

115TH CONGRESS
2D SESSION

H. R. 5878

To provide for a national strategy to address and overcome Lyme disease
and other tick-borne diseases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 2018

Mr. SMITH of New Jersey introduced the following bill; which was referred
to the Committee on Energy and Commerce

A BILL

To provide for a national strategy to address and overcome
Lyme disease and other tick-borne diseases, 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 “National Lyme and
5 Tick-Borne Diseases Control and Accountability Act of
6 2018”.

7 **SEC. 2. OFFICE OF OVERSIGHT AND COORDINATION FOR**
8 **TICK-BORNE DISEASES.**

9 (a) ESTABLISHMENT.—The Secretary of Health and
10 Human Services shall establish in the Office of the Sec-

1 retary the Office of Oversight and Coordination for Tick-
2 Borne Diseases, to be headed by a director appointed by
3 the Secretary—

4 (1) to oversee the creation and updating of an
5 integrated national strategy to overcome Lyme dis-
6 ease and other tick-borne diseases; and

7 (2) to oversee and coordinate Lyme disease and
8 other tick-borne disease programs and activities
9 across the agencies and offices of the Department of
10 Health and Human Services.

11 (b) OBJECTIVE OF OFFICE.—In carrying out sub-
12 section (a), the Director of the Office shall facilitate and
13 work to ensure accomplishment of the following activities:

14 (1) Expansion and enhancement of epidemiolog-
15 ical research and basic, translational, and clinical bi-
16 ological and biomedical research.

17 (2) Expansion and improvement of the surveil-
18 lance and reporting of Lyme disease and other tick-
19 borne disease, including coinfections with agents of
20 more than one tick-borne disease.

21 (3) Development of effective diagnostic tests to
22 accurately and timely diagnose Lyme disease and
23 other tick-borne disease, including direct detection
24 tests.

1 (4) Development of treatments to cure or im-
2 prove the lives of those who are infected with Lyme
3 disease or other tick-borne disease or who suffer
4 from a tick-induced disorder.

5 (5) Design and conduct of clinical trials of suf-
6 ficient size and duration to support clinical rec-
7 ommendations.

8 (6) Development and maintenance of one or
9 more registries of patients and their experiences re-
10 lating to exposure to, diagnosis for, and treatment
11 of tick-borne disease, including outcomes, which reg-
12 istries shall protect the confidentiality and safety of
13 patient data.

14 (7) Systematic documentation of the experi-
15 ences of health care professionals in diagnosing and
16 treating tick-borne disease, including diagnostic and
17 treatment outcomes.

18 (8) Inclusion of individuals with chronic Lyme
19 disease in clinical, research, and service efforts.

20 (9) Coordination with international bodies to in-
21 tegrate and inform the fight against Lyme disease
22 and tick-borne disease globally.

23 (c) INTEGRATION OF TICK-BORNE DISEASE WORK-
24 ING GROUP FINDINGS AND RECOMMENDATIONS.—In car-
25 rying out this section, the Director of the Office shall, as

1 directed by the Secretary, with any modifications made by
2 and as otherwise determined appropriate by the Secretary,
3 oversee and coordinate integration and implementation,
4 into the activities of the Office and the activities and pro-
5 grams of the agencies and offices of the Department of
6 Health and Human Services, of the recommendations to
7 the Secretary and the findings and conclusions in the lat-
8 est report of the Tick-Borne Disease Working Group sub-
9 mitted to the Secretary and congressional committees.

10 (d) PRIORITY BASED ON DISEASE BURDEN.—In car-
11 rying out this section, the Director of the Office shall give
12 priority to Lyme disease and other tick-borne disease
13 based on assessments of disease burden in the United
14 States.

15 **SEC. 3. NATIONAL STRATEGY.**

16 (a) IN GENERAL.—The Secretary, in coordination
17 with the Director of the Office, and in consultation with
18 the Tick-Borne Disease Working Group, the agencies and
19 offices of the Department of Health and Human Services,
20 and other Federal agencies outside of the Department of
21 Health and Human Services as appropriate, shall—

22 (1) not later than 2 years after the date of en-
23 actment of this Act, develop and submit to the Con-
24 gress a national strategy for the conduct and sup-

1 port of Lyme disease and other tick-borne disease or
2 disorder programs and activities; and

3 (2) not less than every 2 years thereafter, up-
4 date such strategy.

5 (b) CONTENTS.—The strategy under subsection (a)
6 shall include—

7 (1) proposed budgetary requirements;

8 (2) an assessment of all federally funded pro-
9 grams and activities related to surveillance, diag-
10 nosis, treatment, education, or prevention with re-
11 spect to Lyme disease or other tick-borne disease, an
12 evaluation of progress and performance based on
13 mission and purpose, and a description of significant
14 challenges or barriers to performance, including an
15 assessment of Federal grants awarded;

16 (3) a strategy for improving diagnosis, treat-
17 ment, and prevention, including increasing the im-
18 pact of grants awarded by the National Institutes of
19 Health, the Centers for Disease Control and Preven-
20 tion, and other agencies and offices of the Depart-
21 ment of Health and Human Services;

22 (4) a strategy for improving outcomes of indi-
23 viduals with Lyme disease and other tick-borne dis-
24 eases and disorders, including progress related to
25 chronic or persistent symptoms and chronic or per-

1 sistent infection and coinfections, including plans for
 2 evaluating the potential value of and supporting the
 3 conduct of observational studies, comparative effec-
 4 tiveness research, patient-centered outcomes re-
 5 search, or other real world evidence;

6 (5) the appropriate benchmarks to measure
 7 progress in achieving the improvements described in
 8 paragraphs (3) and (4);

9 (6) a strategy for improving interactions, co-
 10 ordination, and partnerships with other Federal
 11 agencies, State and local governments, and global
 12 entities; and

13 (7) the latest recommendations of the Tick-
 14 Borne Disease Working Group and the steps taken
 15 by the agencies and offices of the Department of
 16 Health and Human Services to implement those rec-
 17 ommendations.

18 **SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS,**
 19 **SURVEILLANCE, AND PREVENTION OF, AND**
 20 **RESEARCH ON, LYME DISEASE AND OTHER**
 21 **TICK-BORNE DISEASES AND DISORDERS.**

22 (a) IN GENERAL.—The Secretary, in coordination
 23 with the Director of the Office, acting as the Secretary
 24 determines appropriate through the Director of the Cen-
 25 ters for Disease Control and Prevention, the Director of

1 the National Institutes of Health, the Commissioner of
2 Food and Drugs, the Director of the Agency for
3 Healthcare Research and Quality, the Administrator of
4 the Health Resources and Services Administration, the Di-
5 rector of the Indian Health Service, and the heads of other
6 Federal agencies, and in consultation with the Tick-Borne
7 Disease Working Group, shall provide for—

8 (1) the conduct or support of the activities de-
9 scribed in paragraphs (1) through (8) of subsection
10 (b); and

11 (2) the coordination of all programs and activi-
12 ties of the Department of Health and Human Serv-
13 ices related to Lyme disease and other tick-borne
14 diseases and disorders and Bartonella.

15 (b) ACTIVITIES.—The activities to be conducted or
16 supported under subsection (a)(1) consist of the following:

17 (1) EXPANSION AND ENHANCEMENT OF RE-
18 SEARCH.—

19 (A) IN GENERAL.—The Secretary shall ex-
20 pand and intensify epidemiological, basic,
21 translational, and clinical research regarding
22 Lyme disease and other tick-borne disease and
23 disorders and bartonellosis to better under-
24 stand—

1 (i) the pathophysiology of *Borrelia*
2 *burgdorferi* and other tick-borne micro-
3 organisms that are human pathogens and
4 of *Bartonella*;

5 (ii) pathophysiological changes over
6 time, including pathogen persistence pro-
7 files for patients with differing treatment
8 histories;

9 (iii) activation and deactivation of im-
10 mune system processes; and

11 (iv) whether, and what species of,
12 *Bartonella* are transmitted by ticks.

13 (B) CLINICAL OUTCOMES RESEARCH.—The
14 Secretary shall conduct or support clinical out-
15 comes research to—

16 (i) establish epidemiological research
17 objectives to determine the long-term
18 course of illness for Lyme disease and
19 other tick-borne diseases and disorders;

20 (ii) establish patient-centered treat-
21 ment outcome objectives to allow for the
22 comparative effectiveness of different treat-
23 ment modalities; and

24 (iii) establish patient-centered re-
25 search objectives to help elucidate prom-

1 ising treatment protocols for individuals
2 suspected of harboring coinfections with
3 more than one tick-transmitted pathogen.

4 (C) COLLABORATIVE, MULTIDISCIPLINARY
5 RESEARCH.—The Secretary shall encourage the
6 solicitation of proposals for collaborative, multi-
7 disciplinary research that would—

8 (i) result in innovative approaches to
9 study emerging scientific opportunities or
10 eliminate gaps in research to improve the
11 research portfolio, including application of
12 successful and promising advances in the
13 study of other types of diseases, such as
14 upregulating or downregulating immune
15 system cells or processes;

16 (ii) outline key research questions,
17 methodologies, and knowledge gaps;

18 (iii) expand the number of research
19 proposals that involve collaboration be-
20 tween 2 or more national research insti-
21 tutes or national centers of the National
22 Institutes of Health, including proposals
23 for research through the Common Fund
24 pursuant to section 402(b)(7) of the Public

1 Health Service Act (42 U.S.C. 282(b)(7))
2 to improve the research portfolio;

3 (iv) expand the number of collabo-
4 rative multi-institutional research grants
5 related to tick-borne disease; and

6 (v) involve additional national re-
7 search institutes and national centers of
8 the National Institutes of Health in intra-
9 mural and extramural research on tick-
10 borne disease, such as the National Insti-
11 tute of Neurological Disorders and Stroke
12 conducting or sponsoring research on
13 neurologic Lyme disease.

14 (D) EVALUATION.—Not later than 2 years
15 after the date of enactment of this Act, the Sec-
16 retary shall evaluate and make findings on—

17 (i) the feasibility and potential value
18 to the research community of establishing
19 a deidentified human subjects database for
20 Lyme disease and other tick-borne diseases
21 and disorders;

22 (ii) existing government or private
23 biorepositories for Lyme disease and other
24 tick-borne diseases and disorders and
25 whether—

1 (I) specimens and samples are
2 adequate and available to meet re-
3 searcher needs; or

4 (II) there are problems or chal-
5 lenges for researcher acquisition of
6 samples and specimens; and

7 (iii) the scope and use of specimens
8 and samples from cadavers, the questions
9 and answers such research may provide,
10 and the need for additional support of re-
11 searchers using cadaver specimens.

12 (E) PRIORITY.—In carrying out this para-
13 graph, the Secretary shall make it a priority to
14 determine the extent of posttreatment persist-
15 ence of *Borrelia burgdorferi* and the clinical sig-
16 nificance of such persistence.

17 (2) DEVELOPMENT OF NEW AND IMPROVED DI-
18 AGNOSTIC TESTS.—

19 (A) IN GENERAL.—The Secretary, in co-
20 operation with the Director of the Office, and
21 acting through the Directors of the Centers for
22 Disease Control and Prevention and the Direc-
23 tor of the National Institutes of Health, shall
24 conduct and support research to—

1 (i) provide for the timely evaluation of
2 promising new and improved diagnostic
3 methods, including direct-detection tests,
4 antibody-based tests, and tests based on
5 biosignature and biomarker profiles to
6 make a specific diagnosis or aid in dif-
7 ferential diagnoses;

8 (ii) improve the sensitivity of Lyme
9 disease tests at all stages of disease pro-
10 gression;

11 (iii) develop a Lyme disease test capa-
12 ble of distinguishing between past and ac-
13 tive infections;

14 (iv) improve timely, sensitive, and spe-
15 cific diagnostic tools and tests for Rocky
16 Mountain spotted fever; and

17 (v) improve the performance (timeli-
18 ness and accuracy) of tools and tests for
19 other tick-borne diseases found in the
20 United States.

21 (B) STRATEGIES FOR EXPEDITING CLEAR-
22 ANCE.—The Secretary shall direct the Commis-
23 sioner of Food and Drugs to design and pro-
24 pose or implement, as appropriate within the
25 authorities and public health priorities vested in

1 the Secretary by other provisions of law, strate-
2 gies for facilitating and expediting the clearance
3 or approval of improved diagnostic tests for
4 Lyme disease and other tick-borne disease, par-
5 ticularly where—

6 (i) there are no cleared diagnostic
7 tests; or

8 (ii) cleared diagnostic tests lack a
9 high level of specificity or sensitivity or are
10 unable to confirm the presence or absence
11 of active infection.

12 (3) ENSURING SAFETY AND EFFICACY OF VAC-
13 CINES.—The Secretary shall—

14 (A) ensure the safety and efficacy of any
15 new, renewed, or modified human vaccine for
16 Lyme disease, other tick-borne disease, or a
17 combination of such diseases; and

18 (B) require the Commissioner of Food and
19 Drugs to submit to the Secretary prior to final
20 approval of the vaccine being reviewed, a report,
21 with appropriate provisions for commercial con-
22 fidentiality, detailing the safety of the vaccine
23 and contrasting its safety profile based on its
24 mechanisms of action to safety concerns ex-
25 pressed to the Food and Drug Administration

1 regarding the human vaccine withdrawn from
2 the market in 2002 and how those concerns
3 with the withdrawn vaccine have been addressed
4 or why they are not relevant.

5 (4) MONITORING AND UNDERSTANDING HUMAN
6 CASES OF LYME DISEASE AND OTHER TICK-BORNE
7 DISEASES.—

8 (A) IN GENERAL.—The Secretary shall—

9 (i) establish and maintain a statis-
10 tically sound, scientifically credible surveil-
11 lance system to be known as the National
12 Tick-Borne Disease Surveillance System;

13 (ii) enhance and expand infrastructure
14 and activities to track the epidemiology of
15 Lyme disease and other tick-borne diseases
16 and disorders; and

17 (iii) incorporate information obtained
18 through such activities into the National
19 Tick-Borne Disease Surveillance System.

20 (B) RESEARCH.—The Secretary shall en-
21 sure that the National Tick-Borne Disease Sur-
22 veillance System is designed in a manner that
23 facilitates further research on Lyme disease and
24 other tick-borne diseases and disorders.

1 (C) CONTENT.—In carrying out subpara-
2 graph (A), the Secretary—

3 (i) shall provide for the collection and
4 storage of information on the incidence
5 and prevalence of tick-borne disease in the
6 United States—

7 (I) while continuing to support
8 activities in the 14 States with the
9 highest number of reported cases of
10 Lyme disease, and intensifying efforts
11 in other States where Lyme disease
12 has been reported and where all re-
13 ported cases cannot be affirmatively
14 associated with out-of-State travel in
15 order to better determine where the
16 disease is emerging;

17 (II) working with the States and
18 treating physicians, in consultation
19 with the Council of State and Terri-
20 torial Epidemiologists (in this clause
21 referred to as the “CSTE”), to im-
22 prove evaluation of the feasibility of
23 capturing data on cases that do not
24 meet surveillance criteria of the CSTE

1 and the Centers for Disease Control
2 and Prevention;

3 (III) in consultation with the
4 CSTE, working with States that are
5 using averaging or similar techniques
6 to estimate case reports to ensure that
7 data produced by that process are
8 able to be reported out by the Centers
9 for Disease Control and Prevention;

10 (IV) in consultation with the
11 CSTE, working with the States to en-
12 courage and improve laboratory re-
13 porting of Lyme disease and other
14 tick-borne diseases, and evaluate the
15 feasibility of creating a national uni-
16 form reporting system including man-
17 datory reporting by States and physi-
18 cians and laboratories in each State;

19 (V) including in the surveillance
20 system bartonellosis transmitted by
21 any vector and, if it is known, by the
22 vector of transmission; and

23 (VI) tracking incidence and prev-
24 alence data for tick-borne disorders;
25 and

1 (ii) to the extent practicable, shall
2 provide for the collection and storage of
3 other available information on Lyme dis-
4 ease and other tick-borne diseases and dis-
5 orders, including information related to
6 persons who have been diagnosed with and
7 treated for tick-borne disease who choose
8 to participate, such as—

9 (I) demographics, such as age,
10 race, sex, geographic location, and
11 other information, as appropriate;

12 (II) family history and experience
13 with tick-borne disease or tick induced
14 disorder;

15 (III) history of exposure and
16 known tick bites;

17 (IV) progression of signs and
18 symptoms;

19 (V) diagnostic and treatment his-
20 tory and outcomes; and

21 (VI) additional screening con-
22 ducted and related data, such as bio-
23 logical markers.

24 (D) CONSULTATION.—In carrying out this
25 paragraph, the Secretary shall consult with in-

dividuals with appropriate expertise, which may include—

(i) epidemiologists with experience in disease surveillance or registries;

(ii) representatives of national patient advocacy and research organizations that focus on tick-borne disease and have demonstrated experience in research, data collection, or patient access to care;

(iii) health information technology experts or other information management specialists;

(iv) clinicians with expertise in Lyme disease or other tick-borne diseases or disorders; and

(v) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(E) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this paragraph.

1 (F) COORDINATION WITH FEDERAL,
2 STATE, AND LOCAL AGENCIES.—Subject to sub-
3 paragraph (H), the Secretary shall—

4 (i) establish agreements and mecha-
5 nisms, as appropriate, for improved col-
6 lecting and reporting of tick-borne disease
7 surveillance data under subparagraphs (A),
8 (B), and clause (i) of subparagraph (C)
9 and other available information under
10 clause (ii) of subparagraph (C) from com-
11 munity health centers funded by the
12 Health Resources and Services Administra-
13 tion and medical facilities of the Indian
14 Health Service;

15 (ii) establish formal agreements, as
16 appropriate and may be worked out, to
17 provide for improved collection and report-
18 ing of surveillance data under subpara-
19 graphs (A), (B) or clause (i) of subpara-
20 graph (C) and other available information
21 under clause (ii) of subparagraph (C), ob-
22 tained from hospitals and medical clinics
23 run by other Federal departments and
24 agencies;

1 (iii) make information and analysis in
2 the National Tick-Borne Disease Surveil-
3 lance System available, as appropriate, to
4 all components of the Department of
5 Health and Human Services, to other Fed-
6 eral agencies, and to State and local agen-
7 cies; and

8 (iv) identify, build upon, leverage, and
9 coordinate among existing data and sur-
10 veillance systems, surveys, registries, and
11 other Federal public health infrastructure,
12 wherever practicable.

13 (G) PUBLIC ACCESS.—Subject to subpara-
14 graph (H), the Secretary shall ensure that in-
15 formation and analysis in the National Tick-
16 Borne Disease Surveillance System are avail-
17 able, as appropriate, to the public and other in-
18 terested parties on the website of the Depart-
19 ment of Health and Human Services.

20 (H) PRIVACY.—The Secretary shall ensure
21 that information and analysis in the National
22 Tick-Borne Disease Surveillance System are
23 made available only to the extent permitted by
24 applicable Federal and State law, and in a
25 manner that protects personal privacy, to the

1 extent required by applicable Federal and State
2 privacy law, at a minimum.

3 (5) EDUCATION AND PREVENTION.—

4 (A) CONSUMER AND COMMUNITY EDU-
5 CATION.—The Secretary shall increase public
6 education related to Lyme disease and other
7 tick-borne diseases and disorders through the
8 expansion of the community-based education
9 programs of the Centers for Disease Control
10 and Prevention to include development and
11 publication of a consumer tick disease pam-
12 phlet, available online and by hard copy, ad-
13 dressing—

14 (i) ticks and tick-borne diseases com-
15 mon to the geographic area, tick-borne dis-
16 ease that could be acquired while on do-
17 mestic or international travel, and ticks
18 that, while not common to the geographic
19 area, could migrate to the area;

20 (ii) signs and symptoms of such tick-
21 borne disease;

22 (iii) tick removal instructions;

23 (iv) the most effective actions individ-
24 uals can take to reduce risk of exposure to
25 ticks and risk of disease transmission; and

1 (v) additional community-based ac-
2 tions to reduce risk of exposure to ticks.

3 (B) COORDINATION.—In carrying out sub-
4 paragraph (A), the Secretary, acting through
5 the Director of the Centers for Disease Control
6 and Prevention, shall coordinate with legally in-
7 corporated Lyme disease or other tick-borne
8 disease organizations.

9 (C) DISSEMINATION.—The Administrator
10 of the Health Resources and Services Adminis-
11 tration and the Director of the Indian Health
12 Service shall make available in rural health cen-
13 ters and clinics which they operate or fund—

14 (i) the consumer tick disease pam-
15 phlets developed under subparagraph (A);
16 or

17 (ii) such other appropriate consumer
18 tick disease pamphlets as the Administra-
19 tion or Service may develop or acquire.

20 (D) PHYSICIAN EDUCATION.—The Sec-
21 retary shall carry out a physician education
22 program that addresses the full spectrum of sci-
23 entific research related to Lyme disease and
24 other tick-borne diseases and disorders, includ-
25 ing—

- 1 (i) the role of clinical diagnosis;
- 2 (ii) the limitations of serological diag-
3 nostic tests;
- 4 (iii) enhanced, validated diagnostics
5 available from laboratories certified under
6 section 353 of the Public Health Service
7 Act (42 U.S.C. 263a) that may aid the
8 physician;
- 9 (iv) guidelines available on the Na-
10 tional Guideline Clearinghouse;
- 11 (v) the voluntary nature of clinical
12 practice guidelines;
- 13 (vi) the complexities presented by co-
14 infections relating to symptomology, diag-
15 nosis, and treatment, including prudently
16 acting in the patient's interest in non- or
17 low-incidence States; and
- 18 (vii) the identification of significant
19 research gaps most impacting diagnosis
20 and treatment, and significant research
21 being conducted to address those gaps.

22 (E) PROCESS FOR DEVELOPING PHYSICIAN
23 EDUCATION PROGRAM.—The Secretary of
24 Health and Human Services shall—

1 (i) conduct a public meeting to solicit
2 input for the design of the physician edu-
3 cation program under subparagraph (D);

4 (ii) give the public notice of such
5 meeting at least 45 days in advance;

6 (iii) also solicit input on the design of
7 the physician education program from the
8 Tick-Borne Disease Working Group;

9 (iv) publish a proposed syllabus for
10 the physician education program not more
11 than 120 days after the public meeting;

12 (v) allow for a 60-day public comment
13 period before publishing such syllabus in
14 final form; and

15 (vi) publish on the public website of
16 the Department of Health and Human
17 Services a summary of the comments re-
18 ceived from the public under this subpara-
19 graph before conducting the first training
20 program under subparagraph (D).

21 (6) MONITORING, UNDERSTANDING, AND CON-
22 TROLLING VECTORS AND ANIMAL RESERVOIRS OF
23 LYME DISEASE AND OTHER TICK-BORNE DISEASE.—

24 (A) TICK SURVEILLANCE AND TESTING.—

25 The Secretary, in coordination with the Direc-

1 tor of the Office, acting through the Director of
2 the Centers for Disease Control and Prevention
3 and other agencies and offices of the Depart-
4 ment of Health and Human Services as appro-
5 priate, shall—

6 (i) not later than 180 days after the
7 date of enactment of this Act, provide a re-
8 port to the Congress describing the tick
9 surveillance and pathogen testing activities
10 of the Department and entities funded by
11 the Department, including—

12 (I) a detailed description of the
13 tick surveillance and tick pathogen
14 testing activities and planned activi-
15 ties of the Vector-Borne Disease Re-
16 gional Centers of Excellence as estab-
17 lished under Funding Opportunity
18 Announcement RFA-CK-17-005,
19 Catalog of Federal Domestic Assist-
20 ance Number 93.084; and

21 (II) within such description, the
22 roles of participating academic, gov-
23 ernmental, and private institutions;

24 (ii) not later than 2 years after the
25 date of enactment of this Act, in consulta-

1 tion and coordination with other Federal
2 agencies and State and local government
3 agencies, as appropriate, and established
4 academic or nonprofit tick-testing centers,
5 develop a framework and an implementa-
6 tion plan for a comprehensive nationwide
7 strategy for the surveillance and testing of
8 ticks for human pathogens and microorga-
9 nisms with unknown pathogenicity, includ-
10 ing a plan for a network of tick identifica-
11 tion and testing laboratories;

12 (iii) not later than 2 years after the
13 date of enactment of this Act, establish
14 agreements and procedures for sharing
15 data on surveillance and testing of ticks
16 with other Federal departments and agen-
17 cies engaged in such activities; and

18 (iv) consult and coordinate with the
19 American Veterinary Medical Association
20 and the Companion Animal Parasite Coun-
21 cil on obtaining and sharing data on the
22 surveillance and testing of ticks and tick-
23 borne pathogens, including geographic in-
24 formation from veterinary encounters.

1 (B) INVESTIGATION.—In carrying out sub-
2 paragraph (A), the Secretary, in coordination
3 with the Director of the Office, acting through
4 the Director of the Centers for Disease Control
5 and Prevention, in consultation and coordina-
6 tion with other Federal agencies that conduct
7 or support tick surveillance or testing activities,
8 as appropriate, and public and private labora-
9 tories, shall—

10 (i) investigate and, where appropriate,
11 promote the use of advanced new tech-
12 nologies, such as tools to discover all
13 known and all previously unidentified
14 microorganisms in a vector; and

15 (ii) while being informed by previous
16 surveillance studies, allow for the possi-
17 bility of rapid geographic migration of tick
18 vectors and pathogens and unexpected
19 findings.

20 (C) TICK CONTROL AND PREVENTION.—
21 The Secretary, in coordination with the Direc-
22 tor of the Office, acting through the Director of
23 the Centers for Disease Control and Prevention
24 and the Director of the National Institutes of
25 Health, shall, as appropriate and pursuant to

1 authorities vested in the Secretary by other pro-
2 visions of law, support activities of and coordi-
3 nate and share, information with other Federal,
4 State, and local government agencies, involved
5 or interested in tick prevention and control ac-
6 tivities on—

7 (i) the development of safer and more
8 effective tick repellents, both natural and
9 chemical;

10 (ii) the use of acaricides or other
11 chemical interventions;

12 (iii) nonchemical environmental meas-
13 ures to lessen human exposure to ticks;

14 (iv) genetic therapies for vectors or
15 animal hosts to interfere with the life cycle
16 of pathogens; and

17 (v) the development of vector or res-
18 ervoir host vaccines.

19 (D) Leveraging existing tick management
20 resources.—In carrying out this paragraph, the
21 Secretary, in coordination with the Director of
22 the Office, acting through the Director of the
23 Centers for Disease Control and Prevention,
24 shall identify, build upon, leverage, and coordi-
25 nate among existing tick surveillance, testing,

1 and management resources and infrastructure
2 wherever practicable.

3 (E) Public access to data.—In carrying out
4 this paragraph, the Secretary, in coordination
5 with the Director of the Office, acting through
6 the Director of the Centers for Disease Control
7 and Prevention, in coordination and consulta-
8 tion with other Federal agencies and State and
9 local agencies as appropriate, make data on tick
10 surveillance, testing, control and prevention
11 available to the public on the website of the De-
12 partment of Health and Human Services.

13 (7) CONFERENCES, SYMPOSIA, SEMINARS, AND
14 OTHER PUBLIC MEETINGS.—

15 (A) SENSE OF CONGRESS.—It is the sense
16 of the Congress that public meetings, con-
17 ferences, symposia, and seminars (including
18 webinars) sponsored by the Federal Govern-
19 ment are a valuable input to strategic and oper-
20 ational programmatic planning within Federal
21 agencies and to the work of the Tick-Borne
22 Disease Working Group.

23 (B) REQUIREMENTS.—The Secretary and
24 the Director of the Office, in cooperation with
25 the Director of the Centers for Disease Control

1 and Prevention, the Director of the National
2 Institutes of Health, and the Tick-Borne Dis-
3 ease Working Group, shall—

4 (i) no later than 24 months after the
5 date of enactment of this Act, sponsor a
6 state-of-the-science conference on Lyme
7 disease and other tick-borne disease includ-
8 ing identification of research gaps and top
9 research priorities;

10 (ii) for any scientific or medical con-
11 ference on Lyme disease or other tick-
12 borne disease that is organized, sponsored,
13 or paid for by the Department of Health
14 and Human Services, ensure that a con-
15 trolling statement of work and significant
16 modifications thereto, whether in the con-
17 tract or as a separate document, issued to
18 the vendor organizing or conducting the
19 conference are in writing and made avail-
20 able to the public prior to the conference;

21 (iii) not later than 120 days after the
22 conclusion of the conference under clause
23 (i), make available a final report on the
24 conference to the Tick-Borne Disease
25 Working Group and to the public;

1 (iv) not later than 18 months after
2 the date of enactment of this Act, working
3 through the Director of the Agency for
4 Healthcare Research and Quality, sponsor
5 a symposium on the use of real-world evi-
6 dence (meaning data from sources other
7 than randomized clinical trials, such as ob-
8 servational studies, comparative effective-
9 ness and patient-centered outcomes re-
10 search, and patient clinical data or human
11 subject data), including the standards and
12 methodologies for collection and analysis of
13 real-world evidence in managing Lyme dis-
14 ease and other tick-borne disease;

15 (v) include in such symposium identi-
16 fication and analysis of existing data
17 sources, such as patient registries and
18 human subjects' databases;

19 (vi) sponsor a researcher workshop on
20 challenges and solutions for clinical trial
21 design and implementation for Lyme dis-
22 ease to be held no later than 24 months
23 after the date of enactment of this Act,
24 which workshop may consider other tick-
25 borne disease or coinfections with more

1 than one tick-borne pathogen as may be
2 feasible and practicable;

3 (vii) not later than 9 months after the
4 date of enactment of this Act, in consulta-
5 tion with the Tick-Borne Disease Working
6 Group, design a survey instrument or in-
7 struments targeted to patients and patient
8 advocates, physicians and health care pro-
9 viders, and researchers regarding rec-
10 ommended subjects and agendas for feder-
11 ally sponsored meetings, conferences, and
12 seminars, including webinars, on Lyme dis-
13 ease and other tick-borne disease;

14 (viii) not later than 6 months after
15 the conduct of the survey, provide an anal-
16 ysis of the results of the survey to the
17 Tick-Borne Disease Working Group and
18 publish such results in the Federal Reg-
19 ister for a 60-day public comment period;
20 and

21 (ix) provide a final analysis and a pro-
22 posed schedule and agenda for public
23 meetings, conferences, and seminars, in-
24 cluding webinars, for incorporation into the
25 national strategy under section 3 as appro-

1 priate and to the Tick-Borne Disease
2 Working Group.

3 (8) COMMON RESEARCH BIBLIOGRAPHY.—The
4 Secretary, in coordination with the Director of the
5 Office, shall direct the Director of the Agency for
6 Healthcare Research and Quality to assemble a bib-
7 liography of peer-reviewed literature of tick-borne
8 diseases and disorders in the United States, as well
9 as for bartonellosis from whatever cause, appro-
10 priately organized for use by the scientific commu-
11 nity, treating physicians, and the public. The bibliog-
12 raphy should include literature relating to possible
13 mechanisms of persistent infection with *Borrelia*
14 burgdorferi or other types of *Borrelia*.

15 (c) PRIORITY BASED ON DISEASE BURDEN.—In con-
16 ducting and supporting activities under this section, the
17 Secretary shall give priority to Lyme disease and other
18 tick-borne diseases based on assessments of disease bur-
19 den in the United States.

20 **SEC. 5. BIENNIAL REPORTS.**

21 (a) IN GENERAL.—Not later than 24 months after
22 the date of the enactment of this Act, and biennially there-
23 after, the Secretary shall submit to the Congress a report
24 on the activities carried out under this Act and the activi-
25 ties of the Tick-Borne Disease Working Group.

1 (b) CONTENT.—Reports under subsection (a) shall
2 contain—

3 (1) a scientifically qualified assessment of Lyme
4 disease and other tick-borne disease, including a
5 summary of prevalence, geography, important expo-
6 sure characteristics, disease stages and manifesta-
7 tions or symptoms of those stages, based on a syn-
8 thesis of the broad spectrum of empirical evidence of
9 treating physicians, as well as published peer-re-
10 viewed data, to include for each tick-borne disease a
11 state-of-the-science diagnosis and treatment;

12 (2) a description of all programs and activities
13 funded by the Department of Health and Human
14 Services that are related to the surveillance, diag-
15 nosis, treatment, education, or prevention of Lyme
16 disease or other tick-borne disease, and an evalua-
17 tion of progress and performance based on mission
18 and purpose, and discussion of significant challenges
19 or barriers to performance, to include—

20 (A) for the initial report under this section,
21 a description of the intramural and extramural
22 research portfolios of the Centers for Disease
23 Control and Prevention, the National Institutes
24 of Health, and other agencies and offices of the
25 Department of Health and Human Services

1 which conducted or contracted for research
2 projects related to Lyme disease or on other
3 tick-borne disease or disorder, including infor-
4 mation on—

5 (i) the award amount, institution, pri-
6 mary investigator, principal investigative
7 question or questions, and significant con-
8 clusions; and

9 (ii) studies that received Federal
10 funds and were terminated, in progress, or
11 initiated in the fiscal year including the
12 date of enactment of this Act and the 5
13 prior fiscal years;

14 (B) for reports in subsequent years, all of
15 the information described in subparagraph (A),
16 except the reference in subparagraph (A)(ii) to
17 Federal funds terminated, in progress, or
18 awarded in the 6 prior fiscal years shall be
19 treated as reference to such funds in the 2 prior
20 fiscal years;

21 (C) a status and summary report on the
22 National Tick-Borne Disease Surveillance Sys-
23 tem, including—

24 (i) the type of information collected
25 and stored in the System;

1 (ii) the use, distribution, and avail-
2 ability of such information, including
3 guidelines for such use; and

4 (iii) the use and coordination of sur-
5 veillance and patient information data-
6 bases; and

7 (D) information on agreements, partner-
8 ships, cooperation, coordination, and data shar-
9 ing with external entities, such as State and
10 local governments, other Federal agencies,
11 working groups, and global entities;

12 (3) a description of major externally funded re-
13 search, surveillance, education, or other programs
14 and initiatives impacting the management or science
15 of tick-borne disease;

16 (4) recommendations for addressing research
17 gaps in scientific understanding of Lyme disease and
18 other tick-borne diseases and disorders and relevant
19 to development of effective diagnostic tools and
20 treatment protocols for Lyme disease and other tick-
21 borne diseases and disorders;

22 (5) a description of clinical practice guidelines
23 for any tick-borne disease published on the National
24 Guideline Clearinghouse;

1 (6) recommendations for addressing research
2 gaps in tick biology and tick management;

3 (7) a description of activities for the promotion
4 of public awareness and physician education initia-
5 tives to improve the knowledge of health care pro-
6 viders and the public in support of clinical and be-
7 havioral decision making in relationship to Lyme
8 disease and other tick-borne disease; and

9 (8) a copy of the most recent annual report
10 issued by the Tick-Borne Disease Working Group
11 and an assessment of progress in achieving rec-
12 ommendations of that Working Group.

13 (c) BIENNIAL REPORTS OF NIH.—The Secretary
14 shall ensure that each biennial report under title III of
15 the Public Health Service Act (42 U.S.C. 241 et seq.) or
16 each triennial report under section 403 of such Act (42
17 U.S.C. 283) includes information on actions undertaken
18 by the National Institutes of Health to carry out research
19 with respect to Lyme disease and other tick-borne disease.

20 **SEC. 6. DEFINITIONS.**

21 In this Act:

22 (1) BARTONELLOSIS.—The term “bartonello-
23 sis” means disease caused by Bartonella infection
24 from any vector or source, unless otherwise speci-
25 fied.

1 (2) DISORDER.—The term “disorder” means a
2 disorder caused by ticks, but not inducing human in-
3 fection, such as tick paralysis and Alpha-Gal meat
4 allergy.

5 (3) OFFICE.—The term “Office” means the Of-
6 fice of Oversight and Coordination for Tick-Borne
7 Diseases established under section 2.

8 (4) OTHER FEDERAL AGENCY.—Other Federal
9 agency means a Federal Department, agency or of-
10 fice outside of the U.S. Department of Health and
11 Human Services.

12 (5) SECRETARY.—The term “Secretary” means
13 the Secretary of Health and Human Services.

14 (6) TICK-BORNE DISEASE.—The term “tick-
15 borne disease” means a disease that is known to be
16 transmitted by ticks in the United States, unless
17 otherwise specified, or that may be discovered to be
18 transmitted by ticks in the United States.

19 (7) TICK-BORNE DISEASE WORKING GROUP.—
20 The term “Tick-Borne Disease Working Group”
21 means the Tick-Borne Disease Working Group es-
22 tablished under section 2062 of the 21st Century
23 Cures Act (42 U.S.C. 284s).

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