112TH CONGRESS
1ST SESSION

S. 1662

To amend the Federal Food, Drug, and Cosmetic Act to establish a nanotechnology regulatory science program.

IN THE SENATE OF THE UNITED STATES

OCTOBER 6, 2011

Mr. PRYOR (for himself and Mr. CARDIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a nanotechnology regulatory science program.

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 "Nanotechnology Regulatory Science Act of 2011".

SEC. 2. NANOTECHNOLOGY PROGRAM.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Nanotechnology Regulatory Science Act of 2011, the Secretary, in consultation with the Secretary of Agriculture, shall establish within the Food and Drug Administration a program for the scientific investigation of nanomaterials included or intended for inclusion in products regulated under this Act, to address the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems.

''(b) PROGRAM PURPOSES.—The purposes of the program established under subsection (a) shall be to—

''(1) assess scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to Food and Drug Administration;

''(2) in cooperation with other Federal agencies, develop and organize information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

''(3) promote intramural Food and Drug Administration programs and participate in collabo-

rative efforts, to further the understanding of the science of novel properties at the nanoscale that might contribute to toxicity;

''(4) promote and participate in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

''(5) collect, synthesize, interpret, and disseminate scientific information and data related to the interactions of nanomaterials with biological systems;

''(6) build scientific expertise on nanomaterials within such Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

''(7) ensure ongoing training, as well as dissemination of new information within the centers of such Administration, and more broadly across such Administration, to ensure timely, informed consideration of the most current science;

''(8) encourage such Administration to participate in international and national consensus standards activities; and

''(9) carry out other activities that the Secretary determines are necessary and consistent with

the purposes described in paragraphs (1) through (8).

''(c) PROGRAM ADMINISTRATION.—

''(1) PROGRAM MANAGER.—In carrying out the program under this section, the Secretary, acting through the Commissioner of Food and Drugs, shall designate a program manager who shall supervise the planning, management, and coordination of the program.

''(2) DUTIES.—The program manager shall—

''(A) develop a detailed strategic plan for achieving specific short- and long-term technical goals for the program;

''(B) coordinate and integrate the strategic plan with activities by the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative; and

''(C) develop intramural Food and Drug Administration programs, contracts, memoranda of agreement, joint funding agreements, and other cooperative arrangements necessary for meeting the long-term challenges and achieving the specific technical goals of the program.

''(d) REPORTS.—Not later than March 15, 2014, the Secretary shall submit to Congress a report on the program carried out under this section. Such report shall include—

''(1) a review of the specific short- and long-term goals of the program;

''(2) an assessment of current and proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities; and

''(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2013, $16,000,000 for fiscal year 2014, and $17,000,000 for fiscal year 2015. Amounts appropriated pursuant to this subsection shall remain available until expended.''.

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