# THEY SHALL NOT BE LEFT TO ROT: THE EMERGING LAW OF LYME DISEASE

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* J.D. University of Michigan; B.S. Economics, Major in Finance, Wharton School, Undergraduate Division, University of Pennsylvania. I am grateful to *Belmont Law Review* for the opportunity to critique laws designed to redress health care problems presented by Lyme disease. Despite a pervasive presence and severe symptoms, Lyme disease is widely misunderstood by the medical community and too often goes untreated or improperly treated. While we await advances in medical science, the law can help those who suffer. I recognize and thank the International Lyme and Associated Diseases Society and its many contributors, who have deepened my understanding of medical problems associated with Lyme disease. These insights have influenced positively the form of the work I now submit.

## INTRODUCTION

This article critiques laws designed to redress healthcare problems presented by Lyme disease. Lyme disease has existed for over five thousand years,[1] but was not medically classified until the early 1980s. Lyme disease is difficult to detect and treat. Symptoms are persistent and severe. These debilitating symptoms often result in disability, unemployment, discrimination in education and employment, inability to conduct normal family life, and social alienation. The medical community largely misunderstands Lyme disease, and the disease often goes untreated or improperly treated. There is a continual shortage of physicians skilled in treating Lyme disease. Laws have been enacted at the Federal and state levels to address these shortcomings, and this article will analyze the efficacy of these laws' attempts to improve conditions for those who suffer from Lyme disease. This article proceeds in three sections. Section I describes Lyme disease and why it is medically controversial. Section II discusses how the law has treated problems associated with Lyme disease. Section III critiques existing law and identifies unresolved legal problems.

1. BRIAN A. FALLON & JENNIFER SOTSKY, CONQUERING LYME DISEASE 11 (2018).

This article draws two principal legal conclusions: First, the inconsistency of state Lyme disease laws means patients in many states will continue to experience inadequate care and staggering medical expenses. Appropriate state legislation (outlined below) will help address this problem, but does not fully solve it. State law solutions, while helpful, have flaws. Second, by adversely influencing the scientific and medical communities, free from legal and ethical constraints, the United States Centers for Disease Control and Prevention ("*CDC*") and the Infectious Disease Society of America ("*IDSA*") have worsened problems associated with Lyme disease. Accordingly, the CDC and IDSA will stand as stumbling blocks to progress against the disease. Experience and the passage of considerable time have demonstrated the IDSA and CDC positions to be intractable. Legislation and litigation have not yet changed these positions. As the discussion that follows will show, this means doctors will continue to refuse to both treat Lyme patients and educate themselves about the disease. An effective legal counterweight to these forces does not yet exist. Federal laws now on the books, though helpful, will not solve this problem.

## I. WHAT IS LYME DISEASE AND WHY IS IT MEDICALLY CONTROVERSIAL?

### A. What is Lyme Disease?

Lyme is a multisystem[2] infectious disease spread through microbes and is medically classified as *Borrelia Burgdorferi*. Lyme spreads when a certain species of tick[3] attaches to a mammalian host.[4] This tick species maintains a presence in much of the United States, with a large concentration in the Northeast and upper Midwest, where the majority of reported cases occur. Ticks that have acquired Lyme disease by feeding on a mammal's blood (typically a mouse or a deer) will spread this disease to human hosts. Ticks may also attach to birds, which means the disease is susceptible to the geographic spread now occurring. Ticks may inflict disease at all three stages of their development: larvae, nymph, and adult. Tiny larvae and nymphs the size of a poppy seed usually feed without detection, and, even in the case of the adult, the tick's bite locally

2. This would contrast to localized diseases such as Chronic Obstructive Pulmonary Disease, commonly known as *COPD.*

3. The *Ixodes scapularis* or deer tick is proven to transmit Lyme disease. Others known to transmit tick-borne diseases include the *Amblyomma americanum* or lone star tick and the *Dermacentor variabilis* or dog tick.

4. This article does not discuss whether Lyme disease can be sexually or gestationally transmitted, contracted through breast milk or the blood supply, or transmitted by mosquitoes, fleas and spiders. The science in these areas is unresolved and the vast majority of cases occur through the bite of a deer tick.

anesthetizes its victim, making initial detection challenging. At the same time, ticks secrete an anticoagulant that enables uninterrupted feeding. Because of the way Lyme disease is spread, it is classified as a vector-borne illness. Based on 2016 data, the disease is the most common[5] vector-borne illness and the sixth most common of all nationally-identifiable diseases.[6] The CDC estimates more than 300,000 Lyme disease cases are diagnosed each year.[7]

The debilitating symptoms of Lyme disease include extreme fatigue, headaches, neuropathy, mood swings, skin rashes, facial palsy, joint pain, muscle pain, hyperacuities and hypersensitivities to sound and light, fever, night sweats, urticaria (hives), meningitis, carditis, brain fog, flu-like symptoms, and insomnia.[8] These symptoms demonstrate typically a level of pain equivalent to one experiencing congestive heart failure or one having just undergone surgery and a level of fatigue similar to multiple sclerosis.[9] Using questions developed by the CDC and the Agency for Healthcare Research, a patient survey, "Severity of Chronic Lyme Disease Compared to Other Chronic Conditions: A Quality of Life Survey,"[10] contains some notable information. The survey collected the percentage of certain disease populations, reporting their health as "fair or poor," and arrived at the following:

General Population: 16%

Depression: 32%

Multiple Sclerosis: 37%

Diabetes: 46%

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5. Unless otherwise noted, statistics derive from experience in the United States and not the rest of the world. Lyme disease is present outside the United States and many cases have been detected in, among other places, Canada, Europe, Australia and Asia.

6. TICK-BORNE DISEASE WORKING GROUP 2018 REPORT TO CONGRESS 14 (2018) [hereinafter WORKING GROUP REPORT].

7. FALLON & SOTSKY, *supra* note 1, at 1, 24, 29 (page 1 lists this number at 330,000 and page 29 at 300,000); *Lyme Disease: Data and Surveillance*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/lyme/datasurveillance/index.html [https://perma.cc/2MJX-PUC7].

8. FALLON & SOTSKY, *supra* note 1, at 30, 31, 35, 36, 37, 38, 45, 52.

9. FALLON & SOTSKY, *supra* note 1, at 105–06; Lorraine Johnson & Dr. Elizabeth Maloney, The Ad Hoc Patient and Physician Coalition Comments of [sic] the IDSA Proposed Lyme Guidelines 8 (2019) [hereinafter Coalition Comments].

10. LORRAINE JOHNSON, MYLYMEDATA: 2019 CHART BOOK 9 (2019), https://www.lymedisease.org/2019-mylymedata-highlights.pdf [https://perma.cc/529A-PNQ7] [hereinafter Registry Report].

Fibromyalgia: 59%

Congestive Heart Failure: 62%

Chronic Lyme Disease: 72%[11]

At the onset of the disease, an infected person may develop a skin rash, often shaped like a bullseye, called an erythema migrans ("*EM*") rash.[12] However, in many cases, infected persons never display any rash. Antibiotics comprise the standard treatment for Lyme disease. Antibiotics may worsen Lyme symptoms when, in the process of killing off Lyme microbes, the body releases inflammatory molecules called cytokines. This worsening of symptoms caused by cytokines is called a Jarisch-Herxheimer reaction.[13] The inflammation caused by the cytokines causes pain and can actually impede recovery by breaking down tissues.[14]

Lyme disease microbes have a corkscrew shape with heads and tails (flagella). These motile microbes, referred to as spirochetes, may occupy the blood stream, heart, brain, spinal column, nervous system, and other bodily organs and tissues. Spirochetes may occupy cell walls or take intracellular form; they may also form protective biofilms and can assume a dormant state. The protected microbes are especially resistant to antibiotics. A person may carry the disease in this manner for long periods of time while the microbes are in a quiescent state, only to become ill after the microbes become active.[15] These disease locations and forms make Lyme disease especially difficult to eradicate, and each form may require a different treatment protocol.

Lyme disease law originates in part from patients' undue suffering, and this undue suffering results from the diverging views of health care professionals, the CDC, and influential medical societies. These experts disagree on whether an illness with Lyme-like symptoms over a longer term evidences an altogether different illness. Medical studies demonstrate that administering antibiotics over a few weeks often fails to cure Lyme disease.[16] Many experts identify a meaningful percentage of Lyme patients

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11. *Id.*

12. *Lyme Disease (Borrelia burgdorferi) 2017 Case Definition*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://wwwn.cdc.gov/nndss/conditions/lyme-disease/case-definition/2017/ [perma.cc/5T2A-KRNG] [hereinafter *2017 Case Definition*].

13. RICHARD I. HOROWITZ, WHY CAN'T I GET BETTER? 98 (COLUM. U. Press 2013).

14. WILLIAM RAWLS, UNLOCKING LYME 59 (2017).

15. FALLON & SOTSKY, *supra* note 1, at 45.

16. FALLON & SOTSKY, *supra* note 1, at 11–13.

that exhibit symptoms lasting months or years.[17] This condition is referred to as "post treatment Lyme disease syndrome" ("*PTLDS*"), "persister Lyme," "late Lyme," or "chronic Lyme disease."[18] These terms have not gained complete medical acceptance and have been rejected, constrained, differentiated, parsed, or minimized by certain segments of the medical community. Some professionals use only ambiguous terms such as "late Lyme" and eschew other labels. The IDSA takes a mechanistic, time-measured approach to unsolved Lyme cases and recognizes only PTLDS to include patients who have been (in the IDSA view) adequately treated with antibiotics and remain symptomatic.[19] The CDC largely aligns its view with the IDSA. The CDC describes PTLDS as a scientifically-unexplained phenomenon and cites a long list of studies that conclude PTLDS should not be treated with long-term (generally beyond four weeks) antibiotics.[20] The CDC makes and influences public policy with respect to infectious disease, and these views affect everything from medical practice to health insurance coverage determinations. As the discussion below will demonstrate, the CDC's and the IDSA's impact on the medical community has prompted emerging legal reforms and will foment the need for additional legal redress. To understand the legal implications, the reader should understand neither the IDSA nor the CDC recognizes "chronic Lyme disease" as a medical term or a medical condition.[21] IDSA expresses this view most clearly and dramatically in the Draft *Clinical Practice Guidelines by the Infectious Disease Society of America, American Academy of Neurology and American College of Rheumatology: 2019*

17. FALLON & SOTSKY, *supra* note 1, at 59 (estimating five to twenty percent of patients suffer for months or years); The International Lyme and Associated Diseases Society estimates that 40% of Lyme disease patients do not respond to short-term antibiotics and even the most conservative estimates place the percentage of unresponsive patients in the vicinity of 20%.

18. FALLON & SOTSKY, *supra* note 1, at 59.

19. RAWLS, *supra* note 14, at 30.

20. *Lyme Disease: Post-Treatment Lyme Disease Syndrome*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/lyme/postlds/ [https://perma.cc/SD9X-G9XG].

21. LANTOS ET AL., DRAFT CLINICAL PRACTICE GUIDELINES BY THE INFECTIOUS DISEASES SOCIETY OF AMERICA (IDSA), AMERICAN ACADEMY OF NEUROLOGY (AAN), AND AMERICAN COLLEGE OF RHEUMATOLOGY (ACR): 2019 GUIDELINES FOR THE PREVENTION, DIAGNOSIS AND TREATMENT OF LYME DISEASE 63 (2019), https://www.idsociety.org/globalassets/idsa/practice-guidelines/lyme/draft-lyme-disease-guidelines.pdf [https://perma.cc/BAK4-7W26] [hereinafter Draft Practice Guidelines] (stating that IDSA does not recognize chronic Lyme Disease); *Lyme Disease: Lyme Disease Frequently Asked Questions (FAQ)*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/lyme/faq/index.html [https://perma.cc/85B3-P7JG] (click on the plus sign to the right of the question "What is chronic Lyme disease?") (stating that the CDC does not recognize chronic Lyme Disease).

*Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease*.[22] These Draft Practice Guidelines state: "Thus, our current body of clinical literature does not support the hypothesis that persistent symptoms should be interpreted as clinical infection, or that antibiotic re-treatment is safe and effective."[23]

The recognition of Lyme disease in a chronic form or the lack thereof has immense societal implications. It will influence the level of investment in cures, treatment, and testing. It will also determine whether patients who suffer should bear treatment costs, or if, like most other serious diseases, private health insurers, Medicare, and Medicaid should shoulder these costs. The cost to society of Lyme disease in its chronic form is ten times higher than the cost when viewed as a mere acute infection, easily and quickly cured by antibiotics.[24] This state of affairs also places a premium on early detection to avoid the staggering costs often experienced when the disease is undetected and prolonged. This article will identify why, under present medical methods, early detection is often very problematic and unreliable.

### B. Lyme Disease Detection and Diagnosis

This subsection explores some of the problems with Lyme disease detection and diagnosis. These problems have wide ranging effects, including worsening of a potentially otherwise-treatable illness, improper diagnosis (resulting in improper treatment), and evidentiary challenges in proving Lyme disease in litigation. As noted, an EM rash often does not appear in an infected patient, and debilitating symptoms may surface much later. In cases where Lyme disease is suspected, there is a two-tiered testing regimen.[25] The first test, the enzyme-linked immunosorbent assay (*"ELISA"*), must test positive for the patient to proceed to the second test, the Western Blot.[26] Neither test detects the presence of microbes causing the disease. Instead, they detect the antibodies that respond to the infection. Because only certain antibodies respond to Lyme disease, the presence of these antibodies determines the presence of the infection.[27] Among the problems with this approach is disagreement on which antibody responses actually evidence Lyme disease. More fundamentally, an infected patient

22. Draft Practice Guidelines, *supra* note 21, at 64.

23. Draft Practice Guidelines, *supra* note 21, at 63.

24. HOROWITZ, *supra* note 13, at 56.

25. WORKING GROUP REPORT, *supra* note 6, at 21.

26. Paul Mead, Jeannine Petersen & Alison Hinckley, U.S. Ctrs. for Disease Control & Prevention & U.S. Dep't of Health and Human Servs., *Morbidity and Mortality Weekly Report: Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease*, 68 MMWR 32, 703 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a4-H.pdf [https://perma.cc/WB2T-5DUZ].

27. FALLON & SOTSKY, *supra* note 1, at 64.

may not show an antibody response at all if his or her immune system fights off the infection. This will result in the false negatives commonplace in Lyme testing. Conversely, someone who long ago suffered the infection and recovered may register a positive response when showing no symptoms due to the lingering presence of antibodies.[28]

To measure the efficacy of testing, medical science has arrived at two metrics: sensitivity and selectivity.[29] Sensitivity is the ability of the test to accurately detect everyone who has the disease. Selectivity measures the extent to which the test detects only those with the disease and excludes false positives. For example: in a test of 100, only two patients actually have the disease. If the test shows positive results for all 100 subjects, the test has perfect sensitivity but atrocious selectivity. Both the ELISA and Western Blot have poor sensitivity.[30] Sensitivity is a major problem when it comes to Lyme disease. There is proof that less than half actually-infected patients test positive for Lyme disease.[31] Among the reasons for poor sensitivity is the timing of the testing in relation to the course of the infection and the manifestation of symptoms.[32] The false negatives associated with the poor sensitivity cause suffering among the patient population, which often moves from expert to expert in a vain search for a cure.

Within the universe of antibodies tested in the Western Blot, there are two sub-classifications denoted as immunoglobins (*Ig*), and these are expressed in relevant part as "IgG" and "IgM." Both IgG and IgM are organized into bands and measured separately for purposes of determining the presence of Lyme disease. IgM manifests an acute infection, and IgG manifests a later acute or chronic infection.[33] However, patients may display IgM even after long stretches of disease symptoms. The bands that measure the antibody response contain a numeric assignment that corresponds to molecular weight measured in kilodaltons. There are three relevant IgM bands and ten relevant IgG bands. Under CDC surveillance criteria, in order to test positive for Lyme disease, the patient's Western Blot results must show the presence of at least five of ten IgG bands and/or two of three IgM bands.[34] Surveillance criteria is used for reporting of infectious disease and is not intended to establish standards of medical

28. *Id.*

29. M. M. G. Leeflang, *Systematic Reviews and Meta-Analyses of Diagnostic Test Accuracy*, 20 CLINICAL MICROBIOLOGY AND INFECTION 105, 105–06 (2013).

30. LymeDisease.org, *Raphael Stricker, M.D. Speaking at IDSA LD Review Hearings July 30, 2009*, YOUTUBE (July 6, 2015), https://youtu.be/BSxLfkoY8Po [https://perma.cc/4ED4-7BDD].

31. FALLON & SOTSKY, *supra* note 1, at 65.

32. FALLON & SOTSKY, *supra* note 1, at 66.

33. RAWLS, *supra* note 14, at 124.

34. FALLON & SOTSKY, supra note 1, at 73; HOROWITZ, *supra* note 13, at 61–62; RAWLS, *supra* note 14, at 128; 2017 Case Definition, supra note 12.

practice. Surveillance criteria relies solely on serologic testing and considers symptoms to be irrelevant. Nevertheless, the CDC surveillance criteria influence diagnostic and treatment events as well as health insurance determinations.[35] Estimates vary, but some have concluded the CDC surveillance criteria and the practices they foster result in one in five patients having Lyme disease evading detection when the disease actually exists.[36] These patients must suffer in silence or flail for a solution. Some contend that the failure to detect true positives is much higher; some estimate as high as forty percent.[37] Even CDC experts have acknowledged the inaccuracy of the two-tiered testing regimen, especially in the early stages of the disease.[38] In early stages, it can take four to six weeks after introduction of the infection for the antibodies to appear. The unfortunate reality is the disease is not often detected enough in the early stages when a cure is most readily available. A paradox exists through the poor detection in early stages, followed by improved accuracy in the late stages where the very existence of disease is denied in many quarters. There is a paradox because one cannot say that testing in late stages is improved and, at the same time, deny the very existence of the disease at late stage. Problems arise because treatment is more efficacious at early stages where detection failure rates are highest. This assures a pipeline of hard-to-cure chronic Lyme sufferers who too often are then told there is nothing wrong or are treated but do not improve.

Testing measures only certain bands thought to evidence Lyme antibodies. There is controversy whether certain additional bands that also detect Lyme disease have been excluded,[39] casting more doubt on the sensitivity of the test. Even if the test includes all the right bands, present testing technology may not pick up antibodies because they fail to attach to the material designated to collect the antibody known as a laboratory substrate.[40] If the patient is testing while being medicated with antibiotics, these medications may blunt the immune system response, meaning the test will not detect antibodies even when the patient is quite ill.[41] A final factor

35. FALLON & SOTSKY, *supra* note 1, at 111.

36. FALLON & SOTSKY, *supra* note 1, at 325.

37. PAMELA WEINTRAUB, CURE UNKNOWN: INSIDE THE LYME EPIDEMIC 119 (2013).

38. *HHS Federal Research Updates on Lyme Disease Diagnostics: Update on Tickborne [sic] Disease Diagnostics – 2017*, CTRS. FOR DISEASE CONTROL AND PREVENTION (June 8, 2017), https://www.cdc.gov/lyme/diagnosistesting/HHS-research-updates.html [perma.cc/3529-Z5QY]; this presentation involves CDC panelists who expressly disclaim its contents as expressing the views of CDC. Nevertheless, the relevant fact is the panelists hold positions of importance with the CDC pertaining to the subject matter.

39. WEINTRAUB, *supra* note 37, at 10.

40. WEINTRAUB, *supra* note 37, at 116.

41. WEINTRAUB, *supra* note 37, at 305.

impairing accuracy is the existence of at least a dozen species of Borrelia that can cause Lyme disease and hundreds of strains.[42] Yet, testing usually only detects Borrelia Burgdorferi.[43]

Despite the problems discussed in the preceding paragraph, the IDSA assigns near touchstone significance to the two-tiered serologic Lyme testing regime and finds nothing to quarrel with relative to the sensitivity or selectivity of tests. The Draft Practice Guidelines state: "IgG seronegativity in a patient with prolonged symptoms (months to years) essentially rules out the diagnosis of Lyme disease, barring laboratory error or a rare host immune deficiency affecting humoral immunity."[44]

Because of unreliable testing and symptoms that mimic other ailments, Lyme disease is often confused and misdiagnosed as fibromyalgia, chronic fatigue syndrome, lupus, arthritis, multiple sclerosis, psychiatric disorders, and other diseases.[45] In addition to unreliable testing, misdiagnosis may result both from lack of reliable testing and the effects that Lyme has on the immune system, causing a diagnosis of autoimmune disease of various types.[46]

## C. Lyme Disease Treatment Regimens

### *1. IDSA v. ILADS*

There is an important disagreement between medical societies as to the appropriate treatment regimens for Lyme disease. While the IDSA recognizes that the choice of antibiotic depends on a variety of circumstances,[47] it generally recommends that "patients with [an] EM [rash] be treated with either a 10-day course of doxycycline or a 14-day course of amoxicillin, cefuroxime axetil or phenoxymethylpenicillin *rather than longer treatment courses*."[48] IDSA's insistence on limiting antibiotic treatment furnishes grounds for insurance companies to deny coverage for long-term antibiotic treatment and for medical licensing boards to discipline physicians who prescribe such treatments.[49] Contrasted to the IDSA approach is that of the International Lyme and Associated Diseases Society ("*ILADS*"). ILADS views the Lyme treatment decision as a series of

42. RAWLS, supra note 14, at 119; WEINTRAUB, *supra* note 37, at 118.

43. RAWLS, *supra* note 14, at 119; IGeneX Inc. has developed an immunoblot test that measures a variety of Lyme species. *The Best Test for Lyme Disease*, IGENEX INC., https://igenex.com/tick-talk/the-best-test-for-lyme-disease/ [https://perma.cc/53HQ-KY77].

44. Draft Practice Guidelines, *supra* note 21, at 10.

45. HOROWITZ, *supra* note 13, at 57.

46. HOROWITZ, *supra* note 13, at 57–58.

47. Draft Practice Guidelines, *supra* note 21, at 13.

48. Draft Practice Guidelines, *supra* note 21, at 30 (emphasis added).

49. Coalition Comments, *supra* note 9, at 7.

tradeoffs between the benefits of treatment and their associated harms.[50] When this article refers to the "ILADS view," or like terms, it will most often be referring to the position expressed by ILADS as part of a coalition of Lyme-disease-related medical societies. ILADS reviews outcomes critically important to patients under the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) system.[51] In the context of Lyme disease patients, this can be largely reduced to four outcomes critical to patients that should be considered when making a treatment decision. These outcomes include: (1) quality of life, by any validated measure; (2) cure (resolution of symptoms); (3) reduction of clinical symptoms; and (4) avoidance of relapse.[52] The IDSA position proscribing long-term (beyond a few weeks) antibiotic treatment is "strong," meaning it should be followed largely without exceptions.[53] ILADS' critique of this position is that it does not comport with GRADE standards. ILADS takes the view that rather than a "strong" recommendation, a "weak" recommendation is called for.[54] A weak recommendation, "is called for when: the gradient between benefits and harms is narrow or unclear, the evidence quality is low, and patient values and preferences vary significantly or are uncertain." [55] Because the Lyme diagnostic and treatment protocols frequently fail, the ILADS' position provides that greater flexibility must enter into the treatment decision.[56] Specifically, this would mean a patient who becomes symptomatic after removal of antibiotics, under the IDSA guidelines, would be able to continue his or her medications for a more indefinite period with the GRADE standards in mind. The use of antibiotics beyond a typical regimen of a few weeks is not the only point of difference between IDSA and ILADS, but it is among the most visible and the most impactful on the patient community.

In an environment of evolving and unsettled science, under the ILADS approach, patients would receive treatment options. The experience with cancer offers some analogues. Someone diagnosed with prostate cancer may pursue several options, including watchful waiting, surgery, radiation, and hormone replacement therapy. Likewise, a breast cancer patient may have the choice between a mastectomy or lumpectomy, together with other options. IDSA guidelines offer no such treatment options and rest on the false assumption that Lyme disease is easy to diagnose and easy to cure.

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50. Coalition Comments, *supra* note 9, at 22.

51. Brian P. Kavanagh, *The GRADE System for Rating Clinical Guidelines*, PLOS MEDICINE, Sept. 15, 2009, at 1; Coalition Comments, *supra* note 9, at 17.

52. Coalition Comments, *supra* note 9, at 17.

53. Coalition Comments, *supra* note 9, at 22.

54. Coalition Comments, *supra* note 9, at 23–24.

55. Coalition Comments, *supra* note 9, at 34–35.

56. Coalition Comments, *supra* note 9, at 23.

At bottom, the IDSA relies on a select group of scientific studies to form its treatment guidelines, ignoring many important studies. Tellingly, IDSA and its allied medical societies lack any credible representation by Lyme disease patients and the physicians who treat them. A number of explanations beyond science have been posited for IDSA's stern and rigid views, including economic interests in patents held by its panelists and protection of insurance industry consulting fees and expert witness fees in support of Lyme denial in litigation.[57] IDSA's denial of the existence of chronic Lyme disease heightens both the apprehension of and exposure to medical malpractice liability arising from failure to detect the disease or failure to improve the patient's condition.[58] One patient's experience with an infectious disease specialist at Northwestern Memorial Hospital in Chicago dramatizes this attitude. When asked if the physician would take the case, the physician's assistant answered the call and asked the patient's mother how long the patient had suffered the illness. The patient's mother could not answer with any certainty, so the physician's assistant replied with the question: "Has he had this for more than six weeks?" When the patient's mother responded affirmatively, the physician's assistant said that the medical office could not help due to the time span the patient had suffered the illness. After testing positive for both Lyme disease and Q fever, that same patient later sought infectious disease care in Texas. The physician there told him she would treat his Q fever, but not his Lyme disease. These examples dramatize the "let them rot" attitude displayed by many physicians and medical practices, some at respected, flagship institutions.

*2. Coinfections and their Effect on Treatment*

Quite often, a patient suffering from Lyme disease experiences concomitant additional illnesses called co-infections, also spread by various species of ticks. Among other things, these may include babesia, bartonella, ehrlichiosis, anaplasmosis, tularemia, Q Fever, Epstein-Barr virus, Powassan virus, and rickettsia (Rocky Mountain Spotted Fever).[59] This complicates both diagnosis and treatment.[60] For example, babesia is a parasitic disease similar to malaria and is treated with different medications than Lyme, so the medication that may eradicate Lyme disease may have

57. Plaintiffs' First Amended Complaint at 20, Torrey v. Infectious Diseases Society of America, No. 5:17-cv-00190-RWS (E.D. Tex. Mar. 25, 2019) [hereinafter Complaint] ("Several of the [IDSA] panelists, however, subsequently disclosed financial interests in drug companies, Lyme disease diagnostic tests, patents, and consulting arrangements with insurance companies."); Weintraub, supra note 37, at 357.

58. HOROWITZ, *supra* note 13, at 13–14.

59. HOROWITZ, *supra* note 13, at 110, 112, 121, 128, 143, 155, 156.

60. HOROWITZ, *supra* note 13, at 109, 134.

little or no effect on the various co-infections. The co-infections also strain and ultimately weaken the immune system, making it more difficult for the patient's immune system to fight Lyme disease. Other tick-borne infections can be quite severe. The recent and sudden death of Senator Kay Hagan (D-N.C.), caused by Powassan virus, dramatizes this reality.[61]

### D. Lyme Disease is not a Research Priority

Despite the large number of cases and disastrous effects on patients and their families, Lyme disease is not a research priority in either the public or private sector. The 2018 Working Group Report to Congress, issued pursuant to the 21st Century Cures Act,[62] acknowledged the discrimination and inattention experienced by Lyme patients and noted that both the CDC and the National Institute of Health ("*NIH*") have underfunded the resources and neglected the priorities that should be applied to Lyme disease. To furnish perspective on these skewed priorities, the NIH and CDC spend $77,355 and $20,293, respectively, per new surveillance case of HIV/AIDS and $36,063 and $11,459 per new case of hepatitis C, but only $768 and $302 for Lyme.[63] The NIH spends 100 times as much per case on HIV/AIDS as Lyme, and the CDC spends sixty-seven times as much per case on HIV/AIDS as Lyme. While untreated HIV/AIDS is more virulent than Lyme, hepatitis C, a disease of comparable virulence with typical symptoms of no greater severity, receives forty-seven times as much from the NIH and thirty-eight times as much from the CDC. While the 2018 Working Group Report had the salutary effect of publicizing these gross and unjustified disparities,[64] these priorities will not change anytime soon without a funding mandate. Private investment has also been stifled by the practical reality that Lyme disease is treated by antibiotics that have been off patent for many years.[65] Pharmaceutical manufacturers concentrated in antibiotics experience pervasive failure.[66] Except for the possibility of a game changing cure, large pharmaceutical concerns will have no incentive to undertake the research investment to address Lyme

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61. Adam Edelman, *Illness linked to tick bite kills ex-N. Carolina Sen. Kay Hagan at 66*, NBC NEWS (OCT. 28, 2019, 12:25 PM), https://www.nbcnews.com/politics/congress/former-north-carolina-sen-kay-hagan-dead-66-n1072891 [https://perma.cc/J7WX-Q6TN].

62. 21st Century Cures Act, 42 U.S.C. § 2062 (2016).

63. WORKING GROUP REPORT, *supra* note 6, at 3.

64. WORKING GROUP REPORT, *supra* note 6, at 4.

65. Kris Newby, *It Felt Like the Flu. It Took 10 Doctors, A Year, and $60,000 to Get an Answer*, VOX (June 25, 2019, 10:55 AM), https://www.vox.com/the-highlight/2019/6/18/18677511/lyme-disease-diagnosis-health [https://perma.cc/456N-5LMZ].

66. Denise Roland, *Antibiotic Makers Struggle, Hurting the War on Superbugs*, WALL ST. J., Jan. 6, 2020, at B.1 col. 4.

disease. Similarly, a vaccine introduced in the late 1990s quickly disappeared from the market over both health and efficacy concerns,[67] and commercialization of a workable vaccine is both distant and uncertain.[68]

## II. LYME DISEASE LEGAL ISSUES

### A. IDSA and CDC Set Treatment Standards

#### *1. Effects on Quality and Availability of Care*

This section sets out existing legal issues surrounding Lyme disease and includes IDSA guidelines and their effect on care. Topics of discussion include antitrust implications, corrective state legislation, caselaw, and corrective federal legislation.

The CDC Lyme disease surveillance guidelines are not guidelines for treatment.[69] However, the surveillance criteria have been assigned near mandatory diagnostic significance by the medical community.[70] This attitude is easy to understand, given that the medical community is largely uneducated about Lyme disease and (for good reasons) has great concerns over malpractice liability. In most jurisdictions, refusal to treat violates no medical code,[71]and physicians can and do shun Lyme patients.[72] This leads to a continual shortage of physicians willing to treat Lyme disease, at great cost to patients.[73] Lyme disease patients face the triple obstacle of much increased medical needs, inadequate services, and insurance reimbursement denials. This is borne out by the statistics presented in the Working Group Report:

> In a 2009-2010 survey of nearly 2,500 chronic Lyme disease patients in the United States with positive laboratory testing and chronic symptoms, 49.5% of respondents reported traveling 51 miles or more to see a treating doctor (Johnson, Aylward, & Stricker, 2011). Half of the respondents reported seeing at least seven physicians

67. WEINTRAUB, *supra* note 37, at 323 (according to Weintraub, Glaxo Smith Kline cited "'poor sales'" as the reason it withdrew the vaccine).

68. WEINTRAUB, *supra* note 37, at 323.

69. *2017 Case Definition*, *supra* note 12, at 60.

70. HOROWITZ, *supra* note 13, at 59–60.

71. WEINTRAUB, *supra* note 37, at 218.

72. FALLON & SOTSKY, *supra* note 1, at 104.

73. Report of the Access to Care Services and Support to Patients Subcommittee to the Tick-Borne Disease Working Group, U.S. Dep't of Health & Hum. Srvs. (May 9, 2018), https://www.hhs.gov/ash/advisory-committees/tickbornedisease/reports/access-to-care-2018-5-9/index.html [https://perma.cc/3TGJ-U4DF].

> before the diagnosis of chronic Lyme disease was made. And most respondents experienced symptoms lasting six months or more despite receiving at least 21 days of antibiotic treatment. The follow-up survey in 2013 indicated that chronic Lyme disease patients made an average of 19.4 doctor visits per year, compared to the general population, which makes on average 3.7 visits (Johnson, Wilcox, Mankoff & Stricker, 2014). As evidenced by the survey results, those who currently have chronic tick-borne disease in the United States are unlikely to receive a proper diagnosis from the first provider they see.[74]

Of course, the IDSA guidelines do not advocate that physicians decline to treat, and, as noted in the findings of the Working Group Report, Lyme patients seek and obtain treatment. However, the treatment is too often ineffectual.[75] A fortunate few find help that resolves their symptoms only after much trial and error and staggering expenses. Noteworthy here is the IDSA's position that actually advocates for treatment, but instead of recommending treatment for Lyme, the IDSA recommends treatment for other ailments such as arthritis. The American Academy of Neurology and the American College of Rheumatology co-sponsor the Draft Practice Guidelines with the IDSA, which offer treatment suggestions helpful to the members of the medical societies and the physicians they represent.[76] For example, the Draft Practice Guidelines take pains to offer suggestions to address "antibiotic refractory Lyme" with anti-rheumatic drugs, biologic agents, intra-cellular steroids, or arthroscopic synovectomy.[77] In stark contrast to the grave concerns about long-term antibiotics, nowhere do the Draft Practice Guidelines discuss safety and the side effects of these procedures and treatments. There is only a general statement of effectiveness, unsupported by medical evidence. This is but one example in which the persons authoring the Draft Practice Guidelines display bias and favoritism to the interests they serve.[78]

Physicians desirous of treating Lyme patients face both professional and economic challenges. State medical boards may challenge a physician's credentials based on a complaint submitted to a licensing board by an insurance company or other party. Reporting may occur by an emergency room physician who obtains medical histories and treatments

74. WORKING GROUP REPORT, *supra* note 6, at 60.
75. WORKING GROUP REPORT, *supra* note 6, at 1–2.
76. Draft Practice Guidelines, *supra* note 21, at 2, 57, 60.
77. Draft Practice Guidelines, *supra* note 21, at 57–58.
78. Complaint, *supra* note 57, at 8–9.

that, on their face, do not make sense.[79] Other conflicting parties include IDSA panelists who jealously guard their medical position in the name of continued employment as expert witnesses in litigation against Lyme patients and in an effort to perpetuate insurance industry consulting fees. Reporting is legally favored and protected. For example, in New York, any person can report professional misconduct.[80] Making this risk of professional discipline especially real and perilous is the fact that the state statutes enable anonymous reporting, with no opportunity to cross-examine the reporting party to determine motives and bias. For example, recent antitrust and racketeering litigation against IDSA and various other defendant co-conspirators, Lyme claimants describe how attempts to subpoena the Texas Medical Board were quashed by the operation of a Texas statute that attaches privileged and confidential status to third party reports to the Texas Medical Board.[81] Many states also immunize from liability anyone who reports to a medical board, even if the information is false and defamatory or given in bad faith.[82] Delaware requires licensees to report violations and immunizes them from liability for reports submitted in good faith (which is presumed) and without gross and wanton negligence.[83] Those Lyme practitioners brave enough to carry on in this environment will find themselves situated differently from other specialists. Unlike other specialists, there is no recognized professional designation for competency in Lyme disease. Within the Lyme community, there is the moniker of the Lyme-literate M.D., but this is not one conferred by established, reviewable professional standards. Indeed, the "Lyme-literate" designation attracts attacks by Lyme naysayers who contend the designation can be earned merely through attendance at a few ILADS conferences and, therefore, lacks rigor.[84]

Insurers will also squeeze physicians treating Lyme disease either directly or indirectly. They may do so directly by terminating their relationship with physicians they deem to be prescribing excessively, even

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79. Carl Schneider has noted that "much of the attack on doctors' reasoning comes from medicine itself." Carl E. Schneider, The Practice of Autonomy: Patients, Doctors and Medical Decisions 106 (1998).

80. N.Y. EDUC. L. § 6510(1)(a) (2020).

81. Complaint, *supra* note 57, at 14–15 (citing TEX. OCC. CODE ANN. § 164.007(c) (2020)).

82. CAL. BUS. & PROF. CODE § 2318 (2020) (any person reporting unprofessional conduct by a board licensee shall not be liable for "any damages in any civil action on account of the communication of the information to the board." There is no exception for false and defamatory reports).

83. DEL. CODE ANN. tit. 24, § 3919(b) (2020).

84. Jann Bellamy, *More Political Science: Proposed Laws Protect "Lyme Literate" Doctors from Discipline*, SCIENCE-BASED MED. (Mar. 15, 2018), https://sciencebasedmedicine.org/more-political-science-proposed-laws-protect-lyme-literate-doctors-from-discipline/ [https://perma.cc/LY49-HZAW].

when the prescriptions are medically necessary.[85] Insurers may indirectly undermine the physician by refusing to pay for prescribed medications.[86] Rejections may occur for submission of incorrect treatment codes or, if a valid treatment code appears, the insurer may deem the treatment "experimental."[87] A typical definition of "experimental" states:

> EXPERIMENTAL/INVESTIGATIONAL SERVICES AND SUPPLIES…..means they use of any treatment, procedure, facility, equipment, drug, device or supply not accepted as Standard Medical Treatment for the condition being treated or any of such items requiring Federal or other governmental agency approval, such approval was not granted at the time services were provided. Approval by a Federal agency means that the treatment, procedure, facility, equipment, drug, device, or supply has been approved for the condition being treated and, in the case of a drug, in the dosage used on the patient.
>
> As used herein, medical treatment includes medical, surgical, mental health treatment, Substance Use Disorder Treatment or dental treatment.
>
> Standard Medical Treatment means the services or supplies that are in general use in the medical community in the United States and have been demonstrated in peer reviewed literature to have scientifically established medical value for curing or alleviating the condition being treated; are appropriate for the Hospital or Other Facility Provider in which they were performed; and the Physician or Other Professional Provider has had the appropriate training and experience to provide the treatment or procedure.[88]

Note the definition of Standard Medical Treatment requires, among other things, that the treatment be in "general use" and "demonstrated in peer reviewed literature to have scientifically established medical value for

85. HOROWITZ, *supra* note 13, at 145; WEINTRAUB, *supra* note 37, at 307.

86. Patti Neighmond, *When Insurance Won't Cover Drugs, Americans Make 'Tough Choices' About Their Health*, NPR (Jan. 27, 2020, 5:05 AM), https://www.npr.org/sections/health-shots/2020/01/27/799019013/when-insurance-wont-cover-drugs-americans-make-tough-choices-about-their-health [https://perma.cc/EW5E-Q5Y8].

87. *Blue Cross Blue Shield of Illinois Policy of Health Insurance IL-I-BC-EX2019*, at 93, https://www.bcbsil.com/policy-forms/2019/SP5H30BCEIILP.pdf [https://perma.cc/F2WA-32HB].

88. *Id.* at 13–14.

curing or alleviating the condition . . . ." This latter requirement of scientific establishment in peer-reviewed literature affords wide latitude to reject coverage for treatments and medications. It is insufficient merely to demonstrate common practice or even to demonstrate efficacy in the field. The treatment must instead be validated by peer-reviewed studies that are frequently biased toward an industry that funds the study or simply do not exist for the relevant topic or problem. Likewise, a treatment or procedure lacking governmental approval will be rejected as "experimental."

*2. Antitrust Implications*

IDSA treatment guidelines influence medical practice and health care reimbursement standards concerning Lyme disease. If the IDSA uses its standards for the benefit of its members who practice medicine concerning Lyme disease patients and insurance companies who issue coverage for those patients, the arrangement may be considered an agreement or conspiracy in restraint of trade. Section 1 of the Sherman Antitrust Act provides "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."[89] A conspiracy in restraint of trade requires: (1) a contract, conspiracy, or concerted action; (2) at least one defendant in the conspiracy acting for the furtherance of the conspiracy; and (3) the agreement constitutes an unreasonable restraint of trade in interstate commerce.[90] To state a claim, plaintiffs should specify the market subject to the conspiracy in restraint of trade.[91]

The first question to address in these circumstances is whether there is any restraint at all. In *Schacher v. American Academy of Opthalmology, Inc.,*[92] physicians brought an antitrust claim against a medical society for issuing a press release urging "patients, ophthalmologists, and hospitals to approach [radial keratotomy] with caution until additional research is completed."[93] The physicians' livelihoods depended in large measure on performing the surgical procedure called radial keratotomy to correct nearsightedness in patients. The physicians contended the press release

89. 15 U.S.C. § 1 (2020).

90. Jung v. Ass'n of Am. Med. Coll., 300 F. Supp.2d 119, 157–58 (D.D.C. 2004); Robinson v. Magovern, 521 F. Supp. 842, 892 (W.D. Pa. 1981), *aff'd*, 688 F.2d 824 (3d Cir. 1982), *cert. denied*, 459 U.S. 971 (1982).

91. Torrey v. Infectious Disease Soc'y of Am., No. 5:17-CV-00190-RWS, 2018 WL 10124894, at *7 (E.D. Tex. Sept. 27, 2018) (citing Wampler v. Sw. Bell Tel. Co., 597 F.3d 741, 744 (5th Cir. 2010)). *Torrey* also includes claims under the Racketeer Influence and Corrupt Organizations Act and this article does not analyze that law as applied to *Torrey* or Lyme-related claims generally.

92. 870 F.2d 397 (7th Cir. 1989).

93. *Id.* at 398.

harmed them and restrained trade. The Seventh Circuit found no restraint because the medical society "did not expel or discipline or even scowl at members who performed radial keratotomies."[94] *Schacher* teaches that, when a trade association furnishes its seal of approval but does not constrain others to follow its recommendation, it does not violate antitrust laws. An organization's towering reputation does not preclude it from speaking out on matters it considers important. When challenged, IDSA contends that its guidelines are not mandatory, it has no enforcement power over them, and no control over the acts of its members. This makes IDSA, on the surface, look like the benign practices upheld in *Schacher*. While it is a mixed question of law and fact, there are allegations made in Federal court that insurance companies and physicians view IDSA guidelines as mandatory. Proof exists, among other places, in the proceedings brought to medical licensing boards[95] initiated by insurance companies and IDSA members. IDSA members also serve as experts to uphold the IDSA guidelines both in these proceedings, in correlative malpractice proceedings, and in defending workers' compensation, insurance, and disability claims. Lyme patients suffer from limited choice, diminished service, and limited or nonexistent support from health insurance carriers.[96] The mandatory nature of the IDSA guidelines may be capable of demonstration.

An antitrust claim against IDSA may require a showing that: (1) the IDSA is a trade association of competing physicians; (2) the IDSA guidelines specify the services that can be rendered in the treatment of Lyme disease; and (3) through their mandatory nature, the IDSA guidelines restrict the range of services available to Lyme patients in the market for treatment of chronic Lyme disease. It is not necessary to show that IDSA members benefit economically from the guidelines, although the fact that they do could be relevant to showing motives for restricting services available to Lyme disease patients and participating in a conspiracy. There is a great diffusion and dispersion of impacts on Lyme patients and Lyme-literate M.D.s, ranging from insurance denials, to numerosity in medical visits, to disciplinary actions against Lyme-literate M.D.s. There are real-world examples occurring regularly that necessitate factual inquiry.

Cases arising under Section 1 of the Sherman Act can be classified as those involving *per se* violations and those that should be evaluated under the rule of reason.[97] This antitrust review framework will be

94. *Id.*

95. *See generally* Torrey v. Infectious Disease Soc'y of Am., No. 5:17-CV-00190-RWS, 2018 WL 10124894 (E.D. Tex. Sept. 27, 2018); Complaint, supra note 57. Being privileged, the records of reporting will not be easily accessed.

96. *See supra* notes 69–74 and accompanying text.

97. *Identifying Sherman Act Violations*, U.S. DEP'T OF JUST. ARCHIVES (Nov. 2017), https://www.justice.gov/archives/jm/antitrust-resource-manual-2-antitrust-division-field

meaningful to pleading and discovery, and this is not always clear from the facts available at the outset of the case. Agreements among competing market participants to fix prices, to restrict supply, to tie products or services, or to effectuate group boycotts are *per se* violations.[98] One example might be a hospital's decision not to treat Lyme patients where more than sixty days have passed since their diagnosis. While this is a supply restriction, it is not entirely clear it has arisen as a result of a conspiracy in restraint of trade. A conspiracy to restrict supply would also be required to bring successful antitrust claims against IDSA, certain of its members and insurers denying coverage for Lyme claims.[99] Insurers will contend they do not set IDSA standards; instead, they merely follow them. In this respect, the relationship of IDSA members as consultants paid by the insurance industry and as experts in Lyme disease litigation over health and disability insurance should be relevant. This may support an inference of a reciprocal arrangement constituting a conspiracy under antitrust laws. This is a question of fact, as would be the relationship of IDSA members in testifying before state medical licensing boards. The inference to be made is the IDSA guidelines facilitate the activities from which certain IDSA members and insurers benefit. Likewise, the restriction of physician supply supports the medical and research practices of certain IDSA members.

When the arrangements discussed in the last paragraph merely have an adverse effect on prices or supply, they are evaluated under the rule of reason.[100] To establish restraint of trade liability in rule of reason cases, two criteria must be met: (1) the defendants must have market power and (2) any pro-competitive features of the restraint do not outweigh its anti-competitive characteristics.[101] Challenges under the rule of reason may be made for both collusive and exclusionary conduct.[102] Exclusionary conduct might exist through the operation of the IDSA guidelines, which subject

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offices#:~:text=The%20most%20common%20violations%20of%20the%20Sherman%20Act,as%20describe%20the%20methods%20of%20detecting%20these%20violations [https://perma.cc/SU4W-D9SC].

98. *Elements of the Offense*, U.S. DEP'T OF JUST. ARCHIVES (Nov. 2017), https://www.justice.gov/archives/jm/antitrust-resource-manual-1-attorney-generals-policy-statement [https://perma.cc/B6QD-9K56].

99. *IDSA Violates Lyme Antitrust Settlement Agreement with Connecticut Attorney General*, LYME DISEASE ASS'N (Feb. 4, 2010), https://lymediseaseassociation.org/news/news-releases/idsa-violates-lyme-antitrust-settlement-agreement-with-connecticut-attorney-general/ [https://perma.cc/YD9G-8VX7].

100. U.S. DEP'T OF JUST. ARCHIVES, *supra* note 97.

101. Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679 (1978); Maris Distrib. Co. v. Anheuser Busch, Inc., 302 F.3d 1207, 1213 (11th Cir. 2002), *cert. denied*, 537 U.S. 1190 (2003); Graphic Prod. Distrib., Inc. v. ITEK Corp., 717 F.2d 1560 (11th Cir. 1983).

102. Herbert J. Hovenkamp, *The Rule of Reason and The Scope of the Patent*, 52 SAN DIEGO L. REV. 515, 516 (2015), https://digital.sandiego.edu/cgi/viewcontent.cgi?article=1111&context=sdlr [https://perma.cc/6VHA-83ZU].

those who treat chronic Lyme disease to discipline and deny patients insurance coverage. Effects on the market would therefore need to be proven, but such effects can be demonstrated. As will be discussed below, critical to the analysis will be determination of the market.

In the leading case in the professional services context, *National Society of Professional Engineers v. United States*,[103] a professional engineering society forbade members, comprised of engineers, from quoting prices until hired for projects. This restriction effectively precluded competitive bidding by the engineers. The society defended the policy as necessary to protect the public. According to the society, competitive bidding would reduce the quality of engineering, leading to various calamities of an unspecified nature. The society's position was that the rule of reason should validate the restriction. The United States Supreme Court rejected this position, and this decision limited rule of reason justifications to restraints that offer countervailing pro-competitive effects. In so doing, the Court signaled it would not seek to validate demonstrable restraints of trade by other diffuse and non-economic justifications. There is also no antitrust exception for medicine or any other learned profession.[104] This means patient safety, while assuredly a worthy goal, would not furnish any pro-competitive justification for anti-competitive restraints. More than twenty years after *Professional Engineers,* the Supreme Court took a different approach to regulation of professionals in *California Dental Ass'n v. F.T.C.*[105] There, the Court upheld California Dental Association rules that curtailed price advertising for dentists. The stated purpose of the restriction was to protect patients from false and misleading advertising. The Court largely accepted, uncritically and without economic analysis, the rationale of the California association. Rather than giving effect to non-economic benefits of patient protection, the Court instead reasoned that the restrictions themselves were in some way pro-competitive. Viewed in that manner, it was not necessary to engage in the balancing analysis between anti-competitive and pro-competitive effects set forth in *Professional Engineers*. The Court also copiously cited secondary sources that differentiated the professions from ordinary commerce with reference to price discovery.[106] These references suggest antitrust law should analyze differently the professions but leave no clear guidance.

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103. 435 U.S. 679 (1978). *See also* F.T.C. v. Indep. Fed'n of Dentists, 476 U.S. 447, 460–61 (1986) (proof of detrimental effects can obviate the need for an inquiry into market power; invalidating under the rule of reason a dental practice association work rule agreeing to withhold X-rays from dental insurers); Am. Med. Ass'n v. F.T.C., 638 F.2d 443 (7thth Cir. 1980), *aff'd*, 455 U.S. 676 (1982); Bay Area Surgical Mgmt. LLC v. Aetna Life Ins. Co., No. 15-cv-01416-BLF, 2016 WL 3880989 (N.D. Cal. July 18, 2016).

104. Goldfarb v. Va. State Bar, 421 U.S. 773 (1975).

105. 526 U.S. 756 (1999).

106. *Id.* at 772.

Rule of reason analysis contains its own set of challenges. First, there would need to be a clear delineation of the market. The relevant market is the area of effective competition in which the seller operates and buyers can turn for supply. Relevant to market determination is its degree of segregation from and independence of other markets.[107] The market could be viewed under a number of scenarios such as the market for Lyme disease, the market for vector-borne illnesses, or the market for infectious disease. For the rare Lyme patient that experiences an EM rash and promptly treats the illness, the market could be one for all infectious diseases, where the average emergency room or walk-in clinic could address the problem with a ten days supply of antibiotics. For the cases that do not meet these characteristics, the market differs considerably. Examining the other possibilities, defining the market with respect to other vector-borne illnesses such as West Nile and Zika makes little sense due to the far different sets of challenges associated with each illness. Someone who treats West Nile or Zika likely knows little about Lyme and does not treat Lyme disease in a meaningful way. The correct choice in these circumstances is the market for treatment of chronic Lyme disease.

Once the market is defined, the defendant's power over the market must be established. This can be measured by the availability of substitutes to replace the supply removed from the market.[108] Here, the removed supply constitutes the physicians that cannot treat Lyme patients due to professional discipline arising from the guidelines and whose patients are deprived of otherwise available insurance reimbursement. Because the IDSA guidelines create an absolute bar to treatment of chronic Lyme disease, M.D.s are effectively precluded from this market. There are no substitutes in the population of M.D.s. Proof of this effect exists in the market reaction now on display. The market reaction has been to facilitate a host of alternative treatments either not using M.D.s or using M.D.s in different capacities. Examples include mold and toxicity management,[109]

107. Wampler v. Sw. Bell Tel. Co., 597 F.3d 741, 744–45 (5th Cir. 2010).

108. Torrey v. Infectious Disease Soc'y of Am., No. 5:17-CV-00190-RWS, 2018 WL 10124894, at *10 (E.D. Tex. Sept. 27, 2018). *Torrey* also includes claims for monopolization under Section 2 of the Sherman Act. *Id.* For an antitrust ruling concerning a Lyme-literate MD seeking redress for disciplinary actions, see Jemsek v. N.C. Med. Bd., No. 5:16-CV-59-D, 2017 WL 696721 (E.D.N.C. Feb. 21, 2017) (unpublished) (denying recovery for antitrust claims against the North Carolina Medical Board and its members because 1) defendants were entitled to Eleventh Amendment immunity from suit; 2) injunctive relief requested was inappropriate because plaintiff alleged no ongoing injury; and 3) plaintiff lacked standing to sue board members who had no capacity to redress his grievances).

109. SURVIVING MOLD, https://www.survivingmold.com/ [https://perma.cc/P27V-BWKX].

diet and nutritional supplements,[110] chiropractic,[111] physical therapy,[112] hyperbaric therapy,[113] hyperthermia therapy,[114] herbal protocols,[115] aromatherapy,[116] rife therapy,[117] stem cell treatment,[118] and other alternative methods. Patients may also seek these treatments outside the United States in countries that are more accommodating to treatments deemed experimental. Stem cell treatments in Mexico and India are one example.[119] IDSA would view some of these as evidence of Lyme quackery that

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110. Michael Edwards, *Best Supplements to Kill Lyme Disease and Everything Else You Ever Wanted to Know About Lyme Disease,* ORGANIC LIFESTYLE MAG. (May 2, 2018), https://www.organiclifestylemagazine.com/best-supplements-to-kill-lyme-and-everything-else-you-ever-wanted-to-know-about-lyme-disease [https://perma.cc/L2J4-2UJB].

111. Tricia Soderstrom, *The Benefits of Chiropractic Care for Those with Lyme*, ABOUNDING IN HOPE WITH LYME (Jan. 26, 2017), https://aboundinginhope withlyme.com/the-benefits-of-chiropractic-care-for-those-with-lyme/ [https://perma.cc/WMQ4-VS8U].

112. *The Role of Physical Therapy for Lyme Disease*, ARROW PHYSICAL THERAPY & REHAB. LLC (Oct. 18, 2017), https://www.arrowptr.com/physical-therapy-lyme-disease/ [https://perma.cc/78AH-74QD].

113. *HBOT and Lyme Disease*; HYPERBARIC HEALING INST., http://www.oxygenunderpressure.com/category/lyme-disease/ [https://perma.cc/LN2U-7RJF]; See also Jemsek v. N.C. Med. Bd., No. 5:16-CV-59-D, 2017 WL 696721 (E.D.N.C. Feb. 21, 2017) (unpublished) (among the grounds for discipline was Dr. Jemsek's administration of hyperbaric oxygen therapy to Lyme disease patients).

114. Michelle McKeon, *Answering Questions About Hyperthermia Treatment for Lyme Disease*, LYMDISEASE.ORG (Sept. 3, 2019), https://www.lymedisease.org /hyperthermia-treatment-lyme/ [https://perma.cc/PNY7-UXHD].

115. Stephen Buhner, *The Protocols*, BUHNER HEALING LYME (JULY 11, 2017), http://buhnerhealinglyme.com/the-protocols/ [https://perma.cc/U287-MC FU].

116. Ana Sandoiu, *These 10 Essential Oils Can Kill Persistent Lyme Disease*, MEDICAL NEWS TODAY (Dec. 4, 2018), https://www.medicalnewstoday.com /articles/323881.php#1 [https://perma.cc/52YE-F4ZQ].

117. *Rife for Lyme Disease*, LYME WARRIOR, http://lymewarrior.us/rife-treatment [https://perma.cc/98HN-654K] (last visited July 17, 2020).

118. Richard Horowitz & Phyllis Freeman*, Improvement of Common Variable Immunodeficiency Using Embryonic Stem Cell Therapy in a Patient with Lyme Disease: A Clinical Case Report*, 6 CLINICAL CASE REP. 1166 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986024/ [https://perma.cc/3J9E-BGMQ].

119. *Stem Cell Therapy in Mexico?*, STEM CELL THERAPY MEX. https://www.stemcellmexico.org/ [https://perma.cc/B7WM-FSTM]; Melanie Earley*, Multiple Sclerosis Sufferer Says Stem Cell Treatment in India has "Saved Her Life,"* (Apr. 14, 2020), https://www.stuff.co.nz/national/120951628/multiple-sclerosis-sufferer-says-stem-cell-treatment-in-india-has-saved-her-life [https://perma.cc/6GE3-5FUL].

justifies its strict guidelines.[120] However, in barring qualified M.D.s from administering therapies proven helpful both by studies and clinical experience, the IDSA may actually proliferate ineffectual or even unscrupulous alternatives. IDSA's refusal to even acknowledge legitimate competing views means many views may develop outside its purview for the many patients that continually suffer. In any case, when one views the market as M.D.s available to treat Lyme disease, there is a case to be made that IDSA, its members, and adherents (such as insurers) have market power and exercise it to the detriment of patients and Lyme-literate M.D.s.

IDSA's resistance to antitrust challenges remains highly relevant and telling. IDSA's rigid position relative to treatment of Lyme patients attracted the attention of the Connecticut Attorney General who launched an investigation of IDSA's 2006 Guidelines for the Assessment, Treatment, and Prevention of Lyme Disease.[121] The investigation culminated in a Settlement Agreement, dated April 30, 2008, between the Connecticut Attorney General and the IDSA.[122] The Connecticut Settlement Agreement required the IDSA to undertake certain governance changes related to its 2006 Lyme Disease Guidelines, including an Action Plan of governance procedures. The Action Plan required, among other things, the appointment of a Review Panel that would consist of persons other than those who oversaw the 2006 Lyme Disease Guidelines.[123] The Action Plan states that the "principle [sic] function of the Review Panel shall be to make an individual determination whether each of the recommendations in the 2006 Lyme disease guidelines is medically/scientifically justified in light of all the evidence and information provided."[124] To do this, the Action Plan required panelist conflicts disclosures.[125] The Action Plan also made

120. *See* FINAL REPORT, *infra* note 128 at 10 (listing procedures, regimens and medications not recommended for treatment of Lyme disease to include, inter alia, "long-term antibiotic therapy, anti-Bartonella therapies, hyperbaric oxygen, ozone, fever therapy, intravenous immunoglobulin, cholestyramine, intravenous hydrogen peroxide, specific nutritional supplements and others").

121. *The IDSA Lyme Guidelines*, LYMEDISEASE.ORG, https://www.lymedisease.org/get-involved/take-action/why-we-protest-against-the-idsa/ [https://perma.cc/WX8X-2U6V].

122. *An Agreement Between the Attorney General of the State of Connecticut and the Infectious Disease Society of America*, NCBI (Apr. 30, 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901226/ [https://perma.cc/R5PZ-68JK] (follow "Additional file 1: IDSA Agreement with CT AG" and click on the "Click here for file" hyperlink to download agreement) [hereinafter *Connecticut Settlement Agreement*].

123. *Connecticut Settlement Agreement*, *supra* note 122, Exhibit I, Action Plan, at 1.

124. *Connecticut Settlement Agreement*, *supra* note 122, Exhibit I, Action Plan, at 4.

125. *Connecticut Settlement Agreement*, *supra* note 122, Exhibit I, Action Plan, Appendix I.

modest demands as to the composition of the Review Panel. For example, the Review Panel was required to include "at least one physician with clinical experience in treating Lyme disease patients."[126] Additionally, the Action Plan required the Review Panel to convene an open public hearing to offer a forum for presentation of information on Lyme disease.[127] On April 22, 2010, the Review Panel issued its Final Report of the Lyme Disease Review Panel of the Infectious Disease Society of America.[128] The Final Report unanimously validated all of the recommendations of the 2006 IDSA guidelines.[129] Telling is the fact that there were no dissenters among the panelists, not even on one of the many issues addressed. While ILADS's members offered comments and hearing testimony, not one ILADS member served on the Review Panel. The Connecticut Settlement Agreement gave too much latitude to IDSA in selecting the Review Panel, and the Review Panel ended up being handpicked[130] by IDSA. For this

126. *Connecticut Settlement Agreement*, *supra* note 122, Exhibit I, Action Plan, at 2.

127. *Connecticut Settlement Agreement*, *supra* note 122, Exhibit I, Action Plan, at 3.

128. CAROL J. BAKER, MD ET AL., FINAL REPORT OF THE LYME DISEASE REVIEW PANEL OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA (IDSA) (2010), https://www.idsociety.org/globalassets/idsa/topics-of-interest/lyme/idsalymedisease finalreport.pdf [https://perma.cc/3FYJ-54CG] [hereinafter FINAL REPORT].

129. *Id.* One 2006 Recommendation stating that "there is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease," was ratified by a 7-1 vote. FINAL REPORT, *supra* note 128, at 18. All the other numerous decisions received unanimous ratification and there is no record of any dissenting opinions.

130. The author was not privy to the appointment process and so this assertion relies on inference. The author will offer some facts that might support this conclusion. Some Review Panel members hold memberships in the IDSA. Paul Lantos published an article in the IDSA's publication, concluding that Lyme disease is frequently misdiagnosed. *See* Takaaki Kobayashi et al., *Misdiagnosis of Lyme Disease with Unnecessary Antimicrobial Treatment Characterizes Patients Referred to Academic Infectious Disease Clinic*, OPEN FORUM INFECTIOUS DISEASES (2019), https://academic.oup.com/ofid/article/6/7/ofz299/5527068 [https://perma.cc/M7U5-X2BQ]. Gerald Medoff was a longstanding IDSA member. *In Memoriam*, INFECTIOUS DISEASE SOC'Y OF AM. (Jan. 23, 2019), https://www.idsociety.org/idsa-newsletter/january-23-2019/in-memoriam/ [https://perma.cc/XHP2-TVW8]. Paul Duray "was a renowned expert in Lyme's [sic] disease and was part of a team at Yale University to discover and diagnose the disease." *Colonel Paul H. Duray, Sr. MD (Ret.)*, LEGACY.COM, https://www.legacy.com/obituaries/name/paul-duray-obituary?pid=160360102 [https://perma.cc/KX58-EP55]. Duray also published with Allen Steere of Yale. *See* P.H. DURAY & A.C. STEERE, *Clinical Pathological Correlations of Lyme Disease by Stage*, 539 ANN. N.Y. ACAD. OF SCI. 65 (1988), https://nyaspubs.onlinelibrary.wiley.com/doi/abs/10.1111/j.1749-6632.1988.tb31

reason, the Settlement Agreement failed to attain its goals. However, to the extent a reviewing court needs to examine the motives of IDSA or its members, the Final Report may furnish legal cover to these persons. Findings by a body, with an appearance of independence, tends to undercut assertions that the guidelines disregarded opposing views for the personal gain of certain IDSA members. Additionally, the Final Report reminded the public that IDSA "considers adherence to [its] guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances."[131] Disclaimers of this sort call into question the mandatory nature of the guidelines. The rejoinder to this view is that the true practice of physicians and the insurance industry is to treat the guidelines as mandatory.

As noted in the preceding paragraph, the Connecticut Settlement Agreement has had no effect on IDSA's guidelines.[132] The Draft Guidelines now being considered contain in material respects the same treatment methodologies as the 2006 Lyme Disease Guidelines scrutinized under the Settlement Agreement. The Connecticut investigation never went to trial and in the end the Settlement Agreement, despite its noble intentions and encouraging text, did nothing to advance its intended purposes. At bottom, the procedural and governance undertakings by the IDSA have had no effect on its substantive positions. For example, ILADs and Lyme patients with true stakes in the outcomes continue to have no voice at IDSA. Importantly, IDSA has done nothing to incorporate an alternative medical perspective or to acknowledge that Lyme science, testing, and medicine are unsettled. Leaving no alternatives, this unbending position reinforces the argument that IDSA guidelines should be viewed as mandatory. It likely further means the IDSA is confident of its legal position, given what it assuredly views as vindication furnished by the Final Report.

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839.x?sid=nlm%3Apubmed [https://perma.cc/9MRF-JC5G]. Steere's influence on ISDA positions is well established. *See* WEINTRAUB*, supra* note 37, at 17-18. Steere is also a defendant in Torrey v. Infectious Disease Soc'y of Am. *See generally* Complaint, *supra* note 57. These support the inference that the Review Panel was comprised of persons who shared the worldview of the IDSA. The Connecticut Attorney General cannot really be faulted for this state of affairs because all Review Panelists are well credentialed and competent in the field of infectious disease. However, like other experiences with IDSA, the Review Panel completely lacked any panelists with competing views. Review panelists would assuredly understand both the legal and medical consequences of any attempt to question the 2006 Lyme Disease Guidelines and in retrospect, developed a predictable response.

131. FINAL REPORT, *supra* note 128, at 26.

132. When this article refers to "IDSA guidelines" or terms of like import, it is referring to all IDSA guidelines other than the Draft Practice Guidelines now being finalized, which have been herein specifically defined and critiqued. For example, "IDSA guidelines" include IDSA's 2006 Guidelines for the Assessment, Treatment and Prevention of Lyme Disease.

The CDC also promulgates guidance for Lyme patients, which adds to the complexity of any case brought against IDSA and its members. The CDC presents antibiotic regimens similar to the IDSA guidelines for early Lyme disease.[133] For late Lyme disease and PTLDS, the CDC refers the reader to various studies, including those conducted by the National Institute of Health.[134] To the extent the CDC position coincides with or does not contradict the IDSA guidelines, the CDC pronouncements may obscure the critical question of the IDSA's influence on the marketplace. This article does not analyze whether CDC might itself be caught in its own antitrust conspiracy, and, as a governmental entity, any such allegations would be subject to different legal rules.[135] Whether or not the CDC is a wrongdoer, its public positions complicate the scrutiny of the IDSA to the extent what the CDC says (and not what the IDSA says) is being followed by the medical community.

In the pending litigation of *Torrey v. Infectious Disease Society of America*,[136] plaintiff Lyme patients contend the IDSA is a standard setting organization or standard development organization.[137] The Lyme patients cite *Allied Tube v. Indian Head, Inc.*[138] to establish a governing legal proposition that standard setting can constitute anti-competitive action in violation of antitrust laws when these standards have an economic impact on market participants and when the standards are not voluntary.[139] *Allied Tube* involved the National Fire Association, which promulgated a National Electrical Code and its decision to approve, under that Code, only the use of steel conduits and not those comprised of polyvinyl chloride (PVC). Because the Code influenced many local building codes, upholding this restriction would have grave consequences for the PVC industry. In this circumstance, it was easy to find anti-competitive effects. Instead, the Court decided the issue of whether the association was entitled to antitrust immunity attaching to legislative activity because its standards were widely adopted into law by state and local governments. The Court denied such immunity. Critical to this line of attack is whether the IDSA standards are

133. *Lyme Disease Treatment*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/lyme/treatment/index.html [https://perma.cc/DTS6-R6Y6].

134. *Id.*

135. For a discussion of special rules applicable to state actors, see N.C. State Bd. of Dental Exam'rs v. Fed. Trade Comm'n, 574 U.S. 494 (2015). *Dental Examiners* involved a state dentistry licensing board and did not rule on the question of whether similar rules would apply to Federal agencies. *See also* Parker v. Brown, 317 U.S. 341 (1942).

136. Complaint, *supra* note 57.

137. Complaint, *supra* note 57, at 29.

138. Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492 (1988); Complaint, *supra* note 57, at 29.

139. Complaint, *supra* note 57, at 29–30.

mandatory, which is a mixed question of both fact and law. The enactment by states of Lyme protective laws,[140] at odds with IDSA guidelines, tends to undercut the position that these are mandatory because the laws counteract the influence of the IDSA guidelines. However, the majority of claimants in *Torrey* reside in states with no meaningful Lyme protections, including the states of Texas, Florida, Pennsylvania, Ohio, Alabama, Michigan, Georgia, Nevada, and Arkansas.[141]

## B. State Lyme Disease Legislation

Certain states have enacted legislation to redress the problems noted above. What follows will identify and analyze how these statutes operate and critique their efficacy. Most of the laws have been enacted in the Northeast, where Lyme disease presents the greatest problem. However, other states have also enacted these laws. Despite these strides, most states have no Lyme disease protective statutes. The discussion addresses the following categories: (1) insurance coverage mandates; (2) professional standards; (3) Lyme testing disclosures; (4) safe harbors; (5) awareness, prevention and government support; (6) Lyme disease awareness month; (7) insurance company reporting requirements; (8) Lyme research; (9) compulsory treatment; (10) veterinary reporting; (11) tick-borne disease warning signs; and (12) workers' compensation.

### *1. Health Insurance Coverage Mandates*

To address the widespread problem of health insurance coverage denials, states have enacted laws that mandate insurance coverage for specified medical treatments for Lyme disease. Massachusetts and West Virginia formulate similarly their coverage mandates, providing that an insurer of any form "shall provide coverage for long-term antibiotic therapy for a patient with Lyme disease when determined to be medically necessary and ordered by a licensed physician after making a thorough evaluation of the patient's symptoms, diagnostic test results or response to treatment."[142] Rhode Island offers a similar formulation with some substantive differences. First, Rhode Island requires insurers to cover "diagnostic testing." Second, the physician must be acting according to the Rhode Island Professional Code (which does not conflict with this formulation) in "medically necessary" circumstances. Third, the physician must consider the patient's "symptoms, diagnostic test results and response to treatment."[143] This means the physician must consider all three factors,

140. *See infra* notes 152 through 158 and accompanying text.

141. Complaint, *supra* note 57, at 2.

142. MASS. GEN. LAWS ch. 112, §§ 4JJ(b), 47HH(b) (2020); W. VA. CODE §§ 33-6-38, -5-4p, -16-3zz, -25A-8p (2020).

143. 27 R.I. GEN. LAWS § 27-19-53 (2020).

whereas in West Virginia and Massachusetts, the phrase "symptoms, diagnostic test results or response to treatment" is phrased in the disjunctive. This means a strict reading of the Rhode Island statute might not support long-term antibiotics if diagnostic test results were negative or indecisive, and there is a high probability some cases would have those traits.

Connecticut's mandatory coverage statute has some built-in limitations not present in Massachusetts, Rhode Island, and West Virginia. Health insurance coverage in Connecticut must provide for "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. . . ."[144] In Connecticut, use of antibiotics beyond initially-permissible levels depends on whether the patient is under the care of a rheumatologist, infectious disease specialist or neurologist. While there is no one typical Lyme disease treatment experience other than seeing far more than the average number of experts, one must wonder if the Lyme-literate M.D., which has no recognized professional certification, would meet the definition of "infectious disease specialist." If not, many patients will bear an undue financial burden. When defined, "long-term antibiotic therapy" means "the administration of oral, intramuscular or intravenous antibiotics, singly or in combination, for periods of time in excess of four weeks."[145]

Lyme disease patients frequently ingest a variety of medications and supplements on a daily basis. It is not unusual for patients to require several dozen of these each day. This presents the question of the scope of the mandatory health insurance provisions, which refer to "antibiotics." One Lyme-literate M.D. has obtained, in some cases, excellent results prescribing Dapsone, a sulfone drug typically used to fight leprosy.[146] Bactrim, a sulfa drug, may be prescribed as well, and, in some cases, it is used to address co-infections. These drugs may in certain cases be important in the treatment of Lyme disease. Some of the statutes address this by setting guidelines for experimental drugs and off-label use. Off-label use is the application of a drug to treat a condition not the same as the condition the drug was designed and approved to treat. Dapsone and Bactrim for Lyme disease would be two examples. Disulfiram, a drug

144. CONN. GEN. STAT. §§ 38a-492h, -518h (2020). Connecticut recognizes supervision by professionals in other states "whose requirements for practicing in such capacity are substantially similar to or higher than those of this state."

145. MASS. GEN. LAWS ch. 112, § 12DD(a) (2020); 5 R.I. GEN. LAWS § 5-37.5-3(2) (2020). Connecticut also uses this same definition in the context of medical practice standards. CONN. GEN. STAT. § 20-14m(a)(1) (2020).

146. Dorothy Kupcha Leland, *Touched by Lyme: Leprosy Drug Shows Promise for Lyme Treatment*, LYMEDISEASE.ORG (May 8, 2016), https://www.lymedisease.org/touched-by-lyme-dapsone/ [https://perma.cc/KP5P-6UC6].

approved to treat alcoholism, has been shown to kill Lyme microbes *in vitro*. It has also attained success in patients and is another example of off-label use.[147] The Massachusetts insurance coverage statute handles this question with the following provision:

> An experimental drug shall be covered as a long-term antibiotic therapy if it is approved for an indication by the United States Food and Drug Administration; provided, however, that a drug, including an experimental drug, shall be covered for an off-label use in the treatment of Lyme disease if the drug has been approved by the United States Food and Drug Administration.[148]

When a drug is "approved for an indication," this means the United States Food and Drug Administration ("FDA") has approved a drug for the use presented by its manufacturer. Once the FDA has approved the drug, it may be put to other uses because the FDA does not regulate the practice of medicine. This is the "off-label" treatment to which the statute refers, namely, the use of the drug for a purpose different than that approved by the FDA. The statute gives effect to this use, which may be useful in Lyme treatment. Rhode Island furnishes broader insurance protection for experimental medications and procedures. It requires coverage for treatment characterized as "unproven, experimental or investigational in nature."[149] Importantly, Rhode Island requires coverage for diagnostic testing and not mere antibiotics. This addition is critical to the welfare of Lyme disease patients because one diagnostic test can cost $1,500 or more, and insurance companies may be reluctant to pay, even when medically prescribed.

Minnesota has among the most functional and helpful health insurance statutes. The statute simply provides that health plans "must cover treatment for diagnosed Lyme disease."[150] Importantly, Minnesota forbids the insurer from applying special deductibles, copayments, waiting periods, or other restrictions specific to treatment of Lyme disease.[151]

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147. Daniel A. Kinderlelehrer, *Disulfiram – Breakthrough Drug for Lyme and Other Tick-borne Diseases?*, LYMEDISEASE.ORG (July 11, 2019), https://www.lymedisease.org/disulfiram-kinderlehrer/ [https://perma.cc/E58H-SGGD].

148. MASS. GEN. LAWS ch. 175, § 47HH(b), ch. 176B, § 4JJ(b), ch. 176A, § 8JJ(b) (2020). The author notes an off-label use now proposed for treatment of COVID-19. At the time of this writing, hydroxychloroquine, an FDA-approved malaria medication, has been proposed for use in treating COVID-19. This medication has been prescribed, on an off-label basis, for treatment of Lyme disease.

149. 27 R.I. GEN. LAWS §§ 27-19-53, -41-65 (2020).

150. MINN. STAT. § 62.A265 (2020).

151. *Id.*

There is interplay between insurance coverage provisions and professional standards for physicians and other medical professionals. For example, some statutes share the same definition of "long term antibiotic therapy" for purposes of insurance reimbursement and professional standards. At times, however, there is discord between the insurance provisions and professional standards, which leads to the next topic of discussion.

*2. Professional Standards*

To curtail abuses wrought by medical licensing boards against medical professionals treating Lyme disease, states have now codified certain practices considered by some to be questionable or improper. In some states, whether a physician can retain his or her license to practice medicine may turn on these laws, and some of these laws address a history of egregious abuses by medical boards meted out to physicians doing good for their patients.[152] These laws focus principally on enabling long-term antibiotic therapy. Connecticut's statute typifies this approach:

> [A] licensed physician or a licensed advanced practice registered nurse may prescribe, administer or dispense long-term antibiotic therapy to a patient for a therapeutic purpose that eliminates such infection or controls a patient's symptoms upon making a clinical diagnosis that such patient has Lyme disease or displays symptoms consistent with a clinical diagnosis of Lyme disease, provided such clinical diagnosis and treatment are documented in the patient's medical record by such licensed physician or licensed advanced practice registered nurse.[153]

Maine, Massachusetts, and Rhode Island have very similar statutes except they protect only licensed physicians and not advanced practice registered nurses.[154] Interestingly, the Connecticut professional standards statute does not mesh with its insurance statute. The professional standards statute immunizes a physician for prescribing long-term antibiotics. However, the insurance statute sets time limits, after which the insurance company must

152. *See, e.g.*, N.Y.Dep't of Health, Admin. Review Bd. for Prof'l Med. Conduct, In re Joseph Burrascano, MD, Determination Order No. OI-265 *as reported in* CASEWATCH, https://www.casewatch.net/board/med/burrascano/order.shtml [https://perma.cc/PK8L-2KMJ]; WEINTRAUB, *supra* note 37, at 102. *See also* Complaint, *supra* note 57, at 15-16.

153. CONN. GEN. STAT. § 20-14m(b) (2020).

154. ME. STAT. tit. 32, § 3282-B (2020); MASS. GEN. LAWS ch. 48, § 12DD(b) (2020); 5 R.I. GEN. LAWS § 5-37.5-4(a) (2020).

extend coverage only if the medications are prescribed by a board-certified rheumatologist, infectious disease specialist, or neurologist. The professional standards statute has no such limitation. This inconsistency means insurance companies cannot threaten the license of physicians prescribing long-term antibiotics but, in certain cases, can refuse to cover the antibiotics they prescribe.

Illinois furnishes broader protection to professionals than the New England states and does not limit protections to prescription of long-term antibiotics. It does this as follows:

> 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: (1) based solely upon the recommendation of the physician to an eligible patient regarding, or prescription for, or treatment with an investigational drug, biological product, or device; or (2) 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.[155]

Illinois goes beyond the allowance of long-term antibiotics and permits more latitude in the use of drugs generally, biologic products, and devices. The statute does not define "long-term antibiotics," although this ambiguity might actually benefit physicians. The medical usage of "investigational drug" includes drugs approved by the FDA for testing on people and would also include off-label drugs.[156] "Biological products" (also called "biologics") are FDA-regulated products with complex and (unlike drugs) sometimes uncertain chemical structures.[157] The latitude accorded by the Illinois statute enables medical practice to evolve as it should, instead of merely rectifying a glaring problem with antibiotics (it also addresses this problem). California's law also accommodates emerging medicines and practices, and this will be discussed under the category of "safe harbors" below.[158]

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155. 225 ILL. COMP. STAT. § 60/22(c) (2020).

156. *Investigational Drug*, NATIONAL CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-drug [https://perma.cc/AJ39-4HAB].

157. *FDA 101: Regulating Biological Products*, EIN PRESSWIRE (Feb. 14, 2020, 17:42 GMT), https://www.einnews.com/pr_news/509756084/fda-101-regulating-biological-products [https://perma.cc/QS2E-VZSS].

158. CAL. BUS. & PROF. CODE § 2234.1(c) (2020).

*3. Lyme Testing Disclosures*

Some states require patient disclosures concerning the accuracy of Lyme disease laboratory testing. These alert patients that laboratory testing may be unreliable and explain that a negative result does not conclusively determine whether the patient has Lyme disease. Some of the statutes apply to the laboratory performing the test and others to the medical professional who orders or administers the test.[159] The Rhode Island statute furnishes a typical example:

> Every physician or his/her office designee, who orders a laboratory test for the presence of Lyme disease shall provide to the patient or his/her legal representative the following information.
>
> "ACCORDING TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION, AS OF 2011 LYME DISEASE IS THE SIXTH FASTEST GROWING DISEASE IN THE UNITED STATES."
>
> YOUR HEALTH CARE PROVIDER HAS ORDERED A LABORATORY TEST FOR THE PRESENCE OF LYME DISEASE FOR YOU. CURRENT LABORATORY TESTING FOR LYME DISEASE CAN BE PROBLEMATIC AND STANDARD LABORATORY TESTS OFTEN RESULT IN FALSE NEGATIVE RESULTS, AND IF DONE TOO EARLY, YOU MAY NOT HAVE PRODUCED ENOUGH ANTIBODIES TO BE CONSIDERED POSITIVE BECAUSE YOUR IMMUNE RESPONSE REQUIRES TIME TO DEVELOP ANTIBODIES. IF YOU ARE TESTED FOR LYME DISEASE AND THE RESULTS ARE NEGATIVE THIS DOES NOT NECESSARILY MEAN YOU DO NOT HAVE LYME DISEASE. IF YOU CONTINUE TO EXPERIENCE SYMPTOMS, YOU SHOULD CONTACT YOUR HEALTH CARE PROVIDER AND INQUIRE ABOUT THE APPROPRIATENESS OF RETESTING OR ADDITIONAL TREATMENT."[160]

Maryland's disclosure is very similar to Rhode Island's concluding paragraph above, but it adds a reference to false positives in addition to the

159. *See* VA. CODE ANN. § 32.1-137.06A (2020) (applying the disclosure to the laboratory); *but see* 5 R.I. GEN. LAWS § 5-37.5-6(a) (2020) (applying the disclosure to the medical professional).

160. 5 R.I. GEN. LAWS § 5-37.5-6(a) (2020).

reference to false negatives (it also does not appear in all upper case letters).[161] Virginia has a Lyme disease testing disclosure statute, but it applies to laboratories and not physicians.[162] Also, the Virginia disclosure is not focused on false negatives (as is Rhode Island's disclosure) and, instead, merely states that Lyme disease tests may be inaccurate and patients may not be able to rely on a positive or negative result.[163] The Virginia disclosure concludes with a statement that health care providers (physicians and nurse practitioners, not laboratories) are encouraged to discuss Lyme disease test results with the patient for whom the test was ordered.[164] This statement, while well intended, does not really fit because the laboratory is producing the disclosure and giving it to the patient. However, the health care provider will assuredly be copied on the laboratory results.

Delaware's disclosure must be issued by a "health care provider who draws the blood of a patient to perform a laboratory test for Lyme disease"[165] and requires the following disclosure at the time of drawing of blood:

> Your health-care provider has ordered a laboratory test for the presence of Lyme disease for you. Current laboratory testing for Lyme disease, like all standard laboratory tests, can result in false negatives and false positives. If you continue to experience unexplained symptoms, you should contact your health-care provider and inquire about the appropriateness of retesting or initial or additional treatment.[166]

In Delaware, unless the health care provider draws the blood for submission to the laboratory, the notice need not be given. Delaware considerably dilutes the contents of the notice, lumping Lyme tests together with all others. This potentially creates a false impression that Lyme testing is no less reliable than other tests, which is questionable as a scientific matter.

Making the disclosures may also protect the health care provider or laboratory from liability. Rhode Island provides that "[p]hysicians shall be immune from civil liability for the provision of the written information required by this section absent gross negligence or willful misconduct."[167] The phrase "absent gross negligence or willful misconduct" suggests the protection may extend to conduct beyond the mere giving of the disclosure.

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161. MD. CODE ANN., HEALTH-GEN. § 20-1701(a) (2020).
162. VA. CODE ANN. § 32.1-137.06A (2020).
163. *Id.*
164. *Id.*
165. DEL. CODE ANN. tit. 16, § 3001N(a) (2020).
166. *Id.*
167. 5 R.I. GEN. LAWS § 5-37.5-6(b) (2020).

After all, the professional either gives the notice or does not, and the civil immunity should merely arise for delivery of an incorrect notice. The notice could be incorrect if it states incorrect or insufficient medical facts, but there is nothing the professional, who is duty bound to issue the notice, can do about that. Virginia confers the same civil immunity formulation to a laboratory that furnishes the notice.[168] Delaware's disclosure immunity states: "Notwithstanding any other law, this section does not create a cause of action or create a standard of care, obligation or duty that provides a basis for a cause of action."[169] It further provides that information required, or evidence that a person violated the disclosure provision, is inadmissible in any civil, judicial, or administrative proceeding.[170] Delaware therefore attaches no legal consequences to failure to furnish the notice, and failure to furnish the notice would be inadmissible in any related malpractice or other proceeding. Maryland's immunity clause operates somewhat differently. It provides that the "provision by a health care provider or medical laboratory of the notice required . . . may not be the sole basis for a cause of action."[171] This clause might be more meaningful if it referred to a failure to notify, but it instead provides that a properly delivered notice is not the sole basis for a cause of action. The immunity clause may exist to address the circumstance where the required notice is proven to be scientifically incorrect or insufficient. If so, it would not, standing alone, give rise to a cause of action. Omri Ben-Shahar and Carl Schneider have pointed out deficiencies in FDA-mandated drug labeling as an example that might explain why the states have enacted these protections. In the cases they describe, state courts held liable drug companies on grounds of labeling insufficiency when they furnished federally compliant FDA-mandated labels to patients.[172] In those cases, the fact that the drug companies furnished the disclosure required by law did not spare them from liability.

168. VA. CODE ANN. § 32.1-137.06B (2020).

169. DEL. CODE ANN. tit. 16, § 3001N(b) (2020).

170. *Id.*§ 3001N(c).

171. MD. CODE ANN., HEALTH-GEN. § 20-1701(d) (2020).

172. OMRI BEN-SHAHAR & CARL E. SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE 150 (2014) [hereinafter MORE THAN YOU WANTED TO KNOW]. The labeling of medicine has been the subject of litigation brought against a pharmacy by a Lyme patient. In Rite Aid Corp. v. Levy-Gray, 162 Md. App. 673, 876 A.2d 115 (Md. Ct. App. 2005), *aff'd*, 391 Md. 608, 894 A.2d 563 (Md. 2006), a plaintiff suffering from Lyme disease brought claims against a pharmacy for faulty disclosures issued in connection with medication. The pharmacy's disclosures stated that the medication could be taken with milk and the plaintiff alleged that doing so reduced the efficacy of doxycycline prescribed to treat Lyme disease, worsening, and prolonging her symptoms. The Maryland appeals court affirmed the jury's award of damages for the materially inaccurate and damaging disclosure accompanying the medication.

Ben-Shahar and Schneider have also explored the failings of consumer disclosure,[173] and it is likely that the testing disclosure regime will suffer from the same infirmities as other consumer disclosures that are either ignored or misunderstood. In states like Maryland and Virginia that have disclosure requirements applicable to testing, the symptomatic patient who obtains a negative result believing to be false (based on the disclosure) may face a dilemma. Enjoying no Lyme-specific protections for digging deeper and pursuing non-traditional treatments such as long-term antibiotics, medical professionals in those states may simply accept at face value the serologic test and declare the patient not to suffer from Lyme disease. Given the states' immunity provisions related to the notice, this posture is one that can be safely taken by the professional with diminished fear of liability. In the meantime, the perplexed patient's conditions will not improve and, given the stress and frustration from being declared free from disease, will not be improved by the giving of the notice. Disclosures generally operate to educate and inform decisions, but in this case, what kind of decision can be made when a physician may permissibly, and quite respectably, adhere to negative laboratory results and tell a sick patient he or she does not suffer from the disease? Should the patient fire the doctor and search for someone else? The benefit of disclosure in these circumstances does not immediately appear to this author. For these reasons, the author concludes laboratory testing disclosures will either have no effect or do harm.

*4. Safe Harbors*

Safe harbors are a form of professional standard setting. They operate differently than the professional standards discussed in subsection 2. Instead of codifying practices previously deemed questionable, safe harbors enable the physician to perform various unspecified procedures that might be questioned, provided the physician meets certain conditions. Informed consent is an important component of the typical safe harbor, but is not the sole component. As the discussion below will demonstrate, safe harbors contain ambiguities that cause them to lack the certainty they were intended to furnish. The California Business and Professions Code illustrates this problem and provides:

> (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c) or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine, including the treatment of

173. MORE THAN YOU WANTED TO KNOW, *supra* note 172, at 55–107 ("Why Disclosures Fail").

> persistent Lyme Disease if treatment or advice meets all the following requirements: (1) it is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being. (2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices. (3) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient. (4) It does not cause death or serious bodily injury to the patient.
>
> (b) For the purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.
>
> (c) Since the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases, particularly those that are not yet broadly recognized in California.[174]

The California requirement of informed consent and good faith examination, accompanied by either a medical indication or need to provide for health or well-being, presents at least two questions. First, the extent to which "good faith examination" differs from standard practices. The phrase "good faith" rather than "standard," "competent," or "reasonable" suggests a different standard applies. "Good faith" in commercial matters involves honesty in fact,[175] not a standard of reasonableness or customary standards. The second issue revolves around informed consent. One would reasonably surmise this would track standards for informed consent under California law. This standard requires the doctor to disclose to the patient all material

174. CAL. BUS. & PROF. CODE § 2234.1 (2020).
175. U.C.C. § 1-201(20) (AM. LAW INST. & UNIF. LAW COMM'N 2012).

information necessary to the decision, including a reasonable explanation of the procedure, its likelihood of success, the risks involved in accepting or rejecting the proposed procedure, and any other information a skilled practitioner would disclose to the patient under the same or similar circumstances.[176] The second requirement, to communicate to the patient the physician's or surgeon's "education, experience and credentials," concerning the alternative or complementary medicine and information concerning conventional treatment, raises the question of adequacy. The statute merely requires "information" and does not specify what will suffice. It further presumes the physician or surgeon understands what is the "conventional treatment." The conventional treatment may be to do nothing, given the inability to diagnose the disease, as would be the case with false negatives. This may also be the protocol for those who deny the existence of chronic Lyme disease, and it will certainly vary by medical subspecialty. Different conventional treatments will exist for the neurologist, rheumatologist, allergist, infectious disease specialist, and other specialists. Does the Lyme-literate M.D. need to address all these, only those applicable to the case, or something else? There is also the requirement that the alternative or complementary treatment not delay or discourage traditional diagnosis. In many cases, the patient pursues alternative or complementary treatments when conventional methods have failed. In that circumstance, it is difficult to envision that the alternative treatment delayed or discouraged the treatment that preceded it, but this will not always be the case. The use of the word "diagnosis" rather than "treatment" may resolve this question. The provision under evaluation merely calls for no interference with or discouragement of the "traditional diagnosis" and not the conventional treatment. There remains the difficulty of determining what is a "traditional diagnosis." As noted, the traditional diagnosis may be to conclude the patient does not suffer from Lyme disease. If so, does a doctor who purports to actively treat Lyme disease by his very acts interfere or conflict with that diagnosis? If the physician or surgeon meets all the elements of the safe harbor, he or she may treat Lyme disease without disciplinary exposure. While the harbor may be safe, it cannot be easily reached from stormy seas.

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176. Cobbs v. Grant, 502 P.2d 1, 11 (Cal. 1972) (besides disclosure of known risk of death or serious harm, "a doctor must also reveal to his patient such additional information as a skilled practitioner of good standing would provide under similar circumstances"); Daniel C. v. Miller, No. B282595, 2019 WL 5204159 (Cal. Ct. App. Oct. 16, 2019) (denying recovery for "wrongful life" for failure to disclose birth defects because there is no duty to disclose a later-term abortion treatment option when the procedure is not available in California); Traxler v. Varady, 12 Cal. App. 4th 1321, 1332 (Cal. Ct. App. 1993) (physician has a duty to disclose conflicting schools of thought applicable to a diagnosis but only if the physician is aware of the conflicting schools of thought); Mathis v. Morrisey, 11 Cal. App. 4th 332, 343 (Cal. Ct. App. 1992).

Iowa also has a safe harbor with fewer problems than California. The state merely requires an "examination" and "informed consent,"[177] and does not employ the opaque concept of good faith examination. Iowa also has no requirement that the treatment not discourage or delay traditional diagnosis.

Unless medical boards and courts construe safe harbor statutes charitably, laws like California's, although very well intended, will furnish no panacea. Until clarified by judicial or administrative interpretation, the California law will offer uncertain protection to Lyme-literate M.D.s. Safe harbors appeal to those in the bioethics school who have confidence in the informed consent regime that now reigns over medical jurisprudence. Informed consent affords paramountcy to patient autonomy. Ben-Shahar and Schneider have offered commentaries on the failings of informed consent.[178] Based on observation and study, they concluded informed consent too often fails either because patients do not understand what requires their consent, or would prefer their doctors to make medical decisions for them. Under the first of these, consent cannot be said to be informed. Under the second, consent simply does not exist. For this reason, even if the informed consent protects the physician, it does not in many cases offer patients the protections it was designed to furnish. Giving weight to these considerations means even common sense laws like Iowa's may not attain their goals.

*5. Awareness, Prevention, and Government Support*

Several states have organized government resources related to Lyme disease in various manifestations and degrees. Many of these occur through a state's department of public health. The following states have enacted these laws in one form or another:

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| California[179] | New York[180] |
| Delaware[181] | Pennsylvania[182] |
| Illinois[183] | Rhode Island[184] |
| Maine[185] | Wisconsin[186] |

177. IOWA CODE § 147.56 (2020).

178. More Than You Wanted to Know, *supra* note 172, at 55–107.

179. CAL. HEALTH & SAFETY CODE § 104191 (2020).

180. N.Y. PUB. HEALTH LAW § 2797 (McKinney 2020).

181. DEL. CODE ANN. tit. 16, § 140 (2020).

182. 35 PA. CONS. STAT. § 6235 (2020).

183. 410 ILL. COMP. STAT. §§ 450/10, /15 (2020).

184. 16 R.I. GEN. LAWS § 16-22-25 (2020) (Rhode Island law makes "Lyme disease awareness and prevention resources available for all public school students in the state").

185. ME. REV. STAT. ANN. tit. 22, § 1645 (2020).

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| New Jersey[187] | |

Some of these laws establish mechanisms to track data about the incidence of Lyme disease and the ticks that originate it. These are usually accomplished through specialized task forces, advisory committees, and other similar collective bodies comprised of various appointed experts. In Illinois, the Department of Public Health establishes a Lyme Disease Prevention, Detection, and Outreach Program that, among other things, furnishes information on the incidence of Lyme disease and tick populations by county. It does this through a partnership with the University of Illinois.[188] Wisconsin also provides for disease tracking and, in a separate statutory subsection, requires that research be conducted on "the serological prevalence of Lyme disease."[189] Applied as written, this subsection requires specific data be tracked on the presence of Lyme antibodies in the highly problematic Lyme testing methodologies. As noted, serological measurements for Lyme disease are inherently inaccurate, and data in the wrong hands could be used counterproductively. California forms an advisory committee and concentrates on providing information and educating the public.[190] Delaware establishes a Lyme Disease Education and Oversight Board appointed by the Governor. As its name suggests, the Board determines the content of Lyme disease medical education (including continuing professional education) and is expected to educate health care professionals. Delaware has recognized the scientific discord over the disease and has codified a requirement to include "the philosophies of the Centers for Disease Control [and Prevention], the guidelines established by the International Lyme and Associated Diseases Society, as well as the latest scientific evidence and research."[191] The Maine statute goes farther than all the others. It not only mandates disease tracking, but it also requires that professional standards for Lyme disease treatment be set and that professionals be educated in them. The statute also requires reporting of peer-reviewed Lyme disease medical literature and Lyme disease laws of other states.[192] If well executed, the Maine statute will create a wealth of information for those interested in treating, combating, and studying Lyme disease, as well as a good model for the rest of the states. New Jersey and Rhode Island direct their health and educational agencies to coordinate including Lyme disease education in

186. WIS. STAT. § 254.52 (2020).
187. N.J. REV. STAT. § 26:2P-1, -2 (2020).
188. 410 ILL. COMP. STAT. § 450/10 (2020).
189. WIS. STAT. § 254.52(2)(f) (2020).
190. CAL. HEALTH & SAFETY CODE §§ 104191, 104193 (2020).
191. DEL. CODE ANN. tit. 16, § 140(c)(1) (2020).
192. ME. REV. STAT. ANN. tit. 22, § 1645 (2020).

their public school curricula.[193] New York establishes a "tick-borne disease institute" that administers relevant provisions of law and coordinates state policy concerning Lyme disease.[194]

*6. Lyme Disease Awareness Months*

The month of May is designated as Lyme Disease Awareness Month or Tick-Borne Disease Awareness Month, either by statute,[195] executive proclamation,[196] or legislative resolution.[197] By executive proclamation, North Carolina has designated the month of April as "Tick and Mosquito Awareness Month."[198] Each statute or executive proclamation merely makes this designation and furnishes neither a budget, nor any further directives. Like other illnesses, lawmakers believe public awareness is relevant to making progress in combating the disease. Additionally, there are numerous state agencies, task forces, boards, and other bodies that may wish to incorporate the designation into educational and communication materials or use the month as a time to concentrate

193. N.J. REV. STAT. § 18A:35-5.1 (2020); 16 R.I. GEN. LAWS § 16-22-25 (2020).

194. N.Y. PUB. HEALTH LAW § 2797 (McKinney 2020).

195. CONN. GEN. STAT. § 10-29a(a)(76) (2020); ME. REV. STAT. tit. 1, § 150-E (2020); N.H. REV. STAT. ANN. § 4:13-u (2020); N.J. REV. STAT. § 36:2-111 (2020); OHIO REV. CODE ANN. § 5.2237 (West 2020).

196. State of Arkansas Executive Department Proclamation (April 30, 2018); State of Colorado, Proclamation of Governor John W. Hickenlooper (May 1, 2018); By the Governor of the State of Georgia, A Proclamation Lyme and Tick-Borne Disease Awareness Month (May 21, 2019); State of Maine, Proclamation of Governor Paul R. LePage (May 1, 2018); State of New Hampshire, Proclamation of Governor Christopher T. Sunnunnu (May 3, 2018). The following executive proclamations (among others) from the year 2017 appear at the web site of the Lyme Disease Association, https://lymediseaseassociation.org/news/may-declared-lyme-awareness-month/ [https://perma.cc/H5V3-7A8H]: Proclamation of the Governor of Alabama (May 1, 2017); Proclamation from the Governor of the State of Maryland: Tick-Borne Disease Awareness Month, May 2017 (May 1, 2017); Commonwealth of Massachusetts, Joint Proclamation of Governor, Lieutenant Governor and Secretary of the Commonwealth (March 20, 2017); Proclamation of Rick Snyder, Governor of Michigan Proclaiming May 2017 as Lyme Disease Awareness Month; State of New Jersey Executive Department Proclamation (May 1, 2017); State of Oregon, Proclamation, Office of the Governor (March 27, 2017).

197. H.R. Gen. Assemb., 2018 Sess. (N.Y. 2018); H.R. 38, 2019 Gen. Assemb., 2019 Sess. (Pa. 2019); The following legislative resolution (among others) from the year 2017 appears at *May Declared Lyme Disease Awareness Month*, LYME DISEASE ASS'N, INC. (2017), https://lymediseaseassociation.org/news/may-declared-lyme-awareness-month/ [https://perma.cc/FC4Y-L6ZL]: J.R. 2017 Gen. Assemb., 2017 Sess. (N.J. 2017).

198. State of North Carolina, Proclamation of Governor Roy Cooper (March 29, 2018).

efforts. The states that recognize Lyme Disease Awareness Month do not necessarily have other meaningful Lyme-supportive laws. Arkansas, Colorado, New Hampshire, North Carolina, and Ohio are a few examples. Lyme Disease Awareness Month also receives publicity and support by medical societies, not-for-profits,[199] and private enterprise.[200] At the federal level, the Working Group Report states that more efforts should be made to "inform doctors, insurers, state and local health departments, the press and the public through official communication channels" that "Lyme disease surveillance criteria are not to be used for diagnostic purposes. . . ."[201] While Lyme Disease Awareness month presents such an opportunity to educate, these admonitions too often reach deaf ears, given well-established habits in the medical community.

*7. Insurance Company Reporting Requirements*

Maine requires health insurers to annually report total claims made for diagnosis and treatment of Lyme disease and other tick-borne illnesses, the total dollar amount of these claims, the number of claim denials, the reasons for those denials, and the number and outcome of internal and external appeals.[202] The insurance carrier files this report with the Superintendent for Insurance who in turn reports it to the joint standing committee of the Legislature having jurisdiction over health insurance matters.[203] This report is a matter of public record. The Maine Report on 2018 Claims for Treatment of Lyme Disease and Other Tick-Borne Illnesses shows that insurance carriers paid 85.87% of claims submitted in the relevant measurement period.[204] Note this reports the percentage of claims and not the percentage of monetary values. Also, there is no comparison to claims experience in the general population. Predictably, the explanations for rejections are opaque. By far the greatest number of rejections arose from "Other Reasons for Denial" and "More Information

199. *Lyme Disease Awareness Month*, LYMEDISEASE.ORG, https://www.lymedisease.org/get-involved/take-action/lyme-awareness-month/ [https://perma.cc/J4AS-ZSZM] (last visited July 20, 2020).

200. *Lyme Disease Awareness Month 2019*, TERMINIX (2019), https://www.terminix.com/blog/whats-buzzing/lyme-disease-awareness-month. [https://perma.cc/Q4L8-JN3J].

201. WORKING GROUP REPORT, *supra* note 6, at 20; *Lyme Disease (Borrelia burgdorferi) 2017 Case Definition*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2017), https://wwwn.cdc.gov/nndss/conditions/lyme-disease/case-definition/2017/ [https://perma.cc/6TUL-SRVW].

202. ME. REV. STAT. tit. 24-A, § 4302(5) (2020).

203. *Id.*

204. ME. BUREAU OF INS., REPORT ON 2018 CLAIMS FOR TREATMENT OF LYME DISEASE AND OTHER TICK-BORNE ILLNESSES, MAINE BUREAU OF INSURANCE (2019).

Requested/Not Received." Recall also that Maine law mandates certain health insurance coverage for Lyme disease, putting downward pressure on insurance rejections. Insurance companies track claims by medical treatment codes, and some physicians may not report the treatment code assigned to Lyme disease. For example, the physician may instead report he or she is treating knee pain, meningitis, arthritis, neurologic disorders, or chronic fatigue. Many of these have special codes tied to Lyme disease, but these may not be reported in that manner. An 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. Insurance is predominantly regulated at the state level, and, therefore, collecting these important statistics nationally is not presently available and will be challenging to obtain.[205] However, requiring insurance companies to report at the state level in a manner similar to Maine has beneficial effects. Insurers that report rejection rates at statistically significantly higher rates than other claims will have some explaining to do. In states that mandate coverage, the data may be cause to investigate violations of law. Insurers will know and understand these forces, so public reporting can be meaningful to the welfare of Lyme patients and the professionals who treat them.

*8. Lyme Research*

States have neither the expertise nor the financial resources to perform effective Lyme disease research, other than tracking data on the incidence of the disease and the presence of ticks. Many of the statutes referenced in subsection B5 do this. Despite the inherent limitations, states may do things to foster research, and some even authorize scientific research. As noted, Wisconsin law provides for research on the serological presence of Lyme disease.[206] Some states pursue novel means of funding research for the operation of their Lyme disease laws. For example, Pennsylvania provides that the Department [of Health] must "[i]dentify and apply for public and private grants and funding in order to carry out the provisions of this act."[207] Delaware maintains a "Delaware Health Fund" that holds, among other things, the proceeds of litigation settlements with

205. Fair Health, Inc. has analyzed private insurance claims data pertaining to Lyme disease. *See* FAIR HEALTH, TRENDS AND PATTERNS IN LYME DISEASE: AN ANALYSIS OF PRIVATE CLAIMS DATA (2019), https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Trends%20and%20Patterns%20in%20Lyme%20Disease%20-%20An%20Analysis%20of%20Private%20Claims%20Data%20-%20A%20FAIR%20Health%20White%20Paper.pdf [https://perma.cc/4EG5-XVTZ].

206. WIS. STAT. § 254.52(2)(f) (2020).

207. 35 PA. CONS. STAT. § 6235(f)(8) (2020).

tobacco manufacturers.[208] Moneys from the Delaware Health Fund are to be spent for Delaware citizens on, among other things, "innovative and/or cost effective testing regimens to detect and identify lesser-known but devastating and costly illnesses, such as sarcoidosis and hemochromatosis, fibromyalgia, lupus, Lyme disease and chronic fatigue immune deficiency syndrome."[209] States generally have no duty to account for these monies or justify their efficacy. Their focus on a multiplicity of problems under management by uneducated or uncaring bureaucrats may dilute their effect. Most laws concentrate on detection, surveillance, and awareness.

*9. Compulsory Treatment*

Under the laws of most states, physicians are generally free to accept or reject patients and to decline to treat patients. New York provides a limited exception for physicians practicing in Suffolk, Westchester, and Nassau counties. These physicians must review the medical records of patients diagnosed with juvenile rheumatoid arthritis and review the circumstances of such diagnosis in order to reconsider if the patient instead (or in addition) has Lyme disease. In the event the records examined indicate the patient may currently, or in the past have, suffered from Lyme disease, the physician must take such action he or she deems necessary to inform that patient or his or her parent or guardian, conduct additional tests, administer other necessary treatments, or refer such patient to another physician for further diagnosis and/or treatment.[210] The law is drastic in its retroactivity. The treatment periods to be examined span more than forty years, meaning that many physicians subject to the law will have long since retired. Even active practitioners acting in good faith would be loath to second guess their own prior advice, and their lawyers would advise them not to do so. The law anticipates this reaction through a non-compliance provision that allows the commissioner to order physicians to produce records, but the law is not clear if the physician or the commissioner makes the disease determination in those cases. The law also relies solely on the "records" which, for reasons that should now be obvious to the reader, may not shed much light on whether the patient in fact suffers or previously suffered from Lyme disease. However, the law does provide for "additional tests," which presumably would be determined by what the records show. Physicians who determine the existence of Lyme disease are not required to treat the patient, but in the event the physician declines, he or she must refer the patient to another physician for further diagnosis and/or treatment.[211]

208. DEL. CODE ANN. tit. 16, § 137(b) (2020).
209. *Id.* at § 137(c)(5).
210. N.Y. PUB. HEALTH LAW § 206-b (McKinney 2020).
211. *Id.*

*10. Veterinary Reporting*

Mammals, in particular deer and mice, carry Lyme disease and figure prominently in the spread of the disease. It is therefore fitting that animals be studied, including household pets that can also succumb to the disease. Ohio's statute permits a veterinary professional who orders a test for the presence of Lyme disease for an animal under his or her care to report that test result to the department of health.[212] The reporting is entirely voluntary and does not include reporting of mere testing, but rather testing followed by positive results. The voluntary nature of the reporting and the fact that it does not track all tests (whether positive or negative) diminishes the statistical value of the data.

*11. Tick-Borne Disease Warning Signs*

New York directs its Office of Parks, Recreation, and Historic Preservation to assess the appropriateness of installing signage to warn its park users (including trails) of "possible Lyme and tick-borne infections."[213] The statute is phrased to warn of the disease when what was intended was to warn of ticks that carry the disease. The meaning is nevertheless clear. The statute does not apply to private property such as golf courses and ski resorts; however, it may establish a baseline for duties of care owed by business owners to their customers and could influence the private sector, which may choose to warn in order to limit liability. The author expects this law has not been embraced by New York's tourism industry. Wisconsin directs its Department of Natural Resources, in consultation with its Department of Health Services, to "design signs to raise awareness of Lyme disease, inform how to prevent tick bites, and encourage people to check for ticks after visits to state parks, state trails, state recreational areas, and campgrounds."[214] Wisconsin also requires its Department of Natural Resources, where feasible, to furnish insect repellant for sale in "every state park and state forest."[215] The locations for sale of repellant do not precisely mesh with the signage statute and the author cannot determine if this discrepancy is intentional or inadvertent.

212. OHIO REV. CODE ANN. § 4741.49 (2020).
213. N.Y. PARKS REC. & HIST. PRESERV. LAW § 13.28 (McKinney 2020).
214. WIS. STAT. § 23.118 (2020).
215. *Id.* § 23.1165.

*12. Workers' Compensation*

Lyme disease presents workers' compensation issues,[216] especially for those working outdoors. A claimant must first establish he or she suffers from the disease.[217] When an outdoor worker contracts Lyme disease, there remains an issue whether the infection arose in the course of employment. When California employees belonging to the state's Conservation Corps contract Lyme disease, the state's law creates a rebuttable presumption that the disease arose in the course of employment.[218] Because these employees generally spend considerable time in the outdoors as part of their assigned duties, the law brings them into the applicable workers' compensation regime without an obligation to prove they contracted Lyme disease on the job. Instead, the defense must rebut this presumption.

**C. Lyme Disease Caselaw**

There are hundreds of Lyme disease cases in state and federal courts and these are not confined to states that have enacted Lyme disease laws. These concentrate principally on: (1) determinations of disability; (2) wrongful discharge and employment discrimination; (3) medical standards and malpractice determinations; (4) health insurance coverage disputes; and (5) workers' compensation. This subsection will discuss these areas. By now, it should come as no surprise that Lyme disease cases suffer severe problems of proof associated with whether a litigant suffers from the disease and whether its symptoms form the basis for a legally-cognizable claim.

*1. Determinations of Disability*

The cases determining disability include claims under social security and the Federal Employers Liability Act,[219]employer-sponsored

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216. Foxbilt Electric v. Stanton, 583 So. 2d 720 (Fla. Dist. Ct. App. 1991), *dismissing review*, 589 So. 2d 290 (Fla. 1991).

217. Shaw v. East Ohio Gas Co., No. 2001CA00102, 2001 WL 951702 (Ohio Ct. App. Oct. 20, 2001).

218. CAL. LAB. CODE § 3212.12 (2020).

219. Summers v. Colvin, 634 F. App'x 590 (7th Cir. 2016); Toland v. Colvin, 761 F.3d 931 (8th Cir. 2014); Stark v. Astrue, 278 F. App'x 661 (7th Cir. 2008); Fleury v. Berryhill, No. 3:17-cv-30139-KAR, 2019 WL 2712548 (D. Mass. Apr. 15, 2019); Clemons v. Berryhill, No.18-cv-00578-EDL2019, 2019 WL 3852495 (N.D. Cal. June 27, 2019); McKinnon v. Berryhill, No. 18-cv-10695-IT, 2019 WL 3860382 (D. Mass. Aug. 16, 2019); Lujan v. Berryhill, 298 F. Supp. 3d 1323 (E.D. Cal. 2018); Emerick v. Berryhill, No. 3:17-cv-00658, 2018 WL 4300118 (D. Conn. Sept. 10, 2018); Andrade-Hermort v. Berryhill, 296 F. Supp. 3d 356 (D. Mass. 2017); Kinder v. Berryhill, 247 F. Supp. 3d 1112 (C.D. Cal. 2017); Kasak v.

group disability and other forms of private insurance,[220] together with disability plans for government employees.[221] This article does not attempt

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Berryhill, No. 15-CV-0108-CJW, 2017 WL 1055969 (N.D. Iowa Mar. 20, 2017); Kelly v. Berryhill, No. 5:15-cv-00075, 2017 WL 1194716 (W.D. Va. Mar. 30, 2017); Potega v. Berryhill, No. 16 CV 50110, 2017 WL 2461549 (N.D. Ill. June 7, 2017); Spaulding v. Berryhill, No. 16-cv-6298, 2017 WL 3922878 (N.D. Ill. Sept. 7, 2017) ("an ALJ may not disregard or discount a claimant's testimony 'simply because it is not corroborated by objective medical evidence'" (citing Hill v. Colvin, 807 F.3d 862, 869 (7th Cir. 2015));Woodie v. Colvin, 190 F. Supp. 3d 242 (D. Mass. 2016); Moores v. Colvin, 173 F. Supp. 3d 989 (E.D. Cal. 2016); Kalloch v. Colvin, No. 14-cv-520-SM, 2016 WL 1171506 (D. N.H. Mar. 24, 2016) (a claimant's evidence of physical or mental impairment must be supported by medical evidence consisting of signs, symptoms and laboratory findings and not the claimant's mere statement of symptoms (citing 20 C.F.R. §§ 404.1508, 404.1527, 404.1528 (2017)); DiMeglio v. Colvin, No. 2:13cv413, 2015 WL 925762 (E.D. Va. Mar. 2, 2015); Gadbois v. Colvin, No. 2:15–cv–1072015, WL 10323034 (E.D. Va. Dec. 28, 2015); Thornton v. Colvin, No. C13–2038, 2014 WL 2558466 (N.D. Iowa June 6, 2014); Fallstead v. Astrue, No. C 12–00156 CRB, 2013 WL 5426223 (N.D. Cal. Sept. 27, 2013); McCollum v. Astrue, No. 11-30079-KPN, 2012 WL 2244798 (D. Mass. June 14, 2012); Kalloch v. Astrue, No. 11–cv–522–JL, 2012 WL 4930986 (D. N.H. Sept. 18, 2012); Tenhet v. Astrue, No. 1:08cv0870 DLB, 2009 WL 799148 (E.D. Cal. Mar. 24, 2009); DeLeonardis v. Astrue, No. 5:07CV00050, 2008 WL 597793 (W.D. Va. Feb. 22, 2008); Thornton v. Barnhart, No. Civ.A. 505CV00055, 2006 WL 259672 (W.D. Va. Mar. 21, 2006); Hodges v. Barnhart, 399 F. Supp. 2d 845 (N.D. Ill. 2005); Foley v. Barnhart, 432 F. Supp. 2d 465 (M.D. Pa. 2005); Lopes v. Barnhart, 372 F. Supp. 2d 185 (D. Mass. 2005); Grano v. Long Island R.R. Co., 818 F. Supp. 613 (S.D.N.Y. 1993) (FELA case).

220. Dutkewych v. Standard Ins. Co., 781 F.3d 623 (1st Cir. 2015); Parker v. Vulcan Materials Long Term Disability Plan, 413 F. App'x 987 (9th Cir. 2011) (reversing District Court abuse of discretion standard for denial of benefits in a case where District Court relied on CDC criteria to uphold benefits denial); Gent v. CUNA Mut. Ins. Soc'y, 611 F.3d 79 (1st Cir. 2010); Ingram v. Martin Marietta Long Term Disability Income Plan, 244 F. 3d 1109 (9th Cir. 2001) (reversing District Court abuse of discretion standard for denial of benefits in case where District Court denied benefits in reliance on expert who testified the plaintiff showed no evidence of tick bite and no EM rash); Dorris v. Unum Life Ins. Co., No. 16-CV-508-SMY-DGW, 2018 WL 1993186 (S.D. Ill. Apr. 27, 2018); Cannon v. Aetna Life Ins. Co., No. 14–cv–12546, 2015 WL 7566674 (D. Mass. June 17, 2015); Curran v. United of Omaha Life Ins. Co., 38 F. Supp. 3d 1184 (S.D. Cal. 2014), aff'd. 697 F. App'x 558 (9th Cir. 2017); Spears v. Liberty Life Assurance Co. of Boston, No. 3:11–cv–1807 (VLB), 2015 WL 1505844 (D. Conn. Mar. 31, 2015), subsequent opinion appearing at No. 3:11-cv-1807 (VLB), 2019 WL 4766253 (D. Conn. Sept. 30, 2019) (finding, inter alia, that insurer's peer review report was fatally flawed and did not support denial of benefits); Al-Abbas v. Metropolitan Life Ins. Co., 52 F. Supp. 3d 288 (D. Mass. 2014); Brown v. Federal Express Corp., 62 F. Supp. 3d 681 (W.D. Tenn. 2014), *aff'd.*, 610 F. App'x 498 (6th Cir. 2015); DeCorpo v. Unum Life Ins. Co. of America, No. 13–cv–484–LM, 2014 WL 4794345 (D. N.H. Sept. 25, 2014); Feher v. Unum Life Ins. Co. of

to compare or evaluate the differing standards between social security, the Federal Employers Liability Act, state government employee law, and private insurance. Instead, this discussion is about the defining characteristics of Lyme disease disability cases. Sometimes, cases rule against determinations of disability by reason of inconclusive evidence of Lyme disease.[222] At other times, the court must decide whether Lyme disease even qualifies as a disability under applicable law.[223] A conclusion that Lyme disease is a psychiatric condition or has psychiatric effects (which it does have) may form the basis to limit disability coverage periods.[224] This is the case because private disability insurance frequently limits coverage periods for psychiatric illnesses. The First Circuit's opinion in *Dutkewych v. Standard Insurance Company*,[225] illustrates this problem. The case involved a claim against the administrator of a long-term disability plan.[226] The court upheld a psychiatric condition coverage limitation where the claimant had a history of drug abuse, major depression disorder, obsessive compulsive disorder, and generalized anxiety.[227] These were determinative factors for a finding of mental disorder, even if accompanied by Lyme disease.[228] Importantly, the claimant tested negative under a Western Blot test but positive under alternative criteria developed by iGeneX, Inc.[229] Experts for the defense discredited the iGeneX findings and questioned the existence of chronic Lyme disease.[230] *Dutkewych* is one of the cases where the parties contest the existence of Lyme disease through

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America, No. 3:14–CV–334 (RNC), 2014 WL 7271927 (D. Conn. Dec. 18, 2014); Bistany v. Reliance Standard Life Ins. Co., 55 F. Supp. 3d 956 (S.D. Tex. 2014) (denying benefits and rejecting treating physician's Lyme disease diagnosis in favor of examining physician's conclusion of mental disorder); Faulkner v. Hartford Life and Accident Ins. Co., 860 F. Supp. 2d 1127 (E.D. Cal. 2012); Heimeshoff v. Hartford Life & Accident Ins. Co., No. 3:10cv1813 (JBA), 2012 WL 171325 (D. Conn. Jan. 16, 2012); Lamanna v. Special Agents Mut. Benefit Ass'n, 546 F. Supp. 2d 261 (W.D. Pa. 2008); Pikulas v. DaimlerChrysler, 397 F. Supp. 2d 883 (E.D. Mich. 2005).

221. Kleja v. State Teachers Ret. Bd., No. 08AP–326, 2009 WL 1175533 (Ohio Ct. App. Apr. 30, 2009); Yocum v. Sch. Emp.s Ret. Bd., No. 05AP–791, 2007 WL 902099 (Ohio Ct. App. Mar. 27, 2007).

222. Dunn v. Standard Ins. Co., 156 F. Supp. 2d 227 (D. Conn. 2001).

223. Cook v. Gregory Press Inc., No. A-5646-13T3, 2016 WL 4216656 (N.J. Super. Ct. App. Div. Aug. 11, 2016) (unpublished opinion holding that Lyme disease qualifies as a disability under applicable New Jersey law and that the defendant failed to offer a reasonable accommodation to plaintiff employee).

224. Schwob v. Standard Ins. Co., 248 F. App'x 22 (10th Cir. 2007).

225. 781 F.3d 623 (1st Cir. 2013).

226. *Id.* at 625.

227. *Id.* at 627.

228. *Id.*

229. *Id.*

230. *Id.* at 629.

competing findings of medical laboratories.[231] Even when Lyme disease is found or stipulated, the disease symptoms may be found not to impair an employee's ability to work.[232] In this respect, the MyLymeData patient registry tracks and compares Lyme symptoms to other diseases.[233] MyLymeData is a fully-consented, opt-in, Lyme patient registry with over 12,000 participants. Among other things, its quality of life and symptoms surveys help establish that Lyme disease can inflict symptoms that constitute disability under applicable laws and insurance contracts. While MyLymeData covers a large database, because it relies on voluntary reporting by those in the public who suffer from the disease, it does not necessarily represent an unbiased, random cross section of patients.

Also on display in Lyme disease disability cases is the IDSA influence on expert evidence presented before the courts. An unpublished New Jersey Superior Court opinion, *Raimondi v. Morris County Park and Police Commission*,[234] describes this reality. In *Raimondi*, the court upheld a compensation judge's award of compensation and reimbursement for hyperbaric oxygen therapy[235] administered to a police officer diagnosed with Lyme disease.[236] The officer served in the mounted unit, patrolling parks where she was frequently exposed to ticks, brushing them from her clothing and body with regularity.[237] The defending Police Commission used a medical expert to challenge whether the officer actually suffered from Lyme disease.[238] Among his sworn statements before the court, the

231. *See also* Cannon v. Aetna Life Ins. Co., No. 14-cv-12546, 2015 WL 7566674 (D. Mass. June 17, 2015); Al-Abbas v. Metropolitan Life Ins. Co., 52 F. Supp. 3d 288 (D. Mass. 2014).

232. Seekins v. Astrue, No. 3:11CV00264(VLB)(TPS), 2012 WL 4471266 (D. Conn. Aug 14, 2012).

233. Registry Report, *supra* note 10, at 9.

234. No. A-0106-12T1, 2013 WL 5975726 (N.J. Super. Ct. App. Div. Nov. 12, 2013).

235. Hyperbaric Oxygen Therapy (HBOT) involves breathing pure oxygen in a pressurized environment and is typically used to treat decompression sickness. *See, e.g.*, *Hyperbaric Oxygen Therapy*, MAYO CLINIC, https://www.mayoclinic.org /tests-procedures/hyperbaric-oxygen-therapy/about/pac-20394380 [https://perma.cc/4KDY-MQPM] (last visited July 9, 2020). The current underlying medical theory is that Lyme spirochetes do not survive in a pure oxygen environment. For more information on HBOT for Lyme Disease, see *HBOT and Lyme Disease*, HYPERBARIC HEALING INSTITUTE, http://www.oxygenunder pressure.com/category/lyme-disease/ [https://perma.cc/8VSS-VHSZ] (last visited July 9, 2020). *See also* M.M. & S.O. v. Catastrophic Illness in Children Relief Fund Commission, No. A-2298-17T4, A-2344-17T2, 2019 WL 1552384 (N.J. Super. Ct. App. Div. Apr. 14, 2019).

236. *Raimondi*, 2013 WL 5975726, at *9.

237. *Id.* at *1.

238. *Id.* at *4-5.

expert stated that the IDSA is the only infectious disease medical society.[239] This is an untruth, but likely what he meant was IDSA is the only infectious disease medical society worthy of judicial recognition. He reflexively relied on IDSA standards, which expressly excluded hyperbaric therapy, even though the officer improved when subjected to such treatments.[240] The case ended up as a battle between experts and this time the compensation judge considered the officer's expert more credible.[241] The case underscores the weaponization of the IDSA standards used by experts to either deny the existence of chronic Lyme disease or discredit its treatments. The author notes the plenitude of these cases, many of which are unpublished. Skirmishes between experts in disability cases may not make for sweeping legal pronouncements worthy of publication, but they are at the core of much litigation over Lyme disease.

*2. Wrongful Discharge and Employment Discrimination*

Cases have been brought requesting accommodations under the Americans with Disabilities Act and comparable state law.[242] Under these laws, the claimant must first establish the disability and then the parties would need to sort out what is a reasonable accommodation.[243] Likewise, Lyme disease may serve as grounds for retaliatory dismissal claims under the Family Medical Leave Act.[244]

*3. Medical Standards and Malpractice Determinations*

A medical malpractice case may arise for failure to diagnose or treat[245] Lyme disease or misdiagnosis. The Connecticut Supreme Court case

239. *Id.* at *6.

240. *Id.* at *6.

241. *Id.* at *6.

242. Levine v. Smithtown Cent. School Dist., 565 F. Supp. 2d 407 (E.D.N.Y. 2008) (plaintiff failed to proffer sufficient evidence to establish a prima facie showing of disability under the Americans with Disabilities Act); Worster v. Carlson Wagon Lit Travel, 353 F. Supp. 3d 257 (D. Conn. 2005) (employee with Lyme disease subjected to transfer did not experience an "adverse action" under the Connecticut Fair Employment Practices Act, his HIV positive status did not merit legal redress under the Americans with Disabilities Act, and he did not experience retaliation for his illnesses under the Family Medical Leave Act).

243. Cook v. Gregory Press, Inc., No. L–3189–11, 2016 WL 4216656 (N.J. Super. Ct. App. Div. Aug. 11, 2016) (unpublished opinion).

244. Majocha v. Eversource Energy Service Company, No. 3:16-CV-00742 (VLB), 2018 WL 1122353 (D. Conn. Mar. 1, 2018); Nurse v. Windham Community Memorial Hospital, No. 3:10–CV–00177 CSH, 2012 WL 6727620 (D. Conn. Dec. 28, 2012).

245. Bratt v. Laskas, 845 So. 2d 964 (Fla. App. 2003); Wieland v. Mountainside Hosp., 2006 WL 2089885 (N.J. Super. Ct. Law Div. July 26, 2006)

of *Tetrault v. Eslick*[246] dramatizes the problems for both patients and professionals. In *Tetrault*, a family sought pediatric help for their child suffering from a variety of severe symptoms.[247] The pediatrician diagnosed the child as suffering from dermatitis and prescribed antihistamines.[248] The child's condition did not improve and one acute attack caused him to be treated in an emergency room, where antibiotics were prescribed.[249] The family later sought care from a specialist who prescribed, among other things, the intravenous administration of Rocephin.[250] The child's condition did not improve and, likely as a result of the ensuing complications associated with the specialist's treatment, the child was required to have his gallbladder removed.[251] The family's attempt to hold the pediatrician liable for failure to diagnose Lyme disease failed on the grounds that the later treatments were supervening causes of the injury.[252] *Tetrault* illustrates the "everyone loses" circumstances of Lyme disease. Professionals rightfully shun the cases because the disease can neither be diagnosed nor treated. This contributes to the continual shortage of support and adds to the suffering of patients, who also do not receive legal redress. The author does not reflexively advocate greater legal redress for Lyme litigants in this setting. Indeed, the legal community and judiciary would do well to understand that the science and cures are very inconclusive and professional standards are difficult to establish. Misdiagnosis of Lyme disease is another area where malpractice claims have occurred.[253]

*4. Health Insurance Coverage Disputes*

Health insurance coverage litigation has revolved around denials where the insurer considers the treatment medically unnecessary[254] or experimental. Insurers will continue to reject medicinal reimbursement claims in states that have not enacted specific legislation authorizing long-term antibiotics. Insurers will narrowly construe laws mandating

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(medical malpractice case over failure to treat Lyme disease); Nicolaou v. Martin, 195 A.3d 880 (Pa. 2018).

246. 857 A.2d 888 (Conn. 2004).

247. *Id.* at 890.

248. *Id.*

249. *Id.*

250. *Id.*

251. *Id.* at 891.

252. *Id.* at 892-93.

253. Schur v. Zackrison, No. 1:15-cv-01013 (JCC/IDD), 2015 WL 8484441 (E.D. Va. Dec. 8, 2015).

254. Lamb v. Time Ins. Co., 800 N.W.2d 755 (Iowa App. 2011); Egan v. N.Y. Care Plus Ins. Co., 277 A.D.2d 652, 716 N.Y.S.2d 430 (N.Y. App. Div. 2000); Logan v. Empire Blue Cross and Blue Shield, 275 A.D.2d 187, 714 N.Y.S.2d 119 (N.Y. App. Div. 2000).

medications and will continue to reject diagnostic testing if legally permitted to do so. Even in protective states, critical restorative supplements such as Glutathione will escape coverage. States with laws requiring insurers to cover Lyme disease claims have in part alleviated this problem.

*5. Workers' Compensation*

Employees infected by Lyme disease in the course of employment may be entitled to workers' compensation.[255] As noted, for certain public conservationist employees, California presumes their Lyme infections to have arisen in the course of employment.[256] Unless a special statute like California's applies, the employee will generally bear the burden to prove the disease arose in the course of employment.[257]

North Carolina Lyme disease workers' compensation cases illustrate how judicial outcomes may differ dramatically based on misunderstandings of Lyme disease. In *Kashino v. Carolina Veterinary Specialists Medical Services,* the appellate court upheld the denial of workers' compensation because, among other things, the plaintiff failed to establish she contracted Lyme disease on the job.[258] In contrast, in *Lassiter v. Town of Selma,* the court upheld a workers' compensation award for Lyme disease contracted in the course of employment.[259] In doing so, it distinguished *Kashino* on grounds of much stronger evidence, including the existence of an EM rash and proximity of symptoms to the tick bite causing the disease.[260] But these evidentiary differences were merely better proofs for the existence of the disease and not whether it was contracted on the job. Nevertheless, these factors influenced the court and this thinking may lurk in many other contexts. Requiring touchstone evidence, such as display of an EM rash, is inappropriate in Lyme cases.

*6. Summary of Lyme Litigation*

Proving or ruling out the existence of Lyme disease has been a continual challenge in litigation and, until testing methods improve dramatically, will continue to plague litigants. Physicians desirous of avoiding malpractice liability will seek a standard of care against which

255. Cigna Ins. Co. of Tex. v. Evans, 847 S.W.2d 417 (Tex. App. 1993); Ross, France & Ratliff, Ltd. v. Blevins, Nos. 1054–00–4, 1069–00–4, 2000 WL 1593647 (Va. App. Oct. 24, 2000).

256. *See supra* note 218 and accompanying text.

257. Bird v. Somerset Hills Country Club, 309 N.J. Super. 517, 707 A.2d 1033 (App. Div. 1998).

258. 186 N.C. App. 418, 650 S.E.2d 839 (N.C. Ct. App. 2007).

259. 680 S.E.2d 903, 2009 WL 2138489 (N.C. Ct. App. 2009).

260. *Id.* at *5.

they will be judged. These professionals will discover their search has been in vain. The polarized positions of IDSA and CDC versus ILADS may mean the standard of care is open to debate. More likely (and unfortunately for many) the IDSA and CDC will set the standards unless prevented from so doing by state law.[261] This likely explains the dearth of Lyme-literate M.D.s because most will pursue less risky careers. In this respect, protecting professionals from licensing discipline is only a partial solution because of the heightened risk of breach of an inappropriate and unworkable standard of care. The knee-jerk solution to this state of affairs is to handle departures from standard by informed consent and safe harbors like those enacted in California. However, as the author has noted, these are not real solutions. No amount of informed consent will alleviate malpractice arising from horror story cases like those occasionally appearing in the excessive administration of antibiotics.[262]

### D. Federal Lyme Disease Laws: The 21st Century Cures Act

The United States Department of Health and Human Services ("*HHS*") operates to enhance and protect the health and wellbeing of all Americans.[263] HHS has eleven operating divisions, including eight in the U.S. Public Health Service and three human service agencies. The 21st Century Cures Act directs HHS to "conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases."[264] Pursuant to this law, HHS established a Tick-Borne Disease Working Group, which has studied Lyme disease and made recommendations in the form of the Working Group Report to Congress.[265] The Working Group Report brings to the surface through statistics the difficulties confronted by Lyme disease patients and their families. It further highlights the gross disparities in spending on Lyme versus other infectious diseases of comparable virulence.[266] In passing the

261. State laws say nothing about treatment standards. However, by mandating treatments prohibited by the IDSA, state law can have the effect of overriding IDSA guidelines. Physicians who consult the guidelines may decide to follow them to avoid liability or simply out of habit.

262. *See* State of New York: Department of Health, *Administrative Review Board for Professional Medical Conduct*, In re Joseph Burrascano, MD, Determination Order No. OI-265 as reported in Casewatch, https://www.casewatch.net/board/med/burrascano/order.shtml [https://perma.cc/8N68-UQNE] (improper administration of medication was among the charges brought against Dr. Burrascano). *See also* Complaint, *supra* note 57, at 15–16.

263. *See About HHS*, HHS.GOV, https://www.hhs.gov/about/index.html [https://perma.cc/JN6P-2E9V] (last visited July 21, 2020).

264. 42 U.S.C. § 284s(a) (2020).

265. WORKING GROUP REPORT, *supra* note 6.

266. *See supra* notes 62–64 and accompanying text.

21st Century Cures Act, Congress charged the Tick-Borne Disease Working Group with identifying "gaps in research, education, prevention and access to care."[267] The Working Group Report identifies not only unjustified funding disparities, but a worsening of this problem by the under reporting of Lyme disease and other tick-borne illnesses caused by unduly burdensome reporting criteria and inconsistencies in surveillance data gathering.[268] The Working Group Report contains five core concerns: 1) epidemiology and ecology, 2) prevention, 3) diagnosis, 4) treatment, and 5) access to care/patient outcomes. With respect to access to care and patient outcomes, Chapter 7 of the Working Group Report sets out the following recommendations:

> **Recommendation 7.1** Create a Federal repository for information on Lyme disease and other tick-borne diseases.
>
> **Recommendation 7.2** Allocate increased funding for tick-borne disease in the areas of research, treatment and prevention proportional to the burden of the illness and need.
>
> **Recommendation 7.3** Protect patients from employment discrimination.
>
> **Recommendation 7.4** Protect students of all ages from discrimination.
>
> **Recommendation 7.5** Protect patients from health care and disability insurance coverage and reimbursement policies that are unduly burdensome.
>
> **Recommendation 7.6** Protect the rights of licensed and qualified clinicians to use individual clinical judgment, as well as recognized guidelines, to diagnose and treat patients in accordance with the needs and goals of each individual patient.[269]

These recommendations, while directionally helpful, are only the starting point in developing bodies of law that will alleviate the suffering caused by Lyme disease. First, they are merely recommendations and while publicly influential, lack legal force. The second critique is that to attain their goals, they largely require passage of laws at the state level, especially with reference to recommendations 7.5 and 7.6. Nowhere do the

267. WORKING GROUP REPORT, *supra* note 6, at 5.
268. WORKING GROUP REPORT, *supra* note 6, at 20.
269. WORKING GROUP REPORT, *supra* note 6, at 59.

recommendations suggest that the Federal government would begin to regulate the business of insurance and medical standards now largely reserved to the states. This would leave it up to the states to act and many will not. Some states go so far as to deny entirely the incidence of Lyme disease in their state. The Federal repository of Lyme disease information would further rely on states to collect the data. Nearly all states (even Florida and Texas) require reporting of Lyme disease in some form to state and local health departments.[270] However, states will apply a variety of disparate criteria to track and report Lyme disease. Many state Lyme disease case reporting requirements rely on data reported by laboratories and health-care providers.[271] State regulations differ as to when a patient

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270. ALA. ADMIN. CODE r. 420-4-1 (2020); ALASKA ADMIN. CODE tit. 7 § 27.005 (2020); ARIZ. ADMIN. CODE § R9-6-352 (2020) (Arizona's regulation goes beyond reporting to provide that the "local health agency shall . . . [c]onduct an epidemiologic investigation of each reported Lyme disease case or suspected case . . . and . . . [f]or each Lyme disease case submit to the Department . . . the information required. . . . "); 016-22 ARK. CODE R. § 012 App. B (Volume MMXXI, Number 10, April 2020); CAL. CODE REGS. tit. 17, § 2500(b) (2020); 6 COLO. CODE REGS. § 1009-1 App. A (LexisNexis 2020); 16 DEL. ADMIN. CODE § 4000-4202 (2020); FLA. ADMIN. CODE ANN. r. 64D-3.029 (2020); ILL. ADMIN. CODE tit. 77 §§ 690.100, 690.698 (2020); 410 IND. ADMIN. CODE 1-2.5-75 (2020); IOWA ADMIN. CODE r. § 653-13.14 (2020); KAN. ADMIN. REGS. § 28-1-2 (2020); 902 KY. ADMIN. REGS. 2:020 (2020); LA. ADMIN. CODE tit. 51, Pt. II § 105 (2020); 10-144 ME. CODE R. Ch. 208 § 9, App. B, Ch. 258 § 2 (2020); MD. CODE REGS. 10.06.01.03 (2020); 105 MASS. CODE REGS. § 300.100 (2020); MINN. R. 4605.7030, 4605.7040 (2020); 15 MISS. CODE R. Pt. 11, Subpt. 55, App. B (2020); MO. CODE REGS. ANN. tit. 19, § 20-20.020 (2020); MONT. ADMIN. R. § 37.114.204 (2020); 173 NEB. ADMIN. CODE Ch. 1, § 1-004 (2020); NEV. ADMIN. CODE § 441A.240 (2020); N.H. CODE ADMIN. R. ANN. He-P 301.02 (2020); N.J. ADMIN. CODE § 8:57-1.5(b) (2020); N.M. CODE R. § 7.4.3 (2020); N.Y. COMP. CODES R. & REGS. tit. 10, §§ 2.1, 44.50 (2020); 10A N.C. ADMIN. CODE 41A.0101 (2020); OHIO ADMIN. CODE 3701-3-02, 03, 04, 05 (2020); OKLA. ADMIN. CODE § 310:515-1-4 (2020); OR. ADMIN. R. 333-018-0015 (2020); 28 PA. CODE §§ 27.21a, 27.22 (2020); 216 R.I. CODE R. § 30-05-1.5 (LexisNexis 2020); S.D. ADMIN. R. 44:20:01:04 (2020); 25 TEX. REG. 97.3 (Jan. 7, 2020); UTAH ADMIN. CODE r. 386-702-3 (2020); 13-140-007 VT. CODE R. § 5-0 (2020); 12 VA. ADMIN. CODE § 5-90-80 (2020); WASH. ADMIN. CODE §§ 246-101-105, 246-101-201, 246-101-301, 246-101-305 (2020); W. VA. CODE R. § 64-7-3 (2020); WIS. ADMIN. CODE DHS 145 App. A (2020).

271. ALA. ADMIN. CODE r. 420-4-1 (2020); ALASKA ADMIN. CODE tit. 7 § 27.005 (2020); ARIZ. ADMIN. CODE § R9-6-352 (2020) (Arizona's regulation goes beyond reporting to provide that the "local health agency shall . . . [c]onduct an epidemiologic investigation of each reported Lyme disease case or suspected case . . . and . . . [f]or each Lyme disease case submit to the Department . . . the information required. . . . "); 016-22 ARK. CODE R. § 012 App. B (Volume MMXXI, Number 10, April 2020); CAL. CODE REGS. tit. 17, § 2500(b) (2020); 6 COLO. CODE REGS. § 1009-1 App. A (LexisNexis 2020); 16 DEL. ADMIN. CODE §

has Lyme disease and many will simply work from CDC surveillance criteria, which depends on the notoriously insensitive Western Blot. Kentucky is one example of CDC influence. Its reporting regulations provide that a health professional and health facility must notify the Kentucky Department of Public Health if "(a) the health professional makes a probable diagnosis of a disease . . . and (b) the diagnosis is supported by . . . [c]linical or laboratory criteria and [c]ase classifications published by the Centers for Disease Control and Prevention . . . or [a] health professional's medical opinion that the disease is present."[272] In any event, case tracking is only as good as the mechanisms designed and implemented to report accurate data. While to a certain extent this is endemic to all medical reporting, Lyme test data is materially less reliable than testing for many other diseases that also must be reported.

The wide range of state responses to Lyme disease leaves denizens of many states with few treatment options, causing them to travel across state lines for proper care. The Working Group Report highlights this in documenting the comparatively long distances travelled by Lyme patients.[273] As the discussion immediately to follow will show, laws concerning telemedicine, while helpful, do not solve this problem.

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4000-4202 (2020); FLA. ADMIN. CODE ANN. r. 64D-3.029 (2020); ILL. ADMIN. CODE tit. 77 §§ 690.100, 690.698 (2020); 410 IND. ADMIN. CODE 1-2.5-75 (2020); IOWA ADMIN. CODE § 653-13.14 (2020); KAN. ADMIN. REGS. § 28-1-2 (2020); 902 KY. ADMIN. REGS. 2:020 (2020); LA. ADMIN. CODE tit. 51, Pt. II § 105 (2020); 10-144 ME. CODE R. Ch. 208 § 9, App. B, Ch. 258 § 2 (2020); MD. CODE REGS. 10.06.01.03 (2020); 105 MASS. CODE REGS. § 300.100 (2020); MINN. R. 4605.7030, 4605.7040 (2020); 15 MISS. CODE R. Pt. 11, Subpt. 55, App. B (2020); MO. CODE REGS. ANN. tit. 19, § 20-20.020 (2020); MONT. ADMIN. R. § 37.114.204 (2020); 173 NEB. ADMIN. CODE Ch. 1, § 1-004 (2020); NEV. ADMIN. CODE § 441A.240 (2020); N.H. CODE ADMIN. R. ANN. He-P 301.02 (2020); N.J. ADMIN. CODE § 8:57-1.5(b) (2020); N.M. CODE R. § 7.4.3 (2020); N.Y. COMP. CODES R. & REGS. tit. 10, §§ 2.1, 44.50 (2020); 10A N.C. ADMIN. CODE 41A.0101 (2020); OHIO ADMIN. CODE 3701-3-02, 03, 04, 05 (2020); OKLA. ADMIN. CODE § 310:515-1-4 (2020); OR. ADMIN. R. 333-018-0015 (2020); 28 PA. CODE §§ 27.21a, 27.22 (2020); 216 R.I. CODE R. § 30-05-1.5 (LexisNexis 2020); S.D. ADMIN. R. 44:20:01:04 (2020); 25 TEX. REG. 97.3 (Jan. 7, 2020); UTAH ADMIN. CODE r. 386-702-3 (2020); 13-140-007 VT. CODE R. § 5-0 (2020); 12 VA. ADMIN. CODE § 5-90-80 (2020); WASH. ADMIN. CODE §§ 246-101-105, 246-101-201, 246-101-301, 246-101-305 (2020); W. VA. CODE R. § 64-7-3 (2020); WIS. ADMIN. CODE DHS 145 App. A (2020).

272. 902 KY. ADMIN. REGS. 2:020 (2020).

273. *See* WORKING GROUP REPORT, *supra* note 6, at 60.

## E. Telemedicine

### *1. Telemedicine/Telehealth*

Telemedicine (also sometimes referred to as "telehealth") is the rendition of medical advice through interaction by videoconference, remote monitoring, or other electronic means and not through face-to-face office visits. Telemedicine could be especially useful in the treatment of Lyme disease because many Lyme-literate M.D.s lack geographic proximity to patients. The Health Insurance Portability and Accountability of 1996 Act ("*HIPAA*")[274] establishes privacy and security protections for records pertaining to individuals' health information. Among other things, HIPAA requires health-care providers such as medical practices and hospitals to protect personal health information concerning patients if the health-care provider obtains electronic reimbursement for its services, such as through insurance. Health-care providers not receiving reimbursement by insurance should not be subject to HIPAA; however, they may nonetheless be subject to state laws protecting medical records. HIPAA generally does not preempt state law in that it enables states to impose their own, more stringent, requirements. A practitioner of telemedicine must meet the same professional standards as one operating a brick-and-mortar practice and this requirement exists independent of HIPAA. However, HIPAA presents the additional technological obstacle concerning the proper encryption of communications and this may challenge the resources of small medical practices. It therefore comes as no surprise that larger, well-funded players are now aggressively launching telemedicine practices and expect them to grow rapidly.[275]

In addition to HIPAA, state regulation of medical practice may present obstacles to an effective telemedicine practice related to Lyme disease. These come into play in various circumstances, including prescribing of medications. Anyone treated for Lyme is very likely to have been prescribed a number of medications. State law may require the physician to physically examine the patient before prescribing any medication. A physician practicing in such a state will need to devote part

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274. Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936 (1996). The Secretary of Health and Human Services has the power to waive HIPAA requirements in the event of an emergency such as the COVID-19 pandemic. *See HIPAA Compliance and COVID-19 Coronavirus*, HIPAA JOURNAL (Apr. 3. 2020), https://www.hipaajournal.com/hipaa-compliance-and-covid-19-coronavirus/ [https://perma.cc/84WW-EC42]. However, no such exceptions apply to Lyme disease.

275. *American Well Partner to Launch Digital Health Company*, CLEVELAND CLINIC NEWSROOM (Oct. 21, 2019), https://newsroom.clevelandclinic.org/2019/10/21/cleveland-clinic-american-well-partner-to-launch-digital-health-company/ [https://perma.cc/SKR2-YXAY].

of his or her practice to a brick-and-mortar setting. Reformative Lyme disease statutes do not address this situation. For example, in *Jones v. Connecticut Medical Examining Board*, the court upheld the discipline of a physician for violating standards of care applicable to two children diagnosed with gestational Lyme disease for, among other things, (1) prescribing an antibiotic to a patient he did not know and did not examine and (2) prescribing antibiotics for half a year without a repeat examination.[276] Cases like *Jones* will dissuade physicians from taking interstate or remote patients where patients are unable to physically visit the medical office. This means patients in states whose medical communities are late to awaken to the problem of Lyme disease will not find telemedicine to be a reliable option.

Recognizing the requirements and limitations described above, some Lyme-literate M.D.s have developed multiple classes of services. One level of service entails in-office visits pursuant to which, among other things, medications can be prescribed. A second class of telemedicine service involves general consultation without the ability to prescribe medications.[277] This enables the Lyme-literate M.D. to extend his or her services across state lines on a limited basis without requiring patients to travel unreasonably long distances. Patients may also opt to visit in-person interspersed with telemedicine appointments in order to expand the range of available treatments. Even without issuance of prescriptions, a general consultation should still require a license in the state where the patient resides, as will be addressed in the next paragraph.

Some states that have enacted telemedicine statutes generally make available these practices solely for patients and health-care providers located on their soil. Delaware requires health insurers to recognize and reimburse medical treatments delivered by telemedicine. Delaware's insurance protections apply if the patient is located in Delaware during the administration of the telemedicine and must receive the telemedicine from a health care provider legally allowed to practice in the state.[278] Given that insurance is the statute's subject matter, and insurance is regulated by states for activities within their boundaries, these rules make sense. However, the intrastate geographic restriction also means these laws do not accommodate the full benefits offered by telemedicine. New York identifies approved

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276. 129 Conn. App. 575, 19 A.3d 1264 (2011), *aff'd*, 309 Conn. 727, 72 A.3d 1034 (2013).

277. *Appointments,* MARTY ROSS MD HEALING ARTS, https://martyrossmd .com/appointment_[https://perma.cc/8AMM-JGEB] (last visited July 14, 2020). Prescribing controlled substances (within the meaning of the Federal Food, Drug and Cosmetic Act) through telemedicine may be limited or prohibited under the Ryan Haight Online Pharmacy Consumer Protection Act, 21 U.S.C. § 829(e) (2012). *See* Dillon Vaughn, Note, *Amending the Ryan Haight Act: Elevating Telemedicine Laws to New Heights*, 7 TEX. A&M L. REV. 475 (2020).

278. DEL. CODE ANN. tit. 18 § 3370 (2020).

sites where services can be rendered by telemedicine. Among these is the patient's residence in the state of New York.[279] The New York provider of telemedicine must be licensed to practice in the state, but need not be physically present there when he or she administers care.[280] California generally requires health insurance coverage for services provided through telemedicine.[281] Additionally, in Texas, intrastate restrictions on telemedicine have been invalidated on antitrust grounds.[282] Some state telemedicine statutes impose interstate restrictions through licensing mechanisms. Telehealth is understandably subject to the same professional standards as those applicable to in-person services and this should include licensing requirements.[283] Substantially all states require physicians practicing telemedicine to be licensed where the patient is located.[284] Illinois provides that "[a] person who engages in the practice of telemedicine without a license . . . shall be subject to penalties. . . ."[285] Anyone delivering telemedicine services to Illinois residents must be licensed in Illinois, which is a perfectly reasonable regulatory posture, but one that impedes telemedicine across state lines. Addressing the telemedicine interstate problem through licensing leaves open the question of multistate licensing. This problem will be addressed in the next subsection.

*2. Multistate Licensing Compacts*

Twenty nine states are now party to the Interstate Medical Licensing Compact.[286] The Interstate Compact offers an economic,

279. N.Y. PUB. HEALTH LAW § 2999-CC(3)(g) (McKinney 2020).

280. N.Y. PUB. HEALTH LAW § 2999-CC(1) - (2) (McKinney 2020).

281. CAL. INS. CODE § 10123.85(c) (West 2020).

282. The United States District Court for the Western District of Texas enjoined (on antitrust grounds) the Texas Medical Board from prohibiting the practice of telemedicine in Texas. The court followed *Professional Engineers, see supra* note 103, finding the practice harmful to competition and rejecting as insufficient and unpersuasive the Texas Medical Board's evidence that telemedicine presented dangers to patients. Teledoc, Inc. v. Texas Medical Bd., 112 F. Supp. 3d 529 (W.D. Tex. 2015). In 2017, Texas enacted a telemedicine statute, TEX. OCC. CODE § 111.001 *et seq.* (West 2020).

283. CAL. BUS. & PROF. CODE §§ 686, 2290.5 (West 2020).

284. FEDERATION OF STATE MEDICAL BOARDS, TELEMEDICINE POLICIES: BOARD BY BOARD OVERVIEW (2019), http://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf [https://perma.cc/4S4F-NACX].

285. 225 Ill. Comp. Stat. § 60/49.5(b) (2020).

286. *Information for Physicians,* INTERSTATE MEDICAL LICENSURE COMPACT (2020), https://imlcc.org/ [https://perma.cc/WAQ8-AYH7]. To address the COVID-19 pandemic, most states have temporarily recognized the licenses of out-of-state practitioners authorized and in good standing to practice in their state of licensure. Some limit activities to addressing COVID-19 and may also limit

efficient, and expedited means of attaining multistate medical licensing. The Interstate Compact

> adopts the prevailing standard for licensure and affirms that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter, and therefore, [sic] requires the physician to be under the jurisdiction of the state medical board where the patient is located. State medical boards that participate in the Compact retain the jurisdiction to impose an adverse action against a license to practice medicine in that state issued to a physician through procedures in the Compact.[287]

The Interstate Compact directs and empowers medical boards in member states to determine if the physician is entitled to expedited licensure and to issue a letter of qualification after which the medical board issues an expedited license.[288] Each participating physician must designate a member state as the state of principal license and that state must be supported by principal residency or practice.[289] While streamlining licensing, the Interstate Compact may add risk to practitioners. For example, a licensing revocation in the state of principal license results in a revocation by all other medical boards. Additionally, disciplinary action by any member board, even in a state other than that of the principal license, may trigger discipline by other member boards.[290] There is therefore a potential cross-violation and cascade effect. There is also potential incongruity between subspecialties and designations between the state of principal license and other states. Finally, the most populous states, including California, Texas, New York, Florida, Ohio, and New Jersey have not enacted the Interstate Compact. Nevertheless, the Compact has been used by more than 3,000 physicians to secure over 5,400 medical licenses.[291]

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activities to certain facilities, impose time restrictions and other limitations and conditions. Substantially all exist to address emergency conditions brought about by COVID-19. Many accomplish this through temporary, out-of-state practice permits. *See* FEDERATION OF STATE MEDICAL BOARDS, U.S. STATES AND TERRITORIES MODIFYING LICENSURE REQUIREMENTS FOR PHYSICIANS IN RESPONSE TO COVID-19 (2020), https://www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declarations-licensures-requirementscovid-19.pdf [https://perma.cc/6AG6-H87A].

287. INTERSTATE MEDICAL LICENSURE COMPACT (2015), § 1, p. 1, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf [https://perma.cc/6YFP-ZDYK] [hereinafter *Interstate Compact*].

288. *See* INTERSTATE COMPACT, *supra* note 287, § 5 at 6-7.

289. *See* INTERSTATE COMPACT, *supra* note 287, § 4(a), at 5.

290. *See* INTERSTATE COMPACT, *supra* note 287, § 10(a), at 10.

291. AMERICAN MEDICAL ASSOCIATION, ESTABLISHED PATIENT RELATIONSHIPS AND TELEMEDICINE, Resolution 215-I-18 at 5 (2019),

By designating the patient's location as the place where medicine is practiced, the Interstate Compact generally meshes with Telemedicine laws. Until enacted by more states, the Interstate Compact will have limited utility to those desirous of a fifty-state practice. This means patients will continue to face expensive and inconvenient travel to obtain treatment.

## III. UNRESOLVED LEGAL ISSUES

This section addresses unresolved legal issues associated with Lyme disease, appearing both in the statutes and caselaw. It concludes that state legislation that facilitates medical practice in the real-world treatment of Lyme disease and reimbursement by health insurers for that treatment, while imperfect, are necessary and helpful. However, unless more states enact these measures, many Lyme patients will remain either untreated or peripatetic. Federal legislation, both enacted and proposed, is helpful, but standing alone will not address unresolved problems.

### A. Problems Created by IDSA and CDC Guidance

Among the largest impediments to humane treatment of Lyme disease is the unbending position of the IDSA and CDC with respect to PTLDS/chronic Lyme disease. As noted, the IDSA denies the existence of these conditions[292] and furnishes a "strong" recommendation to avoid a long-term antibiotic as a treatment regimen.[293] In this context, "strong" has a specific meaning, namely, that the IDSA prescription must be followed largely without exceptions and without regard to actual patient experience. The CDC position is no better. While the CDC recognizes the large number of cases, its public communications contain stories of the horrors of Lyme disease misdiagnosis[294] and the perils of long-term antibiotic treatment.[295] The CDC presents one case of someone misdiagnosed with Lyme disease when in fact the shoddy testing experience shows the much bigger problem is not finding people who actually suffer from the disease.[296] While state laws protecting physicians from professional discipline and requiring

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https://www.ama-assn.org/system/files/2019-12/i19-cms-report1-patient-relations-telemedicine.pdf [https://perma.cc/3HQS-XQJE].

292. *See supra* note 21 and accompanying text.

293. *See supra* note 53 and accompanying text.

294. The United States Centers for Disease Control and Prevention, *Feeling Worse After Treatment? Maybe It's Not Lyme Disease*, YOUTUBE (Jan. 1, 2019), https://youtu.be/823jkRIaLgA.

295. *Post-Treatment Lyme Disease Syndrome* (see studies cited after paragraph 4), CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/lyme/postlds/ [https://perma.cc/SD9X-G9XG] (last reviewed Nov. 8, 2019).

296. Registry Report, *supra* note 10, at 18.

insurers to pay for long-term antibiotics are helpful for those choosing to help Lyme patients, they do not fully alleviate the shortage of Lyme-literate M.D.s. One reason is the average infectious disease specialist will see the IDSA guidelines and give up trying to heal Lyme patients by incorrectly concluding they suffer from another disease. Physicians also rightfully fear malpractice liability and the IDSA and CDC positions set standards against which they will be judged. Thus, no amount of informed consent and immunities from professional discipline will protect the physician who prescribes long-term antibiotics that actually cause damage, which could occur in certain cases. The IDSA guidelines are sufficient to either dissuade physicians from entering the Lyme disease subspecialty or, for those brave enough to practice it, to curtail legitimate treatment regimens.

This does not mean there have been no attempts to rectify this state of affairs. The Working Group Report points to deficiencies in testing, discrimination against Lyme patients and their physicians, together with unfair practices by insurance companies.[297] Recently enacted federal legislation in the form of the "Kay Hagan Tick Act"[298] responds to some of the recommendations manifested in the Working Group Report. Earlier bills had established a separate Office of Oversight and Coordination for Vector-Borne Diseases to create and oversee a national strategy concerning Lyme disease and other vector-borne diseases.[299] The separate office was not enacted into law. The Kay Hagan Tick Act instead tasks the Secretary of Health and Human Services, together with various other agencies, with the responsibility to develop a national strategy to combat and treat vector-borne diseases, including Lyme disease. In developing the strategy, the new law also requires the Secretary to "coordinate with the Tick-Borne Disease Working Group established under Section 2061 of the 21st Century Cures Act" and to "consult with non-Federal individuals with appropriate expertise, which may include . . . representatives of patient advocacy and research organizations that focus on vector-borne diseases, including those that focus specifically on tick-borne diseases and have demonstrated experience in related research, public health, data collection or patient access to care. . . ."[300] Such individuals have been represented in the working group that published the Working Group Report and the Working Group Report reflects a balance of perspectives between the IDSA and CDC views and those who actually treat patients in the field. It is unclear if the Kay Hagan Tick Act will assist agencies such as the CDC in attaining the perspective of those who suffer from the disease and those who treat it.

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297. *See supra* note 269 and accompanying text.

298. Kay Hagan Tick Act, Pub. L. 116-94, § 404 (codified at 42 U.S.C. § 247b-22 (2020)) [hereinafter *Kay Hagan Tick Act*].

299. Ticks: Identify, Control and Knockout Act, H.R. 3073, 116th Cong. (2019) § 2(a) (this bill was not enacted and was superseded by the Kay Hagan Tick Act).

300. *See* Kay Hagan Tick Act, *supra* note 298, § 2(b)(2)(B)(ii), at 12–16.

The Kay Hagan Tick Act only requires the Secretary to "consult" with non-Federal individuals and is free to reject their advice. The Secretary must "coordinate" with the CDC but need only "consult" with the non-Federal individuals. Given the CDC's standing as a governmental agency, this dichotomy is understandable. Nevertheless, it means the Secretary need only listen to non-Federal individuals and need not act on their advice or involve them in any decisions. Agency resistance can surely be anticipated. Indeed, the experience with the IDSA Draft Guidelines, which are, on a restricted basis, made public for comments, is a case in point to anticipate the utmost resistance. IDSA has consistently rejected thoughtful public comments and has clung to its rigid position despite emerging real-world evidence and studies that undercut its position. In addition to consultation with non-Federal individuals, the Kay Hagan Tick Act also directs the new office to "coordinate" with the working group that published the Working Group Report.[301] Finally, the Kay Hagan Tick Act provides for separate Federal granting authorities for, respectively, educational and state entities (including Indian tribes). Grants to educational institutions will be used to establish regional centers of excellence in vector-borne diseases. Grants are also made available to state entities to "increase capacity to identify, report, prevent and respond to [vector-borne] diseases and related outbreaks."[302]

IDSA is not a government agency. It is a not-for-profit organization and operates as a medical society concentrating on infectious disease issues. It has no legal obligation to lack bias, and, subject to relevant laws, it is free to lobby or advocate public positions. Its members can and do accept roles conflicting with the welfare of Lyme patients, such as testifying as experts in litigation on behalf of insurance companies, issuance of patents on Lyme vaccines, consulting contracts with the health care and insurance industries, and similar roles. However, this freedom also means the IDSA is nothing more than a collection of non-Federal individuals, in the parlance of the Kay Hagan Tick Act. As such, its views should be accorded the same degree of respect as ILADS or any other non-Federal individual – no more and no less. The IDSA should not set medical practice standards, nor should it be a gatekeeper of research. It is simply an organization that promotes the interests of its members--a perfectly legitimate role. The difficulty is the IDSA role has been elevated to in fact influence greatly the standards applied at both state and federal levels. To the extent the IDSA sets standards, it is conflicted. IDSA members should not benefit from standards they set. The question is, who bears the burden to reject these standards?

IDSA contends its guidelines do not set standards for medical practice and insurance and further points out it lacks any authority to enforce the guidelines. This position ignores the practical reality of professional standards, where anyone viewed as a maverick is shunned and

301. *See* Kay Hagan Tick Act, *supra* note 298, § 2(b)(2)(A), at 13–15.
302. *See* Kay Hagan Tick Act, *supra* note 298, § 3(a), at 18–19.

exposed to liability and loss of license. This means the IDSA standards are, for all practical purposes, mandatory in most quarters and otherwise highly influential. IDSA members own patents, have consulting contracts with the insurance and pharmaceutical industries, and testify before courts and legislative bodies in favor of the IDSA position. When confronted about these activities, the IDSA will say the acts of its members are not to be attributed to it. But this is a symbiotic relationship, where the IDSA position aids these members in their various private pursuits.

Because it is a government agency and part of HHS, problems with the CDC are different. While the 21st Century Cures Act and the Kay Hagan Tick Act give voice to the practical experience of Lyme-literate MDs and the sufferings of their patients, there is nothing requiring CDC to change or even to listen. CDC has already taken pains to state that its surveillance standards are not intended to set medical standards.[303] However, that qualification has done little to blunt the influence the CDC surveillance standards have had on medical practices or lack thereof. Also very damaging is the rigid criteria the CDC sets for the very existence of chronic Lyme disease,[304] all predicated on what even the CDC admits are inaccurate testing methods.[305] In the end, the Kay Hagan Tick Act gives practitioners a voice, but offers no assurance the CDC will listen.

### B. Inconsistent, Jurisdiction-Specific Protections

Because states regulate both the practice of medicine and the administration of insurance, Lyme disease patient rights must for the most part be created at the state level. Only eighteen states[306] have laws that, in various forms, address Lyme disease and even among these, some only promote awareness and do no more. And as the discussion above has shown, even among the states, these vary considerably. One salutary aspect of this diversity of protections means experiences can be studied and compared. However, while study is important, in the meantime, some will suffer in places that offer insufficient protections. Those suffering from Lyme disease in the majority of states, including heavily populated states like Florida and Texas, will continue to experience challenges as to care and, when care is available, insurance may not cover that care. Federal legislation does nothing to alleviate this problem and the studies it fosters, while helpful in progressing to improved treatments or even a cure, do nothing to help the many now suffering.

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303. *See* 2017 Case Definition, *supra* note 12.

304. *See supra* notes 20–21 and accompanying text.

305. *See supra* note 38 and accompanying text.

306. California, Connecticut, Delaware, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, West Virginia and Wisconsin.

The majority of states have no Lyme disease laws. There, the legislative thrust should be in three areas: (1) insurance reforms; (2) physician disciplinary guidance; and (3) disease tracking and reporting. Concerning insurance reforms, at a minimum, physician-supervised prescription of long-term antibiotics and Lyme disease diagnostic testing (serologic or otherwise) should be codified as legitimate practices subject to reimbursement by insurance and, as Minnesota has done, reimbursed on the same terms as other approved medical expenses. Rhode Island, together with the noted Minnesota provision, furnish good models for these laws. These laws have been criticized as too prescriptive and even dangerous, but these considerations should be weighed against benefits that many find in antibiotics administered over longer periods. These prescriptive provisions are a very understandable reaction to an otherwise skeptical and often hostile insurance environment. Physician disciplinary guidance reform means, at a minimum, that states will not discipline physicians for prescribing the long-term antibiotics that insurers should reimburse. Also helpful will be laws that protect doctors from scrutiny for pursuing medications and treatments deemed "experimental" or non-traditional. Because reporting to medical licensing boards is largely a privileged and confidential matter, physicians seldom have any opportunity to confront persons who report their alleged misdeeds and omissions. Opening confidential whistle blowing to public challenge may have deleterious effects if legitimate abuses go unreported. This is why the blunt instrument of immunizing the health professional from discipline for specified and limited conduct may be a necessary solution. There is a two-fold difficulty with this. First, it may immunize abusive practices from discipline. Second, the protection may not extend to other practices considered non-traditional. The author believes the solution to be imperfect but nonetheless necessary and important. To accommodate scientific advancement in treatments and perhaps one day a cure, the laws should, as Illinois has done, protect doctors from discipline for methods deemed experimental. The third needed law, disease tracking, is critical because the practice of medicine is regulated at the state level and state departments of health are generally best positioned to collect information on the prevalence of ticks and the disease. Collecting, aggregating, and analyzing data is critical for several reasons. It will help shape funding priorities for prevention, treatment, and investments to improve testing and treatments. Data also improves research on what works and what does not. Additionally, tracking builds the public awareness necessary to make the prevention efforts needed by the public. Because it collects claims information from insurers, Maine has among the best public Lyme disease reporting laws. Insurance information, while not without its own drawbacks, should be studied because it tracks an important part of the economic impact expressed as medical costs, and these can be instructive as to other effects on public welfare. Like other data, insurance information is imperfect. Insurance information would not pick up

uninsured claims not submitted to any insurance carrier and may not be entirely reliable to the extent Lyme disease is reported as another ailment.

There are critiques of the reforms described in the preceding paragraph with particular reference to insurance reforms and physician disciplinary guidance. These critiques derive principally from the notion that physicians and patients should not be entirely free to develop methods to treat a disease. Instead, the treatment must be validated through the application of "evidence-based medicine."[307] When applied to antibiotics, evidence-based medicine would look to randomized, controlled trials that measure effectiveness of the antibiotic versus a placebo.[308] Clinical and anecdotal experience are unimportant to evidence-based medicine and it discards these real-world considerations. According to this critique, laws that require insurers to reimburse the cost of long-term antibiotics and that immunize from discipline physicians who prescribe them present undue risks to the public. These take the form of harms caused to patients by antibiotics and a much larger risk that there will develop new strains of antibiotic-resistant microbes. As to the first concern, doing harm to patients, these concerns rely principally on specific cases that amount to horror stories. And so those who decry the use of long-term antibiotics as lacking in scientific support posit scant scientific evidence to prove the harms. The second concern, that antibiotic resistant microbe strains will develop, is also not scientifically proven. Here, the problem lies principally in hospital and nursing home environments involving patients with compromised immune systems. While the CDC's *2015 National Action Plan for Combating Antibiotic-Resistant Bacteria* cites the curbing of "[m]issue and over-use of antibiotics in healthcare" among its five principal goals, it contains no specific findings that point to long-term antibiotic therapy as a major contributor to the problem.[309] In the CDC's Biggest Threats and Data, 2019 AR Threats Report, of the five urgent threats cited, three arise predominantly in health care facilities and nursing homes and a fourth includes drug-resistant gonorrhea.[310] It's difficult to see the connection between these urgent threats and the prescribing of long-term antibiotics for Lyme disease. The fifth urgent threat, *Clostridivides difficile (C. difficile)* "causes life threatening diarrhea and colitis . . . mostly in people who have

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

308. *Id.* at 212.

309. CTRS FOR DISEASE CONTROL AND PREVENTION, NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 5 (2015), https://www.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf [https://perma.cc/6467-9FHL].

310. *Antibiotic/Antimicrobial Resistance (AR/AMR): Biggest Threats and Data,* CTRS FOR DISEASE CONTROL AND PREVENTION (2019), https://www.cdc.gov/DrugResistance/biggest-threats.html [https://perma.cc/3QZA-4FXU].

had recent medical care and antibiotics."[311] Lyme-literate M.D.s acknowledge this threat, monitor it, and take steps to prevent it.[312] To conclude that long-term antibiotic regimens for Lyme disease patients contributes to antibiotic-resistant disease is scientifically unproven and a red herring in the enactment of laws designed to protect Lyme patients and their doctors. Intravenous administration of antibiotics is another area where Lyme naysayers point to risks. While any intravenous procedure has risks, the risk of complication from intravenous antibiotics is no greater than intravenous placebo.[313]

This leaves unanswered the scientific question of whether long-term antibiotics make a difference in patient health. The studies challenging the efficacy of long-term antibiotics rest on a foundation of sand because (as discussed) the serologic testing for Lyme disease is inherently unreliable. Even reliable testing would still not resolve the controversy over which serologic bands should apply. Despite these admitted shortcomings, chronic Lyme naysayers will point to the studies that support their position. The naysayers also offer no treatment regimen for chronic Lyme disease and instead merely admonish against long-term antibiotics with no therapeutic suggestions, much less any solutions. The best they can offer is palliative care.

Given the dearth of physicians willing to treat Lyme patients and the treatment accorded those who do so by insurance companies and state medical boards, law reform should come as no surprise. It is, however, true that casting medical regulation to accommodate today's medical technology may not leave room for future, to-be-developed medical programs that help patients. As noted, the disparate state legislative positions create opportunities for comparative analysis. Now, more than a decade after passage of the first Lyme-oriented statutes, we would do well to evaluate their effects. If, as Lyme naysayers contend, reforms add risk to the system, there are now opportunities to evaluate those risks. The critique of state Lyme reform laws also ignores the fact that patients harmed can and do make claims for medical malpractice, battery, breach of warranty and other causes of action for physicians that negligently, recklessly, or intentionally cause harm.

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311. Pfizer has now published Phase 2 study results for its Clostridium difficile vaccine. *Clostridium Difficile Vaccine Efficacy Trial*, PFIZER, https://www.pfizer.com/science/find-a-trial/nct03090191 [https://perma.cc/7UUE-7EXU] (last updated Apr. 15, 2020).

312. *See* HOROWITZ, *supra* note 13, at 160.

313. Raphael Stricker, Remarks at *IDSA Lyme Disease Review Hearings,* YOUTUBE (July 30, 2009), https://youtu.be/BSxLfkoY8Po.

## CONCLUSION

This article has identified and critiqued laws designed to redress and alleviate suffering caused by Lyme disease. In cases where laws have not met their goals, the article has discussed whether further law reform would alleviate the plight of Lyme patients and their families. It concludes that state legislation to immunize Lyme-literate M.D.s from licensing scrutiny for the prescribing of long-term antibiotics and non-traditional care, together with correlative requirements for health insurers to cover this care, medication, and testing, are necessary tools to offer some relief to Lyme patients. However, these laws function as highly prescriptive blunt instruments and may fail to accommodate evolving Lyme science and practice. Emerging medical practices can be accommodated by laws such as California's safe harbor, but this depends on an elaborate and ineffectual system of disclosure and informed consent. Many well-counseled practitioners will draw little comfort from these protections and they may also not be especially good for patients.

Irrespective of law, Lyme disease remains misunderstood and misdiagnosed. A federal Lyme registry that records cases and symptoms in a realistic fashion will help the medical community understand the Lyme disease problem is widespread and severe. Due to its intractable position concerning chronic Lyme disease, the CDC should not oversee this registry. Instead, an independent federal body, like that proposed in Federal legislation that failed,[314] should undertake responsibility for the registry. This body should include representatives of national patient advocacy and research organizations that specialize in vector-borne disease. The patient registry should track not only the existence of cases, but their symptoms, severity, and impact on human welfare. Technology and privately-collected Lyme data, while imperfect, will help gain insights into the myriad of conditions and symptoms and this will justify much needed research and investment.

Despite extensive criticism and a Connecticut antitrust investigation, IDSA's position concerning the existence of chronic Lyme disease remains intractable. The marketplace, ranging from health insurers to medical licensing boards, has viewed these to have mandatory consequences. Unless corrected by antitrust decree or other judicial ruling, this position will stand no matter what the emerging science. A modest, piecemeal counterweight to this problem has occurred in the enactment of laws in some states that address this problem. These include the aforementioned immunities offered to physicians and insurance coverage mandates. To date, these have appeared in a minority of states and therefore afford incomplete protections for affected populations. Patients should not count on relief arising under antitrust laws or other litigation and may do

314. *See supra* note 299 and accompanying text.

better to press for reform at state levels. However, even states like New York with large numbers of Lyme patients are reluctant to address the problem and there appear few grounds for legislative compromise often needed to enact helpful laws.

Lyme disease remains misunderstood because it cannot be reliably tested, it thrives with numerous co-infections, and its symptoms can be mistaken for many other diseases treated by entirely different methods. Ultimately, medical science and not the law must resolve these problems. While we wait, Lyme patients should not be left to rot and, as this article has shown, the law can do something about that.