FISCAL YEAR 2027

APPROPRIATIONS REQUESTS

Center for Lyme Action

1. Fund CDC Lyme and Tick-Borne Disease Programs

$74.5M Total Requested

Division of Vector-Borne Disease
National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services

Kay Hagan Tick Act Justification ($30M Requested)

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 to increase capacity to identify, report, prevent, and respond to such diseases and related outbreaks.

Lastly, the Kay Hagan Tick Act required 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 various agencies and departments. 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 to support the implementation of this strategy is needed to ensure the United States is adequately prepared to respond to these threats.

CDC Lyme and Tick-borne Disease Programs Justification ($40M Requested)

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.

Additional funding for the CDC is required to:

- Develop safer and more effective tick repellents.
- 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 these three public health priorities, as identified in the CDC 2023 report.[1]
- Support the division's addition of parasitic diseases, including tick-borne Babesiosis, at no less than $5M.
- Execute the Lyme and tick-borne disease portion of the National Strategy for Vector-borne Disease.

[1] SOURCE: www.cdc.gov/mmwr/volumes/72/wr/mm7230a2.htm

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CDC Alpha-Gal Syndrome Justification (4.5M Requested)

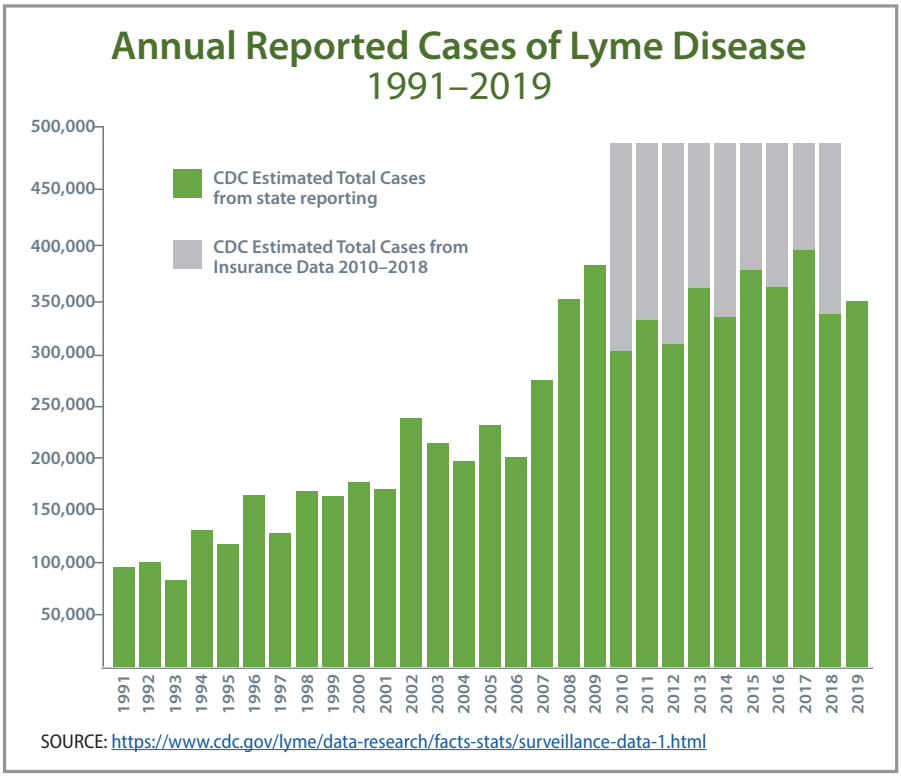
Alpha-gal syndrome (AGS) is an emerging tick-borne condition and allergy characterized by a potentially life-threatening hypersensitivity to galactose-alpha-1,3- galactose (alpha-gal). AGS is a growing clinical and public health concern in the United States. Exploding lone star tick populations are driving an alarming increase in cases. Health care provider education on AGS is limited. CDC survey data reports that 78% of providers report having little to no knowledge of AGS.

Moreover, 1 in 5 providers were somewhat or very confident they could diagnose or manage patients with AGS. Not surprisingly, AGS is significantly underdiagnosed and misdiagnosed. On average, it takes over 7 years for a patient with AGS to be diagnosed. During this long time, people with AGS often experience debilitating symptoms—over half require emergency department treatment, 7% require multiple hospitalizations, and many are subject to unnecessary, invasive procedures and surgeries—at a high cost to our healthcare system and to the affected individuals.

Funding to increase awareness of AGS among healthcare providers and education in the diagnosis and management of AGS is a critical first step towards improved, faster diagnosis, better patient care, and reduced economic burden on both patients and the healthcare system. We would encourage CDC to focus on high or growing prevalence states and to increase its collaboration and partnership with local governments and the health, education, community, non-profit, and faith-based sectors in those high-incidence communities.

Funding History: CDC Lyme and Tick-borne Disease Programs

Fiscal Year	Kay Hagan Tick Act	CDC Lyme & TBD	CDC Alpha-gal Syndrome	Total
FY19	$0M	$12M	$0M	$12M
FY20	$0M	$14M	$0M	$12M
FY21	$4M	$16M	$0M	$20M
FY22	$16M	$20.5M	$0M	$36.5M
FY23	$18.5M	$26M	$0M	$44.5M
FY24	$19.5M	$27M	$0M	$46.5M
FY25 Spend Est.	$19.5M	$27M	$0M	$46.5M
FY26 House	$19.5M	$27M	$0M	$46.5M
FY26 Senate	$20.5M	$29M	$0M	$49.5M
FY27 CLA Request	**$30M**	**$40M**	**$4.5M**	**$74.5M**



SOURCE: https://www.cdc.gov/lyme/data-research/facts-stats/surveillance-data-1.html

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2. Fund HHS LymeX Innovation Accelerator Implementation

$5M Total Requested

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

Funding History:	
Fiscal Year	**$ in millions**
FY19	$0M
FY20	$0M
FY21 Allocation	$2M
FY22	$0M
FY23	$0M
FY24	$5M
FY25 Spend Est.	$5M
FY26 House	$5M
FY26 Senate	$5M
FY27 CLA Request	**$5M**

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. In Phase 4, 7 teams will execute their clinical validation plans, complete regulatory submissions to the FDA, and receive awards up to $3M in prizes.

LYME
DIAGNOSTICS PRIZE

LymeX - Now in Phase 4

BlueArc Biosciences
Drexel University College of Medicine
HELIXBIND
Northwestern Medicine Feinberg School of Medicine
GNOMX
GALAXY
MGH 1811 Massachusetts General Hospital

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/phase-4-launches/

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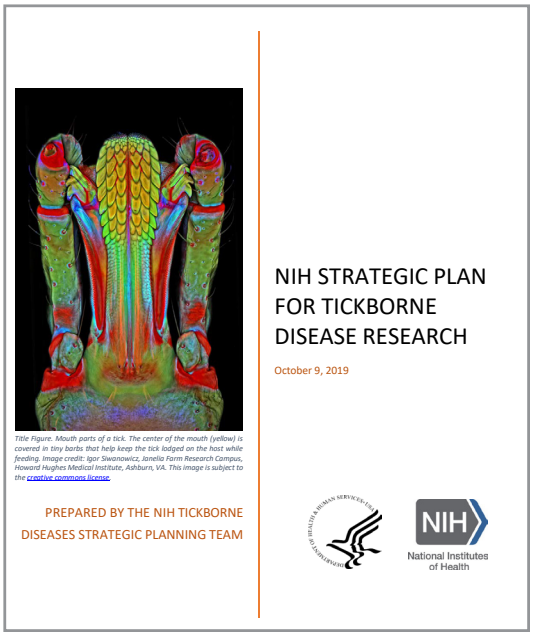
3. Fund NIH NIAID Lyme and Tick-borne Disease & Conditions Research

$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. The FY26 House and Senate Appropriations Committees both called for a minimum spend of $110M for NIH NIAID Lyme and tick-borne disease.



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.

Priority topics for tick-borne disease 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 the treatment and management of Alpha-gal Syndrome
- Clinical studies for immunological symptoms and responses as a result of a tick bite

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

Funding History:	
Fiscal Year	**$ in millions**
FY19	$32M
FY20	$40M
FY21	$96M
FY22	$119M
FY23	$99M
FY24	$122M
FY25	$122M
FY26 House	$110M min.
FY26 Senate	$110M min.
FY27 CLA Request	**$135M**

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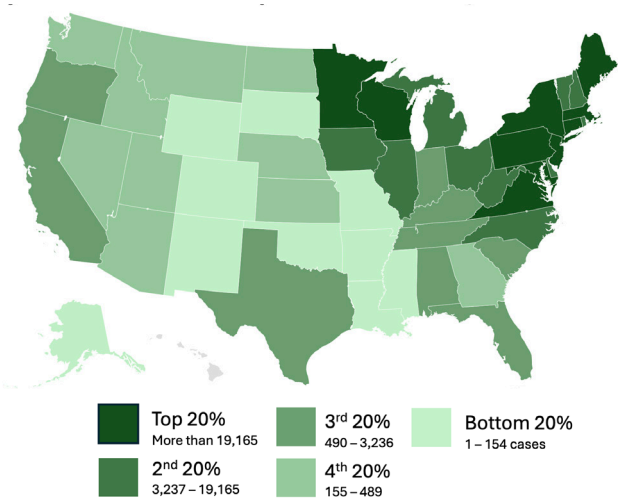
4. Fund ARPA-H TICK Clinical Trials Network (Request: $50M)

Advanced Research Project Agency – Health (ARPA-H)
U.S. Department of Health and Human Services Justification

FY26 House Appropriations Committee stated, "The committee recognizes the value of and encourages ARPA-H to evaluate the potential benefits of supporting research and development projects related to TBD." TICK Clinical Trials Network will serve as an innovative clinical trials program to improve federal research in therapeutic or diagnostic solutions for the Lyme and tick-borne disease community. TICK stands for Tick-borne Innovation, Collaboration, and Knowledge.

Clinical trials for Lyme and tick-borne disease therapeutics are not funded by the private sector due to high risk, lack of financial return, and even the uncertain structure of a clinical trial in a disease area with no accurate diagnostic. Consequently, innovation and leadership are required to develop actionable clinical trial protocols that will validate the safety and effectiveness of compounds and diagnostic approaches to treat Lyme and tick-borne disease. In addition, clinical trials are also needed to study the persistent Lyme disease patient population to better understand disease outcomes.

In partnership with industry, HHS agencies, and across the Office of the Secretary staff divisions, this initiative builds upon the existing Lyme and Tick-Borne Disease Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.



Lyme Disease Cases Reported to the CDC By State, 2008-2023

The disease affects the entire population of the continental U.S. with growing incidence nationwide.

SOURCE: Generated from CDC Surveillance data.

Table 1. Tickborne Diseases of the United States

Pathogen Type	Disease	Pathogen (U.S.)	Tick vector (U.S.)
Bacteria	Lyme disease	*Borrelia burgdorferi* *Borrelia mayonii*[1]	Blacklegged tick, western blacklegged tick[1]
	Borrelia miyamotoi infection	*Borrelia miyamotoi*[2]	Blacklegged tick
	Tickborne relapsing fever	*Borrelia hermsii, B. turicata, B. parkeri* and others	Soft ticks (*Ornithodoros* 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

Table 1

[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

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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 War

Funding History:	
Fiscal Year	**$ in millions**
FY19	$5M
FY20	$7M
FY21	$7M
FY22	$7M
FY23	$7M
FY24	$7M
FY25 Spend Est.	$0M
FY26 House	$7M
FY26 Senate	Not Specified
FY27 CLA Request	**$9M**

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 16% of the "compliant applications" received in Fiscal Year 2024. 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.

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 the 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."

SOURCES: https://cdmrp.health.mil/
https://cdmrp.health.mil/tbdrp/pdfs/HT942524TBDRPIDA-TDRA_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
FY 2023	$7M	37	7
FY 2024	$7M	43	7

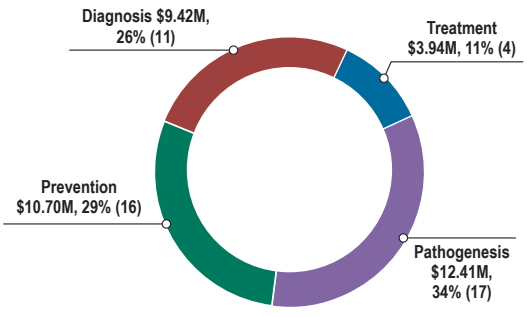

Figure 1: FY16-FY22 Portfolio by Focus Area

SOURCE: https://cdmrp.health.mil/tbdrp/pdfs/TBDRP%20Strategic%20Plan%202023.pdf

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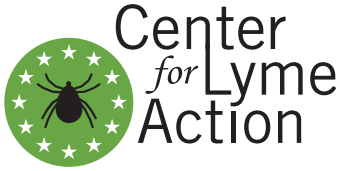

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