

CDC Evades Accountability in Lyme Epidemic

The Centers for Disease Control and Prevention (CDC) is the federal agency that bears the greatest responsibility for protecting the health and welfare of the United States population from infectious diseases (ID). The CDC also has a mandated role in global ID leadership.

This analysis will show how the CDC evades accountability in the Lyme epidemic by: (1) asserting its programs are advancing Lyme diagnostics, prevention and treatment of the disease when there is no demonstrable evidence of such claims; (2) downplaying the spread of the epidemic and the devastations caused by the disease; (3) demonstrating low priority for Lyme in terms of resource allocation; (4) adopting language that shunts Lyme patients into palliative care rather than active treatment for infections; and (5) neglecting the human impact of the Lyme epidemic.

Over the last 40 years, Lyme has expanded from a neighborhood cluster in Lyme, Connecticut to a national epidemic. In addition to being a national epidemic, it is also recognized as a global epidemic. It is widely recognized that Lyme is a life altering, complex and serious illness that is often complicated by coinfections.

In the last 25 years, between 1991 and 2016, the CDC devoted staff and spent approximately 205 million tax dollars on activities to address the Lyme epidemic.[i] In 1991, the CDC spent \$7 million or 15.4 percent of its overall ID budget on Lyme activities.

By 1998, Lyme cases had increased and Lyme groups and elected officials had begun to question the CDC's commitment to protecting the public from the disease. For example, despite a significant increase in the ID budget, Lyme allocations were lowered to 4.7 percent of the CDC's 1998 ID budget.

The CDC recognizes that Lyme infection can cause death. Furthermore, in 2013 the CDC announced that "the total number of people diagnosed with Lyme disease is roughly 10 times higher than the yearly reported number" or an estimated 300,000 or more infections per year. [ii]

However, in 2014 the CDC devoted a mere 2.3 percent of their ID budget to address the epidemic. Therefore, the recognition of this 1000 percent increase in Lyme infections did not result in the CDC increasing budget allocations to tackle the epidemic.

The CDC's pattern of resource allocation for Lyme differs from that of other infectious diseases, including vectorborne diseases. For example, the United States (US) recorded its first case of West Nile virus (WNV) back in 1999. Since then, the disease has spread across the lower 48

states. Similar to Lyme disease, persons infected with WNV can develop serious neurological problems, including seizures, swelling in the brain or spinal cord (encephalitis and meningitis) and even death.[iii]

In 2014, there were 2,122 cases of WNV compared to over 300,000 estimated cases of Lyme. By 2004, CDC's support to state and local jurisdictions for WNV surveillance and prevention [reached \\$24 million per year](#) . [iv]

The amount spent on the 2004 WNV surveillance and prevention activities is 200 percent more than CDC monies spent on all Lyme activities that year. Furthermore, the CDC spent approximately \$11,300 thousand per case of WNV compared to an estimated \$26 to \$30 per case of Lyme.

The CDC's response and related resource allocation for WNV is justifiable. However, the CDC's lack of action and resources for the Lyme epidemic is unjustifiable given the estimated hundreds of thousands in this country who have been debilitated, disabled and bankrupted by this complex and life altering illness.

In addition to the low resource allocation for Lyme related activities, the CDC has made little progress in containing the epidemic. The Lyme epidemic is now in all 50 states and both the risk and the rate of infection has steadily increased. According to the CDC, Lyme infection rates are now estimated at over 1000% the rate they were one decade ago.

Over the past 25 years, the CDC Lyme program has shown little demonstrable progress regarding advancement on Lyme diagnostics, prevention and treatments. This lack of advancement has prompted Congress to make numerous formal inquiries regarding the effectiveness of CDC's Lyme policies and programs.

In 2001, a third-party review of the CDC and NIH Lyme program was undertaken by the US General Accounting Office (GAO). The June 2001 [GAO Report to Congressional Requesters - LYME DISEASE HHS Programs and Resources](#) reviewed how the CDC Lyme program responded to recommendations made by external advisers and reviewers and Congress during the period of 1991 to 1998.[v]

According to the 2001 GAO Lyme report, the CDC "instituted a system for the surveillance of Lyme disease, helped to standardize diagnostic testing, conducted and funded basic research on Lyme disease and on its prevention, and developed patient and practitioner educational materials. CDC has initiated most activities recommended by external reviewers and congressional appropriations committees regarding changes to its programs." [vi]

It should be noted that the 2001 GAO Lyme report uses the term chronic Lyme throughout the document. It states that "Chronic Lyme disease is a condition of persisting symptoms in

patients who have been treated for Lyme disease...chronic Lyme disease suggests persisting infection..." Furthermore, in 2001, the term 'post treatment Lyme disease syndrome' or PTLDS had yet to be adopted and disseminated by the CDC.

The term PTLDS denies persistent infection. The CDC adopted the term PTLDS approximately one decade ago. This has resulted in the CDC recommending palliative care to healthcare providers and Lyme patients. Rather than providing recommendations that would bring the infection under control, the CDC diverts the patient to seeking counseling, pain management and treatments for Fibromyalgia and Myalgic encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS). The CDC recommends that patients with PTLDS 'share their feelings with a counselor' and consider taking antidepressants, powerful and addictive pain medications and hydrocortisone. Hydrocortisone is a steroid, and steroids can cause immune suppression, high blood pressure, diabetes and osteoporosis. Recommending a path to immune suppressing steroid treatment for a Lyme patient with persistent infections shows a lack of medical knowledge - such a recommendation can be interpreted as reckless endangerment.

In addition, the 2001 GAO report is one in a series of official documents presented over a 25 year period wherein the CDC asserts it is implementing programs that effectively combat the Lyme epidemic.

For example, the June 2001 GAO report was preceded by the April 2001 *CDC 2000, 2001 and 2002 Performance Plans and Report* written for Congress. This report opens with "during the 1970s, several new IDs were identified including Lyme disease...IDs remain the leading cause of death worldwide...increasingly threaten public health and contribute significantly to the escalating costs of health care. [vii] The CDC goes on to making a series of commitments to Congress and the United States (US) population in this Performance Report.

The CDC commits to addressing the Lyme epidemic by strengthening epidemiologic and laboratory capacity for surveillance and ID response, establishing the Emerging Infections Program to conduct active surveillance, engaging in applied research for prevention and intervention measures and providing awards to assist in development and improvement of Lyme diagnostic tests.[viii]

However, this Performance Report repeated many claims made by the CDC in earlier reports. Therefore, in [October 2001, Congress](#) again enumerated a series of concerns; these emphasized the human suffering and impact of the epidemic. Examples follow:

"The Committee is deeply concerned about the safety of the Lyme disease vaccine (LymeRix). Over 1,000 adverse event reports were filed with the Food and Drug Administration from December 1998 to October 2000."

“The Committee recognizes that the current state of laboratory testing for Lyme disease is very poor. The situation has led many people to be misdiagnosed and delayed proper treatment...The ramifications of this deficit in terms of unnecessary pain, suffering and cost is staggering.”

“The Committee directs CDC to work closely with the Food and Drug Administration to develop an unequivocal test for Lyme disease.”

“The Committee is distressed in hearing of the widespread misuse of the current Lyme disease surveillance case definition...the definition is reportedly misused as a standard of care for healthcare reimbursement, product (test) development, medical licensing hearings, and other legal cases.”

“The CDC is encouraged to aggressively pursue and correct the misuse of this definition. This includes issuing an alert to the public and physicians, as well as actively issuing letters to places misusing this definition.”

The Committee recommends that the CDC strongly support the re-examination and broadening of the Lyme disease surveillance case definition...Voluntary and patient groups should have input into this process.”

“The CDC is encouraged to include a broad range of scientific viewpoints in the process of planning and executing their efforts. This means including community-based clinicians with extensive experience in treating these patients, voluntary agencies who have advocacy in their mission, and patient advocates in planning committees, meetings, and outreach efforts.” [ix]

In the years between this Committee Report and 2010, the CDC spent roughly \$84 million on Lyme activities. In addition, the CDC testified in an antitrust Lawsuit regarding ethical and medical concerns related to the Lyme Guidelines promoted by the CDC.

However, in this same time period, CDC efforts did not result in apparent advancements. Therefore, the [2010 Appropriations Bill to fund the CDC](#) again restated many of Congress’ 2002 Lyme recommendations. [x] [xi] The 2010 language also noted that Lyme and chronic Lyme may have complications from other tickborne diseases and the CDC Lyme program needed to include these considerations.

Between 2010 and 2015, the CDC spent roughly \$54 million on Lyme activities. By this time, many states had mobilized to pass laws to protect Lyme patients and increase Lyme awareness. Furthermore, the CDC had announced the Lyme epidemic was 1000 percent larger than previously recognized.

In 2015, the CDC Lyme program was again brought to task by the Congress. The CDC was again required to report on progress with regards to Lyme diagnostics, prevention and treatments. This response is included as part of 524 page [CDC 2016 Justification of Estimates for Appropriation Committees Report](#). [xii]

The CDC [2016 Justification Report](#) provides comprehensive details regarding all CDC programs, including their broad objectives, budgets and the performance criteria used to measure their effectiveness. The report covers the wide range of health responsibilities for the CDC including: immunization, respiratory diseases, HIV/AIDS, viral hepatitis, sexually transmitted infections, tuberculosis, chronic diseases such as diabetes and arthritis, birth defects, developmental disabilities, disabilities, environmental health concerns such as asthma and lead poisoning, work safety, domestic violence, a number of global health programs, foodborne illnesses and other emerging infections, including zoonotic infections. [xiii]

As with all federal agencies, the CDC is required to have measurable criteria that demonstrates they are meeting their goals and federal mandates. These performance criteria are elaborated in reports to Congress. Such reports inform Congress and the American public as to how effectively tax dollars are used to meet federal mandates.

In this 2016 Report, the CDC included different types of performance measurements. For example, ‘established a targeted number of surveillance centers’ measures an activity that should inform about disease prevalence.

The 2016 Report also details measurements called ‘people level indicators’ - such measurements indicate how people have been served by the CDC program. For example, ‘a reduction by 20 percent of people ill from tuberculosis’ is a people level indicator.

However, unlike the other disease categories, the CDC has developed no people level indicators for the Lyme epidemic. The lack of people level Lyme indicators means the CDC can avoid reporting on an array of important measures.

For example, many patient groups, including Lyme patients, experience a period of time from when they are infected to when they receive an accurate diagnosis. Undiagnosed Lyme becomes a systemic illness that can wreak havoc and permanent damage to the entire body including the neurological system, endocrine system, musculoskeletal system, each and every major organ and so forth. The CDC measures this ‘infection-to-diagnosis-timeframe’ for many patient groups, but not for Lyme patients.

In addition, the 2016 Report misrepresents how common Lyme disease is compared to other infectious diseases. The report states Lyme is the seventh most-commonly reported infectious disease in the country. According to the CDC, the real number is roughly 10 times higher than the yearly reported number. [xiv]

Furthermore, a review of the 2015 CDC statistics on Lyme shows 34,390 cases of Lyme reported in 2015. [xv] Therefore, the 2015 adjusted figure of Lyme infections is estimated at 343,900, making Lyme the third most common infection in the US.

Therefore, the CDC is not assessing how the third most common infection in the US is affecting a national population that includes both current and future Lyme patients and their families. It should be noted this report was written for Congress. Therefore, the CDC report is misrepresenting the scale of the Lyme epidemic to elected officials representing a population of constituents that include many hundreds of thousands of Lyme patients.

The 2016 report also demonstrates a lack of advancement regarding Lyme diagnostics, treatments and prevention. This 'lack of advancement' regarding Lyme is striking when compared to similar CDC efforts in other infectious diseases.

For example, some 15 years back, the CDC committed to better diagnostics, prevention and treatments for Hepatitis C. [According to the CDC](#), there were an estimated 30,500 cases of acute hepatitis C virus infections reported in the US in 2014.[xvi] Today, healthcare providers routinely recommend that adults born between 1946 and 1964 test for Hepatitis C regardless of symptom status and such tests are quite accurate. Furthermore, there are now two available treatment protocols for Hepatitis C that can reduce the virus to undetectable levels.

On the other hand, inaccurate Lyme diagnostics are an illustrative example of how the CDC has failed its mandate to protect the population from the Lyme epidemic. As noted, Congress has repeatedly requested the CDC to improve the accuracy of Lyme diagnostics. Since 1991, the CDC has claimed to be improving Lyme diagnostics. However, the CDC's website and multiple articles provide a markedly different message:

- On April 18, 2014, the CDC posted an article titled [Concerns Regarding a New Culture Method for *Borrelia burgdorferi* Not Approved for the Diagnosis of Lyme Disease](#). Seven of the eight authors are officials at the CDC's Lyme program in the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) DVBD. According to the article, there are no new improved Lyme diagnostics. Patients and healthcare providers should continue to use the 1995 two-tiered Lyme tests [developed for surveillance purposes].
- During the June 2016 FOX 5 special, "Lyme and Reason: The Cause and Consequence of Lyme Disease," CDC Senior official Mead echoes this message. He states the "we recommend a two-step process to this where the blood is tested essentially in two steps to identify whether or not the person has evidence of infection with *Borrelia burgdorferi*."

- A [March 05, 2012 posted CDC and Medscape Webinar on testing for Lyme disease](#) makes the same claims as the 2014 article. [xvii]
- The CDC/NCEZID Office of the Director posted a December 2010 article, [Improved Serodiagnostic Testing for Lyme Disease: Results of a Multicenter Serologic Evaluation](#). Six of the 10 authors were CDC officials. However, the article that was posted in 2010 was written in April 1996 and also states that patients and healthcare providers should continue to use the 1995 two-tiered Lyme tests [developed for surveillance purposes]. [xviii]

It should also be noted that over the arc of this 25 year time period, one official for the CDC Lyme program filed three Lyme-related patents, two of which were for Lyme diagnostics. To date, these patents have not become available tests. [xix]

Altogether, it can be said that the CDC has not advanced any Lyme diagnostics. Furthermore, the 1995 tests were developed for surveillance purposes and not for clinical diagnosis.

In addition, the CDC has not advanced any Lyme treatments since the 1990s. For example, the CDC's singular preference for the 2006 Lyme guidelines developed by the Infectious Diseases Society of America (IDSA) describe protocols that go back to the 1990s. Furthermore, the expansion of the epidemic is evidence of an ineffective CDC prevention program.

Conclusions

Over the last 40 years, the Lyme epidemic has expanded from a neighborhood cluster in Lyme Connecticut to being recognized as a national and global epidemic.

Nevertheless, the CDC has misrepresented the scale and scope of the Lyme epidemic. In CDC's '2016 Justification of Estimates for Appropriation Committees Report to Congress', the CDC states that Lyme disease is the seventh most-commonly reported infectious disease in the country. According to the CDC's own calculations, Lyme is estimated to be the third most common infectious disease in the country.

The CDC does not make routine requests for Lyme resources. Furthermore, the CDC's pattern of resource allocation for Lyme differs significantly from that of other infectious diseases, including vectorborne diseases. For example, the 2004 CDC tax dollar allocations for West Nile Virus was approximately \$11,300 per WNV case compared to the estimated \$26 to \$30 for Lyme cases.

Additionally, the estimated 1000 percent increase in Lyme infections did not result in the CDC allocating more monies to Lyme. Despite being a national epidemic and being a disease that

can be debilitating, disabling and fatal, Lyme has received a low percentage of CDC resources and low amounts compared to other diseases with similar symptoms.

Unlike the other diseases, the CDC does not measure the people level impact of Lyme. This means that important Lyme disease control measures are overlooked, e.g. reducing the time between infection and diagnosis.

In addition, the lack of Lyme-related people level indicators contributes to making Lyme patients invisible to the readership of official documents. Such persons would include policymakers, elected representatives, government officials, medical societies and healthcare professionals.

In addition to making Lyme patients less visible than other patient groups, the CDC has dismissed the strong evidence of persistent Lyme infection and chronic Lyme. Most CDC material states there is no chronic Lyme and that patients with symptoms after treatment have a post treatment Lyme disease syndrome. They recommend palliative care rather than active treatment for infection. They recommend such patients 'share their feelings with a counselor' and consider taking antidepressants, powerful and addictive pain medications and hydrocortisone. Recommending a path to immune suppressing steroid treatment for a Lyme patient with persistent infections shows a lack of medical knowledge - such a recommendation can be interpreted as reckless endangerment.

The CDC's dismissal of persistent infection, apparent ignoring of Lyme patients and low resource allocation to the epidemic demonstrate institutionalized practices of bias against Lyme patients. This bundle of behaviors and outcomes appear unique when comparing Lyme to similar CDC efforts in other infectious diseases. In addition to this institutional bias, the poor performance of the CDC's Lyme program indicates its activities are ill conceived and/or poorly implemented.

Over the past 25 years, the CDC Lyme program has shown little demonstrable progress regarding advancement on Lyme diagnostics, prevention and treatments. Such failures and waste of resources will continue until the CDC acknowledges how people are affected by the Lyme epidemic.

In 2001, the GAO Lyme Report did not distinguish between program implementation versus program effectiveness. In this case, the GAO Lyme Report did not assess whether the CDC Lyme programs met its mandates to protect the public.

Over 25 years, the CDC Lyme program has evaded numerous efforts by Congress to hold it accountable. Furthermore, multiple Secretaries of the Department of Health and Human Services appear to have had no influence over the Lyme program's squandering and inferior performance.

In addition, repeated formal complaints to the Inspector General regarding the CDC's preferential treatment for the noncompliant IDSA Lyme Guidelines have yielded no visible actions or changes; the CDC continues its exclusive promotion of the IDSA Guidelines. It is well documented that the CDC's preference for the IDSA Lyme guidelines contributes to denying Lyme patients access to federally sanctioned, evidence based and patient-centered Lyme treatment protocols.

The CDC Lyme program has shown a clear pattern of discrimination against patients handicapped by persistent Lyme infection and Lyme and coinfections and in this regard its officials "do not adhere to all laws and regulations that provide equal opportunity for all Americans regardless of race, color, religion, sex, national origin, age, or handicap." The term equal opportunity includes equal access to federally sanctioned Lyme treatments.

The CDC Lyme program shows no indications for course correction. The time has arrived for the Department of Justice to investigate the CDC Lyme program for Waste and Institutionalized Discrimination.

Bio - Jenna Luché-Thayer's expertise includes government transparency and accountability and the integration of marginalized groups. Luché-Thayer is informed by three decades of professional policy and grassroots experience in 40 countries. She has extensive experience in congressional relations, testimony and legislation. She has worked with governments, the United Nations, nonprofits and the corporate world and has over 65 sponsored publications. Luché-Thayer received the International Woman's Day Award for Exemplary Dedication and Contributions to Improving the Political and Legal Status of Women (US government) and built the Highest Ranking Technical Area in Accomplishment, Innovation & Comparative Advantage for United Nations Capital Development Fund.

Endnotes

[i] <http://www.gao.gov/new.items/d01755.pdf> - In 2000, the CDC' Division of Vector-Borne Infectious Diseases (DVBD) had 24 full-time employees working on Lyme disease activities. Fourteen of those employees devoted 100 percent of their time to Lyme disease activities, and 10 employees spent from 10 to 90 percent of their time on Lyme disease.

sources for budget information:

<http://www.gao.gov/new.items/d01755.pdf>

<http://www.hhs.gov/asl/testify/t040129.html>

<http://healthyamericans.org/reports/budget04/FederalFunding.pdf>

<https://www.cdc.gov/budget/documents/fy2011/fy-2011-operating-plan-summary.pdf>

<https://www.cdc.gov/budget/documents/fy2017/ezid-factsheet.pdf>

<https://www.cdc.gov/budget/documents/fy2012/fy-2012-budget-request-summary.pdf>

<http://www.hhs.gov/about/budget/budget-in-brief/cdc/index.html#infectious>

[ii] <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html>

- [iii] There are many examples of how the CDC's allocations for Lyme are much less than diseases with similar symptoms and complications - West Nile Virus is just one example.
- [iv] <http://www.cste2.org/docs/VBR.pdf> - This budget allocation for WNV prevention and surveillance has been reduced since 2004, but is still significantly higher than similar allocations for Lyme.
- [v] <http://www.gao.gov/new.items/d01755.pdf>
- [vi] <http://www.gao.gov/new.items/d01755.pdf> - Page 2 and 3
- [vii] Found under Page 124, under 2.8 Infectious Disease Control, 2.8.1 Program Description, Context and Summary of Performance.
- [viii] Found on Page 139 and 140 under Performance Goal and Measures
- [ix] <https://www.congress.gov/107/crpt/srpt84/CRPT-107srpt84.pdf>
Senate Report 107-084 - DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATION BILL, 2002
- [x] According to the 2001 GAO Lyme Report, such formal communications began in 1991.
- [xi] <http://www.lymediseaseassociation.org/index.php/archive/2010-appropriations-bill/632-2010-hhs-appropriations-bill-language>
- [xii] Found in the CDC Fiscal Year 2016 Justification of Estimates for Appropriation Committees Report under Significant Items in the FY 2015 OMNIBUS APPROPRIATIONS REPORTS – pages 511 and 512. OMNIBUS - Occasionally Congress packages several of the twelve appropriations bills into one larger bill called an omnibus spending bill or an omnibus appropriation measure. Often the bills are considered separately at the beginning and get combined later because inability to pass bills individually has led to the exigency of a potential government shutdown. Omnibus bills can "veto-proof" items.
- [xiii] <http://www.cdc.gov/budget/documents/fy2016/fy-2016-cdc-congressional-justification.pdf>
- [xiv] <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html>
- [xv] http://wonder.cdc.gov/mmwr/mmwr_2015.asp?mmwr_year=2015&mmwr_week=52&mmwr_table=2H&request=Submit&mmwr_location= Morbidity and Mortality Weekly Report (MMWR) TABLE II. (Part 8)
- [xvi] <https://www.cdc.gov/hepatitis/hcv/cfaq.htm>
- [xvii] <http://www.cdc.gov/lyme/healthcare/> <http://www.medscape.com/viewarticle/758995>
- [xviii] http://wwwnc.cdc.gov/eid/article/2/2/96-0211_article
- [xix] Johnson's Lyme diagnostic patents are [Compositions and Methods for Improved Lyme Disease Diagnosis](#) (January 21, 2013); and for [Recombinant P37/FlaA as a Diagnostic Reagent for the detection of Lyme disease](#) (1999). Johnson also filed a patent for a Lyme vaccine in 2014 [Ospa fusion protein for vaccination against Lyme disease](#) (September 23, 2014).