CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

April 27, 2007

S. 1082
Prescription Drug User Fee Amendments of 2007

As reported by the Senate Committee on Health, Education, Labor, and Pensions on April 24, 2007

S. 1082 would authorize the collection and spending of user fees by the Food and Drug Administration (FDA) for activities related to the approval and marketing of prescription drugs and medical devices and for monitoring the safety of prescription drugs when they are on the market. Such fees would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

The bill also would establish a surveillance system to monitor post-marketing drug safety, enhance FDA's authority to regulate drugs once they have entered the market, expand tracking of clinical trials involving drugs and medical devices, and reauthorize and expand programs that focus on evaluation of drugs and devices for use by children. S. 1082 would extend the authority for FDA to administer an incentive program that grants market exclusivity to manufacturers that voluntarily conduct studies on the use of drugs in certain pediatric populations. The bill would require that the period of market exclusivity be extended by six months (three months for certain "blockbuster" drugs) if the manufacturer meets specified requirements.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

S. 1082 would affect both discretionary and direct spending. The costs of this legislation fall primarily within budget functions 550 (health) and 570 (Medicare). Enacting the bill also would affect revenues.

Spending Subject to Appropriation

Assuming appropriation action consistent with the bill, CBO estimates that implementing S. 1082 would reduce net discretionary outlays by $157 million in 2008, primarily because the spending of fees lags somewhat behind their collection. CBO estimates that gross spending in subsequent years would exceed the amounts collected from user fees (because

some of that spending under the bill would not be offset by fees), and that the net cost of implementing the bill would amount to $547 million over the 2008-2012 period, assuming the appropriation of the necessary amounts (see Table 1). Because most of the cost of FDA activities would be offset by user fees, the largest component of the net discretionary cost of implementing S. 1082 would be an estimated $432 million in spending over the 2008-2012 period for pediatric research conducted by the National Institutes of Health.

Direct Spending

The provision extending market exclusivity for certain prescription drugs would delay the entry of lower-priced generic versions of those drugs, which would affect both direct spending and federal revenues. CBO estimates that direct spending for Medicare, Medicaid, the Federal Employees Health Benefits (FEHB) program, and the TRICARE for Life program would increase by an estimated $5 million over the 2008-2012 period and $150 million over the 2008-2017 period (see Table 2). (CBO estimates that the market exclusivity provisions would increase discretionary spending by the FEHB program, Department of Veterans Affairs, Department of Defense, and other federal health benefits programs by $2 million over the 2008-2012 period. Those effects are included under "Other Provisions" in Table 1.)

Revenues

Higher spending for prescription drugs would increase the cost of premiums for private health insurance. Higher premiums, in turn, would result in more of an employee's compensation being received in the form of nontaxable employer-paid premiums, and less in the form of taxable wages. As a result of this shift, federal income and payroll tax revenues would decline. CBO estimates that the proposal would have a negligible effect on federal tax revenues over the 2008-2012 period and would reduce federal revenues by $32 million over the 2008-2017 period (see Table 2). Social Security payroll taxes, which are off-budget, would account for $11 million of that total.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 1082 would preempt any state or local government law that requires manufacturers of medical devices or drugs to register clinical trials and related information in a database. That preemption would be an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA) because it would limit the application of state law. However, the costs of the mandate would be minimal and would be far below the threshold established in

UMRA ($66 million in 2007, as adjusted for inflation). Because the bill would delay entrance into the market of some generic drugs, CBO estimates that states would spend an additional $26 million over the 2009-2017 period for Medicaid.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill would place a number of requirements on the manufacturers of prescription drugs and medical devices that would be private-sector mandates as defined in UMRA, including requiring those entities to pay fees to the FDA. CBO estimates that the direct cost of those mandates would exceed the annual threshold specified in UMRA ($134 million in 2008, adjusted annually for inflation) in each of the five years that the mandates would be effective.

ESTIMATE PREPARED BY:

Federal Costs: Julia Christensen and Sarah Evans
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Stuart Hagen

ESTIMATE APPROVED BY:

Peter H. Fontaine
Deputy Assistant Director for Budget Analysis

TABLE 1. ESTIMATED IMPACT OF S. 1082 ON DISCRETIONARY SPENDING

	By Fiscal Year, in Millions of Dollars				
	2008	2009	2010	2011	2012
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Collections from User Fees					
Prescription Drug Fees	-478	-547	-619	-695	-841
Advertising Fees	-13	-7	-7	-8	-8
Medical Device Fees	-48	-53	-57	-62	-67
Total, Estimated Authorization Level	-539	-606	-684	-765	-916
Total, Estimated Outlays	-539	-606	-684	-765	-916
Spending of User Fees					
Prescription Drug Fees	478	547	619	695	841
Advertising Fees	13	7	7	7	8
Medical Device Fees	48	53	57	62	67
Total, Estimated Authorization Level	539	606	684	765	916
Total, Estimated Outlays	345	606	677	756	840
Net Changes in User Fees					
Estimated Authorization Level	0	0	0	0	0
Estimated Outlays	-194	0	-6	-9	-76
Other Proposed Changes:					
Drug Safety					
Estimated Authorization Level	45	64	69	70	72
Estimated Outlays	26	57	68	70	73
Pediatric Medical Products					
Program for Pediatric Research					
Estimated Authorization Level	0	75	150	200	225
Estimated Outlays	0	19	79	144	190
Other Provisions	14	20	25	24	25
Estimated Authorization Level	11	20	24	24	25
Estimated Outlays					
Total Changes					
Estimated Authorization Level	59	159	243	294	322
Estimated Outlays	-157	96	165	230	213

TABLE 2. CHANGES IN DIRECT SPENDING AND REVENUES UNDER S. 1082

	By Fiscal Year, in Millions of Dollars											
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2008-2012	2008-2017
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	0	*	*	1	4	8	14	22	39	62	5	150
Estimated Outlays	0	*	*	1	4	8	14	22	39	62	5	150
CHANGES IN REVENUES												
Estimated Revenues												
On-budget	0	*	*	*	-1	-1	-2	-3	-5	-9	-1	-21
Off-budget	0	*	*	*	0	-1	-1	-2	-3	-4	0	-11
Total	0	*	*	*	-1	-2	-3	-5	-8	-13	-1	-32

Note: * = less than $500,000.