CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 11, 2012

S. 2516
Food and Drug Administration Safety and Innovation Act

As reported by the Senate Committee on Health, Education, Labor, and Pensions on May 7, 2012

SUMMARY

S. 2516 would authorize the collection and spending of fees by the Food and Drug Administration (FDA) for certain activities to expedite the marketing approval of prescription drugs and medical devices and to regulate drugs after they enter the market. The bill would provide the FDA with additional regulatory authority to improve the safety of the drug supply chain and establish an early warning notification system to mitigate or prevent critical drug shortages. It also would create a new approval procedure for breakthrough drug therapies and offer financial incentives to drug sponsors to produce certain antimicrobial drugs. In addition, the legislation would streamline the process for reclassifying medical devices and permanently reauthorize programs that evaluate the use of drugs by children.

CBO estimates that enacting S. 2516 would:

- Reduce direct spending, on net, by $71 million over the 2013-2017 period and by $358 million over the 2013-2022 period.

- Increase federal revenues, on net, by $5 million over the 2013-2022 period.

Considering both the direct spending and revenue effects, we estimate that enacting S. 2516 would reduce budget deficits by approximately $71 million over the 2013-2017 period and by $363 million over the 2013-2022 period. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending and revenues.

Implementing S. 2516 would also have several effects on spending subject to appropriation. CBO estimates that the bill would authorize increased funding for a variety

of FDA activities, but the majority of the gross increase in FDA spending would be offset by increased collections of fees that would be credited against discretionary spending. On balance, CBO estimates that net discretionary spending (primarily by FDA) would rise by about $330 million over the 2013–2017 period, assuming appropriation actions consistent with the bill.

S. 2516 contains both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Extending the requirement to pay fees for medical devices and expanding the registration standards applied to drug manufacturers would be intergovernmental mandates as defined in UMRA for state, local, or tribal governments that manufacture medical devices for commercial purposes. However, CBO estimates that the costs of complying with those mandates would be minimal and well below the threshold established in UMRA for intergovernmental mandates ($73 million in 2012, adjusted annually for inflation).

The legislation contains several mandates on the private sector as defined in UMRA. The most costly of those mandates would require that manufacturers of different types of drug and device products pay fees to the FDA. CBO estimates that the direct cost of all private-sector mandates in the bill would greatly exceed the annual threshold specified in UMRA ($146 million in 2012, adjusted annually for inflation) in each of the five years that the mandates would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 2516 is shown in the following table. The effects of this legislation fall primarily within budget functions 550 (health) and 570 (Medicare).

BASIS OF ESTIMATE

For the estimate, CBO assumes that the legislation will be enacted by the end of fiscal year 2012 and that the Congress will take appropriation actions consistent with the bill for the funding of FDA activities and for triggering the collections of fees to offset the costs of some of those activities.

S. 2516 would reauthorize FDA’s branded prescription drug and medical device fee programs through 2017 and would establish new fee programs covering generic drugs, biosimilar biological products, and certain accreditation bodies that would oversee the conduct of drug quality and safety audits. (Biological drugs are products derived from living organisms; biosimilars are those products that meet certain statutory requirements and are determined by FDA to be highly similar to drugs originally licensed to innovator drug companies.) In addition, the legislation would authorize a number of other activities that are not supported by fees that would modify how the FDA regulates drugs and devices in a broad range of areas.

	By Fiscal Year, in Millions of Dollars					
	2013	2014	2015	2016	2017	2013-2017
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Collections from Fees						
Prescription Drugs	-720	-756	-800	-847	-945	-4,068
Medical Devices	-98	-115	-129	-133	-134	-609
Generic Drugs	-299	-306	-315	-323	-332	-1,575
Biosimilar Biological Products	-20	-21	-23	-28	-36	-128
Accreditation for Third-Party Auditors	-4	-8	-13	-13	-14	-52
Subtotal, Estimated Authorization Level	-1,141	-1,206	-1,280	-1,344	-1,461	-6,432
Subtotal, Estimated Outlays	-1,141	-1,206	-1,280	-1,344	-1,461	-6,432
Spending of Fees						
Prescription Drugs	720	756	800	847	945	4,068
Medical Devices	98	115	129	133	134	609
Generic Drugs	299	306	315	323	332	1,575
Biosimilar Biological Products	20	21	23	28	36	128
Accreditation for Third-Party Auditors	4	8	13	13	14	52
Subtotal, Estimated Authorization Level	1,141	1,206	1,280	1,344	1,461	6,432
Subtotal, Estimated Outlays	724	1,046	1,337	1,453	1,488	6,048
Net Changes from Fees						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	-417	-160	57	109	27	-384
Other Proposed Changes						
Provisions Affecting Pediatric Populations (Title V)						
Estimated Authorization Level	59	74	76	78	87	374
Estimated Outlays	30	62	72	75	83	322
Provisions Affecting Prescription Drugs (Titles VII-X)						
Estimated Authorization Level	25	42	59	67	76	270
Estimated Outlays	19	35	52	62	72	241
Provisions Affecting Medical Devices (Title VI)						
Estimated Authorization Level	9	18	26	27	28	109
Estimated Outlays	5	13	22	26	28	95
Miscellaneous Provisions and Other Effects						
Estimated Authorization Level	11	13	14	14	11	64
Estimated Outlays	8	12	13	13	11	58
Total Changes in Discretionary Spending						
Estimated Authorization Level	104	147	176	187	202	816
Estimated Outlays	-355	-37	217	286	221	332

Continued

	By Fiscal Year, in Millions of Dollars					
	2013	2014	2015	2016	2017	2013-2017
CHANGES IN DIRECT SPENDING[a]						
Estimated Budget Authority	*	-1	-5	-19	-46	-71
Estimated Outlays	*	-1	-5	-19	-46	-71
CHANGE IN REVENUES[a]						
Estimated Revenues	0	*	*	*	*	*

Note: * = between -$500,000 and $500,000; components may not sum to totals because of rounding.

a. CBO estimates that enacting the bill would reduce direct spending by $358 million over the 2013-2022 period and increase revenues by $5 million over that period. There would be a small reduction in spending for health benefits by the United States Postal Service, which is classified as off-budget. CBO estimates those amounts would be below $500,000 in each year over the 2013-2022 period.

Spending Subject to Appropriation

Assuming appropriation action consistent with the bill, CBO estimates that implementing S. 2516 would reduce net discretionary outlays primarily for FDA by $355 million in 2013 and by $37 million in 2014, mostly because the spending of fees lags somewhat behind their collection. CBO estimates that gross FDA spending in subsequent years would exceed the amounts collected from fees (because some of the spending under the bill would not be offset by fees) and that the net discretionary cost of implementing the bill would amount to $332 million over the 2013-2017 period.

Fee Programs Administered by FDA. S. 2516 would authorize five different fee programs within FDA to cover specific costs relating to the approval and marketing of prescription drugs (branded, generic, and biosimilar biological products) and medical devices, and for administering a system to accredit third-party auditors of activities relating to drug safety. In fiscal year 2012, CBO estimates that FDA will collect $760 million in fees associated with the existing branded prescription drug and medical device fee programs that expire at the end of the year.

CBO estimates that FDA would assess about $6.4 billion in aggregate fees over the 2013-2017 period. Of that amount, $1.8 billion in collections would be generated by the new fee programs for generic and biosimilar biological drugs and for accreditation activities created under the legislation and $4.7 billion in collections would be generated by the fee programs for branded prescription drugs and medical devices reauthorized by

the bill. Most of the fee programs authorized under the bill would expire at the end of fiscal year 2017; the accreditation fee program would not expire.

S. 2516 specifies that all drug and medical device fees would be collected and made available for obligation only to the extent, and in the amounts, provided in advance in appropriation acts, with one exception. The bill would allow certain new fees authorized for generic and biosimilar biological drugs to be collected and spent during the first program year (fiscal year 2013) until the date of enactment of a law providing appropriations through September 30, 2013.

By allowing the assessment and spending of fee collections outside of an appropriation action, S. 2516 could generate increases in revenue or direct spending attributable to such fees. However, for this estimate, CBO assumes that both enactment of S. 2516 and the necessary appropriation action will occur before the end of fiscal year 2012. Thus, we expect that any fees assessed and spent for fiscal year 2013 would be classified as offsetting collections (that is, as an offset to discretionary spending).

CBO estimates that appropriation action consistent with the bill's authorizations would reduce net discretionary outlays (primarily for FDA) by $384 million over the 2013-2017 period. Because FDA would have the authority to spend the collections, the estimated budget authority for collections and spending would offset each other exactly for each fiscal year, while the spending of fee collections would initially lag behind the collections and thus generate net discretionary savings over the 2013-2017 period.

Costs for Activities Not Supported by Fees. S. 2516 would require that FDA modify certain agency procedures relating to the oversight of prescription drugs and devices; costs for many of the new activities would not be covered by fees. CBO estimates that activities not supported by fees under the bill would cost $716 million over the 2013-2017 period, assuming the appropriation of the necessary amounts.

Provisions Affecting Pediatric Populations (Title V). S. 2516 would permanently authorize FDA's pediatric drug programs. The bill would make permanent:

- An incentive program that grants market exclusivity to manufacturers that voluntarily conduct specified studies on the use of drugs in certain pediatric populations, the so-called "pediatric exclusivity program[1];" and

- FDA's authority to require that drug manufacturers conduct tests on drugs for pediatric populations and make necessary labeling changes to reflect the appropriate information.

[1] During such period of pediatric exclusivity, FDA will not permit another manufacturer to market a version of the drug.

The legislation also would permanently authorize funding for the research program at the National Institutes of Health for pediatric studies on drugs. In addition, it would extend and enhance the incentive program for device manufacturers to develop medical devices specifically designed for pediatric patients.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing provisions that affect pediatric populations in title V of the bill would have a discretionary cost of $322 million the over 2013-2017 period.

Provisions Affecting Prescription Drugs (Titles VII through X). S. 2516 would enhance FDA's regulatory authorities relating to prescription drugs in several key areas. It would expand advance notification requirements for potential drug shortages and strengthen FDA's authority to expedite drug reviews and inspections of facilities that address critical drug shortages. The bill would also increase FDA's oversight authority of the drug supply chain both in the United States and overseas through new registration, recordkeeping, and inspection requirements. To advance the development of breakthrough drug therapies, S. 2516 would create a new approval procedure for such products. CBO estimates that implementing such provisions and complying with other requirements specified in titles VII through X would increase FDA's costs by about $241 million over the 2013-2017 period.

Provisions Affecting Medical Devices (Title VI). Title VI would modify regulatory procedures under which FDA evaluates and approves medical device applications and tracks the safety of such devices. Among those changes the bill would:

- Streamline FDA's administrative process to change a device's classification (specific sets of regulatory rules govern different device classes);

- Include devices in FDA's system for identifying risks after a product is on the market;

- Require FDA to provide manufacturers with a substantive summary of the scientific and regulatory rationale for denying a clearance or approval of a report or application; and

- Establish a review process with FDA for manufacturers that have been denied such a clearance or approval.

CBO estimates that the provisions affecting the regulation of medical devices under title VI would increase FDA's costs by about $95 million over the 2013-2017 period, assuming the appropriation of necessary amounts.

Miscellaneous Provisions (Title XI) and Other Effects. CBO estimates that implementing the provisions of title XI would cost $66 million over the 2013-2017 period, assuming the appropriation of the necessary amounts. Such provisions include reauthorizing the Critical Path program that establishes partnerships with private entities to foster the innovation and safety of medical products, and enhancing the federal oversight of medical gases.

Several provisions in the bill that would affect when lower-priced drugs enter into the market would reduce costs. Changing the timing of availability of lower-priced drugs affects spending in federal health programs that pay for prescription drugs and biological products. We expect that enacting the bill would lower the average price of drugs in the market slightly over the 2013-2017 period. CBO estimates that spending for federal health programs subject to appropriation—such as those operated by the Departments of Veterans Affairs and Defense—would fall by $8 million over the 2013-2022 period, assuming that appropriation actions reflect the estimated reductions in costs.

Direct Spending

CBO estimates that enacting S. 2516 would reduce direct spending for federal health programs by $71 million over the 2013-2017 period and by $358 million over the 2013-2022 period. That net impact reflect an *increase* in direct spending for provisions that would delay market entry of certain drugs (causing some federal health care programs to have higher spending than under current law) and a *decrease* in direct spending for other provisions of the bill that would lower average prices paid for some drugs (allowing federal health care programs to reduce their costs).

On balance, CBO expects that enacting the bill would lower the average price of drugs in the market slightly over the next 10 years. Consequently, spending by federal health programs that purchase prescription drugs or provide or subsidize health insurance that covers such drugs would decrease over that period.

Provisions that are expected to delay entry of lower-priced generic or biosimilar biological drugs are those that provide market exclusivity—periods during which FDA will not permit another manufacturer to market a version of the drug. Those provisions are aimed at encouraging the development of certain types of anti-microbial medications, innovative single enantiomer drugs[2], and pediatric indications and formulations for drugs. CBO estimates that such provisions would increase prices of certain drugs and thereby increase direct spending for mandatory health programs such as Medicare, Medicaid, subsidies for enrollees in health insurance exchanges, and the Federal Employees Health Benefits and TRICARE-for-Life programs, by $395 million over the 2013-2022 period.

[2] Enantiomers are a class of molecules which are arranged as mirror images to one another. Such molecules can be found together in a mixture that forms the basis of many drugs.

CBO expects that other provisions of S. 2516 would reduce the average price charged for drugs in the market. We estimate that the provision with the greatest effect on market entry by lower-priced generic and biosimilar biological drugs is section 1131 of the bill. That provision would create an administrative procedure for FDA to facilitate acquisition of sufficient samples of innovator drugs for generic and biosimilar manufacturers to conduct testing in order to obtain future marketing approval. CBO expects that such a process at FDA would lead to earlier marketing of lower-priced drugs.

Under current law, FDA can require that a manufacturer follow a certain procedure called a Risk Evaluation and Mitigation Strategy (REMS) to assure safe use of its product. In some cases, a REMS may prohibit the sale of the drug outside a tightly controlled distribution system. In recent years, some brand companies have refused to sell drugs subject to such restrictive distribution systems for use in testing by manufacturers of generic drugs. Without such samples, the generic manufacturer is unable to conduct the necessary tests required to compile a marketing application. CBO expects that implementing section 1131 could facilitate acquisition of drug samples by manufacturers of generic and biosimilar drugs in these cases, leading to earlier market entry by lower-priced generic and biosimilar drugs under the bill.

CBO estimates that implementing section 1131, along with other provisions in the bill that that would reduce barriers to market entry for lower-priced drugs arising from certain labeling exclusivities, would reduce direct spending for mandatory health programs by $753 million over the 2013-2022 period.

Revenues

S. 2516 would affect revenues in two ways. First, CBO expects that enacting S. 2516 would reduce the average cost for prescription drugs resulting in slightly lower costs for private health insurance plans. In turn, lowering of the costs of health insurance plans would reduce federal subsidies for health insurance purchased through an exchange. The portion of those tax credits that exceed taxpayers' liabilities are classified as outlays (and those effects are included in the direct spending estimate above), while the portions that reduce taxpayers' liabilities are recorded as changes in revenues. CBO estimates that S. 2516 would increase federal revenues by $5 million over the 2013-2022 period.

In addition, the bill would make certain violations of new requirements subject to criminal and civil money penalties. Collections of such penalties are classified as federal revenues. Criminal fines are deposited in the Crime Victims Fund, and later spent; however, CBO estimates that any net effects would not be significant in each year because of the small number of cases likely to be affected.

PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting on-budget direct spending or revenues. The net changes in outlays and revenues that are subject to those pay-as-you-go procedures are shown in the following table.

CBO Estimate of Pay-As-You-Go Effects for S. 2516 as reported by the Senate Committee on Health, Education, and Labor on May 7, 2012

	By Fiscal Year, in Millions of Dollars												
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2012-2017	2012-2022
NET INCREASE OR DECREASE (-) IN THE ON-BUDGET DEFICIT													
Statutory Pay-As-You-Go Impact	0	0	-1	-5	-19	-46	-66	-44	-72	-71	-39	-71	-363

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

By continuing FDA's fee program, the bill would extend a requirement to pay fees on state, local, or tribal governments that manufacture medical devices for commercial purposes. That requirement would be an intergovernmental mandate as defined in UMRA, but CBO is unaware of any case in which a state, local, or tribal entity manufactures such devices for commercial purposes. CBO is aware of public institutions of higher education that manufacture drugs and are subject to FDA's registration, recordkeeping, and inspection standards. Thus, the provisions in the bill that increase the stringency of those standards would impose an intergovernmental mandate. Because few public institutions of higher education would be required to comply with the new standards, CBO estimates that the costs of complying with the mandates in S. 2516 would be minimal and well below the threshold established in UMRA ($73 million in 2012, adjusted annually for inflation).

Because the bill's requirements would result in lower costs for prescription drugs provided under the Medicaid program, CBO estimates that state spending for Medicaid would decrease by about $6 million over the 2013-2017 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The legislation contains several mandates on the private sector as defined in UMRA. The most costly of those mandates would require that manufacturers of branded prescription

drugs, generic drugs, biosimilar biological products, and medical devices pay fees to FDA. CBO estimates that the direct cost of all private-sector mandates in the bill would greatly exceed the annual threshold specified in UMRA ($146 million in 2012, adjusted annually for inflation) in each of the five years that the mandates would be effective.

In addition to imposing an increase in fees, the legislation also would impose a number of other mandates on the private sector. For example, several provisions in the bill would grant periods of market exclusivity for certain types of drugs. Those provisions impose a mandate by preventing manufacturers of generic or biosimilar versions of the drug from entering the market during that period. Other mandates include imposing additional reporting requirements on applicants for new drugs or biological products who have been granted a deferral or extension for required pediatric studies. The legislation also would expand existing registration requirements on certain entities involved in the manufacture, preparation, propagation, compounding, or processing of drugs and require that manufacturers of certain drugs notify the FDA before discontinuing production of those drugs. In addition, title XI would impose a mandate on drug manufacturers subject to risk evaluation and mitigation strategies by preventing those manufacturers from using regulatory elements for ensuring safe use imposed by FDA to prohibit the sale of a drug to developers of generic or biosimilar drugs.

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