AMENDMENT IN THE NATURE OF A SUBSTITUTE

TO H.R. _____

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing Act of 2021''.

SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN ADVANCED AND 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 ADVANCED AND 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 Advanced and Continuous

Pharmaceutical Manufacturing Act of 2021, receive requests from institutions of higher education, or consortia of institutions of higher education, to be designated as a National Center of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a 'National Center of Excellence') to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing; and

''(2) shall so designate not more than 5 institutions of higher education or consortia of such institutions that—

''(A) request such designation; and

''(B) meet 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, or consortium of institutions 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 in-

stitution of higher education, or consortium of institutions of higher education, are that the institution or consortium has, as of the date of the submission of a request under subsection (a) by such institution or consortium—

''(1) physical and technical capacity for research, development, implementation, and demonstration of advanced and continuous pharmaceutical 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 relevant entities;

''(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

''(4) a track record for creating, preserving, and transferring knowledge with respect to advanced and continuous pharmaceutical manufacturing;

''(5) the proven ability to facilitate training of an adequate future workforce for research on, and implementation of, advanced and continuous pharmaceutical manufacturing; and

''(6) experience in participating in and leading advanced and continuous pharmaceutical manufacturing technology partnerships with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other relevant entities—

''(A) to support companies seeking to implement advanced and continuous pharmaceutical manufacturing in the United States;

''(B) to support Federal agencies with technical assistance and employee training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

''(C) with respect to advanced and continuous pharmaceutical manufacturing, to organize and conduct research and development activities needed to create new and more effective technology, develop and share knowledge, create intellectual property, and maintain technological leadership;

"(D) to develop best practices for designing and implementing advanced and continuous pharmaceutical manufacturing processes; and

"(E) to assess and respond to the national workforce needs for advanced and continuous pharmaceutical manufacturing, including the development and implementing of training programs.

"(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 90 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 or consortium of institutions of higher education enter into an agreement with the Secretary under which the institution or consortium 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 research organizations or contract manufacturers that carry out drug development and manufacturing activities) and another institution or consortium designated under this section, if any, a roadmap for developing an advanced and continuous pharmaceutical manufacturing workforce;

''(4) to develop, along with industry partners and other institutions or consortia of such institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions of higher education or consortia thereof; and

''(5) to provide an annual report to the Food and Drug Administration regarding the institution's or consortium's activities under this section, includ-

ing a description of how the institution or consortium continues to meet and make progress on the criteria specified in subsection (e).

''(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 advanced and continuous pharmaceutical manufacturing, including such improvements as may enable the Centers—

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

''(B) to expand capacity for research on, and development of, advanced and continuous pharmaceutical manufacturing; and

''(C) to implement research infrastructure in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to emerging medical threats, such as emerging drug shortages, quality issues disrupting the supply chain, epidemics and pandemics, and other such situations requiring the rapid devel-

opment of new products or new manufacturing processes.

''(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 advanced and continuous pharmaceutical 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 $100,000,000 for the period of fiscal years 2022 through 2026.

''(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 des-

ignation 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 advanced and continuous pharmaceutical manufacturing, including—

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

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

''(C) a plan for development of Federal regulations or guidance for how advanced and continuous pharmaceutical manufacturing will be reviewed by the Food and Drug Administration; and

''(D) appropriate feedback solicited from the public, which may include other institutions of higher education, large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers.

''(h) DEFINITIONS.—In this section:

''(1) ADVANCED.—The term 'advanced', with respect to pharmaceutical manufacturing, refers to an approach that incorporates novel technology, or uses an established technique or technology in a new or innovative way, that enhances drug quality or improves the performance of a manufacturing process.

''(2) CONTINUOUS.—The term 'continuous', with respect to pharmaceutical manufacturing, refers to a process—

''(A) 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) that consists of an integrated process that consists of a series of two or more simultaneous 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.

Amend the title of the bill to read as follows: ''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 advanced and continuous pharmaceutical manufacturing as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing, and for other purposes.''

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