

115TH CONGRESS  
2D SESSION

# H. R. 5568

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

APRIL 18, 2018

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 2018”.

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 this section,  
13 receive requests from institutions of higher edu-  
14 cation to be designated as a National Center of Ex-  
15 cellence in Continuous Pharmaceutical Manufac-  
16 turing (in this section referred to as a ‘National  
17 Center of Excellence’) to support the advancement  
18 and development of continuous manufacturing; and

19 “(2) shall so designate any institution of higher  
20 education that—

21 “(A) requests such designation; and

22 “(B) meets the criteria specified in sub-  
23 section (c).

24 “(b) REQUEST FOR DESIGNATION.—A request for  
25 designation under subsection (a) shall be made to the Sec-  
26 retary at such time, in such manner, and such information

1 as the Secretary may require. Any such request shall in-  
2 clude a description of how the institution of higher edu-  
3 cation meets or plans to meet each of the criteria specified  
4 in subsection (c).

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

10 “(1) physical and technical capacity for re-  
11 search and development of continuous manufac-  
12 turing;

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

18 “(3) proven capacity to design and demonstrate  
19 new, highly effective technology for use in contin-  
20 uous manufacturing;

21 “(4) a track record for creating and transfer-  
22 ring knowledge with respect to continuous manufac-  
23 turing;

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

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

10                   “(A) to support companies with continuous  
11                   manufacturing in the United States;

12                   “(B) to support Federal agencies with  
13                   technical assistance for continuous manufac-  
14                   turing;

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

21                   “(D) to standardize systems and ap-  
22                   proaches for designing continuous manufac-  
23                   turing; and

24                   “(E) to develop a plan to establish a con-  
25                   tinuous manufacturing workforce.

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

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

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

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

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

24               “(4) to develop, along with industry partners  
25       and another institution or institutions designated

1 under this section, if any, a roadmap for developing  
2 a continuous manufacturing workforce.

3 “(f) FUNDING.—

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

10 “(A) to continue to meet the conditions  
11 specified in subsection (e);

12 “(B) to submit reports under subsection  
13 (e)(3); and

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

16 “(2) AUTHORIZATION OF APPROPRIATIONS.—  
17 There are authorized to be appropriated to carry out  
18 this subsection \$80,000,000 for the period of fiscal  
19 years 2019 through 2023.

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

25 “(g) ANNUAL REVIEW AND REPORTS.—

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

5           “(A) submit to Congress a report describ-  
6 ing the activities, partnerships and collabora-  
7 tions, Federal policy recommendations, previous  
8 and continuing funding, and findings of, and  
9 any other applicable information from, the Na-  
10 tional Centers of Excellence designated under  
11 this section; and

12           “(B) make such report available to the  
13 public in an easily accessible electronic format  
14 on the website of the Food and Drug Adminis-  
15 tration.

16           “(2) REVIEW OF NATIONAL CENTERS OF EX-  
17 CELLENCE AND POTENTIAL DESIGNEES.—The Sec-  
18 retary shall periodically review the National Centers  
19 of Excellence designated under this section to ensure  
20 that such National Centers of Excellence continue to  
21 meet the criteria for designation under this section.

22           “(3) REPORT ON LONG-TERM VISION OF FDA  
23 ROLE.—Not later than 2 years after the date on  
24 which the first designation is made under subsection  
25 (a), the Secretary, in collaboration with the National

1 Centers of Excellence designated under this section,  
2 shall submit a report to the Congress on the long-  
3 term vision of the Department of Health and  
4 Human Services on the role of the Food and Drug  
5 Administration in supporting continuous manufac-  
6 turing, including—

7 “(A) a national framework of principles re-  
8 lated to the implementation and regulation of  
9 continuous manufacturing; and

10 “(B) a plan for the development of Federal  
11 regulations and guidance for how continuous  
12 manufacturing can be incorporated into the de-  
13 velopment, review, and approval process for  
14 drugs and biological products.

15 “(h) DEFINITIONS.—In this section:

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

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

22 “(A) means a process where the input ma-  
23 terials are continuously fed into and trans-  
24 formed within the process, and the processed

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

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

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

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

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

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

○