Congress of the United States
Washington, DC 20515

May 23, 2025

The Honorable Robert Aderholt
Chairman
Subcommittee on Labor, HHS,
Education, and Related Agencies
House Committee on Appropriations
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, HHS,
Education, and Related Agencies
House Committee on Appropriations
Washington, DC 20515

Dear Chairman Aderholt and Ranking Member DeLauro:

As you prepare the Fiscal Year (FY) 2026 Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, we appreciate the funding in Division H, Title II of HR 2882, the Further Consolidated Appropriations Act, 2024 (codified as P.L. 118-47), including a $2M increase for Lyme and Vector-Borne Diseases (VBD) in CDC, and $5M for the LymeX program in the Office of the Secretary, and not less than $100,000,000 for research into Lyme and other Tick-Borne Diseases (TBD) at NIH's National Institute of Allergy and Infectious Diseases (NIAID).

We respectfully request that the Committee increase funding at CDC by $2 million for TBD, including to intensify review and evaluation of the content on its website for TBD and to support development of additional TBD educational materials for distribution to the public and physicians. We also request an increase in funding of $2 million for CDC's Epidemiology and Laboratory Capacity (ELC) program to be used for ELC's VBD core area program to improve surveillance of TBD.

Lyme disease diagnostics are unreliable and there is no cure. Better diagnostics are required to determine if a Lyme disease therapy or cure is in fact working and therefore must be given research priority. In 2019, the NIH released the NIH Strategic Plan for Tickborne Disease Research, which provides an excellent framework to attack the problem, but NIAID requires more funding to execute this strategy. As such, we respectfully request Lyme and tick-borne disease funding in the NIH NIAID research budget to be funded at a level of no less than $135M in FY26 to help develop reliable diagnostics and therapies to address this increasing U.S. health concern affecting over 476,000 Americans annually. Lyme disease accounts for the lion share or approximately 70% of reported tickborne diseases. Accordingly, at least 70% of the increase for tick-borne diseases should be allocated towards Lyme disease research.

Efficient targeting of prevention efforts and prompting clinicians to diagnose and consider treatment for specific TBD requires sufficient understanding of the incidence, prevalence, and geographic distribution of individual TBD. Separate from the issue of test quality, clinicians may not even contemplate diagnostics that could be potentially lifesaving, nor

do clinicians always understand the serious health consequences, even the possibility of death if not treated promptly, such as for some rickettsial and viral diseases.

We also request a sustained budget of $5 million for DHHS' contribution to the LymeX Innovation Accelerator (LymeX) public-private partnership, to achieve the goals allotted for this five-year program. On March 26, 2025, the Steven & Alexandra Cohen Foundation launched Phase 4 of the LymeX Diagnostics Prize, by inviting 7 teams to submit novel diagnostics for active Lyme disease infection to the FDA and will award up to $3 million in prizes.

Additionally, we request that the Kay Hagan Tick Act be fully funded to its authorization level. The Centers for Disease Control and Prevention (CDC) would be provided $10,000,000 to award grants, contracts, or cooperative agreements to institutions of higher education for the establishment or continued support of regional centers of excellence in vector-borne diseases. The purpose is to address vector-borne diseases with an emphasis on Lyme and other tick-borne diseases. CDC should give greater funding weight to Lyme disease as the most common vector-borne disease according to the CDC, with the following objectives (1) facilitate collaboration between academia and public health organizations for public health surveillance, prevention, and response activities; (2) provide training for public health entomologists and other health care professionals, as appropriate; (3) conduct research to develop and validate prevention and control tools and methods, including evidence-based and innovative, evidence-informed tools and methods to anticipate and respond to disease outbreaks; (4) prepare for and respond to outbreaks of vector-borne diseases, including Lyme and tick-borne diseases. We further ask that the CDC be provided $20,000,000 for purposes of entering into cooperative agreements with health departments of States, political subdivisions of States, and Indian Tribes and Tribal organizations in areas at high risk of Lyme and other vector-borne diseases in order to increase capacity to identify, report, prevent, and respond to such diseases and related outbreaks.

During each appropriations cycle, the Committee on Appropriations and the Subcommittee on Labor, HHS, Education and Related Agencies demonstrate a strong commitment to helping those afflicted by a TBD and to prevent future occurrences of TBD in humans. We once again look to the Committee for its assistance in facilitating quick results-oriented actions by responsible federal agencies to make tangible progress in developing the tools to effectively control and prevent TBD, including newly created innovative programs within HHS' offices and agencies.

We respectfully request that the Committee include the language below in its report which accompanies the FY2026 Labor, Health and Human Services, Education and Related Agencies Appropriations Act. We recommend the inclusion of the following language because of the comprehensive nature of these initiatives and reports, which reflect meaningful collaboration with a broad range of stakeholders. We believe it is important to recognize the people – federal staff and selfless stakeholders – and to recognize the initiatives themselves as models of effective collaboration among countless participants/contributors.

The Committee would like to commend the Office of the Assistant Secretary of Health (OASH) and the Centers for Disease Control and Prevention (CDC), the co-leads, in a four-year collaboration among six federal departments and the EPA to develop "The

National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People," mandated by the Kay Hagan Tick Act, and released on February 6, 2024. The VBD National Public Health Strategy, referred herein as the VBDPHS, identifies and describes federal priorities to detect, prevent, respond to, and control diseases and conditions caused by vectors in the United States. The Committee desires to recognize this largest federal coordination effort on VBD prevention and control with contributions from across 17 federal agencies, with input solicited from public stakeholders, which also aligns with objective 3.1 of the October 2022 National Biodefence Strategy and NIH's October 2019 Strategic Plan for Tick-Borne Disease Research, updated in 2023. Of importance to this Committee, a key element of this strategy is ensuring the necessary resources and capacity for its implementation.

While the implementation of the VBDPHS lies mostly in the future, this Committee strongly desires to commend the process as a model of collaboration and seeking input from a broad range of stakeholders. For example, on November 21, 2022, OASH had published in the Federal register (Vol. 87, No. 223) a 13-page Request for Information (RFI) seeking input on the VBD National Public Health Strategy. The RFI described 5 goals, 19 strategic priorities, objectives and sub-objectives. The RFI also included a crosswalk of the 55 recommendations in the 2018 and 2020 TBDWG reports to Congress against the proposed Goals and Strategies of the VBD National Strategy.

The TBDWG was consulted during development of the VBDPHS and the Strategy references the three reports to Congress, with more than 70 recommendations. The Committee commends OASH and CDC for building upon the six years of dedication of numerous TBDWG participants. Although the TBDWG is now sunset, the Committee sincerely thanks its participants and other stakeholders, including patients, patient advocates, researchers, clinicians, and federal staff, who made sacrifices from their professional and personal lives in the hope of helping patients and their care providers.

Office of the Secretary

Complex diseases often overlap multiple NIH Institutes and Centers; funding may or may not also overlap multiple Institutes and Centers. We respectfully request the inclusion of the following report language:

"The Committee encourages the Office of the Secretary to work with the Director of NIH to evaluate the potential benefits of expanding the TBD portfolio to other Institutes and Centers in addition to NIAID. Because of the profound neurologic involvement of TBD, such as Lyme disease, NINDS and NIMH may make major contributions to the study of TBD, such as developing novel treatments for neurologic symptoms, including severe neurologic symptoms in children. Because of the severe impacts of TBD on children, the National Institute of Child Health and Human Development (NICHD) may also greatly enhance NIH accomplishments in developing tools to manage pediatric cases of TBD."

"The Committee strongly encourages the Secretary to establish within OASH a Tick-Borne disease coordinating office to track, monitor and provide technical assistance on TBD disease activities throughout DHHS, including its operating divisions,

and to serve as a DHHS-wide facilitator for TBD activities. The coordinating office shall monitor and report to the Secretary on implementing "The National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People."

"The Committee further recommends that the OASH TBD Coordinating Office establish a program for temporary agency/stakeholder panels or commissions to address a need or gap related to TBD goals and objectives in an DHHS agency or across agencies. The agency/stakeholder panels shall consist of a range of stakeholders, similarly to the TBDWG's, except on a much smaller scale, to operate for a short period of time, e.g., 120 days, to address a particular need or gap in the TBD knowledge base or TBD activity. The overarching purpose is to facilitate transitioning products to patients, health care practitioners, researchers, academia – including VBD Centers of Excellence, industry, state and local governments."

We believe that what is needed for developing and transitioning to the public and their medical providers tangible solutions for TBD, is a strike force or special forces type of operation and requests the following report language:

"The Committee recognizes the value of and encourages the Secretary to evaluate the potential benefits of having a TBD portfolio within the Advanced Research Projects Agency for Health (ARPA-H). Functional or disease specific subsets of a broad TBD portfolio also should be placed within ARPA-H, such as a TBD diagnostics hub or a Bartonella unit."

As background, Page 2 of the 2022 TBDWG Report to Congress, notes the establishment of the ARPA-H in 2022 and states, "The deficiencies in the Tick-Borne disease diagnostics and therapeutics discovery pipelines align with the … future role of ARPA-H. Development of a Tick-Borne Disease portfolio would likely improve coordination across agencies and accelerate progress toward improving patient care." Goal 6 of the FY24-FY26 ARPA-H Strategic Plan, includes "transitioning programs and capabilities out of the agency and into the policies, products, and services that reach all Americans."

Underlying the ARPA-H vision is "an unwavering commitment to supporting groundbreaking solutions to society's most daunting health challenges." An objective is to "Lead initiatives to enhance public awareness and education." These and many other goals and objectives of ARPA-H constitute an excellent description of a pathway to preventing and controlling Lyme and other TBD.

In previous years, the Committee has encouraged progress on diagnostics and new diagnostic technologies. It is admirable that the VBDPHS has included timelines, such as, "Develop pathogen-detection tests, including rapid tests within 1 year of identifying a novel pathogen" (a pathogen not previously found in humans) and "develop serologic tests and biomarker tests within 1 year of identifying a novel pathogen." Regarding tests available for known VBD pathogens, there are good objectives, but no timelines, while noting that highly sensitive tests for some VBDs are not available, including early Lyme disease and the life-threatening Rocky Mountain Spotted Fever (RMSF), which CDC calls the world's deadliest TBD. Test results can take weeks, so healthcare providers are advised by CDC to recommend

antibiotic treatment before test results are available. In addition to filling those gaps, a priority goal should be a test to confirm active infection for Lyme disease.

The pathogen for RMSF was identified prior to 1910, and the pathogen for Lyme disease was identified in the early 1980's. While we want to be prepared for novel pathogens, we also need to have a sense of urgency for diagnostic shortcomings regarding known pathogens, including setting target timelines. Researchers have recently noted that, in general, TBD diagnostics are not of high quality, and in addition to a direct detection test for Lyme disease, prominent TBD researchers have recommended that priority be given to bringing improved diagnostics to market for Bartonella, Babesia, RMSF and the pathogen *Borrelia* miyamotoi.

We request the committee include the following report language:

> *"OASH, in coordination with CDC and NIH, shall within six months of passage of publication of the House Report for the FY2025 Labor/HHS/Ed Appropriations Act, provide to this Committee a table listing each TBD known to infect humans in the US, the responsible pathogen, the availability of diagnostic tests to clinicians, and the accuracy and quality of such tests. In addition, OASH shall provide to this Committee a report on the status within the diagnostics pipeline of the most promising testing technologies employing PCR, Biomarkers or other OMICS, and Improved Serologic tests and for what TBD pathogen. Within such report, OASH shall include a report on the status of tests to confirm or rule out active infection with the Lyme disease pathogen and progress on developing higher quality and more rapid tests for RMSF."*

CDC

Given the broad reach of federal websites, it is critical that they provide accurate, objective, and current evaluations of TBD research and information, including a state-of-the-science, which identifies, what is known, what is unknown, what is uncertain, and what continues to be debated. Presenting an overly simplified picture of the state-of-the-science is misleading and severely limits the ability of clinicians to make informed choices and the best decisions for their patients' clinical care.

> "*The Committee directs CDC to, within 120 days of this report, develop a two-year plan (FY2026 - FY2028) for conducting evaluation reviews of the information on its website for TBDs, including any TBD overview and for individual TBDs and for alpha-gal syndrome (AGS), the not well understood, non-infectious allergic disease related to a tick-bite that is less understood than other allergic conditions, and for developing educational materials for clinicians and the public for each TBD and Tick-Borne condition, with priority based on disease burden, determined by prevalence and level of disability. The two-year plan also shall describe the anticipated media to be used, e.g., website, physician notifications, educational pamphlets for distribution by local health departments, public health clinics, medical treatment and diagnostic facilities, and physicians' offices."*

Because of the long-standing controversies surrounding Lyme disease, we further recommend an enhanced evaluation process for review and evaluation of Lyme disease

information on CDC's website and requests the following report language:

> "*For Lyme disease, the Committee strongly encourages, CDC to establish a panel of expert outside stakeholders to evaluate the Lyme disease information on its website for its inclusion of a balance of scientifically valid perspectives, primarily regarding the state of the science for diagnostics and treatments. The stated goals and purposes of the review and the identity of review participants, including the balanced panel of experts, including experienced TBD clinicians, researchers, and educators, shall be fully transparent."*

Education and prevention strategies are very significant for workers at high risk for tick bites. Foresters and farmers, including migrant farm workers, are the most exposed categories. The state of California is of particular concern for farm workers and other high-risk occupations. CDC also has published on the spread of tick populations expanding into and becoming established in more rural areas of the Midwest and South where farmers and foresters together make up a large percent of the workforce, yet data has shown few doctors and health departments in most of those areas are aware of the increasing numbers of Lyme and other TBD or the problems of diagnosing and treating TBD, especially Lyme disease. Education strategies to be implemented to improve awareness of the spread among vulnerable workers, utilizing public health agencies and labor/civil organizations to inform workers of risks and the need to seek medical care. We request the following report language:

> "*The Committee directs CDC to incorporate into its efforts to develop and disseminate TBD educational materials, steps to educate high risk workers and their employers regarding the occupational risks of TBD."*

With the rapid spread of the Lonestar tick, we are concerned that the agent or cause of Southern Tick-Associated Rash Illness (STARI) has not been identified. We are similarly concerned that there is a lack of knowledge by the public and some medical providers of the scope of the problem with AGS. We therefore request the inclusion of the following report language:

> "*Within 120 days of this report, submit to this Committee a report on STARI including its prevalence, the tick-vector or vectors causing STARI and progress in identifying the causative pathogen of STARI or any suspected non-infectious disease-causing mechanism."*
>
> *"Within 120 days of this report, submit to this Committee a status report on alpha-gal syndrome, including prevalence, etiology, treatment, outcomes, and prognosis."*

Maternal-fetal transmission of Lyme Disease.— In its 2022 report to Congress, the HHS TBDWG recognized Lyme disease and pregnancy an issue of special concern and importance given that both mother and baby are at a particularly sensitive time for health and development, and that, although rare in humans, the Lyme bacteria can be transmitted across the placenta from mother to offspring, as acknowledged by CDC and NIH. As stated in the 2022 report to Congress, significant data gaps remain regarding how Lyme disease can impact pregnancy – with questions about diagnostic sensitivity and effective treatment approaches in both mother and baby. The TBDWG 2020 report to Congress recommended funding be provided

for a registry and for more studies to determine the extent of maternal-fetal transmission of Lyme disease and of any congenital Lyme disease.

There also is a need for better education of clinicians, and interim clinical guidelines for Lyme disease during pregnancy could provide healthcare providers with guidance in several important areas. As reported by the TBDWG, CDC has begun efforts to understand the incidence and impact of Lyme during pregnancy; however, much remains to be investigated. We recommend the following report language:

> *"Within 180 days of enactment of this Act, the Committee requests a report on CDC's plans to better understand maternal-fetal transmission of Lyme disease and gestational Lyme disease and plans to improve education for the public and for healthcare providers about the risks of Lyme disease during pregnancy and adverse birth outcomes. This report should identify resources required and potential obstacles to progress."*

NIH

The infectious etiology of chronic diseases and syndromes, including infections from *Borrelia* burgdorferi, *Bartonella* henselae, West Nile virus, and many other infectious agents, have been known or suspected for several decades. Of major significance to suffering patients, there is a current recognition and resurgence of research in treating the severe mental health and psychological symptoms of chronic diseases and disabilities, with promising results – such as dramatically lessening chronic depression, successfully treating obsessive-compulsive disorder, and reducing fear and stress for cancer patients, and long-term sufferers with chronic Lyme disease.

In House report 117-403 (July 5, 2022), the Committee asked NIH to consider the value of establishing a work group on long-term, not well understood outcomes for different diseases with similar long-term sequelae, particularly SARS-CoV-2 infection and Lyme disease, considering the input of patients not fully recovered. We are pleased that in July of 2023, the National Academies of Science (NAS) convened a workshop on a Common Research Agenda in Infection-Associated Chronic Illnesses, addressing several diseases that share overlapping symptoms, including COVID, myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), persistent or posttreatment Lyme disease syndrome, and multiple sclerosis (MS). Studies by Harvard School of Public Health researchers and others have linked MS to infection with Epstein-Barr virus (EBV).

The report on the NAS workshop was recently released, "Toward a Common Research Agenda in Infection-Associated Chronic Illnesses," National Academies Press, Washington, DC. CDC was a workshop sponsor, and several well-known Lyme academic researchers and at least one social researcher/advocate participated. To cite only one statement in the report, CDC's Lyle Peterson noted that "elucidating the development and persistence of these chronic illnesses remains an area of active research." (Pages 1-2 of the Introduction).

We recognize the importance of pursuing research into the commonalities of these infection-associated chronic illnesses. We request the inclusion of the following report

language:

"The Committee encourages NIH to establish a panel to meet periodically to review progress on activity to address infection-triggered chronic illnesses, such as long Covid, long Lyme, Bartonella henselae, West Nile virus, and multiple sclerosis and to produce a brief status report on progress."

Neurologic symptoms of Lyme disease are a significant public health problem, including in children. We remain concerned about reports that undiagnosed and untreated Lyme disease in a child, whether acquired gestationally or through a tick bite, can severely compromise their physical health, mental health and capacity to learn and adversely impact their entire life trajectory.

We are thankful that the Children's National Research Institute at the Children's National Medical Center (Washington, DC) is conducting a clinical trial (clinicaltrials.gov ID NCT06026969) on "Pregnancy and Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure." The purpose of the pilot study is to assess the feasibility of longitudinal neurodevelopmental evaluation of fetuses and infants exposed to Lyme disease in utero. Pregnancies will be monitored, and infant development will be assessed in infants from birth to 18 months.

We request the following report language:

"Within 180 days of enactment of this Act, the Committee requests a report on NIH, including NIAID and NICHD, plans to advance research on pediatric Lyme disease, including the impact on children who are infected in utero."

"The Committee encourages NIH, including NIAID, NINDS and NIMH, to increase study of neurologic symptoms of Lyme disease, including in children, increasing surveillance of neurologic symptoms and investigating novel treatments of neurologic symptoms."

We continue to recognize an urgent need to establish academic clinical research centers of excellence for TBD. Many diseases have academic centers of excellence for clinical research which extend from a handful of academic nodes for one disease to over 30 academic nodes for another. We request the following report language:

"The Committee directs the Office of the Secretary and NIH, in consultation with CDC and FDA, to enter into discussions on the potential benefits of establishing a National Network of Academic Research and Clinical Centers of Excellence for Tick-Borne Diseases."

A well-respected clinician and researcher for Lyme disease has expressed an urgent need for clinical centers at several sites throughout the country to evaluate, treat, and conduct research on children with infection-triggered neuropsychiatric syndromes. The frontal lobes which govern executive skills and impulse control aren't fully developed until after age 21. Prior to that time, infections and related central nervous system inflammation can lead to dangerous

infection-related neuropsychiatric syndromes, include suicidal behaviors, mania, and psychosis. These infections may include, but are not limited to, bacteria such as *Borrelia* burgdorferi (the Lyme pathogen), Bartonella, and Group A Strep, and viruses such as SARS-COV-2, the herpes viruses and others.

These children and their families need help which can best be provided by comprehensive inpatient evaluation and treatment by a multi-disciplinary team at major medical centers.

We thank you for your consideration of our request.

Sincerely,

Christopher H. Smith
Member of Congress

Lloyd Doggett
Member of Congress

Brian K. Fitzpatrick
Member of Congress

Chellie Pingree
Member of Congress

Pete Stauber
Member of Congress

Julia Brownley
Member of Congress