Policy Analysis

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Executive Summary

Since its inception in 1938, regulation of the medical device industry by the Food and Drug Administration has increased in scope, detail, and cost to the American people. Historically, legislative authority and regulatory stringency have made several discreet leaps, each prompted by shocking revelations widely disseminated by the news media. To demonstrate their devotion to protecting the public health, legislators and regulators have augmented the regulations, emphasizing the alleged benefits and disregarding the negative consequences for the industry and the patients it ultimately serves.

In the past four years the FDA has drastically slowed the rate at which it approves new or improved medical devices. It has pursued an aggressive enforcement strategy that treats all regulated firms as suspected felons, restricting its communication and cooperation with them and substantially increasing the number of punitive actions. In response, increasing numbers of firms have moved their operations abroad or begun planning to do so.

The FDA's regulation of medical devices has produced little if any benefit but imposed large and increasing costs. Those costs are not just economic; they also include deaths and human suffering. Ideally, the laws authorizing the FDA's regulation of medical devices would be repealed. At a minimum, Congress should alter the FDA's authority, making the administration an agency for certifying products instead of an agency for outlawing products, micromanaging the operations of the device firms, and impeding innovation.

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making the administration an agency for certifying products instead of an agency for outlawing products, micromanaging the operations of the device firms, and impeding innovation.

Introduction

Since World War II medical devices have become increasingly important in the practice of medicine for diagnosis, monitoring, and treatment. More than 6,000 types are currently used, and the various models and brands constitute a set with nearly 750,000 distinct elements.[1]

The device industry in the United States has grown rapidly and now comprises some 13,000 mostly small firms employing about 280,000 workers. In 1993 the industry produced output in the United States valued at $43 billion, or 46 percent of world production. About 23 percent of the U.S. output was exported. The industry has been highly competitive internationally--it generated a trade surplus of $4.7 billion in 1993. Including the output produced in facilities operated abroad, American firms had a 52 percent share of the world market.[2]

Despite that apparent flourishing, participants in the U.S. device business--producers, purchasers, medical practitioners, and the ultimate beneficiaries, the patients--are deeply troubled. More and more device firms are moving or considering moving their research and manufacturing facilities to Europe. Doctors, hospitals, and emergency medical services increasingly find that devices available elsewhere in the world are not available in the United States, and thousands of patients are suffering as a result.

The cause of those woes is evident: perplexing, costly, and time-consuming regulations promulgated and enforced by the U.S. Food and Drug Administration.[3] Kshitij Mohan, an industry executive and former FDA official, recently observed that "the pendulum may swing back eventually, but the pendulum at FDA is more like a wrecking ball."[4]

Regulation intended to protect the public and enhance its health has indeed become a wrecking ball. Since 1938 the FDA has gained greater and greater authority to impose sweeping regulations on most aspects of the device industry. Recently, in response to scandals, news media disclosures about allegedly faulty devices, and demands by congressional overseers, David A. Kessler, FDA commissioner since late 1990, has adopted a more aggressive enforcement strategy. FDA regulation of medical devices today has serious problems in both form and implementation, adversely affecting producers, practitioners, and patients. To ensure that medical devices that protect public health get to market quickly and inexpensively, policymakers should review the threat to health posed by the FDA itself.

A Framework for Analysis

There is a large literature on how the FDA gained and exercised greater authority over the pharmaceutical industry and on the continuing controversy over the adverse consequences of FDA regulations.[5] Regulation of medical devices has attracted much less attention from scholars--in fact, hardly any. Yet one can usefully employ the same analytical framework to study drug regulation and device regulation. The immediate task is to sketch that framework.

The enlargement of the FDA's powers can be viewed as a process of "punctuated politics." Ordinarily, the main actors--the FDA itself, members of Congress, organized interest groups including self-appointed consumer advocacy groups as well as trade associations, the news media, and the public--conduct their affairs in a more or less stable policy environment. The FDA has fixed statutory authority; it conducts its regulation in a certain manner; and its actions have somewhat predictable consequences for others-- including the general public, which normally plays a passive role--involved in the process.

From time to time, however, the normal condition changes dramatically as Congress gives the agency sweeping new authority or, less frequently, as the agency markedly alters the conduct of its regulation, including perhaps the enforcement of longstanding rules.

A normal condition is not static. At any time the agency is restrained or enveloped by limitations inherent in existing enabling legislation and court decisions. The envelope, however, has a somewhat indefinite locus, and the agency takes actions or drafts new regulations that "push the envelope." Like any normal government bureaucracy, the FDA prefers more power to less, larger budgets to smaller, more employees to fewer. In jockeying to enhance its power and

resources in a particular normal condition, the agency works with members of Congress, especially the chairmen of pertinent committees and their staffs, with lobbyists and representatives of organized interest groups, including so-called consumer advocates, and with the news media. In the familiar phrase of political science, that activity constitutes "iron triangle politics" among bureaucrats, interest groups, and members of Congress, who benefit from increased regulations. FDA officials argue for new regulations in informal discussions with interested parties, formal hearings, press conferences, and news releases. The fruits of those activities appear first in the Federal Register and ultimately in the Code of Federal Regulations. The current CFR, revised April 1, 1992, contains eight volumes pertaining to the FDA, in Title 21. The volume with Subchapters H and J, which relate to medical devices, contains 528 pages of small print. In addition, the FDA produces many letters, announcements, manuals, guidance documents, and so forth that elaborate and dilate its regulatory regime. A normal condition is one of creeping regulatory augmentation, as the FDA pushes its current envelope.

Occasionally, the news media bring forth a shocking revelation about the danger or, less often, the ineffectiveness of a medical product. The revelations about unsanitary meatpacking plants in Upton Sinclair's novel The Jungle catalyzed passage of the Food and Drugs Act of 1906. The Elixir Sulfanilamide tragedy--more than 100 persons died after taking a medicine--provoked passage of the Federal Food, Drug, and Cosmetic Act of 1938. The Thalidomide tragedy--babies were born deformed because their mothers had taken a dangerous sedative--gave rise to the Kefauver-Harris Drug Amendments of 1962. In the history of device regulation, the most important shocking revelations were those related to faulty intrauterine contraceptive devices (IUDs) and cardiac pacemakers in the early 1970s, which stimulated passage of the Medical Device Amendments of 1976; those related to fractures of the Bjork-Shiley convexo-concave heart valve, which hastened enactment of the Safe Medical Devices Act of 1990; and those related to diseases and injuries allegedly caused by leaking silicone gel-filled breast implants, which prompted the FDA to undertake an aggressive enforcement campaign in the early 1990s. Such shocking revelations produce public clamor that prompts Congress to create new statutory authority for the FDA or leads the FDA itself to undertake more stringent enforcement of existing regulations. That kind of change periodically creates a new normal condition, a bigger envelope against which the FDA pushes as before.

Figure 1 is a schematic representation of the dynamics just described. The process as it occurs within a given normal condition is shown by the entities connected by broad arrows of influence along the top and right side of the figure. The remaining entities in the figure, connected by narrow arrows of influence, come into play when a periodic shocking revelation causes public clamor and thereby catalyzes the creation of broad new statutory authority or dramatically heightened enforcement activity.

Figure 1

Regulatory Process for Drugs and Medical Devices
[Flow Chart Omitted]

The upshot of the process, as far as patients, doctors, purchasers, and providers of medical goods are concerned, is diminished scope of individual action: what one previously could choose to do, one no longer can do; what one previously did not have to do, one now must do; and everyone must act in the same way. In short, the tendency is for varied and decentralized decisionmaking to give way to uniform and centralized decisionmaking, either by Congress directly or, under broad congressional authority, by the FDA in its rulemaking and enforcement capacities.

Device Regulation

Before 1976

The FDA first received authority to regulate medical devices when Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 (FDC Act), which, as amended, remains the fundamental enabling statute. The act defined devices as "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."[6] The act prohibited all interstate dealings in "adulterated" or "misbranded" devices and authorized the FDA to seize such devices by proceeding against their manufacturers in federal courts.[7] "Adulterated" meant contaminated by filth, and "misbranded" meant that the

labeling was "false or misleading in any particular."[8] Although the 1938 statute required premarket approval (PMA) of new drugs, it imposed no such requirement on devices. Therefore, the FDA could not prevent a device from coming onto the market; it could only ask a court to stop the continued sale or enjoin the production of a device already introduced into interstate commerce.[9] Under that authority, the FDA removed from the market scores of fraudulent or "quack" devices in the 1940s and 1950s.[10]

After World War II the device industry began to introduce legitimate products of much greater sophistication and complexity. New materials and technological advances in electronics gave rise to cardiac pacemakers, renal catheters, surgical implants, artificial vessels and heart valves, IUDs, replacement joints, and many other innovations. Faulty design, inadequate workmanship, or improper operation could make the new products harmful to patients. In some cases, as when they were implanted in the patient's body, inspection of the devices and their performance was difficult or impossible.

FDA regulators wanted the power to require premarket testing of devices for safety and effectiveness, the same power they had over new drugs under the 1962 amendments to the FDC Act. Increasingly, device manufacturers were contesting the FDA's actions in the courts, and the regulators bridled at the need "to develop extensive evidence that would hold up during long legal proceedings to remove an unsafe device from the market."[11] Pushing the envelope, they resorted to a "regulatory fiction" that embraced the very notion Congress had rejected before enactment of the FDC Act in the 1930s and again while amending the law in 1962, namely, that devices are drugs for purposes of regulation.[12] During the 1960s the FDA regulated intraocular lenses, soft contact lenses, weight-reducing kits, certain IUDs, and some in vitro diagnostic products as if they were drugs, requiring the manufacturers to provide satisfactory evidence of safety and effectiveness before placing the products on the market.[13] Although that legal legerdemain survived two important court challenges in 1968 and 1969, FDA officials recognized that it could be only a stopgap and sought congressional authorization for expanded regulation of devices.[14]

To prepare the ground for seeking new legislation, the then-Department of Health, Education, and Welfare (HEW) formed a study group headed by Dr. Theodore Cooper, director of the National Heart and Lung Institute and later assistant secretary for health at HEW. The Cooper committee surveyed the literature and found evidence that during the previous decade medical devices had been associated with some 10,000 injuries, about 8,000 of them involving IUDs, and 731 deaths, including 512 involving heart valves and 89 involving pacemakers.[15] The committee recommended enactment of legislation requiring the establishment of legal standards for medical devices and premarket FDA approval of safety and effectiveness for the riskiest devices.[16]

The Cooper committee's report, released in September 1970, became the point of departure for several congressional committee hearings on bills introduced during the early 1970s. In the House, attention was effectively focused on medical devices in 1972 by Government Operations Subcommittee hearings chaired by L. H. Fountain (D-N.C.), which dealt with the safety of IUDs.[17] In the Senate, Edward Kennedy (D-Mass.) spearheaded the push for device regulation as chairman of the Health Subcommittee of the Labor and Public Welfare Committee, which heard extensive testimony criticizing faulty IUDs and supporting a new law.

Enactment of that law did not occur, however, until public clamor had been magnified by further shocking revelations and interest groups had exerted more pressure. The Senate passed the Medical Devices Amendment of 1973 on February 1, 1974, but the House failed to act.[18] In January 1975 Senator Kennedy's subcommittee held hearings focused on the hazards of the Dalkon Shield IUD, which had been associated with 260 reported spontaneous septic abortions, 15 of them fatal. Subsequently, the Senate passed the Medical Device Amendments of 1975, which were identical to the bill it had passed the previous year in the preceding Congress.[19] Meanwhile, cardiac pacemakers were receiving much attention from the news media. In 1975 the controller general reported that since 1972 more than 22,000 pacemakers had been recalled.[20] At the same time, the burgeoning feminist movement was giving powerful organized expression to the demand for more stringent regulation of IUDs.[21] Impelled by the growing volume of publicity about faulty medical devices and increasing interest-group pressures, early in 1976 the House voted 362 to 32 to approve a device bill reported by the Interstate and Foreign Commerce Committee. A lone dissenter to the committee's report, Rep. James M. Collens (R-Tex.), decried "another layer of federal bureaucracy and paperwork." After conferees reconciled the Senate and House bills, opting mostly for the more detailed regulatory procedures in the House version, the bill was approved by both houses on May 13 and signed into law on May 28.[22]

The 1976 Law

The Medical Device Amendments of 1976 conferred gate-keeping powers on the FDA.[23] The act refined the old definitions, distinguishing a device from a drug by the condition that the former "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and . . . is not dependent upon being metabolized for the achievement of any of its principal intended purposes."[24] The FDA was required to classify devices into three groups.[25] Class I devices, the least risky, were made subject to general controls, including requirements that manufacturers keep certain records, file certain reports, and follow "good manufacturing practices" (GMP). Class II devices were made subject to general controls and product-specific performance standards to be developed by the FDA in cooperation with panels of experts. Class III devices, the riskiest, were made subject to general controls and PMA. In all cases the objective was to "provide reasonable assurance of the safety and effectiveness of the device," to be determined

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.[26]

Neither the statute nor the legislative history gave substantive guidance as to how the FDA should make the required classifications or weigh the risks against the benefits. Hence the law gave the regulators enormous discretion in life-and-death matters.[27]

Unless it were found "substantially equivalent" to a "preamendment device," a product already on the market before passage of the Medical Device Amendments, any new device was automatically placed in Class III and thereby made subject to PMA. "Transitional devices," those previously regulated as drugs, were also subject to PMA unless the manufacturer successfully petitioned for a reclassification. Obtaining PMA required presentation of extensive test data, including the results of clinical trials, to satisfy the FDA that the product was safe and effective. (See Figure 2 for the general approval scheme.) The FDA could also require submission of PMA data from manufacturers of "old," or preamendment, Class III devices, but meanwhile the device could remain on the market. During the first 15 years after passage of the 1976 amendments, the makers of only 9 percent of "old" Class III devices were required to submit PMA applications.[28] Moreover, claiming a lack of resources, the FDA never created the performance standards for Class II devices required by the 1976 law.[29] Therefore, in practice the FDA's closest control over the manufacture of Class II and most Class III devices came in its GMP requirements and its regulation of new versions of "old" devices.[30]

To sell a new version of a preamendment device, the manufacturer had only to file a premarket notification Form 510(k). It would turn out that the great majority, about 98 percent, of products being introduced to the market arrived via the 510(k) route, so how the FDA dealt with those notifications would prove critical to the operation of the device industry.[31] As Figure 3 indicates, a successful 510(k) had to show that the product had the same intended use as well as the same technological and descriptive characteristics as a "predicate device." In deciding whether the similarities were sufficient to establish "substantial equivalence," the FDA exercised great discretion and, as documented below, eventually made increasingly arbitrary demands for additional information, so that the 510(k) evolved from a simple premarket notification to, in many cases, an application for PMA. According to Peter Barton Hutt, former chief counsel at the FDA, the reviewers "sent back 510Ks with so many trivial, unimportant questions that they eventually became the same as a PMA."[32]

Figure 2

Post-1976 FDA Device Approval Process
[Flow Chart Omitted]

The FDA gained a variety of new enforcement powers from the the 1976 amendments. It could ban a device. It could require manufacturers to notify users of risks or to repair or replace products or to give refunds.[33] Aggrieved parties

could seek judicial review of FDA actions, but the tables had been turned. Before the 1976 amendments, the FDA had been required to proceed through the courts before it could exercise its enforcement powers. Now, it could exercise its powers at will, and the offended party bore the burden of contesting the action in court.

Congressional Oversight

After passage of the 1976 amendments, the FDA began to carry out its newly authorized activities with all deliberate speed, emphasizing deliberateness more than speed. The agency never did adopt standards for Class II products. Six years after enactment of the statute, the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, both chaired by John D. Dingell (D-Mich.), found that the FDA had yet to complete the classification of devices and that it had not even begun the review of preamendment Class III devices as envisioned by the framers of the act.[34]

Figure 3

Details of 510(k) "Substantial Equivalence" Decisionmaking Process
[Flow Chart Omitted]

Thereafter, subcommittee staff made monitoring and hectoring the FDA a substantial part of their daily grind. Dingell, one of the most powerful figures in Washington, publicly harangued FDA officials about their failings-- "cavalier disregard for potential consequences" and "bureaucratic neglect for public health and safety that shocks the conscience"--while the crestfallen bureaucrats sweated under the glare of television lights.[35] At FDA headquarters in Rockville, Maryland, Dingell's incessant inquiries and demands came to be known as "dingellgrams." The agency's answer was always the same: not enough staff, not enough money.[36]

FDA officials sometimes expressed appropriate contrition. In an interview in 1986, John Villforth, director of the agency's Center for Devices and Radiological Health (CDRH), confessed that "many of the brickbats FDA has received for its implementation of the medical device law have been justified." But he insisted that not all device problems could be laid at the feet of the regulators. "With devices, the performance of the user is a major determinant of whether the patient is at risk. And the way you deal with that problem isn't necessarily through more regulations about how the equipment is manufactured. It's by working with those users--whether they're physicians, nurses, technicians or patients--to improve their understanding and their use of medical devices."[37] That was an astute observation but, unfortunately, one that the FDA would disregard as its regulatory activities evolved during the following decade.[38]

Dingell's subcommittee showed no interest in enhancing the capabilities of device users. The staff concentrated on the FDA's failure to carry out specific legislatively prescribed activities and the agency's alleged "unwillingness and/or inability to . . . take decisive enforcement action when device manufacturers could not, or did not, comply with regulations, and continued to market defective devices despite evidence of increasing numbers of serious or catastrophic device failures."[39] In pursuit of dragons for Chairman Dingell to be seen slaying, the staff undertook several case studies, accompanied by well-publicized hearings and reports.[40] One of the most notable inquiries involved an artificial heart valve.

The Bjork-Shiley Heart Valve

The Bjork-Shiley convexo-concave heart valve was approved by the FDA in 1979, manufactured by a Pfizer subsidiary, and eventually implanted in some 86,000 patients worldwide, including 31,000 in the United States. By 1994 approximately 450 of the valves, including 196 in the United States, had fractured causing some 300 deaths, including 130 in the United States. Negative publicity and lawsuits mounted as the product was recalled by the manufacturer three times between 1980 and 1983. Pfizer stopped selling it in 1986. The company later consented to set aside $375 million for research on detecting cracks in implanted valves, surgery to replace defective ones, and compensation of harmed recipients. It was alleged that the company had made false claims to the FDA, and in 1994 Pfizer agreed with the U.S. Department of Justice to a $10.75 million settlement, plus reimbursement of U.S. government expenses associated with valve replacements financed by government health programs.[41]

Undoubtedly, the staff of Dingell's subcommittee had the Bjork-Shiley valve in mind when they referred to "serious or catastrophic device failures" that the FDA had failed to prevent. In February 1990 the subcommittee held hearings on that product and issued a report entitled "The Bjork- Shiley Heart Valve: 'Earn as You Learn,' Shiley Inc's Breach of the Honor System and FDA's Failure in Medical Device Regulation." In its report of May 1993 the staff revisited that example.[42]

Without belittling the distress of patients worried about the possible failure of the Bjork-Shiley valves implanted in their hearts, it is instructive to ask whether the performance of that product really constituted a "catastrophe," as asserted by Dingell and others. A Pfizer executive observed, "These people [using the valves] were going to die anyway, and they are alive today because of the valve."[43] Granted, some of the valves fractured with fatal consequences, but the Bjork-Shiley valve is a mechanical contrivance, and all mechanical contrivances are subject to possible failure. The 450 deaths associated with valve fractures occurred among 86,000 persons who received the valve--that is 1 death per 191 users. Looking at the positive side, one sees that 99.5 percent of the users had not died because of the valve. As late as 1992 some 51,000 of them were still alive.[44] That is a rather striking survival rate, considering that all of those persons suffered from heart disease severe enough to warrant replacement of one or more of their own heart valves. Recall, too, that if the recipients of the Bjork-Shiley valve had not received it, they probably would have received either another brand of mechanical valve, also subject to failure, or a porcine valve, subject to progressive tissue degeneration and the subsequent need for a replacement requiring risky surgery.[45] In short, although it is certainly unfortunate that any of the Bjork-Shiley valves failed, it is improper to employ perfection as a standard for judging the product and important to remember that 99.5 percent of the implanted Bjork- Shiley valves operated satisfactorily with life-saving effect on the recipients. Alternative treatments probably would have saved a few lives, but some of the people who died when their Bjork-Shiley value fractured would have died even with a different replacement valve. "Catastrophe" seems much too strong a word for what actually happened even in that especially regrettable case.

In any event, the extensive publicity generated by Dingell and his staff regarding the Bjork-Shiley valve clearly helped to tip the congressional balance toward approval of the Safe Medical Devices Act (SMDA), signed into law on November 28, 1990. That law capped a series of legislative efforts over a period of seven years led in the House by Dingell and Henry A. Waxman (D-Calif.), then chairman of the Subcommittee on Health and Environment of the Committee on Energy and Commerce, and in the Senate by Kennedy, then chairman of the Committee on Labor and Human Resources.[46]

The Safe Medical Devices Act

The SMDA broadened FDA authority in several ways. It requires every "device user facility" to report "information that reasonably suggests that there is a probability that a device has caused or contributed to the death of a patient . . . [or] to the serious illness of, or serious injury to, a patient . . . not later than 10 working days after becoming aware of the information." Manufacturers had been required by regulation to make similar reports since 1984.[47] Device user facilities include hospitals, ambulance services, surgical facilities, nursing homes, and outpatient treatment facilities. Death reports go directly to the FDA, illness or injury reports to the manufacturer of the suspect device.[48] Failure to report is punishable by a civil penalty--a maximum of $15,000 per violation and $1 million for all violations adjudicated in a single proceeding--assessed by the FDA.[49]

In view of the heavy penalties for failure to report, users need a clear definition of a reportable event. Yet the FDA put the burden of making the proper distinctions on the users themselves. According to FDA official Kay Chesemore, "Facilities have to decide for themselves what constitutes a reportable event and what device or devices are implicated in the death or serious injury."[50] So the FDA in effect is saying to device users, "You decide what to do, and later we'll decide whether to punish you for your decision." FDA inspectors have acted inconsistently in identifying reportable events and, therefore, violations of the statutory requirement.[51] As late as May 1994, the FDA still had not clarified the requirement. Bryan H. Benesch, an agency enforcement official, confessed that "the lack of a final regulation has caused a great deal of confusion. Many people just don't know what they're supposed to do."[52]

The number of medical device reports (MDRs) increased from 27,883 in 1990 to 88,265 in 1993, but it is doubtful that any benefits accrued as firms and institutions incurred the substantial costs of piling up those papers.[53] Annual costs

of the MDR system were estimated at more than $42 million, but in responses to a three-state investigation between November 1992 and June 1993, most user facility risk managers indicated that "SMDA [which requires the reporting] does not save lives."[54] Of the MDRs received in fiscal year 1993, the FDA reviewed only 51.5 percent, so nearly half of them just lay in storage taking up space to no purpose. With the number of reports projected to reach 246,000 in 1995, the prospect looms that more effort will be wasted by the involuntary reporters.[55]

Because many illnesses, injuries, and deaths to which a device may have contributed actually result from operator error or improper maintenance rather than defects in the design or manufacture of a device, the reporting requirements in effect call for users who have made mistakes to report themselves to the feds.[56] Even though the statute forbids admission of the reports into evidence in civil actions, device users understandably have feared that lawyers would use the Freedom of Information Act to secure the reports and "have a field day with medical device litigation."[57] According to Dr. Joel Nobel, the respected head of ECRI, a private testing organization whose publications are known as "the Consumer Reports of medical technology," the reporting requirements create a "nightmare for health professionals. It's like throwing them in a tank of sharks."[58]

The fear is not misplaced, but personal liability litigation is only one of the risks. MDRs also invite abuse by incompetent, irresponsible, sensationalistic news media or opportunistic publicity seekers who call themselves consumer advocates, whose scurrilous pronouncements can cause irreparable harm. Grossly misleading journalistic exploitation of device reports has played an important part in leading the FDA to shut down entire companies. The closure of Physio-Control Corporation is a case in point.

The Physio-Control Case

Physio-Control makes defibrillators, devices that emit a powerful electrical shock intended to restore the normal heart rhythm of a person who is clinically dead as a result of a heart attack. Physio-Control produced the first commercial defibrillator more than 30 years ago and remains the leading producer, with sales in more than 70 countries. Its products are used by 90 percent of U.S. hospitals and most emergency medical services.

In 1990 WRC-TV, an NBC affiliate in Washington, D.C., broadcast a program called "Fatal Flaws," highlighting the large number of MDRs by Physio-Control during the past six years and incorrectly interpreting the reports as evidence that the company's products must be defective.[59] Reporter Lea Thompson did not seem to understand the situation on which she was reporting. First, defibrillators are used only on persons who are clinically dead. Second, in the great majority of cases, the patient is not revived. Third, in such cases, when a defective device might have been at fault, the incident must be reported quickly. Fourth, reporting is required too quickly to permit a thorough investigation.

During the years in question, Physio-Control's defibrillators had the largest market share and were used more than a million times per year. So it is hardly surprising that, as WRC's Thompson announced in scandalized tones, Physio-Control's products were "linked" more often than any other device to reported deaths.[60] Further, to say that the defibrillators killed people, even when they did malfunction, distorts the events in question. As Mary Newman, a contributing editor of the Journal of Emergency Medical Services, has written, "Defibrillators do not cause death; they are, by definition, used to restore life to the clinically dead. . . . Even in the best of circumstances, they are not Lazarus machines--they simply cannot bring everyone back."[61]

In July 1992 WRC-TV aired a sequel to the "Fatal Flaws" program, noting that recently Physio-Control had stopped production. The company had voluntarily done so in order to bring its procedures and paperwork into full compliance with new FDA regulations. Thompson again accused the company of making defective products, spicing her theatrical presentation of accusations with scenes of grief-stricken relatives of two persons whose deaths were attributed to failure of Physio-Control defibrillators. The next morning NBC's Today Show featured portions of Thompson's program, exposing a national audience to what Jim Page, the editor of the Journal of Emergency Medical Services, later called "a scurrilous 'hit piece.'"[62]

While Page was expressing regret that "opportunistic 'consumer reporters' have created unwarranted public anxiety about defibrillator safety," the political process passed quickly through its predictable phases. Newspapers and radio and television broadcasts across the nation repeated NBC's misinformation. Omnipresent consumer advocate Dr. Sidney Wolfe, head of Public Citizen's Health Research Group, demanded that the FDA clamp down on Physio-

Control. Representative Dingell, having already dispatched his staff to obtain the FDA's records on the company, voiced his usual deep concern for protecting the public health and said on television that the FDA was "not doing its job."

Taking the hint, the FDA proceeded to make a harsh example of Physio-Control. After the intimidated company signed an oppressive consent decree to avoid a sweeping injunction, it endured a series of administrative abuses and was not permitted to resume production of all its products until more than two years after the initial shutdown. Losing more than $70 million out-of-pocket and $100 million in sales during the downtime, the company survived only by reaching into the deep pockets of its corporate parent, Eli Lilly & Co.[63] After resuming full production, Physio-Control found that its two-year concentration on regulatory compliance had caused it to lose a lot of ground to competitors whose research and development had not been similarly fettered. More important, lives had been lost as defibrillator orders went unfilled.

New Regulatory Requirements

The SMDA also required creation of a tracking system for implantable and life-supporting devices, augmented the data requirements for 510(k) applications, and repealed the 1976 law's requirement that performance standards be developed for all Class II products.[64] It imposed new reporting requirements on manufacturers, importers, and distributors, who must now inform the FDA of any removal or correction of a product undertaken to reduce a health risk or remedy a violation of regulations.[65] The new law gave the FDA authority to require product recalls and, for certain devices, postmarket surveillance.[66] In view of all the new reports required by the act, it seemed that the extra "layer of federal bureaucracy and paperwork" feared by a lone congressional dissenter back in 1976 had become a reality with not one but many additional layers.

The SMDA changed the character of the 510(k) procedure through which the great majority of new products had entered the market after passage of the Medical Device Amendments in 1976.

The 510(k) process is no longer simply a notification, but an approval process. SMDA defines the terms "substantially equivalent" and "substantial equivalence," and further stipulates that manufacturers submitting a 510(k) must wait to market a device until notified by FDA that their premarket notification has been found substantially equivalent.[67]

That change in the 510(k) procedure led almost immediately to longer waiting times for manufacturers trying to place improved versions of their devices on the market.[68] Changes, no matter how small, might cause a product to be consigned to an indefinite stay in preapproval purgatory; 510(k)s, it was charged, "seem to have fallen into a black hole" or "appear to be in eternal limbo." Manufacturers therefore had a reduced incentive to make the minor improvements that, over time, could greatly improve the performance of their products.[69]

As the FDA began to require more and more 510(k) applications to be supported by clinical trials, the distinction between a 510(k) application and a PMA application became progressively blurred.[70] Increasingly, the FDA required both types of applicants to employ test protocols like those used in drug trials, which is not an easy requirement to satisfy, as some elements of a drug test (e.g., the placebo in the double-blind setup for drug testing) have no equivalent in a device trial.[71]

Finally, the 1990 law gave the FDA authority to impose civil penalties for all violations of the act up to $15,000 per violation and $1 million for all violations adjudicated in a single proceeding.[72] When imposing such fines, the FDA is required to "take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require," but it "may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed."[73] In other words, the FDA may impose fines, not impose fines, or change its mind about previous fines as it pleases, and whatever it does has statutory sanction.[74] In view of the FDA's practically unlimited discretion, industry representatives must have been dismayed when Ronald Johnson, director of the CDRH's Office of Compliance, told them at a trade association meeting early in 1994 that imposition of civil penalties would become a "mainstay" of the agency's enforcement activities.[75]

Passage of the SMDA, which authorized such enormous additional regulatory power to be exercised by the FDA,

ordinarily would have created a jubilant mood at the agency. But 1991 and 1992 ranked among the worst years for the men and women of Rockville's regulatory colossus. Largely because of a 1989 headline-capturing scandal, involving the bribery of several FDA officials by companies seeking expedited approval to market generic drugs, the agency was in crisis mode.[76] Stung by pervasive criticism from Congress and the news media, FDA personnel were hunkering down, trying to protect themselves by avoiding anything, including product approvals, that might expose them to further censure.[77] As the staff report of Dingell's subcommittee observed, "Reluctant to make a decision that may result in criticism from FDA management or from the outside, some reviewers make endless requests for information from applicants to avoid doing so."[78]

In addition, David Kessler had become commissioner in November 1990, his appointment prompted by the scandal. He was shaking up the organization with new appointments, reassignments, and a new agenda featuring unprecedented emphasis on aggressive enforcement and more stringent regulation.[79] The unsettled situation in 1991 and 1992, which produced a "devastating slowdown in device clearances," was aptly described as "chaos in U.S. medical device regulation."[80] In the midst of the turmoil, late in 1991, a new storm struck, the furor over silicone gel-filled breast implants.

Silicone Breast Implants

Silicone breast implants have a long history. Their commercial marketing in the United States began in 1964. Since then millions of women (sources differ on exactly how many) have used them. When the Medical Device Amendments were enacted in 1976, the implants continued on the market as grandfathered preamendment devices. From time to time the FDA received complaints from users, and advisory panels raised some questions about the safety of implants, but the agency took no formal action to require data on them until 1988, when it finally classified them as Class III devices. The classification triggered a requirement that manufacturers submit evidence of safety and effectiveness to obtain PMAs not later than July 9, 1991.[81]

On December 13, 1991, a federal court awarded a plaintiff $7.3 million for injuries from connective tissue disease allegedly caused by the rupture of her Dow Corning silicone implants.[82] The news media, not to mention the product liability lawyers, went into a feeding frenzy. According to lawyer Wayne L. Pines,

Never before has so much media and public attention been paid to medical devices--not during the debate that led to enactment of the 1976 Medical Devices Act, nor even during discussions over the provisions of the 1990 Medical Devices Act. Further, never before have there seemed to be so many congressional hearings on medical devices. . . . The saga of the Food and Drug Administration's (FDA) regulation of breast implants riveted media and public attention in late 1991 and early 1992. As the issue unfolded, literally dozens, if not hundreds, of stories appeared in the media.[83]

Appearances on popular TV talk shows by women blaming their implants for a variety of health problems fed the flames.

On January 6, 1992, FDA commissioner Kessler placed a 45-day moratorium on the sale of silicone implants. In March Dow Corning announced it would no longer make such implants, which left only two manufacturers, McGhan Medical and Mentor, in the business. In April Kessler limited the use of silicone implants to patients enrolled in clinical trials, which would be open to any woman needing an implant for reconstruction but to only a limited number of women seeking breast augmentation.[84] All of those actions were the result of the media excitement; the FDA had no compelling new scientific evidence, no large clinical trials, to justify the new restrictions.[85]

Later, thousands of lawsuits were consolidated in a class-action suit against the manufacturers of silicone gelfilled breast implants, and in 1994 a settlement was reached for $4.25 billion, the largest product liability award in history, to compensate plaintiffs for alleged past and future injuries.[86]

As the settlement was being approved, reports of epidemiological studies that cast doubt on the plaintiffs' allegations began to appear. Neither a University of Michigan study nor a University of Maryland study found any association between implants and scleroderma. Mayo Clinic researchers found no association between implants and "rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis and other diseases of the connective tissue--all of which are

among the autoimmune and other ailments cited during FDA and congressional hearings on implant safety." A Harvard Medical School study of 121,700 nurses, including some with implants, "found no evidence that implants played a role" in causing scleroderma or several other diseases including lupus and rheumatoid arthritis. The editors of the Wall Street Journal opined that the federal court had made a "$4.3 billion mistake."[87]

It would seem that both the courts and the FDA had acted hastily on the basis of anecdotal and unsystematic evidence. While the courts might be forgiven because cases before them have to be decided somehow, it is appropriate to hold the FDA to the same high scientific standards it imposes on those it regulates. Undoubtedly, the agency's moratorium early in 1992 and its subsequent restriction of implants to women participating in approved clinical studies helped to establish a climate of opinion in which the legal claims being made against silicone implants were viewed as well founded when in fact they were not.

Confronted with the epidemiological studies showing no evidence of a link between breast implants and any of the ailments allegedly caused by them, the FDA's Bruce Burlington, head of CDRH, said that the agency would maintain the course it had set before the studies were reported. The editors of the Wall Street Journal fumed, "This, after billions of dollars have been put up to pay off the plaintiffs' lawyers, after mastectomy patients were terrorized, and after companies and careers associated with the implants have needlessly washed over the falls."[88]

The Great Slowdown in the Approval Process

From 1983 through 1990 the FDA received about 80 PMA applications, on average, per year and approved about 45.[89] In 1991 it approved only 27, fewer than in any year since 1979, when the approval process was just getting started.[90] In 1992 only 12 PMAs were approved, as the process ground nearly to a halt. The following two years witnessed a rebound to 24 approvals in 1993 and 26 in 1994, but those numbers were still only a little more than half the average for the period 1981-90.[91]

In the late 1980s the average review time before FDA approval of a PMA was about 150 days. In 1991 it was 285 days, in 1992 it was 186 days (that average is misleading because 6 of the 12 approvals were licensing agreements with no data review), and in 1993 it was 437 days and still rising. Preliminary data for 1994 showed an average approval time of 604 days. The total time elapsed between filing and approval of an application was substantially longer, nearly 800 days in 1993 and nearly 900 days in 1994. In extreme cases the process could eat up several years. C. R. Bard and Collagen filed a PMA application for their Contigen incontinence device in March 1989. The FDA did not approve the application until four and a half years later. Jonathan Kahan, an attorney specializing in device law and regulation, attests that "there are numerous other examples of years of delay for devices which could have an important medical impact."[92]

The 510(k) process for "substantially equivalent" devices, through which vastly more applications for marketing approval are processed, experienced a similar slowdown. In the 1980s the number of applications tended upward. By the early 1990s manufacturers were submitting about 6,000 Form 510(k)s per year. In 1993 there were 6,288 submitted, and in 1994 there were 6,247, according to preliminary data. FDA decisions on those applications also tended upward in the 1980s, reaching more than 6,000 per year in 1989 and 1990, then dropping to 5,367 in 1991, to 4,862 in 1992, and to 5,073 in 1993. The number of 510(k)s approved fell every year from 1989 to 1992 before rebounding slightly in 1993, as shown in Table 1.

In 1994, according to the preliminary data, the FDA, under intense criticism for the slowdown, made 7,101 decisions, including 5,463 approvals, but that rebound hardly indicated a reversal of trend. Even CDRH chief Bruce Burlington admitted that much of the 1994 resurgence had been achieved by what industry critics called "cherry picking," or attending to the easiest cases first, and by temporarily diverting personnel from other tasks.[93]

Table 1
FDA 510(k) Approvals

Fiscal Year	Number
1989	4,867

1990	4,748
1991	4,294
1992	3,776
1993	4,007

As the approval rate dropped in the early 1990s, the 510(k) backlog at the FDA grew much larger. At the end of FY91 there were 2,291 applications awaiting disposition; in 1992 there were 3,951; in 1993 there were 5,l57; and in 1994, according to the preliminary data, there were still 4,303. The average active review time increased from less than 90 days in the 1980s to 102 days in 1992 and 182 days in 1994. Counting the time the average application spent "on hold," awaiting the arrival of additional information requested by an FDA reviewer, the total time spent waiting for clearance of a 510(k) reached 214 days in FY94--up more than 100 percent in three years.

Early in 1993 someone leaked to the Wall Street Journal the FDA's internal record of 510(k)s pending more than 90 days, and the newspaper published a striking graph of the monthly figures on its editorial page. In November 1991 only two 510(k)s were pending more than 90 days. The number then grew exponentially, reaching 713 a year later. The Journal's editorialists linked the growing backlog to "the aftermath of the Kessler-Congress jihad against breast implants."[94] Six months later the number of overdue 510(k)s had reached about 1,400, and at the end of December 1993 it peaked at 1,894 before being reduced by the agency's "cherry picking" in 1994.[95] The buildup of the huge backlog in 1992 and 1993 led bewildered applicants to speak of a "black hole" and an "eternal limbo."

In August 1994 at the International Medical Device Congress in Salt Lake City, the FDA's Susan Alpert, director of the Office of Device Evaluation, presented a graph showing "a steady decline since fiscal year 1988 in the percentage of 510(k)s acted on within 90 days. While approximately 80% met the deadline in 1988, only about 60% did so in 1991 and 40 percent in 1993."[96] A study by the Health Care Technology Institute, based on a sample of applications classified by year of submission, showed even greater deterioration--only 23 percent of the 510(k)s submitted in 1993 received a decision within 90 days--before a turnaround in 1994 that left the agency's completion rate for reviews still far below its pre-1992 level.[97]

When the approval slowdown had become apparent to everybody and industry executives appealed to Congress for relief, Representative Dingell sent the FDA an angry letter in the summer of 1992, calling for an end to the "unconscionable" paralysis. At Rockville, agency personnel were dumbstruck. After all, Dingell's unrelenting criticism of them for approving applications too readily had been a major reason for their increased deliberateness. As recently as March and June 1992, Dingell had held hearings to flagellate them for regulatory lapses. Reminded of his apparent inconsistency, Dingell replied that the FDA had overreacted.[98]

More Aggressive Enforcement

The FDA is a full-service government bureaucracy. Within broad and often vague statutory limits, it makes the rules; monitors compliance without inconveniences such as search warrants; and, with wide discretion, punishes those it finds guilty. It is promulgator, police, judge, jury, and executioner all rolled into one.

The agency's actions are subject to formal judicial review, but aggrieved parties go to court only as a last resort. Apart from the likelihood that they will lose in a court of law, where judges usually countenance a wide range of agency action, they will eventually lose in any event, because as long as they remain in business they will be subject to the agency's enormous and ill-defined regulatory powers, and the agency will take its revenge sooner or later.[99] Its vindictiveness is notorious. Kim Pearson, publisher of the Food & Drug Insider Report, "found that 84% of companies polled in 1991 reported declining to file a complaint against the FDA for fear of retaliation."[100] After drug company executives blew the whistle on corrupt FDA officials and precipitated the generic drug scandal in 1989, the FDA rewarded them by trying to drive them out of business with repeated inspections, in which "violations" of good manufacturing practices (GMP) regulations can always be found, and long delays in approving their products for marketing.[101] An FDA official reportedly said, "We have depended on the ability to selectively target companies . . . and to issue findings without fear of being second- guessed by some tinhorn judge."[102] Separation of powers is not a popular constitutional doctrine at agency headquarters in Rockville.[103]

Before Kessler took command of the agency, it tended to use its powers with some restraint and some appreciation of the value of expediting the marketing of innovative products of great benefit to the public. According to Richard A. Merrill, the FDA's chief counsel from 1975 to 1977,

the first managers of the FDA's new Bureau of Medical Devices believed that regulators, inventors, and manufacturers should work cooperatively. Most did not share the suspicion of manufacturers' motives held by many FDA field inspectors and some reviewers of drugs. And they took seriously the claims by architects of the 1976 amendments that regulation should not discourage the development of new devices.[104]

In the eyes of some observers, those attitudes had fostered "inefficient, and often ineffective, enforcement practices."[105] Agency critics had often faulted it for going too lightly on the firms it regulated.

With Kessler's arrival, aggressive enforcement moved to the top of the agency's agenda. The new commissioner delegated more enforcement authority to the District Offices and encouraged them to use it. Compliance officials encouraged a philosophy of "act now, talk later."[106] District Offices responded by finding more GMP violations, issuing more warning letters, and taking a variety of other enforcement actions at an increased rate. Says former FDA chief counsel Peter Barton Hutt, "The more enforcement actions, the more FDA employees showed they were protecting the public health."[107]

The correlation, however, was spurious. There was no evidence that products had become any safer as a result of the agency's stepped-up compliance program.[108] But if the public did not actually benefit, Kessler did, as his "get tough" policy resulted in much publicity for his fearless protection of health and safety.[109]

Companies must admit to their facilities and respond to the questions of FDA inspectors who appear with a Form 482 notice of inspection. However, inspectors frequently appear without a 482 and conduct inspections, during which they may obtain evidence that can be used in subsequent criminal prosecutions. Companies that admit the inspectors without a 482 are deemed to have waived their Fourth Amendment right against illegal search and seizure notwithstanding the absence of a search warrant. In the wake of the generic drug scandal, inspectors have searched more diligently for criminal violations.[110]

FDA inspectors proceed on the assumption that the company being inspected is violating the law; their attitude "resembles that of a police detective toward suspected felons."[111] Said an official of the Office of Compliance, "We're cops and that's part of the cop psychology."[112] That attitude predisposes the inspectors to be unreasonable--the government routinely treats the creators of highly beneficial and often life-saving products as suspected felons. And during the past three years, under increased goading by their superiors, they have become even more unreasonable. According to the report of Dingell's subcommittee, "Companies report an increasing and often inexplicable change in regulatory attitude by device inspectors. The new attitude is characterized by greater hostility and less communication."[113]

Moreover, many of the inspectors are ill trained or wholly unqualified to deal with the technologies they scrutinize.[114] According to the Dingell subcommittee report, "FDA now takes aggressive enforcement action, yet lacks the controls and training to avoid inconsistent or arbitrary decisions."[115]

In general, the FDA has failed to clarify for companies precisely what actions constitute compliance. The result, contends the Dingell subcommittee report, has been "an enforcement program that is perceived by industry as disorganized, inconsistent, and often inappropriately harsh" and, in the words of Elizabeth R. Porter, "a confused, demoralized industry no better able to comply with the law."[116]

There is no way to measure exactly how much the FDA has increased its enforcement activity during the past few years. The agency's own reports give conflicting figures on the number of various kinds of enforcement actions taken, and even with consistent data no single index tells the whole story. Issuance of regulatory warning letters more than doubled, increasing from 235 in FY91 to 548 in FY92, 543 in FY93, and, according to preliminary data, 549 in FY94--a reflection of the unleashing of the District Offices.[117]

Nearly 70 percent of the warning letters pertain to GMP violations, which are often the sort of transgression visible only to an inspector who wants to see it.[118] Despite the name, "good manufacturing practice" violations usually have nothing to do with actual manufacturing or with the quality of the product that reaches the customer; they almost always consist of failures to fill out countless forms in the minute detail that only a bureaucrat could care about.[119] The period 1992-94 also witnessed an average of 34 seizure actions annually. In addition, in the three fiscal years combined, the FDA's general counsel sought 21 injunctions, brought 7 criminal prosecutions, and assessed 5 civil penalties against device manufacturers. Virtually all industry sources agree that the FDA not only has stepped up enforcement activities markedly but has taken those actions in a way that seems more focused on punishing the industry than on working with it to ensure the rapid delivery of safe and effective products to the market. The report of Dingell's oversight subcommittee concluded, "FDA enforcement practices have demoralized and perplexed the medical device industry."[120]

Perhaps the most perplexing enforcement initiative was the FDA's adoption of a "reference list," known in the industry as the "black list," in April 1992. The FDA places on the list companies at which inspectors have identified "serious uncorrected or unresolved violations" of GMP or, in about 5 percent of cases, other regulations. The FDA then refuses to process applications from those firms for 510(k)s and certain PMA supplements. Every company issued a warning letter is put on the list, but others also may be.[121] The number of companies on the list quickly grew to about 600.[122] The FDA gives no notice to a company when it is placed on the reference list, and the criteria for removal are vague. The Health Industry Manufacturers Association (HIMA) has questioned the FDA's legal authority to link GMP requirements with agency determinations of a product's "substantial equivalence" to a preamendment device. It also protests that the way in which the FDA uses the list denies the listed companies due process of law, because it does not conform to the procedural requirements for notice-and-comment rulemaking.[123] Suppose, for example, that a company is mistakenly placed on the list or mistakenly not removed from it and then finds that its 510(k) applications go nowhere. Such a firm has entered a bureaucratic twilight zone and has no way of knowing how it got there or how to escape. Although firms want to be informed of their placement on the reference list, they do not want the list to be made public, not even through Freedom of Information Act disclosures, for fear that publicity of inclusion on the list might damage their reputation with customers or attract product liability suits. HIMA has sought to have the FDA formally promulgate a rule binding itself to not release the names of listed companies.[124] On September 2, 1994, the law firm Hyman, Phelps & McNamara filed a citizens' petition urging the revocation of the reference list because it "deprives those companies [listed] of rights to adequate notice and opportunity to be heard, property rights, and liberty interests guaranteed by the Constitution."[125]

Early in 1994 the FDA began to employ a devastating new sanction--device lawyer Jonathan Kahan calls it "the nuclear weapon in the FDA arsenal"--the complete shutdown of several facilities of a multiplant company.[126] Not content to require correction of cited deficiencies or to close only the facility where violations have been observed, the FDA now goes after the entire product line of a corporate entity, excepting only the production of spare parts and the servicing of products already in use. In that way, says CDRH's compliance chief Johnson, the agency seeks to rectify a "corporate attitude" of noncompliance, to compel corporate managers to "look at their overall corporate philosophy" or "corporate culture."[127] Remarkably, the FDA has not even alleged that deaths or serious injuries have occurred because of the GMP violations at issue in those firms. The agency is effectively saying to them, "We don't like your attitude; and until we do, we are not going to permit you to sell your products in the United States."

Each of the three companies with multiple facilities shut down early in 1994, Puritan-Bennett, National Medical Care (NMC), and Siemens Medical Systems (SMS), chose to sign a consent decree rather than fight the FDA's request for a court injunction to enforce the closures. Both NMC and SMS pledged to bring into GMP compliance not only their U.S. facilities but all their foreign facilities manufacturing certain products for sale in the United States. SMS, which had U.S. sales of $1.8 billion in the fiscal year ending in September 1993, stood to lose 8 percent of those sales, about $144 million, from the shutdown, which extended to only some of the firm's product lines. That is a hefty penalty for what SMS president Robert Dumke described as "primarily procedural and record-keeping issues--not the safety or effectiveness of our equipment."[128] Puritan-Bennett, a much smaller firm than SMS, undertook to bring one of its two closed plants into compliance with GMP and MDR regulations but decided to abandon a plant in Boulder, Colorado, explaining, "It is no longer economically feasible for this relatively small operation to continue trying to satisfy expanding regulatory requirements." The plant's 100 workers had to look for new jobs, and the consumers who would have benefited from the product, a portable home ventilator, had to turn to less satisfactory alternatives. Puritan-

Bennett indicated that it would transfer its manufacturing of the ventilator to Ireland and continue to sell it overseas.[129]

Effects on the Device Industry

The men and women of the U.S. medical device industry display remarkable tolerance of the regulations under which they labor. As the 1993 report of the Dingell subcommittee noted, they are willing "to do almost anything that the Agency wants, so long as it is clearly stated, with minimal room for interpretation."[130] Yet no matter how forgiving they may be, they can go only so far. Unless they can get their products to market, keep their costs low enough, and predict future regulatory burdens with some confidence, they cannot continue to operate.

The recent changes in FDA policies and conduct have increased the device firms' costs of research and development, product approval, manufacturing, and postmarketing surveillance of product performance. In the estimation of venture capitalist Robert Daly, "The new regulations and delays mean adding $10 million to $20 million to a company's budget, and several years until the device gets to market. At that rate, most [venture capital] deals don't make sense."[131] Increased costs mean that some investments are no longer expected to generate a satisfactory return, some innovations are no longer worthwhile to develop, and ultimately some patients will suffer and die as a result.

The FDA now requires many device firms to conduct clinical trials similar to those required of drug firms. Before beginning a trial, a company must gain FDA approval, known as an Investigational Device Exemption (IDE), for its plan to conduct the tests. Like PMAs and 510(k)s, those applications lately have become subject to extended and often inexplicable delays. A consultant who wrote to Dingell's oversight subcommittee in 1993 asked the legislators to "imagine the frustration a clinician/researcher feels when a faceless bureaucrat, often without medical training or any familiarity with the clinical environment, produces an endless stream of unrealistic questions effectively casting a 'no' vote on a research application."[132]

Venture capitalists increasingly have responded to that situation as did Grant Heidrich of the Mayfield Fund: "We counsel our companies, 'Don't screw around with the F.D.A; let's move these trials to Europe where there's a reasonable process.'"[133] Indeed, U.S. device firms increasingly are shifting their trials to Europe, even though they must still meet all FDA requirements to get approval to sell their products in the United States. Said Rob Michiels, president of Interventional Technologies, which manufactures an innovative catheter used to clear arteries, "By the time we're approved in the U.S., that product will have been available in Europe on the free market for three to four years."[134] David Summers, chairman of American Biomed, a small company that also manufactures catheters, echoes Michiels: "We're having to move out of the United States. We just can't take it anymore."[135]

Heightened Uncertainty and Lack of Communication

If the FDA simply took longer to approve products, manufacturers could factor the increased delay into their planning, minimizing the harm to their programs for developing and marketing new or improved products. But the FDA's approval times are not just longer; they are also more variable and more difficult to fathom. Said John Wright, vice president for engineering at Ultracision, "It's the inconsistency and the impossibility of predicting when you are going to hear from them that makes planning impossible."[136] Commissioner Kessler, on the other hand, evidently thinks that the unpredictability of his agency's actions, especially enforcement actions, is a good thing; it keeps the companies on their toes.[137]

Many producers complain that the approval process tends to be frustratingly reiterative. Said Phil Schein, president of CDX Corporation, a manufacturer of noninvasive monitoring devices, "You spend a lot of time doing a lot of work, trying to meet all the requirements. And yet, once you've met the requirements, they come back and say, 'You need to do this.'"[138] In a Gallop survey of 58 medical device company executives in 1994, 57 percent of the respondents affirmed that the FDA had applied guidance instructions retroactively to their approval submissions.[139] Elsewhere a manufacturer observed that "the delays are often over issues of form rather than scientific substance. Once the FDA takes a position, reason and logic have little influence over the outcome of decisions."[140] In a 1993 survey of its readers by the trade publication Devices & Diagnostics Letter, 85 percent of the respondents "said requests for data on submissions were reaching them late in the review cycle; 63% said such requests were arriving 90 or more days after filing"; and 48 percent characterized the FDA's requests as "unreasonable." One respondent commented that the FDA

had asked the company "'to re-prove well accepted scientific principles' and when some questions did not make sense, 'the reviewer would not talk to me to clarify' them."[141]

Nothing frustrates device companies more than the FDA's refusal to communicate and the cryptic nature of the communications they do get. For example, plant inspectors cite firms for GMP violations, expressed in very general terms, but refuse to provide any guidance about how the violations ought to be remedied. The agency places firms on the Reference List but refuses to spell out exactly what a firm must do for removal from the list. Injunctions and consent decrees list violations with references to vaguely worded sections of the FDC Act and the Code of Federal Regulations, leaving firms puzzled as to precisely how they must tweak the nuts and bolts of their production process to comply.[142]

To divine what they should do to get past the enforcers or the product reviewers, firms often hire consultants who specialize in regulatory compliance. In consent decrees, the FDA routinely requires that a firm, at its own expense, hire such a consultant to certify compliance before the FDA will reconsider the firm's compliance status. Surprise: such consulting firms are staffed by former FDA employees.[143]

In May 1992, when FDA personnel were feeling especially beleaguered, the Office of Device Evaluation (ODE) adopted a policy on telephone communications between product reviewers and manufacturers that can only be described as paranoid. The announcement of the new rules noted that ODE intended "to avoid the kind of circumstances that arose within the generic drug program," in which a bribery scandal had occurred in 1989. The rules described in excruciating detail what sorts of calls could be made or accepted and required a detailed recording of all calls. Among other things,

ODE staff members may not accept calls from manufacturers concerning pending submissions under review. . . . The only information that may be given to a manufacturer . . . concerning the status of a submission is that "the submission is under review"; therefore, it would be a waste of time to entertain such inquiries. . . . ODE staff members may accept calls from manufacturers concerning a pending submission if the call from the manufacturer is in response to a telephone call or letter from ODE about the submission. . . . Unless there is a need to discuss specific, official ODE business, there is no requirement upon the part of any ODE staff member to return a call from a manufacturer. . . . A written record of all telephone conversations with manufacturers shall be made for future reference.[144]

That restrictive policy held industry applicants virtually incommunicado. Minor problems that might have been resolved easily by a telephone conversation went unresolved for weeks or months. Companies lingered in limbo, unable to make financial or production plans or to inform customers about the scheduling of future deliveries. The FDA was essentially telling applicants, "Don't speak unless spoken to; otherwise we'll ignore you." Meanwhile the fate of businesses and the care of ill and dying patients were effectively being decided in the silence.[145] During Physio-Control's two-year travail of complete or partial shutdown, for example, the company's employees complained bitterly and often that they could not get the FDA to respond to their telephone messages. As company president Richard Martin told the Wall Street Journal, "Weeks can go by without our phone calls being returned."[146]

In February 1993 ODE adopted a somewhat less restrictive policy on phone contacts with industry, but the improvement was slight, and device company personnel continued to voice a variety of complaints about the poor quality of their communication with the regulators.[147]

Like many others, Physio-Control's Martin complained that in dealing with the FDA, "The process is absolutely arbitrary."[148] Just how arbitrary was dramatically illustrated by an experiment conducted by R S Medical, a small firm that manufactures muscle stimulators. When the FDA denied a 510(k) application and rescinded an earlier approval, R S Medical reapplied twice--under its own name and separately under the name of a consulting firm retained to act as a front. The disguised application sailed through the approval process, but the firm's own was rejected. The FDA was not amused when the company revealed what it had done. R S Medical then went to court seeking an order to restrain the FDA from blocking its sales. Amazingly, the company won. In December 1993, on the recommendation of Federal Judge John Primomo, the court permanently enjoined the FDA from stopping R S Medical's sales. Judge Primomo noted "the agency's seemingly biased attitude towards R S Medical" and concluded that "a substantial likelihood exists that the reasons given for the denial of substantial equivalence findings were a mere

pretext." His opinion catalogued a number of "arbitrary and capricious" actions by the regulators, including their different treatment of the two identical applications, which the judge called a "blatant inconsistency."[149]

Capital Flight

As noted above, few firms challenge the FDA in court. Doing so makes sense only for those that are desperate and will not survive unless they receive judicial protection. Even the very few who win in court cannot expect to survive the agency's subsequent retribution; a court victory can only buy time for the firm to minimize its losses. The only effective escape is to flee the country, which more and more device firms reluctantly are choosing to do. According to analyst Daniel Lemaitre, "There isn't a company that isn't thinking of moving its research and development, and its manufacturing, overseas."[150]

Several recent surveys confirm that increasing numbers of device firms are leaving or considering leaving the United States. In a 1992 survey by attorney Jeffrey Gibbs of representatives of 168 firms attending regulatory affairs seminars, almost 60 percent of the respondents indicated that in the future they would introduce new products outside the United States first, and almost 75 percent were planning to manufacture at least some of their products abroad. They gave the difficulty of U.S. product approval as the reason for shifting their production overseas.[151]

Early in 1994 HIMA, the largest medical device trade association, reported the findings to date of three of its own industry surveys, which indicated an increasing movement offshore. In a survey encompassing 98 companies, the regulatory environment ranked highest as a "decision factor in expected international expansions and new operations"; 40 percent of the respondents gave FDA regulation as the most important reason for moving abroad.[152] In a Strategic Business Decisions Survey, HIMA found that companies "cited the regulatory climate here as their top reason for planning to shift to overseas operations in the next four years--double the number that cited it for the earlier period [1991- 93]."[153] In December 1994 a HIMA official confirmed that the shift of operations to Europe represented a trend, not a transitory action.[154]

In April and May 1994 the Minneapolis Star Tribune conducted a survey of medical device firms in Minnesota, where many such firms do business. The newspaper secured responses to its questionnaire from 148 firms in device manufacturing or research and development. The survey showed that firms selling Class III devices, the most heavily regulated ones, had 7 percent of their personnel employed overseas five years ago and 12 percent currently and expected to have 16 percent abroad in 1999. Respondents complained of "costly and cumbersome regulation" in the United States and cited it as a "leading reason for investing abroad before investing at home."[155]

In November 1994 Medtronic, a Minnesota firm that describes itself as "the world's leading therapeutic medical device company," announced plans to move the headquarters of its Corporate Ventures organization to Europe, explaining that the relocation was being undertaken "because of pressures related to the current unpredictability of regulatory and reimbursement processes in the United States."[156]

In June 1994 the American Electronics Association (AEA) announced the results of a survey, conducted by the Gallop Organization, of 58 U.S. medical device companies. Of the firms surveyed, 40 percent said they had reduced the number of U.S. employees because of FDA delays; 29 percent said they had shifted investment spending offshore; and 22 percent said they had relocated jobs to overseas facilities. Bob DeHaven, vice chairman of association, warned that the U.S. medical device industry faces decline "unless the FDA regulatory process is re-engineered."[157]

Data on capital outflows confirm the survey findings and related reports. From 1989 to 1991, U.S. medical technology firms invested almost the same amount abroad each year, in the range of $321 million to $333 million. Then in 1992, when the FDA abruptly made its enforcement and approval policies more onerous, capital outflow jumped more than 200 percent, to $993 million. HIMA interprets the increase as a verification that "as the FDA approval process has become more burdensome and slow, U.S. companies have moved to establish overseas facilities at a much faster rate."[158] Because during 1991-93 Europe was wallowing in its worst recession since the 1930s and labor and other variable costs there may exceed U.S. levels, it would appear that the recent movement offshore represents a regulatory push out of the United States rather than an economic pull toward Europe.

Finally, the stock market registered unmistakably the reversal of prospects for the U.S. device industry produced by the

changes in FDA behavior that reached their full force in 1992. Goldman Sachs has constructed an index of the average stock price of a composite of publicly traded medical device companies relative to the Standard and Poors 500. From its base of 1.0 in 1989, the index rose steadily to a peak of about 4.0 late in 1991. It then began to fall steadily, losing about half its value in the following two years.[159] Clearly, under the new regime at the FDA the device industry's financial future looks much bleaker not only to venture capitalists but also to investors in established firms.

Concluding Observations

The preceding account has been rather detailed because, in regulatory matters, the devil really is in the details. But with regard to the FDA, the devil is in the basic principles, too. The enabling statutes that undergird the FDA's device regulations are essentially misguided. They rest on a paternalistic foundation that is inconsistent with the maximization of consumer welfare and the preservation of a free society.[160]

They also reflect a naive faith in central planning that flies in the face of all experience by empowering the FDA to act as a politburo for an industry in which 13,000 firms produce more than 6,000 heterogeneous products in facilities scattered across the United States and around the world. Little wonder that the simple legal categories and one-size-fits-all rules only create bewilderment for those who bear their brunt. As Nobel aptly remarked, "On the face of it, the legislation may make sense to amateurs. But if you have experience and knowledge in this field, it is foolish as well as costly."[161]

The FDC Act, as amended, gives broad and ill-defined discretion to the FDA. Public-choice theory leads us to expect that a regulatory agency equipped with such discretion will use it to promote the interests of government officials rather than the public interest.[162] The evidence shows quite plainly that the course of device regulation has been driven by the personal and political motives of both congressional overseers and FDA officials, as they have sought to continue in office and to enhance their power and perquisites while reacting to the shocking revelations of sensationalistic, incompetent, and irresponsible news media and, in turn, making complaisant media the mouthpieces for their propaganda.[163]

Large Costs, Small Benefits

American consumers have suffered. They have had to pay the higher prices caused by the higher costs that manufacturers must bear to comply with ever-expanding FDA regulations. More important, they have had to wait for extended periods to gain access to new or improved products, and as a result they have experienced much unnecessary suffering and many have died prematurely. The FDA can cause many deaths by a single regulatory action, and it does so frequently. For example, Nobel's "best guess" is that the FDA's recall of the Bunnell infant jet ventilator in 1993 caused "anywhere from 10 to several hundred infant deaths."[164] Dr. Richard Cummins, a leading authority on defibrillation, believes that the FDA's shutdown of Physio-Control might have caused a thousand deaths.[165]

Finally, consumers have suffered, and will continue to suffer, from an invisible effect of the FDA's costly and unsettling regulations, namely, the loss of innovations that under less hostile conditions would make available new products of great benefit. Asks manufacturer Bert Bunnell, "Can anyone deny the development and introduction of new, more advanced devices is stifled, obstructed and---as time goes by--destroyed before it even starts?"[166] In the circumstances, it is remarkable that the device industry continues to operate as well as it does--another example, no doubt, of what Adam Smith had in mind when he spoke of there being "much ruin in a nation."

Unfortunately, no appreciable offsetting benefits exist. As Nobel concludes, the medical device legislation "has not made devices safer."[167] The protection the FDA claims to have produced for the public has been largely illusory. According Marybeth Burke,

Neither the FDA nor ECRI can say with certainty how many deaths or serious injuries result annually from medical devices. Difficulties exist with differentiating device-related error from userrelated error. Factoring in the contribution of a patient's own illness to death or injury only compounds the difficulty, experts say.[168]

How can the FDA claim to have improved a situation if it has no firm idea what the situation was in the first place or is now?

In May and June 1994, the Gallop Organization surveyed 58 executives of U.S. medical device companies. Among the questions asked was, "What effect, if any, have new FDA policies had upon product safety?" Some 79 percent of the respondents said "no effect," 14 percent said the policies improved safety "somewhat," and just 2 percent (i.e., a single respondent) said the policies improved safety "significantly."[169]

HIMA correctly asserts that "there is no evidence which indicates that products available in these major overseas markets [but still unapproved by the FDA for sale in the United States] are any less safe than products available in the United States."[170] Reporters Tom Hamburger and Mike Meyers echo the point: "Although patients in these countries may be taking risks Americans don't take, there's little evidence that they are harmed."[171] Isolated examples that the FDA might adduce in support of its actions cannot overturn the general conclusion.

The lack of demonstrable benefits from FDA device regulation is hardly surprising. Even if the FDA did not exist, normal market incentives combined with the terrors of product liability litigation would be more than sufficient to encourage manufacturers to produce reasonably safe and effective products.[172] The emergency care providers, hospital administrators, and medical practitioners who purchase the bulk of the devices have experience, knowledge, and access to ample expert information about products from reliable sources such as ECRI, TUV Product Service, and a variety of trade and professional publications. They fervently desire to help, not hurt, the patients they serve, and their reputations depend on their success in doing so. In short, neither device purchasers nor patients need the FDA's "help." The agency's intrusion has clearly created far more cost than benefit for virtually all parties except the politicians, bureaucrats, consultants, and lawyers who have enjoyed the benefits of office and income associated with the operation of an extensive legal and regulatory regime.[173]

In Nobel's words, "The basic legislative concepts and methods prescribed by Congress have been wrong."[174] The entire undertaking, root and branch, will not bear informed and disinterested scrutiny. As Nobel observes, it has plausibility to amateurs but not to people who really understand the workings of the technology, the industry, and the market. All in all, it is best characterized as an egregious example of the politically motivated pretense of protection that proves viable only when propped up by government propaganda and coercive force. Can anyone suppose that the FDA would survive if it had to operate as a firm in the free market for information?

Reflecting on the slipping away of America's technological leadership in medical devices to competitors in Europe and Japan, Dr. Robert Hauser, a cardiologist at the Minneapolis Heart Institute and former chief executive of Cardiac Pacemaker, mused, "It's incredible what we're doing to ourselves."[175] That is a common but misleading formulation. In truth, "we" are not deliberately harming ourselves; Congress and the FDA are the guilty parties, the former more so than the latter. Citizens who support the official actions are either ill informed, ideologically misguided, or devoted to somehow gaining personally from a process in which the great majority of people lose. Unfortunately, some strategically situated parties, such as the congressional committee staff members, most of the so-called investigative reporters on television, and nearly all so-called consumer advocates, suffer from all three disabilities simultaneously.[176]

Perfection: The Wrong Standard

At the root of the public's misplaced support of strict FDA regulation of medical devices is a widely accepted two- part misconception: that medical devices should operate perfectly, and that when they do not, Congress and the FDA should do something to make them operate perfectly.[177] This is a specific instance of the public's general desire for complete security and for the federal government to intervene whenever risks of harm become evident. The public wants the impossible and has faith that the government can deliver it. In the prophetic words of Bertrand de Jouvenel, the government "comes to be looked on as a sort of living umbrella, and its proliferation is received not only with complacency but with enthusiasm."[178]

Unfortunately, medical devices cannot be made to operate perfectly. Nothing, from cars to televisions to computers to ink pens, does. Medical devices can be made safer, but making them safer is costly. The lower the risk level already achieved, the greater the cost of the next increment of risk reduction. Eventually, making a device even a little bit safer can be achieved only at prohibitive cost. Long before a device has been made as safe as technically possible, it will have become so expensive to produce that nobody will be willing to pay for it. Sad to say, on this side of heaven,

people must make trade-offs. If we cannot achieve perfection and we are unwilling to bear the cost of approaching it very closely, we are necessarily left with devices that will sometimes fail. That outcome is nobody's fault. Human contrivances cannot be made to work perfectly--and should not be even if it were possible.

How Large Is the Risk?

Though products cannot be made perfect, they can be made amazingly good. Many American medical devices, even some that have been heavily criticized in the news media, have compiled very impressive performance records. As indicated above, even the notorious Bjork-Shiley heart valve worked satisfactorily in 99.5 percent of its uses.

Physio-Control's defibrillators, rabidly attacked by the news media and Public Citizen's Health Research Group, have compiled a superb record. From 1985 through 1991, the FDA received 630 MDRs involving a death associated with use of the company's products.[179] Recall that submission of an MDR does not signify that the product actually caused the death, although the news media and so-called consumer advocates commonly embrace the fallacy that it does. To make the most outrageously unjustified case against Physio-Control's products, suppose that every one of the 630 deaths did result from defibrillator failure. Is the implied rate of failure high? Consider that more than 100,000 of the company's defibrillators were in use, being used on average at least 10 times per year.[180] Therefore, for the seven-year period the rate of fatal failure is 630 divided by more than 7,000,000, or less than 0.00009. In other words, the products functioned properly in more than 99.991 percent of their uses, even though many of them were used in abusive environments by fire fighters or paramedics who treat the defibrillators roughly in the field. As documented above, most MDRs for defibrillators have been shown by follow-up investigations to be caused by operator error or improper maintenance rather than equipment failure. Therefore, the actual failure rate is less than half of that hypothetically constructed above, which means that the products actually performed flawlessly in more than 99.995 percent of their uses, which is to say that they failed less than once in every 22,222 uses. Those are the same products that Public Citizen's Health Research Group, in a widely publicized letter to David Kessler on August 26, 1993, described as "Physio-Control's deadly devices." In the letter the group urged Kessler to initiate criminal prosecution of Physio-Control "for its widespread and ongoing noncompliance with GMP and MDR violations."[181]

Other cases of allegedly poor product performance also look rather different when placed in the context of the number of products involved. Pfizer subsidiary Infusaid, for example, was assessed the first civil penalty imposed by the FDA under the new authority granted by the SMDA, a fine of $290,000 for GMP violations and for marketing an altered device without prior FDA approval.[182] The company had attracted the FDA's attention when it recalled 3,923 drug infusion pumps about which it had received 10 complaints of product failure and patient injury. Ten failures were surely regrettable, but the rest of the pumps, 99.75 percent of them, evidently had performed properly.[183]

In April 1994 the FDA issued a warning letter to U.S. Surgical Corporation for failing to report 15 cases of malfunctioning of its surgical stapler. The letter said that in three cases the malfunctioning may have caused injury to a patient. A company representative said U.S. Surgical had not reported the incidents because they occurred when users improperly loaded staple cartridges into the device, not because of faults in the device itself.[184] But suppose the product had failed, causing injury, in the three instances. The company has sold more than a million of the devices since 1991.[185] Assuming that they have been used an average of at least three times, the injury-causing failure rate is 3 divided by more than 3,000,000, or one in more than a million, which implies a successful use rate in excess of 99.9999 percent. The works of man can scarcely come any closer to perfection than that.

Recent FDA Policy Initiatives

Criticisms leveled at the FDA in 1993 and 1994 by representatives of industry, by a few prominent reports in the news media, and, most important, by Dingell's subcommittee prompted the agency to initiate several changes ostensibly designed to speed product approvals and clarify regulations.[186]

Claiming that budgetary limitations prevented a more expeditious processing of PMA and 510(k) applications, the FDA proposed that applicants pay a "user fee" with their submissions. That argument cannot withstand scrutiny; after all, the agency had processed applications much faster in the 1980s and presumably could do so again if it wanted to. But eventually many companies reluctantly concluded that, if user fees would hasten the reviews, they were willing to pay.[187] However, the proposed user fee failed to gain congressional approval in 1994, and enthusiasm for it waned

even within the agency, where an official reported that it would "create an environment of haves versus have-nots" by protecting user-fee-supported personnel from budget cuts and staff reductions.[188]

The FDA also brought forth a draft guidance document, "Deciding When to Submit a 510(k) for Change to an Existing Device." That complex "guidance" elicited no sighs of relief from industry, which described it as a "disaster" that "would require considerable paperwork, regulatory oversight and delays in product approvals."[189]

The FDA also sent out a recommendation that District Offices discontinue an inspection after finding a single deficiency. The manufacturer would then be required to hire consultants to perform an audit and certify the firm's full compliance with all regulations before FDA inspectors would return to conduct their own inspection. Repeat offenders would be required to submit, always at their own expense, annual certifications by external experts for up to three years. What constitutes "repeated violations" remains vague.[190]

Finally, to cap the industry's other tribulations, the FDA undertook to revise its GMP regulations, extending their requirements and adding to their costs by, inter alia, insisting that manufacturers document in "excruciating detail" their preproduction design controls.[191] A study commissioned by the FDA estimated that compliance with the new GMP rules would cost industry $84.5 million, but HIMA feared the actual costs would be much greater, reporting that many members of the association thought the costs could be "great enough to force small- and medium-sized companies out of business."[192] Device attorney William H. E. von Oehsen warned that, besides increasing costs significantly, the new GMP requirements "could increase considerably management's exposure to regulatory actions and tort liability."[193]

With the possible exception of quicker product approvals financed by user fees, if they should ever be authorized, none of the FDA's 1994 initiatives promises to diminish the burdens on the device industry and hence the harm to the ultimate consumers of the products, the patients. The measures do not create any genuine benefits for consumers. The near-term prospect remains as it has been for the past several years--long delays in getting products to market, reduced investment, reduced innovation, and industry flight to the less hostile regulatory climate of Europe.

Long-Term Prospect: More of the Same

Even if somehow the FDA could be induced to lighten its regulatory burdens and abandon the rules for which costs are especially great in relation to benefits, the longer term outlook would remain bleak. The underlying problem remains that Congress has given the agency enormously broad and discretionary powers, and the people who control the exercise of those powers--on the surface Kessler and other FDA officials but more fundamentally the congressional overseers-- remain embedded in the political process shown in Figure 1. In Merrill's words, "The political climate in which the FDA operates" and "the law under which the FDA functions" fail to "significantly constrain the FDA's appetite for elegant and costly information" and "reward caution and facilitate delay."[194] The next time the news media amplify a shocking revelation with respect to a medical device, all the actors will react in a predictable way. The politicians and the regulators will alter the law and the regulations to demonstrate their deep commitment to protecting the public health, and once again the FDA's powers will be increased. As long as the news media and the public continue to play their present roles, the former crying wolf to get an audience and the latter demanding that the federal government be an all-purpose savior, the industry will continue to lose what little room for innovative maneuver it still possesses, and the well-being of patients will continue to fall far short of what it could be in the absence of government regulation.

Requisites of Real Reform

With the Republican takeover of Congress, some people think that the outlook is somewhat brighter. As one reporter observes, "Congressional investigations of medical device manufacturers will probably cease" and "attention is likely to turn instead to the regulators," as conservative legislators seek to lighten the industry's regulatory burden.[195] One should not expect a revolution, however, merely because Republicans have replaced Democrats as the controlling party in Congress. While the departure of Kennedy, Dingell, and Waxman from their committee chairmanships promises some relief for the medical device industry and the patients who depend on its products, the Republicans will occupy the same position the Democrats have occupied in the causal structure depicted in Figure 1. They will face

similar incentives and constraints and hence will probably act similarly, especially when faced with some purported "crisis."

If the Republicans were really serious about repairing the defects of the regulatory system for medical devices, they would repeal the laws enacted in 1976 and 1990. As long as those laws remain in force, the FDA, where the same personnel continue to operate, will be extremely difficult to control, and regulation will be carried out more or less as before. The current device legislation, as documented in detail above, gives broad discretion to the regulators, and FDA officials, with ample assistance from the news media and other well-placed friends, know well how to play the game with Congress to preserve the agency's powers and budget.

Of course, any proposal to repeal the device laws will elicit cries of astonishment and outrage: how could anyone seriously propose to remove such vital protection of the public health? One can respond to that question in two ways.

First, one can explain and document, as in this study, how the world actually works. Because the protection afforded by the current system is illusory and indeed the current system on balance wreaks massive harm, scrapping it would be a blessing to the general public. Whether one can convince anyone is another matter. A deep-seated belief in beneficent and effective government protection is not easily overcome.

Second, with more likelihood of success, one can propose, not that the FDA be abolished outright, but merely that its activity be legislatively altered so that, instead of engaging in excruciatingly detailed rulemaking and law enforcement, the agency would occupy itself with product certification. After all, as articulated in mainstream, neoclassical economics, the rationale for FDA-type action rests on an alleged "market failure" having to do with "imperfect information." Specifically, because of the public-good character of information, consumers are presumed to act on the basis of an "inadequate" amount of information and hence to bear more than the "optimal" amount of risk.[196] If inadequate information is really the problem, then let the FDA supply information.

The FDA could issue to products that meet its standards a seal of approval. Consumers would then know that a certified product had passed whatever tests the FDA considered appropriate to demonstrate its safety and efficacy. Consumers would be free, however, to disregard that information if they did not value it. They would be free to purchase products lacking FDA certification, and sellers would be free to sell uncertified products without government obstruction or penalty. Note that no one would be forced to use products lacking FDA certification. People who value FDA testing would be able to enjoy its benefits, while those who do not value it would not be coerced to act in accordance with the choices made by a handful of bureaucrats in Rockville.

If the government really believes it has something of value to provide consumers, then it should be content just to give it to them. If they reject it, their rejection will be a sure sign that they do not value it. There is absolutely no defensible justification for forcing people at gunpoint to do "what's best for them." Doing so is sheer paternalism. Treating responsible adult citizens as if they were children is tyrannical. Citizens who value liberty should have no trouble rejecting a system that simultaneously harms the public health and deprives people of their ability to make vital choices about their own health.

Notes

[1] Bruce Goldfarb and Doug Wolfberg, "Feds Focus on Medical Devices," Journal of Emergency Medical Services 17 (July 1992): 35. Cited hereafter as JEMS.

[2] Health Industry Manufacturers Association, The Global Medical Device Market Update: Markets for Medical Technology Products, 1994 ed., HIMA Pub. 94-1, January 1994, pp. 40, 59, 68, 153.

[3] "FDA Driving Device Manufacturers Out of the US?" Clinica 532 (December 23, 1992): 13; and "US Manufacturers Moving Out," Clinica 596 (March 28, 1994): 1.

[4] Quoted in Lawrence M. Fisher, "Frustration for Medical Innovators," New York Times, June 30, 1993, p. D5.

[5] Standard references include Peter Temin, Taking Your Medicine: Drug Regulation in the United States

(Cambridge, Mass.: Harvard University Press, 1980); and Henry G. Grabow ski and John M. Vernon, The Regulation of Pharmaceuticals: Balancing the Benefits and Risks (Washington: American Enterprise Institute for Public Policy Research, 1983). More recent appraisals include Joanna E. Siegel and Marc J. Roberts, "Reforming FDA Policy: Lessons from the AIDS Experience," Regulation 14 (Fall 1991): 71-77; Michael R. Ward, "Drug Approval Overregulation," Regulation 15 (Fall 1992): 47-53; C. Frederick Beckner III, "The FDA's War on Drugs," Georgetown Law Journal 82 (December 1993): 529-62; and Ronald W. Hansen, "Regulation of the Pharmaceutical Industry," in American Health Care: Government, Economic Processes and the Public Interest, ed. Simon Rottenberg (forthcoming).

[6] 52 U.S. Stat. 1040 (June 25, 1938), p. 1041.

[7] Ibid., pp. 1042, 1044. At the time, the FDA was in the Department of Agriculture, and the statutory language actually gave authority to the secretary of agriculture. The secretary delegated the authority to the FDA.

[8] Ibid., pp. 1049, 1050.

[9] A 1934 draft bill defined devices as drugs and subject ed them to the same legal requirements, but that definition did not survive congressional reworking of the statutory language. See Susan Bartlett Foote, "Loops and Loopholes: Hazardous Device Regulation under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act," Ecology Law Quarterly 7 (1978): 106-7.

[10] Peter Barton Hutt, "A History of Government Regulation of Adulteration and Misbranding of Medical Devices," Food Drug Cosmetic Law Journal 44 (1989): 105; and Peter Barton Hutt and Richard A. Merrill, Food and Drug Law: Cases and Materials, 2d ed. (Westbury, N.Y.: Foundation Press, 1991), p. 735.

[11] Ibid., p. 736; quotation from "Medical Device Regulation," Congressional Quarterly Almanac, 1976, p. 535.

[12] Hutt, pp. 102-8. A bill introduced in 1961, and in every succeeding Congress until passage of the Medical Device Amendments, required a premarket showing of safety and effectiveness for devices. Congress chose not to include that provision in the important 1962 drug law amendments. See Foote, "Loops and Loopholes," p. 108; and Hutt and Merrill, p. 743.

[13] Food and Drug Administration, Regulatory Requirements for Medical Devices, HHS Pub. FDA 89-4165, May 1989, p. 1.

[14] Foote, "Loops and Loopholes," pp. 108-10; and Richard A. Merrill, "Regulation of Drugs and Devices: An Evolution," Health Affairs 13 (Summer 1994): 56-57. Speaking for the court in the Bacto-Unidisk case, decided in 1969, Chief Justice Earl Warren said, "Remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." Quoted in Hutt and Merrill, pp. 731-32.

[15] "Legislative History of the Medical Device Amendments of 1976," United States Code, Congressional & Administrative News, 94th Cong., 2d sess., 1976, vol. 3, p. 1076.

[16] Food and Drug Administration, Regulatory Requirements for Medical Devices, p. 2; and Hutt and Merrill, p. 744.

[17] "Medical Device Regulation," p. 537.

[18] "Legislative History of the Medical Device Amendments of 1976," pp. 1071, 1076. Notwithstanding the failure of Congress to enact the legislation, the FDA proceeded in 1974 to establish the Bureau of Medical Devices and Diagnostic Products "in anticipation of the Medical Device Amendments that were passed two years later." See Michael Brannon, "Organizing and Reorganizing FDA," in Seventy-Fifth Anniversary Commemorative Volume of the Food and Drug Law (Washington: Food and Drug Law Institute, 1984), pp. 153, 155.

[19] "Legislative History of the Medical Device Amendments of 1976," p. 1071; and Herbert Burkholz, The FDA Follies (New York: Basic Books, 1994), p. 66.

[20] Foote, "Loops and Loopholes," p. 102.

[21] Ibid., pp. 128-31.

[22] "Medical Device Regulation," pp. 535-36; and Hutt, pp. 110-12.

[23] 90 U.S. Stat. 539 (May 28, 1976). In the statute the powers are vested in the secretary of health, education, and welfare. In practice, the powers are delegated to the secretary's subordinate, the commissioner of food and drugs, who heads the FDA.

[24] Ibid., p. 575.

[25] A year before the law was enacted, the FDA established 14 panels and began classifying devices. Hutt, who was the FDA's chief counsel at the time, notes that "these adminis- trative initiatives by the FDA concerned members of Congress and their staff, who argued that the FDA should have waited for specific statutory authority before acting. Neverthe less, they served a very important function, i.e., keeping pressure on Congress to enact the new legislation." Hutt, p. 111. See also Foote, "Loops and Loopholes," p. 114.

[26] 90 U.S. Stat., p. 541. Foote observes that for devices employed by health professionals "the House Report makes clear that evaluation of safety and effectiveness information of these devices should be with reference to their suitability for use by professionals rather than laypersons . . . [and take into account] whether the device will be used primarily in hospitals or solely in the home." Foote, "Loops and Loopholes," p. 112.

[27] Ibid., pp. 115, 116, 121, 123. In the latitude allowed the regulators, this statute was typical. As Hutt and Merrill observe, "FDA has enjoyed unusual freedom to adopt and revise regulatory approaches." Hutt and Merrill, p. 20.

[28] 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, p. 8. Cited hereafter as Less Than the Sum.

[29] Hutt maintains that "development of performance standards for class II devices . . . was not made mandatory and was left to the sole discretion of the FDA according to agency priorities and resources." Hutt, pp. 112-13. Others disagree. See Hutt and Merrill, p. 772.

[30] Less Than the Sum, pp. 7-9.

[31] Merrill, p. 68.

[32] Quoted in "International Markets Embrace Novel Devices," In Vivo, June 1994, p. 13. In 1988 FDA officials noted that a House bill requiring clinical test data for 510(k) applications "would merely codify current agency policy" in effect since June 1986 in selected cases. See Congressional Quarterly Almanac, 1988, p. 320. Agency reviewers believed that "the law provides great latitude in assessing whether 510(k) applications are substantially equivalent to a predicate device." Less Than the Sum, p. 39.

[33] 90 U.S. Stat., pp. 560-64.

[34] Less Than the Sum, p. 10.

[35] U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Medical Device Regulation: The FDA's Neglected Child, 98th Cong., 1st Sess., committee print 98-F, May 1983, pp. iii-iv, quoted in Susan Bartlett Foote, "Coexistence, Conflict, and Cooperation: Public Policies toward Medical Devices," Journal of Health Politics, Policy and Law 11 (Fall 1986): 517. Dingell used almost identical phrasing when berating the FDA at hearings in May 1987. See Congressional Quarterly Almanac, 1988, p. 320.

[36] Ibid.; Burkholz, pp. 13-14, 47-48; and Peter Brimelow and Leslie Spencer, "Food and Drugs and Politics," Forbes 152 (November 22, 1993): 118. The staff of Dingell's oversight subcommittee did not accept the FDA's standard excuse, commenting that "the FDA's inability to manage its resources effectively is well known to those who have monitored the Agency for any length of time." Less Than the Sum, p. 15 (also pp. 41, 43).

[37] "The Medical Device Amendments: l0 Years After," FDA Consumer, May 1986, pp. 30-31.

[38] In 1992 Jim Page, the editor of JEMS, assailed the FDA for "concentrating their attention on manufacturers rather than on the much bigger problems of user training and operator error." Page "Can You Trust Your FDA?" JEMS 17 (August 1992): 91.

[39] Less Than the Sum, p. 12.

[40] "A hearing is not a hearing in Washington, D.C. unless the media shows up, and a function of any congressional investigatory staff is to maximize publicity." Wayne L. Pines, "Handling External Audiences: A Guide for the Medical Device Industry," Food & Drug Law Journal 47 (1992): 577.

[41] Medical Devices, Diagnostics & Instrumentation, July 4, 1994, pp. 2-3; and Yolanda van der Graaf et al., "Risk of Strut Fracture of Bjork-Shiley Valves," Lancet 339 (February 1, 1992): 257-61. According to the staff report of Dingell's oversight subcommittee, 501 fractures had been reported by the end of January 1993, but no source is given for this higher figure. Less Than the Sum, p. 23.

[42] Ibid., pp. 12, 21-23.

[43] William C. Steere, quoted in Burkholz, p. 76.

[44] Medical Devices, Diagnostics & Instrumentation, July 4, 1994, p. 3.

[45] Ken Taylor, "Acute Failure of Artificial Heart Valves: The Risk Is Small," British Medical Journal 297 (October 22, 1988): 996-97.

[46] 104 U.S. Stat. 4511 (1990); "Legislative History of the Safe Medical Devices Act of 1990," U.S. Code, Congressional and Administrative News, 101st Cong., 2d sess., 1990, vol. 8, pp. 6305-35; and "New Regulations for Medical Devices," Congressional Quarterly Almanac, 1990, pp. 579-81. In 1988 the House had passed a similar bill, sponsored by Dingell and Waxman, but the Senate did not act on it. The administration opposed the bill because, inter alia, it would "inundate the FDA with data which would require a staggering amount of effort to process and analyze." Congressional Quarterly Almanac, 1988, p. 319.

[47] Manufacturers must report to the FDA by telephone not later than 5 calendar days and in writing not more than 15 working days after receipt of the information. 49 Federal Register 36326-45 (September 14, 1984): 36349.

[48] 104 U.S. Stat., p. 4511.

[49] Ibid., p. 4527. Again, the statute actually vests the powers in the secretary of human services, but in practice the secretary delegates them to the commissioner of food and drugs.

[50] Quoted in Goldfarb and Wolfberg, p. 46.

[51] Less Than the Sum, p. 72.

[52] Quoted in Thomas M. Burton, "Law Concerning Medical Devices Is Often Ignored," Wall Street Journal, May 2, 1994.

[53] Ibid.; and Marybeth Burke, "Hospitals Wary of Interpretation of Medical Device Reporting Law," Hospitals, October 20, 1991, p. 42, citing an advisory from ECRI, a private testing firm, that expresses doubt "whether such massive amounts of data will add much in the way of meaningful information."

[54] "Device User Facility Civil Penalties Will Go into Effect," Medical Devices, Diagnostics & Instrumentation, May 23, 1994, pp. 17-19.

[55] Medical Devices, Diagnostics & Instrumentation, March 21, 1994, p. 5. Dr. Joel J. Nobel, president of ECRI, describes the user reporting scheme as "a horribly flawed concept" and presents it as a "bizarre example" of how "Congress passes legislation that demands safe devices and micromanages the process by prescribing in great detail unworkable, inefficient methods." Address to Utah Biomedical Congress, 1993, p. 8.

[56] Jack Olshansky calls user error "unquestionably the most frequent contributor to MDRs." Olshansky, "How the Investment Community Views the Food and Drug Administration's Approval Process and Clinical Outcomes," Food Drug Cosmetic Law Journal 45 (1990): 506.

[57] 104 U.S. Stat., p. 4512; and Goldfarb and Wolfberg, p. 45.

[58] Quoted in ibid.

[59] The program also made false claims about fatality- causing failures of Physio-Control defibrillators in the Washington, D.C., area. Knowing the claims to be false, Melinda Duncan, executive director of the Northern Virginia Emergency Medical Services Council, made repeated requests to WRC-TV for documentation. Although WRC promised to provide the documentation, it never did. Duncan said that the emergency services providers in her jurisdiction had never had any problem with Physio-Control equipment. Video taped 1992 interview of Duncan in the author's possession.

[60] ECRI issued a press release calling the "Fatal Flaws" program misleading and inflammatory and urging the public to ignore the show. ECRINet System News, August 7, 1992. Medical investigations have shown that "most MDRs for defibrillators involve operator errors in performance or maintenance rather than device errors or failures." Mary Newman, "To Focus on the Forest: Recognizing the Value of Early Defibrillation Despite Isolated Failures," JEMS 19 (May 1994): 17, 20nn. 16-18.

[61] Ibid., p. 17.

[62] Page, p. 5.

[63] Brent Bowers, "Entrepreneurs Find FDA Can Make or Break Them," Wall Street Journal, April 12, 1994; and Marcia A. Ludwig, "Physio-Control Gets Final OK to Ship Defibrilla tor," Journal American (Bellevue, Washington), May 20, 1993.

[64] 104 U.S. Stat., pp. 4514-19. Legal authorities had disputed whether the Class II performance standards were required or merely permitted by the 1976 amendments.

[65] Ibid., p. 4520.

[66] Ibid., pp. 4520-23.

[67] U.S. Food and Drug Administration, Center for Devices and Radiological Health, "FDA Begins Implementing New Device Legislation," Medical Devices Bulletin 9 (May 1991): 3.

[68] Larry Pilot, Washington counsel for the Medical Device Manufacturers Association, commented that the 510(k) application process "has spun out of control. People talk about a 'drug lag' in the U.S. This is worse; we're going to become a laughing-stock." Quoted in "MDMA Focuses on FDA Process," Clinica 604 (May 23 1994): 11.

[69] Jonathan Kahan, "The Changing 510(k) Process," Clinica 529 (December 2, 1992): 13; "U.S. Rethinking Device Evaluation Priorities," Clinica 547-8 (April 21, 1993): 13, 15; and "510(k) Decision-Making Process Should Remain with Manufacturer," Medical Devices, Diagnostics & Instrumentation, July 4, 1994, pp. 20-21. "There is apparently no

system for differentiating between applications for new devices, and manufacturing changes for currently marketed devices. . . . [Manufacturers] cannot improve their competitive position in the market if they cannot make rapid chang es in the manufacturing process of devices. . . . Inspectors are . . . indicating that the manufacturer has committed a violation by failing to file a new 510(k) application, even when the manufacturer considers the manufacturing change to be minor." Less Than the Sum, p. 51.

[70] Merrill reports that "FDA's past practice . . . had resulted in requests for clinical data for just over 5 percent of all 510(k) notifications. Since 1990, however, that rate has tripled to 15 percent." Merrill, p. 64.

[71] Jonathan Kahan, "1993--A Roller Coaster Ride for US Industry," Clinica 585 (January 10, 1994): 23-25; idem, "Use of Clinical Data in Support of US and EU Device Clearances," Clinica 604 (May 23, 1994): 8-9. Merrill notes that the FDA's regulation of devices "seems to be moving inexorably toward the 'drug model.'" Merrill, pp. 48, 62-63.

[72] 104 U.S. Stat., pp. 4526-28.

[73] Ibid., p. 4527.

[74] When the FDA first used its authority to impose civil penalties by fining Infusaid, a Pfizer subsidiary, $290,000 in late 1993, it was rewarded by the demagoguery of Rep. Ron Wyden (D-Ore.), who assailed the FDA for going too lightly on the company. See Medical Devices, Diagnostics & Instrumentation, February 28, 1994, pp. 3-5. In contrast, the FDA levied a whopping $1,580,000 civil penalty on a small company, Lexicor, and its founder, Michael Hickey, in September 1993. The fine amounted to twice the firm's 1993 revenue and led it to devote more than half its staff time to compliance with FDA regulations. Said Lexicor's lawyer, "This is a good, cheap PR lesson to scare the hell out of other small businesses." Quoted in Bowers.

[75] Medical Devices, Diagnostics & Instrumentation, February 21, 1994, p. 3.

[76] Burkholz, pp. 47-62.

[77] Jyoti Thottam, "Generic-Drug Makers Prepare for Their Next Battle: Scandal-Tainted Industry Faces Heightened Competition and Regulation," Wall Street Journal, August 9, 1993. For discussion of draconian controls over telephone communication of FDA personnel with industry, see Less Than the Sum, pp. 225-30

[78] Ibid., p. 45 (see also pp. 46-48). According to Jonathan Kahan, "The drastic increase in the amount of data being requested by reviewers . . . is a reflection of an effort by reviewers to ensure that there is sufficient data in the 510(k) to withstand scrutiny by internal FDA auditors and outside parties, including the Inspector General and Congressman John Dingell. Reviewers fear accusations of not properly assuring the safety and efficacy of devices and react by 'papering the file.' . . . There is no clear guid ance at this time as to what data are needed to support 510(k) notices for the various types of devices. Each 510(k) sponsor is shooting at a moving target with the reviewer having complete discretion as to what data to request in connection with each filing." Kahan, "The Changing 510(k) Process," pp. 13-14. See also Bruce Ingersoll, "FDA Attacked for Holding Up Medical Devices," Wall Street Journal, September 9, 1992. Ingersoll remarks on the irony that "one of the main reasons for the slowdown [heavily criticized by Dingell in 1992 and 1993] was intense pressure from prominent lawmakers, including Rep. Dingell himself."

[79] Less Than the Sum, pp. 65-75; Kathryn Gleason, "US Enforcement Trends in the '90s," Clinica Supplement (October 1993): 13-15; and Peter Brimelow and Leslie Spencer, "Just Call Me 'Doc,'" Forbes 152 (November 22, 1993): 108-10. [80] Jonathan S. Kahan, "US Medical Device Regulation in 1992," Clinica 533 (January 6, 1993): 21.

[81] Less Than the Sum, pp. 26-27.

[82] Thomas M. Burton, "Breast Implants Raise More Safety Issues," Wall Street Journal, February 4, 1993.

[83] Pines, "Handling External Audiences," p. 571. "This adverse publicity quickly spilled over to encompass all medical devices and now the media are ready to report any controversial story involving medical devices." "Medical Device Industry Vulnerable to Media Sensationalism," Clinica 521 (October 7, 1992): 12.

[84] This discrimination made no sense on safety grounds, and some observers attributed it to Kessler's close connections with Naderites and left-liberal feminists. See Brimelow and Spencer, "Just Call Me 'Doc,'" p. 110.

[85] Burton, "Breast Implants"; "Review of 1992," Clinica 533 (January 6, 1993): 3-4; U.S. Food and Drug Administration, Center for Devices and Radiological Health, "FDA Allowing Limited Use of Silicone Gel-Filled Breast Implants," Medical Devices Bulletin 10 (May 1992): 1-2.

[86] Medical Devices, Diagnostics & Instrumentation, April 18, 1994, pp. 8-9; Thomas M. Burton, "Women with Breast Implants Receive Court Deadlines for Joining Settlement," Wall Street Journal, April 20, 1994; and idem, "U.S. Judge Clears Breast-Implant Accord," Wall Street Journal, Septem ber 2, 1994.

[87] Gina Kolata, "Scleroderma and Breast Devices: No Tie Is Seen," New York Times, May 29, 1994; John Schwartz, "Mayo Study on Breast Implants Raises Questions," Seattle Times, June 16, 1994 (reprinted from Washington Post); Jonathan Bor, "Studies Weaken Disease-Implant Link," Seattle Times, October 25, 1994 (reprinted from Baltimore Sun); and "The $4.3 Billion Mistake," Wall Street Journal, June 17, 1994.

[88] Ibid.

[89] The data for those years have been compiled by Mary Olson, "Regulatory Agency Discretion among Competing Industries: Inside the FDA," Political Economy Working Paper no. 173, Washington University, April 1993. The years mentioned in this section are federal government fiscal years.

[90] Ibid.

[91] Unless otherwise noted, these data and those that follow are drawn from Medical Devices, Diagnostics & Instrumentation, January 3 and July 25, 1994, and January 30, 1995; Clinica, March 17, 1993, and March 28, 1994; and data provided by the Health Industry Manufacturers Association (courtesy of Gabrielle Williams).

[92] Kahan, "1993--A Roller-Coaster Ride for US Industry," p. 24. See also the anguished letters from Drs. Marcus, Wilkinson, and O'Neill and the list of 49 important products awaiting U.S. approval (but already being sold abroad) reprinted in Less Than the Sum, pp. 152-57, 231-33, 238-43.

[93] John Schwartz, "FDA Quickly Whittles Down Stack Of Applications for Medical Devices," Washington Post, November 29, 1994.

[94] "Kessler's Devices," editorial, Wall Street Journal, February 10, 1993.

[95] The 1992 figure is from "FDA Outlines Steps to Speed Up Reviews of Medical Devices," Wall Street Journal, June 25, 1993. The 1993 figure is from Medical Devices, Diagnostics & Instrumentation, January 30, 1995.

[96] "FDA-Industry Interaction in Guidance Development Welcomed," Medical Devices, Diagnostics & Instrumentation, August 22, 1994, p. 3.

[97] "Understanding FDA Medical Device Review Statistics," Insight (a quarterly update prepared by the Health Care Technology Institute), September 1994, p. 8.

[98] Ingersoll; Less Than the Sum, p. 17 (on the March and June hearings). The latter report was the product of Dingell's anomalous phase of concern about the harm to industry and patients caused by the FDA's overzealous regulation. See "Industry Sways Dingell to Its side," Clinica, September 9, 1992.

[99] "Litigation with the FDA is a very costly and risky adventure." Jonathan Kahan, "Corporate-Wide Medical Device Compliance Initiatives," Clinica 612 (July 18, 1994): 8. Hutt and Merrill note that administrative discretion is "characteristic of the regulatory process, but FDA has enjoyed unusual freedom to adopt and revise regulatory approaches." Hutt and Merrill, p. 20.

[100] Brimelow and Spencer, "Food and Drugs and Politics," p. 116. Attorney Dvorah A. Richmond has highlighted "the industry's unwillingness to fight as one reason for FDA's increasingly aggressive actions, giving the FDA the ability to bully the industry into submission." Quoted in Elizabeth R. Porter, "David Kessler's High-Wire Act on Enforcement," Medical Industry Executive, January 1994, p. 21. Dr. Nobel warns industry executives that those who oppose the regulators "will become a permanent member of CDRH's hit list. The agency does maintain long-term vendettas against specific companies. How do we know this? Because FDA's staffers tell us in chapter and verse how disgusted they are by the practice." Nobel, p. 23.

[101] Burkholz, pp. 48-62. Peter Barton Hutt, former general counsel at the FDA, attests that "the broad mantle of GMP enforcement can be used for other agency agendas." Quoted in "International Markets Embrace Novel Devices," p. 12.

[102] Brimelow and Spencer, "Food and Drugs and Politics," p. 117 (quoting Food & Drug Insider Report).

[103] "Of all the government regulatory agencies created by Congress, the FDA has been the most expansive and the most punitive in inhibiting speech." John Seigenthaler, "Introduction: Far from the Founding Fathers," in Bad Prescription for the First Amendment: FDA Censorship of Drug Advertising and Promotion, ed. Richard T. Kaplar (Washington: Media Institute, 1993), p. xiii. It seems to me that the FDA routinely violates the rights of citizens as guaranteed not only by the First Amendment to the Constitution but also by the Fourth, Fifth, and Tenth Amendments. Evidently, the root of the evil is, as usual, the Supreme Court's expansive reading of the commerce clause. See Sidney A. Shapiro and Joseph P. Tomain, Regulatory Law and Policy (Charlottes ville, Va.: Michie, 1993), pp. 488-93. Hutt and Merrill devote only a few pages to constitutional issues; they limit their discussion to Fourth Amendment questions, on which federal judges have taken the seemingly absurd position that citizens entering into a type of business "long subject to close supervision and inspection" or "pervasively regulated" thereby forfeit their Fourth Amendment protection. Hutt and Merrill, pp. 1104-7.

[104] Merrill, p. 59.

[105] Less Than the Sum, p. 65.

[106] "Compliance and Enforcement--Past, Present, and Future: An Interview with William H. Damaska," Medical Device & Diagnostic Industry (July 1993): 32. Damaska had recently retired as director of the Division of Compliance Operations in the Office of Compliance and Surveillance at the FDA's Center for Devices and Radiological Health.

[107] Quoted in Porter, p. 19.

[108] Dingell's oversight subcommittee observed that, not withstanding the increase in enforcement actions, "there is no evidence that medical device companies have greater compliance problems now than they ever have had in the past." Less Than the Sum, p. 82.

[109] See, for example, Hilary Stout and Rose Gutfeld, "Vigorous FDA Is Seen as Chief Is Reappointed," Wall Street Journal, March 1, 1993; and John Schwartz, "Building New Consensus to Improve Public Safety," Washington Post, July 15, 1993.

[110] "SOPs Needed as Protection against FDA Criminal Investigations," Medical Devices, Diagnostics & Instrumentation, July 4, 1994, p. 22. For court decisions and other materials relevant to the FDA's inspection authority, see Hutt and Merrill, pp. 1102-21.

[111] Porter, p. 19. Hutt and Merrill observe, "Many FDA employees have devoted their lives to gathering proof of statutory violations in preparation for court enforcement proceedings, and this adversary experience has engendered suspicion of regulated firms. This suspicion has in turn produced a desire to devise requirements that cannot be escaped or subverted" (p. 20).

[112] Quoted in Burkholz, p. 58.

[113] Less Than the Sum, p. 83. According to device lawyer Jonathan Kahan, "It has become more difficult to deal with FDA enforcement actions and negotiate a reasonable resolution to problems." Kahan, "Honour Lost to Tougher Device Enforcement," Clinica 500 (May 13, 1992): 17. Gleason notes that the FDA has singled out certain companies, such as Physio-Control, to make examples of, approaching them "with a predisposition to remedy compliance concerns through injunctive or other forms of formal legal action rather than through voluntary compliance." Gleason, p. 14.

[114] Says Nobel, "Beyond incompetent, they are stubborn" (p. 7).

[115] Less Than the Sum, p. 88. On "untrained inspectors who cannot, or will not, distinguish between 'significant' and 'nonsignificant' GMP violations," see ibid., p. 66, and details on pp. 69-70, 73.

[116] Ibid., p. 66; and Porter, p. 21.

[117] Figures for 1991 and 1992 are from "The Enforcement Story," an internal FDA document issued by the Office of Enforcement in the Office of Regulatory Affairs; figures for 1993 and 1994 come from the Office of Enforcement as report ed in data sheets provided to me by the Health Industry Manufacturers Association.

[118] "International Markets Embrace Novel Devices," p. 12, quoting lawyer Peter Barton Hutt for the 70 percent estimate. Ronald Johnson, director of the Office of Compliance and Surveillance, confirmed that GMP had been made "the central focus of our enforcement programme." "FDA's Regulatory Priorities for 1994," Clinica 585 (January 10, 1994): 27.

[119] For GMP "the FDA simply issued a series of broadly- defined and wide-ranging regulations that provided its reviewers and inspectors with maximum flexibility, and largely failed to follow up with detailed guidelines to better advise industry." Less Than the Sum, p. 74. Accord ing to Nobel, whose opinion in this regard deserves more weight than anyone else's, "There is no known relationship between GMP paperwork and actual product performance in the field" (p. 22).

[120] Ibid., p. 85.

[121] "The Reference List: What It Is and What It Is Not," enclosure sent to all registered medical device companies with letter from Ronald M. Johnson, director, Office of Compliance and Surveillance, January 21, 1993, reprinted in ibid., pp. 215-18.

[122] Ibid., p. 217; and Kahan, "1993--A Roller Coaster Ride," p. 26.

[123] "HIMA Advocates Clarity of Reference List Procedures," Clinica 592 (February 28, 1994): 9; and "Hearings for Device Firms Facing Placement on FDA's 'Reference List,'" Medical Devices, Diagnostics & Instrumentation, February 28, 1994, pp. 12-14.

[124] "HIMA Advocates Clarity," p. 9; and "Hearings for Device Firms," p. 14.

[125] "FDA 'Reference List' Violates Constitutional Due Process Protections," Medical Devices, Diagnostics & Instrumentation, September 19, 1994, pp. I&W 7-8.

[126] Kahan, "Corporate-Wide Medical Device Compliance Initiatives," p. 8.

[127] Quoted in ibid., pp. 6-7.

[128] Quoted in "Siemens Shipment Suspensions under Consent Decree Affect 8% of U.S. Sales," Medical Devices, Diagnostics & Instrumentation, February 28, 1994, p. 5.

[129] "Puritan-Bennett Closing Two Manufacturing Facilities under Consent Decree," Medical Devices, Diagnostics & Instrumentation, January 10, 1994, p. I&W 1.

[130] Less Than the Sum, p. 84.

[131] Quoted in Laura Jereski, "Block That Innovation!" Forbes, January 18, 1993, p. 48. See also the statements of venture capitalist Chuck Hadley quoted in "Venture Capital ists Still Investing, But Selectively," Primus (newsletter of the Health Industry Manufacturers Association) 4 (May 1994): 5. Even before the recent changes, venture capitalists felt immense frustration with FDA regulation. See the 1990 observations of venture capitalist Jack Olshansky in "How the Investment Community Views the Food and Drug Administration's Approval Process."

[132] Quoted in Less Than the Sum, p. 80.

[133] Quoted in Lawrence M. Fisher, "Frustration for Medical Innovators," New York Times, June 30, 1993.

[134] Quoted in ibid.

[135] Quoted in ibid.

[136] Quoted in Adrien Seybert, "Waiting and Waiting on the FDA," Providence Journal, July 19, 1994.

[137] Less Than the Sum, p. 81n. 139.

[138] Quoted in Seybert, "Waiting and Waiting."

[139] Gallop Organization, "Survey of Medical Device Manufacturers Concerning the Strategic and Economic Impact of the Federal Regulatory Process," June 1994, p. 14.

[140] Quoted in Less Than the Sum, p. 81.

[141] "No Improvement in Communication with FDA, Readers Say," Devices & Diagnostics Letter, July 30, 1993, p. 5.

[142] See, for example, United States of America v. Physio-Control Corporation, Complaint for Injunction, U.S. District Court, Western District of Washington, July 21, 1992, pp. 3-5.

[143] Trade publications often carry advertisements such as that for the Medical Device Inspection Company, which appeared in Medical Industry Executive, April 1993, p. 32. The ad gives prominent notice that the firm is "staffed by former FDAers and industry experts."

[144] ODE Integrity Memorandum no. I92-2, May 1, 1992, reprinted in Less Than the Sum, pp. 225-30.

[145] Not returning phone calls extended beyond product approval reviewers. Enforcement officers in the District Offices often behaved similarly. See Less Than the Sum, pp. 46-47.

[146] Quoted in Bowers, "Entrepreneurs Find FDA Can Make or Break Them." Similarly, Medtronic spokesman Dick Reid said that when company employees tried to find out why their implantable defibrillator had not been approved during the 17 months elapsed since the FDA's advisory panel had recommended its approval, they "found phone inquiries to be futile." Quoted in Ingersoll, "FDA Attacked."

[147] "No Improvement in Communication with FDA, Readers Say," pp. 4-5.

[148] Quoted in Bowers, "Entrepreneurs Find FDA Can Make or Break Them."

[149] Ibid.; and "FDA's 'Arbitrary and Capricious' Denial of R S Medical's 510(k)s," Medical Devices, Diagnostics & Instrumentation, August 16, 1993, pp. 9-11.

[150] Quoted in Jereski, "Block That innovation!"

[151] "FDA Driving Device Manufacturers Out of the US?" Clinica 532 (December 23, 1992): 13.

[152] "US Manufacturers Moving Out," p. 1; and "Preliminary Findings, Strategic Survey" (compilation provided by Gabriel Williams of HIMA).

[153] "Member Surveys Track Regulatory, Business Actions," Primus 4 (May 1994): 4.

[154] Interview with Matthew S. Gallivan, HIMA associate vice president for Europe and the Americas, December 9, 1994.

[155] Mike Meyers, "Losing the Edge: Survey Shows That State's Med-Tech Pioneers Are Sending Money, Jobs, Products Overseas," Minneapolis Star Tribune, June 27, 1994.

[156] Medtronic News Release, Minneapolis, November 22, 1994.

[157] American Electronics Association News Release, Washington, June 23, 1994.

[158] HIMA, "The Global Medical Device Market Update," HIMA publication 94-1, January 1994, pp. 76-77.

[159] Values taken from a chart reproduced in "Innovation Threatened by Lack of Venture Capital?" Clinica 601 (May 2, 1994): 15. See also "Trends in Venture Capital Funding for the Medical Device Industry," Insight, March 1994, p. 5.

[160] Robert Higgs, "Banning a Risky Product Cannot Improve Any Consumer's Welfare (Properly Understood), with Applications to FDA Testing Requirements," Review of Austrian Economics 7 (1994): 3-20; and idem, "Should the Government Kill People to Protect Their Health?" Freeman 44 (January 1994): 13-17.

[161] Nobel, p. 15.

[162] William C. Mitchell and Randy T. Simmons, Beyond Politics: Markets, Welfare, and the Failure of Bureaucracy (Boulder, Colo.: Westview, 1994), passim.

[163] Porter notes that in the news media "FDA is most often portrayed as a crusader protecting the unwary public from greedy, negligent medical product manufacturers." Porter, p. 21.

[164] Quoted in ibid., p. 20. That FDA action was so manifestly harmful that some 60 hospitals simply ignored the order and continued to use the Bunnell ventilator, which had no effective substitute and without which some babies would surely die. The episode was described on ABC's 20/20 television program, August 12, 1994. The FDA's actions were savaged by Nobel, who said, "I simply do not have strong enough words to express my anger over this" (p. 12).

[165] Cummins's statement was made on ABC's 20/20, August 12, 1994.

[166] Quoted in Porter, pp. 19-20. See also Candace L. Littell, "FDA Hang-Ups Stifle Medical Innovations," Wall Street Journal, May 17, 1994. Littell is executive director of Health Care Technology Institute.

[167] Nobel, p. 15.

[168] Burke, "Hospitals Wary," p. 42. Hospital administrators quoted by Burke say that equipment breakdown is "a rare occurrence" and "medical device problems are infrequent."

[169] Gallop Organization, "Survey of Medical Device Manufacturers," p. 38.

[170] Less Than the Sum, p. 237.

[171] Hamburger and Meyers. I have found no systematic evidence that Europeans experience more harm.

[172] Robert Higgs, "Allocation of Risks Associated with Medical Goods," Journal of Private Enterprise 9 (Summer 1993): 59-69.

[173] Peter Barton Hutt, one of the architects of the FDA's device regulation, offered a quite different evaluation: "FDA has succeeded in exerting sufficient regulatory control to protect the public health, while at the same time avoid ing over-regulation that would discourage medical device innovation and harm the public health." Hutt, p. 113. One wonders whether he would reaffirm that 1989 judgment today.

[174] Nobel, p. 14.

[175] Quoted in Hamburger and Meyers.

[176] For a superb account of the role played by so-called consumer groups, explicitly in relation to FDA drug regulation but equally applicable to device regulation, see C. Frederick Beckner III, "The FDA's War on Drugs," Georgetown Law Journal 82 (December 1993): 548-49.

[177] Porter, p. 19, citing Bunnell.

[178] Bertrand de Jouvenel, On Power: The Natural History of Its Growth (1945; Indianapolis: Liberty Fund, 1993), p. 391.

[179] Eric B. Schoch, "7 Months after Shutdown, Lilly Awaits FDA Ruling to Open Plant," Indianapolis Star, December 6, 1992.

[180] Ibid.; and Physio-Control Corporation press release, July 7, 1992.

[181] Besides receiving the usual serious notice in the respectable news media, that letter prompted a lurid story in a tabloid, "Code Blue--It's an Outrage--Faulty Heart Zappers Killed 322," National Examiner, September 28, 1993. Publicizing its demands for criminal prosecution of medical device manufacturers is a common tactic of the Public Citizens Health Research Group. See, for example, "FDA Urged to Prosecute Siemens-Elema," Clinica 514 (August 19, 1992): 1.

[182] "Infusaid Assessed $290,000 Civil Penalty for Unapproved Modifications," Medical Devices, Diagnostics & Instrumentation, November 29, 1993, p. 4.

[183] For a comparative perspective on rates of device failure, consider that "as many as 30% of hospitalized patients may experience an adverse drug event (ADE) during their hospital stay" and "fatal ADEs are expected in approximately 0.31% of hospitalized patients (60,000 to 140,000 patients annually) in the United States." David C. Classen et al., "Computerized Surveillance of Adverse Drug Events in Hospital Patients," Journal of the American Medical Association 266 (November 27, 1991): 2847.

[184] "U.S. Surgical Receives FDA Warning Letter for Stapler Product," Wall Street Journal, April 8, 1994.

[185] Ibid.

[186] The editors of the Wall Street Journal have been con- sistently critical of the FDA's device regulation. Other prominent critical reports include Brimelow and Spencer's articles in Forbes and, in part, Burkholz's book. The trade literature of the device, hospital, and emergency services industries contains the most detailed and reliable information about and criticism of the FDA, but the general public has no awareness of that information.

[187] "FDA/Industry User Fee Negotiations," Medical Devices, Diagnostics & Instrumentation, January 10, 1994, pp. 3-4; "User Fee Legislation Nears Capitol Hill," Clinica 602 (May 9, 1994): 7; "User Fees Heat Up on Capitol Hill," Primus 4 (July-August 1994): 1, 5; and "US Legislation Update," Clinica 618-9 (September 5, 1994): 10.

[188] "End of US Medtech User Fees?" Clinica 625 (October 17, 1994): 9.

[189] "Implantable Device Manufacturing Process Changes Require 510(k) Clearance," Medical Devices, Diagnostics & Instrumentation, April 11, 1994, pp. 1-5; and "Draft 510(k) Modifications Policy a 'Disaster,'" Clinica 601 (May 2,

1994): 8.

[190] "Revised FDA Inspection Guide Puts Onus on Industry," Clinica 610 (July 4, 1994): 10.

[191] "GMP Changes Would Add $84.5 Mil. to Annual Industry Costs," Medical Devices, Diagnostics & Instrumentation, November 22, 1993, pp. 3-7; and "GMP Proposed Reg's 'Prescriptive' Detail Should Be Moved to Guidance Documents," Medical Devices, Diagnostics & Instrumentation, April 11, 1994, pp. 5-6.

[192] "HIMA Presses for Changes in Proposed GMP," Primus 4 (July-August 1994): 5.

[193] William H. E. Oehsen, "FDA's Proposed GMPs: Taking an Inch or a Yard?" Medical Industry Executive, January 1994, p. 7.

[194] Merrill, p. 65.

[195] "Future of Healthcare Reform Post-Elections," Clinica 630 (November 21, 1994): 7.

[196] On the neoclassical economics rationale for FDA regulation, see, for example, Joseph E. Stiglitz, Economics of the Public Sector, 2d ed. (New York: Norton, 1988), pp. 78-79; and F. M. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry," Journal of Economic Perspectives 7 (Summer 1993): 98-99, 101. For criticism of the neoclassical rationale, see Higgs, "Banning a Risky Product."