

112TH CONGRESS  
2D SESSION

# S. 3560

To provide for scientific frameworks with respect to recalcitrant cancers.

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## 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.

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 “Recalcitrant Cancer  
5       Research Act of 2012”.

1 **SEC. 2. SCIENTIFIC FRAMEWORK FOR RECALCITRANT CAN-**  
 2 **CERS.**

3 Subpart 1 of part C of title IV of the Public Health  
 4 Service Act (42 U.S.C. 285 et seq.) is amended by adding  
 5 at the end the following:

6 **“SEC. 417G. SCIENTIFIC FRAMEWORK FOR RECALCITRANT**  
 7 **CANCERS.**

8 “(a) DEVELOPMENT OF SCIENTIFIC FRAMEWORK.—

9 “(1) IN GENERAL.—For each recalcitrant can-  
 10 cer identified under subsection (b), the Director of  
 11 the Institute shall develop (in accordance with sub-  
 12 section (c)) a scientific framework for the conduct or  
 13 support of research on such cancer.

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

17 “(A) CURRENT STATUS.—

18 “(i) REVIEW OF LITERATURE.—A  
 19 summary of findings from the current lit-  
 20 erature in the areas of—

21 “(I) the prevention, diagnosis,  
 22 and treatment of such cancer;

23 “(II) the fundamental biologic  
 24 processes that regulate such cancer  
 25 (including similarities and differences  
 26 of such processes from the biological

1 processes that regulate other cancers);  
2 and

3 “(III) the epidemiology of such  
4 cancer.

5 “(ii) SCIENTIFIC ADVANCES.—The  
6 identification of relevant emerging sci-  
7 entific areas and promising scientific ad-  
8 vances in basic, translational, and clinical  
9 science relating to the areas described in  
10 subclauses (I) and (II) of clause (i).

11 “(iii) RESEARCHERS.—A description  
12 of the availability of qualified individuals  
13 to conduct scientific research in the areas  
14 described in clause (i).

15 “(iv) COORDINATED RESEARCH INI-  
16 TIATIVES.—The identification of the types  
17 of initiatives and partnerships for the co-  
18 ordination of intramural and extramural  
19 research of the Institute in the areas de-  
20 scribed in clause (i) with research of the  
21 relevant national research institutes, Fed-  
22 eral agencies, and non-Federal public and  
23 private entities in such areas.

24 “(v) RESEARCH RESOURCES.—The  
25 identification of public and private re-

1 sources, such as patient registries and tis-  
2 sue banks, that are available to facilitate  
3 research relating to each of the areas de-  
4 scribed in clause (i).

5 “(B) IDENTIFICATION OF RESEARCH  
6 QUESTIONS.—The identification of research  
7 questions relating to basic, translational, and  
8 clinical science in the areas described in sub-  
9 clauses (I) and (II) of subparagraph (A)(i) that  
10 have not been adequately addressed with re-  
11 spect to such recalcitrant cancer.

12 “(C) RECOMMENDATIONS.—Recommendations  
13 for appropriate actions that should be  
14 taken to advance research in the areas de-  
15 scribed in subparagraph (A)(i) and to address  
16 the research questions identified in subpara-  
17 graph (B), as well as for appropriate bench-  
18 marks to measure progress on achieving such  
19 actions, including the following:

20 “(i) RESEARCHERS.—Ensuring ade-  
21 quate availability of qualified individuals  
22 described in subparagraph (A)(iii).

23 “(ii) COORDINATED RESEARCH INI-  
24 TIATIVES.—Promoting and developing ini-

1           tiatives and partnerships described in sub-  
2           paragraph (A)(iv).

3           “(iii) RESEARCH RESOURCES.—Devel-  
4           oping additional public and private re-  
5           sources described in subparagraph (A)(v)  
6           and strengthening existing resources.

7           “(3) TIMING.—

8           “(A) INITIAL DEVELOPMENT AND SUBSE-  
9           QUENT UPDATE.—For each recalcitrant cancer  
10          identified under subsection (b)(1), the Director  
11          of the Institute shall—

12               “(i) develop a scientific framework  
13               under this subsection not later than 18  
14               months after the date of the enactment of  
15               this section; and

16               “(ii) review and update the scientific  
17               framework not later than 5 years after its  
18               initial development.

19           “(B) OTHER UPDATES.—The Director of  
20          the Institute may review and update each sci-  
21          entific framework developed under this sub-  
22          section as necessary.

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

1 of the framework, the Director of the Institute  
2 shall—

3 “(A) submit such framework to the Com-  
4 mittee on Energy and Commerce and Com-  
5 mittee on Appropriations of the House of Rep-  
6 resentatives, and the Committee on Health,  
7 Education, Labor, and Pensions and Committee  
8 on Appropriations of the Senate; and

9 “(B) make such framework publically  
10 available on the Internet website of the Depart-  
11 ment of Health and Human Services.

12 “(b) IDENTIFICATION OF RECALCITRANT CANCER.—

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

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

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

22 “(2) ADDITIONAL CANCERS.—The Director of  
23 the Institute may, at any time, identify other recal-  
24 citrant cancers for purposes of this section. In iden-  
25 tifying a recalcitrant cancer pursuant to the previous

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

4 “(c) WORKING GROUPS.—For each recalcitrant can-  
5 cer identified under subsection (b), the Director of the In-  
6 stitute shall convene a working group comprised of rep-  
7 resentatives of appropriate Federal agencies and other  
8 non-Federal entities to provide expertise on, and assist in  
9 developing, a scientific framework under subsection (a).  
10 The Director of the Institute (or the Director’s designee)  
11 shall participate in the meetings of each such working  
12 group.

13 “(d) REPORTING.—

14 “(1) BIENNIAL REPORTS.—The Director of  
15 NIH shall ensure that each biennial report under  
16 section 403 includes information on actions under-  
17 taken to carry out each scientific framework devel-  
18 oped under subsection (a) with respect to a recal-  
19 citrant cancer, including the following:

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

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

1           vival rates) for individuals diagnosed with such  
2           cancer.

3           “(C) An update on activities pertaining to  
4           such cancer under the authority of section  
5           413(b)(7).

6           “(2) ADDITIONAL ONE-TIME REPORT FOR CER-  
7           TAIN FRAMEWORKS.—For each recalcitrant cancer  
8           identified under subsection (b)(1), the Director of  
9           the Institute shall, not later than 6 years after the  
10          initial development of a scientific framework under  
11          subsection (a), submit a report to the Congress on  
12          the effectiveness of the framework (including the up-  
13          date required by subsection (a)(3)(A)(ii)) in improv-  
14          ing the prevention, detection, diagnosis, and treat-  
15          ment of such cancer.

16          “(e) RECOMMENDATIONS FOR EXCEPTION FUND-  
17          ING.—The Director of the Institute shall consider each  
18          relevant scientific framework developed under subsection  
19          (a) when making recommendations for exception funding  
20          for grant applications.

21          “(f) DEFINITION.—In this section, the term ‘recal-  
22          citrant cancer’ means a cancer for which the five-year rel-  
23          ative survival rate is below 50 percent.”.

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