

Calendar No. 483

107TH CONGRESS
2D SESSION

S. 2059

To amend the Public Health Service Act to provide for Alzheimer's disease research and demonstration grants.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2002

Ms. MIKULSKI (for herself, Mr. KENNEDY, Mr. HUTCHINSON, Mr. DODD, Mr. TORRICELLI, Mr. MILLER, and Mr. COCHRAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 3, 2002

Reported under the authority of the order of the Senate of June 26, 2002,
by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to provide for Alzheimer's disease research and demonstration grants.

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 "Alzheimer's Disease*
5 *Research, Prevention, and Care Act of 2002".*

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Alzheimer's disease is a disorder that de-
4 stroys cells in the brain. The disease is the leading
5 cause of dementia, a condition that involves gradual
6 memory loss, decline in the ability to perform rou-
7 tine tasks, disorientation, difficulty in learning, loss
8 of language skills, impairment of judgment, and per-
9 sonality changes. As the disease progresses, people
10 with Alzheimer's disease become unable to care for
11 themselves. The loss of brain cells eventually leads
12 to the failure of other systems in the body.13 (2) In the United States, 4,000,000 people have
14 Alzheimer's disease and 19,000,000 people say that
15 they have a family member with the disease. By
16 2050, 14,000,000 people in the United States will
17 have Alzheimer's disease unless science finds a way
18 to prevent or cure the disease.19 (3) One in 10 people over the age of 65, and
20 nearly half of those over the age of 85 have Alz-
21 heimer's disease. Younger people also get the dis-
22 ease.23 (4) The Alzheimer's disease process may begin
24 in the brain as many as 20 years before the symp-
25 toms of Alzheimer's disease appear. A person will

1 live an average of 8 years and as many as 20 once
2 the symptoms of Alzheimer's disease appear.

3 (5) The average lifetime cost of Alzheimer's dis-
4 ease, per person, is \$174,000. The total annual cost
5 of Alzheimer's disease care in the United States
6 today is not less than \$100,000,000,000.

7 (6) In 2000, medicare alone spent
8 \$31,900,000,000 for the care of individuals with
9 Alzheimer's disease and this amount is projected to
10 increase to \$49,300,000,000 in 2010.

11 (7) Forty-nine percent of medicare beneficiaries
12 who have Alzheimer's disease also receive medicaid.
13 Of the total population dually eligible for medicare
14 and medicaid, 22 percent have Alzheimer's disease.

15 (8) Seven in 10 people with Alzheimer's disease
16 live at home. While almost 75 percent of home care
17 is provided by family and friends, the average an-
18 nual cost of paid care for people with Alzheimer's
19 disease at home is \$12,500.

20 (9) At least half of all nursing home residents
21 have Alzheimer's disease or another dementia. The
22 average annual cost of Alzheimer's disease nursing
23 home care is \$42,000 but exceeds \$70,000 in some
24 areas. Medicaid pays nearly half of the total nursing
25 home bill and helps 2 out of 3 residents pay for

1 their care. Medicaid expenditures for nursing home
2 care for people with Alzheimer's disease are esti-
3 mated to increase from \$18,200,000,000 in 2000 to
4 \$33,000,000,000 in 2010.

5 (10) In fiscal year 2002, the Federal Govern-
6 ment will spend an estimated \$585,000,000 on Alz-
7 heimer's disease research, a modest investment when
8 compared with the annual \$100,000,000,000 cost of
9 the disease. If science can find a way to delay the
10 onset of Alzheimer's disease symptoms for even 5
11 years, our Nation will save at least \$50,000,000,000
12 in annual health and long term care costs.

13 (11) Seventy percent of people with Alzheimer's
14 disease live at home where families provide at least
15 75 percent of their care.

16 (12) A study commissioned by the United Hos-
17 pital Fund estimated that the annual value of this
18 informal care system is \$196,000,000,000. Family
19 caregiving comes at enormous physical, emotional,
20 and financial sacrifice, putting the whole system at
21 risk.

22 (13) One in 8 Alzheimer's disease caregivers be-
23 comes ill or injured as a direct result of caregiving.
24 One in 3 uses medication for problems related to
25 caregiving. Older caregivers are 3 times more likely

1 to become clinically depressed than others in their
2 age group.

3 (14) Elderly spouses strained by caregiving are
4 63 percent more likely to die during a given 4-year
5 period than other spouses their age.

6 (15) Three of 4 caregivers are women. One in
7 3 has children or grandchildren under the age of 18
8 living at home. Caregiving leaves them less time for
9 other family members and they are much more likely
10 to report family conflicts because of their caregiving
11 role.

12 (16) Most Alzheimer's disease caregivers work
13 outside the home before beginning their caregiving
14 careers, but caregiving forces them to miss work, cut
15 back to part-time, take less demanding jobs, choose
16 early retirement, or give up work altogether. As a
17 result, in 2002, Alzheimer's disease will cost Amer-
18 ican business an estimated \$36,500,000,000 in lost
19 productivity, as well as an additional
20 \$24,600,000,000 in business contributions to the
21 total cost of care.

22 **SEC. 3. PURPOSE OF THE NATIONAL INSTITUTE ON AGING.**

23 Section 443 of the Public Health Service Act (42
24 U.S.C. 285e) is amended by inserting "Alzheimer's dis-
25 ease and related disorders," after "aging process".

1 **SEC. 4. ALZHEIMER'S DISEASE PREVENTION INITIATIVE.**2 Section 444 of the Public Health Service Act (42
3 U.S.C. 285e-1) is amended—4 (1) in subsection (d), by inserting “and train-
5 ing” after “conduct research”; and

6 (2) by adding at the end the following:

7 “(e) The Director of the Institute shall, in collabora-
8 tion with the directors of the other relevant institutes and
9 centers of the National Institutes of Health, and with vol-
10 unteer organizations and other stakeholders, undertake an
11 Alzheimer's Disease Prevention Initiative to—12 “(1) accelerate the discovery of new risk and
13 protective factors for Alzheimer's disease;14 “(2) rapidly identify candidate diagnostics,
15 therapies, or preventive interventions or agents for
16 clinical investigation and trials relating to Alz-
17 heimer's disease;18 “(3) support or undertake such investigations
19 and trials; and20 “(4) implement effective prevention and treat-
21 ment strategies, including strategies to improve pa-
22 tient care and alleviate caregiver burdens relating to
23 Alzheimer's disease.”.

1 **SEC. 5. ALZHEIMER'S DISEASE CLINICAL RESEARCH.**

2 (a) CLINICAL RESEARCH.—Section 445F of the Pub-
3 lie Health Service Act (42 U.S.C. 285e-8) is amended to
4 read as follows:

5 **“SEC. 445F. ALZHEIMER'S DISEASE COOPERATIVE STUDY**6 **GROUP.**

7 “(a) IN GENERAL.—The Director of the Institute,
8 pursuant to subsections (d) and (e) of section 444, shall
9 establish and support a national consortium for coopera-
10 tive clinical research regarding Alzheimer's disease. Such
11 a consortium shall—

12 “(1) investigate therapies, interventions, and
13 agents to detect, treat, slow the progression of, or
14 prevent Alzheimer's disease;

15 “(2) enhance the national infrastructure for the
16 conduct of clinical trials;

17 “(3) develop and test novel approaches to the
18 design and analysis of such trials;

19 “(4) facilitate the enrollment of, and expand
20 the range of, patients for such trials, including pa-
21 tients from diverse populations;

22 “(5) develop improved diagnostics and means of
23 patient assessment for Alzheimer's disease; and

24 “(6) include, as determined appropriate by the
25 Director of the Institute, the Alzheimer's Disease

1 Centers and Alzheimer's Disease Research Centers
2 established under section 445.

3 **“(b) EARLY DIAGNOSIS AND DETECTION RE-**
4 **SEARCH.**

5 **“(1) IN GENERAL.**—The Director of the Insti-
6 tute, in consultation with the directors of other rel-
7 evant institutes and centers of the National Insti-
8 tutes of Health, shall conduct, or make grants for
9 the conduct of, research related to the early detec-
10 tion and diagnosis of Alzheimer's disease and of
11 mild cognitive impairment or other potential precur-
12 sors to Alzheimer's disease.

13 **“(2) EVALUATION.**—The research described in
14 paragraph (1) may include the evaluation of diag-
15 nostic tests and imaging techniques.

16 **“(c) VASCULAR DISEASE.**—The Director of the Insti-
17 tute, in consultation with the directors of other relevant
18 institutes and centers of the National Institutes of Health,
19 shall, conduct or make grants for the conduct of, research
20 related to the relationship of vascular disease and Alz-
21 heimer's disease, including clinical trials to determine
22 whether drugs developed to prevent cerebrovascular dis-
23 ease can prevent the onset or progression of Alzheimer's
24 disease.

1 “(d) NATIONAL ALZHEIMER’S COORDINATING CEN-
2 TER.—The Director of the Institute may establish a Na-
3 tional Alzheimer’s Coordinating Center to facilitate col-
4 laborative research among the Alzheimer’s Disease Cen-
5 ters and Alzheimer’s Disease Research Centers established
6 under section 445.”.

7 (b) ALZHEIMER’S DISEASE CENTERS.—Section
8 445(a)(1) of the Public Health Service Act (42 U.S.C.
9 285e-2(a)(1)) is amended by inserting “, and outcome
10 measures and disease management” after “treatment
11 methods”.

12 **SEC. 6. RESEARCH ON ALZHEIMER’S DISEASE CAREGIVING.**

13 Section 445C of the Public Health Service Act (42
14 U.S.C. 285e-5) is amended—

15 (1) by striking “SEC. 445C. (a)” and inserting
16 the following:

17 **“SEC. 445C. RESEARCH ON ALZHEIMER’S DISEASE SERV-
18 ICES AND CAREGIVING.**

19 “(a) SERVICES RESEARCH.—”;

20 (2) by striking subsections (b), (c), and (d);

21 (3) by inserting after subsection (a) the fol-
22 lowing:

23 “(b) INTERVENTIONS RESEARCH.—The Director
24 shall, in collaboration with the directors of the other rel-
25 evant institutes and centers of the National Institutes of

1 Health, conduct, or make grants for the conduct of, clinical, social, and behavioral research related to interventions designed to help caregivers of patients with Alzheimer's disease and related disorders.", and

5 (4) in subsection (d) by striking "(d) the Director" and inserting "(e) MODEL CURRICULA AND
6 TECHNIQUES.—The Director".

7 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

9 (a) IN GENERAL.—Section 445J of the Public Health
10 Service Act (42 U.S.C. 285e-11) is amended by striking
11 "\$500,000,000 for fiscal year 1994, and such sums as
12 may be necessary for each of the fiscal years 1995 and
13 1996." and inserting "\$1,500,000,000 for fiscal year
14 2003, and such sums as may be necessary for each of the
15 fiscal years 2004 through 2007."

16 (b) AGING PROCESS REGARDING WOMEN.—Section
17 445H(b) of the Public Health Service Act (42 U.S.C.
18 285e-10(b)) is amended by striking "2003" and inserting
19 "2007".

20 (c) CLINICAL RESEARCH AND TRAINING AWARDS.—
21 Section 445I(d) of the Public Health Service Act (42
22 U.S.C. 285e-10a(d)) is amended by striking "2005" and
23 inserting "2007".

1 **SEC. 8. ALZHEIMER'S DISEASE DEMONSTRATION GRANTS.**2 Section 398B(e) of the Public Health Service Act (42
3 U.S.C. 280c-5(e)) is amended—4 (1) by striking “and such” and inserting
5 “such”; and6 (2) by inserting before the period “,
7 \$25,000,000 for fiscal year 2003, and such sums as
8 may be necessary for each of the fiscal years 2004
9 through 2007”.10 **SECTION 1. SHORT TITLE.**11 *This Act may be cited as the “Alzheimer’s Disease Re-
12 search, Prevention, and Care Act of 2002”.*13 **SEC. 2. FINDINGS.**14 *Congress makes the following findings:*15 *(1) Alzheimer’s disease is a disorder that de-
16 stroys cells in the brain. The disease is the leading
17 cause of dementia, a condition that involves gradual
18 memory loss, decline in the ability to perform routine
19 tasks, disorientation, difficulty in learning, loss of
20 language skills, impairment of judgment, and person-
21 ality changes. As the disease progresses, people with
22 Alzheimer’s disease become unable to care for them-
23 selves. The loss of brain cells eventually leads to the
24 failure of other systems in the body.*25 *(2) In the United States, 4,000,000 people have
26 Alzheimer’s disease and 19,000,000 people say that*

1 *they have a family member with the disease. By 2050,*
2 *14,000,000 people in the United States will have Alz-*
3 *heimer's disease unless science finds a way to prevent*
4 *or cure the disease.*

5 *(3) One in 10 people over the age of 65, and*
6 *nearly half of those over the age of 85 have Alz-*
7 *heimer's disease. Younger people also get the disease.*

8 *(4) The Alzheimer's disease process may begin in*
9 *the brain as many as 20 years before the symptoms*
10 *of Alzheimer's disease appear. A person will live an*
11 *average of 8 years and as many as 20 once the symp-*
12 *toms of Alzheimer's disease appear.*

13 *(5) The average lifetime cost of Alzheimer's dis-*
14 *ease, per person, is \$174,000. The total annual cost*
15 *of Alzheimer's disease care in the United States today*
16 *is not less than \$100,000,000,000.*

17 *(6) In 2000, medicare alone spent*
18 *\$31,900,000,000 for the care of individuals with Alz-*
19 *heimer's disease and this amount is projected to in-*
20 *crease to \$49,300,000,000 in 2010.*

21 *(7) Forty-nine percent of medicare beneficiaries*
22 *who have Alzheimer's disease also receive medicaid.*
23 *Of the total population dually eligible for medicare*
24 *and medicaid, 22 percent have Alzheimer's disease.*

1 (8) *Seven in 10 people with Alzheimer's disease*
2 *live at home. While almost 75 percent of home care*
3 *is provided by family and friends, the average annual*
4 *cost of paid care for people with Alzheimer's disease*
5 *at home is \$12,500.*

6 (9) *At least half of all nursing home residents*
7 *have Alzheimer's disease or another dementia. The av-*
8 *erage annual cost of Alzheimer's disease nursing home*
9 *care is \$42,000 but exceeds \$70,000 in some areas.*
10 *Medicaid pays nearly half of the total nursing home*
11 *bill and helps 2 out of 3 residents pay for their care.*
12 *Medicaid expenditures for nursing home care for peo-*
13 *ple with Alzheimer's disease are estimated to increase*
14 *from \$18,200,000,000 in 2000 to \$33,000,000,000 in*
15 *2010.*

16 (10) *In fiscal year 2002, the Federal Government*
17 *will spend an estimated \$585,000,000 on Alzheimer's*
18 *disease research, a modest investment when compared*
19 *with the annual \$100,000,000,000 cost of the disease.*
20 *If science can find a way to delay the onset of Alz-*
21 *heimer's disease symptoms for even 5 years, our Na-*
22 *tion will save at least \$50,000,000,000 in annual*
23 *health and long term care costs.*

1 (11) *Seventy percent of people with Alzheimer's
2 disease live at home where families provide at least
3 75 percent of their care.*

4 (12) *A study commissioned by the United Hos-
5 pital Fund estimated that the annual value of this in-
6 formal care system is \$196,000,000,000. Family
7 caregiving comes at enormous physical, emotional,
8 and financial sacrifice, putting the whole system at
9 risk.*

10 (13) *One in 8 Alzheimer's disease caregivers be-
11 comes ill or injured as a direct result of caregiving.
12 One in 3 uses medication for problems related to
13 caregiving. Older caregivers are 3 times more likely
14 to become clinically depressed than others in their age
15 group.*

16 (14) *Elderly spouses strained by caregiving are
17 63 percent more likely to die during a given 4-year
18 period than other spouses their age.*

19 (15) *Three of 4 caregivers are women. One in 3
20 has children or grandchildren under the age of 18 liv-
21 ing at home. Caregiving leaves them less time for
22 other family members and they are much more likely
23 to report family conflicts because of their caregiving
24 role.*

(16) *Most Alzheimer's disease caregivers work outside the home before beginning their caregiving careers, but caregiving forces them to miss work, cut back to part-time, take less demanding jobs, choose early retirement, or give up work altogether. As a result, in 2002, Alzheimer's disease will cost American business an estimated \$36,500,000,000 in lost productivity, as well as an additional \$24,600,000,000 in business contributions to the total cost of care.*

10 SEC. 3. PRIORITY TO ALZHEIMER'S DISEASE RESEARCH.

11 *Section 443 of the Public Health Service Act (42*
12 *U.S.C. 285e) is amended—*

15 (2) by adding at the end the following:

16 “(b) *PRIORITIES*.—The Director of the Institute shall,
17 in expending amounts appropriated under this subpart,
18 give priority to conducting and supporting Alzheimer’s dis-
19 ease research.”.

20 SEC. 4. ALZHEIMER'S DISEASE PREVENTION INITIATIVE.

21 *Section 444 of the Public Health Service Act (42*
22 *U.S.C. 285e-1) is amended—*

23 (1) in subsection (d), by inserting “and train-
24 ing” after “conduct research”; and

25 (2) by adding at the end the following:

1 “(e) *The Director of the National Institutes of Health*
2 *shall, in collaboration with the Director of the Institute, the*
3 *directors of other relevant institutes, and with volunteer or-*
4 *ganizations and other stakeholders, undertake an Alz-*
5 *heimer’s Disease Prevention Initiative to—*

6 “(1) *accelerate the discovery of new risk and pro-*
7 *tective factors for Alzheimer’s disease;*

8 “(2) *rapidly identify candidate diagnostics,*
9 *therapies, or preventive interventions or agents for*
10 *clinical investigation and trials relating to Alz-*
11 *heimer’s disease;*

12 “(3) *support or undertake such investigations*
13 *and trials; and*

14 “(4) *implement effective prevention and treat-*
15 *ment strategies, including strategies to improve pa-*
16 *tient care and alleviate caregiver burdens relating to*
17 *Alzheimer’s disease.”.*

18 **SEC. 5. ALZHEIMER’S DISEASE CLINICAL RESEARCH.**

19 (a) *CLINICAL RESEARCH.—Section 445F of the Public*
20 *Health Service Act (42 U.S.C. 285e–8) is amended to read*
21 *as follows:*

22 **“SEC. 445F. ALZHEIMER’S DISEASE CLINICAL RESEARCH.**

23 “(a) *IN GENERAL.—The Director of the Institute, pur-*
24 *suant to subsections (d) and (e) of section 444, shall conduct*

1 and support cooperative clinical research regarding Alzheimer's disease. Such research shall include—
2

3 “(1) investigating therapies, interventions, and
4 agents to detect, treat, slow the progression of, or prevent Alzheimer's disease;

5 “(2) enhancing the national infrastructure for
6 the conduct of clinical trials;

7 “(3) developing and testing novel approaches to
8 the design and analysis of such trials;

9 “(4) facilitating the enrollment of patients for
10 such trials, including patients from diverse populations;

11 “(5) developing improved diagnostics and means
12 of patient assessment for Alzheimer's disease; and

13 “(6) as determined appropriate by the Director
14 of the Institute, the Alzheimer's Disease Centers and
15 Alzheimer's Disease Research Centers established
16 under section 445.

17 “(b) **EARLY DIAGNOSIS AND DETECTION RE-**
18 **SEARCH.**—

19 “(1) **IN GENERAL.**—The Director of the Institute,
20 in consultation with the directors of other relevant institutions and centers of the National Institutes of
21 Health, shall conduct, or make grants for the conduct
22 of, research related to the early detection and diag-

1 *nosis of Alzheimer's disease and of mild cognitive im-*
2 *pairment or other potential precursors to Alzheimer's*
3 *disease.*

4 "(2) *EVALUATION.*—*The research described in*
5 *paragraph (1) may include the evaluation of diag-*
6 *nostic tests and imaging techniques.*

7 "(c) *VASCULAR DISEASE.*—*The Director of the Insti-*
8 *tute, in consultation with the directors of other relevant in-*
9 *stitutes and centers of the National Institutes of Health,*
10 *shall conduct or make grants for the conduct of, research*
11 *related to the relationship of vascular disease and Alz-*
12 *heimer's disease, including clinical trials to determine*
13 *whether drugs developed to prevent cerebrovascular disease*
14 *can prevent the onset or progression of Alzheimer's disease.*

15 "(d) *NATIONAL ALZHEIMER'S COORDINATING CEN-*
16 *TER.*—*The Director of the Institute may establish a Na-*
17 *tional Alzheimer's Coordinating Center to facilitate collabo-*
18 *rative research among the Alzheimer's Disease Centers and*
19 *Alzheimer's Disease Research Centers established under sec-*
20 *tion 445.*".

21 "(b) *ALZHEIMER'S DISEASE CENTERS.*—Section
22 445(a)(1) of the Public Health Service Act (42 U.S.C. 285e-
23 2(a)(1)) is amended by inserting “, and outcome measures
24 and disease management” after “treatment methods”.

1 **SEC. 6. RESEARCH ON ALZHEIMER'S DISEASE CAREGIVING.**2 *Section 445C of the Public Health Service Act (42*3 *U.S.C. 285e-5) is amended—*4 *(1) by striking “SEC. 445C. (a)” and inserting*5 *the following:*6 **“SEC. 445C. RESEARCH ON ALZHEIMER'S DISEASE SERV-**7 **ICES AND CAREGIVING.**8 *“(a) SERVICES RESEARCH.—”;*9 *(2) by striking subsections (b), (c), and (e);*10 *(3) by inserting after subsection (a) the fol-*
11 *lowing:*12 *“(b) INTERVENTIONS RESEARCH.—The Director shall,*
13 *in collaboration with the directors of the other relevant in-*
14 *stitutes and centers of the National Institutes of Health,*
15 *conduct, or make grants for the conduct of, clinical, social,*
16 *and behavioral research related to interventions designed to*
17 *help caregivers of patients with Alzheimer's disease and re-*
18 *lated disorders and improve patient outcomes.”; and*19 *(4) in subsection (d), by striking “(d) the Direc-*
20 *tor” and inserting “(c) MODEL CURRICULA AND*
21 *TECHNIQUES.—The Director”.*22 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**23 *(a) IN GENERAL.—Section 445J of the Public Health*
24 *Service Act (42 U.S.C. 285e-11) is amended by striking*
25 *“\$500,000,000 for fiscal year 1994, and such sums as may*
26 *be necessary for each of the fiscal years 1995 and 1996.”*

1 and inserting “\$1,100,000,000 for fiscal year 2003,
2 \$1,200,000,000 for fiscal year 2004, \$1,300,000,000 for fis-
3 cal year 2005, \$1,400,000,000 for fiscal year 2006, and
4 \$1,500,000,000 for fiscal year 2007.”.

5 (b) AGING PROCESS REGARDING WOMEN.—Section
6 445H(b) of the Public Health Service Act (42 U.S.C. 285e-
7 10(b)) is amended by striking “2003” and inserting
8 “2007”.

9 (c) CLINICAL RESEARCH AND TRAINING AWARDS.—
10 Section 445I(d) of the Public Health Service Act (42 U.S.C.
11 285e-10a(d)) is amended by striking “2005” and inserting
12 “2007”.

13 **SEC. 8. ALZHEIMER’S DISEASE DEMONSTRATION GRANTS.**

14 Section 398B(e) of the Public Health Service Act (42
15 U.S.C. 280c-5(e)) is amended—

16 (1) by striking “and such” and inserting “such”;
17 and
18 (2) by inserting before the period “, \$20,000,000
19 for fiscal year 2003, and such sums as may be nec-
20 essary for each of the fiscal years 2004 through 2007”.

Calendar No. 483

107TH CONGRESS
2D SESSION **S. 2059**

A BILL

To amend the Public Health Service Act to provide
for Alzheimer's disease research and demonstra-
tion grants.

JULY 3, 2002

Reported under the authority of the order of the Senate
of June 26, 2002, with an amendment