116TH CONGRESS
2D SESSION

S. 3432

To support the advanced manufacturing technologies program of the Food and Drug Administration, to establish National Centers of Excellence in Advanced Pharmaceutical Manufacturing, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 10, 2020

Mrs. BLACKBURN (for herself and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To support the advanced manufacturing technologies program of the Food and Drug Administration, to establish National Centers of Excellence in Advanced Pharmaceutical Manufacturing, 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 ''Securing America's Medicine Cabinet Act of 2020''.

SEC. 2. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Securing America's Medicine Cabinet Act of 2020, the Secretary shall continue in effect the program to evaluate and approve new drug manufacturing technologies that are included in an application, or supplement to an application, for a drug under subsection (b) or (j) of section 505 of this Act or for a biological product submitted under subsection (a) or (k) of section 351 of the Public Health Service Act.

''(b) DESIGNATION.—The Secretary shall designate a method of manufacturing a drug as an advanced manufacturing technology under this section if the drug manufacturer demonstrates that such technology is likely to—

''(1) prevent or resolve a drug shortage;

''(2) maintain an adequate supply of critical medications for national emergencies; or

''(3) promote the adoption of innovative approaches to drug product design and manufacturing.

''(c) CONSULTATION.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology under this section, the Secretary shall take actions to expedite the development and implementation of such method of manufacture for purposes of approval of the application under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act, which may include, as appropriate—

''(1) holding meetings between the sponsor of the application and appropriate Food and Drug Administration staff throughout the development of the technology;

''(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the technology; and

''(3) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing.

''(d) EVALUATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

''(1) PACKAGE.—A sponsor who receives designation of an advanced manufacturing technology under this section shall provide the Secretary with a

package of scientific evidence supporting the implementation of the advanced manufacturing technology in a particular context-of-use.

''(2) EVALUATION.—Within 90 days of receiving the package, the Secretary shall determine whether a designated advanced manufacturing technology is validated for the proposed context of use based on the scientific merit the supporting evidence provided by the sponsor.

''(3) EFFECT OF APPROVAL.—Upon approval, the same sponsor may rely upon the advanced manufacturing technology for use across multiple manufacturing product lines within the same context-of-use without having to re-submit data to the Secretary validating the underlying technology.

''(e) IMPLEMENTATION AND REPORTING.—

''(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than 1 year after the date of enactment of the Securing America's Medicine Cabinet Act of 2020 to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the program under this section.

''(2) PROGRAM GUIDANCE.—The Secretary shall—

''(A) not later than 1 year after the date of enactment of the Securing America's Medicine Cabinet Act of 2020, issue draft guidance regarding the goals and implementation of the program under this section; and

''(B) not later than 2 years after the date of enactment of the Securing America's Medicine Cabinet Act of 2020, issue final guidance with respect to the implementation of such program.

''(3) REPORT.—The Secretary shall make available on the internet website of the Food and Drug Administration an annual report on the progress of the program under this section.''.

SEC. 3. NATIONAL CENTER OF EXCELLENCE IN ADVANCED PHARMACEUTICAL MANUFACTURING.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1015. NATIONAL CENTER OF EXCELLENCE IN ADVANCED PHARMACEUTICAL MANUFACTURING.

''(a) IN GENERAL.—The Secretary shall designate institutions of higher education as National Centers of Excellence in Advanced Pharmaceutical Manufacturing, including continuous pharmaceutical manufacturing.

''(b) ELIGIBILITY.—To be eligible for designation under subsection (a) an entity shall—

''(1) be an institution of higher education;

''(2) demonstrate—

''(A) the physical and technical capacity for research and development of advanced pharmaceutical manufacturing;

''(B) a record of transferring scientific knowledge to the marketplace;

''(C) scalable manufacturing knowledge, which may be through collaborations of other institutions of higher education, biopharmaceutical manufacturers, or other entities;

''(D) the ability to train a future workforce for research on and implementation of advanced pharmaceutical manufacturing; and

''(E) the ability to support Federal agencies with technical assistance for advanced pharmaceutical technologies, with an emphasis

on creating a secure national pharmaceutical stockpile and the ability to rapidly address drug shortages; and

''(3) submit an application to the Secretary at such time, in such form, and in such manner as the Secretary may require.

''(c) TERMINATION.—The Secretary may terminate the designation of an entity designated under subsection (a) upon a determination that the entity no longer meets the requirements of subsection (b).

''(d) ANNUAL REPORT.—Not later than 1 year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall submit a report to Congress on the activities of the entities designated under such subsection.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $100,000,000 for the period of fiscal year 2021 through 2025.''.

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