

In the House of Representatives, U. S.,

August 8, 1994.

Resolved, That the bill from the Senate (S. 725) entitled “An Act 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”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause, and insert:

1 ***SECTION 1. PROGRAMS OF CENTERS FOR DISEASE CON-***
2 ***TROL AND PREVENTION.***

3 *Part B of title III of the Public Health Service Act*
4 *(42 U.S.C. 241 et seq.), as amended by section 703 of Public*
5 *Law 103–183 (107 Stat. 2240), is amended by inserting*
6 *after section 317F the following section:*

7 *“PREVENTION OF TRAUMATIC BRAIN INJURY*

8 *“SEC. 317G. The Secretary, acting through the Direc-*
9 *tor of the Centers for Disease Control and Prevention, may*
10 *carry out projects to reduce the incidence of traumatic*
11 *brain injury. Such projects may be carried out by the Sec-*
12 *retary directly or through awards of grants or contracts to*
13 *public or nonprofit private entities. The Secretary may di-*
14 *rectly or through such awards provide technical assistance*

1 *with respect to the planning, development, and operation*
2 *of such projects.*

3 “(b) *CERTAIN ACTIVITIES.*—Activities under sub-
4 *section (a) may include—*

5 “(1) *the conduct of research into identifying ef-*
6 *fective strategies for the prevention of traumatic brain*
7 *injury; and*

8 “(2) *the implementation of public information*
9 *and education programs for the prevention of such in-*
10 *jury and for broadening the awareness of the public*
11 *concerning the public health consequences of such in-*
12 *jury.*

13 “(c) *COORDINATION OF ACTIVITIES.*—The Secretary
14 *shall ensure that activities under this section are coordi-*
15 *nated as appropriate with other agencies of the Public*
16 *Health Service that carry out activities regarding trau-*
17 *matic brain injury.*

18 “(d) *DEFINITION.*—For purposes of this section, the
19 *term ‘traumatic brain injury’ means an acquired injury*
20 *to the brain. Such term does not include brain dysfunction*
21 *caused by congenital or degenerative disorders, nor birth*
22 *trauma, but may include brain injuries caused by anoxia*
23 *due to near drowning. The Secretary may revise the defini-*
24 *tion of such term as the Secretary determines necessary.’.*

1 **SEC. 2. PROGRAMS OF NATIONAL INSTITUTES OF HEALTH.**

2 *Section 1261 of the Public Health Service Act (42*
3 *U.S.C. 300d-61) is amended—*

4 *(1) in subsection (d)—*

5 *(A) in paragraph (2), by striking “and”*
6 *after the semicolon at the end;*

7 *(B) in paragraph (3), by striking the period*
8 *and inserting “; and”; and*

9 *(C) by adding at the end the following*
10 *paragraph:*

11 *“(4) the authority to make awards of grants or*
12 *contracts to public or nonprofit private entities for*
13 *the conduct of basic and applied research regarding*
14 *traumatic brain injury, which research may in-*
15 *clude—*

16 *“(A) the development of new methods and*
17 *modalities for the more effective diagnosis, meas-*
18 *urement of degree of injury, post-injury monitor-*
19 *ing and prognostic assessment of head injury for*
20 *acute, subacute and later phases of care;*

21 *“(B) the development, modification and*
22 *evaluation of therapies that retard, prevent or*
23 *reverse brain damage after acute head injury,*
24 *that arrest further deterioration following injury*
25 *and that provide the restitution of function for*
26 *individuals with long-term injuries;*

1 “(C) the development of research on a con-
 2 tinuum of care from acute care through rehabili-
 3 tation, designed, to the extent practicable, to in-
 4 tegrate rehabilitation and long-term outcome
 5 evaluation with acute care research; and

6 “(D) the development of programs that in-
 7 crease the participation of academic centers of
 8 excellence in head injury treatment and rehabili-
 9 tation research and training.”; and

10 (2) in subsection (h), by adding at the end the
 11 following paragraph:

12 “(4) The term ‘traumatic brain injury’ means
 13 an acquired injury to the brain. Such term does not
 14 include brain dysfunction caused by congenital or de-
 15 generative disorders, nor birth trauma, but may in-
 16 clude brain injuries caused by anoxia due to near
 17 drowning. The Secretary may revise the definition of
 18 such term as the Secretary determines necessary.”.

19 **SEC. 3. PROGRAMS OF HEALTH RESOURCES AND SERVICES**
 20 **ADMINISTRATION.**

21 Part E of title XII of the Public Health Service Act
 22 (42 U.S.C. 300d–51 et seq.) is amended by adding at the
 23 end the following section:

1 **“SEC. 1252. STATE GRANTS FOR DEMONSTRATION**
2 **PROJECTS REGARDING TRAUMATIC BRAIN**
3 **INJURY.**

4 “(a) *IN GENERAL.*—The Secretary, acting through the
5 Administrator of the Health Resources and Services Admin-
6 istration, may make grants to States for the purpose of car-
7 rying out demonstration projects to improve access to health
8 and other services regarding traumatic brain injury.

9 “(b) *STATE ADVISORY BOARD.*—

10 “(1) *IN GENERAL.*—The Secretary may make a
11 grant under subsection (a) only if the State involved
12 agrees to establish an advisory board within the ap-
13 propriate health department of the State or within
14 another department as designated by the chief execu-
15 tive officer of the State.

16 “(2) *FUNCTIONS.*—An advisory board established
17 under paragraph (1) shall advise and make rec-
18 ommendations to the State on ways to improve serv-
19 ices coordination regarding traumatic brain injury.
20 Such advisory boards shall encourage citizen partici-
21 pation through the establishment of public hearings
22 and other types of community outreach programs.

23 “(3) *COMPOSITION.*—An advisory board estab-
24 lished under paragraph (1) shall be composed of—

25 “(A) representatives of—

1 “(i) the corresponding State agencies
2 involved;

3 “(ii) public and nonprofit private
4 health related organizations;

5 “(iii) other disability advisory or
6 planning groups within the State;

7 “(iv) members of an organization or
8 foundation representing traumatic brain in-
9 jury survivors in that State; and

10 “(v) injury control programs at the
11 State or local level if such programs exist;
12 and

13 “(B) a substantial number of individuals
14 who are survivors of traumatic brain injury, or
15 the family members of such individuals.

16 “(c) MATCHING FUNDS.—

17 “(1) IN GENERAL.—With respect to the costs to
18 be incurred by a State in carrying out the purpose
19 described in subsection (a), the Secretary may make
20 a grant under such subsection only if the State agrees
21 to make available, in cash, non-Federal contributions
22 toward such costs in an amount that is not less than
23 \$1 for each \$2 of Federal funds provided under the
24 grant.

1 “(2) *DETERMINATION OF AMOUNT CONTRIB-*
2 *UTED.—In determining the amount of non-Federal*
3 *contributions in cash that a State has provided pur-*
4 *suant to paragraph (1), the Secretary may not in-*
5 *clude any amounts provided to the State by the Fed-*
6 *eral Government.*

7 “(d) *APPLICATION FOR GRANT.—The Secretary may*
8 *make a grant under subsection (a) only if an application*
9 *for the grant is submitted to the Secretary and the applica-*
10 *tion is in such form, is made in such manner, and contains*
11 *such agreements, assurances, and information as the Sec-*
12 *retary determines to be necessary to carry out this section.*

13 “(e) *COORDINATION OF ACTIVITIES.—The Secretary*
14 *shall ensure that activities under this section are coordi-*
15 *nated as appropriate with other agencies of the Public*
16 *Health Service that carry out activities regarding trau-*
17 *matic brain injury.*

18 “(f) *REPORT.—Not later than 2 years after the date*
19 *of the enactment of this section, the Secretary shall submit*
20 *to the Committee on Energy and Commerce of the House*
21 *of Representatives, and to the Committee on Labor and*
22 *Human Resources of the Senate, a report describing the*
23 *findings and results of the programs established under this*
24 *section, including measures of outcomes and consumer and*
25 *surrogate satisfaction.*

1 “(g) *DEFINITION.*—For purposes of this section, the
 2 term ‘traumatic brain injury’ means an acquired injury
 3 to the brain. Such term does not include brain dysfunction
 4 caused by congenital or degenerative disorders, nor birth
 5 trauma, but may include brain injuries caused by anoxia
 6 due to near drowning. The Secretary may revise the defini-
 7 tion of such term as the Secretary determines necessary.

8 “(h) *AUTHORIZATION OF APPROPRIATIONS.*—There
 9 are authorized to be appropriated to carry out this section
 10 such sums as may be necessary for each of the fiscal years
 11 1995 through 1997.”.

12 **SEC. 4. STUDY; CONSENSUS CONFERENCE.**

13 (a) *STUDY.*—

14 (1) *IN GENERAL.*—The Secretary of Health and
 15 Human Services (in this section referred to as the
 16 “Secretary”), acting through the appropriate agencies
 17 of the Public Health Service, shall conduct a study for
 18 the purpose of carrying out the following with respect
 19 to traumatic brain injury:

20 (A) In collaboration with appropriate State
 21 and local health-related agencies—

22 (i) determine the incidence and preva-
 23 lence of traumatic brain injury; and

24 (ii) develop a uniform reporting sys-
 25 tem under which States report incidences of

1 *traumatic brain injury, if the Secretary de-*
2 *termines that such a system is appropriate.*

3 *(B) Identify common therapeutic interven-*
4 *tions which are used for the rehabilitation of in-*
5 *dividuals with such injuries, and shall, subject to*
6 *the availability of information, include an anal-*
7 *ysis of—*

8 *(i) the effectiveness of each such inter-*
9 *vention in improving the functioning of in-*
10 *dividuals with brain injuries;*

11 *(ii) the comparative effectiveness of*
12 *interventions employed in the course of re-*
13 *habilitation of individuals with brain inju-*
14 *ries to achieve the same or similar clinical*
15 *outcome; and*

16 *(iii) the adequacy of existing measures*
17 *of outcomes and knowledge of factors influ-*
18 *encing differential outcomes.*

19 *(C) Develop practice guidelines for the reha-*
20 *bilitation of traumatic brain injury at such time*
21 *as appropriate scientific research becomes avail-*
22 *able.*

23 *(2) DATES CERTAIN FOR REPORTS.—*

24 *(A) Not later than 18 months after the date*
25 *of the enactment of this Act, the Secretary shall*

1 *submit to the Committee on Energy and Com-*
2 *merce of the House of Representatives, and to the*
3 *Committee on Labor and Human Resources of*
4 *the Senate, a report describing the findings made*
5 *as a result of carrying out paragraph (1)(A).*

6 *(B) Not later than 3 years after the date of*
7 *the enactment of this Act, the Secretary shall*
8 *submit to the Committees specified in subpara-*
9 *graph (A) a report describing the findings made*
10 *as a result of carrying out subparagraphs (B)*
11 *and (C) of paragraph (1).*

12 *(b) CONSENSUS CONFERENCE.—The Secretary, acting*
13 *through the Director of the National Center for Medical Re-*
14 *habilitation Research within the National Institute for*
15 *Child Health and Human Development, shall conduct a na-*
16 *tional consensus conference on managing traumatic brain*
17 *injury and related rehabilitation concerns.*

18 *(c) DEFINITION.—For purposes of this section, the*
19 *term “traumatic brain injury” means an acquired injury*
20 *to the brain. Such term does not include brain dysfunction*
21 *caused by congenital or degenerative disorders, nor birth*
22 *trauma, but may include brain injuries caused by anoxia*
23 *due to near drowning. The Secretary may revise the defini-*
24 *tion of such term as the Secretary determines necessary.*

1 (d) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
 2 *authorized to be appropriated to carry out this section such*
 3 *sums as may be necessary for each of the fiscal years 1995*
 4 *through 1997.*

5 **SEC. 5. STATE STANDARDS.**

6 (a) *PREEMPTION.*—*Section 403A(a) of the Federal*
 7 *Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)) is*
 8 *amended—*

9 (1) *in paragraph (1), by inserting at the end the*
 10 *following: “except that this paragraph does not apply*
 11 *to a standard of identity of—*

12 “(A) *a State or political subdivision of a*
 13 *State for maple syrup which is of the type re-*
 14 *quired by sections 401 and 403(g), or*

15 “(B) *a State for fluid milk which is of the*
 16 *type required by sections 401 and 403(g) and*
 17 *which specifies a higher minimum level of milk*
 18 *components than is provided for in the cor-*
 19 *responding standard of identity promulgated*
 20 *under section 401,”*

21 (2) *in paragraph (2), by inserting at the end the*
 22 *following: “except that this paragraph does not apply*
 23 *to a requirement of a State or political subdivision of*
 24 *a State which is of the type required by section 403(c)*
 25 *and which is applicable to maple syrup,”*

1 (3) in paragraph (3), by inserting at the end the
 2 following: “except that this paragraph does not apply
 3 to a requirement of a State or political subdivision of
 4 a State which is of the type required by section
 5 403(h)(1) and which is applicable to maple syrup.”,
 6 and

7 (4) by adding at the end the following: “For pur-
 8 poses of paragraph (1)(B), the term ‘fluid milk’
 9 means liquid milk in final packaged form for bev-
 10 erage use and does not include dry milk, manufac-
 11 tured milk products, or tanker bulk milk.”.

12 (b) *PROCEDURE*.—Section 701(e)(1) of such Act (21
 13 U.S.C. 371(e)(1)) is amended by striking “or maple syrup
 14 (regulated under section 168.140 of title 21, Code of Federal
 15 Regulations)”.

16 **SEC. 6. SELENIUM.**

17 The stay (published at 58 Fed. Reg. 47962) of the 1987
 18 food additive regulation relating to selenium (21 Code of
 19 Federal Regulations 573.920) is suspended until December
 20 31, 1995.

Attest:

Clerk.

103D CONGRESS
2D SESSION

S. 725

AMENDMENT