CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

Revised November 6, 2001

H.R. 2887
Best Pharmaceuticals for Children Act

As ordered reported by the House Committee on Energy and Commerce on October 11, 2001

SUMMARY

H.R. 2887 would extend 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.

The bill would create a new research fund within the National Institutes of Health (NIH) to test the use for children of drugs that lack patent or other market exclusivity protections. It would also create a non-profit foundation to collect funds and award grants for research on pediatric uses of qualifying drugs. The bill would modify the review and labeling processes associated with pediatric supplements and would promote the reporting and collecting of information on adverse reactions to drugs.

H.R. 2887 would clarify 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 would also amend the approval process for generic drugs when pediatric information is added to the labeling. In addition, the bill would establish an Office of Pediatric Therapeutics within the FDA and would authorize several studies related to the pediatric exclusivity program and pediatric research.

Assuming the appropriation of the necessary funds, CBO estimates that H.R. 2887 would increase federal outlays for discretionary programs by $11 million in 2002 and by $698 million over the 2002-2006 period. Those costs consist of amounts required to implement and administer the activities authorized under the bill and the effect of H.R. 2887 on the costs of certain discretionary programs that purchase drugs or contribute toward the pharmacy costs of beneficiaries.

The bill would result in higher prices for certain drugs that would be granted an extended period of market exclusivity, but would also accelerate the entry of generic versions of some drugs, which would lead to lower prices. CBO estimates that the net effect of the bill would 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 would reduce the costs of federal programs that purchase prescription drugs or provide health insurance that covers prescription drugs. CBO estimates that savings to programs subject to appropriation—such as health insurance provided to active workers through the Federal Employees Health Benefits (FEHB) program, the Coast Guard, the Public Health Service (PHS), and health programs of the Departments of Veterans Affairs (VA) and Defense (DoD)—would total $3 million in 2002 and $33 million over the 2002-2006 period.

Lower prices would also reduce direct spending—for Medicaid and for health insurance provided to annuitants by FEHB, DoD, and the Coast Guard—by $2 million in 2002 and by $32 million over the 2002-2006 period. However, H.R. 2887 would 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.

Grants made by the newly created foundation would be direct spending, because they would not be subject to the availability of appropriations. CBO expects expenditures by the foundation for grants would begin in 2003; therefore, there would be no direct spending in 2002. CBO estimates that awards made by the foundation would increase direct spending by $25 million over the 2002-2006 period and by $59 million over the 2002-2011 period.

The bill would also affect revenues in two ways. First, donations and gifts received by the foundation would increase federal revenues. Secondly, CBO assumes that part of the savings or costs from changes in health insurance costs would be passed on to workers as increases or decreases, respectively, in taxable compensation. Lower prices for prescription drugs under the bill would initially reduce premiums for private health insurance (compared with premiums under current law). Higher drug prices would subsequently push premiums higher. CBO estimates the bill would 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. Because enacting H.R. 2887 would affect direct spending and revenues, pay-as-you-go procedures would apply.

H.R. 2887 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). State, local and tribal governments, as administrators of the Medicaid program and as providers of health care coverage for their employees, may realize both costs and savings as a result of provisions in the bill. Provisions affecting market and pediatric

exclusivity would result in added costs, and requirements for prompt approval of some generic drugs would result in savings.

The bill would impose several requirements on pharmacists and on manufacturers of both generic and brand-name drugs that would be considered private-sector mandates under UMRA. CBO estimates that the direct cost of the mandates would not exceed the threshold specified in UMRA ($113 million 2001, adjusted annually for inflation) in any of the first five years during which the mandates would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2887 is shown in Table 1. The costs of this legislation would fall within budget functions 050 (national defense), 550 (health), and 700 (veterans' benefits and services.)

BASIS OF ESTIMATE

For this estimate, CBO assumes that the bill will be enacted in the fall of 2001 and that outlays will follow historical spending rates for the authorized activities. Where H.R. 2887 specifies the amounts authorized to be appropriated, CBO assumes that such appropriations will be made. Where appropriations of such sums as necessary are authorized, CBO assumes that the estimated amounts will be provided for each fiscal year.

Spending Subject to Appropriations

Assuming appropriation of the necessary amounts, CBO estimates that enacting H.R. 2887 would result in higher outlays for discretionary federal programs of $11 million in 2002 and $698 million over the 2002-2006 period. The NIH and the FDA are the agencies responsible for carrying out most of the provisions in H.R. 2887. CBO estimates that implementing the bill would cost FDA $11 million in 2002 and $154 million over the 2002-2006 period (net of collections of user fees), assuming the appropriation of the necessary amounts. Costs to NIH would increase by $1 million in 2002 and by $571 million over the 2002-2006 period. Table 2 shows the estimated authorization levels and outlays under H.R. 2887 for fiscal years 2002 through 2006.

TABLE 1. ESTIMATED BUDGETARY IMPACT OF H.R. 2887

	By Fiscal Year, in Millions of Dollars					
	2001	2002	2003	2004	2005	2006
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law						
Estimated Budget Authority [a]	21,482	22,024	22,504	22,987	23,468	23,974
Estimated Outlays	18,341	20,322	21,537	22,362	23,093	23,152
Proposed Changes						
Estimated Authorization Level [b]	0	217	94	246	161	109
Estimated Outlays	0	11	94	216	213	165
Spending Under H.R. 2887						
Estimated Authorization Level	21,482	22,241	22,598	23,233	23,629	24,083
Estimated Outlays	18,341	20,333	21,631	22,578	23,306	23,317
CHANGES IN DIRECT SPENDING						
Estimated Budget Authority	0	4	3	0	-2	-6
Estimated Outlays	0	-2	1	2	-1	-6
CHANGES IN REVENUES						
Estimated Revenues	0	6	6	6	6	9

a. The 2001 level is the amount appropriated for that year for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). The NIH and the FDA are the agencies responsible for implementing and administering the activities authorized in the bill. Current-law amounts for those programs during the 2002-2006 period assume appropriations remain at 2001 levels, with adjustments for inflation.

b. The estimated amounts reflect the costs to the NIH and the FDA for implementing and administering activities authorized under H.R. 2887 and the effects of the bill on pharmacy costs of other federal discretionary programs.

Research Fund for the Study of Drugs Lacking Exclusivity. Section 3 of H.R. 2887 would create a research fund to pay for pediatric studies of certain drugs lacking market exclusivity. Market exclusivity refers to the exclusive rights conveyed to manufacturers on their drugs. Those rights may stem either from patent protection or through the marketing approval process governed by the FDA.

Under certain circumstances, if manufacturers fail to pursue pediatric testing requested in writing by the FDA, the fund could award contracts to pay for studies on drugs with market exclusivity remaining. The fund would be administered by the NIH.

H.R. 2887 would authorize the appropriation of $200 million for the fund in 2002, and such sums as necessary each year until 2007. CBO estimates that the combined outlays for FDA and NIH activities to set up the fund, make awards from the fund, and process the pediatric supplements under new program requirements would be about $1 million in 2002 and $639 million during the 2002-2006 period, assuming appropriation of the necessary funds. (Pediatric supplements are the applications filed by manufacturers to amend the information provided to the FDA for its use in approving the use of the product by children.)

TABLE 2. ESTIMATED AUTHORIZATIONS AND OUTLAYS UNDER H.R. 2887

	By Fiscal Year, in Millions of Dollars					
	2001	2002	2003	2004	2005	2006
SPENDING SUBJECT TO APPROPRIATION						
National Institutes of Health (NIH)						
Estimated Authorization Level	0	200	43	204	133	91
Estimated Outlays	0	1	73	182	178	137
Food and Drug Administration (FDA)						
Estimated Authorization Level	0	16	53	48	35	30
Estimated Outlays	0	11	23	38	42	39
Other Programs						
Veterans' Administration (VA) Health Program						
Estimated Authorization Level	0	-1	-1	-3	-4	-6
Estimated Outlays	0	-1	-1	-3	-4	-6
Department of Defense (DoD) Health Program						
Estimated Authorization Level	0	-1	-1	-2	-3	-4
Estimated Outlays	0	-1	-1	-2	-3	-4
Federal Employees Health Benefits (FEHB) Program						
Estimated Authorization Level	0	*	*	-1	-1	-1
Estimated Outlays	0	*	*	-1	-1	-1
Public Health Service and Other Programs, Excluding NIH and FDA						
Estimated Authorization Level	0	3	*	*	*	-1
Estimated Outlays	0	1	1	*	1	*
Total Changes						
Estimated Authorization Level	0	217	94	246	161	109
Estimated Outlays	0	11	94	216	213	165

* = Less than $500,000 in costs or savings.

Under the bill, the NIH, in consultation with the FDA, would establish a priority list of drugs without market exclusivity that warrant additional testing for children. Certain drugs with market exclusivity could also be referred to that list by the Secretary of Health and Human Services (HHS) for study financed by the fund. Except in those special referral cases, the bill would set up a contracting process that allows the holders of the approved application for the drug the right of first refusal to receive payment from the fund to conduct the requested studies. If no response is received to FDA's request within 30 days, a competitive contracting process outlined by the bill would be set in motion. H.R. 2887 would specify the reporting procedures for data resulting from the studies and the process for incorporating any necessary new information on drug labels.

CBO expects that roughly 150 non-referral drugs ultimately might qualify for study financed by the new fund. That estimate is based on data showing that 170 drugs on the FDA's May 2000 List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population currently lack patent or other market exclusivity protections. Additional candidates for study under the fund would include drugs coming off patent or otherwise losing market exclusivity in the next few years. Moreover, one interpretation of the provision may allow a broader group of biologicals to qualify for study financed by the fund. CBO assumes that given the rapid advancement in therapies, some products potentially qualifying for study ultimately would not be studied. CBO also estimates that up to 15 drugs that retain market exclusivity protections would likely be studied over the 2002-2006 period because of referral by the Secretary of HHS. CBO estimates that the average cost of conducting the studies requested by the FDA would be about $4 million per drug. In total, CBO estimates that about $660 million in contracts to study drugs would be awarded from the fund over the 2002-2006 period.

Changes to Written Request and Response Procedure for Drugs that Have Market Exclusivity. Section 4 of H.R. 2887 would change the written request procedure for drugs that have market exclusivity by requiring a response by the manufacturer to the FDA request within 180 days of receiving the request. If the Secretary of HHS determined there is a continuing need for information on a drug for which the manufacturer did not agree to conduct the requested studies, the Secretary would have to refer the drug to the newly created Foundation for Pediatric Research for consideration. If the foundation certified to the Secretary of HHS that insufficient funds are available to conduct the requested studies, the Secretary would be required to refer the drug for inclusion on the priority list associated with the fund established under section 3. CBO expects that the FDA would process fewer than 10 pediatric supplements over the 2002-2006 period as a result of referred studies funded by foundation grants.

CBO estimates that referral and coordination activities plus costs associated with processing supplements associated with foundation-sponsored studies would increase the administrative costs of the FDA and NIH by less than $500,000 in 2002 and by $4 million during the 2002-2006 period.

Modifications to the Existing Pediatric Exclusivity Program. 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 will continue under current 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 will have the authority under current law to grant pediatric exclusivity if the standard requirements set forth by the existing program are met.

Furthermore, CBO assumes that FDA will retain authority under current 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.

Section 5 of the bill would affect the review and labeling processes associated with pediatric supplements. Such modifications include eliminating the waiver of user fees for pediatric supplements, identifying all pediatric supplements as priority supplements, and defining a process for timely pediatric labeling changes. Taken together, these provisions would increase FDA's costs for administering the existing program and processing supplements anticipated under current law. CBO estimates that fulfilling these new requirements for current law supplements would increase FDA's costs, on net, by $2 million in 2002 and by $34 million during the 2002-2006 period, assuming appropriation of the necessary funds.

CBO's estimate reflects collections from user fees only in fiscal year 2002 because the authority to collect fees under the Prescription Drug User Fee Act (PDUFA) of 1992, as amended by the FDA Modernization Act of 1997, will expire at the end of fiscal year 2002. CBO also assumes that manufacturers submitting supplements for studies conducted under both the new research fund and the foundation would not be required to pay any user fees because the supplements would refer to that clinical data "by reference."

Office of Pediatric Therapeutics. H.R. 2887 would establish an Office of Pediatric Therapeutics within the FDA. The office would be responsible for oversight and coordination of FDA 's activities involving pediatric issues. CBO estimates that the office

would consist of five full-time employees. We estimate that the new office would cost less than $500,000 in 2002 and $2 million over the 2002-2006 period, assuming appropriation of the necessary amounts.

Reauthorization of the Pediatric Exclusivity Program. The bill would grant an additional six months of market exclusivity to pharmaceutical manufacturers that conduct pediatric studies on certain drugs. In total, CBO estimates that the reauthorized program would cost $6 million in 2002 and $63 million over the 2002-2006 period, subject to the appropriation of the necessary funds. (This reauthorization would also cause an increase of $28 million in direct spending over the 2002-2006 period. That effect is discussed later.)

The reauthorized program would grant 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) an approvable 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 would 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 would conduct pediatric trials and receive pediatric exclusivity on upwards of 100 drugs under the reauthorized program. Assuming appropriation of the necessary funds, CBO estimates that FDA's cost to administer the reauthorized program under the new requirements outlined in section 5 of the bill would be $5 million in 2002 and $34 million over the 2002-2006 period.

Extending market exclusivity under the reauthorized program would increase costs for discretionary federal programs by less than $500,000 in 2002 and $29 million over the 2002-2006 period, assuming appropriation of the necessary funds. Programs of the PHS and the VA would be affected, as would pharmacy costs incurred by FEHB, DoD, and the Coast Guard for active workers.

To estimate the costs associated with higher drug prices paid by federal purchasers, CBO identified a set of about 30 approved drugs that would 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 accrue to government purchasers at generic entry under current law. The amount of such savings lost to the federal government would be 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 would 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.

Dissemination of Pediatric Information. H.R. 2887 would require the FDA to make available to the public a summary of the medical and clinical pharmacological reviews of pediatric studies conducted under the program. CBO estimates that this provision would cost the FDA an additional $1 million in 2002 and $7 million during the 2002-2006 period.

Clarification of the Interaction between Certain Market Exclusivity Periods. H.R. 2887 would clarify 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 would increase the costs of certain federal discretionary programs by $1 million in 2002 and by $5 million over the 2002-2006 period. CBO estimates that the FDA would need to spend less than $500,000 over the 2002-2006 period to implement the provision.

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 marking of the ANDA product, whichever is earlier. In the event that the 180-day generic exclusivity period overlaps with the pediatric exclusivity period, the bill would specify the amount of time that is restored to the generic manufacturer's 180-day exclusivity period.

Under the bill, if the 180-day generic exclusivity period expires at some point after the pediatric exclusivity period, the 180-day period would 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 would 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 would not be restored to the generic manufacturer under the bill.

Restoring a portion of the effective 180-day generic exclusivity would allow 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 would 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 would be slightly higher during the restored period because of this provision.

However, CBO assumes that a significant overlap in the periods of market exclusivity would occur relatively infrequently. The most likely scenario would 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 was 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 bill, CBO assumes that there would be no guarantee in any particular case that a generic manufacturer would 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. H.R. 2887 would amend the approval process for generic drugs when pediatric information is added to the labeling. The bill would require 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 bill would allow the Secretary of HHS to require certain statements and warnings on the affected generic labels. That provision would take effect immediately upon enactment with respect to all new applications and to those that are approved or pending. CBO estimates that implementing these provisions would cost the FDA less than $500,000 over the 2002-2006 period.

In directing the FDA to approve generic applications lacking pediatric labeling under certain circumstances, these provisions would accelerate entry of lower-cost generic products onto the market. Under current law, CBO assumes an average delay of three years for the generic products that might face a moratorium on their marketing approval because of pediatric labeling exclusivity. 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 would result in savings to federal discretionary health programs of about $4 million in 2002 and $67 million over 2002-2006 period.

Adverse Event Reporting. H.R. 2887 would require manufacturers to label all drugs with the toll-free number maintained by HHS for the reporting of adverse drug events. In addition, the bill would require that all manufacturers receiving pediatric exclusivity report any adverse event to the FDA during the one-year period following the granting of such exclusivity. Those reports would have to be reviewed by the Office of Pediatric Therapeutics and reported to the Pediatric Advisory Subcommittee of the Anti-infective Drugs Advisory Committee. CBO estimates that implementing this provision would cost the FDA less than $500,000 in 2002 and $1 million over the 2002-2006 period.

Foundation for Pediatric Research. The bill would create a non-profit corporation called the "Foundation for Pediatric Research" to collect funds and award grants for pediatric research on drugs that are on the priority list established under section 3. It would require that all reporting, labeling, and other requirements specified under section 3 be applicable to drugs studied with foundation grants. The bill would authorize the appropriation of such sums as necessary for 2002 and subsequent years to carry out the activities associated with the foundation.

CBO expects that donations and gifts collected by the foundation would be considered revenues to the federal government. Grants made by the foundation would be direct spending, because they would not be subject to the availability of appropriations. We expect

that, on average, the foundation would collect amounts sufficient to sponsor the study of one to two drugs annually.

The bill also would direct the NIH to provide support services to the foundation. H.R. 2887 would require annual reports on the activities of the foundation and would allow the foundation to assess fees for the provision of specific types of services in amounts determined reasonable. CBO estimates that establishing and administering the foundation would cost almost $1 million in 2002 and $3 million over the 2002-2006 period, assuming appropriation of the necessary funds. NIH's costs associated with the foundation would be less than $500,000 in 2002 and $1 million over the 2002-2006 period.

Studies on Pediatric Exclusivity Program and Pediatric Research. H.R. 2887 would require the Secretary of HHS to contract with the Institute of Medicine to conduct a study on federal regulations and issues surrounding pediatric research. CBO estimates the cost of implementing this provision would total about $1.5 million from 2002 through 2003. In addition, the bill would require the General Accounting Office to conduct two studies—one evaluating the effectiveness and economic impact of amendments to the pediatric exclusivity program made by H.R. 2887 and one evaluating the representation of ethnic and racial minorities in pediatric studies under the program. CBO estimates that those studies would cost almost $1 million in 2002 and $3 million over the 2002-2006 period.

EFFECT ON DIRECT SPENDING

H.R. 2887 would increase federal direct spending over the 2002-2011 period by $219 million, CBO estimates, but direct spending would be lower in 2002 (by about $2 million) and over the 2002-2006 period (by about $7 million). The three provisions of the bill that would affect the price of drugs for discretionary health programs discussed earlier would also affect direct spending by federal health programs characterized as mandatory (that is, not requiring appropriation action). Reauthorizing the pediatric exclusivity program would 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 would 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 would be generated by requiring prompt approval of generic applications under certain circumstances. That provision would 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.

Grants made by the newly created Foundation for Pediatric Research would be direct spending, because they would not be subject to the availability of appropriations. CBO expects that expenditures by the foundation for grants would begin in 2003; therefore, there would be no direct spending in 2002. CBO estimates that awards made by the foundation would increase direct spending by $25 million over the 2002-2006 period and by $59 million over the 2002-2011 period.

EFFECT ON REVENUE

CBO estimates that H.R. 2887 would 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 bill would affect federal revenues in two ways. First, donations and gifts collected by the foundation, averaging an estimated $6 million to $7 million a year, would be considered revenues to the federal government.

Secondly, CBO assumes that changes in drug prices would affect the costs of private health insurance premiums, and a portion of those amounts would be returned to workers through changes in taxable compensation. H.R. 2887 would 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 would 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, would be higher as a result of H.R. 2887. 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 would be offset by changes in profits and by behavioral responses of employers and employees. The remaining 40 percent would be passed through to workers as changes in taxable compensation and would lead to changes in federal tax revenues.

From 2002 through 2007, federal tax revenues would increase slightly under the bill. However, CBO estimates that federal tax revenues would 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.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The following table displays CBO's estimate of the effects of H.R. 2887 on direct spending and receipts. For the purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

	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

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2887 contains no intergovernmental mandates as defined in UMRA. Because the bill would delay the entry into the marketplace of some generic drugs, CBO estimates that costs would increase for the Medicaid programs and for health care for state, local, and tribal employees. However, the bill also would require prompt approval of generics in certain cases. Those provisions would result in savings for the same programs. CBO estimates that state spending for Medicaid would decrease by a net of about $18 million over the 2002-2006 period, but that over the 2002-2011 period, states would incur net costs for Medicaid of about $95 million. CBO has not completed estimates of the effect of the provisions on health care programs offered to employees of state, local, and tribal governments. However, those programs would similarly realize net savings over the 2002-2006 period and incur net costs over the 2002-2011 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains a number of private-sector mandates on manufacturers of both generic and brand-name drugs and on pharmacists. First, it would prohibit generic drug manufacturers, under certain conditions, from producing generic versions of drugs for a period of six months. Based on expected patent expirations and current rates of new drug development, CBO estimates that the number of drugs receiving new pediatric exclusivity under the

provision would be relatively small in any of the first five years the mandate would be effective. The forgone profits from sales of generic drugs over the six-month period also would be small in each of those years.

Second, the bill would remove a provision enacted under PDUFA that waives user fees for all applications for pediatric supplements, thereby imposing a new private-sector mandate on sponsors of those applications. PDUFA will expire at the end of fiscal year 2002, so the mandate would have no effect after that date. CBO estimates that total costs in fiscal year 2002 for all such supplements would be less than $10 million.

Third, brand-name drug companies that receive pediatric exclusivity would effectively be required to comply with any changes in labeling requested by the Food and Drug Administration. Failure to comply could cause the drug to be deemed as mislabeled and removed from the market. The cost of this requirement to affected companies would be minimal.

Finally, the bill would require all drug manufacturers to include on all labels the toll-free telephone number maintained by HHS for reporting adverse drug events. That requirement would necessitate a one-time change in labels and could also require pharmacists to include the phone number with all prescriptions. Those required changes constitute private-sector mandates, but the added costs would be small.

CBO estimates that the direct cost of the mandates contained in the bill—on both generic and brand-name drug manufacturers—would not exceed the annual threshold specified in UMRA ($113 million in 2001, adjusted annually for inflation) in any of the first five years the mandates would be effective.

COMPARISON WITH PREVIOUS ESTIMATES

On November 2, 2001, CBO prepared an estimate for H.R. 2887 that did not treat spending of revenue collected by the Foundation for Pediatric Research as direct spending. This estimate corrects that error.

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