



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

November 18, 1997

Proposed Demonstration Project to Fund Biomedical Research

Draft legislative language as of October 28, 1997

SUMMARY

CBO estimates that the proposed demonstration project would increase both federal outlays and federal revenues over the 1998-2002 period, with the increase in revenues exceeding the increase in outlays. During the 2003-2007 period, however, outlays would increase more than revenues, and the deficit would rise. Because the bill would affect direct spending and receipts, pay-as-you-go procedures would apply.

Beginning in 1999, the proposal would increase costs for Medicaid, the Federal Employees Health Benefits Program (FEHBP), and Medicare. Outlays would increase by \$12 million in 1999 and \$236 million over the 1998-2002 period. The proposal would increase revenues through collections of royalty payments, but it would reduce federal income and payroll tax revenues by raising the costs of employer-sponsored health insurance and correspondingly reducing the amount of taxable compensation. On balance, revenues would increase by \$19 million in 1998 and \$458 million over the 1998-2002 period.

The proposal contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 (UMRA). However, extending market exclusivity for certain drugs would increase costs for state Medicaid programs, other programs that provide prescription assistance, and employee benefit programs at the state, local and tribal level.

The proposal would constitute a private-sector mandate as defined in UMRA because it would prohibit the production of generic versions of the brand-name drugs eligible to participate in the demonstration. CBO estimates that the cost of this mandate would surpass the \$100 million statutory threshold established in UMRA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of the proposed amendment is shown in the following table. The costs of this legislation fall within budget functions 550 (Health) and 570 (Medicare).

	By Fiscal Year, in Millions of Dollars									
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
DIRECT SPENDING										
Medicaid	0	0	1	28	123	185	191	206	199	190
FEHB	0	0	0	1	3	8	13	20	27	34
Medicare	<u>0</u>	<u>12</u>	<u>21</u>	<u>24</u>	<u>24</u>	<u>25</u>	<u>12</u>	<u>2</u>	<u>0</u>	<u>0</u>
Total	0	12	22	52	151	219	216	228	226	224
REVENUES										
Royalty Payments	19	34	59	177	219	203	224	202	207	53
Income and Payroll Taxes	<u>0</u>	<u>0</u>	<u>0</u>	<u>-6</u>	<u>-44</u>	<u>-76</u>	<u>-86</u>	<u>-91</u>	<u>-87</u>	<u>-88</u>
Total	19	34	59	171	175	127	138	111	120	-35

BASIS OF ESTIMATE

The proposed demonstration project to fund biomedical research would grant up to 10 years of additional market exclusivity for certain drugs and antibiotics. In return for the extension of market exclusivity, manufacturers would make royalty payments to the federal government to help fund biomedical research—subject to authorization and appropriation—and agree to spend an equal amount on biomedical research.

Products eligible to be included in the program are those for which a new drug application (NDA) was filed and approved under sections 505(b)(1) or 507 of the Food Drug and Cosmetic Act (FD&CA) during the five years preceding enactment of the proposal. Manufacturers of these drugs could elect to participate in the demonstration project through the end of fiscal year 2002. For the purposes of this estimate, CBO assumes that a manufacturer would not elect to participate in the program until the patent on its product was about to expire.

The proposal would prohibit the Food and Drug Administration (FDA) from accepting, reviewing, or approving any application for a drug containing the active ingredient(s) of an eligible product. This prohibition would extend for ten years after the approval of the NDA filed under section 505(b)(1) or 507 of the FD&CA.

To obtain extended market exclusivity, the manufacturer of an eligible product would agree to pay the Secretary 3 percent of its net U.S. sales of the eligible products—including all forms and dosages—and to spend an equal amount of money on biomedical research. Subject to authorization and appropriation, the royalty payments would be available to the Secretary of Health and Human Services to fund biomedical research projects approved by the Director of the National Institutes of Health (NIH).

It is unclear how the proposal would affect abbreviated new drug applications (ANDAs) that have already been filed under the FD&CA and are pending FDA approval. The proposal does not address whether the FDA could continue reviewing these ANDAs or whether it would have to stop work on them until the end of the ten-year exclusivity period. It is clear, however, that manufacturers of generics who were preparing to submit ANDAs—but have not yet done so—would be penalized financially if the proposal were enacted.

Outlays

The award of additional years of market exclusivity would increase costs for Medicaid, FEHBP, and Medicare by delaying the availability of generic products. Medicaid currently has a very high generic substitution rate because the program requires pharmacists to dispense lower-cost generic products once they are available, unless the prescribing physician specifies otherwise. Additionally, many states have laws permitting generic substitution with the patient's consent. Therefore, CBO assumes that Medicaid would usually substitute generic for brand-name products. Generic substitution would probably occur at a slower rate among health plans participating in FEHBP and in Medicare.

Under the proposal, spending for Medicaid, FEHBP, and Medicare would increase by \$236 million over the 1998-2002 period. CBO estimated this increase in spending by comparing the level of spending that would occur in the absence of generic entry with projected spending under current law. To estimate payments by Medicaid, FEHBP, and Medicare under current law for the set of drugs that would be affected by the proposal, CBO adjusted 1995 spending to account for projected inflation and the reduction in prices that would occur as generic entry took place. Using information from *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"), CBO determined when patents would expire under current law for affected drugs and calculated the incremental period of exclusivity. For Medicaid, the estimate takes into account rebates paid by manufacturers.

For Medicare, the estimate takes into account the change in payment rates under the Balanced Budget Act of 1997.

Revenues

The proposed demonstration project would affect revenues in two ways. First, it would increase revenues because of the royalty payments made by participating drug manufacturers. CBO estimates that these payments would total \$19 million in 1998, and just over \$500 million over the 1998-2002 period. For the purposes of this estimate, CBO assumed that a manufacturer would not choose to participate in the demonstration until the patent on its product was about to expire and that it would stop participating at the end of the exclusivity period. Because the federal government's collection of the royalties would stem from its sovereign powers, these funds would be classified as governmental receipts.

Second, the proposal would affect income and payroll tax revenues. By delaying generic entry for eligible drugs, it would increase the prices insurers paid for pharmaceuticals, leading to higher premiums for employer-sponsored health insurance. Correspondingly, the amount of employee compensation subject to income and payroll taxes would decrease. CBO estimates federal income and payroll tax revenues would fall by \$50 million through 2002.

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 proposal would affect direct spending and receipts, pay-as-you-go procedures would apply. For purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

The proposal would place no enforceable duty on state, local, or tribal governments, and thus it contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995. However, the delayed availability of generic drugs would result in increased costs for health care. State and local governments would thus face higher costs both in the Medicaid program and in their employee health insurance programs.

CBO estimates that the state government portion of Medicaid costs would increase by \$114 million over five years. In addition, any state, local or tribal government that offers health insurance coverage to its employees would face increased pharmaceutical costs. Based on the number of these employees who receive pharmaceutical benefits, CBO estimates that governments would face additional costs of approximately \$23 million over five years. Economists generally believe, and CBO's cost estimates have long assumed, that workers as a group bear most of the cost of employers' health insurance premiums. The primary reason for this conclusion is that the supply of labor is relatively insensitive to changes in take-home wages. Because most workers continue to work even if their take-home pay declines, employers have little trouble shifting most of the increase for health care costs to workers' wages or other fringe benefits. Consequently, after the first few years, state and local governments would likely shift these costs to their employees.

Also, some states provide assistance for low-income individuals who are not eligible for Medicaid. States that provide this type of prescription assistance would face additional costs for these programs. At this time, CBO does not have sufficient information on the number of states that provide this type of assistance and on the types of prescriptions covered to provide an estimate of these costs.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The proposal contains a private-sector mandate over the statutory threshold (\$100 million in 1996, adjusted annually for inflation) in 2001 and 2002 because it would prohibit generic manufacturers from producing copies of certain brand-name drugs containing an active ingredient that was initially approved by the FDA during the last five years. CBO estimates that prohibition would cost the generic drug industry over \$500 million in lost profits (after taxes) between 1998 and 2002. Also, many purchasers would pay more for certain prescription drugs because of the reduced competition from generic manufacturers. CBO estimates that those indirect costs to prescription drug purchasers would total \$1 billion over the 1998 to 2002 period, net of the increased costs to the Medicare, Medicaid and FEHBP.

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