FISCAL YEAR 2022
APPROPRIATIONS REQUESTS

Center for Lyme Action

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1. Fund the Kay Hagan Tick Act

$30M Total = +$26M (FY22) + $4M (FY21)
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-risk Lyme disease

The Kay Hagan Tick Act was signed into law as part of the FY2020 Further Consolidated Appropriations Act (LHHSED, AG, Energy Water, Interior, Leg. Branch, MCVA, State-For. Ops, T-HUD), H.R. 1865; P.L. 116-94, signed 12/20/2019, DIVISION N—HEALTH AND HUMAN SERVICES EXTENDERS; TITLE I—HEALTH AND HUMAN SERVICES EXTENDERS; Subtitle D—Public Health Provisions; Sec. 404. Kay Hagan Tick Act.

Report Language

The Centers for Disease Control and Prevention (CDC) is 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. CDC shall give greater funding weight to Lyme disease as the most common vector-borne disease according to the CDC, with the following objectives (1) facilitate collaboration between academia and public health organizations for public health surveillance, prevention, and response activities;(2) provide training for public health entomologists and other health care professionals, as appropriate,; (3) conduct research to develop and validate prevention and control tools and methods, including evidence-based and innovative, evidence-informed tools and methods to anticipate and respond to disease outbreaks; (4) prepare for and respond to outbreaks of vector-borne diseases, including Lyme and tick-borne diseases.

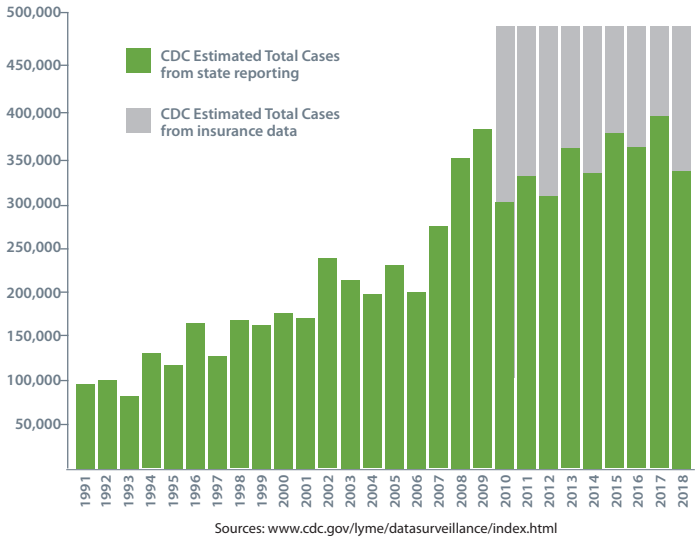
The CDC is further provided $20,000,000 for purposes of entering into cooperative agreements with health departments of States, political subdivisions of States, and Indian Tribes and Tribal organizations in areas at high risk of Lyme and other vector-borne diseases in order to increase capacity to identify,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

CDC Fiscal Year Operating Plans

Lyme Disease

Fiscal Year	$s in millions
FY15	$10.633
FY16	$10.633
FY17	$10.675
FY18	$10.7
FY19	$12
FY20	$14
FY21	$16M +$4M (KH Tick ACT)
CLA FY22 Request	**$16M + $30M (KH Tick ACT)**

Annual Reported Cases of Lyme Disease
1991–2018



Sources: www.cdc.gov/lyme/datasurveillance/index.html
wwwnc.cdc.gov/eid/article/27/2/20-2731_article

2. Lyme Disease and Other Tick-borne Diseases

$101M Total = +$20 (FY22) + (FY21) $81M
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
U.S. Department of Health and Human Services

The FY2021 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.

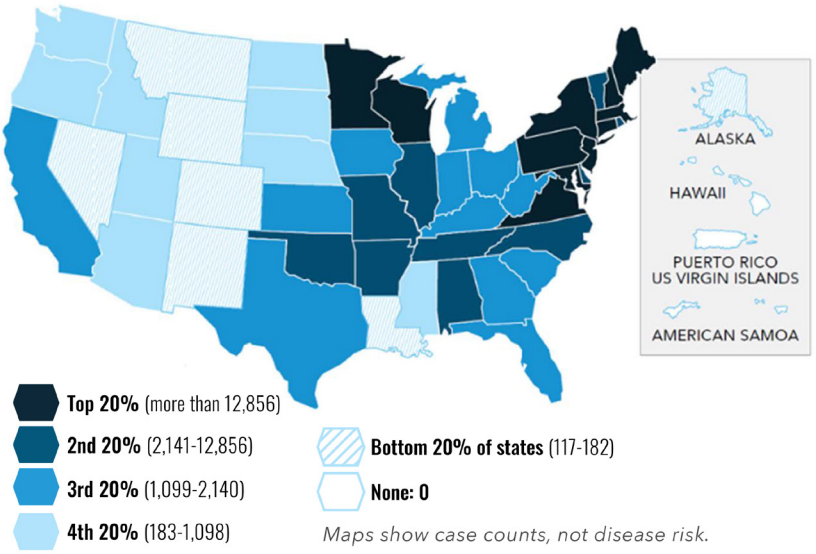
Report Language

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 with a patient and therefore be given research priority. Lyme disease accounts for the lion share or approximately 80% of reported tickborne diseases. Accordingly, at least 80% of the increase for tickborne diseases is allocated towards Lyme disease research.

NIH Funding for Lyme Disease Research over decades

Fiscal Year	$s in millions
FY00	$26
I	
FY08	$22
I	
FY15	$24
FY16	$28
FY17	$22
FY18	$30
FY19	$32
FY20	$34
FY21	$81
FY22 CLA Request	$101

Reported Cases of Lyme Disease in the US: 2004–2016



Source: Tick-borne Disease Working Group 2018 Report to Congress

3. Peer-reviewed Tickborne Disease Research

Congressionally Directed Medical Research Program (CDRMP)
$12M Total = +$5M + (FY21) $7M
TITLE VI
Other Department of Defense Programs
Defense Health Program
U.S. Department of Defense

Report Language

Additional funding of $5M to $12M in FY 2022 for tick-borne disease research is well-justified as the tick-borne disease research program has funded just 13% of the "compliant applications" received in Fiscal Year 2019.

Background

Programmatic Mission:
"To understand the pathogenesis of Lyme disease and other tick-borne illnesses, to deliver innovation 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

Fiscal Year	$s in millions
FY16	$5
FY17	$5
FY18	$5
FY19	$5
FY20	$7
FY21	$7
FY22 CLA Request	**$12M**

CDMRP Managed Program	FY2019	Applications	Funded
Tick-borne diseases	$5M	62	8

4. Fund the National Public Health Framework for Prevention and Control of Vector-borne Diseases in Humans

$5M Total = +$5M (FY22) + $0 (FY21)
Office of the Secretary
U.S. Department of Health and Human Services

Excerpt from the Kay Hagan Tick Act which requires the HHS Office of the Secretary to implement a national strategy for vector-borne disease including tick-borne diseases:

(a) IN GENERAL.—The Secretary shall— (1)(A) ensure the development and implementation of a national strategy to address vector-borne diseases, including tick-borne diseases, that— (i) identifies and assesses gaps and any unnecessary duplication in federally-funded programs; and (ii) identifies strategic goals to address such diseases and appropriate benchmarks to measure progress toward achieving such goals; (B) update such strategy, as appropriate; and (2) coordinate programs and activities, including related to data collection, research, and the development of diagnostics, treatments, vaccines, and other related activities, to address vector-borne diseases, including tick-borne diseases, across the Department of Health and Human Services and with other Federal agencies or departments, as appropriate. (b) CONSULTATION.—In carrying out subsection (a)(1), the Secretary shall consult with the Tick-Borne Disease Working Group established under section 2062 of the 21st Century Cures Act (42 U.S.C. 284s) and other individuals, as appropriate, such as— (1) epidemiologists with experience in vector18 borne diseases; (2) representatives of patient advocacy and research organizations that focus on vector-borne diseases, including such organizations that have demonstrated experience in related research, public health, data collection, or patient access to care; (3) health information technology experts or other information management specialists; (4) clinicians, entomologists, vector management professionals, public health professionals, and others with expertise in vector-borne diseases; and (5) researchers, including researchers with experience conducting translational research.

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"Americans are at an increasing risk of vector-borne diseases, and the United States is not adequately prepared to respond to these threats. To address the growing threat to public health, CDC, five federal departments [Health and Human Services, Agriculture, Defense, Homeland Security, Interior] and the Environmental Protection Agency developed a joint National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans."

– *A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans,* Atlanta, Georgia – September 2020
cdc.gov/ncezid/dvbd/pdf/Brochure_National_Framework_VBDs-P.pdf

GOALS:

1. Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases
2. Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases
3. Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases
4. Develop and assess drugs and treatment strategies for vector-borne diseases
5. Disseminate and support the implementation of effective public health and vector control products, tools, and programs to prevent, detect, diagnose, and respond to vector-borne disease threats

Report Language

Lyme and tickborne disease accounts for over 70% of all vector-borne diseases. Initial $5 million seed funding would be applied to the significant interagency scientific research and coordination to commence work on achieving the five Framework Goals in A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans.

Fiscal Year	$s in millions
FY17	$0
FY18	$0
FY19	$0
FY20	$0
FY21	$0
FY22 CLA Request	**$5**

5. Fund HHS LymeX Innovation Accelerator Implementation

$5M Total = +$3M (FY22) + $2M (FY21)
Chief Technology Officer
Office of the Secretary
U.S. Department of Health and Human Services

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. The LymeX, an innovative public-private partnership with the department of Health and Human Services and **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 Cohen Foundation has generously provided $25M towards this incredible effort to accelerate therapies and diagnostics, but the Department requires funding to implement the goals of LymeX:

LymeX Goals

- **Foster Breakthroughs in Education and Awareness**
- **Engage Stakeholders to Facilitate Patient-Centered Innovations**
- **Accelerate Development of Next-Gen Diagnostics**

Report Language

Initial seed funding of $2M was provided out of the existing HHS Office of the Secretary budget in FY21, but a sustained budget of $5M annually is required to achieve the goals allotted for this five-year program.

Fiscal Year	$s in millions
FY17	$0
FY18	$0
FY19	$0
FY20	$0
FY21	$2
FY22 CLA Request	**$5**

6. Fund Lyme and Tick-borne Disease Chronic Disease Prevention and Health Promotion

$5M Total = +$5M (FY22) + $0 (FY21)
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services

Report Language

Initial $5M funding is required to begin surveillance and address what has now become chronic Lyme disease—the most common vector-borne disease in the United States, with over 476,000 Americans diagnosed and treated annually and affecting Americans in all 50 States.

A chronic disease, as defined by the U.S. National Center for Health Statistics, is a disease lasting three months or longer. Many of those diagnosed develop chronic conditions called Persistent Lyme Disease (PLD) (CDC: Post-Treatment Lyme Disease Syndrome). According to the Bay Area Lyme Foundation, the largest public charity funding Lyme disease research, "Research has shown that up to 20% of Lyme patients have ongoing symptoms, which in some cases can be severe and debilitating. The cause of these lingering symptoms is the existence of persistent infection of Borrelia burgdorferi, the bacteria that causes Lyme disease, according to many clinicians and researchers as well as scientific studies. While the CDC calls these lingering symptoms "post-treatment Lyme disease syndrome" (PTLDS), it is our belief that the more accurate term is persistent Lyme disease (PLD) or "chronic Lyme disease." The term PLD supports the scientific belief that the disease can live on beyond treatment. The studies demonstrate the existence of persistent infection, giving validity to the terms "persistent" and "chronic." Some of these are funded by Bay Area Lyme Foundation, and all are published in reputable journals by accomplished researchers."

Fiscal Year	**$s in millions**
FY17	$0
FY18	$0
FY19	$0
FY20	$0
FY21	$0
FY22 CLA Request	**$5**