CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 8, 2005

S. 1392
FTC Reauthorization Act of 2005

As ordered reported by the Senate Committee on Commerce, Science, and Transportation on July 21, 2005

SUMMARY

S. 1392 would authorize funding for the Federal Trade Commission (FTC) through 2010. The bill also would amend the Federal, Food, Drug, and Cosmetic Act (FDCA) to modify provisions governing the importation of prescription drugs to the United States. It would require the Secretary of Health and Human Services (HHS) to permit pharmacies, wholesalers, and individuals (for personal use) to import prescription drugs into the United States under certain new conditions from selected countries.

On balance, CBO estimates that implementing S. 1392 would have net discretionary costs of $1.7 billion over the 2006-2010 period. We also estimate that enacting the bill would reduce direct spending by $1.6 billion over the 2006-2010 period and by $6.1 billion over the 2006-2015 period. Finally, we estimate that enacting S. 1392 would increase federal revenues by $1.2 billion over the next five years and by $4.6 billion over the 10 years through 2015.

FTC Operations

The bill would authorize the appropriation of about $1.25 billion for FTC operations over the 2006-2010 period. A portion of this spending would likely be offset, however, by certain fees authorized to be collected under current law. Assuming future appropriation acts allow the FTC to continue to collect these fees, we estimate that the net discretionary cost to reauthorize FTC funding would total $0.4 billion over the 2006-2010 period.

Importing Prescription Drugs

The provisions permitting importation of prescription drugs into the United States would affect spending subject to appropriation, direct spending, and revenues.

Given the uncertainty surrounding how the Food and Drug Administration (FDA) would design the new program for importing prescription drugs, it is difficult to calculate the total resources necessary to administer it. CBO estimates that administering the new drug importation program would cost federal agencies about $1.5 billion over the 2006-2010 period, assuming appropriation of the necessary amounts.

CBO estimates that enacting S. 1392 would reduce total prescription drug expenditures in the United States by roughly 1 percent, or about $50 billion, over the 2006-2015 period. Those savings would result principally from the importation of brand-name drugs that are protected by patents in the United States. The proportional reduction in spending by federal programs for prescription drugs would be somewhat smaller—roughly one-half of one percent—because those programs generally already pay among the lowest prices in the market. CBO estimates that enacting S. 1392 would reduce federal direct spending—primarily for Medicare, Medicaid, annuitants in the Federal Employees Health Benefits (FEHB) program, and the TRICARE For Life (TFL) program—by $6.1 billion over the 2006-2015 period. Spending on pharmaceuticals by health programs subject to appropriation—largely for active workers in the FEHB program and health programs for military personnel and veterans—would be reduced by $0.2 billion over the 2006-2010 period, CBO estimates.

CBO estimates that enacting S. 1392 would increase federal revenues by $4.6 billion over the 2006-2015 period. The bill would affect revenues in several ways. The majority of the increased revenues reflect higher receipts from income and payroll taxes and new fees created under the bill. The bill would reduce spending on health benefits for firms that provide health insurance. CBO assumes that a portion of the savings would be returned to workers as other forms of compensation—resulting in higher taxable income, thus increasing tax revenues by about $2.5 billion over the next 10 years. Administrative costs for the drug importation program would be funded, in part, by fees paid by importers and exporters registered under the program and by manufacturers. CBO estimates that fee receipts—which would be classified as federal revenues—would result in a net revenue increase of $2.2 billion over the 2006-2015 period.

Intergovernmental and Private-Sector Mandates

S. 1392 would preempt state laws that govern certain transactions involving foreign pharmacies and effectively, under some circumstances, preempt state laws limiting the sale of prescription drugs by foreign entities to individuals within the state. Those preemptions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that any costs resulting from the mandates would be minimal and thus would not exceed the threshold established in UMRA ($62 million in 2005, adjusted annually for inflation). CBO estimates that the bill also would result in savings to state Medicaid programs of about $0.9 billion over the 2006-2015 period.

The bill contains a number of mandates on private-sector manufacturers of prescription drugs, Internet pharmacies, and certain financial institutions. CBO estimates that the direct cost of those new requirements would significantly exceed the annual threshold specified in UMRA ($123 million in 2005, adjusted for inflation) starting in the second year following implementation.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 1392 is shown in Table 1. The costs of this legislation would fall within budget functions 050 (national defense), 370 (commerce and housing credit) 550 (health), 570 (Medicare), 700 (veterans benefits and services) and 750 (administration of justice).

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 1392 will be enacted near the start of fiscal year 2006, and that the amounts necessary to implement the bill will be appropriated for each year.

Spending Subject to Appropriation

Implementing S. 1392 would increase federal costs by $2.5 billion over the 2006-2010 period, subject to the appropriation of the necessary amounts—before accounting for any offsets to such spending. Some of those costs would be funded by fees either authorized under current law or newly established under the bill.

Table 1. Estimated Budgetary Impact of S. 1392, the FTC Reauthorization Act of 2005

	By Fiscal Year, in Millions of Dollars				
	2006	2007	2008	2009	2010
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
FTC Operations					
Gross FTC Spending					
Authorization Level	213	241	253	264	276
Estimated Outlays	196	239	252	263	275
Offsetting Collections[a]					
Estimated Authorization Level	-138	-156	-164	-173	-180
Estimated Outlays	-138	-156	-164	-173	-180
Net FTC Spending					
Estimated Authorization level	75	85	89	91	96
Estimated Outlays	58	83	88	90	95
Prescription Drug Importation Program					
Federal Administrative Costs[b]					
Estimated Authorization Level	40	170	330	570	590
Estimated Outlays	10	150	290	500	560
Estimated Federal Outlays for Prescription Drugs					
Estimated Authorization Level	0	-10	-50	-85	-90
Estimated Outlays	0	-10	-50	-85	-90
Subtotal, Drug Importation Program					
Estimated Authorization Level	40	160	280	485	500
Estimated Outlays	10	140	240	415	470
Total Changes					
Estimated Authorization Level	115	245	369	576	596
Estimated Outlays	68	223	328	505	565
CHANGES IN DIRECT SPENDING					
Estimated Federal Spending for Prescription Drugs					
Estimated Budget Authority	0	-70	-300	-570	-640
Estimated Outlays	0	-70	-300	-570	-640

(Continued)

Table 1. Continued

	By Fiscal Year, in Millions of Dollars				
	2006	2007	2008	2009	2010
CHANGES IN REVENUES					
Estimated Fee Collections under Drug Importation Program[c]	8	80	120	200	220
Estimated Income and HI Payroll Taxes (on-budget)	0	15	65	138	177
Subtotal, On-budget Revenues	8	95	185	338	397
Estimated Social Security Payroll Taxes (off-budget)	0	7	28	60	76
Total Changes, Estimated Revenues	8	102	213	398	473

Notes: FTC=Federal Trade Commission; HI= Hospital Insurance (under the Medicare program).
Components may not sum to totals because of rounding.

a. The FTC is authorized to collect fees that partly offset the agency's annual appropriation.

b. Amounts primarily reflect costs for the Food and Drug Administration and the Bureau of Customs and Border Protection of the Department of Homeland Security to administer the drug importation program created by S. 1392.

c. Amounts shown capture the net increase in federal revenues after accounting for the deductibility of new fees as business expenses.

CBO estimates that the discretionary cost to reauthorize funding for FTC operations would total $0.4 billion over the 2006-2010 period, net of fee collections contingent on future appropriation acts. We estimate that federal costs to administer the proposed prescription drug importation program would be about $1.5 billion over the 2006-2010 period. (Fees collected under the bill to pay a portion of those costs would be classified as federal revenues and would not be recorded as an offset to federal outlays.) In addition, CBO estimates that implementing S. 1392 would reduce spending subject to appropriation for federal health programs by $0.2 billion over the 2006-2010 period.

Reauthorization of the Federal Trade Commission. S. 1392 would authorize the appropriation of about $1.25 billion for the operations of the FTC over the 2006-2010 period. Assuming appropriation of the amounts specified in the bill, CBO estimates that reauthorizing the FTC would have a gross cost of about $1.2 billion over the 2006-2010 period. (That amount also reflects enforcement costs for the FTC under the proposed drug importation program.) A portion of this spending would likely be offset, however, by fees

authorized to be collected under current law for both pre-merger notification filings and the Do Not Call program. Assuming future appropriation acts allow the FTC to continue to collect these fees, we estimate that the net discretionary cost would total $0.4 billion over the 2006-2010 period.

Prescription Drug Importation Program. Current law directs the Secretary of HHS to permit the importation of prescription drugs into the United Statues from Canada if the Secretary certifies that those drugs pose no additional risk to public health and safety and that such imports would provide significant savings to Americans. To date, the Secretary has declined to make such a certification under the available legal authorities.

Under existing law, only certain drugs can be legally imported into the United States, primarily those that are manufactured in FDA-inspected facilities abroad and adhere to FDA-approval standards (including labeling requirements). Although importation of prescription drugs by individuals for personal use is illegal, the FDA has some enforcement discretion and has not strictly enforced a ban on all such imports.

Regulatory Activities Required under S. 1392. The bill would expand FDA's regulatory authorities surrounding importation of prescription drugs and would permit such importation for both commercial resale and personal use from selected countries. It would also increase inspection activities by the Bureau of Customs and Border Protection (BCBP) to monitor the legal entry of drug imports into the United States from parallel trade. (Parallel trade is the legal movement of products across borders.)

The bill would require that prescription drugs imported into the United States comply with sections of the FDCA that pertain to approval, misbranding, and adulteration of drugs. It would establish registration requirements for importers and exporters of qualifying prescription drugs. The bill would direct the Secretary of HHS to inspect manufacturing facilities and other places of business, verify chains of custody of drug products, and develop other regulatory requirements necessary to ensure public safety.

S. 1392 also would give the FTC authority to enforce prohibitions on drug company pricing and supply practices intended to limit the availability of U.S. drug imports.

The bill would modify how Internet pharmacies are regulated. It also would authorize the appropriation of $100,000 each year for fiscal years 2005 through 2007 for the FDA to award a grant or contract to the National Clearinghouse on Internet Prescribing to report on Internet sites operating in violation of federal and state laws.

Administrative Costs for Federal Agencies. Given the uncertainty surrounding how the FDA would design the new program for importing prescription drugs, it is difficult to calculate the

total resources necessary to administer it. The federal agencies that would be primarily responsible for administering the program—the FDA and the BCBP—have not completed their analyses of the estimated costs to implement the bill.

The report on prescription drug importation released in December 2004 by the HHS Task Force on Drug Importation provides some insight into the potential magnitude of the administrative costs. It states that based on FDA's current experience with drugs imported for personal use that the total cost of inspecting each package at current volumes could reach $3 billion a year. However, CBO anticipates that the comprehensive program created by the bill would result in the majority of imported drugs being delivered through the commercial wholesale market. For the remainder of drugs supplied for personal importation, we expect that the inspection requirement may be less frequent than reflected in the task force's analysis.

CBO anticipates that the resources necessary to regulate the commercial market likely would be significantly lower than those required to ensure the safety of use of personally imported drugs—even with significant expansions in the volume of drugs imported into the United States. Assuming that the funds necessary to administer the new program are roughly one-quarter of those estimated by the task force for full-scale inspection of the current volume of personal shipments, CBO estimates that the federal costs could exceed $500 million annually—once the program becomes fully operational. (Actual costs could be much higher than that amount if FDA determines that more intensive inspection rates closer to those reflected in the HHS report would be necessary to guarantee public safety.) Fees established under the bill to pay for the program's cost also would be significantly less than that amount.

Spending by Federal Health Programs. The bill aims to allow U.S. purchasers—including public programs that pay for prescription drugs—access to lower prices for prescription drugs imported from other industrialized countries. 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 health programs because of access to lower priced drugs would be less than savings that accrue nationally—ultimately about one-half of one percent of federal spending on pharmaceuticals under current law. As a result, CBO estimates that enacting S. 1392 would reduce federal spending on pharmaceuticals by programs subject to appropriation—largely for active workers in the FEHB program and health programs for military personnel and veterans—by $0.2 billion over the 2006-2010 period.

Estimating Savings to U.S. Purchasers of Prescription Drugs from Importation. Savings to U.S. purchasers of prescription drugs would depend on the differences in the prices between

drugs distributed in the United States and those distributed in the source countries and on the quantity of drugs that would be imported.

Relative prices of drugs in the United States and foreign countries. 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 in 2002 were about 45 percent lower than U.S. manufacturer prices.

However, CBO estimates that current average price differences are smaller because of the recent decline in the strength of the dollar relative to currencies in other industrialized countries. The narrower price gap reduces the potential savings from purchasing imported drug products. Furthermore, the drop in the relative value of the dollar since the analysis of 2002 relative prices would reduce the set of drugs for which importation to the U.S. makes economic sense, pushing down the likely volume of drug imports under current exchange rates. Taken together, those changes decrease potential savings significantly.

Savings from expanded parallel trade also would not reflect the full difference in average price because a portion of that differential would be retained by intermediaries who bring the imported product to market in the United States. A portion of the price difference accruing to such firms would represent physical costs—such as for transportation and possible relabeling and repackaging of products—and would potentially reflect added liability insurance costs. Some of the difference also would be earnings retained by firms.

Potential U.S. prescription drug imports. The amount of savings from the new importation program to U.S. purchasers hinges on the import volume that flows to the United States. That volume would reflect the size of the total drug market in source countries. CBO reviewed the literature on parallel trade in the European Economic Area to estimate the quantity of prescription drugs that might be available for importation under S. 1392. Based on that experience, and taking into account the relative size of the markets in the United States and the countries from which drugs could be imported under S. 1392, CBO assumes that about 10 percent of the current U.S. market would be supplied through parallel trade, before factoring in the effect of recent trends in exchange rates or changes in U.S. drug consumption. We expect that such an increase in U.S. drug import volume would reflect a substantial increase in initial sales to source countries that would be made available for transshipment to the United States.

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. However, the bill would address—often by explicitly prohibiting—many of

the strategies that manufacturers could pursue to restrict supply. General prohibitions include:

- Engaging in activities that restrict, prohibit, or delay the importation of qualifying drugs in an attempt to limit potential imports;

- Establishing and enforcing contracts with wholesalers that restrict the selling of drugs to entities that export to the United States;

- Discriminating against exporters or importers by charging different prices under certain circumstances; and

- Introducing differences to prescription drugs distributed in the United States and other permitted countries.

In response to enactment of a comprehensive importation program in the United States, CBO expects that some foreign countries would act to restrict the export of prescription drugs to the United States to maintain sufficient domestic supply for domestic use at current prices. Canadian officials have already announced that they may limit drug exports if parallel trade presents a threat to the availability of affordable drugs in Canada.

CBO expects that actions by manufacturers and foreign countries—even in light of the anti-discrimination provisions and other prohibitions—would reduce the potential quantity of pharmaceuticals supplied through parallel trade. However, the expected size of the parallel trade market is much greater because of the provisions designed to increase available supply of cheaper drugs to the U.S. market than if those provisions were not included in the legislation.

Based on our review of relevant analyses and information from industry and government experts, CBO estimates total prescription drug expenditures in the United States would fall by roughly 1 percent, or by about $50 billion over the 2006-2015 period.

Comparison of savings in drug spending with estimates from the 108th Congress. On November 19, 2003, CBO transmitted an estimate for H.R. 2427, the Pharmaceutical Market Access Act of 2003, as passed by the U.S. House of Representatives on July 25, 2003. CBO estimated that the ultimate effect of implementing that bill would be to reduce U.S. spending for prescription drugs by 1 percent. (The HHS task force report also estimated savings of 1 percent to 2 percent of national spending on drugs.) Compared to H.R. 2427, S. 1392 contains provisions, as noted above, that would increase significantly the expected volume of prescription drugs that would likely be exported to the United States from industrialized countries. In fact, before taking into account recent changes in exchange rates, we expect

that S. 1392 could generate roughly three times the volume of imports compared with the program established under H.R. 2427 from the last Congress.

However, the percentage savings in drug spending appear comparable to those earlier estimates because the benefits of higher import volume are offset, in part, by lower estimates of the effective price differential between drugs currently marketed in this country and those potentially imported from abroad. That reduction in the price gap reflects the recent changes in exchange rates and the drop in the buying power of the U.S. dollar abroad plus slightly higher estimates of transaction costs that intermediaries would incur to comply with the regulatory requirements of S. 1392. This estimate also reflects relatively higher U.S. consumption of drugs directly resulting from the availability of lower-priced products. The previous estimate also applied the 1 percent savings factor to total U.S. drug spending. CBO's current analysis finds that savings from importation should solely accrue to the acquisition costs of the drugs, and should not be applied to other costs along the distribution chain.

Direct Spending

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 health programs because of access to lower priced drugs 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 S. 1392 would reduce federal direct spending—primarily for Medicare, Medicaid, annuitants in the FEHB program, and TFL—by $6.1 billion over the 2006-2015 period (see Table 2).

Revenues

CBO estimates that enacting S. 1392 would increase federal revenues by $4.6 billion over the 2006-2015 period. The bill would affect revenues in several ways. The majority of the increased revenues reflect higher receipts from income and payroll taxes and new fees created under the bill.

Table 2. Estimated Changes in Direct Spending and Revenues for S. 1392

	By Fiscal Year, in Millions of Dollars											
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2006-2010	2006-2015
CHANGES IN DIRECT SPENDING												
Federal Spending for Prescription Drugs												
Estimated Budget Authority	0	-70	-300	-570	-640	-710	-790	-890	-1,000	-1,120	-1,580	-6,090
Estimated Outlays	0	-70	-300	-570	-640	-710	-790	-890	-1,000	-1,120	-1,580	-6,090
CHANGES IN REVENUES												
Fee Collections under Drug Importation Program[a]	8	80	120	200	220	250	270	310	340	380	628	2,178
Income and HI Payroll Taxes (on-budget)	0	15	65	138	177	208	238	268	302	340	395	1,751
Subtotal, On-budget Revenues	8	95	185	338	397	458	508	578	642	720	1,023	3,929
Social Security Payroll Taxes (off-budget)	0	7	28	60	76	86	96	107	120	135	171	715
Total Changes, Estimated Revenues	8	102	213	398	473	544	604	685	762	855	1,194	4,644

Notes: Components may not sum to totals because of rounding.
HI = Hospital Insurance (under Medicare program).

a. Amounts shown capture the net increase in federal revenues after accounting for the deductibility of new fees as business expenses.

Individual Income and Payroll Taxes. Under S. 1392, CBO assumes the savings to employer-sponsored plans from reduced spending on health insurance for workers (because of access to lower-priced drugs) would be returned to workers as other forms of compensation—that is, as higher wages and fringe benefits. On balance, the composition of compensation packages would shift toward taxable wages and pensions and away from nontaxable health benefits. As a result, CBO estimates that enacting S. 1392 would cause an increase in federal income and payroll taxes of $2.5 billion over the 2006-2015 period. Social Security receipts, which are off-budget, would account for about $0.7 billion of that total.

Fees on Importers, Exporters, and Manufacturers of Drugs. S. 1392 would establish a fee program to partially cover the cost of the drug importation program. CBO expects that the

collection of fees required under S. 1392 would be classified as revenues. However, fee receipts would be available to spend only when the funds are appropriated; as a result, all spending of those amounts by the FDA and the BCBP to implement the drug importation program would be classified as discretionary spending.

Fees established under the bill would be assessed separately on importers and exporters who are registered under the program. Assessments on importers would be capped at 1 percent of the total price of qualifying drugs imported into the country for commercial resale, and the assessments on exporters also would be capped at 1 percent of the total price of qualifying drugs imported into the country by exporters for personal use. The bill would authorize one-time registration fees of $10,000 per firm.

The bill would set aggregate inspection fees initially at $10 million each for exporters and importers in 2006 and at $100 million for importers in 2007. (The bill does not provide a benchmark for inspection fees assessed on exporters in 2007.) The bill aims to allow inspection fees to be adjusted each year to reflect the cap of 1 percent of the total price of qualifying drugs based on the actual experience of the program.

The bill also would require manufacturers to submit to the FDA a notice of differences between FDA-approved drugs marketed in the U.S. and similar drugs sponsored by the firm distributed in other countries that qualify for importation under the program. Additional fees would be paid by any manufacturer required to provide certain types of submissions for FDA's review of those differences.

CBO estimates that implementing the bill would increase federal revenues from the assessments and application fees by $2.9 billion over the 2006-2015 period. Those fees would be tax-deductible business expenses, therefore reducing income and payroll taxes by an estimated 25 percent of the gross amounts. As a result, overall federal revenues attributable to the new fees would increase by $2.2 billion over the 2006-2015 period.

Civil and Criminal Fines. There also would be potential for higher revenues through civil and criminal fines and penalties imposed by the FDA, the FTC, or the BCBP for violations of federal laws under their respective jurisdictions related to imported drugs under the bill. Such collections are recorded in the budget as revenues. Unlike civil fines, any criminal fines collected would be deposited in the Crime Victims Fund and later spent. (Such expenditures are classified as direct spending.) CBO expects that any additional receipts and direct spending would not be significant, primarily because a relatively small number of cases would be affected.

Federal Reserve Costs. The bill also would direct the Board of Governors of the Federal Reserve System to promulgate regulations requiring certain U.S. firms to institute procedures that would prevent illegal transactions involving the purchase of prescription drugs from

unregistered foreign pharmacies. Budgetary effects on the Federal Reserve are recorded as changes in revenues. CBO estimates that the cost for the Board of Governors to promulgate regulations required by S. 1392 would be negligible.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 1392 would preempt state laws under some circumstances, and those preemptions would be intergovernmental mandates as defined in UMRA. CBO estimates that the costs of the mandates in the bill would be small and would not exceed the threshold established in UMRA ($62 million in 2005, adjusted annually for inflation).

The bill would allow individuals to import prescription drugs for their own personal use or for the use of one of their family members, as long as the prescription drug is imported from a registered exporter. Registered exporters would not have to be licensed by state pharmacy boards. States generally require sales of prescription drugs to their residents to be completed by entities that are licensed by the state; thus, allowing such transactions would preempt state regulations and would be a mandate as defined in UMRA. However, the bill would require that any person who dispenses a prescription drug pursuant to an Internet transaction to be authorized to dispense in the buyer's state. Consequently, the mandate would be limited to non-Internet transactions. Any costs associated with the mandate would result from a small loss in fees for licensing pharmacies.

The bill also would preempt any state law that prohibits or otherwise limits the operations of payment systems, financial institutions, credit card issuers, or entities that process financial transactions simply because one of the parties in such a transaction is a foreign pharmacy. This mandate would impose no duty on states that would result in significant costs or revenue losses.

Finally, the bill would result in savings to state Medicaid programs. CBO estimates that states would realize $0.9 billion in savings as a result of lower Medicaid expenditures over the 2006-2015 period.

Other provisions of the bill, notably the reauthorization of the FTC, would not affect the budgets of state, local or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains a number of mandates on private-sector manufacturers of prescription drugs, Internet pharmacies, and certain financial institutions. CBO estimates that the direct cost of those new requirements would significantly exceed the annual threshold specified in UMRA ($123 million in 2005, adjusted for inflation) starting in the second year following implementation.

Mandates on Prescription Drug Sales by Manufacturers

The bill would place a number of new requirements on drug manufacturers relating to sales to exporters and importers. Among other requirements, it generally would make it unlawful for a manufacturer—directly or indirectly—to:

- Discriminate against exporters by charging a higher price for a prescription drug sold to an exporter than it charges to another purchaser in that same country;

- Discriminate against importers by charging a higher price for a prescription drug sold to an importer than it charges to another purchaser in the United States that does not import a qualifying drug (an exception is made in the case of formularies); and

- Discriminate by denying, restricting, or delaying supplies of a prescription drug to exporters or importers.

The effect of these provisions would be to require drug manufacturers to sell qualifying drug products to parties who would be expected to engage in parallel trade with those products. The cost to manufacturers of complying with these mandates consists of forgone revenue from sales of products to exporters and importers that would otherwise have been sold at higher prices. CBO estimates that this direct cost is likely to exceed the annual threshold specified in UMRA starting in 2007 and in each of the following three years. Once the program is fully operational, such costs could reach $5 billion per year.

Other Mandates

The bill also would place new notification requirements on drug manufacturers, and impose new rules on Internet pharmacies and certain financial institutions. Depending on the Secretary's actions, manufacturers and intermediaries may face new packaging requirements that could include anti-counterfeiting measures.

The bill would require drug manufacturers to notify the Secretary of HHS of differences in the drug products that they distribute in the U.S. and those that they distribute in permitted importation countries and pay certain fees to the federal government where applicable.

The bill would require Internet pharmacies to disclose on their Web sites certain information, including addresses and telephone numbers of each place of business, and names of individuals, including names of pharmacists and the states in which they are licensed to practice.

In addition, the bill would require certain financial entities, including credit card companies, to comply with regulations (to be promulgated by the Board of Governors of the Federal Reserve System) designed to prevent certain types of restricted transactions involving the purchase of prescription drug products, including transactions involving unregistered foreign pharmacies.

CBO estimates that the direct costs of each of these mandates would be small relative to the costs of the provisions concerning sales of qualifying prescription drugs by manufacturers.

Other Effects

By lifting the existing prohibition on importation of prescription drugs that were originally distributed in foreign markets, the bill would allow for the legal operation of firms (exporters and importers) engaging in parallel trade in qualifying prescription drugs in the U.S. market. While the bill would impose fees and certain restrictions on their operations, its net effect would be an expansion in the opportunities of these intermediary firms. These firms would therefore face no net mandates as defined in UMRA.

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