

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Securing America’s
5 Medicine Cabinet Act of 2020”.

1 **SEC. 2. ADVANCED MANUFACTURING TECHNOLOGIES PRO-**
2 **GRAM.**

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

6 **“SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES**
7 **PROGRAM.**

8 “(a) IN GENERAL.—Not later than 1 year after the
9 date of enactment of the Securing America’s Medicine
10 Cabinet Act of 2020, the Secretary shall continue in effect
11 the program to evaluate and approve new drug manufac-
12 turing technologies that are included in an application, or
13 supplement to an application, for a drug under subsection
14 (b) or (j) of section 505 of this Act or for a biological
15 product submitted under subsection (a) or (k) of section
16 351 of the Public Health Service Act.

17 “(b) DESIGNATION.—The Secretary shall designate a
18 method of manufacturing a drug as an advanced manufac-
19 turing technology under this section if the drug manufac-
20 turer demonstrates that such technology is likely to—

21 “(1) prevent or resolve a drug shortage;

22 “(2) maintain an adequate supply of critical
23 medications for national emergencies; or

24 “(3) promote the adoption of innovative ap-
25 proaches to drug product design and manufacturing.

1 “(c) CONSULTATION.—If the Secretary designates a
2 method of manufacturing as an advanced manufacturing
3 technology under this section, the Secretary shall take ac-
4 tions to expedite the development and implementation of
5 such method of manufacture for purposes of approval of
6 the application under subsection (c) or (j) of section 505
7 of this Act or subsection (a) or (k) of section 351 of the
8 Public Health Service Act, which may include, as appro-
9 priate—

10 “(1) holding meetings between the sponsor of
11 the application and appropriate Food and Drug Ad-
12 ministration staff throughout the development of the
13 technology;

14 “(2) providing timely advice to, and interactive
15 communication with, the sponsor regarding the de-
16 velopment of the technology; and

17 “(3) involving senior managers and experienced
18 staff of the Food and Drug Administration, as ap-
19 propriate, in a collaborative, cross-disciplinary review
20 of the method of manufacturing.

21 “(d) EVALUATION OF AN ADVANCED MANUFAC-
22 TURING TECHNOLOGY.—

23 “(1) PACKAGE.—A sponsor who receives des-
24 ignation of an advanced manufacturing technology
25 under this section shall provide the Secretary with a

1 package of scientific evidence supporting the imple-
2 mentation of the advanced manufacturing technology
3 in a particular context-of-use.

4 “(2) EVALUATION.—Within 90 days of receiv-
5 ing the package, the Secretary shall determine
6 whether a designated advanced manufacturing tech-
7 nology is validated for the proposed context of use
8 based on the scientific merit the supporting evidence
9 provided by the sponsor.

10 “(3) EFFECT OF APPROVAL.—Upon approval,
11 the same sponsor may rely upon the advanced man-
12 ufacturing technology for use across multiple manu-
13 facturing product lines within the same context-of-
14 use without having to re-submit data to the Sec-
15 retary validating the underlying technology.

16 “(e) IMPLEMENTATION AND REPORTING.—

17 “(1) PUBLIC MEETING.—The Secretary shall
18 publish in the Federal Register a notice of a public
19 meeting to be held no later than 1 year after the
20 date of enactment of the Securing America’s Medi-
21 cine Cabinet Act of 2020 to discuss and obtain input
22 and recommendations from stakeholders regarding
23 the goals and scope of, and a suitable framework
24 and procedures and requirements for, the program
25 under this section.

1 “(2) PROGRAM GUIDANCE.—The Secretary
2 shall—

3 “(A) not later than 1 year after the date
4 of enactment of the Securing America’s Medi-
5 cine Cabinet Act of 2020, issue draft guidance
6 regarding the goals and implementation of the
7 program under this section; and

8 “(B) not later than 2 years after the date
9 of enactment of the Securing America’s Medi-
10 cine Cabinet Act of 2020, issue final guidance
11 with respect to the implementation of such pro-
12 gram.

13 “(3) REPORT.—The Secretary shall make avail-
14 able on the internet website of the Food and Drug
15 Administration an annual report on the progress of
16 the program under this section.”.

17 **SEC. 3. NATIONAL CENTER OF EXCELLENCE IN ADVANCED**
18 **PHARMACEUTICAL MANUFACTURING.**

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

1 **“SEC. 1015. NATIONAL CENTER OF EXCELLENCE IN AD-**
 2 **VANCED PHARMACEUTICAL MANUFAC-**
 3 **TURING.**

4 “(a) IN GENERAL.—The Secretary shall designate in-
 5 stitutions of higher education as National Centers of Ex-
 6 cellence in Advanced Pharmaceutical Manufacturing, in-
 7 cluding continuous pharmaceutical manufacturing.

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

10 “(1) be an institution of higher education;

11 “(2) demonstrate—

12 “(A) the physical and technical capacity
 13 for research and development of advanced phar-
 14 maceutical manufacturing;

15 “(B) a record of transferring scientific
 16 knowledge to the marketplace;

17 “(C) scalable manufacturing knowledge,
 18 which may be through collaborations of other
 19 institutions of higher education, biopharma-
 20 ceutical manufacturers, or other entities;

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

24 “(E) the ability to support Federal agen-
 25 cies with technical assistance for advanced
 26 pharmaceutical technologies, with an emphasis

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

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

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

11 “(d) ANNUAL REPORT.—Not later than 1 year after
12 the date on which the first designation is made under sub-
13 section (a), and annually thereafter, the Secretary shall
14 submit a report to Congress on the activities of the entities
15 designated under such subsection.

16 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there are authorized to be appro-
18 priated \$100,000,000 for the period of fiscal year 2021
19 through 2025.”.

○