CONGRESSIONAL BUDGET OFFICE
PAY-AS-YOU-GO ESTIMATE

January 14, 2002

S. 1789
Best Pharmaceuticals for Children Act

As cleared by the Congress on December 18, 2001,
and signed into law by the President on January 4, 2002

SUMMARY

S. 1789 (enacted as Public law 107-109) extends expiring pediatric exclusivity provisions of the Food and Drug Administration (FDA) Modernization Act of 1997. Pediatric exclusivity refers to a six-month period during which the FDA will not permit another manufacturer to market a generic version of a drug. Such exclusivity is granted in exchange for the manufacturer conducting studies, requested by the FDA, of the effect of drugs when taken by children.

S. 1789 clarifies the interaction of market exclusivity awarded to certain generic manufacturers and pediatric exclusivity awarded to innovator drug companies when the two periods of market exclusivity overlap. It also amends the approval process for generic drugs when pediatric information is added to the labeling.

In total, CBO estimates that the act will increase direct spending of the federal government by $219 million and increase federal revenues by $15 million over the 2002-2011 period.

The largest effect on direct spending will result from the act's impact on the prices of prescription drugs. The act will result in higher prices for certain drugs that will be granted an extended period of market exclusivity, but will also accelerate the entry of generic versions of some drugs, which will lead to lower prices. CBO estimates that the net effect of S. 1789 will be to reduce the average price of prescription drugs slightly through 2007 and to increase prices in subsequent years.

In the near term, lower drug prices will reduce the costs of federal programs that purchase prescription drugs or provide health insurance that covers prescription drugs. Those lower prices will reduce direct spending—for Medicaid and for health insurance provided to annuitants by the Federal Employees Health Benefits (FEHB) program, the Department of Defense (DoD), and the Coast Guard—by $2 million in 2002 and by

$32 million over the 2002-2006 period. However, S. 1789 will increase federal direct spending on those programs by $160 million over the 2002-2011 period, reflecting higher average drug prices, on balance, in later years.

S. 1789 also allows a non-profit foundation within the National Institutes of Health (NIH) to collect funds and award grants specifically designated for pediatric research and the study of pediatric uses of qualifying drugs. Grants made by the foundation will be direct spending because they will not be subject to the availability of appropriations. CBO expects that the foundation will begin to disburse grants in 2003, and that awards made by the foundation will increase direct spending by $25 million over the 2003-2006 period and by $59 million over the 2003-2011 period.

The act also will affect revenues in two ways. First, donations and gifts received by the foundation will increase federal revenues. Secondly, CBO assumes that part of the savings or costs from changes in health insurance costs will be passed on to workers as increases or decreases, respectively, in taxable compensation. Lower prices for prescription drugs under the act will initially reduce premiums for private health insurance (compared with premiums under current law). Higher drug prices will subsequently push premiums higher. CBO estimates the act will increase federal revenues by $6 million in 2002, by $33 million over the 2002-2006 period, and by $15 million over the 2002-2011 period.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO's estimate of the budgetary effects of provisions that will affect direct spending and receipts are shown in the following table. For the purposes of enforcing pay-as-you-go procedures, only the effects through fiscal year 2006 are counted. The budgetary impact of the act falls under budget functions 050 (national defense), 550 (health), and 700 (veterans benefits and services).

	By Fiscal Year, in Millions of Dollars									
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Change in Outlays	-2	1	2	-1	-6	-3	20	49	70	89
Change in Revenues	6	6	6	6	9	7	3	-3	-9	-16

Provisions affecting outlays

S. 1789 will increase federal direct spending over the 2002-2011 period by $219 million, CBO estimates, but direct spending will be lower in 2002 (by about $2 million) and over the 2002-2006 period (by about $7 million). Three provisions of the act will affect the price of drugs paid for by the government's mandatory health programs. Reauthorizing the pediatric exclusivity program will increase direct spending (for Medicaid and for annuitants covered by health insurance offered through FEHB, DoD, and the Coast Guard) by less than $500,000 in 2002, $28 million over the 2002-2006 period, and $320 million over the 2002-2011 period. Clarifying the interaction between the 180-day generic market exclusivity and pediatric exclusivity periods when they overlap will increase federal direct spending for health programs by about $1 million in 2002, $5 million over the 2002-2006 period, and $10 million over the 2002-2011 period. However, CBO estimates that significant savings will be generated by requiring prompt approval of generic applications under certain circumstances. That provision will save those federal health programs about $4 million in 2002, $65 million over the 2002-2006 period, and about $170 million over the 2002-2011 period.

Reauthorization of the Pediatric Exclusivity Program. The act grants an additional six months of market exclusivity to pharmaceutical manufacturers that conduct pediatric studies on certain drugs. CBO estimates that extending market exclusivity under the reauthorized program will increase costs for federal programs by less than $500,000 in 2002, by $28 million over the 2002-2006 period, and by $320 million over the 2002-2011 period.

It is unclear how the sunset provisions of the pediatric exclusivity program authorized under the FDA Modernization Act of 1997 will apply after January 1, 2002. For the purposes of this estimate, CBO assumes that the authority to grant pediatric exclusivity to certain targeted drugs would have continued under prior law. For any drug (active moiety) for which both a new drug application is submitted and a written request received by January 1, 2002, CBO assumes that FDA retains the authority to grant pediatric exclusivity if the standard requirements set forth by the program authorized under prior law are met.

Furthermore, CBO assumes that FDA retains authority under prior law to issue written requests and grant pediatric market exclusivity beyond January 1, 2002, to certain drugs if FDA perceives a continuing need for information relating to the drug. To qualify, the drug must meet the following criteria:

- The drug must have been in commercial distribution as of November 21, 1997;
- The drug must appear on the FDA's January 1, 2002, "List"; and
- The drug must meet the standard requirements set forth by the program.

The reauthorized program grants a six-month extension for a drug provided that: (1) FDA has issued a written request for pediatric studies on the drug on or before October 1, 2007; (2) a new drug application for the drug has been submitted on or before October 1, 2007; and (3) the requirements of the program have been met. The benefit under reauthorization generally will accrue to approved drugs introduced since November 22, 1997, that have not yet received a written request from the FDA for pediatric studies, and to new drugs pending marketing approval.

CBO expects that manufacturers will conduct pediatric trials and receive pediatric exclusivity on upwards of 100 drugs under the reauthorized program. To estimate the costs associated with higher drug prices paid by federal purchasers, CBO identified a set of about 30 approved drugs that qualify for pediatric exclusivity under the reauthorized program. Using 2000 sales data and the date of market approval for those products, CBO projected sales for each drug based on an average drug sales curve calculated by FDA for its January 2001 Status Report to the Congress on the Pediatric Exclusivity Provision. CBO identified sales in the year of anticipated expiration of market exclusivity and estimated the reduction in pharmaceutical costs to federal programs that would have accrued to government purchasers at generic entry under prior law. The amount of such savings lost to the federal government during the six months of pediatric exclusivity is the cost of extending pediatric exclusivity to each drug. CBO's methodology incorporated recent market trends that suggest a more rapid loss of market share to generics in the first months after generic entry than previously estimated by the CBO. Pending further study of these market dynamics, CBO assumes that generic products, on average, account for roughly 30 percent of total market volume and cost about 70 percent of the brand price after three months on the market. After six months, CBO assumes that generic drugs will account for roughly 40 percent of total market volume and cost about 60 percent of the brand price.

To estimate the cost of new drugs obtaining pediatric extensions under the reauthorized program, CBO assumed that 30 new drugs would be introduced each year and one-half of them would qualify for pediatric exclusivity. CBO estimated the average first full-year sales by inflating FDA's estimate of $125 million per drug in 1999. (CBO assumed an average annual rate of increase in launch price of about 10 percent since 1999.) Using data from several industry sources, CBO assumed that roughly one out of five new drugs getting pediatric exclusivity extensions under the reauthorized program would lose market exclusivity between 2002 and 2011. After identifying sales in the year of anticipated expiration of market exclusivity protections, CBO estimated the cost associated with new drugs receiving an additional six months of exclusivity in the same manner as outlined above for existing drugs.

Clarification of the Interaction between Certain Market Exclusivity Periods. S. 1789 clarifies Congressional intent regarding the interaction between 180-day generic exclusivity and pediatric exclusivity when the two periods of market exclusivity overlap. CBO estimates

that this provision will increase the costs of certain federal mandatory health programs by $1 million in 2002, by $5 million over the 2002-2006 period, and by $10 million over the 2002-2011 period.

Under certain conditions, the first generic manufacturer that files a substantially complete abbreviated new drug application (ANDA) challenging an innovator's patent claim under a "paragraph IV" filing may be awarded 180 days of generic market exclusivity. During the 180-day generic exclusivity period, the FDA cannot approve a subsequently filed ANDA for a generic version of that specific drug product. This provision of law may provide the first generic "paragraph IV" filer an opportunity to recoup some of the risk of litigation costs by providing that manufacturer with market exclusivity for its version during the first 180 days of generic marketing.

The 180-day generic exclusivity period begins after a court decision finding the challenged patent invalid, unenforceable, or not infringed, or the date of first commercial marketing of the ANDA product, whichever is earlier. In the event that the 180-day generic exclusivity period overlaps with the pediatric exclusivity period, the act specifies the amount of time that is restored to the generic manufacturer's 180-day exclusivity period.

Under the act, if the 180-day generic exclusivity period expires at some point after the pediatric exclusivity period, the 180-day period will be extended by the number of days of the overlap. Alternatively, if the 180-day generic period expires during the pediatric exclusivity period, the 180-day generic exclusivity will be extended by six months. CBO assumes that any portion of overlap between the 180-day generic exclusivity and a valid patent that remains in force will not be restored to the generic manufacturer under the act.

Restoring a portion of the effective 180-day generic exclusivity allows the first generic "paragraph IV" filer to charge higher prices during that period because of the lack of pricing competition from other generic companies. CBO assumes that the generic manufacturer enjoying market exclusivity will charge, on average, 10 percent more for the generic version during the effective period of market exclusivity. As a result, the costs to public and private purchasers of drugs will be slightly higher during the restored period because of this provision.

However, CBO assumes that a significant overlap in the periods of market exclusivity will occur relatively infrequently. The most likely scenario will occur when a first generic "paragraph IV" challenger wins a court case on one patent—and that patent is declared invalid, unenforceable, or not infringed—while at least one other patent on the drug product remains in force after the decision. To date, only one similar situation has been identified surrounding a drug patent case argued before the courts in 2000.

CBO anticipates that the recent case may be an indicator of the potential for overlaps of 180-day generic and pediatric periods of market exclusivity in the future. We assumed that there would be a 50 percent probability that the same percent of sales for brand drugs losing market exclusivity in future years (as seen in 2001 associated with the recent case) may be subject to an overlap scenario. CBO further assumed that an average of three effective months of the 180-day generic exclusivity for the generic "paragraph IV" challenger would be restored under the provision. (Under the act, CBO assumes that there will be no guarantee in any particular case that a generic manufacturer will be able to commercially market with effective market exclusivity if overlap remains between pediatric exclusivity and existing patent or other market exclusivity protection.) For this estimate, CBO assumed generics generally would gain about 30 percent of market share after three months and be priced at roughly 70 percent of the brand version.

Amendments to the Generic Drug Approval Process. S. 1789 amends the approval process for generic drugs when pediatric information is added to the labeling. The act requires prompt approval of a generic drug that otherwise meets all other applicable requirements even when its labeling omits pediatric information that is protected by patent or other market exclusivity protections. The act allows the Secretary of the Department of Health and Human Services to require certain statements and warnings on the affected generic labels. That provision will take effect immediately upon enactment with respect to all new applications and to those that are approved or pending.

By directing the FDA to approve generic applications lacking pediatric labeling under certain circumstances, these provisions could accelerate the entry of lower-cost generic products onto the market. CBO assumed an average delay of three years for the generic products that might face a moratorium on their marketing approval because of pediatric labeling exclusivity. CBO assumed that, under prior law, there was a 50 percent probability that the FDA would delay the entry of the generic version of a drug based on claims by an innovator drug company to exclusive rights to the pediatric labeling and a potential threat to the health of children if the generic product is marketed without the pediatric use information.

To estimate the savings associated with this provision, CBO assumed that at the end of the three years, generics would constitute roughly 70 percent of market volume and cost about 50 percent of the brand product's price. CBO estimates that eliminating the delay in the entry of lower-priced generics will result in savings to mandatory health programs of about $4 million in 2002, $65 million over the 2002-2006 period, and about $170 million over the 2002-2011 period.

Foundation for the National Institutes of Health. The act allows an existing non-profit corporation within the NIH, called the Foundation for the National Institutes of Health, to collect funds and award grants specifically designated for pediatric research and the study of pediatric uses of qualifying drugs.

CBO expects that donations and gifts collected by the foundation will be considered revenues to the federal government. Grants made by the foundation will be direct spending because they will not be subject to the availability of appropriations. We assume that, on average, the foundation will collect amounts sufficient to sponsor the study of one to two drugs annually. CBO expects that expenditures by the foundation for grants will begin in 2003; therefore, there will be no direct spending in 2002. CBO estimates that awards made by the foundation will increase direct spending by $25 million over the 2003-2006 period and by $59 million over the 2003-2011 period.

Provisions affecting revenues

CBO estimates that S. 1789 will increase federal revenues by $6 million in 2002, by $33 million over the 2002-2006 period, and by $15 million over the 2002-2011 period.

The act will affect federal revenues in two ways. First, donations and gifts collected by the foundation, averaging an estimated $6 million to $7 million a year, will be considered revenues to the federal government.

Secondly, CBO assumes that changes in drug prices will affect the costs of private health insurance premiums, and a portion of those amounts will be returned to workers through changes in taxable compensation. S. 1789 will increase costs for employer-sponsored health plans because of the changes in the costs of pharmacy benefits resulting from the extension of pediatric exclusivity to some drugs and from clarifying the interaction of any overlap between 180-day generic market exclusivity and pediatric exclusivity. However, the savings generated by promoting prompt approval of generics will lead to overall lower costs in certain years, mostly during the earlier part of the 2002-2011 period. After 2007, however, pharmacy costs, on net, will be higher as a result of S. 1789. Higher net pharmacy costs translate into higher premium payments for employer-sponsored plans during those years, and thus lower taxable compensation for employees.

CBO assumes that 60 percent of the change in the cost of health premiums will be offset by behavioral responses of employers and employees. The remaining 40 percent will be passed through to workers as changes in taxable compensation and will lead to changes in federal tax revenues.

From 2002 through 2007, federal tax revenues will increase slightly under the act. However, CBO estimates that federal tax revenues will begin to fall starting in 2009 when the effect of declining revenues from lower taxable income overwhelms the effect of higher revenues from incoming donations and gifts to the foundation.

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