I

116TH CONGRESS
1ST SESSION

H. R. 4633

To amend the 21st Century Cures Act to reauthorize funding for FDA innovation projects, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 11, 2019

Ms. ESHOO (for herself and Mr. PETERS) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the 21st Century Cures Act to reauthorize funding for FDA innovation projects, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Investing in Safety and Innovation Act of 2019''.

SEC. 2. REAUTHORIZATION OF FDA INNOVATION PROJECTS.

(a) TRANSFER OF DIRECT SPENDING SAVINGS.—Section 1002(b)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended—

(1) in the matter preceding clause (i), by striking ''2025'' and inserting ''2029''; and

(2) by striking clauses (iv) through (ix) and inserting the following:

''(iv) For fiscal year 2020, $746,000,000.

''(v) For fiscal year 2021, $551,000,000.

''(vi) For each of fiscal years 2022 through 2024, $531,000,000.

''(vii) For fiscal year 2025, $536,000,000.

''(viii) For each of fiscal years 2026 through 2029, $531,000,000.''.

(b) FDA ACTIVITIES.—Paragraph (4) of section 1002(b) of the 21st Century Cures Act (Public Law 114–255) is amended to read as follows:

''(4) FDA ACTIVITIES.—The activities authorized to be funded under this section shall consist of the following, and of the total amounts authorized to be appropriated under paragraph (3) there are authorized to be appropriated to each category of activities a total amount not to exceed the following:

''(A) In addition to the allocations specified in subparagraphs (B) through (K), for the

activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act:

"(i) For fiscal year 2020, $75,000,000.

"(ii) For fiscal year 2021, $70,000,000.

"(iii) For each of fiscal years 2022 through 2024, $50,000,000.

"(iv) For fiscal year 2025, $55,000,000.

"(v) For each of fiscal years 2026 through 2029, $50,000,000.

"(B) For modernization of the technical infrastructure of the Food and Drug Administration, including enhancements such as interoperability across the agency, and additional capabilities to develop an advanced information technology infrastructure to support the agency's regulatory mission:

"(i) For fiscal year 2020, $300,000,000.

"(ii) For each of fiscal years 2021 through 2029, $200,000,000.

"(C) For support for continuous manufacturing of drugs and biological products, including complex biological products such as regenerative medicine therapies, through grants to institutions of higher education and nonprofit organizations and other appropriate mechanisms, for each of fiscal years 2020 through 2029, $50,000,000.

"(D) For support for the Commissioner of Food and Drugs to engage experts, such as through the formation and operation of public-private partnerships or other appropriate collaborative efforts, to advance the development and delivery of individualized human gene therapy products:

"(i) For fiscal year 2020, $50,000,000.

"(ii) For each of fiscal years 2021 through 2029, $10,000,000.

"(E) For support for inspections and enforcement activities across the Food and Drug Administration, including foreign and domestic

facility inspections across products, for each of fiscal years 2020 through 2029, $82,500,000.

"(F) For support for activities of the Food and Drug Administration related to customs and border protection to provide improvements to technologies, inspection capacity, and international mail facilities in which the Food and Drug Administration operates, for each of fiscal years 2020 through 2029, $25,000,000.

"(G) To further advance the development of a coordinated postmarket surveillance system for all medical products, including drugs, biological products, and devices, linked to electronic health records in furtherance of the Food and Drug Administration's postmarket surveillance capabilities:

"(i) For fiscal year 2020, $100,000,000.

"(ii) For each of fiscal years 2021 through 2029, $50,000,000.

"(H) For support for Food and Drug Administration activities to keep pace with the projected product development of regenerative therapies, including human somatic cellular and

gene therapies, for each of fiscal years 2020 through 2029, $25,000,000.

''(I) For support for the development of non-opioid pharmacological therapies as alternatives for opioids, for each of fiscal years 2020 through 2029, $3,500,000.

''(J) For carrying out section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a; relating to hiring authority for scientific, technical, and professional personnel), for each of fiscal years 2020 through 2029, $20,000,000.

''(K) For the Food and Drug Administration to support improvements to the technological infrastructure for reporting and analysis of adverse events associated with the use of drugs and biological products, for each of fiscal years 2020 through 2029, $15,000,000.''.

(c) ANNUAL REPORTS.—Section 1002(c)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''2026'' and inserting ''2029''.

(d) SUNSET.—Section 1002(e) of the 21st Century Cures Act (Public Law 114–255) is amended by striking

"September 30, 2026" and inserting "September 30, 2029".

○