CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 24, 2012

H.R. 5651
Food and Drug Administration Reform Act of 2012

As ordered reported by the House Committee on Energy and Commerce on May 10, 2012

SUMMARY

H.R. 5651 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. The legislation would require FDA to publish the scientific or regulatory rationale for significant decisions issued by the agency regarding a device and establish an expedited process to appeal such decisions. In addition, the bill would permanently reauthorize FDA's programs that evaluate the use of drugs by children.

CBO expects that enacting the bill would affect the average price of prescription drugs available in the market. Some provisions in the bill would result in higher average prices for certain drugs; other provisions would accelerate the entry of generic versions of some drugs, which would lead to lower average prices. CBO estimates that the net effect of enacting H.R. 5651 would be to reduce the average price of prescription drugs slightly through 2017 and to increase prices in subsequent years.

CBO estimates that enacting H.R. 5651 would:

- Reduce direct spending, on net, by $72 million over the 2013-2017 period but increase direct spending by $244 million over the 2013-2022 period.

- Increase federal revenues by less than $500,000 over the 2013-2017 period but lower revenues, on net, by about $3 million over the 2013-2022 period.

Considering both the direct spending and revenue effects, we estimate that enacting H.R. 5651 would reduce budget deficits by approximately $72 million over the 2013-2017 period and increase them by $247 million over the 2013-2022 period. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending and revenues.

Pursuant to section 504 of H. Con. Res. 112, the Concurrent Resolution on the Budget—Fiscal Year 2013, CBO estimates H.R. 5651 would increase direct spending by more than $5 billion in at least one of the four consecutive 10-year periods starting in 2023.

Implementing H.R. 5651 would also have several effects on spending subject to appropriation. The bill would authorize increased funding for a variety of FDA activities, but CBO estimates that 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 $337 million over the 2013–2017 period, assuming appropriation actions consistent with the bill.

H.R. 5651 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 medical 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 first five years that the mandates would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 5651 is shown in the following table. The effects of this legislation fall primarily within budget functions 550 (health) and 570 (Medicare).

	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
Priority Review Vouchers	0	-6	-6	-6	-6	-23
Subtotal, Estimated Authorization Level	-1,137	-1,204	-1,273	-1,337	-1,453	-6,403
Subtotal, Estimated Outlays	-1,137	-1,204	-1,273	-1,337	-1,453	-6,403
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
Priority Review Vouchers	0	6	6	6	6	23
Subtotal, Estimated Authorization Level	1,137	1,204	1,273	1,337	1,453	6,403
Subtotal, Estimated Outlays	721	1,043	1,329	1,446	1,481	6,021
Net Changes from Fees						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	-416	-160	57	109	28	-383
Other Proposed Changes						
Provisions Affecting Prescription Drugs (Titles VIII and IX)						
Estimated Authorization Level	59	68	77	77	77	359
Estimated Outlays	31	58	72	75	76	313
Provisions Affecting Pediatric Populations (Title V)						
Estimated Authorization Level	46	61	62	63	71	303
Estimated Outlays	24	52	59	62	69	266
Provisions Affecting Medical Devices (Title VII)						
Estimated Authorization Level	14	23	32	32	33	134
Estimated Outlays	10	18	27	31	33	118
Other Provisions and Effects						
Estimated Authorization Level	3	5	5	6	6	25
Estimated Outlays	3	4	4	6	6	23
Total Changes in Discretionary Spending						
Estimated Authorization Level	122	157	176	178	187	821
Estimated Outlays	-349	-28	219	283	212	337

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	By Fiscal Year, in Millions of Dollars					
	2013	2014	2015	2016	2017	2013-2017
CHANGES IN DIRECT SPENDING[a]						
Estimated Budget Authority	-14	-12	-15	-16	-14	-72
Estimated Outlays	-14	-12	-15	-16	-14	-72
CHANGE IN REVENUES[a]						
Estimated Revenues	0	*	*	*	*	*

Note: * = less than $500,000; components may not sum to totals because of rounding.

a. CBO estimates that enacting the bill would increase direct spending, on net, by $244 million over the 2013-2022 period and decrease revenues by about $3 million over that period. There would be a small effect on spending for health benefits by the United States Postal Service, which is classified as off-budget. CBO estimates those amounts would be between -$500,000 and $500,000 annually over the 2013-2022 period.

BASIS OF ESTIMATE

For this 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.

H.R. 5651 would reauthorize FDA's branded prescription drug and medical device fee programs through 2017 and would establish new fee programs covering generic drugs and biosimilar biological products. (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 for which licenses were originally granted to innovator drug companies.) The bill also would establish a new fee program that provides vouchers for priority drug reviews to sponsors of marketing applications for drugs that treat rare pediatric diseases.

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.

Spending Subject to Appropriation

Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5651 would reduce net discretionary outlays, primarily for FDA, by $349 million in 2013 and $28 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 $337 million over the 2013-2017 period.

Fee Programs Administered by FDA. H.R. 5651 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 to cover costs of conducting priority drug reviews through an incentive program that awards redeemable vouchers for such reviews to sponsors of certain applications for drugs that treat rare pediatric diseases. 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.

Under the bill, CBO estimates that FDA would assess about $6.4 billion in aggregate fees over the 2013-2017 period. Of that amount, $1.7 billion in collections would be generated by the new fee programs for generic and biosimilar biological drugs and for priority review vouchers 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. Except for the voucher program, the fee programs authorized under the bill would expire at the end of fiscal year 2017. The authority to award vouchers expires one year after the third voucher is awarded, but there is no limit on when the voucher can be redeemed.

H.R. 5651 specifies that 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, H.R. 5651 could generate increases in revenue or direct spending attributable to such fees. However, for this estimate, CBO assumes that both enactment of H.R. 5651 and the necessary appropriation action will occur before the end of fiscal year 2012. As a result, we expect that any fees assessed and spent in 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 for fee programs would reduce net discretionary outlays for FDA by $383 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. H.R. 5651 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 $720 million over the 2013-2017 period, assuming the appropriation of the necessary amounts.

Provisions Affecting Prescription Drugs (Titles VIII and IX). H.R. 5651 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 increase FDA's oversight authority of the drug supply chain both in the United States and overseas through new registration and inspection requirements. The bill also would allow FDA to destroy certain counterfeit or adulterated imports valued at less than $2,000. To advance the development of breakthrough drug therapies, H.R. 5651 would create a new approval procedure for such products. CBO estimates that implementing such provisions and complying with other requirements contained in titles VIII and IX would increase FDA's costs by about $313 million over the 2013-2017 period.

Provisions Affecting Pediatric Populations (Title V). H.R. 5651 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.

The legislation also would authorize the appropriation of $25 million per year to extend the research program at the National Institutes of Health for pediatric studies on drugs for each year from 2013 through 2017. The bill would also authorize the appropriation of $30 million annually over the 2013-2017 period to extend FDA's grant and contracts program for orphan products.

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

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 $266 million the over 2013-2017 period.

Provisions Affecting Medical Devices (Title VII). Title VII 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:

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

- Require FDA to publish the scientific and regulatory rationale for any significant decision regarding a report or application;

- Establish a process for manufacturers that are seeking to submit or that have submitted a report or application to review with FDA the agency's documentation of significant decisions;

- Require FDA to regularly publish detailed decision summaries for each clearance of certain devices; and

- Extend and enhance the incentive program for device manufacturers to develop medical devices specifically designed for pediatric patients.

CBO estimates that the provisions affecting the regulation of medical devices under title VII would increase FDA's costs by about $118 million over the 2013-2017 period, assuming the appropriation of the necessary amounts.

Other Provisions and Effects. CBO estimates that implementing title VI and preparing certain regulatory science reports not covered by fees would cost $31 million over the 2013-2017 period, assuming the appropriation of the necessary amounts.

Several provisions in the bill would affect when lower-priced drugs enter the market. 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 reduce 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 that period, assuming that appropriation actions reflect the estimated reductions in costs.

Direct Spending

CBO estimates that enacting H.R. 5651 would reduce direct spending for federal health programs by $72 million over the 2013-2017 period but would increase direct spending by $244 million over the 2013-2022 period. That net impact reflects an *increase* in direct spending owing to provisions that would delay market entry of certain drugs (causing some federal health programs to have higher spending than under current law) and a *decrease* in direct spending owing to other provisions that would lower average prices paid for some drugs (allowing federal health programs to reduce their costs). CBO estimates that direct spending, on net, would begin to increase starting in 2018, when the effects of provisions that would delay the entry of lower-priced drugs exceeds the effects of provisions that would lead to earlier entry of lower-priced drugs.

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, and pediatric indications and formulations for drugs.[2]

Section 862 would change the rules governing when a generic drug manufacturer forfeits its rights to market exclusivity because of failure to receive tentative approval from FDA. The legislation would increase the allowable time period to obtain such approval—now set at 30 months after filing an application—before forfeiture occurs. Thus, the bill would allow affected firms to retain sole marketing rights. In cases where fewer generic firms compete on products because a forfeiture is avoided, we anticipate that higher average prices would be charged in the market. Because CBO expects that the implementation of the fee program for the review of generic drugs will accelerate review times and lead to fewer forfeitures, holding all else equal, the estimated costs for section 862 reflect the incremental effect of this provision beyond the effect of the fee program.

Taken together, CBO estimates that provisions delaying the entry of generic or biosimilar biological drugs would increase the average 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 $412 million over the 2013-2022 period.

CBO expects that other provisions of H.R. 5651 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 drugs is section 863. It would reduce by 30 days the statutory timeframe for final agency action relating to certain citizen petitions that ask for a stay of

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

FDA approval on a pending generic drug application. (Under the bill, the limitation on the determination period would be 150 days.)

When *both* approval of the generic application and marketing of the drug hinge on the final determination date, earlier administrative action under the bill could lead to earlier generic entry. (Sometimes patents or market exclusivities delay entry of generics regardless of the date on which a citizen petition is resolved.) Thus, in certain cases, CBO expects that reducing the statutory timeframe by 30 days could lead to earlier marketing of lower-priced drugs.

CBO estimates that implementing section 863 and other provisions that shorten administrative timeframes for review of certain petitions would reduce direct spending for mandatory health programs by $168 million over the 2013-2022 period. CBO anticipates that the implementation of the fee program in title III would allow FDA to use its resources in such a manner that we can reasonably expect that the average review times for certain petitions would also fall over time because of that program. Thus, estimated savings generated by provisions that would shorten administrative timeframes in the bill reflect the incremental effect of such provisions beyond the effect of the fee program.

Revenues

H.R. 5651 would affect revenues in two ways. First, CBO expects that enacting H.R. 5651 would result in slightly higher costs for private health insurance plans over the 2013-2022 period. In turn, raising the costs of health insurance plans would increase 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 H.R. 5651 would lower federal revenues by $3 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 H.R. 5651 as ordered reported by the House Committee on Energy and Commerce on May 10, 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	-14	-12	-15	-16	-15	7	73	61	66	112	-73	247

Note: Components may not sum to totals because of rounding.

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 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 H.R. 5651 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 first five years that the mandates would be effective.

In addition to imposing an increase in fees, H.R. 5651 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. The bill also would expand requirements relating to the approval of pediatric drugs and would expand registration requirements on certain entities involved in the manufacture, preparation, propagation, compounding, or processing of drugs. Title VIII also would authorize the Secretary of Health and Human Services to destroy certain drugs intended for import that are refused admission to the United States. Title IX would require that manufacturers of certain drugs notify the FDA before discontinuing production of those drugs.

PREVIOUS CBO ESTIMATE

On May 11, 2012, CBO transmitted a cost estimate for S. 2516, the Food and Drug Administration Safety and Innovation Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on May 7, 2012. Both the House and Senate bills would make significant changes to the regulatory authority of the Food and Drug Administration relating to prescription drugs and devices. Although the bills contain many similar provisions, H.R. 5651 would address certain regulatory issues in different ways. CBO's cost estimates reflect those differences.

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