S 2700

FDA and NIH Workforce Authorities Modernization Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 17, 2016
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 427.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 427. (Apr 18, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/2700

Sponsor

Name: Sen. Alexander, Lamar [R-TN]
Party: Republican • **State:** TN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Murray, Patty [D-WA]	D · WA		Mar 17, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 18, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 5414	Related bill	**Jun 8, 2016:** Referred to the House Committee on Energy and Commerce.
114 HR 2435	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2439	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.

Summary (as of Apr 18, 2016)

FDA and NIH Workforce Authorities Modernization Act

(Sec. 2) This bill amends the Public Health Service Act to revise the Silvio O. Conte Senior Biomedical Research Service to: (1) increase the limit on the number of members, (2) expand eligibility for appointment, (3) set a maximum pay rate, and (4) remove the option for members to contribute to the retirement system of an institution of higher education. The Government Accountability Office (GAO) must report on these amendments.

(Sec. 3) This bill amends the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration (FDA) additional hiring authority for scientific, technical, or professional positions that support the development, review, and regulation of medical products. The FDA must report on its need for qualified individuals for such positions and must include a recruitment and retention plan. The GAO must report on the FDA's ability to hire, train, and retain qualified staff.

(Sec. 4) The FDA must establish one or more Intercenter Institutes. Each institute must coordinate activities applicable to a major disease area among the FDA centers that review products. Activities may include coordinating staff with relevant expertise, streamlining product review, and enhancing interactions with patients, sponsors, and the biomedical community.

(Sec. 5) Scientific meetings directly related to the duties of a Department of Health and Human Services (HHS) professional must not be considered conferences for purposes of certain reporting requirements and restrictions on conference travel. Each division of HHS must report on scientific meeting attendance and related travel spending.

(Sec. 6) The bill revises Board of Directors membership, Executive Director compensation, and accounting for the Reagan-Udall Foundation for the FDA.

(Sec. 7) The Paperwork Reduction Act does not apply to National Institutes of Health research.

(Sec. 9) For certain indications, the FDA may rely upon a summary of clinical data to approve a supplemental application for a drug.

(Sec. 10) The bill revises provisions regarding: (1) FDA screening of the Adverse Event Reporting System, and (2) evaluation of elements to assure safe use of drugs.

The FDA must publish: (1) best practices for using the Adverse Event Reporting System, (2) criteria for publishing adverse event information, and (3) best practices for drug safety surveillance activities for newly approved medications. The FDA no longer must prepare a summary analysis of adverse drug reaction reports for recently approved drugs.

(Sec. 11) Biological products are not subject to provisions that refer to an official compendium of drug information.

(Sec. 12) The manufacturer or distributor of an investigational drug for a serious condition must publish a policy for compassionate use of the drug.

(Sec. 13) HHS must finalize the guidance entitled "Expanded Access to Investigational Drugs for Treatment Use--Qs & As." The guidance must explain how HHS uses adverse drug event data from compassionate use.

(Sec. 14) This bill amends the Orphan Drug Act to authorize HHS to defray all the costs of development of orphan drugs (drugs for rare conditions), instead of only certain testing expenses.

(Sec. 15) HHS must facilitate the development of standards to support development and review of regenerative medicine and advanced therapies.

(Sec. 16) FDA guidance must include specified information, including the statutory provisions or regulations that are the basis for policy decisions.

(Sec. 17) The Paperwork Reduction Act does not apply to voluntary collection of information during a public health emergency or while determining whether there is a public health emergency.

(Sec. 18) The bill revises provisions regarding:

- movement of impounded drugs,
- pediatric study plans,
- reporting on drug shortages,
- reporting on inspections of establishments manufacturing drugs or medical devices,
- requests to classify medical devices,
- priority review of qualified infectious disease products,
- use of clinical investigation data from outside the United States, and
- medical gasses.

The bill makes technical changes to various provisions regarding medical products.

Actions Timeline

- **Apr 18, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Apr 18, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 427.
- **Apr 6, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 17, 2016:** Introduced in Senate
- **Mar 17, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.