S 2113

TREAT Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 15, 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. (Feb 15, 2012)
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Sponsor

Name: Sen. Hagan, Kay R. [D-NC]
Party: Democratic • **State:** NC • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Mar 27, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 15, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 15, 2012)

Transforming the Regulatory Environment to Accelerate Access to Treatments or TREAT Act - Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS) to establish an advisory council within the Food and Drug Administration (FDA) to be known as the Management Review Board in order to provide advice to the Secretary regarding the FDA's management and organization.

Directs the Secretary to: (1) establish within the Office of the Commissioner an office to be known as the Office of the Chief Innovation Officer (CIO); and (2) appoint a Chief Innovation Officer to lead such Office.

Sets forth the following duties for the CIO: (1) to identify promising new scientific and regulatory approaches to ensure the rapid development, testing, and review of new drugs and devices; (2) to ensure that such approaches are integrated into operations at all applicable levels of the FDA and harmonized with approaches of other agencies; (3) to consider the recommendations of internal and external bodies involved in advancing innovation in regulatory science activities and to make such recommendations available on the FDA website; (4) to develop pilot programs to implement and incorporate such recommendations into the regulatory review and approval process; and (5) to implement other pilot programs and to ensure participation by cross-disciplinary teams in such implementation.

Directs the Secretary to establish an Office of the Chief Medical Policy Officer within each of the following FDA offices: (1) The Office of the Director of the Center for Drug Evaluation and Research, (2) The Office of the Director of the Center for Biologics Evaluation and Research, and (3) The Office of the Director of the Center for Devices and Radiological Health.

Sets forth the following duties for each Chief Medical Policy Officer: (1) to develop proactive and consistent approaches for FDA centers and divisions that review applications for drug or device approval to address emerging medical and scientific policy issues bearing on new product review processes, (2) to promote earlier and improved utilization of advisory committees throughout the drug and device development and review processes, (3) to improve reviewer access to external experts outside of the advisory committee process, (4) to periodically solicit input from industry, academia, and patient advocacy and disease research organizations on emerging scientific and medical policy issues bearing on new product review processes, and (5) to coordinate with the Chief Innovation Officer in the implementation of pilot programs.

Directs the Secretary, at the request of the sponsor of a new drug, to facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition.

Permits the Secretary to approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint, including an endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity or rarity of the condition and the availability of alternative treatments.

Permits the Secretary, under specified conditions, to withdraw approval of a product approved under accelerated approval using expedited procedures.

Directs the Secretary to appoint, within the Office of the Commissioner, a Clinical Informatics Coordinator to: (1) develop

a process to validate the use of health information technology in clinical research and encourage the use of new health information technologies in clinical research protocols, and (2) establish pilot programs to explore and evaluate the methods of incorporating emerging health information technology to make the clinical research process more efficient.

Actions Timeline

- **Feb 15, 2012:** Introduced in Senate
- **Feb 15, 2012:** Sponsor introductory remarks on measure. (CR S702)
- **Feb 15, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.