

Calendar No. 478

113TH CONGRESS
2D SESSION**S. 315**

To reauthorize and extend the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 13, 2013

Ms. KLOBUCHAR (for herself, Mr. WICKER, Mr. SANDERS, Ms. COLLINS, Mr. MENENDEZ, Mr. ISAKSON, Ms. MIKULSKI, Mr. LEAHY, Mr. LAUTENBERG, Mr. NELSON, Mr. SCHUMER, Mr. COCHRAN, Mrs. BOXER, Mr. KING, Mr. BENNET, Ms. STABENOW, Mr. BLUNT, Mrs. SHAHEEN, Mr. MARKEY, Mrs. GILLIBRAND, Mr. BROWN, Mr. TESTER, Mr. GRAHAM, Mr. COONS, Ms. WARREN, Ms. CANTWELL, Mr. PRYOR, Mr. BOOKER, Mr. FRANKEN, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 23, 2014

Reported by Mr. HARKIN, with an amendment and an amendment to the title
[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To reauthorize and extend the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008.

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 “Paul D. Wellstone
3 Muscular Dystrophy Community Assistance, Research and
4 Education (MD-CARE) Amendments of 2013”.

5 **SEC. 2. INITIATIVE THROUGH THE DIRECTOR OF THE NA-**
6 **TIONAL INSTITUTES OF HEALTH.**

7 Section 404E of the Public Health Service Act (42
8 U.S.C. 283g) is amended—

9 (1) in subsection (a)(1)—

10 (A) by striking “Muscoskeletal” and in-
11 serting “Musculoskeletal”; and

12 (B) by inserting “Becker, myotonic,
13 facioSCapulohumeral muscular dystrophy (re-
14 ferred to in this section as ‘FSHD’), Congenital
15 muscular dystrophy, Limb-girdle muscular dys-
16 trophy,” after “Duchenne,”

17 (2) in subsection (b)—

18 (A) in paragraph (2), by inserting “cardiac
19 and pulmonary function,” after “imaging, ge-
20 netics,”; and

21 (B) in paragraph (3), by inserting “and
22 sharing of data” after “regular communica-
23 tion”;

24 (3) in subsection (d)—

25 (A) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking “15” and inserting “18”; and

(ii) in subparagraph (A), by striking “children with muscular dystrophy, such as the Department of Education” and inserting “children and adults with muscular dystrophy, such as the Department of Education, the Social Security Administration, the United States Administration for Community Living”; and

(B) in paragraph (4)(B), by inserting “, and shall meet no less than two times per calendar year” before the period;

(4) in subsection (c)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking “through the national research institutes” and inserting “through the represented Federal agencies”; and

(ii) in subparagraph (A), by striking “and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities” and inserting

“public resources, and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities, health economic studies to demonstrate the cost-effectiveness of providing independent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy”; and

(B) in paragraph (2), by adding at the end the following:

“(F) The development of clinical interventions to improve the health of adults with various forms of muscular dystrophy.”; and

(5) in subsection (g), by striking “for the various forms of muscular dystrophy by prioritizing the achievement of the goals related to this topic in the plan under subsection (c)(1)” and inserting “and shall, not later than 6 months after the date of enactment of the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2013, in coordination with appropriate Federal agencies, including

1 relevant offices within the Food and Drug Adminis-
 2 tration and supported by the National Institutes of
 3 Health and Department of Defense, develop a plan
 4 to expedite the evaluation and approval of emerging
 5 therapies and personalized medicines that have the
 6 potential to decrease fatal disease progression across
 7 the various forms of muscular dystrophy”.

8 **SEC. 3. SURVEILLANCE AND RESEARCH REGARDING MUS-**
 9 **CULAR DYSTROPHY.**

10 Section 317Q of the Public Health Service Act (42
 11 U.S.C. 247b–18) is amended—

12 (1) in the second sentence of subsection (b), by
 13 inserting before the period the following: “and en-
 14 sure that the program captures data from different
 15 racial and ethnic populations, and that such data
 16 are made publicly available to investigators con-
 17 ducting public or private research on muscular dys-
 18 trophy”; and

19 (2) in subsection (c), by adding at the end the
 20 following: “The Secretary shall also foster ongoing
 21 engagement and collaboration between the surveil-
 22 lance program and centers of excellence.”.

23 **SEC. 4. INFORMATION AND EDUCATION.**

24 Section 5(e) of the Muscular Dystrophy Community
 25 Assistance, Research and Education Amendments of 2001

1 ~~(42 U.S.C. 247b–19(c))~~ is amended by adding at the end
 2 the following:

3 “(4) Update and widely disseminate existing
 4 Duchenne-Becker muscular dystrophy care consider-
 5 ations for pediatric patients; develop and widely dis-
 6 seminate Duchenne-Becker muscular dystrophy care
 7 considerations for adult patients; and develop and
 8 widely disseminate acute care considerations for all
 9 muscular dystrophy populations. The care consider-
 10 ations should build upon existing efforts currently
 11 underway for congenital muscular dystrophy,
 12 fascioscapulohumeral muscular dystrophy, limb-gir-
 13 dle muscular dystrophy, and myotonic muscular dys-
 14 trophy, and incorporate strategies specifically re-
 15 sponding to the findings of the national transitions
 16 survey of minority, young adult and adult commu-
 17 nities of muscular dystrophy patients.”.

18 **SECTION 1. SHORT TITLE.**

19 *This Act may be cited as the “Paul D. Wellstone Mus-*
 20 *cular Dystrophy Community Assistance, Research and*
 21 *Education Amendments of 2014”.*

22 **SEC. 2. INITIATIVE THROUGH THE DIRECTOR OF THE NA-**
 23 **TIONAL INSTITUTES OF HEALTH.**

24 *Section 404E of the Public Health Service Act (42*
 25 *U.S.C. 283g) is amended—*

1 (1) *in subsection (a)(1)—*

2 (A) *by striking “Muscoskeletal” and insert-*
3 *ing “Musculoskeletal”; and*

4 (B) *by inserting “Becker, congenital mus-*
5 *cular dystrophy, limb-girdle muscular dys-*
6 *trophy,” after “Duchenne,”;*

7 (2) *in subsection (b)—*

8 (A) *in paragraph (2)—*

9 (i) *by striking “genetics,” at the second*
10 *place it appears; and*

11 (ii) *by inserting “cardiac and pul-*
12 *monary function, and” after “imaging,”;*
13 *and*

14 (B) *in paragraph (3), by inserting “and*
15 *sharing of data” after “regular communication”;*

16 (3) *in subsection (d)—*

17 (A) *in paragraph (2)—*

18 (i) *in the matter preceding subpara-*
19 *graph (A), by striking “15” and inserting*
20 *“18”; and*

21 (ii) *in subparagraph (A)—*

22 (I) *by striking “and the Food and*
23 *Drug Administration” and inserting “,*
24 *the Food and Drug Administration,*

1 *and the Administration for Commu-*
 2 *nity Living”;*

3 (II) *by inserting “and adults”*
 4 *after “children”; and*

5 (III) *by striking “such as the De-*
 6 *partment of Education” and inserting*
 7 *“including the Department of Edu-*
 8 *cation and the Social Security Admin-*
 9 *istration”; and*

10 (B) *in paragraph (4)(B), by inserting “,*
 11 *but shall meet no fewer than two times per cal-*
 12 *endar year” before the period; and*

13 (4) *in subsection (e)—*

14 (A) *in paragraph (1)—*

15 (i) *in the matter preceding subpara-*
 16 *graph (A), by striking “through the na-*
 17 *tional research institutes” and inserting*
 18 *“through the agencies represented on the Co-*
 19 *ordinating Committee pursuant to sub-*
 20 *section (d)(2)(A)”;* and

21 (ii) *in subparagraph (A)—*

22 (I) *by inserting “public services,”*
 23 *before “and rehabilitative issues”; and*

24 (II) *by inserting “, studies to*
 25 *demonstrate the cost-effectiveness of*

1 *providing independent living resources*
 2 *and support to patients with various*
 3 *forms of muscular dystrophy, and*
 4 *studies to determine optimal clinical*
 5 *care interventions for adults with var-*
 6 *ious forms of muscular dystrophy”*
 7 *after “including studies of the impact*
 8 *of such diseases in rural and under-*
 9 *served communities”; and*

10 *(B) in paragraph (2)(D), by inserting after*
 11 *“including new biological agents” the following:*
 12 *“and new clinical interventions to improve the*
 13 *health of those with muscular dystrophy”.*

14 **SEC. 3. SURVEILLANCE AND RESEARCH REGARDING MUS-**
 15 **CULAR DYSTROPHY.**

16 *The second sentence of section 317Q(b) of the Public*
 17 *Health Service Act (42 U.S.C. 247b–18(b)) is amended by*
 18 *inserting before the period the following: “and, to the extent*
 19 *possible, ensure that data be representative of all affected*
 20 *populations and shared in a timely manner”.*

21 **SEC. 4. INFORMATION AND EDUCATION.**

22 *Section 5(c) of the Muscular Dystrophy Community*
 23 *Assistance, Research and Education Amendments of 2001*
 24 *(42 U.S.C. 247b–19(c)) is amended—*

25 *(1) in paragraph (2)—*

1 (A) by inserting “for pediatric and adult
2 patients, including acute care considerations,”
3 after “issuance of care considerations”;

4 (B) by inserting “various” before “other
5 forms of muscular dystrophy”; and

6 (C) by striking “and” at the end;

7 (2) by redesignating paragraph (3) as para-
8 graph (4);

9 (3) by inserting after paragraph (2) the fol-
10 lowing:

11 “(3) in developing and updating care consider-
12 ations under paragraph (2), incorporate strategies
13 specifically responding to the findings of the national
14 transitions survey of minority, young adult, and
15 adult communities of muscular dystrophy patients;
16 and”; and

17 (4) in paragraph (4), as redesignated, by insert-
18 ing “various” before “other forms of muscular dys-
19 trophy”.

Amend the title so as to read: “A bill to amend the
Public Health Service Act relating to Federal research on
muscular dystrophy, and for other purposes.”.

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A BILL

To reauthorize and extend the Paul D. Wellstone
Muscular Dystrophy Community Assistance, Re-
search, and Education Amendments of 2008.

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Reported with an amendment and an amendment to the
title