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It’s About Lyme: Why Congress Must Enact Medical Insurance Coverage Laws for Lyme Disease Patients Now

*Jennifer Barrett**

> *“In the fullness of time, the mainstream handling of*
> *chronic Lyme disease will be viewed as one of the most*
> *shameful episodes in the history of medicine because*
> *elements of academic medicine, elements of government*
> *and virtually the entire insurance industry have colluded*
> *to deny a disease.”*
>
> *—Dr. Kenneth Liegner*[1]

Dr. Neil Spector was a prominent oncologist who began experiencing heart problems of an unknown origin in 1994 at the age of thirty-seven.[2] He had no recollection of a tick bite or rash, but he suspected Lyme disease was the cause of his illness because he spent years hiking and jogging in New England.[3] Unfortunately, his first two Centers for Disease Control and Prevention (CDC) approved blood antibody tests for Lyme disease came back inconclusive.[4] As a result, his doctor diagnosed him with third-degree heart block of an unknown origin and gave him a pacemaker.[5] Frustrated by the test results, Dr. Spector began researching

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[1] Letter from Kenneth B. Liegner, Kenneth B. Liegner, M.D., P.C. & Assocs. to Lonnie King, Trevonne Walford, Christine M. Coussens, Members of the IOM Comm. Panel for “Lyme Disease & Other Tick-borne Diseases: State of Science,” Inst. of Med. of the Nat’l Acad. of Scis. (Sept. 14, 2010), *in* KENNETH B. LIEGNER, IN THE CRUCIBLE OF CHRONIC LYME DISEASE 769–70 (2015).

[2] NEIL SPECTOR, GONE IN A HEARTBEAT: A PHYSICIAN’S SEARCH FOR TRUE HEALING 42–44 (2015).

[3] *Id.* at 62.

[4] *Id.* at 73–74. Dr. Spector’s antibodies were abnormal, but he did not meet the CDC standard for a positive test; thus, his doctor ruled the test a false-positive. *Id.*

[5] *Id.* at 60.

Lyme and realized that his symptoms, including heart block, arthritis, and weight loss, were all symptoms of Lyme disease.[6] In his book, *Gone in a Heartbeat*, Dr. Spector wrote: "Despite my instincts and research into the field, I was largely being discounted by the medical community. If this can happen to a physician-scientist with extensive knowledge of medicine, just imagine what is happening to others who lack a medical background."[7] In 1997, Dr. Spector's third Lyme test finally came back positive, but it was too late for antibiotics therapy—the common treatment for Lyme disease—to reverse the damage to his heart.[8] Dr. Spector required a heart transplant in 2009 at the age of fifty-three and died in 2020.[9]

Vicki Logan was a thirty-nine year old pediatric ICU nurse with unexplained symptoms of gait disturbance and chronic meningitis with no history of rash or tick bite.[10] Her CDC-approved blood antibody test for Lyme disease came back negative in 1989.[11] Suspecting her illness might be related to Lyme, her doctor treated her with twenty-one days of intravenous (IV) antibiotics, "thought to be curative for the illness," and an additional four months of oral antibiotics, yet she did not get better.[12] Without a clear diagnosis, her doctor discontinued treatment.[13] A year later, with her condition worsening, Ms. Logan begged her doctor for another test.[14] Obliging, her doctor sent spinal fluid to the CDC, where scientists cultured Lyme bacteria from Ms. Logan's spinal fluid, a first for an American patient who had received "curative antibiotic treatment."[15] Despite a confirmed diagnosis, Ms. Logan struggled to receive reimbursement from her private insurance company, which claimed her treatment was "not medically necessary" and "experimental."[16] While on IV antibiotics, she experienced improvements, but her condition deteriorated each time she stopped.[17] Ms. Logan died in 2003 at the age of

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[6] *Id.* at 77.

[7] *Id.* at 78.

[8] *Id.* at 88, 106–08.

[9] *Id.* at 185. Dr. Spector died in June 2020 at the age of sixty-three. Julie Poucher Harbin, *Gone Too Soon: Dr. Neil Spector Passes Away*, DUKE CANCER INST. (June 17, 2020), http://www.dukecancerinstitute.org/news/gone-too-soon-dr-neil-spector-passes-away [https://perma.cc/N6CN-ZAPB].

[10] Pamela Cocks, *The Case of Vicki Logan*, LYME TIMES, Spring 2015, at 8, 8; KENNETH B. LIEGNER, IN THE CRUCIBLE OF CHRONIC LYME DISEASE 789–90 (2015).

[11] Cocks, *supra* note 10; LIEGNER, *supra* note 10.

[12] LIEGNER, *supra* note 11, at 790.

[13] *Id.*

[14] *Id.*; Cocks, *supra* note 11.

[15] LIEGNER, *supra* note 11, at 790.

[16] *Id.* at 791–92.

[17] *Id.* at 790–95.

fifty-three during a pause in treatment awaiting Medicaid preauthorization.[18]

Dr. Spector's and Ms. Logan's deaths highlight the suffering that many patients with persistent Lyme disease face due to the complexity of the disease, the inaccuracy of the current CDC-approved blood antibody test for Lyme disease, and insurance companies' denial of coverage. While scientists hope to find a cure and develop better tests in the coming years, current Lyme patients cannot wait; they need help now. That is why I urge Congress to pass a law requiring insurance companies to pay for treatment and provide valuable tracking information on how many people are suffering from this disease, as outlined in this Note.

INTRODUCTION

Borrelia burgdorferi (Lyme disease) is a bacterial infection, which is transmitted primarily through tick bites.[19] It was discovered in Lyme, Connecticut in 1976 after several children fell ill with juvenile arthritis of an unknown origin.[20] Today, the Centers for Disease Control and Prevention (CDC) estimates that approximately 476,000 Americans fall ill to Lyme disease each year,[21] and patients with Lyme disease reside in all fifty states.[22] Despite the prevalence of Lyme disease, the National Institute of Health (NIH) spent $40 million on research in 2020 compared to $275 million on research for Malaria, [23] which averages only 2,000 new diagnoses per year in the United States.[24] Patients who receive early treatment for Lyme disease typically recover with a short course of antibiotics, but up to 160,000 new patients each year may experience

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[18] PAMELA WEINTRAUB, CURE UNKNOWN: INSIDE THE LYME EPIDEMIC 312–13 (rev. ed. 2013).

[19] *The History of Lyme Disease*, IGENEX, https://igenex.com/tick-talk/the-history-of-lyme-disease/ [https://perma.cc/8B5Z-YZC5].

[20] *Id.*

[21] *How Many People Get Lyme Disease?*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 13, 2021), https://www.cdc.gov/lyme/stats/humancases.html [https://perma.cc/T4VH-R4CF] [hereinafter *How Many People Get Lyme Disease?*].

[22] Linda Searing, *The Big Number: Lyme Disease is Now in 100 Percent of the U.S.*, WASH. POST (Aug. 4, 2018), https://www.washingtonpost.com/national/health-science/the-big-number-lyme-disease-is-now-in-100-percent-of-the-us/2018/08/03/d35768ec-965e-11e8-810c-5fa705927d54_story.html [https://perma.cc/MK7D-4QCA].

[23] *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NAT'L INST. OF HEALTH (June 25, 2021), https://report.nih.gov/funding/categorical-spending/ [https://perma.cc/MA7F-CUMA] [hereinafter *NIH Estimates of Funding*] (noting that the Malaria number includes $64 million for the Malaria vaccine).

[24] *About Malaria*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 12, 2020), https://www.cdc.gov/malaria/about/ [https://perma.cc/TX4B-JANP] [hereinafter *About Malaria*].

persistent symptoms, which could last for years.[25] Due to the ongoing medical debate on how to treat persistent Lyme, insurance companies freely restrict access to treatment, leaving patients to bear much of the financial burden.[26]

This Note urges Congress to enact legislation mandating insurance companies to pay for clinically diagnosed Lyme disease and co-infections treatment, based on the International Lyme and Associated Diseases Society's Guidelines, to reduce the financial burden unfairly placed on Lyme disease patients. Congress should also enact legislation that requires insurance companies to report all claims, including treatment denials, to hold them accountable and provide much needed analytical information on how many people suffer from this disease. Although some litigants have attempted to hold insurance companies and medical associations accountable through antitrust litigation, the process can be slow and may not address the widespread issue, necessitating federal legislation. Parts I and II provide an overview of Lyme disease and discuss how the medical debate about Lyme disease restricts patients' access to proper medical care. Parts III and IV discuss legal issues and treatment costs. Parts V and VI outline Lyme specific state insurance law mandates and the World Health Organization's new Lyme disease codes for persistent infection. Part VII provides proposed federal legislation based on state Lyme legislation and federal laws for other illnesses.

I. LYME DISEASE OVERVIEW

Lyme disease is caused by spiral shaped bacteria (spirochetes) and is spread primarily through tick bites,[27] although scientists have also documented cases of mother to fetus transmissions.[28] Early Lyme disease often has flu-like symptoms including headache, fever, migrating arthritic-like joint pain, and Bell's palsy.[29] At this early stage, the disease can

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[25] Up to 35% of patients develop persistent Lyme (476,000 x 0.35 = 166,600). TICK-BORNE DISEASE WORKING GROUP, 2020 REPORT TO CONGRESS 62–63 (2020) [hereinafter 2ND REPORT TO CONGRESS].

[26] *See, e.g.*, UNITEDHEALTHCARE OXFORD, UNITEDHEALTHCARE OXFORD CLINICAL POLICY: LYME DISEASE 1–2 (2020) [hereinafter UNITEDHEALTHCARE OXFORD CLINICAL POLICY]; *see also Clinical Policy Bulletin Number 0215: Lyme Disease and Other Tick-Borne Diseases*, AETNA (Mar. 17, 2021), http://www.aetna.com/cpb/medical/data/200_299/0215.html [https://perma.cc/65GP-HQAL] [hereinafter *Aetna Clinical Policy*]; *see also* WEINTRAUB, *supra* note18, at 307.

[27] *Frequently Asked Questions About Lyme Disease*, INT'L LYME & ASSOCIATED DISEASES EDUC. FOUND., https://iladef.org/education/lyme-disease-faq/ [https://perma.cc/6NMU-U5YW].

[28] *See* Lisa A. Waddell, Judy Greig, L. Robbin Lindsay, Alison F. Hinckley & Nicholas H. Ogden, *A Systematic Review on the Impact of Gestational Lyme Disease in Humans on the Fetus and Newborn*, PLOS ONE, Nov. 12, 2018, at 1, 1.

[29] *See* Elizabeth L. Maloney, *The Need for Clinical Judgment in the Diagnosis and Treatment of Lyme Disease*, 14 J. AM. PHYSICIANS & SURGEONS 82, 82–83 (2009).

usually be treated with a short course of antibiotics without repercussions.[30]

If left untreated, however, symptoms often worsen and the risk of treatment failure increases.[31] Late stage Lyme disease can result in neurologic issues including cognitive dysfunction, memory loss, and headache; fatigue; chest pain; shortness of breath; difficulty sleeping; lightheadedness; and psychiatric symptoms such as depression, anxiety, and mood swings.[32] In addition, an estimated 50% of patients suffer from co-infections, such as Babesia or Bartonella, which can exacerbate symptoms and require additional treatment.[33]

Practitioners often fail to diagnose Lyme disease due to the disease's non-specific symptoms, poor laboratory tests, and painless rashes from tick bites that often go unnoticed.[34] The most accurate way to diagnose Lyme disease is by identifying the disease's signature bull's-eye rash, yet only about 68% of people with Lyme disease develop a rash,[35] and only 14% of patients remembered being bitten in one study.[36] If people do not know they have been bitten by a tick, they likely will not be on the lookout for a painless rash.

Another way to diagnose Lyme disease is through a CDC-approved blood antibody test, which uses two-tier antibody testing. However, scientists found the test has a sensitivity of only 35.2% in patients presenting with a rash.[37] In addition to the flaws typically found in antibody testing,[38] the CDC-approved Lyme disease test is limited by the following: (1) it looks for antibodies developed from a single European

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[30] 2ND REPORT TO CONGRESS, *supra* note 25, at 46.

[31] Daniel J. Cameron, *Consequences of Treatment Delay in Lyme Disease*, 13 J. EVALUATION CLINICAL PRAC. 470, 471–72 (2007).

[32] Maloney, *supra* note 29, at 83; *Lyme Disease Basics for Providers*, INT'L LYME & ASSOCIATED DISEASES SOC'Y, https://www.ilads.org/research-literature/lyme-disease-basics-for-providers/ [https://perma.cc/ET28-RHSE].

[33] Co-infections are other diseases transmitted via tick bite along with Lyme disease. *About Lyme Disease Co-Infections*, LYMEDISEASE.ORG, https://www.lymedisease.org/lyme-basics/co-infections/about-co-infections/ [https://perma.cc/CJ5P-J47W].

[34] Maloney, *supra* note 29, at 82–83.

[35] *Id.* at 82.

[36] *Id.* at 83.

[37] Gary P. Wormser, Martin Schriefer, Maria E. Aguero-Rosenfeld, Andrew Levin, Allen C. Steere, Robert B. Nadelman, John Nowakowski, Adriana Marques, Barbara J. B. Johnson & J. Stephen Dumler, *Single-Tier Testing with the C6 Peptide ELISA Kit Compared with Two-Tier Testing for Lyme Disease*, 75 DIAGNOSTIC MICROBIOLOGY INFECTIOUS DISEASE 9,9 (2013). The state of Rhode Island requires doctors to notify patients that a negative test result does not rule out Lyme disease. 5 R.I. GEN. LAWS § 5-37.5-6 (2014).

[38] The problem with testing antibodies, in general, is that they only show the body's response to infection, take weeks to develop, and may still exist after infections are gone. *Diagnosis and Testing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 20, 2019), https://www.cdc.gov/lyme/diagnosistesting/index.html [https://perma.cc/67LE-YVL8].

strain of the bacteria, without regard to the hundreds of other strains found in the U.S. and around the world; (2) it is based on antibodies created by patients with early arthritic symptoms, as opposed to patients with later neurologic symptoms; and (3) it relies on non-specific antibodies, which could be attributed to other illnesses, while excluding antibodies more specific to Lyme disease.[39] As a result, 22% of patients with early stage Lyme disease test negative and roughly half of patients with late-stage, neurologic Lyme disease also test negative.[40]

Given the flaws in rash identification and blood tests, doctors must rely on symptoms to accurately diagnose patients.[41] This requires doctors to evaluate the unique, systemic nature of the illness: "[A] single symptom means little but four or five may, for all practical purposes, make the case. . . . [T]he combination of fatigue, [tingling], [joint pain], and memory complaints presenting in a single patient commands the attention of physicians."[42] Thus the full body, systemic nature of the illness allows doctors to accurately diagnose the illness clinically.

II. THE MEDICAL DEBATE

Two medical societies—Infectious Diseases Society of America (IDSA)[43] and International Lyme and Associated Diseases Society (ILADS)[44]—currently provide guidelines on Lyme disease treatment based on expert opinion and scientific research, but their guidance varies widely, especially on the topic of persistent illness, resulting in drastic and disparate consequence for patients. Insurance companies presumably follow the IDSA Guidelines because they require only minimal treatment, leaving patients who seek additional treatment in-line with ILADS Guidelines to bear most of the costs of additional treatment out-of-

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[39] WEINTRAUB, *supra* note18, at 10, 320.

[40] Maloney, *supra* note 29, at 82 (discussing the flaws associated with requiring a positive test to confirm diagnosis).

[41] Lorraine Johnson & Raphael B. Stricker, *Treatment of Lyme Disease: A Medicolegal Assessment*, 2 EXPERT REV. ANTI-INFECTIVE THERAPY 533, 535 (2004) [hereinafter *Medicolegal Assessment*].

[42] Maloney, *supra* note 29, at 84.

[43] "The [IDSA] is a community of over 12,000 physicians, scientists and public health experts who specialize in infectious diseases. Our mission is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases." *About IDSA*, INFECTIOUS DISEASES SOC'Y AM., https://www.idsociety.org/about-idsa/about-idsa/ [https://perma.cc/AA3Q-4PC6].

[44] "ILADS is a nonprofit, international, multidisciplinary medical society dedicated to the appropriate diagnosis and treatment of Lyme and associated diseases. ILADS promotes understanding of Lyme and associated diseases through research, education[,] and policy. We strongly support physicians, scientists, researchers and other healthcare professionals dedicated to advancing the standard of care for Lyme and associated diseases." *Mission & Goals*, INT'L LYME & ASSOCIATED DISEASES SOC'Y, https://www.ilads.org/about/mission/ [https://perma.cc/J4FG-HSR2].

pocket.[45] This is one of several reasons why it is imperative that Congress enacts legislation that allows patients to seek coverage aligned with either set of guidelines for patients diagnosed with Lyme disease.

The medical debate on persistent infection hinges on the accuracy of tests and clinical diagnoses, duration of treatment, and the cause of persistent symptoms. The IDSA categorizes Lyme as a disease that is difficult to get and easy to cure.[46] Further, the IDSA claims symptoms that persist after treatment are the result of unexplained, subjective symptoms it calls post-Lyme disease syndrome (PLDS).[47] ILADS, on the other hand, recognizes Lyme disease as a complex disease that can cause complications if not caught early or treated effectively.[48] ILADS states that persistent symptoms lasting more than six months are the result of persistent infection, which it calls "chronic Lyme disease."[49] The term "chronic Lyme disease" is steeped in controversy because IDSA doctors believe the diagnosis constitutes medical fraud;[50] whereas, ILADS doctors believe the term accurately describes patients with complex infection beyond the acute phase.[51] Despite the controversy, the term "chronic Lyme disease" will be used throughout this Note because it is central to the need for insurance coverage.

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[45] *See* 2ND REPORT TO CONGRESS, *supra* note 25, at 63, 101–02.

[46] Gina Kolata, *Lyme Disease Is Hard to Catch and Easy to Halt, Study Finds*, N.Y. TIMES (June 13, 2001), https://www.nytimes.com/2001/06/13/us/lyme-disease-is-hard-to-catch-and-easy-to-halt-study-finds.html [https://perma.cc/MS4Q-76NL].

[47] Gary P. Wormser, Raymond J. Dattwyler, Eugene D. Shapiro, John J. Halperin, Allen C. Steere, Mark S. Klempner, Peter J. Krause, Johan S. Bakken, Franc Strle, Gerold Stanek, Linda Bockenstedt, Durland Fish, J. Stephen Dumler & Robert B. Nadelman, *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America*, 43 CLINICAL INFECTIOUS DISEASES 1089, 1120–21 (2006) [hereinafter *2006 IDSA Guidelines*]. PLDS is synonymous with PTLDS (Post-Treatment Lyme Disease Syndrome).

[48] *See* Daniel J. Cameron, Lorraine B. Johnson & Elizabeth L. Maloney, *Evidence Assessments and Guideline Recommendations in Lyme Disease: The Clinical Management of Known Tick Bites, Erythema Migrans Rashes and Persistent Disease*, EXPERT REV. ANTI-INFECTIVE THERAPY 1103, 1104 (2014) [hereinafter *2014 ILADS Guidelines*].

[49] Samuel Shor, Christine Green, Beatrice Szantyr, Steven Phillips, Kenneth Liegner, Joseph Burrascano Jr., Robert Bransfield & Elizabeth L. Maloney, *Chronic Lyme Disease: An Evidence-Based Definition by the ILADS Working Group*, ANTIBIOTICS, Dec. 16, 2019, at 1, 1–2 [hereinafter *An Evidence-Based Definition*].

[50] *See* Lawrence Zemel & Paul G. Auwaerter, *Treating 'Chronic Lyme Disease:' Is it Medical Fraud?*, CT MIRROR (Dec. 13, 2019), https://ctmirror.org/category/ct-viewpoints/treating-chronic-lyme-disease-is-it-medical-fraud-lawrence-zemel/ [https://perma.cc/Q6R4-NPHG].

[51] *See Controversies & Challenges in Treating Lyme and Other Tick-Borne Diseases*, INT'L. LYME & ASSOCIATED DISEASES SOC'Y, https://www.ilads.org/research-literature/controversies-challenges/ [https://perma.cc/73AZ-FM7C].

A. The Infectious Diseases Society of America

The IDSA produces guidelines on Lyme disease treatment for early stages of the disease but restricts diagnosis and treatment in many ways by limiting the freedom of prescribing doctors and offering few options to those patients who fail to improve after the initial round of treatment. First, the 2006 IDSA Guidelines instruct doctors not to treat patients for Lyme disease without a rash or positive lab test.[52] Even in cases of suspected heart block caused by Lyme carditis, the authors urge "the clinical manifestations of Lyme carditis are too nonspecific to warrant a purely clinical diagnosis" because "[t]he vast majority of patients . . . are seropositive at the time of presentation."[53] Yet, as illustrated in Dr. Spector's medical history above, heart block caused by Lyme disease is entirely plausible, despite negative test results, and failure to treat early can be catastrophic.

Second, the 2006 IDSA Guidelines restrict access to antibiotic treatment by defining symptoms of fatigue, musculoskeletal pain, and cognitive difficulties, which are present at least six months after antibiotic treatment, as "post-Lyme disease syndrome" (PLDS) rather than chronic Lyme disease and recommend against further antibiotic treatment.[54] The IDSA Guidelines attribute these symptoms to be "more related to the aches and pains of daily living rather than to either Lyme disease or a tickborne coinfection."[55] As a result, many patients who fail IDSA's recommended Lyme disease treatment are diagnosed with fibromyalgia or chronic fatigue syndrome, which are diseases of unknown origins.[56] Maya Dusenbery, author of *Doing Harm*, argues "it's hard not to see the tendency to shift Lyme patients who failed to get better after antibiotic treatment into these diagnostic categories as a way of dismissing them as hysterics and hypochondriacs without coming right out and saying so."[57] Doctors who follow the IDSA Guidelines treat patients who do not recover with palliative care, which is intended to treat symptoms only and cutoff patients from further antibiotics, in direct contradiction to ILADS guidance.[58]

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[52] *See generally 2006 IDSA Guidelines*, *supra* note 47, at 1089–90, 1101, 1107, 1108. Throughout the document, the authors note that a purely clinical diagnosis should not be used.

[53] *Id.* at 1108.

[54] *Id.* at 1120–21 ("To date, there is no convincing biologic evidence for the existence of symptomatic chronic [Lyme disease] infection among patients after receipt of recommended treatment regimens for Lyme disease.").

[55] *Id.* at 1115.

[56] MAYA DUSENBERY, DOING HARM: THE TRUTH ABOUT HOW BAD MEDICINE AND LAZY SCIENCE LEAVE WOMEN DISMISSED, MISDIAGNOSED, AND SICK 287 (2018).

[57] *Id.*

[58] *See 2014 ILADS Guidelines*, *supra* note 48, at 1122.

Third, the new 2020 IDSA Guidelines, which replaced the 2006 Guidelines, caution practitioners against testing for Lyme disease at all if patients do not meet specific criteria because the IDSA fears patients will test positive for Lyme disease when they might not have it.[59] However, the IDSA Guidelines fail to consider the opposite issue of false negatives: those who in fact have Lyme disease, but test negative due to the inaccuracy of the test. For example, the 2020 Guidelines recommend against testing for Lyme disease in patients exhibiting symptoms of Multiple Sclerosis; Parkinson's; cognitive decline; psychiatric illness in adults; or developmental, behavioral or psychiatric disorders in children, although the IDSA notes this recommendation is weak and based off low-quality evidence.[60] However, a patient survey conducted by LymeDisease.org found 72% of survey respondents were originally misdiagnosed with other illnesses such as a psychiatric disorder, Multiple Sclerosis, learning disabilities, and Parkinson's, and were later diagnosed with Lyme disease.[61] Thus the fear of false positives could exacerbate the problem of misdiagnoses for people who have Lyme because doctors are told not to test for Lyme unless certain strict criteria are met. In addition, the 2020 IDSA Guidelines conclude patients with extended symptoms most likely have other illnesses, such as rheumatoid arthritis or depression, and should not be treated further with antibiotics.[62] Again, this leaves patients whose doctors follow the IDSA guidelines without a solution to their continued medical issues.

The 2020 IDSA Guidelines emphasize three reasons not to extend antibiotic treatment beyond the minimum amount, but each reason contains flaws. First, it argues that there are no high-quality studies showing persistent infection.[63] Second, it argues that there is no clinical or laboratory proof of persistent infection. Third, it argues that the extended

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[59] Paul M. Lantos, Jeffrey Rumbaugh, Linda K. Bockenstedt, Yngve T. Falck-Ytter, Maria E. Aguero-Rosenfeld, Paul G. Auwaerter, Kelly Baldwin, Raveendhara R. Bannuru, Kiran K. Belani, William R. Bowie, John A. Branda, David B. Clifford, Francis J. DiMario Jr., John J. Halperin, Peter J. Krause, Valery Lavergne, Matthew H. Liang, H. Cody Meissner, Lise E. Nigrovic, James J. Nocton, Mikala C. Osani, Amy A. Pruitt, Jane Rips, Lynda E. Rosenfeld, Margot L. Savoy, Sunil K. Sood, Allen C. Steere, Franc Strle, Robert Sundel, Jean Tsao, Elizaveta E. Vaysbrot, Gary P. Wormser & Lawrence S. Zemel, *Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR): 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease*, 72 CLINICAL INFECTIOUS DISEASES e1, e10 (2021). [hereinafter *2020 IDSA Guidelines*] ("Because of this potential for false positive results, clinicians should be selective when ordering tests in patients with a low probability of Lyme disease.").

[60] *Id.* at e3–e4.

[61] LYMEDISEASE.ORG,2019 CHART BOOK: MYLYMEDATA REGISTRY 18 (2019) [hereinafter MYLYMEDATA REGISTRY].

[62] *2020 IDSA Guidelines*, *supra* note 59, at e36–e37.

[63] *Id.* at e37.

use of antibiotics is harmful for patients, such as infection of the IV catheters.[64] However, 700 studies conducted by ILADS researchers show evidence of persistent infection after treatment, confirmed through PCR testing;[65] and at least four IV antibiotic studies show the risk of infection of antibiotic IV catheters was no greater than that of an IV placebo.[66] In addition, scientific author, Mary Beth Pfeiffer, points to the fact that compared to other "pharmaceuticals with alarming toxic side effects" antibiotics are "among the safest [drugs] there are."[67] In contrast to the IDSA, ILADS believes that doctors and patients should be able to weigh the potential risks of harm caused by antibiotics versus the morbidity of harm caused by persistent infection.[68]

The IDSA's statement on the ineffectiveness of antibiotics after failure of an initial course of antibiotics relies on a study by Mark Klempner, an author of the 2006 IDSA Guidelines. The study aimed to determine whether prolonged antibiotic treatment helped patients, but it was cut short when the safety and monitoring board found no significant improvement.[69] During the trial, patients were given thirty days of IV antibiotics followed by 200 milligrams of doxycycline for sixty days.[70] The study found 55% of patients in the antibiotic groups improved while 53% in the placebo groups also improved.[71] In contrast, 14% of the antibiotic group reported a worse outcome compared to 19% of the control group.[72] From these results, Klempner concluded that Lyme disease patients have "considerable impairment in their health-related quality of life . . . . [However, t]he patients . . . did not have evidence of persistent infection . . . ."[73]

Shortly after the publication of Klempner's study, members of ILADS reviewed the merits of the study and found multiple methodological weaknesses, including: "patient selection bias, sub-optimal antibiotic treatment regimes, faulty analysis and/or exclusion of

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[64] *Id.* at e36–e37.

[65] Plaintiffs' First Amended Complaint at 18, Torrey v. Infectious Diseases Soc'y of Am., No. 5:17-cv-00190-RWS (E.D. Tex. Mar. 25, 2019).

[66] Raphael Stricker, *Raphael Stricker, M.D. Speaking at IDSA LD Review Hearings July 30, 2009*, YOUTUBE (July 6, 2015), https://youtu.be/BSxLfkoY8Po [https://perma.cc/H3MC-4C23] (Dr. Raphael Stricker is a prominent Lyme-literate doctor).

[67] MARY BETH PFEIFFER, LYME: THE FIRST EPIDEMIC OF CLIMATE CHANGE 37 (2018).

[68] *2014 ILADS Guidelines*, *supra* note 48, at 1122, 1104.

[69] Mark S. Klempner, Linden T. Hu, Janine Evans, Christopher H. Schmid, Gary M. Johnson, Richard P. Trevino, DeLona Norton, Lois Levy, Diane Wall, John McCall, Mark Kosinski & Arthur Weinstein, *Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease*, 345 NEW ENG. J. MED. 85, 85 (2001).

[70] *Id.* at 86.

[71] *Id.* at 88.

[72] *Id.*

[73] *Id.* at 91.

data, and disregard for *B. Burgdorferi* microbiology and pathogenesis."[74] ILADS members noted many patients enrolled in the study had already failed a similar treatment regimen.[75] Furthermore, the dosage of doxycycline was too low to help patients experiencing neurologic symptoms, making it more likely that these patients would fail treatment again.[76] Finally, ILADS notes that Lyme disease patients often experience a flare in symptoms known as a "herx" reaction[77] from the initiation of antibiotic therapy, which makes patients feel worse before they feel better.[78] Despite these shortcomings, the IDSA continues to cite Klempner's study in its 2020 Guidelines as proof that persistent symptoms are not associated with persistent infection.[79] The IDSA's denial of persistent symptoms is seen by many as the force behind insurance claim denials for extended antibiotic therapy[80] and emphasizes the need for congressional intervention.

B. The International Lyme and Associated Diseases Society

ILADS offers an entirely different perspective on disease prognosis and treatment. It defines chronic Lyme disease as "a multisystem illness with a wide range of symptoms and/or signs that are either continuously or intermittently present for a minimum of six months. The illness is the result of an active and ongoing infection [of Lyme disease]."[81] Thus, a significant difference in ILADS Guidelines is the acknowledgment that continued symptoms are likely the result of continued infection.

In 2014, ILADS produced its most recent guidelines for treatment, emphasizing the importance of clinical judgment in the absence of strong scientific evidence.[82] For patients experiencing persistent symptoms,

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[74] Steven E. Phillips, Robert Bransfield, Virginia T. Sherr, Stephen Brand, Harold A. Smith, Kathleen Dickson & Raphael Sticker, *Evaluation of Antibiotic Treatment in Patients with Persistent Symptoms of Lyme Disease: An ILADS Position Paper*, 10, conference paper [hereinafter *ILADS Position Paper*].

[75] *Id.* at 6.

[76] *Id.*

[77] Formally known as a Jarisch-Herxheimer reaction, this flare in symptoms is attributed to inflammation caused by bacteria die-off. Lonnie Marcum, *Lyme Sci: The Dreaded Jarisch-Herxheimer Reaction*, LYMEDISEASE.ORG (July 31, 2017), https://www.lymedisease.org/lymesci-herxing/ [https://perma.cc/9CV3-5LF7] ("According to Dr. Joseph Burrascano, Jr., for patients who have chronic or late-stage Lyme, the worst reaction is typically around the fourth week of treatment . . . .").

[78] *ILADS Position Paper*, *supra* note 74, at 8.

[79] *2020 IDSA Guidelines*, *supra* note 59, at e36 & n.377.

[80] *Why is Lyme Disease Not Covered by Insurance?*, MED. BILL GURUS, https://www.medicalbillgurus.com/2017/09/why-isnt-lyme-disease-covered-by-insurance/ [https://perma.cc/3MWF-8RMT]; UNITEDHEALTHCARE OXFORD CLINICAL POLICY, *supra* note 26; *Aetna Clinical Policy*, *supra* note 26.

[81] *An Evidence-Based Definition*, *supra* note 49, at 1.

[82] *2014 ILADS Guidelines*, *supra* note 48, at 1104.

ILADS 2014 Guidelines emphasize the following: "Ongoing symptoms at the completion of active therapy were associated with an increased risk of long-term failure in some trials and therefore clinicians should not assume that time alone will resolve symptoms."[83] The guidelines further emphasize that individualized care should be taken in deciding whether to continue antibiotic treatment by assessing the risks of treatment complications along with the burden of the disease.[84] Burdens of disease include "the risks of continuing to suffer significant morbidity or permitting a serious systemic infection to progress."[85] Due to the risk of underlying persistent infection, ILADS Guidelines recommend against palliative care, which treats the symptoms but not the underlying illness.[86] Doctors who treat patients based on ILADS Guidelines are referred to as Lyme-literate medical doctors and Lyme-literate naturopathic doctors, who are licensed doctors trained in a range of medical backgrounds with years of experience treating patients with Lyme disease.[87]

ILADS recently compiled a list of over 700 peer-reviewed studies showing persistent infection caused by Lyme disease.[88] This Note will speak of three studies specifically. The first is a 2012 study involving Rhesus monkeys, who were chosen as hosts to provide objective results that are not possible in humans due to vague, non-specific symptoms, and inaccurate blood tests.[89] After the monkeys were infected with Lyme and given a high dose of antibiotics, scientists found both Lyme RNA in tissue samples, indicating live organisms, and Lyme bacteria, recovered from sterile ticks feeding off monkeys post treatment.[90] These discoveries suggest the possibility of persistence in humans as well.[91] Critics of animal studies, including the IDSA, believe studies on animals cannot provide a hypothesis for persistent infection in humans because animals do not

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[83] *Id.* at 1108.

[84] *Id.* at 1109, 1122.

[85] *Id.* at 1104.

[86] *Id.* at 1122.

[87] Shona Curley, *What Is a Lyme-Literate Doctor, and How to Find the Right One*, PROHEALTH (Dec. 2, 2019), https://www.prohealth.com/library/what-is-a-lyme-literate-doctor-and-how-to-find-the-right-one-92738 [https://perma.cc/E6RL-M7AQ]; *see also What Makes a Doctor Lyme Literate?*, IGENEX, https://igenex.com/tick-talk/what-makes-a-doctor-lyme-literate [https://perma.cc/9KMU-23ET] [hereinafter *What Makes a Doctor Lyme Literate?*].

[88] Plaintiffs' First Amended Complaint, *supra* note 65, at 18.

[89] Monica E. Embers, Stephen W. Barthold, Juan T. Borda, Lisa Bowers, Lara Doyle, Emir Hodzic, Mary B. Jacobs, Nicole R. Hasenkampf, Dale S. Martin, Sukanya Narasimhan, Kathrine M. Phillippi-Falkenstein, Jeanette E. Purcell, Marion S. Ratterree & Mario T. Philipp, *Persistence of* Borrelia Burgdorferi *in Rhesus Macaques Following Antibiotic Treatment of Disseminated Infection*, PLOS ONE, Jan. 11, 2012, at 1, 1–2 (Rhesus monkeys specifically were chosen because they manifest many of the same symptoms as humans with Lyme disease).

[90] *Id.* at 6.

[91] *Id.* at 8.

match the biology of humans and cannot show human fatigue or pain.[92] However, animal studies are likely the only way to show large scale unified results for Lyme disease because conducting similar studies that require withholding antibiotic therapy from human patients would be unethical.[93]

A second study found Lyme spirochetal clusters as well as Lyme DNA sequences in multiple organ samples from a deceased patient who received approximately sixteen years of extensive antibiotic treatment.[94] The study produced "several lines of evidence that suggest that [Lyme disease] can persist in the human body," despite years of antibiotic treatment and may be the cause of persistent symptoms.[95]

A third retrospective human study cultured Lyme spirochetes from three patients with persistent symptoms who had previously undergone months of antibiotic therapy, contradicting IDSA Guidelines in three ways.[96] First, the patients lived in Georgia and Florida, which are not endemic regions according to the IDSA Guidelines.[97] Second, each patient tested negative for Lyme disease using the CDC-approved antibody blood test, pointing to the inaccuracy of antibody testing.[98] Third, each patient underwent antibiotic therapy previously but were still culture positive, proving that bacteria persisted after initial treatment.[99]

Because reaching a consensus on the cause and proper treatment of persistent infection could be decades away, federal legislation is needed to help patients currently struggling with the financial burden of Lyme disease. Patients whose doctors decide to treat persistent infection

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[92] *2020 IDSA Guidelines*, *supra* note 59, at e36.

[93] *See* Marcus Davidsson, *The Financial Implications of a Well-Hidden and Ignored Chronic Lyme Disease Pandemic*, HEALTHCARE, Feb. 13, 2018, at 1, 41–42; *see also* Cameron, *supra* note 31, at 470–72.

[94] Eva Sapi, Rumanah S. Kasliwala, Hebo Ismail, Jason P. Torres, Michael Oldakowski, Sarah Markland, Gauri Gaur, Anthony Melillo, Klaus Eisendle, Kenneth B. Liegner, Jenny Libien & James E. Goldman, *The Long-Term Persistence of* Borrelia Burgdorferi *Antigens and DNA in the Tissues of a Patient with Lyme Disease*, ANTIBIOTICS, Oct. 11, 2019, at 1, 1.

[95] *Id.* at 1, 19.

[96] N. Rudenko, M. Golovchenko, M. Vancova, K. Clark, L. Grubhoffer & J. H. Oliver, Jr., *Isolation of Live* Borrelia Burgdorferi *Sensu Lato Spirochaetes from Patients with Undefined Disorders and Symptoms Not Typical for Lyme Borreliosis,* 22 CLINICAL MICROBIOLOGY & INFECTION 267.e9, 267.e11–12 (2016) [hereinafter *Isolation of Live* Borrelia Burgdorferi]; *see also* PFEIFFER, supra note 67, at 150-53.

[97] *Isolation of Live* Borrelia Burgdorferi, *supra* note 96, at 267.e11–12. The IDSA lists three endemic regions in its Guidelines: the Northeast, from Virginia through eastern Canada; the upper Midwest; and Northern California. *2020 IDSA Guidelines*, *supra* note 59, at e6; *see also* PFEIFFER, supra note 67, at 151.

[98] *Isolation of Live* Borrelia Burgdorferi, *supra* note 96, at 267.e11–12; *see also* PFEIFFER, supra note 67, at 151–52.

[99] *Isolation of Live* Borrelia Burgdorferi, *supra* note 96, at 267.e11-12; *see also* PFEIFFER, supra note 67, at 152.

according to ILADS Guidelines should have a right to receive insurance coverage for their medical expenses, just as they would if their doctors followed IDSA Guidelines.

III. LEGAL ISSUES

A. IDSA Anti-Trust Claims

In 2007, former Connecticut Attorney General, Richard Blumenthal, investigated the IDSA for potential antitrust law violations associated with the IDSA's 2006 Guidelines. Three factors significant to the antitrust claims included the following: (1) the exclusion of IDSA members on the guidelines panel who had opposing views on how to treat chronic Lyme disease;[100] (2) the reliance by medical societies, government agencies, and insurance companies on the IDSA Guidelines, which they view as mandatory because the Guidelines do not provide treatment alternatives or allow for clinical judgment; and (3) the strong influence IDSA has over medical journals, hospitals, and medical boards.[101] The combination of these three factors has the effect of excluding doctors who treat patients using the alternative guidelines.[102] In 2008, Blumenthal concluded his investigation, stating:

> The IDSA's 2006 Lyme disease guideline panel undercuts its credibility by allowing individuals with financial interests–in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies–to exclude divergent medical evidence and opinion. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result, medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.[103]

As a result of the investigation, the IDSA entered into an agreement with the Connecticut Attorney General's Office to form an independent

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[100] Lorraine Johnson & Raphael B. Stricker, *Attorney General Forces Infectious Diseases Society of America to Redo Lyme Guidelines Due to Flawed Development Process*, 35 J. MED. ETHICS 283, 284 (2009) ("In its previous guidelines panel, IDSA summarily tossed off the panel one researcher who disagreed with the panel chair on the best approach for treatment of chronic Lyme disease."); *see also* Lorraine Johnson & Raphael B. Stricker, *The Infectious Diseases Society of America Lyme Guidelines: A Cautionary Tale About the Development of Clinical Practice Guidelines*, PHIL., ETHICS, & HUMANS. MED., 2010, at 1, 3 [hereinafter *A Cautionary Tale*].

[101] *A Cautionary Tale*, *supra* note 100, at 1–3.

[102] *Id.* at 1–3.

[103] Press Release, Richard Blumenthal, State of Conn. Att'y Gen., Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guidelines, Install Independent Arbiter (May 1, 2008) (on file with author).

review panel to assess the need for revision of the guidelines.[104] In 2010, a final report by the IDSA panel, consisting exclusively of IDSA members,[105] found revision of the guidelines to be unnecessary.[106] While the agreement by the attorney general's office was laudable, the lack of third party review of the IDSA Guidelines allowed the IDSA to continue its questionable behavior without oversight and thus allowed insurance companies to continue denying treatment to those who did not follow the IDSA Guidelines.

Despite the analysis by the 2010 review panel, the 2006 IDSA Guidelines continue to receive considerable pushback. In 2016, the National Guidelines Clearinghouse removed the guidelines from their database because the guidelines did not meet the Institute of Medicine's standards.[107] Then, in 2017, the link to the guidelines was removed from the CDC's website.[108] Lyme disease activists further point to flaws in the IDSA treatment method. Lorraine Johnson, CEO of LymeDisease.org, and Dr. Raphael B. Stricker explain:

> There have been no trials demonstrating the efficacy of the 30-day antibiotic treatment duration[; t]here is currently no diagnostic test that can establish the eradication of *B. burgdorferi*[; and t]here is no evidence to support the hypothesis that the sole cause of the continuing symptoms is the presence of immune complexes.[109]

Federal legislation requiring treatment coverage based on ILADS Guidelines is therefore important because the IDSA may resist changing its guidelines due to potential exposure to malpractice liability. As Dr. Kenneth Liegner states: "[I]f [IDSA doctors] acknowledge they are wrong, they are liable for medical neglect–for failure to diagnose and failure to treat. So[,] they are doing the only thing they can–denying that chronic Lyme disease even exists."[110] There are many hypotheses as to why the IDSA refuses to acknowledge the existence of chronic Lyme disease, from

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[104] An Agreement Between the Attorney General of the State of Connecticut and the Infectious Diseases Society of America 1, 1 (April 30, 2008) (on file with author).

[105] Lorraine Johnson, *IDSA Lyme Guidelines Removed from NGC; ILADS Guidelines Still There,* LYMEDISEASE.ORG (Feb. 12, 2016), https://www.lymedisease.org/idsa-guidelines-removed-ngc/ [https://perma.cc/4W9G-54G2] [hereinafter *IDSA Lyme Guidelines Removed*].

[106] Paul M. Lantos, William A. Charini, Gerald Medoff, Manuel H. Moro, David M. Mushatt, Jeffrey Parsonnet, John W. Sanders & Carol J. Baker, *Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America*, 51 CLINICAL INFECTIOUS DISEASES 1, 1 (2010).

[107] *IDSA Lyme Guidelines Removed*, *supra* note 105.

[108] Dorothy Kupcha Leland, *CDC Website Removes Link to IDSA Guidelines. Just Lipstick on a Pig?,* LYMEDISEASE.ORG (Dec. 2, 2017), https://www.lymedisease.org/touchedbylyme-cdc-lipstick-on-pig/ [https://perma.cc/REM3-2YXV].

[109] *Medicolegal Assessment*, *supra* note 41, at 537.

[110] WEINTRAUB, *supra* note 18, at 141.

fear of malpractice to deals with insurance companies, as outlined in Part III.B.

B. Does the IDSA Conspire with Insurance Companies?

Insurance companies presumably support the IDSA Guidelines because the guidelines restrict treatment and thus reduce the overall expense of Lyme disease for insurance companies. In the lawsuit *Torrey v. IDSA*, filed by patients against the IDSA and eight insurance companies, plaintiffs claim that the IDSA and the insurance companies worked in collusion to deny antibiotic treatment to chronic Lyme disease patients.[111] In their second amended complaint, the plaintiffs alleged that defendants violated antitrust laws by:

> (1) denying the existence of chronic Lyme disease, (2) condemning the use of long-term antibiotics, (3) allowing doctors who treat chronic Lyme patients to be sanctioned by medical boards, and (4) using the guidelines as a basis to deny insurance coverage of chronic Lyme treatments. The power of the IDSA, the IDSA Panelists, and the Settling Insurance Companies restrains trade, therefore, the IDSA guidelines have significantly reduced the Lyme treatment market.[112]

As a result, the plaintiffs claim they, along with all others suffering from Lyme disease, were wrongfully deprived of proper diagnosis, treatment, and insurance coverage.[113] Since the initiation of the case, all eight insurance companies settled with the plaintiffs.[114] Although the judge dismissed both the RICO and antitrust claims citing lack of evidence of a conspiring agreement,[115] plaintiffs filed a notice of appeal to the Fifth Circuit in regards to their negligent and fraudulent misrepresentation claims.[116]

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[111] *See* Plaintiffs' Second Amended Complaint at 7–9, Torrey v. Infectious Diseases Soc'y of Am., No. 5:17-cv-00190-RWS (E.D. Tex. Jan. 7, 2021); *see also* Mary Beth Pfeiffer, *A Lawsuit on Behalf of Lyme Disease Patients*, FIRST EPIDEMIC (June 1, 2021), https://www.thefirstepidemic.com/lyme-lawsuit-1 [https://perma.cc/GZ23-FGVT] [hereinafter *A Lawsuit on Behalf of Lyme Disease Patients*].

[112] Plaintiffs' Second Amended Complaint, *supra* note 111, at 31; *see also A Lawsuit on Behalf of Lyme Disease Patients*, supra note 111.

[113] Plaintiffs' Second Amended Complaint, supra note 111, at 12.

[114] Plaintiffs' Second Amended Complaint, supra note 111, at 3; *A Lawsuit on Behalf of Lyme Disease Patients*, supra note 111.

[115] Order at 1, 16–19, Torrey v. Infectious Diseases Soc'y of Am., No. 5:17-cv-00190-RWS (E.D. Tex. Sept. 1, 2021).

[116] Plaintiffs' Notice of Appeal at 1, Torrey v. Infectious Diseases Soc'y of Am., No. 5:17-cv-00190-RWS (E.D. Tex. Oct. 19, 2021); *A Lawsuit on Behalf of Lyme Disease Patients*, supra note 111.

C. Insurance Companies Target Lyme-Literate Doctors; State Laws Aim to Protect Them

Although reporting to medical boards is anonymous, the plaintiffs in *Torrey v. IDSA* and others believe "[m]any of the doctors . . . are reported by insurance companies" to reduce the number of physicians willing to treat chronic Lyme disease.[117] As a result of this threat by medical boards and insurance companies, many doctors have left the field, forcing chronic Lyme disease patients, desperate for care, to travel hundreds of miles for treatment.[118]

Dr. William Brown of Portland, Oregon was one of the first physicians to be targeted by an insurance company in 1994, when a reviewer from an HMO insurance company reported Brown to Oregon's Board of Medical Examiners.[119] Despite the fact that five of the six patients included in the investigation showed drastic improvement based on his prescribed treatment, the Medical Board permitted Brown to continue practicing medicine only if he agreed to stop treating Lyme disease patients.[120]

In 1993, Dr. Joseph Burrascano, Jr., a Lyme-literate doctor who was one of the first to treat patients for Lyme disease in Long Island, testified to the Senate that:

> There is in this country a core group of university-based Lyme disease researchers and physicians whose opinions carry a great deal of weight. Unfortunately, many of them act unscientifically and unethically. They adhere to outdated, self-serving views and attempt to personally discredit those whose opinions differ from their own. They exert strong, ethically questionable influence on medical journals, which enables them to publish and promote articles that are badly flawed. They work with Government agencies to bias the agenda of consensus meetings and have worked to exclude from these meetings and scientific seminars those with [alternate] opinions….

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[117] Plaintiffs' Second Amended Complaint, supra note 111, at 12, 16; *See also* LIEGNER, *supra* note 11, at 784–85.

[118] *See e.g.*, *Relating to Lyme Disease; and Declaring an Emergency: Hearing on S.B. 916 Before the H. Comm. on Health Care*, 2015 Leg., 78th Sess. 3 (Or. 2015) (statement of Marty Ross) ("I have a number of colleagues in California and Washington State who treat Oregonians because care is not available in state."). Dr. Marty Ross was personally targeted by the medical board in Washington state in 2018, yet no violations were found, and he resumed practice in late 2019. Marty Ross, *Story: Passion. Experience. Service. Compassion. We Get It.*, MARTY ROSS MD HEALING ARTS, https://martyrossmd.com/story [https://perma.cc/94SP-6M9C].

[119] WEINTRAUB, *supra* note 18, at 223; *see also* Phyllis Mervine, *Threat of Disciplinary Action Creates Tense Atmosphere for Lyme Docs*, LYME TIMES (Oct. 1994), https://www.lymenet.org/newsletter/deet/domino/nl.nsf/b18db4ad8571a779852565e3007d9d16/996155967e71fb8f852565e30012f1c0_OpenDocument [https://perma.cc/W33Q-QRF3].

[120] WEINTRAUB, *supra* note 18, at 223–24.

> And indeed, I have to confess that today I feel that I am taking a personal risk, a large one, because I am stating these views publicly, for fear that I may suffer some repercussions despite the fact that many hundreds of physicians and many thousands of patients all over the world agree with what I am saying here today.[121]

As Dr. Joseph Burrascano predicted, the medical board of New York opened an investigation shortly thereafter.[122] In 2001, thirty-seven of the thirty-nine charges[123] against him were cleared and the state medical board's hearing committee admitted: "The issues raised in this case pertained primarily to a medical debate in this field, rather than a demonstrated lack of competency by the Respondent."[124] The committee further noted, "We are . . . acutely aware that it was not this Committee's role to resolve this medical debate . . . ."[125] In response to this investigation, and similar investigations of other Lyme-literate doctors, eight states have passed laws to protect doctors who treat patients with antibiotics for more than twenty-eight days.[126]

In 2002, the New York State Assembly adopted Resolution 2155 stating:

> WHEREAS, Insurance companies can and do file complaints with the New York State office of Professional Medical Conduct against doctors who treat chronic Lyme disease, and have thus injected themselves into the debate; and WHEREAS, Doctors . . . who continue to provide treatment if they feel such treatment is medically necessary, have noted significant improvement in the condition of their patients . . . . [T]his Legislative Body . . . request[s] that insurance companies and the Office of Professional Medical Conduct cease and desist from targeting physicians . . . until such time as

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[121] *Lyme Disease: A Diagnostic and Treatment Dilemma: Hearing on Examining the Adequacy of Current Diagnostic Measures and Research Activities in the Prevention and Treatment of Lyme Disease Before the Comm. on Lab. & Hum. Res.*, 103rd Cong. 54–55, 57–58 (1993) [hereinafter *1993 Senate Hearing*] (statement of Dr. Joseph Burrascano, Jr.). For more information on the history of Lyme disease and Dr. Burrascano's role, see ILADS, *2018 ILADS Webinar–History of Lyme Disease by Joseph Burrascano, Jr. MD*, VIMEO (Dec. 18, 2018), https://vimeo.com/306846706 [https://perma.cc/677Y-RRMS].

[122] WEINTRAUB, *supra* note 18, at 228–32.

[123] Of the two remaining charges, one related to treating a patient for *Ehrlichia*, who did not have the specific symptoms, despite positive blood test results. The second was for failure to stop a medication after a patient experienced a seizure, even though the patient had seizures prior to using the medication. *Id.* at 232.

[124] Joseph Burrascano, M.D., 265 B.P.M.C. 1, 43 (2001) (Levin, Arb.); *see also* WEINTRAUB, *supra* note 18, at 232.

[125] Joseph Burrascano, M.D., 265 B.P.M.C. 42; See also WEINTRAUB, *supra* note 18, at 232.

[126] *See* CAL. BUS. & PROF. CODE § 2234.1 (2006); CONN. GEN. STAT. § 20-14m (2021); 225 ILL. COMP. STAT. § 60/22(c) (2021); IOWA CODE § 147.56 (2017); MD. CODE, HEALTH OCC. § 1-604 (2020); MASS. GEN. LAWS ch. 112, § 12DD (2010); ME. REV. STAT. tit. 32, § 3282-B (2015); 5 R.I. GEN. LAWS § 5-37.5-4 (2020).

> medical research and the medical community have determined the appropriate parameters for the diagnosis and treatment of tick-borne illnesses . . . .[127]

Illinois law offers an example of state legislation aimed at protecting Lyme-literate doctors.[128] Specifically, it states:

> The Department shall not revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action against the license or permit issued under this Act to practice medicine to a physician… for experimental treatment for Lyme disease or other tick-borne diseases, including, but not limited to, the prescription of or treatment with long-term antibiotics.[129]

The Illinois law is effective because it is broad in scope, allows for any type of experimental treatment, and does not allow the state medical board to revoke licensure solely for prescribing long-term antibiotics. Legal scholar, Creighton Meland, argues that despite minor flaws existing in state laws offering physician protection for Lyme-literate doctors, such laws are exceedingly important in helping doctors who provide care to those who are chronically ill.[130]

Opponents to legislative action protecting Lyme-literate doctors claim Lyme disease activists "spurred legislative efforts to subvert evidence-based medicine and peer-reviewed science,"[131] and argue that legislation allowing for the extended use of antibiotic treatment will lead to antibiotic resistance.[132] However, opponents fail to acknowledge flaws in IDSA's own "evidenced based science," as explored in Part I. And, while antibiotic resistance is a serious issue, the CDC does not list the treatment of Lyme disease as a factor leading to resistance.[133] Meanwhile,

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[127] Assemb. Res. 2155, 225th Ann. Sess. (N.Y. 2002); Plaintiffs' Second Amended Complaint, *supra* note 111, at 13.

[128] *Id.*

[129] 225 ILL. COMP. STAT. § 60/22(c) (2021).

[130] Creighton R. Meland, Jr., *They Shall Not Be Left to Rot: The Emerging Law of Lyme Disease*, 8 BELMONT L. REV. 95, 159 (2020).

[131] Paul G. Auwaerter, Johan S. Bakken, Raymond J. Dattwyler, J. Stephen Dumler, John J. Halperin, Edward McSweegan, Robert B. Nadelman, Susan O'Connell, Eugene D. Shapiro, Sunil K. Sood, Allen C. Steere, Arthur Weinstein & Gary P. Wormser, *Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease*, 11 LANCET INFECTIOUS DISEASES 713, 713 (2011).

[132] *See generally* Joseph B. Franklin, Note, *Antibiotic Maximalism: Legislative Assaults on the Evidence-Based Treatment of Lyme Disease*, 90 WASH. U. L. REV. 199 (2012).

[133] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 64 (rev. 2019). *See also* Meland, *supra* note 130, at 160–61. Not to mention the fact that antibiotics are commonly used in our food stream, which does lead to antibiotic resistant bacteria. *See* Celeste Robb-Nicholson, *By the Way, Doctor: Are the Antibiotics in Poultry Dangerous?*, HARVARD HEALTH PUBL'G (Mar. 2014),

activists around the country continue to push for additional state legislation to protect doctors and increase access to care.

IV. THE COST OF LYME DISEASE

A. The Cost of Limited Government Funding

One of the major obstacles to uncovering the cause of chronic Lyme disease and finding a cure is the lack of government funding for research as compared to other vector-borne diseases.[134] In 1993, the U.S. Senate Committee on Labor and Human Resources held a hearing entitled: *Lyme Disease: A Diagnostic and Treatment Dilemma*.[135] After hearing patient stories, Senator Bill Bradley noted: "This is an enormous national problem that we are refusing to address . . . . NIH has to get its act together . . . ."[136] Senator Metzenbaum followed, stating:

> I think [the testifying constituents] have sounded a clarion call that we ought to get off our butts and do something about this. Frankly, I think it is an illness that has been swept under the carpet, and not many people have paid attention to it…. I have heard of Lyme disease, but it hasn't struck me with the strength of your testimony today.[137]

Yet, despite the Senators' concerns, it appears Congress did little to help.

A few years later in 1998, Senator Christopher J. Dodd of Connecticut highlighted the issue in his proposal for a $3 million amendment to the Department of Defense budget for Lyme disease research, stating "[l]ong term treatment expenses can exceed $100,000 per person—a phenomenal cost to society. But an even greater price is paid by the victims and their families. We can put no price tag on the emotional costs associated with this disease."[138] And in relation to the military, he noted: "The growing number of cases has led the Department of Defense to recognize that Lyme Disease and other tick-borne illnesses pose a potentially serious health threat to our troops, civilian employees, and residents at military installations all over the world—and thus a threat to

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https://www.health.harvard.edu/newsletter_article/By_the_way_doctor_Are_the_antibiotics_in_poultry_dangerous [https://perma.cc/3JWY-U3X3].

[134] Vector-borne diseases are caused by parasites, viruses, and bacteria that are typically transmitted to humans via blood sucking insects. *Vector-Borne Diseases*, WORLD HEALTH ORG. (Mar. 2, 2020), https://www.who.int/news-room/fact-sheets/detail/vector-borne-diseases [https://perma.cc/EPL3-Q6SP].

[135] *1993 Senate Hearing*, *supra* note 121, at 1.

[136] *Id.* at 39 (statement of Sen. Bill Bradley).

[137] *Id.* at 51 (statement of Sen. Howard Metzenbaum).

[138] 105 CONG. REC. S7,136 (daily ed. June 25, 1998) (statement of Sen. Christopher Dodd).

our military readiness."[139] Yet, as of today, Lyme disease is missing from the U.S. Wartime Disability Compensation Statute.[140]

By 2019, little had changed in terms of government assistance in finding a cure for Lyme disease. The CDC estimates around 476,000 Americans are diagnosed with Lyme disease each year, yet the NIH dedicated only $32 million to research the disease in 2019.[141] In contrast, the CDC estimates only 2,000 U.S. residents are infected with malaria each year, and most cases are from travelers abroad.[142] But the NIH spent $254 million on research for malaria and the malaria vaccine.[143] Breaking the research dollars down by diagnosis shows the NIH spent $127,000 in research for each malaria diagnosis in 2019 and only $67 for each Lyme disease diagnosis.[144]

The Kay Hagan Tick Act, passed in 2019 and the Omnibus Appropriations bill of 2021 expand research funding but do so with a caveat and provide little help to those currently suffering from the disease. The Kay Hagan Tick Act provides $10 million for new centers for excellence in vector-borne diseases and $20 million for enhanced support for health departments.[145] But before passing the bill, senators removed all mention of the word "Lyme" and removed the requirement for proportional funding based on the disease burden in the U.S., which would have made Lyme disease first in line for funding.[146] As a result activists fear a larger portion of the funding will now go to other vector-borne illnesses like Zika, Malaria, and West Nile Virus, which have received more funding than Lyme disease in past years.[147] The Fiscal Year 2021

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[139] *Id.*

[140] *See* 38 U.S.C. § 1112. Although chronic disease and tropical diseases are covered, it is likely that Lyme disease patients fall through the cracks because the CDC fails to recognize Lyme disease as a chronic illness. Jenna Luché-Thayer, former Senior Advisor to the U.S. Government and United Nations and author of *$lyme*, reasons "[c]ost containment and liability may be a forceful reason behind the government downplay of persistent infection that requires ongoing care." Jenna Luché-Thayer, *Seventy Post Treatment Lyme Disease Syndrome Publications Ignore Infection*, LINKEDIN (Aug. 14, 2020), https://www.linkedin.com/pulse/seventy-post-treatment-lyme-disease-syndrome-ignore-luche-thayer/ [https://perma.cc/5YNL-QFAN].

[141] *How Many People Get Lyme Disease?*, *supra* note 21; *NIH Estimates of Funding*, *supra* note 23.

[142] *About Malaria*, *supra* note 24.

[143] *NIH Estimates of Funding*, *supra* note 23.

[144] ($254 million ÷ 2,000 cases = $127,000); ($32 million ÷ 476,000 cases = $67).

[145] Kay Hagan Tick Act, sec. 404, 133 Stat. 3116-17 (2019) (codified as 42 U.S.C. § 247b-23).

[146] *Important Information You Need to Know About the Tick Act*, LYME DISEASE ASS'N. (Nov. 20, 2019), https://lymediseaseassociation.org/government/federal-government/important-information-you-need-to-know-about-the-tick-act/ [https://perma.cc/R4DZ-K8YR].

[147] *Id.*; *NIH Estimates of Funding*, *supra* note 24; *see Zika Virus – Digital Media Kit,* NAT'L INST. HEALTH, https://www.nih.gov/news-events/zika-virus-digital-media-kit#:~:text=Funding%20for%20Zika%20Research,-

Omnibus Appropriations bill requires an additional $10 million be spent on Lyme disease research on top of the $53 million proposed by the NIH, which is the most funding provided for Lyme disease research in years.[148] But while additional funding for research is instrumental to future diagnosis and treatment, and is long overdue, research funding does little to help patients currently suffering from chronic Lyme disease who continue to face high costs for treatment and insurance coverage denials.

B. The Cost of Limited Insurance Coverage

For patients, frequent outpatient visits and expensive medications attribute to the high cost of Lyme disease treatment, which is exacerbated by insurance claim denials.[149] Direct medical costs for treatment of Lyme disease are estimated to be between $712 million and $1.3 billion a year in the U.S.[150] From an individual cost perspective, patients with Lyme disease incur $2,968 more in medical expenses each year than the average insured person without Lyme disease and patients with one or more chronic symptom spend $3,798 more than Lyme patients without chronic symptoms.[151] The high cost of treatment, particularly IV antibiotics, meant Lyme disease became a financial burden for insurance companies beginning in the 1990s.[152] To alleviate the burden on the insurance companies' bottom line, many companies began tightening requirements for proof of illness.[153] For example, some began requiring patients to meet the CDC surveillance criteria before providing coverage, despite the CDC's warning that its surveillance criteria should not be used for diagnosis due to its strict requirements.[154]

Currently, patients are forced to incur treatment expenses because insurance companies pre-define what treatment is medically necessary.

Zika%20virus%20does&text=In%20FY%202017%20NIAID%20obligated,5325 [https://perma.cc/T2LY-3EGD].

[148] Bonnie Crater, *Historic Increase in Lyme Funding Passes Congress: Now Goes to President*, LYMEDISEASE.ORG (Dec. 27, 2020), https://www.lymedisease.org/historic-increase-in-lyme-funding/ [https://perma.cc/HVG3-HUVC].

[149] 2ND REPORT TO CONGRESS, *supra* note 25, at 63.

[150] Emily R. Adrion, John Aucott, Klaus W. Lemke & Johnathan P. Weiner, *Health Care Costs, Utilization and Patterns of Care Following Lyme Disease*, PLOS ONE, Feb. 4, 2015, at 1, 12.

[151] *Id.* at 1–2.

[152] WEINTRAUB, *supra* note 18, at 303–04.

[153] *Id.*

[154] *Id.* at 304; *see also Chronic Lyme Disease and Long-Term Antibiotic Treatment: Hearing Before the Assemb. Standing Comm. on Health*, 2001 Leg., 224th Ann. Sess. 16 (N.Y. 2001) (statement of Patricia Smith) [hereinafter *Chronic Lyme Hearing NY*]; *Lyme Disease (*Borrelia burgdorferi*) 2017 Case Definition*, CTRS. DISEASE CONTROL & PREVENTION (Apr. 16, 2021), https://ndc.services.cdc.gov/case-definitions/lyme-disease-2017/ [https://perma.cc/RX4W-T5SK] ("Surveillance case definitions are not intended to be used by healthcare providers for making a clinical diagnosis or determining how to meet an individual patient's health needs.").

United Healthcare Oxford's current clinical policy lists IV antibiotic treatment for Lyme disease as "not medically necessary" for patients with the policy's defined Post-Treatment Lyme Disease Syndrome (PTLDS).[155] It defines PTLDS as "Fatigue, [w]idespread musculoskeletal pain[, and c]omplaints of cognitive difficulties" if the symptoms persist more than six months after antibiotic treatment.[156] Similarly, Aetna lists treatment for PTLDS as "experimental" and "investigational."[157] By defining treatment as "experimental" or "investigatory," insurance companies narrowly craft definitions within their contracts and refuse to pay for treatment.[158]

Patients do have some power to push back through internal appeals and civil lawsuits, but the process is costly and may require patients to wait for pre-authorization without treatment. Further, judges are often put in the position of determining medical necessity.[159] Under the Employee Retirement Income Security Act (ERISA),[160] for example, a patient can bring a civil suit after internal appeal for denial of benefits.[161] However, leaving it up to the courts to decide whether a treatment is medically necessary can be ineffective, time consuming, and, for cases raised in different jurisdictions, inconsistent.[162] With diseases such as Lyme that are still under considerable medical debate, courts may be forced to decide between one medical expert who deems the treatment experimental, and another who states the opposite.[163] Meanwhile, the patient will continue to suffer symptoms, which can worsen over time without treatment. In *Fuja v. Benefit Trust Life Insurance Co.*, a case about whether a certain breast cancer treatment could be denied insurance coverage because the treatment was pursued "in connection with medical or other research"[164] the court stated:

> [C]ases of this nature pose troubling social as well as ethical questions that go well beyond the legal issues. As a court of law[,] we are empowered to decide legal issues presented by specific cases

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[155] UNITEDHEALTHCARE OXFORD CLINICAL POLICY, *supra* note 26, at 1.

[156] *Id.* at 2.

[157] *Aetna Clinical Policy*, *supra* note 26.

[158] *See* Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 796 (1994).

[159] Sharona Hoffman, *A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. 203, 220 (1999).

[160] ERISA "sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans." *ERISA*, U.S. DEP. LAB., https://www.dol.gov/general/topic/health-plans/erisa#:~:text=The%20Employee%20Retirement%20Income%20Security,for%20individuals%20in%20these%20plans [https://perma.cc/N9BT-F2JU].

[161] 29 U.S.C. § 1132(a)(1)(B).

[162] Hoffman, *supra* note 159, at 218–19.

[163] Fuja v. Benefit Tr. Life Ins. Co., 18 F.3d 1405, 1412 (7th Cir. 1994).

[164] *Id.* at 1409. *See also* Hoffman, *supra* note 159, at 209.

> or controversies. The greater social questions must be decided by the political branches of government which can engage in "legislative fact-finding" and "benefit from public hearings and constituent expression of opinion."[165]

Thus, some judges argue that the medical coverage debate is best left to the legislators instead of the courts.

Legislation offers the best hope for patients to receive reimbursement for their treatment from insurance companies. A law can uniformly prevent unfair denial of treatment based on poor scientific studies, such as Klempner's study,[166] and will remove the delay caused by the appeal process. Finally, federal legislation will reduce the burden on judges, who are currently forced to decide on social and ethical issues well outside the scope of legal issues.

V. STATES THAT MANDATE INSURANCE COVERAGE FOR LYME TREATMENT

Eight states have passed legislation specific to insurance coverage for Lyme disease.[167] In addition, Pennsylvania, New Jersey, and New York have recently proposed legislation to mandate insurance coverage.[168] This Part will briefly discuss the positive and negative aspects of current state legislation beginning with Connecticut, which requires:

> Each individual health insurance policy… shall provide coverage for Lyme disease treatment including not less than thirty days of intravenous antibiotic therapy, sixty days of oral antibiotic therapy, or both, and shall provide further treatment if recommended by a board certified rheumatologist, infectious disease specialist or neurologist….[169]

The issue with the law as written, however, is that most Lyme-literate doctors who treat chronic Lyme disease are not certified in the

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[165] *Fuja*, 18 F.3d at 1412 (quoting Wangen v. Ford Motor Co., 294 N.W.2d 437, 469 (Wis. 1980) (Coffey, J., dissenting)).

[166] *See supra* Part II.

[167] CONN. GEN. STAT. § 38a-492h (2000); 215 ILL. COMP. STAT. 5/356z.33 (2020); MASS. GEN. LAWS ch. 175, § 47HH (2017); ME. REV. STAT. tit. 24-A, § 4302 (2019); MINN. STAT. § 62A.265 (1996); N.H. REV. STAT. § 415:18-ee (2021); R.I. GEN. LAWS § 5-37.5-5 (2004); R.I. GEN. LAWS § 27-18-62 (2004); W. VA. CODE § 33-6-38 (2018); *see also* Michelle Treseler, *Advocacy Q&A*, YOUTUBE (Oct. 29, 2021), https://www.youtube.com/watch?v=bPby5kvqm04 [https://perma.cc/887E-FXNR] (Ms. Treseler speaks about many of the state Lyme insurance laws in this video).

[168] H.B. 1033, 205th Gen. Assemb., Reg. Sess. (Pa. 2021) (*see also* S.B. 100, 205th Gen. Assemb., Reg. Sess. (Pa. 2021) for Senate version); Assemb. B. 7495, 244th Ann. Legis. Sess. (N.Y.); Assemb.730, 220th Leg., 2022 Sess. (N.J. 2022).

[169] CONN. GEN. STAT. § 38a-492h (2018).

specializations listed in the statute.[170] Interestingly, Connecticut treatment laws for Lyme disease allow extended treatment by certified physicians, physician assistants, and advanced practice registered nurses,[171] but the state limits insurance coverage to only those who seek care from a rheumatologist, infectious disease specialist or neurologist. Thus, if a patient wants to obtain care from a Lyme-literate doctor, who may not fit into one of the specified medical sub-divisions, the State will not require an insurance provider to cover that patient's care.

The Massachusetts law, on the other hand, does not exclude any category of physician and requires coverage of medication even if it is considered experimental.[172] Coverage of experimental medication is necessary because insurance companies often label antibiotic treatment for chronic Lyme disease as experimental.[173] Finally, the law requires coverage based on "patient's symptoms, diagnostic test results or response to treatment."[174] Use of the word "or" is important because patients with chronic Lyme disease do not always test positive due to the low quality of the CDC-approved blood test, as explained in Part I.[175]

New Hampshire's law builds on Massachusetts's law by expanding coverage to all tick-borne illnesses and forbidding insurance companies from charging higher deductibles, co-payments, or coinsurance than other illnesses. It states:

> Each insurer . . . shall provide . . . coverage for long-term antibiotic therapy for tick-borne illness when determined to be medically necessary and ordered by a licensed infectious disease physician after making a thorough evaluation of the patient's symptoms, diagnostic test results or response to treatment. Benefits provided under this section shall not be subject to any greater co-payment, deductible, or coinsurance than any other similar benefits provided by the insurer.[176]

There are two flaws to this law, however. First, the law requires treatment by an infectious disease doctor, which is an issue because many Lyme-literate doctors are not infectious disease doctors, as noted above.

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[170] *What Makes a Doctor Lyme Literate?*, *supra* note 87.

[171] CONN. GEN. STAT. § 20-14m(b) (2021).

[172] MASS. GEN. LAWS ch. 175, § 47HH (2017).

[173] For example, Aetna states the following: "Aetna considers additional antibiotic therapy in post-treatment, persistently fatigued patients (post-Lyme disease syndrome) experimental and investigational because IV antibiotic therapy has not been shown to be effective for this indication." *Aetna Clinical Policy*, *supra* note 26.

[174] MASS. GEN. LAWS ch. 175, § 47HH (2017).

[175] Treseler, *supra* note 167.

[176] N.H. REV. STAT. § 415:18-ee (2021).

And second, the law limits coverage to antibiotics, which may mean that non-antibiotic drugs are not covered.

Finally, while Maine has not yet passed an insurance coverage mandate for Lyme disease, the State does require insurance accountability:

> [A]ll carriers shall file with the superintendent for the most recent calendar year for all covered individuals in the State the total claims made for the diagnosis and treatment of Lyme disease and other tick-borne illnesses. The filing must include information on the number of claims made for the diagnosis and treatment of Lyme disease and other tick-borne illnesses, the total dollar amount of those claims, the number of claim denials and the reasons for those denials, the number and outcome of internal appeals and the number of external appeals related to the diagnosis and treatment of Lyme disease and other tick-borne illnesses.[177]

Maine's statute requires insurance companies to report whether Lyme disease patients are receiving reimbursement for their treatment, which provides the State with an accurate picture of the cost of the illness and the number of individuals seeking treatment. The statute also likely encourages insurance companies to apply fair standards because the companies know denials are being tracked.[178] Even so, without an insurance coverage mandate, some patients' treatment costs may fall through the cracks in Maine.

State insurance tracking is important, but as Meland points out, "[a]n inherent shortcoming in statewide initiatives is that they do not fully assist in solving a national problem. Instead, they are merely pieces of a larger puzzle."[179] In order to solve this national dilemma, Congress must pass comprehensive national legislation requiring insurance coverage and tracking. New Hampshire's insurance law with minor modifications could form a strong basis for a federal insurance mandate. In addition, Maine's insurance tracking law could provide a key framework for ensuring compliance.

VI. THE WORLD HEALTH ORGANIZATION RECOGNIZES CHRONIC LYME DISEASE

A recent human rights report presented to the World Health Organization (WHO) highlighted human rights violations associated with Lyme disease in an effort to update the International Classification of

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[177] ME. REV. STAT. tit. 24-A, § 4302 (2019).

[178] Meland, *supra* note 130, at 137.

[179] *Id.*

Diseases Codes (ICD codes).[180] ICD codes "are used globally to identify and record diseases, injuries[,] and deaths. In many countries, ICD codes are tied to insurance plans and reimbursement for medical care."[181] The current ICD10 codes for Lyme disease are limited and do not characterize chronic Lyme disease in healthcare databases.[182] Thus, insurance companies who use the codes for reimbursement purposes may not feel obligated to provide full payment.

The human rights report highlighted ten human rights violations against Lyme disease patients and six defender human rights violations against physicians treating Lyme disease patients caused by denial of care and the targeting of treating physicians.[183] It cites government failure to require healthcare coverage for Lyme disease as an "obstruction to necessary medical care for those with insufficient economic resources to pay out-of-pocket."[184]

As a result of the human rights report and the WHO's review of new scientific studies, in 2018 the WHO acknowledged the complexity of Lyme disease by publishing new, expanded medical codes specific to Lyme disease as part of ICD11.[185] The number of medical complications associated with Lyme disease will increase from three in ICD10 to fourteen in ICD11, five of which acknowledge life-threatening complications, and thirteen of the fourteen apply to chronic Lyme.[186] Notably, ICD11 diagnosis codes do not include the condition "Post-Lyme Disease Syndrome," which is the term the CDC, IDSA, and many insurance companies use to deny treatment for chronic Lyme disease.[187]

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[180] JENNA LUCHÉ-THAYER, $LYME: HOW MEDICAL CODES MORTALLY WOUND CORRUPTION AND SCIENTIFIC FRAUD 10, 74 (2018) [hereinafter $LYME].

[181] *Id.* at 10.

[182] *See id.* at 82–85.

[183] *See* JENNA LUCHÉ-THAYER, HOLLY AHERN, ROBERT BRANSFIELD, JOSEPH BURRASCANO, ANNE FIERLAFIJN, THERESA DENHAM, HUIB KRAAIJEVELD, JENNIFER KRAVIS, MUALLA MCMANUS, CLEMENT MESEKO, JACK LAMBERT, SIN HANG LEE, KENNETH LIEGNER, CHRISTIAN PERRONNE, KENNETH SANDSTRÖM, URSULA TALIB, TORBEN THOMSEN & JIM WILSON, THE SITUATION OF HUMAN RIGHTS DEFENDERS OF LYME AND RELAPSING FEVER BORRELIOSIS PATIENTS 13–15 (1st ed. 2018).

[184] *Id.* at 14.

[185] *See ICD-11 for Mortality and Morbidity Statistics*, ICD, https://icd.who.int/browse11/l-m/en (follow ICD-11 hyperlink; then search "Lyme") *See also* T. BEDIRHAN ÜSTÜN, ROBERT JAKOB, CAN ÇELIK, PIERRE LEWALLE & NENAND KOSTANJSEK, PRODUCTION OF ICD-11: THE OVERALL REVISION PROCESS, WHOFIC NETWORK 4 (Mar. 2007) https://www.who.int/classifications/icd/ICDRevision.pdf [https://perma.cc/3P62-MV5C] (explaining the WHO's revision process).

[186] *Id.*; $LYME, *supra* note 180, at 84–85. After publication of $LYME, the WHO removed the code for congenital Lyme. *See* John S. Lambert & Christian Perronne, *Time to Recognise Congenital Lyme: An Open Letter to the WHO*, LYME RES. CTR. (June 24, 2020), https://www.lymeresourcecentre.com/who-letter-20200624 [https://perma.cc/VPH9-H56V].

[187] *Id.* at 86.

The U.S. will soon begin the process of adopting the new ICD11 codes for use in all medical facilities.[188] The new ICD11 codes should help convince Congress to create legislation enforcing insurance coverage for chronic Lyme disease treatment.

VII. PROPOSAL

A. Outlining Legislation

Congress must pass a bill requiring insurance coverage and the tracking of insurance claims for chronic Lyme disease treatment based on clinical diagnoses and ILADS Guidelines. Scientists have collected overwhelming evidence of persistent infection associated with Lyme disease, and the WHO acknowledges persistent manifestations of Lyme disease through its adaptation of ICD11. Failure to implement insurance mandates for treatment and track insurance claim denials will result in continued denial of desperately needed medical treatment for patients across the country by allowing the IDSA and insurance companies to control the market, restrict access for patients seeking care under the ILADS Guidelines, and reduce the number of Lyme-literate doctors. Therefore, the proposed legislative solution has two parts: (1) mandatory coverage and (2) mandatory claims reporting, as outlined below.

1. Part 1: Mandating Insurance Coverage

Part one of the new federal legislation must mandate insurance coverage for all insurance types, including private insurance, Medicare, and Medicaid, for Lyme disease diagnostic testing, treatment, and doctors' visits even if such treatment is listed as experimental or investigational by insurance companies. Denial of access to healthcare is a human rights violation. Without insurance or government provided healthcare coverage, Lyme disease treatment continues to be unavailable to low-income patients who are unable to pay for large medical bills out-of-pocket. Patients along with their physicians should have the ability to choose between the two treatment guidelines, IDSA or ILADS, based on individual considerations and the risk of chronic infection.

Studies have shown that Lyme is a regressive illness, meaning that failure to treat at an early stage could lead to future treatment failure and chronic illness.[189] Therefore, mandatory treatment coverage could result in fewer complications from the illness, fewer claims for extended

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[188] Margaret A. Skurka, *ICD-11: U.S. Lags in Adoption*, ICD10 MONITOR (Nov. 2, 2020), https://www.icd10monitor.com/icd-11-u-s-lags-in-adoption [https://perma.cc/PS3N-G7MS].

[189] *See, e.g.*, Cameron, *supra* note 31, at 470, 471–72.

treatment required to cure chronic Lyme disease, and potentially fewer long-term disability and social security claims. Mandatory treatment coverage has potential benefits for insurance companies as well. As Richard Blumenthal testified, "[G]ood medicine and humane treatment of patients and consumers often can be good business for these HMOs and insurers…. [O]ften, by treating early or adopting preventative medical care, in the long run there's less expense."[190] Mandating coverage would also remove the need for internal costs related to preauthorization and oversight because there would no longer be a question of whether or not treatment should be covered.[191] In addition, a 2014 Massachusetts study revealed that monthly premiums would only increase between a negligible amount and $0.11 or 0.02% per year if long term antibiotic treatment for Lyme disease were covered based on the proposed Massachusetts state bill.[192]

Congress should implement New Hampshire's law with four modifications: (1) remove the requirement for the prescribing doctor to be an infectious diseases doctor because many experienced Lyme-literate doctors are not infectious disease doctors, (2) expand the definition of therapy to include any drug type, not just antibiotics, (3) add coverage of both experimental and investigational treatment so that drugs used off-label[193] are covered and (4) include doctors' visits as well. These proposed changes and safeguards will help to ensure the most coverage for the most patients.

2. Part 2: Mandating Insurance Claim Tracking

Part two of the new federal legislation must require insurance companies to track insurance claims similar to Maine's statutory scheme.[194] According to the Institute of Medicine's report on chronic infections, "[h]aving better data will inform planning, development, implementation, and evaluation of public health policies, programs, and

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[190] *Chronic Lyme Hearing NY*, *supra* note 154, at 79–80 (Statement of Richard Blumenthal, Atty Gen. Connecticut).

[191] *See id.* at 75. (Blumenthal is referring to Anthem, which eliminated prior authorization review for IV antibiotics in the wake of Connecticut's Lyme disease insurance mandate law).

[192] MANDATED BENEFIT REVIEW OF H.B. 989: AN ACT RELATIVE TO LYME DISEASE TREATMENT COVERAGE, CTR. FOR HEALTH INFO. & ANALYSIS 2 (2014); *see also* S.B. 100, 205th Gen. Assemb., Reg. Sess. (Pa. 2021).

[193] The term "off-label" refers to the use of an FDA approved drug for an unapproved use. *Understanding Unapproved Use of Approved Drugs "Off Label*,*"* U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label [https://perma.cc/CT48-2ZN8] (The FDA provides the following example of off-label drug use on its website: "when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.").

[194] ME. REV. STAT. tit. 24-A, § 4302 (2019).

community-based interventions for individuals living with chronic illness."[195] Current tracking for Lyme disease is limited to cases reported to the CDC, general records from insurance collection databases, and patient surveys, each of which have their own limitations.

First, the CDC receives approximately 35,000 reports of Lyme disease each year, but estimates the true number of cases may be closer to 476,000 due to undercounting.[196] Undercounting is especially prevalent in southern and western states where the CDC implements stricter criteria for confirmed cases.[197]

Second, the IBM Watson Health MarketScan Commercial Claims and Encounters Databases, used as part of the CDC's case estimate, only compile general healthcare claims from approximately 25 million privately insured U.S. residents.[198] But given the U.S.'s population of approximately 330 million[199] and the study's exclusion of people aged 65 and older, as well as individuals without private insurance,[200] the data can only be viewed as an incomplete estimation and appears to lack information on claim denials and appeals.

Finally, LymeDisease.org publishes important studies on access to treatment and the burden of care for Lyme disease patients, but data is limited to patients who enroll in MyLymeData voluntarily, and thus only provides a snapshot of the larger national issue.[201]

National legislation, which matches Maine's insurance reporting requirements, is the only viable solution to harness an accurate count of Lyme disease diagnoses. Mandating data on the number of Lyme disease claims, claim denials, and appeals from insurance companies, Medicare, and Medicaid, will hold insurance companies accountable and provide a more accurate count of people who are diagnosed, treated, and denied coverage. Further, the proposed legislation will fill information gaps

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[195] Inst. of Med., *Living Well with Chronic Illness: A Call for Public Health Action*, 180 MIL. MED. 485, 486 (2015) [hereinafter *Living Well with Chronic Illness*].

[196] *How Many People Get Lyme Disease?*, *supra* note 21.

[197] Lorraine Johnson, *How Much Does the CDC Undercount Lyme Cases? It Depends on Where You Live*, LYMEDISEASE.ORG (Feb. 2, 2021), https://www.lymedisease.org/cdc-lyme-disease-cases-undercount/?fbclid=IwAR14kZJXotZgvwrNFT3LTuH_jvLpvTngBtSRihB01zrJwHei0IeXu9a07bw [https://perma.cc/W6PV-2ZK2]; *see also* 2ND REPORT TO CONGRESS, *supra* note 25, at 91.

[198] Kiersten J. Kugeler, Amy M. Schwartz, Mark J. Delorey, Paul S. Mead & Alison F. Hinckley, *Estimating the Frequency of Lyme Disease Diagnoses, United States, 2010–2018*, 27 EMERGING INFECTIOUS DISEASES 616, 616 (2021) [hereinafter *Estimating the Frequency*].

[199] *U.S. and World Population Clock*, U.S. CENSUS BUREAU (Jan. 23, 2021), https://www.census.gov/popclock/ [https://perma.cc/LSC3-QFYR].

[200] *Estimating the Frequency*, *supra* note 198, at 616.

[201] *See* MYLYMEDATA REGISTRY, *supra* note 61, at ii, 24.

identified by the CDC. [202] Without data on claim denials, the government will be unable to pursue insurance companies who fail to comply with part one of this legislation.

B. National Problems Require National Solutions

While some may argue that states are more equipped to handle insurance related needs than the federal government, federal legislation on insurance mandates for specific illnesses do exist, and have increased over the years.[203] For example, federal law requires insurance companies to cover reconstructive surgery after mastectomies, hospital stays post birth for a minimum amount of time, and mental health needs equivalent to physical health needs, in addition to the expanded requirements under the Affordable Care Act.[204] Further, since Lyme disease patients live in all fifty states,[205] the current state legislation found in only eight states is woefully inadequate to help the hundreds of thousands of people who are diagnosed each year throughout the country. Federal legislation will afford all Lyme disease patients equal access to insurance coverage, regardless of their geographic location or insurance type, and will smooth out inconsistencies currently seen in state legislation.[206]

A federal mandate like this is not unprecedented. The Women's Health and Cancer Rights Act, Section 1185b of ERISA, requires coverage for reconstructive surgery of both breasts following a mastectomy for symmetrical appearance.[207] The Legislative hearing on the Women's Health and Cancer Rights Act of 1997 provides insight into why Congress believed federal, rather than state law, was necessary to provide such coverage.[208] Senator D'Amato testified that an identical bill was passed in the New York State Legislature, but because ERISA preempts state laws for healthcare covered by employer paid plans, a full 40% of the insured population did not receive benefits from the state law.[209] Similarly, ERISA law likely preempts state insurance laws on Lyme disease for some patients. In addition, because most cases of Lyme disease occur in specific regions of the U.S., patients in states with lower incident rates are less

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[202] *Estimating the Frequency*, *supra* note 198, at 618 ("Further studies of coding patterns and improved access to and use of electronic health records could fill . . . data gaps, enabling more robust and precise estimates in the future.").

[203] *See* NICOLE HUBERFELD, ELIZABETH WEEKS, KEVIN OUTTERSON, THE LAW OF AMERICAN HEALTH CARE 223 (2nd ed. 2018).

[204] *Id.*

[205] Searing, *supra* note 22.

[206] *See generally* Hoffman, *supra* note 159, at 240.

[207] 29 U.S.C. § 1185b.

[208] *See Women's Health and Cancer Rights Act of 1997: Hearing on S. 249 Before the Subcomm. on Health Care*, 105th Cong. 6 (1997) (statement of Sen. Alfonse D'Amato).

[209] *Id.*

likely to successfully campaign for legislative insurance coverage because Lyme disease may not be a priority for their states' legislature.

Additionally, under the Mental Health Parity Act, Congress ensures people with mental health (MH) and substance use disorders (SUD) receive comparable medical care to people with other forms of illness.[210] The Act mandates that insurance companies, who provide MH and SUD coverage, provide as much coverage for MH and SUD as they do for any other medical or surgical procedure.[211] Cost was one of the major concerns among insurers and employers when the original 1996 law was expanded in 2008, but new research offered evidence that the expanded parity bill would only raise premiums by 0.9%.[212] This new research convinced coverage providers that the federal mandate would not be cost prohibitive.[213] Insurance providers are likely to have similar cost concerns over the coverage of Lyme disease treatment, but monthly premiums may only increase by 0.02% per year if long term antibiotic treatment for Lyme disease were covered, per a Massachusetts study.[214]

The proposed Lyme insurance law is like the Mental Health Parity Law in many ways. First, the Parity Law requires almost all insurance plans to follow the Federal Parity Law including small and large employers, individual, Children's Health Insurance Program (CHIP), government employer, and some Medicaid plans.[215] The vast coverage pool is important to achieve maximum benefits for a large portion of the population, a similar concern for Lyme disease patients. Second, the federal Parity Law requires full coverage of prescription drugs equal to those provided for medical or surgical reasons.[216] Full prescription drug coverage is essential for Lyme patients because they are often denied coverage for antibiotics after a certain amount of time, regardless of the success of treatment. For comparison, similar denial of medication for patients with other chronic infectious diseases, like HIV, would be unheard of.[217] The similarities between the Parity Law and the proposed Lyme disease insurance coverage law show why an insurance mandate for Lyme is well within Congress's power to mandate.

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[210] *See* 29 U.S.C. § 1185a(a)(1)(A), (B).

[211] *Id.*

[212] Colleen L. Barry, Haiden A. Huskamp & Howard H. Goldman, *A Political History of Federal Mental Health and Addiction Insurance Parity*, 88 MILBANK Q. 404, 413–14 (2010).

[213] *Id.* at 414–15.

[214] MANDATED BENEFIT REVIEW OF H.B. 989: AN ACT RELATIVE TO LYME DISEASE TREATMENT COVERAGE, CTR. FOR HEALTH INFO. & ANALYSIS 2 (2014).

[215] HEALTH INSURANCE FOR ADDICTION & MENTAL HEALTH CARE, LEGAL ACTION CTR.10 (2016).

[216] *Id.* at 20.

[217] Davidsson, *supra* note 93, at 41.

Congress is willing and able to create federal insurance mandates for specific illnesses when it sees the need. Lyme disease insurance laws at the state level are ineffective for two reasons. First, due to preemption by ERISA, many patients will fall through the cracks, as Senators from New York found after a full 40% of their state's population did not receive benefits from the reconstructive surgery post mastectomy state law.[218] Second, a lack of legislative interest in states with perceived low-incidence rates means that Lyme patients in those states will be discriminated against by insurance companies based solely on their current geographic location. Federal legislation will remove restrictions based on geographic locations and will likely result in nominal changes in costs of coverage as seen in the Massachusetts study.[219]

Without specific federal legislation addressing the discrimination of patients with Lyme disease by insurance companies, insurance companies will continue to deny medical treatment to chronic Lyme disease patients. Federal legislation is therefore necessary to ensure that Lyme disease patients receive insurance coverage, whether it be through private insurance or government subsidized plans.

VIII. CONCLUSION

As the medical industry continues to debate the scientific aspects of Lyme disease, thousands of patients, particularly chronically ill patients, fight their illness with little to no help from health insurance providers. Without federal legislation to ensure access to reimbursement, most patients will continue to face financial challenges, and some will be forced to discontinue treatment, which can have fatal consequences, as illustrated by Ms. Logan's story. Therefore, Congress has a duty to Lyme disease patients to pass comprehensive Lyme disease insurance coverage legislation. By creating insurance mandates for all treatment and doctors' visits, even if they are considered experimental, insurance companies will no longer be able to discriminate against Lyme disease patients. In addition, by mandating that insurance companies report claims and denials to Congress, the U.S. government will finally have an accurate understanding of the number of people suffering from the illness, the true cost of Lyme disease, and an enforcement mechanism to ensure compliance.

The Institute of Medicine proclaims: "living with chronic illnesses has not been given the attention it deserves by health care funders, health

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[218] *Women's Health and Cancer Rights Act of 1997: Hearing on S. 249 Before the Subcomm. on Health Care*, 105th Cong. 6 (1997) (statement of Sen. Alfonse D'Amato).

[219] *See* MANDATED BENEFIT REVIEW OF H.B. 989: AN ACT RELATIVE TO LYME DISEASE TREATMENT COVERAGE, CTR. FOR HEALTH INFO. & ANALYSIS 2 (2014).

systems, policy makers, and public health programs and agencies."[220] Now is the time for the federal government to act.

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[220] *Living Well with Chronic Illness*, *supra* note 195, at 487.