

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 725

To amend the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

APRIL 1 (legislative day, MARCH 3), 1993

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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## A BILL

To amend the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes.

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.**

4 This Act may be cited as the “Traumatic Brain In-  
5 jury Act of 1993”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress finds that—

1           (1) the incidence of head injury in the United  
2 States is increasing, with over 2,000,000 head inju-  
3 ries per year resulting from automobile crashes,  
4 sports, recreational activities, assaults, violence and  
5 other falls and incidents;

6           (2) a majority of all head injuries are caused by  
7 motor vehicle accidents;

8           (3) individuals between the ages of 15 and 24  
9 are at greatest risk for sustaining head injuries;

10          (4) of the individuals who sustain head injuries  
11 each year, approximately 500,000 require hos-  
12 pitalization, and 75,000 to 100,000 of such individ-  
13 uals die within hours of the injury;

14          (5) of the individuals who survive head injuries  
15 each year, approximately 70,000 to 90,000 will suf-  
16 fer irreversible debilitating loss of function, 5,000  
17 will develop epilepsy as a result of the injury, and  
18 2,000 will exist in a coma;

19          (6) a significant number of individuals with  
20 traumatic brain injury are not easily restored to so-  
21 ciety and require years of rehabilitation, medical fol-  
22 low-up and integrated community services, which are  
23 costly and frequently not readily available;

24          (7) individuals sustaining traumatic brain in-  
25 jury require coordinated and specialized services, in-

1 cluding post-injury supervised programs facilitating  
2 reentry into the community;

3 (8) many health and social service agencies,  
4 both public and private, overlook, exclude or inad-  
5 equately serve individuals surviving traumatic brain  
6 injury;

7 (9) society bears an economic cost of approxi-  
8 mately \$25,000,000,000 per year for the direct and  
9 indirect costs of traumatic brain injury, which in-  
10 clude medical treatment, rehabilitative and support  
11 services and lost income;

12 (10) a program to develop national standards  
13 for helmets used by bicyclists and others is needed;  
14 and

15 (11) a national plan to provide services for indi-  
16 viduals surviving traumatic brain injuries and their  
17 families is needed.

18 (b) PURPOSE.—It is the purpose of this Act to—

19 (1) facilitate the conduct of research and the  
20 collection and compiling of accurate statistical data  
21 on traumatic brain injury;

22 (2) raise public awareness concerning the risks  
23 and consequences of such injuries and the distinct  
24 needs of individuals (and their families) following  
25 survival from traumatic brain injury;

1           (3) promote the creation of innovative programs  
2           and policies to prevent traumatic brain injury and to  
3           rehabilitate those individuals who have survived such  
4           injuries;

5           (4) designate a Federal agency to oversee and  
6           promote projects relating to the prevention of, and  
7           rehabilitation from, traumatic brain injury;

8           (5) create State advisory boards to coordinate  
9           citizen participation in community programs dealing  
10          with traumatic brain injury;

11          (6) create a registry to advance epidemiologic  
12          research on such trauma;

13          (7) establish standards for the marketing of  
14          brain injury services;

15          (8) require the Secretary to publish various re-  
16          ports concerning the activities of the Department of  
17          Health and Human Services in this area, including  
18          an annual review of relevant activities; and

19          (9) provide for the initiation of a program to  
20          establish national standards for helmets used by  
21          bicyclists and others.

22 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

23          Title XII of the Public Health Service Act (42 U.S.C.  
24          300d et seq.) is amended—

25                 (1) by redesignating part C as part D;

1 (2) in section 1232(a) (42 U.S.C. 300d–32(a)),  
2 by inserting “other than part C,” after “carrying  
3 out this title,”; and

4 (3) by inserting after part B, the following new  
5 part:

6 “PART C—TRAUMATIC BRAIN INJURY

7 **“SEC. 1225. DEFINITIONS.**

8 “As used in this part:

9 “(1) ADMINISTRATOR.—The term ‘Adminis-  
10 trator’ means the Administrator of the Agency for  
11 Health Care Policy and Research.

12 “(2) DIRECTOR.—The term ‘Director’ means  
13 the Director of the Centers for Disease Control and  
14 Prevention.

15 “(3) TRAUMATIC BRAIN INJURY.—The term  
16 ‘traumatic brain injury’ means an acquired injury to  
17 the brain caused by an external physical force. Such  
18 term does not include brain dysfunction caused by  
19 congenital or degenerative disorders, nor does such  
20 term include birth trauma. Such term is synonymous  
21 with the term ‘head injury’.

1 **“SEC. 1225A. AGENCY FOR HEALTH CARE POLICY AND RE-**  
2 **SEARCH STUDY OF EFFECTIVENESS OF TRAU-**  
3 **MATIC BRAIN INJURY INTERVENTIONS.**

4 “(a) IN GENERAL.—The Secretary, acting through  
5 the Administrator, shall conduct a study concerning trau-  
6 matic brain injury.

7 “(b) MAJOR FINDINGS.—The study conducted under  
8 subsection (a) shall seek to—

9 “(1) identify common therapeutic interventions  
10 which are used for the rehabilitation of individuals  
11 with traumatic brain injuries, and shall include an  
12 analysis of—

13 “(A) the effectiveness of each such inter-  
14 vention in improving the functioning of individ-  
15 uals with brain injuries; and

16 “(B) the comparative effectiveness of inter-  
17 ventions employed in the course of rehabilita-  
18 tion of individuals with brain injuries to achieve  
19 the same or similar clinical outcome; and

20 “(2) develop practice guidelines for the rehabili-  
21 tation of traumatic brain injury.

22 “(c) REPORTING REQUIREMENTS.—Not later than 4  
23 years after the date of enactment of this part, the Sec-  
24 retary shall prepare and submit to the appropriate com-  
25 mittees of Congress, a report containing the results of the  
26 studies conducted under this section.

1       “(d) AUTHORIZATION OF APPROPRIATION.—There  
2 are authorized to be appropriated to carry out this section,  
3 \$2,000,000 for fiscal year 1994, and such sums as may  
4 be necessary for each of the fiscal years 1995 through  
5 1996.

6       **“SEC. 1225B. CENTERS FOR DISEASE CONTROL AND PRE-**  
7                                   **VENTION STUDY OF TRAUMATIC BRAIN IN-**  
8                                   **JURY OCCURRENCE.**

9       “(a) IN GENERAL.—The Secretary, acting through  
10 the Director, and in cooperation with other Public Health  
11 Service agencies as may be necessary, shall conduct stud-  
12 ies concerning traumatic brain injury, and shall establish  
13 a reporting system under subsection (b).

14       “(b) REPORTING SYSTEM.—To assist in data and in-  
15 formation gathering, the Director shall establish a uniform  
16 reporting system under which hospitals, State and local  
17 health-related agencies will report to the Director on mat-  
18 ters including—

19               “(1) the occurrence of traumatic brain injuries;  
20           and

21               “(2) the health insurance status of individuals  
22           with traumatic brain injury.

23 The reporting system should be established to permit the  
24 Director to make an accurate assessment of resource  
25 needs and long term outcomes.

1 “(c) SURVEY AND COOPERATIVE AGREEMENTS.—

2 “(1) SURVEY.—The Director shall determine  
3 which Federal, State, local or other entities collect  
4 data on traumatic brain injury and the means by  
5 which such entities collect such data.

6 “(2) COOPERATIVE AGREEMENTS.—The Direc-  
7 tor may enter into cooperative agreements with  
8 other agencies, and provide assistance to other enti-  
9 ties with responsibility for data collection, to estab-  
10 lish traumatic brain injury as a specific reportable  
11 condition in existing and future reporting systems.  
12 Any data systems established in conjunction with  
13 such agencies should be compatible with other such  
14 data systems.

15 “(d) MAJOR FINDINGS OF STUDIES.—The studies  
16 conducted under subsection (a) shall seek to—

17 “(1) determine the major causes of traumatic  
18 brain injury;

19 “(2) determine the preventive efforts that are  
20 being used by States and non-profit agencies to re-  
21 duce the occurrence of such injuries;

22 “(3) determine the number of individuals sur-  
23 viving traumatic brain injuries, and the cost of  
24 treatment and other related costs;

1           “(4) develop a uniform reporting system to fa-  
2           cilitate the reporting to the Centers for Disease Con-  
3           trol and Prevention concerning the occurrence of  
4           traumatic brain injury;

5           “(5) identify States and localities that have ap-  
6           proved mandated helmet use laws for bicyclist and  
7           others;

8           “(6) determine the health insurance status of  
9           individuals with traumatic brain injury; and

10          “(7) initiate a program of prevention research  
11          to develop effective prevention of traumatic brain in-  
12          jury.

13          “(e) REPORTING REQUIREMENTS.—Not later than 4  
14          years after the date of enactment of this part, the Sec-  
15          retary shall prepare and submit to the appropriate com-  
16          mittees of Congress, a report containing the results of the  
17          studies conducted under this section.

18          “(f) BIENNIAL REPORT.—The Secretary shall bienni-  
19          ally prepare a report containing recommendations for the  
20          prevention of traumatic brain injuries. The report shall  
21          also identify States that have mandated helmet laws for  
22          bicyclists and others. Such reports shall be disseminated  
23          to State health officers.

24          “(g) AUTHORIZATION OF APPROPRIATION.—There  
25          are authorized to be appropriated to carry out this section,

1 \$2,000,000 for fiscal year 1994, and such sums as may  
2 be necessary for each of the fiscal years 1995 through  
3 1996.

4 **“SEC. 1225C. SPECIAL PREVENTION PROJECTS.**

5       “(a) IN GENERAL.—The Secretary shall cooperate  
6 with, and may provide assistance to, public and private  
7 nonprofit entities to reduce the incidence of traumatic  
8 brain injury through the establishment and effectuation  
9 of prevention projects. In carrying out this section, the  
10 Secretary may award grants to State and local entities,  
11 and to public or non-profit private entities, to support—

12               “(1) special prevention and public awareness  
13 initiative projects;

14               “(2) model traumatic brain injury prevention,  
15 research and support programs;

16               “(3) projects that study the service needs of in-  
17 dividuals with traumatic brain injury; and

18               “(4) projects involving grants for services co-  
19 ordination.

20       “(b) REQUIREMENTS.—To be eligible to receive as-  
21 sistance under subsection (a), an entity shall—

22               “(1) prepare and submit to the Secretary an  
23 application, at such time, in such manner, and con-  
24 taining such information as the Secretary may re-  
25 quire; and

1           “(2) provide assurances to the Secretary that  
2 any preventive measures implemented under a pre-  
3 vention project funded under this section may in-  
4 clude—

5           “(A) behavioral and environmental inter-  
6 ventions (such as physical restraints or helmets  
7 for individuals using bicycles, in-line roller  
8 skates, and skateboards);

9           “(B) the use of innovative and proven  
10 model prevention approaches;

11           “(C) the promotion of activities that will  
12 minimize brain injury risk in athletes (such as  
13 the use of head protection gear); and

14           “(D) the improvement of community-level  
15 access to data-base systems to assist in design-  
16 ing, developing, and implementing traumatic  
17 brain injury prevention programs.

18           “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
19 are authorized to be appropriated to carry out this section,  
20 \$4,000,000 for fiscal year 1994, and such sums as may  
21 be necessary for each of the fiscal years 1995 and 1996.

22 **“SEC. 1225D. BASIC AND APPLIED RESEARCH.**

23           “(a) IN GENERAL.—The Secretary, acting through  
24 the Director of the National Institutes of Health, may pro-  
25 vide assistance to public and private nonprofit entities to

1 support the conduct of basic and applied research concern-  
2 ing traumatic brain injury, especially with respect to the  
3 biomechanics of brain injury, the molecular and cellular  
4 characteristics of primary and secondary injury to the  
5 brain and the development of improved experimental brain  
6 injury models.

7       “(b) SPECIFIC RESEARCH.—Research to be con-  
8 ducted with assistance provided under subsection (a) shall  
9 be determined by the Secretary, prior to the provision of  
10 such assistance, to contribute to the strategies that will  
11 limit primary and secondary mechanical, biochemical and  
12 metabolic insults to the brain and minimize the extent,  
13 severity and progression of resulting dysfunctions. In im-  
14 plementing this section the Secretary shall emphasize—

15               “(1) the development of new methods and mo-  
16 dalities for the more effective diagnosis, measure-  
17 ment of degree of injury, post-injury monitoring and  
18 prognostic assessment of head injury for acute,  
19 subacute and later phases of care;

20               “(2) the development, modification and evalua-  
21 tion of therapies that retard, prevent or reverse  
22 brain damage after acute head injury, that arrest  
23 further deterioration following injury and that pro-  
24 vide the restitution of function for individuals with  
25 long-term injuries;

1           “(3) the integration of basic research into clinical care settings;

2           “(4) the development of a continuum of care from acute care through rehabilitation, designed, to the extent practicable, to integrate rehabilitation and long-term outcome evaluation with acute care research;

3           “(5) the development of programs that increase the participation of academic centers of excellence in head injury treatment and rehabilitation research and training; and

4           “(6) the conduct of national consensus conferences on managing head injury and related rehabilitation concerns, the findings of which shall be published.

5           “(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$5,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

6           **“SEC. 1225E. STATEWIDE PROGRAM FOR TRAUMATIC BRAIN INJURY.**

7           “(a) GRANTS.—The Secretary shall award grants to States for the establishment of programs related to traumatic brain injury. Such programs shall include State advisory boards, patient advocacy and service coordination

1 systems, and State registries concerning individuals af-  
2 fected by traumatic brain injuries. Services may also be  
3 provided under this section, within the limits of service  
4 availability, to individuals whose deficits are not due to  
5 traumatic brain injury. To be eligible for such services,  
6 such individuals should be comparable to traumatic brain  
7 injury patients in regard to the range of services needed,  
8 the severity and duration of deficits, and the etiology of  
9 their deficits being due to a nonprogressive and non-  
10 recurring disorder.

11       “(b) GENERAL ELIGIBILITY REQUIREMENTS.—To be  
12 eligible to receive a grant under subsection (a), a State  
13 shall—

14               “(1) prepare and submit to the Secretary an  
15 application, at such time, in such manner, and con-  
16 taining such information as the Secretary may re-  
17 quire;

18               “(2) provide assurances that it will prepare and  
19 submit to the Secretary reports describing the activi-  
20 ties undertaken under the State system established  
21 under the grant; and

22               “(3) provide for the establishment of a State-  
23 wide program that includes a State registry for trau-  
24 matic brain injury information, a program of patient  
25 advocacy and service coordination, and a State advi-

1 sory board with respect to activities under this sec-  
2 tion.

3 “(c) SPECIFIC PROGRAM REQUIREMENTS.—

4 “(1) STATE REGISTRY.—To be eligible to re-  
5 ceive a grant under subsection (a), a State shall—

6 “(A)(i) establish and maintain, through  
7 the utilization of procedures to ensure privacy  
8 and maintain the confidentiality of information,  
9 which are acceptable to the Secretary, a central  
10 registry of persons who sustain traumatic brain  
11 injury in order to—

12 “(I) collect information to facilitate  
13 the development of injury prevention,  
14 treatment, and rehabilitation programs;  
15 and

16 “(II) report data to the Director on  
17 an annual basis for State reporting re-  
18 quirements; and

19 “(ii) a violation of such privacy and con-  
20 fidentiality procedures or the unauthorized use  
21 of such information may result in a loss of sup-  
22 port under this section; and

23 “(B) provide summary registry data or  
24 data that is not personally identifiable to public  
25 and private entities to conduct studies using

1 data collected by the traumatic brain injury  
2 registry established under subparagraph (A),  
3 for which the coordinator may charge a fee for  
4 all expenses associated with the provision of  
5 data or data analysis.

6 “(2) ADVOCACY AND SERVICE COORDINA-  
7 TION.—To be eligible to receive a grant under sub-  
8 section (a), a State shall—

9 “(A) designate a State coordinator for  
10 traumatic brain injuries who—

11 “(i) shall establish policies and stand-  
12 ards for coordinating services within the  
13 State for individuals with traumatic brain  
14 injury;

15 “(ii) may contract with qualified agen-  
16 cies or employ staff to provide services  
17 under this section on a statewide basis to  
18 eligible individuals;

19 “(iii) shall be responsible for a pro-  
20 gram of activities related to preventing and  
21 reducing the rate of traumatic brain inju-  
22 ries in the State according to standards es-  
23 tablished by the Centers for Disease Con-  
24 trol and Prevention; and

1           “(iv) shall, after consultation with the  
2           State advisory board established under  
3           paragraph (3), establish standards regard-  
4           ing the marketing of services (by hospitals  
5           and other providers) to traumatic brain in-  
6           jury patients or family members, dissemi-  
7           nate the standards to case management  
8           programs, and furnish information on such  
9           standards to individuals who sustain trau-  
10          matic brain injuries (and the family mem-  
11          bers of such individuals) at the earliest ap-  
12          propriate opportunity after the individual  
13          has sustained the injury (such standards to  
14          include (at a minimum) a rule prohibiting  
15          payments under a case management pro-  
16          gram under this section for referring pa-  
17          tients);

18           “(B) provide assurances that a protection  
19          and advocacy system established under this sec-  
20          tion will—

21           “(i) provide legal, administrative and  
22          other appropriate remedies or approaches  
23          to ensure the protection of, and advocacy  
24          for, the rights of individuals with trau-  
25          matic brain injury within the State who

1 are or may be eligible for treatment, serv-  
2 ices, or rehabilitation;

3 “(ii) provide information and referral  
4 to programs and services addressing the  
5 needs of individuals with traumatic brain  
6 injuries; and

7 “(iii) provide for the investigation of  
8 incidents of abuse and neglect of individ-  
9 uals with traumatic brain injuries when in-  
10 cidents are reported for the provision of  
11 excessive or unnecessary services or other  
12 complaints relating to the care of such in-  
13 dividuals, and payment for the referral of  
14 patients;

15 “(C) ensure the provision to persons with  
16 traumatic brain injury of information regarding  
17 appropriate public or private agencies that pro-  
18 vide rehabilitative services so that injured per-  
19 sons or individuals responsible for such persons  
20 may obtain needed service to alleviate injuries  
21 and avoid secondary problems; and

22 “(D) for purposes of identifying the serv-  
23 ices required to prevent the institutionalization  
24 or to minimize the need for residential rehabili-  
25 tation in the case of traumatic brain injuries,

1 establish a services coordination program that  
2 shall—

3 “(i) provide for the initial assessment  
4 of the individual’s need for traumatic brain  
5 injury services;

6 “(ii) provide for the reassessment of  
7 each patient at regular intervals to deter-  
8 mine the extent of each patient’s progress,  
9 to ascertain whether a patient is being  
10 kept too long in a given setting or provided  
11 services inappropriately, or to determine  
12 whether the patient would be better served  
13 by other services or in another setting;

14 “(iii) prepare a treatment plan for  
15 each individual requiring services coordina-  
16 tion, within an appropriate period after the  
17 individual sustains the injury, based on a  
18 consultation with the individual (other  
19 than an individual who is comatose in  
20 which case consultation shall be with a  
21 person with legal responsibility over such  
22 individual) and any person named by the  
23 individual (preparation of the plan may be  
24 delayed based on a certification, including  
25 a brief explanation of the reason for the

1 delay, by a physician attesting that such a  
2 delay is in the individual's best interests  
3 with a copy of the treatment plan and any  
4 modifications to the plan being presented  
5 to the individual or the individual's legal  
6 representative);

7 “(iv) ensure that each individual's  
8 treatment plan is regularly updated (based  
9 on consultation with the individual and the  
10 person responsible for the injured individ-  
11 ual) with data and information about  
12 treatments and services provided, as well  
13 as specific measures of the individual's  
14 current performance or activity relative to  
15 goals previously established;

16 “(v) assist the individual in obtaining  
17 services necessary to allow the individual to  
18 remain in the community;

19 “(vi) coordinate home care services  
20 with other services;

21 “(vii) ensure appropriate, accessible,  
22 and cost-effective services;

23 “(viii) assist the individual with prob-  
24 lems related to the provision of home care  
25 services;

1           “(ix) ensure the quality of home care  
2 services;

3           “(x) assess the individual’s need for  
4 and level of home care services at appro-  
5 priate intervals during the course of the in-  
6 dividual’s treatment under the program;  
7 and

8           “(xi) explore efforts to include serv-  
9 ices coordination provisions under the  
10 State’s medicaid program under section  
11 1931 of the Social Security Act.

12           “(3) STATE ADVISORY BOARD.—

13           “(A) IN GENERAL.—To be eligible to re-  
14 ceive a grant under subsection (a), a State shall  
15 establish an advisory board within the appro-  
16 priate health department of the State or within  
17 another department as designated by the chief  
18 executive officer of the State.

19           “(B) FUNCTIONS.—An advisory board es-  
20 tablished under subparagraph (A) shall be cog-  
21 nizant of findings and concerns of Federal,  
22 State and local agencies, citizens groups, and  
23 private industry (such as insurance, health care,  
24 automobile, and other industry entities). Such  
25 advisory boards shall encourage citizen partici-

1           pation through the establishment of public  
2           hearings and other types of community out-  
3           reach programs.

4           “(C) COMPOSITION.—An advisory board  
5           established under subparagraph (A) shall be  
6           composed of—

7                   “(i) representatives of—

8                           “(I) the corresponding State  
9                           agencies involved;

10                           “(II) public and nonprofit private  
11                           health related organizations;

12                           “(III) other disability advisory or  
13                           planning groups within the State;

14                           “(IV) members of an organiza-  
15                           tion or foundation representing trau-  
16                           matic brain injury survivors in that  
17                           State; and

18                           “(V) injury control programs at  
19                           the State or local level if such pro-  
20                           grams exist; and

21                           “(ii) a substantial number of individ-  
22                           uals who are survivors of traumatic brain  
23                           injury, or the family members of such indi-  
24                           viduals; and

1       “(d) REPORT.—Not later than 2 years after the date  
2 of enactment of this part, the Secretary shall prepare and  
3 submit to the appropriate committees of Congress a report  
4 concerning the findings and results of the programs estab-  
5 lished under this section, including measures of outcomes  
6 and consumer and surrogate satisfaction.

7       “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
8 are authorized to be appropriated to carry out this section,  
9 \$27,000,000 for fiscal year 1994, and such sums as may  
10 be necessary for each of the fiscal years 1995 and 1996.”.

11 **SEC. 4. NATIONAL HEAD INJURY AWARENESS MONTH.**

12       The month of October, 1993, is hereby designated as  
13 “National Head Injury Month” and the President is re-  
14 quested to issue a proclamation calling on the people of  
15 the United States to observe such month with appropriate  
16 ceremonies and activities.

17 **SEC. 5. EFFECTIVE DATE.**

18       This Act shall become effective on October 1, 1993.

○

S 725 IS—2