

LYME MOONSHOT

Lyme Moonshot: Cure Lyme Disease by 2030

A Policy Paper from Center for Lyme Action

October 2020



*This policy paper was created in memory of Dr. Neil Spector, dedicated and beloved physician, world-class cancer researcher, author of *Gone in a Heartbeat: A Physician's Search for True Healing*, and Lyme disease patient. A very kind person who is missed.*

TABLE OF CONTENTS

Executive Summary	5
Challenge and Opportunity	7
Public Health Agencies and CDC in Preparing the Nation to Address Vector-Borne Diseases Threats	8
Epidemiology and Laboratory Capacity (ELC) Funding for Vector-Borne Diseases	9
Vector-Borne Disease Regional Centers of Excellence	9
Need for Local and Professionally Staffed Integrated Tick-Management Programs	9
The Role of Congress in Combatting Lyme Disease	10
FIVE STRATEGIES FOR A LYME MOONSHOT	11
STRATEGIC GOAL 1: Lead from the Top	11
<i>Recommendation 1.1: Establish a White House TICK Office with a Lyme Leader who has authority, accountability, and resources to drive systemic change across government.</i>	
<i>Recommendation 1.2: Establish a HHS TICK Office to support and execute the Lyme disease goals and national strategy led by the White House TICK Office; consider establishing the HHS TICK Office within the Office of the Secretary at HHS.</i>	
<i>Recommendation 1.3: Form a Lyme Moonshot Blue Ribbon Task Force with diverse perspectives from researchers, clinicians, patients, industry, non-profit organizations, and government to provide expertise and guidance to the TICK Office and Lyme Leader.</i>	
STRATEGIC GOAL 2: Catalyze New Scientific Breakthroughs for Evidence-Based Solutions	12
<i>Recommendation 2.1: Increase federally funded science, research and development:</i>	
• <i>Execute 2019 NIH Strategic Plan for Tick-borne Disease</i>	
• <i>Advance the CDC's ability to monitor and provide health advice to citizens with Lyme and other tick-borne diseases and deliver on tick-borne research as funded by the Kay Hagan Tick Act of 2019</i>	
• <i>Establish New Centers of Academic Excellence for Lyme and Tick-borne Disease with new funding at Universities</i>	
<i>Recommendation 2.2: Foster an HHS/DOE/interagency "One Health" Lyme Moonshot</i>	
<i>Recommendation 2.3: Mitigate the impact of tick-borne disease on military readiness, Service Members, Veterans and their families.</i>	

STRATEGIC GOAL 3: Unleash the Power of Data

15

Recommendation 3.1: Create a Federal repository with shared data standards for TICK information that will facilitate information sharing and drive data-driven decisions across government, research, and public health.

Recommendation 3.2: Leverage existing IT infrastructure and authorities, including but not limited to:

- *Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer’s Act of 2018*
- *Pandemic and All-Hazards Preparedness Act of 2019*
- *Foundations for Evidence-Based Policymaking Act of 2018*
- *Grant Reporting Efficiency and Agreements Transparency Act of 2019*

Recommendation 3.3: Require grantees of federally funded research to share their Lyme disease data and results in the Federal repository for TICK Information, per laws and policies that advance U.S. Open Science (open access), Open Data, and Open Source Code.

Recommendation 3.4: Infuse data ethics into every aspect of the Lyme Moonshot.

STRATEGIC GOAL 4: Improve Patient Outcomes and Access to Care

19

Recommendation 4.1: Protect the rights of licensed clinicians to treat Lyme disease with freedom to use their clinical judgment individualized to meet individual needs of each unique patient.

Recommendation 4.2: Create a Federal repository for Educational information on Lyme disease and other tick-borne diseases.

- *Increase Availability of Educational Materials for Patients, Physicians, and the General Public*
- *Empower Patients with Data*
- *Protect Vulnerable and High-Risk Populations*
- *Reduce the Administrative Burden for Health Care, Health Insurance, and Disability Coverage*
- *Adopt Shared Medical Decision-Making and Patient-Centered Care*

Recommendation 4.3: Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care.

STRATEGIC GOAL 5: Accelerate Impact through Public-Private Partnerships

26

Recommendation 5.1: Establish public-private partnerships (PPPs) to accelerate mission delivery.

Recommendation 5.2: Match every federal dollar 1:2 with twice as many private-sector investments into Lyme disease science, research, and development.

Recommendation 5.3: Launch the “Lyme Moonshot”—analogous to the “Manhattan Project” that transformed the globe with nuclear science breakthroughs—with large-scale scientific collaborations and investment to revolutionize Lyme diagnostics, treatments, and patient outcomes.

Conclusion

28

Executive Summary

Americans should be aware that tick-borne diseases (TBDs) and especially Lyme disease are sharply on the rise in the U.S., highlighted by the combination of climate change, international travel, changing land use, deforestation, and urbanization of rural areas. The number of reported cases has been increasing annually with a steady increase in tick-borne diseases. There are several challenges to preventing TBDs, including the lack of vaccines and effective vector control tools, insecticide resistance, and eroding technical capacities in public health entomology at federal, state, and local levels.¹ For these reasons, a national strategy is needed to address TBD threats and to reverse the alarming trend in morbidity and mortality associated with these diseases. The White House should establish a TICK Office and launch a Lyme Moonshot to diagnose, treat, manage and cure Lyme and other tick-borne diseases by 2030. TICK stands for Tick-borne Innovation, Collaboration, and Knowledge. In 2020 we have seen how an infectious disease like Covid-19 can have a major impact on all aspects of American life and even our national security. Like Covid-19, Lyme disease affects hundreds of thousands—actually more than 300,000 US citizens² each year. 1–2 million people suffer from Persistent Lyme Disease with debilitating symptoms and the economic cost of Lyme disease is “potentially a \$50- to \$100-billion-dollar problem for the United States, although more research is needed.”^{3,4} The effect of Lyme disease is felt by Americans across all ages, all walks of life—our military, our hospitals, our schools, our children, and our businesses. Since Lyme patients have no reliable diagnostic, no vaccine, and no working therapy for persistent conditions, we propose a 5-pronged federal approach to accelerate positive health outcomes for Lyme patients. The Lyme Moonshot will leverage a Whole of Government effort in collaboration with the private sector, research institutions, and healthcare providers.

*“We choose to go to the moon in this decade
and do the other things, not because they are easy,
but because they are hard...”*

- President John F. Kennedy

¹ Petersen LR, Beard CB, Visser SN. Combatting the Increasing Threat of Vector-Borne Disease in the United States with a National Vector-Borne Disease Prevention and Control System. *Am J Trop Med Hyg.* 2019;100(2):242-245. doi:10.4269/ajtmh.18-0841

² Hinckley, A. F., Connally, N. P., Meek, J. I., Johnson, B. J., Kemperman, M. M., Feldman, K. A., . . . Mead, P. S. (2014). Lyme disease testing by large commercial laboratories in the United States. *Clinical Infectious Diseases*, 59(5), 676-681. doi:10.1093/cid/ciu397

³ Zhang, X., Meltzer, M. I., Pena, C. A., Hopkins, A. B., Wroth, L., & Fix, A. D. (2006). Economic impact of Lyme disease. *Emerging Infectious Diseases*, 12(4), 653-660. doi:10.3201/eid1204.050602

⁴ Tick-borne Disease Working Group Report to Congress. <https://www.hhs.gov/sites/default/files/tbdwg-report-to-congress-2018.pdf>

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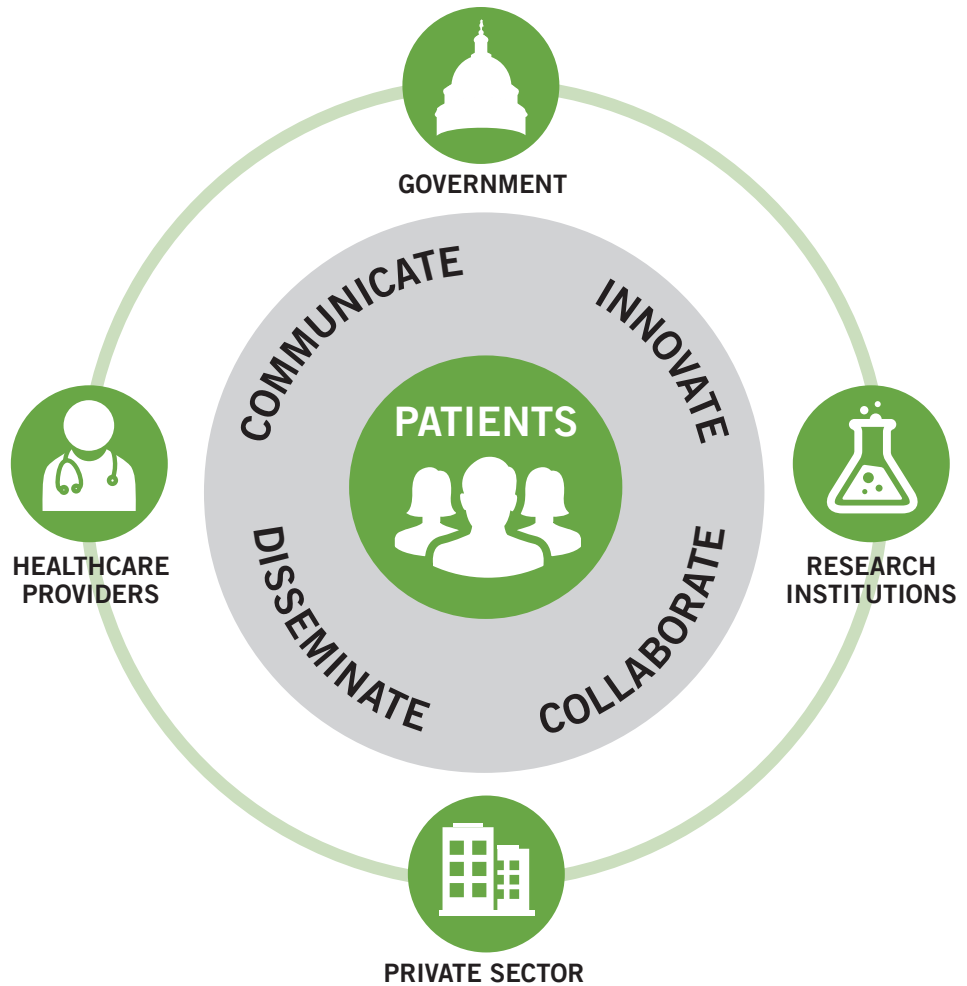
MISSION

Dramatically accelerate efforts to diagnose, treat, and prevent Lyme and other tick-borne diseases

WHY NOW

Growing numbers of patients with devastating Lyme and other tick-borne diseases

And immense scientific and technological capabilities positioning us for a quantum leap



THE PROMISE FOR PATIENTS

The Lyme Moonshot catalyzes innovation, accelerates progress, and acts on new knowledge to cure Lyme and other Tick-borne Diseases.



Effective therapeutics



Improved prevention



Improved diagnostics



Better Information

Figure 1. Lyme Moonshot Overview.

Challenge and Opportunity

Increased Federal funding, prioritization, and leadership are needed to reverse the alarming trends associated with tick-borne diseases. People bitten by a tick and struck by Lyme have lost their livelihoods, retirement savings, marriages, children have lost their childhoods, and some have lost their lives. These people go undiagnosed by our medical establishment often for years because the diagnostics are unreliable. Once diagnosed, no cure or reliable therapies exist. When the private sector cannot deliver, we need to involve the Federal Government for assistance. Yet, despite several decades of research, prevention, and educational activities, Federal funding for tick-borne diseases remains less per new surveillance case than that of other diseases. The overall public health threat posed by ticks and tick-borne diseases in the United States is steadily increasing to include new human populations because major vector ticks are expanding their geographic ranges.^{5,6} The negative societal effects of ticks and tick-borne diseases in the United States, including a general feeling that family members are not safe during outdoor activities in the backyard and elsewhere, has reached the point where we need to rethink the basic concepts of how to counter this threat.

The U.S. National Institutes of Health (NIH) and CDC spend \$77,355 and \$20,293, respectively, per new surveillance case of HIV/AIDS, and \$36,063 and \$11,459 per new case of hepatitis C virus, yet only \$768 and \$302 for each new case of Lyme disease. Federal funding for tick-borne diseases today is order of magnitude lower, compared to other public health threats, and it has failed to increase as the problem has grown.^{7,8} In June 2019, months after a U.S. Congress–mandated working group sounded the alarm about tick-borne illnesses and urged more federal action and money, the National Institutes of Health (NIH) released \$6 million for vaccine proposal which represents a significant boost; NIH spent \$23 million last year (2019) on Lyme disease, by far the most common tick-borne illness, within \$56 million devoted to tick-borne diseases overall.⁹

Lyme disease is the most commonly reported tick-borne disease in the eastern United States, where the two primary causative agents (*B. burgdorferi* across the eastern half and *B. mayonii* in the upper Midwest) are transmitted by *I. scapularis* ticks.¹⁰ However, several other tick-borne illnesses, as well as co-infections with Lyme disease, are on the rise and increasingly recognized as serious health threats. Lyme disease was the near absolute focus among tick-borne diseases, most of human infections occurred in the northeastern United States, and residential properties were pinpointed as the most common location for encounters with *I. scapularis* ticks in Lyme disease-endemic areas. The difficulty in accessing these residential high-risk environments presented (and still presents) a major impediment for development of community-driven tick control, and the main focus was therefore

⁵ Eisen RJ, Eisen L, Beard CB. County-scale distribution of *Ixodes scapularis* and *Ixodes pacificus* (Acari: Ixodidae) in the continental United States. *J Med Entomol.* 2016;53:349–86.

⁶ Sonenshine DE. Range expansion of tick disease vectors in North America: implications for spread of tick-borne disease. *Int J Environ Res Public Health.* 2018;15:478.

⁷ Source: Tick-borne Disease Working Group Report to Congress. <https://www.hhs.gov/sites/default/files/tb-dwg-report-to-congress-2018.pdf>

⁸ Cdc.gov. Lyme Disease Charts and Figures: <https://www.cdc.gov/lyme/stats/graphs.html>

⁹ <https://www.sciencemag.org/news/2019/04/long-underfunded-lyme-disease-research-gets-injection-money-and-ideas>

¹⁰ Rosenberg R, Lindsey NP, Fischer M, Gregory CJ, Hinckley AF, Mead PS, et al. Vital signs: trends in reported vectorborne disease cases—United States and Territories, 2004–2016. *MMWR Morb Mortal Wkly Rep.* 2018;67:496–501

on devising tick suppression approaches intended for use in backyards and tick-bite prevention measures for personal protection.¹¹

Vector-borne diseases (VBDs), which include tick-borne diseases, cause significant morbidity and mortality each year in the United States. Between 2004 and 2017, there were about 700,000 cases of vector-borne cases reported to the CDC, and ticks accounted for 75 percent of those cases.¹² Reported cases of vector-borne diseases in the United States have more than tripled since 2004, characterized by steadily increasing incidence of tick-borne diseases.¹³ (The number of actual infections was likely ten to seventy times greater than the number reported to the CDC).¹⁴

Public Health Agencies and CDC in Preparing the Nation to Address Vector-Borne Diseases Threats

Federal public health agencies have generated new strategic plans aiming to strengthen both research and operational capacity to counter the threat of ticks and tick-borne diseases more effectively.^{12, 15, 28} The Entomological Society of America produced a position paper on tick-borne diseases¹⁶ highlighting the formation of a new coalition “The Vector-Borne Disease Network”, which includes the Entomological Society of America and a wide range of scientific and medical societies, professional associations, and the 5 Centers for Disease Control and Prevention–funded Regional Centers for Excellence in Vector-Borne Diseases.¹⁷

CDC has established a national surveillance system for ticks and the pathogens they carry and is leading efforts across six federal departments to develop a national strategy for addressing vector-borne diseases. In the United States, national surveillance of reportable tick-borne diseases is achieved through the National Notifiable Diseases Surveillance System.¹⁸ National surveillance of ticks and pathogens found in ticks was launched recently as part of the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases program of the Centers for Disease Control and Prevention, which provides funding to states, cities, and territories.¹⁹ Collectively, these national surveillance programs provide information on when and where humans are at greatest risk for exposure to ticks and tick-borne pathogens at state and county scales. However, significant obstacles hinder successful implementation of these public health strategies.

¹¹ Eisen L, Dolan MC. Evidence for personal protective measures to reduce human contact with blacklegged ticks and for environmentally based control methods to suppress host-seeking blacklegged ticks and reduce infection with Lyme disease spirochetes in tick vectors and rodent reservoirs. *J Med Entomol.* 2016;53:1063–92.

¹² Beard CB, Visser SN, Petersen LR. The Need for a National Strategy to Address Vector-Borne Disease Threats in the United States. *J Med Entomol.* 2019;56(5):1199-1203. doi:10.1093/jme/tjz074

¹³ Eisen RJ, Kugeler KJ, Eisen L, Beard CB, Paddock CD. Tick-borne zoonoses in the United States: persistent and emerging threats to human health. *ILAR J.* 2017;58:319–35

¹⁴ CDC.gov. Lyme Disease Charts and Figures: <https://www.cdc.gov/lyme/stats/graphs.html>.

¹⁵ CDC.gov. A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans: <https://www.cdc.gov/ncezid/dvbd/framework.html>

¹⁶ Entomological Society of America. ESA position statement on tick-borne diseases [cited 2019 Nov 118]. https://www.entsoc.org/sites/default/files/files/Science-Policy/2019/EntSocAmerica_PolicyStatement_TickBorneDiseases-2019.pdf

¹⁷ Entomological Society of America. Vector-borne disease network [cited 2019 Nov 18]. <https://www.entsoc.org/sci-pol/VBD-Network>

¹⁸ Centers for Disease Control and Prevention. National notifiable diseases surveillance system (NNDSS) [cited 2019 Nov 18]. <https://www.cdc.gov/nndss/>

¹⁹ Centers for Disease Control and Prevention. Epidemiology and laboratory capacity for prevention and control of emerging infectious diseases (ELC) [cited 2019 Nov 18]. <https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html>

Epidemiology and Laboratory Capacity (ELC) Funding for Vector-Borne Diseases

Through ELC, CDC's Division of Vector-Borne Diseases²⁰ provides funding and technical assistance to implement and maintain surveillance for human disease and their vectors, improve diagnostics, and to implement and evaluate prevention strategies. Core activities include active human surveillance, investigation and response to vector-borne disease cases, educational outreach, laboratory testing, hiring, or training of personnel and vector surveillance and control. Currently, Department of Vector Borne Diseases (DVBD) has made vector-borne threats a priority.

Vector-Borne Disease Regional Centers of Excellence

In 2017, five universities were established as regional centers of excellence (COE) to help prevent and rapidly respond to emerging vector-borne diseases across the United States. CDC's Division of Vector-Borne Diseases (DVBD) awarded a total of \$48 million for five years, through 2021, to these universities to The Northeast Regional COE at Cornell University; The Pacific Southwest COE at the University of California, Davis and Riverside; The Southeastern Regional COE at the University of Florida; The Western Gulf COE at the University of Texas Medical Branch in Galveston and The Midwest COE at the University of Wisconsin, Madison.

Need for Local and Professionally Staffed Integrated Tick-Management Programs

For ticks, every year brings a seasonally predictable emergency situation, risk habitats are diffuse and include both private and public lands, and current options for area-wide tick suppression are limited and have weak evidence bases for impact on human tick bites and disease. The most productive way of exploring the concept of integrated tick-management programs would be (well-funded) demonstration projects focused on geographic locations with strong existing mosquito management programs and severe problems with a wide range of tick species and tick-borne diseases.

Potential solutions that have emerged over the past two decades include a wide array of approaches to prevent tick bites through personal protection measures or to suppress host-seeking ticks or disrupt enzootic pathogen transmission through environmentally based control methods, but evidence for their impact on human tick bites or illness is limited.²¹ Moreover, uptake of these solutions by the public remains weak because of limited acceptability of some methods with perceived risk to the environment, pets, or family members, as well as low willingness to pay, combined with the consideration that the lowest-cost methods (e.g., use of tick repellents and daily tick checks) require high levels of daily vigilance over several months each year.²² We remain optimistic that the recent U.S. EPA approval of Nootkatone, a natural organic compound, may play a role in improving prevention. To suppress ticks more effectively in the environment and reduce human tick bites and tick-borne diseases, we need to invest in studies to optimize the effect of existing technologies, as well as stimulate the development of novel approaches.

²⁰ Content source: [Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases \(NCEZID\), Division of Vector-Borne Diseases \(DVBD\)](#)

²¹ Eisen L, Gray JS. Lyme borreliosis prevention strategies: United States versus Europe. In: Braks MA, Van Wierer SE, Takken W, Sprong H, editors. Ecology and prevention of Lyme borreliosis. Wageningen (The Netherlands): Wageningen Academic Publishers; 2016. p. 429–50.

²² Niesobecki S, Hansen A, Rutz H, Mehta S, Feldman K, Meek J, et al. Knowledge, attitudes, and behaviors regarding tick-borne disease prevention in endemic areas. *Ticks Tick Borne Dis.* 2019;10:101264.

The Role of Congress in Combatting Lyme Disease

In 2016, Congress provided CDC with \$350 million in supplemental funding to perform the critical work needed to prevent, detect, and respond to the public health emergency posed by Zika virus. The funding is vital to protect areas at highest risk of impact from Zika. Building on that investment, a strong, sustained, national infrastructure for vector-borne disease is needed. This infrastructure must advance innovation and discovery and build comprehensive vector programs. To contribute improved strategies and better tools to suppress ticks, reduce human tick bites, and roll back tick-borne diseases, Congress has established a Tick-Borne Disease Working Group in 2016, as part of the 21st Century Cures Act,²³ and subsequently, initiated the first biannual Tick-Borne Disease Working Group whose report was published in 2018.²⁴

The bipartisan Kay Hagan Tick Act²⁵ authored by Senators Susan Collins (R-ME) and co-sponsored by Tina Smith (D-MN) and 32 Senators was signed by the President on Dec 20, 2019, after incorporation into the FY2020 minibus Appropriations bill as S.1657, a bill “To provide assistance to combat the escalating burden of Lyme disease and other tick and vector-borne diseases and disorders.” The Act was named after the former Democratic Senator from North Carolina who died last year from a tick-borne disease. The Tick Act makes positive, initial steps towards bringing the high-level attention to this under acknowledged chronic disease, including authorizing \$150M to the Centers for Disease Control and Prevention (CDC) over the next 5 years. Additionally, it assigns the Secretary of Health and Human Services (HHS) responsibility for coordinating “programs and activities, including related to data collection, research, and the development of diagnostics, treatments, vaccines, and other related activities” among Federal agencies. Given that this disease has grown steadily in severity over the last two decades, from being just a “New England problem” to nearly all 50 States, we believe it requires the addition of White House-level direction, a dedicated individual supported by a team, to help drive and support interagency funding and policy for viable diagnostics, therapies and a cure.

It is essential that funding and resources be allocated to support a comprehensive, interagency program to address the mounting challenges identified. All research, prevention, and education initiatives should be inclusive of special populations such as children, who suffer disproportionately from tick-borne diseases. Patients whose lives continue to be disrupted by the lasting effects of these illnesses are counting on emerging scientific research, evidence-based policy, and the health care establishment—including the Federal Government with Congressional and Executive leadership—to provide solutions. Despite a groundswell of support to increase funding for Lyme disease research from Congress and the current Administration’s proposed increases for Lyme disease research in their latest budget request, the decades-long Executive Branch leadership vacuum for Lyme and tick-borne disease has led to a lack of Federal policy direction and gross underfunding of scientific research for the disease. We must act now to turn this around.

We propose **five strategies** to do just that—to achieve a viable diagnostic and therapies for Lyme and tick-borne diseases that will restore the lives of so many Americans taken down by this too often debilitating disease.

²³ <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act>

²⁴ Tick-Borne Disease Working Group. Report to Congress, 2018 [cited 2019 Nov 18]. <https://www.hhs.gov/sites/default/files/tbdwg-report-to-congress-2018.pdf>

²⁵ <https://www.congress.gov/bill/116th-congress/senate-bill/1657/text/is>

Five Strategies for a Lyme Moonshot

STRATEGIC GOAL 1: Lead from the Top

“Human experience shows that people, not organizations or management systems, get things done.”

– Admiral Hyman Rickover, the “Father of the Nuclear Navy”,
speech at Columbia University, 1982

Recommendation 1.1: Establish a White House TICK Office with a Lyme Leader who has authority, accountability, and resources to drive systemic change across government.

Recommendation 1.2: Establish a HHS TICK Office to support and execute the Lyme disease goals and national strategy led by the White House TICK Office; consider establishing the HHS TICK Office within the Office of the Secretary at HHS.

Recommendation 1.3: Form a Lyme Moonshot Blue Ribbon Task Force with diverse perspectives from researchers, clinicians, patients, industry, non-profit organizations, and government to provide expertise and guidance to the TICK Office and Lyme Leader.

We propose establishing a White House “Tick-borne Innovation, Collaboration, and Knowledge” or TICK Office led by a Lyme Leader under the auspices of the National Security Council in close coordination with the Domestic Policy Council to coordinate interagency Lyme and tick-borne disease funding and assessments associated with the Lyme Moonshot. We also propose the creation of the Lyme Moonshot National Science Technology Council Committee under the White House Office of Science and Technology Policy and Chaired by the Vice President to coordinate interagency efforts and drive resolution of the Administration’s Moonshot priorities. Agencies to serve on White House NSTC Lyme Moonshot Committee or “Lyme Moonshot Council” include the NIH, the CDC, Departments of Defense, Energy (with its national laboratory assets), Veterans Affairs, Agriculture, Interior, Homeland Security, State, and the U.S. EPA.

We further propose a Blue Ribbon Task Force on Lyme Disease consisting of researchers, clinicians, patients, industry, non-profit organizations, and government to advise the Vice President with the NSTC Lyme Moonshot Committee and the White House TICK office. The Blue Ribbon Task Force will deliver a final report with findings and recommendation no later than March 1, 2022 to permit consideration in the FY2023 President’s Budget Request and legislative proposals.

The HHS would remain the lead agency on implementation of the interagency coordination. The Secretary would also establish a new Tick-borne Innovation, Collaboration, and Knowledge Office (“TICK Office”) reporting to the Secretary to ensure continued and lasting attention to this under acknowledged public health crisis. The Office would bolster the Lyme and tick-borne disease related activities of the CDC and ensure Lyme and tick-borne disease receives research priority at the National Institutes of Health (NIH) and its National Institute of Allergy and Infectious Diseases (NIAID) as well as staff the White House Lyme Moonshot initiative.

We have learned that unfortunately private industry will not invest in Lyme disease therapies or a cure to help current patients with workable solutions through therapies or a cure. Although diagnostics have received some investment because of the financial promise and return of diagnostic testing, diagnostic development needs to be accelerated, specifically to help researchers to determine if their therapies are indeed working and, of course, to relieve sick patients in search of a diagnosis. Increased funding at HHS while leveraging DOD’s DARPA Biological Technologies Office given the health impacts of Lyme on our military personnel, veterans and their families could be that critical catalyst for developing diagnostics and therapies that has long been overlooked and underfunded—apart from the generosity of private foundations. DOD force readiness with its significant U.S. taxpayer investment has been impacted by Lyme disease. To move Lyme disease beyond basic research to clinical trials and to market, the substantial costs range from [\\$161M to \\$2B](#) lasting on average 7.5 years.²⁶ Lyme disease R&D funding across the entire Federal government has never even reached \$50M. The market will not support these investments in Lyme because the therapies are not profitable—or profitable enough. Placing Lyme and tick-borne disease at the top of a DARPA R&D agenda could infuse the disease with significant funding yet unrealized to bring diagnostics and therapies to patients and the medical community.

STRATEGIC GOAL 2: Catalyze New Scientific Breakthroughs for Evidence-Based Solutions

“We are a caring nation, and our values should also guide us on how we harness the gifts of science.”

– President George W. Bush

Recommendation 2.1: Increase federally funded science, research and development:

- Execute 2019 NIH Strategic Plan for Tick-borne Disease
- Advance the CDC’s ability to monitor and provide health advice to citizens with Lyme and other tick-borne diseases and deliver on tick-borne research as funded by the Kay Hagan Tick Act of 2019
- Establish New Centers of Academic Excellence for Lyme and Tick-borne Disease at NIH with new funding at Universities

Recommendation 2.2: Foster an HHS/DOE/interagency “One Health” Lyme Moonshot

Recommendation 2.3: Mitigate the impact of tick-borne disease on military readiness, Service Members, Veterans and their families.

²⁶ “Examination of Clinical Trial Costs and Barriers for Drug Development,” submitted to U.S. Department of Health and Human Services Assistant Secretary of Planning and Evaluation (ASPE) by Aylin Sertkaya, Anna Birkenbach, Ayesha Berlind, John Eyraud, Eastern Research Group, Inc, July 25, 2014.

The TICK Office must increase federally funded science, research, and development for Lyme disease by four orders of magnitude. Research budgets must go from \$55M/year to \$1B/year, as the U.S. government did for Alzheimer’s research over the last decade. Science is the way to solve the complexities surrounding Lyme disease including federal investments in prevention, diagnostics, and the next-generation of therapeutics and treatments.

Number of Clinical Trials in Infectious Diseases

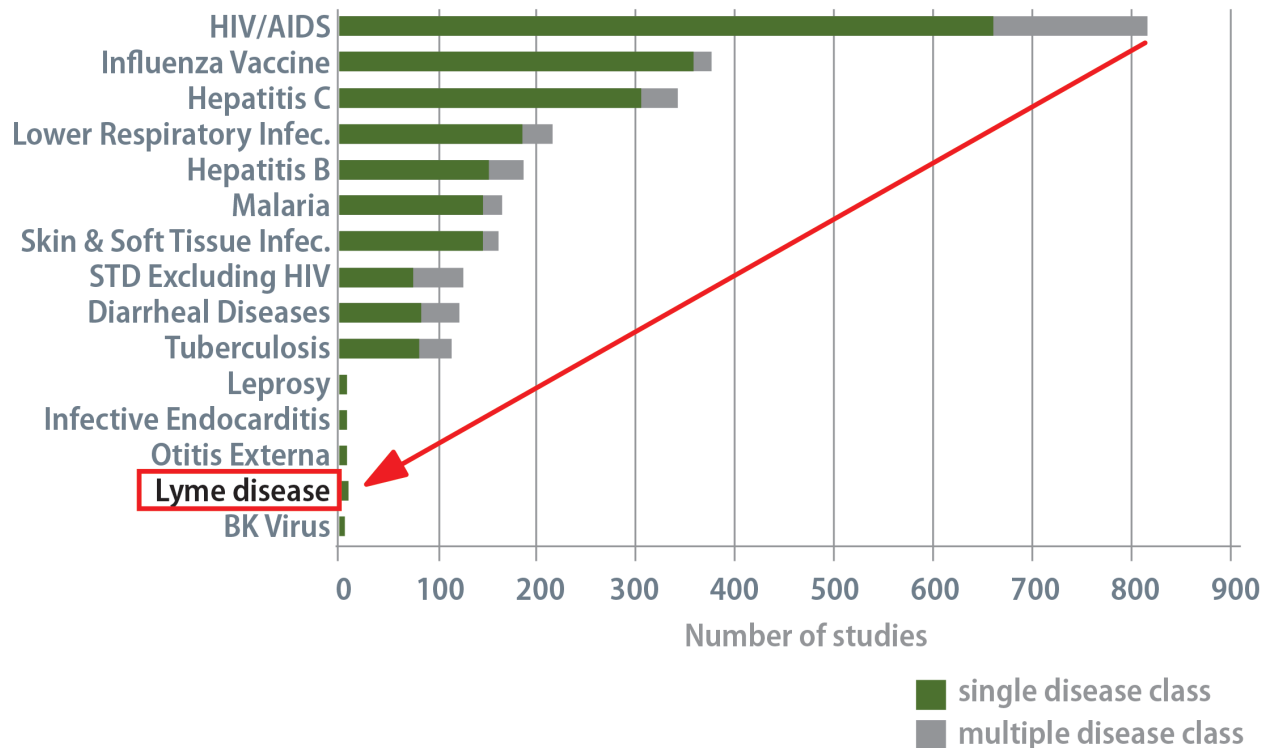


Figure 2: Number of Clinical Trials in Infectious Diseases.²⁷

All of these objectives are outlined in detail in the 2019 NIH Strategic Plan for Tick-borne Disease.²⁸

CDC

The Lyme Moonshot will grow CDC’s ability to monitor and provide health advice for Lyme and other TBDs including treatment resistance, and prevention, including maternal-fetal and transplantation/transfusion transmission risk.

As part of the Zika response, the CDC created 5 Regional Centers of Excellence to help prevent and rapidly respond to emerging vector-borne diseases across the United States. The Kay Hagan Tick Act authorizes the CDC to convert these Zika centers to focus on vector and tick-borne Disease. There are five centers located at top universities in New York, California, Florida, Texas, and Wisconsin.

²⁷ NIH.gov. Removing the Mask of Average Treatment Effects in Chronic Lyme Disease Research Using Big Data and Subgroup Analysis: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6316052/>

²⁸ NIH Strategic Plan for Tickborne Disease. <https://www.niaid.nih.gov/sites/default/files/NIH-Strategic-Plan-Tick-borne-Disease-Research-2019.pdf>

Establish New Centers of Academic Excellence for Lyme and Tick-borne Disease

The Lyme Moonshot will work with NIH National Center for Advancing Translational Sciences (NCATS) to create new Lyme Centers of Academic Excellence around the United States. These centers of excellence will be located at academic institutions and are based on the National Cancer Institute academic centers, known as the NCI-Designated Cancer Centers. The NCI-Designated cancer centers were created as part of the National Cancer Act of 1971²⁹ and serve as a key anchor for the nation's cancer research effort. Similarly, the Lyme Moonshot would work with the NIH NCATS to develop key research centers around the country that meet rigorous standards for multi-disciplinary, state-of-the-art research and will focus on new and better approaches to prevention, diagnostics, and therapies.

HHS/DOE/Interagency "One Health" Lyme Moonshot

In addition to the work by the NIH, the Lyme Moonshot will include interagency work to apply the One Health approach for tick-borne diseases. Led by the new HHS TICK Office in close collaboration with CDC, NIH, Department of Energy (DOE), and its National Laboratories, the Department of Veterans Affairs, DOD and its DARPA, this basic science will further our understanding of the tick microbiome and the relationship between microbes and their tick hosts.

This science will facilitate the rapid identification of new tick-borne pathogens, which is essential for U.S. public health as well as national security, preparedness, and emergency response to introduced diseases or carriers of these diseases, like the Asian longhorn tick introduced into the United States in 2017.³⁰ The conventional methods for detecting and identifying causative agents for tick-borne diseases should be supplemented with novel, powerful molecular approaches.

Interagency collaboration like this exists today for COVID-19, suicide prevention, heart health—and is easily extensible to Lyme and tick-borne disease science—with an HHS data enclave on DOE supercomputers. DOE National Laboratories, like Oak Ridge National Laboratory (ORNL), house the world's fastest and most powerful computers. This enables big-data analysis with artificial intelligence (AI) and emerging-technology capabilities to yield transformative advances in science. DOE has immense capacity in multi-omics to advance Lyme science through its DOE-NIH Joint Genome Institute, the multi-scale modeling capabilities developed within the Machine Learning (ML) initiatives, and the high performance computing capabilities of ORNL, National Energy Research Scientific Computing Center (NERSC), and their leadership-class computers.

DoD and the VA

The Lyme Moonshot will work with the Department of Defense (DoD) to study tick-borne disease incidence and prevalence of active duty Service Members, their families, and dependents. Compile data on the impact of tick-borne diseases on military readiness. Create education and preparedness programs that specifically address the unique risks faced by Service members in training and on deployment and by their families. For the U.S. Department of Veterans Affairs (VA), the Lyme Moonshot will study tick-borne disease incidence and prevalence of Veterans and Veterans' families and dependents.

The TICK Office can leverage VA infrastructure to transform scientific discoveries into new clinical practices. The VA hospital system offers a path for applied translational medicine "from bench to

²⁹ Barker, Anna D. and Jodan, Hamilton, "Legislative History of the National Cancer Program", NCBI website (access 10/11/20): <https://www.ncbi.nlm.nih.gov/books/NBK13873/>

³⁰ U.S. Centers for Disease Control and Prevention (CDC), "What you need to know about the Asian longhorn ticks - A new tick in the United States", CDC website (accessed 6/18/20): <https://www.cdc.gov/ticks/long-horned-tick/index.html>

bedside” because approximately 70% of U.S. doctors train at VA hospitals at some point in their medical career.³¹ VA hospitals are also important to all American citizens, beyond only Veterans, because the VA system provides a medical “safety net” for everyone. The VA treats civilian patients when the U.S. medical system is beyond capacity and/or during times of crisis, as we are seeing today with COVID-19 patients. Harnessing VA’s translational science capabilities will facilitate the adoption of next-gen technologies and scientific breakthroughs to improve Lyme disease care for everyone.

STRATEGIC GOAL 3: Unleash the Power of Data

“Without big data, you are blind and deaf and in the middle of a freeway.”

– Geoffrey Moore

Recommendation 3.1: Create a Federal repository with shared data standards for TICK information that will facilitate information sharing and drive data-driven decisions across government, research, and public health.

Recommendation 3.2: Leverage existing IT infrastructure and authorities, including but not limited to:

- Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer’s Act of 2018
- Pandemic and All-Hazards Preparedness Act of 2019
- Foundations for Evidence-Based Policymaking Act of 2018
- Grant Reporting Efficiency and Agreements Transparency Act of 2019

Recommendation 3.3: Require grantees of federally funded research to share their Lyme disease data and results in the Federal repository for TICK Information, per laws and policies that advance U.S. Open Science (open access),³² Open Data,³³ and Open Source Code.³⁴

Recommendation 3.4: Infuse data ethics into every aspect of the Lyme Moonshot.

The next generation of solutions will be data driven. Today’s researchers and patients generate an unprecedented amount of data from telemedicine, wearables, electronic health records (EHRs), genomic information, and many other datasets from clinical, environmental, and public health information. Managing information and sharing it across conventional boundaries will yield discoveries when new audiences gain access to the ever-growing amounts of data with the collective

³¹ <https://www.blogs.va.gov/VAntage/18655/mcdonald-academic-affiliations-a-source-of-strength-for-the-va-medical-schools/#:~:text=They’re%20why%20about%2070,in%20other%20health%20fields%2C%20annually>

³² Science.gov. Your Gateway to U.S. Federal Science: <https://www.science.gov/>

³³ Data.gov. The Home of the U.S. Government’s Open Data: <https://www.data.gov/>

³⁴ Code.gov. Sharing America’s Code: <https://code.gov/>

goal to transform data into information and knowledge, which will guide real-world action and decision making.

Create a Federal Data Repository

The TICK Office will create a Federal repository with shared data standards for TICK information and facilitate the sharing of information between and among Federal, State, local, tribal, and territorial public health agencies and hospital systems related to Lyme and tick-borne diseases. The TICK Office and its Blue Ribbon Task Force will work with industry, academia, and non-profit groups including patient registries to co-create a shared, federated database or IT system. This system should support all sectors—government, industry, academia, and non-profit organizations—working on the Lyme Moonshot.

This TICK repository will facilitate the sharing of information between and among Federal, State, local, tribal, and territorial public health agencies, hospital systems, academic institutions, and tissue biobank repositories for Lyme and tick-borne diseases. Development and standardization of biomarkers to understand how immunotherapies work in some Lyme patients, and to predict patient response to treatment, are urgently needed for data-driven understanding of emerging options for care. The TICK repository shall include a mechanism to track the interdisciplinary facets of One Health (see Recommendation 2.2), from the tick and environment to clinical care and patient outcomes. The TICK repository shall regularly and periodically make available summary statistics and data, which will be aggregated and anonymized as open data for the public consistent with applicable law (see Recommendation 3.3).

Leverage Existing IT Infrastructure and Statutory Authorities

The TICK Office should extend existing laws and IT Infrastructure to the maximum extent possible. Repurposing or building upon existing law, policy, and infrastructure will expedite data-driven objectives and advance Lyme Moonshot goals. Specific legislation to align with the Lyme Moonshot includes, but is not limited to, the:

- **Building our Largest Dementia (BOLD) Infrastructure for Alzheimer’s Act BOLD Act;** (Pub. L. 115- 406) The BOLD Act of 2018 established IT infrastructure for data sharing of brain science to accelerate Alzheimer’s breakthroughs. This data-sharing infrastructure can be extended for Lyme and tick-borne disease, which often manifest with neurological symptoms that impair brain function like dementia. Expanding the BOLD infrastructure to other human organ systems, since Lyme disease is a multi-systemic condition including the brain, will advance Lyme Moonshot goals. It will improve the timeliness of Lyme disease reporting, data sharing, data analysis, and data-driven decision making with standards, interoperability, and governance.
- **Pandemic and All-Hazards Preparedness Act (PAHPA;** Pub. L. 109-417) The TICK Office could leverage the PAHPA of 2019 to combat growing threats from Lyme and other tick-borne diseases. According to the CDC, over the past 20 years, seven new tick-borne germs that cause human illness have been identified in the United States.³⁵ More alarmingly, novel pathogens are likely to continue to be discovered, whether due to improved diagnostics and/or novel hosts such as exotic tick species introduced in the United States.³⁶ PAHPA amends the Public Health

³⁵ U.S. Centers for Disease Control and Prevention (CDC), “Lyme and Other Tickborne Diseases Increasing”, CDC website (accessed 6/18/20): <https://www.cdc.gov/media/dpk/diseases-and-conditions/lyme-disease/index.html#:~:text=New%20germs%20identified,parkeri%2C%20and%20Rickettsia%20species%20364D>

³⁶ U.S. Centers for Disease Control and Prevention (CDC), “What you need to know about the Asian longhorn

Service Act and improves “the Nation’s public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural.” Lyme and tick-borne diseases are a natural emergency. The United States must improve the capacity of its states and localities to prepare for and respond to public health needs. U.S. capacity for the Lyme Moonshot would include resources for modern IT/data infrastructure, which is foundational for modern public health response, interagency collaborations, public-private partnerships, coordinated bio surveillance networks, and harnessing the power of emerging technologies like artificial intelligence (AI), telehealth, and smart hospitals.

- **Foundations for Evidence-Based Policymaking Act of 2018** (Evidence Act; Pub.L. 115–435) The Evidence Act, enacted in January 2019, establishes Chief Data Officers across federal government and puts agency priority on data management, program evaluation, and statistical expertise. It establishes new expectations for open data, data inventories, and improved data management—all necessary to advance data-driven innovations, insights, and decision making for Lyme and tick-borne diseases.
- **Grant Reporting Efficiency and Agreements Transparency Act** (GREAT Act; Pub. L. 116-103) The GREAT Act of 2019 modernizes U.S. grant reporting by directing federal agencies to improve grantee reporting, transparency, and accountability with data and automated technologies. Recipients of federal grants include extramural researchers, public health agencies, non-profit organizations, and governmental services with local, state, and tribal governments. The TICK Office can leverage the GREAT Act to ensure that recipients of federal funds related to Lyme disease will use a standardized structure for data reporting, sharing, and publishing to make information publicly accessible while protecting individual privacy and proprietary information.

Default to Open with Open Science, Open Data, and Open Source Code

The TICK Office will “default to open” and enhance information exchange to accelerate the pace of scientific discovery, improve the quality and reproducibility of the science, and increase transparency so that all stakeholders have insight and access. The TICK Office shall regularly and periodically make available to the public aggregated information and anonymized data from the TICK information repository (Recommendation 3.1), as consistent with applicable law.

Transparency and openness with information will help build trust in the Lyme Moonshot. This is especially important with Lyme disease stakeholders who believe that U.S. policy and government have failed them. Trust, which can be defined as consistency over time, will be built for the Lyme Moonshot by consistently and repeatedly sharing science, data, and computer code with the American public.

The TICK Office should require federal grant recipients to share their research and results consistent with the U.S. Open Science (open access),³⁷ Open Data,³⁸ and Open Source Code³⁹ policies. Federal agencies should award research grants and allocate discretionary funding only to those entities in compliance with these policies and the TICK information repository (Recommendation 3.1).

ticks - A new tick in the United States”, CDC website (accessed 6/18/20): <https://www.cdc.gov/ticks/long-horned-tick/index.html>

³⁷ Science.gov. Your Gateway to U.S. Federal Science: <https://www.science.gov/>

³⁸ Data.gov. The Home of the U.S. Government’s Open Data: <https://www.data.gov/>

³⁹ Code.gov. Sharing America’s Code: <https://code.gov/>

Infuse Data Ethics into Every Aspect of the Lyme Moonshot

The Lyme Moonshot must “lead by example” with data ethics and ethical modernization. This must include but is not limited to: prioritization of patient partnerships, informed consent, shared data governance with patients, and collective self-governance for ethical data sharing and use of patient data.

Patients today have moved past the challenges of misunderstood roles⁴⁰ and mismatched priorities⁴¹ to make practical contributions that broaden the research agenda including patient/clinician relevant outcome measures,^{42,43} reduced costs, and acceleration of the clinical research pace without a loss in quality.⁴⁴ Patient research partnerships are reported as delivering value through every stage of the research process while increasing health self-management and research literacy.^{24,45}

Guided by ethical modernization principles, participatory gains are reported within private research initiatives such as Verily Project Baseline.⁴⁶ The Robert Wood Johnson Foundation is funding patient-led research for the development of practical tools to improve quality of life for those with Parkinson’s disease as well as the prototype and delivery of the first open source artificial pancreas project. These are open access research projects developed by patients.^{47, 48, 49}

The Precision Medicine Initiative (All of Us) and the Million Veteran Program are exemplars of high-impact, long-term, patient-driven initiatives that have the full backing of the White House²⁶ with continuity across Administrations. Such research offers sustainability, scalability, and reach that would not be possible without the patients and members who are full partners in the research.^{26,27} Policy documents establishing the Precision Medicine Initiative stated, that “[a]dvancing the science of medicine also calls for a change in the culture of medical practice and medical research to engage individuals as active collaborators—not just as patients or research subjects.”⁴⁶

Patients and participants retained to provide expertise through the lived patient experience may transcend this role to work with professional researchers in developing testable hypotheses and

⁴⁰ Snow R, Crocker JC, Crowe S. Missed opportunities for impact in patient and carer involvement: a mixed methods case study of research priority setting. *Res Involv Engagem.* 2015;1:7.

⁴¹ Crocker JC, Boylan AM, Bostock J, Locock L. Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study. *Health Expect.* 2017;20(3):519-528.

⁴² de Wit M, Abma T, Koelewijn-van Loon M, Collins S, Kirwan J. Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences. *BMJ Open.* 2013;3(5).CTTI's Patient Groups and Clinical Trials Project. *Therapeutic Innovation & Regulatory Science.* 2017:1-10.

⁴³ de Wit MP, Abma TA, Koelewijn-van Loon MS, Collins S, Kirwan J. What has been the effect on trial outcome assessments of a decade of patient participation in OMERACT? *J Rheumatol.* 2014;41(1):177-184.

⁴⁴ Levitan B GK, Eisenstein E, Goldberg M, Harker M, Hesterlee S, Patrick-Lake B, Roberts JN, DiMasi J. Assessing the Financial Value of Patient Engagement: A Quantitative Approach from Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical trials: An overview of systematic reviews. *J Eval Clin Pract.* 2017.

⁴⁵ Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical trials: An overview of systematic reviews. *J Eval Clin Pract.* 2017.

⁴⁶ House W. Precision Medicine Initiative: Privacy and Trust Principles. 2016.

⁴⁷ Verily. Project Baseline. 2017; <https://www.projectbaseline.com/>. Accessed 12/9/2017, 2017.

⁴⁸ Riggare S, Unruh KT, Sturr J, et al. Patient-driven N-of-1 in Parkinson’s Disease. Lessons Learned from a Placebo-controlled Study of the Effect of Nicotine on Dyskinesia. *Methods Inf Med.* 2017;56(99):e123-e128.

⁴⁹ Lewis D. Setting Expectations for Successful Artificial Pancreas/Hybrid Closed Loop/Automated Insulin Delivery Adoption. *J Diabetes Sci Technol.* 2017:1932296817730083.

practical solutions to solve disease challenges.⁶ Increasingly, patients are turning to science and medical evidence, to adopt first proofs of principle, using their own methods and publishing the research findings as lead authors in peer-reviewed literature.^{28, 29, 50}

There is ample opportunity for progress and yet despite these benefits, our research shows patient voices at medical convenings represent less than 3% of the stakeholder mix.⁵¹ This 3% supplies the force behind 1.4 billion social media impressions and yet patients routinely report facing limited meaningful inclusion in the biomedical research process.⁵² The Lyme Moonshot will push for an ethical and moral imperative where researchers, clinicians, funding agencies, and academic publishers must reform their current model of academic scholarship to allow for full and meaningful partnership with patients and participants throughout the biomedical research enterprise: from research conception and design to conduct, analysis, publication and planning for the dissemination process. The current research enterprise, by failing to optimally include patient and participant expertise throughout the process, harms society and increases healthcare costs.

STRATEGIC GOAL 4: Improve Patient Outcomes & Access to Care

“The secret in care for the patient is to care for the patient”

– Jim Demaine

Recommendation 4.1: *Protect the rights of licensed clinicians to treat Lyme disease with freedom to use their clinical judgment individualized to meet individual needs of each unique patient.*

Recommendation 4.2: *Create a Federal repository for educational information on Lyme disease and other tick-borne diseases.*

- *Increase Availability of Educational Materials for Patients, Physicians, and the General Public*
- *Empower Patients with Data*
- *Protect Vulnerable and High-Risk Populations*
- *Reduce the Administrative Burden for Health Care, Health Insurance, and Disability Coverage.*⁵³
- *Adopt Shared Medical Decision-Making and Patient-Centered Care*

⁵⁰ Lewis D, Leibrand S, Open APSC. Real-World Use of Open Source Artificial Pancreas Systems. *J Diabetes Sci Technol.* 2016;10(6):1411.

⁵¹ Utengen A, Rouholiman D, Gamble JG, et al. Patient Participation at Health Care Conferences: Engaged Patients Increase Information Flow, Expand Propagation, and Deepen Engagement in the Conversation of Tweets Compared to Physicians or Researchers. *Journal of medical Internet research.* 2017;19(8):e280.

⁵² Locock L, Boylan AM, Snow R, Staniszewska S. The power of symbolic capital in patient and public involvement in health research. *Health Expect.* 2017;20(5):836-844.

⁵³ TBDWG 2018. Tick-Borne Disease Working Group Report with 28 recommendations to Congress and the HHS Secretary: <https://www.hhs.gov/sites/default/files/tbdwg-report-to-congress-2018.pdf>

Recommendation 4.3: *Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care.*

Recommendation 4.1: Protect the rights of licensed clinicians

In endemic states, many providers who treat persistent Lyme disease and other tick-borne diseases with long-term antibiotics risk their livelihoods and reputations to do so. Other clinicians accuse them of compromising the health of the patient, and state medical boards prosecute them for operating outside the IDSA guidelines. These prosecutions have led many doctors to feel hesitant about handling chronic or recurrent cases.

IDSA and ILADS Guidelines

Diagnosis and treatment of tick-borne diseases is divided into (1) the Infectious Diseases Society of America (IDSA) and other medical societies, AND (2) International Lyme and Associated Diseases Society (ILADS). The IDSA guidelines promote the diagnosis of Lyme disease through the diagnosis by two-tiered serological testing and the IDSA guidelines usually recommend 10 to 21 days of antibiotic treatment. In contrast, the ILADS guidelines promote the use of clinical judgment with an emphasis on both signs and symptoms of disease when diagnosing and treatment and do not restrict the long-term use of antibiotics. Despite the existence of two peer-reviewed, evidence-based treatment guidelines, there is an apparent governmental and insurance industry bias for use of the IDSA standards and guidelines exclusively. Physicians who choose to follow the ILADS guidelines are often penalized by state medical boards, causing many providers to avoid treating chronically ill patients.

The IDSA guidelines for treating Lyme disease – a Note

It is important to realize that guidelines⁵⁴ cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to patients or special clinical situations. The Infectious Diseases Society of America considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances. Despite the footnote, state licensing boards subject medical providers to disciplinary action and fines for choosing to determine the direction of their patients' treatments based on their clinical judgment, other recognized diagnostic and treatment guidelines, individual circumstances, and previous treatment responses. Therefore, it falls on each state to produce legislation or policy solutions to promote public awareness and protection for patients and providers.

CDC Surveillance Criteria Misuse

The inappropriate use of the CDC surveillance criteria for Lyme disease compounds the problem, as insurance companies routinely use the CDC surveillance case definition as the recognized clinical criteria for diagnosis and subsequent treatment. They, therefore, deny coverage and

⁵⁴ Gary P. Wormser, et al., The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America, *Clinical Infectious Diseases*, Volume 43, Issue 9, 1 November 2006, Pages 1089–1134, <https://doi.org/10.1086/508667>

treatment reimbursement for patients who do not meet the criteria. When these patients find themselves without options, they are vulnerable to the exploitation of unscrupulous practitioners offering costly and ineffective treatments.

Managed Care and HMOs

Most Lyme doctors are typically not part of managed care systems due to imposed compliance with insurance guidelines for care and low levels of reimbursement for the time spent with patients. Those clinicians are largely inaccessible to patients who must obtain care within their provider group. However, those doctors most often do not directly bill insurance companies, leaving the patient to pay for care out of pocket, incur higher co-pays, and submit claims to the insurance companies for reimbursement.

Recommendation 4.2: Create a Federal repository for information on Lyme disease and other tick-borne diseases

Increase Availability of Educational Materials for Patients, Physicians, and the General Public

Education is a vital first step in the prevention of Lyme disease and other tick-borne diseases. A Federal repository for accurate, up-to-date information on Lyme disease and other tick-borne diseases is warranted to allow for the dissemination of consistent messaging throughout the United States.

- **Public Education:** Educating the public is multifaceted and includes individual education, as well as how to translate what works for individuals into community solutions at the local, regional, state, and national scales. Many patient advocacy websites provide free access to up-to-date curriculum for teachers, outdoor educators, science teachers, health educators, students, and parents. Many of these organizations are the mouthpieces for research, publicly sharing the latest diagnostic tools and treatment options along with information about newly discovered strains of tick- and vector-borne diseases, while some also directly fund research on Lyme disease and other tick-borne diseases.
- **Patient Education:** Most primary care providers do not customarily offer information about support group meetings and resources to Lyme disease and tick-borne disease patients like they would for cancer or diabetes patients. Advocacy groups and organizations are the frontrunners in sharing this information directly with patients and the public.
- **Clinician Education:** The complexity and controversy of tick-borne disease(s) discourages many health care providers and clinicians from even attempting to treat patients with Lyme disease and other tick-borne diseases. This results in a shortage of health care providers who are willing and sufficiently trained to treat patients. Moreover, many practitioners are unable to recognize and then distinguish tick-borne diseases in their various stages.⁵⁵ Both medical and mental health professionals need to be better trained to understand patients who suffer from infection-induced neuropsychiatric and neuropsychological symptoms, working together in a coordinated, multidisciplinary, treatment-team approach that utilizes the

⁵⁵ Hirsch AG, Herman RJ, Rebman A, et al. Obstacles to diagnosis and treatment of Lyme disease in the USA: a qualitative study. *BMJ Open*. 2018;8(6):e021367. Published 2018 Jun 11. doi:10.1136/bmjopen-2017-021367

relevant expertise of these respective fields. Physician and clinician training for tick-borne diseases may be improved through two primary avenues:

- 1) Curricula taught and tested in medical schools, in teaching hospitals, and by the United States Medical Licensing Examination to earn a U.S. license; and
- 2) Continuing medical education (CME) credits that physicians must annually complete to maintain their U.S. licenses.

Empower Patients with Data

The western blot test results and reporting for Lyme disease can be problematic for patients and clinicians because laboratories report only western blot bands used in CDC surveillance criteria. Congress and the HHS Secretary could direct FDA to update and clarify its requirements on western blot tests for Lyme disease, explicitly allowing patients to access their own health data, including their own laboratory results. This direction aligns with societal and government-wide initiatives to empower patients to access, control, share, and use their own medical records and health care information. Data-driven decisions are key to improving their health outcomes.

Data collection and scientific understanding have evolved, yet Lyme disease diagnostics and surveillance criteria remain unchanged. It is time to revisit by convening a meeting of all relevant stakeholders—including government scientists, academic researchers, industry leaders, treating clinicians, patients, family members, and advocates—to review the evidence and interpretive criteria using all of the newest diagnostic methodologies, techniques, technologies, and emerging science. Diverse stakeholders, the Working Group, CDC, NIH, FDA, and CSTE could examine the science and “real-world evidence”—including clinician data and patient registries—to co-create new outcomes and criteria that supersede outdated ones.

Protect Vulnerable and High-Risk Populations

Certain segments of the population are particularly vulnerable to tick-borne disease for a variety of reasons. They should be of special consideration when allocating funds for research, treatment, and prevention.

- **Children:** Children are one of the highest-risk groups for contracting tick-borne diseases. Students with tick-borne diseases often experience severe disruption in their education. Frequent non-specific symptoms, such as forgetfulness and difficulty concentrating, can result in academic problems such as falling behind in schoolwork and declining grade point averages, as well as social consequences, such as loss of friends and isolation from peers. School field trips into Lyme disease-endemic areas and playgrounds place children at risk for contracting Lyme disease. Prevention and awareness measures must be implemented in these situations, including, but not limited to, appropriate notification and balanced information regarding risk and prevention provided to parents and supervising staff members.
- **Pregnant Women:** Gestational tick-borne disease can be transmitted to unborn children in utero and has the potential to cause premature labor and fetal death. One priority research area involves the risks of maternal-fetal transmission for various tick-borne diseases, as well as how to treat this population if exposed during pregnancy and needing treatment while pregnant.

- **Behavioral Health Patients:** Thousands of articles show associations between infections and neuropsychiatric manifestation of illness. Patients who experience Lyme disease and tick-borne disease-induced neuropsychiatric symptoms are at risk for misdiagnoses with primary psychiatric disorders. Given the challenges with diagnostic testing, physicians sometimes fail to identify a medical explanation for a patient’s physical symptoms and erroneously attribute them to emotional factors, such as anxiety or depression. This results in inadequate medical treatment and adds to the patient’s distress and despair. There is a need for dual-diagnosis inpatient units equipped to treat patients with infection-induced neuropsychiatric symptoms.
- **Military Servicemembers, Military Families, and Veterans:** Because the military is under-resourced and understaffed, many military Servicemembers and their families do not receive consistent care over time with the same provider. Military Servicemembers, their families, and Veterans are a high-risk population because of exposure to global species and strains of tick-borne disease.
- **Hispanic or Latino Populations:** According to the U.S. Department of Labor, Hispanic or Latino populations comprise 43.1% of grounds maintenance workers and 44.3% of workers in farming, forestry, and fishing industries, leading to higher rates of exposure to ticks and potentially tick-borne diseases (“Labor Force Statistics from the Current Population Survey,” 2017). Moreover, 15.5% of the Hispanics or Latinos studied reported delaying or not seeking medical intervention.⁵⁶
- **Migrant Workers:** Due to outdoor working habits, migrant workers are at high risk for exposure to tick-borne diseases. With limited or no health care, they often lack the means for adequate diagnosis and proper treatment.
- **Hunters, Hikers, Golfers, and Outdoor Enthusiasts:** Those with outdoor occupations or avocations are at increased risk. A healthy outdoor lifestyle can increase exposure to ticks and risk for tick-borne disease, especially without proper precautions in high-risk regions. This high-risk population includes hunters, hikers, golfers, anglers, park rangers, campers, landscapers, and others who spend significant time outdoors.

Reduce the administrative burden for Health Care, Health Insurance, and Disability Coverage

Federal providers of health care and health insurance—beginning with VA, CMS, and DoD—need to standardize and streamline reimbursement policies for tick-borne disease. Diagnostic coding should be standardized across all Federal systems, so that patient records and reimbursement processes are more easily navigable and consistent for everyone, including Servicemembers, Veterans, and civilians. Federal benefits for people with disabilities should be similarly streamlined and improved, so that claims are consistently processed without unduly burdening those disabled by tick-borne disease. The Federal Government can achieve this by, first, recognizing the severity of tick-borne disease and, second, mapping the disabling consequences of tick-borne disease to DoD, VA, and U.S. Social Security Disability Insurance programs. Institutional recognition that tick-borne diseases can disable some—with measurable criteria and codes for disabilities related to tick-borne disease—will expedite processing and, for those who qualify, receipt of earned benefits.

⁵⁶ Nelson CA, Starr J, Kugeler KJ, Mead PS. Lyme Disease in Hispanics, United States, 2000–2013. *Emerg Infect Dis.* 2016;22(3):522-525. <https://dx.doi.org/10.3201/eid2203.151273>

Adopt Shared Medical Decision-Making and Patient-Centered Care

Beyond Federal health care and insurance programs, the Federal Government can lead by example with patient-centered care. Federal momentum already exists to empower patients to share in their own health care decisions. The Centers for Medicare & Medicaid Services (CMS), in conjunction with the White House Office of American Innovation and VA, has implemented MyHealthEData, which allows patients to choose the provider that best meets their needs and then give that provider secure access to their data, leading to greater competition and reduced costs. Patient-centered tools such as this allow patients to address their own unique health care needs, have a better understanding of their overall health, prevent disease, and make more informed decisions about their care.

Recommendation 4.3: Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care.

Of utmost importance is that we need to ensure the rights of patients, health care workers and the clinicians dealing with Lyme disease and tick-borne diseases and conditions. To accomplish this goal should reduce the burden of the processes under which patients are currently diagnosed and treated and by which they access care and also ensure that the medical personnel are protected in their clinical decisions and management policies. Basic protections must include, but not necessarily be limited to, those that:

- Protect Lyme disease patients from employment discrimination
- Facilitate the process for employer accommodations due to employee
- Protect students and underrepresented minorities of all ages from discrimination
- Facilitate Individual Education Plans for students with Lyme disease who need accommodation
- Protect Lyme disease patients about disability insurance coverage, life insurance policies, and medical insurance policies

Eliminating recognized barriers to affordable, appropriate, and patient-centered diagnosis, treatment, and care

The path to diagnosis and treatment, for Lyme patients is filled with misinformation and a difficult decision point for clinician due to various systemic pitfalls. In a 2009–2010 survey of nearly 2,500 chronic Lyme disease patients in the United States with positive laboratory testing and chronic symptoms⁵⁷ and a follow-up survey in 2013 indicated that chronic Lyme disease patients made an average of 19.4 doctor visits per year,⁵⁸ often traveling 51 miles or more to see a treating doctor. Half of the respondents reported seeing at least seven physicians before the diagnosis of chronic Lyme disease was made and most respondents experienced symptoms lasting six months or more despite receiving at least 21 days of antibiotic treatment.

Major Challenges and Societal Issues

Tick-borne disease patients and their caregivers experience the loss of the role they play in their

⁵⁷ Johnson L, Aylward A, Stricker RB. Healthcare access and burden of care for patients with Lyme disease: a large United States survey. *Health Policy*. 2011;102(1):64-71. doi:10.1016/j.healthpol.2011.05.007

⁵⁸ Johnson L, Wilcox S, Mankoff J, Stricker RB. Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey. *PeerJ*. 2014;2:e322. Published 2014 Mar 27. doi:10.7717/peerj.322

communities, at school, at work, and within their families. Finances become strained as they tend to the unpredictable day-to-day needs and condition of the patient and many report significant strains on their relationships that affect the overall quality of life and well-being of the individual, the family, and the entire support network. The illness itself can prevent self-advocacy, given the association of tick-borne disease with chronic pain, fatigue, and resultant cognitive impairment.

Protect patients from employment discrimination

The highest risk of exposure to Lyme disease and other tick-borne diseases falls on people who work outside in regions where ticks are known to occur. Those individuals make up the majority of workers who file compensation claims for tick-borne disease contracted on the job; however, even employees who work in urban areas, far from tick habitats, occasionally file tick-borne disease compensation claims as well.⁵⁹

The Federal Government should ensure that existing workers' compensation laws protect workers who have contracted tick-borne disease on the job from denial of insurance compensation claims. In addition, existing laws that provide for reasonable accommodations under the Americans with Disabilities Act (ADA) must be enforced for those workers who are ill due to Lyme disease and other tick-borne diseases.

Protect students of all ages from discrimination

Students with Lyme disease all too often face the added burden of needing to convince school authorities of the reality and credibility of their ongoing illness. They require flexible attendance policies without fear of truancy charges. Current educational systems often present the options of either school attendance or home instruction. The Department of Education (DoED) should examine its policies and procedures to ensure that individuals with Lyme disease and other tick-borne diseases are protected from discrimination in schools. This involves protecting and enforcing the rights of these students under the ADA. DoED should investigate to determine if all such policies and procedures are being adhered to throughout the United States and needs to proactively communicate that Lyme disease and tick-borne diseases fall under anti-discrimination laws, such as existing laws that guarantee a free and appropriate education for students with tick-borne diseases under the Individuals with Disabilities Education Act.

Protect patients from health care and disability insurance coverage and reimbursement policies that are unduly burdensome

As detailed in the Systemic Barriers section, insurance companies regularly deny medical care to tick-borne disease patients who do not meet the CDC surveillance criteria for Lyme disease. Until new laws are passed, private insurance companies cannot be required to cover Lyme disease and other tick-borne diseases. In the interim, the Federal Government is urged to change its own systems and lead by example.

Update Patient Diagnostic and Reimbursement Processes

The Lyme Moonshot will work to update HHS Medicare/Medicaid, VA, and DoD diagnostic and reimbursement process for Lyme disease treatments and care, consistent with latest science and evidence-based care.

⁵⁹ <https://lymediseaseassociation.org/book-list/lyme-disease-update-science-policy-law-by-marcus-a-cohen/?print=print>

STRATEGIC GOAL 5: Accelerate Impact through Public-Private Partnerships

“If everyone is moving forward together, then success takes care of itself.”

– Henry Ford

Recommendation 5.1: Establish public-private partnerships (PPPs) to accelerate mission delivery.

Recommendation 5.2: Match every federal dollar 1:2 with twice as many private-sector investments into Lyme disease science, research, and development.

Recommendation 5.3: Launch the “Lyme Moonshot” — analogous to the “Manhattan Project” that transformed the globe with nuclear science breakthroughs — with large-scale scientific collaborations and investment to revolutionize Lyme diagnostics, treatments, and patient outcomes.

Establish Public-Private Partnerships to Accelerate Mission Delivery

Partnerships can serve as force multipliers. This includes partnerships among federal departments and agencies, between the government and industry, and cross-sector partnerships facilitated by the federal government. An effective response requires participation of government, industry, academia, non-profit organizations, and every American citizen. Strategic partnerships and collaborations led by the TICK Office will achieve higher returns on investment, reduce unnecessary duplication, create efficiencies, leverage assets, and advance shared goals—delivering better results in less time for less cost, compared to government working alone. Both Republican and Democratic Administrations have endorsed the PPP model, as it coalesces diverse stakeholders around shared goals. Through PPPs, we will transform the Lyme landscape together.

The TICK Office could work with organizations, like the Foundation for the National Institutes of Health (FNIH)⁶⁰ and the CDC Foundation,⁶¹ to form strategic partnerships for Lyme mission delivery. One exemplar PPP to emulate is the five-year Partnership for Accelerating Cancer Therapies (PACT)⁶² with FNIH to advance the Cancer Moonshot. The TICK Office could similarly:

- Work together to leverage existing partnerships, to create new partnerships, and to share best practices, data, user facilities, and other resources to the extent possible
- Recommend how Lyme R&D investments across government, industry, academia, and non-profit organizations will collectively deliver maximum value with defined measures of success

⁶⁰ Foundation for the National Institutes of Health (FNIH): <https://fnih.org/>

⁶¹ CDC Foundation: <https://www.cdcfoundation.org/>

⁶² Partnership for Accelerating Cancer Therapies (PACT), Foundation of the National Institutes of Health: <https://fnih.org/what-we-do/programs/partnership-for-accelerating-cancer-therapies>

- Strengthen relationships and build coalitions to form a “Lyme Collaborative”—an ecosystem of diverse problem solvers who foster new understanding, share resources, and build trust through consistent engagement over time to achieve shared goals
- Share human capital and expertise across disciplines and conventional boundaries
- Improve coordination to identify win-win synergies and to reduce redundancies, which will streamline regulatory and administrative processes from lab-to-market
- Align incentives to facilitate multi-sector engagement and encourage multi-sector investment

An organizational and scientific challenge as complex as the TICK Office and Lyme disease cannot be addressed effectively by any one organization acting alone. It requires the energy, intellectual capabilities, and financial resources of multiple partners working together in close collaboration.

On October 10, 2020, HHS and the Steven & Alexandra Cohen Foundation announced the “LymeX” Innovation Accelerator, a \$25M public private partnership (PPP) to “to strategically advance Lyme and tickborne disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government.” This PPP is the largest public private partnership not just for Lyme and Tick-borne disease, but for any PPP in history. The partnership will focus on stakeholder engagement, education and awareness, and next generation diagnostics.⁶³ The Lyme Moonshot will use this PPP as an example for others in the future.

Match Federal Investments with 2x Matching Private-Sector Investments

Develop a new method for funding Lyme disease research at academic cancer centers through private investment and philanthropy. Emulating methods pioneered by the White House Cancer Moonshot; the TICK Office could establish a new mechanism for matching private-sector investors with commercially viable research. The TICK Office could provide the technical infrastructure and an innovation incubator that would serve as a “match-maker” to connect Angel investors, venture capitalists (VCs), exercise rather than a granting mechanism,” Weiner said to The Cancer Letter. “We hope those with private capital will get excited enough by some of these ideas that they will be willing to help support them.”

Launch the “Lyme Moonshot” as the 21st-Century Manhattan Project

The U.S. Department of Energy (DOE) is the second largest supporter of the civilian agencies when it comes to federally funded science and basic research, second only to HHS. In response to the Tick-Borne Disease Working Group 2018 report and its recommendations, DOE National Laboratories drafted a white paper to summarize their capabilities, which can be harnessed for tick-borne diseases: tick genome sequencing, microbiome architecture, data analytics, predictive modeling, multi-omics capacities, super computer processing, AI, machine learning, etc. The staggering magnitude of the Lyme epidemic, affecting 300,000 reported Americans, probably representing 1,000,000 infected cases annually, coupled with its possible chronic predisposition of its various clinical manifestations, should be treated as a public health burden that needs to be rapidly addressed – and tackled. A coordinated “Manhattan project” like the one against the HIV/AIDS epidemic is urgently needed to address the serious worldwide threat of Lyme disease.

⁶³ HHS and the Steven & Alexandra Cohen Foundation Announce \$25 Million “LymeX” Innovation Accelerator —Largest Lyme Public-Private Partnership in History: <https://www.hhs.gov/about/news/2020/10/10/hhs-steven-alexandra-cohen-foundation-announce-25-million-lymex-innovation-accelerator.html>

We still need a human Lyme disease vaccine⁶⁴ and new tick and pathogen control and tick-bite prevention technologies are on the horizon.^{65,66} With these considerations in mind, the relentless increase in ticks and tick-borne diseases in the United States raises two important points: First, is it possible to turn the tide of tick-borne diseases while control of ticks and their associated disease agents remain an individual responsibility or will this ultimately require a shift to also include a strong community-based effort? Second, can we develop local, professionally staffed programs capable of working with the public to reduce the risk for tick bites on both public and private land? And, at the root of the growing problem with ticks and tick-borne diseases lies the problem of who will be responsible for implementing the solutions?

The overall public health threat posed by ticks and tick-borne diseases in the United States is steadily increasing to include new human populations because major vector ticks are expanding their geographic ranges.^{67,68} The negative societal effects of ticks and tick-borne diseases in the United States, including a general feeling that family members are not safe during outdoor activities in the backyard and elsewhere, has reached the point where we need to rethink the basic concepts of how to counter this threat.

Lyme disease is the most common tick-borne infection in both North America and Europe. In the United States, Lyme disease is caused by *Borrelia burgdorferi*, which is transmitted by the bite of the tick species *Ixodes scapularis* and *Ixodes pacificus*. Clinical manifestations most often involve the skin, joints, nervous system, and heart. Prevention, epidemiology, clinical manifestations, diagnosis, and treatment must be based on evidence-based guidelines for the management of patients with Lyme Disease and appropriate guidelines for the healthcare workers that will take care of them. An appropriate definition of disease symptomology and the post-Lyme syndrome needs to be proposed due to the diseases' chronic lingering ranging from six months to a lifetime. Easy access to care, patient right protections as well as safety for the licensed practitioners to be able to operate with knowledge based clinical interventions and management are essential.

Conclusion

“That’s one small step for [a] man, one giant leap for mankind.”

– Neil Armstrong

We believe that our five-pronged Moonshot Lyme proposal can aggressively transition our society towards a realistic goal of screening, diagnosing, managing, and eventually curing Lyme by 2030 and meanwhile, keeping Americans safe from Lyme Disease in their outdoor pursuits.

⁶⁴ Embers ME, Narasimhan S. Vaccination against Lyme disease: past, present, and future. *Front Cell Infect Microbiol.* 2013;3:6.

⁶⁵ Eisen L, Gray JS. Lyme borreliosis prevention strategies: United States versus Europe. In: Braks MA, Van Wierer SE, Takken W, Sprong H, editors. *Ecology and prevention of Lyme borreliosis.* Wageningen (The Netherlands): Wageningen Academic Publishers; 2016. p. 429–50.

⁶⁶ de la Fuente J. Controlling ticks and tick-borne diseases... looking forward. *Ticks Tick Borne Dis.* 2018;9:1354–7.

⁶⁷ Eisen RJ, Eisen L, Beard CB. County-scale distribution of *Ixodes scapularis* and *Ixodes pacificus* (Acari: Ixodidae) in the continental United States. *J Med Entomol.* 2016;53:349–86.

⁶⁸ Sonenshine DE. Range expansion of tick disease vectors in North America: implications for spread of tick-borne disease. *Int J Environ Res Public Health.* 2018;15:478.

