CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 31, 2013

H.R. 1919
Safeguarding America's Pharmaceuticals Act of 2013

As ordered reported by the House Committee on Energy and Commerce on May 15, 2013

SUMMARY

H.R. 1919 would require the Food and Drug Administration (FDA) to establish national standards for monitoring the movement of prescription drugs through the drug distribution system. The "drug distribution system" encompasses the network of companies that produce, handle, distribute, and dispense drug products. The legislation would impose new regulatory requirements on such companies relating to the handling of drug products and recordkeeping of transactions, and would create notification rules concerning drugs that are potentially unsuitable for distribution.

The bill also would require the FDA to establish a licensing program for certain third parties that provide logistic services to support pharmaceutical manufacturers, wholesalers, and dispensers. The bill would authorize FDA to collect and spend fees to cover the costs of the licensing program.

CBO estimates that enacting H.R. 1919 would increase federal revenues by $19 million over the 2015-2018 period and by $24 million over the 2015-2023 period. Pay-as-you-go procedures apply because enacting the legislation would affect revenues.

CBO estimates that implementing H.R. 1919 would have a discretionary cost of $39 million over the 2014-2018 period, assuming annual appropriation actions consistent with the bill.

H.R. 1919 would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by requiring public and private-sector entities to comply with standards for monitoring the movement of prescription drugs through the distribution system. Because few public entities manufacture, distribute, or dispense prescription drugs, CBO estimates that the costs to public entities to comply with the mandates in the bill would be small and below the intergovernmental threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). CBO

estimates that the costs to private entities would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1919 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2014	2015	2016	2017	2018	2014-2018
CHANGES IN REVENUES[a]						
Collection of Licensing Fees						
Estimated Revenues[b]	0	6	6	6	1	19
Penalties						
Estimated Revenues	0	*	*	*	*	*
Total Changes in Revenues						
Estimated Revenues	0	6	6	6	1	19
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Spending of Licensing Fees						
Estimated Authorization Level	0	7	7	8	1	23
Estimated Outlays	0	6	7	8	2	23
Activities not Related to Fees						
Estimated Authorization Level	3	5	5	2	2	17
Estimated Outlays	2	4	5	3	2	16
Total Changes in Discretionary Spending						
Estimated Authorization Level	3	12	12	10	3	40
Estimated Outlays	2	10	12	11	4	39

Note: * = less than $500,000.

a. CBO estimates that enacting the bill would increase revenues by $24 million over the 2015-2023 period.

b. CBO estimates that the assessments in H.R. 1919 would reduce income and payroll taxes because assessments on firms are indirect business charges that reduce the tax base of income and payroll taxes. Numbers here reflect net receipts to the Treasury.

BASIS OF ESTIMATE

For the estimate, CBO assumes that the legislation will be enacted by the end of fiscal year 2013, and that the Congress will take appropriation actions consistent with the bill for the funding of FDA activities. We also assume that outlays will follow historical patterns for similar activities.

H.R. 1919 would authorize FDA to expand its oversight of the drug distribution system in the United States. The legislation aims to improve the safety of the U.S. drug supply by requiring enhanced monitoring of the chain of transactions from the manufacturer of a drug to the party that ultimately dispenses the drug to the consumer.

Key provisions of H.R. 1919 include new requirements on entities in the drug distribution system relating to:

- Storage and handling of prescription drug products,
- Maintenance of records,
- Mandatory inspections of wholesaler facilities,
- Mandatory use of uniform identification numbers (UIDs) on packages or cases,[1] and
- Identification and notification rules concerning products that are potentially counterfeit, diverted, stolen or otherwise appear unfit for distribution.

Revenues

CBO estimates that enacting H.R. 1919 would increase federal revenues by $19 million over the 2015-2018 period and by $24 million over the 2015-2023 period. The legislation would affect revenues in two ways:

- Authorizing the FDA to assess fees on certain third parties to cover the costs of licensing and conducting periodic inspections would increase governmental receipts; and
- Collecting fines associated with violations of certain new requirements imposed by the bill that would be recorded as federal revenues.

[1] After 2027, the bill would require that identifiers be applied to individual units of drug products.

Collection of Licensing Fees. H.R. 1919 would require the FDA to license and oversee certain third parties that provide logistic services for a pharmaceutical manufacturer, wholesaler, or distributor. For example, services provided by such entities include warehousing and transporting drug products without taking ownership or responsibility for the sale or disposition of the products. The bill would require all such facilities to be licensed by a state or the FDA. The bill would authorize the collection and spending of fees by FDA to cover the costs of activities related to issuing those licenses such as periodic inspections.

CBO expects FDA would begin licensing facilities in fiscal year 2015, thus we expect fee collections would start in that year. CBO expects that FDA would set fees to cover $23 million in estimated gross costs over the 2015-2018 period (as described below under "Spending Subject to Appropriation"). However, because those fees are expected to reduce the tax base for income and payroll taxes, CBO estimates revenues from those sources would be reduced. Overall, CBO estimates net receipts to the Treasury would increase by $19 million over the 2015-2018 period.

Penalties. Civil monetary penalties could be assessed on the facilities in the drug distribution system for violations of new requirements under H.R. 1919. Based on enforcement actions of violations, CBO expects that any additional revenues from the imposition of penalties would not be significant because of the small number of additional cases likely to be affected.

Spending Subject to Appropriation

Assuming appropriation actions consistent with the bill, CBO estimates that implementing H.R. 1919 would have a discretionary cost of $39 million over the 2014-2018 period.

Spending of Licensing Fees. H.R. 1919 would authorize FDA to collect fees to help defray the costs of establishing a licensure program for third parties that provide logistic services. The spending of fees would be subject to future appropriation action. (CBO expects that the collections from licensing fees would be classified as revenues, as discussed above in the "Revenues" section.)

Based on information on costs of similar oversight programs, CBO estimates the costs to the FDA of implementing those provisions of H.R. 1919 would be $23 million over the 2015-2018 period. CBO expects higher start-up costs through 2017 to fund information technology systems and other activities necessary to implement the program.

Activities Not Related to Fees. H.R. 1919 would require FDA to establish a number of standards to enhance the safety and security of prescription drugs as those drugs are distributed from the manufacturer to the pharmacy, hospital, or other persons authorized

to dispense or administer prescription drugs to consumers. In developing those standards the FDA would be required to host numerous public meetings, implement at least one pilot project, and promulgate regulations. CBO estimates the costs to FDA of implementing those provisions would be about $16 million over the 2014-2018 period, subject to appropriation of the necessary amounts.

PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in 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. 1919, as ordered reported by the House Committee on Energy and Commerce on May 15, 2013

	By Fiscal Year, in Millions of Dollars												
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2013-2018	2013-2023
NET DECREASE (-) IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	0	-6	-6	-6	-1	-1	-1	-1	-1	-1	-19	-24

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 1919 would impose both intergovernmental and private-sector mandates as defined in UMRA by requiring public and private-sector entities to comply with standards for monitoring the movement of prescription drugs through the distribution system.

Effects on the Private Sector

To monitor the movement of prescription drugs, the bill would impose a number of mandates, as defined in UMRA, on drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies), and third parties that provide logistic services (TPLs). Such entities would be required to:

- Maintain records of the transaction history of all drug products for three years,
- Only accept or transfer ownership of drug products with a UID,

- Identify suspect or illegitimate drug products and notify the FDA of such a discovery,

- Identify, quarantine, dispose, and maintain records of illegitimate drug products, and

- Pay fees to cover the costs of licensing.

Because existing law in California affects nearly all manufacturers, repackagers, wholesale distributors, and TPLs, CBO estimates that the cost of the mandates contained in H.R. 1919 for those private-sector entities would be small. However, independent pharmacies and pharmacies based in hospitals–currently unaffected by existing laws in California–would face new costs to comply with the mandates. According to data from the National Community Pharmacy Association, roughly 20,000 independent pharmacies operate outside of California, most of which would incur new costs in complying with the requirements in H.R. 1919.

The cost of compliance would vary across pharmacies and would depend on the type of data systems developed by manufacturers, wholesale distributors, TPLs, and repackagers. A study by Accenture in 2011 estimated that the cost of complying with a federal standard for tracing prescription drugs would cost the average independent pharmacy roughly $84,000 per pharmacy store in the first year.[2] Even if the first-year costs to independent and hospital-based pharmacies that operate outside of California were half that amount, the costs to comply with the mandate in that year would exceed $800 million. Thus, CBO estimates the costs to those pharmacies of complying with the standards in H.R. 1919 would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation) in at least one of the first five years in which the mandate would be in effect.

Effects on State, Local, and Tribal Governments

Because few pharmacies are public entities, CBO estimates that the intergovernmental costs of the mandates would be small and below the threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). The bill also would preempt state laws that require tracing prescription drugs through the distribution system. In addition, the legislation would preempt state licensing laws that govern wholesale drug distributors or TPLs if those laws are less stringent than the standards established by the bill. Because they would limit the application of state law, those preemptions would be intergovernmental mandates as defined in UMRA; however, they would impose no duty on states that would result in additional spending.

[2] "Current Status of Safety of the U.S. Prescription Drug Distribution System," June 2008, Updated for NACDS March 2011, Accenture.

ESTIMATE PREPARED BY:

Federal Costs: Ellen Werble, Lisa Ramirez-Branum, and Barbara Edwards
Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum
Impact on the Private Sector: Michael Levine

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis