S 2862

Regulatory Transparency, Patient Access, and Effective Drug Enforcement Act of 2014

Congress: 113 (2013–2015, Ended)
Chamber: Senate
Policy Area: Crime and Law Enforcement
Introduced: Sep 18, 2014
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Sep 18, 2014)
Official Text: https://www.congress.gov/bill/113th-congress/senate-bill/2862

Sponsor

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

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Whitehouse, Sheldon [D-RI]	D · RI		Sep 18, 2014
Sen. Paul, Rand [R-KY]	R · KY		Nov 13, 2014

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Sep 18, 2014

Subjects & Policy Tags

Policy Area:

Crime and Law Enforcement

Related Bills

Bill	Relationship	Last Action
113 HR 4299	Related bill	**Sep 19, 2014:** Placed on the Union Calendar, Calendar No. 451.
113 HR 4709	Related bill	**Jul 30, 2014:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Sep 18, 2014)

Regulatory Transparency, Patient Access, and Effective Drug Enforcement Act of 2014 - Amends the Controlled Substances Act to direct the Attorney General, within 45 days of receiving a recommendation from the Secretary of Health and Human Services (HHS) to add a drug or substance that has never been marketed in the United States to a schedule of controlled substances, to issue an interim final rule under the exception for good cause, placing it into the schedule recommended, effective immediately.

Allows a person who submits an application for registration to manufacture or distribute a controlled substance to indicate on the registration application that the substance will be used only in connection with clinical trials of a drug. Requires the Attorney General to: (1) make a final decision on such application within 180 days, or (2) provide written notice to the applicant of the outstanding issues that must be resolved to reach a final decision and the estimated date on which such decision will be made.

Defines: (1) "factors as may be relevant to and consistent with the public health and safety," and (2) "imminent danger to the public health or safety."

Requires an order to show cause as to why a registration should not be denied, revoked, or suspended to notify the registrant of the opportunity to submit a corrective action plan on or before the date of appearance before the Attorney General. Requires the Attorney General, upon review of any such plan, to determine whether denial, revocation, or suspension proceedings should be discontinued or deferred for purposes of modification or clarification of such plan. Makes these requirements inapplicable to the issuance of an immediate suspension order.

Directs the Secretary, acting through the Commissioner of Food and Drugs (FDA) and the Director of the Centers for Disease Control and Prevention (CDC), to identify: (1) obstacles to legitimate patient access to controlled substances; (2) issues with diversion of controlled substances; and (3) how collaboration between federal, state, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.

Actions Timeline

- **Sep 18, 2014:** Introduced in Senate
- **Sep 18, 2014:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.