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108TH CONGRESS
2D SESSION

H. R. 5000

To require the Secretaries of Health and Human Services, Defense, and Homeland Security to carry out activities toward bringing to market effective medical countermeasures to radiation from a nuclear or radiological attack.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2004

Mr. WELDON of Pennsylvania (for himself and Mr. ISSA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services and Select Homeland Security, 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 require the Secretaries of Health and Human Services, Defense, and Homeland Security to carry out activities toward bringing to market effective medical countermeasures to radiation from a nuclear or radiological attack.

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 ''Radioprotectant Procurement Act of 2004''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) The threat of a radiological or nuclear attack on the American people is one of the greatest potential threats now faced by the United States, considering the potential number of deaths, injuries, illnesses and economic devastation such an attack on American civilians or military personnel could have.

(2) There are at least 30,000 known nuclear weapons deployed around the world today and the proliferation of nuclear weapons technology continues to pose an enormous threat to the United States, its people, and its interests and allies around the world.

(3) Even a crude radiological weapon, using conventional explosives combined with widely available radiological materials, could cause death, radiation sickness, and widespread panic and economic hardship if detonated in an urban center of the United States, and such an attack would dramatically strain our public health resources.

(4) Numerous government and private studies, including the findings of several leading medical journals, have concluded that a nuclear weapon detonated in a large urban center would cause widespread death, sickness, and physical and economic

damage. For example, in February 2002, the British Medical Journal estimated that a 12.5 kiloton nuclear bomb (approximately the size of the bomb used at Hiroshima), if detonated in New York City, would cause 50,000 immediate deaths, 200,000 short-term deaths from high-exposure radiation injury, and 700,000 cases of radiation sickness.

(5) There are 103 nuclear power plants in the United States, each with the potential to expose area residents to high levels of radiation in the event of a successful attack.

(6) For potentially stockpiled radioprotectants to be most effective, they must be administered soon after exposure to radiation, so the procurement of a radioprotectant must be large enough and located in enough regions of the country to facilitate the rapid treatment of the hundreds of thousands and potentially millions of Americans who would be exposed to radiation, as well as the many ''worried well'' who will flood emergency rooms should a nuclear or radiological attack or large accident occur.

(7) Considering the need to rapidly administer a radioprotectant, Federal procurement of an effective radioprotectant should be comparable to stock-

piles of other drugs designed to counter the effects of chemical or biological agents.

(8) Current treatment options for acute radiation exposure are wholly inadequate, with potassium iodide being the only widely stockpiled countermeasure currently available. This treatment protects against the long-term risk of thyroid cancer, and does nothing to counteract short-term radiation sickness and possible death within the first 30 days of exposure.

(9) Effective medical countermeasures to both acute and long-term exposure of radiation are presently in development at the Armed Forces Radiobiology Research Institute (AFRRI) and among pharmaceutical companies, including at least one compound that has demonstrated efficacy in preventing radiation sickness and death caused by the destruction of bone marrow from acute radiation exposure.

(10) While the Departments of Health and Human Services, Homeland Security, and Defense are appropriately dedicating substantial resources to the development and procurement of countermeasures to biological threats, including smallpox and anthrax vaccines, few resources to date have

been dedicated to bring to market and procure an effective, whole-body radioprotectant.

(11) In enacting the Homeland Security Act of 2002, it was and is the intent of Congress that the development and procurement of radiological and nuclear countermeasures be given full and appropriate consideration and dedication of resources.

SEC. 3. AMENDMENT TO THE HOMELAND SECURITY ACT OF 2002.

Section 304 of the Homeland Security Act of 2002 (6 U.S.C. 184; Public Law 107–296) is amended by adding at the end the following subsection:

''(d) DEVELOPMENT AND PROCUREMENT OF RADIATION MEDICAL COUNTERMEASURES.—For the purpose of rapidly developing, bringing to market, and procuring whole-body radioprotectants, the Secretaries of Health and Human Services, Homeland Security, and Defense shall utilize and expend such funds as may be necessary, including funds appropriated by Congress, and not otherwise prohibited from being used for such purpose, under the appropriations headings 'Public Health Programs', 'Strategic National Stockpile', 'Nuclear and Radiological Countermeasures', 'Biodefense Countermeasures', 'Research, Development, Acquisition and Operations', 'Biological Countermeasures', and 'Chem-Bio Defense Initia-

tive', as well as relevant departmental and subagency operations budgets, subject to the appropriations Act involved.''.

SEC. 4. REPORT REGARDING EFFECTIVE RADIOPROTECTANTS; DEVELOPMENT AND PROCUREMENT.

(a) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Homeland Security (referred to in this section as the ''Secretary'') shall, in consultation with the Secretary of Health and Human Services and the Secretary of Defense, submit to the Congress a report providing a determination by the Secretary of—

(1) the extent to which there is a threat of a nuclear or radiological attack against the United States; and

(2) the availability of effective radioprotectant medical countermeasures against the threat.

(b) DEVELOPMENT AND PROCUREMENT.—

(1) IN GENERAL.—If in carrying out subsection (a) the Secretary determines that one or more effective radioprotectants are currently available, or may become available within a reasonable amount of time, then not later than 90 days after the submission of the report under such subsection, the Sec-

retary shall enter into one or more agreements with one or more private companies for the development and procurement of one or more effective, safe, stable, and low-cost radioprotectants, subject to the availability of funds under an appropriations Act.

(2) ADEQUATE PROTECTION.—An agreement under paragraph (1) shall provide for the procurement and stockpiling of enough dose regimens of the radioprotectants involved to provide for adequate protection of the people of the United States, including adequate response to a multi-location attack scenario, if in carrying out subsection (a) the Secretary determines that such a scenario is plausible.

(3) CERTAIN AUTHORITIES.—

(A) DEVELOPMENT.—With respect to an agreement under paragraph (1) that provides funds for the development of a radioprotectant, the Secretary may use the same authorities as are described in subsections (b) through (e) of section 319F–1 of the Public Health Service Act.

(B) PROCUREMENT.—With respect to an agreement under paragraph (1) that provides funds for the procurement of a radioprotectant, the Secretary may use the same authorities as

are described in section 319F–2(c)(7) of the Public Health Service Act.

(C) CONDITIONS.—An agreement under paragraph (1) may contain such reasonable conditions in addition to the conditions required in paragraph (2) as the Secretary determines to be appropriate, including—

(i) the condition that the final procurement be contingent upon approval of the radioprotectants by the Food and Drug Administration, subject to section 564 of the Federal Food, Drug, and Cosmetic Act; and

(ii) the condition that the company or companies that produce such radioprotectants may be required to assume the development costs of improvements to the radioprotectants.

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