

Union Calendar No. 111

117TH CONGRESS
1ST SESSION

H. R. 4369

[Report No. 117-151]

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

IN THE HOUSE OF REPRESENTATIVES

JULY 6, 2021

Mr. PALLONE (for himself and Mr. GUTHRIE) introduced the following bill;
which was referred to the Committee on Energy and Commerce

OCTOBER 19, 2021

Reported with amendments, committed to the Committee of the Whole House
on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on July 6, 2021]

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 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 “National Centers of Ex-*
 5 *cellence in Advanced and Continuous Pharmaceutical Man-*
 6 *ufacturing Act of 2021”.*

7 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN ADVANCED**
 8 **AND CONTINUOUS PHARMACEUTICAL MANU-**
 9 **FACTURING.**

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

12 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN AD-**
 13 **VANCED AND CONTINUOUS PHARMA-**
 14 **CEUTICAL MANUFACTURING.**

15 *“(a) IN GENERAL.—The Secretary of Health and*
 16 *Human Services, acting through the Commissioner of Food*
 17 *and Drugs—*

18 *“(1) shall solicit and, beginning not later than*
 19 *one year after the date of enactment of the National*
 20 *Centers of Excellence in Advanced and Continuous*
 21 *Pharmaceutical Manufacturing Act of 2021, receive*
 22 *requests from institutions of higher education, or con-*
 23 *sortia of institutions of higher education, to be des-*
 24 *ignated as a National Center of Excellence in Ad-*
 25 *vanced and Continuous Pharmaceutical Manufac-*

1 *turing (in this section referred to as a ‘National Cen-*
 2 *ter of Excellence’)* to support the advancement, devel-
 3 *opment, and implementation of advanced and contin-*
 4 *uous pharmaceutical manufacturing; and*

5 *“(2) shall so designate not more than 5 institu-*
 6 *tions of higher education or consortia of such institu-*
 7 *tions that—*

8 *“(A) request such designation; and*

9 *“(B) meet the criteria specified in sub-*
 10 *section (c).*

11 *“(b) REQUEST FOR DESIGNATION.—A request for des-*
 12 *ignation under subsection (a) shall be made to the Secretary*
 13 *at such time, in such manner, and containing such infor-*
 14 *mation as the Secretary may require. Any such request*
 15 *shall include a description of how the institution of higher*
 16 *education, or consortium of institutions of higher education,*
 17 *meets or plans to meet each of the criteria specified in sub-*
 18 *section (c).*

19 *“(c) CRITERIA FOR DESIGNATION DESCRIBED.—The*
 20 *criteria specified in this subsection with respect to an insti-*
 21 *tution of higher education, or consortium of institutions of*
 22 *higher education, are that the institution or consortium has,*
 23 *as of the date of the submission of a request under subsection*
 24 *(a) by such institution or consortium—*

1 “(1) *physical and technical capacity for re-*
2 *search, development, implementation, and demonstra-*
3 *tion of advanced and continuous pharmaceutical*
4 *manufacturing;*

5 “(2) *manufacturing knowledge-sharing networks*
6 *with other institutions of higher education, large and*
7 *small pharmaceutical manufacturers, generic and*
8 *nonprescription manufacturers, contract manufactur-*
9 *ers, and other relevant entities;*

10 “(3) *proven capacity to design, develop, imple-*
11 *ment, and demonstrate new, highly effective tech-*
12 *nologies for use in advanced and continuous pharma-*
13 *ceutical manufacturing;*

14 “(4) *a track record for creating, preserving, and*
15 *transferring knowledge with respect to advanced and*
16 *continuous pharmaceutical manufacturing;*

17 “(5) *the proven ability to facilitate training of*
18 *an adequate future workforce for research on, and im-*
19 *plementation of, advanced and continuous pharma-*
20 *ceutical manufacturing; and*

21 “(6) *experience in participating in and leading*
22 *advanced and continuous pharmaceutical manufac-*
23 *turing technology partnerships with other institutions*
24 *of higher education, large and small pharmaceutical*
25 *manufacturers, generic and nonprescription manufac-*

1 *turers, contract manufacturers, and other relevant en-*
2 *tities—*

3 *“(A) to support companies seeking to imple-*
4 *ment advanced and continuous pharmaceutical*
5 *manufacturing in the United States;*

6 *“(B) to support Federal agencies with tech-*
7 *nical assistance and employee training, which*
8 *may include regulatory and quality metric guid-*
9 *ance as applicable, and hands-on training, for*
10 *advanced and continuous pharmaceutical manu-*
11 *facturing;*

12 *“(C) with respect to advanced and contin-*
13 *uous pharmaceutical manufacturing, to organize*
14 *and conduct research and development activities*
15 *needed to create new and more effective tech-*
16 *nology, develop and share knowledge, create in-*
17 *tellectual property, and maintain technological*
18 *leadership;*

19 *“(D) to develop best practices for designing*
20 *and implementing advanced and continuous*
21 *pharmaceutical manufacturing processes; and*

22 *“(E) to assess and respond to the national*
23 *workforce needs for advanced and continuous*
24 *pharmaceutical manufacturing, including the de-*

1 *velopment and implementing of training pro-*
 2 *grams.*

3 “(d) *TERMINATION OF DESIGNATION.—The Secretary*
 4 *may terminate the designation of any National Center of*
 5 *Excellence designated under this section if the Secretary de-*
 6 *termines such National Center of Excellence no longer meets*
 7 *the criteria specified in subsection (c). Not later than 90*
 8 *days before the effective date of such a termination, the Sec-*
 9 *retary shall provide written notice to the National Center*
 10 *of Excellence, including the rationale for such termination.*

11 “(e) *CONDITIONS FOR DESIGNATION.—As a condition*
 12 *of designation as a National Center of Excellence under this*
 13 *section, the Secretary shall require that an institution of*
 14 *higher education or consortium of institutions of higher*
 15 *education enter into an agreement with the Secretary under*
 16 *which the institution or consortium agrees—*

17 “(1) *to collaborate directly with the Food and*
 18 *Drug Administration to publish the reports required*
 19 *by subsection (g);*

20 “(2) *to share data with the Food and Drug Ad-*
 21 *ministration regarding best practices and research*
 22 *generated through the funding under subsection (f);*

23 “(3) *to develop, along with industry partners*
 24 *(which may include large and small biopharma-*
 25 *ceutical manufacturers, generic and nonprescription*

1 *manufacturers, and contract research organizations*
2 *or contract manufacturers that carry out drug devel-*
3 *opment and manufacturing activities) and another*
4 *institution or consortium designated under this sec-*
5 *tion, if any, a roadmap for developing an advanced*
6 *and continuous pharmaceutical manufacturing work-*
7 *force;*

8 *“(4) to develop, along with industry partners*
9 *and other institutions or consortia of such institu-*
10 *tions designated under this section, a roadmap for*
11 *strengthening existing, and developing new, relation-*
12 *ships with other institutions of higher education or*
13 *consortia thereof; and*

14 *“(5) to provide an annual report to the Food*
15 *and Drug Administration regarding the institution’s*
16 *or consortium’s activities under this section, includ-*
17 *ing a description of how the institution or consortium*
18 *continues to meet and make progress on the criteria*
19 *specified in subsection (c).*

20 *“(f) FUNDING.—*

21 *“(1) IN GENERAL.—The Secretary shall award*
22 *funding, through grants, contracts, or cooperative*
23 *agreements, to the National Centers of Excellence des-*
24 *ignated under this section for the purpose of studying*
25 *and recommending improvements to advanced and*

1 *continuous pharmaceutical manufacturing, including*
2 *such improvements as may enable the Centers—*

3 “(A) *to continue to meet the conditions*
4 *specified in subsection (e);*

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

8 “(C) *to implement research infrastructure*
9 *in advanced and continuous pharmaceutical*
10 *manufacturing suitable for accelerating the de-*
11 *velopment of drug products needed to respond to*
12 *emerging medical threats, such as emerging drug*
13 *shortages, quality issues disrupting the supply*
14 *chain, epidemics and pandemics, and other such*
15 *situations requiring the rapid development of*
16 *new products or new manufacturing processes.*

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

22 “(A) *help to further the advancement of ad-*
23 *vanced and continuous pharmaceutical manufac-*
24 *turing through the National Center of Excellence;*
25 *and*

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

3 “(3) *RULE OF CONSTRUCTION.*—Nothing in this
4 section shall be construed as precluding a National
5 Center for Excellence designated under this section
6 from receiving funds under any other provision of
7 this Act or any other Federal law.

8 “(g) *ANNUAL REVIEW AND REPORTS.*—

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

13 “(A) submit to Congress a report describing
14 the activities, partnerships and collaborations,
15 Federal policy recommendations, previous and
16 continuing funding, and findings of, and any
17 other applicable information from, the National
18 Centers of Excellence designated under this sec-
19 tion;

20 “(B) include in such report an accounting
21 of the Federal administrative expenses described
22 in subsection (i)(2) over the reporting period;
23 and

24 “(C) make such report available to the pub-
25 lic in an easily accessible electronic format on

1 *the website of the Food and Drug Administra-*
2 *tion.*

3 “(2) *REVIEW OF NATIONAL CENTERS OF EXCEL-*
4 *LENCE AND POTENTIAL DESIGNEES.—The Secretary*
5 *shall periodically review the National Centers of Ex-*
6 *cellence designated under this section to ensure that*
7 *such National Centers of Excellence continue to meet*
8 *the criteria for designation under this section.*

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

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

23 “(B) *a plan for the development of Federal*
24 *regulations and guidance for how advanced and*
25 *continuous pharmaceutical manufacturing can*

1 *be incorporated into the development of pharma-*
2 *ceuticals and regulatory responsibilities of the*
3 *Food and Drug Administration;*

4 *“(C) a plan for development of Federal reg-*
5 *ulations or guidance for how advanced and con-*
6 *tinuous pharmaceutical manufacturing will be*
7 *reviewed by the Food and Drug Administration;*
8 *and*

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

14 *“(h) DEFINITIONS.—In this section:*

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

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

24 *“(A) where the input materials are continu-*
25 *ously fed into and transformed within the proc-*

1 *ess, and the processed output materials are con-*
 2 *tinuously 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.—The*
 7 *term ‘institution of higher education’ has the meaning*
 8 *given such term in section 101(a) of the Higher Edu-*
 9 *cation 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 *“(i) AUTHORIZATION OF APPROPRIATIONS.—*

14 *“(1) IN GENERAL.—There is authorized to be ap-*
 15 *propriated to carry out this section \$100,000,000 for*
 16 *the period of fiscal years 2022 through 2026.*

17 *“(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of*
 18 *the amounts made available to carry out this section*
 19 *for a fiscal year, the Secretary shall not use more*
 20 *than eight percent for Federal administrative ex-*
 21 *penses, including training, technical assistance, re-*
 22 *porting, and evaluation.”.*

23 *(b) TRANSITION RULE.—Section 3016 of the 21st Cen-*
 24 *tury Cures Act (21 U.S.C. 399h), as in effect on the day*
 25 *before the date of the enactment of this section, shall apply*

1 *with respect to grants awarded under such section before*
 2 *such date of enactment.*

3 (c) *CLERICAL AMENDMENT.*—*The item relating to sec-*
 4 *tion 3016 in the table of contents in section 1(b) of the 21st*
 5 *Century Cures Act (Public Law 114-255) is amended to*
 6 *read as follows:*

*“Sec. 3016. National Centers of Excellence in Advanced and Continuous Pharma-
 ceutical Manufacturing.”.*

Amend the title so as to read: “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 pharmaceutical manufacturing as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing, and for other purposes.”.

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