FOIA Number: 2018-0758-F

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Issues - FDA [Food and Drug Administration] Reform

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NORA - 9/8/97

FDA Reform

Kay Holcombe - staff - House Commerce

⇒ Senate bill 830

- notice of discontinuance
- Phase IV trials
- issue w/ Senator Kennedy & state authority
- single clinical trial

⇒ House Commerce Comm. doesn't currently have bill

- HHS sent letter to House Comm. - not a veto letter

① state regs on labeling & packaging of otc drugs & cosmetics
(does not prohibit state action on safety of cosmetics)

② medical devices - FDA may not ask for info about product other than that included in labeling
- problem is w/ off-label use of products
~ copy-cat products still not req'd. to provide any safety data

③ env. impact statement req'd of biological product manufacturers -

④ user-fee triggers
S830 requires greater increase in FDA approps. in order to collect user fees

Others

talk to Earnest about report language on LHHS

Oct. 20th

603 Maryland

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

September 24, 1997
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 830 - FDA Modernization and Accountability Act of 1997
(Sen. Jeffords (R) VT)

The Administration applauds the Senate for its bipartisan effort to improve S. 830 since it was reported by the Senate Committee on Labor and Human Resources, and appreciates the Senate's responsiveness to concerns that have been raised. Because of the importance of obtaining a five-year extension of the Prescription Drug User Fee Act (PDUFA), the Administration has no objection to passage of the bill by the Senate at this time. However, the Administration finds that the provisions identified below are unacceptable and as the legislative process continues, will work to ensure that our remaining concerns are resolved.

In general, this legislation represents a significant step toward accomplishing our mutual goal of assuring the agency's optimum performance while protecting the health of the American public. The Administration, however, continues to have two major concerns with the bill.

First, section 404 of the bill would lower the review standard for marketing approval by precluding the Food and Drug Administration (FDA) from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Second, the PDUFA trigger as proposed in S. 830 undercuts the bipartisan budget agreement (BBA) by requiring budget increases for FDA not envisioned by the BBA, and would interfere with HHS' ability to allocate resources appropriately throughout the Department.

In order to be able to support the final bill, the Administration will continue to work with the House of Representatives and in conference to resolve these and other identified issues.

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A6 10/8/97

Bills OKd to Accelerate FDA Approval Process

By MARLENE CIMONS
TIMES STAFF WRITER

WASHINGTON—Swiftly following action by the Senate, the House on a voice vote Tuesday resoundingly approved legislation aimed at streamlining the Food and Drug Administration's approval process for new drugs and medical devices.

Like the Senate bill, the measure establishes new programs to try to accelerate the review of experimental medical devices and drugs, as well as to expand the access of unapproved therapies to desperately ill people who have no other alternatives.

The two measures also would renew the popular Prescription Drug User-Fee Act, a popular program in which drug companies contribute to a fund used to hire extra personnel to prevent drug-review logjams. The program already has resulted in a speedup in the agency's review process.

The one significant difference between the House and Senate versions involves the question of unapproved uses of medical devices.

The House bill would permit the FDA to determine if a medical device is likely to be used for a purpose other than declared on the label. If so, and if that use is found harmful, the agency can require the maker to specify that the product is not authorized for the secondary purpose.

The Senate bill would prohibit the agency from reviewing so-called off-label uses of devices. That provision had delayed Senate action on the legislation for weeks and prompted a veto threat by President Clinton.

A statement from the administration hailed the change made by the House. As a result, it said that the bill "represents a significant step toward accomplishing the mutual goal of assuring the [FDA's] optimum performance while protecting the health of the American public."

California Rep. Anna Eshoo (D-Atherton), one of the lawmakers who helped craft the revised language on medical devices, said: "While partisan conflict . . . produced verbal fireworks in the Senate, bipartisan cooperation . . . produced consensus in the House."

A conference committee of House and Senate members now must resolve the differences between the two bills.

Efforts to change the FDA initially were spurred by the 1994 Republican takeover of Congress. GOP leaders accused several public health and safety agencies, including the FDA, of "over-regulation."

Attempts to pass a tougher bill—which many Democrats and public interest groups maintained would weaken the FDA—fizzled during the last session.

Rep. Henry A. Waxman (D-Los Angeles) was one of those steadfastly opposing efforts to reform the FDA in ways that he believed would hurt the agency. Commenting on the current House bill, he said that it was "a compromise that makes no one completely happy."

More effusive about the bill was Rep. Thomas J. Bliley Jr. (R-Va.), chairman of the House Commerce Committee. "We have built a stronger, better, more efficient FDA," he said. "We're going to help a lot of people. Medicines will be approved faster. Medical devices will reach people faster. When you're sick, when you're suffering, every minute counts."

Although FDA critics have attacked the agency for acting too slowly, several nonpartisan studies have credited the agency for markedly improving its performance, particularly in the drug area. The agency also has streamlined its device review procedures, although FDA officials have acknowledged that it could do better still.

Both the Senate and the House measures attempt to address this by expanding a pilot program to allow most experimental medical devices to be reviewed by outside experts chosen and paid for by the manufacturer. The FDA, however, would certify these reviewers in advance and make final decisions.

Also, these outside reviewers would not be permitted to review the riskiest devices, such as heart valves and other implantable items.

The bills "represent a major milestone in ensuring patient access to new medical technology," said Greg Raab, a spokesman for the Health Industry Manufacturers Assn., a medical device trade group.

The two measures would give terminally ill patients access to experimental drugs and devices that are still under study, even if the patients are not part of formal clinical trials or do not qualify for such studies.

Both bills also would allow drug companies to circulate among physicians the results of studies of off-label uses of licensed drugs, as long as manufacturers agree to seek formal approval ultimately for those uses from the FDA.

Attacking this provision was Maura Kealey of the consumer group, Public Citizen, which has campaigned against the FDA overhaul. Pointing to recent heart valve problems linked to unapproved uses of diet drugs, she warned that the provision could "blow up in [the] faces" of those supporting the legislation.

The bills would allow companies to add health and nutritional claims to their food labels if the benefits have been substantiated by a federal scientific body, such as the National Cancer Institute. The FDA would have the option of reviewing the claim and—if it disagreed—blocking or postponing it.

Driving both chambers to act quickly was universal support to continue the drug-user fee program. Rep. John D. Dingell (D-Mich.), ranking minority member of the Commerce Committee noted that the program is popular with consumers, regulators and industry. "When that happens, you know you have a winner," he said.

Wall Street J. B8
10/8/97

Bill to Speed FDA Reviews Passes House

By Jennifer Corbett Dooren
Dow Jones Newswires

WASHINGTON – Capping a nearly three-year effort to overhaul the Food and Drug Administration, the House approved legislation intended to speed the government's review of new medical devices, drugs and food products.

"Medicines will be approved faster, medical devices will get to people sooner," said Commerce Committee Chairman Thomas Bliley Jr., a Virginia Republican.

In contrast to previous efforts, this year's legislation had broad support from both Republicans and Democrats. The Senate cleared a similar bill last month.

The measures aim to speed the review of medical devices by expanding an existing FDA pilot program that allows private third parties to review some kinds of devices. They would also create a "fast-track" approval process for drugs intended to treat life-threatening illnesses and would give some seriously ill people access to experimental drugs.

In addition, the Prescription Drug User Fee Act, which expired Oct. 1, would be extended. Under the expired law, fees charged to pharmaceutical companies help finance the FDA reviews of drug safety and effectiveness reviews. The law has been credited with speeding the drug-approval process.

There are differences between the Senate and House bills that will have to be worked out in a conference committee.

For example, the Senate bill would bar the FDA from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Supporters say the provision will speed the review and allow the FDA to concentrate on approving complex medical devices.

The House bill seeks a middle ground by giving the FDA a 10-day period to determine whether a device is likely to be used for an unintended purpose and could cause harm. It is unclear if the House language will satisfy some Democrats and consumer groups, though.

The House bill also would let drug manufacturers distribute information to physicians about off-label uses for drugs. Some Democrats have criticized the provision in light of the recent problems with two diet drugs that were pulled off the market last month. The drugs, fenfluramine and phentermine, used together were linked to possible heart-valve risks in some people. While the FDA approved both drugs separately, it never approved the combination of drugs, which was commonly known as the fen-phen combination.

The House bill directs the FDA to act within 60 days on a petition to permit the use of radiation in processing red meat. Radiation can kill harmful bacteria and also extend the shelf life of the meat. Currently, the FDA allows irradiation of poultry, pork, fruits, vegetables and spices. The Senate bill doesn't contain the irradiation language.

House Approves Bill to Speed Review of Medicines

By JERRY GRAY

WASHINGTON, Oct. 7 — The House passed a Food and Drug Administration modernization bill today that would allow faster approval of new medicines for AIDS, cancer and other diseases and would make it easier for doctors to prescribe experimental drugs.

The bill would also set new guidelines for the Federal Government's regulation of prescription drugs, medical devices and food labeling, and extend for five years the fees that pharmaceutical companies pay to the F.D.A. to help defray the cost of speeding up reviews.

The House passed the measure on a unanimous voice vote. The Senate passed its version on Sept. 24 by a vote of 98 to 2, but only after a weeklong filibuster by Democrats over a provision that would limit the F.D.A.'s ability to regulate new medical devices.

The White House, which had threatened to veto the Senate bill because of the language on medical devices, praised the House bill in a statement as "a significant step toward accomplishing the mutual goal of assuring the Food and Drug Administration's optimum performance while protecting the health of the American people."

Differences between the two bills [illegible] resolved by a conference committee. But a senior Republican aide to the House Commerce Committee said today that the differences were minor and that he expected the two chambers to reach quick agreement.

Congress began the job of trying to rework the food and drug act three years ago.

"We have reached our objectives," Representative Thomas J. Bliley Jr., the Virginia Republican who heads the House Commerce Committee, said on the floor today before the vote. "Medicines will be approved faster, medical devices will get to people sooner, and those with serious and life-threatening diseases will get access to the best experimental new drugs that modern medicines can provide."

At the heart of the overhaul was a move to streamline the F.D.A.'s regulatory procedures to make it easier for new drugs and medical devices to reach the public.

Mr. Bliley's committee said in a report that it took an average of 12 years and $350 million for a new medicine to be reviewed and approved by the F.D.A.

The House bill requires the agency to establish a faster approval system for drugs and biological products like vaccines and blood products that treat serious and life-threatening illnesses. And the bill would expand and codify the practice of allowing patients with certain life-threatening illnesses to use drugs before the F.D.A. had completed its evaluation of them.

The House was able to avoid much of the rancor over the bill that occurred in the Senate by working out bipartisan agreements before the legislation reached the floor today, especially on the issue of regulating medical devices.

Under the Senate bill, the F.D.A. would be able to review only the uses of a medical device that are specified on the label by the manufacturer. Critics have complained that the provision would limit the Government's power to prevent misuse of a new device.

The House bill would limit the F.D.A.'s review of a medical device to the uses listed on the label, unless the agency determined, after consultation with the manufacturer, that the device could cause harm if it were used for some other purpose.

The bill would make several changes to rules on food labeling. For example, manufacturers would be allowed to print health claims on food labels using the findings of a Federal scientific agency like the National Institutes of Health or the Centers for Disease Control and Prevention.

NY Times A16 10/8/97

Dear Senator:

We urge you to oppose S. 830, The FDA Modernization and Accountability Act, which will likely be before you for a vote this week.

Despite strong concerns expressed by more than 100 organizations representing a broad spectrum of American patients and consumers, S. 830 still contains provisions that pose a significant threat to the health of all Americans. Among the worst provisions in the bill are:

Privatization of Review of Medical Devices -- This provision requires the FDA to broadly implement a system of medical device review and approval built upon a foundation of conflict of interest, in which for-profit review firms, whose primary concern is their bottom line and not patient safety, will compete for business.

Marketing of Unproven "Off-label" Drug Use -- Undermining the basic effectiveness standard upon which U.S. drug regulation is based, this provision allows drug companies to actively promote new uses of drugs that have never been proven safe and effective. If recent history is any lesson, this provision will have deadly consequences for thousands of Americans.

Preemption of States' Rights -- S. 830 nullifies state and local consumer protection laws relating to cosmetics. There is virtually no federal oversight of cosmetic products, which lead to an estimated 47,000 emergency room visits a year, and states will be barred from initiating their own efforts to protect their residents. This provision is vigorously opposed by the National Governors' Association and the National Conference of State Legislatures.

Unproven Health Claims on Foods -- S. 830 allows food and dietary supplement firms to make scientifically unsubstantiated health and nutrition claims about their claims about their products, which are now prohibited by the Nutrition Labeling and Education Act (NLEA).

We strongly support reauthorization of the Prescription Drug User Fee Act (PDUFA), now held hostage to the controversial unrelated provisions of S. 830, and urge separate and swift action on reauthorization to assure continuity of this critical program.

We also understand that several pro-consumer amendments may be offered in an attempt to make critically important improvements to this seriously flawed bill. We strongly urge you to support the following amendments.

1. Notification of Discontinuance - This amendment would ensure that patients with serious and life-threatening diseases are given sufficient advance warning whenever the sole manufacturer of their drug decides voluntarily to cease production. When a company stops making the only effective treatment for a disease, a patient's condition worsens and, in some cases, patients die. In these cases, a timely notification of discontinuance will provide the FDA and patient advocacy groups with the opportunity to seek out another company to begin making the drug, thus avoiding a devastating shortage.

2. Reject Preemption of State Safety Laws on Cosmetics - There is practically no federal regulation to protect consumers from dangerous cosmetics; preempting state laws in this area leaves the public completely unprotected.

3. Strict Conflict of Interest Prohibition for Private Medical Device Reviewers - S. 830 permits medical device manufacturers to select, negotiate terms with, and directly pay private for-profit firms to review and recommend approval of their products in lieu of the FDA's professional staff. Conflict of interest is generally inherent in this system: companies will not choose reviewers whose reports are unfavorable; reviewers who do not get repeat orders will not stay in business.

   At a minimum, private reviewers should be subject to the same personal conflict of interest standards as FDA staff: they and their families must be prohibited from having any financial stake in or accepting gifts from the companies for which they review products, with financial disclosure reports to ensure compliance.

4. Maintain mandatory tracking and surveillance for high risk medical devices such as heart valves - S. 830 changes mandatory tracking and surveillance of medical devices that are implantable for more than a year to discretionary. It seems inconceivable that auto makers are required to track new car buyers so that they may be notified of defective parts, but heart valve manufacturers are not required to keep a record of persons with the device implanted in them. In a resources-strapped FDA - even more so after S. 830 has added about $80 million annually in new, unfunded costs - discretionary functions will be lower priority. Tracking and surveillance of high-risk medical devices like heart valves are high priorities, and must remain mandatory.

   Sections 605 and 606 of the bill, which change mandatory tracking and postmarket surveillance of high-risk medical devices to discretionary, should be struck from the bill.

5. Exempt tobacco from S. 830 - Several sections of S. 830 may weaken the FDA's authority to regulate tobacco. A general disclaimer stating that nothing in this bill has any bearing on the regulation of tobacco should be added.

6. Prohibit misleading labels from limiting FDA review of medical devices - Section 404 prohibits the FDA from looking beyond the "conditions of use proposed on the label" of a medical device, even if there is good reason to believe the device will be used for other purposes - for example, a needle labeled for use in biopsies that could also be used in surgery to remove small tumors. Amend Section 404 to permit the FDA to consider all material facts that bear upon safety and effectiveness in reviewing a medical device.

7. Permit the FDA to withhold approval from medical devices known to be dangerous - Section 406 prevents the FDA from withholding initial classification of a device because of good manufacturing violations by a firm, even if those violations mean the device cannot be safely manufactured: for example, surgical gloves produced by defective

machinery that actually punched holes in the gloves. Section 406 shoud be amended to permit the FDA to withhold approval of devices it knows cannot be safely manufactured.

8. Strengthen FDA Enforcement Powers - Unlike most federal agencies, the FDA lacks subpoena, mandatory recall, and civil monetary penalty authority for the products it regulates. This lack of FDA enforcement powers leaves Americans dangerously unprotected.

   Amend S. 830 to give the FDA the same subpoena, recall, and civil monetary penalty authority over all the products it regulates as the Administration is proposing for food in the wake of the exposure of millions of Americans to contaminated hamburger and salmon.

9. Keep Environmental Protection - S. 830 contains a sweeping exemption of FDA actions from NEPA, the National Environmental Protection Act. This is bad policy and bad precedent, and should be struck from the bill.

Thank you for your consideration of these crucial issues and we hope that when it is time to cast your vote, you will stand up for the health and safety of your constituents and all Americans by opposing S. 830.