

117TH CONGRESS
1ST SESSION

S. 2589

To amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on advanced and continuous manufacturing as National Centers of Excellence in Continuous Pharmaceutical Manufacturing, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2021

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 amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on advanced and continuous manufacturing as National Centers of Excellence in Continuous 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 2021”.

1 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN AD-**
 2 **VANCED AND CONTINUOUS PHARMA-**
 3 **CEUTICAL MANUFACTURING.**

4 (a) IN GENERAL.—Section 3016 of the 21st Century
 5 Cures Act (21 U.S.C. 399h) is amended to read as follows:

6 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN AD-**
 7 **VANCED AND CONTINUOUS PHARMA-**
 8 **CEUTICAL MANUFACTURING.**

9 “(a) IN GENERAL.—The Secretary of Health and
 10 Human Services, acting through the Commissioner of
 11 Food and Drugs—

12 “(1) shall solicit and, beginning not later than
 13 one year after the date of enactment of the Securing
 14 America’s Medicine Cabinet Act of 2021, receive re-
 15 quests from institutions of higher education, or con-
 16 sortia of institutions of higher education, to be des-
 17 ignated as a National Center of Excellence in Ad-
 18 vanced and Continuous Pharmaceutical Manufac-
 19 turing (in this section referred to as a ‘National
 20 Center of Excellence’) to support the advancement,
 21 development, and implementation of advanced and
 22 continuous pharmaceutical manufacturing; and

23 “(2) shall so designate not more than 5 institu-
 24 tions of higher education or consortia of such insti-
 25 tutions that—

26 “(A) request such designation; and

1 “(B) meet the criteria specified in sub-
2 section (c).

3 “(b) REQUEST FOR DESIGNATION.—A request for
4 designation under subsection (a) shall be made to the Sec-
5 retary at such time, in such manner, and containing such
6 information as the Secretary may require. Any such re-
7 quest shall include a description of how the institution of
8 higher education, or consortium of institutions of higher
9 education, meets or plans to meet each of the criteria spec-
10 ified in subsection (c).

11 “(c) CRITERIA FOR DESIGNATION DESCRIBED.—The
12 criteria specified in this subsection with respect to an in-
13 stitution of higher education, or consortium of institutions
14 of higher education, are that the institution or consortium
15 has, as of the date of the submission of a request under
16 subsection (a) by such institution or consortium—

17 “(1) physical and technical capacity for re-
18 search, development, implementation, and dem-
19 onstration of advanced and continuous pharma-
20 ceutical manufacturing;

21 “(2) manufacturing knowledge-sharing net-
22 works with other institutions of higher education,
23 large and small pharmaceutical manufacturers, ge-
24 neric and nonprescription manufacturers, contract
25 manufacturers, and other relevant entities;

1 “(3) proven capacity to design, develop, imple-
2 ment, and demonstrate new, highly effective tech-
3 nologies for use in advanced and continuous phar-
4 maceutical manufacturing;

5 “(4) a track record for creating, preserving,
6 and transferring knowledge with respect to advanced
7 and continuous pharmaceutical manufacturing;

8 “(5) the proven ability to facilitate training of
9 an adequate future workforce for research on, and
10 implementation of, advanced and continuous phar-
11 maceutical manufacturing; and

12 “(6) experience in participating in and leading
13 advanced and continuous pharmaceutical manufac-
14 turing technology partnerships with other institu-
15 tions of higher education, large and small pharma-
16 ceutical manufacturers, generic and nonprescription
17 manufacturers, contract manufacturers, and other
18 relevant entities—

19 “(A) to support companies seeking to im-
20 plement advanced and continuous pharma-
21 ceutical manufacturing in the United States;

22 “(B) to support Federal agencies with
23 technical assistance and employee training,
24 which may include regulatory and quality met-
25 ric guidance as applicable, and hands-on train-

1 ing, for advanced and continuous pharma-
2 ceutical manufacturing;

3 “(C) with respect to advanced and contin-
4 uous pharmaceutical manufacturing, to orga-
5 nize and conduct research and development ac-
6 tivities needed to create new and more effective
7 technology, develop and share knowledge, create
8 intellectual property, and maintain technological
9 leadership;

10 “(D) to develop best practices for design-
11 ing and implementing advanced and continuous
12 pharmaceutical manufacturing processes; and

13 “(E) to assess and respond to the national
14 workforce needs for advanced and continuous
15 pharmaceutical manufacturing, including the
16 development and implementing of training pro-
17 grams.

18 “(d) TERMINATION OF DESIGNATION.—The Sec-
19 retary may terminate the designation of any National Cen-
20 ter of Excellence designated under this section if the Sec-
21 retary determines such National Center of Excellence no
22 longer meets the criteria specified in subsection (c). Not
23 later than 90 days before the effective date of such a ter-
24 mination, the Secretary shall provide written notice to the

1 National Center of Excellence, including the rationale for
2 such termination.

3 “(e) CONDITIONS FOR DESIGNATION.—As a condi-
4 tion of designation as a National Center of Excellence
5 under this section, the Secretary shall require that an in-
6 stitution of higher education or consortium of institutions
7 of higher education enters into an agreement with the Sec-
8 retary under which the institution or consortium agrees—

9 “(1) to collaborate directly with the Food and
10 Drug Administration to publish the reports required
11 by subsection (g);

12 “(2) to share data with the Food and Drug Ad-
13 ministration regarding best practices and research
14 generated through the funding under subsection (f);

15 “(3) to develop, along with industry partners
16 (which may include large and small biopharma-
17 ceutical manufacturers, generic and nonprescription
18 manufacturers, and contract research organizations
19 or contract manufacturers that carry out drug devel-
20 opment and manufacturing activities) and another
21 institution or consortium designated under this sec-
22 tion, if any, a roadmap for developing an advanced
23 and continuous pharmaceutical manufacturing work-
24 force;

1 “(4) to develop, along with industry partners
2 and other institutions or consortia of such institu-
3 tions designated under this section, a roadmap for
4 strengthening existing, and developing new, relation-
5 ships with other institutions of higher education or
6 consortia thereof; and

7 “(5) to provide an annual report to the Food
8 and Drug Administration regarding the institution’s
9 or consortium’s activities under this section, includ-
10 ing a description of how the institution or consor-
11 tium continues to meet and make progress on the
12 criteria specified in subsection (c).

13 “(f) FUNDING.—

14 “(1) IN GENERAL.—The Secretary shall award
15 funding, through grants, contracts, or cooperative
16 agreements, to the National Centers of Excellence
17 designated under this section for the purpose of
18 studying and recommending improvements to ad-
19 vanced and continuous pharmaceutical manufac-
20 turing, including such improvements as may enable
21 the Centers—

22 “(A) to continue to meet the conditions
23 specified in subsection (e);

“(B) to expand capacity for research on, and development of, advanced and continuous pharmaceutical manufacturing; and

“(C) to implement research infrastructure in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to emerging medical threats, such as emerging drug shortages, quality issues disrupting the supply chain, epidemics and pandemics, and other such situations requiring the rapid development of new products or new manufacturing processes.

“(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall agree to consider any input from the Secretary regarding the use of funding that would—

“(A) help to further the advancement of advanced and continuous pharmaceutical manufacturing through the National Center of Excellence; and

“(B) be relevant to the mission of the Food and Drug Administration.

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—

2 There is authorized to be appropriated to carry out
3 this subsection \$80,000,000 for the period of fiscal
4 years 2022 through 2026.

5 “(4) RULE OF CONSTRUCTION.—Nothing in
6 this section shall be construed as precluding a Na-
7 tional Center for Excellence designated under this
8 section from receiving funds under any other provi-
9 sion of this Act or any other Federal law.

10 “(g) ANNUAL REVIEW AND REPORTS.—

11 “(1) ANNUAL REPORT.—Beginning not later
12 than one year after the date on which the first des-
13 ignation is made under subsection (a), and annually
14 thereafter, the Secretary shall—

15 “(A) submit to Congress a report describ-
16 ing the activities, partnerships and collabora-
17 tions, Federal policy recommendations, previous
18 and continuing funding, and findings of, and
19 any other applicable information from, the Na-
20 tional Centers of Excellence designated under
21 this section; and

22 “(B) make such report available to the
23 public in an easily accessible electronic format
24 on the website of the Food and Drug Adminis-
25 tration.

1 “(2) REVIEW OF NATIONAL CENTERS OF EX-
2 CELLENCE AND POTENTIAL DESIGNEES.—The Sec-
3 retary shall periodically review the National Centers
4 of Excellence designated under this section to ensure
5 that such National Centers of Excellence continue to
6 meet the criteria for designation under this section.

7 “(3) REPORT ON LONG-TERM VISION OF FDA
8 ROLE.—Not later than 2 years after the date on
9 which the first designation is made under subsection
10 (a), the Secretary, in consultation with the National
11 Centers of Excellence designated under this section,
12 shall submit a report to Congress on the long-term
13 vision of the Department of Health and Human
14 Services on the role of the Food and Drug Adminis-
15 tration in supporting advanced and continuous phar-
16 maceutical manufacturing, including—

17 “(A) a national framework of principles re-
18 lated to the implementation and regulation of
19 advanced and continuous pharmaceutical manu-
20 facturing;

21 “(B) a plan for the development of Federal
22 regulations and guidance for how advanced and
23 continuous pharmaceutical manufacturing can
24 be incorporated into the development of phar-

1 maceuticals and regulatory responsibilities of
2 the Food and Drug Administration;

3 “(C) a plan for development of Federal
4 regulations or guidance for how advanced and
5 continuous pharmaceutical manufacturing will
6 be reviewed by the Food and Drug Administra-
7 tion; and

8 “(D) appropriate feedback solicited from
9 the public, which may include other institutions
10 of higher education, large and small biopharma-
11 ceutical manufacturers, generic and non-
12 prescription manufacturers, and contract manu-
13 facturers.

14 “(h) DEFINITIONS.—In this section:

15 “(1) ADVANCED.—The term ‘advanced’, with
16 respect to pharmaceutical manufacturing, refers to
17 an approach that incorporates novel technology, or
18 uses an established technique or technology in a new
19 or innovative way, that enhances drug quality or im-
20 proves the performance of a manufacturing process.

21 “(2) CONTINUOUS.—The term ‘continuous’,
22 with respect to pharmaceutical manufacturing, re-
23 fers to a process—

24 “(A) where the input materials are con-
25 tinuously fed into and transformed within the

1 process, and the processed output materials are
2 continuously removed from the system; and

3 “(B) that consists of an integrated process
4 that consists of a series of two or more simulta-
5 neous unit operations.

6 “(3) INSTITUTION OF HIGHER EDUCATION.—
7 The term ‘institution of higher education’ has the
8 meaning given such term in section 101(a) of the
9 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

10 “(4) SECRETARY.—The term ‘Secretary’ means
11 the Secretary of Health and Human Services, acting
12 through the Commissioner of Food and Drugs.”.

13 (b) TRANSITION RULE.—Section 3016 of the 21st
14 Century Cures Act (21 U.S.C. 399h), as in effect on the
15 day before the date of the enactment of this section, shall
16 apply with respect to grants awarded under such section
17 before such date of enactment.

