## 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

## 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 2008".
- 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.

- (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, not-withstanding 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.

- 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.
  - (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.

1	(14) The United States must enhance its re-
2	sponse to the issues raised in the Report of the
3	Lung Cancer Progress Review Group, and this can
4	be accomplished through the establishment of a co-
5	ordinated effort designed to reduce the lung cancer
6	mortality rate by 50 percent by 2015 and targeted
7	funding to support this coordinated effort.
8	SEC. 3. SENSE OF THE SENATE CONCERNING INVESTMENT
9	IN LUNG CANCER RESEARCH.
10	It is the sense of the Senate that—
11	(1) lung cancer mortality reduction should be
12	made a national public health priority; and
13	(2) a comprehensive mortality reduction pro-
14	gram coordinated by the Secretary of Health and
15	Human Service is justified and necessary to ade-
16	quately address and reduce lung cancer mortality.
17	SEC. 4. LUNG CANCER MORTALITY REDUCTION PROGRAM.
18	(a) In General.—Subpart 1 of part C of title IV
19	of the Public Health Service Act (42 U.S.C. 285 et seq.)
20	is amended by adding at the end the following:
21	"SEC. 417E. LUNG CANCER MORTALITY REDUCTION PRO-
22	GRAM.
23	"(a) In General.—Not later than 6 months after
24	the date of enactment of the Lung Cancer Mortality Re-
25	duction Act of 2008, the Secretary, in consultation with

1	the Secretary of Defense, the Secretary of Veterans Af-
2	fairs, the Director of the National Institutes of Health,
3	the Director of the Centers for Disease Control and Pre-
4	vention, the Administrator of the Food and Drug Adminis-
5	tration, the Director of the Centers for Medicare & Med-
6	icaid Services, the Director of the National Center on Mi-
7	nority Health and Health Disparities, and other members
8	of the Lung Cancer Advisory Board established under sec-
9	tion 6 of the Lung Cancer Mortality Reduction Act of
10	2008, shall implement a comprehensive program to
11	achieve a 50 percent reduction in the mortality rate of
12	lung cancer by 2015.
13	"(b) REQUIREMENTS.—The program implemented
14	under subsection (a) shall include at least the following:
15	"(1) With respect to the National Institutes of
16	Health—
17	"(A) a strategic review and prioritization
18	by the National Cancer Institute of research
19	grants to achieve the goal of the program in re-
20	ducing lung cancer mortality;
21	"(B) the provision of funds to enable the
22	Airway Biology and Disease Branch of the Na-
23	tional Heart, Lung and Blood Institute to ex-
24	pand its research programs to include pre-
25	dispositions to lung cancer, the interrelationship

1	between lung cancer and other pulmonary and
2	cardiac disease, and the diagnosis and treat-
3	ment of these interrelationships;
4	"(C) the provision of funds to enable the
5	National Institute of Biomedical Imaging and
6	Bioengineering to expand its Quantum Grant
7	Program and Image-Guided Interventions pro-
8	grams to expedite the development of computer
9	assisted diagnostic, surgical, treatment and
10	drug testing innovations to reduce lung cancer
11	mortality; and
12	"(D) the provision of funds to enable the
13	National Institute for Environmental Health
14	Sciences to implement research programs rel-
15	ative to lung cancer incidence.
16	"(2) With respect to the Food and Drug Ad-
17	ministration—
18	"(A) the establishment of a lung cancer
19	mortality reduction drug program under sub-
20	title G of chapter V of the Federal Food, Drug
21	and Cosmetic Act; and
22	"(B) compassionate access activities under
23	section 561 of the Federal Food, Drug, and
24	Cosmetic Act (21 U.S.C. 360bbb).

- 1 "(3) With respect to the Centers for Disease 2 Control and Prevention, the establishment of a lung 3 cancer mortality reduction program under section 4 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.
- 23 "(c) AUTHORIZATION OF APPROPRIATIONS.—There 24 is authorized to be appropriated to carry out this section—

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- 1 "(1) \$25,000,000 for fiscal year 2009 for the 2 activities described in subsection (b)(1)(B), and such 3 sums as may be necessary for each of fiscal years 4 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;
- 9 "(3) \$10,000,000 for fiscal year 2009 for the 10 activities described in subsection (b)(1)(D), and such 11 sums as may be necessary for each of fiscal years 12 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.".
- 17 (b) FOOD, DRUG, AND COSMETIC ACT.—Chapter V
  18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
  19 351 et seq.) is amended by adding at the end the fol-
- 20 lowing:

1	Subchapter G—Lung Cancer Mortanty
2	Reduction Programs
3	"SEC. 581. LUNG CANCER MORTALITY REDUCTION PRO-
4	GRAM.
5	"(a) In General.—The Secretary shall implement
6	a program to provide incentives of the type provided for
7	in subchapter B of this chapter for the development of
8	chemoprevention drugs for precancerous conditions of the
9	lung, drugs for targeted therapeutic treatments and vac-
10	cines for lung cancer, and new agents to curtail or prevent
11	nicotine addiction. The Secretary shall model the program
12	implemented under this section on the program provided
13	for under subchapter B of this chapter with respect cer-
14	tain drugs.
15	"(b) Application of Provisions.—The Secretary
16	shall apply the provisions of subchapter B of this chapter
17	to drugs, biological products, and devices for the preven-
18	tion or treatment of lung cancer, including drugs, biologi-
19	cal products, and devices for chemoprevention of
20	precancerous conditions of the lungs, vaccination against
21	the development of lung cancer and therapeutic treatment
22	for lung cancer.
23	"(c) Board established under section
24	6 of the Lung Cancer Mortality Reduction Act of 2008

- 1 shall monitor the program implemented under this sec-
- 2 tion.".
- 3 (c) Access to Unapproved Therapies.—Section
- 4 561(e) of the Federal Food, Drug, and Cosmetic Act (21
- 5 U.S.C. 360bbb(e)) is amended by inserting before the pe-
- 6 riod the following: "and shall include providing compas-
- 7 sionate access to drugs, biological products, and devices
- 8 under the program under section 581, with substantial
- 9 consideration being given to whether the totality of infor-
- 10 mation available to the Secretary regarding the safety and
- 11 effectiveness of an investigational drug, as compared to
- 12 the risk of morbidity and death from the disease, indicates
- 13 that a patient may obtain more benefit than risk if treated
- 14 with the drug, biological product, or device.".
- 15 (d) CDC.—Title XV of the Public Health Service Act
- 16 (42 U.S.C. 300k et seq.) is amended by adding at the end
- 17 the following:
- 18 "SEC. 1511. LUNG CANCER MORTALITY REDUCTION PRO-
- 19 GRAM.
- 20 "(a) In General.—The Secretary shall establish
- 21 and implement an early disease research and management
- 22 program targeted at the high incidence and mortality rates
- 23 among minority and low-income populations.

1	"(b) Authorization of Appropriations.—There
2	is authorized to be appropriated, such sums as may be
3	necessary to carry out this section.".
4	SEC. 5. DEPARTMENT OF DEFENSE AND THE DEPARTMENT
5	OF VETERANS AFFAIRS.
6	The Secretary of Defense and the Secretary of Vet-
7	erans Affairs shall coordinate with the Secretary of Health
8	and Human Services—
9	(1) in the development of the Lung Cancer
10	Mortality Reduction Program under section 417E;
11	(2) in the implementation within the Depart-
12	ment of Defense and the Department of Veterans
13	Affairs of an early detection and disease manage-
14	ment research program for military personnel and
15	veterans whose smoking history and exposure to car-
16	cinogens during active duty service has increased
17	their risk for lung cancer; and
18	(3) in the implementation of coordinated care
19	programs for military personnel and veterans diag-
20	nosed with lung cancer.
21	SEC. 6. LUNG CANCER ADVISORY BOARD.
22	(a) In General.—The Secretary of Health and
23	Human Services shall establish a Lung Cancer Advisory
24	Board (referred to in this section as the "Board") to mon-
25	itor the programs established under this Act (and the

- 1 amendments made by this Act), provide annual reports to
- 2 Congress concerning benchmarks, expenditures, lung can-
- 3 cer statistics, and the public health impact of such pro-
- 4 grams.
- 5 (b) Composition.—The Board shall be composed
- 6 of—
- 7 (1) the Secretary of Health and Human Serv-
- 8 ices;
- 9 (2) the Secretary of Defense;
- 10 (3) the Secretary of Veterans Affairs; and
- 11 (4) two representatives each from the fields of
- 12 clinical medicine focused on lung cancer, lung cancer
- 13 research, imaging, drug development, and lung can-
- cer advocacy, to be appointed by the Secretary of
- 15 Health and Human Services.
- 16 SEC. 7. AUTHORIZATION OF APPROPRIATIONS.
- 17 For the purpose of carrying out the programs under
- 18 this Act (and the amendments made by this Act), there
- 19 is authorized to be appropriated such sums as may be nec-
- 20 essary for each of fiscal years 2009 through 2013.

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