

112TH CONGRESS
2D SESSION

H. R. 733

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2012

Received

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Recalcitrant Cancer
3 Research Act of 2012”.

4 **SEC. 2. SCIENTIFIC FRAMEWORK FOR RECALCITRANT CAN-**
5 **CERS.**

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

9 **“SEC. 417G. SCIENTIFIC FRAMEWORK FOR RECALCITRANT**
10 **CANCERS.**

11 “(a) DEVELOPMENT OF SCIENTIFIC FRAMEWORK.—

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

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

20 “(A) CURRENT STATUS.—

21 “(i) REVIEW OF LITERATURE.—A
22 summary of findings from the current lit-
23 erature in the areas of—

24 “(I) the prevention, diagnosis,
25 and treatment of such cancer;

1 “(II) the fundamental biologic
2 processes that regulate such cancer
3 (including similarities and differences
4 of such processes from the biological
5 processes that regulate other cancers);
6 and

7 “(III) the epidemiology of such
8 cancer.

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

15 “(iii) RESEARCHERS.—A description
16 of the availability of qualified individuals
17 to conduct scientific research in the areas
18 described in clause (i).

19 “(iv) COORDINATED RESEARCH INI-
20 TIATIVES.—The identification of the types
21 of initiatives and partnerships for the co-
22 ordination of intramural and extramural
23 research of the Institute in the areas de-
24 scribed in clause (i) with research of the
25 relevant national research institutes, Fed-

1 eral agencies, and non-Federal public and
2 private entities in such areas.

3 “(v) RESEARCH RESOURCES.—The
4 identification of public and private re-
5 sources, such as patient registries and tis-
6 sue banks, that are available to facilitate
7 research relating to each of the areas de-
8 scribed in clause (i).

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

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

1 “(i) RESEARCHERS.—Ensuring ade-
2 quate availability of qualified individuals
3 described in subparagraph (A)(iii).

4 “(ii) COORDINATED RESEARCH INI-
5 TIATIVES.—Promoting and developing ini-
6 tiatives and partnerships described in sub-
7 paragraph (A)(iv).

8 “(iii) RESEARCH RESOURCES.—Devel-
9 oping additional public and private re-
10 sources described in subparagraph (A)(v)
11 and strengthening existing resources.

12 “(3) TIMING.—

13 “(A) INITIAL DEVELOPMENT AND SUBSE-
14 QUENT UPDATE.—For each recalcitrant cancer
15 identified under subsection (b)(1), the Director
16 of the Institute shall—

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

21 “(ii) review and update the scientific
22 framework not later than 5 years after its
23 initial development.

24 “(B) OTHER UPDATES.—The Director of
25 the Institute may review and update each sci-

1 entific framework developed under this sub-
2 section as necessary.

3 “(4) PUBLIC NOTICE.—With respect to each
4 scientific framework developed under subsection (a),
5 not later than 30 days after the date of completion
6 of the framework, the Director of the Institute
7 shall—

8 “(A) submit such framework to the Com-
9 mittee on Energy and Commerce and Com-
10 mittee on Appropriations of the House of Rep-
11 resentatives, and the Committee on Health,
12 Education, Labor, and Pensions and Committee
13 on Appropriations of the Senate; and

14 “(B) make such framework publically
15 available on the Internet website of the Depart-
16 ment of Health and Human Services.

17 “(b) IDENTIFICATION OF RECALCITRANT CANCER.—

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

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

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

4 “(2) ADDITIONAL CANCERS.—The Director of
5 the Institute may, at any time, identify other recal-
6 citrant cancers for purposes of this section. In iden-
7 tifying a recalcitrant cancer pursuant to the previous
8 sentence, the Director may consider additional
9 metrics of progress (such as incidence and mortality
10 rates) against such type of cancer.

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

20 “(d) REPORTING.—

21 “(1) BIENNIAL REPORTS.—The Director of
22 NIH shall ensure that each biennial report under
23 section 403 includes information on actions under-
24 taken to carry out each scientific framework devel-

1 oped under subsection (a) with respect to a recal-
2 citrant cancer, including the following:

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

6 “(B) An assessment of the progress made
7 in improving outcomes (including relative sur-
8 vival rates) for individuals diagnosed with such
9 cancer.

10 “(C) An update on activities pertaining to
11 such cancer under the authority of section
12 413(b)(7).

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

23 “(e) RECOMMENDATIONS FOR EXCEPTION FUND-
24 ING.—The Director of the Institute shall consider each
25 relevant scientific framework developed under subsection

1 (a) when making recommendations for exception funding
2 for grant applications.

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

Passed the House of Representatives September 19,
2012.

Attest:

KAREN L. HAAS,
Clerk.