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S. 3560

To provide for scientific frameworks with respect to recalcitrant cancers.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 19, 2012

Mr. WHITEHOUSE (for himself, Mr. LUGAR, Ms. MIKULSKI, Mr. GRASSLEY, Mr. AKAKA, Ms. COLLINS, Mr. REED, Mr. PRYOR, Ms. STABENOW, Mr. BROWN of Massachusetts, Mr. LAUTENBERG, Mr. BLUNT, Mr. BROWN of Ohio, Mr. RUBIO, Mr. BLUMENTHAL, Mr. WICKER, Mr. TESTER, and Mr. WARNER) 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 provide for scientific frameworks with respect to recalcitrant cancers.

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 ''Recalcitrant Cancer Research Act of 2012''.

SEC. 2. SCIENTIFIC FRAMEWORK FOR RECALCITRANT CANCERS.

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. SCIENTIFIC FRAMEWORK FOR RECALCITRANT CANCERS.

''(a) DEVELOPMENT OF SCIENTIFIC FRAMEWORK.—

''(1) IN GENERAL.—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall develop (in accordance with subsection (c)) a scientific framework for the conduct or support of research on such cancer.

''(2) CONTENTS.—The scientific framework with respect to a recalcitrant cancer shall include the following:

''(A) CURRENT STATUS.—

''(i) REVIEW OF LITERATURE.—A summary of findings from the current literature in the areas of—

''(I) the prevention, diagnosis, and treatment of such cancer;

''(II) the fundamental biologic processes that regulate such cancer (including similarities and differences of such processes from the biological

processes that regulate other cancers); and

"(III) the epidemiology of such cancer.

"(ii) SCIENTIFIC ADVANCES.—The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

"(iii) RESEARCHERS.—A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

"(iv) COORDINATED RESEARCH INITIATIVES.—The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

"(v) RESEARCH RESOURCES.—The identification of public and private re-

sources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

''(B) IDENTIFICATION OF RESEARCH QUESTIONS.—The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

''(C) RECOMMENDATIONS.—Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i) and to address the research questions identified in subparagraph (B), as well as for appropriate benchmarks to measure progress on achieving such actions, including the following:

''(i) RESEARCHERS.—Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

''(ii) COORDINATED RESEARCH INITIATIVES.—Promoting and developing ini-

tiatives and partnerships described in subparagraph (A)(iv).

''(iii) RESEARCH RESOURCES.—Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

''(3) TIMING.—

''(A) INITIAL DEVELOPMENT AND SUBSEQUENT UPDATE.—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

''(i) develop a scientific framework under this subsection not later than 18 months after the date of the enactment of this section; and

''(ii) review and update the scientific framework not later than 5 years after its initial development.

''(B) OTHER UPDATES.—The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

''(4) PUBLIC NOTICE.—With respect to each scientific framework developed under subsection (a), not later than 30 days after the date of completion

of the framework, the Director of the Institute shall—

''(A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate; and

''(B) make such framework publically available on the Internet website of the Department of Health and Human Services.

''(b) IDENTIFICATION OF RECALCITRANT CANCER.—

''(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this section, the Director of the Institute shall identify two or more recalcitrant cancers that each—

''(A) have a 5-year relative survival rate of less than 20 percent; and

''(B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

''(2) ADDITIONAL CANCERS.—The Director of the Institute may, at any time, identify other recalcitrant cancers for purposes of this section. In identifying a recalcitrant cancer pursuant to the previous

sentence, the Director may consider additional metrics of progress (such as incidence and mortality rates) against such type of cancer.

''(c) WORKING GROUPS.—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings of each such working group.

''(d) REPORTING.—

''(1) BIENNIAL REPORTS.—The Director of NIH shall ensure that each biennial report under section 403 includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

''(A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.

''(B) An assessment of the progress made in improving outcomes (including relative sur-

vival rates) for individuals diagnosed with such cancer.

''(C) An update on activities pertaining to such cancer under the authority of section 413(b)(7).

''(2) ADDITIONAL ONE-TIME REPORT FOR CERTAIN FRAMEWORKS.—For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, detection, diagnosis, and treatment of such cancer.

''(e) RECOMMENDATIONS FOR EXCEPTION FUNDING.—The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

''(f) DEFINITION.—In this section, the term 'recalcitrant cancer' means a cancer for which the five-year relative survival rate is below 50 percent.''.

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