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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R.

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

Mr. PALLONE 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,*

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 2019”.

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
12 180 days after the date of enactment of the National
13 Centers of Excellence in Continuous Pharmaceutical
14 Manufacturing Act of 2019, 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) scalable manufacturing knowledge-sharing
17 networks with other institutions of higher education,
18 large and small biopharmaceutical manufacturers,
19 generic 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 continuous
6 manufacturing; and

7 “(6) the potential to participate in and lead a
8 continuous manufacturing technology partnership
9 with other institutions of higher education, large and
10 small biopharmaceutical 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 for continuous manufac-
17 turing;

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

1 “(D) to standardize systems and ap-
2 proaches for designing continuous manufac-
3 turing; and

4 “(E) to develop a plan to establish a con-
5 tinuous manufacturing workforce.

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

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

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

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

1 “(3) to provide an annual report to the Food
2 and Drug Administration regarding the institution’s
3 activities under this section; and

4 “(4) to develop, along with industry partners
5 and another institution or institutions designated
6 under this section, if any, a roadmap for developing
7 a continuous manufacturing workforce.

8 “(f) FUNDING.—

9 “(1) IN GENERAL.—The Secretary shall award
10 funding to the National Centers of Excellence des-
11 ignated under this section for the purpose of study-
12 ing and recommending improvements to continuous
13 manufacturing, including such improvements as may
14 enable the Centers—

15 “(A) to continue to meet the conditions
16 specified in subsection (e);

17 “(B) to submit reports under subsection
18 (e)(3); and

19 “(C) to expand capacity for research on,
20 and development of, continuing manufacturing.

21 “(2) AUTHORIZATION OF APPROPRIATIONS.—

22 There is authorized to be appropriated to carry out
23 this subsection \$80,000,000 for the period of fiscal
24 years 2021 through 2025.

1 “(3) 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 collaboration 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; and

16 “(B) a plan for the development of Federal
17 regulations and guidance for how continuous
18 manufacturing can be incorporated into the de-
19 velopment, review, and approval process for
20 drugs and biological products.

21 “(h) DEFINITIONS.—In this section:

22 “(1) BIOLOGICAL PRODUCT.—The term ‘bio-
23 logical product’ has the meaning given such term in
24 section 351(i) of the Public Health Service Act (42
25 U.S.C. 262(i)).

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

3 “(A) means a process where the input ma-
4 terials are continuously fed into and trans-
5 formed within the process, and the processed
6 output materials are continuously removed from
7 the system; and

8 “(B) consists of an integrated process that
9 consists of a series of two or more unit oper-
10 ations.

11 “(3) DRUG.—The term ‘drug’ has the meaning
12 given such term in section 201 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 321).

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

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

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