HR 2956

Accutane Safety and Risk Management Act

Congress: 109 (2005–2007, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 16, 2005
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jul 1, 2005)
Official Text: https://www.congress.gov/bill/109th-congress/house-bill/2956

Sponsor

Name: Rep. Stupak, Bart [D-MI-1]
Party: Democratic • **State:** MI • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 1, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jun 16, 2005)

Accutane Safety and Risk Management Act - Requires the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to withdraw approval within 30 days for the sale of drugs that contain isotretinoin as an active ingredient, including Accutane.

Allows the Secretary to approve subsequent supplemental applications for such drugs subject to certain restrictions, including safety reporting. Requires that distribution of such subsequently approved drugs be limited, including by: (1) allowing distribution only directly from manufacturers to pharmacists; (2) requiring pharmacists to register, receive education on side effects, dispense only those prescriptions from physicians at certified treatment centers, and file a statement of compliance; (3) developing educational materials for patients, including monthly questionnaires for patients to monitor the development of adverse side effects; (4) requiring patients to register, receive counseling on the drug, sign a statement providing informed consent for treatment, and undergo appropriate tests; and (5) limiting prescriptions to a 30-day supply with no refills.

Specifies conditions for a clinic to be certified as a treatment center for a drug containing isotretinoin, including requiring each practitioner to meet certain conditions, such as requirements for registration, an agreement to prescribe in accordance with this Act, and reporting of adverse events.

Requires the Secretary to monitor the distribution of such drugs to determine whether the drug is being distributed in accordance with this Act.

Specifies conditions under which the Secretary may approve a drug that contains isotretinoin as an active ingredient for a new use.

Requires manufacturers and distributors of isotretinoin to report any information on adverse events associated with the drug to the Secretary.

Requires the Secretary to conduct and support studies to explore the effects of isotretinoin on the central nervous system and behavior, including depression, suicide, and violent behavior.

Actions Timeline

- **Jul 1, 2005:** Referred to the Subcommittee on Health.
- **Jun 16, 2005:** Introduced in House
- **Jun 16, 2005:** Introduced in House
- **Jun 16, 2005:** Referred to the House Committee on Energy and Commerce.