CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 12, 2006

S. 3546
Dietary Supplement and Nonprescription Drug and Consumer Protection Act

As reported by the Senate Committee on Health, Education, Labor, and Pensions on September 5, 2006

SUMMARY

The Dietary Supplement and Nonprescription Drug Consumer Protection Act would require the Food and Drug Administration (FDA) to establish systems for collecting data about serious adverse reactions that people experience while using certain nonprescription drugs and dietary supplements. Under the bill, manufacturers, packers, or distributors of such products would have to submit reports to FDA about serious adverse events based on specific information that they receive from the public. CBO estimates that implementing S. 3546 would result in additional discretionary outlays of $3 million in 2007 and $50 million over the 2007-2011 period, assuming the appropriation of the necessary amounts.

CBO estimates that enacting S. 3546 would increase federal revenues by $5 million over the 2008-2016 period, primarily because violations of new requirements specified under the bill could result in the imposition of criminal fines. Collections of criminal fines are recorded in the budget as revenues, deposited in the Crime Victims Fund, and later spent. Such expenditures are classified as direct spending. As a result, we estimate that direct spending would increase by about $4 million over the 2010-2016 period.

S. 3546 would preempt state laws that require systems for reporting adverse reactions to certain nonprescription drugs or dietary supplements. Those preemptions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the preemption would not affect the budgets of state, local, or tribal governments; although it would limit the application of state law, it would impose no duty on states that would result in additional spending.

S. 3546 also would impose private-sector mandates, as defined in UMRA, on manufacturers, packers, and distributors of nonprescription drugs and dietary supplements. CBO expects that the cost of those mandates would not exceed the annual threshold specified in UMRA ($128 million in 2006, adjusted annually for inflation) in any of the first five years in which the mandate would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 3546 is shown in the following table. The costs of this legislation fall within budget functions 550 (health) and 750 (administration of justice).

	By Fiscal Year, in Millions of Dollars				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	4	9	11	14	15
Estimated Outlays	3	8	11	14	15
CHANGES IN DIRECT SPENDING					
Estimated Budget Authority	0	0	0	1	1
Estimated Outlays	0	0	0	1	1
CHANGES IN REVENUES					
Estimated Revenues	0	*	1	1	1

Note: * = less than $500,000.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 3546 will be enacted near the start of fiscal year 2007 and that the amounts necessary to implement the bill will be appropriated for each year. Estimates of spending are based on information from FDA and historical spending patterns of similar activities of the agency.

Spending Subject to Appropriation

S. 3546 would require FDA to establish systems for collecting data about serious adverse reactions that people experience while or after using certain nonprescription drugs and dietary supplements. The bill also would require manufacturers, packers, or distributors of such products to submit reports to FDA about serious adverse events involving such products based on specific information that they receive from the public. Serious adverse events are defined in the bill as those experiences that result in death, a life-threatening situation, an inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. A serious adverse event could also be one that requires medical or surgical intervention to prevent such serious outcomes (based on reasonable medical judgment.)

CBO expects that FDA would modify its existing reporting programs to comply with the bill's requirements. S. 3546 would authorize the appropriation of such sums as necessary to implement the new reporting programs. CBO estimates that implementing the bill would cost FDA $3 million in 2007 and $50 million over the 2007-2011 period, assuming the appropriation of the necessary amounts. (FDA's 2006 appropriation is $1.5 billion, net of collections from fees.)

FDA's Existing Requirements for Reporting on Postmarketing Safety. FDA currently administers two reporting programs for collecting information on adverse events associated with the use of drugs and dietary supplements. Regulations governing the submission of postmarketing safety reports differ by type of product. (A postmarketing safety report is a report submitted to FDA that contains information about adverse events that occur after a product enters the market.)

Drugs. FDA's Center for Drug Evaluation and Research (CDER) collects data on adverse events that may be associated with the use of medical products regulated by FDA and provides safety information to both health care professionals and the public. Under current law, if manufacturers, packers, or distributors of certain drugs become aware of a reportable adverse experience associated with their products, they must prepare a safety report and submit it to FDA. Mandatory reporting requirements apply to both serious and nonserious adverse events, as specified in regulation. Some nonprescription drugs, however, are currently excluded from such requirements. In 2005, FDA received 300,000 reports of serious adverse events and 140,000 reports of nonserious adverse events from drug manufacturers.

In addition, the program allows health care professionals and consumers to report—on a voluntary basis—any health-related problems that they suspect are associated with FDA-regulated medical products, including experiences involving nonprescription drugs. FDA

received 25,000 reports concerning suspected adverse events associated with drug use directly from individuals in 2005.

Dietary Supplements. Reporting adverse events related to dietary supplements is not mandatory under current law. FDA's Center for Food Safety and Applied Nutrition (CFSAN) collects safety information on foods, dietary supplements, and cosmetics that is submitted voluntarily by industry, health care providers, and consumers. In 2005, that program received almost 500 reports of suspected adverse events relating to dietary supplements.

Expanded Reporting Programs Established Under S. 3546. The bill would require FDA to establish systems for collecting data concerning serious adverse events associated with the use of certain nonprescription drugs and dietary supplements that currently are not subject to mandatory reporting requirements. Under the bill, manufacturers, packers, or distributors of such products would have to report to FDA specific information about serious adverse events that they receive from the public concerning such products. Such reporting would no longer be voluntary as under current law.

Under the bill, responsible entities would also be required to maintain records of all reports of adverse events received from the public, subject to inspection by FDA. In addition, S. 3546 would mandate that product labels provide contact information for individuals, in the form of a domestic address or domestic phone number.

S. 3546 would modify FDA's oversight of a sizable number of products currently marketed in the United States. The mandatory reporting requirements would apply to nonprescription drugs that are legally sold over the counter (OTC) without receiving marketing approval through a new drug application. Those OTC drugs are referred to as "monographed" OTC drugs. They are "generally recognized as safe and effective" and are manufactured, labeled, and marketed according to FDA regulations. No reliable estimates currently exist for the number of monographed OTC drugs on the market today. Some industry estimates suggest that there are about 100,000 OTC products on the market (reflecting all package sizes, dosage forms, and strengths of drugs sponsored by individual companies). Monographed OTC drugs most likely account for the majority of all nonprescription drugs. The new requirements also would apply to roughly 30,000 dietary supplements currently on the market.

Based on information from FDA, CBO anticipates FDA might receive an additional 10,000 to 15,000 reports of serious adverse events annually because of the new mandatory reporting requirements specified by the bill. However, significant uncertainty surrounds that estimate. Data are not available on the total number of reports of serious adverse events associated with nonprescription drugs currently reported on a voluntary basis. Also, coding limitations

in the existing database make it difficult to identify the total number of serious adverse event reports that are currently filed for nonprescription drugs on a mandatory basis. Furthermore, any data available from the existing reporting system for dietary supplements are likely to understate the number of adverse events because they are voluntarily reported. (One analysis suggests that FDA's voluntary reporting system for dietary supplements captures less than one percent of actual adverse events. For serious adverse events, however, CBO expects a greater proportion of serious adverse events might already be reported on a voluntary basis.)

Initial Implementation Costs. To implement the new requirements under the bill, CBO expects that FDA would expand its existing data systems. Initial costs also would cover updating listings of monographed OTC drugs in FDA's drug registry, reviewing product labels for compliance with the new labeling requirements, conducting outreach activities, promulgating new regulations, and providing instruction to the industry concerning how to comply with the new requirements. CBO estimates that such activities would cost $3 million in 2007 and $6 million over the 2007-2011 period, assuming the appropriation of the necessary amounts.

Ongoing Administrative Costs to Operate New Reporting Programs. Under the bill, CDER and CFSAN would incur ongoing administrative costs starting in 2008 to administer the expanded reporting programs. Specifically, such activities would include:

- Operating the expanded data systems, including data entry of new reports;
- Maintaining the drug registry for monographed OTC drugs;
- Reviewing reports of adverse events;
- Overseeing compliance with new labeling and reporting requirements;
- Inspecting records and other activities.

Based on information provided by FDA, CBO estimates that ongoing activities to implement the new requirements imposed under S. 3546 would cost $23 million over the 2008-2011 period. If the actual number of reports of serious adverse events were significantly lower or higher than those that we project, the costs to administer the programs would be different.

Costs Relating to FDA's Enforcement Activities. CBO expects that implementing the new reporting requirements would require a significant expansion of the FDA's activities relating

to criminal investigations because of the large volume of affected products. Based on information from FDA, we estimate that such activities would cost $22 million over the 2008-2011 period.

Enforcement of the expanded reporting requirements under S. 3546 would be administered by FDA's Office of Regulatory Affairs, primarily through the Office of Criminal Investigations (OCI). CBO anticipates that new criminal investigations would be launched primarily to identify firms that intentionally falsify or fail to transmit reports and to pursue additional violations of the Federal Food, Drug, and Cosmetic Act that may be uncovered.

Revenues

CBO estimates that enacting S. 3546 would increase federal revenues by $2 million over the 2008-2011 period and by $5 million over the 2008-2016 period. The bill would affect revenues in three ways. First, violations of new requirements specified under the bill could generate the payment of criminal fines; collections of criminal fines are recorded in the budget as revenues. Because of the relatively small number of cases likely to be involved, we estimate that such fines would average $500,000 annually, starting in 2009. Second, FDA could prosecute certain offenses prohibited under the bill through civil court actions. Any payments awarded by the court to reimburse FDA for its costs of enforcement also would be classified as federal revenues. We expect that any such amounts would be negligible. Lastly, S. 3546 would require firms to reimburse the federal government for certain expenses associated with imported products that violate the bill's new requirements. Such payments also would be recorded in the budget as federal revenues. CBO anticipates that reimbursements paid by firms to cover federal costs would be less than $500,000 over the 2008-2016 period.

Direct Spending

Enacting S. 3546 would increase direct spending by an average of $500,000 a year, totaling $4 million over the 2010-2016 period, CBO estimates, as a result of the collection of additional criminal fines assessed for violations of the reporting requirements and other offenses. Collections of criminal fines are recorded in the budget as revenues, deposited in the Crime Victims Fund, and later spent. Such expenditures are classified as direct spending.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 3546 would preempt state laws that require systems for reporting adverse reactions to nonprescription drugs or dietary supplements. Those preemptions would be intergovernmental mandates as defined in UMRA. CBO estimates that the preemption would not affect the budgets of state, local, or tribal governments; although it would limit the application of state law, it would impose no duty on states that would result in additional spending.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 3546 would make changes to the Federal Food, Drug, and Cosmetic Act that would impose mandates on manufacturers, packers, and distributors of nonprescription drugs and dietary supplements. Manufacturers, packers, and distributors would be required to report to the FDA within 15 business days any serious adverse events reported to them and maintain records for six years of all adverse events reported to them. Based on data provided by FDA, CBO expects the total annual cost to implement those mandates would be less than $2 million. Additionally, manufacturers, packers, and distributors of nonprescription drugs and dietary supplements would be required to include on their product labels either a domestic phone number or a domestic address to which an adverse event could be reported. CBO expects that the total cost of the mandates in S. 3546 would not exceed the annual threshold specified in UMRA ($128 million in 2006, adjusted annually for inflation) in any of the first five years in which the mandates would be effective.

Current law requires makers of nonprescription drugs and dietary supplements to include a place of business on their labels. Federal regulations allow this requirement to be met with the city, state and zip code only, when the street address can be found in a current city directory or telephone directory. Many makers of nonprescription drugs and dietary supplements exercise this option and omit the street address from their labels.

In cases where a phone number is not listed, S. 3546 would require makers of nonprescription drugs and dietary supplements to include an address on their labels. CBO interprets an address to be a description of the location of a person or organization, including all information necessary for the Postal Service to deliver mail, which is more information than is required for a place of business. Therefore, we assume that many makers of nonprescription drugs and dietary supplements would be required to include a street address on their labels.

The total cost of compliance with the labeling requirement would, however, be low. The address requirement would not apply to those businesses listing a phone number on their

label. Moreover, the requirement would apply only to those products labeled later than one year following enactment of the bill, allowing makers of nonprescription drugs and dietary supplements ample time to add a single line to their labels.

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