

April 28, 2021

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

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

Dear Chairwoman DeLauro and Ranking Member Cole:

As you prepare the Fiscal Year (FY) 2022 Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, we respectfully request that you provide a significant increase in funding for Centers for Disease Control's (CDC) Lyme disease program to allow the agency to intensify its efforts on developing improved diagnostics, critical surveillance and prevention of Lyme disease.

Enacted as part of the *Further Consolidated Appropriations Act for FY2020* (P.L. 116-94), the Kay Hagan Tick Act authorizes \$10 million for FY 2022 for the CDC's Regional Centers of Excellence for Vector Borne Disease, and \$20 million for FY 2022 for a grant program that would allow CDC to enter into cooperative agreements with State and Tribal health departments for the purposes of improving data collection and analysis of Lyme and other tick-borne diseases (TBD). We request that the Committee fund these two programs at the authorized levels, with the understanding that the greater percent of the monies are used commensurate with the burden of disease, the greatest burden which is Lyme disease. A CDC *MMWR* 2018 report states from 2004-2016, tick-borne diseases more than doubled and were 77% of all vector-borne disease reports. Lyme disease was 82% of all those TBD cases.

We also request that you include the language we have provided below in your Committee report. Specifically, we request the following language:

The Committee commends HHS and the CDC for launching in September 2020, "A National Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans," with coordination and collaboration among HHS agencies and outside agencies (DOD, DOI, EPA, USDA), to address identified significant challenges to improve our nation's ability to detect and respond to vector-borne disease threats.

These frameworks are steps forward, but in reality, the lack of progress and existent impediments to improving outcomes over nearly four decades for 70% of all VBD in the US, Lyme disease, leave patients and other stakeholders, i.e., our constituents, disheartened, and without help to restore them to health.

Vaccine development for Lyme disease is certainly a worthy goal; however, we cannot rely on that occurring and cannot neglect hundreds of thousands, if not millions, of our constituents living with Lyme and TBD. The Committee is committed to supporting the development of effective prevention methodologies, diagnostics and treatments, and we believe that we must accelerate tangible, measurable progress toward those goals. A necessary and first step to improving health outcomes is to remove impediments to progress, such as unwarranted biases and continued reliance on studies with outdated data.

OFFICE OF THE SECRETARY OF HHS

The Committee commends the Office of the Secretary and its Chief Technology Officer, for the Lyme Innovation Initiative, launched November 2018, and the LymeX Innovation Accelerator – announced in October 2020, a \$25M public-private partnership between HHS and the Steven & Alexandra Cohen Foundation to accelerate innovation in prevention, diagnostics, and treatments for Lyme and other TBD. The Committee provides an additional \$5M for the Office of the Secretary's contribution in FY2022 to the public-private partnership LymeX.

Previously the Committee requested that the Secretary develop and provide to the Committee a multi-year plan outlining innovation initiatives for conquering Lyme disease, such report is due December 27, 2021.

NATIONAL INSTITUTES OF HEALTH (NIH)

*The Committee recognizes that due to the COVID pandemic, it was not possible for NIH to hold a workshop on the numerous molecular and functional mechanisms that *Borrelia burgdorferi* (Bb) employs to evade and subvert the immune system of the human host and the immune responses and consequences and also how these mechanisms and responses can subvert the effectiveness of antibiotics. The Committee encourages NIH to hold such a workshop within six months after such gatherings are resumed at NIH. It is critical that the multiple, well-documented, defense mechanisms of Bb be evaluated and recognized, as understanding these mechanisms and their significance underpins the ability to develop effective diagnostics and treatments. The Committee supports inclusion of other TBD pathogens to consider shared and unique characteristics of the pathogens as NIH determines practical for the workshop.*

The Committee encourages NIH to improve early diagnosis and treatment of Lyme and other TBD to prevent the development of late stage disease and more serious and longer-term disability, but also to intensify research on diagnosis and treatment of late stage and chronic disease. Priority should be based on disease burden which CDC has indicated for Lyme disease to be approximately 476,000 people diagnosed and treated annually in the US. Lyme has a significant patient population who are not diagnosed until late stage when treatment is more difficult and a significant percentage of patients who relapse and go on to develop chronic symptoms. Along with development of highly sensitive and specific diagnostics for all stages of disease, a goal should be to develop diagnostics with appropriate sensitivity and specificity for the detection of subclinical or low-level infection for use in disease eradication. Treatments for all stages of Lyme and other TBD, determining optimal combinations of new candidate or older

drugs and exploring novel combinations should be developed. Although a cure may be defined to include sustained remission, a goal of treatment should be eradication of the pathogen, in which case resurgence is not possible.

The Committee is gratified that NIH officials have recognized the need for further exploration of maternal-fetal or vertical transmission of Lyme disease and the occurrence of adverse outcomes among women with untreated and disseminated Lyme disease during pregnancy. We encourage NIH to intensify research on adverse outcomes related to Lyme disease during pregnancy and to continue to participate with Lyme advocacy organizations on these issues.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Committee applauds CDC's National Public Health Framework for the Prevention and Control of VBD in Humans. We make the following recommendations for and requests of CDC in support of the challenges and goals articulated in that Framework.

Improve surveillance and the problem of Lyme disease underreporting so that US Lyme disease burden can be more accurately determined. Burden should be defined by the Disability Adjusted Life Years and should include estimates for the burden on the U.S. economy include indirect medical costs, nonmedical costs, and productivity losses. The Committee is aware that CDC increased its estimate of the annual new cases of Lyme disease from 300,000 to 476,000, a 58% increase, based on insurance claims made. The Committee also is aware that the data show that when compared to insurance claims, CDC data reflect a 7-fold undercount for what CDC deems high-incidence states and a 50-fold undercount for what CDC deems low-incidence states. To address these large discrepancies and the problems people in low incidence states face in getting a diagnosis and treatment due to this classification system, the Committee encourages CDC to reevaluate the practice of utilizing the classification of states as high or low incidence as surveillance criteria.

Improve early diagnosis of Lyme and other TBD to prevent the development of late stage disease and more serious and long-term disability, but also intensify research on diagnosis of late stage and chronic disease. As noted above, priority should be based on disease burden. We know that Lyme disease has a high public health burden in the US, has a significant patient population who are not diagnosed until late stage when treatment is more difficult, and has a significant percentage of patients who relapse and go on to develop chronic symptoms. A goal also should be to develop diagnostics with appropriate sensitivity and specificity for the detection of subclinical or low-level infection for use in disease eradication.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The Committee is concerned about the experiences of low income, minority, and migrant populations with Lyme and other TBD. We believe better data should be developed on the incidence of TBD in these populations and the experiences of those populations in accessing care for suspected TBD, including provider awareness of TBD, diagnostic tools, treatment protocols, and health outcomes. Being aware of AHRQ's expertise in research tools and networks, the Committee directs AHRQ to coordinate with the Health Resources & Services

Administration (HRSA) and its Bureau of Primary Health Care and the Office of Rural Health Policy and other HRSA Bureaus and Offices as appropriate and the Indian Health Service to develop a plan for exploratory research to assess the extent of the problem of TBD in the low income, minority, and migrant populations and in the national network of clinics and health centers which provide health care, and which in turn receive a large portion of payments from Centers for Medicare and Medicaid Services (CMS).

With 1,400 grantee health centers serving 27 million patients in over 10,000 delivery sites. Federally Qualified Health Centers (FQHC), which provide comprehensive primary and preventative health care to individuals with low incomes who are uninsured or underinsured, as well as other vulnerable populations, are an enormous and, in many ways, unique source of information on the quality of health care to underserved populations. 22.6% of health center patients identify as African Americans and 35.4% identify as Hispanic or Latino. The Committee is concerned that these patients are undercounted or underserved in relationship to the many serious TBD, especially the TBD with the highest disease burden, Lyme disease. In addition to improving public health and reducing health disparities, it is important to have a better understanding of the economic costs to the federal government and to society from TBD.

Thank you very much for your time and attention to this request and we look forward to working with you to assist patients with Lyme and other tick-borne diseases.

Sincerely,

CHRISTOPHER H. SMITH
Co-Chair, Lyme Disease Caucus