S 2292

PATIENTS' FDA Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 17, 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. (Apr 17, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/2292

Sponsor

Name: Sen. Burr, Richard [R-NC]
Party: Republican • **State:** NC • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Coburn, Tom [R-OK]	R · OK		Apr 17, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 17, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 17, 2012)

Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act of 2012 or the PATIENTS' FDA Act - Requires the Secretary of Health and Human Services (HHS) to develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decision making.

Expands reporting requirements related to Food and Drug Administration (FDA) progress reports, generic drugs, and biosimilar products.

Requires the Secretary to: (1) document the scientific and regulatory rationale for any significant decision regarding drugs, biologics, or medical device applications; and (2) review all regulations and guidance of the FDA with respect to human medical products to ensure consistency with the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and specified regulatory principles.

Amends the FFDCA to require the Secretary to assess the safety and effectiveness of a medical device from the perspective of a reasonable patient in the intended use population.

Sets forth provisions governing determinations by the Secretary of a lack of reasonable assurance of safety of a device.

Requires the Secretary to implement a structured benefit-risk assessment framework in the new drug approval process.

Directs the FDA to foster and encourage uniform, scientifically-driven clinical trial standards around the world.

Sets forth provisions governing investigational exemptions for medical devices.

Requires the Office of the Chief Counsel in the FDA to review a warning letter with respect to a drug or device before it is issued.

Sets forth provisions related to FDA advisory committees.

Revises provisions governing medical devices, including to require the Secretary to: (1) assign a tracking number to a medical device and assign an experienced reviewer to review the application; (2) revise the device submission acceptance criteria; and (3) regularly publish detailed decision summaries for each clearance of a device, substantial equivalence determination for a device, and each initial classification of a device. Sets forth the circumstances under which a medical device classification report must be submitted for a modification of a device.

Exempts medical devices modified to meet the individual needs of a specific patient from requirements to meet specified performance standards and premarket approval clearance if specified requirements are met.

Revises and extends through October 1, 2017, provisions authorizing accredited persons to provide classification reports for a medical device and to inspect class II or class III device facilities.

Requires the Secretary to submit a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

Directs the Secretary to contract with a consulting firm to conduct a comprehensive assessment of the process for the review of drug, device, and biologics applications.

Requires the Comptroller General to report on activities under this Act.

Actions Timeline

- **Apr 17, 2012:** Introduced in Senate
- **Apr 17, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.