

116TH CONGRESS  
2D SESSION

# H. R. 6708

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 HOUSE OF REPRESENTATIVES

MAY 5, 2020

Mr. BUCHANAN introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## 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.”.

○