

117<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# **H. R. 4369**

---

## **AN ACT**

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.

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 Advanced and Continuous Pharmaceutical  
6 Manufacturing Act of 2021”.

7 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN AD-**  
8 **VANCED AND CONTINUOUS PHARMA-**  
9 **CEUTICAL MANUFACTURING.**

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  
17 Food 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  
23 consortia of institutions of higher education, to be  
24 designated as a National Center of Excellence in Ad-  
25 vanced and Continuous Pharmaceutical Manufac-

1 turing (in this section referred to as a ‘National  
2 Center of Excellence’) to support the advancement,  
3 development, and implementation of advanced and  
4 continuous pharmaceutical manufacturing; and

5 “(2) shall so designate not more than 5 institu-  
6 tions of higher education or consortia of such insti-  
7 tutions 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  
12 designation under subsection (a) shall be made to the Sec-  
13 retary at such time, in such manner, and containing such  
14 information as the Secretary may require. Any such re-  
15 quest shall include a description of how the institution of  
16 higher education, or consortium of institutions of higher  
17 education, meets or plans to meet each of the criteria spec-  
18 ified in subsection (c).

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

1           “(1) physical and technical capacity for re-  
2           search, development, implementation, and dem-  
3           onstration of advanced and continuous pharma-  
4           ceutical manufacturing;

5           “(2) manufacturing knowledge-sharing net-  
6           works with other institutions of higher education,  
7           large and small pharmaceutical manufacturers, ge-  
8           neric and nonprescription manufacturers, contract  
9           manufacturers, 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 phar-  
13          maceutical manufacturing;

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

17          “(5) the proven ability to facilitate training of  
18          an adequate future workforce for research on, and  
19          implementation of, advanced and continuous phar-  
20          maceutical manufacturing; and

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

1 manufacturers, contract manufacturers, and other  
2 relevant entities—

3 “(A) to support companies seeking to im-  
4 plement advanced and continuous pharma-  
5 ceutical manufacturing in the United States;

6 “(B) to support Federal agencies with  
7 technical assistance and employee training,  
8 which may include regulatory and quality met-  
9 ric guidance as applicable, and hands-on train-  
10 ing, for advanced and continuous pharma-  
11 ceutical manufacturing;

12 “(C) with respect to advanced and contin-  
13 uous pharmaceutical manufacturing, to orga-  
14 nize and conduct research and development ac-  
15 tivities needed to create new and more effective  
16 technology, develop and share knowledge, create  
17 intellectual property, and maintain technological  
18 leadership;

19 “(D) to develop best practices for design-  
20 ing 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

1           development and implementing of training pro-  
2           grams.

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

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

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

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

24               “(3) to develop, along with industry partners  
25               (which may include large and small biopharma-

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

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

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

21        “(f) FUNDING.—

22            “(1) IN GENERAL.—The Secretary shall award  
23        funding, through grants, contracts, or cooperative  
24        agreements, to the National Centers of Excellence  
25        designated under this section for the purpose of

1 studying and recommending improvements to ad-  
2 vanced and continuous pharmaceutical manufac-  
3 turing, including such improvements as may enable  
4 the Centers—

5 “(A) to continue to meet the conditions  
6 specified in subsection (e);

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

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

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



1           “(A) help to further the advancement of  
2           advanced and continuous pharmaceutical manu-  
3           facturing through the National Center of Excel-  
4           lence; and

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

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

12          “(g) ANNUAL REVIEW AND REPORTS.—

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

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

24           “(B) include in such report an accounting  
25          of the Federal administrative expenses de-

1           scribed in subsection (i)(2) over the reporting  
2           period; and

3           “(C) make such report available to the  
4           public in an easily accessible electronic format  
5           on the website of the Food and Drug Adminis-  
6           tration.

7           “(2) REVIEW OF NATIONAL CENTERS OF EX-  
8           CELLENCE AND POTENTIAL DESIGNEES.—The Sec-  
9           retary shall periodically review the National Centers  
10          of Excellence designated under this section to ensure  
11          that such National Centers of Excellence continue to  
12          meet the criteria for designation under this section.

13          “(3) REPORT ON LONG-TERM VISION OF FDA  
14          ROLE.—Not later than 2 years after the date on  
15          which the first designation is made under subsection  
16          (a), the Secretary, in consultation with the National  
17          Centers of Excellence designated under this section,  
18          shall submit a report to the Congress on the long-  
19          term vision of the Department of Health and  
20          Human Services on the role of the Food and Drug  
21          Administration in supporting advanced and contin-  
22          uous pharmaceutical manufacturing, including—

23                  “(A) a national framework of principles re-  
24                  lated to the implementation and regulation of

1 advanced and continuous pharmaceutical manu-  
2 facturing;

3 “(B) a plan for the development of Federal  
4 regulations and guidance for how advanced and  
5 continuous pharmaceutical manufacturing can  
6 be incorporated into the development of phar-  
7 maceuticals and regulatory responsibilities of  
8 the Food and Drug Administration;

9 “(C) a plan for development of Federal  
10 regulations or guidance for how advanced and  
11 continuous pharmaceutical manufacturing will  
12 be reviewed by the Food and Drug Administra-  
13 tion; and

14 “(D) appropriate feedback solicited from  
15 the public, which may include other institutions  
16 of higher education, large and small biopharma-  
17 ceutical manufacturers, generic and non-  
18 prescription manufacturers, and contract manu-  
19 facturers.

20 “(h) DEFINITIONS.—In this section:

21 “(1) ADVANCED.—The term ‘advanced’, with  
22 respect to pharmaceutical manufacturing, refers to  
23 an approach that incorporates novel technology, or  
24 uses an established technique or technology in a new

1 or innovative way, that enhances drug quality or im-  
2 proves the performance of a manufacturing process.

3 “(2) CONTINUOUS.—The term ‘continuous’,  
4 with respect to pharmaceutical manufacturing, re-  
5 fers to a process—

6 “(A) where the input materials are con-  
7 tinuously fed into and transformed within the  
8 process, and the processed output materials are  
9 continuously removed from the system; and

10 “(B) that consists of an integrated process  
11 that consists of a series of two or more simulta-  
12 neous unit operations.

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

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

20 “(i) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) IN GENERAL.—There is authorized to be  
22 appropriated to carry out this section \$100,000,000  
23 for the period of fiscal years 2022 through 2026.

24 “(2) FEDERAL ADMINISTRATIVE EXPENSES.—  
25 Of the amounts made available to carry out this sec-

1       tion for a fiscal year, the Secretary shall not use  
2       more than eight percent for Federal administrative  
3       expenses, including training, technical assistance, re-  
4       porting, and evaluation.”.

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

10       (c) **CLERICAL AMENDMENT.**—The item relating to  
11       section 3016 in the table of contents in section 1(b) of  
12       the 21st Century Cures Act (Public Law 114-255) is  
13       amended to read as follows:

“Sec. 3016. National Centers of Excellence in Advanced and Continuous Phar-  
maceutical Manufacturing.”.

Passed the House of Representatives October 19,  
2021.

Attest:

*Clerk.*

117<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

---

---

**H. R. 4369**

**AN ACT**

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.