CONGRESSIONAL BUDGET OFFICE
PAY-AS-YOU-GO ESTIMATE

December 30, 1997

S. 830
The Food and Drug Administration Modernization Act of 1997

As cleared by the Congress on November 9, 1997

SUMMARY

S. 830 reauthorizes 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. It amends the Food, Drug, and Cosmetic Act and the Public Health Service Act to change the regulatory and approval processes for drugs, biologics, antibiotics, devices, and food products. These provisions would affect spending subject to appropriation but would have no effect on direct spending or revenues.

The act allows extensions of market exclusivity for pharmaceutical manufacturers who conduct pediatric studies on select prescription drugs. It also makes certain antibiotics eligible for patent extensions under the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act). CBO estimates that the provisions providing for additional market exclusivity will increase outlays by $113 million and reduce revenues by $111 million over the 1998-2007 period, as shown in the following table.

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	2	7	5	19	16
Change in revenues	0	-5	-15	-26	-17	-5	-6	-6	-15	-16

BASIS OF THE ESTIMATE

Two provisions in S. 830 will affect direct spending and receipts. Section 111 of the act sets conditions under which additional market exclusivity may be granted to pharmaceutical manufacturers who commence pediatric studies on drugs. Section 125 of the act makes certain antibiotics eligible for patent extensions under the Hatch-Waxman Act.

Section 111 directs the Secretary of Health and Human Services, through the Commissioner of the FDA, to issue a list of drugs for which additional pediatric information may yield a health benefit. Manufacturers of targeted drugs who submit pediatric studies to the FDA before January 1, 2002, will receive a six-month extension of market exclusivity for their products. This benefit will accrue to both approved drugs and those awaiting approval. Manufacturers of an approved drug who have received an extension under this provision may receive an additional six months of exclusivity for a supplemental application.

After January 1, 2002, a drug can receive an additional six-month extension if the Secretary determines that there is a continuing need for data on the use of the drug in children. To be eligible for additional six-month extensions, a drug must have been on the market as of the date of enactment of S. 830 and must have been included on the Secretary's list as of January 1, 2002. A manufacturer can receive multiple extensions for a drug after January 1, 2002, if the Secretary makes repeated determinations regarding the necessity of pediatric data for the drug.

By precluding competition, section 111 will increase the cost of prescription drugs for Medicaid, the Federal Employees Health Benefit Program (FEHBP), Veterans Affairs 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 would have had access to less expensive generic products. In the case of Medicaid and FEHBP, the additional costs of this provision represent direct spending. This provision will not affect spending in 1998 but will increase federal outlays for Medicaid and FEHBP by $101 million over the 1998-2007 period.

To estimate the costs of this provision, CBO identified drugs with patents expiring during the next ten years and assumed that half of these products will be eligible for extensions. Using data on annual Medicaid spending on the eligible products, we calculated the cost of buying brand-name drugs for an additional six months. We calculated Medicaid costs under prior law, which allowed for generic entry immediately after the expiration of market exclusivity for the affected products. The costs of this provision equal the difference between these two cost streams. CBO's estimate accounts for the split in market share

between generic and brand-name products, the ratio of generic to brand-name prices, and the date when generic products would have entered the market.

Section 125 of the bill makes certain antibiotics eligible for patent extensions under the Hatch-Waxman Act. To estimate the costs of this section, CBO assumed that two new antibiotics will be approved each year and that sales of these drugs over their life cycles will follow historical patterns. For each year, we calculated the likelihood that, in the absence of this provision, the new drugs would have had a period of market exclusivity ranging from one to 14 years and would have received Hatch-Waxman extensions of from one to five years. CBO assumed that the likelihood of these drugs having any of the 70 possible combinations of exclusivity and extension would follow historical patterns. We then estimated total expected costs by multiplying projected sales of the drugs by the difference between brand-name and generic prices for each combination of years of exclusivity and extension, and summing over all the possibilities. CBO assumed that the share of the increase incurred by Medicaid and FEHBP would be proportional to their shares of prescription drug sales. The effects of this provision on spending and revenues are small during the 1998-2002 period. During the 2003-2007 period, CBO estimates that outlays will increase by $12 million.

Sections 111 and 125 will also reduce federal income and payroll tax revenues by raising the costs of employer-sponsored health insurance and correspondingly reducing the amount of taxable compensation. Section 111 will reduce revenues by $99 million over ten years, while section 125 will decrease revenue collections by $12 million.

PREVIOUS CBO ESTIMATES

On June 27, 1997, CBO prepared an estimate for S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997, as ordered reported by the Senate Committee on Labor and Human Resources on June 18, 1997. On October 1, 1997, CBO issued an estimate for H.R. 1411, the 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.

Both S. 830 and H.R. 1411 would have granted extensions of market exclusivity for eligible drugs to manufacturers who conducted pediatric studies on their products before January 1, 2002, but not after that date. CBO estimated provision in S. 830 would have cost Medicaid $65 million over the 1998-2002 period. The costs to Medicaid and FEHBP of the provision contained in H.R. 1411 were estimated at $68 million over the 1998-2002 period.

H.R. 1411 would also have made antibiotics eligible for patent extensions under the Hatch-Waxman Act. At the time the estimate of H.R. 1411 was issued, CBO could not estimate the costs of this provision.

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