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

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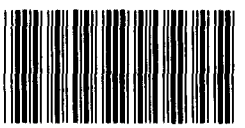
MEDICAL TECHNOLOGY

For Some Cardiac Pacemaker Leads, the Public Health Risks Are Still High



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Program Evaluation and
Methodology Division

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September 23, 1992

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

Dear Mr. Chairman:

On March 5, 1991, you asked us to investigate a citizen's report to us of deficiencies in the actions of the Food and Drug Administration (FDA) that preceded the 1984 recall of the model 6972 cardiac pacemaker lead manufactured by Medtronic. (See appendix I.) You also asked us to assess the extent of any continuing threat to public health posed by 14 other Medtronic pacemaker lead models that contained the same technological characteristics as the model 6972.

As of 1984, 15 new Medtronic polyurethane-insulated pacemaker leads had been marketed since the first was introduced in 1977. Because each new lead was determined to be "substantially equivalent" to a previously marketed lead, including the model 6972 introduced to the market in 1979, each one "piggybacked" on its predecessors through FDA's 510(k) review process. This process does not require FDA to determine that any of these models are safe and effective—and FDA has not done so.[1]

Objectives

With the concurrence of the Subcommittee staff, we pursued answers to the following questions:

1. How adequate were FDA's information base and decision-making process for its assessment of the health risks posed by the polyurethane insulation used in 15 Medtronic polyurethane-insulated lead models?

2. How adequate were FDA's efforts to ensure that patients who were implanted with the model 6972 or similar leads were notified of potential safety problems?

[1]The 15 lead models consist of six atrial leads (4502, 4511, 6957J, 6990U, 6991U, 4512), one myocardial lead (4951), and eight ventricular leads (4002, 4011, 4012, 6957, 6959, 6971, 6972, 6993). (See "atrial," "myocardial," and "ventricular lead" in the glossary.)

3. To what extent do existing FDA policies, procedures, or regulations serve as an "early-warning" function for potential problems with pacemaker leads?

4. What, if any, are the incremental health care costs to the federal government for defective pacemaker leads?

This letter presents our findings, conclusions, and recommendations. (See appendix II for a discussion of our study scope and methodology.)

On April 21, 1992, we provided FDA with the findings of our analysis of potential problems with certain pacemaker leads, and since then, FDA has taken several actions. In May 1992, the agency sent letters to all manufacturers and importers of pacemaker leads notifying them that postmarket surveillance is required for all models of permanent implantable pacemaker leads on the market in the United States on or after January 1, 1982, regardless of their current marketing status. In June 1992, FDA issued a 518(a) letter to Medtronic regarding the model 6990U lead performance and held consultations with Medtronic officials.[2] FDA has also contacted Intermedics about the performance of its model 486-01.

Results in Brief

GAO found that FDA did not have an information base equal to the task of accurately assessing the health risks posed by the 15 Medtronic lead models. Before the model 6972 recall, FDA did not have the appropriate data—nor did it request the collection of such data—to adequately evaluate the risk posed by the polyurethane insulation used in these leads. FDA's reliance on the manufacturer to voluntarily provide the appropriate data for analysis resulted in several months' delay in removing the model 6972 from the market. A total of 43,248 model 6972 leads were manufactured and sold from July 1979 through March 1984. And from October 1983, when Medtronic became aware of potential defects, to March 1984, when it ceased marketing the device, nearly 2,500 units were sold and patients were unnecessarily exposed to the risk of lead failure. Further, the polyurethane insulation and manufacturing problems with the pacemaker leads that became evident in the early 1980s continue to occur today.

FDA's efforts to ensure that patients receiving pacemaker leads knew about potential safety problems did conform with existing policies and

[2]The 518(a) letter is an FDA request to a device manufacturer to notify device users of an unreasonable risk of substantial harm to the public health associated with its product.

procedures. Nonetheless, a substantial number of patients still were not informed about potential problems with their device. These patients included those who were implanted with one of the 15 Medtronic leads, as well as those implanted with various other makes and models with similar technological characteristics. Patients whose heartbeat absolutely depends on a properly functioning pacing system could experience adverse health consequences ranging from light-headedness to loss of consciousness to death.

We estimate that 103,400 patients received one of the Medtronic recalled or safety-alerted model leads—4002, 4012, 6972, and 6991U—or the 6990U model, which has not been recalled or safety-alerted, but which we found to be experiencing a failure rate of 7 percent or higher.[3] This means that 7 out of every 100 of these patients will likely experience a lead failure.

FDA's current policies and procedures for monitoring the postmarket safety and effectiveness of pacemaker leads do not provide the agency with an adequate early warning of potential problems. There is at least one case, involving several thousand patients, in which FDA's current policies and procedures have failed to identify leads, currently in use, that may be seriously defective. (See below, Principal Findings, question 3.)

We estimate that the minimum potential cost to the federal government through the Medicare program for additional medical services required by the possibly defective leads identified in our review is between $50 million and $56 million.

Background

A cardiac pacemaker is a medical device consisting of two components that are permanently implanted in the body to assist the heart's natural beat. One of them is a pulse generator, which produces an electric pulse. The other is one or more leads inserted through a blood vessel, which transmit small electric pulses to the heart and return electrical signals to the pulse generator. In this report, we discuss the second component of a pacemaker, the lead.

Current estimates indicate that there are nearly one-half million people in the United States with implanted pacing systems. The majority are 65 and older and are eligible for coverage under the Medicare program,

[3]The failure rates for those recalled or safety-alerted models were provided by the manufacturer and cited by FDA as the basis for its decisions to recommend a recall or safety alert. We obtained the model 6990U's failure rate from the Implantable Lead Registry data base maintained by the Montefiore Medical Center in New York. (See appendix IV.)

administered by the Health Care Financing Administration (HCFA). In most cases, the pacing system has been prescribed to improve a patient's quality of life by allowing greater activity and providing symptomatic relief from a variety of problems associated with inadequate heart functioning. However, between 5 and 30 percent of patients receiving pacemakers are "dependent" on their pacing system, and its failure could result in serious injury or death.[4] The term "pacemaker dependency" has been used to indicate which patients are at a substantial risk should a pacing system fail. For practical purposes, a patient is pacemaker-dependent if the sudden loss of pacing would result in serious injury or death, but widely different definitions are used by experts. (See "pacemaker dependency" in the glossary.)

Between February and July 1984, Medtronic ceased marketing—and recalled—its model 6972 pacemaker lead because it was prone to failure from insulation or wire breakage as a function of its design, insulation material, or manufacture. When the insulation material around the lead cracks or otherwise fails, bodily fluids can reach the metal wires and interrupt the flow of small electrical pulses. A short circuit between the outer and inner insulation can also cause rapid depletion of the pulse generator battery. Thus, the benefit of the pacemaker would be lost, either totally or intermittently. (See "polyurethane degradation" in the glossary.)

On March 13, 1984, the House Subcommittee on Oversight and Investigations conducted a hearing on issues related to the safety and effectiveness of medical devices. The hearing was a follow-up to a 1982 congressional oversight inquiry into FDA's administration of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1938 and a 1983 Subcommittee report on medical device regulation.[5]

The focus of the 1984 hearing was a case study of the Medtronic model 6972 pacemaker lead and related issues. During the hearing, the Subcommittee reviewed FDA actions in allowing the device to be first marketed, in monitoring the increasing number of reports of problems with the device, and in responding to the need to inform and protect the

[4]See Seymour Furman, "Pacemaker Follow-up," Modern Cardiac Pacing, S. Barold, ed. (Mt. Kisco, N.Y.: Futura Publishing Company, 1985), pp. 889-918.

[5]U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, FDA Oversight: Medical Device Hearings, July 16, 1982, 98th Cong., 1st sess. (Washington, D.C.: U.S. Government Printing Office, 1982) and Medical Device Regulation: The FDA's Neglected Child, An Oversight Report on FDA's Implementation of the Medical Device Amendments of 1976 (Washington, D.C.: U.S. Government Printing Office, 1983).

public.[6] The Subcommittee also reviewed the actions of the device manufacturer to ascertain whether it had met the requirements of the law and whether it had behaved responsibly in light of the facts. Since the 1984 hearing, we have received additional information from several sources that suggest that many of the public health and congressional concerns raised during the hearing have not been adequately resolved. The sources include reports from individuals, device industry publications, consultations with our expert review panel, and the results of our series of related studies since the hearing. (See Related GAO Products at the end of this report.)

Since 1984, FDA has issued three additional safety alerts for polyurethane-insulated pacemaker leads because of problems similar to those of model 6972. The latest was issued in September 1991. Each of these safety alerts involved leads from a set of 15 devices manufactured by Medtronic that were identified during the 1984 hearing as potentially defective. Additionally, several models manufactured by other firms have been subject to a device safety alert and recall because of similar problems.

Principal Findings

Question 1: Adequacy of Information and Decision-Making

In February 1984, FDA classified Medtronic's recall of the model 6972 pacemaker lead as a class II recall. In May 1984, the agency upgraded the recall to a class I. (See "recall" in the glossary.) FDA had received estimates of the number of deaths that could occur as a result of lead failure from its Health Hazard Evaluation Committee, convened to evaluate certain Medtronic lead models. FDA's February and May 1984 decisions to classify Medtronic's actions as recalls were based on the best data available to FDA. However, the agency could have requested—but did not—that the manufacturer provide a critical component of the information upon which the decisions were based: clinical failure rate data, information the manufacturer already had.

Both the manufacturer and FDA recognized that the type of problems with the model 6972 lead could be generic to the technology of polyurethane

[6]Department of Health and Human Services (HHS), Office of the Inspector General, "Review of the Food and Drug Administration's Actions Relative to the Recall of the Medtronic Model 6972 Pacemaker Lead," A-03-86-62006 (July 1987) and "Follow-up Review of the Food and Drug Administration's Actions Relative to the Recall of the Medtronic Model 6972 Pacemaker Lead," A-03-90-00613 (October 16, 1990).

insulation and that other models with similar technology may be at risk of unacceptable rates of failure. In 1982, the agency undertook laboratory and animal studies of the polyurethane-insulated leads to determine whether polyurethane insulation would degrade and cause a break in the wire or insulation within an unacceptably short period of time.

Additionally, in 1982, FDA acknowledged the critical importance of clinically-based failure rate information for accurately assessing the risk of pacemaker leads. However, FDA decided to use its traditional sources for postmarket information—sources that did not include clinical experiences. FDA reviewed user complaints from manufacturers' files and other postmarket surveillance information, including manufacturers' analyses of explanted and returned leads. (The clinical difficulties and medical risks involved in explanting leads from the heart preclude the removal and return of most leads. Therefore, explant analysis is unlikely to provide an accurate estimate of the number and causes of lead failures.)

FDA concluded that its studies did not demonstrate consistent problems with polyurethane, nor establish whether a polyurethane-insulated lead was more likely to fail than silicone-insulated leads. Further, study results did not allow the agency to determine if there were design and material weaknesses in model 6972 leads. FDA's review did not indicate any lead performance problems with other model leads that would suggest the need for additional studies or regulatory action.

As noted, in 1984, FDA convened a Health Hazard Evaluation Committee to evaluate the health risk that might be associated with Medtronic pacemaker lead models 6990U, 6991U, and 4502. In 1985, FDA convened another committee to assess the risk posed by the model 4002. These committees concluded that no regulatory action was needed. Since 1987, Medtronic has reported in its "Product Performance Report" that the model 6990U's performance did not match its other atrial leads' performance and noted that while insulation failures had been detected, they had occurred primarily in the outer insulation where the model 6990U's frequent use with certain pacemaker generators would not impair the clinical functioning of the pacing system.

Our research showed that, as early as 1982, explanted pacemaker leads and physician complaints indicated that there were problems with the model 6972. From 1982 through 1984, Medtronic tried, but failed, to determine the cause of those problems. As of May 1983, the company recognized that explanted leads could not provide an accurate failure rate

assessment and began collecting clinically-based data. Medtronic completed its clinically-based study in October 1983, which officials said contradicted its analyses of explanted leads, which did not indicate a problem. However, while Medtronic had clinical data showing a high failure rate, it did not inform FDA of these results until February 1984. In March, FDA issued a cease-marketing order on the model 6972. This 5-month delay allowed nearly 2,500 potentially defective devices to be marketed.

Three years later, based primarily on data produced by the manufacturer, at least two additional leads of the 15 Medtronic models we studied were found by FDA to pose a public health risk. On the basis of the FDA's analysis of clinically-based failure rate changes over time, the agency decided that a potentially serious public health risk existed and requested that Medtronic issue a safety alert for models 4002 and 6991U in 1987. The design and manufacturing problems associated with the failures of models 6972, 4002, and 6991U tended to occur early in the life of the lead—2 to 3 years after implant. The 6972 failure rate increased rapidly after 1 year, and after several years, remained steady. (A failure rate, an indicator of the risk of lead failure, is the proportion of all implanted leads that failed. See "failure rate" in the glossary.) Model 4002 exhibited a failure rate of over 9 percent 4 years after implant, and model 6991U exhibited a failure rate of nearly 12 percent 5 years after implant. These are clinically-based failure rates plus other implant-related complications obtained from Medtronic's Chronic Lead Study published in its "Product Performance Report" in October 1986.

Since 1986, other pacemaker lead manufacturers have also recalled various models of their product. Intermedics recalled five models of pacemaker leads for problems related to polyurethane insulation: model 431-02 in September 1986 and models 476-04, 476-06, 484-02, and 484-03 in July 1987. In 1989, Cordis also recalled its Encor Bipolar Active Fixation lead due to insulation separation problems. Later in 1991, Pacesetter recalled two of its lead models for polyurethane insulation problems: models 1016T and 1026T. The number of leads manufactured for these models is not publicly available.

Medtronic model 4012, which was initially marketed in 1983, was put on safety alert in 1991 for reasons similar to the problems with the models 6972, 4002, and 6991U. All 15 Medtronic models have the same polyurethane insulation formulation—Pellethane 2363-80A. (Pellethane, discussed in appendix III, is a registered trademark of the Dow Chemical

Co., and the code 2363-80A represents the specific series and formulation of polyurethane elastomer.) Three of the four recalled or safety-alerted models (4002, 4012, and 6972) are bipolar in design; model 6991U is unipolar. (See "bipolar and unipolar leads" in the glossary.)

Singularly or in combination, these two characteristics—Pellethane 80A and bipolar design—may be critical factors in pacemaker lead longevity.[7] Other manufacture-related factors that may affect pacemaker lead failure are insulation and conducting materials, treatment of the component materials, and differences in the manufacturing processes. However, we also observed that not all leads with high failure rates possess these characteristics (for example, Medtronic model 6991U), and some leads with these characteristics have performed well (for example, Medtronic model 4512). Because this study assessed the risks—not the causes —of failures, we could not focus further on the specific reasons for failure.

Our analysis of the current risk of failure posed by the set of 15 Medtronic pacemaker leads indicates that there is a wide range of failure rates. (See appendix IV, table IV.1.) A few models had low (zero percent) and several had high (8 percent and above) failure rates 3, 4, 5, or 7 years after implant.

In looking at other models of polyurethane-insulated pacemaker leads, we also found a range of failure rates—from zero to 8 percent, 5 years after implant. However, most of the competitively marketed models of other manufacturers we reviewed experienced zero failure rates. All the Cordis/Telectronics models we reviewed, for instance, showed low or zero failure rates 5 years after implant.

We asked FDA officials why the agency had not requested that the device manufacturers collect clinical data earlier. FDA became aware of problems associated with the model 6972 lead as early as December 1980 and acknowledged the need for such data as early as 1982. FDA officials told us that—before enactment of the Safe Medical Devices Act of 1990—after a device had been approved for marketing, the agency did not have the authority to require manufacturers to collect data that they did not "normally" collect.

[7]Ross Fletcher et al., "Effect of Pellethane 80A Polyurethane on Lead Survival," unpublished conference paper presented at "CARDIOSTIM 92" (St. Cloud, France: June 1992). The study was based on data from the Veterans Administration's Pacemaker Surveillance Center in Washington, D.C. (See appendix IV.)

We found that FDA did have the statutory authority but did not exercise it. Sections 515 and 519 of the Federal Food, Drug, and Cosmetic Act authorized FDA to require device manufacturers to provide such information as necessary to ensure the safety and effectiveness of their device. However, FDA did not take the initiative to issue a regulation and obtain needed clinical data on the safety and effectiveness of leads.

The 1990 Safe Medical Devices Act specifically includes a postmarket surveillance provision designed to provide an early-warning system to alert the health care community to any potential problem with a given device within a reasonable time of its initial marketing. The manufacturer is required to submit a postmarket study protocol to FDA within 30 days of the first introduction or delivery for introduction of a device into interstate commerce. The study variables are to include data on patient survival rates, device failure rates, morbidity and mortality associated with the device, and so forth.

The postmarket surveillance provision mandates studies for three types of devices marketed after January 1, 1991: (1) permanent implants, "the failure of which may cause serious, adverse health consequences or death"; (2) devices that are "intended for use in supporting or sustaining human life"; and (3) devices that "potentially" present "a serious risk to human health." FDA also has discretion to call for postmarket studies for any other device it thinks necessary, regardless of the date first marketed.[8]

FDA is applying the mandatory postmarket surveillance provision to devices cleared for marketing on or after November 8, 1991, although it applies to devices first marketed after January 1, 1991. Pacemaker leads submitted for FDA review are among the first set of devices to which FDA proposes to apply the new provision.

Question 2: Patient Notification

In accordance with FDA's existing policies and procedures, on February 20, 1984, Medtronic issued a "physician's advisory" letter to the 33,000 known physician users of its pacemaker leads. The letter stated that model 6972 leads manufactured between December 1979 and February 1982 had exhibited a failure rate of about 1 percent during the first year after implantation, about 4 percent after 2 years, and about 10 percent after 3 years. Representatives of Medtronic provided us with documents indicating that 26,721 of what are referred to as "early production" leads

[8]FDA has made use of the postmarket surveillance provision in two discretionary cases. The agency has asked Surgitek to study its polyurethane-coated breast implants and Collagen Corp. to evaluate its Zyderm/Zyplast injectable collagen products.

were sold in the United States. We noted that this letter advised physicians retrospectively about leads that had not been manufactured for 2 years.

Medtronic's letter also advised physicians that monthly transtelephonic monitoring would detect the problem before recurrence of the patient's original symptoms. (See "transtelephonic monitoring" in the glossary.) FDA agreed with Medtronic's advice that physicians should decide whether to implant new leads based upon each patient's medical condition. Physicians may also decide that a lead replacement necessitates replacement of the generator as well.

According to FDA documents, the manufacturer's notification about the pre-February 1982 pacemaker leads achieved a 98-percent "effectiveness check." That is, 98 percent of the physicians to whom the notification was directed actually received the firm's advisory about the high failure rates. Pursuant to FDA policy, Medtronic notified physicians—not patients. Traditionally, FDA has left patient notification up to the physician. Once notified, the physician would make a medical judgment about informing the patient, considering the individual's needs.

Between February 1982 and late 1983, Medtronic made significant modifications to the model 6972 pacemaker lead. According to statements provided to us by company representatives, the problems with the early production leads were believed to be solved by the series of changes. The company manufactured and distributed 16,279 "modified" model 6972 leads during this period. In 1984, to inform health professionals and the public about model 6972 problems, FDA implemented several outreach activities. These included producing FDA Talk Papers and articles in the Center for Devices and Radiological Health's "Medical Devices Bulletin" and "FDA Consumer Magazine" and directly notifying health profession organizations.

On March 2, 1984, FDA determined that Medtronic had violated regulations by marketing a modified model 6972 without submitting a premarket notification as required by section 510(k) of the 1976 Medical Device Amendments, and the agency issued a "cease-marketing order" to the company. A Medtronic representative recalled the events for us as follows. After receiving the FDA order on March 3, 1984, the company's sales force was instructed not to deliver any more model 6972 leads. Medtronic then revoked all product releases for the 6972 pacemaker lead from its facilities, and to its knowledge, from this point on, no more 6972s were released.

However, Medtronic took 4 more months—to July 1984—to notify FDA that its February 1982 manufacturing changes had not succeeded in significantly lowering the failure rate of the model 6972 lead. According to the company's data, the failure rate for the post-February 1982 model 6972 implants was approximately 4 percent within 2 years after implant. This was a similar rate to the earlier version of the lead.

On July 12, 1984, Medtronic issued a second letter to physicians and consignees expanding the 6972 recall to include the post-February 1982 production units and requesting that all unused 6972 pacemaker leads be returned. FDA records indicate that over 98 percent of Medtronic consignees received the second notification. FDA also instituted an expanded effectiveness check to ensure that consignees had both received notification and took "appropriate" action. The record of termination of the recall indicates that almost every consignee was advised of the recall. However, pacemaker leads are not perishable commodities and may be purchased in advance of their use. From the time FDA issued its "cease-marketing" order in March 1984 to its July 1984 order requiring the "return to the manufacturer" of all unused leads, nearly 2,500 potentially defective leads remained on hospital shelves or medical warehouse inventories or were implanted in patients.

Between January and October 1987, Medtronic sent out a medical device safety alert package to 37,732 U.S. consignees for pacemaker lead models 4002 and 6991U. Nearly 5,000 were physicians who had used these leads. The problem with the 4002 was described by FDA as a tendency to "oversense or undersense with normal capture." And the model 6991U lead might cause "muscle stimulation and intermittent sensing [abnormalities] with normal capture." The combination of insufficient manufacturing quality control and improper polyurethane-insulated coating were cited by FDA as the causes for the unacceptable pacemaker lead failure rates. Consignees were advised to monitor patients in accordance with Medicare's "Pacemaker Guidelines," which indicated that units should be checked bimonthly for 36 months and monthly thereafter.

According to FDA records, Medtronic received 100-percent "proof-of-delivery" from Federal Express, showing that all consignees received the safety alert notification. Further, an FDA audit check of a sample of these consignees confirmed that about 75 percent received the alert and took "appropriate" action. However, in spite of the high validation rate of the physicians' receipt of both advisories, our investigation suggests that many patients were both unaware of the recall

of the pacemaker leads and concerned about their leads' safety and effectiveness.

Indeed, we reviewed records and documents of the Pacemaker Recall Data Bank, a Florida-based nonprofit "watchdog" organization mentioned in a publication of the American Association of Retired Persons.[9] Our review revealed several thousand letters from persons who were unaware that their pacemaker leads had been the subject of recalls, or safety alerts, or had been included among the set of 15. Some of the letters indicated that patients had experienced problems with their device but had not been advised by their physician that they might be related to a defective lead. The majority of these letters indicated that the correspondents were willing to pay for information both now and in the future about the status of their device.

The problems with patient notification are addressed directly in section 3(b) of the 1990 Safe Medical Devices Act. The act mandates that not later than August 1991, FDA propose regulations requiring manufacturers of certain devices to adopt a method of device tracking. The two types of devices subject to the new tracking requirements are: (1) devices whose failure could have serious adverse health consequences and are either permanent implants or life-sustaining or life-supporting devices used outside of a device user facility, and (2) any other device that FDA may designate.

The purpose of the new traceability authority is to give FDA and manufacturers sufficient information to locate patients and inform them of potential problems, including recalls. If a recall is necessary, FDA may develop a notice to users with the assistance of health professionals who prescribed or implanted the device for those individuals. If a significant number of individuals cannot be identified, FDA is required to attempt to notify such individuals under its authority to publish information regarding devices posing an imminent danger to health.

Notification to users of defective medical devices is not an entirely new concept. Under section 518(a) of the Medical Device Amendments of 1976, FDA could order patient notification if (1) a device presents an "unreasonable risk of substantial harm to the public health" and such notification is necessary to eliminate the unreasonable risk and (2) no other practical means are available to eliminate the risk. Under section 518(a), FDA ordered Shiley in 1991 to notify patients of the risk of a strut

[9]"Pacemaker Recalls May Do Your Heart Good," Modern Maturity (December 1986-January 1987), p.16.

fracture in certain heart valves. Shiley has been trying to notify patients, either through a doctor or directly.

In 1982, the Senate Special Committee on Aging released a report entitled, "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry," which cited problems regarding the performance and cost of pacemakers and other related issues. The report stated that the Congress should consider enacting legislation for a nationwide pacemaker registry, the establishment of which was subsequently mandated by the Deficit Reduction Act of 1984 (P.L. 98-369).

In 1987, FDA published the final rule implementing the mandatory provisions of the pacemaker registry section of Public Law 98-369 (establishment of the registry for Medicare-covered pacemakers and leads and submission of certain information by physicians and providers) and one discretionary provision (denial of Medicare payments to physicians and providers who do not submit the required information). This information is principally useful in meeting the legislative objective of assisting HCFA in making Medicare reimbursement decisions.

The lack of full implementation of the discretionary provisions of the pacemaker registry section of Pubic Law 98-369 limits the usefulness of the registry. Some provisions not yet implemented include the return of explanted pacemakers and leads by providers to manufacturers for testing, sharing of test results with providers, and FDA participation in the testing. These provisions would aid in collecting critical clinical performance information, providing an early warning of potential device problems, and subsequently notifying patients, health care providers, and device manufacturers.

FDA officials said that the pacemaker registry now contains information on at least 400,000 procedures. We did not evaluate the registry; however, FDA officials conceded that the agency has not validated the registry's contents and the quality of the data and other resource limitations have severely limited its usefulness.

The provisions of the 1990 act that related to FDA's capacity to notify device users of a recall without having to find that there are no other practical means to eliminate the risk further expand the agency's authority to notify device users of potential problems. These provisions provide a statutory basis for FDA's actions that may result in patients' greater participation, with their health care provider, in their own health care and

respond to concerns about a patient's right to be informed about defective devices. In October 1991, for example, FDA issued an order to Vitek to (1) notify surgeons to tell their patients receiving temporomandibular implants that they may be at risk because the company's device could break down and cause jawbone disintegration, (2) run a public health advisory in the media, and (3) provide a toll-free 800 telephone number for patients to call for further information.

Question 3: Early Warning

Our comparative analysis of pacemaker lead performance points to a significant gap in FDA's postmarket surveillance system and highlights the critical importance of collecting clinical data to monitor the performance of devices such as pacemaker leads.

Our data show that at least one pacemaker lead model that has not been safety-alerted or recalled has exhibited the same—or a higher—failure rate as those leads that have been the subject of a safety alert or recall. This is Medtronic's model 6990U. Based on an analysis of clinical data of lead performance 5 years after implant, we found that this model had a failure rate of 10 percent; that is, 10 out of every 100 leads are likely to fail within 5 years. (See appendix IV, table IV.1.) This rate is similar to the rate 5 years postimplant for Medtronic model 6991U (12 percent), which was the subject of a safety alert, and is the same 3-year postimplant rate as model 6972 (10 percent), which was the subject of a recall.

FDA officials told us that based on information generated by their existing postmarket surveillance procedures for pacemaker leads—which do not include collecting clinical data—they were not aware of potential problems with the Medtronic model 6990U and, therefore, had not initiated any regulatory actions. To the contrary, they said that they had received far fewer problem reports associated with this lead than the other models that have been recalled or the subject of a safety alert. After we informed FDA about the model 6990U's potential problems, the agency requested that Medtronic notify physicians to monitor their patients closely for symptoms of pacemaker lead failure and be prepared to provide appropriate treatment in the event of failure.

FDA has not established a failure rate threshold for pacemaker leads; however, a minimum level of 7 percent may be assumed based on the regulatory action FDA has taken on previously recalled or safety-alerted leads. This minimum level or threshold of 7 percent was defined by the lowest failure rate (6.8 percent) of the four recalled or safety-alerted

Medtronic models, using FDA's failure rate information. Several experts contend that a failure rate threshold of 1-5 percent is more reasonable.

Our analyses of clinical data, combined with manufacturers' sales data, indicate that nearly 103,400 persons have been implanted with one or more Medtronic leads that have a failure rate that meets or exceeds FDA's implicit failure rate threshold of 7 percent. (See appendix IV, table IV.2.) The level of risk ranges from an identified problem as indicated by a safety alert or recall, to a hidden problem, where FDA is not aware that a problem exists.

Question 4: Costs to the Government

The majority of pacemaker recipients (86 percent) are elderly and eligible for Medicare coverage for pacemaker-related procedures. Consequently, the potential cost to the federal government for defective devices can be considerable.[10]

We identified the incremental costs of treating patients who received pacemaker leads that exceed FDA's implicit failure rate standard. If a lead fails, there are two types of expense: the replacement operation and additional transtelephonic monitoring of patients who did not receive a replacement lead.[11] We estimate that the minimum total cost beyond routine Medicare coverage for all five models would be $50 million; this would rise to $56 million if another potentially problematic model were found to experience significantly high failure rates. (See appendix V, table V.1.)

Section 518(b) of the Federal Food, Drug, and Cosmetic Act, as amended, contains the so-called 3R's: repair, replace, or refund the cost of the device. It is one of the few provisions in the act that allows FDA to impose on the manufacturer or other responsible parties the economic cost associated with eliminating a risk based upon finding fault on the part of the responsible party. Another provision is section 1862(b) of the Social Security Act, which gives the government the authority to bring an action to recover, or be subrogated to the right of a patient to recover, any Medicare expenditures for services for which payment may be made under a liability insurance policy. In 1987, in response to the U.S. Department of

[10]See U.S. Congress, Senate Special Committee on Aging, Fraud, Waste, and Abuse in the Medicare Pacemaker Industry: An Information Paper, September 2, 1982, 97th Cong., 2nd sess. (Washington, D.C.: U.S. Government Printing Office, 1982) and Pacemakers Revisited: A Saga of Benign Neglect, Hearings on May 10, 1985, 99th Cong., 1st sess. (Washington, D.C.: U.S. Government Printing Office, 1985).

[11]See Fraud, Waste, and Abuse in the Medicare Pacemaker Industry, p. 1.

Justice's intent to sue under section 1862(b) of the Social Security Act, Medtronic and Justice reached an out-of-court compromise settlement of $3 million to cover the cost of replacement surgery and additional monitoring for patients who had received the model 6972 pacemaker lead.

The aforementioned section 518(b) appears, in theory, to be useful in cases involving pacemaker leads. However, FDA has rarely invoked it, primarily because of the need to establish that the device was improperly designed and manufactured relative to the state of the art at the time of its design and manufacture. The House report on the 1976 amendments explains that this provision was included in the law because of a concern about economic redress when it states:

> "'the repair, replacement, or refund provision' is designed to reduce or eliminate risks associated with devices as well as provide an administrative procedure whereby consumers can attain economic redress when they have been sold defective medical devices that present unreasonable risks."

Conclusions

Our analysis shows that the health risks associated with defective pacemaker leads are real; indeed, their failure could prove fatal. Many current pacemaker lead patients are concerned about the safety and effectiveness of their device and have indicated that they feel they have a right to know about any potential problems associated with their device and to participate in the decisions made regarding their own health care.

Increased postmarket performance monitoring, early problem identification, and notification of all affected persons and organizations are among the factors that could reduce or even prevent the occurrence of adverse health consequences caused by defective pacemaker leads. To aid in identifying flawed devices and notifying patients, FDA should collect the clinically-based data essential to adequately monitoring the postmarket performance of pacemaker leads. Our analysis shows that the current FDA monitoring procedures—which do not include a regular review of clinical data—failed to identify at least one additional lead model we found that had a high failure rate. The postmarket surveillance provision under the Safe Medical Devices Act of 1990 adds to FDA's authority to obtain clinical data. However, unless FDA uses this discretionary authority, it will not obtain this critical information about all leads currently on the market or in use.

We found a consensus of opinion among experts and in the technical literature that failure rate analysis is useful in identifying pacemaker leads that have manufacturing or design problems. The information gained from failure rate analysis can reduce patient exposure to the potentially life-threatening risks from flawed pacemaker leads. However, FDA has no formal performance standard that requires manufacturers or FDA to initiate remedial actions based on the results of such analyses, and the agency has no comprehensive data system in place to identify and track patients and device performance. Having these data and Medicare's pacemaker-related expenditure data would aid in estimating the costs reimbursable to the government and to patients for flawed devices.

Recommendations

To ensure the safety and effectiveness of polyurethane-insulated pacemaker leads, we recommend that the Commissioner of FDA take the following actions:

- include in the development of regulations to implement the postmarket surveillance provisions of the Safe Medical Devices Act of 1990 a requirement that manufacturers conduct retrospective studies of postmarket performance of pacemaker leads currently on the market or in use, using criteria similar to those delineated in the act;
- establish a minimum standard for pacemaker lead performance or other appropriate benchmark to measure postmarket performance; and
- fully implement the discretionary provisions of the pacemaker registry provisions of Public Law 98-369 in conjunction with HCFA and with pacemaker and pacemaker lead manufacturers to develop a comprehensive, high-quality system to identify and track patients and device performance.

In addition, we recommend that the Administrator of HCFA conduct an analysis to determine the costs associated with defective pacemaker leads, and if so indicated, invoke section 518(b) of the Federal Food, Drug, and Cosmetic Act, as amended, or other appropriate statutes for reimbursement of such cost to the federal government.

The Department of Health and Human Services (HHS) should pursue any legislative changes necessary to implement our recommendation. Further, since HCFA has not been delegated the authority to invoke section 518(b), the Secretary of HHS should so delegate.

Agency Comments

We obtained written comments from officials at the Department of Health and Human Services. They agreed with our recommendations regarding the need for retrospective studies of pacemaker leads currently on the market, the establishment of a minimum standard for lead postmarket performance, and federal cost recovery for defective leads. However, in the latter case, HHS noted that there were substantial problems associated with such cost recovery under existing Medicare statutes. As a result of HHS' comments, we have revised this recommendation.

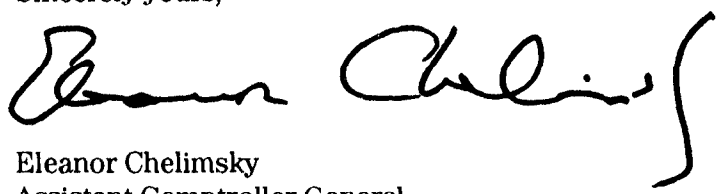
HHS also agreed with our recommendation regarding the need to facilitate patient notification when a pacemaker lead was determined to be defective, but stated that the recommended registry would be redundant to the existing HCFA and FDA national cardiac pacemaker registry. Although we have modified our recommendation somewhat, to take account of HHS' comments, we do not believe the existing registry is structurally or operationally adequate for performance monitoring and subsequent patient notification. The existing registry is designed to obtain information about only those leads covered by Medicare, which does not include the entire population and may not be representative of all lead models. The lack of full implementation of the discretionary provisions of the pacemaker registry section of Public Law 98-369 limits the usefulness of the registry for collecting clinically-based performance information and serving as an early warning of potential device problems.

We believe that the full implementation of existing mandatory and discretionary statutory provisions, developed in cooperation with device manufacturers, could provide a comprehensive and centralized repository for high-quality and useful data. This registry would include the clinically-based performance data collected by device manufacturers under the postmarket surveillance requirement of the 1990 act, which would minimize the cost to the federal government. FDA and HCFA would provide oversight, and the registry would be accessible to all manufacturers, physicians, patients, and other interested parties.

As we arranged with your office, we plan no further distribution of this report until 30 days from its date of issue, unless you publicly announce its contents earlier. We will then send copies to officials of HHS, FDA, and HCFA. We will also make copies available to interested organizations, as appropriate, and to others upon request.

If you have any questions or would like additional information, please call me at (202) 275-1854 or Kwai-Cheung Chan, Director of Program Evaluation in Physical Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix VIII.

Sincerely yours,



Eleanor Chelimsky
Assistant Comptroller General

Contents

Abbreviations

FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
VA	Department of Veterans Affairs

Request Letter

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U.S. House of Representatives
Committee on Energy and Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515

March 5, 1991

The Honorable Charles A. Bowsher
U.S. General Accounting Office
441 G Street, N.W.
Room 7000
Washington, D.C. 20515

Dear Mr. Bowsher:

As you know, in March of 1984, Congressional hearings were held before the House Energy and Commerce Subcommittee's Subcommittee on Oversight and Investigations on failed cardiac pacemaker leads. At that time, serious questions were raised about the safety and efficacy of polyurethane-insulated leads.

In recent months Mr. Charles Stein of the Pacemaker Recall Databank has brought serious concerns to the Subcommittee's attention concerning the 1984 recall of Medtronic, Inc's Model 6972 pacemaker lead. Mr. Stein alleges that the problems identified with the Model 6972 lead are present in other pacemakers and that the 6972 recall is as yet incomplete.

This information raises questions concerning the extent to which the FDA adequately evaluated the technological characteristics of the 6972 lead which may have caused it to be recalled. Consideration of this possibility would be important to determining whether this technology is used in other pacemakers which may, like the model 6972, present safety concerns. I note that the Department of Health and Human Services recently issued a survey by the National Center for Health Care Statistics indicating that 27 percent of pacemaker users report problems with the device.

I would like for GAO to conduct a brief review to determine the nature and potential scope of risks to the public health associated with the 6972 and similar pacemaker leads. Discussion between Committee staff, and staff from your Program Evaluation and Methodology Division indicated that such a review is feasible. In addition I would appreciate your assessment of the adequacy of FDA efforts to assure that patients with pacemakers subject to the 6972 recall have been notified of the potential safety problems either by the manufacturer, the FDA or their physician.

Please report your findings at the earliest appropriate date. Once again, I appreciate the valuable contribution that your office has made to our understanding of the medical device law and regulatory system, and I look forward to this new effort. If you have any questions, please contact me or Ripley Forbes of the Subcommittee staff, at (202) 226-7620.

With every good wish, I am,

Sincerely,

Henry A Waxman

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

Scope and Methodology of Our Study

Our study design required the collection of both qualitative and quantitative data. We obtained and reviewed official FDA documents that described the agency's assessment of the health and other risks posed by model 6972 and 14 other pacemaker leads. We also obtained and reviewed assessments of the events that took place before, during, and after the 1984 recall of Medtronic's model 6972 lead. We reviewed the policies, procedures, and regulatory and statutory authority as they existed at the time of the recall and changes to them reflected in the Safe Medical Devices Act of 1990. Additionally, we conducted a selective review of the available empirical and technical literature related to our study's issues and objectives.

We conducted structured and semi-structured interviews with FDA and Medtronic officials, representatives of other pacemaker manufacturers, and other knowledgeable persons to confirm and clarify the documentary evidence.

The quantitative information used in this study was primarily extant data, which included failure rate, market share, and manufacturers' data on the number of various products sold. We conducted secondary analysis of these data, as appropriate, to answer our evaluation questions. In addition, we developed a cost model to estimate the potential cost to the federal government for defective pacemaker leads. (See appendix V for a discussion of the development and use of the cost model.)

We obtained technical advice at all stages of the study including design, implementation, data analysis, and review of the draft report. Members of our expert panel are listed in appendix VI.

Our review was conducted in accordance with generally accepted government auditing standards. We assessed the reliability of the computer-generated data provided to us by the Department of Veterans Affairs Pacemaker Surveillance Center in Washington, D.C., and the Montefiore Medical Center's Implantable Lead Registry in New York. We reviewed relevant general controls in the data systems and concluded that the data were sufficiently reliable for our needs in meeting this assignment's objectives. The data for this study were collected between March 1991 and March 1992 .

Dow Chemical's Pellethane: Its Use in Long-Term Implants

Pellethane is the registered trademark of the Dow Chemical Co. for its 2363 series polyurethane elastomers. The series consists of nine polyether-based polyurethane polymers.[1] According to the manufacturer, these polymers are well suited for use in biomedical applications because of their physical properties, such as tensile strength, chemical and solvent resistance, elasticity, and ability to be sterilized.

In 1985, Dow Chemical purchased the Pellethane formula from Upjohn. In 1989, Dow Chemical sent a letter to its customers and distributors in which it said that the company does not have test data to support the use of Pellethane in long-term implant applications. Further, Dow Chemical wrote that there have been published reports that have indicated that in certain applications, such as pacemaker leads, thermoplastic polyurethanes could crack following long-term implantation.

The letter stated that as of April 1, 1992, Dow Chemical will no longer knowingly sell directly or permit authorized distributors to sell Pellethane polyurethane elastomers to those purchasers who intend to use Pellethane for long-term (that is, greater than 30 days) implant applications. This date was to allow time to assess the qualifications of a replacement material. As of 1989, Dow Chemical also included a note in its promotional literature that contained very similar information.

In October 1991, representatives of Dow Chemical told us that the company had decided to continue to sell Pellethane polyurethane elastomers to be used in the manufacture of pacemaker leads until April 1995. They also told us the company would cease selling Pellethane polyurethane elastomers for use in the manufacture of all other long-term implants in April 1992. The representatives indicated that these decisions were based on business considerations, including a desire to be fair to pacemaker lead manufacturers.

[1]The 2363 series includes: 80A, 80AE, 90A, 90AE, 55D, 55DE, 65D, 75D, and 80ARD0120.

Methodology and Findings of Failure Rate Analysis

Introduction

To determine the current risk to patients receiving any one of the set of 15 Medtronic polyurethane-insulated pacemaker leads, we reviewed the clinical performance or failure rates of the 15 models from available data. These models, though, are only a few of many different leads made by Medtronic and by other firms. Since a number of firms manufacture pacemaker leads, we also reviewed the performance of their polyurethane-insulated leads.

We identified 13 competitively marketed polyurethane-insulated pacemaker leads manufactured by Intermedics, Telectronics, and Cordis/Telectronics. We included these models in our study because their failure rate data were available in the Veterans Administration (VA) or Implantable Lead Registry data bases. They consist of ventricular leads, except for three atrial leads (C327-752, C328-752, and C329-748) and one (I479-01) that is used in either chamber. The results of our analyses are limited to the leads reviewed and are not representative of any other set or group of pacemaker leads.

The majority of the clinical performance data used in our analysis were obtained in the form of cumulative failure rate tables from the Implantable Lead Registry managed by the Montefiore Medical Center in New York City and the VA Pacemaker Surveillance Center, Washington, D.C. The Implantable Lead Registry consists of data on pacemaker leads implanted at six different public and private hospitals from 1979 through 1989 and is voluntary. The VA data consist of the pacemaker leads implanted by VA hospitals, nationally, between 1982 and 1992.

Medtronic also has its own pacemaker lead performance data base, which includes lead survival rate data for many of its models. Since 1983, when the company started collecting data on the model 6972, Medtronic has conducted its Chronic Lead Study. We did not use Medtronic's failure rate data because it uses a different definition of lead failure than the other two data bases, it is sponsored by the manufacturer, and it has not been validated by FDA. (See "failure rate" in the glossary.) For the recalled or safety-alerted models, we used failure rate data available from FDA—data the agency had used in making its health hazard decisions—some of which were from Medtronic's own Chronic Lead Study.

The two data bases together provided the best comparable data available even though they do not include all pacemaker lead models. Data were not available in either data base for 3 of the 15 Medtronic models—4502, 6959, and 6993—so we omitted them from our analyses.

We have no reason to believe that failure rates would be either higher or lower in these groups of patients relative to the entire pacemaker lead patient population. The data from these two data bases represent a "convenience" sample for illustrative purposes. Therefore, our findings cannot be generalized to the universe of all available pacemaker leads. (See table IV.1.)

Table IV.1: Five-Year Failure Rates of Selected Medtronic and Other Competitively Marketed Pacemaker Lead Models

Model[a]	Failure rate[b]	Number of cases[c]	Range of failure rates[d]
Selected Medtronic			
M4502	[e]	[e]	[e]
M6959	[e]	[e]	[e]
M6993	[e]	[e]	[e]
M4511	0	121	0
M4512	0	17	0
M4951	0	22	0
M4011	0.15%	248	0-0.30%
M6957J	0.79	435	0.42-1.16
M6957	0.89	508	0.48-1.30
M6971	1.58	627	1.10-2.06
M4012[f]	6.80	[g]	[g]
M4002[f]	9.40	[g]	[g]
M6990U	9.56	32	4.93-14.19
M6972[f]	10.00	[g]	[g]
M6991U[f]	11.90	[g]	[g]
Selected other			
C327-152	0	126	0
C327-162	0	270	0
C328-162	0	20	0
C328-752	0	21	0
C329-158	0	306	0
C329-748	0	197	0
T30-284	0	14	0
I479-01	0	13	0
I493-03	0	34	0
C327-752	0.37	247	0-0.74
I476-03	3.57	21	0.06-7.01
I476-07	5.16	13	1.56-8.76
I486-01	8.09[h]	21	2.91-13.27

(Table notes on next page)

[a]These are all the polyurethane-insulated pacemaker lead models for which we had data. "M" designates a lead manufactured by Medtronic. "C" designates a lead that was originally marketed by Cordis and is currently marketed by Telectronics. "T" designates a lead manufactured by Telectronics. "I" designates a lead manufactured by Intermedics. We know some of these models are no longer sold, but we do not know about the other models because all manufacturers do not publish this information. Even if a model is no longer sold, the leads may still be in use. Data were not available for three Medtronic models (4502, 6959, and 6993). Five-year postimplant data were not available for five other manufacturers' models. All the models reviewed are transvenous leads; that is, implanted through a vein. Model 4951 can also be fixed to the outer surface of the heart.

[b]These rates were based on cumulative failure rate information from one of two available data bases on lead performance. These are 5-year failure rates unless otherwise noted. The rates reflect failures that occurred within 5 years after implant—not within a specific 5-year time period. (See "failure rate" in the glossary.)

[c]The number of cases is the number of implanted leads for each model in the respective data base after 5 years.

[d]The range of rates was estimated from the standard error of the cumulative failure rate provided in the data bases. The standard error was added and subtracted from the failure rate for each model, excluding negative values, to establish the range within which the model would be expected to fail. Since the failure rates are based on the total population of each data base, the standard error is used here as an indicator of the range—not an exact measure of the confidence interval. The standard error's size is, in part, a function of the number of cases. The models with a zero failure rate had a zero standard error so there is no range.

[e]No data were available in the VA or Implantable Lead Registry data bases.

[f]Failure rates for these models were provided by the manufacturer and cited by FDA as the basis for its decisions to recommend a recall or safety alert. The models recalled or put on safety alert were based on failure data 3 years after implant (M6972), 4 years (M4002), 5 years (M6991U), or 7 years (M4012).

[g]Documents FDA provided, such as "recall termination recommendation" and "close-out of voluntary safety alert" memorandums and Health Hazard Evaluation Committee reports did not indicate the standard error or the number of cases (implanted pacemaker leads) upon which the failure rates were based.

[h]This model's observed high failure rate may not reflect its true failure rate because of the small number of cases on which it is based, and thus the model cannot, unequivocally, be considered a problem pacemaker lead.

The clinical data we obtained provided cumulative failure rates and their standard errors for each lead at different time periods.[1] In these clinical

[1]The cumulative failure rate tables (also known as survival rate tables) included the following types of information: (1) the number of leads implanted, (2) the number of failed leads, and (3) the number of leads removed for other reasons at regular time intervals, such as annually or quarterly. The failure rate is the difference between perfect performance (100 percent) and the cumulative survival rate of the lead at a specific time period. The failure rate is based on the percentage of failed leads out of the total number of that model implanted at the end of the time interval. The number of patients receiving a model also includes an estimated number of patients who were in the study initially but were later removed (because for example, they died or moved away) during the time interval. In the two data bases we reviewed, failure rates were only reported for models for which there were at least 40 implants. The standard error of each failure rate is a function of the number of participants in the study—the fewer the number of participants, the larger the standard error—and provides the basis for calculating the range of possible failure rates for a specific model. (See S.J. Cutler and F. Ederer, "Maximum Utilization of the Life Table Method in Analyzing Survival," Journal of Chronic Diseases (December 1958), pp. 699-712, for further discussion of survival rate analysis.)

data, pacemaker lead failure is defined as lead insulation deterioration, lead wire fracture, or connector failure as a result of a design, materials, manufacturing flaw, or some combination of these factors that is diagnosed by the pacemaker implant physician.[2] The failure rate of this type of defective lead may be high early in the normal life of a lead (2-3 years after implant), then the rate may return to a normal level. The well-manufactured and -designed lead would fail much later as the result of normal wear and tear.

Our analysis consisted of (1) assessing the range of failure rates of the set of 15 models and the set of 13 models, and (2) comparing the failure rates of each model lead. The duration of the implant was based on the actual number of months or years the lead was implanted. The expected number of failed leads was estimated from the number of implanted leads and the model's failure rate.

Definition of Lead Sets

To determine the clinical performance of the two sets of pacemaker leads, we needed to determine the number of leads implanted per model and the expected number of lead failures. Medtronic's published sales reports indicated that there were more than 237,675 patients who received one of the 15 polyurethane-insulated leads. (Medtronic adjusted its sales figures for normal patient mortality to estimate the number of leads in patients still alive.)

Since the other manufacturers do not publicly report pacemaker lead sales or the number of their implanted leads, we used each manufacturer's market share of pacemakers sold in 1990, as reported by industry sources, to estimate the number of their leads implanted. The relative market share held by these manufacturers in 1990 is similar to the relative share in 1988, except for Intermedics' share, which declined from 15 to 12 percent. The market share is based on data derived from hospital invoices on the number of leads sold per firm and collected by a market research firm.

Intermedics accounted for 12 percent of the market share, and Telectronics/Cordis, 9 percent. These numbers are based on estimates of sales, and they do not include all the models sold by any of the firms.

[2]We excluded implant complications from the definition, since they are affected by implant methods and physician error. Nevertheless, the failure rate can be affected by different implant procedures, although this source of variation is reduced by averaging over numerous physicians using various implant methods.

Pacesetter Systems held a 16-percent share, while the other 13 percent of the market was held by several other firms, each with a much smaller share of the market.

In 1988 (the most current data available), the total number of pacemakers in use was 460,000.[3] We weighted a firm's estimated number of leads sold by the percentage of that model lead represented in the data bases to find the number of patients who received a particular model. We assumed the number of pacemakers to be the same as the number of leads implanted, although the number of leads used per generator may vary by type. All patients have at least one lead, and some could have two leads at one time—but there would be no fewer than 460,000 leads.

This estimated number of pacemaker leads implanted per model is presented in table IV.2. These numbers, while not confirmed implants, allowed us to examine other competitively marketed models.

Table IV.2: Expected Pacemaker Lead Failures by Selected Lead Models[a]

Failure rate[b]	Model[c]	Total implants[d]	Expected patient lead failures[e]
Zero	M4511	6,900	
	M4512	7,800	
	M4951	10,200	
	C327-152	3,044	
	C327-162	7,080	
	C328-162	969	
	C328-752	1,061	
	T30-284	1,637	
	C329-158	13,861	
	C329-748	7,772	
	I479-01	9,378	
	I493-03	11,509	
Total		**81,212**	**0**
0.1-1 percent	C327-752	6,435	
	M4011	42,800	
	M6957	15,200	
	M6957J	17,600	
Total		**82,035**	**147-578**

(continued)

[3]Abigail J. Moss et al., "Use of Selected Medical Device Implants in the United States—1988," advance data from Vital and Health Statistics, No. 19 (Hyattsville, Md.: National Center for Health Statistics, 1990).

Failure rate[b]	Model[c]	Total implants[d]	Expected patient lead failures[e]
1.1-6.7 percent	M6971	30,100	
	I476-03	8,738	
	I476-07	12,148	
Total		**50,986**	**526-2,303**
6.8-12 percent	M4002	10,600	
	M4012	64,800	
	M6972	21,900	
	M6990U	3,000	
	M6991U	3,100	
Total		**103,400**	**5,732-10,765**

[a]For the models recalled or put on safety alert, we reported failure rates provided by the manufacturer and cited by FDA. Other failure rates were obtained from the VA or Implantable Lead Registry data bases, which were based on a more restricted definition of failure.

[b]Taken from table IV.1.

[c]"M" designates a pacemaker lead manufactured by Medtronic. "C" designates a lead that was originally marketed by Cordis and is currently marketed by Telectronics. "T" designates a lead manufactured by Telectronics. "I" designates a lead manufactured by Intermedics. We know some of these models are no longer sold, but we do not know about other models because all manufacturers do not publish this information. Even if a model is no longer sold, the leads may still be in use.

[d]These are the number of leads Medtronic reported sold for these models, adjusted for normal patient mortality. The estimates for the other manufacturers' models were based on the firms' market share and the proportion of each model's leads to all of the firm's polyurethane-insulated leads represented in the data base. These do not represent all the models of any of the firms.

[e]This is a projection of the number of patients implanted with pacemaker leads that could fail based on the failure rate and the number of implants per model. The low and high numbers for each group of failure rates (i.e., 1.1-6.7) are the sum of the number of leads sold times the low (or high) end of the range for each model (see table IV.1 for the range) in the failure rate group. Model 4002's failure rate was 4 years after implant; model 4012's was 7 years after implant, and model 6972's was 3 years after implant. The other models' failure rates are 5 years after implant.

Findings

Table IV.1 shows that the overall range of failure rates for 15 Medtronic pacemaker leads was 0 to 12 percent. Twenty-five percent of the Medtronic leads showed a zero failure rate.

The range of failure rates for the 13 competitive pacemaker leads was 0 to 8 percent. None of the competitively marketed leads had failure rates meeting or surpassing FDA's implicit lead performance threshold of approximately 7 percent (except for Intermedics model 486-01, whose failure rate may not be accurately reflected by the data base because of a

very small sample size).[4] At 5 years postimplant, almost 70 percent of the competitively marketed leads showed a failure rate of zero. All the Cordis/Telectronics models experienced a low or zero failure rate at 5 years.

Forty-eight percent of all models we studied exhibited a zero failure rate 5 years after implant. In fact, the majority of models experienced very low failure rates, with 66 percent of all the models exhibiting a 1-percent (or less) failure rate 5 years after implant.

With the exception of Medtronic model 6990U and Intermedics model 486-01, all the models that exhibited a failure rate of approximately 7 percent or higher have been recalled or have been the subject of a safety alert. All the high failure rate models we reviewed had a common polyurethane formulation (Pellethane 80A), and most were bipolar in design, except the unipolar 6991U. Several Intermedics models used the same formulation, but all the other competitively marketed leads used other formulations.

Our analyses indicate that a substantial number of persons may receive a pacemaker lead that exceeds a zero failure rate. (See table IV.2.) We estimated that as many as 578 leads are expected to fail after 5 years, out of more than 82,000 implanted leads with a failure rate of between 0.1 and 1 percent. When we combined the number of persons with leads that exhibit a failure rate of 1 percent or less with the number whose model shows a failure rate between 1.1 and 6.7 percent, we found that there were almost 3,000 expected failures. We estimated that the number of persons who have been implanted with leads that have failure rates between 6.8 and 12 percent is 103,400, with between 5,000 and 10,000 of these leads expected to fail by 3, 4, 5, or 7 years after implant. We estimated the total number of implants of all nonzero failure rate models to be over 236,000, with between 6,000 and 13,000 of these leads expected to fail by 7 years after implant.

[4]The M4012 was associated with a safety alert when the failure rate was reported at 6.8 percent. The other Medtronic models were associated with a safety alert when the failure rate was higher than 6.8 percent. (The use of a relatively high failure rate such as 7 percent may be necessary to offset the inaccuracies associated with small sample sizes.)

Model, Assumptions, and Findings of the Cost Analysis

Cost Model

Approximately 86 percent of all patients receiving pacemaker leads are eligible for Medicare. The model we used to estimate the costs to Medicare for each patient consists of the following:

- physician and inpatient hospital costs for a pacemaker lead replacement operation and additional transtelephonic monitoring; and
- the expected number of patients subject to these charges.

The costs include physician charges of $369, which is 80 percent of the total physician charges that Medicare will reimburse, and inpatient hospital payments of $4,691, for the lead replacement operations. These costs are fiscal year 1991 national averages as reported by the Health Care Financing Administration. (After a deductible—$628 in 1991—Medicare pays for all inpatient hospital care according to Medicare's prospective payment system, and the program covers 80 percent of physician charges.) In addition, there are 6, 12, or 18 (for patients with leads implanted for 1, 2, or 3 years) extra transtelephonic monitoring physician charges of $28 each, which is 80 percent of total monitoring charges per patient.

The national average cost to Medicare of $4,691 represents only partial payments to hospitals for covered care rendered to Medicare patients. This amount may be viewed as representing the minimum overall hospital payment associated with the procedure under the prospective payment system. It does not include additional costs incurred by the Medicare program for items such as nonoperating expenses, running intern and resident programs, and bad debts attributable to deductibles and coinsurance amounts related to covered services received by beneficiaries, which are also reimbursed using a modified reasonable cost method or a special schedule. Nor does it represent the national average hospital charge for this procedure of slightly more than $9,000. The approximately $4,300 difference, per patient, between the average amount reimbursed by Medicare and the average amount that hospitals charge for the procedure is absorbed by the hospitals, insurance companies, and patients and contributes to the overall cost of the nation's health care.

The expected number of patients subject to these charges are all those covered by Medicare who would receive additional transtelephonic monitoring and those who would need a pacemaker lead replacement operation. The expected number of failed leads for those models that demonstrated a high failure rate was derived from the number of implanted leads and each model's failure rate (that is, the failure rate times the total number of implanted leads). Five models exhibited a high failure

rate. The data for M6972 were based on 3 years after implant, M4002 on 4 years, M6990U and M6991U on 5 years, and M4012 on 7 years.

Assumptions

We made the following assumptions about our cost model:

- Only operations to replace failed pacemaker leads are included.
- All lead recipients had monthly transtelephonic monitoring sessions. (The number of additional monitoring sessions covered is a function of Medicare policy.)
- The dollar value of a replacement lead or credit for a failed lead provided under warranty by the manufacturer and other reasonable uninsured medical costs reimbursable by the manufacturer are not included.

We included only operations to replace failed leads, even though this excluded other elective procedures, such as pulse generator replacement where the pacemaker is also replaced and lead replacements for patients whose leads are expected to fail but have not yet failed. These procedures may not be subject to manufacturer reimbursement even though they may constitute good medical practice. In one instance in which the government sought manufacturer reimbursement (for M6972), the settlement was based only on lead replacement operations and additional monitoring. Replacing a pulse generator in addition to the lead almost doubles the cost per procedure.

Monthly transtelephonic monitoring has been recommended for patients who received problem models. Since 1985, Medicare has routinely reimbursed transtelephonic monitoring physician services every other month (6 times per year) for the first 36 months, and then 12 per year thereafter. To provide monthly monitoring for recipients of problem models, 6 additional monitoring sessions are needed for each of the first 3 years a patient has the lead; no extra monitoring is needed thereafter.

We had no information regarding the number of leads implanted for 3 years, 2 years, or 1 year, and we also had no way of knowing how long leads had been implanted before the recall or safety alert was issued. Therefore, we assumed that for each year up to 3 years after implant, there would be 6 extra monitoring sessions per year. (We used an estimated average annual number of leads sold and implanted per year by model.) For the leads implanted 3 years, we added 18 extra monitoring sessions; for leads implanted 2 years, 12 extra monitorings; and for leads implanted only 1 year, an extra 6 monitorings. The total number of extra monitorings

for each model is the sum of extra monitorings for leads implanted in the previous 1, 2, and 3 years.

We assumed that all lead manufacturers provide some warranty for replacement and that the cost of the replacement lead would be covered by the firm's warranty. Medtronic, for example, has a limited warranty providing full credit equal to the original unit purchase price or a replacement Medtronic lead at no charge. In addition, Medtronic has agreed to provide patients with up to $600 for "reasonable uninsured medical expenses" associated with lead replacement. The warranty also helps defray patient expenses not covered by Medicare, such as the deductible or copayment. The model we described provides an estimate of the additional costs to the Medicare program excluding these provisions.

Findings: Estimated Costs

If the U.S. government determines that it should be reimbursed for additional Medicare expenses associated with specific problem leads, this cost model provides a basis for estimating those expenses. Table V.1, below, provides an estimate of the additional costs to Medicare if five models were determined to be subject to reimbursement. They include three models for which a safety alert was issued (M4002, M4012, and M6991U), one that was recalled (M6972), and one other that we found with a similarly high failure rate (M6990U). There is another possible problem lead (I486-01), which could increase the minimum total estimated Medicare costs of $50 million to almost $56 million. These projected costs are for a 3-year period.

Table V.1: Cost Estimates for Five Model Lead Failures[a]

Model	Failure rate	Cost
4002	9.40%	$7,712,785
4012	6.80	31,626,703
6972	10.00	13,599,762[b]
6990U	9.56	2,207,151
6991U	11.90	2,647,760
Total[c]		**$57,794,160**
Total Medicare[d]		**$49,702,978**
Total Medicare including I486-01[e]		**$55,884,641**

[a]These five models have been recalled, subject to a safety alert, or merely experienced high failure rates. The cost estimates are the additional costs to Medicare for each lead model. The failure rates were taken from table IV.1.

[b]Medtronic has already made payment to the government to partially cover the costs of replacing and monitoring this lead; thus, we reduced the estimated costs for model 6972 by the amount of that settlement—$3 million.

[c]This is the total cost for the five Medtronic models.

[d]This is Medicare's share of costs for 86 percent of patients receiving these leads.

[e]This is Medicare's share should Intermedics 486-01 be found to experience a high failure rate.

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Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Washington, D.C. 20201

JUL 9 1992

Ms. Eleanor Chelimsky
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Chelimsky:

Enclosed are the Department's comments on your draft report, "Medical Technology: Public Health Risks Unacceptably High for Some Cardiac Pacemaker Leads." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

For Richard P. Kusserow
Inspector General

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) COMMENTS ON THE DRAFT GENERAL ACCOUNTING OFFICE (GAO) REPORT "MEDICAL TECHNOLOGY: PUBLIC HEALTH RISKS UNACCEPTABLY HIGH FOR SOME CARDIAC PACEMAKER LEADS," GAO/PEMD-92-20, May 1992

GENERAL COMMENTS

We appreciate the opportunity to review and comment on the draft report. The Food and Drug Administration (FDA) takes seriously questions raised by the draft report about the failure rates for two pacemaker lead models (Medtronic's model 6990U and Intermedics' model 486-01). These lead models are no longer marketed, but unlike other lead models identified in the report as having unusually high failure rates, they have not been the subject of a safety alert or recall monitored by FDA. Based upon information provided by GAO, FDA issued a letter to Medtronic, Inc., under section 518(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act initiating consultation with the firm about the risks presented by the model 6990U lead. The FDA is also contacting Intermedics about the performance of the model 486-01 lead.

It should be noted that when pacemaker lead models recalls have been monitored by FDA, the agency followed the then-existing policies and procedures and pursued other means of notifying pacemaker lead recipients about potential safety problems as well. Information was disseminated to professional associations, talk papers were issued, and articles directed to consumers and other audiences were published.

The report makes brief mention of two recent efforts by FDA that more directly involve patients when notifications of potential safety hazards are issued. While neither involved pacemaker leads, FDA is currently building upon these experiences to develop general criteria/guidance for future patient notification decisions. Moreover, FDA has published proposed regulations required by the Safe Medical Devices Act of 1990 (SMDA) that would require manufacturers of pacemaker leads, among other devices, to establish effective systems for device tracking. The device tracking information will facilitate patient notification, should it become necessary.

As currently drafted, the report may contribute to concerns about the safety of polyurethane-pacemaker leads that were implanted in the past or are currently being implanted. The basic thrust of the report, that some pacemaker leads have unacceptably high failure rates, appears to be based on the five or six recalled or otherwise discontinued lead models. Four of these lead models were the subject of safety alerts or recalls monitored by FDA. Furthermore, in one case (Medtronic's model 6972 pacemaker lead), the recall occurred nearly 8 years ago.

GAO RECOMMENDATION

To ensure the safety and effectiveness of polyurethane-insulated pacemaker leads, we recommend that the Commissioner of FDA take the following actions:

> Include in the development of regulations to implement the postmarket surveillance provisions of the Safe Medical Devices Act of 1990 a requirement that manufacturers conduct retrospective studies of postmarket performance of pacemaker leads currently on the market, using similar criteria as those delineated in the act.

HHS COMMENT

We agree with the intent of the recommendation. However, we believe that action can be taken without issuance of a regulation. Section 522(a)(2) of the FD&C Act, as amended by SMDA, provides FDA with authority to require, at the Agency's discretion, that a manufacturer conduct postmarket surveillance for a device if FDA determines that postmarket surveillance is necessary to protect the public health or to provide safety or effectiveness data for the device. On May 18, 1992, FDA sent letters to all manufacturers and importers of permanent pacemaker leads notifying them that postmarket surveillance is required for all models of permanent pacemaker leads on the market in the United States on or after January 1, 1982, regardless of their current marketing status. This notification supplemented action already taken under section 522(a)(1) of the FD&C Act, as amended. This section of the Act directs FDA to require manufacturers of certain permanent implants and life-supporting or life-sustaining devices first marketed after January 1, 1991, to conduct postmarket surveillance. As noted in the draft report, FDA had already determined that permanent pacemaker leads meet the criteria of section 522(a)(1) and had instituted procedures whereby permanent pacemaker lead manufacturers are notified of this requirement as they receive marketing clearance for new or modified pacemaker lead models.

GAO RECOMMENDATION

> Establish a minimum standard for pacemaker lead performance or other appropriate benchmark to measure postmarket performance.

HHS COMMENT

We agree it would be useful to have a valid, accepted benchmark for pacemaker lead survival which could be used in assessing postmarket performance. The FDA will appoint a working group

this fiscal year to begin an in-depth review of the medical literature and other available information and to consult with, and gather information from, the affected professional association(s), clinicians, and manufacturers. At least one pacemaker lead manufacturer (Medtronic) already has established a survival rate specification for its leads. Both the manufacturer and FDA currently assess the performance of the manufacturer's leads against this internal specification. There are, however, differing opinions within the medical community as to what survival rate is acceptable for pacemaker leads. In addition, simply stating what survival rate is acceptable does not address the issue of consistency in definitions, criteria, and methodology used to measure pacemaker lead survival. (A manufacturer who uses more stringent definitions, follow-up procedures, etc., than another manufacturer will have more difficulty satisfying a given survival rate benchmark, even when both manufacturers' leads, in actuality, perform equally well.) Also, review of the postmarket surveillance protocols submitted as a result of the actions described under the above recommendation will help ensure that pacemaker lead manufacturers collect and report postmarket data in a consistent manner.

GAO RECOMMENDATION

Consider the feasibility of establishing a joint FDA, HCFA, and private sector national pacemaker lead registry.

HHS COMMENT

While we agree with the need to facilitate patient notification when a pacemaker lead is determined to be defective, we believe that the recommended registry would be redundant with other systems and requirements.

The FDA and the Health Care Financing Administration (HCFA) have already established a national registry for all cardiac pacemakers and pacemaker leads for which payment is made under Medicare. Establishment of this registry was required by the Deficit Reduction Act of 1984 (P.L. 98-369, enacted July 18, 1984), under section 2304, "Pacemaker Reimbursement, Review, and Reform." Regulations establishing the registry were published in July 1987, although HCFA actually began collecting data in April 1985 based on the statutory requirements. The HCFA's regulations require that hospitals implanting pacemakers and/or pacemaker leads report the necessary information directly to HCFA, whereupon it is forwarded to FDA for entry into the pacemaker/lead registry. If a hospital fails to furnish the required information, HCFA will deny payments for pacemaker procedures in that hospital. The registry currently

contains records of more than 400,000 lead implants. The draft report does not mention the existence of this registry.

Other, equally important steps are being taken to ensure that a system is in place to identify and track pacemaker lead recipients for the purpose of patient notification. As mentioned in GAO's report, SMDA included a requirement that FDA issue regulations requiring manufacturers of certain high-risk devices to adopt an effective method of device tracking. The FDA published proposed regulations (57 FR 10702) for device tracking on March 27, 1992. Permanent pacemaker leads were included in an illustrative list of devices subject to tracking that was included in the proposed rule. The FDA reviewed comments submitted in response to the proposed rule and published a revised proposal on May 29, 1992. Implementation of device tracking will obviate the need for another registry.

GAO RECOMMENDATION

> In addition, we recommend that the Administrator of HCFA conduct an analysis to determine the costs associated with defective pacemaker leads and, if so indicated, invoke section 518(a) of the Federal Food, Drug, and Cosmetic Act, as amended, or other appropriate statutes for reimbursement of such costs to the federal government.

HHS COMMENT

Although we agree that undertaking an analysis to ascertain costs to the government associated with defective pacemaker leads may be a valuable study, we note that there are substantial problems associated with recovery of such funds under the existing Medicare statutes.

With respect to services associated with replacing a defective device, warranty payments, if any, for such services are generally limited to the patient's reasonable uninsured medical expenses. As a practical matter, the benefit obtained under most replacement warranties is a full or prorated credit with respect to the replacement device itself. Moreover, such warranties are generally limited to replacement with the same or similar device from the same manufacturer. Consequently, any replacement with a device from a different manufacturer would not result in any warranty obligation on the part of the original manufacturer. In any event, a hospital paid under the prospective payment system (PPS) would be entitled to keep any money recovered under a manufacturer's warranty. This is because PPS payment rates take such recoveries into account.

In addition, HCFA's ability to recover under section 1862(b) of the Social Security Act could be impractical in many cases.

That section of the law gives Medicare a direct right of recovery against, and subrogates Medicare to the right of any other entity to recover from, a liability insurer. This authority could permit HCFA through the Department of Justice (DOJ) to recover any Medicare payments related to replacement of the defective device. A recovery program predicated on case-by-case litigation, however, would be prohibitively expensive.

Moreover, DOJ may not be willing to pursue such claims on an individual basis, even if they were cost effective, because it can be difficult to prove negligence if the alleged injured party is unwilling to file suit. While aggregated out-of-court claims settlements, such as the one cited by GAO between the government and Medtronic in 1987 (page 23, footnote 30) are feasible, they are by nature a hit-or-miss remedy.

Thus, effective recovery of Medicare funds associated with defective pacemaker leads would require legislative changes.

It should be noted that, while FDA has authority to invoke section 518(b) of the FD&C Act (the appropriate citation for repair, replacement, or refund provisions), HCFA has not been delegated authority to do so. It should also be noted that FDA explored obtaining relief under section 518(b) after the 1984 recall of the Medtronic model 6972 pacemaker lead. The FDA determined that it would have been difficult to satisfy the statutory threshold, which, at that time, required a determination that the device was not properly designed and manufactured with reference to the state of the art at the time.

Major Contributors to This Report

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Glossary

Atrial Lead	An atrial lead is a type of permanent implantable cardiac pacemaker lead that is positioned in the atrial chamber of the heart. It is a transvenous lead that is implanted through a vein. This type of lead can fail and not necessarily have catastrophic effects on the patient.
Audit Check	FDA audit checks are methods to determine the adequacy of a firm's performance in ensuring that all consignees (device purchasers) have received notification of a recall and are taking appropriate action. They may be personal visits, telephone calls, or some combination. FDA decides on an audit program and selects an audit check level after evaluating the firm's recall strategy. The audit check level will either be based upon the effectiveness check level provided in the U.S. Code of Federal Regulations, chapter 21, or on other statistically valid plans. FDA may be assisted by cooperating federal, state, or local officials in the performance of the audit checks.
Bipolar and Unipolar Leads	Bipolar leads have two electrodes or conductors. One end of the conductor makes contact with the metal plate of the pacemaker and the other end of each conductor makes contact with the inner surface of the heart. The unipolar lead is typically thinner and has only one electrode or conductor.
Confidence Level	A number, stated as a percentage, that expresses the degree of certainty associated with an interval estimate of a population parameter.
Confidence Interval	An estimate of a population parameter that consists of a range of values bounded by statistics called upper and lower confidence limits. For this study, a value is the rate at which a lead fails at a given time interval.
Effectiveness Check	Effectiveness checks are actions taken to verify that all consignees (device purchasers) at the level specified by the recall strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or some combination. These checks are conducted by the recalling firm as part of its recall strategy.

Effectiveness Check Level

The effectiveness check level represents the extent to which effectiveness checks will be made within the distribution chain, including consumers or patients where appropriate. The range includes level A, which entails contacting 100 percent of the consignees, through level D, which entails contacting only 2 percent.

Failure Rate

The rate at which a lead has failed over time for a given number of patients. It has been defined in the two data bases we analyzed as the proportion of lead failures to all implanted leads. Lead failures consist of lead integrity problems such as conductor break and insulation break. These factors are affected by lead design and differences in the manufacturing process, insulation and conducting materials, and the treatment of the component materials.

A failure is determined by the physician based on an analysis of the pacemaker system's performance by electrocardiogram readings or X-rays. The pacemaker system would register sensing or pacing problems. (See "transtelephonic monitoring.") A lead failure is inferred by the physician based on a series of tests, which would assist the physician in distinguishing lead problems from generator malfunctions. Lead failure does not include surgeon-related complications with the lead, such as infections and perforations of the heart tissue.

Clinically-based failure rates reflect actual performance and lead longevity in patients. The standard life-table method was used to calculate failure rates. This method takes into account patients' death or loss to study follow-up. The failure rate is the proportion of all implanted leads that fail within a given time interval. The number of leads at a given time (4-5 years) is the number of patients receiving the lead at the start of the interval less the total number of failed leads, deaths, and people lost to follow-up or deceased patients during the interval. The principal advantage of the life-table method is that it makes possible the use of all survival information accumulated up to the cut-off date for a given time interval. It also reduces the standard error of the survival rate.

These clinically-based failure rates are based on lead longevity in patients aggregated across different hospitals. They include all participating hospitals' experience with a specific model, but the failure rate may not be the same as an individual hospital's own calculated failure rate for that model.

There is no nationwide data base on lead performance for many or all models. The existing data bases contain a portion of all lead performance; they may use different definitions of lead failure and, therefore, may report different failure rates. For example, according to Medtronic data in its Chronic Lead Study, the model 6990U has a much lower failure rate than we report. Medtronic's data also indicates a higher failure rate for some of the other models reviewed in this report.

Failure rates are also calculated by lead manufacturers and are based on the number of failed leads returned to the manufacturer and confirmed to have failed. Since leads are often not removed, the number of failed leads returned probably does not include all failed leads.

Medical Device

The term "medical device" is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act of 1938 (as amended by the Medical Device Amendments of 1976) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official National Formulary or the U.S. Pharmacopeia or any supplement to them; that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or intended to affect the structure or any function of the human body or bodies of other animals; and that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes.

The 1976 amendments enlarged the 1938 definition to include devices intended for use in diagnosis of conditions other than diseases (such as pregnancy); in vitro diagnostic products; and specific products previously regulated as new drugs, including soft contact lenses, bone cements, and sutures.

Myocardial Lead

A myocardial lead is a type of permanent implantable cardiac pacemaker lead that is fixed to the surface of the heart. This type of lead is less frequently used in the United States than the transvenous atrial and ventricular leads that are implanted in the chambers of the heart.

Pacemaker Dependency

"Pacemaker-dependent" is a widely used term to describe patients' reliance on their pacemakers. The term has no generally agreed-upon definition or defining criteria. One way physicians may determine a patient's dependency is by preventing pacemaker output during a clinical visit and then assessing the condition of the heart's unaided rhythm. Patients may be categorized as dependent, moderately dependent, substantially dependent, or not pacemaker-dependent. Their degree of dependency may vary over time.

Polyurethane Degradation

Polyurethane degradation is the breakdown or deterioration of the polyurethane insulation of the implanted lead. All polyurethane degrades, but factors such as increased moisture and stress (user- or manufacturer-induced) can increase the rate of deterioration. Rapid deterioration brings about a premature lead failure.

Polyurethane refers to a series of polymer formulations with different properties. The 15 Medtronic models were insulated with one of two common formulations, Pellethane 80A and 55D, made by Dow Chemical Co. Intermedics also used these formulations, and there are other polyurethane formulations used in other leads manufactured by other firms.

Recall

A medical device "recall" is the removal from the market of a particular product, correction of a marketed product, or correction of labeling or of promotional material that FDA considers in violation of the laws it administers. FDA has designated three classes of recall in descending order of the potential degree of health risk from class I to class III. (See U.S. General Accounting Office, Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6, Oct. 1989, app. III.)

Before enactment of the Safe Medical Devices Act of 1990, FDA could request that a firm initiate a product recall. However, FDA had 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 could request a recall, but had no statutory authority to impose or seek sanctions for a manufacturer's refusal to carry out the recall. However, FDA could take administrative action on the underlying violation that led to the agency's request. For example, it could seize a violative product and prosecute those responsible for distributing it.

Repair, Replace, or Refund	Section 518(b) of the Federal Food, Drug, and Cosmetic Act, as amended, authorizes FDA to order manufacturers, importers, or distributors of a device to repair, replace, or refund the purchase price of the device (and pay all associated costs) in cases where the agency can make the following four findings: (1) the device presents an unreasonable risk of substantial harm to public health; (2) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture; (3) there are reasonable grounds to believe that the unreasonable risk was not caused by the failure of a person other than a manufacturer, importer, distributor, or retailer to exercise due care in the installation, maintenance, repair, or use of the device; and (4) notification under section 518(a) would not be sufficient to eliminate the risk, and repair, replacement, or refund is necessary to eliminate the risk.
Safety Alert	A voluntary communication issued by the manufacturer, distributor, or other responsible person (including FDA) to inform professionals of a situation that may present an unreasonable risk of substantial harm to the public health from a device in commercial distribution and intended for human use and to reduce or eliminate the risk. This is a notification that is sufficient to eliminate the unreasonable risk to health posed by the device.
Statistical Significance	A statistical measure that indicates whether the difference between two or more groups is real or a chance variation.
Substantial Equivalence	Section 510(k) of the 1976 amendments requires all device manufacturers to notify FDA at least 90 days before they intend to introduce a device into the market either for the first time or so significantly changed or modified in its intended use so as to affect its safety and effectiveness. FDA reviews the manufacturer's claims that a device is "substantially equivalent" to some other device marketed before 1976. (See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14, Aug. 17, 1988.)
Transtelephonic Monitoring	Transtelephonic monitoring is a procedure whereby an electrocardiogram reading of a patient's heart activity and a measurement of the pacemaker rate are accomplished by a telephone call between the patient and a

monitoring center. The electrocardiogram is received and interpreted by a health care professional.

The consensus of expert opinion is that transtelephonic monitoring detects most types of irregularities in the operations of a pacing system (such as undersensing, oversensing, and loss of capture) and a heart's normal electrical patterns. It would detect pacemaker lead problems such as insulation breakage or fracture and electrical conductor breakage and others that would cause a change in the electrical current between the pulse generator and the patient's heart.

Other methods of monitoring are "in-clinic" or in a physician's office. "In-clinic" monitoring is frequently supplemented by transtelephonic monitoring, generally includes in-depth electrical testing of the generator and lead performance, and is typically performed one to four times a year depending on the institution. A visit to the physician's office might not include the diagnostic tests of the pacemaker and lead.

Neither method can detect every impending lead fracture associated with insulation deterioration, but both can usually detect most indications in advance of the event itself. For most patients, the combination of transtelephonic and in-clinic monitoring is considered the best available treatment regime for persons who are implanted with potentially faulty leads. Patients dependent on pacemakers may require a new implantation.

Ventricular Lead

A ventricular lead is a type of permanent implantable cardiac pacemaker lead that is positioned in the ventricular chamber of the heart. If this type of lead fails, it can have immediate harmful effects on the patient.

Related GAO Products

Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority (GAO/PEMD-92-10, Feb. 13, 1992).

Medical Device Recalls: Examination of Selected Cases (GAO/PEMD-90-6, Oct. 19, 1989).

Medical Device Recalls: An Overview and Analysis 1983-88 (GAO/PEMD-89-15BR, Aug. 30, 1989).

Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation (GAO/PEMD-89-10, Feb. 17, 1989).

Medical Devices: FDA's 510(k) Operations Could Be Improved (GAO/PEMD-88-14, Aug. 17, 1988).

Medical Devices: FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640 (GAO/PEMD-88-30, July 11, 1988).

"Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting," Statement by Eleanor Chelimsky (GAO/T-PEMD-87-4, May 4, 1987).

Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting (GAO/PEMD-87-1, Dec. 19, 1986).

Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision (GAO/HRD-85-39, Feb. 26, 1985).

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