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TICK-BORNE DISEASE RESEARCH ACCOUNTABILITY AND TRANSPARENCY ACT OF 2014

SEPTEMBER 8, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 4701]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4701) to provide for scientific frameworks with respect to vector-borne diseases, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Tick-Borne Disease Research Accountability and Transparency Act of 2014".

SEC. 2. LYME DISEASE AND OTHER TICK-BORNE DISEASES.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

"PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES

"SEC. 399OO. RESEARCH.

"(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

"(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

"SEC. 399OO–1. WORKING GROUP.

"(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–2 referred to as the 'Working Group'), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

"(b) RESPONSIBILITIES.—The Working Group shall—

"(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

"(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

"(B) advances made pursuant to such research;

"(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

"(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

"(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

"(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

"(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

"(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

"(c) MEMBERSHIP.—

"(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

"(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

"(i) the Office of the Assistant Secretary for Health;

"(ii) the Food and Drug Administration;

"(iii) the Centers for Disease Control and Prevention;

"(iv) the National Institutes of Health; and

"(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

"(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

"(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

"(ii) Scientists or researchers with expertise.

"(iii) Patients and their family members.

"(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

"(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

"(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

"(A) one shall be appointed by the Speaker of the House of Representatives; and

"(B) one shall be appointed by the Majority Leader of the Senate.

"(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the Majority Leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.

"(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.

"(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.

"(e) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—

"(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommendations under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;

"(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and

"(3) shall allow any member of the Working Group to include in any such report minority views.

"SEC. 399OO–2. STRATEGIC PLAN.

"Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—

"(1) proposed budgetary requirements;

"(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;

"(3) a plan for improving diagnosis, treatment, and prevention;

"(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and

"(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the Working Group to the public, including health care providers, public health departments, and other relevant medical groups.".

Amend the title so as to read:

A bill to provide for research with respect to Lyme disease and other tick-borne diseases, and for other purposes.

PURPOSE AND SUMMARY

H.R. 4701, the "Tick-Borne Disease Research Accountability and Transparency Act of 2014" was introduced on May 21, 2014, by Rep. Christopher Gibson (R–NY) and referred to the Committee on Energy and Commerce.

The legislation would establish a working group at the Department of Health and Human Services to review Federal efforts concerning Lyme and other tick-borne diseases.

BACKGROUND AND NEED FOR LEGISLATION

Lyme disease is caused by a bacterium and is transmitted to humans through the bite of an infected tick. Lyme symptoms can include a skin rash along with fever, headache, and fatigue. When left untreated, the infection can spread and affect the joints, heart, and nervous system. Diagnosis is based on physical symptoms, lab testing, and exposure.[1] Approximately 10 to 20% of patients treated for Lyme disease can have lingering symptoms beyond antibiotic treatment. The exact cause of these lingering symptoms is not known.[2]

Prior to 2012, the Centers for Disease Control and Prevention (CDC) reported about 30,000 new cases each year in the U.S., with 95% of those cases in 13 States concentrated in the Northeast and upper Midwest. Using more indicators, including medical insurance claims, the CDC now estimates that around 300,000 people in the U.S. are diagnosed each year with Lyme disease, making it a substantial and vexing public health problem.[3]

H.R. 4701, the "Tick-Borne Disease Research Accountability and Transparency Act of 2014" would help to accelerate improved methods for prevention, diagnosis, and treatment of Lyme disease. The bill would establish a working group to prepare a report that would summarize Federal research efforts related to Lyme disease and other tick-borne diseases. Informed by the report prepared by the working group, the Secretary of Health and Human Services (HHS) would develop a strategic plan to improve health outcomes.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On June 19, 2014, the Subcommittee on Health met in open markup session and forwarded H.R. 4701, as amended, to the full Committee consideration, by a voice vote. On July 30, 2014, the Committee met in open markup session and approved H.R. 4701, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering approved H.R. 4701. A motion by Mr. Upton to order H.R. 4701 reported to the House, with amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held hearings on this legislation.

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[1] http://www.cdc.gov/lyme/stats/index.html
[2] http://www.cdc.gov/lyme/postLDS/index.html
[3] http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(1) of rule XIII of the House of Representatives, the goal of the legislation is the continuation of research and the establishment of working group on Lyme disease and other tick-borne diseases.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4701 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4701 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

H.R. 4701—Tick-Borne Disease Research Accountability and Transparency Act of 2014

Summary: H.R. 4701 would amend the Public Health Service Act to require the Secretary of the Department of Health and Human Services (HHS) to conduct or support research of Lyme and other tick-borne diseases. The National Institutes of Health (NIH) currently administers research programs related to such diseases. The authority for discretionary research programs at the NIH expired at the end of fiscal year 2009. For each year from 2010 through 2014, however, the Congress appropriated funds for the NIH to continue operating its discretionary programs across all areas of research.

The bill also would require that the Secretary of HHS (in its biennial reports to the Congress) describe actions taken by NIH to support research of Lyme and other tick-borne diseases and report on the progress toward improving the outcomes of such diseases. In addition, the bill would require the Secretary to establish a permanent interagency working group on Lyme and tick-borne diseases and to periodically submit to the Congress a strategic plan for the conduct and support of tick-borne disease research.

CBO estimates that implementing H.R. 4701 would cost $338 million over the 2015–2019 period, assuming appropriation of amounts similar to appropriations provided in recent years for NIH activities related to Lyme and other tick-borne diseases. Pay-as-

you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

H.R. 4701 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 4701 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2015	2016	2017	2018	2019	2015–2019
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level[a]	83	85	86	88	90	432
Estimated Outlays	24	65	78	84	88	338

Note: Numbers may not add to totals because of rounding.

[a] The amounts shown in the table are roughly equivalent to estimated funding provided in recent years for NIH activities related to Lyme and other tick-borne diseases, with adjustments for anticipated inflation.

Basis of estimate: For this estimate, CBO assumes that H.R. 4701 will be enacted early in fiscal year 2015, that the necessary amounts will be appropriated each year, and that outlays will follow historical spending patterns for the affected programs.

CBO estimates that implementing H.R. 4701 would cost $338 million over the 2015–2019 period, assuming the appropriation of the necessary amounts. The NIH currently administers research programs related to Lyme and other tick-borne diseases. Authority for discretionary research programs at NIH expired at the end of fiscal year 2009. However, since 2009 the Congress has appropriated funds for NIH to continue operating its research programs. The Congress appropriated about $30 billion to NIH for fiscal year 2014. CBO estimates that, of that total, NIH allocated $82 million for activities related to Lyme and other tick-borne diseases. The agency plans to allocate a similar amount to such activities in 2015.

H.R. 4701 would direct NIH to conduct or support research activities related to Lyme and other tick-borne diseases. Because authority for discretionary research programs funded by NIH has expired under section 402A of the Public Service Act, estimated changes in discretionary costs associated with implementing H.R 4701 reflect the total costs of all NIH-funded research activities related to Lyme and tick-borne diseases for fiscal years 2015 through 2019, assuming the availability of appropriated funds. CBO estimates that the annual costs for such research activities in each of years 2015 through 2019 would be similar to appropriated funds allocated for research on Lyme and tick-borne diseases at NIH in recent years. CBO expects that the bill would primarily affect research activities supported by NIH. However, the legislation could also affect programs administered by other HHS agencies, such as the Centers for Disease Control and Prevention.

H.R. 4701 also would establish a permanent interagency working group on Lyme and tick-borne diseases by expanding an existing working group within HHS to consist of 14 individuals (including nonfederal members of the public). The working group would be required to meet at least twice a year and to submit a report to the Congress on its activities every 24 months. The bill would also require that the Secretary submit to the Congress a strategic plan for the conduct and support of research relating to Lyme and other

tick-borne diseases every five years (starting the third year after the date of enactment of the bill). CBO estimates that those activities would cost about $1 million a year, subject to the availability of appropriated funds.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 4701 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Jamease Miles; Impact on state, local, and tribal governments: J'nell L. Blanco; Impact on the private sector: Alexia Diorio.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4701 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4701 would not specifically direct a rulemaking within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 states the legislation may be cited as the "Tick-Borne Disease Research Accountability and Transparency Act of 2014".

Section 2. Lyme disease and other tick-borne diseases

Section 2 would authorize the Secretary of HHS to conduct or support research regarding Lyme disease and other tick-borne diseases and include information on Lyme disease in the National Institutes of Health (NIH) biennial report.

The section would establish a permanent working group known as the Interagency Lyme and Tick-Borne Disease Working Group and include Federal and non-Federal members appointed by the Secretary of HHS and Congress. The working group would prepare a report that summarizes Federal activities related to Lyme disease and other tick-borne diseases and submit the results to the Secretary and Congress within 24 months.

The Committee believes it is important to form an Interagency Lyme and Tick-Borne Disease Working Group to examine Lyme and tick-borne disease research that complies with Federal Advisory Committee Act (FACA) and facilitates an opportunity to ensure people work together to improve patient health outcomes. To that end, the Working Group should represent a balanced set of viewpoints. Members should be highly qualified Lyme disease experts whose interests do not conflict with the goals of the working group. The Committee intends that the non-Federal public physicians and other medical providers, scientists, or researchers appointed to serve on the Working Group shall have appropriate expertise, education, and scientific credentials to be qualified and experienced in diagnosing, treating, or researching Lyme disease and other tick-borne diseases.

To ensure compliance with applicable conflict of interest requirements, the Committee expects that the Secretary will deem all non-Federal employee appointees to the Working Group as Special Government Employees (SGEs). As such, the Committee strongly urges the Secretary to identify a balanced and qualified working group and avoid conflicts of interest that would not improve health outcomes for patients with Lyme or other tick-borne diseases. In determining whether a potential appointee to the Working Group has a financial conflict of interest, the Committee strongly encourages the Secretary to examine issues related to significant financial gain from treating patients diagnosed with Lyme disease.

The Committee intends that the Working Group examine Lyme disease and other tick-borne diseases, including Rocky Mountain Spotted Fever, ehrlichia, anaplasma, babesiosis, Borrelia miyamotoi, Ehrlichia muris, Rickettsia parkeri, and Powassan virus.

The Committee would like the report of the Working Group to be shared with Congress at the same time that it is shared with the Secretary.

The Committee supports the current research efforts at HHS and urges communication and coordination among all working groups at HHS that work on Lyme disease and other tick-borne diseases. Therefore, the Committee encourages HHS to review the work of any other Lyme working groups that operate at HHS and share that information with the working group established in this legislation.

The section would authorize the Secretary of HHS to submit a strategic plan, informed by the report of the working group, to improve health outcomes for those suffering from Lyme disease and other tick-borne diseases.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill,

as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES

SEC. 399OO. RESEARCH.

(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

SEC. 399OO–1. WORKING GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–2 referred to as the "Working Group"), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

(b) RESPONSIBILITIES.—The Working Group shall—

(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

(B) advances made pursuant to such research;

(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

(i) the Office of the Assistant Secretary for Health;

(ii) the Food and Drug Administration;

(iii) the Centers for Disease Control and Prevention;

(iv) the National Institutes of Health; and

(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

(A) one shall be appointed by the Speaker of the House of Representatives; and

(B) one shall be appointed by the Majority Leader of the Senate.

(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the Majority Leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.

(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.

(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.

(e) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—

(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommenda-

tions under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;

(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and

(3) shall allow any member of the Working Group to include in any such report minority views.

SEC. 399OO–2. STRATEGIC PLAN.

Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—

(1) proposed budgetary requirements;

(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;

(3) a plan for improving diagnosis, treatment, and prevention;

(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and

(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the Working Group to the public, including health care providers, public health departments, and other relevant medical groups.

○