



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

November 19, 2003

H.R. 2427 **The Pharmaceutical Market Access Act of 2003**

As passed by the U. S. House of Representatives on July 25, 2003

SUMMARY

H.R. 2427 would require the Secretary of Health and Human Services (HHS) to issue regulations permitting pharmacists, wholesalers, and individuals (for personal use) to import prescription drugs into the United States from 25 countries, including Australia, Canada, the European Economic Area, Israel, Japan, New Zealand, and South Africa. Imported drugs would have to comply with sections 501, 502, and 505 of the Food, Drug, and Cosmetic (FD&C) Act, which pertain to approval, misbranding, and adulteration of drugs.

The act would require the pharmacist or wholesaler that imports a drug to provide the Secretary of HHS with information and records regarding: the name and amount of the active ingredient, the date of shipment and quantity shipped, points of origin and destination, the prices paid and charged by the importer, and the manufacturer's lot or control number for the product.

H.R. 2427 would require that the packaging of prescription drugs incorporate counterfeit-resistant technology similar to that used by the Bureau of Engraving and Printing to secure U.S. currency. The act also would require wholesalers that import prescription drugs to test the product, unless the product is subject to section 505B of the FD&C Act (which pertains to counterfeit-resistant technology).

CBO estimates that enacting H.R. 2427 would reduce total prescription drug expenditures in the United States by about 1 percent, or \$40 billion, over the 2004-2013 period. Those savings would result primarily from the importation of brand-name drugs that are protected by patents in the United States. Savings to federal programs would be lower—about one-half of a percent of federal spending on prescription drugs—because those programs generally already pay among the lowest prices in the market. CBO estimates that enacting H.R. 2427 would reduce federal direct spending—for Medicaid, annuitants in the Federal Employees Health Benefits (FEHB) program, TriCare for Life, and Medicare Part B—by \$100 million in 2005 and \$2.9 billion over the 2004-2013 period. Spending on pharmaceuticals by

programs subject to appropriation—largely for active workers in the FEHB program and health programs for military personnel and veterans—would be reduced by \$400 million over the 2004-2013 period, CBO estimates.

The act would reduce spending on health benefits for firms that provide health insurance. As a result, more of employees' and retirees' compensation would be in the form of taxable income, thus increasing tax revenues. CBO estimates that H.R. 2427 would increase federal revenues by \$1.5 billion over the 2004-2013 period. Social Security payroll taxes, which are off-budget, account for about one-third of that increase.

H.R. 2427 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that states would save about \$240 million in Medicaid spending over the 2004-2008 period because of lower pharmaceutical costs.

The act contains a private-sector mandate on the manufacturers of prescription drugs by requiring them to incorporate counterfeit-resistant technologies into the packaging of both imported and non-imported drugs. CBO estimates that the direct cost of this requirement to affected entities would exceed the annual threshold specified in UMRA (\$120 million in 2003, adjusted annually for inflation) in each of the first five years for which the mandate would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2427 is shown in the following table. The costs of this legislation would fall within budget functions 050 (national defense), 550 (health), 570 (Medicare), and 700 (veterans benefits and services).

BASIS OF ESTIMATE

Under current law, only the manufacturer of a drug product is allowed to import a drug from another country and sell it in the United States. H.R. 2427 would require the Secretary of HHS to issue regulations permitting pharmacists, wholesalers, and qualifying individuals to import prescription drugs into the United States from certain countries. The regulations would require that prescription drugs imported into the United States comply with sections of the Food, Drug and Cosmetic Act that pertain to approval, misbranding, and adulteration of drugs. CBO estimates that implementing H.R. 2427 would reduce federal direct spending by \$2.9 billion and spending subject to appropriation by \$400 million over the 2004-2013 period.

	By Fiscal Year, in Billions of Dollars											
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2004-2008	2004-2013
Change in Direct Spending												
Federal Outlays for Prescription												
Drugs	0	-0.1	-0.1	-0.3	-0.3	-0.3	-0.4	-0.4	-0.5	-0.5	-0.8	-2.9
Change in Revenues												
Income and HI Payroll Taxes												
(on-budget)	0	*	*	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	1.1
Social Security Payroll Taxes												
(off-budget)	0	*	*	*	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Change in Spending Subject to												
Appropriation												
Federal Outlays for Prescription												
Drugs	0	*	*	*	*	*	*	-0.1	-0.1	-0.1	-0.1	-0.4

Notes: The estimated changes in budget authority for spending programs would be the same as the estimated changes in outlays.
 * = Costs or savings of less than \$50 million.

The savings associated with enacting H.R. 2427 would depend on the relative prices of domestic and imported prescription drugs and the quantity of prescription drugs that would be imported. CBO reviewed the literature regarding the relative prices in the United States and other industrialized countries of prescription drugs subject to patent protection. Based on that literature, CBO estimates that, on average, foreign prices for such drugs currently are between 45 percent and 65 percent of U.S. manufacturer prices. However, for reasons discussed below, CBO expects that the price spread would be smaller for prescription drugs imported under H.R. 2427.

CBO reviewed the literature on parallel trade in the European Economic Area—parallel trade is the legal importing and exporting of pharmaceuticals without the explicit consent of the manufacturer—to estimate the quantity of prescription drugs that might be available for importation under H.R. 2427. In Europe, parallel trade into the five higher-priced countries accounts for approximately 5 percent of the total pharmaceutical sales in the source countries. Based on that experience, and taking into account the relative size of the markets in the United States and the 25 countries from which drugs could be imported under H.R. 2427, CBO estimates that between 10 and 15 percent of the U.S. market could potentially be supplied through parallel trade—if such trade were as free of impediments as in the European market today.

However, CBO expects that requirements imposed by the Food and Drug Administration (FDA), as well as actions by manufacturers and foreign countries, would substantially limit the quantity of pharmaceuticals supplied through parallel trade. The act would require the FDA to issue regulations permitting the importation of prescription drugs into the United States. CBO expects that the FDA would require imported drugs to meet the FDA's current requirements for an approved drug in the United States, including the requirement that drugs be produced in an FDA-approved facility. CBO also expects that the FDA would issue regulations permitting wholesalers and pharmacists to repackage and relabel patented prescription drugs being imported into the United States. Although CBO assumes that those regulations would not be crafted to impede parallel trade, it is likely that the regulations—such as the requirements that drugs have counterfeit-resistant packaging and be produced in an FDA-inspected facility—would be used by manufacturers to limit the supply of prescription drugs that would be eligible for parallel trade.

Manufacturers of prescription drugs would have incentives to restrict the supply of drugs available for importation through parallel trade because they would earn less if domestic sales at relatively high prices are displaced by drugs originally sold in other countries at lower prices. Manufacturers could pursue multiple strategies to restrict that supply, including:

- Limiting the quantity shipped to foreign countries to the expected level of each country's domestic consumption;
- Establishing and enforcing contracts with wholesalers that restrict the selling of drugs to entities that export to the United States;
- Supplying drugs to foreign countries in packaging that does not satisfy the U.S. requirement for counterfeit-resistant technology;
- Shifting the site of production of products for sale in foreign markets to facilities that have not been approved by the FDA; and
- Raising the price of drugs sold in foreign countries.

Foreign countries also might act to restrict the export of prescription drugs to the United States to maintain their access to a sufficient supply for domestic consumption at relatively low prices. Such actions of foreign countries would be more likely if manufacturers were not successful at restricting the supply of prescription drugs available for import into the United States on their own.

Such actions by manufacturers and foreign countries, combined with the FDA's requirements, would limit the quantity of pharmaceuticals available for importation through parallel trade, and probably would increase the price at which drugs are sold in foreign countries. The price differential would be further eroded by transaction costs incurred by importers. Currently, distributors of pharmaceuticals imported by manufacturers are indemnified by the manufacturers for liability resulting from harm caused by the drugs. That indemnification would not be provided to importers engaged in parallel trade. CBO expects that liability insurance, in addition to other costs—such as relabeling and repackaging to meet the criteria of an FDA-approved product, transportation, and distribution—would substantially reduce the price spread between pharmaceuticals obtained through traditional distribution channels and those obtained through parallel trade.

The bill also might affect the price of pharmaceuticals marketed through traditional distribution channels. On the one hand, the requirements for counterfeit-resistant packaging would increase the cost of producing prescription drugs, and some or all of those costs would be passed through to consumers. On the other hand, competition from drugs obtained through parallel trade would likely slow the rate of increase in prices of drugs distributed through traditional channels. On balance, CBO expects the net effect of those changes on aggregate spending for pharmaceuticals to be small.

Based on information from the FDA and various industry experts regarding the range of possible actions that the interested parties could take, CBO estimates total prescription drug expenditures in the United States would fall by \$40 billion over the 2004-2013 period. (That estimate represents a 0.5 percent decline in drug spending in 2005 and 2006, and a 1 percent decline in drug spending over the 2007-2013 period.)

Federal programs, which use mechanisms such as the “best price” provision in Medicaid and the federal supply schedule, already pay among the lowest prices in the market. Therefore, CBO estimates that the percentage reduction in spending by federal programs would be smaller—ultimately about one-half of one percent of federal spending on pharmaceuticals under current law. As a result, CBO estimates that enacting H.R. 2427 would reduce federal direct spending—for Medicaid, annuitants in the FEHB program, TriCare for Life, and Medicare—by \$100 million in 2005 and \$2.9 billion over the 2004-2013 period. CBO estimates that spending on pharmaceuticals by programs subject to appropriation—largely for active workers in the FEHB program and health programs for military personnel and veterans—would be reduced by \$400 million over the 2004-2013 period.

Under H.R. 2427, CBO assumes the savings to employer-sponsored plans would be returned to active workers and retirees as other forms of compensation—that is, as higher wages, pensions, and fringe benefits. On balance, the composition of the compensation packages

of employees and retirees would shift toward taxable wages and pensions and away from nontaxable health benefits. As a result, CBO estimates that enacting H.R. 2427 would cause an increase in federal revenues of \$1.5 billion over the 2004-2013 period. Social Security receipts, which are off-budget, would account for about \$500 million of that total.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2427 contains no intergovernmental mandates as defined in UMRA. CBO estimates that states would save about \$240 million in Medicaid spending over the 2004-2008 period because of lower pharmaceutical costs.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

Section 5 of the act contains a private-sector mandate on the manufacturers of prescription drugs, requiring them to incorporate counterfeit-resistant technologies into the packaging of both imported and non-imported drugs. The technology would have to be similar to that used by the Bureau of Engraving and Printing to secure U. S. currency, and would have to be incorporated into multiple elements of the physical packaging of the drugs. The Food and Drug Administration has estimated that this provision could raise the cost of prescription drugs by as much as \$2 billion in the first year. While the precise cost of this requirement would depend on specifications to be determined by the Secretary of Health and Human Services, CBO estimates that the cost would be significant and would exceed the annual threshold specified in UMRA (\$120 million in 2004, adjusted annually for inflation) in each of the first five years for which the mandate would be effective.

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