments, and (3) classify all devices according to risk and regulate them through a series of mechanisms, including premarket approval and the development of performance standards. To obtain some indication of the nature and extent of medical device problems and the manner in which devices were being regulated, we interviewed 68 persons in positions to have considerable knowledge about devices.

The report, which is based to a considerable extent on comments by these experts, describes FDA's implementation of certain provisions of the 1976 Medical Device Amendments, identifies actions FDA needs to take to strengthen its administration of the law, and presents several matters for consideration by the Congress involving possible legislative changes. Our review was made because a comprehensive survey of medical device regulation identified problems with FDA's implementation of the underlying legislation.

We are sending copies of this report to the Director, Office of Management and Budget, and the Secretary of Health and Human Services.

Charles A. Bowsher
Comptroller General
of the United States

D I G E S T

The 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act require the Food and Drug Administration (FDA) to regulate medical devices during all phases of development, testing, production, and use. Medical devices range from simple instruments, such as tongue depressors and thermometers, to complex ones, such as kidney dialysis machines and artificial organs. The amendments were enacted on the premise that devices presented major risks to patients and that such risks would increase without regulation.

The amendments require FDA to (1) classify devices according to degrees of risk, (2) review all devices on the market before passage of the amendments (preenactment devices), (3) determine as a condition for market entry whether new devices are substantially equivalent to pre-enactment devices, (4) review the safety and effectiveness of certain new devices before marketing, (5) develop performance standards for some devices, and (6) require manufacturers to develop and adhere to good manufacturing practices.

GAO's objective was to review the focus and extent of Federal regulation of medical devices. During the survey phase of its work, GAO found that FDA did not have a comprehensive system to collect and analyze data on medical device problems and their causes and severity. To obtain an indication of the nature and extent of medical device problems and the manner in which devices were being regulated, GAO conducted interviews with 68 persons in positions to have considerable knowledge about devices.

These experts included 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. (See pp. 5 to 7.)

Many of the experts interviewed believed the Congress should reconsider some of the amendments' provisions. They expressed the opinion that full implementation of the amendments was not necessary, would require significant agency resources, and would take years to complete.

GAO could not independently corroborate the experts' views. But the fact that a broad cross-section of experts, representing the medical community as well as consumers, expressed concerns about the 1976 amendments leads GAO to conclude that the appropriate congressional committees should explore with the experts, FDA, and other interested parties the need for modifying several provisions of the law.

FDA NEEDS COMPREHENSIVE
MEDICAL DEVICE INFORMATION SYSTEM

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

GAO is recommending that FDA improve its data collection and analysis efforts by

- developing and promulgating a mandatory experience reporting requirement for manufacturers and
- developing the capability to provide information on trends and generic problems. (See p. 18.)

FDA could also use its improved information system to give the private sector better information on user and maintenance problems.

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.

While FDA has not yet completed the final classification process, panels convened to work on this matter have recommended that more than 1,000 devices be placed in Class II, thereby requiring the development of performance standards. Many device experts interviewed by GAO questioned the feasibility and utility of developing standards for so many devices and told GAO that

--standards do not assure safe and effective devices and

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

Because of these concerns and the fact that FDA has not yet developed any performance standards, GAO believes 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. (See p. 50.)

REVIEW OF OLDER DEVICES
WILL TAKE YEARS

The amendments require that all Class III devices on the market before 1976 (preenactment devices) be reviewed for safety and effectiveness. FDA may not be able to implement this provision for many years since (1) it has not yet reviewed any preenactment devices; (2) a large number of devices, about 1,000, probably will be involved; and (3) FDA's experience in conducting similar reviews of "old" drugs indicates the process is time consuming. The views of the experts GAO interviewed were mixed on the issue of whether this effort would be worth the time and money required.

Should the Congress decide that a review of all Class III preenactment devices is not feasible or necessary, it could consider giving FDA the flexibility to decide which ones need to be reviewed. (See p. 62.)

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. FDA's review of risky new devices on the basis that they are substantially equivalent to preenactment devices is not effective because FDA has not reviewed preenactment devices for safety and effectiveness as required by the amendments. Moreover, FDA does not require safety and effectiveness data for devices found to be substantially equivalent to preenactment devices.

A recent device approved through the substantial equivalence process, for example, was so seriously flawed that it was later determined to be a health hazard. Some experts told GAO that the substantial equivalence process is being used as a means to avoid the requirement for a more lengthy premarket approval.

Because of Class III devices' inherent potential for harm, GAO is suggesting 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. In addition, GAO is recommending that FDA's process for determining the substantial equivalency of certain risky Class II devices include consideration of safety and effectiveness data. (See p. 54.)

AGENCY COMMENTS
AND GAO EVALUATION

The Department of Health and Human Services stated that the report correctly focuses attention on pressing issues in the regulation of medical devices, such as the need for a more useful medical device information system and whether the agency should be required to develop performance standards for all Class II devices. The Department agreed with recommendations to improve FDA's medical device information system and disseminate information on medical device problems to the private sector.

The Department stated that GAO's recommendations merit consideration and that FDA is undertaking or considering a number of initiatives that are in concert with them. These include:

- Reviewing its information system to determine (1) what aspects of the system need to be modified and what, if any, additional components need to be added and (2) what is the feasibility of increasing the system's capability to do trend analyses.
- Considering a legislative proposal that would grant FDA the discretionary authority to determine which Class II devices require performance standards.
- Studying whether the current requirement that FDA perform a safety and effectiveness review of all preenactment devices is necessary.

The Department offered no comment on GAO's proposal that all new Class III devices go through premarket approval rather than receive approval on the basis that the device is substantially equivalent to a preenactment device. The Department disagreed with GAO's recommendation to

identify risky new Class II devices and develop guidelines for documenting their safety and effectiveness. Present practices do not require that safety and effectiveness data be considered on substantial equivalence determinations.

According to the Department, instituting GAO's proposal would significantly alter the classification and marketing procedures for Class II devices. GAO believes that there may be some Class II devices that pose significant health risks and whose safety and effectiveness should be reviewed by FDA.

GAO's rationale for recommending safety and effectiveness documentation for certain Class II devices is similar to the reasons why safety and effectiveness reviews are necessary for Class III devices. In neither case has FDA determined the safety and effectiveness of the preenactment device for which the new device is considered substantially equivalent. For Class III devices, FDA is required to make a safety and effectiveness determination for the preenactment device, but has not done so. For new Class II devices, FDA must determine whether they are substantially equivalent to a preenactment device, but is not required to establish whether the preenactment device is safe and effective. Consequently, a safety and effectiveness review is not conducted for either the substantially equivalent or preenactment device. Implementation of GAO's recommendation would provide assurances that risky new Class II devices are safe and effective.

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ABBREVIATIONS

BMD	Bureau of Medical Devices
DEN	Device Experience Network
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
IDE	Investigational Device Exemption

CHAPTER 1

INTRODUCTION

Each year millions of Americans use, wear, or otherwise come in contact with medical devices. Such devices run the gamut from the very simple to the very complex--from tongue depressors and thermometers to kidney dialysis machines and artificial limbs. Special devices--such as heart valves and artificial hips--become part of the body, making normal life possible, while appendage devices--such as dentures and hearing aids--improve everyday functioning. In addition to these direct-use devices, other devices, such as respirators and X-ray and electrocardiograph machines, are used to treat patients and diagnose diseases in doctors' offices, hospitals, and other health care facilities.

In the past two decades, the use of medical devices to diagnose, monitor, and treat disease and illnesses has increased. The medical device industry is diverse; more than 8,500 foreign and domestic establishments have registered with the Food and Drug Administration (FDA). Industry sales are estimated between \$12 billion and \$14 billion annually, and 95 percent of registered establishments have fewer than 500 employees.

Although diagnostic medical devices facilitate more accurate diagnosis and often contribute to life-saving treatment of diseases, device failure or misuse can provide inaccurate diagnostic information, cause patient injury, or contribute to patient death. To protect the public from unsafe or ineffective medical devices and the potential harm that could result, the Medical Device Amendments of 1976 (Pub. L. No. 94-295) were added to make certain revisions to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Before the 1976 amendments, FDA's authority relating to medical devices was contained in the 1938 Federal Food, Drug, and Cosmetic Act. The act provided for regulation of "adulterated" or "misbranded" medical devices that were entered into interstate commerce. The 1938 act, however, did not require, as it did for drugs, any form of premarket approval for devices entered into interstate commerce.

After World War II, medical technology improved and devices became more complicated and more critical to patient care. Technological advances in electronics, plastics, metallurgy, ceramics, and engineering design affected all aspects of medicine.

By the early 1960s, it became clear that the 1938 act was not sufficient to regulate the new and more complex medical devices. For instance, because of the lack of regulation, anyone with an understanding of electronics and the concepts involved in the design of a cardiac pacemaker could produce that item and market it without any standardized testing.

In 1969, the Cooper Committee was formed to examine the problems associated with devices and to develop concepts for new legislation. The group was headed by Dr. Theodore Cooper, then the Director of the Heart and Lung Institute at the National Institutes of Health. During the year after its founding, the Committee met with representatives from the medical profession, industry, consumers, and government agencies to develop strategies that would later serve as a basis for medical device legislation.

The Cooper Committee completed its work and published its final report in September 1970.¹ In 1973, congressional hearings showed that such life-saving and support devices as pacemakers, incubators, and defibrillators caused serious injury and pointed out the need for an increase in FDA's authority to regulate the medical device industry. On May 28, 1976, the Medical Device Amendments of 1976 became law.

PROVISIONS OF THE MEDICAL DEVICE AMENDMENTS OF 1976

The Medical Device Amendments of 1976 authorized FDA to regulate devices during all phases of their development, testing, production, distribution, and use. Devices were to be classified and regulated according to degrees of risks, thereby providing a means for dealing with the diversity of medical device products. Section 513 of the Federal Food, Drug, and Cosmetic Act, as amended by section 2 of the 1976 amendments, created the following three-tiered classification system:

Class I - General Controls--This class applies to devices requiring minimum regulation--devices such as adhesive tapes and bandages, surgical aprons, hydraulic beds, bedpans, specimen collectors, canes, tongue depressors, and mechanical wheelchairs. Devices grouped into Class I must meet only those requirements associated with "general controls," which include

--prohibitions against adulterated or misbranded devices (secs. 501 and 502);

¹Theodore Cooper, M.D., Medical Devices: A Legislative Plan, U.S. Department of Health, Education, and Welfare, September 1970.

- requirements that manufacturers register their establishments and list products manufactured with FDA, and notify FDA 90 days before a product is entered into interstate commerce (sec. 510(k));
- requirements that good manufacturing practices² be used in the manufacture, packing, storage, and installation of a device (sec. 520(f)); and
- authorities to restrict the sale or use of a medical device (sec. 520(e)), to ban devices that are hazardous (sec. 516), to require the repair, replacement, or refund of hazardous devices (sec. 518), and to require manufacturers to maintain certain records and reports (sec. 519).

Class II - Performance Standards--This grouping applies to devices for which general controls are not enough to ensure the devices' safety and effectiveness and for which enough information exists to develop a performance standard. Performance standards can specify materials, construction, components, ingredients, labeling, and other properties of a device. Some of the devices that fall into this category are gas analysers, blood pumps, bone plates, catheters, plastic dentures, electrocardiograph electrodes, hard contact lenses, hearing aids, and electrical heating pads. A Class II device may be life-supporting or life-sustaining; however, a device is placed in Class II if it can be regulated by a performance standard.

Class III - Premarket Approval--The final, most stringent level of control, premarket approval, is for very critical devices; that is, devices that could cause catastrophic results if they came to the marketplace poorly manufactured, poorly designed, or defective. Some of the devices that fall into this group are cardiac pacemakers, mechanical cardiac resuscitators, and heart valve replacements. All of the devices in this class must obtain premarket approval from FDA before they can be introduced into interstate commerce.

Manufacturers of Class II and III devices are also subject to Class I "general controls" and biennial FDA inspections authorized under section 510(h). Newly marketed products, not found to be substantially equivalent to an already marketed product, are assigned to Class III. Once a device has been

²Good manufacturing practices serve as a framework for the development of individualized quality assurance programs. Such practices include controls over manufacturing specifications and processing procedures, device components, packaging and labeling, and manufacturing equipment and records.

assigned to a class, any interested person can petition FDA to have that device reclassified, either to a less stringent or, in some cases, a more stringent class. FDA may also reclassify a device on its own initiative.

In addition, section 515(b)(1) of the Federal Food, Drug, and Cosmetic Act requires that after devices have been classified and regulations issued, all devices placed in Class III that were marketed before the passage of the law (preenactment devices) must undergo premarket approval to determine their safety and effectiveness or be reclassified.

The amendments, under section 520(g)(1), also provide for investigational device exemptions (IDEs) for devices that are in the discovery and development phases. Manufacturers wishing to test their products on human subjects must apply for an IDE before doing so. In making such an application, the manufacturer must demonstrate that

- o testing will be supervised by an institutional review board (see p. 59),
- o appropriate patient consent will be obtained, and
- o records and reports will be maintained.

IDEs are intended only for investigational studies that are undertaken to develop safety and effectiveness data for a particular device and that involve the use of a human subject.

To carry out its mandate under the amendments, FDA in May 1977 established the Bureau of Medical Devices (BMD).³ The approved headquarters and field staffing levels and appropriations for FDA's medical device program for fiscal years 1981-83 were as follows.

<u>Fiscal year</u>	<u>Full-time equivalent staff years</u>	<u>Appropriations (millions)</u>
1981	836	\$32.2
1982	786	31.6
1983	779	32.6

³On October 8, 1982, the Bureaus of Medical Devices and Radiological Health were merged to form the National Center for Devices and Radiological Health.

OBJECTIVES, SCOPE, AND METHODOLOGY

Since 1976, many questions have been raised about the nature and extent of medical device problems and the appropriateness of FDA regulations. Our principal objective was to determine the nature and extent of the problems associated with medical devices and whether the Medical Device Amendments of 1976 were effectively addressing the problems. In this regard we reviewed legislation, legislative histories, and articles and studies on medical device problems and methods of regulation.

Testimony presented by the Assistant Secretary for Health, Education, and Welfare at the 1973 medical device hearings pointed out that precise data on the nature and extent of medical device problems were not available. This is partly because devices are commonly used in critical situations in which a cause-and-effect relationship between the device and the patient's condition cannot be definitively determined. A more important reason for the lack of definitive data, however, is that adverse reaction experience with medical devices is not ordinarily brought to FDA's attention because, for most devices, there is no legal requirement that this be done. Only sponsors with approved IDEs and manufacturers of devices approved through the premarket approval process are required to report.

Since these conditions have not substantially changed since 1973, the best available information on the nature and extent of medical device problems is anecdotal. For this reason, we solicited the opinions and perceptions of a number of medical device experts. In addition, we reviewed the data that were available in various medical device reporting systems and obtained information on the amendments' implementation from FDA officials.

Our review was performed in accordance with generally accepted government auditing standards.

Experts interviewed

The 1976 amendments affect, either directly or indirectly, everyone involved in the design, manufacture, and use of medical devices. We conducted 55 interviews with 68 private sector device experts representing the various affected parties to obtain their perceptions on the nature of the medical device problems and their views on medical device regulation. Persons interviewed were selected from the following groups.

--Hospitals selected by our medical consultant on the basis of size and location. Included were large teaching hospitals in the eastern, mid-western, and western parts of

the country. Hospital representatives were selected by each hospital's administrator on the basis of their familiarity with medical device issues.

- Former classification advisory panelists selected from the rolls of the original panels that did the bulk of the device classifications.
- Consumer groups identified through the literature.
- Biomedical researchers associated with the development of artificial hearts and monoclonal antibodies (see p. 58), based on a review of BMD IDE requests.
- Trade associations identified through the literature.
- Device manufacturing firms selected on the basis of size and product lines. We interviewed representatives from four small firms (fewer than 100 employees), three medium firms (from 100 to 500 employees), and three large firms (more than 500 employees) that produce either diagnostic, general medical, life-sustaining, or implantable devices.
- Professional societies identified through the literature.
- Lawyers specializing in device law selected on the basis of BMD recommendations or identification in the literature, including a former congressional staff member who helped draft the original legislation.
- Professors of biomedical engineering selected from biomedical engineering or medical schools.
- Former regulators, including (1) the former Assistant Secretary for Health who chaired the committee that conducted the Department of Health and Human Services' (HHS') first comprehensive medical device study, (2) a former director of BMD, (3) a former BMD head of compliance, and (4) a former member of FDA's office of general counsel.
- Biomedical consultants selected on the basis of other respondents' recommendations.

Respondents were chosen not only for their affiliation with a group affected by device regulation, but also for their specific expertise with various device products. Areas of respondent expertise included

- life-sustaining and/or implantable devices,

- diagnostic devices, and
- general medical devices.

We did not contact individual users because their views were expressed by professional society representatives and former panelists. User perceptions were also reflected in various medical device reporting systems. The experts interviewed are listed in appendix I. Because we used a judgment sample in selecting the experts we interviewed, no statistically valid projections can be made from our data.

In the interviews we asked questions concentrating on (1) the severity and incidence of device-related injury, (2) the predominant causes of device problems, (3) personal experience with device problems, and (4) the effectiveness and impact of the 1976 amendments. The interviews were face-to-face and most were recorded and transcribed. Some experts did not respond to all of our questions, and we could not complete some interviews because of the experts' time constraints.

Information systems reviewed

We reviewed FDA's medical device reporting system to determine the type of data that existed on the nature, extent, and severity of medical device problems. We also obtained information from several other agencies (including the Department of Defense and the Veterans Administration) concerning adverse incident reports related to medical devices. We obtained data and reports on the type, kind, and number of medical device problems reported; source of the reports; cause of the problems; severity or consequences of the problems; and corrective action taken or needed. We also examined published Health Devices Alerts reports issued by the Emergency Care Research Institute (ECRI).⁴

We met with FDA and ECRI officials involved with medical devices and with representatives of other Federal agencies that gather information or develop, procure, or evaluate medical devices, including the Veterans Administration, Department of Defense, General Services Administration, Consumer Product Safety Commission, Office of Technology Assessment, National Academy of Sciences, and Congressional Research Service.

⁴ECRI is an independent health care research organization that provides a variety of services to over 2,800 hospitals and other groups. The Health Devices Alerts reports are published twice monthly and contain summaries of (1) medical device recalls, (2) reports related to hazards in devices, and (3) problems of misuse of devices and equipment.

FDA officials interviewed

We interviewed various FDA officials, including the (1) former acting director of BMD and (2) current director of the National Center for Devices and Radiological Health. We obtained information on the status of FDA's implementation of the amendments from officials responsible for administering relevant provisions of the law, including

- FDA officials who served as executive secretaries of classification advisory panels,
- the Associate Director for Standards and other standards officials, and
- the coordinators for premarket approval, premarket notification, and preenactment and investigational devices.

We also obtained budget information and internal and FDA-contracted studies relating to medical device issues. Specifically, we reviewed studies (identified throughout the report) on (1) the cost of complying with good manufacturing practices, (2) the causes of medical device problems, (3) manufacturers' reactions to medical device regulations, (4) manufacturers' complaint files, (5) the implementation of the premarket notification process, and (6) standards writing activities in FDA and other Government agencies.

CHAPTER 2

NEED FOR RELIABLE SYSTEM

TO IDENTIFY THE NATURE AND EXTENT

OF MEDICAL DEVICE PROBLEMS

FDA does not have a comprehensive system to collect and analyze information about hazards associated with medical devices, as was recommended to it as early as 1973. FDA's current system, the Device Experience Network (DEN), focuses on individual device problems and the extent to which devices comply with the Federal Food, Drug, and Cosmetic Act. DEN has rarely been used to analyze trends with particular groups of devices. DEN suffers from various problems, including (1) a reluctance on the part of manufacturers and users to report problems, (2) a lack of publicity, and (3) a failure to provide meaningful feedback to those who report problems. In addition, use of the present system is inhibited by a lack of common terminology which would permit the grouping and categorization of data by device in the system and by incomplete coding problems.

1973 STUDY RECOMMENDED THAT FDA ESTABLISH COMPREHENSIVE, MULTIFACETED SYSTEM TO COLLECT AND ANALYZE DATA

FDA, recognizing the emerging issue of medical device control and the likelihood of the need to develop a major device program, awarded a contract to ECRI (see p. 7) to (1) determine the incidence and characteristics of adverse effects among patients and health professionals caused by medical devices and (2) recommend a practical system of measures to identify, report, analyze, and prevent such events.

The 1973 ECRI study found that

- health professionals perceived that hazards with devices may occur occasionally;
- clinical areas in hospitals (intensive care unit, coronary care unit, operating suite, and emergency room) were especially hazardous;
- health professionals even in specialty areas are not well trained in the use of medical devices;
- fragmented efforts were being made in the areas of (1) medical device research, (2) information, and (3) assessment in voluntary, Federal, and non-Federal agencies and institutions; and

--health professionals will report specific device hazards which can be used for trend information and/or as a base for indepth followup investigations of a particular device or classes of devices.

As to the type of information system that FDA should develop, ECRI pointed out that the system

- should be allocated 7 to 15 percent of BMD's total budget;
- should have various components, including a library, a network with existing systems, and central data (problem) collection; and
- should include such activities as
 - . data collection.
 - . specific device and trend analysis.
 - . information to "trace medical devices."
 - . liaison/cooperation with the health community.
 - . education and information disseminating capability.

Using the ECRI study as an outline, FDA developed a strategy for DEN. Conceptually, DEN was to function as FDA's central point for the receipt, processing, and dissemination of all reports concerning adverse and historical experiences relating to medical devices and diagnostic products. The network was also to operate as a clearinghouse with the capability to provide historical data, trend analyses, special studies, and general statistics for FDA, the Congress, consumers, etc. The planned approach was for DEN to interface with existing data sources; specific systems were to be developed as the voluntary sources indicated problem areas. This approach was designed to "inform the FDA about immediate hazards to health and provide historical data for trend analysis." After identifying and analyzing reported hazards, FDA would be able to determine what type(s) of additional data are needed.

FDA IMPLEMENTED DIFFERENT SYSTEM FROM THAT PROPOSED

In 1976, when DEN was fully implemented, it was established in the Division of Compliance as a computerized file of reports of alleged device problems, not as the proposed multifaceted system. Various reasons were given for assigning DEN to the

Division of Compliance, including (1) the recognition that field inspectors would have to serve as the fact gatherers and compliance personnel traditionally dealt with field personnel, (2) an evaluation group was already in place to meet other legislative requirements for classification and the development of premarket approval regulations, (3) resources to develop overall analyses were not available, and (4) there was little management interest in trend analyses and problem identification.

FDA SYSTEM FOCUSES ON
INDIVIDUAL DEVICE PROBLEMS
AND DOES NOT ANALYZE TRENDS

Although the DEN system has been periodically refined and modified since 1976, FDA continues to focus on the collection, evaluation, tracking, and closing out of reports on a case-by-case basis. Although FDA publications highlight the importance of trend analysis, the use of individual reports other than for compliance followup remains limited.

Under the current system, once a report is received, FDA staff make an initial risk assessment of the apparent nature and severity of the problem as reported and assign priorities for inspections by FDA field investigators. The field inspector is the fact gatherer and determines whether the problem is caused by a direct violation of the Food, Drug, and Cosmetic Act. Based on the investigator's report, FDA compliance staff determine appropriate compliance action and the ultimate cause of the reported problem.

FDA has developed a format for collecting and abstracting individual problem report data and a detailed procedure for recordkeeping, initial risk assessment, field investigations, and final problem assessment. Each report of a device problem is included in the computer file and is indexed by specific codes and key words to the device, manufacturer, complaint type, risk, regulatory evaluation, and final problem assessment, along with narrative descriptions of the problem and followup.

The DEN branch chief told us that his staff does not analyze devices by categories for trends and has not published studies based on DEN reports, except for one compilation of tampon reports. He also said that while the DEN system meets compliance needs, there are problems with broader use of this information. For example, an FDA official pointed to the lack of problem assessment and the unvalidated status of most reports as an important limitation in the use of the DEN reports. One expert also told us that in the absence of an assessment, his efforts to make anything meaningful out of the report were thwarted because the information describing the complaint often was too general.

SPECIAL STUDIES SHOW VALUE OF
REVIEWS FOCUSED ON GENERIC PROBLEMS

We identified two special studies FDA made using DEN data to identify generic problems with groups of devices which demonstrate that (1) the generic type of review can provide valuable analyses and (2) the DEN system with certain modifications can be used more extensively than it has been for analyses of trends and identification of problems by groups of devices. The two studies were not initiated by DEN staff but by outside organizations--GAO and the Health Research Group, a private consumer research group--that requested DEN complaint data to confirm patient device problems.

One group of generic devices identified as having problems involved computer software used in medical devices. We reported this problem to FDA in our August 5, 1981, report, "Software Used in Medical Devices Needs Better Controls to Avoid Compromising Patient Safety" (AFMD-81-95). Using DEN data we identified 78 cases involving potentially unreliable computerized medical devices and estimated that about 30 different types of devices were involved. FDA formed a task force composed of in-house experts from the laboratory, standards, compliance, and program operations and chaired by the senior scientist in its Office of Health Affairs to examine this problem in detail. In January 1982, the task force reported that although software did not then present an undue risk, such risks could develop in the future because of the rapid proliferation of computers in medical devices and trends in applied research. Four recommendations were made to help BMD anticipate and resolve future problems.

Three of the task force recommendations were to be implemented as resources permitted, but the fourth--calling for FDA to continue efforts to monitor and assess problems with use of computers and/or software as medical devices--was to be implemented without delay.

The task force, in amplifying on this recommendation, stated that it could be implemented without any current increase in expertise or resources because BMD had enough technical talent to establish a group to monitor the DEN reports. The report added that developing keywords and other procedures to identify readily potential software problems was also within the Bureau's current capability. It stated that this group's availability to advise FDA's Office of Small Manufacturers Assistance on device evaluation, compliance, and standards would assure uniform responses to computer/software problems.

The other generic group of devices identified as having problems involved ventilators and ventilator accessories.¹ The safety of these devices was questioned by the Health Research Group in July 16, 1982, testimony before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce. The Health Research Group identified 290 DEN reports provided by FDA in response to its Freedom of Information Act request for reports on ventilators, resuscitators, anesthesia machines, and anesthesia breathing circuits.

In response to the Health Research Group activity, FDA made a special review of DEN complaints and recalls related to ventilators and ventilator accessories and, based on its review, formulated plans for continuing action in its standards and compliance programs. Specifically, the resulting BMD report of September 17, 1982, called for (1) a review of the individual DEN report files, (2) a review of the 1976 ventilator standard to make sure that all standards-related problem areas were addressed satisfactorily, (3) an assessment of whether other measures were needed, and (4) continued monitoring of an FDA contract study on breathing systems.

CHANGES TO SYSTEM NEEDED TO PERMIT TREND ANALYSIS

Although the previous section shows that reviews of devices by generic problems or groupings of devices to identify trends are possible under special arrangements, existing difficulties need to be corrected before such reviews can be routinely accomplished.

For example, the DEN branch chief told us that the system does not catalog reports according to a product thesaurus (a compilation of words or phrases providing a standardized vocabulary for the information storage and retrieval). Therefore, there is no existing grouping or categorization of similar devices that would facilitate problem report counts by generic grouping.

In addition, the branch chief told us DEN reports are not coded by medical event, which would allow reports to be grouped according to type and severity of medical event. He said currently the "risk" codes in DEN broadly reflect the reporter's allegation of severity--death, actual or potential injury--but there is neither a more specific nor a final medical event categorization.

¹A life-support device used to assist or control a person's breathing. Accessories include gas regulators, tubes, hoses, etc.

the current proposed rule for mandatory experience reporting is uncertain. In our interviews, however, some experts told us that if such a requirement were carefully designed and restricted to necessary information, they would not be opposed to it. Just how much and what kind of data should be reported is a matter of judgment. There will inevitably be disagreement in this area to be worked out. We noted that the Office of Management and Budget, in its initial disapproval of the mandatory experience reporting proposal, nevertheless agreed that some kind of mandatory experience reporting system was warranted.

Other problems that will need to be worked out include sanctions for failure to report and ways to protect the confidentiality of the data submitted by manufacturers. Manufacturers interviewed repeatedly stated that they could not trust FDA with confidential information and feared major lawsuits as a result.

Better feedback to participants
could motivate more people
to report device problems

A comment received from a number of experts was that participants who forwarded problem reports to DEN did not receive adequate feedback about the problems' disposition. Under the U.S. Pharmacopia contract, an acknowledgement letter is sent to the reporter and the manufacturer. Also, the manufacturer will often contact the reporter directly or contact the Pharmacopia, which will contact the reporter. However, experts advised us that the feedback is often unsatisfactory to the reporter, who is looking for meaningful feedback and recognition that based on his or her report, an analysis or investigation found a problem which was corrected. FDA determined a likely cause for device failure in only 13 percent of reported cases. In addition, a long time often elapses between the report date and the reported resolution date of the investigation.

By comparison, ECRI requests problem reports from users, and according to ECRI, perhaps one-third of reported events culminate in a published hazard report, usually within 60 to 90 days. ECRI stated that, because these reports are read by the individuals who reported the event, there is a full cycle of awareness and the reporter receives a sense of personal contribution and accomplishment in improving patient safety.

DEN should be expanded to include device problems contained in literature

Because the DEN system is regarded more as an investigative than an information system, device problems contained in literature reference or BMD definition studies (technical reports) are not included. The device problems identified in these sources would provide supplemental data useful for analyzing the extent and nature of a problem. We noted, for example, that the literature contained a study discussing 15 cases of complications with pneumatic tourniquets.² DEN, however, contained only one report, which involved a rather innocuous problem with a safety guard to protect the user's hands. In another case, the literature contained information on four bone support implants that cracked as a result of problems with the materials and method of manufacture. In one case the rod failed completely. DEN contained only one report, which involved a complaint that packaging did not meet good manufacturing practice requirements.

The full scope of data available in the literature is illustrated by a 1973 ECRI study performed for FDA. This study revealed over 3,000 retrievable sources and about 3,700 reported adverse effects associated with medical devices. The Cooper Committee Report also made extensive use of the literature in developing information on medical device incidents. In addition, other information systems--such as ECRI, FDA's Adverse Drug Reaction System, and its Radiation Incidents Reports System, routinely include information from the literature.

Other benefits of an expanded and more complete information system

FDA could use an improved information system to help determine (1) which devices need performance standards (ch. 5) and (2) which devices that were on the market before 1976 (preenactment devices) should be subject to a premarket approval (ch. 6). As discussed in chapter 4, FDA would also be able to use this system to give the private sector information on user and maintenance problems.

SUMMARY

The effectiveness of FDA's regulation of medical devices depends largely on the quality of its information. FDA needs a comprehensive medical device information system. Its current

²A doughnut-shaped device which after being inflated with air is used to stop blood flow.

system, DEN, has major deficiencies that hinder the development of a useful medical device data base. In addition, FDA does not adequately analyze the information DEN does contain.

RECOMMENDATIONS TO THE SECRETARY OF HHS

To enable FDA to develop a more complete and useful medical device information system, we recommend that the Secretary require the Commissioner of FDA to:

- Expand the DEN system to include available medical device literature and studies.
- Encourage 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.
- Develop and promulgate a mandatory experience reporting requirement for manufacturers. The requirements should seek only new information which is essential to FDA needs, can be effectively used, and will not be unduly burdensome for manufacturers to provide.
- Develop capabilities to permit greater use of the information contained in DEN in order to identify trends and potential problems and to devise appropriate resolutions to those problems. This could be accomplished in part by developing a product thesaurus and medical event codes.

AGENCY COMMENTS

HHS agreed that FDA should develop a more complete and useful device information system and that such a system will enable FDA and others to reduce public exposure to device risks. According to HHS, FDA is reviewing DEN to determine what aspects of the current system need to be modified, and what, if any, components should be added. HHS stated that our findings on the DEN system will be taken into account during this review. Specifically, FDA will be looking at the feasibility of including additional medical device literature and studies, providing more effective feedback to device experience reporters, and increasing the capability to do use and trend analyses.

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 will also require manufacturers and importers to report device malfunctions which, if they recurred, are likely to cause or contribute to death or serious injury.

CHAPTER 3

MANY EXPERTS BELIEVE SOME DEVICE REGULATION

IS NEEDED BUT FULL IMPLEMENTATION

OF THE AMENDMENTS WOULD BE EXCESSIVE

Of the 43 experts who responded, 11 believed that the present level of regulation was justified and 8 were not sure. Twenty-four experts believed, however, that the level of regulation provided for by the amendments is excessive in relation to the problems with medical devices. According to these experts, some findings used to justify the legislation were misleading, and medical device problems were and are not severe or extensive enough to warrant full implementation of the amendments.

According to the experts we interviewed, manufacturer registration, product listing, device labeling, good manufacturing practices, premarket approval of some devices, and the psychological effect of "knowing FDA is out there" are reasonable means for ensuring the safety and effectiveness of medical devices. Other provisions of the amendments, although not yet implemented by FDA, such as developing mandatory performance standards for most medical devices, are viewed by experts as being excessive. Experts we interviewed also believe that determining substantial equivalency of new devices to preenactment devices is not an effective means for ensuring device safety and effectiveness. (See chs. 5 and 6.)

Nine experts believed increased device safety and effectiveness resulted from natural market forces and technological improvements made by manufacturers. Five experts also expressed concerns about the amendments' impact on device innovation and cost.

Interviews were conducted with medical device experts because FDA did not have a comprehensive system to collect or analyze data on medical device problems. The major reason for the lack of definitive data is that for most medical devices, there is no legal requirement to report adverse reactions. Although no statistically valid projections can be made, responses from those interviewed provide insight on medical device issues.

EXPERTS CONSIDER PROPOSED LEVEL OF REGULATION EXCESSIVE

Most experts who responded believed that the level of regulation provided for by the amendments is not justified by

the nature and extent of the problems with medical devices. Most experts we interviewed believed that medical devices do not generally present serious hazards to patients. Three experts considered it fortunate that FDA has not implemented the full level of regulation provided for by the amendments. For example, FDA has not yet promulgated any of the performance standards that are supposed to be written for over 60 percent of the devices now on the market.

Of the 43 experts responding, 26 percent believed that the level of regulation provided for by the amendments was justified, 56 percent felt that it was not justified, and 18 percent were not sure. The following table depicts the experts' responses.

Is the Level of Regulation Provided
for by the 1976 Medical Device Amendments
Justified by the Nature and Extent of the
Problems with Medical Devices?

	<u>Total</u>	<u>Yes</u>	<u>No</u>	<u>Not sure</u>
Academics	4	2	2	-
Professional societies	3	1	2	-
Trade associations	2	-	1	1
Panelists	4	-	4	-
Consumer and research groups	5	2	3	-
Hospitals	10	2	2	6
Lawyers	4	1	3	-
Manufacturers	8	1	6	1
Former regulators	<u>3</u>	<u>2</u>	<u>1</u>	<u>-</u>
Total	<u>43</u>	<u>11</u>	<u>24</u>	<u>8</u>

Two experts stated that the amendments were excessive because the need for medical device legislation was not as great as it was thought to be at the time of enactment. Although the Cooper Committee Report was considered by some experts to be a valid study given the information available at the time, eight experts believed that it was not a sound basis for medical device legislation. The study identified 751 deaths and 10,000 injuries associated with medical devices over a 10-year period; 512 of the deaths and 300 injuries were attributed to heart valves, and 89 deaths and 186 injuries were related to heart pacemakers.

Experts criticized the study because it (1) did not distinguish between device-related and device-caused injuries and

deaths, (2) did not consider the number of medical device incidents in relation to the level of use, and (3) concentrated on first-generation, high-risk devices, such as heart valves and pacemakers, which could be expected to improve over time through state-of-the-art changes.

Experts commented that:

--The Cooper Report's evidence was based on the number of injuries and deaths possibly attributable to medical devices. However, when a death occurs, especially in an emergency, determining what or who was at fault is difficult. Was the device? The doctor? The nurse? It is hard to determine what happened at that crucial point.

--The Cooper Report was not balanced. The number of injuries found was made to seem unacceptably high. But considering the tremendous number of opportunities for mishaps in the practice of medicine, the number of incidents is remarkably small.

--The devices that Cooper was looking at were known to have high risks because many were first-generation devices. But devices evolve through constant improvement, and those that have been used for longer periods have much lower failure rates.

In commenting on the report, Dr. Cooper told us that he believed that the study, at the time, was a useful stimulus to the medical device debate. He was not completely satisfied with the law's final form, because it took a regulatory posture on problems that the report tried to minimize. However, he believed the study served as a basis for dealing with the issues more logically.

Four experts who elaborated on their opinions that the level of regulation is justified by the nature and extent of medical device problems stated that:

--Given the data available and the seriousness of risk posed by many devices, a very critical need exists for comprehensive FDA authority in this area.

--No harm is being done by the present level of regulation.

--The level of regulation is justified, at least the way FDA is currently implementing it. However, if FDA was doing everything required by the law, it would be excessive.

--The legislation is good in that it got rid of the garage-type operations and manufacturers that lacked quality control.

When asked to give their current perceptions of overall device-related patient injury, 92 percent of the respondents believed that the incidence of injury was slight or very slight. The following table depicts the experts' responses.

In Your Opinion, How Great Is the Overall Incidence of Device-Related Injury?

	<u>Total</u>	<u>Very great</u>	<u>Great</u>	<u>Moderate</u>	<u>Slight</u>	<u>Very slight</u>
Academics	4	-	-	-	4	-
Professional societies	1	-	-	-	1	-
Trade associations	3	-	-	-	-	3
Panelists	3	-	-	-	-	3
Consumer and research groups	4	-	-	-	3	1
Hospitals	12	-	-	1	6	5
Lawyers	2	-	-	1	1	-
Manufacturers	7	-	-	1	2	4
Former regulators	<u>4</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>3</u>	<u>1</u>
Total	<u>40</u>	<u>0</u>	<u>0</u>	<u>3</u>	<u>20</u>	<u>17</u>

Experts recognized that medical devices fail but noted that such failures are few in relation to the number of times devices are used. They added that although devices have certain risks, such risks must be balanced against the potential benefits.

Experts specifically noted that:

--Considering all the opportunities for injury or breakdown, the number of device-related incidents of injury is a very small percentage.

--All medical devices must reasonably be expected to have some failure rate, given the state of the art at any time.

--Many life-support devices exist today where none existed before. The risk of using some of these devices is high, but the risk of not using them is much higher.

--A device is safe if it is safer than the organ it replaces. An artificial heart may not work longer than a year, but the device is safer than the heart it replaced. And the expanded life the patient receives is a valuable gift.

Experts believe amendments
have had some impact

Forty-three medical device experts commented about the impact of the amendments on reducing device failure and related injury. Over half believed that the amendments have had some impact, as shown in the following table.

EXPERTS' PERCEPTIONS OF THE AMENDMENTS' IMPACT
ON REDUCING DEVICE FAILURE AND RELATED INJURY

AMENDMENTS' IMPACT	ON REDUCING DEVICE FAILURE	ON REDUCING DEVICE RELATED INJURY
Very great	2%	0
Great	7%	9%
Moderate	21%	12%
Some	37%	44%
Little	33%	35%

Some experts believed that certain provisions of the law have helped improve device safety and effectiveness. Specifically, they stated that

--requiring manufacturers to register their establishments and to provide a list of products manufactured is not burdensome and gives FDA necessary information on device manufacturers and

--prohibiting false and misleading labeling and requiring adequate warnings and directions for use are necessary to insure that devices are safely operated.

Over half of the experts wanted no change or only slight changes to current good manufacturing practices. Two experts noted that good manufacturing practices have been effective in improving quality control and have encouraged manufacturers to accept the idea that good manufacturing requires a good manufacturing system and not just a good end product. One expert commented

that a combination of good manufacturing practices, premarket notification, and overseeing the design and manufacture of a product has made a big difference.

A 1982 statistically valid survey of medical device manufacturers conducted by Louis Harris and Associates also cited positive effects associated with good manufacturing practices.¹ However, 38 percent of the manufacturers they surveyed considered the good manufacturing regulations to be burdensome. Manufacturers objected to excessive paperwork, recordkeeping, and documentation requirements and the additional costs necessary to comply with the regulations.

The Harris survey found that premarket approval of critical devices, which requires manufacturers to submit proof of device safety and effectiveness, was also considered an effective means of protecting the public. Of the Harris survey respondents, 80 percent and 79 percent, respectively, believed that life support devices and implants should be strictly regulated. In addition to the positive impact of the good manufacturing practice and premarket approval requirements, the amendments were also credited with having had a positive psychological impact on the device industry.

Experts we interviewed commented that:

- The amendments have increased manufacturers' awareness. Many companies unfamiliar with regulation before 1976 now know that FDA could be significantly involved in their business.
- Knowing that somebody either is looking over your shoulder or is in a position to do so is a strong motivation to do things more carefully.

Market forces credited
with great impact

Although many experts we interviewed believed that some regulation is needed and that the amendments have had some impact on improving safety and effectiveness, several believed that nonregulatory factors, such as increases in technology, fear of legal liability, and competition among manufacturers, have had the greatest impact on improving device quality.

¹A Survey Of Medical Device Manufacturers, Louis Harris and Associates, Study No. 802005, July 1982.

The Harris survey found that manufacturers rate market forces as being at least as effective as FDA regulations in protecting the public from unsafe or ineffective devices, as shown in the following table.

PROTECTING THE PUBLIC FROM POOR QUALITY
AND UNSAFE MEDICAL DEVICES

	MANUFACTURERS' OWN PRODUCTION PROCEDURES	PRODUCT LIABILITY LAWS	BUYER AWARENESS	FDA REGULATIONS
Very effective	53%	37%	29%	17%
Somewhat effective	36%	33%	30%	44%
Only slightly effective	5%	10%	20%	20%
Not effective at all	2%	14%	16%	15%
Not sure/ no response	4%	6%	5%	4%

As shown, 61 percent of the manufacturers also rated FDA regulations as being very effective or somewhat effective.

In addition, 10 medical device experts who provided comments to support their beliefs stated that increases in technology, fear of legal liability, and competition among manufacturers have had the greatest impact on improving device quality.

Five experts stated that recent improvements in device quality were due to technological changes. They commented that:

- Any improvements in devices since 1976 have resulted from the fact that there is more knowledge and a bigger base to look at and we have learned from past mistakes--not because of the amendments.
- Diagnostic devices are being developed on a better technical basis, and the amendments have had little to do with that.
- Incidents of injury have decreased because of better materials and better knowledge on how the old materials failed.

Other experts believed that manufacturers' fear of legal action was responsible for improving device safety. One of the five that commented stated that our legal environment has done more than FDA to reduce risks. He said that devices built in the 1980s are safer than those built in the 1960s and 1970s. Some of that is due to FDA, but much more is due to product liability.

Four experts stated that device quality depends largely on the competitiveness of the medical device industry. They observed that:

--In this field, competition is healthy. Competition is what brings out new devices and keeps manufacturers on their toes. The key is not meeting FDA requirements, but keeping up with other manufacturers' new products.

--For many devices there are quite a few competitors. The one who makes the best device that will expose the fewest number of people to unreasonable risks of injury will corner the market.

Two experts commented on the need for a combination of factors to protect the public. They noted that:

--For life-supporting and life-sustaining devices, you need Government involvement, but for the rest of the devices, market forces are the best way to police it. There is nothing like having your competitor tell a hospital what is wrong with your product; he will know and he will be the first one to tell.

--Natural market forces alone are probably not sufficient to protect the public.

Amendments' impact on innovation and costs

The Harris survey found that 51 percent of medical device manufacturers reported that their new product introduction had increased over what it had been 5 years earlier. However, the survey also noted that the Class III (see p. 3) designation may have a greater impact on innovation in small firms than in large firms. Specifically, they found that:

"One of the most disturbing findings of the survey lies in the possible effect of medical device regulations on innovation in small establishments. The survey finds that over the past 10 years, the introduction of significant new medical devices is

just as common in small shops as in large plants. Similarly, significant investment in research and development is a shared characteristic of small, medium, and large companies in the medical device field. However, we find that only one-quarter of the establishments with 1-9 employees would still consider developing and marketing Class III devices, even under favorable circumstances. By contrast, 63 percent of the establishments with 500 or more employees would still consider developing and marketing Class III devices. Hence, the Class III designation appears to be more likely to discourage small establishments than large establishments from developing and marketing new medical devices."

Experts who commented on this matter were split on whether the amendments have significantly discouraged device innovation. Five of the eight experts commented that instead of facilitating the development of new products, the amendments have stifled device innovation by imposing additional time and resource costs on developers. Instead of encouraging physicians and researchers to develop new products and maintain America's leadership role in device development, the amount of paperwork and red tape required by the amendments has discouraged some experts from developing new devices and encouraged others to do their research abroad.

Experts commented that:

- The amount of progress made in the first decades of heart surgery will not be duplicated in the next century, largely because of regulation.
- Physicians are not as involved in device development as they once were because they do not want to deal with the incredible amount of work required by the amendments.
- The amendments have taken from us a leadership role--they have caused many small companies to stop innovating and manufacturing.
- The regulations have been an enormous impediment to research in the United States; as a result, many companies are doing their research in other countries.

Three experts who believed that the amendments have not discouraged innovation commented that:

- There are ways of getting good ideas to the marketplace. Creativity will surface.

--Small companies are still being formed because somebody has an idea and is going to pursue it. When the amendments were passed, some big companies persuaded small companies they would not be able to cope with regulations. These small companies were intimidated and sold out unnecessarily.

--No real, genuine idea has lain dormant because of the amendments.

A Harris survey found that 64 percent of all registered device firms have either added new employees, purchased new equipment, or increased outside purchases as a direct result of FDA regulations. According to Harris' estimates, the regulations have increased the industry's annual personnel costs by nearly \$143 million and caused the industry to spend about \$131 million on new equipment and facilities.

An Arthur D. Little study estimated that good manufacturing practice requirements cost the industry \$128 million annually.² Of the manufacturers responding to the Harris survey, 50 percent said that they are able to pass all of the additional costs of FDA regulations on to the consumer in the form of higher prices, while another 26 percent passed on at least some of the costs.

According to four experts, the amendments have escalated the cost of medical devices. A former panelist commented that:

--Although the law has not achieved higher safety and efficacy, it has increased the cost of medical devices exorbitantly.

--Today's cost of medical devices reflects to only a very small degree the actual cost of manufacture. The amendments' requirements have produced a significant increase in prices.

Researchers added that:

--The by-products of the regulatory mechanism have harmed the public. Patients are now bearing the brunt of excessive expense for any type of new product. Before long, products will be so expensive the patient will not be able to afford them.

²Cost of Compliance With Good Manufacturing Practice Regulations by the Medical Device Industry, Arthur D. Little, Inc. Contract No. 223-79-8052, March 1982.

--Regulations are just heaping expense after expense on the consumer. And because there is so much Federal support of health care now, the Federal Government ends up having to pay the bill.

On the other hand, a former regulator commented that there is no solid evidence to support the higher cost claim and that, at least theoretically, the opposite is true in the case of good manufacturing practices. He said good manufacturing practices reduce cost, because they increase yields; manufacturers make better products, which means that fewer defective ones get out and fewer defective ones come back.

SUMMARY

Most experts we interviewed believe that the full implementation of the amendments--particularly the development of mandatory standards--would be excessive in relation to the problems because medical devices, if properly used and maintained, do not generally present serious hazards to patients.

More than half of the experts who responded believe that certain provisions of the amendments have had some effect on improving device safety and effectiveness, while some experts believe that nonregulatory forces, such as technological change, competition, and legal liability, have had a greater effect.

CHAPTER 4

PRIVATE SECTOR AND FDA INITIATIVES

NEEDED TO ADDRESS MOST DEVICE PROBLEMS

More than half of the 39 medical device experts who responded believe that improper use and inadequate maintenance and repair are the leading causes of device failures and injuries. The Medical Device Amendments of 1976 focused control on the development and manufacture of medical devices through premarket approval, performance standards, and good manufacturing practices. Some experts thought that improper use and inadequate maintenance could best be dealt with through the joint efforts of hospitals, device manufacturers, and medical educators. They also believed FDA could make a major contribution by collecting, analyzing, and disseminating information about such problems.

EXPERTS ATTRIBUTE MOST DEVICE FAILURES TO USER AND MAINTENANCE PROBLEMS

Although the amendments focus control on medical device performance and manufacture, most experts who responded believe that user and maintenance problems are the leading causes of device failure. In ranking the top three causes of medical device failure, 25 of 39 experts (64 percent) listed improper use as the primary cause. A 1973 ECRI study found that 66 percent of the respondents believed that operator error was responsible for device failures.¹ In our interviews with medical device experts, inadequate maintenance and repair ran second to improper use with 59 percent ranking it as one of the top three causes of failure. The ECRI study also found deficient maintenance and repair to be the second most frequently cited problem with medical devices. The following table shows the experts' ranking of the most predominant factors contributing to medical device failures.

¹Medical Device Experience Monitoring System, Contract Report by ECRI, June 28, 1973.

CONTRIBUTING FACTOR	PERCENT RANKING IT AS #1 CAUSE
Improper use	64
Inadequate maintenance and repair	13
Faulty design	8
Defective components	2
Improper labeling and instruction	5
Other	8

Although improper use and inadequate maintenance were the most frequently cited factors contributing to device failures, experts believe that such failures frequently involve a combination of factors. Experts drew a distinction between labeling and operator instruction and did not believe that labeling offered an effective means for overcoming most of the problems with improper use and inadequate maintenance and repair. (See p. 34 for proposed solutions.)

Mistakes and judgment errors lead to failure

When doctors, nurses, and technicians apply modern technology to treat patients, a mistake may have serious consequences. According to one expert, studies show that operator errors are responsible for over 50 percent of the performance or safety failures of medical devices. Research at the Massachusetts General Hospital in Boston showed that in certain fields, such as anesthesiology, operator errors account for over 70 percent of the failures analyzed.² 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.

²Jeffrey B. Cooper, Ph.D., Ronald S. Newbower, Ph.D., and Charlene D. Long, M.S., "Learning from Anesthesia Mishaps," QRB/Quality Review Bulletin, March 1981, pp. 10-16.

Mistakes accounted for most of the operator errors described by medical device experts. Among the examples provided were

- a surgeon twisting or turning a clamp in such a way that he inadvertently scratched the device he was implanting,
- an anesthesiologist accidentally turning the wrong knob and giving the patient nitrous oxide instead of oxygen, and
- an electrocardiograph technician getting inaccurate readings because he failed to let the machine warm up sufficiently.

Judgment errors also lead to device failures. One form of judgment error mentioned by an expert was selecting the wrong device to fit the patient's needs. He said that if a failure resulted from using a surgical scalpel on a patient who should have been treated nonsurgically, it would be the surgeon's fault, not the scalpel's. Another judgment error mentioned by experts was deliberate misuse. Deliberate misuse was described as using a device in a manner or for a purpose other than that intended by the manufacturer. A respiratory therapist used the example of nebulizers³ catching on fire to illustrate how misuse can lead to failure. He explained that nebulizers were originally designed to provide operator-supervised, 15-minute aerosol treatments. When used to give continuous, unattended aerosol therapy for longer periods, the devices began catching on fire.

Although operational and judgment errors result from various causes, medical device experts laid most of the blame on inadequate training. This view is supported by analyses of actual mishaps, which indicate that insufficient experience with procedures and inadequate familiarity with the equipment frequently cause operator errors. Similarly, the 1970 Cooper Committee Report found that

"* * * much of the improper usage of devices stems largely from a lack of information on the part of many health professionals, unprepared by their training and experiences to understand the principles of operation and safe usage."

³A mixing device intended to spray liquids (in aerosol form) into gases that are delivered directly to patients.

A biomedical engineer offered the following example to illustrate how inadequate understanding leads to problems:

"If the surgical unit doesn't really understand what the mechanism [of the electrosurgical unit] is, they may not realize how important it is to get a good ground on the patient and so they may not care. So they're very careless about doing it. That's how they get hot spots, that's when they get burns."

Although some operator errors could be prevented by increased training, even highly trained practitioners can make mistakes. One study showed that many operator errors are committed under conditions of stress, haste, or fatigue; others result from carelessness or inattention.⁴ For example, giving a routine intravenous injection can cause injury to a patient if the practitioner does not take the proper care.

Lack of preventive maintenance
also leads to failure

According to the experts we interviewed, inadequate maintenance and repair followed improper use as a leading cause of failure. As with most mechanical and electrical equipment, sophisticated hospital equipment needs preventive maintenance to ensure proper functioning. Some experts believe that many failures could be avoided if hospitals pretested new equipment as part of their maintenance program and routinely inspected older equipment for operating defects, such as

- incorrect calibrations,
- low batteries,
- inadequate plug connections, and
- faulty wiring.

For example, a biomedical engineer who regularly pretests new equipment said that about 30 percent of the equipment purchased by the hospital is not functioning properly when it arrives. A testing laboratory official said that some of the diagnostic equipment his laboratory tested gave readings that were off by as much as 50 percent.

⁴Ibid., p. 31.

Problems identified through testing can often be easily corrected; however, if problems go undetected, they can expose patients to hazard. For example, inaccurate readings obtained from a poorly maintained diagnostic device could result in improper diagnoses and delayed or improper treatment. Maintenance problems can have far more serious consequences. In June 1981, an incubator that was alleged to be improperly maintained caused an infant death when the safety thermostat malfunctioned causing the incubator to overheat.⁵

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. According to one biomedical engineer:

"It depends on what hospital you're in. If you're in a very rich hospital, you replace [a piece of equipment] every five years, or when it gets out of style. If you're at [this hospital] you don't replace it until it dies."

SOLUTIONS TO USER AND MAINTENANCE
PROBLEMS LIE PRIMARILY IN
THE PRIVATE SECTOR, BUT FDA
SHOULD HAVE SUPPORTIVE ROLE

All parties involved in the manufacture and use of medical devices share the responsibility for solving user and maintenance problems. Some experts believe that the most promising solution would be a concerted educational effort on the part of manufacturers, hospitals, medical educators, and professional societies. Most of these groups have recognized the challenges posed by improper use and inadequate maintenance and repair and are striving to reduce the occurrence of user-related failure. Experts believed FDA could share in the responsibility by collecting and analyzing data related to device problems. They do not believe increased use of FDA labeling requirements would be an effective means of overcoming these problems.

⁵"Alleged Failure to Maintain Incubator's Safety Features Blamed in Infant Death," Biomedical Safety and Standards, September 15, 1981, p. 98.

Private sector efforts to correct user
and maintenance problems already underway

Some experts told us that device manufacturers are addressing the user-error problem by providing their clients with more in-service training on the use of their devices. Recognizing that people frequently do not read labels or instruction manuals, manufacturers have begun investing much time and effort into providing personal instruction to purchasers of complex equipment. Increasingly, when a new piece of equipment arrives at a hospital, it is accompanied by a manufacturer's representative, who gives the staff "hands on" training.

Some experts stated that manufacturers could further reduce the occurrence of operator error by employing more human factors engineering in the design of their products. Human factors engineering applies principles derived from user-error incident studies to device designs. For example, a study of anesthesia mishaps at one hospital showed that more than half of the user errors occurred when the edge of a square knob on the anesthesia machine was accidentally struck.⁶ The frequency of error was reduced when square knobs were replaced with less angular ones.

According to several experts, hospitals should supplement manufacturers' in-service training with ongoing in-house training programs. The Joint Commission on Accreditation of Hospitals requires such user education programs as a condition for hospital accreditation. Experts pointed out that hospitals face several obstacles in providing training, including

- rapid changes in technologies used,
- high staff turnovers,
- time limitations, and
- lack of funding.

Despite these obstacles, some experts advised us hospitals were increasing and upgrading the training provided to their staffs. One approach hospitals have taken is to have their in-house biomedical engineering units conduct training sessions scheduled to accommodate the turnover and time limitations of their hospital

⁶"Does Technology Multiply Errors in the Operating Room?" Tech-
nology Review, February/March 1981, pp. 85-86.

staffs. Other hospitals have hired outside consultants to conduct training programs. Another approach suggested by experts was to provide video-taped training that could be used individually.

Two experts said that, in addition to manufacturers and hospitals, various medical professional societies are addressing this issue by providing continuing education to their members on the use of devices. Many professional societies sponsor seminars on the use of devices; others devote a portion of their national conferences to discussions on this topic.

A number of experts said that nursing and medical schools also share the responsibility for solving user problems. These schools could contribute by including more medical technology courses in their undergraduate and graduate curriculums. A few experts noted, however, that including such courses in medical and nursing school curriculums would require trade-offs with other important courses of study.

Some experts we interviewed said that the Joint Commission and hospitals are working on the problem and are making progress. One such Commission effort is to set maintenance standards and require hospitals to have institutional mechanisms to deal with maintenance problems.⁷ In the last few years, according to one expert, many hospitals have hired full-time biomedical engineers to maintain and repair hospital equipment. As one expert stated, that situation will continue to improve as hospitals have more and more clinical engineers who are directly responsible for maintenance. Many small hospitals unable to afford in-house engineers have entered into shared services arrangements with other hospitals. Under these arrangements a number of hospitals jointly contract with engineers and other maintenance personnel to travel from hospital to hospital servicing equipment.

A problem with both of these approaches is that clinical engineers are in short supply. Compounding the shortage problem is the fact that many of the available biomedical engineers are hired by private companies, which offer higher salaries than hospitals. A former hospital administrator explained, "Every time we got people well trained, private industry hires them away at twice the amount per hour." One professional society believes that the solution to these economic problems lies in

⁷"Joint Commission Requirements," Health Devices, ECRI, July 1971, pp. 76-77.

getting reimbursement groups to understand that to get good services, hospitals have to pay wages high enough to attract good people.

FDA can contribute to private sector correction efforts

Several experts believe that some FDA involvement in the user and maintenance problem areas is warranted. According to these experts, FDA could play a useful role by

- providing information on user and maintenance problems to interested parties,
- better using the amendments' restricted device provision, and
- sponsoring seminars to increase awareness of specific problems.

The experts stated that FDA's most useful contribution would be to give users information on user errors and maintenance problems. FDA could facilitate private sector efforts in this area by

- collecting data on user and maintenance failure incidents,
- conducting systematic analyses of specific types of errors and error patterns, and
- disseminating the information gathered to relevant parties.

Several experts told us that systematically collecting and analyzing such data would benefit both FDA and the private sector. The private sector could use the data as a base from which to devise appropriate corrective action for user and maintenance problems. FDA could use the data as a basis for determining whether certain devices should be subjected to the amendments' restricted device provision. If, based on its user-error data, FDA determines that a certain level of skill is needed to use a device safely and effectively, the restricted device provision allows it to restrict the use of the device to qualified users. Except for a regulation making hearing aids a restricted device, FDA has not used the provision because it lacks the data necessary to make restricted use determinations and because of strong

industry opposition. Until FDA develops an adequate device experience network, it will not be able to effectively implement the restricted device provision.

FDA could also use its user-error data to increase user awareness of significant problems and trends. According to some experts, FDA could provide a service by (1) alerting the medical community to specific user problems that occur frequently or (2) sponsoring seminars on specific problems identified through its data collection efforts. As the Cooper Committee found in 1970,

"* * * greater knowledge on the part of professional and technical personnel no doubt would contribute to resolution of an important part of the total hazards problem. Greater knowledge on the part of physician users is needed about the mechanisms of action, the limitations of usefulness, the precautions that must be observed, and the instructions needed to assure proper operation of devices."

SUMMARY

Most of the experts who responded believed improper use and maintenance and repair are the leading causes of device failure. Some experts believe manufacturers and medical community organizations are beginning to address these problems, and progress is being made. FDA could facilitate private sector efforts 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.

RECOMMENDATION TO THE SECRETARY OF HHS

The Secretary should instruct the Commissioner of FDA to (1) collect information on the scope and nature of device problems caused by user error and inadequate maintenance through an expanded device experience reporting network, (2) analyze the data to identify special problems, concentrations, and trends, and (3) disseminate the results internally and to the private sector to aid in developing solutions.

AGENCY COMMENTS

HHS agreed with our recommendation and stated that it would consider the relationship noted in our report between device failures and user misuse of medical products and maintenance problems in its ongoing evaluation of device failures and in determining the appropriate solutions to device problems. HHS indicated that such solutions would include implementing educational programs or restricted use criteria.

CHAPTER 5

DEVELOPMENT OF PERFORMANCE STANDARDS

FOR MOST DEVICES IS

TIME CONSUMING AND EXPENSIVE

The effective implementation of the Medical Device Amendments of 1976 hinged greatly on FDA's classification of medical devices according to degrees of risk and the development of mandatory performance standards. After nearly 7 years, about half of FDA's classification regulations have been published. Expert panels involved in the classification process have recommended that over 1,000 devices be placed in a category which would require that a performance standard be developed for each--a process that many now believe is unrealistic and unnecessary.

As of August 1983, FDA had not promulgated any mandatory standards although it had tried various strategies. Because of the time and resources required to develop standards, FDA believes that developing over 1,000 standards would be an impossible and perhaps unnecessary task. FDA believes that regulatory discretion is needed to resolve the standards dilemma.

Although some devices may need mandatory performance standards, experts we interviewed believe that standards are not needed for over 1,000 devices because

- these devices have been regulated under general controls for the past 7 years without apparent adverse effects,
- market forces create de facto standards,
- voluntary standards are sufficient for most devices, and
- mandatory standards stifle innovation and do not assure safe and effective devices.

Most of the experts we interviewed do not believe that the classification process should be done over, an effort that many believed would be expensive and time consuming. Rather, 68 percent of the experts responding believe that the amendments' provisions requiring mandatory standards should be substantially changed or abolished.

CLASSIFICATION OF MEDICAL DEVICES NOT
COMPLETED AFTER 7 YEARS OF EFFORT

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 as of April 8, 1983. FDA was responsible for final device classification, including publishing in the Federal Register the panel's recommendation and FDA's criteria for device classification. Sixteen device categories were developed for classifying devices.

The expert panels completed their classification efforts in October 1977. As of August 1983, FDA had not finalized classification regulations for 9 of the 16 device categories. Various target dates established by FDA for completing classification have not been met. Proposed classification regulations developed from 13 months to 4 years ago have not been finalized, as shown in the following table.

Status of Device Classification
August 1983

<u>Device category</u>	<u>Date classification proposed</u>	<u>Date classification finalized</u>
Neurology	11/78	9/79
Cardiovascular	3/79	2/80
Obstetrical/Gynecological	4/79	2/80
Hematology/Pathology	9/79	9/80
General Hospital	8/79	10/80
Anesthesiology	11/79	7/82
Microbiology/Immunology	4/80	11/82
Physical Medicine	8/79	*
Clinical Chemistry/Toxicology	1/82	*
Dental	12/80	*
General and Plastic Surgery	1/82	*
Gastroenterology/Urology	1/81	*
Ear, Nose, Throat	1/82	*
Radiology	1/82	*
Ophthalmology	1/82	*
Orthopedic	7/82	*

*Classification not completed.

FDA officials who served as executive secretaries to the panels stated that the classification process was hampered because (1) "boiler plate" language developed for neurological

devices that was to be used for developing classification regulations for other devices was revised and (2) review groups within FDA had problems with the proposed language in the classification regulations, which required extensive rewrites.

MANY DEVICES DESIGNATED
AS NEEDING PERFORMANCE STANDARDS

Seventy-one percent of the experts responding to a question about the amendments' approach to classification believed that the concept of classifying devices according to risk was appropriate. However, only 36 percent responding to a question about FDA's implementation of classification believed the implementation was appropriate, and others criticized the three-tiered concept. Those experts who agreed with the classification concept stated that it was reasonable and useful to classify, and ultimately regulate, devices according to their differing degrees of risk. However, FDA and some experts believe too many devices were placed in Class II. Sixty-three percent of the devices classified have been placed in Class II, which means that performance standards will have to be developed. One expert who helped draft the amendments commented that nobody had any idea so many devices would fall into Class II. According to the experts, several problems contributed to the overloading of Class II, including the natural tendency to pick the middle when confronted with three choices, the panelists' inadequate understanding of the significance of placing devices in Class II, and the panelists' tendency to base classification decisions on the "possibility" rather than the "probability" of patients being injured by medical devices.

Commenting on the three-category approach to classification, experts noted that when there are three choices, things tend to get lumped in the middle category. Some believed that it would have been better to have only two categories, which would have forced people to make decisions, and that 95 percent of devices would wind up under general controls and the rest would require premarket clearance.

According to two experts, classifications were sometimes based on inadequate identification of health risks and insufficient information about how the law was to work. Experts commented that:

--Panelists did not have a clear understanding of the law and how it was going to be enforced.

--In the early days, when most of the classifications were made, panelists did not know enough about the implications of their decisions.

--Panels did not identify real risks that would require performance standards.

--FDA should have advised the panelists that they could not place a device in Class II unless they could identify tangible, demonstrable defects that a standard could prevent.

A former panelist and a former regulator said that some panels, suffering from the "what if" syndrome, classified devices based on the possibility, rather than the probability, of patient injury or evidence that injury had actually occurred. Of the 33 experts responding, 15 felt that classification should be based on a probability of patient injury, while only 2 favored classification based on the possibility of injury. The remaining experts favored other criteria based on evidence of injury, risk/benefit analysis, and clinical tests.

Although five experts believed that many devices were improperly placed in Class II, they do not favor starting over in classifying medical devices. In their opinion, it would be too expensive and time consuming and might not change the results. FDA has stated that doing classification again is not feasible.

FDA UNABLE TO DEVELOP STANDARDS FOR OVER 1,000 DEVICES

Over the past 10 years FDA has made several attempts to develop performance standards. Its contracts with private organizations and the experiences of another FDA bureau and other Federal agencies have shown standards development to be an arduous task. FDA's current policy emphasizes developing mandatory performance standards for Class II devices as required by the amendments--an effort that will take many years and significant resources. In addition, experts commented that standards could be obsolete by the time they are completed because of rapid technological changes in the medical device field.

FDA has attempted to develop performance standards for some devices

Since the early 1970s FDA has used various strategies to develop medical device standards, including (1) contracting with and encouraging private organizations to develop specific device standards (see p. 45), (2) placing greater priority on high-risk devices, and (3) proposing endorsement of voluntary standards. Despite these attempts no mandatory performance standards have been promulgated. FDA's current policy emphasizes that Class II devices require mandatory standards. However, the agency recognizes that developing performance standards for all devices

may not be realistic because of the large resource commitment necessary over a long period of time--an estimated 120 years.

As early as 1974 FDA recognized that many devices would require mandatory performance standards. In 1977, when expert panels completed their classification efforts (see p. 41), FDA was faced with the problem of developing performance standards for over 1,000 Class II devices. FDA noted that the task could not be accomplished in less than several decades and that measures were needed in the interim.

On February 1, 1980, FDA published in the Federal Register a proposed policy for endorsing voluntary standards and a list of 97 highest priority devices. FDA received 10 comments opposing its endorsement of voluntary standards. Opponents noted that

--there is no statutory authority for the voluntary standards policy,

--FDA's endorsement of voluntary standards circumvents the Administrative Procedure Act because there is no opportunity for public comment, and

--FDA's public endorsement and promotion actions of voluntary standards result in de facto regulatory standards.

FDA's General Counsel agreed that the endorsement policy circumvented the Administrative Procedure Act.

In the fall of 1981 FDA decided to abandon voluntary standards endorsement. Its proposed policy was revised to emphasize alternatives that FDA would take before promulgating a mandatory performance standard.

Public comments were again received, which led the National Center for Devices and Radiological Health to propose a new strategy in January 1983, which emphasized that (1) Class II devices would require mandatory standards, (2) priorities will be set for developing mandatory standards that take into account voluntary standards, other regulations, general controls, and other factors that influence safety and effectiveness, and (3) reclassification to Class I or III will be considered. As of February 1983, FDA had not initiated any reclassification actions, but efforts were underway to develop mandatory standards for 11 devices, 6 of which are among the 97 designated high-priority devices.

Mandatory standards are costly
and time consuming to develop

The Director, National Center for Devices and Radiological Health, commented that developing mandatory performance standards for over 1,000 Class II devices will require a large resource commitment over a long period. Previous standards writing efforts have proved this to be true. FDA's former Bureau of Radiological Health found that it took on the average over 3 years to draft a standard at an average total cost of 40 staff years. In addition, the Bureau estimated that enforcement efforts require an additional 24 staff years per standard each year.

A 1979 FDA study noted that other Federal agencies--such as the Occupational Safety and Health Administration, the Environmental Protection Agency, and the Consumer Product Safety Commission--required from 2 to 5.5 years to develop standards. At one agency 6 months to 4 years were required to obtain sufficient data to justify the need for standards.

The time required to develop standards is further compounded by the fact that FDA cannot even begin to write standards for nine device categories because classification has not been completed (see p. 41). In addition, section 514(b) of the Federal Food, Drug, and Cosmetic Act would require at least five Federal Register notices to (1) initiate the standards process, (2) invite offers from any person or Federal agency to develop a standard, (3) accept an existing standard or an offer to develop a standard, (4) proceed to develop (FDA would develop) a standard, and (5) publish a standard or issue notice that the process is terminated.

The long time required to develop standards is illustrated by the following cases.

Cardiac defibrillators--Development of a performance standard for these devices was initiated in 1973. A competitive bid contract was awarded to the Utah Biomedical Testing Laboratory. Open review meetings were held to give manufacturers and users an opportunity for early input on standards development. An initial draft standard was developed in December 1973, and a second draft was developed in April 1974. Three more draft standards were later developed, incorporating input of manufacturers, physicians, hospital engineers, nurses, and government agencies.

FDA submitted the laboratory's final draft of the proposed defibrillation standard to the Association for the Advancement of Medical Instrumentation for endorsement in the fall of 1978 for review and revision. The draft was made available for public comment during 1981. It was submitted to the American National Standards Institute for final approval in January 1982. The institute adopted it as a voluntary standard on April 15, 1982.

Electrocardiographs--Development of a performance standard for these devices was initiated in 1974. The contract for development of a standard was also awarded to Utah Biomedical Testing Laboratory. The first draft was completed in May 1975, and the first public discussion took place in Salt Lake City on July 2, 1975. A second draft standard was prepared and reviewed publicly on November 20, 1975. The third draft standard was received at an international meeting.

The laboratory completed its work in January 1977. The Association for the Advancement of Medical Instrumentation began reviewing the proposed standard in 1979 and made it available for public review during 1982. The association was expected to submit the proposed standard to the American National Standards Institute for final approval in March 1983.

Two medical device experts, commenting on the time and cost to develop standards, said:

--FDA is faced with an impossible task, considering the logistics, the cost, a 4- to 5-year time frame, advancement in the state-of-the-art, the very nature of the technology, and what it is required to do.

--If standards are to be written, there must be a different way of writing them. The current process is too expensive and time consuming.

Medical device experts questioned FDA's ability to develop mandatory standards, citing FDA's lack of trained personnel, the lack of sufficient knowledge to write standards, and the difficulty in finding people who are motivated to do it.

In addition, one expert said that because standards take so long to write, they may be obsolete by the time they are published. Specifically, he told us:

--Six years ago performance standards looked good, but the developments in technology in the last 6 years have been tremendous. Materials change frequently.

--The reliance on performance standards in Class II has probably been a mistake in that developing such standards is an arduous task that may be outpaced by the dynamic nature of the technology.

EXPERTS BELIEVE CERTAIN DEVICES
NEED STANDARDS BUT QUESTION
MANDATORY STANDARDS FOR ALL
CLASS II DEVICES

Of the 43 experts responding, 91 percent believed that certain devices--such as high-technology, diagnostic, and therapeutic devices--need performance standards. However, of the 34 medical device experts who expressed an opinion on the need for mandatory standards, 30 believed that the legal requirement for such standards should be changed. Of these, 23 experts favored abolishing or substantially changing the requirement for mandatory standards.

Experts noted that

--the past 7 years have demonstrated that most devices may be effectively regulated under general controls;

--the market creates de facto standards, which along with voluntary standards, are sufficient to provide safe and effective medical devices; and

--mandatory performance standards do not guarantee the safety and effective use of all devices.

Although the advisory panels and FDA by classification action have indicated that performance standards are necessary to ensure the safety and efficacy of most of the devices now on the market, FDA has not promulgated any standards. As a result, Class I and II devices, lacking performance standards, have been regulated for the past 7 years under Class I general controls.

Experts commented that:

--Since there are no performance standards, the only difference between Class I and Class II is in the mind of FDA.

--The most appropriate amount of regulation is the least amount consistent with the public health. Since we are not hearing any outcry indicating that Class II devices are not being effectively regulated under Class I controls, it may be appropriate to eliminate Class II entirely.

Two experts indicated that competition among manufacturers creates de facto performance standards which are sufficient to ensure quality products. They stated:

--In general, U.S.-made equipment is the best in the world.

--The marketplace creates a de facto standard. When there are problems with devices, the industry usually takes care of them, not by using standards, but more effectively by changing the devices.

Fifteen experts stated that voluntary standards are sufficient to ensure safety and efficacy and are preferable to mandatory standards for most devices. They commented that:

--As a matter of principle, voluntary standards are preferable to mandated ones because they are apt to be more reasonable.

--Mandated standards can be too rigid, while voluntary standards tend to be more flexible.

--For the more sophisticated generation of high-technology devices, performance standards are reasonable. Voluntary standards, however, might be adequate.

--Given the right environment, voluntary standards are many times tougher than regulatory standards, and I am a strong proponent of voluntary standards if the motivation to create them is there.

--Certain devices do need performance standards. I have heard the arguments for both sides for years on voluntary versus mandatory standards, but I still like the voluntary standards if they are used as guidelines.

--Most devices of any complexity or impact on diagnosis or therapy need standards. I feel very strongly, however, that they should be voluntary.

One expert commented that mandatory performance standards do not guarantee safe and effective medical devices. The National Center for Devices and Radiological Health has noted that

for some Class II devices a mandatory performance standard may provide little public health benefit over what is provided by general controls.

Experts stated that:

--A great disadvantage of standards is that they have to be simultaneously both general and specific, both restrictive and permissive. That means standards have limited applications and sometimes education, which is not bound by these difficulties, can do more to improve safety than standards can.

--The real reason for writing a standard is to guarantee safe, effective devices, and I do not think we can do that.

Four experts told us that standards may do more harm than good because, in addition to not ensuring device safety and effectiveness, they may stifle device innovation. The experts commented that:

--Once performance standards are in place, they may defeat initiative.

--Performance standards stifle individual innovation. If you want to change the standard, it has to be rewritten, which is difficult, because a lot of people have to agree on it.

--In developing regulatory standards, you run the risk of being inflexible and of eliminating much of the creativity involved in developing medical equipment.

--The medical device industry contains an enormously imaginative group of people, and if FDA really began to implement this legislation, it would shift the impetus in manufacturing innovation to other countries.

Experts who commented on changing the legislation noted that:

--The standards category should be abolished. I think that standards have a role, but I do not think that is how you assure the safety and effectiveness of over 1,000 devices.

--Whether there should even be authority to develop standards is an open question. FDA has had about 6 years to demonstrate whether it can develop standards, and it

has shown it can't do so. It doesn't have the staff to do the job.

--If FDA is not going to implement the standards section, the law should be amended. FDA should say, "We can't do it--we're sorry--please repeal this authority."

SUMMARY

Most experts we interviewed believe that the provision of the law requiring that performance standards be written for all Class II devices should be modified and questioned FDA's ability to develop over 1,000 standards.

The three-tiered device classification scheme, with each class being subject to a different level of regulation, based upon degrees of risk, has not functioned as envisioned. FDA has not developed any performance standards, and it is not likely that standards for over 1,000 devices currently designated as Class II can be developed in the foreseeable future. For all practical purposes, Class II devices have, for the last 7 years, been regulated under Class I general controls. Although no corroborating data exist, most experts we interviewed point out that there have been no outcries to develop mandatory standards and indicated that no apparent adverse effects have resulted.

MATTERS FOR CONSIDERATION BY THE CONGRESS

Many of the experts we interviewed believed that while certain devices may need standards, developing more than 1,000 standards will be very time consuming, expensive, and impracticable. We were not in a position to independently corroborate the experts' views. However, the fact that a cross-section of the medical community and consumer representatives question the feasibility of and need for compulsory Class II performance standards provides, in our opinion, a sufficient basis for congressional review of the current requirements. If the Congress shares the experts' view, it could give FDA the flexibility to develop standards on a case-by-case basis.

To do this, section 513(a)(1)(B) of the Food, Drug, and Cosmetic Act could be amended to read as follows:

"(B) Class II. Performance Standards.--A device which cannot be classified as a Class I device because the controls authorized by or under section 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for

which there is sufficient information to establish a performance standard to provide such assurance. The Secretary shall identify those Class II devices for which it is considered necessary to establish a performance standard to provide reasonable assurance of their safety and effectiveness and shall do so in accordance with section 514."

AGENCY COMMENTS

HHS advised us that FDA is undertaking a variety of initiatives that are in concert with our report, such as

- considering a legislative proposal that would grant the agency the discretionary authority to determine which Class II devices require mandatory performance standards,
- publishing a notice in the June 17, 1983, Federal Register announcing initiation of standard-setting proceedings for continuous ventilators and the impending initiation of mandatory standard-setting proceedings for 10 other devices, and
- planning to publish an FDA policy statement delineating (1) a mechanism for establishing priorities for development of Class II performance standards and (2) procedures the agency will follow in dealing with the Class II devices.

HHS stated also that it is considering whether the lengthy and complex development process required by section 514 of the Food, Drug, and Cosmetic Act needs to be simplified.

CHAPTER 6

EXPERTS CITED SEVERAL PROVISIONS

OF THE LAW AS UNNECESSARY OR INEFFECTIVE

Many of the experts we interviewed believe that the Medical Device Amendments of 1976 contain several provisions that are unnecessary or ineffective in protecting the public against unsafe or ineffective devices. Specifically, these experts believe that:

- FDA's review of all devices that were on the market before enactment of the amendments (preenactment devices), a process not yet started and that probably will require considerable time and effort, may not be necessary. Some experts stated that the review should be concentrated on devices with a history of adverse incidents.
- FDA's review of critical new devices on the basis that they are substantially equivalent to preenactment devices is not effective because preenactment devices have not been reviewed for safety and effectiveness and FDA does not require such data for the new devices. Also, the review process is being used when going through the more lengthy premarket approval process would be more appropriate.

Some experts also believe that FDA could rely more on institutional review board approval of significant-risk devices in instances where FDA has satisfied itself that patients are being adequately protected by strong review board reviews.

IS PREMARKET APPROVAL OF ALL CLASS III PREENACTMENT DEVICES NECESSARY?

The Medical Device Amendments of 1976 permit devices on the market before the enactment of the legislation to continue in use. The amendments required, however, under section 515(b)(1), that after devices have been classified and regulations issued, all devices placed in Class III that were marketed before the passage of the law (termed preenactment devices), if not reclassified from Class III to Class I or II, had to undergo premarket approval to confirm that they were safe and effective for continued use.

As of February 1983, FDA had not required any preenactment Class III devices to undergo premarket approval for safety or effectiveness because its efforts had been directed at applications for new devices. FDA may not be able to implement this

provision for many years since (1) final classification has not been completed for 9 of 16 device categories, (2) a sizable number of applications, about 1,000, will probably be involved, and (3) FDA's experience in conducting similar reviews of "old" drugs indicates the process is time consuming.

Several experts questioned whether this effort would be worth the time and money required. One expert suggested that a more practical and less costly approach would be for FDA to fully review preenactment devices only when adverse incident reports or device literature showed some indication of problems associated with the safety or effectiveness of a particular device. In addition, as indicated on page 22, about 92 percent of the experts responding do not believe that medical devices, in general, present serious hazards to patients.

Premarket approval of all preenactment devices would be a major undertaking

The amendments require that after certain minimum time requirements keyed to classification and subsequent issuance of regulations for preenactment devices have been met, all Class III preenactment devices, estimated by FDA at about 1,000, must undergo premarket approval or be reclassified. As of February 1983, FDA had not reviewed any preenactment devices for safety or effectiveness.

An FDA official told us that work on guidelines designed to gain information needed for developing regulations for the high-priority preenactment devices is planned to start by the end of 1983. He said, however, that even if this work started on time, it would probably be late 1985 before even the highest priority preenactment devices could be reviewed. He estimates that at least 140 regulations will be needed to cover the entire pre-enactment device field of about 1,000 devices. He said that FDA is planning to require the approval of all preenactment Class III devices.

FDA has done a number of special studies in the drug areas involving review of safety or effectiveness. The time required in these efforts indicates that a premarket approval review of all preenactment devices will be a significant undertaking.

For example, the Over-the-Counter Drug study, undertaken in 1972 to review the safety and efficacy of all over-the-counter drugs, was originally planned for completion in 1977. FDA now estimates that this study will not be completed until 1990. The Drug Efficacy Study Implementation project, started in 1966, was designed to determine the efficacy of about 3,500 prescription drugs that had previously been approved for safety. This study, although substantially complete, is still ongoing.

Some experts question need for premarket approval of all preenactment devices

Several experts expressed the view that since many pre-enactment devices had been used safely for years, there was no need for a full premarket approval review. They said:

--All these devices have been on the market for at least 6 years (and some as many as 20 years), and few problems have been associated with their use.

--Many products have stood the test of time; FDA has looked at the literature and found little or no hazards with them. They are accepted in the profession, and people understand how to use them.

--Requiring manufacturers to file premarket approval applications for products that have proven to be safe and effective over the years would be redundant.

One expert expressed the contrary view that since these devices had been classified by expert panels which said they needed to go through premarket approval to prove their safety and effectiveness, it was difficult to argue that the devices did not need to meet this requirement simply because they had been on the market for a long time.

A former FDA official, who did not believe it was necessary for all preenactment devices to undergo full premarket approval review, expressed the opinion that the best way to implement the requirement would be to grant FDA the authority to decide which devices have to undergo premarket approval and which can be granted a waiver from the requirement. The determination could be based on historical data, including adverse incidence reports and descriptions in the literature.

EXPERTS BELIEVE PREMARKET NOTIFICATION PROCESS SHOULD BE CHANGED

Nearly 63 percent of the 41 medical device experts responding believed that FDA's substantial equivalence review process for new devices (sec. 510(k) of the Federal Food, Drug, and Cosmetic Act)¹ should be changed or abolished, while about

¹The substantial equivalence review or determination for new devices is actually required under section 513. In common terminology, however, these reviews are usually referred to by FDA and manufacturers as section 510(k) premarket notification reviews. We have employed the more commonly used reference.

22 percent believed it should remain as is and 15 percent were not sure. The most serious problem cited was that the review process does not determine the safety and effectiveness of medical devices and is being used when requiring devices to undergo the more lengthy premarket approval process might be more appropriate (see p. 57). Two experts also stated that this review process may have a stifling effect on innovation and that FDA has not developed guidance on the data needed to support a section 510(k) review. The experts who wanted the process to remain as it is said that it gave FDA knowledge about new devices while permitting manufacturers speedy market access for their products. They believed, therefore, that the process, on balance, was working well.

Premarket notification process

Section 510(k) of the Federal Food, Drug, and Cosmetic Act requires manufacturers of new devices to submit a premarket notification to FDA 90 days before the planned marketing date. New devices are placed in class III and must undergo premarket approval unless they are determined to be substantially equivalent to preenactment devices or reclassified into Class I or II (see p. 2).

While the amendments do not specifically define the term "substantially equivalent," the House of Representatives Committee Report (No. 94-853, p. 36) noted that:

"* * * 'Substantially equivalent' is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."

The Senate report (No. 94-33, p. 14) noted that:

"the Committee believes that the potential for harm inherent in a certain device may not be determined solely on the basis of its intended use."

FDA's position is that "substantial equivalency" does not require a determination of safety and effectiveness. An FDA official told us, however, that 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. He added, however, that FDA has not developed guidelines for determining which devices should undergo such a review.

As of December 31, 1982, FDA had reviewed 17,209 section 510(k) applications and had found about 98 percent of them to be substantially equivalent to preenactment devices. An FDA survey of 510(k) applications received during the 6-month period from September 14, 1981, to March 17, 1982, showed that about 10 percent were life-supporting or implant devices and about 5 percent were for high-risk Class III devices.

Some of the experts we interviewed thought the process was working well. They said:

--It is one of the more effective things that FDA is doing. It should not be used to get around premarket approval but to get products on the market in a fashion that lets FDA know about it but does so with a minimum of time and expense. For the most part it is working very smoothly.

--It is probably a good creative way of staying within the general, if not specific, intent of the Congress.

--It is working pretty well as it is currently being used.

The major problem cited by experts we interviewed was that the substantial equivalence review provides no assurance of device safety and effectiveness. A consumer group commented that:

--The review is so superficial that FDA has no basis for evaluating the 510(k) submissions it receives.

--How FDA is doing these evaluations is a "mystery." FDA cannot really determine safety and efficacy because the agency does not have sufficient data on either the new device or the preenactment device FDA is comparing it to.

--What the review essentially comes down to is that, because the reviewer says the device does the same thing in the same way, the application is approved.

--Although the design and materials of a device are substantially equivalent to a preenactment device, there is no guarantee that the new device will perform the same way. Slight variations in design and differences in manufacturing processes may lead to different levels of performance.

A recent patent infringement case, which was the subject of July 16, 1982, hearings by the Subcommittee on Investigations and Oversight of the House Committee on Energy and Commerce, illustrates the inadequacy of the review process. A California-based company has been producing volumetric pump cassettes² for several years. Another company decided to get into the same business and applied to FDA for approval of its volumetric pump cassette on the basis of substantial equivalence to the first company's cassette. When the application was submitted, however, the second company had not as yet developed (and was not required to have developed) its own cassette. Instead, it photographed the first company's cassette and sent the photograph, and specifications modeled after the first company's cassette, to FDA representing the cassette as its own product.

The paperwork for the second company's cassette was reviewed by FDA under the 510(k) process and a determination made that it was substantially equivalent to the preenactment device. No safety and effectiveness tests were performed on the then nonexistent second company's cassette, a Class II device, because none were required by FDA. Although the cassette of the second company was a copy of the first company's cassette and met all of FDA's requirements, it did not, when later developed, perform as well as the first one. In fact, the cassette of the second company was so seriously flawed that FDA tests made on the device after it was marketed determined it had a design deficiency which represented a health hazard. This deficiency eventually necessitated a notification to users by the company at FDA's request.

Experts believe premarket notification
is being used when premarket approval
would be more appropriate

It generally takes FDA about 9 months for approve or disapprove a premarket approval application as compared to 40 days to review and process a 510(k) application. Four experts commented that the 510(k) process is being used for some devices that should go through the more lengthy premarket approval process. Some experts believe that using 510(k) to avoid premarket approval is reasonable; others disagree.

²An infusion pump accessory. Infusion pumps are devices used to pump fluid (blood, glucose, insulin, etc.) into a patient in a controlled manner.

Experts commented that:

--The problem is that neither FDA nor anyone else realized how complex the premarket approval process would be. Using 510(k) is one way to avoid this process.

--FDA knows that it lacks the resources to fully implement premarket approval, so it has stretched the concept of substantial equivalence beyond recognition.

--In using 510(k) to avoid premarket approval, FDA is trying to give itself some latitude while protecting itself against the criticism that it approved something prematurely.

--FDA is wrongly using the 510(k) system as a way of avoiding the premarket approval procedures.

An expert explained that one method of avoiding premarket approval is to "piggyback" new devices through the 510(k) process. In "piggybacking," a 1982 device is approved as substantially equivalent to a 1981 device, which was approved as equivalent to a 1979 device, and so on.

A former FDA official and a consumer group representative commented that:

--Here we are in 1982, with a device that in no way resembles what was in the marketplace before the amendments' enactment, yet is considered to be substantially equivalent to a preenactment device.

--While only two pacemakers have gone all the way through premarket approval, there have been nearly 300 section 510(k)'s for pacemakers. A pacemaker being made today is nothing like one made in 1976. One has to wonder if 510(k) is not getting out of hand.

A more direct method of avoiding premarket approval described by one expert is to submit under section 510(k) what amounts to a premarket approval application. A consumer group representative explained that a 200- to 300-page 510(k) submission for a diagnostic test using monoclonal antibodies³ recently received FDA approval. He said that since most 510(k) submissions are not 200 pages, the manufacturers were clearly submitting a premarket approval application through the 510(k)

³An antibody produced by the fusion of two kinds of cells, usually a spleen and cancer cell.

process. He stated that monoclonal antibodies are an emerging technology and are probably the wave of the future in diagnostic tests, yet FDA is approving them without expert panel review or public comment, which are required under premarket approval.

One of the experts we interviewed, who was involved with the section 510(k) applications discussed above, stated that he was, on balance, happy with the process. He stated that he did not know if the authors of the section 510(k) provision had thought through the fact that something like what occurred in this instance would happen or not. He stated, however, that he knew that, if that diagnostic test involving the use of monoclonal antibodies, which was a real breakthrough, had been subjected to premarket approval, it would still not be on the market. In his view, therefore, the process in this instance, in terms of ultimate results, worked well.

Other experts stated that 510(k) has discouraged innovation and that its requirements are too ambiguous. Experts claim that manufacturers have little incentive to modify or improve products to an extent that a lengthy and costly premarket approval submission would be required when they can avoid this process by introducing products that are substantially equivalent to pre-enactment devices. Manufacturers pointed out that FDA does not provide clear guidance on what information should be submitted with 510(k) applications. Sometimes, they said, 5 pages of data is enough, yet other times 50 pages is necessary.

SOME EXPERTS BELIEVE FDA COULD RELY MORE ON INSTITUTIONAL REVIEW BOARDS

Most of the experts who responded believe that the Investigational Device Exemption (IDE) concept--protecting humans from investigational devices--is valid. Some experts believe, however, that patients can be adequately protected without the present level of FDA involvement. In the view of these experts, FDA does not always have sufficient expertise to provide meaningful input to the process and FDA's involvement in some instances duplicates the efforts of institutional review boards.⁴

FDA's final regulations on IDEs became effective on July 16, 1980. These regulations exempt sponsors of both

⁴Institutional review boards are formally designated groups or committees at the institution (such as a hospital) where the investigation is to take place. The board has the responsibility of protecting the rights, safety, and welfare of human subjects by making judgments on the acceptability and scientific soundness of an investigation.

significant- and nonsignificant-risk medical devices, during the period of their investigations, from having to comply with certain sections of the Federal Food, Drug, and Cosmetic Act, such as those dealing with misbranding, listing, registration, premarket approval, and good manufacturing practices. Before submitting IDE applications to FDA for approval, sponsors must obtain approval of device investigations from an institutional review board. If such a board determines that a device poses a significant risk, the sponsor is required to notify FDA and submit an IDE. IDE applications must be approved or disapproved by FDA within 30 days of submission. As of December 31, 1982, FDA had received 481 IDEs, of which it approved 326 and initially disapproved 120. (Some of the IDEs initially disapproved were later approved.) Thirty-five were withdrawn by sponsor request or returned to the sponsor.

Institutional Review Boards are required to report their name and address on any medical device clinical study. Using this inventory information the bioresearch monitoring staff of the FDA compliance group performs inspections of boards. During fiscal years 1981 and 1982 this group performed about 170 inspections of medical device institutional review boards. The fiscal year 1981 annual report for the monitoring program indicated the need for closer attention for some types of boards than for others. The report noted, for example, that there was a more pressing need to inspect boards not associated with a major research institution.

Some experts believe FDA has struck the right balance between the need to protect patients and the need to allow for development of new and innovative medical products. Other experts believe, however, that FDA's review of IDEs in some instances is unnecessary, causes delays, and could be delegated to institutional review boards.

One expert, an investigator who was involved in the IDE covering the highly publicized first use of a mechanical heart in a patient and who believed FDA's involvement with IDEs was too extensive, said that the FDA review extended approval almost 5 months without adding anything significant to the process. An associate of this expert stated that the FDA review did not serve a useful purpose because the agency did not have the expertise to provide any input on its own, and if it convened independent expert panels, they would simply duplicate the efforts of the hospital's institutional review board. He stated that the boards were probably more cautious and more in tune with what was happening in the medical center than FDA. FDA disagrees with this analysis of its role and believes it contributed to the process by requiring a backup pump which FDA says was eventually used.

Another investigator, a heart surgeon at a major research institution, said that FDA was not knowledgeable enough in these areas. He indicated, however, that a national peer review group of experts might be substituted for FDA if some further assurance beyond local institutional review board approvals was deemed necessary.

Other comments, pro and con, were:

- IDEs are a protective measure. The whole point is to be able to test a device on human subjects without exposing them to undue risk.
- There definitely needs to be some type of screening system.
- FDA could rely more heavily on institutional review boards.
- Vendors getting ready to sell a product should have to get it approved, but a hospital experimenting with a device should not have to get FDA approval as long as it has gone through the hospital's experimental approval process. If FDA gets involved, device development may take years instead of 2 or 3 months.
- As long as you realize you have to get institutional review board approval before you do anything, there's little value in the IDE application.

As noted on page 60, FDA through its compliance group monitors the efforts of institutional review boards. Therefore, FDA could determine which boards have sufficient procedures in place for patient protection and in appropriate circumstances rely on them.

SUMMARY

Although there is merit to requiring eventual FDA approval of some preenactment devices, the magnitude of the effort involved in demonstrating safety and effectiveness for all pre-enactment devices could be significant and some experts believe it is not necessary for all devices. One expert suggested that the Congress could allow FDA the discretion to require premarket approval for devices that have a history of problems, which could be determined by compiling adverse incident reports and examining the literature concerning the device.

Many devices introduced on the market after the passage of the 1976 amendments are not being reviewed for safety and effectiveness because of FDA's interpretation that substantial

equivalency determinations do not require consideration of such factors. Some experts believe that without such determinations, existing substantial equivalence reviews are inadequate to guarantee safety and effectiveness for Class III devices. In addition, according to some experts, the meaning of substantial equivalence has been stretched to a point that it has resulted in substantial equivalence determinations being used to avoid the premarket approval process. Because of their inherent potential for harm, we believe that all new Class III devices should be subject to full premarket approval rather than being reviewed on the basis of substantial equivalence.

In addition, FDA should expand the substantial equivalency determination for certain risky Class II devices to require consideration of safety and effectiveness data. The instance discussed in July 16, 1982, congressional hearings (see p. 57) demonstrates that a finding of substantial equivalence without a corresponding finding that the new device is safe does not adequately protect the public. To guide manufacturers, FDA needs to determine which Class II devices will be subject to increased scrutiny and develop guidelines on the type and extent of information that will be required for determinations of safety and effectiveness.

Some experts intimately involved with IDEs believe that FDA's level of involvement with IDEs could be reduced. They believe FDA could rely more on the reviews of some institutional review boards.

MATTERS FOR CONSIDERATION
BY THE CONGRESS

If the Congress believes that all new Class III devices should be examined for safety and effectiveness before they are allowed on the market, it could eliminate the provision of the act that permits FDA to approve new Class III devices on the basis of substantial equivalence to already marketed devices and require instead that all new Class III devices be subject to a premarket approval review. To implement this change, section 513(f)(1)(A)(i) of the Food, Drug, and Cosmetic Act could be amended to read as follows:

"(A) the device--

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which has been classified in class I or II, or (II) which was not so introduced or delivered before such

date and has been classified in class I or II,
and * * *."

Furthermore, section 515(c)(1) could be amended by substituting the word "shall" for "may."

The experts had mixed views regarding the need for a review of all preenactment devices for safety and effectiveness. The Congress therefore may wish to further explore the need for this requirement. Should the Congress decide that a review of all preenactment devices is not needed, a legislative change would be required. To implement this change, section 515(b)(1) of the Federal Food, Drug, and Cosmetic Act could be amended to read as follows:

"(b)(1) In the case of a class III device which--

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval, when in the opinion of the Secretary, such premarket approval is necessary to assure safety and effectiveness."

RECOMMENDATION TO THE SECRETARY OF HHS

We recommend that the Secretary of HHS require the Commissioner of FDA to (1) identify new Class II devices that pose health risks significant enough to require examination of safety and effectiveness data as part of an adequate finding of substantial equivalency and (2) develop guidelines for determining and documenting the safety and effectiveness of such devices.

AGENCY COMMENTS AND OUR EVALUATION

HHS offered no comment on our proposal to require the submission of safety and effectiveness data for all new Class III devices before they are allowed on the market. We believe that the test for substantial equivalency does not insure device safety. As carried out by FDA, this process does not require submission of safety and effectiveness data (see p. 55) and the

comparison of the new devices to preenactment devices is meaningless because FDA has not substantiated the safety of older devices. FDA anticipates that it will be another 2 years before the safety and effectiveness determination of older devices is begun and, since nearly 1,000 devices need to be reviewed, it will be years before the process is completed. Meanwhile, because of their inherent potential for harm, we continue to believe that all new Class III devices should be required to undergo premarket approval to establish that they are safe and effective.

Regarding our proposal that the Congress consider whether all preenactment Class III devices should be reviewed for safety and effectiveness, HHS stated that it agreed that the matter warranted further review and would study it to determine if any changes should be made.

HHS disagrees with our recommendation to identify new risky Class II devices and develop guidelines for documenting their safety and effectiveness. HHS stated that instituting this procedure would significantly alter the classification and marketing procedures for Class II devices and would be inappropriate for Class I and II devices.

We believe FDA's present procedure for determining substantial equivalency should be sufficient for most low-risk Class I and Class II devices. However, we continue to believe that FDA must identify devices that pose significant health risks and determine that they are safe and effective.

FDA's current position (see p. 55) is that a determination of "substantial equivalency" does not require the submission of safety and effectiveness data for new devices. Only occasionally does FDA obtain safety data. As demonstrated during recent congressional hearings, a finding of substantial equivalence without a corresponding finding that the new device is safe does not always adequately protect the public.

HHS believes the issue of whether FDA should rely more on institutional review board approvals for significant-risk investigational devices warrants further consideration. The preamble to FDA's notice of proposed rulemaking to revise the investigational new drug regulations discusses the issue of outside review boards and requests public comment on this matter. Based upon FDA's review of those comments, the agency will determine whether to formally propose outside review boards in the context of drugs. At that time, the agency will also determine whether it should consider proposing that outside review boards assume scientific review responsibilities for significant-risk IDE applications to the extent allowed in section 520(g)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

MEDICAL DEVICE EXPERTSINTERVIEWED BY GAO

<u>Name and position</u>	<u>Affiliation</u>
<u>Former Regulators</u>	
Dr. Theodore Cooper (former Assistant Secretary for Health, HEW) Executive Vice President	The Upjohn Company
Mr. David Link (former Director, BMD) Vice President for Corporate Development	Mentor O&O, Inc.
Mr. Larry Pilot (former Associate Director for Compliance, BMD)	Rogers, Hoge and Hills
Mr. Marc Bozeman (former member of FDA's Office of General Counsel)	Geller and Bozeman
<u>Former Classification Advisory Panelists</u>	
Dr. Charles Burton, Director	Institute for Low Back Care
Dr. Allen K. Ream, Associate Professor of Anesthesiology, Director of Medical Science and Clinical Evaluation	Institute of Engineering Design in Medicine, Stanford University Medical School
Dr. Harry W. McCurdy, Executive Vice President	American Academy of Otolaryngology
Dr. Richard Clark, Chairman, Medical Device Committee	American College of Surgeons
<u>Professional Societies</u>	
Dr. Leonard Fenninger, Vice President, Medical Education and Scientific Policy	American Medical Association

<u>Name and position</u>	<u>Affiliation</u>
<u>Professional Societies</u>	
Ms. Nancy E. Cahill, Executive Assistant, Medical Education and Scientific Policy	American Medical Association
Mr. Ross N. Rubin, J.D., Director, Department of Federal Legislation	American Medical Association
Mr. Harry N. Peterson, J.D., Director, Division of Legislative Activities	American Medical Association
Mr. Richard diMonda, Director, Engineering Services	American Hospital Association
Ms. Mary Ann Kelly	American Hospital Association
Mr. M. Lee Bancroft	American Association for Respiratory Therapists
<u>Trade Associations</u>	
Mr. Howard Holstein, Vice President and General Counsel	Health Industries Manufacturers Association
Mr. Jeffrey Dow	Health Industries Manufacturers Association
Mr. George F. Smith, Jr., Assistant Vice President for Device Products	Pharmaceutical Manufacturers Association
Mr. Michael J. Miller, Executive Director	Association for the Advancement of Medical Instrumentation
Dr. Clark Watts, Executive Director (elect)	Association for the Advancement of Medical Instrumentation

<u>Name and position</u>	<u>Affiliation</u>
<u>Consumer and Consulting Groups</u>	
Mr. Allen Greenberg	Public Citizen, Health Research Group
Dr. Joel Nobel, President	Emergency Care Research Institute
Malin VanAntwerp, Senior Policy Analyst	Emergency Care Research Institute
Mr. Reed Harker, Director	Utah Biomedical Testing Laboratory
Dr. J. D. Mortenson	Utah Biomedical Testing Laboratory
Mr. Lucien A. Couvillon, Jr.	Arthur D. Little, Inc.
<u>Hospitals</u>	
Mr. Tony Iacovella, Biomedical Engineering	Yale-New Haven Hospital
Dr. Ronald Newbower, Biomedical Engineering	Massachusetts General Hospital
Mr. Bryan Parker, Director, Bioengineering	Montefiori Hospital and Medical Center
Dr. Emanuel Goldberg, Chief of Cardiology	Beth-Israel Medical Center New York
Mr. Ed Young, Director, Biomedical Engineering	Stanford University Hospital
Dr. Melvin Post, Chairman, Orthopaedic Surgery	Michael Reese Hospital and Medical Center
Mr. Tim McFarland, Director, Biomedical Engineering	Good Samaritan Hospital

<u>Name and position</u>	<u>Affiliation</u>
	<u>Hospitals</u>
Dr. Bruce Towe, Senior Staff Scientist	Good Samaritan Hospital
Mr. Wisam Kahn, Director, Biomedical Engineering	Washington Hospital Center
Dr. George Stewart, Head, Biomedical Physics	Temple University Hospital
Mr. Charles Zanes, Director, Technical Services	Temple University Hospital
Mr. Nick Lewis, Director, Clinical Engineering	Cedars-Sinai Medical Center
Mr. Robert Murphy, Medical Electronics	Los Angeles County - University of Southern California Hospital
Dr. Gautum Ray, Director, Biomedical Engineering Research	Mount Sinai Medical Center
Ms. Sarah Lewis, Clinical Investigations Committee	Mount Sinai Medical Center
Dr. James Bachus	Rush-Presbyterian Medical Center
Dr. W. Randolph Tucker, Research Administration	Rush-Presbyterian Medical Center
	<u>Medical Device Manufacturers</u>
Dr. Kenneth R. Michael, Corporate Director of Regulatory Affairs and Quality Assurance	Imed Corporation
Mr. Michael T. Frankenberg, Director of Regulatory Affairs	SciMed Life Systems, Inc.

<u>Name and position</u>	<u>Affiliation</u>
<u>Medical Device Manufacturers</u>	
Mr. Hartmut H. Loch, Manager, Quality Assurance and Regulatory Affairs	Aesculap Instruments Corporation
Mr. Donald Hart, Director, Regulatory Affairs	Smith Kline Medical Diagnostics Smith Kline Corporation
Mr. Peter Schreiber, President	North American Drager
Mr. Gary Leyland, Regulatory Affairs	Survival Technology, Inc.
Mr. James W. Hulse, Vice President, Quality and Regulatory Affairs	Becton-Dickinson and Company
Dr. Francis A. Fagone, Project Leader, Research and Develop- ment InVitro Diagnostics	New England Nuclear
Mr. Joseph McGuire, President	Biotronix Laboratories, Inc.
Dr. Eugene H. LaBrec, Ph.D., Director, Quality Assurance and Regulatory Affairs	Electro-Nucleonics, Inc.
Mr. Peter Sottong	Electro-Nucleonics, Inc.
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Dr. Roger G. Mark, Matsushita Associate Professor of Electrical Engineering in Medicine	Massachusetts Institute of Technology
Dr. W. Sanford Topham, Clinical Engineering Program	Case-Western Reserve University
Mr. Ira Tackel, Director, Clinical Engineering	University of Pennsylvania Hospital
Dr. Philip Katz	Jefferson Medical School

<u>Name and position</u>	<u>Affiliation</u>
<u>Attorneys Specializing in Medical Device Law</u>	
Mr. James R. Phelps	Hyman and Phelps
Mr. Duncan Barr	O'Connor, Cohn, Dillon, and Barr
Mr. John Boyden	Boyden, Kennedy, and Romney
Mr. Stephan E. Lawton	Pierson, Ball, and Dowd
<u>Researchers</u>	
Dr. Willem Kolff, Director	Institute for Biomedical Engineering, University of Utah
Dr. Lee M. Smith, Vice President	Kolff Medical
Dr. Denton Cooley	Texas Heart Institute
Dr. Christopher Reading	M.D. Anderson Hospital
Dr. Emil Freireich	M.D. Anderson Hospital
Dr. Oram Kline, Jr.	Private practice



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D C 20201

JUL 13 1983

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for our comments on your draft of a proposed report "Federal Regulation of Medical Devices--Many Problems Still to Be Overcome." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "R. Kusserow".

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE
COMPTROLLER GENERAL'S DRAFT REPORT, "FEDERAL REGULATION OF
MEDICAL DEVICES -- MANY PROBLEMS STILL TO BE OVERCOME,"
REPORT NO. GAO/HRD-83-52, DATED MAY 2, 1983

General Comments

We appreciate the opportunity to review and comment on the draft report. We believe that the report correctly focuses attention on pressing issues in the regulation of medical devices such as the need for a more useful medical device information system and mandatory performance standards for Class II devices.

In both of these areas, the Food and Drug Administration (FDA) has undertaken a variety of activities that will resolve the issues. For example, FDA agrees that the development of a more useful medical device information system will enable FDA and others to reduce public exposure to device risks. To this end, FDA re-proposed a regulation on May 27, 1983 that would require manufacturers and importers to report all deaths or serious injuries associated with the use of their products. As proposed, the regulation will also require manufacturers and importers to report device malfunctions which, if they recurred, are likely to cause or contribute to death or serious injury. In addition to this proposed regulation, FDA is evaluating its Device Experience Network (DEN) system to determine how it can be better utilized. The General Accounting Office's (GAO's) findings on the DEN system will be taken into consideration during this review.

On the issue of performance standards for Class II devices, FDA is undertaking a variety of initiatives that are in concert with the GAO report. These include:

- (1) consideration of a legislative proposal that would grant the Agency the discretionary authority to determine which Class II devices require mandatory performance standards;
- (2) publication of a notice in the June 17, 1983 Federal Register announcing initiation of standard-setting proceedings for continuous ventilators (also planned are mandatory standard-setting proceedings for ten additional devices);
- (3) publication of an FDA policy statement to establish priorities for development of Class II performance standards and procedures the Agency will follow in dealing with the Class II devices.

GAO's findings on the relationship between device failures and user misuse of medical products and maintenance problems are interesting. We will consider this in our ongoing evaluation of device failures and in determining the appropriate solutions to device problems such as the design and implementation of educational programs or restricted use criteria.

In conducting this audit, GAO solicited the opinions and perceptions of a number of medical device experts. In some instances, GAO identified the number of respondents who espoused a particular view and, in others, did not. We would like to suggest that, to the extent possible, GAO identify the specific number of respondents.

GAO Recommendation

To enable FDA to develop a more complete and useful medical device information system, we recommend that the Secretary require the Commissioner of FDA to:

1. —Expand the DEN system to include available medical device literature and studies.
2. —Encourage 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.
3. —Develop and promulgate a mandatory experience reporting requirement for manufacturers. The requirements should seek only new information which is essential to FDA needs, can be effectively used, and will not be unduly burdensome for manufacturers to provide.
4. --Develop capabilities to permit greater use of the information contained in DEN in order to identify trends and potential problems and to devise appropriate resolutions to those problems. This could be accomplished in part by developing a product thesaurus and medical event codes.

Department Comments

We agree that FDA should develop a more complete and useful device information system. FDA is reviewing the system to determine what aspects need to be modified and what, if any, additional system components should be added. FDA will be looking specifically at the feasibility of including additional literature and studies on the DEN system, providing more effective feedback to device experience reporters, and increasing the capability to do use and trend analyses.

As to promulgating a mandatory experience reporting requirement for manufacturers, FDA has developed a proposed Medical Device Reporting (MDR) regulation that would govern the reporting of device-related deaths or serious injuries as well as device malfunctions whose recurrence would be likely to cause death or serious injury. This proposal was published in the Federal Register on May 27, 1983.

GAO Recommendation

5. —The Secretary should instruct the Commissioner of FDA to
- (1) collect information on the scope and nature of device problems caused by user error and inadequate maintenance through an expanded device experience reporting network,
 - (2) analyze the data to identify special problems, concentrations and trends, and
 - (3) disseminate the results internally and to the private sector to aid in developing solutions.

Department Comment

We concur. We recognize that FDA has an important role in collecting, analyzing, and disseminating information about all device problems including user and maintenance problems as well as design and manufacturing problems both to aid the private sector in its corrective efforts and to provide a basis for regulatory action when appropriate.

As the report points out, the DEN system has not fully answered the need for an adverse experience reporting system. However, the DEN system has been quite valuable in identifying potential hazards, and will become even more effective when the MDR is finalized. Further, FDA is initiating an evaluation of the DEN system to determine how it may be improved to meet the agency's information needs as well as those of the public.

FDA has undertaken a variety of activities to alert users and the general public to the problems associated with the use of medical devices. These include promulgation of classification panel reports that contain information about potential hazards, publication of problem definition studies done to determine whether standards are needed for particular classes of devices, responses to Freedom of Information requests, publication of hazard information in some widely disseminated FDA publications such as the Drug Bulletin and the FDA Consumer, as well as educational efforts to teach users and patients about devices and their hazards. Many sophisticated devices are owned and used outside a hospital or clinic setting to which current safety information is targeted. For this reason, users may not be reached with information relevant to device use and maintenance. Therefore, a multifaceted regulatory and educational approach to controlling medical devices, in our opinion, is appropriate.

6. -- We recommend that the Secretary of HHS require the Commissioner of FDA to (1) identify new Class II devices which pose risks to health significant enough to require examination of safety and effectiveness data as part of an adequate finding of substantial equivalency, and (2) develop guidelines for determining and documenting the safety and effectiveness of such devices.

Department Comment

We do not concur. This procedure would significantly alter the classification and marketing procedures established in the amendments for Class II devices in a way not intended by the Congress. Section 513(f)(1) states:

"Any device intended for human use which has not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in Class III unless -

(A) the device -

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in Class I or II, and
(ii) is substantially equivalent to another device within such type.

The Act also requires in Section 510(k) that manufacturers notify FDA of their intent to market a new device ninety days prior to introducing it into commerce. FDA has devised a review mechanism under the auspices of the above cited Sections of the Act (see, 21 CFR 807.81, 85, and 87) that provides for a determination of substantial equivalency, which includes determining if differences between pre-Amendments and post-Amendments devices are material to safety and effectiveness. If there are such differences, FDA finds the post-Amendments devices to be "not substantially equivalent" and classifies the device as Class III. Implementation of GAO's recommendation would be redundant with existing premarket approval requirements in Section 515 of the Act for Class III devices and would be inappropriate for Class I and II devices, which are subject to other

regulatory controls. Congress' view on this later point is apparent from the House Committee Report (No. 94-853, p 35):

"The challenge has been to develop statutory language that assures that devices will undergo the intensive testing and review provided by premarket approval when necessary to protect the public without mandating premarket approval in instances where it is not justified in view of alternative regulatory mechanisms."

As opposed to being a means for determining safety and effectiveness, the 510(k) process was intended by Congress to be simply a screening mechanism that would: (1) allow "substantially equivalent" post-Amendments devices to enter the market and be regulated like their pre-Amendments predecessors; and (2) identify "not substantially equivalent" post-Amendments devices and automatically place them in the premarket approval category. Congress stated this intent in the House Committee Report (p. 37) when it said 510(k) was:

"... designed to insure that manufacturers do not intentionally or unintentionally circumvent the automatic classification of 'new' devices ... This provision will enable the Secretary to assure that 'new' devices are not marketed until they comply with premarket approval requirements or are reclassified into Class I or II."

We also believe FDA is applying the "substantial equivalency" test in a manner consistent with Congressional intent, though Congress' instructions are not explicit on the interpretation of this term. FDA reviews premarket notifications to determine if the differences between pre- and post-Amendments devices are material to safety and effectiveness. If there are no differences or if the differences do not present unanswered questions of safety and effectiveness, FDA finds post-Amendments devices "substantially equivalent" to their pre-Amendments predecessors. If the differences do present unanswered questions of safety and effectiveness, or if adequate comparisons cannot be made due to unique, new indications, then FDA finds post-Amendments devices "not substantially equivalent." This approach conforms to Congress' view expressed in the House Committee Report (p. 36-37) that "... copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme." Thus, it is not inconsistent with Congressional intent that FDA is finding post-Amendments devices, even those which are life-supporting or life-sustaining, "substantially equivalent" to pre-Amendments devices.

GAO Recommendation [See GAO note.]

7. —Further, to reduce unnecessary FDA involvement in experimental device development, we recommend that the Secretary instruct the Commissioner to rely more on institutional review board approval of significant risk devices in those instances where FDA has satisfied itself that patients are being adequately protected by strong institutional review board reviews.

Department Comment

We believe that this issue warrants further consideration. FDA has begun addressing this issue in the context of local Institutional Review Boards (IRBs) reviewing investigations on new drug products, and FDA solicited public comments on this issue in a September 11, 1981 Federal Register notice. Comments to that notice highlighted the point that IRBs traditionally review only the "ethical" aspects of an investigation, including informed consent not the "scientific" aspects of a study, such as the protocol design or the manufacturing process used to produce the test product. FDA has traditionally performed this "scientific review" and many comments stated that most IRBs, as presently constituted, lack the necessary expertise to assume that review function as well. A number of comments, however, did suggest an optional system whereby a willing and expanded IRB could assume such scientific review responsibility in lieu of FDA. Accordingly, the agency has redirected its consideration of this type of optional system under the general umbrella term of Outside Review Boards (ORBs).

In the preamble to FDA's Notice of Proposed Rulemaking to revise the Investigational New Drug (IND) regulations, expected to be published in the Federal Register shortly, FDA has discussed the ORB issue and has requested public comment on it. Based upon FDA's review of those comments, the agency will determine whether to formally propose ORBs in the context of INDs. At that time, the agency will also determine whether it should consider proposing that ORBs assume scientific review responsibilities for significant risk Investigational Device Exemption applications to the extent allowed in Section 520(g)(3)(A) of the Food, Drug, and Cosmetic Act.

Matters for Consideration by the Congress

1. --If Congress shares the view of the experts it could give FDA the flexibility to develop standards on a case-by-case basis. To do this, section 513(a)(1)(B) of the Food, Drug,

GAO note: Since this issue extends beyond medical devices into the drug area and FDA on June 9, 1983, began gathering information through public comment on a proposed rule for revising its regulations governing the review of investigational new drug applications, we have not included this recommendation in our final report.

basis. To do this, section 513 (a)(1)(B) of the Food, Drug, and Cosmetic Act could be amended to read as follows:

"(B) Class II. Performance Standards.--A device which cannot be classified as a Class I device because the controls authorized by or under section 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance. The Secretary shall identify those Class II devices for which it is considered necessary to establish a performance standard to provide reasonable assurances of their safety and effectiveness and shall do so in accordance with section 514."

Department Comment

We agree that this suggestion merits further consideration and currently have it under review. We are also considering whether the lengthy and complex development process required by Section 514 of the Act needs to be simplified.

Matters for Consideration by the Congress

2. --If Congress believes that all new Class III devices should be examined for safety and effectiveness before they are allowed on the market, it could eliminate the provision of the Act which permits FDA to approve new Class III devices on the basis of substantial equivalence to already marketed devices and require instead that all new Class III devices be subject to a premarket approval review. To implement this change, section 513(f)(1)(A)(i) of the Food, Drug, and Cosmetic Act could be amended to read as follows:

"(A) the device--

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which has been classified in Class I or II, or (II) which was not so introduced or delivered before such date and has been classified in Class I or II, and"

Department Comment

We have no comment to make on this suggestion at this time.

Matters for Consideration by the Congress

3. —Should the Congress decide that a review of all Class III pre-enactment devices is not needed, a legislative change would be required. To implement this recommendation, section 515 (b)(1) of the Food, Drug, and Cosmetic Act could be amended to read as follows:

"(b)(1) In the case of Class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type, the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval, when in the opinion of the Secretary, such premarket approval is necessary to assure safety and effectiveness."

Department Comment

We agree that this suggestion warrants further review and will study it to determine if any changes should be made.

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