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(Original Signature of Member)

117TH CONGRESS  
1ST SESSION

# H. R. 4369

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.

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## IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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# 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 2021”.

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 one year after the date of enactment of the National  
13 Centers of Excellence in Continuous Pharmaceutical  
14 Manufacturing Act of 2021, 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) manufacturing knowledge-sharing net-  
17 works with other institutions of higher education,  
18 large and small pharmaceutical manufacturers, ge-  
19 neric 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 advanced  
6           manufacturing and continuous manufacturing; and

7           “(6) experience in participating in and leading  
8           a continuous manufacturing technology partnership  
9           with other institutions of higher education, large and  
10          small pharmaceutical 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, which may include regu-  
17                 latory and quality metric guidance as applica-  
18                 ble, for advanced manufacturing and continuous  
19                 manufacturing;

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

1           “(D) to develop best practices for design-  
2           ing continuous manufacturing; and

3           “(E) to assess and respond to the work-  
4           force needs for continuous manufacturing, in-  
5           cluding the development of training programs if  
6           needed.

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

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

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

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

4           “(3) to develop, along with industry partners  
5           (which may include large and small biopharma-  
6           ceutical manufacturers, generic and nonprescription  
7           manufacturers, and contract manufacturers) and an-  
8           other institution or institutions designated under  
9           this section, if any, a roadmap for developing a con-  
10          tinuous manufacturing workforce;

11          “(4) to develop, along with industry partners  
12          and other institutions designated under this section,  
13          a roadmap for strengthening existing, and devel-  
14          oping new, relationships with other institutions; and

15          “(5) to provide an annual report to the Food  
16          and Drug Administration regarding the institution’s  
17          activities under this section, including a description  
18          of how the institution continues to meet and make  
19          progress on the criteria listed 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  
24                 designated under this section for the purpose of  
25                 studying and recommending improvements to contin-

1 uous manufacturing, including such improvements  
2 as may enable the Centers—

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

5 “(B) to expand capacity for research on,  
6 and development of, continuing manufacturing.

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

12 “(A) help to further the advancement of  
13 continuous manufacturing through the National  
14 Center of Excellence; and

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

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
18 There is authorized to be appropriated to carry out  
19 this subsection \$80,000,000 for the period of fiscal  
20 years 2022 through 2026.

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

1 “(g) ANNUAL REVIEW AND REPORTS.—

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

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

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

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

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



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

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

11 “(B) a plan for the development of Federal  
12 regulations and guidance for how advanced  
13 manufacturing and continuous manufacturing  
14 can be incorporated into the development of  
15 pharmaceuticals and regulatory responsibilities  
16 of the Food and Drug Administration; and

17 “(C) appropriate feedback solicited from  
18 the public, which may include other institutions,  
19 large and small biopharmaceutical manufactur-  
20 ers, generic and nonprescription manufacturers,  
21 and contract manufacturers.

22 “(h) DEFINITIONS.—In this section:

23 “(1) ADVANCED MANUFACTURING.—The term  
24 ‘advanced manufacturing’ means an approach for  
25 the manufacturing of pharmaceuticals that incor-

1 porates novel technology, or uses an established  
2 technique or technology in a new or innovative way  
3 (such as continuous manufacturing where the input  
4 materials are continuously transformed within the  
5 process by two or more unit operations) that en-  
6 hances drug quality or improves the manufacturing  
7 process.

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

10 “(A) means a process where the input ma-  
11 terials are continuously fed into and trans-  
12 formed within the process, and the processed  
13 output materials are continuously removed from  
14 the system; and

15 “(B) consists of an integrated process that  
16 consists of a series of two or more unit oper-  
17 ations.

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

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

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