

BREAST CANCER AND ENVIRONMENTAL RESEARCH ACT OF 2008

SEPTEMBER 25, 2008.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1157]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1157) to amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Breast Cancer and Environmental Research Act of 2008”.

SEC. 2. EXPANDING COLLABORATIVE RESEARCH ON BREAST CANCER AND THE ENVIRONMENT.

(a) IN GENERAL.—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. 417F. INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.

“(a) INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.—

“(1) ESTABLISHMENT.—Not later than 6 months after the date of the enactment of this section, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the ‘Committee’).

“(2) DUTIES.—The Committee shall—

“(A) share and coordinate information on existing research activities, and make recommendations to the National Institutes of Health and other Federal agencies regarding how to improve existing research programs, that are related to breast cancer research;

“(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

“(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

“(ii) outline key research questions, methodologies, and knowledge gaps;

“(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 402(b)(7) to improve the research portfolio; and

“(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

“(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

“(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

“(i) regarding any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

“(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

“(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

“(iv) on how best to disseminate information on breast cancer research progress; and

“(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

“(3) RULE OF CONSTRUCTION.—For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appro-

appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

“(4) MEMBERSHIP.—

“(A) IN GENERAL.—The Committee shall be composed of the following voting members:

“(i) Not more than 7 voting Federal representatives as follows:

“(I) The Director of the Centers for Disease Control and Prevention.

“(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

“(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

“(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

“(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

“(ii) 12 additional voting members appointed under subparagraph

(B).

“(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

“(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.”.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out research activities under title IV of the Public Health Service Act, including section 417F of such Act as added by subsection (a), there are authorized to be appropriated \$40,000,000 for each of fiscal years 2009 through 2012. Amounts authorized to be appropriated under the preceding sentence shall be in addition to amounts otherwise authorized to be appropriated for such purpose under section 402A of the Public Health Service Act (42 U.S.C. 282a).

PURPOSE AND SUMMARY

The purpose of H.R. 1157, the Breast Cancer and Environmental Research Act of 2007, is to amend the Public Health Service Act to authorize the Secretary of Health and Human Services to establish an Interagency Breast Cancer and Environmental Research Coordinating Committee.

BACKGROUND AND NEED FOR LEGISLATION

Breast cancer is the second most common type of cancer among women in the United States. In the United States, a woman's lifetime risk of breast cancer increased steadily and dramatically over

the course of the 20th century. Between 1973 and 1998, breast cancer incidence rates in the United States increased by more than 40 percent. Today, a woman's lifetime risk of breast cancer is one in eight. In 2008, the National Cancer Institute (NCI) estimates that 182,460 women and 1,990 men will be diagnosed with breast cancer and 40,480 women and 450 men will die as a result of breast cancer.

One of the hopeful messages from cancer research generally is that many cases of cancer are linked to environmental causes and, in principle, can be prevented. Cancer develops over several years and has many causes. Numerous factors both inside and outside the body contribute to the development of cancer. In this context, scientists refer to everything outside the body that interacts with humans as the "environment." Exposure to a wide variety of natural and man-made substances in the environment accounts for at least two-thirds of all the cases of cancer in the United States. These environmental factors include lifestyle choices such as cigarette smoking, excessive alcohol consumption, poor diet, lack of exercise, and excessive sunlight exposure. Other factors include exposure to certain medical drugs, hormones, radiation, viruses, bacteria, and environmental chemicals that may be present in the air, water, food, and workplace.

Environmental factors such as viruses, sunlight, and chemicals interact with cells throughout our lives. Mechanisms to repair damage to our genes and healthy lifestyle choices (wearing protective clothing for sun exposure or not smoking) help to protect us from harmful exposures. Over time, however, substances in the environment may cause gene alterations, which accumulate inside our cells. While many alterations have no effect on a person's health, permanent changes in certain genes can lead to cancer. The chance that an individual will develop cancer in response to a particular environmental agent depends on several interacting factors: how long and how often a person is exposed to a particular substance, his/her exposure to other agents, genetic factors, diet, lifestyle, health, age, and gender.

Because of the complex interplay of many factors and the lack of conclusive evidence about the links between cancer and environmental factors, it is not currently possible to predict whether a specific environmental exposure will cause a particular person to develop cancer. It is known that certain genetic and environmental factors increase the risk of developing cancer, but it is not known exactly which combination of factors is responsible for a person's specific cancer.

With respect to environmental effects on breast cancer, research has varied widely. Some studies have linked alcohol consumption to an increased risk of the most common type of breast cancer. Other studies have suggested that infants exposed to butyl benzyl phthalate (BBP), a chemical additive used in pipes, vinyl floor tiles, carpet-backing, and other household items may affect mammary gland development and perhaps increase the susceptibility to breast cancer. Researchers have also found that bisphenol A, a chemical found in some plastic food and drink packaging, including baby bottles, may be tied to early puberty and prostate and breast cancer. Other research has shown that hormone replacement therapy may increase breast cancer risk. Breast cancer is a complex

disease that occurs in an environmentally complex world. While it is generally believed that environmental factors play some role in the development of breast cancer, the full extent of that role is not yet understood.

In addition to studying environmental impacts, the recently completed Human Genome Project is providing an entirely new avenue of research opportunities to better understand why some women are more likely to develop breast cancer than others. Understanding the relevance of genetic markers and potential predisposition to developing breast cancer are also critically important areas of cancer research that need to be further explored. The Cancer Genome Atlas project is one of several genomic research programs that could help to identify how environmental factors may or may not impact the development of breast cancer.

Currently, there are several sources of Federal funding for research on the links between breast cancer and the environment. The National Institute of Environmental Health Sciences (NIEHS) and NCI have partnered to support a network of research centers in which multidisciplinary teams of scientists, clinicians, and breast cancer advocates work collaboratively on a unique set of scientific questions. The focus is on the interaction of chemical, physical, biological, and social factors in the environment with genetic factors to cause breast cancer. The network is working towards integrating histologic, pathologic, cellular, and sub-cellular changes that occur in normal mammary gland tissue across the lifespan along with comparisons to exposure-induced changes. The seven-year study began in September 2003 with a \$5 million per year budget.

In addition, the Department of Defense (DOD) has a federally-funded Breast Cancer Research Program (BCRP). Since its inception in 1992, the BCRP has funded research targeted toward the program's vision to eradicate breast cancer. Recognizing that the war against breast cancer must be fought on multiple fronts, the DOD BCRP developed a multidisciplinary research portfolio that encompasses a wide spectrum of prevention, detection, diagnosis, and treatment research projects. The BCRP specifically avoids duplication of research funded by other Federal agencies. Research awards are made using a two-tier review process composed of peer and programmatic review. An important element in the BCRP is its partnership with scientists and consumers, who participate during both levels of review. Peer review evaluates the scientific merit of the research proposals, and programmatic review determines the relevance of proposals to the BCRP vision and goals. The Integration Panel, comprised of scientists and consumers, makes final funding recommendations and provides guidance on the BCRP's investment strategies. The program's initial success encouraged Congress to appropriate additional funds to the BCRP in subsequent years, totaling \$1.96 billion through FY 2006. These funds have supported 4,894 awards.

HEARINGS

The Subcommittee on Health held a legislative hearing in connection with the bill reported by the Committee. This hearing was held on May 21, 2008, and was entitled "H.R. 1157, Breast Cancer

and Environmental Research Act of 2007, and H.R. 758, Breast Cancer Patient Protection Act of 2007.”

The Subcommittee on Health heard the testimony of three panels. The witnesses on the first panel were: Deborah Winn, Ph.D., Director, Epidemiology and Genetics Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health.

The witnesses on the second panel were: Ms. Fran Visco, President, National Breast Cancer Coalition; Ms. Sheryl Crow, Singer-Songwriter and breast cancer advocate; and H. Kim Lyerly, M.D., Director and George Barth Geller Professor of Research in Cancer, Duke Comprehensive Cancer Center, Duke University Medical Center.

The witnesses on the third panel were: Kristen Zarfes, M.D., F.A.C.S., St. Francis Hospital, Hartford, CT; and Ms. Alva Williams.

COMMITTEE CONSIDERATION

On Tuesday, September 23, 2008, the full Committee met in open markup session and ordered H.R. 1157 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. No record votes were taken on amendments or in connection with ordering H.R. 1157 reported to the House. A motion by Mr. Dingell to order H.R. 1157 favorably reported to the House, amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Subcommittee on Health held a legislative hearing on H.R. 1157, and the oversight findings of the Committee regarding the bill are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 1157 is to amend the Public Health Service Act to require the Secretary of HHS to establish an Interagency Breast Cancer and Environmental Research Coordinating Committee and to authorize \$40,000,000 for each of fiscal years 2009 through 2012 for the purpose of carrying out research activities under title IV of the Public Health Service Act, including provisions added by this legislation.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1157 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1157 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 1157 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Regarding clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, a cost estimate on H.R. 1157 by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available at the time of the filing of this report.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 1157 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 1157.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 1157 is provided in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 1157 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the bill as the Breast Cancer and Environmental Research Act of 2008.

Section 2. Expanding collaborative research on breast cancer and the environment

Section 2 amends subpart 1 of part C of title IV of the Public Health Service Act (PHSA) to add a new section which requires the Secretary of HHS to establish a committee, to be known as the

Interagency Breast Cancer and Environmental Research Coordinating Committee.

Section 2 sets forth requirements for the composition of the Coordinating Committee and directs that the Coordinating Committee shall be composed of voting and nonvoting members. The voting members of the Coordinating Committee shall select a chairperson from among the members, subject to the approval of the Director of NIH. The Coordinating Committee is required to meet at the call of the chairperson or upon the request of the Director of NIH, but at least once annually.

Section 2 establishes the duties of the Coordinating Committee to include sharing and coordinating information on existing research activities, and making recommendations to NIH and other Federal agencies regarding how to improve existing research programs that are related to breast cancer research. Another required duty of the Coordinating Committee is to develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders.

In addition, section 2 directs the Coordinating Committee to develop a comprehensive strategy and advise NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research. Such research shall focus on proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would: (1) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio; (2) outline key research questions, methodologies, and knowledge gaps; (3) expand the number of research proposals that involve collaboration between two or more national research institutes or centers, including proposals for Common Fund research to improve the research portfolio; and (4) expand the number of collaborative, multidisciplinary, and multi-institutional research grants.

Section 2 also requires that the Coordinating Committee make recommendations to the Secretary regarding any appropriate changes to research activities, including recommendations on how to improve the research portfolio of NIH to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer and environmental research activities. The Coordinating Committee must also make recommendations to the Secretary regarding public participation in decisions relating to breast cancer and environmental research to increase the involvement of patient advocacy and community organizations representing a broad geographical area.

In addition, the Coordinating Committee must make recommendations on how: (1) to ensure that NIH and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort; (2) to disseminate information on progress related to breast cancer and environmental research; and (3) to expand partnerships between public and private entities to expand collaborative, cross-cutting research, particularly related to the study of breast cancer and the environment. All recommendations required by this section must be made to the Secretary not later than two years after the establishment of the Coordinating Committee.

Section 2 provides that, for the purposes of the Coordinating Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this legislation shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

The Committee believes that this clarification is necessary because of the complex interplay in the field of cancer research and science. While the focus of the Coordinating Committee is intended to be on breast cancer and environmental research, the Committee recognizes that oftentimes knowledge and advances in one field of cancer research can have important implications and relevance to other fields of cancer research. For example, scientists using a three-dimensional cell culture system have identified a mechanism by which dormant, metastatic tumor cells can begin growing again after long periods of inactivity. The new findings indicate that the switch from dormancy to proliferative, metastatic growth may be regulated, in part, through signaling from the surrounding micro-environment, which leads to changes in the skeletal architecture of dormant tumor cells. Targeting this mechanism may also provide strategies for inhibiting the switch from dormancy to proliferation. The results of this study by NCI scientists and their collaborators, appeared in the August 1, 2008, issue of "Cancer Research" and has broad implications for all forms of cancer research.

This discovery was not born out of research focused specifically on breast cancer and the environment, but rather it was born out of basic science research focused on understanding how tumors grow. This type of research, though not explicitly focused on breast cancer and the environment, does have a direct impact on the understanding of the etiology of breast cancer. An NIH press release stated, "The recurrence of breast cancer often follows a long latent period in which there are no signs of cancer, and metastases may not become clinically apparent until many years after removal of the primary tumor and follow-up therapy. According to NCI's Jeffrey E. Green, M.D., one of the lead researchers of this study, "Recent evidence suggests that, in many cases, tumor cells have already seeded metastatic sites even when the primary tumor is diagnosed at an early stage." Approximately 30 percent of breast cancer patients diagnosed with early-stage disease have been found to have breast cancer cells in their bone marrow. However, these cells seem to exist primarily as micrometastases that do not manifest themselves clinically in any way."

Another example of how knowledge and advances in one field of cancer research can have important implications and relevance to other fields of cancer research, such as breast cancer, pertains to cancer stem cells. Many cancer researchers believe that the most promising frontier is in the area of cancer stem cells. The hypothesis is that cancers grow from cancer stem cells. When a stem cell divides, it produces two unequal cells—one stem cell, and one that multiplies into cells that are required by its organ. Most cancer therapies target all cells in a tumor as the same, and the function and origin of these cancer stem cells is not fully understood. A researcher studying AML (leukemia) was one of the first to advance this theory. The theory was then tested in breast cancer cells—and

brain, prostate, colon, pancreas, and ovary cells. These stem cell studies might not naturally fall under a heading of breast cancer research, but clearly could be critical to understanding how and why tumor cells multiply.

Because of examples like these, it is the Committee's view that, while the focus of the Coordinating Committee is breast cancer and environmental research, this should not be interpreted in a way that would preclude the Committee from taking into account the important role of basic science research in advancing environmental and genomic research that may be related to the etiology of breast cancer.

Beginning in calendar year 2011, section 2 requires the Secretary of HHS to review the necessity of the Committee at least once every two years.

Finally, section 2 authorizes \$40 million to be appropriated for each of fiscal years 2009 through 2012, for purposes of carrying out research activities under title IV of the PHSA, including provisions added by this legislation. This is intended to be in addition to amounts otherwise authorized to be appropriated for title IV of the PHSA.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE IV—NATIONAL RESEARCH INSTITUTES

* * * * *

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Subpart 1—National Cancer Institute

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SEC. 417F. INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.

(a) *INTERAGENCY BREAST CANCER AND ENVIRONMENTAL RESEARCH COORDINATING COMMITTEE.*—

(1) *ESTABLISHMENT.*—*Not later than 6 months after the date of the enactment of this section, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the 'Committee').*

(2) *DUTIES.*—*The Committee shall—*

(A) *share and coordinate information on existing research activities, and make recommendations to the National Institutes of Health and other Federal agencies regarding*

how to improve existing research programs, that are related to breast cancer research;

(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 402(b)(7) to improve the research portfolio; and

(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

(i) regarding any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

(iv) on how best to disseminate information on breast cancer research progress; and

(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

(3) RULE OF CONSTRUCTION.—For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

(4) MEMBERSHIP.—

(A) *IN GENERAL.*—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) *ADDITIONAL MEMBERS.*—The Committee shall include additional voting members appointed by the Secretary as follows:

(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.

* * * * *

