Bolstering Research And Innovation Now (BRAIN) Act
Section-By-Section Explanation

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

Establishes that this Act may be cited as the "Bolstering Research and Innovation Now Act" or the "BRAIN Act," and delineates the sections of the Act in a table of contents.

SEC. 2. FINDING; PURPOSES

Details incidence, stagnant survival rates and lack of sufficient progress in prevention, early detection and treatment of brain tumors as well as the quality of life of patients so as to establish the need for the BRAIN Act – comprehensive legislation the purposes of which are to strengthen the research and treatment of brain and other recalcitrant cancers, and to improve adequacy, awareness of and access to specialized care.

SEC. 3. FOSTERING TRANSPARENCY OF BIOSPECIMEN COLLECTIONS FOR BRAIN CANCER RESEARCH

Requires public notification of and information about federal government-funded biospecimen collections that due to federal government funding have been created, additions/subtractions to them, and new collections to be publicly reported, well-maintained, searchable, and accessible.

- In cancer research, the ability to access biospecimens (blood, tissue, cerebral spinal fluid, etc. is important to understanding cancers and for evaluating potential treatments and diagnostics, but the current process for a research investigator to locate biospecimen collections and potentially ask about accessing collections can be difficult because there is not a comprehensive and reliable library of all NIH funded cancer biospecimen collections. Establishing a reliable way of knowing which researchers, hospitals, and labs have biospecimen collections can make it easier to figure out who to contact about possible sharing of biospecimens.
- NIH's data sharing policy[1] is largely voluntary and currently does not require researchers to "raise their hand" and report the existence of biospecimen collections (even though they were supported with public dollars).
- NCI already has a specimen resource locator[2] website that could be used for reporting of biospecimen collections. Currently, participation is voluntary and thus, not used very much.
- This policy change does not require actual biospecimen sharing but it would increase transparency of publicly-funded biospecimen collections.
- Exceptions to reporting requirements may be made to maintain legally required confidentiality.
- Cost to government: Minimal

SEC. 4. GLIOBLASTOMA THERAPEUTICS NETWORK; BRAIN TUMOR RELATED CELLULAR IMMUNOTHERAPY, INCLUDING BUT NOT LIMITED TO CAR-T TEAM SCIENCE AWARD.

Increases the National Cancer Institute's Glioblastoma Therapeutics Network's annual budget to at least $50 million annually for fiscal years 2026 through 2030.

- The Glioblastoma Therapeutics Network (GTN) is a network of world-class medical academic centers funded together as a collaborative under an NIH U19 grant to evaluate, in labs and then

[1] U.S. Department of Health and Human Services. (2023). *Data Management and Policy*. National Institutes of Health, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html [2] *Specimen Resource Locator*. National Cancer Institute, https://specimens.cancer.gov/

in human clinical trials, promising treatments for patients with glioblastoma.[3]

- Current institutions include UCSF, Brigham & Women's Hospital, Yale, University of Alabama Birmingham, Mayo Clinic, City of Hope, Northwestern, Stanford, University of Texas Southwestern and Duke.
- The network was developed from the consensus of the National Cancer Institute's Glioblastoma Working Group in 2019[4]
- The network is charged with taking on the most aggressive, treatment-resistant cancer, but its funding levels are insufficient to both conduct laboratory studies and also to conduct early phase clinical trials as intended. Additionally, the National Cancer Institute cut the awardees' funding by 20 percent in the first year after originally promising $6M per year for 5 years.
- This section calls for scaling up the funding for the GTN pay for both laboratory science and desperately needed first in human early phase clinical trials to evaluate treatments for glioblastoma which the National Cancer Institute has called "a disease that is one of the hardest to treat in all of oncology"[5] and more than 13,000 Americans are diagnosed each year.
- Cost: $50M per year FY 26-30

The Secretary shall direct the National Cancer Institute to establish a new collaborative U-type funding award of $10M for each fiscal year 2026 through 2030 to advance promising brain tumor related cellular immunotherapy, including chimeric antigen receptor (CAR-T) immunotherapy research.

- Glioblastomas are immunologically "cold" tumors making it thus far difficult to use immunotherapies that work for other cancers to treat patients with glioblastoma (GBM).
- There is growing scientific evidence and hope behind brain tumor related cellular immunotherapy, including chimeric antigen receptor T-cell therapy (CAR-T), a form of immunotherapy expected to have potential therapeutic benefits for patients with glioblastoma. Now is the time for team science investment to determine if this form of immunotherapy research can advance into effective treatments for adults and children with the most deadly brain tumors.
- Now is also the time to incentivize leading brain tumor related cellular immunotherapy research institutions to work together and conduct team science to better leverage their knowledge and learn from every patient.
- This provision would establish new funding within the National Cancer Institute for a five-year grant mechanism using an NIH "U-type" cooperative agreement"[6] for cellular immunotherapies, including CAR-T, in brain tumors and in doing so would help bring leading cancer centers together, further maximizing their resources.
- Cost: $10M per year FY26-30

SEC. 5. CLINICAL TRIALS AND BIOMARKER TESTING NATIONAL PUBLIC AWARENESS CAMPAIGN

Directs the Secretary of Health and Human Services (HHS) through the Centers for Disease Control (CDC) to conduct a public education campaign to increase the awareness and knowledge of healthcare providers and individuals concerning the importance of cancer clinical trials and biomarker testing in cancer

[3] *Glioblastoma Therapeutics Network (GTN),* Division of Cancer Treatment and Diagnosis. (2021, September 9). Retrieved from https://dctd.cancer.gov/NewsEvents/20210928_glioblastoma_therapeutics_network.htm

[4] *Glioblastoma (GBM) Working Group Report.* National Cancer Institute Clinical Trials and Translational Research Advisory Committee (CTAC). (2019, July 17). Retrieved from

https://deainfo.nci.nih.gov/advisory/ctac/0719/Att_12_GBM%20WG%20Final%20Report%20CTAC%207-17-19_v1.pdf [5] *Can immunotherapy succeed in glioblastoma?* National Cancer Institute. (2018, May 24). Retrieved from ttps://www.cancer.gov/news-events/cancer-currents-blog/2018/immunotherapy-glioblastoma [6] NIH, types of grants, https://grants.nih.gov/grants/funding/funding_program.htm

treatment. Biomarker testing is a way to look for genes, proteins, and other substances (called biomarkers) that can provide cancer information. Each person's cancer including brain tumors has a set of molecular signatures called biomarkers. Some biomarkers affect how certain cancer treatments work. Biomarker testing helps patients and their medical providers diagnose cancer and determine appropriate courses of treatment including eligibility for clinical trials.[7]

Cancer clinical trial participation is very important to the pursuit of finding better treatments and cures and to helping patients to receive sometimes the best therapeutic option for them. However, in adult cancers, the cancer clinical trial participation rates continue to be quite low risking clinical trial accrual rates and limiting trials as an option for more people of all backgrounds.[1]

This section authorizes demonstration projects regarding outreach and education strategies to test, compare, and evaluate different evidence-based outreach and education strategies to increase the awareness and knowledge of patients, their families, physicians, nurses, and other key health professionals concerning cancer clinical trials and biomarker testing. It also authorizes demonstration projects aimed to increase biomarker testing of brain tumor patients.

- This section aims for the Centers for Disease Control, which runs the Comprehensive Cancer Control program, to add cancer clinical trials and biomarker testing as a priority area and to include cancer clinical trials and biomarker testing awareness among the public health campaigns that it funds and promotes.[8]
- The current National Comprehensive Cancer Network's guidelines call for cancer clinical trials to be considered in many cases including in brain tumors.[9]
- If cancer clinical trial awareness and biomarker testing were part of public education efforts across states, it could lead to benefits such as
    - Improved diversity in cancer clinical trials
    - Improved patient knowledge of their cancer, leading to more informed decisions
    - Improved accrual rates
    - Improved matching of patients to treatments based on their biomarkers
- Cost: $10M per year FY26-30

SEC. 6. PILOT PROGRAMS TO DEVELOP, STUDY, OR EVALUATE APPROACHES TO MONITORING AND CARING FOR BRAIN TUMOR SURVIVORS

Authorizes funding to allow the Secretary of HHS through the National Institutes of Health including the National Cancer Institute's Office of Cancer Survivorship[11] to make awards to eligible entities to establish programs to develop, study, or evaluate model systems for monitoring and caring for adult, adolescent, pediatric brain tumor survivors throughout their lifespan, including evaluation of current health care models for transition to post-treatment care and care coordination.

- Quality of life for patients living with brain tumors ranges significantly with many different health outcomes. With so many adult and pediatric survivors of different types of brain tumors, it is

[1] Kumar G, Chaudhary P, Quinn A, Su D. Barriers for cancer clinical trial enrollment: A qualitative study of the perspectives of healthcare providers. Contemp Clin Trials Commun. 2022 May 28;28:100939. doi: 10.1016/j.conctc.2022.100939. PMID: 35707483; PMCID: PMC9189774.

important to develop appropriate innovative care systems for patients and their families including in palliative care and various settings including educational, social, community, and family.

- This provision calls for grants made by the NIH to foster innovation in care delivery.
- Cost: $5M per year FY26-30

SEC. 7. FDA GUIDANCE TO ENSURE BRAIN TUMOR PATIENT ACCESS TO CLINICAL TRIALS

Requires the Secretary of HHS through the Food and Drug Administration, to issue guidance to help identify ways to reduce the exclusion of brain tumor patients and other patients with rare and recalcitrant cancers from clinical trials evaluating treatments for other indications.

- There is no current FDA guidance document that specifically addresses issues related to ways by which to reduce exclusion of brain tumor patients and other patients with recalcitrant cancers from clinical trials evaluating treatments or diagnostics that are not related to that patient's specific form of recalcitrant cancer.
- As a result, brain tumor and other rare and recalcitrant cancer patients may be and too often are unnecessarily excluded from clinical trials evaluating other diseases/conditions simply by virtue of the fact that they have cancer.
- This provision calls for FDA to develop guidance to help sponsors reduce this exclusion problem in ways that maintain and hopefully enhance the quality and validity of clinical trials.