

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 733
OFFERED BY MR. LANCE OF NEW JERSEY**

Strike all after the enacting clause and insert the following:

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.

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

4 “(A) CURRENT STATUS.—

5 “(i) REVIEW OF LITERATURE.—A
6 summary of findings from the current lit-
7 erature in the areas of—

8 “(I) the prevention, diagnosis,
9 and treatment of such cancer;

10 “(II) the fundamental biologic
11 processes that regulate such cancer
12 (including similarities and differences
13 of such processes from the biological
14 processes that regulate other cancers);
15 and

16 “(III) the epidemiology of such
17 cancer.

18 “(ii) SCIENTIFIC ADVANCES.—The
19 identification of relevant emerging sci-
20 entific areas and promising scientific ad-
21 vances in basic, translational, and clinical
22 science relating to the areas described in
23 subclauses (I) and (II) of clause (i).

24 “(iii) RESEARCHERS.—A description
25 of the availability of qualified individuals

1 to conduct scientific research in the areas
2 described in clause (i).

3 “(iv) COORDINATED RESEARCH INI-
4 TIATIVES.—The identification of the types
5 of initiatives and partnerships for the co-
6 ordination of intramural and extramural
7 research of the Institute in the areas de-
8 scribed in clause (i) with research of the
9 relevant national research institutes, Fed-
10 eral agencies, and non-Federal public and
11 private entities in such areas.

12 “(v) RESEARCH RESOURCES.—The
13 identification of public and private re-
14 sources, such as patient registries and tis-
15 sue banks, that are available to facilitate
16 research relating to each of the areas de-
17 scribed in clause (i).

18 “(B) IDENTIFICATION OF RESEARCH
19 QUESTIONS.—The identification of research
20 questions relating to basic, translational, and
21 clinical science in the areas described in sub-
22 clauses (I) and (II) of subparagraph (A)(i) that
23 have not been adequately addressed with re-
24 spect to such recalcitrant cancer.

1 “(C) RECOMMENDATIONS.—Recommendations for appropriate actions that should be
2 taken to advance research in the areas described in subparagraph (A)(i) and to address
3 the research questions identified in subparagraph (B), including the following:

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

6 “(ii) COORDINATED RESEARCH INITIATIVES.—Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

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

8 “(3) TIMING.—

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

10 “(i) develop a scientific framework under this subsection not later than 18

1 months after the date of the enactment of
2 this section; and

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

6 “(B) OTHER UPDATES.—The Director of
7 the Institute may review and update each sci-
8 entific framework developed under this sub-
9 section as necessary.

10 “(b) IDENTIFICATION OF RECALCITRANT CANCER.—

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

15 “(A) have a 5-year relative survival rate of
16 less than 10 percent; and

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

20 “(2) ADDITIONAL CANCERS.—The Director of
21 the Institute may, at any time, identify other recal-
22 citrant cancers for purposes of this section.

23 “(c) WORKING GROUPS.—For each recalcitrant can-
24 cer identified under subsection (b), the Director of the In-
25 stitute shall convene a working group comprised of rep-

1 representatives of appropriate Federal agencies and other
2 non-Federal entities to provide expertise on, and assist in
3 developing, a scientific framework under subsection (a).
4 The Director of the Institute (or the Director's designee)
5 shall participate in the meetings of each such working
6 group.

7 “(d) REPORTING.—

8 “(1) BIENNIAL REPORTS.—The Director of
9 NIH shall ensure that each biennial report under
10 section 403 includes information on actions under-
11 taken to carry out each scientific framework devel-
12 oped under subsection (a) with respect to a recal-
13 citrant cancer, including the following:

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

17 “(B) An assessment of the progress made
18 in improving outcomes (including relative sur-
19 vival rates) for individuals diagnosed with such
20 cancer.

21 “(C) An update on activities pertaining to
22 such cancer under the authority of section
23 413(b)(7).

24 “(2) ADDITIONAL ONE-TIME REPORT FOR CER-
25 TAIN FRAMEWORKS.—For each recalcitrant cancer

1 identified under subsection (b)(1), the Director of
2 the Institute shall, not later than 6 years after the
3 initial development of a scientific framework under
4 subsection (a), submit a report to the Congress on
5 the effectiveness of the framework (including the up-
6 date required by subsection (a)(3)(A)(ii)) in improv-
7 ing the prevention, diagnosis, and treatment of such
8 cancer.

9 “(e) RECOMMENDATIONS FOR EXCEPTION FUND-
10 ING.—The Director of the Institute shall consider each
11 relevant scientific framework developed under subsection
12 (a) when making recommendations for exception funding
13 for grant applications.

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

Amend the title to read as follows: “A bill to provide
for scientific frameworks with respect to recalcitrant can-
cers.”

