

Committee Print

[SHOWING THE TEXT OF H.R. 4866, AS FAVORABLY FORWARDED BY THE
ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH ON MARCH 11, 2020]

116TH CONGRESS
2D SESSION

H. R. 4866

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

M____, _____ introduced the following bill; which was referred to the
Committee on _____

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National Centers of
3 Excellence in Continuous Pharmaceutical Manufacturing
4 Act of 2019”.

5 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN CONTIN-**
6 **UOUS PHARMACEUTICAL MANUFACTURING.**

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

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

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

15 “(1) shall solicit and, beginning not later than
16 one year after the date of enactment of the National
17 Centers of Excellence in Continuous Pharmaceutical
18 Manufacturing Act of 2019, receive requests from
19 institutions of higher education to be designated as
20 a National Center of Excellence in Continuous Phar-
21 maceutical Manufacturing (in this section referred to
22 as a ‘National Center of Excellence’) to support the
23 advancement and development of continuous manu-
24 facturing; and

25 “(2) shall so designate any institution of higher
26 education that—

1 “(A) requests such designation; and

2 “(B) meets the criteria specified in sub-
3 section (c).

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

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

16 “(1) physical and technical capacity for re-
17 search and development of continuous manufac-
18 turing;

19 “(2) manufacturing knowledge-sharing net-
20 works with other institutions of higher education,
21 large and small pharmaceutical manufacturers, ge-
22 neric and nonprescription manufacturers, contract
23 manufacturers, and other entities;

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

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

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

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

16 “(A) to support companies with continuous
17 manufacturing in the United States;

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

23 “(C) with respect to continuous manufac-
24 turing, to organize and conduct research and
25 development activities needed to create new and

1 more effective technology, capture and dissemi-
2 nate expertise, create intellectual property, and
3 maintain technological leadership;

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

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

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

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

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

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

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

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

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

23 “(f) FUNDING.—

24 “(1) IN GENERAL.—The Secretary shall award
25 funding, through grants, contracts, or cooperative

1 agreements, to the National Centers of Excellence
2 designated under this section for the purpose of
3 studying and recommending improvements to contin-
4 uous manufacturing, including such improvements
5 as may enable the Centers—

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

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

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

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

18 “(B) be relevant to the mission of the
19 Food and Drug Administration.

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

24 “(4) RULE OF CONSTRUCTION.—Nothing in
25 this section shall be construed as precluding a Na-

1 tional Center for Excellence designated under this
2 section from receiving funds under any other provi-
3 sion of this Act or any other Federal law.

4 “(g) ANNUAL REVIEW AND REPORTS.—

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

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

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

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

1 “(3) REPORT ON LONG-TERM VISION OF FDA
2 ROLE.—Not later than 2 years after the date on
3 which the first designation is made under subsection
4 (a), the Secretary, in consultation with the National
5 Centers of Excellence designated under this section,
6 shall submit a report to the Congress on the long-
7 term vision of the Department of Health and
8 Human Services on the role of the Food and Drug
9 Administration in supporting continuous manufac-
10 turing, including—

11 “(A) a national framework of principles re-
12 lated to the implementation and regulation of
13 continuous manufacturing;

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

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

25 “(h) DEFINITIONS.—In this section:

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

11 “(2) CONTINUOUS MANUFACTURING.—The
12 term ‘continuous manufacturing’—

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

18 “(B) consists of an integrated process that
19 consists of a series of two or more unit oper-
20 ations.

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

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

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