

HR 639

Improving Regulatory Transparency for New Medical Therapies Act

Congress: 114 (2015–2017, Ended)

Chamber: House

Policy Area: Crime and Law Enforcement

Introduced: Feb 2, 2015

Current Status: Became Public Law No: 114-89.

Latest Action: Became Public Law No: 114-89. (Nov 25, 2015)

Law: 114-89 (Enacted Nov 25, 2015)

Official Text: <https://www.congress.gov/bill/114th-congress/house-bill/639>

Sponsor

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

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

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Green, Gene [D-TX-29]	D · TX		Feb 2, 2015
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Feb 2, 2015
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Mar 16, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 6, 2015
Health, Education, Labor, and Pensions Committee	Senate	Discharged From	Oct 26, 2015
Judiciary Committee	House	Referred to	Feb 3, 2015

Subjects & Policy Tags

Policy Area:

Crime and Law Enforcement

Related Bills

Bill	Relationship	Last Action
114 S 481	Related bill	Oct 1, 2015: Placed on Senate Legislative Calendar under General Orders. Calendar No. 245.

(This measure has not been amended since it was passed by the Senate on October 26, 2015. The summary of that version is repeated here.)

Improving Regulatory Transparency for New Medical Therapies Act

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to delay the effective date of approval of a drug, biological product, or animal drug for which the Food and Drug Administration (FDA) recommends controls under the Controlled Substances Act until the Department of Justice (DOJ) issues a final interim rule for the drug. This delay also applies to conditional approval and indexing of animal drugs.

This bill amends the Controlled Substances Act to require the DOJ to issue a final interim rule for a drug product recommended for controls by the FDA not later than 90 days after DOJ receives a recommendation for controls or the FDA approves the drug. The final interim rule is effective immediately.

For purposes of submitting an application to extend a patent, a drug product recommended for controls is considered to be approved and have permission for commercial marketing and use on the date of FDA approval or the date an interim final rule is issued, whichever is later.

(Sec. 3) Timelines are established for DOJ to either register an applicant to manufacture a controlled substance for a clinical trial or serve an order to show cause upon the applicant.

(Sec. 4) This bill amends the Controlled Substances Import and Export Act to allow exported controlled substances to be re-exported within the European Economic Area.

Actions Timeline

- **Nov 25, 2015:** Signed by President.
- **Nov 25, 2015:** Became Public Law No: 114-89.
- **Nov 19, 2015:** Presented to President.
- **Nov 16, 2015:** Mr. Griffith asked unanimous consent that the House agree to the Senate amendment. (consideration: CR H8212-8213)
- **Nov 16, 2015:** Resolving differences -- House actions: On motion that the House agree to the Senate amendment Agreed to without objection.(text as House agreed to Senate amendment: CR H8212-8213)
- **Nov 16, 2015:** On motion that the House agree to the Senate amendment Agreed to without objection. (text as House agreed to Senate amendment: CR H8212-8213)
- **Nov 16, 2015:** Motion to reconsider laid on the table Agreed to without objection.
- **Oct 27, 2015:** Message on Senate action sent to the House.
- **Oct 26, 2015:** Senate Committee on Health, Education, Labor, and Pensions discharged by Unanimous Consent.(consideration: CR S7495)
- **Oct 26, 2015:** Senate Committee on Health, Education, Labor, and Pensions discharged by Unanimous Consent. (consideration: CR S7495)
- **Oct 26, 2015:** Measure laid before Senate by unanimous consent. (consideration: CR S7495)
- **Oct 26, 2015:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Oct 26, 2015:** Passed Senate with an amendment by Unanimous Consent.
- **Mar 17, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Mar 16, 2015:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 114-41, Part I.
- **Mar 16, 2015:** Committee on the Judiciary discharged.
- **Mar 16, 2015:** Placed on the Union Calendar, Calendar No. 26.
- **Mar 16, 2015:** Mr. Pitts moved to suspend the rules and pass the bill, as amended.
- **Mar 16, 2015:** Considered under suspension of the rules. (consideration: CR H1638-1641)
- **Mar 16, 2015:** DEBATE - The House proceeded with forty minutes of debate on H.R. 639.
- **Mar 16, 2015:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H1638-1639)
- **Mar 16, 2015:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H1638-1639)
- **Mar 16, 2015:** Motion to reconsider laid on the table Agreed to without objection.
- **Feb 6, 2015:** Referred to the Subcommittee on Health.
- **Feb 3, 2015:** Referred to the Subcommittee on Crime, Terrorism, Homeland Security, and Investigations.
- **Feb 2, 2015:** Introduced in House
- **Feb 2, 2015:** 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.