



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

December 27, 2006

S. 3546

Dietary Supplement and Nonprescription Drug and Consumer Protection Act

*As cleared by the Congress on December 9, 2006,
and signed by the President on December 22, 2006*

SUMMARY

The Dietary Supplement and Nonprescription Drug Consumer Protection Act requires 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. Manufacturers, packers, or distributors of such products will have to submit reports to FDA about serious adverse events based on specific information that they receive from the public.

CBO estimates that enacting the legislation will increase federal revenues by \$5 million over the 2008-2016 period, primarily because violations of new requirements specified under the legislation 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 will increase by about \$4 million over the 2010-2016 period. (Implementing S. 3546 also will affect discretionary spending by increasing FDA's costs, but those effects are subject to future appropriation of necessary sums.)

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO's estimate of the budgetary effects of provisions that affect revenues and direct spending is shown in the following table. Effects of direct spending under this legislation fall within budget function 750 (administration of justice).

By Fiscal Year, in Millions of Dollars

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2007- 2016
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CHANGES IN REVENUES

Estimated Revenues	0	*	1	1	1	1	1	1	1	1	5
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CHANGES IN DIRECT SPENDING

Estimated Budget Authority	0	0	0	1	1	1	1	1	1	1	4
Estimated Outlays	0	0	0	1	1	1	1	1	1	1	4

Note: * = less than \$500,000.

BASIS OF ESTIMATE

S. 3546 contains provisions that will increase federal revenues by about \$2 million over the 2007-2011 period and by \$5 million over the 2007-2016 period. The legislation also will increase direct spending by an average of \$500,000 a year, totaling \$4 million over the 2007-2016 period, CBO estimates.

Description of S. 3546

S. 3546 requires 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 legislation also requires 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. CBO expects that FDA will modify its existing reporting programs to comply with the act's requirements.

Enforcement of the expanded reporting requirements under S. 3546 will be administered by FDA's office of Regulatory Affairs, primarily through the Office of Criminal Investigations (OCI). CBO anticipates that new criminal investigations will 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.

Serious adverse events are defined in the legislation 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.)

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 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. 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, have been 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. Prior to enactment of S. 3546, reporting adverse events related to dietary supplements was not mandatory. FDA 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. S. 3546 requires 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 legislation, manufacturers, packers, or distributors of such products will have to report to FDA specific information about serious adverse events that they receive from the public concerning such products. Such reporting are no longer voluntary.

Responsible entities will 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 mandates that product labels provide contact information for individuals, in the form of a domestic address or domestic phone number.

S. 3546 modifies FDA's oversight of a sizable number of products currently marketed in the United States. The mandatory reporting requirements will 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 will 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 legislation. 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.

Revenues

CBO estimates that S. 3546 will increase federal revenues by \$2 million over the 2008-2011 period and by \$5 million over the 2008-2016 period. The act will affect revenues in three ways. First, violations of new requirements specified under the legislation may 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 will average \$500,000 annually, starting in 2009. Second, FDA can prosecute certain offenses prohibited under the legislation through civil court actions. Any payments awarded by the court to reimburse FDA for its costs of enforcement also will be classified as federal revenues. We expect that any such amounts will be negligible. Finally, S. 3546 requires firms to reimburse the federal government for certain expenses associated with imported products that violate the legislation's new requirements. Any such payments also

will be recorded in the budget as federal revenues. CBO anticipates that reimbursements paid by firms to cover federal costs will be less than \$500,000 over the 2008-2016 period.

Direct Spending

Enacting S. 3546 will 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.

PREVIOUS CBO ESTIMATE

On September 12, 2006, CBO transmitted a cost estimate for S. 3546 as reported by the Senate Committee on Health, Education, Labor, and Pensions on September 5, 2006. The two versions of the legislation are identical, as are CBO's estimates. (The previous estimate includes specific information on the potential discretionary cost for implementing S. 3546.)

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