CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 1, 1997

H.R. 1411
Prescription Drug User Fee Reauthorization and Drug Regulatory Modernization Act of 1997

As ordered reported by the House Committee on Commerce
on September 25, 1997

SUMMARY

H.R. 1411 would reauthorize the Prescription Drug User Fee Act (PDUFA) of 1992, which empowers the Food and Drug Administration (FDA) to collect user fees from the pharmaceutical industry. The user fee program would be reauthorized, with some modifications, for an additional five years. The bill would also amend the Food, Drug and Cosmetic Act (FD&CA) and the Public Health Service Act to reform the FDA's regulatory and approval processes for drugs, biologics, and antibiotics. One provision would grant a six-month extension of market exclusivity for pharmaceutical manufacturers who conduct pediatric studies on select prescription drugs. Another would make certain antibiotics eligible for patent extensions under the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).

CBO estimates that enacting H.R. 1411 would result in net additional discretionary spending of $9 million in 1998 and $214 million over the 1998-2002 period, assuming appropriation of the authorized amounts. Reauthorizing the user fee program would yield $601 million in offsetting collections over five years; these amounts would also be authorized to be spent, subject to appropriation. Extending market exclusivity for certain drugs would increase direct spending by $65 million and reduce revenues by $61 million over the 1998-2002 period. The direct cost implications of the provision extending eligibility for Hatch-Waxman extensions to some antibiotics cannot be estimated at this time.

By preempting state and local laws that regulate nonprescription drugs and labeling of cosmetics differently than federal law, H.R. 1411 would impose an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that compliance with this mandate would result in no significant costs for state and local governments.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1411 is shown in the following table. For the purposes of this estimate, CBO assumes that all amounts authorized in the bill would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns for the FDA. The costs of this legislation fall within budget function 550 (Health).

	By Fiscal Year, in Millions of Dollars					
	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law						
Estimated Authorizations						
Authorization Level	887	919	949	982	1,016	1,050
Estimated Outlays	880	905	937	971	1,005	1,038
Collection of User Fees						
Authorization Level	-88	0	0	0	0	0
Estimated Outlays	-88	0	0	0	0	0
Spending of User Fees						
Authorization Level	88	0	0	0	0	0
Estimated Outlays	87	22	4	0	0	0
Proposed Changes						
Estimated Authorizations						
Authorization Level	0	26	64	68	70	70
Estimated Outlays	0	9	31	46	60	68
Collection of User Fees						
Authorization Level	0	-110	-116	-119	-128	-128
Estimated Outlays	0	-110	-116	-119	-128	-128
Spending of User Fees						
Authorization Level	0	110	116	119	128	128
Estimated Outlays	0	82	109	118	126	127

	By Fiscal Year, in Millions of Dollars					
	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION						
Spending Under H.R. 1411						
Estimated Authorizations						
Authorization Level[a]	887	945	1,013	1,050	1,086	1,120
Estimated Outlays	895	923	968	1,017	1,065	1,106
Collection of User Fees						
Authorization Level [a]	-88	-110	-116	-119	-128	-128
Estimated Outlays	-88	-110	-116	-119	-128	-128
Spending of User Fees						
Authorization Level [a]	88	110	116	119	128	128
Estimated Outlays	87	104	113	118	126	127
DIRECT SPENDING AND REVENUES						
Direct Spending						
Estimated Budget Authority	0	0	7	18	28	11
Estimated Outlays	0	0	7	18	28	11
Revenues						
Estimated Revenues	0	0	-6	-15	-25	-15

a. The 1997 level is the amount appropriated for that year.

BASIS OF ESTIMATE

Estimated Authorizations

The bill would reform the FDA's approval and regulatory processes with the intent of accelerating product approvals and reducing regulatory requirements. H.R. 1411 would require the FDA, in coordination with the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), to establish a program to provide information on treatment, detection, and prevention of serious diseases and on clinical trials currently studying these conditions. Other provisions would result in small budgetary savings.

Information Program on Clinical Trials. H.R. 1411 would require the Director of the NIH in coordination with the FDA and the CDC to establish a program to provide information on treatment, detection, and prevention of serious diseases and on clinical trials currently studying these conditions. This program would include establishing a database of all federally and privately funded clinical trials and a toll-free telephone information line available to health care providers, researchers, individuals with serious diseases, and all other members of the public.

The NIH already has such a program for clinical trials that it funds for cancer, AIDS, and rare diseases. Privately-funded clinical trials are also included in these databases on a voluntary basis. The FDA would be able to disclose information on clinical trials, and NIH would be required to expand its current database significantly to accommodate the increase in volume of trials and information. After the system was set up, additional maintenance costs would be incurred to keep up with the status and results of clinical trials, and with new protocols on treatment and prevention of serious diseases and conditions. Costs would also arise to operate the telephone information line, which would be staffed by health professionals.

CBO based its estimate on the cost of maintaining the current data banks and information networks, the estimated portion of clinical trials currently contained in NIH's databases, and on conversations with professionals experienced in this area. CBO assumes that it would take two years to create a system that would meet the minimum requirements specified in the bill, at a cost of $20 million in 1998 and $45 million in 1999. For each year thereafter, CBO estimated a cost of $50 million for maintenance and quality improvement. Costs would total $215 million over the 1998-2002 period.

Dissemination of Off-Label Use Information. H.R. 1411 would permit manufacturers, within one year of enactment, to disseminate to select professional audiences information on a product use not described in the approved labeling of the drug. The only information that could be disseminated would be copies of articles in a peer-reviewed journal or in a reference publication. The manufacturer must also certify that a supplemental application for the product will be submitted to the Secretary within a specified time. The manufacturer must submit to the Secretary biannually a list of the titles of the articles disseminated and a list of the categories of health care providers receiving this information. CBO estimates that this provision would have no federal costs in 1998 but would cost $59 million through 2002.

Regulation of Positron Emission Tomography (PET) and Radiopharmaceuticals. H.R. 1411 would require the FDA to establish an approval process and good manufacturing practice requirements for PET. The agency also could not require the submission of new drug applications or abbreviated new drug applications for PET products that are not adulterated for four years after enactment of the bill. Three FDA notices and rulings regarding the regulation of PET products would also be revoked. Finally, the bill would

direct the FDA to issue regulations for the approval of radiopharmaceuticals used for diagnostic or monitoring purposes. The cost of fulfilling these requirements would be $300,000 in 1998 and approximately $1 million over five years.

Information Systems. The FDA would be required to establish and maintain an information system that would allow the agency to track product applications and systems. Fulfilling these requirements would cost $4 million in 1998 and $13 million over five years.

User Fees

The bill would reauthorize current prescription drug user fees through September 30, 2002. The current authorization expired at the end of fiscal year 1997. Proceeds from these fees would be available for spending, subject to appropriation.

Reauthorization of the Prescription Drug User Fee Act of 1992. As with prior law, the reauthorized program would levy three types of user fees on pharmaceutical manufacturers: application and supplement fees, establishment fees, and product fees. Aggregate amounts of such fees are specified in the bill for each fiscal year through 2002; these amounts would be adjusted to reflect cumulative inflation since 1997. CBO's estimate assumes that the inflation adjustment would apply to the specified authorization, not to the prior year's actual authorization. The amounts collected are authorized to be spent, subject to appropriation. CBO estimates that the FDA would collect $110 million in 1998 and $601 million over five years.

Any fees collected in excess of the amount specified in the appropriations act for a given year would be credited to the FDA appropriations account and subtracted from the amount of fees authorized for the following year. The FDA could not assess the user fees unless appropriations for FDA salaries and expenses, excluding any user fees, were at least equal to appropriations for 1997, adjusted for inflation.

Direct Spending

The bill would grant an additional six months of market exclusivity to pharmaceutical manufacturers that conduct pediatric studies on select drugs. This provision would affect direct spending because it would increase costs for the Medicaid rebate program and the Federal Employees Health Benefit Program (FEHBP). This provision would apply to pediatric studies commenced before January 1, 2002.

The Secretary of Health and Human Services, through the Commissioner of the FDA, would issue a list of drugs for which additional pediatric information may yield a health benefit.

If manufacturers of targeted drugs submitted pediatric studies to the FDA, their product would receive an additional six months of market exclusivity. This benefit would accrue to both approved drugs and those awaiting approval. Manufacturers of an approved drug that received an extension under this provision could, if eligible, receive an additional six months of exclusivity for a supplemental application.

By extending the market exclusivity of certain drugs, this proposal would increase prescription drug costs for Medicaid, FEHBP, Veterans Affairs (VA) facilities, the Department of Defense, and the Public Health Service for the six months of the extension. In the absence of this provision, these programs may have had access to less expensive generic products. In the case of Medicaid and FEHBP, the additional costs of this provision would represent direct spending. At this time, the costs to the VA, the Department of Defense and the Public Health Service cannot be determined. CBO estimates that this provision would have no net budgetary effect in 1998 but would increase federal outlays for Medicaid and FEHBP by $68 million over the 1998-2002 period. This provision would also reduce revenues to the federal government. Private insurers would raise premiums in response to higher pharmaceutical prices. Because individuals would have to pay higher insurance premiums, their taxable income would decrease. Total revenue reductions over five years are estimated at $61 million.

Finally, section 23 of the bill would make certain antibiotics eligible for a patent extension under the Hatch-Waxman Act. Although this provision would increase costs to Medicaid, FEHBP, and other federal programs and would reduce federal revenues, these changes cannot be estimated at this time.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Because the bill would affect direct spending and receipts, pay-as-you-go procedures would apply. The projected changes in direct spending and receipts are summarized in the following table for fiscal years 1998-2002. For purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

Summary of Pay-As-You-Go Effects

	By Fiscal Year, in Millions of Dollars									
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Change in outlays	0	7	18	28	11	0	0	0	0	0
Change in reciepts	0	-6	-15	-25	-15	0	0	0	0	0

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

By preempting state and local laws that regulate nonprescription drugs and cosmetics differently than federal law, H.R. 1411 would impose an intergovernmental mandate as defined in UMRA. CBO estimates that compliance with this mandate would result in no significant costs for state and local governments. Consequently, the threshold established in UMRA ($50 million in 1996, adjusted annually for inflation) would not be exceeded. This mandate would not affect tribal governments.

By granting certain drug manufacturers a six-month extension of market exclusivity for their products, the bill would make prescription drugs provided under Medicaid more expensive. CBO estimates that states' share of these costs would total about $28 million over the next five years. Another provision in the bill would make certain antibiotics eligible for patent extension under the Hatch-Waxman Act. This provision also would result in increased costs for Medicaid; however, CBO is unable at this time to estimate the magnitude of these costs. In any event, these provisions would not constitute mandates under UMRA because prescription drugs under Medicaid are provided at a state's option.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 1411 would impose some new private-sector mandates, and in several instances would replace existing mandates with new, less burdensome requirements. In addition, the bill would reauthorize application fees and certain other fees paid by pharmaceutical companies. However, since these fees do not become effective until Congress appropriates them, they do not constitute a private-sector mandate. Thus, the direct costs of all private-sector mandates in this bill that could be estimated are minimal and the total effect could be a net reduction in mandate costs imposed on the private sector.

Sections 6 and 32 would impose new mandates on the private sector. Section 6 would direct the Secretary of Health and Human Services to establish "a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions." This provision would impose a new mandate on sponsors of such clinical trials by requiring them to forward to the data bank information about eligibility criteria for participation in the trial, the location of the trial, and a point of contact within 21 days after the clinical trials have begun. Section 32 would require manufacturers of drugs, biological products and class III medical devices that are life supporting or prevent a debilitating disease to notify the Secretary of any discontinuation in the manufacture of the product, 6 months in advance. CBO estimates that the costs of these mandates would be minimal.

Section 31 would require the Secretary to promulgate regulations restricting the sale of mercury for use as a drug or dietary supplement if the Secretary believes that the use of the product poses a threat to human health. Because such regulations are contingent on an analysis that has not yet been performed, the FDA was unable to provide any information that would clarify whether the restriction on the sale of mercury would be needed. Thus, CBO is unable to estimate the impact of this section on the private sector.

Several new mandates would cost no more and perhaps less than the current regulatory requirements that they would replace. Section 19 would set new quality standards for positron emission tomography drugs but relieve them of the new drug application process and certain other requirements. Section 21 would establish a single licensing requirement for biological products that would replace current licensing requirements.

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