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2D SESSION

S. 2069

To amend the Public Health Service Act to speed American innovation in research and drug development for the leading causes of death that are the most costly chronic conditions for our Nation, to save American families and the Federal and State governments money, and to help family caregivers.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2012

Ms. MIKULSKI (for herself, Mr. KERRY, Ms. COLLINS, Mr. BLUMENTHAL, and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to speed American innovation in research and drug development for the leading causes of death that are the most costly chronic conditions for our Nation, to save American families and the Federal and State governments money, and to help family caregivers.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Spending Reductions
3 through Innovations in Therapies Agenda Act of 2012”
4 or the “SPRINT Act”.

5 **SEC. 2. FINDINGS.**

6 Congress finds as follows:

7 (1) Half of health care expenses in the United
8 States are spent on 5 percent of the population.
9 Many of the most expensive health conditions to
10 treat are also the leading causes of death.

11 (2) Improving a patient’s quality of life by de-
12 veloping innovative treatments that improve health
13 outcomes and lead to a cure will improve produc-
14 tivity in the United States, reduce government
15 spending, and enhance public health.

16 (3) More than a quarter of all Americans—and
17 2 out of 3 older Americans—have multiple chronic
18 conditions, and treatment for these individuals ac-
19 counts for 66 percent of the health care budget of
20 the United States.

21 (4) Alzheimer’s disease and related dementias,
22 for instance, have a disproportionate health and eco-
23 nomic impact on patients, particularly those suf-
24 fering from multiple chronic conditions. In 2004,
25 Medicare payments per person for beneficiaries aged
26 65 and older with Alzheimer’s disease and other de-

1 mentias were almost 3 times as high as average
2 Medicare payments for other Medicare beneficiaries
3 in the same age group. In addition, Alzheimer's pa-
4 tients often depend on full-time at home or institu-
5 tional care. Medicaid payments per person for Medi-
6 care beneficiaries aged 65 and older with Alz-
7 heimer's disease and other dementias were more
8 than 9 times as great as average Medicaid payments
9 for other Medicare beneficiaries in the same age
10 group.

11 (5) The Medicare program under title XVIII of
12 the Social Security Act (42 U.S.C. 1395 et seq.) and
13 the Medicaid program under title XIX of the Social
14 Security Act (42 U.S.C. 1396 et seq.) cover about
15 70 percent of the total costs of caring for people
16 with Alzheimer's disease. In 2011, Medicare is ex-
17 pected to spend approximately \$93,000,000,000 for
18 the care of individuals with Alzheimer's disease and
19 other dementias, and this amount is projected to in-
20 crease to \$627,000,000,000 in 2050. Medicaid costs
21 are expected to increase nearly 400 percent, from
22 \$34,000,000,000 in 2011 to \$178,000,000,000 in
23 2050.

24 (6) Researchers believe sustained and targeted
25 investment in outcomes oriented research for the

1 leading causes of death will improve health treat-
 2 ments and make cures more obtainable.

3 (7) The United States Government has, in the
 4 past, successfully addressed major research chal-
 5 lenges by committing resources in high-risk and
 6 high-reward basic and applied research.

7 **SEC. 3. SPRINT PROGRAM.**

8 Part A of title II of the Public Health Service Act
 9 (42 U.S.C. 202 et seq.) is amended by adding at the end
 10 the following:

11 **“SEC. 230. SPRINT PROGRAM.**

12 “(a) DEFINITIONS.—In this section:

13 “(1) ADVANCED RESEARCH AND DEVELOP-
 14 MENT.—The term ‘advanced research and develop-
 15 ment’ means activities that predominantly are con-
 16 ducted after basic research through early clinical de-
 17 velopment of novel therapies, naturally occurring
 18 compounds, and repurposed or reformulated drugs,
 19 biological products, and devices in use to treat
 20 chronic conditions.

21 “(2) BIOLOGICAL PRODUCT.—The term ‘bio-
 22 logical product’ has the meaning given such term in
 23 section 351.

1 “(3) DEVICE; DRUG.—The terms ‘device’ and
2 ‘drug’ have the meanings given such terms in section
3 201 of the Federal Food, Drug, and Cosmetic Act.

4 “(4) EARLY-STAGE COMPANY.—The term
5 ‘early-stage company’ means a business enterprise
6 with a limited operating history, such as a start-up
7 enterprise.

8 “(5) FEDERAL HEALTH CARE PROGRAM.—The
9 term ‘Federal health care program’ has the meaning
10 given such term in section 1128B(f) of the Social
11 Security Act.

12 “(6) GROWTH COMPANY.—The term ‘growth
13 company’ means a business enterprise that grows at
14 a greater rate than the United States economy as a
15 whole and that usually directs a relatively high pro-
16 portion of income back into the business.

17 “(7) HIGH-COST CHRONIC CONDITION.—The
18 term ‘high-cost chronic condition’ means a condition
19 as determined by the Secretary under subsection
20 (c)(1).

21 “(8) THERAPY.—The term ‘therapy’ means any
22 drug, device, biological product, or diagnostic identi-
23 fied by the Secretary to treat, prevent, diagnose,
24 delay-onset, cure, or aid recovery of a high-cost
25 chronic condition.

1 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
 2 shall establish the Spending Reductions through Innova-
 3 tions in Therapies Program (referred to in this section as
 4 the ‘SPRINT Program’) to support development of thera-
 5 pies to reduce spending by Federal health care programs
 6 for high-cost chronic conditions.

7 “(c) HIGH-COST CHRONIC CONDITIONS.—

8 “(1) IN GENERAL.—The Secretary shall deter-
 9 mine the high-cost chronic conditions that shall be
 10 the focus of the SPRINT Program. In making such
 11 determination, the Secretary shall select chronic con-
 12 ditions, from the top 10 leading causes of death des-
 13 ignated by the Centers for Disease Control and Pre-
 14 vention, that have—

15 “(A) the highest current and projected cost
 16 to Federal health care programs and high long-
 17 term care costs;

18 “(B) a likelihood of reducing the day-to-
 19 day functioning of an individual and impairing
 20 the ability of the individual to carry out activi-
 21 ties of daily living, which can result in the indi-
 22 vidual becoming dependent on caregivers;

23 “(C) a death rate that has increased and
 24 is projected to increase significantly in future
 25 years; and

1 “(D) a lack of existing therapies to pre-
2 vent, control, or cure the condition or delay cog-
3 nitive decline, if applicable.

4 “(2) ALLOCATION.—In carrying out the
5 SPRINT Program, the Secretary shall allocate fund-
6 ing towards the chronic conditions as determined in
7 paragraph (1).

8 “(d) GOALS.—The SPRINT Program shall be guided
9 by national plans and strategies, as appropriate, and
10 shall—

11 “(1) accelerate advanced research and develop-
12 ment of therapies for high-cost chronic conditions;
13 and

14 “(2) encourage innovation in technologies that
15 may assist advanced research and development to re-
16 duce the time and cost of therapy development.

17 “(e) DUTIES.—The Secretary shall carry out the fol-
18 lowing duties under this section:

19 “(1) Convene meetings and working groups
20 with representatives from relevant industries, aca-
21 demia, other Federal agencies, States, patients, pa-
22 tient and consumer advocacy organizations, inter-
23 national agencies (as appropriate), and other inter-
24 ested persons as the Secretary deems necessary.

1 “(2) Ensure that the activities described in
2 paragraph (1) are coordinated among agencies with-
3 in the Department of Health and Human Services.

4 “(3) Partner with a nonprofit strategic invest-
5 ment entity or entities that will advise the Depart-
6 ment of Health and Human Services regarding, and
7 may make on behalf of such Department, invest-
8 ments in public entities, nonprofit entities, early-
9 stage companies, or growth companies with expertise
10 in advanced research and development of therapies
11 for high-cost chronic conditions that can dem-
12 onstrate a reasonable likelihood of reducing net
13 spending under the Medicare program under title
14 XVIII of the Social Security Act and the Medicaid
15 program under title XIX of such Act within 10
16 years after the date of enactment of the Spending
17 Reductions through Innovations in Therapies Agen-
18 da Act of 2012.

19 “(4) Award contracts, grants, cooperative
20 agreements, or enter into other transactions, such as
21 prize payments, to accelerate advanced research and
22 development of therapies that have the potential to
23 prevent, diagnose, delay-onset, cure, aid recovery, or
24 improve health outcomes for high-cost chronic condi-

1 tions, through the SPRINT Award Program under
2 subsection (f).

3 “(5) Reduce the time and cost barriers between
4 laboratory discoveries and clinical trials for therapies
5 used to treat high-cost chronic conditions.

6 “(6) Facilitate innovative and expedited review
7 by the Food and Drug Administration of the thera-
8 pies developed under subsection (f), which may in-
9 clude—

10 “(A) facilitating regular and ongoing com-
11 munication between the sponsors of such drugs,
12 devices, diagnostics, and biological products and
13 the Food and Drug Administration regarding
14 the status of activities related to such drugs,
15 devices, diagnostics, and biological products;

16 “(B) ensuring that such activities are co-
17 ordinated with the approval requirements of the
18 Food and Drug Administration, with the goal
19 of expediting the development and approval of
20 therapies; and

21 “(C) developing regulatory science, proc-
22 esses, and mechanisms to provide clear, effi-
23 cient pathways for developing and manufac-
24 turing therapies for high-cost chronic condi-
25 tions.

1 “(f) SPRINT AWARD PROGRAM.—

2 “(1) IN GENERAL.—There is established a
3 SPRINT Award Program, under which the Sec-
4 retary may, in consultation or partnership with a
5 nonprofit strategic investment entity, award con-
6 tracts, grants, cooperative agreements, or enter into
7 other transactions, such as prize payments, to sup-
8 port advanced research and the development of
9 therapies, in order to carry out paragraphs (4) and
10 (6) of subsection (e). Awards granted through the
11 SPRINT Award Program shall be funded by the
12 SPRINT Program.

13 “(2) ELIGIBILITY; APPLICATION.—

14 “(A) ELIGIBILITY.—To be eligible to re-
15 ceive an award under this section, an entity
16 shall be a public, nonprofit, early stage com-
17 pany, or growth company, which may include a
18 private or public research institution, an insti-
19 tution of higher education, a medical center, a
20 biotechnology company, a pharmaceutical com-
21 pany, a medical device company, an academic
22 research institution, or other organization spe-
23 cializing in advanced research and development,
24 and shall submit an application to the Secretary
25 as described in subparagraph (B).

1 “(B) APPLICATION.—An entity desiring an
2 award under this subsection shall submit to the
3 Secretary an application at such time, in such
4 manner, and containing such information as the
5 Secretary may require, such as—

6 “(i) a detailed description of the
7 project for which the entity seeks an
8 award;

9 “(ii) a timetable for carrying out such
10 project;

11 “(iii) an assurance that the entity will
12 submit interim reports and a final report
13 at the conclusion of the award period, as
14 determined appropriate by the Secretary
15 under paragraph (3);

16 “(iv) a description of how the project
17 will lead to the development of therapies
18 aimed at preventing, curing, reversing, or
19 slowing the progression of an underlying
20 chronic condition; and

21 “(v) a description of how the project
22 will support efforts to reduce long-term
23 Federal spending on health care.

24 “(3) AWARDEE REPORTING REQUIREMENTS.—

25 An entity that receives an award under this sub-

1 section shall submit reports to the Secretary which
2 may include—

3 “(A) interim reports describing the
4 progress in carrying out the project and compli-
5 ance with all conditions of receipt of such
6 award;

7 “(B) a final report at the conclusion of the
8 award period describing—

9 “(i) the outcomes of the project, in-
10 cluding whether the entity achieved the
11 goals set forth in the application;

12 “(ii) the protocols the entity followed
13 to carry out the research and comply with
14 the research and ethical standards of the
15 National Institutes of Health, if applicable;
16 and

17 “(iii) the standards and regulatory re-
18 quirements of the Food and Drug Admin-
19 istration at all stages of development, man-
20 ufacturing, review, approval, and safety
21 surveillance, if applicable; and

22 “(C) such additional information required
23 by the Secretary.

24 “(4) TERMINATION OF FUNDING.—The Sec-
25 retary may modify or terminate a contract, grant,

1 cooperative agreement, other transaction, or prize to
 2 an awardee that does not meet milestones that are
 3 conditions of the contract, grant, cooperative agree-
 4 ment, other transaction, or prize.

5 “(5) CONSULTATION WITH NONPROFIT STRA-
 6 TEGIC INVESTMENT ENTITY.—In making awards
 7 under this subsection, the Secretary may consult or
 8 partner with a nonprofit strategic investment entity
 9 or entities that—

10 “(A) operate independently of the Depart-
 11 ment of Health and Human Services and con-
 12 sist of experts in neurology, biomedical re-
 13 search, drug and medical technology innovation
 14 and discovery, economics, and venture financ-
 15 ing; and

16 “(B) have a record of—

17 “(i) promoting the development of
 18 therapies; and

19 “(ii) supporting novel technologies
 20 that have the potential to improve the de-
 21 velopment of therapies.

22 “(6) MATCHING FUNDS.—

23 “(A) IN GENERAL.—The Secretary may
 24 not make an award under this section unless
 25 the recipient involved agrees to make available

1 non-Federal contributions, in cash or in-kind,
2 toward the costs of the project in an amount
3 equal to not less than \$2 for each \$1 of Federal
4 funds provided in the award. Such contributions
5 may be made directly or through donations
6 from public or private entities. Amounts pro-
7 vided by the Federal Government, or services
8 assisted or subsidized to any significant extent
9 by the Federal Government, may not be in-
10 cluded in determining the amount of such con-
11 tributions.

12 “(B) EXCEPTION.—The Secretary may
13 waive or modify the matching requirement
14 under subparagraph (A) on a case-by-case basis
15 for each award if the Secretary determines that
16 the goals and objectives of the SPRINT Award
17 Program cannot adequately be carried out un-
18 less such requirement is waived.

19 “(g) NON-DUPLICATION OF EFFORTS.—The Sec-
20 retary shall ensure that the activities under this section
21 complement and extend other efforts of the Department
22 of Health and Human Services.

23 “(h) GIFTS IN SUPPORT OF THE SPRINT AWARD
24 PROGRAM.—The Secretary may accept on behalf of the
25 United States money gifts and bequests made uncondi-

tionally to the SPRINT Award Program under subsection (f) for the benefit of the Award Program or any activity financed through such Award Program.

“(i) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$50,000,000 for fiscal year 2013, and such sums as may be necessary for each of fiscal years 2014 through 2017. Funds appropriated under this section shall be available until expended.”.

10 **SEC. 4. EVALUATION AND REPORT.**

(a) EVALUATION.—The Secretary of Health and Human Services shall evaluate the projects funded under section 230 of the Public Health Service Act (as added by section 3) as necessary and shall make publicly available and disseminate the results of such evaluations on as wide a basis as practicable.

(b) REPORTS.—Not later than 2 years after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to Congress a report that—

(1) describes the specific projects supported under section 230 of the Public Health Service Act (as added by section 3) and progress towards meeting science-based metrics;

1 (2) provides recommendations for Congress to
2 improve the effectiveness of the programs under
3 such section 230;

4 (3) explains why the Secretary waived or modi-
5 fied matching funds requirements for an award
6 under subsection (f) of such section 230, if applica-
7 ble; and

8 (4) describes how advanced research and devel-
9 opment supported through the SPRINT Program
10 under such section 230 is directed towards reducing
11 Federal spending on high-cost chronic conditions (as
12 defined in such section).

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