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Briefing Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

August 1989

MEDICAL DEVICE RECALLS

An Overview and Analysis 1983-88

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Program Evaluation and
Methodology Division

B-233199

August 30, 1989

The Honorable Henry Waxman
Chairman, Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

On February 7, 1989, you asked us to provide you a description of medical device recalls that have been reported to the Food and Drug Administration (FDA) since the promulgation of the medical device reporting regulation on December 14, 1984. Specifically, we were to determine the devices that have been recalled, the problems for which they were recalled, and the mode of market entry of the problem devices. You also asked us to provide descriptions of the problem-solving efforts of FDA and device manufacturing firms. We briefed your staff on our preliminary results on April 25, 1989, and agreed to conduct limited additional work and provide you with a briefing report.

With the concurrence of the subcommittee staff, we have limited this report to a response to your request for a descriptive analysis of medical device recalls. In a future report we will include a description of problem-solving efforts by FDA and device manufacturing firms based on in-depth case study analyses from a sample of medical device recalls. We will also include a review of the way the recall process actually operated with respect to specific devices and, if necessary, suggest ways to improve the overall recall process.

We obtained data for this report from two sources. The first was a computer data tape, provided by FDA, of recalls during fiscal year 1983 through fiscal year 1988. The second source was a series of interviews with FDA officials, program managers, and other staff to clarify technical aspects of the data base, such as the definition of data elements and potentially atypical responses, and to document the agency's recall process.

Our analysis of medical device recalls was based on a total of 1,635 recalls. Class II recalls (medium-serious) were the most frequent at 1,026. This was followed by 561 class III (least serious) and 48 class I recalls (most-serious). The annual number of recalls fluctuated during the 6 years. Prior to 1985, the number did not exceed 200; after 1985, it was consistently near or above 300. Several speculative explanations for

the increase have been offered, such as the implementation of the medical device reporting regulation in December 1984, the increasing complexity of medical devices, and FDA's greater postmarketing surveillance efforts. The descriptive design of our study did not allow an attribution of the increase to any one cause or combination of causes.

Ninety-seven percent of the device recalls in 1983-88 involved circumstances in which FDA analysts judged serious adverse health consequences to be unlikely or remote (recall classes II and III). Devices from every medical practice specialty area were the subject of at least one recall. However, recalls in 8 of the 19 medical practice specialties accounted for 80 percent of all recalls. The top 2, cardiovascular and anesthesiology devices, accounted for slightly more than one fourth of all the recalls.

The devices that were recalled ranged from high-risk, implantable, life-supporting devices, such as replacement heart valves, through medium-risk devices such as suntanning booths, to low-risk dental irrigation syringes. Our analysis showed that all classes of device—including some devices that are considered relatively innocuous—can be associated with problems potentially leading to serious health consequences or death. According to FDA, problems with design and production were the cause of nearly three fourths of all recalls.

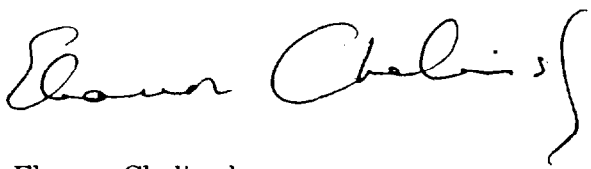
We found that 74 percent, a disproportionate share, of all recalls and the majority of the most-serious recalls were of class 2 (medium risk) devices. This is the class of devices for which performance standards have been mandated but not developed by FDA. Although the most-serious (class I) recalls were more likely than the other recall classes to have a medical device reporting regulation report associated with them, only half of them did have reports when the Center for Devices and Radiological Health (CDRH) evaluated the health hazard of the device problem, classified the recall, and closed the file at CDRH. This suggests that such reports have not served as an effective "early warning" of device problems that lead to recalls.

Overall, the proportion of devices that entered the market through the premarketing approval process (6 percent) was similar to the proportion of recalled devices that followed this process (5 percent). And premarketing-approved devices were more likely to be associated with the most-serious class of recall than either of the two other classes of recall.

As you requested, we obtained informal, oral comments from FDA officials. Their comments were primarily technical and we revised our draft to take account of them where appropriate.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of the report. At that time, we will send copies to the secretary of Health and Human Services, the director of the Center for Devices and Radiological Health, and others who are interested upon request. If you have any questions or would like additional information, please call me at (202) 275-1854 or Dr. Michael J. Wargo, Director of Program Evaluation in Physical Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix V.

Sincerely yours,



Eleanor Chelimsky
Assistant Comptroller General

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Abbreviations

CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration

Introduction

Background on Medical Device Recalls

Medical devices include almost everything, other than drugs, used by health care professionals to diagnose and treat illness, improve human functioning, and support and sustain life. More than 1,700 different types of medical devices are available in the United States today. They represent an industry of nearly $14 billion annually. The Food and Drug Administration (FDA) uses two overlapping systems as its principal means of ensuring the safety and effectiveness of medical devices. The first, premarketing review, is a system of checks, reviews, and controls that are applied before a device is made available to the public. The second, postmarketing surveillance, is a monitoring system designed to provide an "early warning" of problems associated with the devices after they are in general use. Medical device recalls constitute one element of the postmarketing surveillance system.

A medical device "recall" is the removal from the market of a particular product or the correction of labeling or of promotional materials that FDA considers to be in violation of the laws it administers. The agency has a number of administrative actions available to it, including seizure of the device, and a range of civil actions. FDA can exercise recall-related authority in three principal areas: (1) initiating court-ordered recalls, (2) prescribing procedures and requirements concerning how recalls are conducted, and (3) requiring that reports be made to FDA concerning recalls.

FDA may request a firm to initiate a product recall. However, FDA has no authority under the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301), to order a manufacturer to recall a violative product without a court order. Thus, the agency may request a recall, but it has no statutory authority to impose or seek sanctions for a manufacturer's refusal to carry out the recall.[1] In practice, the overwhelming majority of recalls are voluntarily initiated by the manufacturer, with FDA "oversight."

FDA oversight means that after a court-ordered or manufacturer-initiated recall has been declared, FDA exercises its authority under both the 1938 act and the Public Health Service Act of 1944 (42 U.S.C. 241, 262, and 264) to prescribe mandatory procedures and requirements that, among other things, facilitate recalls. Such procedures and requirements help prevent the introduction into commercial channels, or facilitate the

[1]FDA may take administrative action respecting the underlying violation that led to the agency's request. For example, it may seize a violative product and prosecute those responsible for distributing it.

removal from commercial channels, of adulterated, misbranded, or otherwise violative food, drugs, devices, and cosmetics. In addition, FDA has specific authority under section 519 of the act (21 U.S.C. 360i) to require reports by firms that may include reports of recall notifications.

Objectives, Scope, and Methodology

We prepared this report in response to a request from the chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. We were asked to examine medical device recalls that have taken place since the implementation of the medical device reporting regulation on December 13, 1984.[2] In discussions with the subcommittee's staff, we formulated the following evaluation questions:

1. How many medical device recalls occurred between fiscal years 1983 and 1988?

2. How are the recalls distributed among recall classes, medical practice specialties, and device classes?

3. What proportion of the recalled devices were the subject of reports under the medical device reporting regulation?

4. How many of the recalled devices entered the market through FDA's premarketing approval process?

5. What are the characteristics of the problems for which devices are recalled?

6. What are the characteristics of the most frequently recalled medical devices?

7. What are the characteristics of the class I recalls?

In a separate report, we will review the organizational structure and procedures that constitute the recall system and empirically examine the operation of the recall process as it was applied to a sample of devices. In that report, we will also examine variations in the device recall process and its relative effectiveness for different devices and different circumstances.

[2]The congressional request for this report is reproduced in appendix I.

The data in this report come from two sources. One was an FDA computer data tape of all recalls initiated during fiscal years 1983 through 1988. The tape contained descriptive information such as product type, problem cause, and manufacturer's identification for each recall. We did not independently verify the information contained on the data tape or evaluate the internal controls of the computer system that produced the tape. However, we did examine all extreme entries and remove some that were logically impossible.[3] The other source of data was structured interviews with FDA officials, program managers, and other staff who were directly responsible for the agency's recall activities, to clarify technical aspects of the data base, such as the definition of certain data elements and potentially atypical responses, and to document the agency's recall process.

For analysis of the recall data tape, we used the procedures available in the statistical analysis system (SAS) software package. Our analysis includes frequency counts of the relevant variables, crosstabulations of variables that respond to the evaluation questions, and associated statistical tests. Our review and analysis were conducted between February 15, 1989, and April 15, 1989. Our work was performed in accordance with generally accepted government auditing standards.

[3]See appendix II for a discussion of the sources and quality of the data tape.

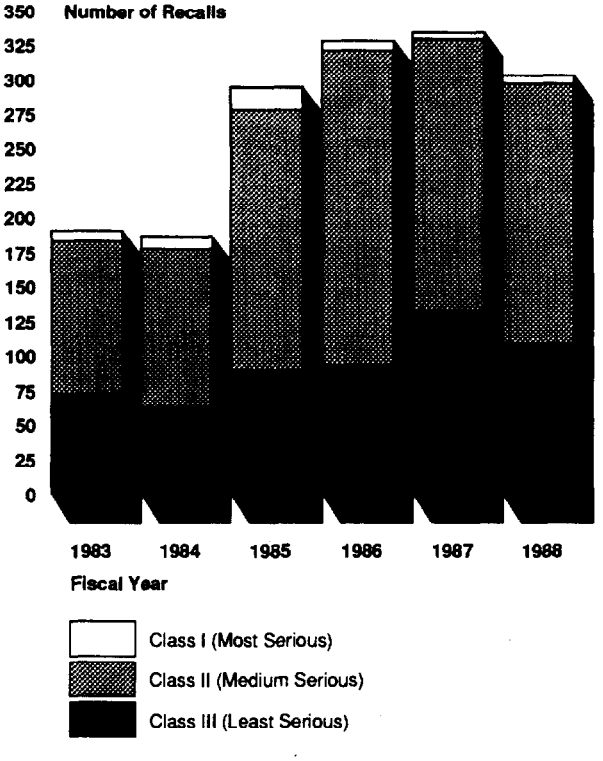
Overall Number and Classification of Recalls

Recall classification is the numerical designation FDA assigns to a particular product recall to indicate the relative degree of health hazard the product presents. There are three classes. In class I, there is a strong likelihood that the use of or exposure to a violative product will cause serious adverse health consequences or death. In class II, the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse health consequences is considered remote. In class III, the use of or exposure to a violative product is not likely to cause adverse health consequences.

Throughout this report, we refer to class I, II, and III recalls as "most serious," "medium serious," and "least serious," respectively.

Our empirical analysis of the number and classification of recalls produced the following results (figure 2.1):

Figure 2.1: Device Recalls by Recall Class[a]



[a]The numbers on which this figure is based are contained in table IV.1 in appendix IV.
Source: FDA recall data tape.

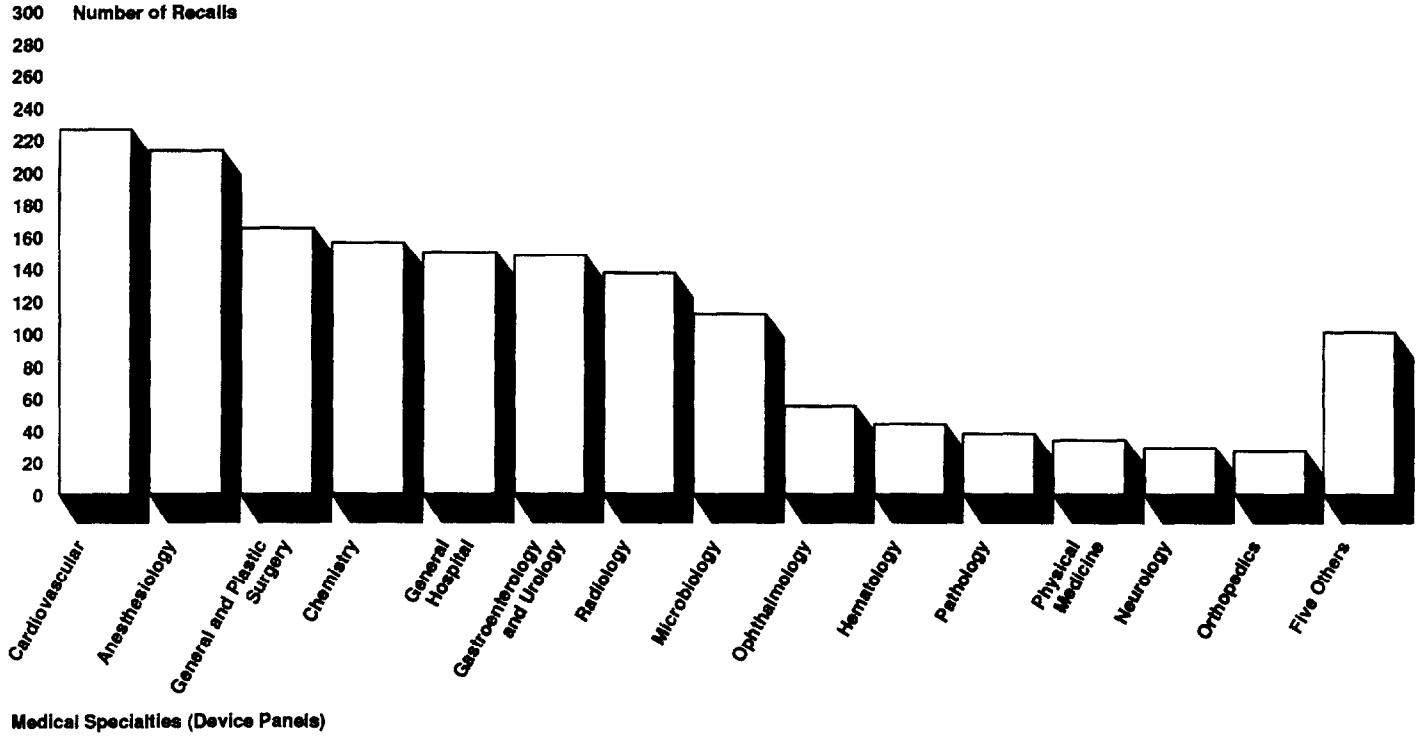
- During the period we studied (1983-88), there was a total of 1,635 recalls.[1]
- Class II (medium-serious) recalls were the most frequent, at 1,026, or 63 percent, of all recalls. There were 561 class III (least serious) recalls, or 34 percent, and 48 class I (most-serious) recalls, or 3 percent.
- In 1983 and 1984, there were about 200 recalls each year.
- After 1984, there were more than 275 recalls each year.
- The largest 1-year increase—of 37 percent, or 108 recalls—occurred between 1984 and 1985.

[1]The data tape we received from FDA contained a total of 3,274 "recall" records. See table III.2 in appendix III for a detailed presentation of the numbers upon which figure 2.1 is based and a comparison with FDA's total.

Recalls Among Medical Practice Specialties

As a result of the enactment of the Medical Device Amendments of 1976, FDA established a panel of experts in each of 19 medical specialties.[1] They were to assign all devices existing prior to the amendments to one of three device classes—class 1, class 2, or class 3.[2] Assigning these devices also provides FDA with an efficient means of organizing and monitoring other medical device issues, including recalls. Our empirical analysis of device recalls and medical practice specialties produced the results shown in figure 3.1.

Figure 3.1: Device Recalls by Medical Specialty in Fiscal Years 1983-88[a]



[a]The numbers on which this figure is based are contained in table IV.3 in appendix IV.

Source: FDA recall data tape.

[1]The medical specialties are anesthesiology; cardiovascular; chemistry; dental; ear, nose, and throat; gastroenterology and urology; general hospital; general and plastic surgery; hematology; immunology; microbiology; neurology; obstetrics and gynecology; ophthalmology; orthopedics; pathology; physical medicine; radiology; and toxicology.

[2]These device classes must not be confused with the three recall classes listed in section 2. See section 4 for a discussion of medical device classification under the 1976 amendments.

- Devices from 8 of the 19 medical practice specialties accounted for 80 percent of all recalls.
- Cardiovascular devices (for example, cardiac pacemakers and artificial heart valves) accounted for 226, or 14 percent, of all recalls.
- Anesthesiology devices (for example, ventilators or respirators and anesthesia gas machines) accounted for 213, or 13 percent, of all recalls.
- No other medical practice specialty accounted for more than 10 percent of all recalls.

Recalls by Device Classification

The centerpiece of the Medical Device Amendments of 1976 was the classification scheme for medical devices by potential risk to assist in identifying differential requirements for ensuring device safety and effectiveness. All new medical devices and those that were marketed before the passage of the amendments are now assigned to one of three device classes by the medical specialty panels. The three device classes are defined as follows.

Class 1, or "low-risk" devices (for example, tongue depressors and ice bags), are not used in supporting or sustaining life, are not important in preventing the impairment of human health, and do not present an unreasonable risk of illness or injury. These devices are subject to minimum regulation.[1] General controls such as registration, premarketing notification, regulation of good manufacturing practices, and prohibitions against adulteration and misbranding are sufficient to provide reasonable assurances of safety and effectiveness.

General controls, such as those mentioned above, were judged by the medical panels to be insufficient to provide reasonable assurances of the safety and effectiveness of class 2, "medium-risk" devices (for example, anesthesia machines and apnea monitors), but scientific information was judged to be sufficient to establish performance standards that will provide such assurances. FDA is authorized to develop and establish performance standards for all class 2 devices, which may include provisions specifying device materials, construction, components, ingredients, and labeling if necessary to ensure their safety and effectiveness.

Class 3, or "high-risk," devices (for example, heart valves and defibrillators) are the most rigidly controlled. They are potentially very hazardous and usually require approval before marketing. These devices are life-supporting or life-sustaining, are substantially important in preventing the impairment of human health, or present a potentially unreasonable risk of illness or injury. General controls are insufficient to provide reasonable assurances of their safety and effectiveness, and sufficient information does not exist to establish performance standards to provide such assurances.

Table 4.1 shows FDA's classification of medical devices and recalls according to risk. It is important to remember that the potential degree

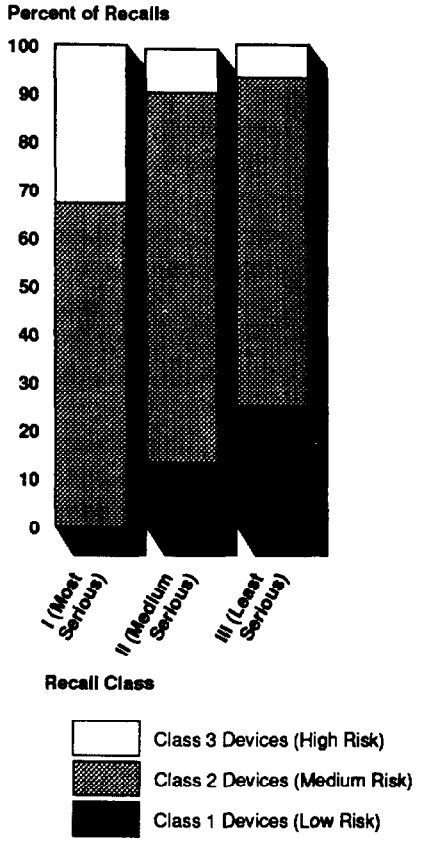
[1]We refer to class 1, 2, and 3 devices as "low-," "medium-" and "high-risk," respectively in order to avoid confusion with the three recall classes, I, II, and III, which we refer to as "most serious," and "least-serious," respectively. These terms are not used in the amendments.

of health risk associated with recall classes is designated in a descending order from class I (high) to class III (low), while the potential risk associated with device classes is designated in an ascending order from class 1 to class 3. Therefore, classes I and 1 have opposite meanings for recall and device classes.

Table 4.1: FDA's Classification of Devices and Recalls According to Risk

Risk	Device class	Recall class
High	3	I
Moderate	2	II
Low	1	III

Figure 4.1: Percentage of Recalls by Device Class Within Recall Class in Fiscal Years 1983-88[a]



[a]The numbers on which this figure is based are contained in table IV.4 in appendix IV

Source: FDA recall data tape.

Our empirical analysis of type of recalls by the class of medical devices produced the results shown in figure 4.1.

- High-risk devices were the subject of 153, or 9 percent, of all recalls.
- Medium-risk devices were associated with 1,203, or 74 percent, of all recalls.
- Low-risk devices totaled 278, or 17 percent, of all recalls.

Our analysis confirmed the expected relationship between a device's risk classification and its recall classification.

- High-risk devices were more likely to be among the most serious recalls, while low-risk devices were more likely to be among the least serious recalls.
- A substantial proportion, 67 percent, of class I recalls were associated with medium-risk devices (class 2), or those that require performance standards to ensure their safety and effectiveness.[2]

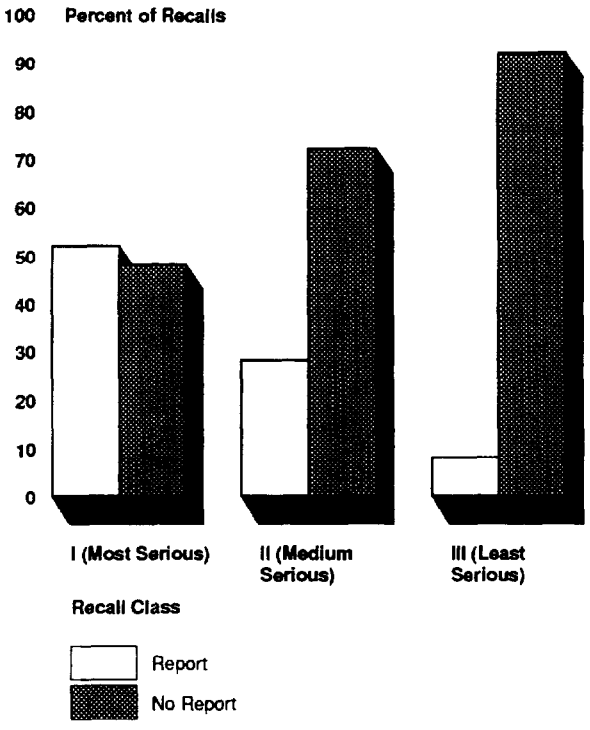
[2]In a previous report, we stated that no performance standards had yet been developed under the procedures detailed in the Medical Device Amendments of 1976 and that the failure to develop performance standards resulted in medium-risk devices under premarketing review being treated in the same manner as the relatively innocuous low-risk devices. The development of such standards would not necessarily have prevented the recall of the devices. See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14 (Washington, D.C.: August 1988).

Recalls and Reports of Medical Device Problems

The medical device reporting regulation, effective on December 13, 1984, requires that a problem report be submitted to FDA whenever a manufacturer or an importer of a medical device becomes aware of information that reasonably suggests that the device may have caused or contributed to serious injury or death or has malfunctioned and, if a malfunction recurs, is likely to cause or contribute to a serious injury or death.[1] FDA and the Congress envisioned that one of the principal benefits of the reporting requirements of the regulation would be its functioning as an "early warning" of device problems. Figure 5.1 shows the relationship between device recall classes and whether at least one problem report was filed by the manufacturer or importer through fiscal year 1988. Our analysis accounts for the 1,245 recalls made from fiscal year 1985 (when the regulation went into effect) through fiscal year 1988.

[1]See U.S. General Accounting Office, Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989), for a detailed discussion of the regulation.

Figure 5.1: Recalls for Which at Least One Medical Device Reporting Regulation Report Was Filed in Fiscal Years 1985-88[a]



[a]The numbers on which this figure is based are contained in table IV.5 in appendix IV.

Source: FDA recall data tape.

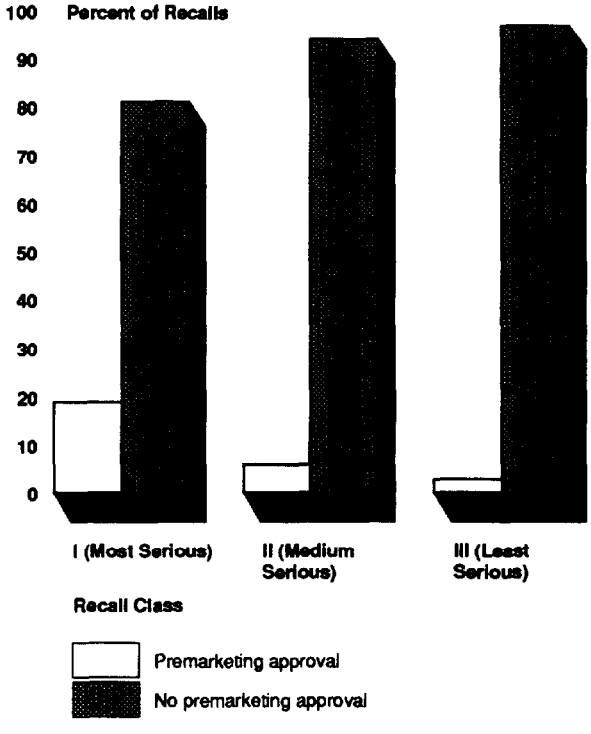
- Since the regulation has been in effect, 274, or 22 percent, of all recalls have had a report associated with them under the regulation.[2]
- There is a positive relationship between the recall class and the existence of a report. That is, the more serious the level of the recall, the more likely it is that a report has been associated with the device problem.
- Nonetheless, only 16, or 52 percent, of the class I recalls occurring in the years since the regulation went into effect have had a report associated with them.

[2]FDA's recall data tape indicates whether any medical device reporting regulation reports had been received when CDRH evaluates the health hazard posed by the device problem and classifies the recall, closing the case in its files. Reports received after the recall has been closed by CDRH are not reflected in these figures.

Recalls and Mode of Market Entry

Since the passage of the Medical Device Amendments of 1976, approximately 36,000 medical devices and device modifications have been marketed after having been reviewed by FDA. Of these, 94 percent were marketed after FDA, in a review process known as premarket notification (or 510(k) review), found them to be "substantially equivalent" to devices on the market prior to 1976.[1] The remaining 6 percent entered the market after undergoing the more stringent scientific and regulatory review required under the premarket approval route to market. Figure 6.1 shows the relationship between recall class and the mode of market entry.

Figure 6.1: Recalls of Devices With and Without Premarketing Approval in Fiscal Years 1983-88[a]



[a]The numbers on which this figure is based are contained in table IV 6 in appendix IV.
Source: FDA recall data tape.

[1]See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14 (Washington, D.C.: August 1988), for a detailed discussion of the premarketing review process.

- Overall, the proportion of devices that entered the market through the premarketing approval process (6 percent) is similar to the proportion of recalled devices that followed this process (5 percent).
- Generally, devices that entered the market through premarketing approval were more likely to be associated with a class I recall (higher risk) than either of the two other classes of recall.

FDA's Causal Attribution System

Analyses at FDA's Center for Devices and Radiological Health (CDRH) led FDA to develop a nine-class scheme of common device problem causes, in order to facilitate tracking and analyzing medical device recalls. Most recalls are assigned to one of the classes by CDRH analysts reviewing narrative statements of the causes of the device problem provided by the manufacturer. The cause classes, their definitions, and examples of each of them are shown in table 7.1.

Table 7.1: FDA's Classification Scheme for Causes of Device Problems

Problem cause	Cause definition	Example of cause
Design of a device, component, packaging, or labeling	One or more elements of design do not perform as intended during use, although the device meets the original approved design specifications; device was not adversely affected by the manufacturing process or the use of defective materials or components, and it was used properly according to labeling	The design of an infant crib was such that if it were improperly assembled or secured during use, an infant could be trapped and strangled between the crib side rails and its security top
Production control	Inadequate execution of the manufacturing plan, including actual implementation of manufacturing process, equipment maintenance, packaging operations, reprocessing procedures, storage and environmental conditions, and manufacturing material removal	The wires leading from the transformer to the circuit board in a multipatient dialysis unit were transposed, which could have resulted in an increase in the dialysate temperature and serious adverse health consequences or the death of a patient undergoing dialysis
Component control	The inclusion in a product of materials or components that are contaminated, degraded, out of manufacturer's specifications, or released prior to receiving conformance test results	A defect in the nickel-cadmium battery a vendor provided to a manufacturer caused the battery to fail prematurely in battery-powered defibrillators, exposing patients to delays in treatment, ineffective resuscitation, and death
Expiration dating and Radiation Control for Health and Safety Act of 1968	Incorrect or no expiration date on product or noncompliance with the 1968 act's standard	An automated cell counter (an in vitro diagnostic device) was distributed with expired components, with potential for misdiagnosis of mononucleosis; an X-ray machine was found not to be in compliance with performance standards for diagnostic X-ray machines, which could have resulted in excessive radiation exposure
Change control	A change is made in specifications, program, procedure, vendor, or the like that defined the component, device, packaging, labeling, software, process, and so on	An "E-clip" added to the oxygen flush valve of an anesthesia machine was intended to prevent the diaphragm from dislodging; however, after 6 months of service, the clip caused a distortion in the diaphragm, and the valve began to leak oxygen intermittently into the common outlet when the valve was closed, causing loss of life-support oxygen

(continued)

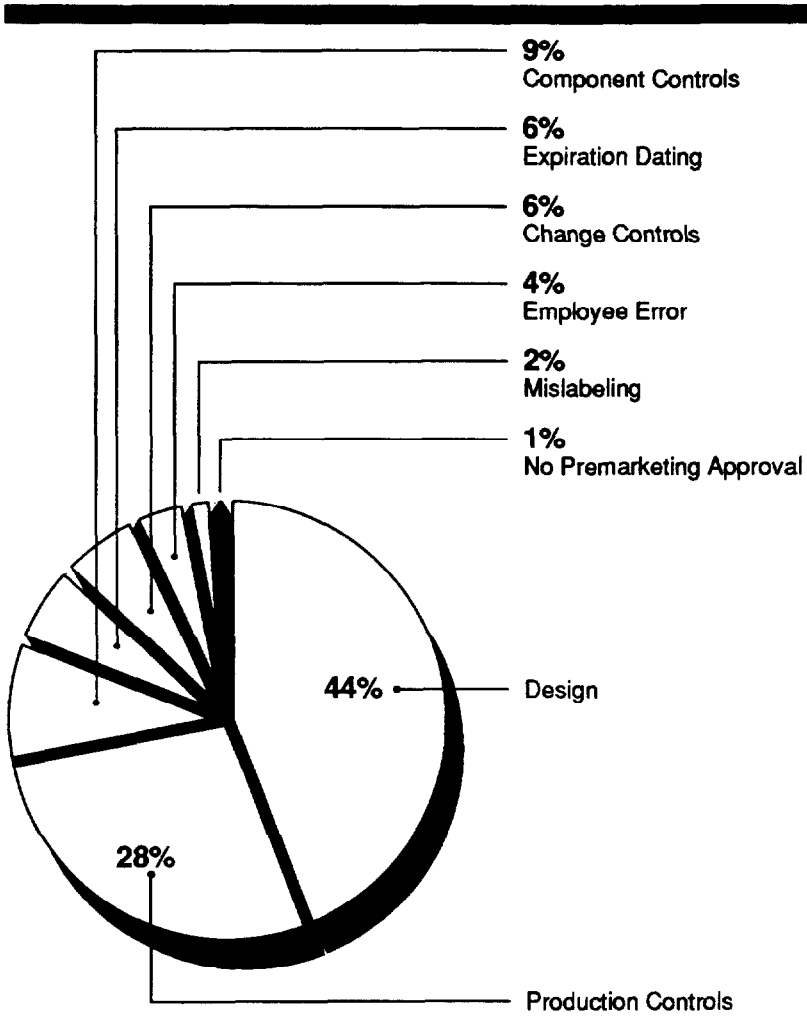
Problem cause	Cause definition	Example of cause
Training	Problem was caused by an inadvertent error made by an employee	A jumper wire was inadvertently added to a pacemaker printed wiring board, resulting in a bipolar rather than a unipolar pacer; therefore, the pacemaker was more susceptible to external and myopotential interference, which could have caused pacemaker malfunction, resulting in serious adverse health consequences or death
Misbranding	Labeling claims that misbrand the device; adequate directions for use cannot be written to allow lay persons or practitioners to use the device safely and effectively; labeling fails to bear adequate directions for use	A hearing aid was labeled with a claim that it could restore hearing for persons with 95-100 percent hearing loss, without any supporting evidence
Premarketing approval	Failure to apply for and obtain premarketing approval	An anesthesia machine was converted from one type of vaporizer and anesthetic agent to others for which it was not originally designed, without a 510(k) approval or application
Other	Miscellaneous; not covered by other categories	A serum produced by the Centers for Disease Control did not meet its standards because of instability of reagents; could have resulted in delayed diagnosis of rickettsia

Source: "Problem Cause/Solution Code Directory," CDRH, FDA.

The results of our analysis of recalls and the device problem causes associated with them for fiscal years 1983-88 are summarized in figure 7.1 on the next page.

- The most frequent cause of product recall was some element of product design, accounting for 715, or 44 percent, of all recalls.
- Problems with production controls accounted for 460, or 28 percent, of the recalls.
- No other cause accounted for more than 9 percent of the recalls.
- During our study period, problems with production and component controls increased while design problems decreased as a proportion of all causes of recalls.
- Noncompliance with the standards under the Radiation Control for Health and Safety Act of 1968 was a frequent cause of recalls in radiology, and good manufacturing practices problems were prominent in specialties such as ophthalmology and pathology, in which sterility controls are important.

Figure 7.1: Causes of Problems Leading to Device Recalls in Fiscal Years 1983-88[a]



[a]The numbers on which this figure is based are contained in table IV.7 in appendix IV.
Source: FDA recall data tape.

The Twenty Most Frequently Recalled Medical Devices

A medical device may be the subject of multiple recalls for the same or different problems.[1] Table 8.1 shows the 20 most frequently recalled devices in fiscal years 1983-88, in the order of their frequency; examples of the types of problems for which devices were recalled; and the health hazard associated with the problems.

Table 8.1: The Twenty Most Frequently Recalled Medical Devices in Fiscal Years 1983-88

Product description	No. of recalls	Example problem description[a]	Associated health hazard
1. Suntanning booth, bed, or lamp	33	Product incorporated timers with 60-minute maximum time intervals instead of the prescribed 15 minutes	Exposure to ultraviolet radiation for intervals longer than 15 minutes may cause severe sunburn and other adverse health effects
2. Ventilator	31	A firm changed the design of unit transformer but did not test unit at all operating conditions and so did not discover that the operation of the alarm caused circuit breakers to trip below stated ratings	Possible anoxemia and death if ventilation and alarm system fail without professional staff present
3. Intravenous (IV) administration set	28	The use of the wrong plastic material to manufacture component resulted in the failure to bond between components	Loss of IV fluid during administration
4. Infusion pump	23	The software did not check for direct current drops of the battery, a condition that occurs when the battery weakens; therefore, the unit's alarm did not function when the solution container became empty	Potential air embolism with resultant cardiopulmonary and neurological complications
5. Anesthesia breathing circuit	21	The contract manufacturer used defective plastic during production; several complaints reported occlusion of the face mask elbows with a plastic webbing blocking the flow of gas being administered	Hypoventilation, hypoxia, and other adverse health consequences; FDA determined that the risk level was moderate
6. Mobile diagnostic X-ray system	20	Noncompliance with regulation's beam quality requirements for adequate beam filtration	Overexposure of patient to radiation
7. Anesthesia gas machine	15	Leaking pressure-sensor shutoff valve and sample pump subject to failure	Complication of general anesthesia, including overdose, hyperoxia, hypoventilation, hypoxia, death
8. Implantable cardiac pacemaker	15	Sudden pacer interruption or cessation caused by growth of metallic "whiskers" from the silver or tin-copper compounds	Potential for serious adverse health consequences including death; according to FDA, product deficiency presents a moderate to high risk to patients dependent on pacemaker
9. Defibrillator battery pack	15	Diode failure created an electrical short-circuit, which causes the battery to fully discharge in a few hours	Potential delay in treatment of patient requiring defibrillation
10. Laser-powered surgical instrument	13	The units did not comply with laser performance standards; specifically, the system did not contain necessary safety features, including remote-control connector and beam attenuator for aiming the beams	Risk of patient's accidental exposure to laser radiation

(Continued)

[1]Different models of a device by the same manufacturer and competing manufacturers of the same generic device type may be subjected to separate recalls.

Product description	No. of recalls	Example problem description[a]	Associated health hazard
11. Fluoroscopic X-ray system	11	Units inadequately designed in that the tube selection (no activation light) was not properly indicated prior to exposure	Accidental exposure to radiation
12. Dialysate concentrate	11	The number and significance of good manufacturing practices deficiencies FDA found at firm indicated a lack of manufacturing controls; product exhibited bacterial and pyrogen contamination	High risk to certain hemodialysis patients; possible septicemia and endotoxin reactions
13. Percutaneous sheath (catheter) introducer kit	10	Introducer needle could separate from needle hub when used	Potential for needle embolism and surgical intervention
14. Prophylactics (condoms)	10	Analysis of sample revealed a defect rate exceeding allowable limits	Defects permit passage of microorganisms or sperm that could result in diseases and unwanted pregnancies
15. Ophthalmic laser	10	Laser did not conform to regulations and allowed accessible radiation from fan and fiber-optic ports	Limited potential for injury to patient and operator by laser radiation
16. High-energy defibrillator (including paddles)	9	Voids in epoxy allowed moisture to enter switch assembly, causing switches to malfunction or fail	Potential inability to defibrillate patient
17. Replacement heart valve	9	Inadequate welding procedures, validation, and stress testing resulted in strut failure	Patient's cardiac failure and death
18. Angiographic catheter	9	Defective lots were manufactured with a batch of raw virgin resin that lacked uniformity, and the tips of the catheters were found to be separating prior to use	Foreign body may be released into patient's vascular system, causing infection or damage to vascular structures
19. Calibrator for multianalyte mixture (IV automated system control)	9	Calibrator lower than label value; specifically, control values for sodium were high, causing erroneously high sodium results in patient's samples	Potential error in diagnosis and treatment of patients undergoing electrolyte, glucose, and nitrogen urea blood tests
20. Culture media	9	Inadequate environmental control in firm's clean-room and aseptic process led to microbial and mold contamination of product	FDA indicates that the contamination was unlikely to present a health risk

[a]Examples do not necessarily represent either the most common or the most serious problems experienced with a device.

Source: FDA recall data tape.

Class I Medical Device Recalls

Class I recalls are the most serious of the three classes of recalls. Unlike class II and III recalls, class I recalls occur in situations in which there is a strong likelihood that the use of or exposure to the product will cause serious adverse health consequences or death for the patient. Table 9.1 describes, in chronological order, all the class I recalls that occurred between fiscal year 1983 and fiscal year 1988.

Table 9.1: Class I Device Recalls in Fiscal Years 1983-88

Recall date	Medical specialty	Product description	Reason for recall	Health hazard	Quantity recalled
1. 10/13/82	Gastroenterology, urology	Bypass valve (hemodialysis machine)	Valve could fail to go into bypass mode	Patient experienced chest pain during hemolysis of blood; cardiac arrest possible	3,215 valves
2. 5/20/83	Anesthesiology	Carbon dioxide absorber	Exhalation port to breathing bag could block, preventing activation of oxygen flush valve	Overpressurization of lungs, hypoxia, arrhythmia, cardiac arrest, respiratory arrest, death	74,000 units
3. 6/20/83	Ophthalmology	Intraocular lens	Nonsterility	Infection	980 lenses
4. 6/21/83	Cardiovascular	Replacement heart valve	Strut failure	Cardiac failure, death	5,770 valves
5. 7/21/83	Anesthesiology	Anesthesia machine	Sticking spool valves could result in excessive or inadequate anesthesia delivery	Hypotension, hypertension, cardiac irregularities, hypoxia, respiratory or cardiac arrest, death	733 units
6. 8/1/83	Gastroenterology, urology	Catheter	Nonsterility	Infection	840 catheters
7. 8/31/83	Cardiovascular	Replacement heart valve	Strut failure	Acute cardiac failure or sudden death	7,400 valves
8. 10/30/83	Gastroenterology, urology	Dialysis unit	Possible miswiring of transformer circuit could cause increase in dialysate temperature	Serious adverse health consequences or death	96 units
9. 12/29/83	Cardiovascular	Pacemaker	Batteries might have shorter-than-predicted service life	Potential adverse health consequences, including death for pacemaker-dependent patients	10,878 pacemakers
10. 1/9/84	Physical medicine	Baby crib	Top might be incorrectly installed or secured	Entrapment of child, death	1,000 cribs
11. 1/18/84	Microbiology	Q-fever-positive human serum, 0.5-ml vials	Product might not meet Centers for Disease Control standard	Delay in diagnosis of rickettsia	210 vials
12. 1/30/84	Cardiovascular	Pacemaker	Devices could abruptly fail from shorting of timing crystal	Serious injury or death	Undetermined[a]

(continued)

Recall date	Medical specialty	Product description	Reason for recall	Health hazard	Quantity recalled
13. 6/7/84	General hospital	Pediatric crib	Design problem could pose risk of entrapment if improperly assembled or secured	Entrapment of infant between crib side rails and security top	76 cribs
14. 7/18/84	General hospital	Pediatric crib	Potential health hazard from design deficiencies and inadequate labeling	Child entrapment and strangulation; entrapment between crib side rails and security top	213 cribs
15. 10/2/84	Anesthesiology	Apnea monitor	Low respiration sensitivity alarm might not function as designed	Undetected apnea in infants; hypercarbia, anoxia, and death	7,000 units
16. 10/8/84	Anesthesiology	Anesthesia machine	Certain vaporizer turrets could develop a loose "T" handle, resulting in inaccurate vaporization of liquid anesthesia agents	Erratic anesthesia output to patient	73 units
17. 10/24/84	Anesthesiology	Silicone tubing	Stiff tubing that could prevent suction cut-off	Retinal tear and permanent loss of vision	674 units
18. 11/8/84	Anesthesiology	Positive pressure volume ventilator	Erratic or stopped cycling, sticking power switch and alarm, etc.	Potentially serious health consequences, including hypoxia or death	252 ventilators
19. 11/14/84	Anesthesiology	Calibrated vaporizers	Units might malfunction from failure of a component (thrust pin) of the temperature compensation mechanism	Overdose from failure of thrust pin	Undetermined[a]
20. 11/20/84	Anesthesiology	Oxygen flush valves	E-clip used in side valve could distort the internal diaphragm and cause an intermittent leak of oxygen	Inadequate oxygen supply resulting in hypoxia	90 valves
21. 2/8/85	General hospital	Apnea monitor and bradycardia detector	Apnea or bradycardia alarms might not sound when infant's breathing or heart rate slows or stops	Serious potential for apoxia, anoxia, and death in infants who have episodes of apnea	2,210 monitors
22. 3/13/85	Cardiovascular	Defibrillator[b]	Batteries could lose discharge capacity abnormally rapidly after being charged and then removed from the charger	Delay in treatment; serious adverse health consequences, including death	3,453 batteries

(continued)

Recall date	Medical specialty	Product description	Reason for recall	Health hazard	Quantity recalled
23. 4/9/85	Cardiovascular	Defibrillator[b]	Batteries could lose a substantial portion of their charge 1 hour to 4 days after being disconnected from the battery charger	Delay in treatment; serious adverse health consequences, including death	60 batteries
24. 4/19/85	Cardiovascular	Pacemaker	Potential for sudden loss of output	Exposes pacemaker-dependent patients to potentially serious adverse health consequences	28,931 pacemakers
25. 5/16/85	Cardiovascular	Defibrillator[b]	Batteries were contaminated with cobalt that could cause battery and defibrillator failure	Serious health consequences or death	8,200 batteries
26. 6/7/85	Gastroenterology, urology	Hemodialysis delivery system and monitor	Sticking or nonfunctional bypass valves	Failure resulting in hemolysis; unsafe dialysate; serious injury or death	12,300 units
27. 6/24/85	Cardiovascular	Defibrillator[b]	The batteries used in the defibrillator could lose part of their electrical charge after their disconnection from the battery charger	Battery failure could result in defibrillator malfunction, causing serious adverse health consequences or death	130 batteries
28. 6/27/85	Cardiovascular	Defibrillator[b]	Batteries could fail at a high rate; abnormally rapid loss of discharge capacity after being charged	Could result in defibrillator malfunction, which could result in serious adverse health consequences or death	152 batteries
29. 7/16/85	Anesthesiology	Vaporizer	Misbranding from conversion of the vaporizers for use with anesthetic agents other than those for which they were designed	Anesthetic overdose	23 units
30. 7/21/85	Cardiovascular	Defibrillator[b]	Premature nickel-cadmium battery failures	Health risk is moderate; defect would cause delay in treatment, which could result in death	3,145 batteries
31. 8/27/85	Gastroenterology, urology	Dialysate delivery system	Problems with bypass mode, blood pump, concentrate rods, and blood pump flow rate indicator	Failure during dialysis could result in serious injury or death	535 units
32. 10/7/85	Anesthesiology	Portable positive pressure respirator	Numerous reports of motor and alarm malfunction, circuit defects, and circuit boards falling out	Risk of serious adverse health consequences and death	5,304 respirators

(continued)

Recall date	Medical specialty	Product description	Reason for recall	Health hazard	Quantity recalled
33. 10/31/85	Cardiovascular	Replacement heart valve	Strut of the valves could fracture	Acute cardiac failure and death	2,752 valves
34. 11/6/85	Cardiovascular	Programmable cardiac pulse generator	Possible loss of function or telemetry from temperature sensitivity of the hybrid circuits	Serious health consequences to pacemaker-dependent patient; may require explantation	690 pacemakers
35. 11/6/85	Anesthesiology	Infant ventilator	Sudden unanticipated increase in positive-end expiratory pressure caused by a component failure	High probability of adverse health outcome	390 ventilators
36. 11/18/85	Cardiovascular	Defibrillator[b]	Battery pack with abnormally rapid loss of discharge capacity after being charged and removed from the charger	Unexpected battery failure may delay treatment; risk of death	Undetermined[a]
37. 7/30/86	Gastroenterology, urology	Sporicide-disinfectant for hemodialyzers	Gram-negative organisms found in dialyzer after use of the disinfectant; patients might experience pyrogen-like reactions and bacteremias	Possible pseudomonas, bacteremia, and pyrogen reactions in dialysis patients; mild to severe reactions	4,000 cases
38. 4/20/87	Cardiovascular	Pacemaker	Sudden output failure caused by "tin whiskers"	Potential for serious adverse health consequences, including death; moderate to high risk, especially for pacemaker-dependent patients	3,727 pacemakers
39. 6/3/87	Radiology	Medical linear accelerator	Software defects could cause fatal, massive, radiation overdoses	High risk of massive radiation overdoses to patients	5 accelerators
40. 8/24/87	Cardiovascular	Implantable pacing leads	Increased lead failure rate manifested by over- and under-sensing, loss, and failure to capture	Intermittent or complete failure to sense or pace	2,197 leads
41. 8/28/87	Cardiovascular	Blood oxygenator with integral filter	Outlet connector of venous reservoir could be loosened to allow air and fluid leakage	Moderate risk of serious adverse health consequences; blood loss or air leakage into extracorporeal circuit	7,218 units
42. 9/29/87	Anesthesiology	Respirator, neonatal ventilator	Could stop functioning during use and take on burnt odor; might develop internal fire	High risk of serious adverse health consequences	65 respirators

(continued)

Recall date	Medical specialty	Product description	Reason for recall	Health hazard	Quantity recalled
43. 10/31/87	Cardiovascular	Pacemaker	Pacemaker failures reported: high rate, no output, no sensing, loss of interrogation capability and telemetry	Improper pacing rate and failure to pace, with high risk of serious adverse health consequences	1,911 pacemakers
44. 3/8/88	Gastroenterology, urology	Sorbent regenerated dialysate delivery system for hemodialysis	Could infuse unsafe levels of potassium or calcium into dialysate because of possible malfunction of sensor in infusate system	Overinfusion of potassium and calcium into dialysate	304 units
45. 3/29/88	Anesthesiology	Volume ventilator	Device had been involved in reports of fire from defective main solenoid	Hypoxia, poisoning, burns, or death	1,467 ventilators
46. 4/7/88	Anesthesiology	Respiratory monitor	Monitor alarm could fail	High risk of serious adverse health consequences and death	4,963 monitors
47. 6/13/88	Cardiovascular	Replacement heart valve	Defective valves from leaflet escape	Sudden congestive heart failure and death if emergency reoperation is not performed	26,000 valves
48. 7/19/88	Cardiovascular	Replacement heart valve	Mechanical failure resulting from disc fracture	High risk of congestive heart failure and death if no emergency reoperation	317 valves

[a]The units being recalled were not clearly indicated in the "quantity recalled" field of the data base

[b]Some recalls were listed in the FDA data base as "defibrillators" and others as "defibrillator batteries." Because some of the former also appear to concern battery problems and because there has been controversy over the accuracy of FDA's descriptions of recalls (see Biomedical Safety and Standards, 19:7 (April 1, 1989), 50-51), we have listed all class I recalls as "defibrillators," but this should be understood to cover cases in which only battery packs or other components were recalled.

Source: FDA recall data tape.

Summary

Our review and analysis of medical device recalls between 1983 and 1988 was based on a total of 1,635 recalls. Class II (medium-serious) recalls were the most frequent at 1,026. This was followed by 561 class III (least-serious) and 48 class I (most-serious) recalls. The annual number of recalls fluctuated during the 6 years. Prior to 1985, the annual number of recalls did not exceed 200; after 1985, the annual number of recalls was near or above 300. Several speculative explanations for the increase have been offered, such as the implementation of the medical device reporting regulation in December 1984, the increasing complexity of medical devices, and FDA's greater postmarketing surveillance efforts. The descriptive design of our study did not allow the attribution of the increase to any one cause or combination of causes.

During the study period (1983-1988), 97 percent of the device recalls involved circumstances in which FDA analysts judged serious adverse health consequences to be unlikely or remote (recall classes II and III). Devices from every medical practice specialty area were the subject of at least one recall. However, recalls in 8 of the 19 medical practice specialties accounted for 80 percent of all recalls. The top 2, cardiovascular and anesthesiology, accounted for 27 percent of the recalls. The devices that were recalled ranged from high-risk, implantable, life-supporting devices such as replacement heart valves through medium-risk devices such as suntanning booths to low-risk dental irrigation syringes. Our analysis showed that all classes of devices—including some devices that are generally considered relatively innocuous—can be associated with problems potentially leading to serious health consequences or death.

Based on final regulations, approximately 53 percent of the devices that existed prior to the Medical Device Amendments of 1976 were placed in class 2 (medium-risk); class 1 (low-risk) devices represent about 38 percent of the total; class 3 (high-risk), 9 percent. However, we found that 74 percent—a disproportionate share—of all recalls were related to class 2 devices. Additionally, we found that the majority of the most serious recalls (class I) were associated with devices for which performance standards have been mandated but not developed by FDA (class 2). Devices that entered the market through the premarketing approval process were more likely to be associated with a class I recall than with either of the other recall classes. Because such devices often employ more complex technology or are more directly related to life support than other devices, such a relationship is to be expected.

Although the more-serious recalls were more likely to have a medical device reporting regulation report associated with them, only half of

even class I recalls had a report associated with them when FDA evaluated the health hazard posed by the device problem and classified the recall, closing the case at CDRH. Thus, FDA became aware of the great majority of device problems associated with a recall in some way other than through the medical device reporting regulation reports and did not have the reports available in the majority of cases when decisions were made about the health hazard and classification of recalls. This suggests that the reports have not served as an effective "early warning" of device problems serious enough to warrant a recall.

According to FDA, problems with design and production were the cause of nearly three fourths of all recalls. Because the proposed solutions to the problems identified in the recalls were not systematically included in FDA's automated data bases, we were not able to analyze their characteristics or appropriateness.

Evaluating the operations, efficiency, and effectiveness of the recall process was beyond the scope of this study. In a future report, we intend to address this and other issues, such as the adequacy of FDA's and device firms' problem-solving efforts. If necessary, we intend to suggest ways of improving the overall recall system.

Request Letter

Congress of the United States
House of Representatives
Committee on Energy and Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515

February 7, 1989

The Honorable Charles Bowsher
Comptroller General
U.S. General Accounting Office
441 G St., N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

I would like to take this opportunity to thank you and your staff from the Program Evaluation and Methodology Division for preparing for me the very excellent U.S. General Accounting Office (GAO) report "Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation." The timely and comprehensive analysis of FDA's major tool for the postmarketing surveillance of medical devices contained in the GAO report will make a significant contribution to this Subcommittee's work in the 101st Congress.

As a result of the findings contained in the medical device regulation report, the Subcommittee requested GAO last year to conduct a follow-up study of FDA's procedures for responding to identified problems with medical devices through the medical device recall process. Specifically, we asked GAO to conduct in-depth case studies of a selected sample of devices, in order to assess the adequacy of existing recall procedures and guidelines. In consultation with the Subcommittee staff, GAO agreed that the sample of devices would include but not be restricted to life-sustaining and implanted devices such as cardiac pacemakers, pacemaker leads and replacement heart valves. On January 23, 1989, your staff provided the subcommittee staff a comprehensive oral briefing on the results of their planning efforts for this job.

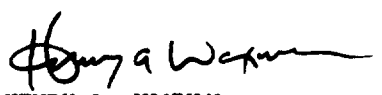
As Chairman of the Health and Environment subcommittee--which has jurisdiction over FDA's medical device activities--I request that your Program Evaluation and Methodology Division extend their audit work for the current study of device recalls to include a descriptive analysis of the device recalls that have been reported to FDA since the promulgation of the MDR rule. This analysis should include a determination of which devices have been recalled, the problems for which they were recalled, how the devices reached the market, that is, through premarket approval or premarket notification (510(k)), and descriptions of the problem solving efforts of FDA and device manufacturers.

In order to meet the Subcommittee's immediate information needs and as one basis of selecting a broader sample of devices for in-depth case studies which could be generalized to the overall recall process, this background analysis should be conducted and reported to the Subcommittee on a priority basis.

Thank you for your cooperation. If you have any questions about this request, please contact Dr. Peter Budetti at 226-7620.

With every good wish, I am,

Sincerely,



HENRY A. WAXMAN
Chairman, Subcommittee on
Health and the Environment

HAW/pbp

Sources and Quality of Data

CDRH maintains the two computerized data bases that were the sources of information we used. The first is the "recall" data base, which is similar to other postmarketing surveillance data bases such as the medical device reporting and problem-reporting program data bases. It was set up primarily to track the processing of individual device recalls at FDA. The second is the "problem" data base, set up to facilitate the recording and analysis of information about device problems that have led to recalls. The complete documentary record for each medical device recall is kept only on paper and microfiche files maintained at FDA's Center for Devices and Radiological Health, but these records are not as accessible for systematic study as the computerized records are.

According to FDA officials, because the recall data base was set up to track the dates of recall-processing events rather than for information storage, it does not contain all the information necessary to reconstruct a recall's history. FDA officials told us that they planned to link the "recall," "problem," "medical device reporting," and "problem-reporting" data bases into one integrated system. However, since the proposed data base integration had not been accomplished at the time of our study, we requested that selected data fields from the two computerized data bases be combined in a single data file.

Our evaluation of the quality of the data in the automated files confirmed FDA's cautions about the use of the data bases. Problems with the data imposed some limits on our analysis and should be borne in mind in interpreting the results. The computerized records related to medical device recalls were described as incomplete and unverified. Within them, many data fields have been deleted since the data bases were first established, and others that would have been useful in our review are not mandatory and were often blank. For a number of data fields that would have provided important information about, for example, the health consequences of device problems, data were missing so frequently that they were unusable. These missing data do not detract from the analyses we did conduct but prevented us from conducting others that were suggested by our initial examination of the listed data fields.

The file also included an undetermined number of data entry errors. FDA officials indicated that CDRH plans a general cleanup of information in the recall data bases, in which information will be verified against hard copy files, but this process was not complete at the time of our study. We did not attempt a complete, systematic error correction as a preliminary to our analyses, but we did locate and, in consultation with CDRH

staff, correct obvious errors such as transposed digits in codes, and we eliminated 17 records that were missing their control numbers as well as information for most other fields. We determined that they represented preliminary records of events that turned out not to be recalls, were not concerned with devices regulated by CDRH, or were aborted data entries. CDRH staff concurred with our decision to drop these records.

Neither the interrater reliability nor the internal consistency of reviewers' and analysts' use of the codes were assessed, but we did observe several instances in which there appeared to be some inconsistency. Different product codes were assigned to what appeared to be the same products: for example, we found different product codes for each of several recalls of "ophthalmic lasers," and "pediatric cribs" were sometimes assigned different product codes or assigned to different medical specialties.

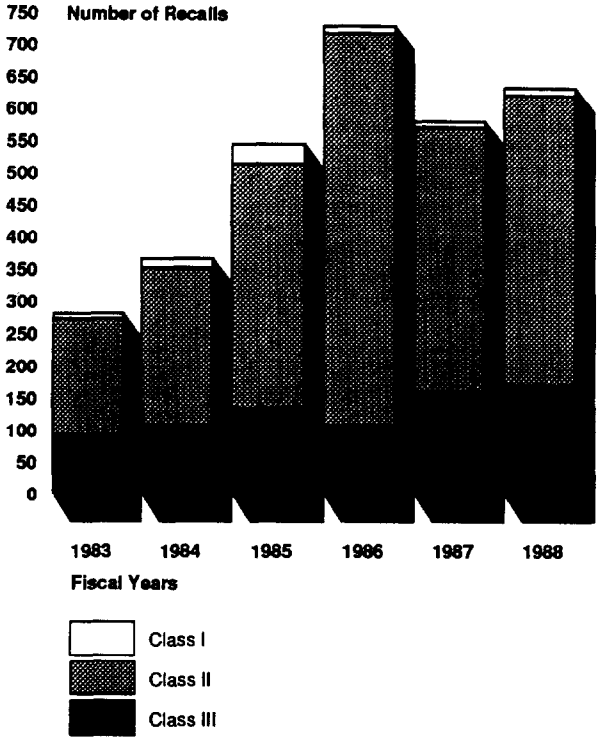
Even after our effort to reduce the number of recalls to an approximation of the number of different occasions in which a single device type was recalled by a particular manufacturer on a particular date for a single reason (see appendix III), there were a number of records that appeared to be describing "the same" or very similar recalls in slightly different words or appeared to be distinguished only by somewhat different recall dates. We could not verify that these different records did not in fact refer to the same "recall." These particular recall events may be seen in the list of class I recalls in table 9.1.

Methodology for Determining the Total Number of Recalls

Differences of opinion are possible over the most appropriate definition of recall. For tracking and processing, FDA typically counts and records each recall of a different device "model" as a separate recall. If, as happened in one case, a firm recalls 110 models of a catheter on the same day because all are subject to the same problem, 110 separate "recalls" would each be assigned its own "control number" and entered into the recall and problem data bases.

The 3,127 records on the data tape provided by FDA represent all such distinct recall control numbers, many of which may refer to the same "recall event" and contain identical information. We chose to combine all recalls of a single device type that occurred on the same date and for the same problem. FDA analysts agreed that this procedure provides a reasonable definition of "recall," and they said that at times they collapse the information in the data bases in similar ways for summary purposes. See figure III.1 for a summary of FDA's count. See also tables IV.1 and IV.2 for a detailed contrast of our tabulation and FDA's count of recalls.

Figure III.1: FDA's Count of Device Recalls by Recall Class[a]



[a]The numbers on which this figure is based are contained in table IV.2 in appendix IV.
Source: FDA recall data tape.

The total number of recalls we used in our analysis is 1,635, or about 50 percent less than the number of cases recorded on the data tape FDA gave us. If a firm recalls one model of a device, and then a few days later decides to recall other models that might be subject to the same problem, these two events would still be counted as "two recalls" by our procedures, since they did not conform to our criteria for combining events. Our review of the data tape showed a number of cases for which it appeared that new recalls were counted for devices that could have been included in a previous recall.

Because, in addition, firms are not required to report recalls to FDA, there could have been more recalls than we counted or even than FDA knew about. According to one industry publication, products are "informally" called back from the market without a notification to FDA.

Tables Supporting Figures

Table IV.1: Our Count of Device Recalls by Recall Class[a]

	1983		1984	
Recall class	No. of recalls	Percent	No. of recalls	Percent
I	7	4%	8	4%
II	110	58	114	62
III	73	38	64	34
Total	**190**	**100%**	**186**	**100%**

Table IV.2: FDA's Count of Device Recalls by Recall Class[a]

	1983		1984	
Recall class	No. of recalls	Percent	No. of recalls	Percent
I	8	3%	13	4%
II	177	63	241	66
III	94	34	111	30
Total	**279**	**100%**	**365**	**100%**

1985		1986		1987		1988		All 6 years	
No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent
15	5%	7	2%	5	2%	6	2%	48	3%
189	64	228	70	197	59	188	62	1,026	63
90	31	93	29	132	40	109	36	561	34
294	**100%**	**328**	**100%**	**334**	**100%**	**303**	**100%**	**1,635**	**100%**

[a]Data are for figure 2.1. Some percentages do not total 100 because of rounding.
Source: FDA recall data tape.

1985		1986		1987		1988		All 6 years	
No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent
30	6%	10	1%	9	2%	12	2%	82	3%
378	70	609	84	408	70	449	71	2,262	72
135	25	110	15	162	28	171	27	783	25
543	**100%**	**729**	**100%**	**579**	**100%**	**632**	**100%**	**3,127**	**100%**

[a]Data are for figure III.1. Some percentages do not total 100 because of rounding.
Source: FDA recall data tape.

Table IV.3: Device Recalls by Medical Specialty in Fiscal Years 1983-88[a]

Medical specialty	No. of recalls	Percent	Cumulative percent
Cardiovascular	226	14%	14%
Anesthesiology	213	13	27
General and plastic surgery	165	10	37
Chemistry	156	10	47
General hospital	150	9	56
Gastroenterology and urology	148	9	65
Radiology	137	8	73
Microbiology	112	7	80
Ophthalmology	55	3	83
Hematology	44	3	86
Pathology	38	2	88
Physical medicine	34	2	90
Neurology	29	2	92
Orthopedics	27	2	94
Obstretics and gynecology	26	2	96
Immunology	24	1	97
Dental	18	1	98
Toxicology	18	1	99
Ear, nose, throat	15	1	100
Total	**1,635**	**100%**	

[a]Data are for figure 3.1.

Source: FDA recall data tape.

Table IV.4: Percentage of Recalls by Device Class Within Recall Class in Fiscal Years 1983-88[a]

	Recall class							
	I		II		III		Total	
Device class	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent
1 (low risk)	0	0%	136	13%	141	25%	278	17%
2 (medium risk)	32	67	792	77	379	68	1,203	74
3 (high risk)	16	33	97	9	40	7	153	9
Total	**48**	**100%**	**1,025**	**100%[a]**	**560**	**100%**	**1,634[b]**	**100%**

[a]Data are for figure 4.1. Some percentages do not total 100 because of rounding.

[b]One recalled device was recorded as "product class 0" because it was released under an investigational device exemption and had not yet been classified.

Source: FDA recall data tape.

Table IV.5: Recalls for Which at Least One Medical Device Reporting Regulation Report Was Filed in Fiscal Years 1985-88[a]

	Report		No report		Total	
Recall class	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent
I	16	52%	15	48%	31	3%
II	223	28	569	72	792	64
III	35	8	387	92	422	34
Total	**274**	**22%**	**971**	**78%**	**1,245[b]**	**100%**

[a]Data are for figure 5.1. Some percentages do not total 100 because of rounding.

[b]Information on whether a report had been filed was missing for 14 of the 1,259 recalls recorded for the fiscal years 1985-1988. A total of 376 recalls occurred during fiscal years 1983 and 1984, before the regulation was implemented.

Source: FDA recall data tape.

Table IV.6: Recalls of Devices With and Without Premarketing Approval in Fiscal Years 1983-88[a]

	Approval		No approval		Total	
Recall class	No. of recalls	Percent	No. of recalls	Percent	No. of recalls	Percent
I	9	20%	37	80%	46	100%
II	58	6	943	94	1,001	100
III	17	3	531	97	548	100
Total	**84**	**5%**	**1,511**	**95%**	**1,595[b]**	**100%**

[a]Data are for figure 6.1.

[b]Information on whether there was premarketing approval for the device was missing for 40 recalls.

Source: FDA recall data tape.

Table IV.7: Causes of Problems Leading to Device Recalls in Fiscal Years 1983-88[a]

FDA's classification of recall cause	No. of recalls	Percent	Cumulative percent
Design	715	44%	44%
Production controls	460	28	72
Component controls	153	9	81
Expiration dating	102	6	87
Change control	92	6	93
Employee error	59	4	97
Mislabeling	36	2	99
No premarketing approval	14	1	100
Other	4	0	
Total	**1,635**	**100%**	

[a]Data are for figure 7.1.

Source: FDA recall data tape.

Major Contributors to This Report

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