109TH CONGRESS
2D SESSION

S. 2793

To enhance research and education in the areas of pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing, analytical technologies, modeling, and informatics.

IN THE SENATE OF THE UNITED STATES

MAY 11, 2006

Mr. LUGAR 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 enhance research and education in the areas of pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing, analytical technologies, modeling, and informatics.

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 ''Pharmaceutical Technology and Education Enhancement Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Developing medical products targeted for important public health needs, less common diseases, prevalent third world diseases, prevention indications, or individualized therapy is increasingly challenging.

(2) A typical compound that is discovered today may not be approved by the Food and Drug Administration for 12 to 15 years.

(3) Current costs of bringing new medicines to market are estimated to be as high as $800,000,000 to $1,700,000,000 and are a major barrier to innovation and investment in higher-risk areas such as rare diseases and genetic conditions.

(4) Product development in areas crucial to public health, such as antibiotics, has slowed significantly in the past decade.

(5) Approximately 50 percent of new drug candidates fail to produce adequate evidence of safety or effectiveness in the late stages of clinical studies and cannot be approved. The resulting overall investments are raising the cost of developing an approved therapy to approximately $1,700,000,000.

(6) Problems in physical design, characterization, manufacturing scale-up, and quality control

routinely derail or delay development programs and delay patient access to new treatments.

(7) Many product failures during development are ultimately attributable to problems relating to the transition from laboratory prototype to industrial product.

(8) Recent data suggests that the investment required to launch a new therapy has risen 55 percent during the last 5 years. Pharmaceutical, biotechnology, and medical device productivity appears to be declining at the same time that the costs to develop treatments are rising.

(9) During the last several years, the number of new drug and biologic applications submitted to the Food and Drug Administration has declined significantly. The number of innovative medical device applications to the Food and Drug Administration also has decreased.

(10) Industry has been hesitant to introduce state-of-the-art science and technology into its manufacturing processes due to concern about potential regulatory impact. This led to high in-process inventories, low factory utilization rates, significant product waste, and compliance problems, driving up the costs and decreasing productivity.

(11) It is crucial that improved methods for design, characterization, and production manufacture are available to improve predictability.

(12) United States academic institutions have the capacity to assist in discovering and introducing science-based standards for product characterization and manufacturing to help reduce the cost of new therapies.

(13) Federal investments in a major pharmaceutical technology and education initiative led by the Food and Drug Administration in collaboration with university research partners will produce multiple benefits in health care quality and access.

SEC. 3. PHARMACEUTICAL TECHNOLOGY RESEARCH AND EDUCATION.

(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

(1) IN GENERAL.—

(A) EXPAND AND INTENSIFY CERTAIN PROGRAMS.—The Commissioner of Food and Drugs (referred to in this Act as the ''Commissioner'') shall expand and intensify certain research and education programs regarding pharmaceutical science and engineering through the National Institute for Pharmaceutical Tech-

nology and Education (referred to in this Act as the ''NIPTE'') and the member institutions of the NIPTE, including Purdue University, Duquesne University, Illinois Institute of Technology, University of Puerto Rico (Mayaguez and San Juan), University of Connecticut, University of Iowa, University of Kentucky, University of Kansas, University of Maryland, University of Minnesota, and Rutgers University.

(B) FOCUS.—The research and education programs described in subparagraph (A) shall focus on medical therapy development and manufacturing, analytical technologies, modeling, and informatics.

(2) COORDINATION.—The Commissioner shall coordinate activities carried out pursuant to this Act with the member institutions of the NIPTE identified in paragraph (1), and other Federal agencies with an interest in such activities, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the National Science Foundation, the Department of Veterans Affairs, and the Department of Defense.

(3) ALLOCATIONS.—The Commissioner shall allocate amounts appropriated to carry out this subsection for each fiscal year to the NIPTE.

(b) COORDINATING COMMITTEE.—

(1) IN GENERAL.—The Commissioner shall assist with and coordinate research and develop strategies to allow for the rapid design, enhanced manufacturing processes, and improved quality related to new medical technology development by establishing a Coordinating Committee pursuant to this subsection.

(2) COMPOSITION.—The Coordinating Committee shall consist of 15 members to be appointed by the Commissioner for 2-year terms, of which—

(A) 8 members shall represent the Federal agencies described in subsection (a)(2) and the Food and Drug Administration; and

(B) 7 members shall be representatives from the public, including a broad cross section of academic, industry, consumer advocacy, and other interested persons affected by the costs of prescription drugs.

(3) CHAIR.—

(A) IN GENERAL.—The Coordinating Committee shall be headed by a Chair who shall

serve as the principal advisor to the Commissioner and to the heads of the Federal agencies represented on the Coordinating Committee.

(B) APPOINTMENT.—The Commissioner shall appoint the Chair of the Coordinating Committee for a 2-year term. The Commissioner may reappoint the Chair for not more than 1 additional 2-year term.

(4) ADMINISTRATIVE SUPPORT.—The Coordinating Committee shall receive necessary and appropriate administrative support from the Food and Drug Administration.

(5) MEETINGS OF THE COORDINATING COMMITTEE.—The Coordinating Committee shall meet as appropriate, as determined by the Commissioner in consultation with the Chair.

(c) PLAN FOR FOOD AND DRUG ADMINISTRATION ACTIVITIES.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Coordinating Committee shall develop a plan for supporting research and education efforts through the NIPTE and the relevant Federal agency participants that—

(A) provides for a broad range of research and education activities to enhance medical technology manufacturing and development;

(B) identifies areas of involvement for the participating Federal agencies; and

(C) reflects input from a broad range of academic, industry, and patient advocacy interests.

(2) CERTAIN ELEMENTS OF THE PLAN.—The plan under paragraph (1) shall provide, with respect to medical technology development and manufacturing, for the following elements, as appropriate:

(A) Basic and applied research.

(B) Information and education programs.

(d) REPORTS TO CONGRESS.—The Coordinating Committee shall submit a biennial report to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives that describes the research, education, and other activities conducted or supported pursuant to this Act.

(e) PUBLIC INPUT.—The Commissioner shall provide for a means through which—

(1) the public can obtain information on the existing and planned programs and activities carried out pursuant to this Act; and

(2) the Commissioner can receive comments from the public regarding such programs and activities.

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this Act, there are authorized to be appropriated $25,000,000 for each of fiscal years 2007 through 2012.

(2) ADDITIONAL AVAILABLE APPROPRIATIONS.—The authorization of appropriations under paragraph (1) is in addition to any other appropriations available for conducting or supporting medical technology development and research activities through the Food and Drug Administration.

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