NOTICE: In lieu of a star print, errata are printed to indicate corrections to the original report.

Calendar No. 446

104TH CONGRESS, *2d Session* | SENATE | REPORT 104–284

ERRATA

FOOD AND DRUG ADMINISTRATION PERFORMANCE AND ACCOUNTABILITY ACT OF 1996

JUNE 20, 1996.—Ordered to be printed

Mrs. KASSEBAUM, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 1477]

CORRECTIONS

On page 1, the paragraph above the contents, line 7, strike, "as amended" and insert, "(as amended)".

On page 2, line 6, strike, "enduring", and insert, "ensuring":

On page 2, paragraph 4, line 1, strike, "PUDFDA", and insert, "PDUFA".

On page 6, line 3, strike the word "dollars".

On page 9, line 2, strike, "Markets", and insert, "International markets".

On page 22, paragraph 2, line 5, strike, "congress", and insert, "Congress".

On page 41, paragraph 5, line 12, insert, "their use. Requiring separate license applications for" after "standards for".

On page 43, paragraph 3, line 1, strike, "Committee", and insert, "committee".

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On page 43, paragraph 3, line 7, strike, "hyphen", and insert a "one em dash".

On page 45, paragraph 2, line 2, strike, "nonprescirption", and insert, "nonprescription".

On page 63, paragraph 3, line 4, strike, "federal", and insert, "Federal".

On page 88, the line that starts, "*Sec. 706.*" strike, "*Times frames*", and insert, "*Time frames*".

On page 90, paragraph 1, line 3, strike, "public law", and insert, "Public Law".

COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 1, 1996.

Hon. NANCY LANDON KASSEBAUM,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1477, the Food and Drug Administration Performance and Accountability Act of 1996, as reported by the Senate Committee on Labor and Human Resources on June 20, 1996. The estimate includes the intergovermental and private sector mandate statements that are required by the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

Because this bill will not affect direct spending or receipts, pay-as-you-go procedures would not apply to this bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1477.

2. Bill title: Food and Drug Administration Performance and Accountability Act of 1996.

3. Bill status: As reported by the Senate Commitee on Labor and Human Resources on June 20, 1996.

4. Bill purpose: S. 1477 would amend the Food, Drug and Cosmetic Act (FDCA) and the Public Health Service Act to reform the Food and Drug Administration's (FDA's) regulatory and approval processes for drugs, biological products, devices, foods, and animal drugs.

5. Estimated cost to the Federal Government: Assuming appropriation of the necessary funds, CBO estimates that the Federal Government would spend an additional $555 million over six years to implement the provisions of S. 1477. The following table summarizes the estimated authorizations and outlays that would result from S. 1477. Most of the additional costs under the bill would result from the increased workload given to the FDA.

[By fiscal year, in millions of dollars]

	1997	1998	1999	2000	2001	2002
Estimated authorization level	99	94	96	96	84	86
Estimated outlays	75	90	96	96	87	86

The costs of this bill fall within budget function 550.

6. Basis of the estimate: S. 1477 would reform the FDA's approval and regulatory processes with the intent of accelerating product approvals and alleviating regulatory requirements. The bill would also establish a separate approval process for radiopharmaceuticals. Additionally, S. 1477 would mandate that the FDA Commissioner create a research and education consortium for drugs, biological products and devices; this program would be authorized through fiscal year 2000. Finally, the bill would reauthorize the FDA-funded clinical pharmacology training program through fiscal year 1998.

Enforced deadlines for FDA action on submissions

S. 1477 would require the FDA to develop performance standards that would, in part, reduce backlogs on applications by January 1, 1998. The bill would also mandate the FDA to act on product submissions essentially within the time limits that exist under current law. If the agency's rate of compliance with these deadlines were to fall below 95 percent in a given year, the Secretary of Health and Human Services would be required to contract with third parties to conduct product reviews. According to both the General Accounting Office and the FDA, average agency review times currently exceed statutory deadlines for action on product submissions, with the exception of drugs reviewed under the Prescription Drug User Fee Act (PDUFA).

Assuming that the volume and quality standards for reviews were to remain constant, the FDA would need additional staff and other resources to reduce review times significantly and to eliminate the backlog of product submissions. Since S. 1477 would relax current FDA regulations somewhat, the number of product applications would probably increase. CBO estimates that the additional personnel and resources necessary to meet the proposed deadlines would exceed any savings realized through regulatory relief offered by S. 1477. These provisions are estimated to cost the federal government $430 million over six years.

Third party review of applications

Several provisions of S. 1477 would establish mechanisms for third-party review of product submissions and manufacturing processes. After July 1998, if the FDA missed statutory deadlines for action on more than 5 percent of product submissions in a year, the agency would be required to contract with outside reviewers. These outside experts would review and make recommendations on new submissions and on any backlog of applications. Within 60 days of receipt, the FDA would have to make a final determination on these recommendations.

The bill would also authorize the Secretary to initiate third-party reviews to improve the FDA's efficiency or its scientific and technical expertise. Within two years of the bill's enactment, the Sec-

retary would be required to report to Congress on the effect of third-party review on the FDA's efficiency. Under this provision, fees collected under PDUFA would fund external reviews of drugs for which such fees were paid. Authority to collect these fees expires at the end of fiscal 1997, however. S. 1477 would also establish a three-year pilot program for outside review and classification of medical devices. Device sponsors could select among FDA-accredited reviewers, with whom they would negotiate compensation for the reviews. The FDA would develop accreditation guidelines that would include criteria for avoiding conflicts of interest on the part of the reviewers. Under this pilot program, final determination on product applications would remain with the FDA.

CBO estimates that contracting with third-party reviewers for product reviews would yield no budgetary savings. Outside reviewers would conduct the same number of reviews, and would be required to meet the same quality standards, as the FDA and therefore would use the same level of resources as the agency currently does in conducting product reviews.

Finally, S. 1477 would direct the Secretary to expedite reviews by accepting medical device performance standards developed by select standard-setting organizations or FDA-accredited organizations. The FDA would certify organizations based on established criteria, and could charge these organizations a one-time certification fee. CBO assumes the FDA would charge a fee equal to its review costs, so that this provision would have no budgetary impact.

Reporting product changes to the FDA

S. 1477 would permit manufacturers to make certain minor changes in the design and manufacturing process for products without first submitting a supplemental application to the FDA. Current law requires FDA approval of a supplemental application before such changes can be made. Under the bill, manufacturing changes that did not affect the ''approved qualitative and quantitative formulation of . . . release specifications'' of certain drugs and biologics could be reported to the FDA annually. This provision would likely increase the number of FDA warnings and product recalls resulting from manufacturing changes that cause safety and efficacy problems. CBO estimates that savings from reductions in FDA review of supplemental applications would be roughly offset by the cost of these additional compliance activities.

The bill would also waive the requirement that manufacturers file an additional application for an exemption for minor changes in the intended use or design of an investigational device. Minor changes are those that would not affect the efficacy or safety of the device. CBO estimates that this provision would save $11 million over six years.

Additional administrative responsibilities for the FDA

Although the proposal would reduce some of the FDA's regulatory activities, it would greatly increase others. Among other requirements, S. 1477 would direct the agency to develop a system for tracking applications, to develop agency performance standards and to hold regularly scheduled meetings with product sponsors. To

fulfill these new responsibilities, the agency would have to hire additional staff, among other measures. CBO estimates that the additional personnel and support activities needed to meet these increased responsibilities would cost $83 million over six years.

Exemption of certain devices from premarket notification requirement

The proposal would waive the premarket notification requirement for certain Class I and Class II devices. Most Class I devices would be exempt from the Section 510(k) reporting requirement, except those that the Secretary determines must be reported in order to protect the public health. The bill would also direct the Secretary to develop a list of the Class II devices exempt from 510(k) reporting requirements for the purpose of furnishing ''reasonable assurance of safety and effectiveness.'' Sponsors could petition the FDA to exempt specific Class II devices from 510(k) reporting requirements; the agency would be required to respond to these requests within 120 days of receipt. This provision would reduce the FDA's administrative activities, saving $1 million over six years.

S. 1477 would also alter the FDA's current practice of automatically designating as Class III products new devices that are not substantially equivalent to a legally marketed predicate device. Under the bill, sponsors of devices designated as Class III could request that an advisory committee review their product and make a classification recommendation. The FDA would have ten days to make a final determination on the committee's recommendation. This provision would reduce the number of premarket applications that the FDA reviews, saving $7 million over six year.

Waiver of environmental impact review requirement

Under current law, FDA action on products is subject to environmental impact reviews. S. 1477 would repeal this requirement unless the FDA office responsible for the product in question demonstrates that the ''environmental impact of the action is sufficiently substantial'' and falls within the agency's purview under FDCA. The office would also have to demonstrate that consideration of this impact would directly affect the agency's decision on the issue. In April 1996, the FDA issued a notice proposing a policy similar to that advanced in S. 1477. Assuming that this policy would not be implemented until fiscal year 1998, CBO estimates savings of $1 million 1997.

New approval process for indirect food additives

S. 1477 would create an alternative approval mechanism for indirect food additives. At least 90 days before bringing a new indirect food additive to market, manufacturers of such additives would be required to submit a notification demonstrating the safety of the product's intended use to the FDA. The FDA would be required to approve or disapprove the notification within 90 days of receipt. If it approved the notification, the agency would be required to issue regulations specifying the conditions under which the additive could safely be used. Assuming that the number and quality of these reviews remained constant, the FDA would likely require ad-

ditional resources in order to review these products within 90 days. At this time, CBO is unable to estimate any costs that might result from this provision.

Separate approval system for radiopharmaceuticals

Within six months of enactment of S. 1477, the Secretary would be required to issue proposed regulations for the approval of radiopharmaceuticals. The bill would also create a new office within the Center for Drug Evaluation and Research, and a separate scientific review group, to handle radiopharmaceutical submissions. Within a year of the bill's passage, the Secretary would be required to issue final regulations on the regulation and approval of radiopharmaceuticals. The estimated cost of establishing and operating the radiopharmaceutical approval system is $7 million over six years.

Other provisions

S. 1477 would reauthorize the pilot program in clinical pharmacology that was established pursuant to P.L. 102–222. The bill would authorize a total of $4 million for this program for fiscal years 1997 through 1998. The Secretary would be directed to establish and fund a consortium for research and education on drugs, devices and biologics. The FDA would also be required to convene on oversight committee to monitor the consortium's activities. The bill would authorize $51 million for these activities for fiscal years 1997 through 2000.

7. Pay-as-you-go considerations: None.

8. Estimated impact on State, local, and tribal government: S. 1477 would preempt state and local laws that regulate nonprescription drugs differently than federal law. This mandate would impose no significant costs on state and local governments. S. 1477 would impose no other direct costs on state, local or tribal governments.

9. Estimated impact on the private sector: This bill would impose new private-sector mandates as defined in Public Law 104–4. It would impose new record keeping requirements on the distributors of veterinary feed directive drugs and on veterinarians that recommend their use. A veterinary feed directive drug is ''a drug intended for use in or on animal feed which is limited . . . to use under professional supervision of a licensed veterinarian.'' Section 805(b) mandates that the veterinarian and the distributor of a veterinary feed directive drug ''maintain a copy of the veterinary feed directive applicable to each such feed.'' Distributors are also required to notify the Secretary of their name and place of business. Both veterinarians and distributors of veterinary feed directive drugs are likely to increase their current record keeping activities to comply with this mandate, resulting in a small increase in their cost of doing business. The cost increase for the industry would be well below the $100 million threshold for private-sector mandates.

10. Previous estimate: None.

11. Estimate prepared by: Federal cost estimate, Anne Hunt; private sector mandate estimate, Anna Cook; State and local cost estimate; John Patterson.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

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