S 3921

Ethical Pathway Act of 2010

Congress: 111 (2009–2011, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Sep 29, 2010
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 29, 2010)
Official Text: https://www.congress.gov/bill/111th-congress/senate-bill/3921

Sponsor

Name: Sen. Sanders, Bernard [I-VT]
Party: Independent • **State:** VT • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Sep 29, 2010

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Sep 29, 2010)

Ethical Pathway Act of 2010 - Directs the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs (FDA), to establish a mechanism by which an applicant for an abbreviated new drug application submitted under the Federal Food, Drug, and Cosmetic Act, for license of a biosimilar biological product submitted under the Public Health Service Act, or for a license to sell in the United States a drug that has been approved for marketing in a foreign country may request a cost-sharing arrangement under which the applicant and the holders of relevant applications or licenses shall make every effort to ensure that any regulatory test data and results of clinical investigations involving humans and vertebrate animals conducted regarding such applications or licenses is shared, including the regulatory test data necessary to obtain marketing approval from the Secretary.

Permits such applicant to request such arrangement if, but for the arrangement: (1) the applicant would be required to conduct clinical investigations involving human subjects that violate Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects in order to obtain the Secretary's approval or licensure; or (2) the duplication of the clinical investigations required for such application would violate other applicable ethical standards concerning the testing of products on humans or other vertebrate animals.

Sets forth provisions regarding: (1) the responsibility of an applicant that intends to perform clinical investigations involving humans or vertebrate animals to verify that those investigations have not been performed or initiated by another person, (2) agreement between an applicant and the holders of the relevant applications or licenses on a fee that is reasonable and fair that permits the applicant to rely upon information from such regulatory test data, and (3) procedures to determine such fee or required payment when such parties fail to reach such an agreement.

Requires the fee for reliance on such regulatory test data to be determined after considering: (1) the actual out-of-pocket costs of the applicable clinical investigations; (2) the risks of the investigations; (3) any federal grants, tax credits, or other subsidies; (4) the expected share of the global market for the product involved; and (5) the amount of time the holders of the relevant applications or licenses have benefited from exclusive rights and the cumulative revenue earned on the products that relied upon the data at issue. Directs the Secretary to adopt procedures and rules under which sufficient information about costs and fees will be made public.

Actions Timeline

- **Sep 29, 2010:** Introduced in Senate
- **Sep 29, 2010:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.