

116TH CONGRESS  
1ST SESSION

# H. R. 4866

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

OCTOBER 28, 2019

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

---

## 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  
5 Excellence in Continuous Pharmaceutical Manufacturing  
6 Act of 2019”.

1 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN CONTIN-**  
2 **UOUS PHARMACEUTICAL MANUFACTURING.**

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

5 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CON-**  
6 **TINUOUS PHARMACEUTICAL MANUFAC-**  
7 **TURING.**

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

11 “(1) shall solicit and, beginning not later than  
12 180 days after the date of enactment of the National  
13 Centers of Excellence in Continuous Pharmaceutical  
14 Manufacturing Act of 2019, receive requests from  
15 institutions of higher education to be designated as  
16 a National Center of Excellence in Continuous Phar-  
17 maceutical Manufacturing (in this section referred to  
18 as a ‘National Center of Excellence’) to support the  
19 advancement and development of continuous manu-  
20 facturing; and

21 “(2) shall so designate any institution of higher  
22 education that—

23 “(A) requests such designation; and

24 “(B) meets the criteria specified in sub-  
25 section (c).

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

8       “(c) CRITERIA FOR DESIGNATION DESCRIBED.—The  
9 criteria specified in this subsection with respect to an in-  
10 stitution of higher education are that the institution has,  
11 as of the date of the submission of a request under sub-  
12 section (a) by such institution—

13               “(1) physical and technical capacity for re-  
14 search and development of continuous manufac-  
15 turing;

16               “(2) scalable manufacturing knowledge-sharing  
17 networks with other institutions of higher education,  
18 large and small biopharmaceutical manufacturers,  
19 generic and nonprescription manufacturers, contract  
20 manufacturers, and other entities;

21               “(3) proven capacity to design and demonstrate  
22 new, highly effective technology for use in contin-  
23 uous manufacturing;

1           “(4) a track record for creating and transfer-  
2           ring knowledge with respect to continuous manufac-  
3           turing;

4           “(5) the potential to train a future workforce  
5           for research on and implementation of continuous  
6           manufacturing; and

7           “(6) the potential to participate in and lead a  
8           continuous manufacturing technology partnership  
9           with other institutions of higher education, large and  
10          small biopharmaceutical manufacturers, generic and  
11          nonprescription manufacturers, contract manufac-  
12          turers, and other entities—

13                 “(A) to support companies with continuous  
14                 manufacturing in the United States;

15                 “(B) to support Federal agencies with  
16                 technical assistance for continuous manufac-  
17                 turing;

18                 “(C) with respect to continuous manufac-  
19                 turing, to organize and conduct research and  
20                 development activities needed to create new and  
21                 more effective technology, capture and dissemi-  
22                 nate expertise, create intellectual property, and  
23                 maintain technological leadership;

1           “(D) to standardize systems and ap-  
2           proaches for designing continuous manufac-  
3           turing; and

4           “(E) to develop a plan to establish a con-  
5           tinuous manufacturing workforce.

6           “(d) TERMINATION OF DESIGNATION.—The Sec-  
7           retary may terminate the designation of any National Cen-  
8           ter of Excellence designated under this section if the Sec-  
9           retary determines such National Center of Excellence no  
10          longer meets the criteria specified in subsection (c). Not  
11          later than 60 days before the effective date of such a ter-  
12          mination, the Secretary shall provide written notice to the  
13          National Center of Excellence, including the rationale for  
14          such termination.

15          “(e) CONDITIONS FOR DESIGNATION.—As a condi-  
16          tion of designation as a National Center of Excellence  
17          under this section, the Secretary shall require that an in-  
18          stitution of higher education enter into an agreement with  
19          the Secretary under which the institution agrees—

20                 “(1) to collaborate directly with the Food and  
21                 Drug Administration to publish the reports required  
22                 by subsection (g);

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

1           “(3) to provide an annual report to the Food  
2 and Drug Administration regarding the institution’s  
3 activities under this section; and

4           “(4) to develop, along with industry partners  
5 and another institution or institutions designated  
6 under this section, if any, a roadmap for developing  
7 a continuous manufacturing workforce.

8           “(f) FUNDING.—

9           “(1) IN GENERAL.—The Secretary shall award  
10 funding to the National Centers of Excellence des-  
11 ignated under this section for the purpose of study-  
12 ing and recommending improvements to continuous  
13 manufacturing, including such improvements as may  
14 enable the Centers—

15                   “(A) to continue to meet the conditions  
16 specified in subsection (e);

17                   “(B) to submit reports under subsection  
18 (e)(3); and

19                   “(C) to expand capacity for research on,  
20 and development of, continuing manufacturing.

21           “(2) AUTHORIZATION OF APPROPRIATIONS.—

22 There is authorized to be appropriated to carry out  
23 this subsection \$80,000,000 for the period of fiscal  
24 years 2021 through 2025.

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

6           “(g) ANNUAL REVIEW AND REPORTS.—

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

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

18                   “(B) make such report available to the  
19 public in an easily accessible electronic format  
20 on the website of the Food and Drug Adminis-  
21 tration.

22           “(2) REVIEW OF NATIONAL CENTERS OF EX-  
23 CELLENCE AND POTENTIAL DESIGNEES.—The Sec-  
24 retary shall periodically review the National Centers  
25 of Excellence designated under this section to ensure

1 that such National Centers of Excellence continue to  
2 meet the criteria for designation under this section.

3 “(3) REPORT ON LONG-TERM VISION OF FDA  
4 ROLE.—Not later than 2 years after the date on  
5 which the first designation is made under subsection  
6 (a), the Secretary, in collaboration with the National  
7 Centers of Excellence designated under this section,  
8 shall submit a report to the Congress on the long-  
9 term vision of the Department of Health and  
10 Human Services on the role of the Food and Drug  
11 Administration in supporting continuous manufac-  
12 turing, including—

13 “(A) a national framework of principles re-  
14 lated to the implementation and regulation of  
15 continuous manufacturing; and

16 “(B) a plan for the development of Federal  
17 regulations and guidance for how continuous  
18 manufacturing can be incorporated into the de-  
19 velopment, review, and approval process for  
20 drugs and biological products.

21 “(h) DEFINITIONS.—In this section:

22 “(1) BIOLOGICAL PRODUCT.—The term ‘bio-  
23 logical product’ has the meaning given such term in  
24 section 351(i) of the Public Health Service Act (42  
25 U.S.C. 262(i)).



1           “(2) CONTINUOUS MANUFACTURING.—The  
2 term ‘continuous manufacturing’—

3           “(A) means a process where the input ma-  
4 terials are continuously fed into and trans-  
5 formed within the process, and the processed  
6 output materials are continuously removed from  
7 the system; and

8           “(B) consists of an integrated process that  
9 consists of a series of two or more unit oper-  
10 ations.

11           “(3) DRUG.—The term ‘drug’ has the meaning  
12 given such term in section 201 of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 321).

14           “(4) INSTITUTION OF HIGHER EDUCATION.—  
15 The term ‘institution of higher education’ has the  
16 meaning given such term in section 101(a) of the  
17 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

18           “(5) SECRETARY.—The term ‘Secretary’ means  
19 the Secretary of Health and Human Services, acting  
20 through the Commissioner of Food and Drugs.”.

21           (b) TRANSITION RULE.—Section 3016 of the 21st  
22 Century Cures Act (21 U.S.C. 399h), as in effect on the  
23 day before the date of the enactment of this section, shall

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

○