(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in scientific peer review process.

(ii) 6 members shall be appointed from members of the general public, who represent individuals with breast cancer.

(C) Nonvoting members

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(5) Chairperson

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH. (6) Meetings

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(b) Review

The Secretary shall review the necessity of the Committee in calendar year 2011 and, thereafter, at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §417F, as added Pub. L. 110-354, §2(a), Oct. 8, 2008, 122 Stat. 3984.)

§285a-13. 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 follow-ing:

(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 resources, 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 initiatives 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 January 2, 2013; 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 publically¹ 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 January 2, 2013, 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 283 of this title 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 survival rates) for individuals diagnosed with such cancer.

(C) An update on activities pertaining to such cancer under the authority of section 285a-2(b)(7) of this title.

(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.

(July 1, 1944, ch. 373, title IV, §417G, as added Pub. L. 112-239, div. A, title X, §1083, Jan. 2, 2013, 126 Stat. 1960.)

SUBPART 2—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

§285b. Purpose of Institute

The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

(July 1, 1944, ch. 373, title IV, §418, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 836.)

§285b-1. Heart, blood vessel, lung, and blood disease prevention and control programs

(a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a) of this section, the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.

(July 1, 1944, ch. 373, title IV, §419, as added Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 836; amended Pub. L. 103-43, title V, §505, June 10, 1993, 107 Stat. 160.)

Amendments

1993—Pub. L. 103–43 substituted subsecs. (a) and (b) for former section which read as follows: "The Director

¹So in original. Probably should be "publicly".