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2014-0046-S

rc1372

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
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FDA Reform

HIMA Position

Problem: FDA approval delays and enforcement practices are denying U.S. patients timely access to life-saving technologies, deteriorating U.S. technological superiority and causing U.S. medical device firms to move production, clinical trials, R&D and jobs overseas.

Recommendations

HIMA has developed a "White Paper" on FDA reform, as well as draft legislation, that contain specific recommendations for improving the regulation of medical technology in the United States. The four main legislative recommendations include:

1) **Ensure more timely reviews by:**

- Focusing FDA resources on riskiest devices:
 - * exempt Class I and lower-risk Class II devices from the 510(k) requirement;
 - * allow accredited third-party review in lieu of FDA review (for Class III 510(k)s, FDA retains ability to overrule third party decision for cause); and
 - * require most device modifications to be reviewed through GMPs rather than through the 510(k) process.
- Clarifying and limiting review criteria:
 - * redefine "effectiveness" to restrict FDA's ability to demand data not essential to showing that the device works according to its labeling (such as requirements to prove clinical outcomes, relative effectiveness, cost effectiveness, and off-label uses—determinations that are better left to the judgment of physicians and providers); and
 - * require FDA to accept company's certification to nationally and internationally recognized consensus standards to demonstrate compliance with review requirements.

- Prescribing action-forcing deadlines for PMA products:
 - * require guaranteed meetings with FDA and expert panels during both the IDE and PMA phases.
- 2) **Promote common sense enforcement practices that help companies comply with FDA's rules by:**
- Allowing accredited third parties to conduct GMP inspections;
 - Achieving harmonization of GMP inspection requirements with those of other countries;
 - Reducing restrictions on the dissemination of legitimate scientific information;
 - Ensuring that a company has a guaranteed period of time to respond to GMP violations before FDA can take enforcement action (unless there is a threat to the public health); and
 - Allowing civil money penalties to be applied toward correction of deficiencies.
- 3) **Streamline postmarket controls by:**
- Limiting FDA's discretion to require postmarket surveillance and tracking to devices that meet specific criteria (and repealing mandatory aspects of these provisions);
 - Allowing the use of patients' social security numbers for tracking;
 - Reviewing device malfunctions (not those causing serious injury or death) through GMPs instead of through MDRs; and
 - Eliminating user and distributor reporting.
- 4) **Ease export restrictions by:**
- Supporting legislation introduced by Congressman Upton (H.R. 1300) and Senator Hatch (S. 593) that would allow for the export of medical devices without regard to U.S. approval status as long as the recipient country is a member of the World Trade Organization.

These major areas of reform would contribute to a more efficient, smooth-functioning FDA and help to ensure that patients in the United States have timely access to safe and effective medical devices. Upon request, HIMA will provide more specific legislative language that can be used to help amend the current law.

Summary of Draft HIMA Legislation on FDA Reform

Summary of Draft Legislation on FDA Reform

Section 1 -- Short Title and Reference

The draft legislation may be cited as "The Medical Device Reform Act of 1995."

Section 2 -- Findings

This section contains the reasons for the legislation.

Section 3 -- Premarket Notification

Class I devices are excluded from the 510(k) requirement and a regulatory process is established to exempt Class II devices without having to downclassify them into Class I. Companies are granted the option of submitting 510(k)s to an accredited body. The agency is prohibited from delaying a 510(k) due to failure to comply with GMPs (thus abolishing the "reference list").

The time frame for reviewing 510(k)s is set forth as 90 days. If not met, the agency must send a letter to the company stating that additional time is required for review together with reasons and an expected completion date. For Class II products, if the company opts for review by an accredited body, that entity has 90 days to make a final determination of substantial equivalence without FDA's involvement. For Class III products, the accredited body has 60 days to make a recommendation to the agency with a 30 day review by the agency. If the agency fails to act, the accredited body's recommendation takes effect and a letter must issue from the agency that so indicates. (Failure to send the letter does not, however, prevent the recommendation from taking effect.) Where a product is able to be marketed due to the agency's failure to act, the agency must go through reclassification procedures to change the status of the product.

A modification to a 510(k) product is no longer subject to premarket clearance by FDA unless it constitutes a major change (including a major modification) in intended use. However, the modification must be supported by appropriate data and must not adversely affect the safety and effectiveness of the device. Appropriate documentation must be maintained as part of the good manufacturing practice document file.

The term "intended use" is clarified through language that specifies that a company may rely on uses that are reasonably included within the general use of a predicate device in establishing substantial equivalence. The agency cannot consider uses not specifically identified in a premarket submission in determining substantial equivalence.

Section 4 -- Effectiveness Determination

The agency must consult with an advisory panel prior to determining that certain types of clinical investigations (i.e., randomized, prospective, concurrently-controlled) are necessary

to demonstrate a device's effectiveness. If they wish, companies may still rely on such studies without going to a panel.

The scope of effectiveness is defined by excluding the following: (1) the evaluation of clinical outcomes if a device provides a medical contribution (unless the labeling contains a claim for a therapeutic effect), (2) the evaluation of relative effectiveness (unless the company compares performance against another drug or device in the labeling), (3) the evaluation of cost effectiveness, and (4) the evaluation of any indication not included in the labeling (unless the company promotes the device for an off-label use).

Section 5 -- The Risk/Benefit Determination

This section specifies that in the context of safety and effectiveness determinations, the persons for whom a device is intended may be determined only by the person responsible for labeling the device.

Section 6 -- Premarket Approval

The agency is allowed to contract out certain parts of the PMA for review but the agency retains final approval authority.

A procedure with specific steps is set up to ensure that the agency's total number of days for the review of a PMA will be no more than 180 days. The steps are as follows: (1) four panel meetings per year are to be scheduled at equal intervals to ensure timely consideration of PMAs; (2) the agency's filing decision must be made within 30 days after receipt of a PMA; (3) a meeting must be held 90 days after PMA receipt (if filed) to discuss the application; prior to the meeting, the agency must identify the deficiencies and the information needed to approve the application; (4) a meeting may be held 115 days after PMA receipt to advise the company on the status of the PMA and any other deficiencies as well as to review labeling and actions taken to correct deficiencies; (5) the agency shall refer the PMA to a panel--with a panel meeting to take place 120 days after receipt of the PMA (or at the next scheduled panel meeting--whichever is later); (6) after the panel meeting, if the PMA cannot be approved, a meeting occurs within 30 days and, prior to the meeting, each basis for denying the PMA must be set forth in writing; if the PMA is approvable, the agency must meet within 10 days of the panel review to inform the company of additional information needed to support the approval decision; if the meeting is waived by the company, the agency must provide the information within 30 days of the panel meeting.

The review "clock" stops whenever the company is required to prepare additional information and restarts upon submission of the information. The agency cannot restart the clock at "zero" upon submission of a major amendment. Reports and explanations must be submitted whenever time requirements are not met. This includes reports to Congress.



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Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry

Impact on Patient Access

Due to delays in the U.S. regulatory process, American patients must wait anywhere from several months to several years longer than people in other countries for breakthrough and cutting-edge medical technologies developed in the United States.

- Sixty-one percent of the companies surveyed said they are now marketing or plan to market products overseas that are not available in the United States.
- Nearly all companies with such plans—specifically, ninety-three percent of established companies and ninety-eight percent of start-up companies—cited FDA premarket review requirements as the reason for delayed introduction of products into the U.S. market.
- Sixty-six percent of the companies introducing their products overseas first expected a delay of one to three years before their products are approved for the U.S. market. Seventeen percent expected a delay of more than three years.
- Companies making the most technologically sophisticated medical devices expect an even greater lag between Europe and the U.S. markets—up to seven years for many breakthrough products. Some high-technology products available in Europe today will not be available to U.S. patients until the year 2000 or later, even though they were developed in this country.
- The new study contains an illustrative list that identifies a selection of 100 specific products available in Europe but not in the United States.
- The study also contains estimates of lost opportunities to improve, even save, thousands of patient lives, and also to save potentially billions of dollars in health care costs. The estimates are based on current analyses of technological advances for ten clinical conditions and an expected three-year delay between European and U.S. introduction—a delay due largely to FDA. One example is a stent graft to repair abdominal aortic aneurysms, which could potentially save 25,500 lives and prevent 3,000 strokes and 10,800 heart attacks.

Elderly patients are currently being denied access to new products and therapies because of restrictive Medicare program policies.

- Seventy-one companies responded that clinical trials of their products had been suspended by hospitals because of Medicare payment policies that deny coverage for new medical devices in a clinical trial. Of these companies:

- Forty percent said that they are limiting clinical trials to non-Medicare patients, in effect denying the elderly access to the latest generation of technology.
- Fifty-nine percent moved projects or clinical trials overseas.
- Fifty-seven percent planned to move future trials overseas.
- Sixty-seven percent of the cardiovascular companies that have had clinical trials suspended as a result of Medicare policies said they are moving research projects or clinical trials overseas as a result of these policies, as they effectively exclude people 65 and over—a necessary patient population—from companies' data gathering.

Companies are postponing or abandoning the development of new medical technology because of regulatory hurdles, market forces and product liability concerns.

- Thirty-nine percent of all the companies surveyed, including 46 percent of start-up companies, said they are cutting back products for use in highly specialized medical niche markets. The companies said the development of such specialized products is hindered by increased regulatory hurdles and the lack of available venture capital funding.

Note: One specialized market likely to suffer from such cutbacks is the treatment of pediatrics, who require specially adapted versions of adult products. Most pediatric markets, including those for open heart surgery products and neonatal catheters, are small and likely will feel the effects of restricted development of new or adapted technology.

- Seventy-three percent of companies making implantable devices reported difficulty in obtaining raw materials because of product liability concerns on the part of their suppliers. Fear of liability lawsuits has caused some suppliers of materials used in permanent medical implants to cease or restrict sales to the manufacturers.

HIMA RECOMMENDATIONS

- Enact FDA reform legislation to provide predictable, consistent and reasonable regulation of medical devices in the United States.
- Revise Medicare payment policies to permit payment for care that involves medical devices used in approved clinical trials.
- Enact national product liability laws that, among other provisions, limit damage awards against device manufacturers and shield raw materials suppliers against lawsuits.

(For more information, see fact sheets on *FDA Reform*, *Medicare Payment Involving Medical Devices in Approved Clinical Trials* and *Product Liability Reform*.)



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Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry

Impact on U.S. Economy

The steady movement offshore of clinical trials, some research and development, and manufacturing operations represents a potentially large loss of high-quality American jobs.

- Until 1993 when it reached a total employment of 282,000, the medical device industry created jobs at a faster annual rate than U.S. manufacturing overall, with jobs increasing by 3.1 percent yearly from 1988 to 1993 compared to an annual 1.4 percent decline in that period for manufacturing jobs nationwide.
- However, medical device industry employment growth has stalled recently. Moreover, forty-eight percent of large, established medical device firms reported that their U.S. manufacturing employment dropped in the past two years.
- More than half of all medical device firms, including start-up firms and established manufacturers, now report that the level of research and development jobs in this country has either declined or remained stagnant over the past two years.
- It is estimated that slower rates of employment growth in the medical device industry, coupled with a shift of many operations overseas, could lead to a potential loss of an opportunity to create 40,000 to 50,000 new jobs in the United States over the next five years.

The United States is losing opportunities to supply the growing global market for medical technology, resulting in a significant loss of potential U.S. export revenues and a slowdown in the very positive contribution that this industry makes to U.S. trade performance.

- Over the past decade, the share of the global medical device market commanded by U.S.-based production has slipped from an estimated 60 percent in the early 1980s to an estimated 46 percent in 1994, a loss of approximately 1.25 percentage points per year.

Note: While the rapid expansion of foreign markets and the fact that companies typically manufacture near major markets may account for some of this decline, it is also attributable to the establishment of manufacturing facilities overseas by U.S. companies as a result of the U.S. regulatory climate—an increasingly important factor in location decisions.

- With the \$93 billion global medical device market growing more than 10 percent annually, each percent of the global market share relinquished by U.S.-based production represents approximately \$1.0 billion in lost trade.

HIMA RECOMMENDATIONS

- Enact FDA reform legislation to provide predictable, consistent and reasonable regulation of medical devices in the United States.
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Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry

Impact on U.S. Technological Leadership

Increased regulatory demands and uncertainty have caused medical device companies to move clinical trials, some research and development programs, and manufacturing operations overseas with a resulting decline in U.S. technological leadership.

- Financial analyses by The Wilkerson Group show that companies can introduce a typical medical product in Europe far more quickly and much more cheaply than in the United States, spending an estimated \$6.9 million less in net development costs and reaching the market a year sooner than in this country.
- Fifty-eight percent of all respondents reported that they are increasing clinical trials in Europe.
- Eighty-seven percent of the start-up companies, and seventy-six percent of firms with sales of over \$100 million, reported that they have increased or plan to increase clinical trials conducted in Europe.
- Nearly two-thirds of the largest, established manufacturers reported they will increase or plan to increase research and development efforts in Europe.
- Forty-three percent of all respondents are increasing offshore manufacturing in Europe, while 33 percent are doing so in the rest of the world. Sixty-three percent cited the uncertainty/unpredictability of FDA as a critical reason for the move; fifty percent also cited FDA export requirements as a reason for the move overseas.

Increased U.S. regulatory burdens and market constraints are jeopardizing financial support for small, start-up companies—the chief sources of innovation in the medical device industry.

- In the last decade, regulatory requirements have added an estimated 2 years and up to \$20 million to the cost of developing a typical medical product and launching it in the U.S. market.
- Venture capitalists are finding the device industry to be a less attractive investment; today they are financing fewer companies—especially start-ups—with a smaller percentage of available capital.

- The industry's share of total venture capital available across the U.S. economy has declined from 14.4 percent to 10.2 percent from 1992 to 1994.
- If current trends continue over the next five years, the number of U.S. medical device firms may decline by 1,500.

HIMA RECOMMENDATIONS

- Enact FDA reform legislation to provide predictable, consistent and reasonable regulation of medical devices in the United States.
- Revise Medicare payment policies to permit payment for care that involves medical devices used in approved clinical trials.
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Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry

Key Study Findings

IMPACT ON PATIENT ACCESS

Delays in the U.S. regulatory process are largely responsible for American patients having to wait anywhere from several months to several years longer than people in other countries for breakthrough and cutting-edge medical technologies developed in the United States.

- Sixty-one percent of the companies surveyed said they are now marketing or plan to market overseas products that are not available in the United States.
- Nearly all companies with such plans—specifically, ninety-three percent of established manufacturers and ninety-eight percent of start-up companies—cited FDA premarket review requirements as the reason for delaying introduction of new products into the U.S. market.
- Sixty-six percent of the companies introducing their products overseas first expected a delay of one to three years before their products are approved for the U.S. market, while 17 percent expected delays over three years.
- Some high-technology products available in Europe today will not be available to U.S. patients until the year 2000 or later, even though they were developed in this country.

Elderly patients are currently being denied access to new products and therapies because of restrictive Medicare payment policies.

- Seventy-one companies surveyed reported that clinical trials had been suspended by hospitals due to Medicare's refusal to reimburse providers for care when investigational devices are used. Of these companies:
 - Forty percent had reacted by limiting clinical trials to non-Medicare patients, in effect denying the elderly access to the latest generation of technology.
 - Fifty-nine percent had moved projects or clinical trials overseas.
 - Fifty-seven percent said they plan to move future trials overseas.

Companies are postponing or abandoning the development of new medical technology because of the cumulative effect of regulatory hurdles, product liability concerns, other public-sector factors, and market forces.

- Increased regulatory hurdles have made it more difficult for companies to justify the development of—or to acquire venture capital funding for—new products, especially those that treat less prevalent diseases or small markets, such as pediatrics. Thirty-nine percent of the companies surveyed, and 46 percent of start-up companies have decreased the number of R&D programs aimed at developing products for such markets.
- The medical device marketplace is fragmented into a large number of small, niche markets. While only 7 percent of these markets exceed \$150 million, most venture capitalists will no longer consider projects for products with a market potential less than \$200 million to \$300 million. As a result, it is more difficult for companies to develop new products to treat unmet clinical needs.

IMPACT ON U.S. ECONOMY

The steady movement offshore of clinical trials, some R&D, and manufacturing capability represents a potentially large loss of high-quality American jobs.

- After years of strong employment growth, overall U.S. employment in R&D and manufacturing is now stagnant or declining at most firms.
- Among the companies that reported a decline in R&D employment, 58 percent of the start-up stage and 33 percent of the established companies cited U.S. regulatory review requirements as the single most important factor responsible.
- The decline in U.S. manufacturing employment is all the more striking because it is occurring during a period in which the global market for medical devices continues to grow more than 10 percent annually.

The United States is losing opportunities to supply the growing global market for medical technology, resulting in a significant loss of potential U.S. export revenues and a slowdown in the very positive contribution that this industry makes to U.S. trade performance.

- From 1989 to 1994, U.S. exports of medical technology grew rapidly, from \$5.5 billion to \$10.2 billion.
- While the U.S. trade surplus in these products also grew during this period from \$2.3 billion to \$4.9 billion, the rate of growth in the trade surplus has slowed dramatically since 1992.
- The movement towards foreign-based production is accelerating today in response to U.S. regulatory uncertainty and delay, to structural forces in the U.S. health care delivery and financing system, and to expanding opportunities abroad.
- With the \$93 billion global medical device market growing more than 10 percent annually, each percent of global market share relinquished by U.S.-based production represents approximately \$1.0 billion in lost trade.

IMPACT ON U.S. TECHNOLOGICAL LEADERSHIP

Increased U.S. regulatory burdens and market constraints are jeopardizing financial support for start-up companies—the engine of medical device innovation. Fewer new product developments provide an adequate return to potential investors and those that do need to be introduced in Europe first.

- Financial analyses conducted by The Wilkerson Group show that regulatory requirements and time for FDA clearance have increased significantly over the past ten years, adding an estimated 2 years and up to \$20 million to the cost of developing a typical medical product and launching it in the U.S. market.
- Accelerated European introduction saves an estimated \$6.9 million in net development costs and decreases the time to positive cash flow by a year, which basically forces companies to introduce new products abroad.

Medical device companies of all sizes, stages of development and product focus are moving clinical trials, some research and development (R&D) programs, and manufacturing overseas, especially to Europe, causing a decline in U.S. technological leadership.

- The prime reason for companies establishing their research, clinical and manufacturing infrastructure overseas is the ability to move their products to market swiftly and to avoid the risk of regulatory uncertainty in the United States.
- Fifty-eight percent of all respondents reported that they are increasing clinical trials in Europe. Nearly two-thirds of the largest, established firms reported they will increase or plan to increase research and development in Europe.
- Forty-three percent of all respondents are increasing offshore manufacturing in Europe, while 33 percent are doing so in other parts of the world. Sixty-three percent cited uncertainty and unpredictability at FDA as a critical reason for the move.
- Ninety-one percent of start-up companies, as well as significant percentages of small (78 percent), medium (68 percent), and large (62 percent) established firms, report that the uncertainty and unpredictability of dealing with FDA was a critical factor in their decision to move R&D offshore.

HIMA RECOMMENDATIONS

- Enact FDA reform legislation to provide predictable, consistent and reasonable regulation of medical devices in the United States.
- Revise Medicare payment policies to permit payment for care that involves medical devices used in approved clinical trials.

- Enact national product liability laws that, among other provisions, limit damage awards against device manufacturers and shield raw materials suppliers against lawsuits.

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HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

December 14, 1995

HENRY A. WAXMAN
29TH DISTRICT, CALIFORNIA

Dear Tom:

I'm glad we had an opportunity to talk about the reauthorization of the Safe Drinking Water Act last night, and that we both share a commitment to continuing to work together on this issue.

We can be proud of the legislation we developed in 1994, and I agree it would be a good starting point for our work. At your convenience, please let me know how you would like to proceed in the weeks ahead.

Again, thank you for your interest. I look forward to again reaching a consensus on this important issue.

With best wishes, I am

Sincerely,

HENRY A. WAXMAN
Member of Congress

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee On Commerce
2241 Rayburn House Office Building
Washington, D.C. 20515

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**Remarks by David A. Kessler, M.D.
Commissioner, Food and Drug Administration**

**Food and Drug Law Institute
Annual Meeting, Washington, D.C.
December 12, 1995**

NOTE: These are the prepared remarks. Dr. Kessler's actual speech may vary.

This is the sixth time that I have come before you as the Commissioner of Food and Drugs. Together, we have seen a lot of changes over the years. In the past, I have come here to tell you about them. And typically, that list was long.

This year is no exception. For example, in the last year, we have certified 10,200 mammography facilities across this country, thereby improving the quality of mammography for all women.

Over the last four years, we have taken important steps to apply a higher level of scientific scrutiny to new devices. This year, we have continued the progress we made last year in bringing review times down.

We have changed the way we regulate drugs made using biotechnology. We simplified the number and types of approvals they need, and, in the process, reduced the hurdles they face in reaching the market. The biotech companies estimate that these changes will save them months of time and tens of millions of dollars.

We have issued the final rules on seafood safety -- HACCP -- which focuses on avoiding problems before they occur and designing safety into the processing of seafood.

This week, we will propose changes in the regulation of health and nutrient content claims, and also expect to announce the release of a report on reinventing food regulation.

We have issued proposed MEDGUIDE rules which will create private market incentives to make patient information available with the sale of prescription drugs.

And, perhaps most important, we have proposed to regulate cigarettes and smokeless tobacco products. Smokers almost always become addicted to nicotine in tobacco during their teenage years. There exists a window, an opening into the world of addiction. While that window is open during the adolescent years, nearly 90 percent of the people who become addicted to nicotine begin to use tobacco. Once that window is closed, at the end of the teenage years, few begin to smoke.

It is for these reasons in August of this year that President Clinton announced FDA's proposed regulations that would minimize the easy access that children have to tobacco, and to limit the appeal that tobacco advertising and promotion exerts on children.

If this were my usual state of the agency speech, the list of things that we have done, or are doing, would go on and on.

But I am not going to do that this year. Instead, I want to focus on one subject. This morning, I want to talk about the drug review process. Specifically, I want to tell you about three reports, two of which I am announcing today for the first time.

One is a report we just delivered to Congress that reviews our progress under the Prescription Drug User Fee Act. The second is an international analysis we conducted to see if patients in other countries have access to important new drugs before patients in the United States. And the last is a recently released study by the General Accounting Office that supports the findings of the other two. This is the first time we can talk about all three reports together.

Even though I am only going to focus on pharmaceuticals today, the work done by the rest of the FDA is just as important.

But the information in these three reports is striking, and they document one of the most fundamental and important changes in the history of the agency. Taken together, these reports show that FDA is a worldwide leader when it comes to reviewing and approving new drugs rapidly and efficiently.

If you are sick, and you need an important new drug that works, you are as likely, if not more likely, to find it first in this country as anywhere else. While there will always be an occasional exception, we approve many important new drugs first.

It is time to put to rest the incorrect perception that American patients generally suffer because of a so-called drug lag. The notion that important, effective drugs are routinely available in other countries, but not here in the United States, is today a myth. In fact, a significant number of therapies that provide important health benefits are available in the United States, but have yet to be approved elsewhere. If there is a drug lag, it is not in America.

The most powerful examples of this have come in the battle against the epidemic of AIDS. Last week we approved saquinavir, a protease inhibitor, in only 97 days. It represents the first new class of AIDS drugs since AZT.

There are six antivirals that now have received approval, five under the accelerated approval regulation: two were done in about three months, three in six months and one in eight-and-a-half months.

The first antiviral, was approved in the United States in March, 1987. We reached the finish line about the same time as France and the United Kingdom, and a month ahead of Germany.

With DDI, we were first in October, 1991: seven months ahead of France; ten months ahead of Germany and twenty-eight months ahead of the U.K.

DDC. Again we were first. We approved it in June 1992; a year and a half ahead of France and Germany, and twenty-seven months ahead of the U.K.

D4T. We were first in June 1994. It hasn't been approved anywhere else yet.

3TC. We were first in November, and it too hasn't been approved anywhere else yet.

Saquinavir, was approved last week, but no where else. Comparing our performance with the U.K, France and Germany, we were first, or tied for first, for all the antivirals.

The United States is the world leader in the development of AIDS therapies. And it is not just because of the FDA. It is because of the research infrastructure -- our colleagues at the NIH, industry and academia.

Some might argue that AIDS is a special case, that it receives extra attention from FDA because of the epidemic. There is no question that increased attention to life-threatening diseases such as AIDS and other serious diseases raised the stakes for speeding up the drug approval process. But the improvement has not come in AIDS drugs alone. The improvement has come for all pharmaceuticals.

For example, Taxol was approved in the United States for ovarian cancer about a year before our international colleagues.

Fludarabine was approved in the United States for chronic lymphocytic leukemia three to four years earlier.

Dornase alpha, also called DNase, or Pulmozyme, for the treatment of cystic fibrosis was approved in the United States three months before France, nine months before Germany, and a year before the United Kingdom.

Interferon beta-1B, also known as Betaseron for use in the treatment of multiple sclerosis was approved in the United States 28 months before it was approved by our European colleagues.

And later today, we will announce the approval of Riluzole for the treatment of patients with Lou Gehrig's disease, or amyotrophic lateral sclerosis. It is being approved in the United States first. The list could go on.

We have not just speeded up the review of drugs for AIDS, or other serious and life-threatening diseases. We have speeded up the review of all new drugs and biologics.

In the report we just submitted to Congress, 93 percent of all new drug and biologic applications, filed in the most recent review year for which we have complete information, were reviewed and acted upon on time. The last three of these were reviewed on-time after our congressional report was prepared. That means 94 of the 98 applications -- or 96 percent -- that we received were reviewed on time.

Let me say that again. Ninety-six percent of new drug and biologic applications in the most recent review cycle were reviewed on time. On-time review is defined as action by the agency within twelve months, and if a major amendment is submitted by the manufacturer late in the process, an additional three months is granted.

This says that if you are a pharmaceutical company, and data supports the safety and efficacy of your product, the regulatory system will allow you to go to market in a predictable and shortened timeframe.

But it's important to remember that speed alone will never be enough. At the same time, we need to remember not to sacrifice science for the sake of speed.

This twelve-month, rapid review has been possible because Congress, and the pharmaceutical and biotechnology industries, gave FDA the resources necessary to do its job in the user fee act, and set some mutually agreed-upon benchmarks against which FDA's performance could be measured.

This, I believe, is the model for reinventing government. Bring together the government experts, the industry, consumers and Congress, and develop a consensus on performance goals. Next, agree on a timetable by which the agency must reach those goals, and then make sure the necessary resources are available.

Finally, let the facts speak for themselves. The facts show we have reached our goals.

What's more, we have reached the goals much faster than was agreed. Under the user-fee program, FDA's goal was to review 55 percent of complete N-D-As and P-L-As that were submitted in fiscal year 1994 within twelve months. We're at 96 percent. That's higher than the performance goal for applications received in FY 95. That's higher than the goal for FY 96. That's even higher than the goal for standard applications received in FY 97, when the goal is for FDA to review and act on 90 percent of the applications in twelve months.

The goal for on-time review of standard applications filed in 1997 is 90 percent. We are at 96 percent today. This is a dramatic change. And it has been coming for some time. It didn't result from a single change at FDA, but from many incremental ones that took place over many years.

It comes from a change in the culture within the agency that has added modern, efficient management techniques to its long-standing, solid scientific base.

There is a quiet pride that goes with a job well done. The men and women that staff the FDA centers have worked extraordinarily hard. They have demonstrated enormous dedication and commitment to advancing the agency's mission, and have every right to be proud of what they have accomplished.

The ongoing improvement is seen most clearly in the report by the General Accounting Office issued in October. GAO found that the time for FDA drug approvals had been going down steadily from 1987 to 1992, the time period immediately before the user-fee act. In its report, GAO concluded that it took an average of thirty-three months for a new drug application to be approved by FDA in 1987. Thirty-three months. Almost three years. That is a long time.

By 1992, in the Center for Drug Evaluation and Research, and the Center for Biological Evaluation and Research, approval times had decreased to 19 months. A 42 percent improvement -- through better management and the hard work of the centers.

In the conclusion of the report, the GAO wrote, and I quote: "The consistency of all our results supports the conclusion that the reduction in time is real." End quote.

The rest of the report on our progress under the user-fee act shows improvements across all categories of pharmaceutical reviews, and I will come back to those in a moment.

To really appreciate how well we are doing, it seemed to us that the one way to evaluate our performance was to compare ourselves to several countries with the most sophisticated drug approval systems, and to examine the kinds of medications available in those countries to see if their citizens had access to therapies not available to American patients. In a separate report we are issuing today, we compared the availability of new drugs in the U.S. to those available in England, Germany and Japan. We chose those countries because, with the United States, they account for 60 percent of global pharmaceutical sales. What happens in these countries pretty much represents the BEST of what happens everywhere else.

Two-hundred and fourteen new drugs have reached the market anywhere in the world in the last five years, between January 1990, and December 1994, according to two independent publications, Scrip World Pharmaceutical News and Scrip Magazine.

Of those 214, 185 had been launched in at least one of the four countries we chose to study. Then, we asked our sister agencies in those countries to tell us which of the 185 drugs they had approved and when.

Once the data base was assembled, we asked a number of questions: First, we wanted a two-country comparison between the U.S. and each of the other three countries to see, comparatively, when drugs were approved.

In every case, for the time period studied, the United States was the first to approve more of the drugs that eventually became available in both countries.

Let's look at some of the specifics from the two-country comparisons between the United States and the other nations.

Of the 58 drugs that were approved in both the U.S. and the U.K., 30 of them were first approved in the United States. It's only a slight edge over the 28 first approved in the U.K., but it clearly shows we are not behind.

For the other two countries, the disparity is much greater. Of the 44 drugs approved in both the U.S. and Germany, we approved 31 of them first, more than twice as many as were first approved in Germany.

And in Japan, we first approved 10 of the 14 compounds eventually used in both countries. Again, that's more than twice as many as were first approved in Japan.

When we looked at the comparison of when these drugs became available to patients, there were other surprises.

Look at the difference between the U.S. and the U.K. Of the 30 drugs that reached the U.S. market first, we were ahead of the British by an average of 17 months. Of the 28 drugs that the U.K. sent to market first, they beat us by an average of almost 16 months. That's pretty close, and I'd say patients in both countries are being well served by their public health officials.

We have an even bigger advantage over the Germans. We get drugs that both countries approve to the market about 18 months faster -- on average -- than the Germans when we market the drug first. They get to market an average of 11 months faster than us when they approve it first.

When a drug is approved in both the U.S. and Japan, the U.S. gets it to market nearly two years -- on average -- before the Japanese. When they approved it first, they did so by an average of about 19 months.

But what about the drugs that have been approved in those other countries, but not approved here? Do European and Asian citizens have important pharmaceuticals available to them that are not available in America? And if they do, are these drugs clinically significant? Are we missing something important?

Of all the therapeutics from these 214 on the market worldwide that we have not approved, only a small handful could be considered important molecular entities. As many of you know, a priority drug offers at least a modest therapeutic advance over existing products, or can be used to treat conditions for which no therapy now exists. Everything else is a standard drug. That means there is already something essentially equivalent already on the American market.

Here is what we found: In England, there are 29 drugs from this group that are not approved in America. Conversely, we have 18 drugs on the market that they do not.

When we studied the list of drugs they had but we didn't, we found two that we thought might be priority drugs. One was remoxipride. It appeared to be a promising new treatment for schizophrenia. The English approved it, but as more and more patients took the drug, a serious side effect emerged. The drug caused the bone marrow in some patients to shut down, causing aplastic anemia, a life-threatening disease.

The other drug was centoxin, a biotech drug produced by an American company to treat sepsis caused by gram negative bacteria. The English approved it, but FDA did not believe that the data submitted demonstrated safety and efficacy. We asked the company to do another study which later showed that the drug did not work, and that it might actually increase the risk of patient death.

Both drugs have been taken off the world market.

In Germany, there are 34 drugs on their market that Americans do not see. At the same time, Americans have access to 32 medicines that Germans do not. For those drugs approved only in Germany, comparable therapies are available in the United States.

And then there is Japan. This, as you can see, is an interesting and special case. There is a large variation between what Japanese pharmaceutical companies sell to their citizens compared to what American drug companies sell in this country. As I understand it, Japanese companies have strong incentives to develop minor chemical modifications to existing compounds because of the way they pay for drugs. Of the 158 drugs approved in either Japan or the U.S., only 14 are approved in both countries. Eighty-two drugs on the Japanese market are not on the American market. And 62 pharmaceuticals are available in the United States but, not in Japan.

Of the Japanese drugs, there were a few that we considered potentially important. The rules that protect proprietary information limit what I can say. But I can say that one of them is already under FDA review. A second is undergoing clinical trials. A third was submitted to the FDA, but the advisory committee decided there was not enough data to recommend approval.

For most of the drugs that were approved in other countries, but not here, we found that Americans had access to essentially similar pharmaceuticals. By that I mean for a chemical used in one country, there was a substantially similar chemical -- and one used for the same purpose -- already in the U.S. For example, the British use epoetin-beta to treat the anemia associated with kidney failure; American doctors use the biotech drug Epogen, an epoetin-alpha. The Germans use cilazapril to dilate blood vessels. American doctors use a host of "prils". These drugs work in almost identical ways, and patients who can tolerate one can usually take the other.

So what does all this mean? While it is true that the U.S. does not stock every product that has been approved worldwide, neither does anyone else. And some of the products that are on the shelves elsewhere, we are happy not to have.

This review showed that Americans have access to essentially all clinically important drugs that are available anywhere else in the world. In short, there is no drug lag. Let me return to the GAO report for a moment, and tell you what it said about drug lag.

Independently, GAO compared the rate at which the FDA approved new drug applications with the Medicines Control Agency, the drug approval system in the United Kingdom, which is considered one of the most sophisticated and most active in the world. Some FDA critics felt that we were falling behind when compared to the U.K.

The GAO said that did not appear to be true. In 1994, the Medicines Control Agency reported that the median time to approval for new molecular entities was 30 months. The fastest approval in England was granted in four months, and the slowest in 62 months. That same year, the FDA's median approval time for a new molecular entity was 18 months. The fastest FDA approval took about six months and the slowest took about 40 months.

That led the GAO to conclude, and I quote, "The latest data published by the regulatory agency in the United Kingdom show that it does not have faster approval times than FDA."

I'd like to now go back to our report on review times under the user-fee program. I said that for the most recent drug review cycle, we already reviewed and acted on 96 percent of the drug and biologic applications on time. But the improvements didn't stop there. We have significantly improved review performance for all types of drug-related applications. Before I wade into the details of that report, let me take a minute to explain how our performance is measured.

To determine whether our performance reaches our goals, new drug and biologic applications are organized into groups, and named for the fiscal year in which they were submitted. Since FDA has up to twelve months to review a new application, fifteen months, if there is a major amendment filed late in the process. It is not possible to completely evaluate our performance until a year after that group's fiscal year closes.

In fact, much of the work on an application submitted in one fiscal year may be completed in the next. For applications sent in during FY 94, for example, much of the work was done in FY 95.

That means the most recent group for which we have complete information is the group of applications submitted during fiscal year 94, which I'll call the 94 group. As for the applications submitted in FY 95, we won't be able to definitively determine how we are doing until the end of 1996. I can say that so far, none of them is late.

Now we can take a look at the details of the applications received in 1994, the 94 group, and see how we did:

Let me start with a comparison.

The rate at which we reviewed and acted on new drug and biologic applications in the 94 group was more than one-third higher than the 69 percent on-time review performance for 93 group.

And when we look at our on-time review in the 1990 and 1991 group, before the user fee program started, we have doubled the number of compounds reviewed and acted upon on time, from 42 percent in the 1990 and 1991 group, to 96 percent for the 94 group. And our performance has not gotten better because we were reviewing fewer applications. For the 93 group, FDA received 96 applications for new drugs and biologics. For the 94 group, industry sent in 98 applications. And for the 95 group, the number jumped to 126.

The report to Congress also shows better than expected on-time review for efficacy supplements sent to the agency in FY 94. These are requests from companies to add a new indication or a new group of patients to be treated with an already approved drug.

Of the efficacy supplements submitted in the 94 group, 73 percent have been reviewed on time. This performance exceeds the goal of 55 percent. And it more than doubles the performance rate of the 90 and 91 group when the on-time review rate was only 33 percent.

Next comes manufacturing supplements. These are requests to change the way an approved drug is made, or a request to make it in a new facility.

As of March 31st, 1995, FDA reviewed and acted upon 69 percent of the supplements in the 94 group on time. Under the user-fee program, our goal is to review and act on these within six months, rather than twelve months. The 69 percent on-time performance exceeds the 55 percent goal established under the user-fee act.

What's more, it more than doubles the 35 percent on-time performance rate for the 90 and 91 groups. And as of September 30th, 1995, FDA has reviewed and acted upon 60 percent of the manufacturing supplements in the 95 group on time.

Of the remaining 40 percent that are pending, only 5 percent have been in review for more than six months and are considered overdue. We won't know the final performance rate until March 31st, 1996, but I expect final on-time performance to exceed 80 percent.

We will reach this goal even though manufacturing supplements have increased about 9 percent a year, from one thousand, two hundred, forty-eight in 1993 to one thousand, five hundred forty-four in 1995.

There was also concern about how fast we reviewed and acted on resubmissions of original applications for new drugs and biologics. These arise when a pharmaceutical company submits its response to questions or deficiencies raised in an approvable or not approvable letter on the original submission. Like the manufacturing supplements I just talked about, FDA has agreed to review and act on resubmissions in six months.

As of March 31, 1995, FDA acted on 81 percent of the resubmissions it received in the 94 group on time. The user fee act only calls on FDA to review and act on 55 percent of these in six months. We have far exceeded that, as well as beating the performance goals for FY 95 and FY 96.

For the 95 group so far, as of September 30th, FDA has acted on 53 percent of the resubmissions within six months. Of the remaining 47 percent, only 3 percent have been at FDA for more than six months, and can be considered overdue. I believe in this category, too, FDA will clearly exceed 80 percent on-time review.

The last thing I would like to talk about as part of the user-fee program is the elimination of the backlog of new drug and biologic applications that were overdue at the end of the 1992 fiscal year. By that definition, 34 new drug applications were overdue, and we agreed to review and act on them in two years.

As of the deadline, July 2, 1995, every one of those backlogged applications has been acted on. We approved about two-thirds of them, 21 of the 34. The pharmaceutical companies withdrew five. Four were rejected as "not approvable."

I want to close by talking about one issue that is not addressed in the user fee act, nor our comparison of approval times with other countries. As FDA's review and approval times have clearly shortened, some of our critics have started to talk about the overall time it takes to develop a drug. They say it is taking longer. If this is true, and it is taking longer for a new chemical entity to go from discovery to market, then that is a potentially important issue that can contribute to the cost of development, and delay a drug from reaching patients who need it.

But first, I must say, it is not clear that overall drug development times are going up around the world.

Although we have not conducted our own study of overall drug development time, there is some data in the literature that challenges the notion that drug development times are going up. According to the Centre for Medicines Research, there has been no real change in drug development times since 1980. In its study of 700 drugs that were developed in 20 countries in the years between 1980 and 1994, the mean development time ranged up and down between 10 and 12 years. In 1994, it was 11.5 years. As most of you know, CMR is a private organization in the U.K. that studies the development and safe use of medicines with support from the Association of the British Pharmaceutical Industry.

In any case, it is important to recognize that drug development time, before an application is submitted to a regulatory agency, is for the most part, influenced by a number of factors, and not under the control of the country that ultimately approves the drug. We are certainly committed to work with companies to help them understand what they must do in their studies to win rapid approval, but we cannot control how long it takes companies to achieve their development milestones, or what companies do before they file an application with us. Certainly, FDA's requirements do contribute to what studies a company needs to undertake.

But as international harmonization of approval requirements continues, all countries will, I believe, be demanding essentially the same kinds of data to approve a new drug. Increasingly, the requirements aren't just the FDA's, they're worldwide.

In fact, data, again from the Centre for Medicines Research, shows in the decade from 1985 to 1995, the regulatory approval times in five countries are converging.

In all these discussions about speed of review, and what country has which drugs, it's important to remember the two guiding principals of the FDA: safety and efficacy. If a drug isn't safe, it shouldn't be approved. If a drug is not effective, it shouldn't be marketed. The American public expects FDA and the industry to be vigilant. Don't underestimate that. Throughout the world, the FDA process of rigorous evaluation has been considered the gold standard for new drug review. FDA approval often equates to automatically confirming a new drugs benefit in many foreign marketplaces.

We are not going to sacrifice those standards. The greatness of our system is that we are fast when we need to be fast, and we are cautious when we need to be cautious. We can have it both ways in this country. We can maintain the highest standards in the world and get drugs on the market as fast as if not faster than our major international colleagues. And while there is always room to do better, we have proven that we can do this job as well as anyone else in the world.

As a result, there is no drug lag. The American pharmaceutical and biotechnology industries, and the United States Congress, deserve much of the credit for their support of the Prescription Drug User Fee Act of 1992.

The progress documented in these three reports is an historic sea change for the agency, and one for which all the employees of the Food and Drug Administration can be proud.

Thank you.

Remarks by David A. Kessler, M.D.
Commissioner, Food and Drug Administration

Food and Drug Law Institute
Annual Meeting, Washington, D.C.
December 12, 1995

CORRECTION

Please note the following correction on Page #3, Paragraph #6 which should read as follows:

Dornase alpha, also called DNase, or Pulmozyme, for the treatment of cystic fibrosis was approved in the United States three months before France, nine months before Germany, and [correction] about a month before the United Kingdom.

COMMERCE COMMITTEE

NEWS RELEASE

EMBARGO UNTIL
TUESDAY, DECEMBER 12, 1995 at 10:30 AM EST

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Remarks of
The Honorable Thomas J. Bliley, Jr., M.C.
Chairman, House Commerce Committee
Food and Drug Law Institute Annual Meeting
J.W. Marriott Hotel - Washington
Tuesday, December 12, 1995

It is an honor to be here with you at the FDLI Annual Meeting. Yours is among the most prestigious of the educational and professional organizations involved in the food, drug and medical device fields, and George Burditt is to be commended for putting together this program.

You've just heard from Commissioner Kessler about the State of the FDA. Later today, you'll hear the perspective of Senator Nancy Landon Kassebaum, who has already articulated a package of FDA reforms that she plans to introduce in the Senate.

I welcome this opportunity to add my views. Doubtless my own perspective is vastly different than the one you heard this morning from Commissioner Kessler.

I'm very concerned about the Food and Drug Administration, about the influence it has on the industries it regulates -- drugs, devices and food additives alike. I'm concerned by studies of the medical device industry that show a prevalent, industry-wide view that the Agency is forcing American jobs and technology overseas. I'm concerned about the impact the Food and Drug Administration is having on research and development.

I'm deeply troubled -- deeply troubled -- by reports of FDA retaliation against its critics. A study released last week by Citizens for a Sound Economy found that nearly half of the executives of drug, device and bio-tech companies believe that retaliation does occur, and that upwards of 77 percent of those executives believe that FDA retaliation can cause significant or irreversible damage to their businesses. That's not how a regulatory agency is supposed to be regarded, not in a free society like ours.

And, as I have said on many other occasions, I'm most concerned that it now costs more than 350 million dollars to gain FDA approval for a new drug, and 12 years to get a drug from the laboratory to the marketplace.

Those concerns are not mine alone. They're shared by the Speaker, and, I believe, by a majority of the Members of the 104th Congress, House and Senate alike.

Those concerns are so widely shared, in fact, that earlier this year, Chairman Joe Barton of our Oversight and Investigations subcommittee launched a series of hearings into the state of affairs at the FDA -- hearings on topics ranging from slow approval of new products to FDA misconduct.

The Barton hearings have laid a solid foundation for legislative hearings in the weeks and months ahead in the Health and Environment Subcommittee, and for comprehensive legislative reforms that I expect will be taken up in the next Session of this Congress. The Barton hearings have ratified our concerns, and then some.

Throughout this year, Chairman Barton has uncovered how the FDA unduly interferes with beneficial access to new products, and how it has crossed the line into censorship of information about potentially valuable uses of those products, as well.

He has uncovered evidence that the FDA is forcing U.S. jobs in the pharmaceutical, device and biotechnology industries to move abroad, where the climate is more conducive to innovation. He has uncovered specific instances of bullying tactics by the FDA -- evidence of FDA threats, and evidence, more troubling, of how those threats are followed through.

In hearings early this summer, Chairman Barton revealed a disturbing new trend of FDA interference in the relationship between patients and their doctors. And -- as each of you know, better than I -- he has made the case that the FDA has fundamentally affected the very investment decisions that will dictate how medical innovation will occur in this country in the years ahead.

I know that many of you are of the opinion that fundamental FDA reforms are long overdue. Let me say that I share that opinion.

In this Session of this Congress, of course, first things had to come first. And we had an impressive, long list of "first things," many of which involved -- as they always do -- the Commerce Committee. First was the Republican "Contract with America," and its provisions on products liability reform. Restructuring the regulatory bureaucracy, with cost-benefit analysis and risk assessment requirements. Product liability reform. And reforms of securities class action litigation. Next came the goal of balancing the budget for the first time in a generation -- restructuring Medicare to save it from bankruptcy, and transforming Medicaid to run the program more fairly, and more efficiently, at the State level. And in between, of course, we restructured the nation's telecommunications laws for the first time since Marconi was alive.

My predecessor used to define the jurisdiction of the Commerce Committee in this way: if the bill begins with the letters, "H.R." it falls under our jurisdiction ! Well, now I know what he meant !

But in case there was any doubt, let me be quite clear here -- there will be a comprehensive package of FDA reforms emerging from my Committee in the next Session of this Congress. Already, as all of you know, there have been significant proposals put forward -- one, in fact, by your next speaker, Senator Kassebaum. I expect there will be others introduced in the days ahead, and we will give each of them the full and fair consideration they deserve.

With all due respect to Commissioner Kessler, however, reform of the FDA cannot be left up to the FDA. And with equal due respect to the Vice President, I am not interested in "reinventing" the FDA, and neither are my colleagues. What's called for is fundamental reform, and it's up to Congress to deliver. That's how the framers of our Constitution intended it, and it's the appropriate role for Congress. And it won't be easy.

This is an Agency marked by two significant attributes -- a remarkable ability to resist change, and an equally remarkable talent for expansion of it's own regulatory turf. That's how the FDA has always managed to dodge the bullet when reforms were suggested by countless panels and commissions and experts in the past.

In the days ahead, as I said, we'll move from making the case to moving legislation. Soon, you'll see legislative hearings examining the full range of FDA activities regarding products it regulates.

We'll look at the burdens FDA imposes as we bring products from the laboratory to the marketplace -- not just the time and expense involved, but the taxpayer resources that are taken up in the process. We'll identify where the regulatory hurdles are, and which ones we can eliminate. And we'll ensure that the FDA uses taxpayer dollars for product approval -- not for self-promotion.

And we'll examine why research and development is moving offshore. As I've said before, it breaks my heart to see American citizens having to travel overseas to get the drugs and devices they need to stay alive. Yet for thousands of Americans, the only way to gain access to an innovative, life-saving drug or device -- drugs and devices developed by American firms -- is to go overseas to be part of a clinical trial. And that's presuming their Doctor knows about the overseas trial in the first place. Like I said, it breaks my heart. And

I'm going to do everything in my power to put a stop to it !

What kind of legislation will ultimately emerge? Only time will tell. But it's appropriate now that we lay out a benchmark of the broad goals we hope to accomplish with this legislation, and I'd like to take this opportunity to do so.

First and foremost, I believe we must consider the overall mission of the Food and Drug Administration. It is NOT, I submit, the job of the FDA to limit the direction a regulated industry is taking, or pace it keeps. Nor is it the job of the FDA to affect private-sector investments in drugs, biologics, devices, food additives and other products because of unnecessary burdensome requirements. Nor, for that matter, is it the job of the FDA to eliminate each and every risk to the American consumer, because this is not a risk-free world, and because in some cases, the risks posed from NOT taking a drug -- from DENYING a therapy, or a device, to a patient -- is greater than the risks of doing so.

No, the mission of the FDA, I submit, is to bring safe drugs and devices to the American people -- as quickly as possible.

Our legislation will also look at the question of oversight of the FDA. In my office, I receive a lot of complaints about FDA -- as every Member of Congress does -- because American citizens simply cannot get the Agency to answer its calls and mail. Let's face it, the FDA is not well-run, at least from a constituent or consumer point of view. As one of my constituents put it, in a typically succinct Richmond way: "The FDA isn't even good enough for government work."

This is not to say that the FDA does not employ a lot of highly competent people. It does. But whether the cause is top-level management personnel or practices, or organizational structure, or good, old-fashioned government hubris, my constituent had a point. There's lots of room for improvement, and that improvement will be part of our legislative effort this coming year.

There are some excellent proposals to establish a high-powered FDA oversight committee within the Department of Health and Human Service -- what I call "oversight with turbo-chargers."

We may consider reorganizing the Agency, or even splitting it up if that's what's called for. One manufacturer group believes the FDA has misapplied the drug model to medical devices, and it has a point that deserves thought. Perhaps there is merit in its proposal to split off the device center from the rest of FDA - especially if we could move the component parts to Richmond !

In any event, however, there is merit to the point that drugs are not devices, and our legislation should take this point into account.

We should remember that the FDA covers a vast array of different products -- and that those products require vastly different levels and types of government oversight. Just as devices are not drugs, so foods are not devices, and we need to ensure that different -- and appropriate -- regulatory schemes are applied to each.

Another area our Committee will be taking into consideration is the absolute monopoly the FDA maintains on product, drug and device approvals. I got into Congress because I believe that competition is the foundation for a free market economy. Well, I believe in regulatory competition too -- particularly when an agency continually and habitually fails to meet the time limits imposed on it by statute, as the FDA has. When that happens, it's nothing short of an abuse of authority. In the FDA's case, I believe the problem can be traced to the FDA's stranglehold on regulatory reviews.

It's time we realize one thing: there are thousands of talented people capable of conducting reviews for innovative research and products -- and most of them do NOT work for the FDA! In my experience, the private sector is usually faster than government, and almost always more efficient. It's time we bring outside expert reviewers, where appropriate, and draft them into service at the FDA.

The idea isn't unprecedented. After all, the National Institutes of Health already relies on private, non-government experts to perform its reviews and to conduct virtually all its research. And they're not the only ones. Other regulatory agencies already rely on the private sector to perform evaluations. All of them do it

because it's quicker and it's cheaper. They've even found that the best and brightest are not necessarily attracted to government service ! There's no reason why the FDA shouldn't implement private sector expert reviewers as well, provided the right oversight model can be developed.

I'm also concerned about how the FDA deals with technological challenges from rapidly emerging technologies and the integration of biology, chemistry, physics and information sciences -- developments that point to a new range of exciting life-saving products.

Now, its not reasonable to expect the FDA to have the expertise to deal with these challenges, but I'm concerned that lacking this capacity, the FDA is acting as an unnecessary "speed bump" on the road to technological development.

We need to consider what level of data is appropriate for the FDA to require. Today, I believe the FDA is in danger of creating "paralysis by analysis," requiring increasingly more information for research and product approvals. The FDA has shown it has a voracious appetite for more and ever-more-complicated information, and it is incapable of self-restraint. It's up to Congress to put it on a diet. Congress must set appropriate limits, consistent with public safety and health.

One of the most important issues for all regulated industries is national uniformity. We will examine the different ways to address this concern so that consumers do not need to bear the extra cost of burdensome levels of regulatory requirements.

And we will consider the all-important issue of access to information. Patients understandably want their doctors to know as much about the possible beneficial uses of marketed drugs -- even if FDA has not approved a particular use.

Yet as the FDA makes approvals more difficult, companies are more likely to narrow the labeling indications to get approved. The result is increased demand for off-label use, and, ultimately, even greater FDA restrictions on the dissemination of information about off-label uses.

Most important of all, however, we will examine the question I hear raised repeatedly, the question of whether the FDA holds back approval of new products because it is dangerously overcautious. Some potent drugs and valuable life-saving devices will pose serious risks -- but as I said earlier, NOT taking those drugs, NOT using those devices, sometimes poses a GREATER risk. We need to address the need for balance here -- and to do that, we need to bring the FDA under control.

Now I realize this is an ambitious agenda, but that's why we're here. That's why you elected us. And as I said earlier, we've already accomplished much -- more, indeed, than our critics ever predicted. But on the question of FDA reform as on no other, we will need your help -- the advice and the support of each one of you in this room. In a very real sense, F-D-L-I is among the most prestigious, one of the most influential, when it comes to the regulation of foods, drugs and medical devices. And as we proceed with this legislation in the weeks and months ahead, I hope I will have the benefits of your insights -- both publicly, in the form of testimony; and privately, in the form of your letters and personal advice.

I'm always surprised, in my new role as Chairman of the Commerce Committee, at all the new friends I didn't know I had ! But in this room, I see many true friends, many familiar faces. My door is always open to each of you -- the old friends, and those I haven't met.

I look forward to your advice, to your suggestions, and -- hopefully, as this process concludes -- to your support.

God bless you all.

###

Abroad at Home

ANTHONY LEWIS

Reform Or Wreck?

1/27

BOSTON

In 1960 the Food and Drug Administration received an application to market in this country a tranquilizer called Thalidomide, said to induce calm and sleep with no side effects. Described as a miracle drug, it had been on sale in Europe for two years.

Dr. Frances Kelsey of the F.D.A. was given the application to review. She was cautious because Thalidomide had an unusual chemical structure. She asked the Merrell Company, which wanted to market it, for more information.

Early in 1961 Dr. Kelsey saw in a British medical journal a doctor's letter saying that patients who had used Thalidomide for a long time developed a nerve inflammation in their fingers. She wondered whether fetuses would be similarly affected if pregnant women took the drug. She asked more questions, irritating Merrell officials.

Over the previous year or two a strange medical phenomenon had appeared in West Germany and Britain. Children were born with grotesque deformities, lacking arms and legs. No one knew the reason.

Then, in November 1961, a German doctor traced the cause to Thalidomide. Women who took the drug early in pregnancy were liable to have deformed children. Thalidomide was withdrawn from the market.

An estimated 10,000 deformed children were born in Europe and elsewhere because of Thalidomide.

But except for one trial distribution, the drug was kept out of the United States — kept out by a skeptical, determined F.D.A. doctor who was denounced, Morton Mintz of The Washington Post wrote at the time, as "a bureaucratic nitpicker."

If Newt Gingrich and his supporters have their way, no F.D.A. doctor like Frances Kelsey will again be able to block distribution of a drug like Thalidomide. For the F.D.A. is a prime target of the radical Republicans.

Speaker Gingrich has described the F.D.A. as "the leading job-killer

in America." That encapsulates a right-wing view that delay in approving new drugs and medical devices is hurting American manufacturers. Mr. Gingrich and other critics say the agency kills not only jobs but people. On NBC's "Meet the Press" last month he showed a Danish cardio-pump that he said increased the survival chances of heart-attack victims "by 54 percent" but that the F.D.A. "makes illegal." In fact, recent medical studies have shown no more benefit from the device than from conventional cardiopulmonary resuscitation.

Two weeks ago the right-wing Washington Legal Foundation ran a full-page newspaper advertisement that called the F.D.A. a killer. It cited the cardio-pump (saying it could have saved "14,000 lives so far") and other equally dubious matters. It said the American Heart Association estimated that delayed approval of a heart defibrillator cost "at least 1,000 lives"; the Heart Association denied making such a claim and deplored the ad.

The tone of the attacks on the F.D.A. is uncommonly brutal. Speaker Gingrich has called its Commissioner, David A. Kessler, who was appointed by President Bush, "a thug."

In all this we can see the real nature of the radical Republican strategy. The talk is of reforming Government. The real intention is to destroy many of its important functions.

Thus there are proposals to eliminate the F.D.A., replacing it with an industry-dominated agency; or to farm out the approval process to private bodies; or to let new drugs and medical devices be sold with a warning that they have not been approved.

Reform and simplification of Federal regulations are necessary. Some have become far too detailed and burdensome. When Washington tries to regulate minutely the practices of thousands of universities all over this vast country, for example, it is as likely to do harm as good.

But there are some things that a civilized society needs government to do. One of them is to protect its citizens from untested drugs that may do terrible harm.

In 1962 President Kennedy gave an award to Dr. Kelsey of the F.D.A. for her "high ability and steadfast confidence" in saving Americans from the Thalidomide tragedy. I do not believe that Americans really want to retreat from that standard to the age of carnival elixirs — or worse.

F.D.A. Becomes Target Of Empowered Groups

By PHILIP J. HILTS
Special to The New York Times

2-12
NYT

WASHINGTON, Feb. 11 — Among the Republicans in Congress and their allies in conservative advocacy groups, the Food and Drug Administration has become the first and biggest target in the push for deregulation.

A coalition of conservative groups, in a series of position papers and advertisements in newspapers, magazines and television, has sought to portray the agency as a prime example of what is wrong with Federal regulation.

An advertisement for the Washington Legal Foundation, which takes legal action against Government regulation and is a member of the coalition, declares: "If a murderer kills you, it's homicide. If a drunk driver kills you, it's manslaughter. If the F.D.A. kills you, it's just being cautious."

Proposals to overhaul the agency vary, but they all make a similar point: Delay in approving drugs and medical devices is harmful, not only to patients but to America's competitive edge.

The attacks on the drug agency are coming at a time it has begun to speed up the approval of drugs by working with the pharmaceutical industry under a new plan, the User Fee Program.

The conservative critics of the agency are motivated not by a desire for practical changes, as the traditional industry opposition has been, but as a matter of political philosophy. Their aim is to reshape the way Government works, rather than make the drug agency work more efficiently, which is what critics have long sought.

The groups in the conservative coalition, who had little influence before the 1994 elections, have major sources of financing from conservative foundations as well as powerful support in Congress. House Speaker Newt Gingrich of Georgia has been an outspoken critic of the F.D.A. He has also received campaign donations from industry donors interested in streamlining the agency's process.

One group, the Competitive Enterprise Institute, an offshoot of the American Enterprise Institute, suggests doing away with the agency's power to approve drugs and to allow all drugs and medical devices to be sold, regardless of safety or effectiveness.

Another group, Citizens for a

Sound Economy, suggests that a large part of the agency's duties be given to those whom it now regulates: private industry or medical groups.

Although the new opponents would seem to align naturally with the pharmaceutical industry on these issues, traditional opponents of the agency say they are uneasy about their new bedfellows.

John Villforth, head of the Food and Drug Law Institute, an industry-sponsored research center, said conservative groups were "throwing out the baby with the bathwater."

"But as frustrated as industry is with F.D.A. progress," he said, "these proposals, if put in place, would set things back disastrously. We would have chaos. We need the F.D.A. in order to have consistency and a serious look at the science of these drugs. We can't farm most of these things out to private enterprise."

Dr. Eve Slater, head of regulatory affairs for Merck & Company, said it would be a mistake to scrap the drug agency. "The tenets F.D.A. enforces, and we live by, ought to remain in place," she said. The problem with the agency is managerial, not fundamental, she said.

A longtime opponent of the agency, Alan Magazine, head of the Health Industry Manufacturers' Association, said he welcomed the attention the conservative groups were bringing to the issues facing manufacturers of medical devices. But he took issue with the specifics.

Mr. Magazine said industry needed a strong and vigilant overseer to maintain the world's confidence in the superiority of American drugs and devices. "We are for a strong F.D.A.," he said. "They are our credibility."

At the same time, industry officials say they do not want to offend the new powers in Washington. Among those they are least eager to alienate is Mr. Gingrich, who has called the Federal agency "the leading job-killer in America."

One source of financing of Mr. Gingrich's college video courses is the Progress and Freedom Foundation, a conservative advocacy group in Washington. Among the foundation's donors are half a dozen companies that do business with the agency, including two for which Mr. Gingrich has personally written letters urging approval of their products, agency documents show.

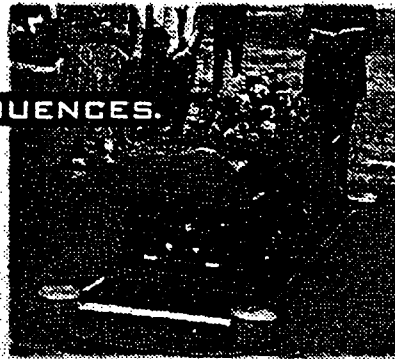
But even some of Mr. Gingrich's

THE FDA CAN **DELAY** MEDICATIONS

AND SAFETY DEVICES FOR **YEARS.**

TOO BAD IT CAN'T DELAY

THE **CONSEQUENCES.**



A coalition of conservative groups has made the Food and Drug Administration its primary target in the push for Government deregulation. In a series of advertisements, members of the coalition have sought to portray the agency as an example of what is wrong with Federal regulation. This ad was by the Washington Legal Foundation.

supporters have urged him to be cautious about encouraging radical change at the agency. At a recent meeting with Mr. Gingrich, Dr. W. Virgil Brown, a Georgia Republican and supporter of Mr. Gingrich who is also a former president of the American Heart Association, gave the Speaker a letter expressing his and the heart association's "great concern" about efforts "under way by some special interest groups to move to quickly dismantle the Food and Drug Administration."

The conservative coalition's agenda "could set public health back into the dark ages," he said.

The organizations in the coalition are ideological groups that take on a variety of social issues in which the Government is involved, working from ideology toward policy, Mr. Villforth of the drug law institute said.

The groups also share many sources of support. Among the groups, and their total contributions to conservative organizations over the past years, are the following:

¶The John M. Olin Foundation, financed by the Olin chemical and munitions fortune. It supports the Heritage Foundation, a research organization, and helped support the writing of "The Real Anita Hill: The Untold Story," by David Brock (Free Press, 1993). At least \$650,000.

¶The David Koch Foundation and other Koch family foundations, which were created from the oil fortune of Fred G. Koch, a founder of the ultra-conservative John Birch Society. More than \$1.7 million.

¶The Smith Richardson Foundation, with money from the Vicks Vaporub and Smith Bros. Cough Drops

fortune, as well as the former Richardson Merrell pharmaceutical company. More than \$500,000.

¶The Sarah Scaife Foundation, created with the Mellon banking fortune. At least \$500,000.

The conservative groups in the coalition have also received large sums from pharmaceutical companies that conduct business before the drug agency, as well as and from the R. J. Reynolds and Philip Morris tobacco companies.

The pharmaceutical company contributions were led by the Lilly Foundation, which receives its money from the Eli Lilly Pharmaceutical Company of Indiana.

Public Citizen's Health Research Group in Washington, a public interest group that has battled the F.D.A. for decades, recently issued a report listing all the drugs that were put on the market in the United States, Germany, France and the Britain, and then had to be withdrawn from the market for safety reasons after people became ill or died after using the medications.

Dr. Sidney Wolfe, director of the group, said that the results showed that since 1970 the agency had marketed only 9 of the 56 hazardous drugs. The other three countries marketed significantly more: France, 31; Germany, 30, and Britain, 23. Dr. Wolfe said the figures showed the margin of safety that the F.D.A. added to drug approval.

The pharmaceutical manufacturers, in reply, released figures showing that the F.D.A. had let fewer unsafe drugs on the market than had been permitted in any other country, but that the difference might not as great as Dr. Wolfe suggested.

Officially Unveils Plan to Replace FDA

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — A think tank with close ties to House Speaker Newt Gingrich officially unveiled an effort to design "a replacement" for the Food and Drug Administration, saying its goal is to get a plan ready by the fall.

The Progress and Freedom Foundation has been preparing for months to launch a major project to find new ways to speed the approval of drugs and medical devices. At a briefing Friday, foundation president Jeffrey Eisenach, a close associate of the Georgia Republican, provided new details and defended the foundation's practice of accepting contributions from drug companies.

Mr. Eisenach said that Louis Sullivan, the secretary of the Department of Health and Human Services during the Bush administration, would serve as chairman of the "Medical Innovation Project." He said the group planned to prepare a draft plan by May or June, and that the final blueprint, if approved by Congress, would take as much as five years to put into effect.

In recent months, Mr. Gingrich, an array of conservative think tanks and the pharmaceutical and medical-device industries have lambasted the FDA as being too slow and cautious in approving products. Several Republican members of Congress are planning to conduct hearings on the FDA, among them the new chairman of the House Commerce Committee, Rep. Thomas Bliley (R., Va.). FDA Commissioner David Kessler so far has maintained a low profile in the face of the assault.

The foundation has been in the spotlight as well. As reported, Mr. Gingrich introduced legislation in the summer of 1993 to suspend duties on ingredients imported by Solvay Pharmaceuticals Inc. At about the same time, Mr. Eisenach asked Solvay, which is located in Mr.

Gingrich's district, for a contribution to the foundation. Solvay, a subsidiary of the Belgian chemical company Solvay SA, made a \$30,000 contribution in early 1994.

Mr. Gingrich also pressed the FDA in a letter in July 1994 to justify its delay in approving Solvay's obsessive-compulsive disorder drug, Luvox. The company has insisted that there wasn't any connection between its donation and Mr. Gingrich's official acts. On Friday, Mr. Eisenach backed up that assertion. "I didn't know he had written a letter or introduced legislation," he said.

Mr. Eisenach, a former executive director of Mr. Gingrich's political-action committee, Gopac, also said Friday that 10% to 15% of the foundation's contributions have come from makers of drugs and medical devices. Among the companies on the foundation's donor list are Genzyme Corp., Johnson & Johnson, Monsanto Co.'s Searle pharmaceutical unit and Glaxo Inc., a unit of Glaxo PLC.

Asked whether such donations would affect the foundation's work on the FDA, Mr. Eisenach said he was confident the work would be objective and withstand academic and political scrutiny.

Jim O'Hara, a spokesman for the FDA, said, "If anyone has serious and substantive proposals to improve the safety and efficacy of drugs and devices, that's fine." But he said the FDA has dealt with some of the issues raised by the foundation.

For example, the foundation's paper says that many prescription drugs used on children haven't been specifically tested and approved for that purpose, and so can't be marketed for pediatric use. But the FDA in December announced a rule change that makes it easier, in some circumstances, for manufacturers to include pediatric information on the label of the products, even without extensive testing in children.

Ganging Up on the FDA

A new coalition of industry critics, conservative groups and powerful Republican lawmakers has been forged to work for a major restructuring of the Food and Drug Administration.

BY PETER H. STONE

The Progress & Freedom Foundation, the think tank affiliated with House Speaker Newt Gingrich, R-Ga., has raised about \$400,000—about half of it since the fall elections—from drug, biotechnology and medical device companies in part to finance a study on restructuring the Food and Drug Administration (FDA), the agency that polices their activities.

Meanwhile, one of the top lawyers at the Washington Legal Foundation, a conservative litigation group that has been running a nationwide advertising campaign attacking the agency's priorities, has gone to Capitol Hill, where he will work on a congressional investigation of the FDA's operations.

And Citizens for a Sound Economy, a conservative advocacy group that has made public a critical opinion survey on the FDA by an influential Republican pollster, is preparing a grass-roots drive to build congressional support for re-vamping the agency.

Welcome to the well-financed, multi-front campaign to overhaul the FDA. With the Republican takeover of Congress, a new coalition of industry critics, conservative groups and powerful Republican lawmakers has been forged to work for a major restructuring of the Health and Human Services Department agency.

The effort, long a goal of many drug and medical device makers who complained of burdensome regulations and lengthy delays in winning approval of their products, dovetails with the Republican agenda for deregulation.

Congressional scrutiny of the FDA's operations is slated to start by the end of the month in the House Commerce Committee. The hearings are being championed by chairman Thomas J. Bliley Jr., R-Va., who also heads the House Biotechnology Caucus and is a close ally of the tobacco industry, which is very worried about the FDA's decision to consider regulating tobacco as a drug.

"My goal is to speed up approval of drugs and devices for the American people," Bliley said in an interview. He added that his committee's hearings have

the full blessing of Speaker Gingrich, who, Bliley said, "has talked to me about oversight of FDA."

Gingrich is the godfather of the FDA reform movement. He has publicly denounced the agency as "the leading job killer in America," and he has branded FDA commissioner David A. Kessler "a thug and a bully." Last fall, he urged an overflow crowd of biotech executives to work with the Progress & Freedom Foundation on its study and brought a top biotech industry executive onto his cable television show to discuss major changes at the FDA.

Gingrich has drawn fire because of his lobbying on behalf of drug companies that made contributions to the foundation.

But the agency's critics, their clout notwithstanding, are diverse, and most of them don't have specific legislative proposals. Some talk of abolishing the FDA altogether, others want to privatize parts of it and still others are seeking more-modest reforms.

Some of them have adopted a two-track policy of calling for long-term reforms that would shift many of the agency's functions to the private sector while also calling for some near-term relief through incremental reforms. "I don't think we have a long window," Carl Feldbaum, the president of the Biotechnology Industry Organization (BIO), said. "So we're pushing very hard. We have a lot of irons in the fire with the FDA."

But the agency's longtime friends stress that too much deregulation could harm its mission of protecting public health. They recall its vital role in the early 1960s when it kept thalidomide—the drug linked to deformity in thousands of infants whose mothers used it during pregnancy—out of the United States. And some congressional backers raise red flags about the intensity and tenor of the attacks on the agency.

"I think they'd like to eviscerate the FDA, but if they can't do that, they'd like to intimidate the FDA," said Rep. Henry A. Waxman of California, the senior

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Democrat on the Commerce Subcommittee on Health and the Environment, which has jurisdiction over the FDA. Waxman also criticized Gingrich for the tone of his attack on the FDA commissioner. "I was stunned by the super-charged words he used against Kessler," Waxman said. "It seems like he's trying to bully the agency."

Some of the agency's critics suggest that the FDA and its friends would be wise to "catch the mood of Congress" and make major changes before the lawmakers act. "If they take steps now, they might be able to forestall draconian legislation," said Peter Barton Hutt, a former FDA general counsel and now a lobbyist with the Washington law firm of Covington & Burling who represents several leading drug companies and trade groups that the FDA regulates.

CHANGING THE LANDSCAPE

Calls for reforming the FDA are old hat in Washington, but the Republicans' stunning congressional victories last fall transformed the lobbying and political landscape and energized companies, trade groups and lobbyists. For many companies, moreover, the stakes in the FDA debate have been raised because under Kessler, who was appointed commissioner by President Bush, the agency has become much more aggressive about enforcement.

The agency's critics have aimed their fire on a broad range of issues. But at the top of almost every list is the time it takes the agency to approve new drugs and devices. Drug and device makers often point to the faster review times for new products in many European countries. In a recently conducted study, the Health Industry Manufacturers Association (HIMA) also noted that the FDA's review times for applications for "substantially equivalent products" have more than doubled since 1989.

"Our major concern is getting drugs out to patients quicker," Stephen Conafay, the chief lobbyist for the Pharmaceutical Research and Manufacturers of America (PhRMA), said. "The companies are reluctant to talk about it because they're afraid of retaliation."

But that reluctance has notably dissipated since the fall elections. Industry critics increasingly complain, for instance, that Kessler's emphasis on enforcement has slowed the product review process, hurting businesses and consumers. Many industry executives have talked about the need to reexamine the agency's dual roles: product approval and enforcement.

Kessler has sparked tensions with many companies and some industries. He initiated a moratorium on all new

implants until they could be proven safe, and he also imposed new rules to prevent AIDS and other diseases from infecting blood and tissue banks.

Still, the FDA commissioner has hardly ignored critics' concerns. He has made some significant moves to improve the agency's performance and efficiency. The FDA, for instance, has slashed its backlog of device applications from thousands to a few hundred.

Last year, too, the agency stepped up the pace of drug approvals, trimming the median approval time for new drugs to 19

months, a cut of 21 per cent. And it said that it expects to meet its 1997 target of cutting the review time of all drugs to less than a year—in part because of 1992 legislation that permits it to charge for applications.

But many critics say that the FDA hasn't done nearly enough, and the demand for more changes has swelled since the election. Congressional leaders, think tanks, advocacy groups and trade groups have all raised the decibel level in recent months and stepped up their activities.

its study, has said that it is seeking to develop a "replacement" for the FDA that will lean heavily on the private sector to fulfill its functions. A draft outline should be available early this summer, but if the plan is approved by Congress, it would take about five years to institute, Eisenach said.

Early contributors included Burroughs

Wellcome Co., Direct Access Diagnostics, Genzyme Corp., Glaxo Inc., Health South Corp., Johnson & Johnson Corp., G.D. Searle & Co. and Solvay Pharmaceuticals Inc., according to a list that the foundation made public.

Some of the companies are frank about their donations. "This was an organization that looked like it was going to have some influence, and we wanted to have some influence with them," said Lisa Raines, the chief Washington lobbyist for Genzyme, which kicked in \$5,000.

Eisenach stressed that the foundation has not asked companies to contribute specifically to the Medical Innovation



Food and Drug Administration commissioner David A. Kessler
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THE FOUNDATION AT WORK

The Progress & Freedom Foundation has mounted the highest-profile drive. The foundation, launched about 20 months ago by Jeffrey A. Eisenach, a longtime Gingrich aide who used to run GOPAC, the Georgian's political action committee, has been busy touting its FDA reform effort.

Largely to help finance the Medical

its study, has said that it is seeking to develop a "replacement" for the FDA that will lean heavily on the private sector to fulfill its functions. A draft outline should be available early this summer, but if the plan is approved by Congress, it would take about five years to institute, Eisenach said.

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\$500,000. But the foundation recently sent out a mailing to several drug, biotech and device companies soliciting more money for the foundation that all but asked directly for money for the project.

Some of the letters asked for "general support grants"—with some companies asked to donate as much as \$50,000—but they zeroed in on the Medical Innovation Project as the key part of the foundation's activities. One such letter, besides asking for money, requested that the company make an "intellectual contribution."

In fact, the foundation is playing more than a purely analytical role in the debate over FDA changes. Indeed, there is clearly cross-fertilization between the foundation, Gingrich and the industries that are leading the lobbying fight for a redesigned FDA.

The foundation, for instance, handles the invitations to potential guests on *Progress Report*, Gingrich's talk show on National Empowerment Television, which reaches about 11 million viewers. A show in December featured Gordon

major reforms; Binder also dined with Gingrich before the show, though there was no discussion of the FDA during dinner, according to Peter Teeley, the company's Washington lobbyist, who was at the dinner. Amgen is considering making a sizable donation to the foundation, Teeley said.

The close links between the foundation and Gingrich have also been underscored by stories in *The Wall Street Journal* recently about how he introduced legislation and interceded with the FDA on behalf of Solvay Pharmaceuticals, a constituent company and the American unit of Solvay S.A., a Belgium-based chemical firm. In 1993, Gingrich introduced three bills that would have suspended tariffs on imports of certain ingredients for Luvox, a Solvay drug for obsessive-compulsive disorders. In early 1994, the Marietta-based drug company donated \$30,000 to the Progress & Freedom Foundation.

Gingrich went to bat for Solvay again last summer, urging the FDA to move faster to approve the same drug. Solvay, the foundation and Gingrich have denied that the \$30,000 donation was linked to Gingrich's efforts on behalf of the company.

Solvay is not the only contributor for whom Gingrich has lobbied. Last fall, he urged the FDA and the White House to move faster in approving a home test kit to detect the AIDS virus that's manufactured by Direct Access Diagnostics, a Johnson & Johnson subsidiary, according to an article in *Roll Call*. Not long afterward, Direct Access chipped in about \$30,000 to the foundation.

Ben Jones, the Georgia Democrat who lost to Gingrich last fall, has filed an ethics complaint alleging fund-raising improprieties by Gingrich that include the foundation's fund-raising activities.

Eisenach defends the foundation's acceptance of large contributions from companies with big stakes in the outcome of the FDA debate. The foundation, he said, won't lobby on the

FDA issue, and its study should be judged solely on the merits of its ideas. "This is a town that's used to the politics of money and power," he said. "The notion that we're a political adjunct is wrong and offensive."

"What you have here are drug companies with enormous economic stakes in what the government policy is, providing huge sums of money to benefit Speaker Gingrich's interest," Fred Wertheimer, the president of Common Cause, said. "The notion that this foundation is not a Gingrich foundation is quaint, but it doesn't measure up to the reality of the foundation."

ALLIES

In January, the foundation began hosting meetings of major trade groups and think tanks that are also working on the FDA issue. The get-togethers, to be held roughly every two weeks, are to be informal affairs aimed at sharing information about what the groups are doing, Eisenach said.

But some participants at the first meeting have discussed the possibility of forming coalitions around specific proposals later in the year. The gatherings have drawn lobbyists from such trade groups as the PhRMA, the BIO and HIMA and such advocacy groups as Citizens for a Sound Economy, all of which are moving ahead with their own FDA campaigns.

For instance, Citizens for a Sound Economy, which boasts of a membership of 250,000, is going forward with its own efforts. The group fired its opening salvo against the agency in January, when it released a poll showing that Americans had some serious doubts about the job that the FDA was doing. The poll, conducted by Luntz Research Co. of Arlington, Va., at a cost of about \$50,000, revealed that 65 per cent of those surveyed did not think that the FDA was "quick and efficient." The firm's head, Frank I. Luntz, is the pollster who helped frame the House GOP's Contract With America.

The group, which is chaired by former Bush White House counsel C. Boyden Gray, also spent about \$60,000 for ads on Washington radio stations publicizing the poll's results and the need for FDA reform, said Brent Bahier, its vice president for communications.

Gray testified on the FDA at a hearing late last month of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies and lambasted the agency's performance. He said that of 22 new drugs approved in the United States last year, 13 were first approved in other countries. He also cited a Tufts University study that revealed that of 46 drugs approved by the FDA, 72 per cent were available abroad 5.5 years earlier, on average. "This kind of delayed approval kills American citizens," he said.



Progress & Freedom Foundation's Jeffrey A. Eisenach. He and his group want a major restructuring of the FDA.

Binder, the chairman of Amgen Corp., a leading California-based biotech company, who has also chaired a BIO committee that has been formulating the industry's agenda for revamping the FDA.

Binder discussed the industry's con-

Richard A. Brown

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Other studies though have shown that there are costs as well as benefits to fast drug approvals by other countries. Public Citizen Health Research Group, a Ralph Nader affiliate, in early February published a report comparing the number of drugs that had to be removed from the market in four countries because of dangerous side effects. From 1990-92, of 56 drugs removed from the market worldwide, only 9 were withdrawn in the United States; 31 were withdrawn in France, 30 in Germany and 23 in the United Kingdom. In three of the nine cases in this country, manufacturers subsequently pleaded guilty to criminal charges for withholding evidence from regulators that the drugs were risky.

Citizens for a Sound Economy is gearing up to mount a nationwide grass-roots lobbying drive similar to one that it did last year during the health care reform battle, Bahler said. "We anticipate this will be a significant undertaking," he said. "We have to identify the committees that have jurisdiction. We're probably talking about a dozen Members on the House side." Key Senators will be targeted later in the year, he said. Sen. Nancy Landon Kassebaum, R-Kan., the chairwoman of the Labor and Human Resources Committee, is expected to hold hearings in late spring that will examine the agency's management.

The group's grass-roots lobbying drive is likely to be coupled with a "targeted media" campaign in the same districts that will use a combination of print, radio and television to "educate their constituents," Bahler said.

The attacks on the FDA are also being subsidized by the Washington Legal Foundation, which in the past few months has spent roughly \$100,000 on a series of print ads. The foundation's ads, some of which graphically feature pictures of coffins and call the FDA a killer, have run in such publications as *The New York Times*, *Roll Call*, *USA Today*, *The Wall Street Journal* and *National Journal*.

The ads have sparked some controversies. The American Heart Association recently wrote a letter to *The New York Times* attacking an ad for falsely stating that the Heart Association had estimated that delayed approval of a heart fibrillator cost "at least 1,000 lives."

The legal foundation, which has about a \$3 million annual budget, did not do any special fund raising for the ad campaign, Daniel J. Popeo, its chairman, said. But in recent years, one of its major backers has been the Lilly Endowment, an Indiana foundation whose funds come from stock in Eli Lilly & Co., the Indianapolis-based drug company. In 1992, the endowment gave the legal group a three-year grant of \$150,000.

The FDA is the nation's "No. 1 health problem," Popeo said in an interview. In addition to the ad blitz, the foundation has sued the FDA at least twice and is active in regulatory proceedings and in filing friend-of-the-court briefs, he said.

But perhaps the foundation's biggest weapon is a recent alumnus, Alan M. Slobodin, who was tapped to be general counsel to the House Commerce Subcommittee on Oversight and Investigations, which is about to begin hearings on the FDA. In his new post, Slobodin will handle much of the organizational work for the forthcoming FDA hearings, including assembling witnesses to testify.

Popeo said that he's talked to Slobodin recently about the hearings and that the foundation has been alerted to make people "available for testimony."

WORKING THE HILL

The trade groups that the FDA polices can also count on plenty of access. And though the major trade groups are still developing their recommendations for FDA reform, some have already started aggressive lobbying drives.

The biotech industry seems particularly well positioned because of Bliley's role as leader of the congressional caucus on biotech issues. Bliley said that he has had one meeting with industry lobbyists, including at least one chief executive. On Feb. 8, about 55 biotech executives made a pilgrimage to Capitol Hill, where they met with several Members, including Rep. Joe L. Barton, R-Texas, the chairman of the Commerce Oversight Subcommittee, to discuss FDA reform, among other subjects.

The industry demonstrated its prowess in last year's health care reform lobbying battle, in which it emphasized biotech's importance as a cutting-edge technology. The industry is likely to play a prominent role again as the FDA debate heats up. At the top of the industry's wish list are steps to speed up the approval process: contracting out some of the FDA's review procedures and functions to private firms and eliminating inconsistencies between the way traditional drugs and new biotech products are reviewed. The industry would also

like to have the right to export its products without going through the FDA if the recipient countries have already approved them. BIO president Feldbaum said.

Makers of medical devices are also already active in the lobbying trenches. "A cornerstone of all our efforts will be to propose a more European-style approach to device approval," Alan H. Magazine, the president of HIMA, said in an interview. The trade group is touting a system of public-private partnerships that in European countries conduct device approvals and plant inspections.

Magazine said that he recently made calls on key Members to press these ideas. He has met with Barton's and Kassebaum's staffs and had a meeting with freshman Rep. David McIntosh, R-Ind., who chairs the new Government Reform and Oversight Subcommittee on



Citizens for a Sound Economy chairman C. Boyden Gray. FDA delay in approving drugs "kills American citizens."

National Economic Growth, Natural Resources and Regulatory Affairs. On Feb. 8, the subcommittee approved a regulatory moratorium.

Ironically, even though the PhRMA, the drug industry group, has long led the battle for FDA changes, it seems to be

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taking a more cautious approach, at least for now. The PhRMA has a board-level committee led by Frederick Lyons Jr., the CEO of Marion Merrell Dow Co. of Missouri, which is putting together reform recommendations that should be ready in a few months.

The company, which also would have benefited from Gingrich's tariff legislation for Solvay, has donated \$41,690 to GOPAC, according to the *Los Angeles Times*. It also gave \$48,500 in "soft" money to the GOP in the most recent election cycle.



Washington Legal Foundation chairman Daniel J. Poppe. The FDA is today the nation's "No. 1 health problem."

Conafay, the PhRMA's chief lobbyist, stressed that FDA reform is a top priority for a variety of reasons, including delays in the approval process, restrictions on advertising and overly aggressive enforcement actions. But the group wants to be sure that its proposals are the right ones before it starts its big lobbying push. "When this gets serious, we'll be in the thick of things," he vowed.

At that time, it will probably turn to several patient groups that it has historically worked with in coalition efforts and will try to mobilize them behind its FDA proposals, Conafay said.

One of these groups, the Illinois-based National Kidney Cancer Foundation, has already been active in recent months. The group, to which the PhRMA has

donated about \$5,000, has held a series of meetings in Washington with key trade groups and think tanks to discuss issues and strategies. "We've made a major effort to stay close to our patients," Conafay said.

Conafay added that the PhRMA is likely to tap a few outside lobbyists to assist in its FDA campaign, including former Rep. Paul G. Rogers, D-Fla., who is now with the Washington law firm of Hogan & Hartson.

The tobacco industry, meanwhile, has been keeping a very low profile and seems to be quietly counting each day that goes by without an FDA announcement that it intends to regulate tobacco as a drug. A veteran tobacco industry hand said that Bliley has asked companies to lay low for their own benefit and his and that he doesn't want to be perceived as "beating the FDA over the head because of tobacco. That message has come through loud and clear."

Reynolds Tobacco Co., however, worked with tobacco grower groups to gather 1.1 million signatures on petitions opposing FDA regulation of tobacco. And the Tobacco Institute, the industry's Washington trade group, last month made public a poll indicating that Americans were divided over such regulation.

The odds seem good that all this clout will translate into legislation this year to roll back the FDA's authority. But it's too early to say how much the agency's critics may achieve.

Democrats who have supported the agency are clearly worried about the hard line that some of the FDA's loudest critics are taking. "I think clearly the Far Right is trying to whip up an ideological frenzy," Rep. Ron Wyden, D-Ore., said. "There are extreme positions being advocated here that give short shrift to patient needs. But more important, a lot of them are going to be opposed by industry." Wyden said that there are some FDA reforms that he would back, including faster approvals for breakthrough drugs.

Even some Gingrich backers have said that certain conservative groups seem to be going too far in their efforts to change the FDA. W. Virgil Brown, a former American Heart Association president and a Georgia Republican, recently wrote to Gingrich, expressing "great con-

cern" about the efforts by "some special-interest groups to move too quickly to dismantle" the FDA.

Despite these criticisms, leading Republicans have a lot riding on the debate over the FDA's restructuring. Besides their support for the Progress & Freedom Foundation and GOPAC, special interests with big stakes in the issue were very generous contributors to the GOP in the 1993-94 election cycle.

The party's leading financial angel in the last cycle was Amway Corp. of Michigan, which donated about \$2.5 million in unregulated "soft" money. Amway, which is allied with the Dietary Supplement Coalition, had a big spat with the FDA last year over what the dietary supplement industry needed to do to substantiate its assertions of health benefits, according to *The Wall Street Journal*.

The Administration has also been feeling pressure to act to preempt the FDA's critics. As part of the reinventing government initiative, top White House officials are seriously weighing changes at the FDA that would make the agency appear to be more responsive to critics' concerns.

For its part, the FDA is publicly pushing ahead with its aggressive enforcement agenda, and its study on whether it should regulate tobacco is still on track, agency officials say.

William B. Schultz, the deputy FDA commissioner for policy, said that the agency is also committed to finding ways to reduce approval times for new drugs and devices. The agency's budget for this year contains a proposal to charge a user fee for device applications—akin to what the agency has done with drugs—that should help reduce approval times significantly, he said.

Schultz also noted that the FDA will be able to approve "important" drugs within six months by 1997. "Anything that's a significant advance over what's on the market today we will do in six months," he said.

More broadly, he added, "we'll continue down this road as long as we can do so without diminishing our basic mission of protecting the public health."

The FDA is undoubtedly feeling the heat from Congress, industry forces and their think-tank allies. And when Congress starts its hearings later this month, that pressure should intensify. Hutt, the Covington lawyer who works for drug companies and other FDA-regulated clients, said, "I'd hope that the FDA would itself begin to think of what changes it could make internally to solve long-standing problems themselves."

The FDA may well opt for a bigger and stronger dose of reform out of fear that Congress might try to force much more painful medicine down its throat.

Representative Bliley's Double Talk

NYT 3-3-95
Representative Thomas J. Bliley Jr. speaks with a forked tongue when he talks about the Food and Drug Administration. In one breath he accuses the agency of pokiness and nitpicking: "It breaks my heart when I think of American citizens having to go to Switzerland or Mexico to get the drugs or devices they need to stay alive because the Washington bureaucracy won't approve them." In the next, he implies that the F.D.A. cannot be poky and nitpicking enough when it comes to reviewing RU-486, the French abortion drug.

Congressman Bliley's is the lead signature on a citizens' petition that Americans United For Life filed with the F.D.A. demanding that it apply the strictest possible review standards for RU-486. The petition also argues that the agency should not use data from foreign studies.

But who besides Mr. Bliley, Americans United for Life and others who share the same anti-choice sentiments has accused the agency of planning to relax its standards for RU-486? Nobody. And do

they realize that drugs on which they themselves may depend would not be available here were it not for data from foreign studies? In any case, facts are not the issue. What is at issue is a politically motivated effort to deny the American market a drug that can make abortion the wholly private decision it should be — a drug that also has potential for treating certain female diseases.

Since 1981, 250,000 women in 20 countries have used RU-486. It would be ridiculous for the F.D.A. to blind its eyes to that large statistical universe. Meanwhile, the nonprofit Population Council is conducting its own clinical trials, with 2,100 women at 12 American sites. Once the trials are finished and when and if RU-486 is submitted for approval, the F.D.A. promises to give it the same rigorous scrutiny it would give any other drug. Such a promise, however, is sure to cut little ice with Mr. Bliley and company. By their lights, it is politics, not science, that decides what pharmaceuticals American women will have access to.

White House Moves to Speed Up Action At FDA as Agency Is Scolded in Senate

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — The Clinton administration took steps to speed up approvals of drugs and medical devices, even as senators scolded the Food and Drug Administration about a "culture of confrontation" and urged more-sweeping changes.

Two of the biggest changes announced by the White House involve creating a pilot program that would use outside experts to review certain low-risk medical devices to determine if they should be approved, and easing restrictions on the export of unapproved drugs and devices to other industrialized countries.

The changes, which administration officials claimed would save industry an estimated \$500 million annually in regulatory-compliance costs, went beyond steps announced at a "reinventing government" news conference held last month at the White House.

Warning From Sen. Mikulski

"Congress is going to roll right over you" if more improvements aren't forthcoming, Sen. Barbara Mikulski (D., Md.) warned FDA Commissioner David Kessler at a hearing of the Senate Labor and Human Resources Committee. Her criticisms were especially notable coming from a Democratic lawmaker. The FDA is located in Sen. Mikulski's state, as are several biotechnology companies that have expressed frustrations with the agency.

Although the senators pointed to some specific difficulties, much of the criticism focused on such intangibles as the general attitude of FDA employees toward industry. Sen. Judd Gregg (R., N.H.) said he hears frequent complaints from constituents about a "culture of confrontation rather than cooperation" at the agency.

The two-year pilot program announced yesterday would allow the agency to explore a notion pushed by many of the FDA's critics — that outside analysts can get certain jobs done more quickly and efficiently than FDA bureaucrats. The agency, however, will have the final word on whether any device is actually approved.

The pilot program also is a nod to critics who say the U.S. should switch to a European-style review process. In Europe, device makers pay a third-party organization to conduct reviews, and if the device gets a favorable rating, it is marketed without prior government approval; the government monitors the device after it goes on the market.

Legislation on Exports

Easing export restrictions on unapproved drugs and devices would require legislation, Dr. Kessler said. Some members of Congress recently have introduced legislation to ease the export rules.

Alan Magazine, president of the Health Industry Manufacturers Association, which represents device makers, called the

changes "important first steps toward ensuring that patients receive more timely access to safe and effective medical technology." Sen. Nancy Kassebaum (R., Kan.), who heads the Labor and Human Resources Committee, said that although the changes announced yesterday "are common sense and long overdue," more are needed.

But the announced changes are unlikely to assuage conservative critics of the agency. For example, the Competitive Enterprise Institute, a Washington-based group, has recommended that drugs and devices that don't meet the FDA's standards shouldn't be banned, but should be available under doctors' supervision with a warning of their unapproved status. Other critics say the FDA's efficacy standard should be weakened or eliminated, allowing the marketplace to decide which treatments work.

After the hearing, Dr. Kessler said, "We're open to thoughtful reforms, but my bottom line is making sure that the agency is able to make these decisions in an environment of independence."

Birth Problems Tied To Alcohol Soared Since 1979, CDC Says

By a WALL STREET JOURNAL Staff Reporter

ATLANTA — The rate of babies born with health problems because their mothers drank alcohol during pregnancy increased sixfold from 1979 through 1993, the Centers for Disease Control and Prevention said.

The federal agency said it didn't know whether the increase was attributable to improved diagnosis by doctors or whether more pregnant women are drinking.

Since the CDC began tracking the number of fetal alcohol syndrome cases in 1979, the rate has jumped from one per 10,000 births to 6.7 per 10,000 births in 1993. A total of 2,032 cases were reported among the 9.4 million births over the 15-year period.

Despite growing awareness that abstaining from alcohol prevents the syndrome, about a fifth of women continued to drink after they learned they were pregnant, the CDC said.

Symptoms of fetal alcohol syndrome are mental retardation, abnormal facial features, central nervous system problems, behavioral problems and growth deficiencies.

Health officials do not know how much alcohol harms a fetus. Many doctors urge abstinence during pregnancy because there is evidence that even small levels of alcohol consumption can harm a fetus.

ONCE OVER

No, the FDA is not killing people

In the early 1960s, an alert scientist at the U.S. Food and Drug Administration kept the sleeping pill thalidomide off the market in the U.S. That protected untold numbers of children from being born deformed in this country. Several thousand European children weren't as lucky.

Since then, the FDA has enjoyed a public profile as a stalwart guardian of public health and a scourge of quacks and profiteers. That is, until the past few months.

The FDA is being attacked by politicians and by foundations with funding from drug companies. They include the Washington Legal Foundation, the Progress and Freedom Foundation, the Competitive Enterprise Institute, and Citizens for a Sound Economy. Such organizations accuse the FDA of menacing Americans' lives and health by tying up beneficial treatments in interminable red tape.

The most lurid charges have come in ads from the Washington Legal Foundation. Next to images of coffins and tombstones,

the ads say: "If a murderer kills you, it's homicide . . . If the FDA kills you, it's just being cautious . . . The problem with health care in America is the FDA."

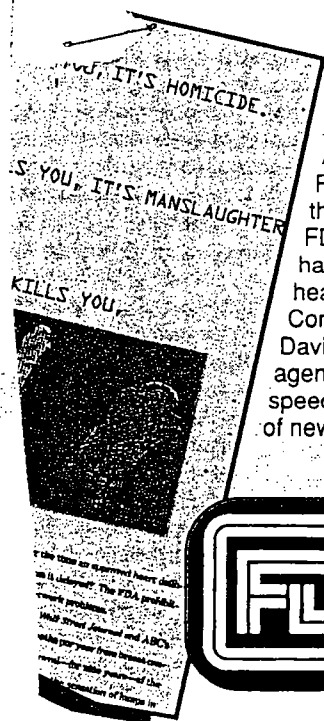
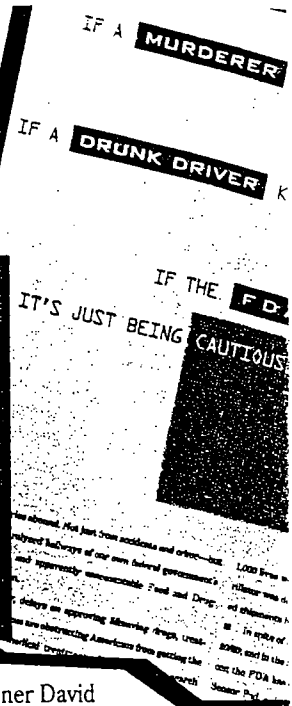
The solution, suggests the Progress and Freedom Foundation, formed by close political associates of House Speaker Newt Gingrich, is to turn most of the FDA's work over to private firms. But we have yet to see any proposal that makes clear how those companies would be held accountable and free of conflicts of interest. Some advocates would even let manufacturers sell any drugs they want, leaving customers to sue doctors or manufacturers if the drugs did harm. (At the same time, some in Congress have long wanted to make it tougher to file such suits.)

The FDA, spending \$900-million a year, is a powerful agency with an awesome responsibility. And it was infamous not long ago for taking years to decide whether products got to market. But the bashing it's now getting isn't justified.



Under Commissioner David Kessler, appointed by President Bush, the FDA has accelerated its approval of genuine breakthrough drugs. Last year, 17 of the 22 drugs it approved were these "priority" compounds. For 10 of those drugs, processed under a new user-fee system, the average approval time was cut in half, to less than a year.

The agency also fares well in international comparisons. Last year, of the world's dozen new drugs considered the most



Attack ads

Recent ads like this suggest the FDA's red tape is hazardous to your health. But under Commissioner David Kessler, the agency has actually speeded up approval of new drugs.



notable therapeutic advances, five were first introduced in the U.S., compared with three in Japan and no more than one in any other country.

The FDA also seems effective at keeping unsafe drugs off the market. Public Citizen's Health Research Group recently studied the 56 drugs withdrawn from the

market in the U.S., England, France, and Germany since 1970 because of safety problems. Only nine had made it onto the market in the U.S., compared with 23 in England, 30 in Germany, and 31 in France.

The FDA's review procedures have revealed time and again that not every promising therapy turns out to work or to be safe. The Washington Legal Foundation's ads claim that people died because specific drugs or medical devices were trapped too long in the review process. Those assertions are misleading.

The foundation claims that "the lives of more than 150,000 heart attack victims may have been saved" if the agency had been faster to approve TPA, a drug that dissolves blood clots. In fact, another, almost equally effective drug, streptokinase, was already on the market before the FDA even started reviewing TPA. Any doctor or hospital was free to use it.

The ad complains that the FDA has "obstructed" approval of the Sensor Pad, a silicon-filled plastic pad that supposedly helps women feel breast lumps, while the product was released for sale in Canada "in less than 60 days." In fact, the FDA kept the product off the market because its manufacturer was unable or unwilling

to do tests to show the pad worked as claimed. Last year, Canadian officials asked for the same information the FDA had sought. They couldn't get it either, and ordered the Sensor Pad off the market.

One gripe with some validity is that the FDA stopped tests of a portable heart resuscitation pump because test subjects—people who collapsed suddenly of massive heart attacks—couldn't, for obvious reasons, give "informed consent" to participate. The agency has belatedly promised new regulations to permit experimentation with resuscitation drugs and equipment.

Those organizing the assault on the FDA insist their motives are philosophical, based on a belief that such government regulation is wrong. But the anti-FDA groups are getting money from drug and medical-device companies that could profit from deregulation. These companies include Burroughs Wellcome, Eli Lilly, Genzyme, Glaxo, Johnson & Johnson, Pfizer, Searle, Siemens, and Solvay. The companies we contacted refused to endorse any of the specific proposals being floated, but said they are interested in hearing the groups' ideas. One company, Merck, has said it opposes dismantling the FDA.

William B. Schultz

We're Not Dragging Our Feet on New Drugs

For years, critics have accused the Food and Drug Administration of moving at a glacial pace to approve new drugs, particularly when compared with its European counterparts. They have also argued that the agency's tardiness denies sick people lifesaving drugs. Neither claim is true.

Between 1970 and 1989, FDA drug approval times consistently between two and three years. In those years, the FDA typically took about one to two years longer than the fastest European countries. But were patients denied lifesaving drugs? Probably not.

The reason is that years ago the agency adopted a fast track for breakthrough drugs—drugs that treat diseases for which there is no other treatment, or that have significant advantages over the drugs already on the market. For example, in 1987 the FDA reviewed and approved AZT, the first drug for the treatment of AIDS, in 3½ months. Today, AIDS and cancer drugs for which adequate

data are presented are typically reviewed and approved in a year or less, sometimes much less.

During the late 1980s and early '90s, the FDA also greatly expanded opportunities for patients to gain access to investigational drugs for life-threatening illnesses for which no other therapy is available. As a result, since 1987, some 75,000 patients have received access to unapproved drugs while the drugs are being studied.

But what about other drugs that were commercially but not medically important? In the past, they were reviewed more slowly than in some foreign countries. This problem has been solved by the Prescription Drug User Fee Act of 1992, enacted under the bipartisan leadership of Sens. Kennedy and Hatch, and Reps. Waxman, Dingell and Bliley. That law requires drug companies to pay application fees that the FDA uses to hire additional drug reviewers and pay

other costs associated with review of drugs.

Under the user fee legislation, which the drug industry strongly supported, the FDA committed itself to several ambitious timeliness goals. By 1997 it will review 90 percent of drug applications within 12 months, and 90 percent of medically important drugs within six months. These represent review times that are so fast they would not have been considered realistic just a few years ago. Yet the evidence available demonstrates that the agency is well on its way to meeting these commitments.

As a result, the U.S. drug review process will, by 1997, be as fast as that of any country in the world. This will be accomplished without diminishing the public health protections the FDA has traditionally maintained.

Significant progress has already been made. During the first two years of the Clinton administration, drug approval times have fallen significantly. In 1994, the average time for

approving prescription drugs that are new chemicals was 20 months, down 33 percent from 1992. In 1994 the average approval time for drugs reviewed under the user fee program was 13 months. Breakthrough drugs were approved even more quickly.

The user fee program is changing the culture at the agency. Drug review deadlines, though ambitious, are realistic, and reviewers are beginning to get the resources they need. The drug industry is benefiting tremendously from earlier approvals because drugs get on the market earlier in the United States and approval here helps to get the product approved abroad. In 1994 more new chemical drugs were launched first in the United States than in any European country.

With FDA's new time frames, there is no longer any credible argument that high safety and efficacy drug approval standards must be weakened in order to get drugs to sick people.

Nonetheless, in fulfilling its funda-

mental public health mission, the FDA must continue to search for ways of eliminating any unnecessary burdens that FDA requirements impose on drug companies, as well as ways the agency could operate more efficiently. As part of Vice President Gore's initiative to reinvent government regulation, the agency will implement significant modifications of some of its requirements later this year.

In the coming months, proposals to radically change the FDA's drug review program will be debated. As we go through this process, it is essential to study the factual record and to keep in mind that the FDA is responsible for making the drug supply in this country the safest in the world. In search of greater efficiency, we should not damage what we already have.

The writer is deputy commissioner for policy at the Food and Drug Administration.

The F.D.A.'s Fear of the Future

By Henry I. Miller

5/25 PALO ALTO, Calif. **P**resident Clinton likes to be seen as a duck hunter, and even referred to his avocation in the State of the Union Message. Now, he should take aim at a regulatory turkey that has been given wing by his Food and Drug Administration.

A proposal under review at the Office of Management and Budget and the Department of Health and Human Services would require that foods derived from certain new plant varieties be registered with the F.D.A. before being sold to consumers. Extra Government scrutiny makes sense when there is uncertainty about health risks or a reason to suspect a problem such as the presence of toxins or allergenic components. But in this irrational proposal, the F.D.A. has decided to require registration only of foods made with the most precise state-of-the-art genetic techniques.

The regulation would confer no public-health advantage and would discourage research that could produce more nutritious, appetizing and varied foods. The inevitable result would be more limited choices for consumers at the supermarket or greengrocer.

For example, the new regulation would require registration of plants like the long-shelf-life tomato — a tomato engineered so as to reduce the enzyme that promotes ripening. But it would not require registration of a genetic hybrid between a commercial tomato and one of its relatives from

the deadly nightshade family, whose fruits are bitter and inedible because they contain potent neurotoxins. (The creation of such hybrids is a common technique for making commercial tomatoes more resistant to disease.)

The proposed regulation, in other words, is not concerned with risk or the traits of the fruit but only with whether new or old genetic techniques were used. One might well argue that the F.D.A. has gotten it backwards, regulating more stringently the more precise and predictable genetic constructions.

New biotechnology, which uses gene-splicing techniques to mimic

Its biotechnology rules would hurt consumers.

and speed up nature's own movement of genes between organisms, should have been freed of much of its excess regulatory red tape years ago. In 1989, the United States National Research Council, the parent organization of the National Academy of Sciences, concluded in a landmark report that new biotech-derived products were environmentally and medically safe.

The council said that with classical techniques of gene transfer a variable number of genes can be transferred but that predicting the precise numbers and kinds of traits that have been transferred is difficult. Moreover, with these older techniques one cannot always predict the behavior or composition of the resulting plant. With the new single-gene transfer

methods, the council added, one is in a significantly better position to make carefully tailored improvements in food plants.

The council also observed that for decades plant breeders have moved genes from one species or genus to another, transcending natural breeding boundaries. Products of this older form of genetic engineering include the oats, wheat, corn, tomatoes, turnips, potatoes, blackcurrants and pumpkins that we buy at the market.

The new policy reverses what for 15 years has been the guiding principle for the F.D.A.'s oversight of biotechnology: regulation should focus on real risks and should not turn on the use of one technique or another. That tenet has provided effective oversight for more than 1,000 new biotechnology products, including drugs, vaccines, diagnostic tests and foods. As recently as May 1982, the F.D.A. reiterated this policy, announcing that new biotechnology foods would be treated no differently from those produced with other techniques.

In several ways, the new policy would create disincentives to the use of the new technology. First, it would entail significant costs for the Government and industry and, therefore, for the public. Second, regulators would make endless demands for additional information, causing delay and uncertainty among manufacturers. Third, the mandatory notification would put every new genetically engineered product squarely in the sights of anti-biotech activists who oppose the basic concept. Manufacturers would have to face the likelihood of endless and expensive defenses against propagandistic attacks.

Fourth, the requirement to register a product with a Government agency would imply to many consumers that there was increased potential hazard. As the president of Consumer Alert, an advocacy group, has said: "For

obvious reasons, the consumer views the technologies that are most regulated to be the least safe ones. Heavy involvement by Government, no matter how well intended, inevitably sends the wrong signals. Rather than insuring confidence, it raises suspicion and doubt." Thus, retailers might be reluctant to offer these overregulated products.

One hears the argument that a little bit of unscientific regulation and unnecessary burden on product development really isn't such a big deal. There can't be anything wrong with "erring on the side of safety," right?

Wrong. Regulatory disincentives are potent. They can kill a technology and, along with it, all of the direct economic benefits and the enhanced living standards that new products can provide. This is especially true of food products, which yield far lower profit margins than, say, pharmaceuticals and whose retailers are sensitive to any public uncertainty about them.

The bottom line is that the policy will discourage research on more varied, appetizing and nutritious foods — research that has given us low-saturated-fat oils, seedless grapes, tangelos and the like. Consumers will thus be deprived of new choices.

The F.D.A. has long complained of inadequate resources for its primary missions of insuring the safety of food and pharmaceuticals and prosecuting the purveyors of snake-oil remedies. For that reason alone, the agency should be loath to seek out new and unnecessary responsibilities.

Unfortunately, it is in the nature of regulators to be overzealous. When he was F.D.A. Commissioner, Frank E. Young used to say that "dogs bark, cows moo and regulators regulate." All of which is true. But the regulations themselves should have intrinsic value and serve a larger public good. This one does not. □

Henry I. Miller is a fellow of scientific philosophy and public policy at the Hoover Institution at Stanford.

Conservative Group Seeks Privatization Of FDA Approvals

* * *

Proposal Would License Firms
To Review, Clear Drugs,
Limiting Agency's Veto

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — The Food and Drug Administration drug-approval process would be mostly privatized under a plan outlined by a think tank with close ties to House Speaker Newt Gingrich.

The Progress and Freedom Foundation's proposal calls on the FDA to license private entities to review and approve drugs, while retaining limited power to block unsafe or ineffective products.

In slashing the FDA's authority, the proposal is sure to draw the ire of consumer advocates. But it also drew an unenthusiastic response from a spokesman for the drug industry, whose own FDA-reform proposals are much more modest. "It isn't how we envision FDA reform," said Steve Berchem, a spokesman for the Pharmaceutical Research and Manufacturers of America. "The public has a great deal of confidence in the FDA's decisions about safety, and we don't want to shake that confidence."

The industry group supports having private groups do certain tasks conducted by the FDA — such as reviewing data when a drug company seeks to market an approved drug for additional uses.

Jeffrey Eisenach, president of the think tank, said yesterday that some big drug makers don't want to change the FDA much because it would increase competition in the industry. His group's proposal calls on the FDA to license private entities known as drug-certifying bodies or device-certifying bodies to run the approval process. The FDA, instead of being a

"certifier of products" would become a "certifier of certifiers," ensuring that the private entities uphold the agency's standards, he said.

FDA spokesman Jim O'Hara said the plan "would dismantle many of the safeguards this country has put in place to protect the public from drugs and devices that are either unsafe or don't work."

Mr. Eisenach is a former executive director of Mr. Gingrich's political-action committee, Gopac. He said yesterday that he hasn't briefed Mr. Gingrich, a critic of the FDA, on the recommendations.

Officials at Progress and Freedom say that about 10% to 15% of its contributions come from drug and medical-device makers. Donors include Genzyme Corp., Johnson & Johnson, Monsanto Co.'s Searle pharmaceutical unit and Glaxo Inc., a unit of Glaxo Wellcome PLC.

FDA: The Extremists Have It All Wrong

In the months since the November election, a consortium of far-right think tanks, lobbyists and public relations gurus have concocted a new mythology: the Food and Drug Administration, responsible for the safety of countless products used or consumed by Americans daily, is in fact an engine of death and unemployment. The message of their well-funded, multi-media advertising campaign is corrosive and blunt: "If a murderer kills you, it's homicide. If the FDA kills you, it's just being cautious."

The new mythology is being stoked by pseudo-facts and half-baked conjecture. And although rational observers can make reasonable criticisms of the FDA, the complete laundry list of complaints by these extremists reads like Grimms' Fairy Tales as rewritten by Stephen King.

Myth 1: The FDA drags its heels at the expense of dying Americans when entrepreneurs bring them experimental new drugs.

Fact: Patients can begin using an unapproved drug or device as soon as the manufacturer makes an investigational new drug (or device) application to the FDA. All the company typically has to do is present information that the drug or device is not inherently dangerous. The FDA and the maker of the product work together to assess the results. When the clinical evidence is solid, commercial distribution is usually approved.

For example, Eli Lilly and Co. received approval earlier this month for an anti-cancer drug under a new, accelerated decision process fashioned specifically for lifesaving products.

Myth 2: The FDA's bureaucracy-driven approval system kills jobs and softens America's competitive edge.

Fact: For small companies, the FDA certification of effectiveness is a guarantor of sales success at home and abroad. It provides small, undercapitalized firms that have tied their future to a single product with a Good Housekeeping seal of approval. Ask small manufacturers if their FDA approval helped them in overseas markets. Device sales alone have created a \$4.7 billion U.S. trade surplus.

Myth 3: The FDA approval process has kept scores of effective, lifesaving products off the market.

Fact: The agency process has kept many unsafe, ineffective and potentially dangerous products from U.S. consumers. In the case of the anti-cancer agent Interleukin 2, FDA trial requirements exposed significant safety problems that even the company eventually agreed were legitimate and reasonable.

In the case of the Sensor Pad, a device for detecting breast cancer tumors, FDA's critics suggested that the U.S. agency had been unreasonably tough while Canadian counterparts had let the device on the market there.

As it turns out, neither statement was correct. In yet another example, FDA's much-criticized approval process kept a new Alzheimer's drug off the market until investigators could figure out treatment methods that would not fatally damage patients' livers.

Myth 4: Industry and independent health experts overwhelmingly believe that a radical overhaul of FDA is warranted.

Fact: While few in the industry will argue FDA's perfection, most accept the fact that independent, unbiased and rigorous assessment of new products by the agency creates a gold standard necessary for global competitiveness.

Lisa Raines, vice president of government affairs for Genzyme Corp., says her company "is not interested in tearing FDA down" but wants to "take a good agency and make it better." Alan Magazine, president of the Health Industry Manufacturers Association, wants process reform, but adds, "I don't think that dismantling the FDA is in the best interests of citizens or the industry."

The American Heart Association, writing to the New York Times last month to protect the use of its name in an anti-FDA advertisement, stated "while we do not always agree with the FDA on particular issues, we believe it is committed to promoting and protecting the public's health."

Myth 5: The FDA's time-consuming, ever-

slowing, rope-a-dope approval system is creating huge backlogs and a stymied industry.

Fact: In some cases, the FDA process has been slow. But the numbers have improved dramatically over the past several years. Despite spurious claims to the contrary, the agency's evaluation time for breakthrough drugs has been cut by 51 percent in the past year alone—from 23.4 months to 12.2 months. The approval time for drugs deemed potentially lifesaving averaged 10.4 months. By 1997, the FDA expects that the approval time for breakthrough drugs, or for drugs with lifesaving potential, could be down to six months.

There's no agency on earth that can't be improved, and the FDA is no exception. Some devices and non-critical applications ought to be dropped from the regulatory system entirely. Requirements for early phase trials could be significantly reformed and streamlined as has been done in Europe. Entrepreneurs could save time and money if more of the agency's approval process were moved out of the Washington-based bureaucracy and into private, third-party reviews.

These and other ideas mark a path for constructive FDA reform. Alternative, myth-shrouded proposals being offered by the extremists would tear the fabric of the world's safest and most effective health care system.

The writer is a Democratic representative from Oregon.

Conservative Foes of Government Regulation Focus on the FDA

By John Schwartz
Washington Post Staff Writer

Conservatives hoping to redefine government's role have chosen the Food and Drug Administration and its commissioner, David A. Kessler, as symbols of regulatory excess, in effect hoping that Kessler will do for them what former interior secretary James G. Watt did for the Sierra Club.

A recent newspaper advertisement by the Washington Legal Foundation said, "If a murderer kills you, it's homicide. If a drunk driver kills you, it's manslaughter. If the FDA kills you, it's just being cautious."

With Republicans taking control of Congress, opponents of regulation are finding that they have powerful friends. House Speaker Newt Gingrich (R-Ga.) has taken aim at the FDA, claiming that it needs a thorough restructuring. He has called the agency "the leading job-killer in America." Gingrich also has been quoted as calling the bespectacled Kessler, a Bush administration holdover, "a thug and a bully." Next week, a House subcommittee will take up a bill that would impose a six-month moratorium on federal regulation, stopping many FDA initiatives in their tracks.

Several conservative organizations and industry groups are polishing proposals for FDA reform. The Cato Institute, the Progress and Freedom Foundation, Citizens for a Sound Economy and the American Enterprise Institute all have the agency in their sights.

Agency officials contend that their best strategy for dealing with the impending attack is to present their record of achievement and improvement. "The best defense for the agency is to do its job," FDA spokesman Jim O'Hara said. "In some in-



DAVID A. KESSLER

... faces GOP moratorium on rules

stances, the critics are sort of shooting at a ghost of FDA past. In other instances, they're simply shooting at ghosts."

Though the vehemence is new, complaints about the agency are not, predating Kessler's 1990 arrival at the Rockville-based agency. Industry executives and physicians long have contended that delays in approving products are crippling companies, driving them overseas, and harming patients who cannot get life-saving devices that are available in other countries. Some conservatives argue that the cost of regulation outweighs the marginal gains in product safety that it provides.

Kessler's zeal has made the FDA one of the most active agencies in the Clinton administration, and with more initiatives comes more criticism.

Changes during his tenure include new rules to keep AIDS and other diseases out of blood and tissue banks, and improved food safety programs. His FDA has brought out new food labels and a simplified system for reporting side effects and problems with drugs and medical devices.

Kessler also launched a moratorium on the use of silicone breast implants until they could be proved safe and worked to broker the entry of the French "morning after" pill, RU-486, into the U.S. drug approval process. He has pursued a major investigation of tobacco company practices and could end up attempting to regulate that politically powerful industry.

At the same time, the FDA has worked to streamline its activities. In the past year, the agency has reduced its backlog of thousands of device applications to a few hundred. It also made progress on drug approvals: In 1994, the FDA cut the median approval time for new drugs to 19 months, 21 percent shorter than the year before.

But Steve Berchem, spokesman for the leading trade group, the Pharmaceutical Research and Manufacturers of America, said that the FDA approval of 85 new drugs last year—including 23 that work in ways different from existing medicines—was inadequate. Although "the evidence is clear that the drug approval time is improving," Berchem said, "it's still taking so long, and why are there so few?"

Now come the reformers, riding a wave of antiregulatory sentiment in the 104th Congress. The FDA has become the focus of a range of plans.

The Health Industry Manufacturers Association (HIMA), the leading trade group for the medical device industry, is working on a plan to speed up device approvals by channeling many reviews through government-certified

bodies, a move that one HIMA official called "semiprivatizing" the agency. Another group would go farther: the Progress and Freedom Foundation, a Gingrich-affiliated think tank, would replace the FDA with an agency designed to put industry executives in charge of product approvals.

Going farther still, the Competitive Enterprise Institute would allow companies to bring products to market that the FDA has not approved. Unapproved drugs and devices would bear a warning of their status; the decision to use them would be up to doctors and patients.

Other reform efforts might focus on the current legal requirement that new drugs and devices be proved not just safe, but effective as well. Compa-

nies complain that proving efficacy adds tremendously to their regulatory burden. (The standard was added to the FDA's mandate in 1962 in the wake of the Thalidomide tragedy.)

But even those who have complaints about the FDA worry that some of the reform plans, if enacted, could do more harm than good. "It's in the best interests of the American public and of patients and of our industry to have a strong, reliable FDA," said HIMA president Alan H. Magazine. "The hallmark of real reform is to look carefully at the institution you're dealing with and articulate a mission, a direction, a responsibility. That kind of analysis doesn't lend itself to sound bites."

Consumer advocates say that the

antiregulatory movement could lead to a proliferation of hazardous products. Sidney M. Wolfe, executive director of the Public Citizen Health Research Group and a longtime FDA critic, said Americans want their drugs safe and that any attempt to weaken the regulatory safety net "will meet with a significant amount of opposition."

One industry official worried that extreme reform plans could spell trouble for more moderate and workable efforts. "Reaction to those kind of ideas will drown out the good, solid reform ideas," he said.

Magazine agreed: "When we talk about reform, we've got to be responsible—and we've got to put patients first."