

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

A BILL

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

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 “Nanotechnology Regu-
5 latory Science Act of 2011”.

6 **SEC. 2. NANOTECHNOLOGY PROGRAM.**

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

1 **“SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE**
2 **PROGRAM.**

3 “(a) IN GENERAL.—Not later than 180 days after
4 the date of enactment of the Nanotechnology Regulatory
5 Science Act of 2011, the Secretary, in consultation with
6 the Secretary of Agriculture, shall establish within the
7 Food and Drug Administration a program for the sci-
8 entific investigation of nanomaterials included or intended
9 for inclusion in products regulated under this Act, to ad-
10 dress the potential toxicology of such materials, the effects
11 of such materials on biological systems, and interaction
12 of such materials with biological systems.

13 “(b) PROGRAM PURPOSES.—The purposes of the pro-
14 gram established under subsection (a) shall be to—

15 “(1) assess scientific literature and data on
16 general nanomaterials interactions with biological
17 systems and on specific nanomaterials of concern to
18 Food and Drug Administration;

19 “(2) in cooperation with other Federal agencies,
20 develop and organize information using databases
21 and models that will facilitate the identification of
22 generalized principles and characteristics regarding
23 the behavior of classes of nanomaterials with biologi-
24 cal systems;

25 “(3) promote intramural Food and Drug Ad-
26 ministration programs and participate in collabo-

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

4 “(4) promote and participate in collaborative ef-
5 forts to further the understanding of measurement
6 and detection methods for nanomaterials;

7 “(5) collect, synthesize, interpret, and dissemi-
8 nate scientific information and data related to the
9 interactions of nanomaterials with biological sys-
10 tems;

11 “(6) build scientific expertise on nanomaterials
12 within such Administration, including field and lab-
13 oratory expertise, for monitoring the production and
14 presence of nanomaterials in domestic and imported
15 products regulated under this Act;

16 “(7) ensure ongoing training, as well as dis-
17 semination of new information within the centers of
18 such Administration, and more broadly across such
19 Administration, to ensure timely, informed consider-
20 ation of the most current science;

21 “(8) encourage such Administration to partici-
22 pate in international and national consensus stand-
23 ards activities; and

24 “(9) carry out other activities that the Sec-
25 retary determines are necessary and consistent with

1 the purposes described in paragraphs (1) through
2 (8).

3 “(c) PROGRAM ADMINISTRATION.—

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

10 “(2) DUTIES.—The program manager shall—

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

14 “(B) coordinate and integrate the strategic
15 plan with activities by the Food and Drug Ad-
16 ministration and other departments and agen-
17 cies participating in the National Nanotechnol-
18 ogy Initiative; and

19 “(C) develop intramural Food and Drug
20 Administration programs, contracts, memo-
21 randa of agreement, joint funding agreements,
22 and other cooperative arrangements necessary
23 for meeting the long-term challenges and
24 achieving the specific technical goals of the pro-
25 gram.

1 “(d) REPORTS.—Not later than March 15, 2014, the
2 Secretary shall submit to Congress a report on the pro-
3 gram carried out under this section. Such report shall in-
4 clude—

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

7 “(2) an assessment of current and proposed
8 funding levels for the program, including an assess-
9 ment of the adequacy of such funding levels to sup-
10 port program activities; and

11 “(3) a review of the coordination of activities
12 under the program with other departments and
13 agencies participating in the National Nanotechnol-
14 ogy Initiative.

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

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