

# Calendar No. 478

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 315

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

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## 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*]

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## 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 sserting “Musculoskeletal”; and

12 (B) by inserting “Becker, myotonic,  
13 facioseapulohumeral 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)—

1 (i) in the matter preceding subpara-  
2 graph (A), by striking “15” and inserting  
3 “18”; and

4 (ii) in subparagraph (A), by striking  
5 “children with muscular dystrophy, such as  
6 the Department of Education” and insert-  
7 ing “children and adults with muscular  
8 dystrophy, such as the Department of  
9 Education, the Social Security Administra-  
10 tion, the United States Administration for  
11 Community Living”; and

12 (B) in paragraph (4)(B), by inserting “,  
13 and shall meet no less than two times per cal-  
14 endar year” before the period;

15 (4) in subsection (c)—

16 (A) in paragraph (1)—

17 (i) in the matter preceding subpara-  
18 graph (A), by striking “through the na-  
19 tional research institutes” and inserting  
20 “through the represented Federal agen-  
21 cies”; and

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

1 “public resources, and rehabilitative issues,  
2 including studies of the impact of such dis-  
3 eases in rural and underserved commu-  
4 nities; health economic studies to dem-  
5 onstrate the cost-effectiveness of providing  
6 independent living resources and support  
7 to patients with various forms of muscular  
8 dystrophy, and studies to determine opti-  
9 mal clinical care interventions for adults  
10 with various forms of muscular dys-  
11 trophy”;

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

14 “(F) The development of clinical interven-  
15 tions to improve the health of adults with var-  
16 ious forms of muscular dystrophy.”;

17 (5) in subsection (g), by striking “for the var-  
18 ious forms of muscular dystrophy by prioritizing the  
19 achievement of the goals related to this topic in the  
20 plan under subsection (e)(1)” and inserting “and  
21 shall, not later than 6 months after the date of en-  
22 actment of the Paul D. Wellstone Muscular Dys-  
23 trophy Community Assistance, Research and Edu-  
24 cation (MD-CARE) Amendments of 2013, in coordi-  
25 nation 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(e)~~) 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”;

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**

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search, and Education Amendments of 2008.

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Reported with an amendment and an amendment to the  
title