

S 2281

ExPERT Act

Congress: 112 (2011–2013, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 29, 2012

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. (Mar 29, 2012)

Official Text: <https://www.congress.gov/bill/112th-congress/senate-bill/2281>

Sponsor

Name: Sen. Whitehouse, Sheldon [D-RI]

Party: Democratic • **State:** RI • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Sanders, Bernard [I-VT]	I · VT		Aug 1, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 29, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 4156	Related bill	Mar 9, 2012: Referred to the Subcommittee on Health.

Expanding and Promoting Expertise in Rare Treatments Act of 2012 or EXPERT Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS) to ensure that opportunities exist for consultation with external experts to promote the efficiency of and inform the review by the Food and Drug Administration (FDA) of drugs and biologic products for rare diseases and drugs and biologic products that are genetically targeted.

Requires the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research to seek the opinion of external experts on topics that may include: (1) rare diseases; (2) the severity of rare diseases; (3) the unmet medical need associated with rare diseases; (4) the willingness and ability of individuals with a rare disease to participate in clinical trials; (5) an assessment of the benefits and risks, including side effects, of current and investigational therapies; (6) the design of clinical trials for rare disease populations and subpopulations; and (7) demographics and the clinical description of patient populations. Authorizes: (1) external experts to request the opportunity to meet with a review division regarding any such topic, and (2) external experts who are consulted to be considered special government employees.

Declares that nothing in this Act shall be construed to: (1) create a right for any external expert to obtain access to proprietary information of a sponsor without that sponsor's permission or a legal right for a consultation on any matter, or (2) require the Secretary to meet with any particular expert.

Actions Timeline

- **Mar 29, 2012:** Introduced in Senate
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