

HR 4299

Improving Regulatory Transparency for New Medical Therapies Act

Congress: 113 (2013–2015, Ended)

Chamber: House

Policy Area: Crime and Law Enforcement

Introduced: Mar 26, 2014

Current Status: Placed on the Union Calendar, Calendar No. 451.

Latest Action: Placed on the Union Calendar, Calendar No. 451. (Sep 19, 2014)

Official Text: <https://www.congress.gov/bill/113th-congress/house-bill/4299>

Sponsor

Name: Rep. Pitts, Joseph R. [R-PA-16]

Party: Republican • **State:** PA • **Chamber:** House

Cosponsors (15 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Mar 26, 2014
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Apr 1, 2014
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Apr 3, 2014
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Apr 8, 2014
Rep. Gingrey, Phil [R-GA-11]	R · GA		Apr 9, 2014
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Apr 9, 2014
Rep. Green, Gene [D-TX-29]	D · TX		Apr 10, 2014
Rep. Latta, Robert E. [R-OH-5]	R · OH		Apr 29, 2014
Rep. Engel, Eliot L. [D-NY-16]	D · NY		May 19, 2014
Rep. Shea-Porter, Carol [D-NH-1]	D · NH		May 19, 2014
Rep. Butterfield, G. K. [D-NC-1]	D · NC		May 20, 2014
Rep. Tonko, Paul [D-NY-20]	D · NY		May 28, 2014
Rep. Johnson, Bill [R-OH-6]	R · OH		May 29, 2014
Rep. Collins, Doug [R-GA-9]	R · GA		Sep 8, 2014
Rep. Harper, Gregg [R-MS-3]	R · MS		Sep 8, 2014

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	May 28, 2014
Judiciary Committee	House	Discharged from	Sep 9, 2014

Subjects & Policy Tags

Policy Area:

Crime and Law Enforcement

Related Bills

Bill	Relationship	Last Action
113 S 2862	Related bill	Sep 18, 2014: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Sep 19, 2014)

Improving Regulatory Transparency for New Medical Therapies Act - Amends the Controlled Substances Act to require any proceedings for the issuance, amendment, or repeal of a rule of the Attorney General for the classification of a controlled substance that are initiated at the request of the Secretary of Health and Human Services (HHS) to control a drug or other substance not previously scheduled, where the Secretary has recommended the drug or other substance be placed in schedule II, III, IV, or V, to be commenced not later than 120 days after receipt of written recommendations from the Secretary. Requires the final rule to be issued not later than 60 days after the date on which both the public comment period has closed and the new drug is the subject of an approved new drug application, unless a hearing on the proposed rule is granted by the Attorney General.

Directs the Attorney General, for the purposes of registration to manufacture a controlled substance in schedule III, IV, or V for use only in a clinical trial, to register an applicant, or serve upon the applicant an order to show cause why registration should not be denied, revoked, or suspended, not later than 180 days after receiving an application and all information necessary to make a determination about whether the issuance of such registration is inconsistent with the public interest.

Directs the Attorney General, for the purposes of registration to manufacture a controlled substance in schedule I or II for use only in a clinical trial, to: (1) issue a notice of application not later than 90 days after receipt of an application and all necessary information to issue such notice; and (2) register an applicant, or serve upon the applicant an order to show cause why registration should not be denied, revoked, or suspended, within 180 days following the close of the comment period and receipt of all information necessary to make a determination about whether the issuance of such registration is consistent with the public interest and with U.S. obligations under international treaties in effect on May 1, 1971, unless a hearing on the application has been granted pursuant to a provision of the Controlled Substances Import and Export Act regarding emergency situations.

Actions Timeline

- **Sep 19, 2014:** Reported (Amended) by the Committee on Judiciary. H. Rept. 113-565, Part II.
- **Sep 19, 2014:** Placed on the Union Calendar, Calendar No. 451.
- **Sep 10, 2014:** Committee Consideration and Mark-up Session Held.
- **Sep 10, 2014:** Ordered to be Reported (Amended) by Voice Vote.
- **Sep 9, 2014:** Subcommittee on Crime, Terrorism, Homeland Security, and Investigations Discharged.
- **Jul 29, 2014:** Reported by the Committee on Energy and Commerce. H. Rept. 113-565, Part I.
- **Jul 29, 2014:** House Committee on the Judiciary Granted an extension for further consideration ending not later than Sept. 19, 2014.
- **Jun 10, 2014:** Committee Consideration and Mark-up Session Held.
- **Jun 10, 2014:** Ordered to be Reported by Voice Vote.
- **Jun 9, 2014:** Committee Consideration and Mark-up Session Held.
- **May 28, 2014:** Subcommittee Consideration and Mark-up Session Held.
- **May 28, 2014:** Forwarded by Subcommittee to Full Committee by Voice Vote .
- **Apr 16, 2014:** Referred to the Subcommittee on Crime, Terrorism, Homeland Security, and Investigations.
- **Mar 28, 2014:** Referred to the Subcommittee on Health.
- **Mar 26, 2014:** Introduced in House
- **Mar 26, 2014:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

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