HR 1919

Safeguarding America's Pharmaceuticals Act of 2013

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: May 9, 2013
Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and
Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jun 4, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/1919

Sponsor

Name: Rep. Latta, Robert E. [R-OH-5]
Party: Republican • **State:** OH • **Chamber:** House

Cosponsors (20 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Blackburn, Marsha [R-TN-7]	R · TN		May 9, 2013
Rep. Burgess, Michael C. [R-TX-26]	R · TX		May 9, 2013
Rep. Cassidy, Bill [R-LA-6]	R · LA		May 9, 2013
Rep. Dingell, John D. [D-MI-12]	D · MI		May 9, 2013
Rep. Guthrie, Brett [R-KY-2]	R · KY		May 9, 2013
Rep. Johnson, Bill [R-OH-6]	R · OH		May 9, 2013
Rep. Matheson, Jim [D-UT-4]	D · UT		May 9, 2013
Rep. McKinley, David B. [R-WV-1]	R · WV		May 9, 2013
Rep. Rogers, Mike J. [R-MI-8]	R · MI		May 9, 2013
Rep. Schneider, Bradley Scott [D-IL-10]	D · IL		May 9, 2013
Rep. Shimkus, John [R-IL-15]	R · IL		May 9, 2013
Rep. Upton, Fred [R-MI-6]	R · MI		May 9, 2013
Rep. Latham, Tom [R-IA-3]	R · IA		May 17, 2013
Rep. Long, Billy [R-MO-7]	R · MO		May 17, 2013
Rep. Olson, Pete [R-TX-22]	R · TX		May 17, 2013
Rep. Valadao, David G. [R-CA-21]	R · CA		May 21, 2013
Rep. Rush, Bobby L. [D-IL-1]	D · IL		May 23, 2013
Rep. Veasey, Marc A. [D-TX-33]	D · TX		Jun 3, 2013
Rep. Walberg, Tim [R-MI-7]	R · MI		Jun 3, 2013
Rep. Walorski, Jackie [R-IN-2]	R · IN		Jun 3, 2013

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 10, 2013
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jun 4, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 HR 3204	Related bill	**Nov 27, 2013:** Became Public Law No: 113-54.

Summary (as of Jun 3, 2013)

Safeguarding America's Pharmaceuticals Act of 2013 - (Sec. 2) Amends the Federal Food, Drug, and Cosmetic Act to establish requirements to facilitate the tracing of drug products through the pharmaceutical supply distribution chain.

Requires the Secretary of Health and Human Services (HHS) to establish standards for the exchange of transaction information.

Requires the Secretary to establish processes to: (1) provide waivers of requirements for undue economic hardship or emergency medical reasons; (2) provide waivers of requirements relating to product identifiers for prescription drug products packaged without sufficient space to bear the information; and (3) determine other prescription drug products or transactions that should be exempt from the requirements of this Act.

Establishes requirements for drug manufacturers, wholesalers, dispensers, and repackagers to ensure that all prior transaction information is provided at each transfer of ownership. Requires such entities to maintain such transaction information for three years. Sets forth exceptions, including for dispensing to a patient and returns.

Requires a manufacturer, wholesale distributor, dispenser, repackager, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, to provide within two business days the applicable transaction documentation upon request by the Secretary or other appropriate federal or state official.

Requires a manufacturer or repackager to affix or imprint a prescription drug product identifier on each package and homogenous case of a prescription drug product.

Requires a manufacturer, wholesale distributor, dispenser, repackager, or third party logistics provider to ensure that each of its trading partners is authorized.

Requires a manufacturer, wholesale distributor, dispenser, repackager, and third party logistics provider to implement systems to: (1) investigate suspected illegitimate prescription drug products or, for a third party logistics provider, notify the owner of a need for such an investigation, and (2) handle illegitimate prescription drug products, including through quarantine, disposal, and appropriate notice to the Secretary and, as necessary, trading partners.

Requires manufacturers, wholesale distributors, repackagers to verify returned products before further distribution.

(Sec. 3) Requires the Secretary to establish projects and hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain.

Directs the Comptroller General (GAO) to examine implementation of the requirements established under this Act in order to inform regulations promulgated to enhance distribution supply chain safety and security.

Directs the Secretary to contract with a private, independent consulting firm with relevant expertise to conduct a technology and software study on the feasibility of dispensers that have 25 or fewer full-time employees conducting interoperable, electronic tracing of prescription drug products at the package level.

Requires the Secretary to issue additional proposed regulations in 2027 to prevent a suspect, illegitimate or counterfeit product, or a product otherwise unfit for distribution from entering into or being further distributed in the supply chain.

(Sec. 4) Requires the Secretary to establish standards for the licensing of wholesale distributors and third party logistics providers. Requires third party logistics providers to be licensed by the state from which the drug is distributed or by the Secretary.

(Sec. 6) Applies specified criminal and civil penalties to violations of standards prescribed under this Act, including a certain enhanced penalty for knowing unlicensed activities, and failure to bear a prescription drug product identifier required by this Act.

(Sec. 7) Preempts state and local requirements related to tracing drugs through the distribution system, and licensure of wholesale distributors or third party logistics provider licensure.

(Sec. 8) Allows certain prescription drug labeling to be provided solely by electronic means.

Actions Timeline

- **Jun 4, 2013:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Jun 3, 2013:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 113-93.
- **Jun 3, 2013:** Placed on the Union Calendar, Calendar No. 65.
- **Jun 3, 2013:** Mr. Latta moved to suspend the rules and pass the bill, as amended.
- **Jun 3, 2013:** Considered under suspension of the rules. (consideration: CR H2968-2984)
- **Jun 3, 2013:** DEBATE - The House proceeded with forty minutes of debate on H.R. 1919.
- **Jun 3, 2013:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H2969-2978)
- **Jun 3, 2013:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H2969-2978)
- **Jun 3, 2013:** Motion to reconsider laid on the table Agreed to without objection.
- **May 10, 2013:** Referred to the Subcommittee on Health.
- **May 9, 2013:** Introduced in House
- **May 9, 2013:** Referred to the House Committee on Energy and Commerce.