

116TH CONGRESS
2D SESSION

H. R. 4866

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 22, 2020

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 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 2020”.

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

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

11 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CON-**
 12 **TINUOUS PHARMACEUTICAL MANUFAC-**
 13 **TURING.**

14 “(a) IN GENERAL.—The Secretary of Health and
 15 Human Services, acting through the Commissioner of
 16 Food and Drugs—

17 “(1) shall solicit and, beginning not later than
 18 one year after the date of enactment of the National
 19 Centers of Excellence in Continuous Pharmaceutical
 20 Manufacturing Act of 2020, receive requests from
 21 institutions of higher education to be designated as
 22 a National Center of Excellence in Continuous Phar-
 23 maceutical Manufacturing (in this section referred to
 24 as a ‘National Center of Excellence’) to support the

1 advancement and development of continuous manu-
2 facturing; and

3 “(2) shall so designate any institution of higher
4 education that—

5 “(A) requests such designation; and

6 “(B) meets the criteria specified in sub-
7 section (c).

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

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

20 “(1) physical and technical capacity for re-
21 search and development of continuous manufac-
22 turing;

23 “(2) manufacturing knowledge-sharing net-
24 works with other institutions of higher education,
25 large and small pharmaceutical manufacturers, ge-

1 neric and nonprescription manufacturers, contract
2 manufacturers, and other entities;

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

6 “(4) a track record for creating and transfer-
7 ring knowledge with respect to continuous manufac-
8 turing;

9 “(5) the potential to train a future workforce
10 for research on and implementation of advanced
11 manufacturing and continuous manufacturing; and

12 “(6) experience in participating in and leading
13 a continuous manufacturing technology partnership
14 with other institutions of higher education, large and
15 small pharmaceutical manufacturers, generic and
16 nonprescription manufacturers, contract manufac-
17 turers, and other entities—

18 “(A) to support companies with continuous
19 manufacturing in the United States;

20 “(B) to support Federal agencies with
21 technical assistance, which may include regu-
22 latory and quality metric guidance as applica-
23 ble, for advanced manufacturing and continuous
24 manufacturing;

1 “(C) with respect to continuous manufac-
2 turing, to organize and conduct research and
3 development activities needed to create new and
4 more effective technology, capture and dissemi-
5 nate expertise, create intellectual property, and
6 maintain technological leadership;

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

9 “(E) to assess and respond to the work-
10 force needs for continuous manufacturing, in-
11 cluding the development of training programs if
12 needed.

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

22 “(e) CONDITIONS FOR DESIGNATION.—As a condi-
23 tion of designation as a National Center of Excellence
24 under this section, the Secretary shall require that an in-

stitution of higher education enter into an agreement with the Secretary under which the institution agrees—

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

“(2) to share data with the Food and Drug Administration regarding best practices and research generated through the funding under subsection (f);

“(3) to develop, along with industry partners (which may include large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers) and another institution or institutions designated under this section, if any, a roadmap for developing a continuous manufacturing workforce;

“(4) to develop, along with industry partners and other institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions; and

“(5) to provide an annual report to the Food and Drug Administration regarding the institution’s activities under this section, including a description of how the institution continues to meet and make progress on the criteria listed in subsection (c).

“(f) FUNDING.—

1 “(1) IN GENERAL.—The Secretary shall award
2 funding, through grants, contracts, or cooperative
3 agreements, to the National Centers of Excellence
4 designated under this section for the purpose of
5 studying and recommending improvements to contin-
6 uous manufacturing, including such improvements
7 as may enable the Centers—

8 “(A) to continue to meet the conditions
9 specified in subsection (e); and

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

12 “(2) CONSISTENCY WITH FDA MISSION.—As a
13 condition on receipt of funding under this sub-
14 section, a National Center of Excellence shall agree
15 to consider any input from the Secretary regarding
16 the use of funding that would—

17 “(A) help to further the advancement of
18 continuous manufacturing through the National
19 Center of Excellence; and

20 “(B) be relevant to the mission of the
21 Food and Drug Administration.

22 “(3) AUTHORIZATION OF APPROPRIATIONS.—
23 There is authorized to be appropriated to carry out
24 this subsection \$80,000,000 for the period of fiscal
25 years 2021 through 2025.

1 “(4) 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 consultation 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;

16 “(B) a plan for the development of Federal
17 regulations and guidance for how advanced
18 manufacturing and continuous manufacturing
19 can be incorporated into the development of
20 pharmaceuticals and regulatory responsibilities
21 of the Food and Drug Administration; and

22 “(C) appropriate feedback solicited from
23 the public, which may include other institutions,
24 large and small biopharmaceutical manufactur-

1 ers, generic and nonprescription manufacturers,
2 and contract manufacturers.

3 “(h) DEFINITIONS.—In this section:

4 “(1) ADVANCED MANUFACTURING.—The term
5 ‘advanced manufacturing’ means an approach for
6 the manufacturing of pharmaceuticals that incor-
7 porates novel technology, or uses an established
8 technique or technology in a new or innovative way
9 (such as continuous manufacturing where the input
10 materials are continuously transformed within the
11 process by two or more unit operations) that en-
12 hances drug quality or improves the manufacturing
13 process.

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

16 “(A) means a process where the input ma-
17 terials are continuously fed into and trans-
18 formed within the process, and the processed
19 output materials are continuously removed from
20 the system; and

21 “(B) consists of an integrated process that
22 consists of a series of two or more unit oper-
23 ations.

24 “(3) INSTITUTION OF HIGHER EDUCATION.—
25 The term ‘institution of higher education’ has the

1 meaning given such term in section 101(a) of the
2 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

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

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

Passed the House of Representatives September 21,
2020.

Attest: CHERYL L. JOHNSON,
Clerk.