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TRANSMISSION RECORD

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MESSAGE:

Information on Transatlantic Business Dialogue Conference per
telcon with Linda Horton.

FACT SHEET:**TRANSATLANTIC BUSINESS DIALOGUE CONFERENCE
SEVILLE, SPAIN
NOVEMBER 10-11, 1995**

- o In an unprecedented step, the U.S. and European governments have agreed to work jointly with the American and European business communities to obtain a business-driven view of what initiatives should be launched to improve transatlantic trade and investment. Over half of the global sales of U.S. foreign affiliates are in Europe, and American business has a vital stake in designing the future of the U.S. - European commercial relationship.
- o November 10-11, in Seville, Spain, approximately one hundred or more U.S. and European CEO's leaders will meet with top government officials in the Transatlantic Business Dialogue (TABD) Conference to develop a vision and agenda for setting the priorities for removing remaining obstacles to trade and investment across the Atlantic.
- o Xerox CEO Paul Allaire, Ford CEO Alexander Trotman, and Secretary of Commerce Ron Brown will be the U.S. co-chairs; and the European co-chairs will be Philips CEO Jan Timmer, European Commission Vice President Sir Leon Brittan, and Commissioner Martin Bangemann. BASF Chairman Jurgen Strabo and other leading European CEO's are also actively supporting the TABD conference in Seville.
- o Because of strong business interest in seeking how to reduce the costs of complying with different U.S. and European standards and regulatory regimes, FCC Chairman Reed Hundt, heads of other U.S. regulatory agencies, and their European counterparts will participate directly in the conference.
- o The conference's conclusions will play an essential role in defining U.S. and European priorities in transatlantic commerce, and will help define the business community's recommendations to the December Summit meeting between President Clinton, European Union President Felipe Gonzalez, and European Commission President Santer in setting the U.S.-European action agenda for the 21st century.
- o This is not a "discussion conference", but one that is going to develop an action agenda that will have a major impact on the steps that will change the governmental environment affecting business across the Atlantic.

- o Participation will be by invitation of the co-chairs. All CEO's will have a direct role in developing the conclusions and recommendations that will come out of the conference, and will be asked to participate on one of four Working Groups where, along with their European CEO counterparts, they will develop recommendations and priorities. The four Working Groups cover the areas business identified as most important to the future:
 1. Standards, Testing/Certification, and Regulatory Climate;
 2. Trade Liberalization;
 3. Investment Climate, and;
 4. Cooperation in Third Countries.

- o Secretary Brown, Vice President Brittan, and Commissioner Bangemann solicited ideas for the dialogue from the transatlantic business community in April when they sent letters to about 1800 U.S. and European businesses. Initial responses to the April letter were distilled in meetings with business representatives in Washington and Brussels in June and July. A business-government steering committee was created, chaired by the U.S. and European business co-chairs, to shape the conference.

- o The conference will begin the evening of Friday, November 10, and will conclude the evening of Saturday, November 11. The Conference will be hosted by the Spanish government, which will bear all costs other than transportation and lodging.

- o For further information on participating in the conference, or questions concerning the working groups contact Marie Geiger at (202-482-6418), fax (202-482-2155).

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THE TRANSATLANTIC BUSINESS DIALOGUE

U.S. WORKING GROUP PAPER I: Standards, Certification & Regulatory Policy

(DRAFT)

AS OF: 23 OCTOBER 1995 (am)

**WORKING GROUP I
STANDARDS, CERTIFICATION & REGULATORY POLICY**

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- Telecommunications
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I INTRODUCTION

Streamlining regulatory requirements and eliminating duplicative certification procedures in the United States (US) and the European Union (EU) would significantly lower costs to business and consumers and remove barriers to bilateral trade. It is estimated, for example, that eliminating non-tariff barriers to global trade would raise Gross Domestic Product (GDP) by several percentage points in the EU and US.

Testing and certification rules affect \$1.7 trillion in two-way trade between the EU and the US. For US producers, over \$66 billion in exports are subject to certification regulations in the EU. Bold reform in standards, and regulatory policy could prove to be one of the strongest engines of increased trade and economic growth into the next century. In many industries, including automobiles, information technology, telecommunications, and medical devices, duplicative requirements exist. Government must move aggressively to remove these costly regulatory barriers to economic efficiency and trade.

We propose a set of concrete recommendations to achieve this goal. Adoption of these recommendations by government could result in significant reduction in costs to consumers and industry by the year 2000. The guiding principle upon which progress will be achieved is acceptance of the "tested once, accepted everywhere," doctrine for trade in goods.

II. GUIDING PRINCIPLES

Recommendation I.1: Recommendation to government by industry regarding standards and technical regulations should be based on the following principles:

I.1a: Initiatives Must Be Consistent with Multilateral Liberalization Efforts

Any future EU-US talks on standards and regulatory reform must be based on principles of open trade, as reflected in multilateral rules and disciplines in the WTO and the Technical Barriers to Trade Agreement.

I.1b: Manufacturer's Declaration as the Model

A key guiding principle for reform in standards and technical requirements centers on the reliance on manufacturer's declaration of conformity to technical regulations set by government.

I.1c: "Tested Once, Accepted Everywhere" Around the Globe

The overall goal of any reform effort in standards and certification should be a one-test, one-certification system whereby products tested anywhere are provided access to markets throughout the world.

To the extent practical, technical requirements should be global. These systems should not be driven by government, but rely on private organizations for testing, certification, and laboratory accreditation. Government's role should be limited to national-level recognition of the competence of these private actors.

I.1d: Private Sector Leadership in Standards Development

The private sector, not government, must drive standards development. We should not seek to establish government programs where there is no compelling need for oversight or control.

I.1e: Equal Access to Standards Systems

National treatment and non-discrimination are the foundations of efficient, modern standards systems. Standards development organizations, and the procedures that drive these bodies must therefore be open to all participants in the EU and US. Equal access and participation by directly affected interests ensures continued economic advancement in both the EU and US.

1.1f: Reliance on performance-based standards

Technical regulations set by government should rely, except in extreme cases of critical public interest, rely on performance standards, and not design specifications or product-specific standards.

III. POLICY ISSUES AND RECOMMENDATIONS

HARMONIZATION

Global trade requires the use of global product standards. The use of product standards from the International Standards Organization and the International Electromechanical Commission will facilitate the expansion of global markets for goods and services.

Recommendation 1.2: The EU and US should encourage the adoption of voluntary international product standards published by ISO and the IEC, where appropriate and supported by industry. The use of international standards in the regulatory and procurement activities of government should be promoted.

PARTICIPATION IN STANDARDS DEVELOPMENT

The American National Standards Institute (ANSI) receives CEN, CENELEC, and ETSI standards only for comment. The U.S. lacks direct access to the European standards system. The EU should open European standards organizations to countries outside Europe on the basis of reciprocity. Open standards systems in Europe would improve economic efficiency and facilitate U.S.-EU trade.

Recommendation 1.3: Standards development organizations and the procedures which drive these bodies must be open to all participants in the EU and US. CEN, CENELEC, and ETSI should extend membership to non-EU standard-setting bodies on the basis of reciprocity.

MANUFACTURER'S DECLARATION

Manufacturers declaration of conformity to standards and technical regulations is efficient, cost effective, and serves to protect public health, safety, and the environment. There is evidence, however, of an increase in mandatory third-party testing and certification rules by government. These rules increase costs to business without any value to consumers.

Recommendation 1.4: Efforts to streamline testing and certification rules must be based primarily on the manufacturer's declaration of conformity to technical regulations. For example, industry should lead in creating a global framework for conformity to ISO 9000 requirements. This system should allow multiple options for demonstrating compliance to the standard, including the Supplier Audit Confirmation Article.

CONFORMITY ASSESSMENT

National regulations which set testing and certification rules often differ across international boundaries. These regulations embody the most serious non-tariff barriers to transatlantic trade. The WTO Technical Barriers to Trade (TBT) Agreement requires the adoption of the least trade restrictive regulatory solutions. Many Member States of the EU, for example, maintain differing certification requirements for similar products. Moreover, the EU does not allow foreign certification organizations to serve as "notified bodies" to test and certify to European requirements for the CE mark which is affixed to regulated products.

Recommendation I.5: The government role in the U.S. and EU in conformity assessment should be limited to recognition of private-sector testing laboratories, and product certifiers. Moreover, government should aggressively move to eliminate duplication in national conformity assessment requirements. As part of these reforms, the EU must extend full national treatment to foreign certification organizations and permit organizations in the US to become "notified bodies."

ENVIRONMENTAL AND QUALITY MANAGEMENT SYSTEM STANDARDS

Various management systems standards, though "voluntary," have become -- or are about to become -- de facto requirements for doing business due to both customer demands and public and private procurement. These standards include the ISO 9000 series for quality management systems, the ISO 14000 series for environmental management systems, and the potential for health, safety, and labor management systems standards. The EU implemented a regulation in April 1995 establishing an Eco-Management and Audit Scheme, which is a voluntary program designed to promote continual improvement in environmental management and performance. The complexity of the various standards, cost, third party certification, compliance and enforcement aspects are of enormous concern to industry on both sides of the Atlantic. The failure of major industrial sectors to accept universal standards for environmental and quality management or the adoption of standards for sector-specific management systems will necessitate multiple registrations that, in addition to significant increases in cost to the consumer, will create transatlantic structural impediments to increased trade.

Recommendation I.6: The U.S. and EU government must help to ensure universal acceptance of international management system standards. Efforts to develop sector-specific programs by government for ISO 9000 and ISO 14000 should be opposed. The draft ISO 14000 series of international environmental standards should be recognized as satisfying the technical requirements for the EU Eco-Management and Audit Scheme. Finally, government should not seek to establish sector specific standards for health, safety, and labor management systems.

IV. SHORT-TERM RECOMMENDATIONS

Completion of Mutual Recognition Agreements (MRAs) in Regulated Product Sectors

Recommendation I.11: *The EU-US agenda for reform must focus on product testing and certification rules in regulated product markets where government exercises control. This is where most of the barriers to economic efficiency and trade exist. Full and complete MRAs must embody the principle "tested once, accepted everywhere" in the EU and US.*

The EU and US have been negotiating MRAs in medical devices, automobile regulatory and safety requirements, telecommunications terminal equipment, information technology products, and other sectors for several years. It is likely that only extremely limited progress will be achieved. Full MRAs in these and other sectors proposed by industry should be concluded before January 1, 1997.

Establishment of a Transatlantic Advisory Committee on Standards and Regulatory Reform

Successful talks on economic and trade relations between the EU and US require on-going participation by senior industry representatives on both sides of the Atlantic.

Recommendation I.12: *At the December 1995 EU-US Summit, government leaders should announce the creation of a Transatlantic Advisory Committee on Standards and Regulatory Reform, comprised of government and industry representatives. The advisory committee would help guide progress on achieving reform in these areas and monitor progress in reaching the goals and timetable set out in this report. The committee would provide expert advice, analysis, and recommendations on a detailed action plan for government.*

Political Commitment to Reform at the Summit

Recommendation I.13: *US President Clinton, European Commission President Santer, and European Council President Gonzalez should issue a statement of priority action on reform in standards, certification, and regulatory policy. This statement will signal a long-term commitment at the highest levels of government to concrete reform in these areas. This commitment must be transparent and transmitted to the responsible officials in both regions.*

MEDICAL DEVICES

Recommendation 1.20: *As a short term goal, the EU and US should conclude a mutual recognition agreement (MRA) for medical devices for both inspections and approvals within a year of the start of any new set of bilateral MRA talks. As part of this goal, government in both the U.S. and EU must commit to meaningful regulatory reform before an MRA can be concluded. By April 1996, the US FDA and EU Commission must report on progress in reaching an MRA in the medical device sector.*

A commitment to take concrete steps to reduce barriers to trade and regulatory redundancy can provide a strong impetus for regulatory reform by government. This commitment is essential to fostering greater EU-US regulatory cooperation in medical devices. The US is also interested in demonstrating its ability to address, as part of its new Trade Barriers Project, the trade barriers of greatest concern to US industry.

For US companies, an MRA for medical devices would help to ensure timely access to the European marketplace by providing for EU acceptance of inspections and approvals carried out by US certification bodies – and vice versa for European firms seeking to enter the US market. In addition, by helping to foster harmonization of key regulatory requirements, an MRA could provide significant regulatory savings for both governments and industry in these countries.

Recommendation 1.20a: *Given the potential benefits that such agreements offer in terms of market access and regulatory savings, the medical device industry strongly encourages EU and US officials to conclude an MRA for medical devices for both inspections and approvals.*

Greater EU-US regulatory cooperation, including an MRA, can reduce regulatory redundancy and unnecessary regulatory barriers to trade. Action to reform FDA would not only promote greater EU-US economic cooperation and growth, it would also stem the massive outward migration of US medical device companies and jobs to other countries.

Recommendation 1.20b: *Government regulators in the U.S. and EU must commit to meaningful regulatory reform before an MRA can be concluded in the medical device sector.*

MRA discussions could also reinforce efforts to reform regulatory processes, including greater use of third-party reviewers in device review and inspection activities. An MRA agreement would reinforce the precedent for government reliance on third-party organizations, for example through FDA acceptance of inspections, tests and reviews carried out by EU bodies. Moreover, it would provide the US with greater experience in working with third parties, as well as with EU regulatory officials, and thus help build mutual confidence in such an approach.

Recommendation 1.20c: *As part of comprehensive regulatory reform, government in the U.S. and Europe should make greater use of third-party reviewers in both device review and inspection activities.*

US and EU officials should seek to put the MRA negotiations for medical devices on a faster "track."

Recommendation 1.20d: *The agreement should initially cover Good Manufacturing Practices (GMP)/quality system inspections and approvals of lower-risk devices. Once experience has been gained under such an agreement, US and EU officials and industry could determine whether the agreement should be broadened to include higher risk (e.g., Class III) devices.*

Emerging markets establishing regulatory systems for medical devices need to develop systems that provide for timely patient access to life-saving medical technologies. Key elements of the regulatory model that should be encouraged include the use of international standards, quality systems approaches, and the acceptance of tests and certificates from other countries, so that products do not have to go through redundant inspections and/or approvals in each market. Such an approach can provide efficiencies and savings for regulatory officials and industry alike, while at the same time ensuring the safety and quality of the more than 85,000 medical devices in world trade.

Recommendation 1.20e: *EU and US officials should encourage health care officials in emerging markets to rely on internationally-accepted approaches when regulating medical devices. This includes reliance on international standards and the acceptance of certificates and approvals from other countries. [INT'L FORUM***]*

By helping to foster harmonization of key regulatory requirements, an MRA agreement could provide significant regulatory savings for both governments and industry alike.

Recommendation 1.20f: *A requirement for harmonization or equivalence of standards or conformity assessment in medical devices as a pre-condition to mutual recognition of approvals, should be rejected. Government should recognize that product safety can be demonstrated in many different and legitimate ways.*

PHARMACEUTICALS

Recommendation 1.21: *The Member States of the EU should abandon drug price regulation. Parallel trade, which spreads the distortion of competition caused by Member States' price*

The EU is actively negotiating and concluding new association agreements with future EU members. These potential new members are the new democracies of central and eastern Europe and Baltic States, which are now recognizing the need to adopt adequate intellectual property (IP) rights locally. The concern is that these new agreements lack any reference to a transitional period which would protect existing IP rights within the EU until such time as new local IP laws take practical effect.

Recommendation I.21c: Future EU association and accession agreements should provide protection against parallel trade for patented products until such times as local IP laws take practical effect - which would be on average 10 years from the date that IP protection is recognized locally.

There are a number of steps that the FDA could take to further re-engineer its regulatory procedures to meet the demands of the 21st century.

It takes too long to develop and gain approval of new medicines. The process took 8.1 years on average in the 1960s - and now it takes almost 15 years. The cost of discovering and developing a new drug likewise has soared. It cost \$54 million on average to develop a new drug in 1976, \$231 million in 1987, and \$359 million in 1990. The increasing length and cost of drug development represent a rising barrier to continuing pharmaceutical innovation.

Although the US has long led the world in discovering new drugs, many new medicines are introduced in other countries before they are made available to American patients. More than 60 percent of the new drugs and biologics approved by the FDA during 1990-1994 were first approved in another country - and 40 of the 92 new therapies approved elsewhere were considered important by the FDA. Currently, more than 40 drugs already approved abroad are still in development in the US or are awaiting approval at the FDA.

Recommendation I.21d: Relevant regulatory officials in the U.S. and Europe should be required to approve safe and effective new medicines quickly.

- The FDA should use summary data in the drug development and approval process, as is the practice in the UK and other European countries, with all supporting data available to the agency when necessary. In addition, the FDA should use expert external reviewers whenever it is efficient to review all or parts of new-drug applications.***
- The FDA should be required to expedite the review of new-drug applications for products that have been approved in the UK, European Medicines Evaluation Agency (EMEA) or are designated for serious and life threatening conditions.***

- *The FDA should allow for the wider dissemination of important scientific and health-economics information.*

TELECOMMUNICATIONS

Recommendation I.22: Due to the fast-paced changes throughout the world in the telecommunications sector, the EU and US must quickly reach an appropriate agreement in the pending WTO negotiations. When the world's two largest trading regions finally do reach agreement, the rest of the WTO parties will be strongly encouraged to join in the Basic Telecommunications Agreement.

Traditionally, the EU telecommunications sector has been dominated by large public monopolies in each Member State. Ongoing global competitive pressures and technological changes are now forcing these incumbent telecommunications operators (TO) to restructure and compete. For example, the EU has committed to open up public switched voice services to competition by January 1998. US companies want the opportunity to compete throughout the EU market on a level playing field.

Recommendation I.22a: US and EU firms should have the freedom to offer basic telecommunications services under commercially viable terms and conditions, including facilities-based offerings (i.e., resale as well as the ability to build, own and operate physical networks.) This market access should include the rights of establishment and non establishment, and no limitations on the number or types of competitors or the types of services offered.

In the ongoing WTO negotiations, as well as in pending US telecom legislation, there have been considerable discussions about national treatment and foreign ownership restrictions. In today's global world of telecommunications, such restrictions are becoming increasingly irrelevant. Telecommunications is increasingly a global business, as is the business of the customers of telecommunications service providers. The ability of service providers to provide those customers with international and in-country service on an end-to-end basis and their ability to obtain fair and open access to foreign markets is critical for their competitiveness.

Recommendation I.22b: There should be no restrictions on US or EU firms' foreign investment or foreign ownership. US and EU firms should have the ability to access the market and operate under the same terms and conditions as national competitors in that market.

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NUMBER OF PAGES W/O FAX COVER: *1*

COMMENTS: *as requested*

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Proposed Policy offered by
Governor Arne H. Carlson

FACILITATING INNOVATION FOR MEDICAL DEVICES AND DRUG RESEARCH

Better health care for all Americans is a paramount national goal. The key to improved health care, especially for persons with serious unmet medical needs, is the rapid development and approval of safe and effective new medical technology. Innovative private sector firms in the medical technology industry have research underway that could revolutionize the practice of medicine. There are new therapies derived from medical technology that will improve the lives of millions of Americans and provide reduced health care costs in many instances.

Minimizing delays between the creation and eventual approval of a new product derived from the genius of medical technology is an important public health goal. Reduction of the development time will reduce the cost of new medical technology products and thus free up needed capital for new research and cures. ~~the~~ excessive and unnecessary regulation of products increases the costs to companies of developing such products which is ultimately paid by the consuming public.

including

~~Fundamental reengineering of the Food and Drug Administration is necessary to facilitate better and more rapid access to new therapies and cures.~~ ^{should} ~~and should include~~ the rapid review and approval of innovative new drugs, biological products, and devices as well as preserving the safety of the public. Public confidence in the safety and efficacy of medical technology can be maintained while making changes in the law to speed medical discoveries from the bench to the bedside.

The competitiveness of the United States biotechnology industry is dependent on relief from outdated and antiquated export laws which encourage companies to locate manufacturing facilities outside of the United States. These laws no longer serve any meaningful public health purpose. ~~Regulatory delays are forcing~~ ^{regulatory delays} United States companies to move their innovation overseas to countries which have regulatory systems, ~~more consistent with the rapid pace of innovation.~~ ^{speedier}

one of a number of factors entering

The exclusive reliance on government employees to perform all of the functions associated with the review of new drugs, biological products, and devices by the Food and Drug Administration ~~is unnecessarily expensive and has resulted in increasing~~ ^{may} times for approvals relative to other developed countries.

The National Governors' Association encourages Congress to ~~make~~ ^{review the laws} ~~fundamental revisions~~ in the Food and Drug Administration, including consideration of third party review, ~~as practiced in Europe.~~ ^{implement} ~~This would improve~~ health care overall for consumers and maintain the excellence of medical innovation in the United States. ^{by}

consistent with improving

duplicate

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TODAYS DATE: *July 26, 1995*

THIS FAX IS FOR: *Chris Jennings*

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FROM: *Bill Hubbard*

NUMBER OF PAGES W/O FAX COVER: *15*

COMMENTS: *Next REGO initiatives*

July 26, 1995

NOTE TO CHRIS JENNINGS

Subject: Next REGO report on drugs/biologics/devices

You asked where we are on the next report. We have a number of new items, both significant and "minor but helpful." Here's a brief rundown:

- o Four initiatives on devices, mostly management improvements, but things done earlier for drugs that were well received by industry (e.g., letting manufacturers submit applications electronically rather than via large written applications).
- o A few new drugs items, such as reform of the IND process (to answer concerns that firms are sending investigations overseas). Also, we need to make a cut on the earlier generic drugs proposal to the V.P. (we have done the "scream memo he requested).
- o Several biologics things that further address the BIO concerns, such as relaxation of lot release requirements, reform of "clinical holds" that stop drug testing, a consolidated license application, changes in the controversial "ELA" requirements, and relaxation of advertising requirements.
- o We're also looking seriously at an enforcement initiative that test, beginning with device firms, the concept of allowing firms with a good record to be inspected by private consultants. This responds to the VP's request for policies giving easier treatment to "good actors."

Attached are some of the written "issue papers" that will go into the next report. Because many of the most significant issues are biotech-related, we could make that the focus. Also, we could issue a separate "biotech report" that would capture all of the things we've done in that area during the Clinton Administration. These attached issue papers have been cleared "in-house" but have not been cleared by HHS. Therefore, they should be considered to be in draft form. Assuming that the clearance process goes smoothly, we are optimistic that we could have a report produced in August.



Bill Hubbard

Enclosure

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FOR NEW MEDICAL DEVICES**

Problem: Medical devices are approved for marketing in two ways: (1) new devices and certain older devices must be tested to demonstrate safety and effectiveness, with the resulting data submitted to FDA in a comprehensive Premarketing Approval (PMA) application; and (2) devices "substantially equivalent" to ones already marketed are reviewed by FDA via a premarket notification (also known as a "510k").

The manufacturer of a truly innovative device, such as the first implantable defibrillator or bone growth stimulator, is required to obtain market approval through the more extensive PMA process. Other products presenting significant risk, such as heart valves, pacemakers, and shunts, also require PMA review.

The overall timeliness of the review process for PMA's needs significant improvement. The statutory direction is for FDA to review PMAs in 180 days. During FY 94, an average of 31 percent of PMAs were more than 180 days since the agency had taken action on them in the current review cycle. The median FDA review time for PMAs, totaled over all review cycles, was 23 months.

Proposal and Justification: Institute a project management system for the PMA review process.

Project management is a process of prospectively planning, organizing, and managing work to accomplish defined objectives that have pre-established time and resource constraints. Such a system divides the review of an application into a series of manageable tasks, schedules the tasks, and then tracks completion of tasks as the review process progresses. The initiative is aimed at better utilization of our resources and increased timeliness of final decisions.

Impact: This initiative aims to provide companies with more predictable timeframes for FDA decisionmaking on PMAs. As a result, companies will be able to make better business decisions in planning for the manufacture and marketing of new products.

The project management system is also expected to result in quicker reviews of PMAs. The goals are for all PMAs with project management to have an agency action within 180 days; that is, none will be overdue on the current cycle. Project-managed high-priority PMAs will have median total FDA review times of 15 months or less and all project managed applications will have a median of 18 months or less total FDA review time to final action.

This will bring innovative products more rapidly to patients. It will also increase the effective patent lives of new products and will thus result in increased industry competitiveness. Lastly, the new management system will bring better utilization of FDA

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resources.

Implementation and Timeline: FDA will test a pilot PMA management system in two PMA review divisions during 1995. Following validation of the models and software used in the pilot, the agency will broaden project management for PMAs across additional review divisions by the end of 1995.

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**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
INTEGRATION OF DESIGN FACTORS INTO DEVICE QUALITY SYSTEMS**

Description: A 1980's study on recall of medical devices for defects that posed serious public health risks showed that roughly one half of these recalls were due to faulty design, and the other half to the failure to understand and comply with current good manufacturing practice regulations for devices (CGMPs). The Safe Medical Devices Act (SMDA) of 1990 authorized FDA to require pre-production design validation controls for devices under its CGMP regulations. Consistent with the SMDA authorization, and in an effort to harmonize more closely with evolving European standards, FDA published a proposed rule in 1993 that would amend its CGMP regulations to include preproduction design validation controls. Public comments received on the proposed rule included criticisms that some of the proposed design controls were not clear, and others were unnecessarily inflexible. In addition, FDA received comments criticizing the proposed new requirements for not harmonizing sufficiently with international device quality standards.

Proposal and Justification: In response to these criticisms, FDA will publish for additional public comment either a tentative final regulation, or a Notice of Availability of a "Working Draft," that eliminates any unnecessarily prescriptive requirements and clarifies the proposed design control requirements. The revision will also contain a number of other changes intended to simplify, streamline, and increase the flexibility of the overall device CGMP requirements and would transform the device CGMPs into a total quality system that is largely compatible with the specifications contained in international quality standards, ISO 9001, "Quality Systems-- Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," revision of 1994.

Impact: Medical device recalls are costly to the public health in terms of the accidents and injuries that prompt them and damaging to the industry in terms of their actual cost and the lost income and litigation that result. By addressing what have been shown to be the two major sources of device recall, the proposed quality system requirements can be expected to result in devices that are better designed, safer to use, and subject to fewer recalls. This in turn means significant public health protection, significant savings to industry, and increased consumer confidence in devices. The compatibility of the quality system requirements with international quality standards will provide additional benefit to American manufacturers by facilitating the international marketing of their devices.

Implementation and Timeframe: In accordance with SMDA, this rulemaking will be the subject of discussion before a public advisory committee scheduled for September 1995. FDA's goal is to publish the tentative final rule or working draft notice by mid-July, hold a public/industry workshop in late August to

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obtain early input and focus the issues for the advisory committee, and hold a public advisory committee meeting in mid-September. Following a public comment period, the agency will review comments received and consider them, along with any advisory committee recommendations, in preparing a final regulation.

DRAFT**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
INTERACTIVE APPROACH TO INVESTIGATIONAL APPLICATIONS**

Description: In order to conduct a clinical study of a medical device that poses a significant risk, a sponsor must submit to FDA's Center for Devices and Radiological Health an application for an investigational device exemption (IDE). FDA may also determine independently that an IDE is required for a clinical investigation and notify the sponsor. An IDE must include thorough information on the device, the risks it poses, and the proposed study, as well as a comprehensive summary of all prior clinical, animal, and laboratory testing of the device. Recent FDA statistics indicate that a disproportionately high percentage of IDEs received by FDA fail to meet these requirements in some way and must be returned to the sponsor for additional work at least once after review has begun. This situation is time-consuming, frustrating to sponsors, and can delay the testing and eventual marketing of new devices.

Proposal and Justification: In order to clarify specific IDE regulations and requirements to sponsors, FDA will encourage sponsors to come in for "pre-IDE" meetings at which relevant guidance documents will be provided. To improve communication between sponsors and FDA reviewers, once an IDE is submitted, reviewers will contact sponsors more frequently to discuss deficiencies in applications, so that these problems may be satisfied in fewer review cycles. If the completed review shows that an IDE is lacking important information to support the initiation of a pivotal clinical trial, FDA will consider allowing a feasibility/pilot study to be undertaken if the study can provide investigators needed experience with the device; help define clinical endpoints, success/failure criteria, and intended patient population; or help address safety concerns. FDA's goal is to improve the IDE program in four ways: (1) improve the overall quality of IDE submissions; (2) increase the approval rate for original IDEs; (3) reduce the number of times IDEs are recycled for additional work; (4) reduce the total review time for IDEs.

Impact: These policies can be expected to impact favorably on industry, the FDA review process, and the public health. Improved understanding of IDE requirements by sponsors and better communication between sponsors and reviewers should significantly shorten the time required for preparation and review of IDEs and, ultimately, the time required for bringing important new devices to market.

Implementation and Timeline: FDA has begun to implement the new policies with staff and outline them in a letter that will be sent to regulatory affairs officials throughout the industry within the next 8 weeks. FDA will also put in place a system to track and evaluate pre-IDE interactions with device firms.

DRAFT**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
ELECTRONIC SUBMISSION OF MEDICAL DEVICE APPLICATIONS**

Description: The current processes for preparation and transmission to FDA of marketing applications for medical devices by manufacturers, and for receipt of and accessing these applications by FDA reviewers, are paper-intensive. As a result, these applications, which may be many pages long, are more time-consuming to prepare, more costly to ship, and more unwieldy to review than would be the case if they could be transmitted in electronic form. FDA has conducted a pilot study, in two phases, of the review of two premarket approval application (PMA) supplements that were submitted on disk cartridges. Problems in document translation and electronic communications with sponsors that were identified in the first phase were addressed in the second phase through use of different software and encryption of sensitive material so that it could be communicated on the Internet.

Proposal and Justification: On the basis of the pilot study, FDA is satisfied that it has identified a feasible methodology for the electronic submission and review of medical device applications. This is not yet an optimal system, but is sufficiently promising that FDA believes an efficient system can be developed over time. The agency will offer to work with medical device manufacturers who are interested in submitting their PMAs in electronic form.

Impact: FDA believes it will be possible, once the system has evolved in terms of efficiency, for both manufacturers and the agency to realize significant savings on paper record generation, and on the storage and retrieval of applications that are transmitted electronically. There should also be significant savings in time spent on both application preparation and review.

Implementation and Timeframe: FDA is already providing medical device reviewers with the training needed to access and work with applications submitted in electronic form, and to communicate with manufacturers on questions that arise during review. The agency is also changing document control procedures in the Center for Devices and Radiological Health to adapt to electronic submission of all types of device applications and will issue detailed guidelines for this process in the next few months.

DRAFT**REVISION OF LOT RELEASE REQUIREMENTS FOR
BIOLOGICAL PRODUCTS**

Background: Biological products have traditionally been complex mixtures of substances produced from living organisms. They include vaccines, products made from human or animal blood, and a variety of materials extracted from living organisms that have been difficult to define by precise tests. Because of the inherent variability of these products, most biological product lots are evaluated and sometimes tested by FDA before being released for marketing by a company.

The lot release requirement has served an appropriate role in the regulation of biological products and has prevented the release of unacceptable lots in the past. Currently, greater control by manufacturers over the production of biological products, genetic engineering, and recent advances in analytical techniques have resulted in a greater ability to evaluate a product by testing it at the end of production. However, biological products are still made from living systems and are therefore unavoidably heterogeneous to some degree. Significant limitations still remain in our ability to completely characterize most biological products.

Proposal and Justification: The FDA will not require agency release of every lot of new biological products without first considering relevant scientific data, regulatory data, and firm compliance history to determine whether lot release, or an alternative to lot release, is appropriate. For currently approved products, the same information will be considered in allowing alternatives to lot release.

Current technical advances both in production and in analysis enable the agency to have adequate assurance of the safety and quality of certain classes of biological products without evaluating individual lots of those products. The agency proposes to issue guidelines that will describe the alternatives to lot release, and the circumstances and categories of products for which those alternatives will apply.

Impact: For many products, the manufacturer will not need to await agency clearance before marketing a specific lot of product. This will result in a savings of time and resources for both the industry and the agency. Products that pose specific regulatory concerns would still be subject to lot release to assure continued safety, purity, and potency.

Implementation and Timeline: FDA intends to publish a guidance document outlining the alternatives to lot release and the procedures for implementing this within 12 months.

DRAFT**REVISION OF THE REQUIREMENTS FOR A RESPONSIBLE
HEAD FOR BIOLOGICAL ESTABLISHMENTS**

Background: Manufacturers of biological products are required to name a "Responsible Head" who is to exercise control of the establishment in all matters relating to compliance with the regulations and who is to represent the manufacturer in all matters with the FDA. This individual is required to have an understanding of the scientific principles and techniques related to the manufacture of biological products.

In the past, biological product manufacturers were typically small companies, such as blood banks, that made products at one location. The requirement that a single responsible head represent the company was practical for such small operations. Today, however, manufacturers of biological products are larger firms with more manufacturing locations and more complex corporate structures. Most companies do not have one person with the knowledge to represent a company in all matters. Firms will typically have regulatory affairs, manufacturing, and medical personnel with the expertise to represent the company in different matters.

Proposal and Justification: FDA proposes to revise its requirements for a "Responsible Head" to allow more flexibility to assign control and oversight responsibility within a company. The revisions will still assure the proper oversight and accountability within a firm, but will conform to current realities.

Impact: Firms will be able to divide management responsibility among appropriate regulatory, medical or manufacturing staff. These individuals will be able to directly communicate with the agency on official matters related to biological products they manufacture.

Implementation and Timeline: FDA intends to publish a proposal to revise the regulation within 9 months.

DRAFT**ELIMINATION OF THE PRE-APPROVAL REQUIREMENT
FOR PROMOTIONAL LABELING**

Background: The Center for Biologics Evaluation and Research currently requires pre-approval of promotional labeling prior to launch of a campaign and for 120 days following approval of a new product. This is inconsistent with what is required by the Center for Drug Evaluation and Research procedures, which require companies to send such information to the agency at the time that the company disseminates it. This is because a specific regulation of Title 21 of the Code of Federal Regulations Part 601.12 (a) requires all changes in labeling for biological products to be approved prior to implementation. This labeling includes promotional labeling for biological products.

Proposal and Justification: The Center for Biologics Evaluation and Research intends to change its procedures to be consistent with those of the Center for Drug Evaluation and Research, which have provided a sufficient level of oversight for the review of promotional labeling.

Impact: Industry will only have to follow one procedure for drug and biological product promotional labeling and will no longer need to await approval of promotional labeling prior to disseminating it. Agency resources will be freed up to accomplish other review activities.

Implementation and Timeline: FDA intends to issue a guidance document and to publish a proposal revising its regulations within 6 months.

DRAFT**CONSOLIDATION OF PRODUCT LICENSE APPLICATION FORMS
INTO A SINGLE USER-FRIENDLY FORMAT**

Background: The Center for Biologics Evaluation and Research currently uses more than 20 different license application forms for companies applying for a product license. Many of the forms are outdated and ask for information that is also requested in other forms such as the establishment license application form. This is very confusing for the industry and does not allow for a standard format for all product license applications. Additionally, because no standard format exists for the application, reviewers are often unable to find information necessary for review. This results in significant delays in the review of marketing applications.

Proposal and Justification: The agency proposes to consolidate the product license application forms for non-blood bank products into one user friendly application format. This format will be structured to be similar to the new drug application format. The agency also intends to include elements from the European format in order to facilitate international harmonization of applications.

Impact: Companies should be able to provide consistent information and higher quality submissions. Time to prepare applications should be reduced because requirements will be clearly indicated. Many of the differences between drug and biologics marketing applications will be eliminated. The Center will reduce 19 applications to 1 application and will enhance international harmonization. The standard format should facilitate easier review by FDA staff and can be used as a basis for electronic submissions.

Implementation and Timeline: FDA intends to forward a revised format to OMB within 12 months.

DRAFT**AGENCY RESPONSES TO DATA SUBMITTED REGARDING CLINICAL HOLDS**

Background: Companies or individuals that intend to study investigational products (drugs or biologics) in humans must first submit an investigational new drug (IND) application to the agency. They may proceed with the study 30 days after the agency receives the application, unless FDA puts the study on clinical hold. A clinical hold is a directive issued by FDA that prevents the clinical study from proceeding. Thus, a researcher or company intending to begin testing a new drug in humans, or in the process of testing a new drug in humans, may not begin or continue the study until FDA releases the clinical hold. Currently, FDA has no internal requirements regarding how much time it may take to evaluate data submitted by the sponsor in response to the clinical hold. While the agency has generally responded in a timely manner, sponsors would like the predictability engendered by an agency commitment to respond within a specified time frame.

Proposal and Justification: FDA will commit itself to review and respond to data submitted in response to a clinical hold within 30 days of receipt of the submission. Absent a response from FDA within that time frame, the investigation may proceed. FDA believes that such a time frame will meet the needs of sponsors, and is within the resource capabilities of the agency.

Impact: The proposed change will prevent delays in agency review of data submitted in response to a clinical hold on an IND, and thus prevent unnecessary delays in the start or continuation of clinical studies.

Implementation and Timeline: FDA intends to publish within 9 months a guidance document establishing new procedures for reviewing data submitted in response to clinical holds on INDs.

REVISION OF BIOLOGIC PRODUCT LICENSING PROCEDURES

Background: Under current FDA regulations and policy, a manufacturer of a biological product holds both the product and establishment licenses. Because of this, a company may not contract all manufacturing of its product, even though it developed and owns the product technology. Companies that develop or own a biological product technology believe that these FDA licensing requirements are unnecessarily restrictive.

Proposal and Justification: FDA proposes to initiate the following changes:

1. Permit the establishment and product license applications to be submitted at different times.
2. Permit different companies to submit and be issued a product and establishment license.
3. Provide procedures for issuance of a product license to the product innovator or developer.
4. Amend labeling regulations to accommodate these changes.

These changes will make it possible to contract out manufacture of a biological product and still be able to hold a license for the product. FDA believes that such a change can be made to provide the industry with the flexibility that it wants, while not compromising the agency's ability to assure control over the manufacture of biological products.

Impact: The proposed changes in licensing procedures, in combination with proposed changes in labeling requirements, will allow companies developing biological products to easily exercise flexibility in manufacturing arrangements. They would be able to contract out manufacture as is now allowed for drugs.

Implementation and Timeline: Companies may begin submitting applications under these procedures immediately after obtaining verbal guidance from FDA. FDA's goal is to publish new and to revise existing guidance documents to describe these procedures within 3 months. It is also FDA's intent to publish proposed revised regulations for labeling and licensing by September of 1995.

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"Reinventing Government" Proposal on Generic Drug Products

This document describes one possible proposal to revise the regulatory process for generic drug products.

Background

Under current law, firms that wish to market a new drug product for human or animal use (a "brand name" product) must submit a marketing application demonstrating that the drug is safe and effective for its intended uses. These marketing applications contain, among other things, information about the product's chemistry and manufacture, a list of the product's components and composition (i.e., formulation), clinical data, and pharmacological and toxicological information. This information, however, is often trade secret, and, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j), and the Trade Secrets Act, 18 U.S.C. 1905, may not be disclosed to third parties.

Companies that wish to market a generic drug product usually begin by using reverse engineering to independently identify the ingredients in the brand name product that are not disclosed on the product's labeling and the amounts of those ingredients and developing a method for producing a generic version of the brand name product. This can be extremely difficult because, as stated earlier, information regarding the brand name product's ingredients and method of manufacturing may be information prohibited from disclosure.

Once the Food and Drug Administration (FDA) receives a generic drug application, it reviews the proposed product's formulation, manufacturing information, and other specifications. FDA informs the applicant of deficiencies, but cannot reveal exact specifications or details about the brand name product if it would disclose trade secret information to do so. This inability of the agency to share formulation and manufacturing information can prolong and complicate the review process and delay the introduction of generic drug products into the marketplace.

The Proposal: Disclosure of Certain Information

The proposal would authorize FDA to disclose the ingredients (and their amounts), method of manufacture, and control specifications for a brand name drug product when the agency approves the marketing application for the brand name product or shortly thereafter. Disclosure of information would simplify the process by which generic drug firms obtain FDA approval to market generic versions of the brand name drug products.

Arguments for the Proposal

Federal and State governments, generic drug firms, health practitioners, and consumers would benefit from the proposal for a variety of reasons.

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- * Disclosure would simplify the development, review, and approval processes for generic drug products because generic drug firms could make a closer copy of the brand name product and conserve resources that would otherwise be devoted to "reverse engineering" on the brand name drug.
- * Generic drug products would be available to consumers more quickly because FDA could provide precise information to address deficiencies in a generic drug application without concerns about inappropriate disclosure.
- * Some FDA resources that are currently assigned to reviewing generic drug product applications could be reassigned to other important review activities.
- * Although currently marketed generic drugs are as safe and effective as brand name products, the proposal would increase the similarity between generic and brand name drug products. This would strengthen the confidence of health practitioners and consumers in substituting generic drug products for brand name products and result in substantial cost savings to consumers, health care institutions, and Federal and State governments. Market analyses suggest that generic drug products are, on average, 27 percent less expensive than comparable brand name products when they enter the market; after one year, generic drug products are 45 percent less expensive; and, after two years, generic drug products are 61 percent less expensive.

Thus, consumers, generic drug firms, health care institutions, and Federal and State governments would receive substantial benefits from the proposal.

Arguments Against the Proposal

Brand name drug firms, as well as some generic drug firms, may vigorously oppose the proposal. Possible arguments against the proposal include:

- * Disclosure would seriously impede new drug innovation and adversely affect a brand name drug firm's ability to compete in the marketplace or, through its subsidiaries or under its own name, to sell its own generic drug products.
- * Brand name firms may claim that the proposal will deter innovative research and delay or eliminate development of new products that can be important to public health.
- * Disclosure would adversely affect the pharmaceutical industry's ability to compete in foreign countries that do not protect intellectual property.

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- * Disclosure of a brand name firm's data and information might be argued by some to constitute a "taking" under the Fifth Amendment to the U.S. Constitution. A statutory change to allow disclosure would effectively eliminate this argument by eliminating the expectation of confidentiality; a similar approach was used in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136(h)(d).
- * Some generic drug firms with high-quality drug development programs may also oppose the proposal. Currently, generic drug firms compete for the first approval of a generic drug product because the first approved generic drug product temporarily commands a large share of the generic drug market. Thus, firms with advanced, scientifically-based development programs may have an advantage in this competition, particularly with respect to drugs that are difficult to manufacture.

Thus, brand name firms and some generic drug firms may oppose the proposal.

In summary, the arguments for and against this proposal are quite complicated and the implications would have to be thoroughly considered before proposing a statutory change.



File (CJ)
FDA

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

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Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

July 30, 1997

The Honorable William J. Clinton
The White House
Washington, DC 20500

Re: S. 830, Sen. Jeffords FDA Rollback Bill

Dear Mr. President:

Public Citizen, together with more than 75 national and state consumer, patients, and public health groups, is strongly opposed to Sen. Jeffords' FDA Rollback Bill, S. 830.

Despite the fact that this measure seriously undermines FDA authority to ensure the safety and effectiveness of U.S. drugs and medical devices - the first major rollback of these public health protections in 91 years - until very recently S. 830 has generated little public attention. The bill's industry and Republican backers have labeled it "moderate" and "modernization." Aye votes from Senate Labor Committee Democrats Dodd, Mikulski, Wellstone, and Murray have provided a veneer of "bipartisanship."

Emboldened by the absence of public scrutiny, industry and their Republican allies have loaded S. 830 up with enough baggage to attract notice.

I am attaching several recent editorials and press stories on some of these provisions:

- the "revolving door" that has propelled Jay Hawkins from medical device industry representative to committee staff in charge of drafting the bill that aids his industry;
- the "off-label" provision, which permits drug and medical device companies to disseminate promotional materials on unapproved uses of their products;
- preemption of state over-the-counter drug and cosmetics laws, including California's successful Proposition 65;
- the closed door process - no public hearing on a bill drafted by industry, administration, and legislative staff, with consumers, patients, and public health groups largely excluded - which, interestingly enough, has attracted particularly heated public comment in Vermont, home of Senate Labor Committee Chair James Jeffords.

Ralph Nader, Founder

1600 20th Street NW • Washington, DC 20009-1001 • (202) 588-1000

The Honorable William J. Clinton
July 30, 1997
Page Two

Also attached is an open letter about S. 830 to Senators from Ralph Nader and Dr. Sidney M. Wolfe, Director of Public Citizen's Health Research Group.

In addition to the lack of attention to the bill's detrimental impact on public health and safety, S. 830 has also escaped serious scrutiny in another area: what it will cost and who will pay.

The CBO score at the Committee markup of \$63 million in 1998 and \$445 million over the 1998-2002 period does not cover post markup changes to the bill, including:

- health claims for foods. The FDA has only 120 days to review health claims submitted by food manufacturers and to issue an interim final rule blocking misleading claims - otherwise the manufacturer can proceed with labeling and marketing. This shifts the burden of proof (not to mention legal and litigation expenses) onto an already strapped agency.
- off-label promotion. The FDA has only 30 days to review for "balance" materials submitted by drug and medical device manufacturers before they begin promoting their products for uses for which have not been proved safe and effective. While the agency does not have authority to prohibit the distribution of a peer-reviewed or medical textbook article, they can require that articles with other points of view are included in the packet. Once again, the cost and time burdens are placed on the agency, not the company initiating the promotion.

In both of these areas, it is to be expected that the volume of materials submitted will be extensive, and that the staff costs to do the job properly will be extremely high.

S. 830's medical device provisions are also extremely costly. For example, secs. 301 and 302 set forth "collaborative" steps FDA must take within specified, very short time frames to assist companies with the application and approval process. Yet paradoxically, the medical device industry has bitterly resisted paying for the additional staff time they are demanding. Instead of taking the successful example of the Prescription Drug User Fee Act (PDUFA) as a model, "just say no" has been the device industry's response to any suggestion of a MDUFA - user fee authority for medical devices.

Medical device companies argue that small companies cannot afford fees. But just as PDUFA exempts from fees firms with fewer than 500 employees filing their first application, so could MDUFA. The large multinational companies that dominate the U.S.' \$50 billion annual medical device market can very well afford to pay fees to expedite approvals of their products. It makes absolutely no sense that medical device user fees have not been on the table - particularly in the context of a bill which is on a legislative fast track in order to reauthorize the successful "sister" program PDUFA.

The Honorable William J. Clinton
July 30, 1997
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Rather than step up to the plate and agree to pay user fees, the medical device industry hopes to use the "government resources are limited" argument to lower standards and reduce enforcement. S. 830's "accredited-party review" (sec. 204) lets companies buy out of the purview of FDA's objective, professional reviewers and hire private, for-profit firms to conduct reviews. If large and small companies alike are willing to pay private companies to review their new products, surely they could pay user fees to the FDA like drug companies do. And inevitably, the gross conflicts of interest in manufacturers hiring their own Contractor/Reviewer will result in serious, costly public harm.

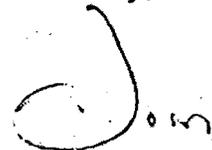
Industry proponents also use "limited government resources" to justify eliminating mandatory tracking and postmarket surveillance of very high risk implantable, life-sustaining and life-supporting devices such as heart valves. Tracking and surveillance for these devices, the failure of which could cause death or serious injury, were enacted in the Safe Medical Device Amendments of 1990 in response to the Bjork-Shiley heart valve and other medical device tragedies. When the FDA finally ordered the manufacturer to notify patients that the valve was prone to fracture, half of them could not be located because there was no tracking system.

In sum, S. 830 poses very negative consequences for U.S. public health and safety. There is no documented basis for undercutting a law that is the Gold Standard for the world, and which provides a major competitive advantage for U.S. approved products. Looking to the future, the insertion of new "discretionary" authorities in this bill could in a different administration become a blunt instrument against public health and safety.

S. 830 also would impose enormous new cost burdens on the FDA. As it now stands, the bill would add more than \$75 million annually in new costs; yet no additional funds are allocated in the bill.

If the FDA is to avoid further harsh critiques and industry assaults about its future performance, the preferred course of action is for the administration to take a strong stand for a clean PDUFA and for the creation of a MDUFA. We urge you to include these recommendations in a tough statement of administration policy and to make those views clear to the public, which backs our position on these issues. To date, the only public objections to this bill have been raised by patients and consumer groups.

Sincerely,



Joan Claybrook

Attachments

Hill's Revolving Door Open For Regulators and Regulated

FDA Bill Points Up Frequent Proximity of the Two

By John Schwartz
Washington Post Staff Writer

In January 1997, James W. Hawkins got a new job, with Sen. James M. Jeffords (R-Vt.). His task: to help draft a broad piece of legislation that would change many ways in which the Food and Drug Administration operates. Hawkins had the experience to do so, having worked as a lobbyist for two medical device companies and lobbied on FDA reform issues the previous year.

When he left the firm he founded, Hawkins and Associates, to work for Jeffords, the companies' representation was picked up by a new company, Washington Healthcare Representatives, with the same phone number as Hawkins's old firm. The registered lobbyist: Heather H. Bremer, Hawkins's wife. Among the topics listed for probable lobbying on her disclosure forms were FDA issues.

No one has openly accused Hawkins of a conflict of interest, and the FDA bill has garnered wide support in Congress, including lawmakers with strong pro-consumer credentials. What Hawkins's role in crafting the bill does illustrate, however, is just how short a trip it can be through the revolving door that separates lobbyists from the people who write the legislation.

Consumer activist Bruce Silverglade declined to comment on Hawkins but contended that the bill was developed in a way that gave short shrift to pro-consumer groups. Silverglade, director of legal affairs for the Center for Science in the Public Interest, arrived at a May 23 meeting hoping to deliver a full presentation on the provisions that his group hoped any FDA bill would include. Instead, staff members handed him a short stack of pages with positions already laid out that, Silverglade said, substantially weakened FDA authority over food safety and labeling. Handwritten notes on the copies he received read "GMA 5/19/97" and "NFPA 5/19/97"—the acronyms for the Grocery Manufacturers of America and the National Food Processors Association.

"We were asked to comment on what was essentially industry's wish list," Silverglade said. "We objected to the fact that the starting point of the debate was what industry wanted."

The bill, now known as the FDA Modernization and Accountability Act of 1997 (S.830), could come up for a vote on the Senate floor Wednesday. It would change regulation of food, drugs, medical devices, cosmetics and other items. More urgently, it reauthorizes a user fee program that has allowed the agency to speed new drugs to market.

Proponents of the bill say that it will improve the agency's performance.

Hawkins would not comment on ethics issues, but a Jeffords staff member defended him, saying that "Jeffords has full confidence in Jay. People make the transition from industry to the Hill all the time—or, on the other side, from organized labor to the Hill." Seasoned lawmakers, the aide said, know how to distinguish "straight advice" from "advice with an agenda."

In Hawkins's case, the aide said, "Jeffords is confident he's getting good advice out of Jay." He also insisted that despite the notation on her disclosure statement, Hawkins's wife did not lobby on FDA issues. If she had, the aide said, it could have constituted a Senate ethics violation for Hawkins.

Another Jeffords staff member said that CSPI's Silverglade was wrong about the nature of the May 23 meeting, because the papers did not reflect already-set provisions of the bill. Instead, the staffer said, "We asked CSPI to evaluate, to critique those proposals" from industry as part of the drafting process. Consumer groups were listened to, the staff member said, and several sections of the bill were rewritten or added at their urging.

Tracy Fox, a lobbyist with the American Dietetic Association, said her group was consulted on food issues but "it would have been nice to have had some of the dialogue a little earlier on." The dietitians worry that provisions loosening the agency's regulatory authority over the kinds of health claims that food companies can make for their products could lead to disinformation and consumer confusion.

Other consumer advocates have stronger views. Frank Clemente, director of Congress Watch, the lobbying arm of Public Citizen, called the proposal "a one-way, pro-industry bill that offers little if anything for consumers. It's not surprising, given that the drug and medical device industries have contributed more than \$34 million in the last three elections."

But Sen. Judd Gregg (R-N.H.), a supporter of the bill, countered that "we're not too impressed with the activist groups," which he contended "represent a minority viewpoint."

Kelly Johnston, the executive vice president for government affairs at the National Food Processors Association, dismissed the complaints of consumer groups as "whining... The activist community's whole position has been no change at all."

"We've been fairly effective at educating our friends on Capitol Hill," Johnston said, adding, "It's hardly a case of 'we're getting everything we want in this bill.' Nobody does."

The New York Times

EDITORIALS/LETTERS

THURSDAY, JULY 24, 1997

Don't Weaken the F.D.A.

Congress entertained several proposals last year to reform the Food and Drug Administration in order to force the agency to approve new drugs and medical devices more quickly. But critics argued that the proposals went too far in loosening regulatory safeguards, and no bill emerged. This year, in a new Congress, reform is back on the agenda — as are many of the same criticisms.

The F.D.A.'s task is to insure that drugs and medical devices are safe and effective and that food additives are risk-free. It generally gives approval only after lengthy clinical trials by the manufacturer. But many companies complain that the F.D.A.'s slow responses often escalate costs.

Senator James Jeffords, a Vermont Republican, is pushing legislation that would ease the rules in an effort to speed clinical investigations of new drugs, including breakthrough drugs for life-threatening diseases. Current law calls for "adequate and well-controlled" clinical investigations, which in practice means at least two test runs. The Senate bill crafted mainly by Mr. Jeffords would allow more flexibility so that approval could be based on only one trial. As it stands, the agency sometimes approves a product on the basis of one well-con-

trolled clinical trial. But some patients'-rights groups do not want to see that lower standard carved into law. Their point is well taken. The agency is in the best position to determine, case by case, how many trials are enough.

The proposal would also push the F.D.A. to submit to outside review of new medical devices. These third-party reviews could be loaded with conflicts of interest. The agency's effectiveness as an independent government protector of public health would be further weakened by a provision allowing unsubstantiated health claims on food labels and by a proposed amendment permitting drug and medical-device companies to promote unapproved uses of their products.

Negotiations over these reforms are linked to re-authorization of a law that has helped the agency and drug manufacturers. Under the Prescription Drug User Fee Act of 1992, more than \$300 million collected by the agency from drug companies has been used to hire more reviewers and cut approval times for new drug applications. The law, authorized for five years, deserves to be renewed, but the renewal should not be held hostage to questionable changes in agency procedures.

The Washington Post

AN INDEPENDENT NEWSPAPER

The FDA in the Senate

A RAUCOUS battle could end with a whimper this week if critics and defenders of the Food and Drug Administration get together as promised and pass a Senate bill to "reform" and streamline the agency along lines the agency has said it can live with. More likely, a last-minute goodie for the pharmaceutical industry will be offered on the Senate floor to upset the balance. One that legislators say they expect is a seemingly innocent amendment that would allow the companies to send doctors mass mailings of scientific articles about the use of prescription drugs for purposes the FDA has not yet approved.

This fight about "off-label" marketing of prescription drugs is in many ways typical of the battle over FDA "reform" generally, which has been marked by a high level of regulatory arcaneness (for instance, seeking to legislate—and thus override the agency—on how many patients should be required for a valid scientific study and how long it should take the FDA to approve an application). Off-label uses of a prescription drug by doctors are perfectly legal. But if a company wants to *promote* a drug for a new use, it has to submit further and generally more rigorous studies to the FDA.

The FDA stance has been that if companies could promote off-label uses by mailings of articles, they would have no incentive to do the more rigorous

studies. Opponents brandish long lists of off-label drug uses that seemed fine but that in the larger study proved dangerous or even lethal. A deadlock on an off-label provision last year helped scuttle a compromise-laden bill much like this one; opposition this year has been strong enough that its sponsors avoided introducing it in committee. A floor amendment gives opponents the chance for grand rhetoric about endangering the safety of children.

Such difficulties reflect the contradictory objectives of the industry the FDA regulates. Drug companies say they want the regulatory load lightened. But they also badly need the protection and consumer confidence a strong FDA confers. In particular they want the continued benefits of a program called PDUFA, or the Prescription Drug User Fee Agreement, a 1992 law that allowed them to pay user fees to the FDA for the specific purpose of speeding up prescription-drug reviews.

The PDUFA program must be reauthorized this year or lapse. The only trouble is that to save PDUFA, the drug companies have had to argue that the FDA did a wonderful job with the first four years of user fees, which were earmarked for bureaucratic reforms. This acknowledgment should be matched by another: that the companies benefit, in the end, from being required to do safety studies before marketing their drugs in any form.

Los Angeles Times

Commentary

WEDNESDAY, JULY 23, 1997

Washington Readies a Toxic Bomb

■ **Health:** Prop. 65, which protects Californians from hazardous substances, could be undermined.

By AL MEYERHOFF

California's landmark Proposition 65, aimed at protecting the public from toxic substances, will be subverted if a measure now under consideration in Congress is enacted.

At the behest of powerful trade associations, Sen. James M. Jeffords (R-Vt.) has introduced legislation that would preempt the power of individual states to regulate—or even warn their citizens about—toxic chemicals found in over-the-counter drugs and cosmetics. Food, too, may be added to the list. Proposition 65, passed in 1986, and right-to-know laws like it would simply be voided—this by a Congress that has championed states' rights and principles of federalism.

The preamble to Proposition 65 says that Californians needed to act because governments had "failed to protect us" from the hazards of toxic substances. The premise was simple: When exposed to a significant threat of cancer or reproductive harm, we had a right to be warned. We could then decide whether to buy a product, work in a factory or even breathe polluted air without protest.

In its 10-year life, Proposition 65 has

been widely applauded as an innovative and effective alternative to the often slow machinery of federal regulation. William Reilly, EPA administrator during the Bush administration, said that "beyond simply informing people, Proposition 65 is intended to provide a compelling incentive for industry to remove nonessential carcinogens and reproductive toxins from its products."

A key purpose of Proposition 65 was to fill gaps in federal laws in which whole categories of toxic exposures are simply not addressed. Take cosmetics and over-the-counter drugs, routinely allowed on the market with no testing for the presence of toxic chemicals. According to the Cosmetic Handbook, a Food and Drug Administration publication for the cosmetics industry: "With the exception of color additives and a few prohibited ingredients, a cosmetic manufacturer may, on his own responsibility, use essentially any raw material as a cosmetic ingredient and market the product without approval."

As a result of Proposition 65, California consumers of cosmetics now must be warned if an exposure to a chemical that causes cancer or birth defects is the price of vanity. They can then make an informed choice between brands and the market will do the rest. One example: As a result of legal action brought by environmentalists and the California attorney general, toluene, a potent reproductive toxin, has largely been removed from nail polish. A challenge is now being raised to the presence of lead in hair dyes. Other cosmetics are suspect.

Proposition 65 has also brought about the

removal of lead from drinking water faucets, ceramic ware and crystal glasses and other toxins from a variety of home use products like cleaning solvents and mothballs. But perhaps the best example of the act's effectiveness is the case of calcium supplements and antacids. Three years ago, the FDA concluded that the risks from lead in calcium products (as common as Tums and Rolaids) were far too high and presented especially serious risks to pregnant women and the unborn fetus. But while the agency issued a notice proposing a ruling, it did nothing more.

However, as a result of legal action brought by the California attorney general and the NRDC, agreements have now been reached with most calcium manufacturers, which have agreed to dramatically reduce the lead levels in their products.

California Sen. Dianne Feinstein has voiced opposition to the Jeffords provision and vowed to strike it when the FDA Modernization Act reaches the Senate floor this week. In a rare display of bipartisanship, California's Republican attorney general, Dan Lungren, a likely candidate for governor in 1998, has also announced his opposition to the Jeffords measure. "Proposition 65 has been used successfully to reduce toxic contaminants in consumer products," Lungren said. "The states should be permitted to continue in their historical role as guardians of the welfare of their citizens."

Proposition 65 has served Californians well. Congress should leave it alone.

Al Meyerhoff is an attorney for the Natural Resources Defense Council in San Francisco.

PAGE 6A
Monday, July 28, 1997

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Opinion

A vote for health

Tuesday, the U.S. Senate will vote on an overhaul of the Food and Drug Administration. If these changes are anything less than dangerous to consumers, it will be despite the work of U.S. Sen. James Jeffords.

As chairman of the Senate Labor and Human Resources Committee, Jeffords has spearheaded reform of the FDA. Vermonters should be glad his efforts have not succeeded. Yet.

The FDA regulates almost one-third of the items people consume: foods other than meat and poultry; over the counter and prescription drugs; medical devices from Band-Aids to pacemakers.

For years complaints that the FDA needs streamlining, that drug approvals take too long and that its regulatory arm reaches too far have poured in. Some of these concerns are legitimate, but must be balanced against the danger of sloppy or insufficient review (just ask the 248 people who have died from the faulty Bjork-Shiley heart

Some of the proposed changes to the FDA could endanger public health.

Whom to call

To urge Vermont's U.S. Sen. James Jeffords to cast a pro-consumer vote on FDA reform, call 800-835-5600.

valve).

The Senate's view of this balance is a bill that takes away the FDA's discretion about how many clinical trials a drug receives, which could allow unsubstantiated health claims on

food labels, and which could eliminate states' powers to set higher label standards (such as Vermont's BST labeling law).

Last year, these ideas withered. This year is different because there is a political hostage. For five years the FDA has collected fees from drug companies, with the revenues earmarked solely for faster drug approval. The companies like the faster turnaround and don't mind the fees because they're so small compared with the total cost of developing new medicines.

This smart law expires in September.

Jeffords' staff makes much of the last-minute compromises on this bill, but that's political spin. On his committee's version of the bill, Jeffords backed many provisions that would have weakened consumer protection.

He voted for an amendment by Sen. Judd Gregg, for example, weakening states' powers to control product labels. He voted against several amendments by Sen. Tom Harkin to prevent third parties reviewing new drugs for the FDA from having a financial interest in the outcome.

The best of these measures might survive, and the worst fail, but Jeffords' early stance has hardly been pro-consumer. Likewise, while he has met privately with consumer advocates, his public hearings have favored FDA critics and the companies the FDA regulates.

Last week provided a series of last minute, late night compromises — thanks not to Jeffords but to opposition from Sen. Edward Kennedy. The version of the bill up for vote Tuesday is evolving. Vermonters should help determine its shape by calling Jeffords and urging him to restore his moderate reputation.

The stakes are no less than your health.

THE SUN

Baltimore, Maryland

A bill that threatens America's health

By JOAN CLAYBROOK

BEFORE CONGRESS takes its August recess, the U.S. Senate will likely vote on a bill to reauthorize the Prescription Drug User Fee Act (PDUFA), a little-known but highly effective law that has succeeded in speeding up the safety and efficacy reviews needed before new drugs and medical devices are sold to the public.

Unfortunately, some senators are using this bill as a vehicle to promote the reckless agenda of the pharmaceutical and medical device industries.

Under the guise of "modernizing" the Food and Drug Administration, they are pushing Senate Bill 830, which in addition would roll back two decades of progress in making sure Americans have access to the world's safest, most effective drugs and medical devices.

Mikulski's puzzling stand

What is baffling is why Sen. Barbara Mikulski, D-Maryland, who has in the past championed issues affecting women's health, would support this bill. She voted in favor of it in the Senate Labor and Human Resources Committee even though the committee refused to hold even a single public hearing to get input from those who will be most harmed by its provisions.

What's the rush? Why didn't Senator Mikulski and Sen. James Jeffords (R-Vermont), the committee chairman and bill sponsor, want to hear from consumers before ramming through a bill written largely by well-financed industry lobbyists?

Among other things, this bill lowers FDA standards for approving new drugs; introduces inherent conflicts of interest by allowing medical device companies to select and pay private contractors to review new products in lieu of the FDA; and allows manufacturers to make so-called minor design

and manufacturing changes without FDA approval.

It also eliminates post-market tracking needed to identify recipients of defective devices in time to save their lives; and redefines the FDA as a collaborator with industry rather than its regulator. Further, it would permit companies to make unsubstantiated health claims about food and would eliminate many state laws pertaining to food, drug and cosmetic labeling.

Today, Americans benefit from the toughest drug and device review standards in the world. In fact, we have the gold standard. This bill would melt down that gold standard for the benefit of an industry already bulging with profits.

Reliving old nightmares

If this bill passes, we are doomed to repeat the mistakes of the past. Do we want more Dalkon Shields, more Bjork-Shiley heart valves?

Ask Elaine Levenson of Pittsburgh. Doctors implanted a Bjork-Shiley heart valve in her chest in 1981. Several years later, she discovered that hundreds of other recipients died after their fractured, and many more had emergency coronary surgery that disrupted their lives and livelihoods. Today, she lives with this ticking time bomb in her chest.

After the scope of the Shiley disaster became known, more than half of the people who had received the dangerous device could not be located to be warned. So in 1990, Congress enacted legislation requiring medical device tracking and surveillance to serve as an early warning to the manufacturer and the FDA that a device is defective. This critical statute ensures that all patients can be quickly identified if medical monitoring, removal or replacement of their device is needed.

It's incredible that we have mandatory registration of automobiles so manufacturers can be required to notify owners of safety

defects, yet Mr. Jeffords is proposing the repeal of mandatory tracking for life-and-death devices. And surprisingly, Ms. Mikulski is supporting it.

In 1982, Ms. Mikulski was one of the leading sponsors of the Mammography Quality Standards Act, which established accreditation standards for mammography facilities. This year, she is leading the effort to reauthorize the law, which includes annual inspections and quality assurance standards. Yet, under the FDA bill, new generations of mammography equipment could be reviewed, not by FDA experts, but by private companies under a new "buy your own review" system.

How does Ms. Mikulski, who received \$20,000 in campaign contributions from the drug and medical device industries over the past three election cycles, reconcile these seemingly contradictory stands?

The solution

If the House and Senate don't vote on this bill before August, PDUFA authorization lapses and 600 FDA employees face layoffs, because the fees from pharmaceutical companies will no longer be collected to pay for expedited reviews. Everyone agrees that PDUFA has been a tremendous success. It has provided an additional \$327 million from fees levied on the drug companies, and review times have been cut in half. It should be renewed — but not with the dangerous legislative cargo the current bill contains.

If medical device companies want swifter reviews, the answer is to create a Medical Device User Fee Act that would do the same thing for medical devices that PDUFA does for new drugs. That's what Ms. Mikulski should be supporting, not the dismantling of the safety net provided by the FDS.

Joan Claybrook is president of Public Citizen, one of the nation's oldest and largest consumer advocacy groups.

Vote No on S. 830

July 28, 1997

Dear Senator:

Sen. Jeffords' bill S. 830, which seriously weakens the FDA's ability to protect the American public from dangerous drugs and medical devices, will probably come before you for vote on the Senate floor this week. This legislation constitutes the first rollback of FDA protections in 91 years. There are no data nor documented reasons for this weakening of law and order for public health and safety.

S. 830 invites with near certainty the repetition of disasters like those which led to the strengthening of FDA regulatory authority in 1938, 1962, 1976, and 1990. If S. 830 were to become law:

1. Drug and medical device companies could legally promote their products for purposes for which they have not been proven safe and effective. The lesson which was learned from the tragic experience of the many thousands of women who took DES to reduce morning sickness during pregnancy, although it had never been proven safe and effective for that purpose, will have to be retaught by such future preventable tragedies. The toll of those suffering damage to their heart valves from the recently uncovered "fen-phen" catastrophe would more likely have been numbered in the thousands rather than (as far as have been reported to date) dozens of victims, if promotion of the combination of these two drugs for unapproved uses had been allowed.
2. Medical device companies could bypass FDA's professional staff of civil servants and have the safety and effectiveness of their products judged by private, for-profit firms that they select, negotiate terms with, and pay directly. Collusion between manufacturing and reviewing companies to raise the profits of both will be legally permitted to take precedence over the consumer's right to be confident that the medical devices which they and their doctors rely on are as safe and effective as possible.
3. Simultaneously with the lowering of premarket review standards for medical devices, postmarket controls to provide an "early warning system" to catch and act quickly on defective products will also be reduced by repeal of mandatory tracking and surveillance of very high risk implantable devices such as heart valves. Tragedies like the Bjork-Shiley heart valve or the Vittek jaw implants, in which thousands of patients could not be located to be notified of defective, life-threatening devices, will be more likely to recur when there is no mandatory tracking of such devices.
4. S. 830 would change the passable number of clinical investigations required to establish the safety and effectiveness of drugs from two or more such studies by stating that "one or more clinical investigations" would be acceptable, a significant move toward the

weaker standards for drug approval frequently accepted in Europe. As a result of these weaker European standards there were 45 drugs approved in the United Kingdom, Germany or France between 1970 and 1992 which later had to be banned because they were found to be too dangerous, only after hundreds of people in those countries were injured or killed by the drugs. None of these drugs was approved in the United States because of our stricter standards. These standards are seriously threatened by S. 830.

5. S. 830 also nullifies the right of states to enact consumer protection laws for cosmetics - despite the fact that there are no effective national standards to ensure the safety of any cosmetic product, many of which are made from potent chemicals. These include nonmedicinal douches, lotions, lipstick, eye shadow, mouthwash, and thousands of other products which tens of millions of Americans use daily. This \$20 billion annual U.S. industry is refusing to accept even minimal improvements - not to mention premarket testing - in the FDA's ability to set national safety standards in exchange for preemption of all state authority.

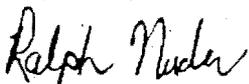
When the first of a series of disasters that will all too predictably follow S. 830's weakening of health and safety standards occurs, all those who voted for it will share responsibility. Senators are being asked to vote for this bill despite:

- Notwithstanding many requests, not one public hearing on this bill has ever been held.
- The text of the bill that is expected to be brought to the floor this week has not yet been made available to most Senators, the public, or the press.
- The bill has been and continues to be negotiated and written behind closed doors by legislative staff, industry, and the administration.

The sorry excuse to justify this secretive rush to vote on S. 830 has been that it reauthorizes the Prescription Drug User Fee Act (PDUFA), which is noncontroversial and universally supported. PDUFA could, and should, be cut free from this lethal baggage and quickly approved on its own.

We strongly urge you under these circumstances to vote against this measure with such critical consequences for the health and safety of American women, children, and men, including you and your family. Even if you do not choose to go forward and strengthen the FDA by providing subpoena power and authority to levy civil monetary penalties for most of the products the FDA regulates - how can you possibly go backwards and significantly degrade the agency's capability to protect the American people?

Sincerely,



Ralph Nader



Sidney M. Wolfe, MD

Public Citizen Health Research Group

The White House
Office of Presidential Letters and Messages



Facsimile from Seth Masket
Voice: (202) 456-5514; FAX: (202) 456-2806

No. of Pages (including cover): ~~3~~ 4 Date: 7/5/95

To: CHRIS JENNINGS

Voice: 6-5560 Fax: 6-7028

Comments: I'VE RECEIVED SEVERAL LETTERS LIKE
THE ENCLOSED REGARDING WOMEN'S HEALTH &
THE FDA. COULD I ASK YOUR ADVICE FOR A
RESPONSE? I'VE ALSO ENCLOSED SOME OF OUR
STANDARD WOMEN'S HEALTH LANGUAGE. PLEASE LET
ME KNOW IF IT WILL WORK AS A RESPONSE.



St. Catharine College

June 16, 1995

The Honorable William J. Clinton
Executive Office of the President
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President,

You elevated women's health care to the forefront of your administration. This was long overdue and it has been wonderful to have a President helping women. This is the reason we need to make sure you a second term.

~~However, I am worried about unfavorable public perception due to the actions of the FDA.~~ Women are still losing the battle against breast cancer and this is because of their inability to properly diagnose breast cancer. The federal government, in the form of the FDA, is actually hindering medical progress in this area.

A safe and effective medical devise for women to use in the discovery of lumps in their breasts during the early stages of this deadly cancer has been developed. The FDA has not taken the quick approval action as required by law, but has instead raided the factory and confiscated the devices. This is horrifying and inexcusable. Obviously, the head of the FDA thinks it is more important that he be allowed to destroy the tobacco industry and regulate bottled water, than it is to approve life saving medical devices.

The FDA gives no indication it cares that women are dying of breast cancer. The FDA commissioner continues to guide this agency in directions opposite the policies of your administration. This could hurt your re-election in 1996. I think you need to tell this agency head to get his agency in line with your programs NOW.

We elected you, we did not elect the FDA commissioner.

Sincerely,

Martha Layne Collins
Governor of Kentucky 1983-1987
President, St. Catharine College

117134



Handwritten:
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COMMITTEES
Education
Insurance and Commerce

STATE OF ARKANSAS

House of Representatives

DISTRICT 49
Part of Columbia County
Part of Ouachita County
Part of Union County

June 15, 1995

The Honorable Bill Clinton
President of the United States
Executive Office of the President
1st Floor, West Wing
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear President Clinton:

I have supported you since you first ran for public office, and I plan to work hard for your re-election. I realize you are constantly contacted about key issues; however, I want to express my feelings regarding FDA and women's health. This is one area that needs your attention.

Breast cancer detection and prevention will remain a critical "women's issue" in 1996. The FDA has not addressed this with the respect and consideration that is needed. The FDA has been slow to approve a device which would aid in early detection of breast lumps. Dr. Kessler needs to give this item the consideration that it so rightly deserves.

You need to reinforce and emphasize your administration's strong commitment to both women's issues and health care.

Sincerely,

Bobby G. Newman
State Representative
District #49

BGN/fk

Thank you for writing to me about breast cancer. I share your concern for the devastating effects that breast cancer has on millions of women and their families each year.

Breast cancer now accounts for nearly one-third of all cancers diagnosed in women, so prevention research must play a more important role in our strategy to eliminate this disease. Some risks can be avoided, and researchers hope that others can be minimized. As you may know, the National Institutes of Health, through its component institutes, including the National Cancer Institute, has launched important studies to assess the extent to which changes in dietary habits can arrest the development of this and other diseases.

Although we still have much to learn, one message is clear: Women should work with their health care providers to detect the signs of breast cancer as early as possible. Too often women are aware of the dangers of this disease but are discouraged from obtaining a diagnostic test because their insurance policies do not cover this service. We must continue to fight for health care reform so that every woman in America can receive guaranteed health care coverage that can never be taken away.

I appreciate hearing your thoughts on this vital issue, and I urge you to continue to take part in the fight against breast cancer for our mothers and daughters and for the generations to come.

Reinventing

DRUG & MEDICAL DEVICE

Regulations



PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

APRIL 1995

Cross-Cutting

Several issues confronting FDA cut across product lines and affect both the pharmaceutical and medical device industries. Two such issues involve exports. One of them is the different mandatory requirements that the Agency must follow in approving exports of drugs and medical devices. The other export issue stems from the varying standards for regulated health care products in the United States and in many of its trading partners. FDA plans to ease some of the current export restrictions. Also, the Agency will intensify its efforts to bring into harmony international standards for health care products, so that firms developing new products will have to deal with only one set of requirements.

Another issue raised by both the drug and device industries is whether FDA requires new products to be shown to be superior, as opposed to equal, to products that are already on the market. An upcoming policy statement will clarify the Agency position. FDA also proposes to take steps to advance the development of an electronic information system to support the review processes, and to implement the second phase of an automated system for the processing of imports.

Drug and Device Exports

Background: Drugs and medical devices not approved for sale in the United States are now exported under different statutory requirements.

Drugs may be exported only to the 21 developed countries listed in the statute if, among other things, (1) the sponsor has an investigational new drug (IND) exemption in effect that permits testing in humans, and (2) the drug is approved in the importing country.

Devices may be exported if FDA determines, based on information supplied by the exporting company, that (1) export of the device does not harm public health and safety, and (2) the device is approved for importation by the importing country.

Manufacturers have contended that these requirements place them at a competitive disadvantage and that FDA review of exportation to foreign countries is both time-consuming and unnecessary.

Proposal and Justification: *It is proposed to allow the export of drugs to any of the countries listed in the statute without an IND.* In addition, the Administration proposes to work with Congress on changes in the current law based on an examination of whether to amend the present list of 21 countries, and whether to adopt other changes.

FDA proposes two new criteria for allowing devices not approved in the United States to be exported for marketing abroad without prior FDA permission: (1) devices can be exported to advanced industrialized countries (the list of which would be determined in consultations with Congress) if the devices conform to the importing country's laws; (2) devices can be exported to countries not on the above-mentioned list if the exporter has an Investigational Device Exemption (IDE) permitting testing on humans in the United States, the importing country has given FDA a letter providing blanket import approval for IDE-type devices, and the device is in compliance with the importing country's laws.

This change from current procedures would significantly relax restrictions on exports to industrialized countries, while leaving intact existing protections for countries that are not industrialized.

Impact: For drugs, companies will be able to export their products for marketing in the 21 developed countries listed in current law, even if they do not have an IND in the United States.

For devices, exports to the most significant markets—industrialized nations such as Japan and the European Community—will be exempt from FDA's oversight. The U.S. industry will be spared the expense of developing and submitting export requests to FDA and would not need to await FDA review, which now averages 16 days but can take as long as 150 days. Furthermore, a firm with an approved IDE will be able to export the unapproved device to less developed countries which have agreed to such importation, without going through FDA review, currently averaging 10 days. The U.S. device industry believes that these changes will encourage firms to remain in the United States rather than moving their operations abroad. FDA could redirect the resources used for the current export approval program to more pressing public health matters.

Implementation and Timeline: Discussions with Congress on both drug and device legislation could begin immediately. Permitting devices with an IDE to be exported without further FDA clearance to countries which have provided prior agreement can be accomplished administratively by FDA, and proposed regulations will be issued within 4 to 6 months.

GAO Report to Congressional Requesters

FDA Drug Approval

Review Time Has Decreased in Recent Years

October 1995