Union Calendar No.

116TH CONGRESS
2D SESSION

H. R. 4866

[Report No. 116–]

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

OCTOBER 28, 2019

Mr. PALLONE (for himself and Mr. GUTHRIE) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY --, 2020

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on October 28, 2019]

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2020".

SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.

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

"SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.

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

"(1) shall solicit and, beginning not later than one year after the date of enactment of the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2020, receive requests from institutions of higher education to be designated as a National Center of Excellence in Continuous Pharmaceutical Manufacturing (in this section referred to as a 'National Center of Excellence') to support the ad-

vancement and development of continuous manufacturing; and

"(2) shall so designate any institution of higher education that—

"(A) requests such designation; and

"(B) meets the criteria specified in subsection (c).

"(b) REQUEST FOR DESIGNATION.—A request for designation under subsection (a) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Any such request shall include a description of how the institution of higher education meets or plans to meet each of the criteria specified in subsection (c).

"(c) CRITERIA FOR DESIGNATION DESCRIBED.—The criteria specified in this subsection with respect to an institution of higher education are that the institution has, as of the date of the submission of a request under subsection (a) by such institution—

"(1) physical and technical capacity for research and development of continuous manufacturing;

"(2) manufacturing knowledge-sharing networks with other institutions of higher education, large and small pharmaceutical manufacturers, generic and

nonprescription manufacturers, contract manufacturers, and other entities;

"(3) proven capacity to design and demonstrate new, highly effective technology for use in continuous manufacturing;

"(4) a track record for creating and transferring knowledge with respect to continuous manufacturing;

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

"(6) experience in participating in and leading a continuous manufacturing technology partnership with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other entities—

"(A) to support companies with continuous manufacturing in the United States;

"(B) to support Federal agencies with technical assistance, which may include regulatory and quality metric guidance as applicable, for advanced manufacturing and continuous manufacturing;

"(C) with respect to continuous manufacturing, to organize and conduct research and de-

velopment activities needed to create new and more effective technology, capture and disseminate expertise, create intellectual property, and maintain technological leadership;

"(D) to develop best practices for designing continuous manufacturing; and

"(E) to assess and respond to the workforce needs for continuous manufacturing, including the development of training programs if needed.

"(d) TERMINATION OF DESIGNATION.—The Secretary may terminate the designation of any National Center of Excellence designated under this section if the Secretary determines such National Center of Excellence no longer meets the criteria specified in subsection (c). Not later than 60 days before the effective date of such a termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for such termination.

"(e) CONDITIONS FOR DESIGNATION.—As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution 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) IN GENERAL.—The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the National Centers of Excellence designated under this section for the purpose of studying and recommending improvements to continuous man-

ufacturing, including such improvements as may enable the Centers—

"(A) to continue to meet the conditions specified in subsection (e); and

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

"(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall agree to consider any input from the Secretary regarding the use of funding that would—

"(A) help to further the advancement of continuous manufacturing through the National Center of Excellence; and

"(B) be relevant to the mission of the Food and Drug Administration.

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

"(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of this Act or any other Federal law.

"(g) ANNUAL REVIEW AND REPORTS.—

"(1) ANNUAL REPORT.—Beginning not later than one year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall—

"(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section; and

"(B) make such report available to the public in an easily accessible electronic format on the website of the Food and Drug Administration.

"(2) REVIEW OF NATIONAL CENTERS OF EXCELLENCE AND POTENTIAL DESIGNEES.—The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that such National Centers of Excellence continue to meet the criteria for designation under this section.

"(3) REPORT ON LONG-TERM VISION OF FDA ROLE.—Not later than 2 years after the date on which the first designation is made under subsection

(a), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the Congress on the long-term vision of the Department of Health and Human Services on the role of the Food and Drug Administration in supporting continuous manufacturing, including—

"(A) a national framework of principles related to the implementation and regulation of continuous manufacturing;

"(B) a plan for the development of Federal regulations and guidance for how advanced manufacturing and continuous manufacturing can be incorporated into the development of pharmaceuticals and regulatory responsibilities of the Food and Drug Administration; and

"(C) appropriate feedback solicited from the public, which may include other institutions, large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers.

"(h) DEFINITIONS.—In this section:

"(1) ADVANCED MANUFACTURING.—The term 'advanced manufacturing' means an approach for the manufacturing of pharmaceuticals that incorporates novel technology, or uses an established technique or

technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within the process by two or more unit operations) that enhances drug quality or improves the manufacturing process.

"(2) CONTINUOUS MANUFACTURING.—The term 'continuous manufacturing'—

"(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and

"(B) consists of an integrated process that consists of a series of two or more unit operations.

"(3) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

"(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.".

(b) TRANSITION RULE.—Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h), as in effect on the day before the date of the enactment of this section, shall apply

with respect to grants awarded under such section before such date of enactment.