

March 13, 2020

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) 2021 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—consistent with the President's FY2021 request—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 FY2021 for the CDC's Regional Centers of Excellence for Vector Borne Disease, and \$20 million for FY2021 for the newly created 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. We request that the Committee fund these two programs at the authorized levels.

Additionally, the Lyme Disease Caucus requests an increase in funding for the Office of the Secretary of Health and Human Services for the purposes of entering into public-private partnerships and awarding highly promising contracts or agreements to enhance resources and to accelerate breakthroughs/solutions in the development of Lyme disease diagnostics and novel, more effective treatments.

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

OFFICE OF THE SECRETARY OF HHS

Given the high health consequences, direct medical costs, lost productivity, and educational consequences, coupled with the obstacles to innovation over several decades, the Committee encourages the Office of the Secretary to sponsor initiatives to spur innovation leading to the development of more effective diagnostics for all stages of Lyme disease and for the development of novel treatments that will return patients to health and eradicate the disease, including innovation in tools and resources – data, technology and scientist collaborations. The Committee is appreciative of the role of the Office of the Chief Technology Officer in promoting

innovation to strengthen agency programs and foster public health solutions. The Committee urges the Secretary to coordinate and collaborate with the Operating Divisions, including NIH, CDC, and FDA, to apply data, technology, and human resources to overcome obstacles and develop solutions to effectively manage and eradicate Lyme disease. The Committee requests that the Secretary develop and provide to the Committee, within one year of enactment, a multi-year plan outlining innovation initiatives for conquering Lyme disease.

The Committee provides an increase for the Office of the Secretary in FY2021 to enter into public-private partnerships and award highly promising contracts or agreements to enhance resources and to accelerate breakthroughs/solutions in the development of Lyme disease diagnostics and novel, more effective treatments.

NATIONAL INSTITUTES OF HEALTH (NIH)

*Lyme and Other Tick-Borne Diseases: The Committee strongly encourages NIH to hold within six months of this appropriations report's publication, 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 supports inclusion of other TBD pathogens to consider shared and unique characteristics of the pathogens as NIH determines practical for the workshop, with participation by researchers who have published peer-reviewed articles describing such mechanisms and immune cell responses, particularly for Bb. 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 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 intensify research on diagnosis and treatment of late stage and chronic disease. Priority should be based on disease burden and should be given to Lyme disease, which has a high public health burden in the U.S., 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. In addition to 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 also should be developed for all stages of Lyme and other TBD, determining optimal combinations of new candidate or older drugs and exploring novel combinations. 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 recognizes that community-based physicians, advocates and patients are potential resources who can add value to a broad range of NIH's TBD activities as they are in other diseases, most prominently, HIV. The Committee encourages NIH to establish a Community-Based Participation (CBP) initiative for TBD and to partner with the Office of

Extramural Research to identify community-based resources – data and people – and to evaluate how community-based perspectives can add significant value to and be incorporated into the broad range of TBD activities, such as strategic planning, research portfolio design, programs, special Initiatives, grant proposals and peer review.

*The HHS Tick-Borne Disease Working Group’s Clinical Aspects of Lyme Disease Subcommittee January 2020 report includes “Further evaluate potential maternal-fetal transmission of Lyme disease and of congenital Lyme disease” as a recommended priority. Given the need for more information on this subject, the Committee urges NIH to evaluate potential maternal-fetal transmission of Lyme disease and congenital Lyme disease and issue requests for proposals and funding opportunity announcements to stimulate researcher interest in these areas. Within 180 days of enactment, the Committee requests a report on NIH plans to address the need for research on maternal-fetal transmission of *B. burgdorferi*, congenital Lyme disease, and adverse outcomes in infants and children from maternal transmission.*

The Committee is concerned about reports that Lyme disease poses special risks for children in terms of neurodevelopmental disorders and psychiatric comorbidities. Therefore, the Committee encourages the National Institutes of Mental Health (NIMH) to conduct studies on the neuropsychiatric manifestations of pediatric Lyme disease.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

In addition to supporting across the board progress in developing innovative solutions to more effectively manage tick-borne diseases, the Committee supports and directs CDC to:

Apply sufficient resources to develop performance indicators to enable monitoring of program effectiveness for Lyme disease and other priority vector-borne diseases (VBD) as directed in the Committee report for FY 2018 appropriations.

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.

Develop more specific and accurate assessments of disease burden for vector-borne diseases - utilizing whatever types of clinical data are required (hospital, medical records, laboratory, insurance, etc.) - are necessary for appropriate establishment of priorities and the application of resources.

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 U.S., 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.

Identify and validate safe and effective prevention and control methods. Controlling and disabling ticks will require innovative technologies and well-designed studies in communities and ecosystems.

Establish a panel to develop content on Lyme disease for the CDC website and to review and evaluate the content of information on CDC's website regarding Lyme disease and other tick-borne diseases. Given the differences in scientific perspectives regarding tick-borne diseases, this panel should include clinical and research experts that represent a broad range of scientific and clinical perspectives, including at least one physician with multiple-years' experience in treating all stages of Lyme disease and at least one member of a patient advocacy organization.

Given the need for more information on the potential maternal-fetal transmission of B. burgdorferi and congenital Lyme disease, the Committee urges CDC to conduct studies of the incidence of maternal-fetal transmission of B. burgdorferi and studies on adverse outcomes for treated and untreated pregnant women. The Committee also encourages CDC to ensure that the public and healthcare providers are adequately informed of the risks of Lyme disease during pregnancy.

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

COLLIN C. PETERSON
Co-Chair, Lyme Disease Caucus