HR 3204

Drug Quality and Security Act

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 27, 2013
Current Status: Became Public Law No: 113-54.
Latest Action: Became Public Law No: 113-54. (Nov 27, 2013)
Law: 113-54 (Enacted Nov 27, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/3204

Sponsor

Name: Rep. Upton, Fred [R-MI-6]
Party: Republican • **State:** MI • **Chamber:** House

Cosponsors (10 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeGette, Diana [D-CO-1]	D · CO		Sep 27, 2013
Rep. Dingell, John D. [D-MI-12]	D · MI		Sep 27, 2013
Rep. Green, Gene [D-TX-29]	D · TX		Sep 27, 2013
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Sep 27, 2013
Rep. Latta, Robert E. [R-OH-5]	R · OH		Sep 27, 2013
Rep. Matheson, Jim [D-UT-4]	D · UT		Sep 27, 2013
Rep. Murphy, Tim [R-PA-18]	R · PA		Sep 27, 2013
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Sep 27, 2013
Rep. Pitts, Joseph R. [R-PA-16]	R · PA		Sep 27, 2013
Rep. Waxman, Henry A. [D-CA-33]	D · CA		Sep 27, 2013

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Sep 27, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 S 959	Related bill	**Jun 19, 2013:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 89.
113 HR 1919	Related bill	**Jun 4, 2013:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
113 S 957	Related bill	**May 15, 2013:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Nov 27, 2013)

(This measure has not been amended since it was introduced. The summary has been expanded because action occurred on the measure.)

Drug Quality and Security Act - **Title I: Drug Compounding** - Compounding Quality Act - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to the regulation of compounding drugs. Exempts compounded drugs from new drug requirements, labeling requirements, and track and trace requirements if the drug is compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility and meets applicable requirements.

Establishes annual registration requirement for any outsourcing facility. Requires a facility to report biannually to the Secretary of Health and Human Services (HHS) on what drugs are compounded in the facility and to submit adverse event reports. Subjects such facilities to a risk-based inspection schedule.

Requires the Secretary to: (1) publish a list of drugs presenting demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug, taking into account the risk and benefits to patients; and (2) convene an advisory committee on compounding before creating the list.

Requires the Secretary to assess an annual establishment fee on each outsourcing facility and a reinspection fee, as necessary.

(Sec. 103) Prohibits the resale of a compounded drug labeled “not for resale,” or the intentional falsification of a prescription for a compounded drug. Deems a compounded drug to be misbranded if its advertising or promotion is false or misleading in any particular.

(Sec. 105) Requires the Secretary to receive submissions from state boards of pharmacy: (1) describing any disciplinary actions taken against compounding pharmacies or any recall of a compounded drug, and (2) expressing concerns that a compounding pharmacy may be violating the FFDCA.

(Sec. 106) Revises compounding pharmacy requirements to repeal prohibitions on advertising and promotion of compounded drugs by compounding pharmacies and repeal the requirement that prescriptions filled by a compounding pharmacy be unsolicited.

(Sec. 107) Requires the Comptroller General (GAO) to report on pharmacy compounding and the adequacy of state and federal efforts to assure the safety of compounded drugs.

Title II: Drug Supply Chain Security - Drug Supply Chain Security Act - (Sec. 202) Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.

Requires the Secretary to establish standards for the exchange of transaction documentation, which shall include transaction information, transaction history, and transaction statements.

Requires the Secretary to establish processes to: (1) provide waivers of requirements, including for undue economic hardship or emergency medical reasons; (2) provide exceptions to requirements relating to product identifiers if a product is packaged without sufficient space to bear the information; and (3) determine other 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 a manufacturer, wholesale distributor, dispenser, and repackager, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, to provide within a reasonable time 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 product identifier on each package and homogenous case intended to be introduced in a transaction into commerce. Excepts from this requirement with respect to unique device identifiers any products required to have a standardized numerical identifier.

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

Requires a manufacturer, wholesale distributor, dispenser, and repackager to implement systems to: (1) investigate suspect products; and (2) handle illegitimate products, including through quarantine, disposal, and appropriate notice to the Secretary and, as necessary, trading partners.

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

(Sec. 203) Prescribes additional requirements related to the tracing of products at the package level (enhanced drug distribution security) which shall go into effect ten years after enactment of this Act.

Authorizes a dispenser to enter into a written agreement with a third party, including an authorized wholesale distributor, that requires the third party to maintain confidentially any information and statements required to be maintained. Requires the Secretary to provide for alternative methods of compliance with such additional drug distribution security requirements.

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

Requires the Secretary to: (1) establish one or more pilot projects and hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain, (2) issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level, and (3) identify and make recommendations with respect to the standards necessary for adoption in order to support the secure interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

(Sec. 204) Requires the Secretary to establish standards for the licensing of wholesale distributors and third party logistics providers.

(Sec. 205) Preempts state and local requirements related to tracing drugs through the distribution system, and licensure of wholesale distributors and third party logistics providers.

(Sec. 206) Subjects violations of this Act to specified criminal and civil penalties.

Deems misbranded any drug failing to bear its required product identifier.

Actions Timeline

- **Nov 27, 2013:** Signed by President.
- **Nov 27, 2013:** Became Public Law No: 113-54.
- **Nov 21, 2013:** Presented to President.
- **Nov 18, 2013:** Considered by Senate. (consideration: CR S8071-8076)
- **Nov 18, 2013:** Cloture motion withdrawn by unanimous consent in Senate. (consideration: CR S8071)
- **Nov 18, 2013:** Motion by Senator Reid to commit to Senate Committee on Health, Education, Labor, and Pensions with instructions to report back forthwith with amendment SA 2035 withdrawn in Senate. (consideration: CR S8071)
- **Nov 18, 2013:** Passed/agreed to in Senate: Passed Senate without amendment by Voice Vote.
- **Nov 18, 2013:** Passed Senate without amendment by Voice Vote.
- **Nov 18, 2013:** Message on Senate action sent to the House.
- **Nov 14, 2013:** Motion to proceed to consideration of measure agreed to in Senate by Voice Vote.
- **Nov 14, 2013:** Measure laid before Senate by motion. (consideration: CR S8026, S8027)
- **Nov 14, 2013:** Motion by Senator Reid to commit to Senate Committee on Health, Education, Labor, and Pensions with instructions to report back forthwith with amendment SA 2035 made in Senate. (consideration: CR S8026; text: CR S8026)
- **Nov 14, 2013:** Cloture motion on the measure presented in Senate. (consideration: CR S8027; text: CR S8027)
- **Nov 13, 2013:** Motion to proceed to measure considered in Senate. (consideration: CR S7973-7996)
- **Nov 12, 2013:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S7949-7950)
- **Nov 12, 2013:** Cloture on the motion to proceed to the measure invoked in Senate by Yea-Nay Vote. 97 - 1. Record Vote Number: 234. (consideration: CR S7949-7950; text: CR S7949)
- **Nov 7, 2013:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S7891-7894, S7909-7920, S7923-7924)
- **Nov 7, 2013:** Cloture motion on the motion to proceed to the measure presented in Senate. (consideration: CR S7923-7924; text: CR S7923-7924)
- **Nov 6, 2013:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S7841-7845, S7846-7864)
- **Nov 6, 2013:** Motion to proceed to consideration of measure withdrawn in Senate. (consideration: CR S7864)
- **Nov 5, 2013:** Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 236.
- **Nov 4, 2013:** Read the first time. Placed on Senate Legislative Calendar under Read the First Time.
- **Sep 30, 2013:** Received in the Senate.
- **Sep 28, 2013:** Mr. Upton moved to suspend the rules and pass the bill.
- **Sep 28, 2013:** Considered under suspension of the rules. (consideration: CR H5946-4965)
- **Sep 28, 2013:** DEBATE - The House proceeded with forty minutes of debate on H.R. 3204.
- **Sep 28, 2013:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H5946-5960)
- **Sep 28, 2013:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H5946-5960)
- **Sep 27, 2013:** Introduced in House
- **Sep 27, 2013:** Referred to the House Committee on Energy and Commerce.

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