

113TH CONGRESS
1ST SESSION

H. R. 1591

To amend the Public Health Service Act to provide for the establishment and maintenance of an undiagnosed diseases network, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2013

Mr. CARTER (for himself, Mr. BURGESS, Ms. SPEIER, Mr. KING of New York, Mr. McCAUL, and Mr. RANGEL) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for the establishment and maintenance of an undiagnosed diseases network, and for other purposes.

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 “Charles August Long
5 Undiagnosed Diseases Research and Collaboration Net-
6 work Act of 2013” or the “CAL Undiagnosed Diseases
7 Research and Collaboration Network Act of 2013”.

1 **SEC. 2. CAL NETWORK OF UNDIAGNOSED DISEASES.**

2 Title III of the Public Health Service Act (42 U.S.C.
3 241 et seq.) is amended by inserting after section 317T
4 the following:

5 **“SEC. 317U. THE NATIONAL CAL NETWORK OF**
6 **UNDIAGNOSED DISEASES.**

7 “(a) ESTABLISHMENT.—The Secretary, acting
8 through the Director of NIH, shall establish and maintain
9 an undiagnosed diseases patient network (in this section
10 referred to as the ‘CAL Network’).

11 “(b) PURPOSES.—The purposes of the CAL Network
12 shall be to—

13 “(1) provide physicians who are handling cases
14 of undiagnosed diseases with a means, consistent
15 with applicable privacy laws, including HIPAA pri-
16 vacy and security law (as defined in section
17 3009(a)(2)), to search for similar cases and to net-
18 work and collaborate with the physicians handling
19 such similar cases in order to find a diagnosis and
20 to improve patient care and outcomes;

21 “(2) better enable and examine cross-disease re-
22 search whereby cases of undiagnosed diseases can be
23 cross-referenced against attributes of common dis-
24 eases and rare diseases to assist in the rendering of
25 a diagnosis; elucidate commonalities; identify atypi-

1 cal presentations, rare subgroups, similar findings;
2 and identify potential treatments;

3 “(3) better describe the types and prevalence of
4 cases of undiagnosed diseases in the United States;

5 “(4) make necessary data available to elucidate
6 appropriate factors (such as genetic, environmental,
7 and occupational factors) that may be associated
8 with the various types of cases of undiagnosed dis-
9 eases reported by individuals specified by the Direc-
10 tor of NIH;

11 “(5) better outline key demographic factors
12 (such as age, race or ethnicity, gender, sex, geo-
13 graphic location, and family medical history) of indi-
14 viduals who are undiagnosed;

15 “(6) provide such data necessary to better un-
16 derstand the length of time for a diagnoses to be
17 rendered in cases of undiagnosed diseases and to
18 identify barriers to diagnoses and reasons for mis-
19 diagnosis of diseases; and

20 “(7) provide such information necessary to de-
21 termine, in order to improve access of individuals
22 with undiagnosed diseases throughout the United
23 States (including those with severe illnesses which
24 limit or restrict travel) to programs similar to the
25 Undiagnosed Disease Program conducted at the Na-

1 tional Institutes of Health, if the needs and number
2 of such individuals support—

3 “(A) the expansion of such Undiagnosed
4 Disease Program, as in existence as of the date
5 of the enactment of this section, to include the
6 establishment of additional undiagnosed dis-
7 eases programs of like scope and nature at
8 other locations throughout the United States;
9 and

10 “(B) the establishment by entities other
11 than the National Institutes of Health of sepa-
12 rate undiagnosed disease programs of like scope
13 and nature to the Undiagnosed Disease Pro-
14 gram at locations throughout the United States
15 under the guidance of and through grants pro-
16 vided by and through such Undiagnosed Dis-
17 eases Program.

18 “(c) CONTENT OF THE CAL NETWORK.—The Sec-
19 retary shall include in the CAL Network such information
20 respecting undiagnosed diseases as the Secretary deems
21 appropriate for the purposes described in subsection (b)
22 and other purposes to facilitate the early recognition,
23 treatment, cure, and control of such diseases.

24 “(d) AVAILABILITY.—

1 “(1) DESIGN REQUIREMENTS.—Subject to
2 paragraph (2), for the purposes described in sub-
3 section (c) and consistent with applicable privacy
4 laws, including HIPAA privacy and security law (as
5 defined in section 3009(a)(2)), the Secretary shall
6 ensure that the CAL Network is designed in such a
7 manner as to—

8 “(A) make the information in the CAL
9 Network available to appropriate health care
10 professionals, patients, and other qualified indi-
11 viduals and organizations, as determined by the
12 Secretary, who are registered to access such
13 network in accordance with such process and
14 requirements as specified by the Secretary;

15 “(B) make epidemiological and other types
16 of information obtained through the CAL Net-
17 work available to Federal agencies and health-
18 related agencies;

19 “(C) provide for different levels and types
20 of access to such network to be granted based
21 on the circumstances and individuals involved;
22 and

23 “(D) allow for an individual to have only
24 the level and type of access to the network so
25 granted.

1 “(2) INFORMATION WHICH MAY NOT BE PUB-
2 LICALLY DISCLOSED.—The design under paragraph
3 (1) shall ensure that the following information is not
4 publicly disclosed:

5 “(A) Individually identifiable information.

6 “(B) Trade secrets or commercial or finan-
7 cial information obtained from a person and
8 privileged or confidential, as provided in section
9 552(b)(4) of title 5, United States Code.

10 “(e) GRANTS.—The Secretary, acting through the
11 Director of NIH, may award grants to, and enter into con-
12 tracts and cooperative agreements with, public or private
13 nonprofit entities for—

14 “(1) the collection, analysis, and reporting of
15 data on cases of undiagnosed diseases and other dis-
16 orders that can often go undiagnosed or be
17 misdiagnosed as other diseases or disorders; and

18 “(2) the establishment of separate undiagnosed
19 disease programs described in subsection (b)(7)(B).

20 “(f) IMPLEMENTATION SCHEDULE.—In carrying out
21 this section, the Secretary shall—

22 “(1) not later than 1 year after the date of the
23 enactment of this section, complete any study, re-
24 search, and development necessary to implement the
25 CAL Network; and

1 “(2) complete the implementation of the CAL
2 Network such that it is fully operational by not later
3 than September 30, 2015.

4 “(g) UNDIAGNOSED DISEASES DEFINED.—For pur-
5 poses of this section, the term ‘undiagnosed disease’
6 means a medically unexplained chronic multi-symptom
7 disease that—

8 “(1) causes the decline of, limitations in, or ces-
9 sation of a person’s developmental status, functional
10 status, quality of life, or any combination thereof;

11 “(2) has not been diagnosed by a medical spe-
12 cialist in a tertiary medical center;

13 “(3) is defined by a cluster of signs or symp-
14 toms; which by history, physical examination, and
15 laboratory tests cannot be attributed to any known
16 clinical diagnosis;

17 “(4) is without conclusive pathophysiology or
18 etiology;

19 “(5) is characterized by overlapping symptoms
20 and signs; or

21 “(6) exhibits an inconsistent demonstration of
22 laboratory abnormalities.

23 “(h) AUTHORIZATION OF APPROPRIATIONS.—

1 “(1) IN GENERAL.—To carry out this section,
2 there are authorized to be appropriated \$5,000,000
3 for the period of fiscal years 2014 through 2019.

4 “(2) OFFSET.—To offset amounts appropriated
5 pursuant to the authorization of appropriations in
6 paragraph (1), the Secretary shall reduce funds that
7 would otherwise be obligated and expended under
8 the account heading ‘National Institutes of Health–
9 Office of the Director’ by \$5,000,000 for the period
10 of fiscal years 2014 through 2019.’”.

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