

111th Congress

1st Session

A DRAFT BILL

To strengthen and intensify the federal effort to develop better treatments for brain tumors and to improve the quality of care for brain tumor patients.

Section 1. Short Title.

This Act may be cited as the **Brain Tumor Care and Cures Act of 2009**.

Section 2. Findings.

Congress makes the following findings:

- (1) More than 50,000 cases of primary malignant and non-malignant brain and central nervous system tumors will be diagnosed in 2009.
- (2) Of the total number of primary brain tumors diagnosed, more than 20,000 are malignant.
- (3) Worldwide, more than 185,000 primary brain tumors will be diagnosed in 2009.
- (4) More than 3,750 children in the United States will be diagnosed with a primary brain tumor in 2009; this total includes more than 2800 tumors in children under the age of 15 years.
- (5) Brain tumors are the second most common childhood cancer and account for 25% of all pediatric cancer cases.
- (6) Childhood brain tumors are the leading cause of solid tumor death in children and the third leading cause of cancer death in young adults from 20 to 39.
- (7) The five-year survival rate after diagnosis with a primary malignant brain and central nervous system tumor is 28.8% for men and 31.6% for women.
- (8) While the five-year survival rates for many other cancers have improved significantly, the survival rate for brain tumors has not improved appreciably in the last 40 years.

- (9) It is estimated that as many as 100,000 Americans will be diagnosed with metastatic brain tumors, which begin as cancer elsewhere in the body and spread, or metastasize, to the brain.
- (10) “Brain tumor” is a misleading term, because there are more than 120 different brain tumors, according to the World Health Organization.
- (11) The report of the National Cancer Institute Brain Tumor Progress Review Group (issued in 2000) described the special problems of treating brain tumors. Surgical removal of the tumor or entire organ with a generous surround of normal tissue cannot be easily accomplished in the case of brain tumors, unlike most tumors elsewhere in the body. Moreover, because most brain tumors are also relatively insensitive to radiation and chemotherapy, treatment of brain tumors is especially difficult.
- (12) The Progress Review Group report captures the fundamental problem of brain tumor research and care with this statement: “Brain tumors represent a unique challenge in that they affect the organ that is the essence of the ‘self’.”
- (13) All forms of brain tumor treatment – surgery, chemotherapy, and radiation – hold the potential to cause lasting side effects. Radiation and chemotherapy may have especially severe effects on children’s developing brains.
- (14) Children treated for brain tumors may face educational and employment challenges, difficulties in living independently, and obstacles to obtaining health insurance coverage.
- (15) There have been modest improvements in the treatment of malignant and non-malignant brain tumors, but patients, families, and researchers agree that progress in improving the length and quality of life for those diagnosed with primary brain tumors is inadequate and that research must forge new approaches to brain tumor research, acute care, and neuro-rehabilitation and survivorship care.
- (16) Brain tumors are diagnosed in the youngest and the oldest Americans, affecting patients at all stages of development and stage of life.
- (17) Advances in understanding the biology of brain tumor and the migration of glial cells may contribute to development of better treatments and may also improve the overall pace of therapeutic development.
- (18) A stronger federal investment is necessary to realize the research aims and goals of the Brain Tumor Progress Review Group report of 2000 and to build upon new insights about the complex biology of these tumors.
- (19) Coordination and communication among brain tumor researchers holds the promise of stimulating creative approaches to research challenges and can create synergies among brain tumor experts to derive novel therapies.

(20) Because of the diversity of brain tumors and their relatively low incidence, special clinical research structures are necessary to ensure an aggressive pace of research on treatment and survivorship care.

(21) Coordination of all elements of brain tumor care will ensure a higher quality of care for brain tumor patients.

Section 3. Brain Tumor Clinical Research Consortia Program

(a) Establishment of Brain Tumor Consortia Program-- The Secretary of Health and Human Services shall establish a program of brain tumor clinical research consortia to accelerate the translation of basic research findings into new brain tumor treatments. The program shall --

(1) Include at least one adult brain tumor consortium and at least one pediatric brain tumor consortium;

(2) Sponsor and coordinate, through the separate adult and pediatric consortia, Phase I and Phase II clinical trials to evaluate new brain tumor treatments; and

(3) Provide adequate funding to support participation of leading brain tumor research sites as clinical trial sites in the consortia; the funding for the consortia shall be adequate to support a sufficient number of sites for efficient accrual and completion of trials.

(b) Standards for institutions participating in consortia. -- Institutions applying for a consortium grant shall evaluate institutions for participation in the consortium according to the following standards: existence of interdisciplinary research and clinical team, number of brain tumor patients evaluated and treated, number of clinical trial participants enrolled, and number of clinical trials undertaken.

(c) Authorization of Appropriations -- For fiscal years 2010 through 2014, such sums as may be necessary are authorized to be appropriated for the brain tumor research consortia program.

Section 4. Brain Tumor Research Coordinating Committee

(a) Establishment of Coordinating Committee -- Not later than 90 days after the enactment of this section, the Secretary, in consultation with the Director of the National Institutes of Health, shall establish a committee to be known as the Brain Tumor Research Coordinating Committee.

(b) Membership -- The Secretary and Director of NIH shall appoint members of the Committee to ensure active participation by the broad cross-section of brain tumor researchers. The Committee shall include:

(1) 5 members representing the National Cancer Institute, National Institute of Neurological Disorders and Stroke, National Institute of Biomedical Imaging & Bioengineering, National Institute of Nursing Research, and National Institute of Child Health and Human Development;

(2) 10 researchers – basic, translational, and clinical -- who represent disciplines involved in brain tumor research and who have received grant support from one of the institutes at NIH;

(3) 4 brain tumor advocates, representing adult and pediatric patient perspectives, including individuals diagnosed with brain tumors or family members of brain tumor patients.

(c) Chair -- The Secretary shall designate the chair of the Coordinating Committee from among its members.

(d) Terms of Members -- The members of the Committee will be appointed for three year terms but may be re-appointed for a second three-year term.

(e) Responsibilities - The Committee shall --

(1) Evaluate the components of brain tumor research supported by NIH, including the major categories of research supported by NIH, the objectives of the program, promising areas of research that may not be adequately supported by NIH, and opportunities for greater coordination and communication among intramural and extramural brain tumor researchers supported by NIH.

(2) Make recommendations for activities and initiatives, including a standing brain tumor research working group, which would facilitate innovative brain tumor research initiatives.

(3) Submit an annual report to the NIH Director regarding the strengths and weaknesses of the brain tumor research program and recommendations for enhancing the overall research effort.

(f) Authorization of Appropriations -- For fiscal years 2010 through 2014, there are authorized to be appropriated such sums as may be necessary to support the activities of the Brain Tumor Research Coordinating Committee.

Section 5. Brain Tumor Therapeutics Development Acceleration Initiative

- (a) Establishment -- The NIH Director will establish a therapeutics development program to accelerate the development of new brain tumor therapies.
- (b) In general -- The program shall support grants to researchers to support partnerships of public and private entities to accelerate development of new brain tumor treatments.
- (c) Standards for grants -- Grants shall be --
 - (1) Awarded to nonprofit research entities for projects aimed at therapeutics development;
 - (2) Awarded to entities for projects that complement and support the research initiatives of the brain tumor research consortia, specialized programs of research excellence (SPOREs) and cancer cooperative groups; and
 - (3) Awarded to grantees with a well-defined plan, including a plan for collaboration with for-profit entities, to move therapies through the development process.
- (d) Authorization of appropriations -- To carry out the Brain Tumor Therapeutics Development Acceleration Initiative, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

Section 6. Conference on Collaborative Brain Tumor Biospecimen Repositories.

- (a) Purpose of Meeting. -- The Secretary shall sponsor a meeting of experts to investigate models of collaborative and multi-institutional brain tumor biospecimen repositories and the feasibility of a coordinated and collaborative repository to be utilized by brain tumor researchers supported by NIH grants.
- (b) Establishment. -- The Secretary shall announce the date for the meeting not more than 120 days after the date of enactment of this Act.
- (c) Standards for Meeting. -- In designing the meeting, the Secretary shall consider:
 - (1) Participants. -- Participants shall include intramural and extramural brain tumor researchers, researchers who administer biospecimen repositories, international researchers with successful biospecimen repository experience, and NIH Institute and Center personnel with experience administering biospecimen repository programs.

- (2) Issues for Review. -- The meeting shall review standards for biospecimen donation and storage, best practices of successful repositories, obstacles to multi-institutional participation in a centralized repository, the benefits of a centralized repository model, and coordination of any new repository with ongoing federal biospecimen programs.
- (d) Authorization of appropriations. -- For the conference on brain tumor biospecimen repositories, there are authorized to be appropriated such sums as may be necessary.

Section 7. Neuro-Rehabilitation Research Program.

- (a) Establishment -- The NIH Director shall establish a neuro-rehabilitation research program to focus on the wide range of disease and treatment side effects experienced by brain tumor patients, including but not limited to loss of speech, loss of hearing, and seizure disorders.
- (b) In general -- The program shall support grants to researchers to undertake basic and applied research to investigate and develop effective strategies for ameliorating the neurological side effects resulting from brain tumors and their treatment.
- (c) Authorization of appropriations -- to carry out the Neuro-Rehabilitation Research Program, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

Section 8. Brain Tumor Survivorship Center Program.

- (a) Establishment. -- The Secretary shall establish a program of Brain Tumor Survivorship Centers to meet the specific and diverse late and long-term effects that may be experienced by survivors of brain tumors.
- (b) In general. -- The survivorship centers program shall focus on the optimal structure for services for brain tumor survivors and shall also include an evaluation component to permit assessment of best practices and facilitate the replication of model programs.
- (c) Agencies -- The Institutes and Centers of NIH, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration shall be involved in planning the survivorship center program, and the Secretary shall designate one of the agencies to administer the program.
- (d) Authorization of appropriations. -- To carry out the Brain Tumor Survivorship Center Program, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.