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116TH CONGRESS
1ST SESSION

H. R. 3044

To establish the Medical Device Sterilization Challenge, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 30, 2019

Mr. LIPINSKI introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Science, Space, and Technology, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish the Medical Device Sterilization Challenge, 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 ''Medical Device Sterilization Challenge Act of 2019''.

SEC. 2. MEDICAL DEVICE STERILIZATION CHALLENGES.

(a) AUTHORITY.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall establish a program to be known as

''Medical Device Sterilization Challenge'' for carrying out prize competitions described in this section under section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719) relating to sterilization of medical devices.

(b) PRIZE COMPETITIONS.—In carrying out the program, the Director shall provide for prize competitions, including at least one prize competition to seek solutions with respect to each of the following goals:

(1) Reduction of the human health hazards associated with ethylene oxide sterilization, including through reduction of—

(A) the exposure to workers in such facilities; and

(B) environmental emissions of ethylene oxide.

(2) Reduction of the amount of time required to effectively sterilize devices by a factor of 2 or more to sterilize the same type and number of devices over commonly-used ethylene oxide technology without a proportional increase in cost.

(3) Achievement of rapid implementation of new sterilization agents or methods that minimize conversion costs without decreasing facility throughput.

(4) Provision of new or improved approaches to measuring, monitoring, and controlling ethylene oxide emissions, including detection at very low levels.

(5) Analysis of public health risks of emissions from currently-available data with respect to emissions of public health or provision of—

(A) new or improved tools that use data to better model emissions over time at the regional or local scale; or

(B) actionable information on the health and environmental impacts of ethylene oxide sterilization to government, industry, and members of the public.

(6) Enabling of minimally disruptive conversion of exiting device sterilization facilities that use ethylene oxide to convert to less-toxic methods of sterilization.

(c) PRIZE COMMITTEES.—

(1) IN GENERAL.—The Director of the Center for Devices and Radiological Health shall assemble a prize committee with respect to each prize competition that shall define the scope and detail of, and provide the requirements for, the prize competitions

under this section. Such committee shall be composed of—

(A) members from the Federal agency, department, or office that most appropriately corresponds with the topic of the prize competition, including—

(i) with respect to a prize competition under subsection (b)(1), the Director or designee of the National Institutes of Health;

(ii) with respect to a prize competition under paragraphs (2), (3), (5), and (6) of subsection (b), the Director or designee of the National Science Foundation; and

(iii) with respect to a prize competition under paragraphs (4) and (5) of subsection (b), the Administrator or designee of the Environmental Protection Agency; and

(B) representatives of any other entities, as determined appropriate by the Director, including State and local governments and the private sector.

(2) DEFINING TOPIC AREAS.—The prize committee may modify and define the scope of the prize

areas described under subsection (b), so long as such modification is in accordance with descriptions in such subsection.

(3) INCENTIVE FOR PRIZE COMPETITION.—The prize committee for each prize competition shall determine the incentive for such prize competition. In determining the incentive, the committee may consider—

(A) a cash prize;

(B) access to Government facilities, a cooperative research and development agreement, or other method;

(C) with respect to for a product of use or promise to the Federal Government, a commitment by the Federal Government to purchase a set number of units of a product from at an agreed-upon price before the product is brought to market;

(D) participation in entrepreneurship mentoring programs;

(E) consultation and mentoring through the regulatory pathway towards approval for use; or

(F) any other incentive provided for by law.

(4) JUDGING CRITERIA.—The prize committee for each prize competition shall establish judging criteria for the competition that shall include—

(A) potential for the solution to become a commercial product or service or advance knowledge to further the public good;

(B) consideration of how likely the solution is to lead to subsequent research, development, or manufacturing in the United States;

(C) the degree to which the solution will reduce the public health burden created by ethylene oxide sterilization of medical devices; and

(D) the degree to which the solution will reduce emissions and the environmental health burden created by ethylene oxide emissions from the sterilization of medical devices.

(5) CONSIDERATION.—In carrying out this section, the committee shall take into consideration the best practices provided for in the challenges and prizes toolkit made publicly available on December 15, 2016, by the General Services Administration.

(d) ACCEPTANCE OF FUNDS.—In addition to such sums as may be appropriated or otherwise made available to the Director to award prizes under this section, the Di-

rector may accept funds from other Federal agencies, and State and local governments to award prizes under this section.

(e) ELIGIBILITY.—Notwithstanding section 24(g)(3) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719(g)(3)), a group may be eligible for an award under this section if 1 member of such group is a citizen or permanent resident of the United States.

(f) COMPLETION OF PRIZE COMPETITIONS.—The prize competitions carried out under this section shall be completed not later than the date that is 5 years after the program is established under subsection (a).

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $20,000,000 to carry out this section, to remain available until expended.

SEC. 3. AGENCY ACTIVITIES TO SUPPORT NOVEL AND EARLY-STAGE TECHNOLOGY FOR MEDICAL DEVICE STERILIZATION.

(a) NATIONAL SCIENCE FOUNDATION.—During the 5 year period beginning on the date of the enactment of this Act, the National Science Foundation shall use existing authority to award grants on a competitive basis to investigator-initiated research projects that may lead to the development, implementation, and assessment of novel

sterilization methods, including traineeships for those who perform this research in academic and industrial settings.

(b) NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health shall—

(1) support or conduct research on the health effects of—

(A) novel sterilization methods, particularly those methods that are well-suited for materials for which ethylene oxide is currently the best available sterilization method, including research on the efficacy of the method on a broad range of materials commonly used in medical devices, on individuals who receive medical devices;

(B) emissions from such novel sterilization methods on individuals in the surrounding communities; and

(C) ethylene oxide, particularly on the morbidity secondary to occupational or environmental exposure at levels measured near sources that emit ethylene oxide; and

(2) award grants, on a competitive basis, to enable institutions to support graduate students and postdoctoral fellows who perform research on novel

sterilization methods in both academic and industry settings.

(c) ENVIRONMENTAL PROTECTION AGENCY.—The Environmental Protection Agency shall support or conduct research on how products, processes, and systems used to produce proposed alternatives to ethylene oxide sterilization will affect the environment.

SEC. 4. GAO REPORT.

Not later than 10 years after the implementation of this Act, the Comptroller General of the United States shall submit to Congress a report on the impact and the effectiveness of the provisions of this Act at achieving the goals described in subsection (b).

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