

118TH CONGRESS
2D SESSION

S. 4739

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

JULY 23, 2024

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

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 CAR-T team science award.

Sec. 5. 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 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 CAR-T TEAM SCIENCE AWARD.**

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

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

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

21 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated \$50,000,000 for each of
23 fiscal years 2026 through 2030, to remain available until
24 expended, to the Director of the Institute to carry out this
25 section.

1 **“SEC. 417I. BRAIN TUMOR CAR-T TEAM SCIENCE AWARD.**

2 “(a) IN GENERAL.—In order to take advantage of
3 significant advancement in the development of chimeric
4 antigen receptor-T (CAR-T) cell therapy approaches in
5 cancer, including many such approaches previously funded
6 by the National Institutes of Health, the Director of the
7 Institute shall make awards, on a competitive basis,
8 through a U series funding mechanism, to support the de-
9 velopment of a multi-institutional team science approach
10 to using CAR-T treatment for adult and pediatric brain
11 tumors.

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

14 “(1) to support collaborative multi-institutional
15 research activities, including pre-clinical and inves-
16 tigational new drug studies; and

17 “(2) for the purpose of supporting clinical trials
18 to evaluate CAR-T therapeutic approaches to treat-
19 ing brain tumors.

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated \$10,000,000 for each of
22 fiscal years 2026 through 2030, to remain available until
23 expended, to the Director of the Institute to carry out this
24 section.”.

25 (b) TRANSITION FOR THE GLIOBLASTOMA THERA-
26 PEUTICS NETWORK.—The Director of the National Can-

cer Institute shall take such steps as may be necessary for the orderly transition from the Glioblastoma Therapeutics Network carried out by the Director, as of the day before the date of enactment of this Act, to the research program authorized under section 417H of the Public Health Service Act, as added by subsection (a). In making such transition, the Director shall ensure that the program authorized under such section 417H is based upon and consistent with the policies and procedures of the Glioblastoma Therapeutics Network carried out by the Director as of the day before the date of enactment of this Act.

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

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

“SEC. 399V-8. CLINICAL TRIALS AND BIOMARKER TESTING NATIONAL PUBLIC AWARENESS CAMPAIGN.

“(a) NATIONAL CAMPAIGN.—

“(1) IN GENERAL.—The Secretary shall carry out a national campaign to increase the awareness and knowledge of health care providers and individuals with respect to the importance of clinical trials in the treatment of cancer.

1 “(2) ACTIVITIES.—

2 “(A) IN GENERAL.—Activities under such
3 national campaign shall include each of the fol-
4 lowing:

5 “(i) WRITTEN MATERIALS.—Main-
6 taining a supply of written and digital ma-
7 terials that provide information to the pub-
8 lic on clinical trials, and distributing such
9 materials to members of the public upon
10 request.

11 “(ii) PUBLIC SERVICE ANNOUNCE-
12 MENTS; PUBLIC ENGAGEMENT.—Providing
13 public service announcements, in accord-
14 ance with applicable law, including through
15 publishing materials in digital or print
16 form, and carrying out other public en-
17 gagement initiatives. Such public service
18 announcements and other public engage-
19 ment initiatives shall include such an-
20 nouncements and initiatives intended to
21 encourage individuals to discuss with their
22 physicians—

23 “(I) what clinical trials are;

24 “(II) the importance of clinical
25 trials in the treatment of cancer;

1 “(III) how to enroll in clinical
2 trials;

3 “(IV) what biomarker testing is;

4 “(V) the importance of biomarker
5 testing in the treatment of cancer;
6 and

7 “(VI) how to access biomarker
8 testing.

9 “(B) TARGETED POPULATIONS.—The Sec-
10 retary shall ensure that the national campaign
11 includes communications, including public serv-
12 ice announcements and other public engage-
13 ment initiatives under subparagraph (A)(ii),
14 that are—

15 “(i) culturally and linguistically com-
16 petent; and

17 “(ii) targeted to—

18 “(I) specific populations that are
19 at a higher risk of cancer, including
20 such populations based on factors in-
21 cluding race, ethnicity, level of accul-
22 turation, and family history;

23 “(II) rural communities; and

24 “(III) such other communities as
25 the Secretary determines appropriate.

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

4 “(A) health care providers;

5 “(B) nonprofit organizations;

6 “(C) State and local public health depart-
7 ments; and

8 “(D) elementary and secondary schools
9 and institutions of higher education.

10 “(b) DEMONSTRATION PROJECTS REGARDING OUT-
11 REACH AND EDUCATION STRATEGIES FOR CANCER AND
12 BRAIN TUMOR PATIENTS.—

13 “(1) IN GENERAL.—The Secretary shall carry
14 out a program to award grants or contracts to pub-
15 lic or nonprofit private entities for the purpose of
16 carrying out demonstration projects to test, com-
17 pare, and evaluate different evidence-based outreach
18 and education strategies to increase the awareness
19 and knowledge of cancer, including brain tumor bio-
20 marker testing and brain tumor clinical trials. Such
21 projects shall focus on the awareness and knowledge
22 of patients (and the families of patients), physicians,
23 nurses, and other key health professionals involved
24 in brain tumor treatment.

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

3 “(A) ensure that information provided
4 through demonstration projects supported by
5 such an award is consistent with the best avail-
6 able medical information; and

7 “(B) give preference to—

8 “(i) applicants with demonstrated ex-
9 pertise in—

10 “(I) biomarker testing and clin-
11 ical trials in brain tumors and other
12 recalcitrant cancers;

13 “(II) brain cancer and other re-
14 calcitrant cancer education or treat-
15 ment;

16 “(III) working with groups of pa-
17 tients and caregivers; and

18 “(IV) reaching geographic areas
19 that have historically low rates of par-
20 ticipation in cancer clinical trials; and

21 “(ii) applicants that demonstrate in
22 their application submitted under para-
23 graph (3) that the project for which they
24 are seeking a grant or contract will involve
25 and connect physicians, nurses, other key

1 health professionals, health profession stu-
 2 dents, hospitals, and payers.

3 “(3) APPLICATIONS.—To seek a grant or con-
 4 tract under this subsection, an entity shall submit
 5 an application to the Secretary in such form, in such
 6 manner, and containing such agreements, assur-
 7 ances, and information as the Secretary may reason-
 8 ably require.

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

13 **SEC. 6. PILOT PROGRAMS TO DEVELOP, STUDY, OR EVALU-**
 14 **ATE APPROACHES TO MONITORING AND CAR-**
 15 **ING FOR BRAIN TUMOR SURVIVORS.**

16 Part B of title IV of the Public Health Service Act
 17 (42 U.S.C. 284 et seq.) is amended by adding at the end
 18 the following:

19 **“SEC. 409K. PILOT PROGRAMS TO DEVELOP, STUDY, OR**
 20 **EVALUATE APPROACHES TO MONITORING**
 21 **AND CARING FOR BRAIN TUMOR SURVIVORS.**

22 “(a) IN GENERAL.—The Director of NIH may, as
 23 appropriate, make awards to eligible entities to establish
 24 pilot programs to develop, study, or evaluate approaches,
 25 including primary care, for monitoring and caring for

1 adult and pediatric brain tumor survivors throughout their
2 lifespan, including evaluating models for transition to
3 post-treatment care and care coordination.

4 “(b) AWARDS.—

5 “(1) ELIGIBLE ENTITIES.—

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

8 “(i) a medical school;

9 “(ii) a children’s hospital;

10 “(iii) a cancer center;

11 “(iv) a community-based medical facil-
12 ity; or

13 “(v) any other entity with significant
14 experience and expertise in carrying out
15 the activities described in subsection (a).

16 “(B) TYPES OF ENTITIES.—Awards under
17 this section shall be made, to the extent prac-
18 tical, to—

19 “(i) small, medium, and large-sized el-
20 igible entities; and

21 “(ii) sites located in different geo-
22 graphic areas, including rural and urban
23 areas.

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

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

8 “(A) evaluating follow-up care, educational
9 accommodations, monitoring, and other survi-
10 vorship programs (including peer support and
11 mentoring programs);

12 “(B) developing and evaluating models for
13 providing multidisciplinary care;

14 “(C) disseminating information to health
15 care providers about culturally and linguistically
16 appropriate follow-up care for brain tumor sur-
17 vivors and their families, as appropriate and
18 practicable;

19 “(D) developing and evaluating existing
20 psychosocial evaluations, counseling, and sup-
21 port programs to improve the quality of life of
22 brain tumor survivors and their families, which
23 may include peer support and mentoring pro-
24 grams;

1 “(E) designing and evaluating tools to sup-
2 port the secure electronic transfer of treatment
3 information and care summaries from brain
4 tumor care providers to other health care pro-
5 viders (including primary care providers), which
6 information and care summaries shall include
7 risk factors and a plan for recommended follow-
8 up care;

9 “(F) developing and evaluating initiatives
10 that promote the coordination and effective
11 transition of care between brain tumor care
12 providers, primary care providers, mental health
13 professionals, and other health care profes-
14 sionals, as appropriate, including models that
15 use a team-based or multi-disciplinary approach
16 to care; and

17 “(G) disseminating information described
18 in subparagraphs (A) through (F), including
19 with respect to models, evaluations, programs,
20 systems, and initiatives described in such sub-
21 paragraphs, to other health care providers (in-
22 cluding primary care providers) and to pediatric
23 brain tumor survivors and their families, where
24 appropriate and in accordance with Federal and
25 State law.

1 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 \$5,000,000 for each of fiscal years 2026 through 2030.”.

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

6 Not later than 1 year after the date of enactment
7 of this Act, the Secretary of Health and Human Services,
8 acting through the Commissioner of Food and Drugs,
9 shall issue guidance to help identify ways to minimize the
10 potential for the exclusion of brain tumor patients and pa-
11 tients with rare and recalcitrant cancers from clinical
12 trials evaluating treatments for other indications.

○