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 great8 er use and access to lung cancer screening tests for
9 at-risk individuals.

10 (11) Additional strategies are necessary to fur11 ther enhance the existing tests and therapies avail12 able 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.

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

 be accomplished through the establishment of a co- ordinated effort designed to reduce the lung cancer mortality rate by 50 percent by 2016 and through targeted funding to support this coordinated effort. SEC. 3. SENSE OF THE SENATE CONCERNING INVESTMENT II is the sense of the Senate Concerning INVESTMENT II 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 pro- gram coordinated by the Secretary of Health and Human Services is justified and necessary to ade- quately 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. 417G. LUNG CANCER MORTALITY REDUCTION PRO- GRAM. "(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Lung Cancer Mortality Re- duction Act of 2009, the Secretary of Veterans Af- fairs, the Director of the National Institutes of Health, 	1	Lung Cancer Progress Review Group, and this can
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	23	duction Act of 2009, the Secretary, in consultation with
25 fairs, the Director of the National Institutes of Health,	24	the Secretary of Defense, the Secretary of Veterans Af-
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the Director of the Centers for Disease Control and Pre-1 2 vention, the Commissioner of the Food and Drug Administration, the Administrator of the Centers for Medicare & 3 4 Medicaid Services, the Director of the National Center on 5 Minority Health and Health Disparities, and other members of the Lung Cancer Advisory Board established under 6 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—

"(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

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

cancer mortality reduction program under section
 1511.

3 "(4) With respect to the Agency for Healthcare
4 Research and Quality, the conduct of a biannual re5 view of lung cancer screening, diagnostic and treat6 ment protocols, and the issuance of updated guide7 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

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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

chemoprevention drugs for precancerous conditions of the
 lung, drugs for targeted therapeutic treatments and vac cines 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 to cer 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 prevention or treatment of lung cancer, including drugs, biologi-11 12 and devices for chemoprevention of cal products, 13 precancerous conditions of the lungs, vaccination against the development of lung cancer, and therapeutic treatment 14 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 sec19 tion.".

(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 infor mation 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.".

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-11GRAM.

"(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.

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.

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 CancerMortality Reduction Program under section 417E of

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

3 (2) in the implementation within the Depart4 ment of Defense and the Department of Veterans
5 Affairs of an early detection and disease manage6 ment research program for military personnel and
7 veterans whose smoking history and exposure to car8 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 diag12 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 Board (referred to in this section as the "Board") to mon-16 17 itor the programs established under this Act (and the amendments made by this Act), and provide annual re-18 19 ports to Congress concerning benchmarks, expenditures, 20 lung cancer statistics, and the public health impact of such 21 programs.

(b) COMPOSITION.—The Board shall be composedof—

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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