

# United States Senate

WASHINGTON, DC 20510

December 20, 2019

Anthony S. Fauci, M.D.  
Director  
National Institute of Allergy and Infectious Disease  
5601 Fishers Lane MSC 9806  
Bethesda, MD 20892

Dear Dr. Fauci:

With the rapidly increasing incidence of Lyme disease disproportionately affecting our states and negatively affecting our constituents, we write to request information about the Lyme disease research and coordination programs at the National Institute of Allergy and Infectious Disease (NIAID). This information is of critical importance for strengthening local responses, improving clinical efficacy, and implementing strategies to prevent the spread of Lyme disease.

For more than 35 years, the NIAID Lyme Disease Research Program has supported basic and clinical research efforts to improve diagnostics, treatment, and prevention for this disease.<sup>1</sup> Since first identified in 1975, Lyme disease has affected the lives of millions of Americans in all 50 states and people in over 65 nations.<sup>2</sup> It is the most common vector-borne disease, the most common tick-borne disease, and one of the fastest-growing infectious diseases in the United States.<sup>3,4</sup>

Projections of Lyme disease activity and distribution indicate that this is a growing epidemic, driven in part by climate change. Climate change has contributed to the expanded range of the tick habitat, and has increased the amount of time each year when ticks are active and therefore capable of spreading the disease. As such, warming temperatures associated with climate change are one factor contributing to the increased risk of Lyme disease in the United States.<sup>5</sup>

Although Lyme disease is clearly an epidemic, its prevalence is underreported, due in part to the lack of a reliable test for the disease. Annually, state public health officials report approximately

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<sup>1</sup> *Current Efforts in Lyme Disease Research*, National Institute of Allergy and Infectious Diseases, 1-13 (2017).  
<https://www.niaid.nih.gov/sites/default/files/NIAIDLymereport2015.pdf>.

<sup>2</sup> Christina A. Nelson et al., *Incidence of Clinician-Diagnosed Lyme Disease, United States, 2005–2010*, 21 *Emerging Infectious Diseases* 9, 1625-1631 (2015).

<sup>3</sup> Amy M. Schwartz, MPH et al., *Surveillance for Lyme Disease — United States, 2008–2015*, 66 *Surveillance Summaries* 22, 1-12 (2017).

<sup>4</sup> *Nationally Notifiable Infectious Diseases and Conditions, United States: Annual Tables* (2018)  
<https://wonder.cdc.gov/nndss/static/2018/annual/2018-table1.html>

<sup>5</sup> Environmental Protection Agency, *Climate Change Indicators in the United States*, Ed. 4, 1-96 (2016).

30,000 cases of Lyme disease to the Centers for Disease Control and Prevention (CDC). However, CDC estimates the true incidence to be ten times higher, with more than 300,000 people infected each year.<sup>6</sup> Lyme disease is significantly underreported due to a multitude of factors, including clinical misdiagnosis. There is currently no reliable diagnostic test for the presence of the bacteria that causes Lyme disease. Instead, the recommended primary diagnostic test, an enzyme-linked immunosorbent assay, relies on the presence of a certain level of antibodies produced by the body in response to Lyme infection. Consequently, testing for infection early in the disease transmission, prior to antibodies developing, or in individuals with weakened immune systems, who have a slow antibody response, can yield unreliable test results.<sup>7,8</sup>

Additionally, treatment for Lyme disease continues to be challenging for many clinicians and patients and typically relies on the use of antibiotics. Which antibiotics are used and for how long depends on many variables, including identification of the infecting organism, duration of the illness, and patient symptoms. Even after Lyme disease has been treated by the typical course of antibiotics, many patients report prolonged symptoms such as fatigue, cognitive dysfunction, and muscle and joint pain that impact daily living. Together these symptoms are referred to as post-treatment Lyme disease syndrome or chronic Lyme.<sup>9,10</sup>

The Northeast region of the United States has been disproportionately impacted by Lyme disease over the past decade, with the incidence of this disease doubling in this region since 1991.<sup>11</sup> As a result, we have all met constituents whose lives, in many instances, have been irrevocably changed by the disease.

Although not specific to Lyme disease, NIH recently released the Strategic Plan for Tickborne Disease Research<sup>12</sup> and the related Notice of Special Interest: Advancing Research for Tickborne Diseases.<sup>13</sup> Together these documents lay out research priorities for tickborne diseases and seek proposals to advance said research priorities. Despite these important steps, many questions remain as to how NIH will realize this strategic plan and the impact the plan will have on Lyme

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<sup>6</sup> Christina A. Nelson et al., *Incidence of Clinician-Diagnosed Lyme Disease, United States, 2005–2010*, 21 *Emerging Infectious Diseases* 9, 1625-1631 (2015).

<sup>7</sup> Amy M. Schwartz, MPH et al., *Surveillance for Lyme Disease — United States, 2008–2015*, 66 *Surveillance Summaries* 22, 1-12 (2017).

<sup>8</sup> Perri Klass, M.D., *The Challenge of Diagnosing Lyme Disease*, N.Y. Times (July 29, 2019), <https://www.nytimes.com/2019/07/29/well/family/the-challenge-of-diagnosing-lyme-disease.html>.

<sup>9</sup> *Post-Treatment Lyme Disease Syndrome*, Centers for Disease Control and Prevention. (November 8, 2019), <https://www.cdc.gov/lyme/postlds/index.html>.

<sup>10</sup> Michael T. Melia, M.D. & Paul G. Auwaerter, *Time for a Different Approach to Lyme Disease and Long-Term Symptoms*, 374 N.E. J. Med., 1277-1278, (2016).

<sup>11</sup> Environmental Protection Agency, *Climate Change Indicators in the United States*, Ed. 4, 1-96 (2016).

<sup>12</sup> NIH Tickborne Diseases Strategic Planning Team, *NIH Strategic Plan for Tickborne Disease Research*, 1-25 (2019).

<sup>13</sup> Notice of Special Interest, NIH, Advancing Research for Tickborne Diseases (TBDs). (Nov. 12, 2019).

disease research. To help us better understand how NIAID is approaching the health threat of Lyme disease, please provide answers to the following questions by January 11, 2020.

1. What research is NIAID conducting or supporting to better understand the development, diagnosis and treatment of Lyme disease? Has research already conducted changed the way clinicians approach the diagnosis and treatment of Lyme disease? If so, in what ways?
2. What research is NIAID conducting to better understand modes of transmission for Lyme disease? What research is the agency planning to conduct or incentivize to improve understanding of modes of transmission, including vertical transmission?
3. What interdisciplinary efforts, if any, does NIAID support to help leverage scientific knowledge from other diseases, such as cancer, to better understand Lyme disease? Will the "Notice of Special Interest" support or encourage interdisciplinary scientific representation?
4. We continue to hear from constituents experiencing persistent symptoms long after the recommended antibiotic treatment. What is NIAID's current understanding of patient experiences with post-treatment Lyme disease syndrome or chronic Lyme? What research is the agency conducting to better understand the progression of these symptoms and how to treat them?
5. What funding is currently being allocated for Lyme disease research and what is the projected increase based on NIH's Strategic Plan for Tickborne Disease Research?
6. Does NIAID think current resources are adequate to meet the challenges of Lyme disease? What other support would improve Lyme disease diagnostics and treatment?
7. Will grant applications in response to the recently released "Notice of Special Interest: Advancing Research for Tickborne Diseases" be required to compete with all other disease grant applications, or will there be a special path of review and granting for Lyme disease?
8. What is the long-term outlook and effectiveness of the current Lyme vaccines in clinical trials?
9. How is NIAID developing an understanding of the entire landscape of Lyme diagnostic and therapy projects in the U.S. and worldwide? Would having a comprehensive understanding of the research landscape help to aid in fostering innovation?
10. What specific actions, if any, is NIAID taking to help expand the pool of researchers interested in studying Lyme disease?
11. What coordination, if any, exists with other federal agencies such as the Centers for Disease Control and Prevention and the Environmental Protection Agency to address the growing threat of Lyme disease? What coordination, if any, exists with private foundations to address the growing threat of Lyme disease?
12. With regard to the priorities and goals laid out in NIH's Strategic Plan for Tickborne Disease Research, does NIAID support the creation of clinical research "Centers of Excellence" as exist for other disease types?

Director Anthony Fauci  
December 20, 2019  
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Thank you for your attention to this request. We look forward to better understanding the work NIAID is doing to address the undue burden Lyme disease places on American communities.

Sincerely,



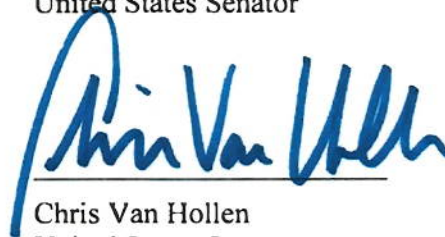
Edward J. Markey  
United States Senator



Susan M. Collins  
United States Senator



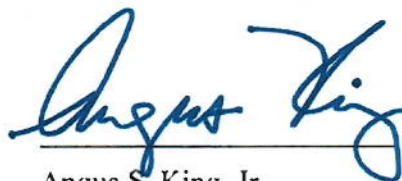
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Chris Van Hollen  
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Elizabeth Warren  
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Angus S. King, Jr.  
United States Senator



Richard Blumenthal  
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