FISCAL YEAR 2026 APPROPRIATIONS REQUESTS



1. Fully Fund the Kay Hagan Tick Act

\$30M Total Requested

Centers for Disease Control and Prevention (CDC) U.S. Department of Health and Human Services

\$10M for the Centers of Excellence \$20M for States and Tribal organizations with high prevalence of Lyme and tick-borne disease

Justification

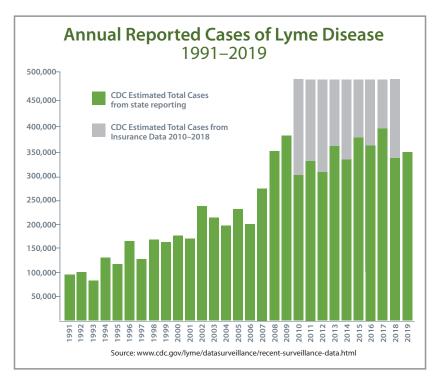
The Kay Hagan Tick Act is authorized at \$30M annually. Center for Lyme Action requests that the Centers for Disease Control and Prevention (CDC) be provided \$10,000,000 to award grants, contracts, or cooperative agreements to institutions of higher education for the establishment or continued support of regional centers of excellence in vector-borne diseases. The purpose is to address vector-borne diseases, with emphasis on Lyme and other tick-borne diseases.

The CDC is further provided \$20,000,000 for purposes of entering into cooperative agreements with health departments of states, political subdivisions of States, and Indian tribes and tribal organizations in areas of high prevalence of Lyme and other vector-borne diseases in order to increase capacity to identify, report, prevent, and respond to such diseases and related outbreaks.

Lastly, the Kay Hagan Tick Act requires the development of a national strategy for vector-borne diseases, including tick-borne diseases, by the Secretary of Health and Human Services in coordination with the Secretary of Defense, the Secretary of A griculture, the Administrator of the Environmental Protection Agency, the Secretary of the Interior, the Secretary of Veterans Affairs, the Secretary of Homeland Security, and others, as appropriate. On February 6, 2024, the HHS and CDC introduced The National Public Health Strategy to Prevent and Control Vector-Borne Diseases (VBD National Strategy).

Funding History

Fiscal Year	\$ in millions
FY19	\$0
FY20	\$0
FY21	\$4M
FY22	\$16M
FY23	\$18.5M
FY24	\$19.5M
FY 25 House	\$18.5M
FY 25 Senate	\$29M
FY26 CLA Request	\$30M



2. Fund HHS LymeX Innovation Accelerator Implementation

\$5M Total Requested

Office of the Secretary U.S. Department of Health and Human Services

Justification

A sustained budget of \$5M of annual federal funding is required to achieve the goals allotted for this five-year program so as not to drain the \$25M in private foundation funding intended for research to finance the Government program management portion.

The LymeX Innovation Accelerator (LymeX) will accelerate Lyme Innovation progress and strategically advance tick-borne-disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government. LymeX is an innovative \$25M public-private partnership with the Department of Health and Human Services and the Steven & Alexandra Cohen Foundation. LymeX is modeled after the success and methods of the KidneyX Innovation Accelerator, a partnership between HHS and the American Society of Nephrology that includes kidney-care patients in every step of its innovation process.

The LymeX partnership has three focus areas:

- 1) patient-centered innovation
- 2) education and awareness
- 3) next-generation diagnostics.

All three focus areas include Lyme disease patients and community at every step of the LymeX innovation process.

Prize challenge awards were funded by the Stephen and Alexandria Cohen Foundation with Phase 1 at \$1M and Phase 2 at \$2M, with an additional \$7M for future phases. Phase 3 winners were announced on January 16, 2025, with awards of \$2.1M. Phase 4 will invite select teams to enter, execute their clinical validation plans, and complete regulatory submissions to the FDA, awarding up to \$3M in prizes.

Funding History

Fiscal Year	\$ in millions
FY19	\$0
FY20	\$0
FY21 Allocation	\$2M
FY22	\$0
FY23	\$0
FY24	\$5M
FY25 House	\$5M
FY25 Senate	Not specified
FY26 CLA Request	\$5M

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BlueArc

M Northwestern Medicine* Feinberg School of Medicine

MASSACHUSETTS GENERAL HOSPITAL

GNOSTICS PRIZE

LymeX Moves to Phase 4

What is LymeX Phase 4?

- Clinical validation plans
- Regulatory submissions to the FDA
- Awards up to \$3 million in prizes
- Additional prizes for FDA clearance

SOURCE: https://www.lymexdiagnosticsprize.com/announcing-the-phase-3-winners/

3. Fund Lyme & Tick-borne Disease Prevention Programs

\$35M Total Requested



Centers for Disease Control & Prevention (CDC) U.S. Department of Health and Human Services (HHS)

Justification

Lyme disease is the most common vector-borne disease in the United States. A recently released estimate based on insurance records suggests that approximately 476,000 Americans are diagnosed and treated for Lyme disease each year. The number of cases has increased more than 5x since 1991 across all states.

Alpha-gal syndrome (AGS) is an emerging tick-borne condition and allergy characterized by a potentially life-threatening hypersensitivity to galactose-alpha-1,3- galactose (alpha-gal). AGS is a growing clinical and public health concern in the United States. Exploding lone star tick populations are driving an alarming increase in cases. Healthcare provider knowledge is limited and can lead to delayed diagnosis and inappropriate treatment. In fact, CDC survey data indicates that only 1 in 5 healthcare providers were somewhat or very confident they could diagnose or manage patients with AGS. The often years-long delayed diagnosis is not only dangerous for affected individuals but leads to inefficient use of health resources.

Additional funding for the CDC is required to:

- Develop safer and more effective tick repellents
- Fund innovative Lyme diagnostics research
- Bolster critical education and awareness programs for Lyme and tick-borne disease
- Promote collaborative approaches to understanding Lyme and tick-borne disease, such as supporting TickNET, funding state health departments to improve surveillance, supporting vector-borne disease Centers of Excellence with increased focus on ticks, discovering new tick-borne diseases, and more.
- Accelerate measures to improve Alpha-gal Syndrome surveillance, patient care, and public awareness with an emphasis on healthcare provider education, in keeping with the three public health priorities identified in the CDC 2023 report.
- Execute the Lyme and tick-borne disease portion of the National Strategy for Vector-borne Disease.

Fiscal Year	\$ in millions
FY19	\$12M
FY20	\$14M
FY21	\$16M
FY22	\$20.5M
FY23	\$26M
FY24	\$27M
FY25 House	\$27M
FY25 Senate	\$29M
FY26 CLA Request	\$35M



SOURCE: https://www.cdc.gov/ticknet/index.html

4. Fund NIH NIAID Lyme and Tick-borne Disease & Conditions Research

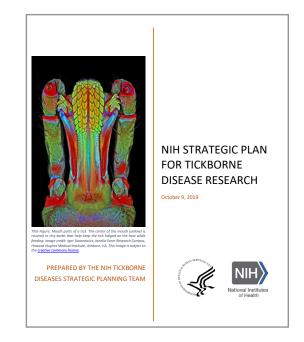
\$135M Total Requested

National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) U.S. Department of Health and Human Services (HHS)

Justification

Lyme and tick-borne disease funding requires an increase in the NIH NIAID research budget to help develop reliable diagnostics and therapies to address this increasing U.S. health concern affecting over 476,000 Americans annually. In 2019, the NIH released the NIH Strategic Plan for Tickborne Disease Research which provides an excellent framework to attack the problem, but NIAID requires substantially more funding to execute this strategy.

Lyme disease diagnostics are unreliable, and there is no cure. Better diagnostics are required to determine if a Lyme disease therapy or cure is in fact working and therefore must be given research priority. Lyme disease accounts for the lion's share or approximately 80% of reported tick-borne diseases. Accordingly, at least 80% of the increase for tick-borne diseases should be allocated towards Lyme disease research.



In FY23, NIAID awarded 7 R01 grants for researchers to study persistent Lyme disease, referred to as PTLDS by the NIH. These grants represent a significant event, as persistent Lyme disease research had previously received little to no funding.

The FY25 Labor-HHS Appropriations Committee Report highlighted a concern about the rise in incidence of Alpha-gal Syndrome (AGS), an emerging, growing, tick bite-associated allergic condition characterized by a potentially life-threatening hypersensitivity to galactose-alpha-1, 3-galactose (alpha-gal). The Committee encourages NIH to accelerate its efforts to deepen our understanding of the immunological mechanisms and natural history of alpha-gal syndrome and to develop new protocols, therapies, and other tools for the management of AGS.

Topics to prioritize for Lyme research awards might include:

- Lyme diagnostic and therapeutic development
- Pediatric Lyme clinical studies
- Pregnancy with Lyme and outcomes in child development
- Neuropsychiatric and mental health effects of Lyme disease
- Clinical studies for treatment and management of Alpha-gal Syndrome
- Clinical studies for immunological symptoms and responses as a result of a tick-bite

Fiscal Year	\$ in millions
FY19	\$32M
FY20	\$34M
FY21	\$96M
FY22	\$119M
FY23	\$99M
FY24	\$100M
FY25 House	\$125M Minimum
FY25 Senate	\$125M Minimum
FY26 CLA Request	\$135M

 ${\small SOURCE:} \ \underline{https://www.niaid.nih.gov/sites/default/files/NIH-Strategic-Plan-Tickborne-Disease-Research-2019.pdf}$



5. Fund Defense Peer-reviewed Tick-borne Disease Research —Congressionally Directed Medical Research Program (CDMRP)



\$9M Total Requested

TITLE VI Other Department of Defense Programs Defense Health Program U.S. Department of Defense

Justification

Additional funding of \$2M to \$9M in FY 2024 for tick-borne disease research is well-justified as the tick-borne disease research program has funded just 20% of the "compliant applications" received in Fiscal Year 2022. More importantly, thousands of our U.S. warfighters have been sidelined and forced to retire because of their or a family member's tick-borne disease, affecting our military readiness and our national security. Many of these warfighters are highly specialized and trained such as fighter pilots who required millions of U.S. taxpayer dollars to be trained and equipped, only to have their careers cut short and removed from military service.

Funding History			
Fiscal Year	\$ in millions		
FY19	\$5M		
FY20	\$7M		
FY21	\$7M		
FY22	\$7M		
FY23	\$7M		
FY24	\$7M		
FY25 House	\$7M		
FY25 Senate	Not specified		
FY26 CLA Request	\$9M		

Programmatic Mission:

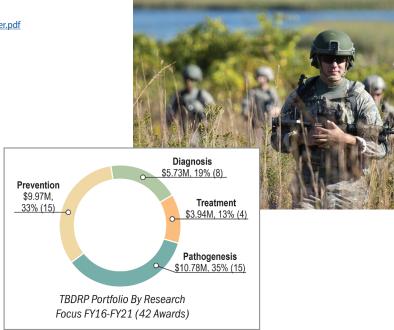
"To understand the pathogenesis of Lyme disease and other tick-borne illnesses, to deliver innovative solutions to prevent, diagnose, and treat their manifestations for the benefit of US Service members and American public, and to disseminate this knowledge."

"The Tick-Borne Disease Research Program (TBDRP) was established in fiscal year 2016 (FY16) to support innovative and impactful research that addresses these fundamental issues and gaps in tick-borne diseases. Hallmarks of TBDRP funding include the involvement of Lyme and tick-borne disease advocates in our two-tier review process, as well as the mission of addressing tick-borne diseases as a threat to military forces and their dependents."

SOURCE: cdmrp.army.mil/tbdrp/default

https://cdmrp.health.mil/tbdrp/pdfs/W81XFWH-21-TBDRP-CDA-IDA InformationPaper.pdf

TBDRP	Funding	Applications	Funded
FY 2019	\$5M	62	8
FY 2020	\$7M	39	8
FY 2021	\$7M	44	8
FY 2022	\$7M	30	6



SOURCE: https://cdmrp.health.mil/tbdrp/pbbks/TBDRP%20Glitz%20Sheet_FY16-21.pdf

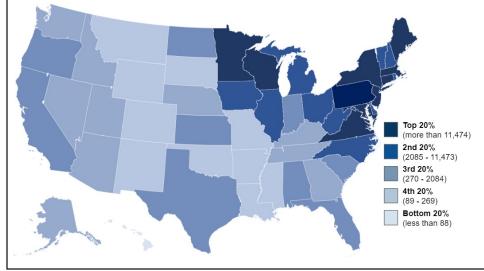
Table 1. Tickborne Diseases of the United States				
Pathogen Type	Disease	Pathogen (U.S.)	Tick vector (U.S.)	
Bacteria	Lyme disease	Borrelia burgdorferi Borrelia mayonii¹	Blacklegged tick, western blacklegged tick¹	
	<i>Borrelia miyamotoi</i> infection	Borrelia miyamotoi²	Blacklegged tick	
	Tickborne relapsing fever	<i>Borrelia hermsii, B. turicata, B. parkeri</i> and others	Soft ticks (<i>Ornithodoros</i> species)	
	Anaplasmosis	Anaplasma phagocytophilum	Blacklegged tick, western blacklegged tick	
	Ehrlichiosis	Ehrlichia chaffeensis Ehrlichia ewingii Ehrlichia muris eauclairensis	Lone star tick Lone star tick Blacklegged tick (possible)	
	Tularemia	Francisella tularensis	American dog tick, Rocky Mountain wood tick, lone star tick	
	Rocky Mountain spotted fever	Rickettsia rickettsii	American dog tick, brown dog tick, Rocky Mountain wood tick	
	Other spotted fever	Rickettsia parkeri	Gulf Coast tick	
	Pacific coast tick fever	Rickettsia philipii	Pacific Coast tick	
Virus	Powassan disease	Powassan virus	Blacklegged tick, groundhog tick	
	Colorado tick fever	Colorado tick fever virus	Rocky Mountain wood tick	
	Bourbon virus	Bourbon virus	Undetermined	
	Heartland virus	Heartland virus	Lone star tick	
Parasite	Babesiosis	Babesia microti, B. duncani	Blacklegged tick	
Unknown	Southern tick- associated rash illness	Unknown	Lone star tick	
None	Alpha-gal syndrome	None	Lone star tick	
	Tick paralysis	None	American dog tick, Rocky Mountain wood tick	

<u>Table 1</u>

¹ Borrelia mayonii is a recently discovered pathogen that causes Lyme disease. It has not to date been associated with the western blacklegged tick.

² Borrelia miyamotoi is a recently discovered pathogen that causes a relapsing fever and is genetically more similar to the relapsing fever Borrelia species.

SOURCE: https://www.niaid.nih.gov/sites/default/files/NIH-Strategic-Plan-Tickborne-Disease-Research-2019.pdf



Lyme Disease Cases Reported to the CDC 2011–2020

Lyme disease cases reported to the CDC by state from 2011–2020. The disease affects the entire population of the continental U.S. with growing incidence nationwide. Source: Generated from CDC Surveillance data.