111TH CONGRESS
1ST SESSION

H. R. 2112

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 27, 2009

Mrs. CHRISTENSEN (for herself, Mr. LOBIONDO, Ms. LEE of California, Mr. MEEKS of New York, Ms. BORDALLO, Mr. PAYNE, Mr. RANGEL, Mr. BISHOP of Georgia, Mr. HINOJOSA, Ms. JACKSON-LEE of Texas, Ms. KILPATRICK of Michigan, and Mr. LANCE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services and Veterans' Affairs, 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 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:

1 (1) Lung cancer is the leading cause of cancer
2 death for both men and women, accounting for 28
3 percent of all cancer deaths.
4 (2) Lung cancer kills more people annually
5 than breast cancer, prostate cancer, colon cancer,
6 liver cancer, melanoma, and kidney cancer combined.
7 (3) Since the National Cancer Act of 1971
8 (Public Law 92–218; 85 Stat. 778), coordinated and
9 comprehensive research has raised the 5-year sur-
10 vival rates for breast cancer to 88 percent, for pros-
11 tate cancer to 99 percent, and for colon cancer to
12 64 percent.
13 (4) However, the 5-year survival rate for lung
14 cancer is still only 15 percent and a similar coordi-
15 nated and comprehensive research effort is required
16 to achieve increases in lung cancer survivability
17 rates.
18 (5) Sixty percent of lung cancer cases are now
19 diagnosed as nonsmokers or former smokers.
20 (6) Two-thirds of nonsmokers diagnosed with
21 lung cancer are women.
22 (7) Certain minority populations, such as Afri-
23 can-American males, have disproportionately high
24 rates of lung cancer incidence and mortality, not-
25 withstanding their similar smoking rate.

1 (8) Members of the baby boomer generation are
2 entering their sixties, the most common age at which
3 people develop lung cancer.
4 (9) Tobacco addiction and exposure to other
5 lung cancer carcinogens such as Agent Orange and
6 other herbicides and battlefield emissions are serious
7 problems among military personnel and war vet-
8 erans.
9 (10) Significant and rapid improvements in
10 lung cancer mortality can be expected through great-
11 er use and access to lung cancer screening tests for
12 at-risk individuals.
13 (11) Additional strategies are necessary to fur-
14 ther enhance the existing tests and therapies avail-
15 able to diagnose and treat lung cancer in the future.
16 (12) The August 2001 Report of the Lung
17 Cancer Progress Review Group of the National Can-
18 cer Institute stated that funding for lung cancer re-
19 search was ''far below the levels characterized for
20 other common malignancies and far out of propor-
21 tion to its massive health impact''.
22 (13) The Report of the Lung Cancer Progress
23 Review Group identified as its ''highest priority'' the
24 creation of integrated, multidisciplinary, multi-insti-
25 tutional 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 CONGRESS CONCERNING INVESTMENT IN LUNG CANCER RESEARCH.

It is the sense of the Congress 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 Services 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:

1 **"SEC. 417G. LUNG CANCER MORTALITY REDUCTION PRO-**
2 **GRAM.**

3 "(a) IN GENERAL.—Not later than 6 months after
4 the date of the enactment of this section, the Secretary,
5 in consultation with the Secretary of Defense, the Sec-
6 retary of Veterans Affairs, the Director of the National
7 Institutes of Health, the Director of the Centers for Dis-
8 ease Control and Prevention, the Commissioner of Food
9 and Drugs, the Administrator of the Centers for Medicare
10 & Medicaid Services, the Director of the National Center
11 on Minority Health and Health Disparities, and other
12 members of the Lung Cancer Advisory Board established
13 under section 6 of the Lung Cancer Mortality Reduction
14 Act of 2009, shall implement a comprehensive program,
15 to be known as the Lung Cancer Mortality Reduction Pro-
16 gram, to achieve a reduction of at least 25 percent in the
17 mortality rate of lung cancer by 2015.

18 "(b) REQUIREMENTS.—The Program shall include at
19 least the following:

20 "(1) With respect to the National Institutes of
21 Health—

22 "(A) a strategic review and prioritization
23 by the National Cancer Institute of research
24 grants to achieve the goal of the Lung Cancer
25 Mortality Reduction Program in reducing lung
26 cancer mortality;

1 "(B) the provision of funds to enable the
2 Airway Biology and Disease Branch of the Na-
3 tional Heart, Lung, and Blood Institute to ex-
4 pand its research programs to include pre-
5 dispositions to lung cancer, the interrelationship
6 between lung cancer and other pulmonary and
7 cardiac disease, and the diagnosis and treat-
8 ment of these interrelationships;
9 "(C) the provision of funds to enable the
10 National Institute of Biomedical Imaging and
11 Bioengineering to expedite the development of
12 computer assisted diagnostic, surgical, treat-
13 ment, and drug testing innovations to reduce
14 lung cancer mortality, such as through expan-
15 sion of the Institute's Quantum Grant Program
16 and Image-Guided Interventions programs; and
17 "(D) the provision of funds to enable the
18 National Institute of Environmental Health
19 Sciences to implement research programs rel-
20 ative to the lung cancer incidence.
21 "(2) With respect to the Food and Drug Ad-
22 ministration—
23 "(A) activities under section 529 of the
24 Federal Food, Drug, and Cosmetic Act; and

1 “(B) activities under section 561 of the
2 Federal Food, Drug, and Cosmetic Act to ex-
3 pand access to investigational drugs and devices
4 for the diagnosis, monitoring, or treatment of
5 lung cancer.

6 “(3) With respect to the Centers for Disease
7 Control and Prevention, the establishment of an
8 early disease research and management program
9 under section 1511.

10 “(4) With respect to the Agency for Healthcare
11 Research and Quality, the conduct of a biannual re-
12 view of lung cancer screening, diagnostic, and treat-
13 ment protocols, and the issuance of updated guide-
14 lines.

15 “(5) The cooperation and coordination of all
16 minority and health disparity programs within the
17 Department of Health and Human Services to en-
18 sure that all aspects of the Lung Cancer Mortality
19 Reduction Program under this section adequately
20 address the burden of lung cancer on minority and
21 rural populations.

22 “(6) The cooperation and coordination of all to-
23 bacco control and cessation programs within agen-
24 cies of the Department of Health and Human Serv-
25 ices to achieve the goals of the Lung Cancer Mor-

1 tality Reduction Program under this section with
2 particular emphasis on the coordination of drug and
3 other cessation treatments with early detection pro-
4 tocols.''.
5 (b) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
6 Subchapter B of chapter V of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 360aaa et seq.) is amended
8 by adding at the end the following:
9 ''DRUGS RELATING TO LUNG CANCER
10 ''SEC. 529. (a) IN GENERAL.—The provisions of this
11 subchapter shall apply to a drug described in subsection
12 (b) to the same extent and in the same manner as such
13 provisions apply to a drug for a rare disease or condition.
14 ''(b) QUALIFIED DRUGS.—A drug described in this
15 subsection is—
16 ''(1) a chemoprevention drug for precancerous
17 conditions of the lung;
18 ''(2) a drug for a targeted therapeutic treat-
19 ments, including any vaccine for, lung cancer; and
20 ''(3) a drug to curtail or prevent nicotine addic-
21 tion.
22 ''(c) BOARD.—The Board established under section
23 6 of the Lung Cancer Mortality Reduction Act of 2009
24 shall monitor the program implemented under this sec-
25 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 expanding access to drugs under section 529, 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''.

(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. EARLY DISEASE RESEARCH AND MANAGEMENT PROGRAM.

''The Secretary shall establish and implement an early disease research and management program targeted at the high incidence and mortality rates of lung cancer among minority and low-income populations.''.

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 (1) in the development of the Lung Cancer
2 Mortality Reduction Program under section 417G;
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 convene a Lung Cancer Advisory
16 Board (referred to in this section as the ''Board'')—
17 (1) to monitor the programs established under
18 this Act (and the amendments made by this Act);
19 and
20 (2) to provide annual reports to the Congress
21 concerning benchmarks, expenditures, lung cancer
22 statistics, and the public health impact of such pro-
23 grams.
24 (b) COMPOSITION.—The Board shall be composed
25 of—

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

10 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

11 (a) IN GENERAL.—To carry out this Act (and the
12 amendments made by this Act), there are authorized to
13 be appropriated such sums as may be necessary for each
14 of fiscal years 2010 through 2014.
15 (b) LUNG CANCER MORTALITY REDUCTION PRO-
16 GRAM.—Of the amounts authorized to be appropriated by
17 subsection (a), there are authorized to be appropriated—
18 (1) $25,000,000 for fiscal year 2010, and such
19 sums as may be necessary for each of fiscal years
20 2011 through 2014, for the activities described in
21 section 417G(b)(1)(B) of the Public Health Service
22 Act, as added by section 4(a);
23 (2) $25,000,000 for fiscal year 2010, and such
24 sums as may be necessary for each of fiscal years

1 2011 through 2014, for the activities described in
2 section 417G(b)(1)(C) of such Act;
3 (3) $10,000,000 for fiscal year 2010, and such
4 sums as may be necessary for each of fiscal years
5 2011 through 2014, for the activities described in
6 section 417G(b)(1)(D) of such Act; and
7 (4) $15,000,000 for fiscal year 2010, and such
8 sums as may be necessary for each of fiscal years
9 2011 through 2014, for the activities described in
10 section 417G(b)(3) of such Act.

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