National Medical Device Coalition
(NMDC)
Medical Device Reform Now!
March 13-14, 1996

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3/15/96

— National Medical Device Coalition
Varian sm. med large companies,

— worked w/ HIMA, NIMA

— Med device ind. severely "threatened"

get copy — RIGO Rpt —

Chris — what can we get done this year —

— Biggest priorities —
— what's doable —
> to take broader approach.

Separate bills for devices and drugs —

98% approved through —

— 3rd Party Review SB/C

— 3-4 years to get a new prod approved. —

Working w/ Agency
to exempt Class I

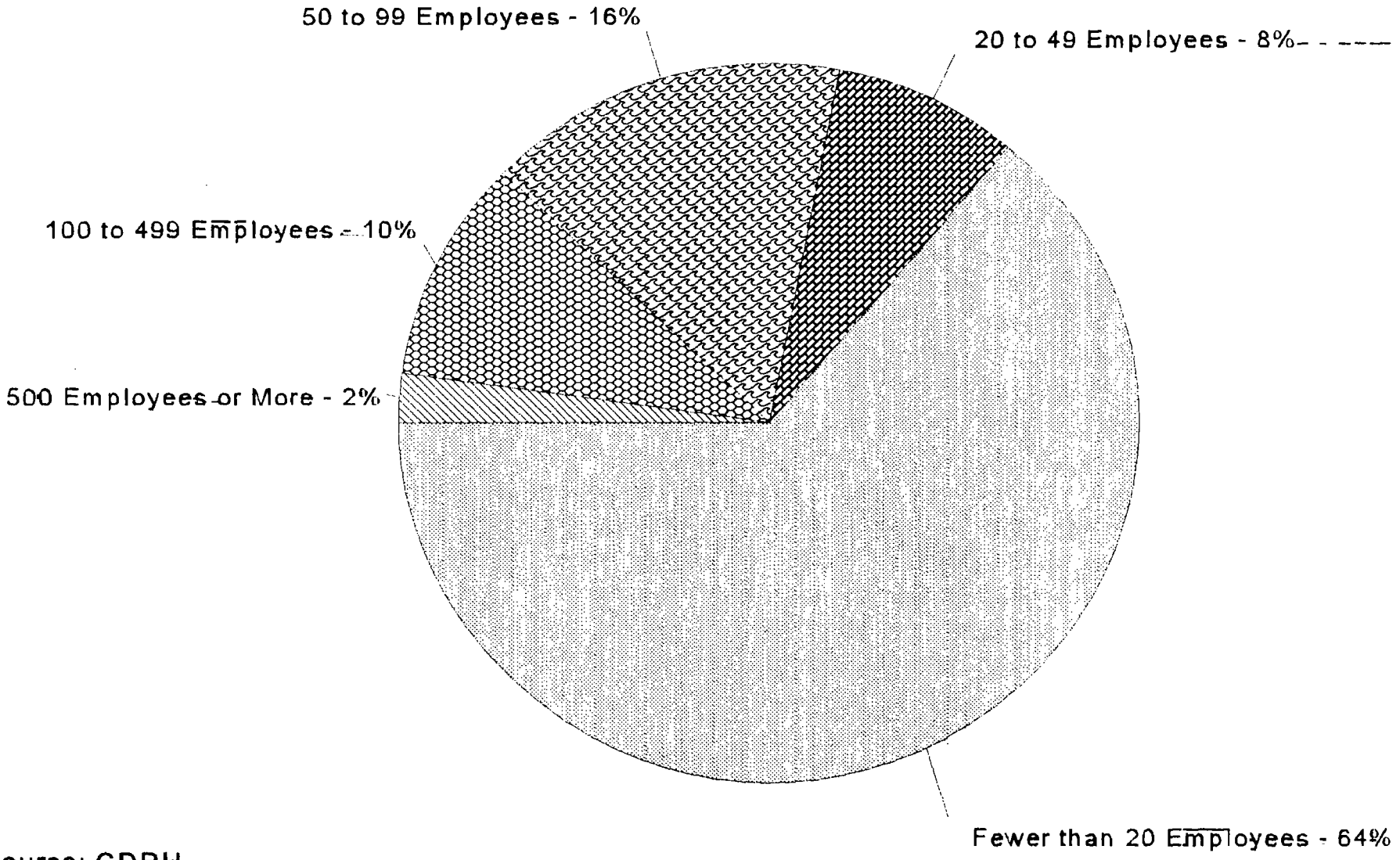
Class I —
Class II — SB ?
Class III —

Chris — are there II's that should be reclassified as I.

- Center for Devices and Rad. Health —
  - was always run by engineer
  - not — Dr. Burlington —
  - kessler
- Med and Biological Engineers. —
- Clinical Studies for
  7000 Companies — ~~[illegible]~~
  $45 B
  $5 B export surplus
- Bottom line is 3rd Party review —
- Bliley hearings on retaliation
- Third party review — not in Kennedy-Kassebaum —

Makeup of the Medical Device Industry

by Company Size



Source: CDRH

NMDC NATIONAL MEDICAL DEVICE COALITION
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Because the device industry is unique and distinctly different from other industries subject to FDA regulation, the NMDC believes the following additions and modifications to the current Senate proposal (S.1477) are necessary for meaningful reform of the provisions of law relating to devices:

1. Implement a procedure to provide the device industry with an option to use qualified third parties for scientific review and quality system certification. The FDA would retain the option to accept or reject any certification as part of the approval or compliance process. There is no evidence to support delay of the is procedure until 1998 or to limit its application to use only by the Secretary.

2. Eliminate the requirement for a premarket notification order by the FDA, and allow applicants the right to engage in commercial distribution after 90 days from notification unless the FDA determines that premarket approval is required.

3. Eliminate civil penalties. At the very least, application of this procedure must not delegated to the FDA and due process discovery must be provided to the accused.

4. Revise advisory committee procedures to eliminate onerous conflict of interest barriers and management of advisory committees by the FDA. Restore premarket approval (PMA) application review by the advisory committee unless the applicant agrees to forego review by the committee.

5. On the export of devices, limit FDA authority to restrict device exports only when presence of the device in the U.S. would clearly expose the public to unreasonable and substantial health risks.

NMDC NATIONAL MEDICAL DEVICE COALITION
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ACTION REQUESTS

WOULD YOU BE WILLING TO SIGN A LETTER TO YOUR LEADERSHIP URGING PASSAGE OF MEDICAL DEVICE REFORM LEGISLATION THIS YEAR? (provide draft letter to member)

THE MEDICAL DEVICE INDUSTRY SEEKS MAJOR CHANGES UNDER FDA REFORM SUCH AS THE FOLLOWING:

1. FDA CERTIFIED THIRD PARTY REVIEW SYSTEM
2. ELIMINATE THE 510 (K) [PREMARKET NOTIFICATION] ORDER
3. SEPARATE THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH OUT OF FDA.

FOR SENATE MEETINGS

NMDC SEEKS TO HAVE THESE REFORMS INCLUDED IN LEGISLATION TO BE ACTED ON BY THE LABOR AND HUMAN RESOURCES COMMITTEE.

WE URGE YOUR SUPPORT FOR THESE REFORMS.

FOR HOUSE MEETINGS

THE HOUSE COMMERCE COMMITTEE IS CURRENTLY DRAFTING LEGISLATION WHICH WILL BE RELEASED SHORTLY.

NMDC EXPECTS THIS LEGISLATION TO INCLUDE MANY OF THE NEEDED REFORMS LISTED ABOVE.

WE NEED YOUR SUPPORT AND YOUR COMMITMENT.

The Honorable Newt Gingrich
Speaker of The House
The Honorable Bob Dole
Senate Majority Leader
The Honorable Dick Gephardt
House Minority Leader
The Honorable Tom Daschle
Senate Minority Leader
U.S. Capitol
Washington, D.C. 20510

Dear Speaker Gingrich, Majority Leader Dole, Minority Leader Gephardt and Minority Leader Daschle,

We are writing to urge you to make the responsible review and reform of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration a top priority before the 104th Congress adjourns in 1996. Specific legislation that would bring permanent reform to the regulatory process for medical devices -- not just cosmetic improvements -- is urgently needed.

Fundamental reform of the approval process for medical devices will save American lives and reduce suffering. It will prevent federal regulators from interfering with the doctor patient relationship. Medical device reform will also end the delays in the approval process that result in the loss of thousands American high tech jobs, the flight of medical device companies overseas, and the erosion of this important export base.

As respective leaders of the House and Senate, we ask that you commit to scheduling floor time for the respective House and Senate considerations of medical-device reform legislation this year.

Sincerely,

THE NEED FOR MEDICAL DEVICE REFORM

1. The problems facing the medical device industry are severe.
   - o Reducing jobs in the United States
   - o Changing focus from breakthrough technologies to incremental technology improvements
   - o Increasing investments in non-U.S. operations
   - o Paperwork burden - especially on small businesses
   - o Erosion of competitiveness of American medical device industry
2. The medical device industry is significantly different from the pharmaceutical industry and therefore requires a different system to regulate this industry. Medical devices are:
   - o manufactured primarily by small businesses
   - o diverse and heterogeneous
   - o generally used by highly trained health care specialists
   - o not well suited to the same kind fo statistical analysis as drugs
3. The public health is also threatened by the FDA's regulatory environment.
   - o Medical technologies are available to patients outside the U.S. first
   - o Innovative life-saving or life-enhancing medical devices take longer to be available to American patients
   - o Declining incentive for innovation on the part of medical device companies
4. Needed Reforms (i.e. the "Industry Consensus Bill") - Key Provisions:
   - o FDA-supervised, third-party system for product approvals and quality assurance systems
   - o Eliminate the 510(k) Order - Return permission for companies to go to market after 90 days if they have not heard back from FDA on their 510(k)
   - o Make the CDRH an independent Center inside the Department of Health and Human Services (NOTE: this is a separate NMDC initiative and not part of the Industry Consensus Bill)
   - o Eliminate Civil Penalties
   - o Eliminate FDA's involvement in granting permission to export

An Economic Analysis of Relocating CDRH and Implementing Third-Party Review of Medical Devices

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American Enterprise Institute (AEI)

Washington, D.C.

March 1996

Prepared for the National Medical Device Coalition

An Economic Analysis of Relocating CDRH and Implementing Third-Party Review of Medical Devices

John E. Calfee, Ph.D.
American Enterprise Institute

SUMMARY

If the Center for Devices and Radiological Health (CDRH) is relocated out of the Food and Drug Administration, recent increases in expenditures for medical device regulation could be reversed. Spending could reasonably revert to 1991 levels, approximately $40 million less than current levels. The reasons are straight forward. Regulation should respect the differences between medical devices and pharmaceuticals. Drugs are unchanging entities surrounded by rapidly changing information. Traditional FDA practice has been to regulate drugs in great detail and a great length, while leaving the market free to explore new uses for drugs. Medical devices, unlike drugs, are continually changing because they are technology-based tools. Medical device regulation in recent years, however, has been reoriented along the lines of drug regulation. This has brought detailed oversight of product development and testing, a slower and more elaborate approval process, regulatory barriers to incremental product improvements, bureaucratic opposition to new or established "off-label" uses, a confrontational enforcement posture, and the use of regulatory "leverage" to establish burdensome policies that have little if any legal foundation. These changes have substantially increased the costs of operating CDRH. Relocating CDRH outside of FDA would reduce the pressure to apply drug regulation methods to medical devices, and increase the likelihood that CDRH would off-load many product approvals and GMP reviews to competent third parties. The likely effect would be not only to prevent further increases in CDRH resources, but also to reduce CDRH's current resource needs to levels consistent with a more reasonable regulation of medical devices.

An Economic Analysis of Relocating CDRH and Implementing Third-Party Review of Medical Devices

John E. Calfee, Ph.D.
American Enterprise Institute

1. Introduction

This is an economic assessment of the impact on federal spending of two proposed reforms of the regulation of medical devices: (1) Relocation of the Center for Devices and Radiological Health (CDRH) out of the Food and Drug Administration (FDA) to become a separate entity with the Department of Health and Human Services (HHS); and (2) Third-party review for product approvals. The primary focus is on the first of these reforms (relocation), because it presents a number of issues peculiar to the regulation of medical devices. This report deals only with how these reforms are likely to affect federal spending for the functions now residing in the CDRH. It does not address wider issues such as federal, state and private spending for health care, or the quality of health care, although I believe the reforms in question would probably have salutary effects in these areas.

The central argument is simple. FDA has developed a cumbersome "drug model" for regulation of the medical device industry. Medical devices are fundamentally different from drugs, however, and regulation should reflect these differences. Any attempt by regulate devices according to a "drug model" of regulation is bound to increase the costs of regulation beyond what is necessary. Since 1976, when legislation first gave FDA positive authority over devices, there has been growing a tension between the clear legislative mandate to treat devices differently from pharmaceuticals, and the inherent tenden-

cies for a pharmaceutical regulation agency to apply its unique traditions and experience to the regulation of devices. This persistent and widely noted grafting of the "drug model" onto device regulation began as early as the early 1980s, and has rapidly accelerated since 1991. There is no reason to believe that this tendency will be reversed by FDA on its own. There are also compelling reasons to believe that the inappropriate use of the drug model has greatly increased the quantity and complexity of FDA's tasks in regulating devices. This has been a major factor in the disparity between escalating CDRH expenditures and declining rates at which new and changed devices are able to reach physicians and their patients. Relocating CDRH outside of FDA is the only reliable way to reverse these trends, and hence is the best way to reduce federal expenditures for medical device regulation rather than accede to FDA's persistent requests for substantial budget increases. There is no reason to believe that the transaction costs of relocation will negate these potential savings.

The case for third-party review is more straight-forward. Decentralized assessment of the numerous and rapidly emerging improvements in medical devices is a natural and strongly market-driven process. The European Union has relied with great success on this method, as have many sectors of the U.S. economy in which the integrity and safety of manufactured products is of paramount importance (examples range from housing to automobile tires and electric appliances). CDRH can save substantial resources by taking advantage of these market forces in order to obtain reasonable assurances about product safety and efficacy, without undertaking elaborate reviews.

The rest of this report lays out this reasoning.

2. Leading Elements of the FDA's "Drug Model" for Regulation

FDA regulation of the medical industry has historically focussed on pharmaceuticals. FDA's pharmaceutical regulation regime is famous for its complexity, opaqueness and slowness. Certain elements of this regime are of particular importance in the attempt

to regulate medical devices along with pharmaceuticals. Some essential elements of FDA's "drug model" of regulation are:

1. A regulatory process organized around products that remain fixed throughout development, review and use: The typical drug is a specific chemical entity that remains essentially unchanged through 10 or 20 years or more. Any changes that do occur — in the drug itself or in manufacturing or packaging — are closely regulated. Thus new and improved products are held in abeyance while the FDA approval process goes through its course.

2. A focus on therapeutic outcomes as part of the product label: FDA's view is that the drug label should provide "a balanced account of all clinically relevant information — the risks and benefits — that can affect a physician's prescribing decision" (Kessler and Pines 1990). The most time-consuming part of drug testing (Phase III trials) is devoted primarily to providing labeling details. FDA has therefore persistently sought to keep firms from providing or subsidizing information about "off-label" uses that have emerged from research and the marketplace but have not been reviewed and approved by FDA.

3. Intimate involvement in product testing and development: This has come to involve FDA participation in designing and executing clinical trials (even small-scale phase I trials at universities), designing and constructing manufacturing facilities, review of marketing materials, and detailed attention to potential linkages between manufacturing changes and clinical outcomes. This involvement typically occurs for several years before approval occurs and continues after approval.

4. A pattern of using enforcement "leverage" to pursue extra-legal policies: For example, it is far from clear that FDA has the power to prevent firms from distributing journal articles about unapproved uses. The FDA has exerted this and other powers over advertising and promotion for the simple reason that it can count on the cooperation of firms that also have new products under review.[1] FDA has also adopted a practice of

[1] One of the FDA staff members in the advertising regulation division noted in a 1987 article that ". . . the FDA licenses the prescription drug products subject to its regulation and

enforcing draft regulations and guidance letters in order to avoid required rule-making procedures.[2]

5. Vague and uncertain regulatory standards: A former FDA General Counsel has described this situation: "Because the vast bulk of FDA policy is not set forth either in the statute or in regulation, it is uniquely a field where experience and judgment play a very large role."[3]

6. An "enforcement mentality," that often places FDA staff at odds with industry personnel: This point is too well-known to require elaboration. The same former FDA General Counsel recently noted that "Pharmaceutical companies uniformly fear retaliation unless they cooperate fully with every request from the [new drug] reviewers" (Hutt 1993 at 212).

7. A long-standing large-firm bias: The sheer magnitude of testing and legal expertise required to introduce, manufacture and market a drug dictates that firms must

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approves labeling which effectively sets the limits on what may be communicated about product performance. This pervasive involvement in the industry's current and future business means that a corporate decisionmaker needs to consider more than just the merits of the company's position in the particular advertising dispute at hand. The executive must also weigh how much disagreement with the FDA staff in a current matter might affect future treatment. No such continuing relationship exists between the FTC and any industry." See Fisherow (1987) at 231. FDA Commissioner Kessler similarly noted that "Companies interested in maintaining positive relationships with the FDA usually agree to the FDA's remedy [in advertising matters]." See Kessler and Pines 1990. More generally, see Calfee (1995).

[2] The Washington Legal Foundation recently filed a lawsuit asking the courts to halt this practice on Constitutional grounds. See Skolnick 1994 on the citizens' petition that preceded this lawsuit.

[3] Hutt (1993) at 212. Hutt continued (p. 231), "It is impossible to generalize about the relationship between drug applicants and FDA reviewers. The Center for Drug Evaluation and Research (CDER) review divisions have quite varied reputations for openness, promptness and cordiality. Thus, discussion between and FDA review division and the applicant varies all the way from virtually no communication to constant discussion. Relations range from friendliness to near hostility. The NDA process is, in short, entirely an *ad hoc* and informal process of negotiation that may go very well or very poorly, and over which the applicant has virtually no control. Attempts to obtain resolution of disputes through the FDA ombudsman or by appealing issues to higher officials are almost never successful and often worsen relations with the NDA reviewers." Also see Calfee (1995).

be large or exceptionally well-financed.[4] It is widely believed that profitable drugs are usually "blockbuster" drugs that must cover losses from numerous drugs with modest sales.

8. What is not regulated: One additional aspect of FDA's pharmaceutical regulation merits special emphasis because of its relevance to device regulation. Except for information from drug firms themselves, information *about* pharmaceuticals and how they are used is completely unregulated. The marketplace is left free develop and disseminate information about new uses, side effects, interactions, and dosages. The result is that approximately half of all drug therapies are for uses not approved by FDA (Skolnick 1994). This uncharacteristic (for FDA) reliance on the marketplace reflects the fact that the information environment operates very rapidly and very effectively (due to inherent market forces). It is widely recognized that the dominant effect of new information is to improve medical care and reduce risk to patients, and that regulatory control would inhibit this process while yielding few if any benefits.

3. Medical Devices vs Pharmaceuticals in the Context of Regulation

Medical devices are fundamentally different from pharmaceuticals. Whereas pharmaceuticals remain basically unchanged for years, devices are always changing. From the layman's perspective, complex medical devices are like laptop computers. Last year's state-of-the-art is only adequate today, and the model of two years ago is now obsolete. As with all high-technology products, market forces drive rapid improvements in medical devices. Many devices combine a variety of dynamic technologies such as imaging methods, numerical algorithms, and computer control. Advances in any one of these technol-

[4] Thomas (1990) concluded that FDA pharmaceutical regulation after the 1962 Amendments apparently reduced competition in the pharmaceutical market and increased the profits of the larger firms at the expense of smaller ones.

ogies can and should be rapidly incorporated into improved versions of numerous and varied medical devices. Thus (in the absence of burdensome regulation) enhanced products — and enhanced manufacturing and packaging methods — arrive with great rapidity as by-products of improvements in related industries. These include faster computer algorithms, better imaging, sharper monitors, smaller manufacturing tolerances, more precisely controlled robotics, new packaging that allows more efficient and more complete sterilization, digitized images to permit more efficient use of radiologists' time, and on and on. The dominant effect is to make medical care better and safer, thus reducing the total risk faced by patients.

This contrast between unchanging drugs and rapidly changing devices is by itself sufficient reason for radically different regulatory regimes for drugs and devices. Pharmaceutical regulation deals with a stationary target — that is, a specific chemical entity — and takes its time in doing so. The part of the pharmaceutical market that *does* change rapidly — information about how to use drugs — is unregulated (except for information from sellers) for fear of disrupting a beneficial process whose benefits arise directly from its dynamism. With devices, the products themselves are moving targets. Stringent regulation of devices — especially regulation of *changes* in products, packaging or manufacturing methods — inevitably inhibits technological improvements and therefore retards progress in health care.

The "dynamism factor," however, is far from the only reason for regulating devices differently from drugs. Most devices are best thought of as tools rather than therapies. In contrast to drugs, which usually are closely related to specific therapies or medical conditions, most devices are tools for surgery, imaging, information tracking, and so on. Their focus is specific tasks, rather than illnesses. Therapeutic improvements typically follow as a matter of course from more precise incisions, sharper images, and so on, without recourse to controlled studies.

Continuing communication between makers and users of devices or tools is essential to proper use and therefore, medical progress. Improvements come from hands-on demonstrations or training, personal observations, and other components of iterative tech-

nological advances in medical practice.[5] Hence advances in tool-using will involve discussions between sellers and physicians. What looks to pharmaceutical regulators like "promotion" of "off-label" uses is likely to be part of an essential learning-by-doing process rather than something that should wait for years while FDA oversees testing and review.

The pharmaceutical model of regulation is directly opposed to these central aspects of medical devices and their role in the medical marketplace. Other nations explicitly recognize this by permitting new and improved devices to enter the market rapidly upon notification and (sometimes) third-party review — for the obvious reason that, just as with information about drugs, detailed regulation would delay advances that reduce medical risks and costs.

These differences between drugs and devices have also undergirded our own legislation. Both the 1976 and 1990 amendments to the Federal Food, Drug and Cosmetic Act (FFDCA) recognized that it would be a mistake to require separate assessment for the numerous improvements that arrive in quick succession in the marketplace, or even to require detailed review of most new products that are essentially superior replacements for tools already in use.[6] FDA practices, however, have tended to vitiate these intended differences in regulatory approaches to devices versus pharmaceuticals.

4. The Ascendancy of the Drug Model in Regulating Devices

The evolution of FDA regulation of medical devices is not easily summarized. Certain aspects stand out, however.

1. Greatly increased demands for data, especially clinical data: This is combined with deeper involvement in the details of clinical testing, even to the point of seeking to

[5] See, e.g., Duesterberg, et al. (1994), chapters 1 and 3.

[6] See, e.g., Merrill (1994).

review product design (including software design) before testing, as well as review of even minor changes in devices and in manufacturing, packaging, and components. This can apply to both 510(k)s and PMAs. Examples are well documented.[7]

2. *Increased focus on so-called "off-label" uses:* Medical tools such as laser surgery equipment often have no single predetermined therapeutic "use." FDA has recently taken the view that when a device is approved (a laser surgery device, for example), it was approved only for specific uses — for surgery for certain cancers, for example. Because medical devices are best developed (and their benefits extended) through consultation among manufacturers and users, this new attention to "off-label" uses has put manufacturers in a difficult position. FDA has even asserted that sellers who are aware of specific uses must put those uses on the label, in which case the product could become "misbranded" and subject to recall. It is even more difficult under the new regime to perform essential hands-on training, which FDA may regard as "promotion." Regulatory attention to emerging uses for approved devices has of course moved FDA closer to regulation of medical practice. Prominent examples of such problems include laser and cryosurgery for the urinary tract, pedicle screws, cardiac ablation catheters, and pacemaker leads. Following a practice developed in pharmaceutical regulation, FDA has stated that *some* (but not all) combinations of approved uses of approved devices will be treated as

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[7] The Temple Report (discussed below) emphasized the need for testing substantial samples rather than one or a few operating devices for testing (cf. Lawrence 1994, who noted, ". . . it appears that FDA has adopted the Temple report's recommendations as de facto agency policy.") On increased FDA attention to designing and reviewing clinical trials, see Lawrence (1994) at 5. On attention to 510(k)s, see MDMA (1994) at 15, and Kahan (May 1994). On *new* data requirements for modest changes in products, see Kahan (Dec. 1992). In 1993, FDA formally proposed detailed regulation of product *design* — including software. See Duesterberg, et al. (1994) at 82, and Strobos (1995) on recent FDA thinking. On tighter control over clinical testing, see Merrill (1994) at 50. Among documented cases in which new data demands have imposed substantial burdens on actual medical practice, see Duesterberg, et al. (1994) at 84-85 and Lawrence (May 1994) at 5 on Johnson and Johnson's cardiac balloon stent (approved in all nations that perform the relevant kind of cardiac therapy). Having stated that PMAs would require more data than in the past, FDA threatened to remove this product from the market pending a new PMA application and review.

off-label uses (just as FDA has done regarding some, but by no means all, unapproved combinations of approved uses for approved drugs).[8]

3. A rapidly advancing "enforcement mentality:" Commentators have observed that FDA attitudes towards the medical device industry were once relatively free of the "enforcement mentality" that is so characteristic of pharmaceutical regulation (cf. Merrill 1994 at 59). This is apparently no longer so. New and more aggressive enforcement policies include numerous threats and use of civil and criminal penalties, often by district offices with an overt suspicion of criminal mentality (Kahan January 1994 and January 1995a); a tendency to issue warning letters without going through intermediate stages such as "letters of adverse finding;" warning letters for failing to report problems that are unlikely to involve health or safety or even a faulty product (as opposed to a careless user); and most striking of all, a period of two years during which FDA product reviewers refused to discuss ongoing reviews with manufacturers or even return phone calls.

4. Use of "leverage" to establish extralegal policies beyond legislative mandates: Such prominent regulatory tools as rescissions of approved 510(k)s, linkage of product approval with Good Manufacturing Practice (GMP) reporting violations (formerly via the widely criticized "reference list"), and enforcement of "draft" regulations without formal notice and comment and other required elements for rulemaking, are all arguably without legal foundation. FDA staff presumably believe that here, as with pharmaceuticals, they

[8] See generally Merrill (1994), especially at 94. Wilkerson (1995) at 69 discusses urinary tract surgery, and other cases. Also see Kahan (October 1994), who notes that FDA has pursued this policy regarding devices at least since 1989, but with greater vigor starting in 1993. On Pedicle screws, see Kahan (October 1994) and especially *FDA Consumer*, March 1994, p. 2-3, "Screws Not Approved For Back Surgery." The FDA story notes, "Despite these uncertainties [lack of proof or FDA approval], pedicle screws have largely replaced the hooks and wires that are approved for use in spine stabilization procedures. Some 30,000 to 70,000 such procedures are performed each year in the United States. About 300,000 people have been implanted with pedicle screws." On cardiac ablation catheters and pacemaker leads, see Kahan (October 1994). Finally, on combinations of approved devices, see Kahan (October 1994).

can "leverage" their power over product approvals to create other powers that have not been granted.[9]

5. Broadened use of shifting and uncertain standards: There are several areas in which FDA has employed strong enforcement methods despite great uncertainty within the industry as to what standards they are supposed to meet. At least two areas are of great importance: field reporting requirements established (but not described) in the 1990 Safe Medical Devices Act (SMDA), and the "significant impact" standard for manufacturing or product changes for which a 510(k) is necessary. In both cases, firms face a dilemma between costly reports or product reviews, on the one hand, versus the overt threat of large civil penalties, criminal penalties, and product recall, on the other.[10]

6. An emerging large-firm bias: It is to be expected that the demands for data, time, legal assistance and financing associated with the trends just described would tend to favor larger firms, just as has happened in the pharmaceutical industry. The new Wilkerson study provides some empirical support for this expectation, even suggesting a tendency toward a situation in which firms will rely upon blockbuster products — as has already happened in the pharmaceutical industry (Wilkerson 1995 at 80).

These are all examples of FDA's attempt to take long-standing principles of pharmaceutical regulation and apply them to device regulation.[11] Many of these tendencies were crystallized in the so-called "Temple Report" of 1993. This report is important because it was written by experienced FDA pharmaceutical regulators, it stated explicitly that "the fundamental principles underlying evaluation of any therapeutic intervention, whether it is a drug, device, diet, or surgical procedure, are the same," it was highly critical of

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[9] See Kahan (October 1994) on 510(k) rescissions. On the "reference list" and GMP-approval linkage, see Kahan (May 1993).

[10] On SMDA reporting requirements, see Wilkerson (1995) at 74, Lawrence (May 1994), Nobel (1995), and Duesterberg, et al. (1994) at 79 and 86 (quoting "Less than the Sum of Its Parts"). On the subjective and uncertain standards for "significant" impact, see Kahan (January 1995b).

[11] See, e.g., Merrill (1994).

CDRH for not adhering to traditional standards for pharmaceutical testing, its conclusions were endorsed by FDA Commissioner Kessler, and it was followed by Kessler's placing experienced pharmaceutical regulators in charge of CDRH.[12] The latter move was widely perceived as a prelude to, among other things, greatly increased demand for data in the approval process.[13]

The Temple Report is best understood, however, as part of a process rather than its singular cause. Movement toward the drug model of regulation had started at least by the 1980s (cf. Merrill 1994 at 59). This trend has arisen from FDA leadership, FDA traditions, the background and training of FDA personnel, and sometimes, Congressional input.

One additional point merits attention. Regulatory attention to the details of how medical devices are designed and used will lead to regulation of medical practice itself, simply because it is the nature of medical devices to be intimate tool-user combinations rather than stand-along therapeutic solutions. This point is significant not merely because of its potential public health consequences (which would be very bad), but also because regulation of medical practice is bound to increase the resource needs of CDRH.

5. Recent and Projected Costs and Performance of CDRH Activities, 1984-2000

Table 1 presents data on FDA expenditures in terms of inflation-corrected dollars and full-time-equivalent employees (FTEs) for medical device regulation from 1987 to the present, including projected requirements for 1995.

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[12] The Temple Report is appended to "Less Than the Sum of Its Parts." The quote is reproduced from Merrill (1994) at 63.

[13] *Wall Street Journal* 1992 ("Mr. Sheridan's ouster was seen by critics as a sign of new resolve at the FDA to require more animal and human testing for medium and high-risk devices after years of only cursory pre-market review.")

TABLE 1: FDA EXPENDITURES AND FTEs FOR MEDICAL DEVICE REGULATION
(expenses in thousands of 1994 dollars)

	1987	1988	1989	1990	1991	1992	1993	1994*	1995**
Surveillance and Enforcement***									
Exp.	$41,646	$42,694	$44,112	$49,058	$55,456	$59,952	$65,516	$74,733	$82,295
FTEs	572	602	611	657	732	812	883	926	979
Product Evaluation									
Exp.	$23,704	$25,884	$25,413	$27,628	$31,559	$34,337	$37,262	$51,149	$66,718
FTEs	335	365	352	370	415	449	459	588	795
Education and Assistance									
Exp.	$12,829	$12,129	$11,769	$11,948	$13,505	$14,217	$15,555	$18,638	$19,433
FTEs	176	171	163	160	178	186	185	182	181
Risk Assessment****									
Exp.	$11,316	$10,209	$9,890	$10,827	$11,830	$13,245	$13,408	$9,181	$15,372
FTEs	155	144	137	145	157	157	156	96	151
Total									
Exp.	$89,496	$90,917	$91,184	$99,461	$112,351	$121,752	$131,741	$153,701	$183,814
FTEs	1238	1282	1263	1332	1482	1604	1683	1,792	2,106

Source: "Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations" for 1995 and earlier years, Hearings before a Subcommittee of the Committee on Appropriations, House of Representatives. All dollars deflated by GDP deflator reported in the 1995 *Economic Report of the President*, converting from 1987 to 1994 as the base year. All years are Fiscal Years.

* Actual 1994 dollars by activity were not listed in the 1995 hearings. 1994 dollars for each activity were imputed by reallocating estimated 1994 dollars (listed in 1994 hearings) in proportion to estimated versus actual FTEs listed in the 1994 and 1995 hearings.

** 1995 figures are FDA estimates, assuming implementation of user fees for medical devices.

*** Until 1994 report, listed as "Monitoring and Quality Performance."

**** Before 1994 report, listed as "Bioeffects Analysis, Test and Measurement Development."

We can see that FDA resources for device regulation have dramatically increased in recent years. Between 1990 and 1994, overall expenditures increased by 50% in real terms, almost all of it coming in the areas of enforcement and product evaluation. Data on FTEs reveal a similar pattern. Moreover, FDA estimated that they would need an additional 200+ FTEs (and a budget increase of some $30 million) starting in 1995, merely to meet long-standing statutory requirements for product reviews.

The data in Table 1 should be assessed in the context of data on CDRH's work-load. The 1976 amendments to the Food, Drug and Cosmetic Act established a three-tier system for medical devices, ranging from the least risky (Class I) to the riskiest (Class III). Except for the least risky, new devices must obtain approval either through the Pre-Market Approval (PMA) process or by using the 510(k) process to establish "substantial equivalence" with a pre-1976 device. Although the bulk of device approvals are through the 510(k) procedure, both routes are important. Table 2 presents historical data on the PMA process, and Table 3, on 510(k)s.

TABLE 2: PMA SUBMISSIONS, APPROVALS AND AVERAGE REVIEW TIMES, 1989-1994

	1988	1989	1990	1991	1992	1993	1994
Submissions	96	84	79	75	65	40	43
Approvals	46	56	47	27	12	24	26
Approvals per FTE (Prod. Eval.)	0.13	0.16	0.13	0.07	0.03	0.05	0.04
Averages for approved PMAs:							
Active FDA Review (days)	262	247	302	335	236	547	649
Total Elapsed Time (days)	337	348	415	633	310	799	823

All years are Fiscal Years.
Note: 1994 figures estimated
Sources: April 3, 1995 Testimony of Alan Magazine, citing CDRH sources
HIMA Reference Guide, 1995, citing CDRH sources

TABLE 3: 510(K) SUBMISSIONS, APPROVALS AND AVERAGE REVIEW TIMES, 1989-1994

	1988	1989	1990	1991	1992	1993	1994
Submissions	5536	7022	5831	5770	6509	6288	6434
Approvals	4432	4867	4748	4294	3776	4007	5498
Approvals per FTE (Prod. Eval.)	12.1	13.8	12.8	10.3	8.4	8.7	9.4
Averages for approved 510(k)s (times in days):							
Active FDA Review (days)	64	66	78	81	102	162	184
Total Elapsed Time (days)	78	82	98	102	126	195	216

All years are Fiscal Years.
Note: 1994 figures estimated
Sources: April 3, 1995 Testimony of Alan Magazine, citing CDRH sources
HIMA Reference Guide, 1995, citing CDRH sources

Three trends are evident from Tables 1-3. First, CDRH has seen a very substantial increase in resources during the past half dozen or so years, almost all the increase being allocated to either enforcement or product evaluation.

Second, there is a continuing emphasis on enforcement. Between FY 1987 and FY 1994, enforcement FTEs increased by 354 while FTEs for product evaluation increased by 253 (a larger percentage increase but from a smaller base, making for an increased disparity in enforcement versus evaluation resources). This is consistent with the tendency described above for FDA to implement pharmaceutical regulation traditions in device regulation.

Third, the rate of approvals actually *declined* while resources increased. This is true by several measures. The absolute number of approvals declined, and has never regained the levels of 1988 for either PMAs or 510(k)s (with the exception of 510(k)s in FY 1994, for which CDRH has conceded approvals were inflated by "cherry-picking" in an attempt to reduce the backlog). Also, the ratio of approvals to submissions (not cal-

culated in the tables, but nonetheless apparent) substantially declined. Finally, approvals per FTE declined dramatically and remains far below the 1988 level.

This slowdown in approvals occurred despite legal and policy changes that should have reduced FDA burden and speeded approvals. When the 1990 SMDA added new requirements for field reporting, these were justified partly on the grounds that they would permit FDA to relax its approval requirements (Merrill 1994 at 64). FDA also moved to reduce its own burden by implementing a "refusal-to-file" policy for new submissions. Since 1990, roughly 70% to 80% of PMAs have been returned to manufacturers as being inadequate to trigger the FDA review process. A similar program for 510(k)s was begun in June 1993, when one-third of a pilot sample of 510(k) applications was returned for further manufacturer work before refiling. This refusal-to-file policy was explicitly justified as a way to reduce FDA workload.[14]

One should also note CDRH's own predictions of future needs and future performance. In their submission to Congress justifying their request for user fees (already in place for pharmaceuticals), CDRH stated it would need hundreds of additional FTEs and some $20 million in additional funds just to meet existing statutory goals for approvals.[15]

6. Sources of Increased CDRH Costs

The fact that increased FDA resources have led to fewer product approvals requires explanation. There are compelling reasons to believe that a leading cause of this pattern is FDA's move toward the more elaborate pharmaceutical model for device regulation. Requirements for new and more complex data for 510(k)s and PMAs, along with greatly increased regulatory attention to the creation of those data, serve to increase the

[14] Kahan (Nov. 1993); Food and Drug Administration (1994).

[15] See FDA (1994) and estimated budgets in the hearings cited for Table 1.

demands on FDA staff. This has been recognized by FDA personnel, who in the course of explaining their new demands from industry would sometimes note that FDA would require additional resources to handle the newly required information.[16] Further evidence comes from FDA requests (in their user fee justification) for additional resources in order to handle the current rate of 510(k) and PMA applications.[17]

Other aspects of the drug model also require additional resources. CDRH has enlarged the scope of its scrutiny, and continues to do so today. It has sought to delve into early stages of product design and has threatened to classify a large body of existing computer software as medical devices subject to FDA regulation (Strobos 1995). It has also provided strong motivation for manufacturers to submit 510(k)s for myriad small changes in manufacturing and packaging. At the same time, CDRH has been reluctant to exempt numerous low-risk Class I products from the (increasingly demanding) 510(k) process.[18]

The impact of more stringent enforcement speaks for itself in the very large increases in enforcement FTEs since 1989. This increased effort is far greater than can be explained by the added responsibilities imposed by the 1990 SMDA, in view of the fact that SMDA mainly provided FDA with discretionary powers (such as civil penalties) and placed primary responsibility for expanded field reporting on industry rather than CDRH. It is worth noting that the most confrontational phase of CDRH-industry relations (when phone calls were not returned by device reviewers and the secret Reference List technique was implemented) occurred shortly after an enforcement crackdown began on the drug side in response to the generic drug scandal and the arrival of a new Commissioner.

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[16] See, e.g., Lawrence (May 1994) at 5, citing the Temple Report.

[17] Again, see FDA (1994) and estimated budgets in the hearings cited for Table 1.

[18] Kahan (January 1995b at 2) notes that it was only after "years of discussion" that in December 1994, FDA finally exempted many Class I products from 510(k) process. FDA announced in March that it would announce in June 1995 another large group of products to be exempted, but the promised list has yet to appear.

These burdensome developments clearly extend well beyond what is required by SMDA or earlier legislation. Indeed, a major effort in SMDA was simply to provide a statutory authority (not a requirement) for FDA's existing (but extra-legal) practice of requiring clinical data for 510(k) approvals. It has been estimated that after passage of SMDA, the proportion of 510(k)s for which CDRH required clinical data increased from approximately 4% to 14%.[19] As was noted in the section on the ascendancy of the drug model of regulation, FDA has exercised discretionary power in its more stringent 510(k) and PMA procedures, and has even moved beyond what is permitted by legislation in such regulatory innovations as 510(k) rescission and linkage between GMPs and product approvals. All this requires resources.

7. The Role of Third-Party Review

Third-party review is probably best seen as an obvious adaptation to the dynamics of the medical marketplace, rather than as a regulatory innovation. The dynamic and diverse nature of the devices market requires decentralized testing and validation. Appropriate mechanisms and procedures will always be in operation, regardless of regulatory pressures, because firms and physicians will test innovations in tools and in tool use as part of the innovation process itself. An obvious regulatory approach is to leverage from these private industry mechanisms in order to obtain reasonable assurances about health and safety without impeding technological progress.

The parallels to pharmaceutical regulation are easily misunderstood. The closest analogue to device regulation is not regulation of drugs themselves, but regulation of information about drugs. I noted that the market for pharmaceutical information is very dynamic and loosely regulated (with the conspicuous exception of information from sellers), out of respect for the benefits of rapid innovation and the dangers of regulating

[19] Kahan (Dec. 1992 and May 1993).

medical practice itself. The conditions surrounding development of medical devices strongly resemble the pharmaceutical information market, indicating that close regulation, again, would threaten to restrain the benefits of innovation and would encroach upon medical practice. Third-party review is the natural outcome of these observations.

Thus third-party review for medical devices is the rule in every advanced nation except the United States. In its recent revamping of medical regulation, the E.U. decided against emulating the FDA regime. Instead, it retains third-party review and uses separate institutions for devices and pharmaceutical regulation.

Third-party review is also far more likely to emerge from a stand-alone CDRH than from the present arrangement. Historical experience has shown that some 98% of 510(k) applications are approved.[20] This indicates that market forces generate a high level of pre-testing, and suggests that off-loading most review functions to outside groups would provide necessary regulatory information while allowing innovation to proceed far more rapidly than under a more centralized regulatory regime. The validity of this thinking is underscored by Europe's successful experience with a largely voluntary approval system.

8. Likely Effects on CDRH Costs

Predicting the future costs of federal agencies is never easy. However, there are compelling reasons to believe that if CDRH is relocated out of FDA, its costs would cease escalating and would probably decline. Implementation of third-party review would also substantially reduce costs, and the likelihood that CDRH would aggressively pursue a third-party review mechanism would be greatly increased by relocating CDRH away from pharmaceutical regulation.

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[20] Merrill (1994) at 60-61, n. 59 citing SMDA; Duesterberg, et al. (1994) at 77, citing a 1992 GAO report.

The fundamental reason for believing that CDRH relocation would reduce costs (or at least prevent further increases) is the fact that the current policy of performing pharmaceutical and device regulation in the same agency introduces anti-synergistic pressures. In other words, the influence of pharmaceutical regulation works to the disadvantage rather than the advantage of efficient regulation of medical devices. The main features of pharmaceutical regulation run directly counter to reasonable regulation of devices. These features have increasingly been brought to bear in device regulation. CDRH costs have accordingly escalated even as product approval rates declined. There is little reason to believe these trends are due primarily to requirements imposed by SMDA. Rather, they appear to be a result of the move towards regulating devices like drugs, a move made even more stringent in view of the recent tightening of drug regulation itself.

A relocated CDRH would probably be a smaller operation. It would have no need to devote so many FTEs to product evaluation because it would be more likely to restore a reasonable consonance between the nature of the devices industry and CDRH's own demands for data and for oversight of product design and manufacturing. CDRH could more easily dispense with the newfound emphasis on confrontational enforcement (borrowed from pharmaceutical regulation), and thus could cease the practice of devoting more resources to enforcement than to product reviews (even if reviews were kept in-house). It would have little reason to devote resources to coordinating 510(k) approvals with such matters as GMP enforcement, or pursuing so-called off-label uses that have little relevance outside the context of pharmaceutical regulation. If, as has been proposed, enforcement responsibility remains within FDA but is exercised in response to demands from the relocated CDRH, the FDA resources needed for enforcement would decline as CDRH refocused on matters more central to device regulation.

The recent tendency to expand medical device regulation by enlarging the range of products subject to regulation and amplifying the data requirements for all products would have far less force in a relocated CDRH because this expansionary campaign is derived directly from the drug model and has occurred mainly after pharmaceutical regulators took over CDRH. A relocated CDRH would pay more attention to the intrinsic

nature of the devices market, would therefore be more inclined to exempt Class I and many Class II products from review, and would be more likely to down-classify products.

The cost savings offered by third-party review (and third-party GMP inspections) are obvious. Most of the work would be done by outside groups at industry expense. Competitive pressures would force parties to do this work more efficiently than it could be done by government. The only issue is whether CDRH would take advantage of such an opportunity. CDRH is far more likely to do so if it is placed beyond FDA control.

Recent patterns in FDA costs allow rough predictions of cost savings if CDRH is relocated and third-party review is implemented. FDA expenditures for device regulation during fiscal year 1994 were approximately $40 million higher than for year 1991, and estimates for 1995 (reflecting FDA estimates to meet statutory standards for product approvals) added another $30 million. Most of these increases reflect a higher level of CDRH activity pursuant to adopting the confrontational drug model for regulation. Thus most of this increase was unnecessary, and could be dispensed with under a more reasonable regulatory regime in a relocated CDRH. In addition, use of third-party review would reduce product evaluation costs even in comparison to a 1991 baseline. It is reasonable, therefore, to expect total device regulation costs to return to no more than the 1991 level of about $112 million (including enforcement activities remaining in FDA after CDRH is relocated) — some $40 million less than 1994 outlays.

9. Conclusions

If the Center for Devices and Radiological Health (CDRH) is relocated out of the Food and Drug Administration, recent increases in expenditures for medical device regulation could be reversed. Spending could reasonably revert to 1991 levels, approximately $40 million less than current levels. The reasons are straight forward. Regulation should respect the differences between medical devices and pharmaceuticals. Drugs are unchanging entities surrounded by rapidly changing information. Traditional FDA practice has

been to regulate drugs in great detail and a great length, while leaving the market free to explore new uses for drugs. Medical devices, unlike drugs, are continually changing because they are technology-based tools. Medical device regulation in recent years, however, has been reoriented along the lines of drug regulation. This has brought detailed oversight of product development and testing, a slower and more elaborate approval process, regulatory barriers to incremental product improvements, bureaucratic opposition to new or established "off-label" uses, a confrontational enforcement posture, and the use of regulatory "leverage" to establish burdensome policies that have little if any legal foundation.

These changes have substantially increased the costs of operating CDRH. Relocating CDRH outside of FDA would reduce the pressure to apply drug regulation methods to medical devices, and increase the likelihood that CDRH would off-load many product approvals and GMP reviews to competent third parties. The likely effect would be not only to prevent further increases in CDRH resources, but also to reduce CDRH's current resource needs to levels consistent with a more reasonable regulation of medical devices. Hence expenditures could reasonably return to 1991 levels, about $40 million less than was spent in 1994.

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