S 481

Improving Regulatory Transparency for New Medical Therapies Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 12, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 245.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 245. (Oct 1, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/481

Sponsor

Name: Sen. Hatch, Orrin G. [R-UT]
Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Whitehouse, Sheldon [D-RI]	D · RI		Feb 12, 2015
Sen. Murray, Patty [D-WA]	D · WA		Sep 15, 2015
Sen. Alexander, Lamar [R-TN]	R · TN		Nov 3, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Oct 1, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 639	Related bill	**Nov 25, 2015:** Became Public Law No: 114-89.

Summary (as of Oct 1, 2015)

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

- **Oct 1, 2015:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Oct 1, 2015:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 245.
- **Sep 30, 2015:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Feb 12, 2015:** Introduced in Senate
- **Feb 12, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.