

119TH CONGRESS
1ST SESSION

S. _____

To advance research to achieve medical breakthroughs in brain tumor treatment and improve awareness and adequacy of specialized cancer and brain tumor care.

IN THE SENATE OF THE UNITED STATES

Mr. BLUMENTHAL (for himself, Mr. ROUNDS, Mr. REED, and Mr. BARRASSO) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To advance research to achieve medical breakthroughs in brain tumor treatment and improve awareness and adequacy of specialized cancer and brain tumor care.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Bolstering Research and Innovation Now Act” or the
6 “BRAIN Act”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings; purposes.

Sec. 3. Fostering transparency of biospecimen collections for brain cancer research.

Sec. 4. Glioblastoma Therapeutics Network; brain tumor related cellular immunotherapy.

Sec. 5. Cancer clinical trials and biomarker testing national public awareness campaign.

Sec. 6. Pilot programs to develop, study, or evaluate approaches to monitoring and caring for brain tumor survivors.

Sec. 7. FDA guidance to ensure brain tumor patient access to clinical trials.

1 SEC. 2. FINDINGS; PURPOSES.

2 (a) FINDINGS.—Congress finds as follows:

3 (1) According to the National Brain Tumor So-
4 ciety, based on data analyzed in 2024, more than
5 1,000,000 people in the United States are living
6 with a brain tumor and approximately 94,000 were
7 estimated to be diagnosed with a primary brain
8 tumor in 2023.

9 (2) Brain tumors do not discriminate and can
10 affect people of all races, genders, and ages. Trag-
11 ically, pediatric brain tumors are the leading cause
12 of cancer-related death among children and young
13 adults ages 19 and younger.

14 (3) For malignant brain tumors, incidence and
15 survival rates have remained stagnant for 45 years,
16 with an average 5-year relative survival rate of 35.7
17 percent and only 6.9 percent for glioblastoma, the
18 most common primary malignant brain tumor.

19 (4) Most primary brain tumors are non-malig-
20 nant, but many still require surgery and radiation.

1 The results of available treatment options can vary
2 from a successful return to normal life to possible
3 disability or a life-threatening condition.

4 (5) Despite the statistics described in para-
5 graphs (1) through (4), there have been very few
6 treatments ever approved by the Food and Drug Ad-
7 ministration to treat brain tumors, thereby resulting
8 in little change in mortality rates for individuals
9 with brain tumors.

10 (6) As of the date of enactment of this Act,
11 there is no prevention and no early detection pro-
12 tocol for brain tumors.

13 (7) All people in the United States have a stake
14 in reducing and eliminating brain tumors.

15 (8) Patients living with a brain tumor and their
16 families want cures. Short of cures, they want safe
17 and effective ways to increase survival rates for such
18 patients and improve the quality of life for such pa-
19 tients.

20 (b) PURPOSES.—The purposes of this Act are to—

21 (1) strengthen research and treatment develop-
22 ment regarding brain tumors; and

23 (2) improve the adequacy and awareness of and
24 access to specialized brain tumor and rare and recal-
25 citrant cancer health care.

1 **SEC. 3. FOSTERING TRANSPARENCY OF BIOSPECIMEN COL-**
2 **LECTIONS FOR BRAIN CANCER RESEARCH.**

3 Part A of title IV of the Public Health Service Act
4 (42 U.S.C. 281 et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 404P. REPORTING OF BRAIN TUMOR BIOSPECIMEN**
7 **COLLECTIONS.**

8 “(a) DEFINITION OF COVERED BIOSPECIMEN COL-
9 LECTION.—

10 “(1) IN GENERAL.—In this section, the term
11 ‘covered biospecimen collection’ means a biospecimen
12 that was collected or acquired in whole or in part
13 through funding from the National Institutes of
14 Health.

15 “(2) BIOSPECIMEN.—For purposes of para-
16 graph (1), the term ‘biospecimen’ means a brain
17 tumor tissue, cerebral spinal fluid, or other specimen
18 type listed by the Specimen Resource Locator of the
19 National Cancer Institute (or a successor database).

20 “(b) ESTABLISHMENT.—The Secretary, acting
21 through the Director of NIH, may establish and maintain
22 a searchable website, or multiple websites, which may in-
23 clude websites existing on the day before the date of enact-
24 ment of this section, for the purpose of making accessible
25 to the public—

1 “(1) information on the existence and location
2 of covered biospecimen collections;

3 “(2) a description of such collections; and

4 “(3) contact information with respect to such
5 collections.

6 “(c) REPORTING REQUIREMENTS.—

7 “(1) EXISTING COLLECTIONS.—Any individual
8 or entity that as of the date of enactment of this
9 section maintains a covered biospecimen collection
10 shall, not later than 180 days after such date of en-
11 actment, submit a report to the Director of NIH
12 containing information with respect to such covered
13 biospecimen collection as the Director of NIH may
14 specify, including at a minimum the information the
15 National Cancer Institute requires for the Specimen
16 Resource Locator (or a successor database).

17 “(2) NEW COLLECTIONS.—Any individual or
18 entity that collects or acquires a covered biospecimen
19 collection on or after the date of enactment of this
20 section shall, not later than 60 days after the date
21 of such collection or acquisition, submit a report to
22 the Director of NIH containing the information re-
23 quired under paragraph (1).

24 “(d) OVERSIGHT.—The Secretary, acting through the
25 Director of NIH, shall establish and carry out an oversight

1 mechanism, which shall include withholding funding to in-
2 dividuals or entities that have committed a repeated or
3 egregious violation of the requirements under subsection
4 (c).”.

5 **SEC. 4. GLIOBLASTOMA THERAPEUTICS NETWORK; BRAIN**
6 **TUMOR RELATED CELLULAR**
7 **IMMUNOTHERAPY.**

8 (a) IN GENERAL.—Subpart 1 of part C of title IV
9 of the Public Health Service Act (42 U.S.C. 285 et seq.)
10 is amended by adding at the end the following:

11 **“SEC. 417H. GLIOBLASTOMA THERAPEUTICS NETWORK.**

12 “(a) IN GENERAL.—The Director of the Institute
13 shall carry out a research program, known as the ‘Glio-
14 blastoma Therapeutics Network’, by awarding, on a com-
15 petitive basis, cooperative agreements, or other awards,
16 through the U19 funding mechanism of the National In-
17 stitutes of Health for collaboration of institutions to im-
18 prove the treatment of glioblastoma by evaluating thera-
19 peutic agents from pre-clinical development studies
20 through completion of early-phase clinical trials in hu-
21 mans.

22 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated \$50,000,000 for each of
24 fiscal years 2026 through 2030, to remain available until

1 expended, to the Director of the Institute to carry out this
2 section.

3 **“SEC. 417I. BRAIN TUMOR RELATED CELLULAR**
4 **IMMUNOTHERAPY.**

5 “(a) IN GENERAL.—In order to take advantage of
6 significant advancement in the development of brain
7 tumor related cellular immunotherapy, including chimeric
8 antigen receptor-T (CAR-T), which may include ap-
9 proaches previously funded by the National Institutes of
10 Health, the Director of the Institute shall make awards,
11 on a competitive basis, through a U series funding mecha-
12 nism, to support the development of a multi-institutional
13 team science approach to using brain tumor related cancer
14 cellular immunotherapy, including CAR-T treatment, for
15 adult and pediatric brain tumors.

16 “(b) USE OF FUNDS.—Funds received through an
17 award under this section shall be used—

18 “(1) to support collaborative multi-institutional
19 research activities, including pre-clinical and inves-
20 tigational new drug studies; and

21 “(2) for the purpose of supporting clinical trials
22 to evaluate brain tumor related cancer cellular
23 immunotherapy, including CAR-T.

24 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
25 is authorized to be appropriated \$10,000,000 for each of

1 fiscal years 2026 through 2030, to remain available until
2 expended, to the Director of the Institute to carry out this
3 section.”.

4 (b) TRANSITION FOR THE GLIOBLASTOMA THERA-
5 PEUTICS NETWORK.—The Director of the National Can-
6 cer Institute shall take such steps as may be necessary
7 for the orderly transition from the Glioblastoma Thera-
8 peutics Network carried out by the Director, as of the day
9 before the date of enactment of this Act, to the research
10 program authorized under section 417H of the Public
11 Health Service Act, as added by subsection (a). In making
12 such transition, the Director shall ensure that the pro-
13 gram authorized under such section 417H is based upon
14 and consistent with the policies and procedures of the
15 Glioblastoma Therapeutics Network carried out by the Di-
16 rector as of the day before the date of enactment of this
17 Act.

18 **SEC. 5. CANCER CLINICAL TRIALS AND BIOMARKER TEST-**
19 **ING NATIONAL PUBLIC AWARENESS CAM-**
20 **PAIGN.**

21 Part P of title III of the Public Health Service Act
22 (42 U.S.C. 280g et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 399V-8. CANCER CLINICAL TRIALS AND BIOMARKER**
2 **TESTING NATIONAL PUBLIC AWARENESS**
3 **CAMPAIGN.**

4 “(a) NATIONAL CAMPAIGN.—

5 “(1) IN GENERAL.—The Secretary shall carry
6 out a national campaign to increase the awareness
7 and knowledge of health care providers and individ-
8 uals, including patients and caregivers, with respect
9 to the importance of clinical trials in the treatment
10 of cancer.

11 “(2) ACTIVITIES.—

12 “(A) IN GENERAL.—Activities under such
13 national campaign shall include each of the fol-
14 lowing:

15 “(i) WRITTEN MATERIALS.—Main-
16 taining a supply of written and digital ma-
17 terials that provide information to the pub-
18 lic on clinical trials, and distributing such
19 materials to members of the public upon
20 request.

21 “(ii) PUBLIC SERVICE ANNOUNCE-
22 MENTS; PUBLIC ENGAGEMENT.—Providing
23 public service announcements, in accord-
24 ance with applicable law, including through
25 publishing materials in digital or print
26 form, and carrying out other public en-

1 gagement initiatives. Such public service
2 announcements and other public engage-
3 ment initiatives shall include such an-
4 nouncements and initiatives intended to
5 encourage individuals to discuss with their
6 physicians—

7 “(I) what cancer clinical trials
8 are;

9 “(II) the importance of clinical
10 trials in the treatment of cancer;

11 “(III) how to enroll in cancer
12 clinical trials;

13 “(IV) what cancer biomarker
14 testing is;

15 “(V) the importance of biomarker
16 testing in the diagnosis and treatment
17 of cancer; and

18 “(VI) how to access cancer bio-
19 marker testing.

20 “(B) TARGETED POPULATIONS.—The Sec-
21 retary shall ensure that the national campaign
22 includes communications, including public serv-
23 ice announcements and other public engage-
24 ment initiatives under subparagraph (A)(ii),
25 that are—

11

1 “(i) culturally and linguistically com-
2 petent; and

3 “(ii) targeted to—

4 “(I) specific populations that are
5 at a higher risk of cancer, including
6 such populations based on factors in-
7 cluding race, ethnicity, level of accul-
8 turation, and family history;

9 “(II) rural communities; and

10 “(III) such other communities as
11 the Secretary determines appropriate.

12 “(3) CONSULTATION.—In carrying out the na-
13 tional campaign under this subsection, the Secretary
14 shall consult with—

15 “(A) health care providers;

16 “(B) nonprofit organizations;

17 “(C) State and local public health depart-
18 ments; and

19 “(D) elementary and secondary schools
20 and institutions of higher education.

21 “(b) DEMONSTRATION PROJECTS REGARDING OUT-
22 REACH AND EDUCATION STRATEGIES FOR CANCER AND
23 BRAIN TUMOR PATIENTS.—

24 “(1) IN GENERAL.—The Secretary shall carry
25 out a program to award grants or contracts to pub-

1 lic or nonprofit private entities for the purpose of
2 carrying out demonstration projects to test, com-
3 pare, and evaluate different evidence-based outreach
4 and education strategies to increase the awareness
5 and knowledge of cancer and brain tumor clinical
6 trials and biomarker testing. Such projects shall
7 focus on the awareness and knowledge of patients
8 (and the families of patients), physicians, nurses,
9 and other key health professionals involved in brain
10 tumor treatment.

11 “(2) AWARDS.—In making awards under para-
12 graph (1), the Secretary shall—

13 “(A) ensure that information provided
14 through demonstration projects supported by
15 such an award is consistent with the best avail-
16 able medical information; and

17 “(B) give preference to—

18 “(i) applicants with demonstrated ex-
19 pertise in—

20 “(I) biomarker testing and clin-
21 ical trials in brain tumors and other
22 recalcitrant cancers;

23 “(II) brain cancer and other re-
24 calcitrant cancer education or treat-
25 ment;

1 “(III) working with groups of pa-
2 tients and caregivers; and

3 “(IV) reaching geographic areas
4 that have historically low rates of par-
5 ticipation in cancer clinical trials; and

6 “(ii) applicants that demonstrate in
7 their application submitted under para-
8 graph (3) that the project for which they
9 are seeking a grant or contract will involve
10 and connect physicians, nurses, other key
11 health professionals, health profession stu-
12 dents, hospitals, and payers.

13 “(3) APPLICATIONS.—To seek a grant or con-
14 tract under this subsection, an entity shall submit
15 an application to the Secretary in such form, in such
16 manner, and containing such agreements, assur-
17 ances, and information as the Secretary may reason-
18 ably require.

19 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
20 purpose of carrying out this section, there is authorized
21 to be appropriated \$10,000,000 for the period of fiscal
22 years 2026 through 2030.”.

1 **SEC. 6. PILOT PROGRAMS TO DEVELOP, STUDY, OR EVALU-**
2 **ATE APPROACHES TO MONITORING AND CAR-**
3 **ING FOR BRAIN TUMOR SURVIVORS.**

4 Part B of title IV of the Public Health Service Act
5 (42 U.S.C. 284 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 409K. PILOT PROGRAMS TO DEVELOP, STUDY, OR**
8 **EVALUATE APPROACHES TO MONITORING**
9 **AND CARING FOR BRAIN TUMOR SURVIVORS.**

10 “(a) IN GENERAL.—The Director of NIH may, as
11 appropriate, make awards to eligible entities to establish
12 pilot programs to develop, study, or evaluate approaches,
13 including primary and specialty care, for monitoring and
14 caring for adult and pediatric brain tumor survivors
15 throughout their lifespan, including evaluating models for
16 transition to post-treatment care and care coordination.

17 “(b) AWARDS.—

18 “(1) ELIGIBLE ENTITIES.—

19 “(A) IN GENERAL.—For purposes of this
20 section, an eligible entity is—

21 “(i) a medical school;

22 “(ii) a children’s hospital;

23 “(iii) a cancer center;

24 “(iv) a community-based medical facil-
25 ity; or

1 “(v) any other entity with significant
2 experience and expertise in carrying out
3 the activities described in subsection (a).

4 “(B) TYPES OF ENTITIES.—Awards under
5 this section shall be made, to the extent prac-
6 tical, to—

7 “(i) small, medium, and large-sized el-
8 igible entities; and

9 “(ii) sites located in different geo-
10 graphic areas, including rural and urban
11 areas.

12 “(2) PEER REVIEW.—In making awards under
13 this section, the Director of NIH shall comply with
14 the peer review requirements in section 492.

15 “(3) USE OF FUNDS.—Funds from awards
16 under this section may be used to develop, study, or
17 evaluate one or more models for monitoring and car-
18 ing for brain tumor survivors, which may include—

19 “(A) evaluating follow-up care, educational
20 accommodations, monitoring, and other survi-
21 vorship programs (including peer support and
22 mentoring programs);

23 “(B) developing and evaluating models for
24 providing multidisciplinary care;

1 “(C) disseminating information to health
2 care providers about culturally and linguistically
3 appropriate follow-up care for brain tumor sur-
4 vivors and their families, as appropriate and
5 practicable;

6 “(D) developing and evaluating existing
7 psychosocial evaluations, counseling, and sup-
8 port programs to improve the quality of life of
9 brain tumor survivors and their families, which
10 may include peer support and mentoring pro-
11 grams;

12 “(E) designing and evaluating tools, which
13 may include tools generated by artificial intel-
14 ligence and machine learning, to support the se-
15 cure electronic transfer of treatment informa-
16 tion and care summaries from brain tumor care
17 providers to other health care providers (includ-
18 ing primary and specialty care providers), which
19 information and care summaries shall include
20 risk factors and a plan for recommended follow-
21 up care;

22 “(F) developing and evaluating initiatives
23 that promote the coordination and effective
24 transition of care between brain tumor care
25 providers, primary and specialty care providers,

1 mental health professionals, and other health
2 care professionals, as appropriate, including
3 models that use a team-based or multi-discipli-
4 nary approach to care; and

5 “(G) disseminating information described
6 in subparagraphs (A) through (F), including
7 with respect to models, evaluations, programs,
8 systems, and initiatives described in such sub-
9 paragraphs, to other health care providers (in-
10 cluding primary and specialty care providers)
11 and to pediatric brain tumor survivors and their
12 families, where appropriate and in accordance
13 with Federal and State law.

14 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated to carry out this section
16 \$5,000,000 for each of fiscal years 2026 through 2030.”.

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

19 Not later than 1 year after the date of enactment
20 of this Act, the Secretary of Health and Human Services,
21 acting through the Commissioner of Food and Drugs,
22 shall issue guidance to help identify ways to minimize the
23 potential for the exclusion of brain tumor patients and pa-
24 tients with rare and recalcitrant cancers from clinical
25 trials evaluating treatments for other indications.