CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 15, 2017

S. 934
FDA Reauthorization Act of 2017

As reported by the Senate Committee on Health, Education, Labor, and Pensions on May 11, 2017

SUMMARY

S. 934 would reauthorize the Food and Drug Administration (FDA) to collect and spend fees to cover the cost of carrying out certain activities to expedite the approval process for marketing prescription drugs and medical devices and to regulate drugs after they enter the market. The bill also would:

- Reauthorize certain programs and grants administered by FDA and the National Institutes of Health (NIH),
- Require the Government Accountability Office (GAO) to report on FDA and NIH activities, and
- Provide drug sponsors the opportunity to effectively restrict competition from generic drugs for a period of time for drugs developed from a particular type of molecule called an enantiomer, by requesting five-year data exclusivity.

Implementing S. 934 would require increased funding for a variety of FDA activities, but most of the increase in FDA spending would be offset by additional fees that would be collected under the bill and used to reduce the need for discretionary appropriations. CBO estimates that net discretionary spending (primarily by FDA) would increase by about $740 million over the 2017–2022 period, assuming appropriation actions consistent with the bill.

CBO also estimates that enacting S. 934 would increase direct spending by $13 million and decrease revenues by $2 million over the 2017-2027 period; therefore, pay-as-you-go procedures apply. Taken together, CBO estimates that enacting S. 934 would increase budget deficits by $15 million over the 2017-2027 period.

CBO estimates that enacting S. 934 would not increase net direct spending or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2028.

S. 934 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on public and private manufacturers of prescription drugs and medical devices. In addition, the bill would preempt state and local laws that interfere with the distribution of over-the-counter hearing aids. CBO estimates that the cost of the mandates on public entities would be small and fall well below the annual threshold established in UMRA for intergovernmental mandates ($78 million in 2017, adjusted annually for inflation). However, in aggregate, CBO estimates that the cost of the mandates on private entities would well exceed the annual threshold established in UMRA for private-sector mandates ($156 million in 2017, adjusted annually for inflation) in each of the first five years the mandates are in effect, primarily because of the requirement to pay fees.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 934 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 this estimate, CBO assumes that the bill will be enacted by the end of fiscal year 2017 and that the estimated collections and appropriations will be provided for each year in an appropriations act.

Spending Subject to Appropriation

CBO estimates that implementing S. 934 would increase collections (which would be recorded as offsets to discretionary spending under the bill) by about $1.7 billion in 2018. In 2017, about $1.2 billion in collections and spending was appropriated for the FDA user fee programs that would be reauthorized by S. 934. Gross discretionary spending would increase by about $1.5 billion in 2018 ($1.3 billion from spending of fees and $0.2 billion from changes not covered by fees), CBO estimates. However, because spending lags somewhat behind collections, net discretionary outlays would decline by about $0.2 billion in 2018. CBO estimates that 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. In total, the net discretionary cost of implementing the bill would amount to $0.7 billion over the 2018-2022 period.

	By Fiscal Year, in Millions of Dollars						
	2017	2018	2019	2020	2021	2022	2017-2022
INCREASES OR DECREASES (-) IN SPENDING SUBJECT TO APPROPRIATION [a]							
Collection and Spending of Fees							
Collections							
Prescription Drugs	0	-938	-999	-1,061	-1,117	-1,174	-5,289
Medical Devices	0	-190	-201	-216	-234	-243	-1,084
Generic Drugs	0	-494	-503	-515	-528	-542	-2,583
Biosimilar Biological Products	0	-45	-46	-47	-49	-51	-238
Subtotal							
Estimated Authorization Level	0	-1,667	-1,750	-1,840	-1,929	-2,009	-9,194
Estimated Outlays	0	-1,667	-1,750	-1,840	-1,929	-2,009	-9,194
Spending							
Prescription Drugs	0	938	999	1,061	1,117	1,174	5,289
Medical Devices	0	190	201	216	234	243	1,084
Generic Drugs	0	494	503	515	528	542	2,583
Biosimilar Biological Products	0	45	46	47	49	51	238
Subtotal							
Estimated Authorization Level	0	1,667	1,750	1,840	1,929	2,009	9,194
Estimated Outlays	0	1,329	1,652	1,820	1,907	1,989	8,696
Net Estimated Authorization Level	0	0	0	0	0	0	0
Net Estimated Outlays	0	-338	-98	-19	-22	-20	-498
Activities Not Covered by Fees							
Generic Drugs							
Estimated Authorization Level	0	110	81	121	156	161	629
Estimated Outlays	0	51	89	114	149	163	566
Medical Devices							
Estimated Authorization Level	0	30	45	55	68	74	271
Estimated Outlays	0	21	38	50	63	71	243
Pediatric Populations							
Estimated Authorization Level	0	31	32	33	33	33	161
Estimated Outlays	0	13	27	31	32	32	136
Miscellaneous Provisions							
Estimated Authorization Level	0	121	46	49	49	49	313
Estimated Outlays	0	57	69	56	57	58	296
Subtotal							
Estimated Authorization Level	0	291	204	257	306	316	1,375
Estimated Outlays	0	141	223	251	301	323	1,241
Total Changes in Discretionary Spending							
Estimated Authorization Level	0	291	204	257	306	316	1,375
Estimated Outlays	0	-197	125	232	279	303	743

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

a. CBO estimates that enacting the bill would increase direct spending by $13 million and decrease revenues by $2 million over the 2017-2027 period.

Collection and Spending of Fees. S. 934 would reauthorize, through 2022, FDA programs through which fees are collected to cover the costs related to approving and marketing branded prescription drugs, medical devices, generic drugs, and biosimilar biological products. (Biological drugs are products derived from living organisms; biosimilars are products that meet certain statutory requirements and that FDA has determined are highly similar to drugs originally licensed to innovator drug companies.) Based on the fee levels and the inflation adjustments specified in the bill, CBO estimates that in aggregate FDA would assess about $9 billion in fees over the 2018-2022 period—$8 billion for prescription drugs and $1 billion for medical devices. The programs authorized under the bill would expire at the end of fiscal year 2022. Because FDA would have the authority to spend collections, the estimated authorization levels for collections and spending would offset each other each fiscal year, while the spending would lag somewhat. Thus, CBO estimates that reauthorizing the fee programs would, on net, decrease spending subject to appropriation by $498 million over the 2018-2022 period. Those savings would be fully offset by increased spending in years after 2022.

Under the bill, fees generally would be collected and made available for obligation only to the extent, and in the amounts, provided in advance in appropriation acts. The bill would allow some fees to be assessed and spent outside of an appropriation action, and if that happened, any fees collected would be classified as revenues. However, CBO assumes that both S. 934 and the necessary appropriation actions will occur before the end of fiscal year 2017. Thus, for this estimate we assume that any fees collected in fiscal year 2018 would be classified as offsetting collections (that is, as an offset to discretionary spending).

Activities Not Covered by Fees. S. 934 would require FDA to modify certain agency procedures related to overseeing and reviewing generic drugs, drugs for pediatric populations, and medical devices. The bill also would reauthorize certain research grant programs and would require GAO to prepare several reports. (The cost of those activities would not be covered by fees.) CBO estimates that implementing those provisions would cost about $1.2 billion over the 2018-2022 period.

Generic Drugs. Title IX would require FDA to expedite its review of certain applications for generic drugs and to collect and publish additional data about such drugs. Based on an analysis of information from FDA, CBO estimates that implementing those provisions would require about 500 additional full-time-equivalent (FTE) positions by 2022 (at an average annual cost of about $300,000 per FTE) and additional funding totaling $14 million per year, on average, to carry out a variety of activities related to information technology. In total, those expenses would increase FDA's costs by about $566 million over the 2018-2022 period. That total includes:

- $385 million to expand the types of generic applicants to which FDA must grant priority review and to provide technical assistance to such applicants;

- $102 million to collect information about generic drugs with three or fewer competitors and to build the necessary information technology infrastructure to gather and publish this information biannually;

- $69 million to re-inspect generic drug manufacturing facilities, in certain instances, if they had a known deficiency that was remedied by the manufacturer; and

- $10 million to collect and publish information about the status of generic drug applications.

Title IX also would express the sense of the Senate that FDA should respond to suitability petitions within 90 days of submission. (Generic drug manufacturers submit suitability petitions to FDA when they would like to submit an application for a product that has a different manner of administration, dosage form, or strength than drugs with the same active ingredient that are currently on the market.) CBO estimates that there would be no budgetary effects from that provision because the bill does not require FDA to follow the 90-day guideline. However, based on information from FDA, CBO expects if FDA did follow that guideline, costs would increase by about $20 million over the 2018-2022 period.

Medical Devices. Section 207 of Title II would require FDA to establish an electronic format for accepting submissions for medical devices. Title VII would modify the regulatory procedures under which FDA evaluates and approves medical device applications and tracks the safety of such devices. Based on an analysis of information from FDA, CBO estimates that implementing those provisions would require more than 200 FTEs (at an average annual cost of about $300,000 per FTE) and about $7 million a year, on average, for information technology and other expenses. In total, those expenses would increase FDA's costs by $243 million over the 2018-2022 period. That total includes:

- $152 million to alter FDA's processes and standards for inspecting domestic and foreign establishments;

- $32 million to update FDA's regulatory procedures, including changes to the way FDA receives data from device manufacturers and its evaluation of certain clinical data;

- $20 million to establish a procedure for increased communication between FDA and device establishments on certain export certificates;

- $20 million to initiate one or more pilot programs for collecting and evaluating data on the post-market safety and effectiveness of cleared or approved devices;

- $11 million to establish a risk-based schedule for inspecting device establishments, and to reauthorize certain inspections by accredited persons; and

- $8 million to develop and implement regulations for an over-the-counter category for certain hearing aid devices.

Pediatric Populations. Title V would affect the research plans of device and drug manufacturers as well as FDA's regulation of pediatric drugs and devices. Those changes would range from requiring FDA to provide assistance to device manufacturers in their development of products to requiring them to provide guidance on the development of pediatric oncology drugs. CBO estimates implementing those provisions would increase costs for FDA and NIH by about $136 million over the 2018-2022 period, primarily for an eight additional FTE positions and about $25 million, on average, per year for grants that under current law will expire at the end of fiscal year 2017. That total includes:

- $102 million to reauthorize an NIH program that funds studies and research in pediatric therapeutic areas;

- $28 million for FDA to develop a structure that would provide technical assistance to pediatric device manufacturers and reauthorize demonstration grants for improving pediatric device availability;

- $4 million to increase the communication between pediatric drug applicants and FDA and permanently add a neonatology expert in the Office of Pediatric Therapeutics at FDA; and

- $2 million for FDA to provide guidance on the development of oncology drugs and biologics directed at molecular targets.

Miscellaneous Provisions. Provisions in title VI would reauthorize several programs administered by FDA through fiscal year 2022 and would require the agency to issue additional guidance to manufacturers that outlines how to demonstrate bioequivalence under certain circumstances. Provisions in title VIII would establish and modify various FDA reporting requirements and would require FDA—with support from NIH—to address issues patients confront when trying to access experimental treatments. Based on information from FDA, CBO estimates that implementing these provisions would require about 40 additional FTE positions by 2022 as well as $33 million, on average, per year for grants. In total, those expenses would cost FDA about $294 million over the 2018-2022 period and includes:

- $138 million to reauthorize the Orphan Products Grants program, which provides grants to public or private entities to encourage clinical development of products to treat rare diseases;

- $105 million for FDA to issue product specific guidance on establishing bioequivalence to complex drugs that are not biological products;

- $28 million to reauthorize the Critical Path program that provides funding for FDA to engage in collaborative agreements with certain entities to foster the innovation and safety of medical products;

- $20 million to streamline and expand upon FDA's current reporting requirements; and

- $4 million for FDA and NIH to convene a public meeting on patient access to experimental treatments and for FDA to issue guidance to establish eligibility criteria for clinical trials and to streamline institutional review board review.

S. 934 would also require GAO to prepare several reports on new regulations for certain hearing devices, FDA's progress in optimizing global clinical trials and use of data, and other topics discussed at the public meeting on patient access. The bill would also require GAO to study the expenses for FDA facility maintenance and renovations from 2012 through 2019. Based on the scope of the reports and the cost of similar activities, CBO estimates that implementing those provisions would cost about $2 million over the 2018-2022 period.

Direct Spending and Revenues

S. 934 would reauthorize a provision in current law that allows sponsors for drugs developed from a particular type of molecule called an enantiomer under certain circumstances to elect five-year data exclusivity. (Five-year data exclusivity begins when the drug is approved by FDA; during that period, FDA will not accept an application for marketing approval of a generic version of the drug because FDA cannot use data submitted for approval of a brand drug to evaluate the generic drug's application.) CBO expects that granting data exclusivity and thereby extending market exclusivity for certain prescription drugs would, in some cases, delay the entry of lower-priced generic versions of those drugs. Delaying the availability of lower-priced generic drugs would raise the cost of pharmaceuticals paid by federal health programs such as Medicare and Medicaid. To date, only one enantiomer product has been granted exclusivity under this authority. CBO analyzed federal spending on that product and estimated the probability of similar products launching in the next five years. Based on that analysis, CBO

estimates that allowing five-year exclusivity for such products would increase direct spending for mandatory health programs by $12 million over the 2017-2027 period.

CBO also expects that enacting this provision would result in slightly higher costs for private health insurance plans over the 2017-2027 period. Those higher costs would increase federal subsidies for health insurance purchased through marketplaces. The portion of those tax credits that exceed taxpayers' liabilities are classified as outlays (and those effects are included in the estimate of direct spending above), while the portion that reduces taxpayers' liabilities is recorded as a change in revenues. CBO estimates that enacting those provisions would decrease federal revenues by $2 million over the 2017-2027 period.

Enacting the bill also could increase criminal penalties for selling counterfeit drugs; criminal penalties are recorded as revenues and deposited in the Crime Victims Fund and can be spent without further appropriation action. However, CBO estimates that any such collections and subsequent direct spending would be insignificant in every year and the net effect on the deficit would be negligible.

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. 934 as reported by the Senate Committee on Health, Education, and Labor on May 11, 2017

	By Fiscal Year, in Millions of Dollars												
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2017-2022	2017-2027
NET INCREASE IN THE ON-BUDGET DEFICIT													
Statutory Pay-As-You-Go Impact	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**3**	**5**	**4**	**1**	**0**	**15**
Memorandum:													
Changes in Outlays	0	0	0	0	0	0	1	3	5	4	1	0	13
Changes in Revenues	0	0	0	0	0	0	0	0	-1	-1	0	0	-2

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

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting S. 934 would not increase net direct spending or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2028.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 934 would impose intergovernmental and private-sector mandates as defined in UMRA. CBO estimates that the cost of the mandates on public entities would be small and fall well below the annual threshold established in UMRA for intergovernmental mandates ($78 million in 2017, adjusted annually for inflation). However, in aggregate, CBO estimates that the cost of the mandates on private entities would well exceed the annual threshold established in UMRA for private-sector mandates ($156 million in 2017, adjusted annually for inflation) in each of the first five years the mandates are in effect.

Mandates That Apply to Both Public and Private Entities

The most costly mandate would extend the requirement that manufacturers of branded prescription drugs, generic drugs, biosimilar biological products, and medical devices pay fees to FDA. CBO estimates that those fees would total about $9 billion over the 2018-2022 period, with private entities responsible for most of the costs. Very few public institutions of higher education manufacture drugs for commercial purposes. Since only those public entities would be subject to FDA's fee assessments, CBO estimates that the total annual cost of the mandate on public entities would be small.

Mandates That Apply to Private Entities Only

In addition to the requirement to pay fees, the bill would impose mandates that fall solely on private entities. Those mandates would:

- Extend FDA's authority to grant drug sponsors an opportunity to elect five years of market exclusivity for certain drugs and thus prevent manufacturers of generic drugs from entering the market during such periods;

- Require drug manufacturers to report information to FDA on generic drug applications owned by affiliates and to notify FDA when they remove a drug from the market; and

- Require drug manufacturers, at the option of FDA, to disseminate additional information about risk evaluation and mitigation studies for selected drugs.

CBO estimates that the cost of those mandates would be low. Granting drugs additional marketing exclusivity would delay the market entry of generic versions of those products. The cost of the mandate for manufacturers of generic products would be the annual net loss of income resulting from the delay. CBO expects that the value of drug sales that could be affected in the first five years that the mandate is in effect would be small, and therefore the cost of the mandate would be relatively small. The reporting and notification requirements on drug manufacturers are incremental to such requirements already in place, and thus, CBO estimates that the incremental cost of compliance would be minor.

Mandates That Apply to Public Entities Only

The bill would preempt state and local laws that interfere with the distribution of over-the-counter hearing aids. Although that preemption would limit the application of state and local laws, it would impose no duty on state or local governments that would result in additional spending or a loss of revenues.

Other Impacts

The provision of the bill that would grant five years of market exclusivity for certain prescription drugs would delay generic manufacturers from entering those markets and could raise the cost of pharmaceuticals paid by mandatory health programs. CBO estimates that this provision would result in an increase of $1 million in Medicaid costs over the 2018-2027 period for states.

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