II

110TH CONGRESS
2D SESSION

S. 3187

To establish a comprehensive interagency response to reduce lung cancer mortality in a timely manner.

IN THE SENATE OF THE UNITED STATES

JUNE 25, 2008

Mr. HAGEL (for himself and Mrs. FEINSTEIN) 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 establish a comprehensive interagency response to reduce lung cancer mortality in a timely manner.

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 ''Lung Cancer Mortality Reduction Act of 2008''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Lung cancer is the leading cause of cancer death for both men and women, accounting for 28 percent of all cancer deaths.

(2) Lung cancer kills more people annually than breast cancer, prostate cancer, colon cancer, liver cancer, melanoma, and kidney cancer combined.

(3) Since the National Cancer Act of 1971 (Public Law 92–218; 85 Stat. 778), coordinated and comprehensive research has raised the 5-year survival rates for breast cancer to 88 percent, for prostate cancer to 99 percent, and for colon cancer to 64 percent.

(4) However, the 5-year survival rate for lung cancer is still only 15 percent and a similar coordinated and comprehensive research effort is required to achieve increases in lung cancer survivability rates.

(5) Sixty percent of lung cancer cases are now diagnosed as nonsmokers or former smokers.

(6) Two-thirds of nonsmokers diagnosed with lung cancer are women.

(7) Certain minority populations, such as African-American males, have disproportionately high rates of lung cancer incidence and mortality, notwithstanding their similar smoking rate.

(8) Members of the baby boomer generation are entering their sixties, the most common age at which people develop lung cancer.

(9) Tobacco addiction and exposure to other lung cancer carcinogens such as Agent Orange and other herbicides and battlefield emissions are serious problems among military personnel and war veterans.

(10) Significant and rapid improvements in lung cancer mortality can be expected through greater use and access to lung cancer screening tests for at-risk individuals.

(11) Additional strategies are necessary to further enhance the existing tests and therapies available to diagnose and treat lung cancer in the future.

(12) The August 2001 Report of the Lung Cancer Progress Review Group of the National Cancer Institute stated that funding for lung cancer research was ''far below the levels characterized for other common malignancies and far out of proportion to its massive health impact''.

(13) The Report of the Lung Cancer Progress Review Group identified as its ''highest priority'' the creation of integrated, multidisciplinary, multi-institutional research consortia organized around the problem of lung cancer rather than around specific research disciplines.

(14) The United States must enhance its response to the issues raised in the Report of the Lung Cancer Progress Review Group, and this can be accomplished through the establishment of a coordinated effort designed to reduce the lung cancer mortality rate by 50 percent by 2015 and targeted funding to support this coordinated effort.

SEC. 3. SENSE OF THE SENATE CONCERNING INVESTMENT IN LUNG CANCER RESEARCH.

It is the sense of the Senate that—

(1) lung cancer mortality reduction should be made a national public health priority; and

(2) a comprehensive mortality reduction program coordinated by the Secretary of Health and Human Service is justified and necessary to adequately address and reduce lung cancer mortality.

SEC. 4. LUNG CANCER MORTALITY REDUCTION PROGRAM.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

"SEC. 417E. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Lung Cancer Mortality Reduction Act of 2008, the Secretary, in consultation with

the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Food and Drug Administration, the Director of the Centers for Medicare & Medicaid Services, the Director of the National Center on Minority Health and Health Disparities, and other members of the Lung Cancer Advisory Board established under section 6 of the Lung Cancer Mortality Reduction Act of 2008, shall implement a comprehensive program to achieve a 50 percent reduction in the mortality rate of lung cancer by 2015.

''(b) REQUIREMENTS.—The program implemented under subsection (a) shall include at least the following:

''(1) With respect to the National Institutes of Health—

''(A) a strategic review and prioritization by the National Cancer Institute of research grants to achieve the goal of the program in reducing lung cancer mortality;

''(B) the provision of funds to enable the Airway Biology and Disease Branch of the National Heart, Lung and Blood Institute to expand its research programs to include predispositions to lung cancer, the interrelationship

between lung cancer and other pulmonary and cardiac disease, and the diagnosis and treatment of these interrelationships;

''(C) the provision of funds to enable the National Institute of Biomedical Imaging and Bioengineering to expand its Quantum Grant Program and Image-Guided Interventions programs to expedite the development of computer assisted diagnostic, surgical, treatment and drug testing innovations to reduce lung cancer mortality; and

''(D) the provision of funds to enable the National Institute for Environmental Health Sciences to implement research programs relative to lung cancer incidence.

''(2) With respect to the Food and Drug Administration—

''(A) the establishment of a lung cancer mortality reduction drug program under subtitle G of chapter V of the Federal Food, Drug, and Cosmetic Act; and

''(B) compassionate access activities under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

''(3) With respect to the Centers for Disease Control and Prevention, the establishment of a lung cancer mortality reduction program under section 1511.

''(4) With respect to the Agency for Healthcare Research and Quality, the conduct of a biannual review of lung cancer screening, diagnostic and treatment protocols, and the issuance of updated guidelines.

''(5) The cooperation and coordination of all minority and health disparity programs within the Department of Health and Human Services to ensure that all aspects of the Lung Cancer Mortality Reduction Program adequately address the burden of lung cancer on minority and rural populations.

''(6) The cooperation and coordination of all tobacco control and cessation programs within agencies of the Department of Health and Human Services to achieve the goals of the Lung Cancer Mortality Reduction Program with particular emphasis on the coordination of drug and other cessation treatments with early detection protocols.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

''(1) $25,000,000 for fiscal year 2009 for the activities described in subsection (b)(1)(B), and such sums as may be necessary for each of fiscal years 2010 through 2013;

''(2) $25,000,000 for fiscal year 2009 for the activities described in subsection (b)(1)(C), and such sums as may be necessary for each of fiscal years 2010 through 2013;

''(3) $10,000,000 for fiscal year 2009 for the activities described in subsection (b)(1)(D), and such sums as may be necessary for each of fiscal years 2010 through 2013; and

''(4) $15,000,000 for fiscal year 2009 for the activities described in subsection (b)(3), and such sums as may be necessary for each of fiscal years 2010 through 2013.''.

(b) FOOD, DRUG, AND COSMETIC ACT.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter G—Lung Cancer Mortality Reduction Programs

"SEC. 581. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall implement a program to provide incentives of the type provided for in subchapter B of this chapter for the development of chemoprevention drugs for precancerous conditions of the lung, drugs for targeted therapeutic treatments and vaccines for lung cancer, and new agents to curtail or prevent nicotine addiction. The Secretary shall model the program implemented under this section on the program provided for under subchapter B of this chapter with respect certain drugs.

''(b) APPLICATION OF PROVISIONS.—The Secretary shall apply the provisions of subchapter B of this chapter to drugs, biological products, and devices for the prevention or treatment of lung cancer, including drugs, biological products, and devices for chemoprevention of precancerous conditions of the lungs, vaccination against the development of lung cancer and therapeutic treatment for lung cancer.

''(c) BOARD.—The Board established under section 6 of the Lung Cancer Mortality Reduction Act of 2008

shall monitor the program implemented under this section.''.

(c) ACCESS TO UNAPPROVED THERAPIES.—Section 561(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(e)) is amended by inserting before the period the following: ''and shall include providing compassionate access to drugs, biological products, and devices under the program under section 581, with substantial consideration being given to whether the totality of information available to the Secretary regarding the safety and effectiveness of an investigational drug, as compared to the risk of morbidity and death from the disease, indicates that a patient may obtain more benefit than risk if treated with the drug, biological product, or device.''.

(d) CDC.—Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) is amended by adding at the end the following:

''SEC. 1511. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish and implement an early disease research and management program targeted at the high incidence and mortality rates among minority and low-income populations.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this section.''.

SEC. 5. DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

The Secretary of Defense and the Secretary of Veterans Affairs shall coordinate with the Secretary of Health and Human Services—

(1) in the development of the Lung Cancer Mortality Reduction Program under section 417E;

(2) in the implementation within the Department of Defense and the Department of Veterans Affairs of an early detection and disease management research program for military personnel and veterans whose smoking history and exposure to carcinogens during active duty service has increased their risk for lung cancer; and

(3) in the implementation of coordinated care programs for military personnel and veterans diagnosed with lung cancer.

SEC. 6. LUNG CANCER ADVISORY BOARD.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a Lung Cancer Advisory Board (referred to in this section as the ''Board'') to monitor the programs established under this Act (and the

amendments made by this Act), provide annual reports to Congress concerning benchmarks, expenditures, lung cancer statistics, and the public health impact of such programs.

(b) COMPOSITION.—The Board shall be composed of—

(1) the Secretary of Health and Human Services;

(2) the Secretary of Defense;

(3) the Secretary of Veterans Affairs; and

(4) two representatives each from the fields of clinical medicine focused on lung cancer, lung cancer research, imaging, drug development, and lung cancer advocacy, to be appointed by the Secretary of Health and Human Services.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out the programs under this Act (and the amendments made by this Act), there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013.

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