Bolstering Research and Innovation Now (BRAIN) Act:

A Timely, Comprehensive, and Complementary Approach Toward Advancing Research to Innovate Treatment of Brain Tumors and Rare & Recalcitrant Cancers

Background: Malignant Brain Tumors are a Vicious and Stubborn Enemy

Today, more than 1 million people in the United States are living with a primary brain tumor. Over 93,000 Americans will likely be diagnosed with a primary brain tumor in 2025, in addition to hundreds of thousands of Americans diagnosed with metastatic brain cancer. A single diagnosis comes with a serious impact for patients and their loved ones—from changes in brain function to decreased independence—and too often is life-threatening.

For malignant brain tumors, incidence and survival rates have remained stagnant for 45 years, despite major improvements made in the treatment of other cancers, with a five-year relative survival rate of only 35.7%. Only a few treatments have been approved for malignant brain tumors. None of these extend survival more than two years on average or are considered to be curative, and there has never been a drug developed and approved uniquely for pediatric brain tumor patients. Tragically, pediatric brain tumors are now the leading cause of cancer-related death among children and young adults ages 19 and younger.

Problem: More Tools and Enhanced Coordination is Needed to Defeat Brain Tumors

In the past decade, the genomics and immunotherapy revolutions in cancer research have ushered in an era of groundbreaking new treatments and precision medicines for patients with many different forms of cancer. However, these advances have yet to demonstrate success in rare and recalcitrant cancers, such as malignant brain tumors.

Despite the increased promise, the reality is that to realize additional meaningful progress against brain tumors, more, better-funded, and collaborative research is required to advance innovative solutions for patients with these stubborn, hard-to-treat, and aggressive cancers. Additionally, the development of model systems of care and public education and awareness will be critical in the effort to generate progress for this area of urgent, unmet medical need. The time is now for comprehensive, holistic legislation to further advance the cause of conquering and curing brain tumors – once and for all.

Proposed Comprehensive Solution: The BRAIN Act

The Bolstering Research and Advancing Innovation Now (BRAIN) Act would benefit patients with brain tumors and research related to rare and highly deadly cancers. The BRAIN Act is complementary to many existing laws and policies. At a high level, it will:

- Increase transparency of federally-funded biobank collections so that researchers are aware of others who possess samples that might be shared to enable important research.
- Sufficiently resource the National Cancer Institute's Glioblastoma Therapeutics Network, so that it can realize its promise of vetting treatments and completing innovative early-phase clinical trials.
- Enable team science to advance brain tumor related cellular immunotherapies engineered to attack brain cancer cells.
- Direct the Centers for Disease Control to conduct a public education campaign around the importance of cancer clinical trials and biomarker testing in cancer treatment.
- Augment and expand funding to develop innovative systems of care models for brain tumor survivors.
- Identify ways to minimize the potential for the exclusion of brain tumor patients and patients with rare and recalcitrant cancers from clinical trials evaluating treatments for other indications.

This bill has been reintroduced in the Senate by Sens. Blumenthal (D-CT), Barrasso (R-WY), Reed (D-RI), and Rounds (R-SD) and in the House by Reps. Trahan (D-MA), Joyce (R-PA), Schrier (D-WA), and Fitzpatrick (R-PA).

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