

117TH CONGRESS
1ST SESSION

H. R. 4369

IN THE SENATE OF THE UNITED STATES

OCTOBER 20, 2021

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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 (c).

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-

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

Passed the House of Representatives October 19,
2021.

HR 4369 RFS