

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

# H. R. 3121

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 22, 1993

Mr. SLATTERY (for himself, Mr. GREENWOOD, Mr. PALLONE, and Mr. QUILLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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  
5 Injury 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) provide the public with all necessary and  
2 relevant information about the prevention of trau-  
3 matic brain injury, in order for individuals to make  
4 informed and educated safety decisions;

5           (4) promote the creation of innovative programs  
6 and policies to prevent traumatic brain injury and to  
7 rehabilitate those individuals who have survived such  
8 injuries;

9           (5) designate a Federal agency to oversee and  
10 promote projects relating to the prevention of, and  
11 rehabilitation from, traumatic brain injury;

12           (6) create State advisory boards to coordinate  
13 citizen participation in community programs dealing  
14 with traumatic brain injury;

15           (7) create a registry to advance epidemiologic  
16 research on such trauma;

17           (8) establish standards for the marketing of  
18 brain injury services;

19           (9) require the Secretary to publish various re-  
20 ports concerning the activities of the Department of  
21 Health and Human Services in this area, including  
22 an annual review of relevant activities; and

23           (10) provide for the initiation of a program to  
24 establish national standards for helmets used by  
25 bicyclists and others.

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

2 Title XII of the Public Health Service Act (42 U.S.C.  
3 300d et seq.) is amended—

4 (1) by redesignating parts C through F as parts  
5 D through G, respectively; and

6 (2) by inserting after part B the following new  
7 part:

8 “PART C—TRAUMATIC BRAIN INJURY

9 **“SEC. 1225. DEFINITIONS.**

10 “As used in this part:

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

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

17 “(3) TRAUMATIC BRAIN INJURY.—The term  
18 ‘traumatic brain injury’ means an acquired injury to  
19 the brain caused by an external physical force. Such  
20 term does not include brain dysfunction caused by  
21 congenital or degenerative disorders, nor does such  
22 term include birth trauma. Such term is synonymous  
23 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  
18 matters 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;

7           “(6) identify States and localities that have im-  
8           plemented unique approaches to encouraging bicycle  
9           helmet use;

10          “(7) determine the health insurance status of  
11          individuals with traumatic brain injury; and

12          “(8) initiate a program of prevention research  
13          to develop effective prevention of traumatic brain in-  
14          jury.

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

20          “(f) BIENNIAL REPORT.—The Secretary shall bienni-  
21          ally prepare a report containing recommendations for the  
22          prevention of traumatic brain injuries. The report shall  
23          also identify States that have mandated helmet laws for  
24          bicyclists, as well as States that have unique bicycle hel-

1 met-use promotion programs in place. Such reports shall  
2 be disseminated to State health officers.

3 “(g) AUTHORIZATION OF APPROPRIATION.—There  
4 are authorized to be appropriated to carry out this section,  
5 \$2,000,000 for fiscal year 1994, and such sums as may  
6 be necessary for each of the fiscal years 1995 through  
7 1996.

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

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

16 “(1) special prevention and public awareness  
17 initiative projects;

18 “(2) model traumatic brain injury prevention,  
19 research and support programs;

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

22 “(4) projects involving grants for services co-  
23 ordination.

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

1           “(1) prepare and submit to the Secretary an  
2 application, at such time, in such manner, and con-  
3 taining such information as the Secretary may re-  
4 quire; and

5           “(2) provide assurances to the Secretary that  
6 any preventive measures implemented under a pre-  
7 vention project funded under this section may in-  
8 clude—

9           “(A) behavioral and environmental tech-  
10 niques, as well as educational and responsible-  
11 use programs;

12           “(B) the use of innovative and proven  
13 model prevention approaches;

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

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

21           “(c) RESTRICTION ON USE OF FUNDS.—A grant  
22 under subsection (a) may not be expended to engage in  
23 advocacy regarding Federal, State, or local laws.

24           “(d) RULE OF CONSTRUCTION.—The Secretary may  
25 not require that, as a condition of the receipt of a grant

1 under subsection (a), a State have in effect a law regard-  
2 ing the use of helmets while operating motorcycles.

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

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

8 “(a) IN GENERAL.—The Secretary, acting through  
9 the Director of the National Institutes of Health, may pro-  
10 vide assistance to public and private nonprofit entities to  
11 support the conduct of basic and applied research concern-  
12 ing traumatic brain injury, especially with respect to the  
13 biomechanics of brain injury, the molecular and cellular  
14 characteristics of primary and secondary injury to the  
15 brain and the development of improved experimental brain  
16 injury models.

17 “(b) SPECIFIC RESEARCH.—Research to be con-  
18 ducted with assistance provided under subsection (a) shall  
19 be determined by the Secretary, prior to the provision of  
20 such assistance, to contribute to the strategies that will  
21 limit primary and secondary mechanical, biochemical and  
22 metabolic insults to the brain and minimize the extent,  
23 severity and progression of resulting dysfunctions. In im-  
24 plementing this section the Secretary shall emphasize—

1           “(1) the development of new methods and mo-  
2           dalities for the more effective diagnosis, measure-  
3           ment of degree of injury, post-injury monitoring and  
4           prognostic assessment of head injury for acute,  
5           subacute and later phases of care;

6           “(2) the development, modification and evalua-  
7           tion of therapies that retard, prevent or reverse  
8           brain damage after acute head injury, that arrest  
9           further deterioration following injury and that pro-  
10          vide the restitution of function for individuals with  
11          long-term injuries;

12          “(3) the integration of basic research into clini-  
13          cal care settings;

14          “(4) the development of a continuum of care  
15          from acute care through rehabilitation, designed, to  
16          the extent practicable, to integrate rehabilitation and  
17          long-term outcome evaluation with acute care re-  
18          search;

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

23          “(6) the conduct of national consensus con-  
24          ferences on managing head injury and related reha-



1           “(1) prepare and submit to the Secretary an  
2 application, at such time, in such manner, and con-  
3 taining such information as the Secretary may re-  
4 quire;

5           “(2) provide assurances that it will prepare and  
6 submit to the Secretary reports describing the activi-  
7 ties undertaken under the State system established  
8 under the grant; and

9           “(3) provide for the establishment of a State-  
10 wide program that includes a State registry for trau-  
11 matic brain injury information, a program of patient  
12 advocacy and service coordination, and a State advi-  
13 sory board with respect to activities under this  
14 section.

15           “(c) SPECIFIC PROGRAM REQUIREMENTS.—

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

18           “(A)(i) establish and maintain, through  
19 the utilization of procedures to ensure privacy  
20 and maintain the confidentiality of information,  
21 which are acceptable to the Secretary, a central  
22 registry of persons who sustain traumatic brain  
23 injury in order to—

24           “(I) collect information to facilitate  
25 the development of injury prevention,

1 treatment, and rehabilitation programs;  
2 and

3 “(II) report data to the Director on  
4 an annual basis for State reporting re-  
5 quirements; and

6 “(ii) a violation of such privacy and con-  
7 fidentiality procedures or the unauthorized use  
8 of such information may result in a loss of sup-  
9 port under this section; and

10 “(B) provide summary registry data or  
11 data that is not personally identifiable to public  
12 and private entities to conduct studies using  
13 data collected by the traumatic brain injury  
14 registry established under subparagraph (A),  
15 for which the coordinator may charge a fee for  
16 all expenses associated with the provision of  
17 data or data analysis.

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

21 “(A) designate a State coordinator for  
22 traumatic brain injuries who—

23 “(i) shall establish policies and stand-  
24 ards for coordinating services within the

1 State for individuals with traumatic brain  
2 injury;

3 “(ii) may contract with qualified agen-  
4 cies or employ staff to provide services  
5 under this section on a statewide basis to  
6 eligible individuals;

7 “(iii) shall be responsible for a pro-  
8 gram of activities related to preventing and  
9 reducing the rate of traumatic brain inju-  
10 ries in the State; and

11 “(iv) shall, after consultation with the  
12 State advisory board established under  
13 paragraph (3), establish standards regard-  
14 ing the marketing of services (by hospitals  
15 and other providers) to traumatic brain in-  
16 jury patients or family members, dissemi-  
17 nate the standards to case management  
18 programs, and furnish information on such  
19 standards to individuals who sustain trau-  
20 matic brain injuries (and the family mem-  
21 bers of such individuals) at the earliest ap-  
22 propriate opportunity after the individual  
23 has sustained the injury (such standards to  
24 include (at a minimum) a rule prohibiting  
25 payments under a case management pro-

1           gram under this section for referring pa-  
2           tients);

3           “(B) provide assurances that a protection  
4           and advocacy system established under this sec-  
5           tion will—

6                   “(i) provide legal, administrative and  
7                   other appropriate remedies or approaches  
8                   to ensure the protection of, and advocacy  
9                   for, the rights of individuals with trau-  
10                  matic brain injury within the State who  
11                  are or may be eligible for treatment, serv-  
12                  ices, or rehabilitation;

13                   “(ii) provide information and referral  
14                   to programs and services addressing the  
15                   needs of individuals with traumatic brain  
16                   injuries; and

17                   “(iii) provide for the investigation of  
18                   incidents of abuse and neglect of individ-  
19                   uals with traumatic brain injuries when in-  
20                   cidents are reported for the provision of  
21                   excessive or unnecessary services or other  
22                   complaints relating to the care of such in-  
23                   dividuals, and payment for the referral of  
24                   patients;

1           “(C) ensure the provision to persons with  
2           traumatic brain injury of information regarding  
3           appropriate public or private agencies that pro-  
4           vide rehabilitative services so that injured per-  
5           sons or individuals responsible for such persons  
6           may obtain needed service to alleviate injuries  
7           and avoid secondary problems; and

8           “(D) for purposes of identifying the serv-  
9           ices required to prevent the institutionalization  
10          or to minimize the need for residential rehabili-  
11          tation in the case of traumatic brain injuries,  
12          establish a services coordination program that  
13          shall—

14                 “(i) provide for the initial assessment  
15                 of the individual’s need for traumatic brain  
16                 injury services;

17                 “(ii) provide for the reassessment of  
18                 each patient at regular intervals to deter-  
19                 mine the extent of each patient’s progress,  
20                 to ascertain whether a patient is being  
21                 kept too long in a given setting or provided  
22                 services inappropriately, or to determine  
23                 whether the patient would be better served  
24                 by other services or in another setting;

1           “(iii) prepare a treatment plan for  
2 each individual requiring services coordina-  
3 tion, within an appropriate period after the  
4 individual sustains the injury, based on a  
5 consultation with the individual (other  
6 than an individual who is comatose in  
7 which case consultation shall be with a  
8 person with legal responsibility over such  
9 individual) and any person named by the  
10 individual (preparation of the plan may be  
11 delayed based on a certification, including  
12 a brief explanation of the reason for the  
13 delay, by a physician attesting that such a  
14 delay is in the individual’s best interests  
15 with a copy of the treatment plan and any  
16 modifications to the plan being presented  
17 to the individual or the individual’s legal  
18 representative);

19           “(iv) ensure that each individual’s  
20 treatment plan is regularly updated (based  
21 on consultation with the individual and the  
22 person responsible for the injured individ-  
23 ual) with data and information about  
24 treatments and services provided, as well  
25 as specific measures of the individual’s

1 current performance or activity relative to  
2 goals previously established;

3 “(v) assist the individual in obtaining  
4 services necessary to allow the individual to  
5 remain in the community;

6 “(vi) coordinate home care services  
7 with other services;

8 “(vii) ensure appropriate, accessible,  
9 and cost-effective services;

10 “(viii) assist the individual with prob-  
11 lems related to the provision of home care  
12 services;

13 “(ix) ensure the quality of home care  
14 services;

15 “(x) assess the individual’s need for  
16 and level of home care services at appro-  
17 priate intervals during the course of the in-  
18 dividual’s treatment under the program;  
19 and

20 “(xi) explore efforts to include serv-  
21 ices coordination provisions under the  
22 State’s medicaid program under section  
23 1931 of the Social Security Act.

24 “(3) STATE ADVISORY BOARD.—

1           “(A) IN GENERAL.—To be eligible to re-  
2           ceive a grant under subsection (a), a State shall  
3           establish an advisory board within the appro-  
4           priate health department of the State or within  
5           another department as designated by the chief  
6           executive officer of the State.

7           “(B) FUNCTIONS.—An advisory board es-  
8           tablished under subparagraph (A) shall be cog-  
9           nizant of findings and concerns of Federal,  
10          State and local agencies, citizens groups, and  
11          private industry (such as insurance, health care,  
12          automobile, and other industry entities). Such  
13          advisory boards shall encourage citizen partici-  
14          pation through the establishment of public  
15          hearings and other types of community out-  
16          reach programs.

17          “(C) COMPOSITION.—An advisory board  
18          established under subparagraph (A) shall be  
19          composed of—

20                 “(i) representatives of—

21                         “(I) the corresponding State  
22                         agencies involved;

23                         “(II) public and nonprofit private  
24                         health related organizations;

1                   “(III) other disability advisory or  
2                   planning groups within the State;

3                   “(IV) members of an organiza-  
4                   tion or foundation representing trau-  
5                   matic brain injury survivors in that  
6                   State; and

7                   “(V) injury control programs at  
8                   the State or local level if such pro-  
9                   grams exist; and

10                  “(ii) a substantial number of individ-  
11                  uals who are survivors of traumatic brain  
12                  injury, or the family members of such indi-  
13                  viduals.

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

20                  “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
21 are authorized to be appropriated to carry out this section,  
22 \$27,000,000 for fiscal year 1994, and such sums as may  
23 be necessary for each of the fiscal years 1995 and 1996.”.

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

2       The month of October, 1993, is hereby designated as  
3 “National Head Injury Month” and the President is re-  
4 quested to issue a proclamation calling on the people of  
5 the United States to observe such month with appropriate  
6 ceremonies and activities.

7 **SEC. 5. EFFECTIVE DATE.**

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

○

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