

111TH CONGRESS
1ST SESSION

S. 332

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

IN THE SENATE OF THE UNITED STATES

JANUARY 27, 2009

Mrs. FEINSTEIN (for herself and Mr. BROWNBACK) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

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 “Lung Cancer Mortality
5 Reduction Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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

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

4 (3) Since the enactment of the National Cancer
5 Act of 1971 (Public Law 92–218; 85 Stat. 778), co-
6 ordinated and comprehensive research has raised the
7 5-year survival rates for breast cancer to 88 percent,
8 for prostate cancer to 99 percent, and for colon can-
9 cer to 64 percent.

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

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

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

19 (7) Certain minority populations, such as Afri-
20 can-American males, have disproportionately high
21 rates of lung cancer incidence and mortality, not-
22 withstanding their similar smoking rate.

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

1 (9) Tobacco addiction and exposure to other
2 lung cancer carcinogens such as Agent Orange and
3 other herbicides and battlefield emissions are serious
4 problems among military personnel and war vet-
5 erans.

6 (10) Significant and rapid improvements in
7 lung cancer mortality can be expected through great-
8 er use and access to lung cancer screening tests for
9 at-risk individuals.

10 (11) Additional strategies are necessary to fur-
11 ther enhance the existing tests and therapies avail-
12 able to diagnose and treat lung cancer in the future.

13 (12) The August 2001 Report of the Lung
14 Cancer Progress Review Group of the National Can-
15 cer Institute stated that funding for lung cancer re-
16 search was “far below the levels characterized for
17 other common malignancies and far out of propor-
18 tion to its massive health impact”.

19 (13) The Report of the Lung Cancer Progress
20 Review Group identified as its “highest priority” the
21 creation of integrated, multidisciplinary, multi-insti-
22 tutional research consortia organized around the
23 problem of lung cancer.

24 (14) The United States must enhance its re-
25 sponse to the issues raised in the Report of the

1 Lung Cancer Progress Review Group, and this can
 2 be accomplished through the establishment of a co-
 3 ordinated effort designed to reduce the lung cancer
 4 mortality rate by 50 percent by 2016 and through
 5 targeted funding to support this coordinated effort.

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

8 It is the sense of the Senate that—

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

11 (2) a comprehensive mortality reduction pro-
 12 gram coordinated by the Secretary of Health and
 13 Human Services is justified and necessary to ade-
 14 quately address and reduce lung cancer mortality.

15 **SEC. 4. LUNG CANCER MORTALITY REDUCTION PROGRAM.**

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

19 **“SEC. 417G. LUNG CANCER MORTALITY REDUCTION PRO-**
 20 **GRAM.**

21 “(a) IN GENERAL.—Not later than 6 months after
 22 the date of enactment of the Lung Cancer Mortality Re-
 23 duction Act of 2009, the Secretary, in consultation with
 24 the Secretary of Defense, the Secretary of Veterans Af-
 25 fairs, the Director of the National Institutes of Health,

1 the Director of the Centers for Disease Control and Pre-
 2 vention, the Commissioner of the Food and Drug Adminis-
 3 tration, the Administrator of the Centers for Medicare &
 4 Medicaid Services, the Director of the National Center on
 5 Minority Health and Health Disparities, and other mem-
 6 bers of the Lung Cancer Advisory Board established under
 7 section 6 of the Lung Cancer Mortality Reduction Act of
 8 2009, shall implement a comprehensive program to
 9 achieve a 50 percent reduction in the mortality rate of
 10 lung cancer by 2016.

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

13 “(1) With respect to the National Institutes of
 14 Health—

15 “(A) a strategic review and prioritization
 16 by the National Cancer Institute of research
 17 grants to achieve the goal of the program in re-
 18 ducing lung cancer mortality;

19 “(B) the provision of funds to enable the
 20 Airway Biology and Disease Branch of the Na-
 21 tional Heart, Lung, and Blood Institute to ex-
 22 pand its research programs to include pre-
 23 dispositions to lung cancer, the interrelationship
 24 between lung cancer and other pulmonary and

1 cardiac disease, and the diagnosis and treat-
 2 ment of these interrelationships;

3 “(C) the provision of funds to enable the
 4 National Institute of Biomedical Imaging and
 5 Bioengineering to expand its Quantum Grant
 6 Program and Image-Guided Interventions pro-
 7 grams to expedite the development of computer
 8 assisted diagnostic, surgical, treatment, and
 9 drug testing innovations to reduce lung cancer
 10 mortality; and

11 “(D) the provision of funds to enable the
 12 National Institute of Environmental Health
 13 Sciences to implement research programs rel-
 14 ative to lung cancer incidence.

15 “(2) With respect to the Food and Drug Ad-
 16 ministration—

17 “(A) the establishment of a lung cancer
 18 mortality reduction drug program under sub-
 19 chapter G of chapter V of the Federal Food,
 20 Drug, and Cosmetic Act; and

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

24 “(3) With respect to the Centers for Disease
 25 Control and Prevention, the establishment of a lung

1 cancer mortality reduction program under section
2 1511.

3 “(4) With respect to the Agency for Healthcare
4 Research and Quality, the conduct of a biannual re-
5 view of lung cancer screening, diagnostic and treat-
6 ment protocols, and the issuance of updated guide-
7 lines.

8 “(5) The cooperation and coordination of all
9 minority and health disparity programs within the
10 Department of Health and Human Services to en-
11 sure that all aspects of the Lung Cancer Mortality
12 Reduction Program adequately address the burden
13 of lung cancer on minority and rural populations.

14 “(6) The cooperation and coordination of all to-
15 bacco control and cessation programs within agen-
16 cies of the Department of Health and Human Serv-
17 ices to achieve the goals of the Lung Cancer Mor-
18 tality Reduction Program with particular emphasis
19 on the coordination of drug and other cessation
20 treatments with early detection protocols.

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

23 “(1) \$25,000,000 for fiscal year 2010 for the
24 activities described in subsection (b)(1)(B), and such

1 sums as may be necessary for each of fiscal years
 2 2011 through 2014;

3 “(2) \$25,000,000 for fiscal year 2010 for the
 4 activities described in subsection (b)(1)(C), and such
 5 sums as may be necessary for each of fiscal years
 6 2011 through 2014;

7 “(3) \$10,000,000 for fiscal year 2010 for the
 8 activities described in subsection (b)(1)(D), and such
 9 sums as may be necessary for each of fiscal years
 10 2011 through 2014; and

11 “(4) \$15,000,000 for fiscal year 2010 for the
 12 activities described in subsection (b)(3), and such
 13 sums as may be necessary for each of fiscal years
 14 2011 through 2014.”.

15 (b) FOOD, DRUG, AND COSMETIC ACT.—Chapter V
 16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 17 351 et seq.) is amended by adding at the end the fol-
 18 lowing:

19 **“Subchapter G—Lung Cancer Mortality**
 20 **Reduction Programs**

21 **“SEC. 581. LUNG CANCER MORTALITY REDUCTION PRO-**
 22 **GRAM.**

23 “(a) IN GENERAL.—The Secretary shall implement
 24 a program to provide incentives of the type provided for
 25 in subchapter B of this chapter for the development of

1 chemoprevention drugs for precancerous conditions of the
2 lung, drugs for targeted therapeutic treatments and vac-
3 cines for lung cancer, and new agents to curtail or prevent
4 nicotine addiction. The Secretary shall model the program
5 implemented under this section on the program provided
6 for under subchapter B of this chapter with respect to cer-
7 tain drugs.

8 “(b) APPLICATION OF PROVISIONS.—The Secretary
9 shall apply the provisions of subchapter B of this chapter
10 to drugs, biological products, and devices for the preven-
11 tion or treatment of lung cancer, including drugs, biologi-
12 cal products, and devices for chemoprevention of
13 precancerous conditions of the lungs, vaccination against
14 the development of lung cancer, and therapeutic treatment
15 for lung cancer.

16 “(c) BOARD.—The Board established under section
17 6 of the Lung Cancer Mortality Reduction Act of 2009
18 shall monitor the program implemented under this sec-
19 tion.”.

20 (c) ACCESS TO UNAPPROVED THERAPIES.—Section
21 561(e) of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 360bbb(e)) is amended by inserting before the pe-
23 riod the following: “and shall include providing compas-
24 sionate access to drugs, biological products, and devices
25 under the program under section 581, with substantial

1 consideration being given to whether the totality of infor-
 2 mation available to the Secretary regarding the safety and
 3 effectiveness of an investigational drug, as compared to
 4 the risk of morbidity and death from the disease, indicates
 5 that a patient may obtain more benefit than risk if treated
 6 with the drug, biological product, or device.”.

7 (d) CDC.—Title XV of the Public Health Service Act
 8 (42 U.S.C. 300k et seq.) is amended by adding at the end
 9 the following:

10 **“SEC. 1511. LUNG CANCER MORTALITY REDUCTION PRO-**
 11 **GRAM.**

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

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

19 **SEC. 5. DEPARTMENT OF DEFENSE AND THE DEPARTMENT**
 20 **OF VETERANS AFFAIRS.**

21 The Secretary of Defense and the Secretary of Vet-
 22 erans Affairs shall coordinate with the Secretary of Health
 23 and Human Services—

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

1 part C of title IV of the Public Health Service Act,
2 as amended by section 4;

3 (2) in the implementation within the Depart-
4 ment of Defense and the Department of Veterans
5 Affairs of an early detection and disease manage-
6 ment research program for military personnel and
7 veterans whose smoking history and exposure to car-
8 cinogens during active duty service has increased
9 their risk for lung cancer; and

10 (3) in the implementation of coordinated care
11 programs for military personnel and veterans diag-
12 nosed with lung cancer.

13 **SEC. 6. LUNG CANCER ADVISORY BOARD.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services shall establish a Lung Cancer Advisory
16 Board (referred to in this section as the “Board”) to mon-
17 itor the programs established under this Act (and the
18 amendments made by this Act), and provide annual re-
19 ports to Congress concerning benchmarks, expenditures,
20 lung cancer statistics, and the public health impact of such
21 programs.

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

24 (1) the Secretary of Health and Human Serv-
25 ices;

- 1 (2) the Secretary of Defense;
- 2 (3) the Secretary of Veterans Affairs; and
- 3 (4) two representatives each from the fields
- 4 of—
- 5 (A) clinical medicine focused on lung can-
- 6 cer;
- 7 (B) lung cancer research;
- 8 (C) imaging;
- 9 (D) drug development; and
- 10 (E) lung cancer advocacy,
- 11 to be appointed by the Secretary of Health and
- 12 Human Services.

13 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

14 For the purpose of carrying out the programs under

15 this Act (and the amendments made by this Act), there

16 is authorized to be appropriated such sums as may be nec-

17 essary for each of fiscal years 2010 through 2014.

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