

Policy Analysis

REPLACE FDA REGULATION OF MEDICAL DEVICES WITH THIRD-PARTY CERTIFICATION

by Noel D. Campbell

Executive Summary

No manufacturer can market a medical device, alter manufacturing processes for a device, or propose a new use for an existing device without the prior approval of the Food and Drug Administration (FDA). The FDA monopoly over market access is a bottleneck, delaying the introduction of new medical devices for up to three years and restricting the flow of information from manufacturer to user about approved devices. These actions not only violate the basic rights of the device manufacturers and consumers who wish to trade with one another--they have resulted in thousands of deaths.

The solution to the problems caused by the FDA's monopoly over market access and dissemination of information is to turn over the certification of medical devices to certification agencies competing in a free market. The best known of the privately funded institutions that certify safety and performance in other markets is Underwriters Laboratories, Inc. UL's and similar organizations' certification of the safety of products provides valuable information to consumers and leaves manufacturers and consumers free to trade with one another--a basic right in a free society.

Unlike proposed reforms that leave FDA's monopoly intact, the market solution ensures that consumers will be able to choose in a market well stocked with safe, effective devices, guided by qualified experts with superior information. Certifying organizations, anxious to maintain their reputation as guardians of safety and efficacy, will protect consumers from a "race to the bottom" and from "fly-by-night" manufacturers. When, as now sometimes happens, unsafe or ineffective products mistakenly reach the market, the court system provides a mechanism for legal redress and government prosecution. The incentives for certifiers in a free market are far more effective for generating good results than the incentives for bureaucrats with monopoly powers.

Introduction

In 1992, FDA Commissioner David Kessler concluded that it is too great a burden for average Americans to make decisions concerning their own health care. He stated,

If members of our society were empowered to make their own decisions . . . then the whole rationale for the agency (FDA) would cease to exist. . . . To argue that people ought to be able to choose their own risks, that government should not intervene . . . is to impose an unrealistic burden on people.¹

Kessler's statement makes clear his opinion about the FDA's role in society and about the necessity for paternalistic government intervention. In his view, the citizen has no freedom to rely on medical advice from professionals of his or her own choosing and to decide along with those professionals which medicines and medical devices to use. Only the government decides.

This study presents a proposal to do away with FDA's monopoly over market access for medical devices and to replace it with third-party certification. This solution to the problems raised by FDA regulation will produce a market with safe, effective devices and wide-open exchange of information. Proposed "reforms" of the FDA system, which are described in this analysis, would leave the agency's monopoly intact and continue FDA's power to restrict the flow of information from manufacturer to consumer.

The Nature of the Problem

The FDA has become a bottleneck, delaying the introduction of new medical devices for up to three years and causing the deaths of thousands of Americans who are denied access to these new devices.² The basic problem with the FDA can be stated with a simple example from statistical theory. FDA makes decisions about whether or not devices are safe and effective, and two types of statistical errors are possible:

- A Type I error occurs when a false hypothesis is accepted as true. It results in an unsafe or ineffective device being marketed.

- A Type II error occurs when a true hypothesis is rejected as false. It prevents or delays the entry of a safe and effective device into the market.

The FDA focuses too much on preventing Type I errors. That is, the FDA spends too much time and too many resources trying to prevent the introduction of devices that may later prove to be unsafe or ineffective. Consequently, the FDA does not spend enough time and resources ensuring that safe and effective devices are not locked out of the market. The result is that safe devices are subject to extremely long and costly delays before they can be marketed.

The FDA behaves that way because it is a public agency that answers to politicians, and Congress and the President pass on the political pressure they feel to the agencies under them. Congress' actions have been described as follows:

First require that the FDA do the unwise or impossible. A few years later, ask the General Accounting Office to tell you if FDA is doing the unwise or impossible as instructed. Express shock and surprise when you learn that it is not. Hold hearings to pistol-whip FDA and industry in order to support the passage of more unwise or impossible-to-implement legislation.³

Another FDA watcher describes how Congress turns agencies into public scapegoats and whipping boys, creating and maintaining the FDA's obsessive desire to minimize Type I errors:

From FDA commissioner to the bureau heads to the individual NDA [New Drug Application] reviewers, the message is clear: if you approve a drug with unanticipated side effects, both you and the agency will face the heat of newspaper headlines, television coverage and congressional hearings. On the other hand, if FDA insists on more and more data from a manufacturer, and finally approves a drug, which should have been on the market months or years before, there is no such price to pay. Drug lag's victims and their families will hardly be complaining, because they won't know what hit them. . . . They only know that there is nothing their doctors can do for them. From the standpoint of . . . politics, they are invisible.⁴

The Perils of Delaying Medical Devices

All regulatory agencies are human institutions. Regardless of motive or enthusiasm, they make mistakes and produce delays. When the FDA makes a mistake and allows unsafe and harmful products on the market, there is a clear result: people die. But what is not so clearly seen is that people also die when the FDA fails to act or acts too slowly in allowing a life-saving device on the market. Moreover, businesses may lose profits, jobs may be destroyed, and consumers may pay more for the goods they purchase.

One can seldom specify the deaths that occurred because the FDA was slow to allow a drug or device on the market. There are, however, some well-known examples:

- Thrombolytic therapy dissolves blood clots in heart attack victims. Every year 700,000 people suffer heart attacks, and 9 percent of them die. The FDA found the therapy reduced heart attack fatalities by 18 percent, but it took two years to approve the new drug application. The result was as many as 22,000 deaths.⁵

- Based on FDA's own calculations, between November 1988 and May 1992, 3,500 kidney cancer sufferers died as the FDA deliberated the approval of Interleukin-2, which was already available in Denmark, France, and seven other European countries.⁶

- Misoprostol prevents bleeding ulcers caused by aspirin and other, similar drugs. These ulcers are common in arthritis sufferers. According to the FDA's own figures, Misoprostol can potentially help 10,000 to 20,000 people every year. During the nine and one-half months it took the FDA to approve the new drug application no one could use the therapy. That means 8,000 to 15,000 Americans may have died because Misoprostol was not available sooner.⁷

Delays in medical devices also cost lives and prolong illness.

- Seven thousand Americans die every year because the AmbuCardioPump, a CPR device used in emergency rooms and available in most industrialized nations, is not available in the United States.⁸

- In 1993 the FDA disallowed the use of a specialized infant ventilator, a machine that helps very sick in-

phants to breathe. The FDA's action cost the lives of 10 to several hundred infants.⁹

- FDA action in 1992 halted production of Physio-Control's cardiac defibrillators for more than two years, before allowing production to resume. A defibrillation authority, Dr. Richard Cummins, estimates "that FDA's shutdown of Physio-Control might have caused a thousand deaths."¹⁰

- "Balloon implants used to plug life-threatening holes in brain arteries were rejected by the FDA because the developers did not properly document their benefits. Some neurosurgeons call the balloons 'the world's standard of care.'"¹¹

- Annually, 40,000 men undergo surgery to correct benign prostate swelling. An American-designed safe, painless, permanent alternative--a tiny implantable wire coil--was still not available in the United States six months after its introduction in Europe.¹²

- Despite the clearly demonstrated safety and accuracy of the home HIV test, FDA delayed its marketing for five years. As a result, an estimated 10,000 people were infected with HIV because people who would have used the test to find out that they were carriers of the virus could not do so.¹³

These numbers reflect only some of the fatalities, pain, and suffering that can be laid at the FDA's door. Quality of life suffers when the FDA refuses to allow drugs and medical devices to be sold until its exhausting, Byzantine approval procedures are completed. Vice President Al Gore's National Performance Review proudly predicted that by 1997 new devices would receive final approval and be marketed within one year.¹⁴ Even had that goal been reached, the FDA would have delayed access to the market for one year, twice the time allowed in the law. In the case of thrombolytic therapy, that would have meant that only 11,000 people would have died.

Taxpayers also bear a large, direct burden because of the FDA. The FDA is a monumental, costly enterprise funded almost entirely by tax dollars (one exception is the FDA program that permits drug manufacturers to make payments to the FDA that are used to hire and keep additional drug review and approval personnel at the agency). The FDA budget has hovered just below \$1 billion annually since 1994.¹⁵

The Alternative

Is there an alternative to entrusting a monopoly agency with coercive powers? Yes. The alternative requires no massive expenditures of the public purse to work. It makes fullest use of millions of bits of knowledge. It is based on individual freedom. It has a proven record of success.

Privatization of the certification of medical devices will save lives and alleviate suffering. It is the efficient, effective alternative to the FDA's current command-and-control approach to regulation.

Privatization is widely regarded as a positive step for most areas of government, but many people are reluctant to privatize an agency concerned with health and safety matters. Will the free market work? It works now and certifies the safety and effectiveness of thousands of products. It can work for medical devices.

Third-Party Certification

What would happen if the FDA were stripped of its monopolistic position over market access? Who would the public turn to for testing and certification of safety and effectiveness? How would the public know medical devices are safe? These questions have answers, and the answers lead to the prospect of an approval process that will be faster and more responsive to the need for new life-improving therapies and products. Not only can consumers get more speedy and flexible approval of safe devices, but they can get it without sacrificing quality and effectiveness and at lower cost.

No one in the market has the capacity to block the sale of new devices, and no one can prevent consumers and their medical advisers from making their own decisions about the medical devices that they use. Without FDA's monopoly over market access, the market will be well stocked with safe and effective devices, and consumers and their advisers--physicians, nurses, pharmacists, physical therapists, and other health professionals--will have the knowledge to use them wisely. Private third parties would certify devices, and the FDA would retain its role in investigating and prosecuting fraud when it occurs. This system is preferable to the current regulatory structure, and it will become a reality when the FDA's monopoly powers over market access and the dissemination of information are removed.

The market, relying on individual initiatives, generates new institutions to spread information through the economy. The other key accomplishment of the market is that it induces and sustains such institutions without coercion, with minimal resource cost, and with a maximum of personal freedom.

Market-created institutions produce and disperse a vast volume of information about safety and quality every day. For example, Consumer Reports and the Washington Checklist tell prospective shoppers about best buys; the American National Standards Institute (ANSI) provides manufacturers with standards for manufacturing and safety so the consumer knows that "brand X FM tuner" will work with "brand Y amplifier." There is no compelling reason to believe that the market would not induce that same information flow about the safety and performance of medical devices.

There are reassuring working examples of market solutions to the same types of issues addressed by the FDA. The best-known example is Underwriters Laboratories, Inc. (UL), which has been certifying product safety for more than 100 years--longer than the FDA has been in existence.

Like the FDA, UL is committed to public safety. Both organizations work to safeguard the public from dangerous products. Both are staffed by expert scientists and technicians. UL's actions, like the FDA's, affect millions of consumers and involve products worth billions of dollars.

- Every day, the public buys and uses products that are UL listed or FDA approved.
- We put on our FDA-approved cosmetics after drying our hair with our UL-listed hair dryers.
- We pour FDA-approved vitamin-enhanced milk over the breakfast cereal we cooked on UL-listed stove tops.
- Driving home from work, we take FDA-approved aspirin while cooling off with UL-listed automotive air-conditioners.

Only the number of products the market produces limits the parallels.

But there are some significant differences. The FDA is a tax-funded public agency, given legal monopoly power over market access and the dissemination of information. Its

relationship to Congress leads the FDA to concentrate on approving only those devices that are extremely likely to be safe. The consequence is that many safe and effective devices never reach consumers. UL is a private organization that receives no tax revenue. Its clients, mostly manufacturers, wholly support it. It has no legally created monopoly over market access; it cannot deny consumers choice; it has no incentive to minimize the chance of a Type I error at the expense of Type II errors. UL's market-created incentives are to test products appropriately, minimizing the probability of both Type I and Type II errors.

Underwriters Laboratories

William Henry Merrill, a fire safety inspector from Boston, founded UL in 1894 as an independent, not-for-profit organization. It provides certifications of safety for thousands of products and writes standards for manufacturing and performance for hundreds of others. It has been so successful and its market acceptance so complete that consumers scarcely ask themselves if many of the products they buy are safe. They make the rational assumption that they will be because UL and similar organizations certify them.

UL's stated, explicit mission is "Testing in the Public Interest." As Inspector Merrill said in 1923, "We are doing something for manufacturers, buyers, users, and property owners everywhere. We are doing something for humanity."¹⁶

- UL certifies more than 14,000 different types of products.
- Every year, UL issues over six billion individual UL marks, the "trademark" symbol affixed to certified items which are UL listed.
- UL has more than 40,000 clients, including manufacturers, retailers, insurers, code officials, architects, and government agencies.
- Among many other products, UL tests and certifies electrical and medical appliances and equipment, automotive and mechanical products, fire-resistant and other "code" materials, bullet-resistant glass, Occupational Safety and Health Administration (OSHA)-designated "hazardous location" products, alarm systems, and chemicals.
- UL writes and maintains 696 different end-use product

standards.

- UL helps develop national and international codes and works toward standards harmonization.¹⁷

UL does not provide the insurance function of underwriting risk. It produces no testimonials, advertisements, or other marketing support for its clients. The sole business of UL is disseminating safety and performance information. UL approval sometimes is conditioned on manufacturers' issuing warning labels, use-and-care booklets, safety tips, and other consumer information. UL itself distributes informational literature, news releases and broadcasts public service announcements to educate the public about the meaning of the UL mark. UL disseminates all this information because the market demands it, not because the government requires it.

How good is UL at what it does? UL's employees are the most expert personnel in their profession. Their professional opinion on a given subject is the best available. Homer Pringle of UL's legal department says, "Put UL personnel on the stand, and they will beat anybody else's expert witnesses."¹⁸

Value Added and No Monopoly

No statutory, regulatory, or court-ordered mandate requires manufacturers to seek UL approval, yet tens of thousands do. Why? Consumers want to buy safe and effective products. The people at UL have staked their time, their reputations, and their livelihoods on providing consumers with accurate and timely information.

The UL organization acts like a performance bond. Manufacturers who pay for UL's services are posting that bond. Consumers recognize this and are willing to buy or pay more for UL-listed products. Thus, manufacturers who produce a good product want UL listing. Companies that make a poor, unsafe product are not listed with UL, many retailers balk at stocking such products, and many consumers think twice before buying them. Product safety is ensured, and the private market has generated value-adding information.

Incentives

Market survival dictates that UL be extremely diligent in avoiding both Type I and Type II errors and in maintaining independence from its clients. If UL were a tool of

certain manufacturers, UL could not avoid listing unsafe products. Were that to happen, consumers and competitors would discover it and the UL mark would no longer add value to products. As a result, manufacturers would stop paying for UL and its services.

It is costly for everyone, including manufacturers and UL, to have poor quality and performance standards and unsafe products. In its 1994 Annual Report, UL said,

The "real" cost . . . is compromised safety, which can ultimately result in product rejection, manufacturing delay, and greater costs. A final result is the loss of the certification organization's credibility and the manufacturer's product acceptance.

The loss of credibility would spell the end of jobs for UL's management and employees. UL, consumers, and manufacturers all want a reliable and independent UL, and all have incentives to keep it that way.

Unlike the FDA, UL has incentives to reduce Type II errors. If UL in any way unnecessarily delays the marketing of a new product, it lowers the value of the UL mark to producers. That means that UL has powerful incentives to certify a product as quickly as possible without unduly increasing the likelihood of committing a Type I error.

UL operating practices contribute to appropriately rapid certification. UL works closely with the manufacturer's product developers from the earliest stages of research, to help them meet the known burden of the applicable standards. Before a sample product or process is even complete, UL may have been able to certify it.

Who Pays?

UL gets its job done efficiently and at low cost. In 1994, UL employed more than 3,900 people, including more than 900 degreed engineers and many more researchers and technicians. In that same year, the FDA employed 1,093 people in the Commissioner's office alone, as well as 984 in the Center for Devices and Radiological Health and 925 in the Center for Food Safety.

In its 1994 income tax return, UL claimed revenues of \$281.1 million.¹⁹ That is a substantial sum, but less than the \$921 million Congress appropriated for the FDA in the

same year. Moreover, UL pays its employees out of revenues it earns from providing valuable services for its customers, whereas FDA staff are paid out of tax dollars that all consumers are required to pay.

Manufacturers pay for UL's services. UL charges a fee based on a cost-of-testing approach then bills out its on-site inspectors at a flat rate. Consumers who do not benefit from UL's services do not have to pay for them. UL is free from pressures to comply with special interests; it must satisfy customers directly. In other words, it is not detached from the people who use its services as tax-supported government agencies are.

For their fees, clients get follow-up services that include frequent, unannounced visits to their production facilities worldwide. In 1994, more than 481,000 on-site follow-up-service visits were conducted for the benefit of UL clients, the manufacturers and merchants who pay for UL's services.²⁰ During such visits, UL personnel check production controls, observe on-site testing, conduct inspections, and select samples for further testing at UL labs. They even check to see if the certification program is posted on the wall. If the facility does not pass inspection, the manufacturer has two weeks to correct the mistakes. After that, UL pulls its certification.

Competition

UL can perform its tasks efficiently because of a simple, understandable reason. Unlike the FDA, UL operates in the private market, and it is not legally protected from competition. Competition in the market for high-quality product safety information has the same effect that competition has in any market. Goods and services produced in a competitive market are produced efficiently, at the lowest cost. Though UL enjoys the widest name recognition in the marketplace, its market is competitive, and UL has competitors. Among many others, these competitors include Electronics Testing Laboratories, a subsidiary of the British conglomerate Inchcape; Factory Mutual of Norwood, Massachusetts; and Canadian Standards Association of Rockville, Ontario. Some competitors use UL standards as the basis of their certification, but others write their own. Some of UL's competitors are for-profit organizations. Others are subsidiaries of other corporate entities. Though UL uses the term "friendly competition,"²¹ the competition is there.

If UL's standards are inappropriate, or if the public loses confidence in the good name of UL, then there

are other organizations ready to serve the market.

UL has incentives to do its job quickly, accurately, and efficiently. If those incentives break down for any reason, the critical point is that even a malfunctioning UL cannot make consumers suffer. Consumers are still able to use the information at hand and make an informed choice. UL tests products and certifies their safety, providing consumers with accurate, timely information, and no more. Consumers can decide for themselves, based on good information, if they want to buy a riskier product or not. No monopolistic government agency prevents their making their own choices.

UL Standards for Safety

How does a "standard for safety," a product standard, get written? The process begins after a product has been submitted for testing to UL. UL then issues an outline of its planned investigation to interested parties and solicits comments and criticisms. Based on that feedback, UL amends the outline and issues the proposed standard to repeat the process. That reiteration produces the published standard in a timely fashion.

The whole process usually takes only three to four months, and amendments to the standard can be published and made available within a day. Based on a standard, UL engineers can write a certification program within a couple of weeks.²² Moreover, UL standards are flexible in that they are designed to accommodate manufacturing innovations, in a manner consistent with the original intent of the standard.

"[B]uilt into UL Standards are requirements that facilitate changes and eliminate undue restrictions on design."²³

Government Agencies Use UL

Private consumers are not the only beneficiaries of UL's services. Government agencies also depend on the company. UL is an active participant in development of "building codes" in over 40,000 local jurisdictions around the country. The UL mark is accepted in all 40,000 of those jurisdictions.²⁴

OSHA recognizes UL as one of its 13 Nationally Recognized Testing Laboratories (NRTLs). OSHA's guiding documents specifically state that an NRTL shall certify all electrical workplace products. Many of the standards for certification were developed by other third-party certifica-

tion organizations--in particular, the American Society for Testing and Materials (ASTM) and the American National Standards Institute (ANSI), but some are UL standards. As an NRTL, UL certifies the safety of products that affect the occupational safety of employees. Most of UL's work as an NRTL involves electrical products, but it also evaluates fire suppressant and elimination products and liquid petroleum gas appliances.²⁵

Even medical equipment carries UL's safety certification. UL tests medical equipment and devices for safety. Turn over most medical equipment, and there will be the UL mark.²⁶ To be sold as medical devices, the equipment must still be approved by the FDA, at enormous cost, but UL has already certified its safety.

As described below, FDA has initiated a study of alternatives to its current regulatory program for medical devices. UL is one of the certified third parties in the program. That does not mean that the FDA is one of UL's clients, but it demonstrates that the FDA recognizes UL's competency.

The Success of Market Certification

In Senate testimony, FDA Commissioner Kessler stated, "The assurance that FDA is there everyday doing its job is so fundamental that we have the luxury of taking it for granted." One implication of his statement is that the FDA is necessary for Americans to feel secure about their medical devices. Extending that logic, do consumers worry that their televisions will start fires, or that they will be injured using their toasters? Is there a strong popular demand for the federal government to certify the safety of consumer products and restrict consumers' access to these products?

There is no such demand because UL and the other competing certifying organizations already fill the role. The market system already produces accurate information about the quality of consumer products.

The FDA and Medical Devices

Developing a medical device is a lengthy process that usually goes through three steps after prototypes are first manufactured: pre-clinical testing on animals, clinical testing involving human beings, and FDA review for approval.

The FDA review process imposes significant delays upon the marketing of new devices.

A Brief History of Medical Device Regulation

The fundamental sanctioning law of the FDA, the Federal Food, Drug, and Cosmetic Act of 1938 (FDC Act), clearly separated medical devices from pharmaceuticals and gave the FDA power of premarket approval over pharmaceuticals but gave it no corresponding power over medical devices. ("Pharmaceuticals" are products that produce an effect through chemical or metabolic action. "Biologics" are products of biological origin that have pharmaceutical properties.) A "medical device," according to the General Accounting Office (GAO), "can be any product used to cure, prevent, diagnose, or treat illness, provided that its principal intended purposes are not achieved primarily by chemical or metabolic action."²⁷ Devices range from Band-Aids and tongue depressors to kidney dialysis units and heart lung machines.

Under the 1938 law, the FDA's options for regulating devices were limited to asking the courts for the authority to block new devices or to remove existing devices from the market. Within that limited sphere, the FDA blocked or removed dozens of fraudulent medical devices during the next quarter century. Following passage of the 1962 amendments to the FDC Act, which expanded the FDA's mandate to require proof of effectiveness as well as safety for drugs and which increased the FDA's enforcement powers, the FDA struggled to secure the same authority over medical devices that it already had over drugs.²⁸

The Medical Device Amendments of 1976 enjoined the FDA to "provide reasonable assurance of the safety and effectiveness of the device[.]" Safety and effectiveness were to be determined with respect to the device's intended user, its prescribed or recommended uses, and its probable benefit weighed against the probable risk of illness resulting from its use.

The most significant aspect of the 1976 amendments was the establishment of the FDA as the gatekeeper over market access for medical devices. Power had clearly shifted to the FDA. Instead of being required to demonstrate its case to the satisfaction of a court, the FDA could now ban devices on its own legal authority, and it was left to the injured party to seek a judicial review.

The next significant event in medical device regulation was the November 1990 passage of the Safe Medical Devices Act (SMDA). The pattern repeated itself. The FDA garnered more power, added more layers of costly reporting and bureaucratic requirements, and gained more powers of interference in the market. The SMDA instituted a massive system of post-market surveillance and a reporting scheme wherein medical device users, of any sort, are required to file reports anytime a device could be implicated in a patient's injury or illness. Often hastily written, these reports are seldom-useful research tools. The FDA requires users to decide for themselves when such a report is necessary.²⁹ In addition, the FDA received new authority to impose civil penalties for violations of the Act, or not to impose the penalties, at the FDA's discretion.

Classes and Tiers and What Difference Do They Make?

The 1976 amendments established three classes of medical devices (Classes I, II, and III), corresponding to devices of low, medium, and high risk. In 1994, the FDA implemented a three-tier system that ranks devices according to the intensity of required review. Tier I devices require the least review. With the combination of the class and tier systems, the FDA can categorize medical devices in nine different ways (e.g., Class I, Tier I; Class II, Tier I; Class III, Tier I; Class I, Tier II; Class II, Tier II, etc.).

Some devices are novel, and some devices are similar, or nearly equivalent, to existing devices. For high-risk novel devices, the FDA requires a full pre-market approval (PMA) review before allowing the marketing of the device. Low-risk novel devices similar to other approved devices are evaluated under a provision called "510(k)" (after a section of the 1976 law). The 510(k) process initially required only that the manufacturers notify the FDA about the device and convince the agency that it was equivalent to an existing device. The FDA does not require full PMAs before considering approval for new uses of approved devices. Those are evaluated as "PMA supplementals" and require only an abbreviated approval process.

These neat distinctions, if they ever existed, have been battered down by the FDA's constantly expanding requirements. The 510(k) process, through arbitrary and baffling FDA requests for more information, ballooned from a simple notification process into a system often tantamount to a full PMA. Former FDA chief counsel Peter Barton Hutt

said that the FDA staff reviewers "sent back 510(k)s with so many trivial, unimportant questions that they eventually became the same as a PMA."³⁰ In an apparent acceptance of reality, the SMDA of 1990 formally altered the 510(k) process from notification to an approval process and augmented the types and quantities of required data.

Approval Rates for Medical Devices

Table 1 shows the number of submissions for FDA approval of medical devices and the number of approvals each year from 1989 through mid-1995. As can be seen, the number of submissions was highest in 1989, probably because of manufacturers' desires to avoid the new requirements expected with the passage of the SMDA in 1990. Since then the number of 510(k) submissions has remained constant at about 6,000 per year. PMAs have fallen from more than 70 per year to the 40s, and PMA Supplementals have fallen from about 600 to about 400.

Approvals per year of 510(k)s have remained nearly constant, and approvals of PMAs and PMA Supplementals have fallen. According to a 1995 GAO report, the FDA has approved 73 percent of the 40,950 510(k) applications received during 1989 through May 1995 and disapproved 2 percent. As

Table 1
Submissions and Approvals for Medical Devices

Year	510(k)s		PMAs		PMA Supplementals	
	Total	Approved	Total	Approved	Total	Approved
1989	7,023	5,258	84	45	804	640
1990	5,835	4,633	77	36	660	557
1991	5,835	4,513	72	21	595	493
1992	6,533	4,888	66	21	605	474
1993	6,306	4,654	40	7	394	311
1994	6,446	4,342	43	3	372	269
1995	3,033	1,429	19	0	210	78

Source: "Medical Devices: FDA Review Time," GAO/PEMD-96-2, October 1995, p. 27.

of May 1995, 4 percent of the 1989 PMAs were unresolved, and 81 percent of the 1994 PMAs were still in review. The FDA is far short of reaching its mandated requirements to complete reviews of 510(k)s in 90 days and PMAs in 180 days.

How Long Does FDA Review Take?

The 1976 law requires the FDA to complete review of 510(k) devices within 90 days and review of PMAs within 180 days. Those requirements have proved unreachable for the FDA.

In 1995, at the request of Representative Joe Barton (R-Tex.), the GAO examined the FDA review times for medical devices from fiscal year 1989 to May 18, 1995.³¹ In its October 1995 report, the GAO found that FDA had failed to meet the review deadlines.

For 510(k)s:

- The median approval time for 510(k) applications was 222 days for applications submitted in 1993.
- The average for all 510(k)s was even greater, 269 days, and will continue to grow as the remaining open cases (3 percent) are gradually closed. If these outstanding reviews were arbitrarily closed at the cut-off date for the GAO's data collection, the mean would jump to 285 days.

For PMAs:

- The median review time for PMAs completed in 1993 was 804 days. The mean was 591 days for all PMAs over the 1989 through 1993 time period.
- Open or unresolved PMAs, for which reviews were not complete, ranged from 4 percent of 1989 submissions to 40 percent of 1992 and 1993 submissions and 81 percent of 1994 submissions.

For PMA Supplementals:

- For PMA Supplementals submitted in fiscal year 1991, the median review time was 154 days, the mean was 261 days, and 3 percent of the submissions remained open.
- The mean time for review of all PMA Supplementals was

238 days.

The GAO analysis showed that the time used by manufacturers to gather new information had held steady during 1989-1993.³² The increases in review times resulted almost entirely from FDA actions.

In its printed response to the GAO report, the FDA maintained that the GAO's figures misrepresented the facts and recommended use of different methods for measuring review times. However, by the FDA's own conventions its performance was even worse in the later years of the study.³³ The FDA also maintained that changes in their administrative process and changes in the nature of new submissions distorted the GAO's numbers. The GAO's response was, "We are not able to verify the effect changes have actually had on review time. To the extent that these changes did affect review time, they are reflected in the review times as presented[.]"³⁴

In a December 12, 1995, speech at the Food and Drug Law Institute's annual meeting, FDA Commissioner Kessler boasted that the FDA had reviewed 96 percent of all pending final applications in 1995.³⁵ That seemingly impressive claim is misleading; it ignores other changes in FDA's review. The FDA has increased the number of trials it requires before approval can be considered and is now changing the requirements again. It has also drastically increased the amount of information it demands before accepting a new device application.³⁶

Moreover, Jeffrey Kimball, the executive director of the Medical Device Manufacturers Association, attributes the FDA's success in reducing its backlog to a simple procedure. The FDA now rejects more new device applications.³⁷ In fact, in the GAO report "Medical Devices: FDA Review Times," the FDA lists "refuse to accept/file policies" as one of the changes instituted to reduce review times.³⁸

The final results are long delays between the development of a device and the time it becomes available to consumers who need it. In addition, FDA's more stringent gate-keeping over which applications it will consent to review may be leading to the rejection of useful devices in order to reduce review times.

Type I Errors Still Occur

Despite the FDA's obsession with Type I errors, some do

"slip through the cracks." The FDA approved the Bjork-Shirley Heart Valve in 1979. The manufacturer, a Pfizer subsidiary, stopped selling the heart valve in 1986 because too many failed. Though the valve failed in only 0.5 percent of all patients between 1979 and 1994, 300 people died worldwide, including 130 in the United States. Despite the low failure rate, the performance of the heart valve qualifies as a Type I error because the FDA expected a failure rate lower than 0.5 percent.

In 1994, Pfizer and the U.S. Department of Justice agreed to a \$10.75 million settlement plus reimbursement of U.S. government expenses associated with valve replacement.³⁹ The lesson learned from the Bjork-Shirley case is that Type I errors will on rare occasions still occur, despite massive government intervention into the marketplace to prevent them.

Reform Is Not the Solution

Responding to the delays and inefficiencies in FDA review, Congress has considered a number of FDA reforms. None has been enacted in the device area. If any had been enacted, they would have changed FDA's marching orders but left its monopoly over market access intact. In addition, the FDA is experimenting with "reform" of medical device review. That experiment is no more than an outsourcing of FDA's work to be paid for by device manufacturers. It, too, leaves FDA's monopoly intact. In any case, it is not expected to accomplish much.

Tightening the Screws

With the exception of 1992's Prescription Drug User Fee Act, which allows manufacturers of certain drugs to pay extra cash to hasten the review process, little FDA reform has been accomplished. That "reform" takes on an odd form, to be sure. The taxpayer-supported FDA failed so miserably at meeting its drug review mandate that Congress now allows drug manufacturers to give money to the FDA so that the agency can employ more staff for drug review. Whatever the merits of the Drug User Fee Act, there is no corresponding user-fee program for medical devices.

Instead there has been a documented tightening of the screws at the FDA.⁴⁰ Consciously stepped-up enforcement activity, coupled with the FDA's own uncertainty in trying to please inconsistent congressional taskmasters,⁴¹ has pro-

duced predictable, distressing results within the medical-device industry.

Indeed, businesses have moved their operations into foreign nations. In a June 1994 survey by the American Electronics Association, 29 percent of the polled firms indicated that they had shifted investment overseas, 22 percent said they had moved personnel overseas, and 40 percent said they had reduced their U.S. payroll as a result of FDA delays.⁴²

Internal Reform at the FDA

In 1994, the FDA began to exempt large numbers of Class I devices from the requirements of the revamped post-SMDA 510(k) process. Now, large numbers of those lowest-risk devices reach the market through notification, much as they would have in the original 510(k) process. Practically, that means that incremental advances in the design, or changes in the manufacture or materials, of such items as bedpans, Band-Aids, sterile gauze, or tongue depressors are no longer automatically kept off the market while the FDA grinds through its review process. The pervasiveness and silliness of the problems addressed by SMDA are illuminated by the fact that the FDA would have automatically blocked the sale of a manufacturer's tongue depressors because of a switch from spruce wood to yellow pine.

The FDA's Trial of Third-Party Review

In August 1996, the FDA initiated a feasibility study of a revised review system for low- to moderate-risk devices.⁴³ As an experiment, FDA accredited outside reviewers to test the design, performance, and safety of at least 10 categories of devices. The outside reviewers make recommendations to the FDA about approval or disapproval, and the FDA makes the final decision.

The FDA's feasibility study, administered through the Division for Small Manufacturer's Assistance, located in the Center for Devices and Radiological Health (CDRH), is very limited in scope. It is an optional fee-for-service program in which fees are negotiated between the third-party review organizations and the manufacturers. The third parties can review, but not certify, those Class I products not already exempt from 510(k) review, and ultimately they will be permitted to review 30 Class II products. Among the Class I products the FDA allows third parties to certify are neona-

tal eye pads and patient examination gloves. Included in the higher-risk, Class II devices are "condoms (latex only)" and "scented or unscented deodorized tampons."⁴⁴ The products, all subject only to 510(k) notification and not PMAs, were chosen so that they would require no clinical studies and little data gathering.

There are two crucial aspects of the pilot program's operation. First, the program amounts to no more than outsourcing of FDA operations. The third parties are simply doing what the FDA would have been doing. Al Bracey of the CDRH Division for Small Manufacturer's Assistance suggested that the program was initiated to save FDA resources and to expedite approval, not to study the impacts of reforming the manner in which the FDA reviews devices.⁴⁵

The second crucial aspect of the program is that the FDA retains complete control of approval. The third parties make recommendations to the FDA, which does what it pleases with them. The FDA retains its full monopoly powers. Bracey believes FDA would make its reasons for disapproval of a recommendation known, but it is not required. He also believes there are no special provisions for manufacturers whose products are not approved within the pilot program. Aggrieved manufacturers would have no more recourse than they currently do, which is limited to attempting to get a court to rein in the FDA.

The FDA used two principal criteria when it selected third-party reviewers for participation in the feasibility study--scientific expertise and avoiding conflicts of interest. In conversation with the author, Al Bracey stressed concerns about conflict of interest over technical expertise. Ten or 11 of the 37 initial applications were not reviewed, primarily because of the FDA's perception of conflict of interest. Seven companies, including UL, made the FDA's final cut.

As of November 15, 1996, the FDA had received only two 510(k) reviews from third parties. Bracey agreed that the program was new, having begun on August 1, 1996, and that the third parties were, in November, only gearing up to market their services. However, in that same length of time, the FDA had received "approximately 300 510(k)s eligible for third-party review."⁴⁶ As a result of the tiny number of third-party reviews, the FDA called for "comments on the reasons for the industry's low utilization rate of the pilot program to date and the steps, if any, that the FDA should take to address this situation."⁴⁷ Whatever the FDA did in response to the information it received has

accomplished little. According to a Senate report⁴⁸ released in July 1997, fewer than 10 submissions for approval of medical devices had gone through the third-party (or "accredited organization") review process in the first 10 months of the program.

Even before the program started, the FDA and the manufacturers were well aware of the weak incentives for manufacturers to use the program. The FDA report of a meeting on June 19, 1996, states

Some industry representatives expressed concern . . . about the limitations of the pilot program that may restrict manufacturers' incentive to participate. In particular they commented that including only low- to moderate-risk devices in the pilot program and limiting third parties' role to making recommendations rather than final decisions might result in marketing clearances that are no faster, and perhaps slower, than those made by FDA alone.⁴⁹

In response, the FDA set itself a 30-day time frame to respond to all submissions made by third parties, under the assumption that 30 days plus the private review time will still be quicker than the FDA's mandated but seldom achieved 90-day review time.⁵⁰

Despite the limited use of third parties, FDA reported,

Potential third parties expressed strong interest in the pilot program and indicated that they have the capability, independence, and controls to conduct sound and unbiased reviews. Most advocated that the FDA rely on existing accreditation systems and criteria for potential third parties, and that the setting of fees should be left to market forces.⁵¹

At the same meeting, some potential third-party reviewers advocated

Standards-based third party reviews rather than reviews focused on substantial equivalence; increased harmonization with international standards; and reliance on existing accreditation systems and criteria for potential third parties.⁵²

The FDA rejected these ideas. It said that the program was

not designed to address innovations in the review process, but to address the feasibility of outsourcing the FDA's workload, and that it could find no accreditation criteria suitable for 510(k) review.

Congressional Calls for Reform

Members of Congress from all points of the ideological spectrum and from both parties have called for reform.

More basic change must occur in the very way FDA sees its mission. FDA . . . must come to understand and believe that . . . consumer protection means not only protecting consumers from unsafe and [in]effective products, but also assuring that individuals have timely access to . . . improvements and breakthroughs in biomedical therapies and food technology. [Then-Sen. Nancy Landon Kassebaum (R-Kan.)]⁵³

[On] the issue of delays. . . . One of the things that emerge from conversations with people in the biotechnology community is that they are deeply concerned that science has now surpassed the regulatory framework of the agency. . . . [T]he regulatory framework . . . [is] from a whole other era and that now science is moving at such a rapid rate that the old mechanisms aren't working. . . . [W]e need a passion for change. If not, I believe that Congress is going to roll right over [FDA]. [Sen. Barbara Mikulski (D-Md.)]⁵⁴

Even FDA Commissioner Kessler said he saw the need for change, or at least saw the congressional sledgehammer hanging over the FDA. "[W]e are working hard to make the FDA more efficient," and "[W]hen it comes to getting needed therapies to dying patients, the riskiest thing we can do is be unwilling to take risk."⁵⁵ Discussing "accelerated approval" of products for life-threatening conditions, Dr. Kessler said, "I think we have an obligation to speed them up." On the same day, he responded to criticism that the FDA is slow, pugnacious, and obstructionist by saying, "We need to fix it."⁵⁶

All of the above quotes are from a single hearing before the Senate Committee on Labor and Human Resources in the 104th Congress in 1995. Despite the apparent urgency, no legislation about the FDA emerged from that Congress.

Actions in the 105th Congress

Both Houses of Congress are considering legislation to reform the FDA, and action is expected because of the pressure generated by the expiration of the Prescription Drug User Fee Act of 1992 on September 30, 1997. Bills in both houses provide for third-party review of medical-device applications, but those bills preserve the FDA's monopoly control over which devices can be marketed.

Senate

The Senate Committee on Labor and Human Resources approved S. 830 in June 1997, and the whole Senate is expected to consider the bill in July. S. 830 directs the secretary of health and human services (HHS) (hereafter "the secretary") to employ third-party firms to review applications for the marketing of medical devices.

S. 830 eases restrictions on the use of unapproved devices when a physician determines that there is no substitute for the device and when the manufacturer of the device is seeking FDA approval for its marketing. This provision directly acknowledges the role of the physician in deciding on the best device for treating the patient. Nevertheless, it reserves to the FDA the power to take that device out of the physician's hands should its review convince the agency (if not the physician) that the device should not be on the market. In any case, the administration of the provision promises difficulties.

The legislation directs the secretary to publish standards for medical devices such that a manufacturer can obtain access to the market by certifying to the secretary that a device meets the suitable standard. The secretary is also directed to accept compliance with any national or international standard as evidence for the marketability of a device. The secretary is granted the power to review the certification statements to ensure that the provisions of the standard are reached.

The legislation directs the secretary to publish a list of Class II devices that do not require 510(k) approval before being marketed. In addition, the secretary is to respond to requests for adding other devices to that list. If enacted, this provision will largely restore the 510(k) process to a notification process as it was originally intended.

Manufacturers whose devices are classified as Class III

are permitted to petition the secretary for reclassification of the device as Class I or II. The secretary has 90 days to classify a device; currently, on average, the FDA takes 137 days for initial classification. The pending legislation would require FDA to respond to a petition for reclassification within 60 days. Were the secretary to make an initial classification decision within 90 days and respond to an appeal for reclassification within 60 days, almost half a year would lawfully pass before the FDA considered the device for approval. In reality, given the FDA record of meeting deadlines, more time would be expected to pass.

Within one year of its enactment, S. 830 directs the secretary to accredit individuals and organizations to review 510(k) applications for devices and to make initial determination of the classification (Class I, II, or III) of a device. The secretary is not directed to accredit individuals or organizations to review applications for devices that are "life supporting," "life sustaining," or "intended for implantation in the human body for a period of over 1 year." Nor is he directed to accredit third-party review for Class III devices, but the secretary is granted the discretion to make such accreditations.

A manufacturer will be able to ask for a third-party review of its device proposal, and the secretary is to offer the manufacturer a choice of at least two review organizations. Compensation for the review is to be worked out between the manufacturer and the review organization.

Initially at least, third-party review will be limited to 510(k) applications; supposedly, all 510(k) reviews will be completed within 90 days. The third-party review can take up to 60 days, and the FDA review of the third party's recommendation is to be completed in an additional 30 days. To reach those goals will surely require changes at the FDA where missed deadlines are common. Moreover, the imposition of the deadlines will surely be met with an FDA request for additional funds for its review activities, even though the third-party review would greatly reduce its workload.

House

On May 21, 1997, Rep. Joe Barton (R-Tex.) and Rep. Anna Eshoo (D-Calif.) introduced the Medical Device Regulatory Modernization Act. It provides for new rules to govern the use of "Investigational Devices" that require the secretary of HHS to define conditions under which devices intended for human use can be exempted from certain requirements of the

Act. In other words, some uses of some devices would be permitted even before the devices were approved for marketing. In addition, manufacturers would be permitted to make minor modifications to devices that are undergoing clinical trials without having to restart the review process with a new application. The bill also provides exemptions for devices that will serve only a tiny patient population and that probably would not be brought to market if the costs of the full review process had to be borne.

The Barton-Eshoo Bill directs the secretary of HHS to publish

notices identifying and adopting applicable nationally or internationally recognized consensus standards to which a person [a manufacturer] may self-certify compliance for the purpose of demonstrating a reasonable assurance that a device is safe or effective or to determine compliance with any requirement of this Act.

This provision reserves to the secretary the decision about which consensus standards to recognize, and a later provision reserves to the secretary the authority to demand all data and information considered by the applicant, thereby maintaining government control. Even so, if consensus standards are published, manufacturers will be spared at least some of the delay now imposed by the FDA.

The bill also directs the secretary to accredit third-party organizations to review applications for 510(k) devices. Third-party accreditation would be limited to Class I and Class II devices (excepting Class II devices that are designed for implantation or that could have life-threatening consequences should they fail). The secretary would provide manufacturers that choose the third-party route with a choice between at least two accredited organizations.

The FDA Monopoly Is Preserved

The bills are a step forward in the review of 510(k) applications, but the FDA retains its powers. As the Senate report says,

The provision maintains a strong, continued role for the FDA in the device approval process. . . .
The FDA alone accredits the pool of qualified private parties to conduct the reviews. . . .

The FDA's role is not limited to accredited-party selection. In addition, the Agency retains all the authority it has under current law to make final product review decisions . . . there is no presumption given to the accredited party's recommendation of approvability or classification of a product.⁵⁷

Although the proposed legislation would probably result in wider use of third-party review, it represents, in effect, outsourcing of an activity currently done by FDA employees. More positively, should either of the bills or a compromise between them become law, the legislation might embolden legislators to further relax the FDA's grip on the marketing of devices.

Beyond Reform

Reforms are designed to improve or amend a system that is not functioning properly, not to replace the system. Reducing the amount of paperwork that goes along with a regulation is a reform. Removing an agency's regulatory power is a remedy, not a reform.

The overriding problem with proposed FDA reforms is that they leave the medical device approval system unchanged in its most important aspect. The FDA will still hold its gatekeeper monopoly, constricting the market for safe medical devices.

Independent Review Panels Are Not Independent

Congress has long favored "independent review panels" as checks on FDA actions, and there are sixteen standing scientific/medical review panels under the Medical Device Committee in the FDA's Office for Device Evaluation. (Each of the required quarterly meetings of each of the 16 panels costs \$20,000.)⁵⁸ In addition to subject matter experts, the medical-device review panels include a consumer's representative and an industry representative, in nonvoting roles. The only difference between panel members and regular FDA personnel is that the members are designated as "special government employees," meaning that they can work for the government only a certain number of hours per year.

Many of the problems with FDA review can be traced to the panels. This is not an indictment of the panel members, but of an FDA structure that produces problems that can be

subsumed under two general categories: expertise and incentive for the panels and timeliness of the process.

The FDA is charged with finding the "best and brightest" among researchers and medical professionals to staff its review panels, but reviewers have few incentives to devote time and energy to review. Most importantly, panel members have other full-time occupations. Although they should be knowledgeable about the devices under review as well as about the theories and practices of clinical testing, they are also required to have no conflicts of interest.

The format of the review process builds in delay. The members of the review panels are required to have no contact with any manufacturer; thus, there is no cooperation between the panel and the manufacturer during product development or between the review panel and the FDA personnel overseeing data collection for device review. This forces the manufacturer to do all of its work separately and submit it to a body that must then take time to review all of the manufacturer's material.

Quite apart from expertise and timeliness, the critical problem in relying more heavily upon the FDA review panels is not the review panels themselves. The problem is that the panels are an extension of the FDA, and an FDA "by any other name" is an instrument of the FDA's monopoly. In the final analysis, the bureaucracy of the FDA, adding its delays and mistakes, still stands between the manufacturer that can provide the device and the consumers who need it.

The potential for third-party review lies in the possibility that third parties will conduct the review process in a fashion different from the FDA's. Specifically, third-party approval must be free of the vagueness and arbitrariness that marks the FDA approval process and able to adapt to changing technological, clinical, and market conditions.

Performance Standards Will Not Eliminate the FDA's Monopoly

Replacing arbitrary command-and-control regulations with written standards, as required in the pending legislation, would be a definite improvement over the current situation. It would, in fact, offer manufacturers a known burden of proof.

However, government automatically approaches new regulations from a "one size fits all" mentality. There is no

reason to assume that product performance standards will be any different. The FDA will look for one standard to apply in every case for particular devices. Products will be evaluated and research conducted to meet exactly that standard and no other. Few incentives will exist for companies to develop devices that outperform the standard. Whether the device far exceeds the standard or barely passes the test, it will still get the same FDA approval. Meeting a government-mandated standard passes along a fixed amount of information about quality in every case. The manufacturers cannot readily internalize the benefits from outperforming the standard when the FDA holds a monopoly on recognition. In any case, use of performance standards and self-certification (in some specific cases decided by the secretary of HHS), by itself, will not change the FDA's behavior. The FDA will still possess the legal power to require submission of data and information for its review.

Product performance standards may introduce another bias into research. Given the cost of developing new devices, manufacturers may concentrate their efforts on producing devices that clearly comply with certain product standards and avoid the cost-increasing uncertainty of innovative device development that may involve classification delays or writing a new standard.

Still a further issue arises. How is the FDA, or a set of its employees, to choose the best or most appropriate standard from among the collection of good standards? In the market for other sorts of goods, consumers, by their choices of what to buy, determine the standards for safety, effectiveness, and quality. Many different marketplace standards exist simultaneously, and the market provides a wide range of goods of varying quality. In a monopoly, the monopolist sets the standards; currently, the FDA has a legally protected monopoly. The question is, how the FDA, or who at the FDA, will be able to make the decision that is best for all people in all circumstances regarding the most appropriate standard. In a specific example, will a standard that requires 70 percent effectiveness for 90 percent of all patients always be better than a standard that is 90 percent effective for 70 percent of all patients?

The incentives for the FDA will not have changed, and the FDA will still overinvest in minimizing Type I errors. The FDA's primary use of other organizations' standards will not change the incentives. The FDA will adopt those standards that do not force the agency to be more concerned with Type II errors.

If, somehow, the FDA is required to accept standards that seem to necessitate a change in philosophy, it can still find a way to delay and obfuscate and slow down the approval process. Even in defiance of the law, that is exactly the history of the FDA.⁵⁹ There are a nearly infinite number of margins along which agents of the FDA can delay approval, even if it technically breaks the law or neglects to follow executive orders.

The FDA's proponents can argue that the FDA is an independent organization insulated from special interests. Technically that is true, but the FDA gets its budget and mandate from Congress, which resists few political pressures. Even if the FDA were staffed with public servants with the purest motives, what they do depends on the money and mandate imposed by Congress. FDA standards cannot help but reflect that congressional pressure. Senator Tom Harkin (D-Iowa) remarked, "The person who pays the piper calls the tune,"⁶⁰ referring to conflicts of interest that may arise when manufacturers are allowed to pay independent reviewers. But, today, the government pays the piper, and it dictates how the FDA sets its performance standards.

The FDA's Trial of Third-Party Review May Doom Significant Change of the Current System

The FDA's third-party certification pilot program may actually limit the possibility for more far-reaching change. In operation it resembles nothing more radical than a user-fee program for devices. The FDA retains its complete sway over approval, and the FDA has handpicked the devices and third parties so that no clinical and no or very little protocol-establishing work will be done.

Some of the predictions made by potential third-party reviewers in June 1996, before the program began, were eerily borne out in comments a year later. According to an official from a firm that offers third-party review, reviewing organizations have the capacity to, and want to, review more complex devices. As it is, the official says, firms with good review resources are not interested in routine "cookbook" reviews⁶¹ of simple devices, and firms that do not have good review resources see the simple devices as a market.⁶² The FDA and other interested parties are aware of the limitations to the pilot program,⁶³ but the attempts to improve it are unlikely to succeed while the FDA maintains its stranglehold on approval.

In practice, the FDA's trial program may block any consideration of alternatives to the FDA's current monopoly.

If the currently proposed legislation does not pass, the FDA can continue to run the pilot program. After studying the "feasibility" of such an approach, the agency may conclude that third-party review is a dismal failure or that it is irrelevant because most manufacturers chose to certify through the FDA anyway. In either case, the FDA would report to Congress that third-party review is not effective. As an agency initiative, the FDA can kill the program outright and declare it a failure. It can also drag out the program for years under continual refunding for more study. While the program is going on (and it can be prolonged indefinitely), it can be used to delay consideration of any legislative proposals for third-party certification. Legislation, it will be said, should be delayed "pending the outcome of the pilot program."

A Case for the Market Solution

The theory of political economy tells us that legislated reform is more costly and harder to achieve than agency reform, but it is more permanent. Common sense tells us that the more power one removes and the more fundamentally and thoroughly that power is reallocated, the harder and less likely is the regrowth of the original system. In the case of device regulation, the most fundamental and thorough reallocation of the FDA's powers, and the most permanent means of altering the monopoly, is legislating the FDA completely out of its monopoly on certifying medical devices. That involves dismantling its device certification approval system and allowing market institutions to certify devices.

The Market Solution: A Question of Rights and Justice

Individuals and groups have the right to trade--that is, to make binding contracts with one another. More specific to the topic of this paper, manufacturers have a right to market medical devices, and consumers have a right to purchase those medical devices, provided that both parties agree to the terms of the contract that binds them.

When the FDA delays or prevents a manufacturer from marketing a medical device, the FDA has violated that manufacturer's right to market that device and the rights of all consumers who wish to purchase the use of that device. Governing bodies are established in America to protect rights, not to violate them.

The FDA or some other enforcement arm of the government

can protect rights by investigating and prosecuting fraud when it occurs. For example, the marketing of a medical device advertised to consumers as safe and effective but later shown to be unsafe and ineffective is fraud. Manufacturers of fraudulent medical devices are guilty of crimes and should be investigated, prosecuted, and punished. However, fraud cannot be established before a product is advertised and marketed; it can only be established after a product has been marketed and evidence exists to prove the fraudulent act in a court of law.

The concept of justice in America is that one is presumed innocent until proven guilty. In the case of medical devices, this concept of justice implies that the FDA would have to prove to a court of law that a manufacturer had engaged in fraud before a product could be legitimately banned from the market. Of course, this is not how the process works under the current system of FDA regulations. These regulations require manufacturers to "prove their innocence" by demonstrating that their medical devices are safe and effective before they market those devices. This regulatory process inverts the concept of justice from "innocent until proven guilty" to "guilty until proven innocent."

Why the Market Model Will Work for Medical Devices

Third-party certification is an undeniable and unqualified success. Under the watchful eyes of UL and its competitors, consumers are certain that literally thousands of the products they use are safe. Within specified limits, bulletproof glass is indeed bulletproof, and smoke detectors go off in the event of a fire. Magnetic resonance imaging (MRI) machines, the Jarvik-7 artificial heart, and cardiac arrest paddles are different from light bulbs, toasters, and cordless telephones. But all are designed to perform specific functions under specified conditions, and they can be certified to work as designed without government monopoly of the certification process. After all, until about a quarter century ago, medical devices reached the market without government approval. With repeal of the government monopoly on approval, they can again reach the market as certified products. Those that work well will be purchased and used, and those that do not will languish unsold. And in cases of fraud, the manufacturer will be held liable.

Businesses try to attain maximum profits, and harming customers does not contribute to that goal. Buying and selling are rarely single, isolated transactions where the

participants never again have any contact. Most buying and selling takes place as repeated interactions in an environment where reputation is important. Customers who are harmed not only withdraw their patronage, but tell others of their experiences as well. It is standard business lore that sellers never hear from satisfied customers, but everyone hears from unsatisfied ones. The larger issue is that companies maximize profits by having a long-standing repeat customer base, not by taking advantage of every new customer. Though the consumer may be only an occasional customer of device manufacturers' products, the doctors and hospitals who prescribe the products and the pharmacies and drug stores that retail them are repeat customers (or customers not at all).

A reputation for honesty and fairness is necessary for generating profits. The longest established, most profitable companies enjoy good reputations. For example, in the market for home appliances, Maytag, General Electric, and Kitchenaid provide quality products and enjoy good reputations. When buying or replacing a major appliance, many consumers consider the brand of refrigerator, range, or dishwasher that has a long-standing reputation for quality.

When the reputation or product begins to slip, so do the fortunes of the company, as in the case of U.S. car-makers in the 1970s. That is doubly true when a product requires a long, expensive development and/or a costly production run, as do some medical devices. The concern is not with simple devices like tongue depressors, but with devices of greater complexity and risk, such as implantable devices and diagnostic machines. Reputation is more important in the medical-device market than in many other markets. To earn their return on investment in such devices, manufacturers need to continue operation for a long while. Such devices are not cars or jeans, sold in a market with many different producers and consumers; they are highly specialized products with relatively limited markets. Generating a profit takes time and repeated interactions. The drive for profit creates powerful incentives for businesses to market quality devices.

Although the market places no restrictions on entry, it places many restrictions on success. Under conditions of free competition, there are no guarantees that a firm will be profitable. Those that prosper are those that provide products and services that perform as advertised.

Government Approval Is No Guarantee of Efficiency or Safety

Certainly not all the best minds, nor all the best people interested in quality output, are drawn into government work. In fact, the argument normally goes the opposite way: the government has difficulty attracting good people. In comparison with private enterprise, the government offers lower pay, poorer amenities, increasingly unstable tenure, and a terrible public image.

In addition to attracting different personnel, government agencies differ from firms in the free market in that they are more likely to be rewarded than punished for failures. When government agencies fail, the typical response from policymakers is that they were underfunded or did not have sufficient powers. The remedy is typically to increase their budgets and augment their powers--in other words, to reward their failures.

The U.S. Department of Agriculture and the 1997 Strawberries Scare. In the spring of 1997, strawberries that were contaminated with the virus that causes hepatitis A were distributed to schoolchildren. When the story broke, the company that had originally shipped the strawberries was blamed, its president quit, and its future was placed in great doubt.

Meanwhile, the U.S. Department of Agriculture (USDA), which is responsible for the school lunch program and which distributed the strawberries to schools, paid no price for its neglect. Instead, calls for more USDA funding are the likely outcome.

The contrast can hardly be more striking. Companies in the private sector pay for their mistakes. Government agencies are excused and often rewarded with more money.

The FDA Drug Approval Process. As already mentioned, drug manufacturers are permitted to pay money to the FDA so the agency can hire additional personnel to review drug applications. FDA failure to meet its legislated mandates to review drug applications in a timely manner made the program necessary.

The "pay-for-review" program more appropriately allocates the cost for drug review, placing it on the manufacturers rather than the taxpayers. But it preserves the FDA's monopoly.

The FDA Trial of Third-Party Review of Medical Devices.

Manufacturers' frustration with the slowness of the medical-device review process was transmitted to the FDA and to Congress. The FDA's trial of third-party review is one response. It represents no more than a direct payment to third-party organizations for doing the work that FDA was supposed to do. But the FDA retains its monopoly.

Protection from Dangerous Devices

To get straight to the heart of consumers' concerns, can a company similar to UL protect the public from dangerous and ineffective medical devices? Yes, the public can be protected to the extent that members of the public desire protection.

In the absence of the FDA monopoly, devices might be marketed without third-party certification, but consumers and their medical advisers or the retailers who have customer contact could decide whether the promise of the device outweighed its risks, instead of having their decisions dictated by bureaucrats. Having more options, rather than fewer, is normally to the consumer's advantage. Consumers averse to risk could limit purchases to certified devices, and others could, if they chose, purchase uncertified ones, as is now the case with nonmedical devices. The lack of compulsory, monopolized certification is not a problem with hair dryers and bulletproof glass, failures of which can be fatal, and there is no reason to expect market certification of medical devices to be any different.

A key argument for FDA regulation of medical devices is that consumers do not have information or the specialized training needed to make good medical decisions. Market certification is the answer to this problem; it allows consumers to draw on highly trained and competent assistance. Consumers would rely heavily on the advice of their physicians as to what they should do, just as they do today. In making recommendations, a doctor would rely heavily on the private certification organizations, knowing that a series of bad recommendations would greatly damage his or her practice.

The knowledge accumulated at the FDA would not disappear. The FDA's competent reviewers would be hired by third-party organizations; few would hire on in the fast food industry. In the absence of FDA-sanctioned gag rules that limit what manufacturers can tell physicians about their products, the medical-device companies themselves would become important sources of information, enabling

doctors to make better decisions.

Doctors and medical practitioners will be reluctant to rely on devices that lack third-party listing. The only consumers who would use such devices would be those willing to bear a great deal of risk. Riskier devices, such as implantables, require a doctor for their installation, and complicated diagnostic and treatment devices that require specialized knowledge for their operation are prohibitively expensive to operate outside of a clinical setting. It is difficult even to conceive of a patient being successful in forcing his doctor to implant an unsafe pacemaker or buying a radiation therapy machine for his own unsupervised use. As a final preventative, there is that store of knowledge the FDA has habitually denigrated or denied: the consumer's common sense.

"Fly-by-night" manufacturers, by definition, are not concerned about the long-run effects of reputation on profits. The market cannot prevent such producers from taking devices to market, but their devices will not be certified.

Shoddy products will not get the mark, and will therefore sell for less. Thus, the market will be protecting itself against fly-by-nighters by supplying two interrelated types of information: a specific certifier's mark, or lack thereof, and the price. Under the current regulatory scheme, one government-mandated amount of information is supposed to cover all contingencies, and there is no information about effective devices that involve more risk than the FDA has decided to allow. There is much less information under the present regime than consumers or their doctors would have in the free market.

Anything man-made can break down and cause disastrous consequences. Likewise, no quality certification scheme can work so efficiently that it never approves an unsafe device. Some FDA mistakes have been mentioned, and UL makes an occasional one as well.

A New York Times reporter summarized the result of one UL mistake:

Two decades ago, hundreds of homes nationwide were damaged and dozens killed or injured in fires caused by aluminum wiring, a product that UL had listed. Numerous other fires were reported in commercial establishments. Investigations showed that aluminum connections at outlets and switches could deteriorate over time and overheat. Eventually, the wiring was no longer installed.⁶⁴

In any testing by any organization, private or public, there is always the chance of certifying an unsafe device. Likewise, there is always the chance that any single copy of any manufactured device will cease to function properly. Perfection cannot be the appropriate standard. The relevant question is whether we should expect more or less failure, specific or categorical, under a free market regime than under a centralized regulatory regime.

Because of the incentives faced by private institutions, a market certification process should result in no more frequent categorical failures than in the FDA regulatory system, and market access for safe devices should be faster. This statement is not to minimize or marginalize the suffering that results when a device fails or is later found to be unsafe. However, keeping useful devices off the market, banning them, or delaying their market delivery also causes deaths and prolongs suffering. Though unsafe devices will be certified and though samples of safe devices will fail, as happens under FDA regulation, only market certification minimizes the chance of both types of errors.

Supply of Effective Devices

Until now, third-party-certification organizations within the United States have been primarily concerned with safety and not with effectiveness or performance. UL and other companies conduct performance tests only for products to protect life and safety, such as smoke alarms and fire extinguishers. In contrast, the FDA evaluates the performance of every device submitted for approval. Can third-party certifiers like UL accommodate performance testing on a much larger basis?

The certification industry would certainly change if the public demanded a general effectiveness mandate in addition to a safety mandate, but the certifying organizations could adapt. Adding effectiveness testing will not change the market incentives for third-party organizations.

The organizations would strive to be involved in research and development from the earliest stages and to produce flexible, adaptable certification systems. The resulting systems would move to include standards that incorporate effectiveness requirements. The standards, based on defined expectations for performance, would be of the appropriate quality, reflecting the consensus of consumers, manufacturers, and standards authorities. Importantly, those companies would still be dealing directly with their final cli-

ents: the consumers and the manufacturers. No special interests or perverse bureaucratic incentives created by congressional oversight would introduce distortions.

A more basic inquiry is whether the market would demand that third parties certify effectiveness. Private certifiers in Europe and much of the rest of the world are required only to certify that the medical device performs as the manufacturer intended. That appears to be sufficient because the European market is well stocked with safe and effective devices, as shown by the large numbers of European-approved devices that are ultimately approved by the FDA.

Europeans seem to have suffered no systematic health problems as a result of their certification system, whereas the benefits of the FDA process are empirically dubious.⁶⁵ In short, if Congress strips the FDA of the power to restrict the actions of other players in the market for medical information, a requirement that a device perform "as the manufacturer intended" may be sufficient to produce effective devices.

Absent any FDA restrictions on the information that manufacturers can make available, the device manufacturers would have a major incentive to contract for performance or effectiveness testing in order to distribute information with their products. The effectiveness data must be strong enough to convince the primary purchasers--the trained doctors to whom consumers entrust medical decisions or the pharmacy and drugstore owners who depend on frequent, repeated shopping trips by their customers.

Several factors would ensure the accuracy of the manufacturer's effectiveness data. First, there are the motives of reputation and profit. Medical devices are purchased to perform certain tasks and not to be admired on the coffee table or bookshelf. Few doctors prescribe, few retailers stock, and few consumers buy a device that is not effective, regardless of whether it is safe or not. Consumers prefer devices that both do not harm them and that help them. If the devices do not help, there is no reason to buy. Second, there are sticks to go with the carrot of profit--that is, tort actions and laws against fraud. The threat of legal action for deliberate misrepresentation will buttress the profit motive and induce manufacturers to market effective devices.

Removing the FDA's monopoly on information and market access will also free up another set of market participants who have their own incentives to qualify the effectiveness of devices. Medical professional organizations and research

physicians put out a lot of information "for free." In fact, medical practice is steered by distribution of information, whether word-of-mouth presentations at conferences or technical journal articles, and it often results in "off-label" uses of drugs and devices. A free market for information about devices will spur these activities. Doctors could build their careers independently from the device manufacturers when they submit their clinical results to peer-reviewed journals and professional meetings. A physician's career, academic standing, and fortune can be built on documenting a new use for a device or on replicating successful trials or on debunking effectiveness claims. Consumers may never read the New England Journal of Medicine, but their physicians do.

No "Race to the Bottom"

Competition in the private market creates powerful incentives to reduce costs. One way to reduce costs is to produce goods or services of a lower quality. Called "race to the bottom" in other situations, this is often cited as a reason for public rather than private provision of goods and services. Would private competition in the market for device certification produce a "race to the bottom"?

The executive officers of certification organizations are keenly aware of the fact that competing to lower the certification hurdles is destructive. If the standards are too lax, the third-party listing becomes meaningless to consumers, and therefore meaningless to manufacturers, who would have no incentive to buy the certifier's services. There will be no change in the incentives that standards-writing companies face if they are allowed to certify medical devices.

Just as the market produces low-quality goods, it also produces high-quality goods, and consumers' desires dictate which products remain on the market. The market for standards and certification is no different. The market will generate a range of appropriate standards, each providing the consumer a specific amount and type of information. Consumers will demand at least some high-quality standards and some labs to perform high-quality testing. Furthermore, the individual consumer need not know what the different marks certify. The consumer's doctor will know because he has much more incentive to know.

The empirical experience of the last century has borne out these observations. As competing organizations have

come into the market, the testing burden has not become easier for manufacturers, and consumers are still confident about the safety of their products. The adoption of UL's standards by other certifying agencies exemplifies this. UL has been the dominant certifying agency for decades, and it has already incurred the development cost of these standards. Instead of creating new, easier standards, the new competitors to UL have adopted the efficient, accepted UL standards and competed on the basis of cost or personal service. The integrity of testing standards and certification has been upheld.

Appropriately Assign Liability

Some defenses of the current regulatory scheme are anchored in liability assignment questions. The argument goes: The possibility of suffering irreparable damage from a liability suit involving medical devices can paralyze research, development, marketing, and distribution, and the FDA's public approval and some degree of immunity from liability are necessary. Such scenarios of market paralysis are offered to justify government regulation as necessary to appropriately assign or mitigate liability. In reality, there is no reason to expect such disasters to occur in markets for medical devices, any more than in markets for fire alarms and fire extinguishers.

Concerning manufacturers' refusal to market devices, Michael Krauss of the George Mason School of Law writes:

Both economic theory and present-day practice suggest that fear of product liability does not stop manufacturers from producing goods. Manufacturers produce motorcycles and ladders despite the absence of pre-market government approval. They are held liable when their product is defectively designed or manufactured.⁶⁶

Krauss goes on to say that except for recent cases involving Class III devices, "FDA approval does not immunize manufacturers from product liability."⁶⁷ Moreover, courts have ruled that FDA approval does not afford protection from liability. Therefore, if it is true that fear of liability judgments would prevent manufacturers from producing devices if there were no FDA, it should prevent them from doing so under the current system as well.

Doctors often prescribe FDA-approved therapies for unapproved uses; such "off-label" uses may account for up to

60 percent of all prescriptions written.⁶⁸ Writing such "off-label" prescriptions exposes doctors to the standards of common-law negligence principles, by which they can be found liable for their actions; yet they continue to prescribe "off-label" rather than accept the truncated liability offered by the FDA. There is no reason to believe that breaking the FDA's approval monopoly would cause radical changes in the common-law standards doctors already face. Without the FDA's approval, a physician would be liable only if the current medical consensus rejected the particular use of a device or if the doctor prescribed a patently unsafe device or a device that could not be made safe for the prescribed usage. Doctors would then rely on the safety mark of the certifier, and the usage guidelines from the manufacturer's information and from medical journals in writing prescriptions. Those guidelines and the safety seal would then be the basis of a doctor's defense in a liability suit.

Expanding third-party certification to medical devices may increase the liability exposure of the certifying organizations. The potential that certifying organizations may be held liable for the manufacturer's products may cause potential certifiers to stay out of the medical device market. However, certifying organizations are not sellers, advertisers, distributors, or manufacturers of products. They do not offer testimonials or underwrite risk. Third-party certification simply states the professional opinion of the certifiers as to the safety and, perhaps, the effectiveness of the good. They can still be sued, but the law does not assign many of the principles of liability to such certification organizations, and there is no principle to hold a certifier liable for an unforeseeable error, provided the certifier was not negligent.

The laws governing fraud and liability protect consumers. An injured consumer still retains all powers of legal redress. Breaking the FDA's legal monopoly on approval of medical devices in no way implies a change in liability law or practice. Currently, the FDA does not especially help or hinder consumers bringing torts before the court, nor does it protect the public by filing individual or class actions on behalf of aggrieved consumers. If the FDA were no longer to exercise monopoly authority, such suits would still be brought, and the relative balance of power between consumers and corporations or physicians would not have changed. The notion that harmed consumers need the FDA to help them collect damages from deep-pocketed medical establishments is specious. Manufacturers of medical devices have never been immune from torts, and removing the FDA blockade to market

access will not change that.

There is, of course, no reason to forbid the FDA to continue in its current role but without its monopoly. It could compete with private certifiers and manufacturers, and consumers could rely on an "FDA mark" as their chosen standard for safety and effectiveness. Other manufacturers, health professionals, and consumers might prefer other marks. Given the record of the FDA, that would be no surprise. The question is not whether devices would be certified, but which organization should certify them.

Conclusion

The U.S. Congress needs to turn over the FDA review and approval of medical devices to independent, privately funded institutions.

Legislation has given the FDA a virtual monopoly over the marketing of medical devices, and political pressure forces the FDA to place too much emphasis on preventing the marketing of unsafe and ineffective devices. In doing so, the FDA permanently blocks or delays for years the marketing of safe and effective devices, some of which would save lives if they were available on the market. The cost of FDA regulation of medical devices is higher medical prices, and, more important, unnecessary deaths and suffering.

Reforming FDA processes is not the solution. The reform proposals discussed in Congress have centered on bringing efficiency and accountability to the FDA. They have been designed to force the FDA to adapt to the increasing pace of innovation and the demands of American consumers. Yet the best efforts of congressional and agency reformers fall short. The sad fact is that the reforms insulate the FDA from the market in important ways. The FDA has powerful incentives to drag its feet and request ever more information, delaying approval while people suffer and die. It will continue to demand more information rather than see its power diminish. It will minimize the risk of approving an unsafe device, at virtually any cost, for fear of congressional repercussions. What is most important is that the FDA retains the power to enforce its decisions. The reforms leave intact the FDA's power to prevent new devices from entering the market.

There is an alternative to reform: abandon the current regulatory process and embrace the free market that has worked so well for so long in other fields.

Third-party certification promises safe and effective devices--quickly and efficiently--and gives consumers the freedom to choose the amount of risk that best suits them. The market provides consumers with the full remedies and protections of our legal system, and it frees businesses from the crippling costs of undue regulation.

The solution is for Congress to reject mere reform of an unwieldy and dangerous agency and to consider the alternative--turning the certification of medical devices over to the free market.

Notes

The author acknowledges the assistance of Cato interns--Craig Farnham, Matthew Brown, and Clay McFaden--in the preparation of this Policy Analysis.

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2. Mike Meyers, "Doctor Went to Japan for Treatment He Couldn't Receive in America," Minneapolis Star Tribune, June 26, 1994, p. 14A.
3. Alexander Volokh, "Clinical Trials--Beating the FDA in Court," Reason, May 1995, p. 24.
4. Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," Journal of Regulation and Social Costs #1, no. 1 (August 1990): 43.
5. Ibid., p. 44.
6. Volokh, p. 23.
7. Kazman, p. 43. The fatality figures are calculated by multiplying the length of time required to approve the new drug application by the number of lives the FDA claims the therapy will save.
8. Volokh, p. 23.

9. Elizabeth Porter, "David Kessler's High-Wire Act on Enforcement," Medical Industry Executive, January 1994, p. 20. See also Robert Higgs, "Wrecking Ball: FDA Regulation of Medical Devices," Cato Institute Policy Analysis no. 235, August 7, 1995.
10. Quoted in *ibid.*, p. 36.
11. Alan M. Slobodin, "The Real Problem with Health Care in America: While Dr. David Kessler Fiddles, Medical Approvals Lag and Americans Die," Legal Background 9, no. 36 (October 8, 1994): 2, quoting Neergaard, "Is Red Tape Sacrificing U.S. Medicine? Doctors, Companies Battle the FDA," The Legal Intelligencer, August 30, 1994, p. 3.
12. Tom Hamburger and Mike Meyers, "Losing the Edge: Overseas Patients Reap the Benefits of U.S. Research While Those Here Wait," Minneapolis Star Tribune, June 26, 1994, p. 1A.
13. Goldberg, "The Kessler Legacy at the FDA," p. 3.
14. Bill Clinton and Al Gore, "Reinventing Drug and Medical Device Regulations," National Performance Review, April 1995, pp. 2-3.
15. Steve Langdon, "FDA Drug Approval Process May Undergo Surgery," Congressional Quarterly Weekly, January 27, 1996, p. 222.
16. Inspector Merrill is quoted in This Inventive Century: The Incredible Journey of Underwriters Laboratories (Northbrook, Ill.: Underwriters Laboratories, Inc., 1994), p. 5.
17. All information comes from author's telephone conversations with UL personnel and from UL's 1992-1994 Annual Reports.
18. Author's telephone conversations with Homer Pringle, UL Legal Department.
19. 1994 Federal Income Tax Return, reported in Barry Meier, "Sparks Fly over Industry Safety Test: Regulators Fault UL on Standard for Device," New York Times, December 24, 1995.
20. Underwriters Laboratories, 1994 Annual Report, p. 16.
21. Author's telephone conversations with Homer Pringle, UL Legal Department.

22. Author's telephone conversations with Frank Brutomesso, UL Standards Department.
23. "Method of Development, Revision and Implementation of UL Standards for Safety" (Northbrook, Ill.: Underwriters Laboratories, Inc.), pp. 10-11.
24. Underwriters Laboratories, 1994 Annual Report, p. 10.
25. Author's telephone conversation with Roy Resnick, Occupational Safety and Health Administration, December 6, 1996.
26. Author's telephone conversations with Frank Brutomesso, UL Standards Department.
27. General Accounting Office, "Medical Device Regulation: Too Early to Assess European System's Value as Model for FDA," March 1996, p. 3.
28. For supporting examples, see Higgs.
29. Higgs, pp. 14-15 and endnotes.
30. Peter Barton Hutt quoted in *ibid.*, p. 9 and endnotes.
31. General Accounting Office, "Medical Devices: FDA Review Time," October 1995.
32. *Ibid.*, pp. 5-16.
33. *Ibid.*, p. 73.
34. *Ibid.*, p. 15.
35. David Masci with Steve Langdon, "Bill to Overhaul FDA Process Gets Nod from Panel," Congressional Quarterly Weekly, March 30, 1996, p. 887.
36. Robert M. Goldberg, "Why Kessler Must Go," Wall Street Journal, April 4, 1996.
37. Steve Langdon, "FDA Drug Approval Process May Undergo Surgery," Congressional Quarterly Weekly, January 27, 1996, p. 223.
38. General Accounting Office, "Medical Devices," p. 75.
39. Higgs, p. 14.

40. For a synopsis, see Higgs, pp. 24-35.

41. For a discussion of the inconsistent standards to which Congress holds the FDA see Higgs. See also "Industry Sways Dingell to Its Side," Clinica, September 9, 1992; and U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health, 103d Cong., 1st sess., Committee Print 103-N, May 1993.

42. American Electronics Association News Release, Washington, June 23, 1994.

43. Much of the following information is derived from author's conversations with Al Bracey, Division for Small Manufacturer's Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration. All references to Bracey result from the author's telephone conversation with him on September 18, 1996. Information not arising from this conversation is available on CDRH Web sites concerning the pilot program, at www.fda.gov/cdrh/3rdprty.html and www.fda.gov/cdrh/ohipfed.html.

44. See the Class II Devices link, at www.fda.gov/cdrh/3rdprty.html.

45. Author's conversation with Al Bracey.

46. See the November 15, 1996, update at www.fda.gov/cdrh/update.html, p.3.

47. Ibid., p. 1.

48. Committee on Labor and Human Resources, U.S. Senate, Report 105-43 (Washington: U.S. Government Printing Office, 1997), p. 22.

49. "Information on Medical devices: Third Party Review of Selected Pre-Market Notifications; Pilot Program," www.fda.gov/cdrh/ohipfed.html, September 17, 1996.

50. Ibid.

51. Ibid.

52. Ibid.

53. Senate Committee on Labor and Human Resources, "The FDA and the Future of American Biomedical and Food Industries, Hearings of the Committee April 5 and 6, 1995." (Washington: U.S. Government Printing Office, 1995), p. 97.
54. Ibid., pp. 119-121.
55. Ibid., pp. 11, 102.
56. Ibid., pp. 125, 126.
57. Senate Report 105-43, 1997, p. 22.
58. Author's conversation with Melpi Jeffries, Center for Devices and Radiological Health, December 6, 1996.
59. For a discussion on how the FDA breaks statutory law by delaying the approval process, see Higgs, pp. 8-10, where he discusses the FDA's ignoring 1976 amendment requirements to solicit PMA submissions on predicate Class III devices, and to produce performance standards for Class II devices. See also Lydia Verheggen, "FDA Review Times: Not Making the Grade," Issue Analysis no. 23, Citizens for a Sound Economy, February 20, 1996. Verheggen details the FDA's violation of its statutory deadlines to approve drugs, devices, animal drugs, and food additives.
60. David Masci with Steve Langdon, p. 888.
61. This term was used in Senate Report 105-43, p. 24.
62. From conversations with a company official, June 27, 1997.
63. See Senate Report 105-43, pp. 22-24.
64. Barry Meier, "Sparks Fly over Industry Safety Test," New York Times, December 24, 1995, section 3, p. 1.
65. See Higgs, especially the text and notes 167-173. See also U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, p. 237: "It is unclear why medical devices that have undergone both regulatory scrutiny and actual market use in Europe, Canada, and Japan are not also approved in the United States within a similar time frame, particularly since U.S. medical device firms generally seek to first market their products in the United States. There is no evidence which indicates

that products available in these major overseas markets are any less safe than products available in the United States."

66. Michael I. Krauss, "Loosening the FDA's Drug Certification Monopoly," George Mason Law Review 4(1996): 457-483 at p. 477.

67. Ibid., p. 477.

68. John Calfee, "The Leverage Principle in FDA's Regulation of Information," in Competitive Strategies in the Pharmaceutical Industry, ed. R. Helms, quoted in *ibid.*, p. 472.

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