

ANTIBIOTIC MAXIMALISM: LEGISLATIVE ASSAULTS ON THE EVIDENCE-BASED TREATMENT OF LYME DISEASE

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INTRODUCTION

Antibiotics, and the deadly pathogens that have evolved to resist them, are one of the major public health concerns of our time. The introduction of penicillin in the early 1940s signaled a new era—not only for the treatment of devastating infections,¹ but also of the out-witting of those antibiotics by fast-evolving bacteria.² If the middle of the twentieth century saw the era of antibiotic innovation,³ the past several years might be labeled the era of antibiotic resistance, when untreatable infections have become a modern scourge.⁴ Methicillin-resistant *Staphylococcus aureus* (MRSA) is the most notorious antibiotic resistant “superbug”;⁵ in a few short years, MRSA infections have become both a leading cause of hospitalization for children⁶ and an enormous problem in hospitals and nursing homes.⁷ In 2011, bills were introduced in both houses of Congress⁸ to encourage the development of new antibiotics to replace those that have become

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¹ See generally Kenneth B. Raper, *Decade of antibiotics*, 154 MYCOLOGIA 1 (1952).

² Harold C. Neu, *The Crisis in Antibiotic Resistance*, 257 SCI. 1064, 1064-65 (1991). Within three years of the 1941 introduction of penicillin-G, *Staphylococcus aureus* (the agent of “staph” infections) had already evolved resistance to that antibiotic. *Id.* The effect of the antibiotic era on bacterial evolution are truly striking; in 1941 “virtually all” strains of *S. aureus* could be killed by penicillin. *Id.* Only 50 years later, in 1991, 95% of *S. aureus* worldwide were resistant to the drug. *Id.*

³ See Raper, *supra* note 1.

⁴ See Gary Taubes, *The Bacteria Fight Back*, 321 SCI. 356, 356 (2008) (“The last decade has seen the inexorable proliferation of a host of antibiotic-resistant bacteria, or bad bugs, not just MRSA but other insidious players as well, including *Acinetobacter baumannii*, *Enterococcus faecium*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Enterobacter* species.”).

⁵ See, e.g., Nicholas D. Kristof, Op-Ed, *The Spread of the Superbugs*, N.Y. TIMES, March 6, 2010, at WK12 (citing the fact that MRSA kills more Americans annually than AIDS).

⁶ AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, STATISTICAL BRIEF #118. HEALTHCARE COST AND UTILIZATION PROJECT (2011).

⁷ Tara Parker-Pope, *More Children Hospitalized With Skin Infections*, N.Y. TIMES WELL BLOG (Aug. 11, 2011), <http://well.blogs.nytimes.com/2011/08/11/more-children-hospitalized-with-skin-infections>.

⁸ Generating Antibiotic Incentives Now (GAIN) Act of 2011. H.R. 2182, 112th Cong. (2011); S. 1734, 112th Cong. (2011).

ineffective.⁹ Yet, unless or until a truly “miracle” antibiotic (i.e., one which may not be resisted by bacteria) is someday developed, the only solution to antibiotic resistance is to reduce the use of antibiotics.¹⁰

Surprisingly, amidst public-health efforts to prevent antibiotic-resistant pathogens by reining in excessive antibiotic use,¹¹ several states have passed laws that legitimize intensive antibiotic regimens even when those regimens contradict the best available medical evidence.¹² Although this unprecedented legislative activity has occurred in the context of a controversial medical diagnosis—chronic Lyme disease—the legal and political repercussions threaten the established role of state medical licensing boards in promoting evidence-based standardization of medical practice. The most intrusive of these statutes¹³ prevents state licensing boards from disciplining physicians who prescribe regimens of “long-term antibiotic therapy” that are specifically proscribed by mainstream clinical practice guidelines (CPG) on Lyme disease treatment.¹⁴ Such laws promote the view of non-standard practitioners¹⁵ who favor the intensive, *maximalist*¹⁶ use of

⁹ Press Release, House Members Introduce Bipartisan Bill to Combat the Rise of Drug Resistant Infections (June 15, 2011), *available at* <http://gingrey.house.gov/News/DocumentSingle.aspx?DocumentID=246729>. (“There are some issues so important they transcend politics-as-usual. Protecting American families from deadly infections is certainly one of them, which is why my colleagues and I are introducing the GAIN Act. With this legislation, we hope to ensure that new drugs will be available to combat the rising numbers of antibiotic-resistant bugs that threaten Americans in hospitals, on the battlefield, in their homes, and in our schools.”)

¹⁰ Taubes, *supra* note 4, at 361 (noting that one expert calls such a miracle antibiotic a “laughable” notion”).

¹¹ The CDC provides three fundamental guidelines for curtailing antibiotic resistance: (1) “Only prescribe antibiotic therapy when likely to be beneficial to the patient,” (2) “Use an agent targeting the likely pathogens,” and (3) Use the antibiotic for the appropriate dose and duration.”

CDC, ANTIBIOTIC RESISTANCE QUESTIONS & ANSWERS, <http://www.cdc.gov/getsmart/antibiotic-use/antibiotic-resistance-faqs.html#i> (accessed Jan. 15, 2011).

¹² See *infra* section I.B.2.

¹³ State legislative responses to this debate have taken a variety of forms, from inaction to resolutions to statutes. This Note will focus most of its attention on laws in Connecticut, Massachusetts, Rhode Island, and California that specifically bar discipline of physicians for defying mainstream practice guidelines. CONN. GEN. STAT. § 20-14m (2011); MASS. GEN. LAWS ch. 112, § 12DD (2011), CAL. BUS. & PROF. CODE § 2234.1; R.I. GEN. LAWS ANN. § 5-37.5-4 (West, 2011).

¹⁴ The mainstream clinical practice guidelines on the treatment of Lyme Disease was developed by the Infectious Disease Society of America (IDSA). Gary P. Wormser et al., *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America*, 43 CLINICAL INFECTIOUS DISEASES 1089 (2006) [hereinafter *IDSA Guidelines*]. IDSA publishes CPGs on treating a variety of infections. See IDSA, PRACTICE GUIDELINES, http://www.idsociety.org/IDSA_Practice_Guidelines (accessed Feb. 4, 2012).

¹⁵ The International Lyme and Associated Diseases Society (ILADS), the primary organization for the promotion of alternative diagnoses and treatments for Lyme disease, publishes its own treatment guidelines. As is explored in more detail below, the ILADS guidelines contradict the IDSA guidelines in many respects, including in their advocacy of long-term antibiotic therapy and other controversial treatments. See Daniel Cameron et al., *The International Lyme and Associated Diseases Society. Evidence-*

antibiotics for a condition that mainstream physicians dispute even exists.¹⁷ In an attempt to protect unnecessary antibiotic regimens, recent legislation legitimizes a treatment paradigm that poses an undue risk of harm to individual patients,¹⁸ and also to the public health.¹⁹

By enacting laws that protect and legitimize repudiated treatments, state legislatures have responded to a movement of non-standard “Lyme-literate medical doctors” (LLMDs)²⁰—a movement that has been described as an “antiscience,” “parallel universe of pseudoscientific practitioners” by a mainstream group of practitioners.²¹ In addition, by interfering with the legal authority of state medical boards to enforce evidence-based standards on antibiotic use, states have also sided with a fringe movement of physicians²² who oppose the “encroachment” of third-parties,²³ including the government, upon the physician-patient relationship.²⁴ These advocates decry the standardizing influence exerted on medical practice by evidence-based clinical guidelines

based guidelines of the management of Lyme disease, 2 EXPERT REV. ANTI-INFECTIVE THERAPY, no. 1, 2004 at S1 [hereinafter “ILADS Guidelines”].

¹⁶ The enthusiastic attitude toward clinical antibiotic use that is championed by (among others) many non-standard Lyme disease practitioners, is referred to herein as *antibiotic maximalism*. See *infra* section I.B.3.

¹⁷ See *infra* section I.B.2.

¹⁸ See *infra* section IV.A.

¹⁹ See *infra* section IV.C.

²⁰ Paul G. Auwaerter et al., *Antiscience and ethical concerns associated with advocacy of Lyme disease*, 11 LANCET 713, 713 (2011).

²¹ Paul G. Auwaerter et al., *Antiscience and ethical concerns associated with advocacy of Lyme disease*, 11 LANCET 713, 713 (2011).

²² A prominent voice in this movement is the Association of American Physicians and Surgeons (AAPS), which “has exerted vocal influence in the country’s health care debate, despite having just 3,000 dues-paying members.” Barry Meier, *Vocal Physicians Group Renews Health Law Fight*, N.Y. TIMES, Jan. 19, 2011, at B3 (noting that the group’s “scientific views often fall outside medicine’s mainstream” and citing their publication of studies that link vaccines to autism and abortions to breast cancer). The AAPS is involved in litigation fighting various provisions of the Patient Protection and Affordable Care Act. Motion of Assoc. of Am. Physicians & Surgeons, Inc. and Alliance for Natural Health USA to Intervene as Respondents, Dept. Health & Human Servs. v. Florida, No. 11-398 (U.S. Dec. 6, 2011). The AAPS advocates for other conservative public health positions, including a recent suit filed against the FDA attempting to vacate the agency’s decision to allow over-the-counter sales of emergency contraceptive to individuals over the age of 18. Ass’n of Am. Physicians v. FDA, 358 F. App’x 179 (D.C. Cir. 2009) (affirming lower court’s dismissal based on plaintiff’s lack of standing), *cert. denied*, 131 S. Ct. 1062 (2011).

²³ See Press Release, Association of American Physicians and Surgeons, Inc., AAPS Comments on IDSA Lyme Guidelines (April 26, 2009) (*available at* <http://www.aapsonline.org/testimony/lyme-disease-guidelines-comments.php>) [hereinafter “AAPS Comments on IDSA Lyme Disease Guidelines”].

²⁴ See, generally, Maxwell J. Mehlman, *Quackery*, 31 AM. J.L. & MED. 349, (2005). Mehlman blames “anti-regulatory, neo-conservative economic philosophy” for “creat[ing] conditions conducive to modern quackery.” *Id.* (citing Republican efforts to pass legislation “that would broaden the ability of licensed health care professionals to treat patients with alternative approaches,” such as the Access to Medical Treatment Act, H.R. 2085, 108th Cong., (2003).

and state medical licensing boards.²⁵ Removing the power of state regulators to discipline physicians for dangerous, non-standard Lyme disease treatment is perceived as an opening salvo in the attack on the legitimacy of state medical oversight.²⁶

Part I of this Note describes clinical practice guidelines generally, including their legal implications, before describing the conflict between two, competing Lyme disease treatment guidelines. Part II examines the political and legal debates that have led to state discipline-preemption statutes. Part III analyzes how new state laws in this area (hereinafter “LLMD-protection” laws) promote the maximalist use of antibiotics championed by non-standard practitioners. Part IV is a discussion of the ramifications of LLMD-protection laws. Though such legislation has mostly been limited to the geographic regions most affected by Lyme disease,²⁷ similar laws are being considered by other states²⁸ as non-standard Lyme disease practice has become a nationwide phenomenon.²⁹ These statutes demonstrate the irrational policies that may result from the politicization of medical science. By repudiating evidence-based clinical practice guidelines, states have put patients at risk of receiving dangerous and unnecessary treatment. Furthermore, by precluding state regulators from disciplining certain maximalist uses of antibiotics, LLMD-protection laws interfere with an important tool in the fight against antibiotic resistance. Part V offers a few concluding remarks.

I. CLINICAL PRACTICE GUIDELINES AND THE CONTROVERSY OVER LYME DISEASE TREATMENT

Before proceeding, it is important to acknowledge that neither the legal nor the scientific discussions of Lyme disease are grounded in absolutes. Clinical practice guidelines (CPGs) are not definitive statements of the standard of care required of physicians, but rather voluntary recommendations that are, ideally, based in the best-available evidence.³⁰ Meanwhile, state medical licensing statutes provide that physicians may be disciplined for vaguely defined offenses such as “unprofessional conduct.”³¹

²⁵ See AAPS Comments on IDSA Lyme Disease Guidelines, *supra* note 23.

²⁶ See *infra* note 166 and accompanying text.

²⁷ Government statistics indicate that Lyme disease is concentrated in the northeastern and upper-Midwestern regions of the United States. Lyme Disease 2010 Map, CDC, <http://www.cdc.gov/lyme/stats/maps/map2010.html> (last visited Feb. 10, 2012).

²⁸ See *infra* note 164 and accompanying text.

²⁹ Reports of non-standard Lyme practitioners, and disciplinary actions taken against them. Complaint at 3-6, State Bd. Registration for the Healing Arts v. Ryser, No. 09-1693 (Mo. Admin. Hearing Comm’n 2009) (alleging that a Missouri physician provided harmful, non-standard Lyme disease care to a patient, including excessive antibiotic therapy); Trine Tsouderos, *Lyme Doc Has Been Disciplined in Two States*, CHI. TRIB., July 13, 2011, at 1 (reporting on the disciplinary actions taken against a non-standard Lyme practitioner in Iowa and Illinois);

³⁰ See *infra*, note 42.

³¹ See, *infra* notes 57-59 and accompanying text.

And, as in any medical field, our scientific understanding of Lyme disease will continue to evolve.

Nevertheless, statutes that legitimize—and arguably promote—diagnoses and treatments that are repudiated by evidence-based medical guidelines challenge the assumption that evidence-based medicine can withstand the pressures of the democratic process. This is a significant revelation, as evidence-based medicine is a cornerstone of modern proposals to reform the healthcare system.³²

The political and legal controversies surrounding Lyme disease treatment are rooted in an intraprofessional disagreement between mainstream and non-standard clinicians over the proper use of antibiotics to treat Lyme disease. In no small part, this disagreement is a product of a movement among some physicians and their patients who, a variety of reasons, resist the modern drive toward standardization in medical practice, particularly by CPGs.³³ This Part first provides an overview of CPGs and their legal significance. Next, this Part examines two conflicting CPGs for Lyme disease treatment, from the mainstream and non-standard physician communities, respectively. Though it is a simplification to portray the Lyme treatment controversy as a binary one, the competing Lyme disease CPGs have become a significant point of contention among advocates and politicians in states that have passed legislation favoring non-standard practitioners.

A. Clinical Practice Guidelines Generally

Standardization of medical practice has been a goal throughout the modern era, aimed at ameliorating variability in medical practice.³⁴ A key vehicle for standardization in modern practice is the CPG,³⁵ which is designed to summarize the best available evidence and recommend courses of action to practicing physicians.³⁶ Modern CPGs,

³² See Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1727, 1734 (2011) (“[I]mprovement of health care generally requires system-wide improvements—reducing medical practice variation by figuring out what works, synthesizing these findings into clinical practice guidelines and best practices, and then applying them to ensure effective treatments.”) (citations omitted).

³³ See, AAPS Press Release, *supra* note 23 (“It is each physician, and often only the physician, who knows the patient’s history, course of illness, severity of presentation, and responsiveness to treatment. AAPS objects to any curtailment of individualized treatment of patients by competent physicians, and no Guidelines should be adopted that infringe on such treatment.”)

³⁴ TIMMERMANS AND BERG, *THE GOLD STANDARD: THE CHALLENGE OF EVIDENCE-BASED MEDICINE AND STANDARDIZATION IN HEALTH CARE* 14-16 (2003). (citing CPG’s and evidence based-medicine, as the solution, historically, to “the lack of scientific working habits in the health care field”).

³⁵ George Weisz et al., *The Emergence of Clinical Practice Guidelines*, 85 MILBANK Q. 691, 692 (2007) (“The proliferation of collectively produced guidelines since the 1980s represents a growing effort to bring order and coherence to a rapidly expanding and heterogenous medical domain.”).

³⁶ REPORT BRIEF: CLINICAL PRACTICE GUIDELINES WE CAN TRUST, INSTITUTE OF MEDICINE, March 2011, *available at* <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust> (accessed October 16, 2011).

such as the IDSA Guidelines on Lyme disease treatment,³⁷ are “consensus statements” of the appropriate therapy or medical response to a particular set of symptoms.³⁸ Intended to summarize the best available evidence for the clinician, CPGs provide “an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment.”³⁹ CPGs are developed by a diverse array of parties, including professional medical societies, health insurance companies, and the government.⁴⁰ CPGs promulgated by professional societies, in particular, “are regarded as highly authoritative.”⁴¹

CPGs are by nature voluntary.⁴² In general, the real effect of CPGs on physician behavior has been questioned by some commentators.⁴³ However, the application of CPGs by certain third parties may bolster the impact of CPGs on clinical decision-making. In particular, CPGs may be used (1) by health insurers (to determine whether a therapy will be reimbursed by health insurance),⁴⁴ (2) by the courts, as evidence of the “standard of care” (applied to physicians in malpractice suits and to health insurers when a plaintiff challenges a denial of insurance coverage)⁴⁵ and, (3) by state licensing boards when they enforce professional standards prescribed by statute.⁴⁶

First, the most important impact of CPGs may be on the reimbursement policies of health insurers. When health insurers or managed-care providers use guidelines to decide whether to reimburse patients for a particular intervention, such decisions undoubtedly affect clinical practice.⁴⁷ The controversy over Lyme disease itself reflects

³⁷ IDSA GUIDELINES, *supra* note 14.

³⁸ Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 647 (2001).

³⁹ IOM REPORT BRIEF, *supra* note 36, at 1.

⁴⁰ Mello, *supra* note 38, at 650

⁴¹ Mello, *supra* note 38, at 650. (citing “both physicians’ expertise and the fact that, unlike insurers, physicians’ financial incentives traditionally have been aligned with providing top-quality care to their patients”).

⁴² TIMMERMANS & BERG, *supra* note 34, at 20-21 (“While third parties might try to enforce standards through sanctions, a distinguishing characteristic of standards is that, in comparison to laws and directives, they remain [an] impersonal and voluntary means of regulation.”)

⁴³ See, e.g., Stefan Timmermans, *From Autonomy to Accountability: The Role of Clinical Practice Guidelines in Professional Power*, 48 Persp. Biology & Med. 490, 494 (2005) (suggesting that the standardizing effect of CPGs has been lower than expected).

⁴⁴ See, *infra*, notes 47-49 and accompanying text.

⁴⁵ Arnold J. Rosoff, *Evidenced-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327, 331 (noting that the issues at stake in cases against doctors and insurance companies are increasingly intertwined, applying the same standard of “quality of care” traditionally reserved for malpractice cases: “With growing frequency, suits are filed claiming that the quality of care was inadequate because benefits owed under the plaintiff’s health plan were withheld, either with or without the plaintiff’s knowledge at the time.”).

⁴⁶ See *infra*, notes 56-62 and accompanying text.

⁴⁷ Evidence supporting or contraindicating the use of a therapy in a certain clinical context may influence the insurance provider’s decision to reimburse for that therapy. Earl P. Steinberg & Bryan R. Luce,

the impact of CPGs on insurance reimbursements. As is explored in more detail, *infra*, the perceived impact of CPGs on insurance reimbursement decisions⁴⁸ has fuelled legal and political action against the authors of the mainstream Lyme disease CPG, who have been accused of colluding with insurance companies.⁴⁹

Second, CPGs may impact medical decisionmaking when they are used to establish the legal standard of care, either in the physician malpractice or insurance coverage setting. The status of CPGs as evidence in malpractice and insurance coverage cases is still evolving.⁵⁰ Several considerations suggest that a CPG alone will be unlikely to provide the standard of care applied in a malpractice trial. For a court to apply a CPG directly to the legal standard would likely require legislation, as it would depart substantially from the traditional standard, based in professional custom.⁵¹ However, CPGs may be used indirectly to establish professional standards; guidelines may be the basis of expert testimony establishing “what the relevant custom is in a particular set of circumstances” (i.e. the legal standard for malpractice).⁵²

Commentators have argued against the use of CPGs to set malpractice standards of care because of the difficulty in assessing the reliability of a particular CPG.⁵³ However, the impact of a CPG—especially one promulgated by a respected professional group⁵⁴—might be a significant factor in establishing customary practice. Furthermore, arguments that courts should “ease, or at least not impede, the adoption of evidence-based practices by clinicians and health plans” generally favor the expanded application of CPGs.⁵⁵

Evidence Based? Caveat Emptor! 24 HEALTH AFFAIRS 80, 89 (2005). As a result, “voluntary, flexible guidelines are more likely to become normative...Physicians are hired, compensated, disciplined, and terminated by provider organizations based on their adherence to guidelines.” TIMMERMANS AND BERG, *supra* note 34, at 103-105 (citing, in particular, health insurance reimbursements that are conditioned upon utilization review, a system of retrospective analysis of treatment decisions) (citations omitted).

⁴⁸ See *infra* section III.D.

⁴⁹ See *infra*, section II.A.

⁵⁰ Rosoff, *supra* note 45, at 335.

⁵¹ Rosoff, *supra* note 45, at 339. The traditional legal standard states that physicians must “possess and exercise that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of their profession under similar circumstances.” 61 AM. JUR. 2D *Physicians, Surgeons, Etc.* § 188 (2011).

⁵² Mello, *supra* note 38, at 660.

⁵³ See, e.g. Mello, *supra* note 38, at 648.

⁵⁴ See Mello, *supra* note 38, at 650 (“CPGs developed by professional medical societies are regarded as highly authoritative, due to both physicians' expertise and the fact that, unlike insurers, physicians' financial incentives traditionally have been aligned with providing top-quality care to their patients.”).

⁵⁵ See Clark C. Havighurst et al., *Evidence: Its Meanings in Health Care and in Law (Summary of the 10 April 2000 IOM and AHRQ Workshop, “Evidence”: Its Meanings and Uses in Law, Medicine, and Health Care)*, 26 J. HEALTH POL. POL'Y & L. 195, 209 (2001).

Third, application of a CPG by state medical regulators may convert otherwise voluntary guidelines into a legal mandate.⁵⁶ State medical licensing statutes provide broad authority to medical boards to discipline physicians for their professional misconduct, including by suspension or revocation of the physician's license to practice.⁵⁷ Some licensing statutes include within the definition of professional misconduct (or "unprofessional conduct") the departure from "prevailing medical practice."⁵⁸ Licensing statutes may explicitly direct medical boards to consider relevant CPGs when determining the prevailing practice standards.⁵⁹ In addition, a CPG may be deployed more informally, as an auxiliary indicator of acceptable professional conduct.⁶⁰ Actual practice aside, a majority of clinicians believe that CPGs may influence professional disciplinary decisions.⁶¹ And, the perception among non-standard physicians, in particular, is that their conduct puts them at risk of being disciplined under "unprofessional conduct" laws.⁶²

B. The Controversy Over Lyme Disease Treatment Guidelines

⁵⁶ For the purposes of this Note, the regulatory effect is state professional licensing is emphasized; accreditation and certification of providers are other mechanisms of regulating medical practice, Richard S. Saver, *In Tepid Defense of Population Health: Physicians and Antibiotic Resistance*, 34 AM. J.L. & MED. 431, n.232 (2008).

⁵⁷ *E.g.* CONN. GEN. STAT. ANN. § 20-13c (2011); N.Y. EDUC. LAW § 6503 (McKinney 2011); CAL. BUS. & PROF. CODE ANN. § 2220 (West 2011)

⁵⁸ *E.g.* 63 PA. STAT. ANN § 422.41(8) (West 2011) ("Unprofessional conduct shall include departure from or failing to conform to an ethical or quality standard of the profession"). N.C. GEN. STAT. ANN. § 90-14 (defining "unprofessional conduct" as the "departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice.") North Carolina makes a specific exception for "experimental," "nontraditional" or otherwise unconventional therapy "unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective." *Id.*

⁵⁹ *See, e.g.*, 63 PA. STAT. ANN. § 422.41(8)(ii) (West 2011); COLO. REV. STAT. ANN. § 12-36-117(bb)(II) (West 2011) ("In determining which activities and practices are not consistent with the standard of care or are contrary to recognized standards of the practice of medicine, the board shall utilize, in addition to its own expertise, the standards developed by recognized and established accreditation or review organizations that meet requirements established by the board by rule.")

⁶⁰ *See, e.g., infra* note 150 and accompanying text (describing a reference to the mainstream Lyme disease treatment recommendations in a disciplinary case, in which the guidelines were cited as "the standard treatment").

⁶¹ It is unclear how extensive is the effect of CPGs on medical board disciplinary decisions. Suggestively, however, a majority of clinicians believe that CPGs may influence professional disciplinary decisions. *See* Tunis et al., *Internists' Attitudes About Clinical Practice Guidelines*, 120 ANNALS INTERNAL MED. 956, Table 4 (1994) (indicating that 68% of physicians surveyed thought CPGs were "[l]ikely to be used in physician discipline").

⁶² *See* MICHAEL H. COHEN, COMPLIMENTARY AND ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES, 87 (1998).

Legislative intervention in the regulatory oversight of Lyme disease treatment, the focus of this Note, is rooted in a controversy between competing clinical philosophies. The controversy surrounding Lyme disease treatment has pitted a grass-roots movement of patients and practitioners (who champion the autonomy of the treating physician) against evidence-based standards promulgated by mainstream professionals (the authors of the mainstream CPG on Lyme disease treatment).

Several characteristics have made the Lyme disease controversy particularly heated. Some skepticism toward mainstream physicians originates in the perception that those physicians under-diagnose Lyme disease, unintentionally⁶³ or even intentionally.⁶⁴ Such negative perceptions of mainstream physicians are advanced by self-styled “Lyme-literate MDs” (LLMDs),⁶⁵ who advance the notion, in contradiction of the scientific evidence, that many Lyme infections persist beyond the recommended antibiotic regimen, which lasts less than one month.⁶⁶ Further, LLMDs advocate the unfounded position that Lyme disease is responsible for a host of subjective, difficult-to-measure symptoms, such as generalized pain, fatigue, and cognitive problems.⁶⁷ Confronted with patients who test negative for Lyme disease infection by all objective measures, LLMDs nevertheless insist that the standard, FDA-approved diagnostic tests are not sensitive enough to detect chronic infections.⁶⁸ Most significantly, advocates of non-standard

⁶³ This perception is even perpetuated by at least one state’s health department. See STATE OF RHODE ISLAND DEPARTMENT OF HEALTH, Seeking Care for Lyme Disease <http://www.health.state.ri.us/diseases/lyme/about/seekingmedicalcare/> (“If you have Lyme, or think you might have Lyme, it is important that you learn about the disease and have a physician who is educated about Lyme. Many people with Lyme disease have been misdiagnosed or not diagnosed at all because they did not understand their symptoms and saw physicians who are unfamiliar with the disease. Rhode Island law protects Lyme disease patients by ensuring that they can receive proper treatment and that their insurance companies cover that treatment.”).

⁶⁴ See Paul G. Auwaerter, et al., *Antiscience and Ethical Concerns Associated With Advocacy of Lyme Disease*, 11 LANCET INFECTIOUS DISEASE 713, 714 (2011) (“By the early 1990s, some activist groups...were accusing university scientists and public health officials of intentionally under-reporting and under-diagnosing cases of Lyme disease.”).

⁶⁵ See Auwaerter et al., *supra* note 21, at 714.

⁶⁶ See *infra* section II.B.2 (discussing the mainstream, evidence-based recommendations for Lyme treatment).

⁶⁷ See ILADS GUIDELINES, *supra* note 15, at S5. Because little evidence links pain and other subjective symptoms to Lyme disease, and because these symptoms mirror those ascribed to other unexplained conditions, Lyme disease has been described as “yet another in a long series of ‘containers’ for ill-defined suffering,” including fibromyalgia and multiple chemical sensitivity. Leonard H. Sigal & Afton L. Hassett, *Contributions of Societal and Geographical Environments to “Chronic Lyme Disease”: The Psychopathogenesis and Apology of a New “Medically Unexplained Symptoms” Syndrome*, 110 ENV. HEALTH PERSP. 607, 608 (2002). Even the ILADS Guidelines acknowledge that “[t]he clinical features of chronic Lyme disease can be indistinguishable from fibromyalgia and chronic fatigue syndrome.” ILADS GUIDELINES, *supra* note 14, at S7.

⁶⁸ See Phillip J. Baker, *The Pain of Chronic Lyme Disease: Moving the Discourse in a Different Direction*, 26 FASEB J. 11, 11 (2012) (noting that LLMDs typically resort to laboratories providing unvalidated tests which provide false-positive results of infection). See also CDC, *Notice to Readers*:

Lyme practice believe that intensive, expensive antibiotic regimens are required⁶⁹ to control what those advocates understand to be a persistent and potentially untreatable, “chronic Lyme disease.”⁷⁰

Mainstream infectious disease experts dispute what they see as an unfounded belief⁷¹ in “chronic Lyme disease”—often vehemently.⁷² From the perspective of LLMDs and their patients, however, the recommendation for limited antibiotic use articulated by the mainstream Lyme disease CPG⁷³ amount to nothing short of medical rationing, cloaked in the guise of evidence and expertise.⁷⁴ The mainstream rejection of Lyme disease as an agent for chronic subjective symptoms frustrates many non-standard physicians and their patients. Their frustration erupts into the political sphere when those parties assert that the professional elite has conspired against effective treatment for illegitimate reasons, including economic interests.⁷⁵

For purposes of this discussion, the disagreements between the mainstream guidelines and the competing recommendation from the major association of LLMDs⁷⁶ may be simplified into two categories. First, the mainstream guidelines explicitly recommend against long-term antibiotic therapy (longer than about thirty days), whereas LLMDs strongly advocate therapy that extends for several months. Second, the mainstream guidelines specifically recommend that any antibiotic treatment of Lyme disease be based on objective manifestations of Lyme disease,⁷⁷ such as a positive result from an approved diagnostic test.⁷⁸ On this second point, LLMDs and their treatment guidelines sharply disagree; they emphasize that the decision to pursue antibiotic therapy be primarily left to the judgment of the physician, regardless of a negative test result.⁷⁹

Caution Regarding Testing for Lyme Disease, 54 Morbidity & Mortality Weekly Report 125 (Feb. 11, 2005), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5405a6.htm> (last accessed Jan. 22, 2012).

⁶⁹ See *infra* section I.B.3.

⁷⁰ See *infra* section I.B.3.

⁷¹ Recent medical literature frequently employs the language of “belief” to explain the community of patients and non-standard physicians who support the diagnosis and treatment of “chronic” Lyme disease that is “contrary to scientific evidence” and associated with “misinformation,” particularly from internet sources. See, e.g., Stanek, *supra* note 80, at 9-10.

⁷² See, generally, Auwaerter et al., *supra* note 21.

⁷³ IDSA GUIDELINES, *supra* note 14.

⁷⁴ See John D. Kraemer & Lawrence O. Gostin, *Science Politics, and Values: The Politicization of Professional Practice Guidelines*, 301 JAMA 665, 666 (2009) (describing the political conflict over the mainstream CPG on Lyme disease treatment).

⁷⁵ See *infra* section II.A (discussing the Connecticut antitrust investigation into the mainstream IDSA Guidelines).

⁷⁶ See *supra* note 15 and accompanying text.

⁷⁷ IDSA GUIDELINES, *supra* note 14, at 1120 (“Having once had objective evidence of *B. burgdorferi* infection must be a condition sine qua non” of antibiotic treatment.)

⁷⁸ Baker *supra* note 68, at 11.

⁷⁹ ILADS GUIDELINES, *supra* note 15, at S5 (“Since there is currently no definitive test for Lyme disease, laboratory results should not be used to exclude an individual from treatment. Lyme disease is a clinical

1. Lyme Disease

Lyme disease is the most common tick-borne infection in North America,⁸⁰ and the fifth most-common “notifiable” infectious disease in the U.S.⁸¹ North American Lyme disease is caused by the bacterium, *Borrelia burgdorferi* (hereinafter *B. burgdorferi*).⁸² In the United States, *B. burgdorferi* is prevalent in certain tick populations in New England, the mid-Atlantic and upper Midwest.⁸³ In humans who become infected from a tickbite, *B. burgdorferi* often causes a distinctly shaped skin rash (termed *erythema migrans*) around area of the bite.⁸⁴ Other symptoms of early Lyme disease may include “fatigue, chills, fever, headache, muscle and joint aches, and swollen lymph nodes.”⁸⁵ The most serious effects of Lyme disease result from infections left untreated. Sixty percent of untreated patient develop manifestations of late-stage Lyme disease, such as severe arthritis, including painful joint swelling.⁸⁶ In rare cases, infected patients may develop distinct, measurable neurological symptoms (e.g. meningitis or facial palsy) or cardiac problems (e.g. disturbances in heartbeat rhythm).⁸⁷ However, even these later-stage symptoms of Lyme disease are usually resolved by a regimen of antibiotic treatment lasting from two to four weeks.⁸⁸

The mainstream medical literature recognizes that a minority of patients (perhaps around fifteen percent) experience long-term, persistent, and subjective symptoms, such as fatigue, and memory problems.⁸⁹ These residual effects in treated individuals are classified as “post-infection” or “post-treatment” syndrome.⁹⁰ Physicians and researchers

diagnosis and tests should be used to support rather than supersede the physician’s judgment.”). This position—one of antibiotic maximalism—is discussed in greater detail, *infra*, in Subsection II.B.3.

⁸⁰ Gerold Stanek, et al, *Lyme borreliosis*, LANCET (*published online* September 7, 2011) at 1.

⁸¹ CDC, NOTIFIABLE DISEASES 2, (2009). As defined by the CDC, a “notifiable disease” for which “which regular, frequent, and timely information regarding individual cases is considered necessary for the prevention and control of the disease.” *Id.* Of several dozen notifiable infectious diseases in 2009, Lyme was behind only Chlamydia, Gonorrhea, Salmonella and Syphilis (in order from most to least prevalent). *Id.*

⁸² Stanek, *supra* note 80, at 1.

⁸³ CDC, SUMMARY OF NOTIFIABLE DISEASES — UNITED STATES, 2009 (Published May 13, 2011, for 2009 / Vol. 58 / No. 53) at 66, *available at* <http://www.cdc.gov/mmwr/PDF/wk/mm5853.pdf>.

⁸⁴ CDC, SIGNS AND SYMPTOMS OF LYME DISEASE http://www.cdc.gov/lyme/signs_symptoms/index.html (last visited Nov. 2, 2011). The characteristic rash is termed *erythema migrans*. *Id.*

⁸⁵ SIGNS AND SYMPTOMS OF LYME DISEASE, *supra* note 84.

⁸⁶ *Id.*

⁸⁷ Stanek, *supra* note 80, at 3-4.

⁸⁸ *Id.* at 8.

⁸⁹ *Id.* at 8-9.

⁹⁰ CDC, POST-TREATMENT LYME DISEASE SYNDROME, <http://www.cdc.gov/lyme/postLDS/index.html> (last visited on Nov. 11, 2011) (“The exact cause of [post-treatment Lyme disease syndrome] is not yet known. Most medical experts believe that lingering symptoms are due to residual damage to the tissues and

are currently seeking an explanation—and a therapy—for these symptoms; however, a substantial body of evidence indicates that post-infection symptoms should not be treated with antibiotics.⁹¹

The terminology of Lyme disease can be confusing. In contrast to “post-infection” syndrome, “chronic” Lyme disease is a diagnosis that has been rejected by many practitioners in the mainstream infectious disease community because it is often applied to patients who have subjective symptoms (e.g. pain, fatigue, cognitive problems) but who do not exhibit measurable, clinical manifestations of infection.⁹² According to a recent, mainstream medical review: “[M]ost patients receiving treatment for chronic Lyme disease have no convincing evidence, by history (sometimes including even absence of tick exposure, physical examination, or laboratory test results) of ever having had *B. burgdorferi*...infection.”⁹³

2. The Mainstream (IDSA) CPG on the Treatment of Lyme Disease

The Infectious Diseases Society of America (IDSA), a physician’s association, publishes evidence-based CPGs for the treatment of numerous infections,⁹⁴ including Lyme disease.⁹⁵ For patients that meet distinct diagnostic criteria indicating Lyme infection,⁹⁶ the IDSA Guidelines recommend antibiotic therapy lasting from ten to twenty-eight days depending on the manifestation and state of progression of the disease.⁹⁷ The IDSA Guidelines also specify a long list of treatments that are *not* recommended, “[b]ecause of a lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient.”⁹⁸ Among these contraindicated treatments is “long-term antibiotic therapy,” as well as other unconventional treatment

the immune system that occurred during the infection. Similar complications and auto-immune responses are known to occur following other infectious diseases....”)

⁹¹See Stanek, *supra* note 80, at 9. Antibiotic retreatment is contraindicated in patients experiencing “post-infection”/“post-treatment” syndrome because of the substantial risks of such treatment, including the negative side effects of antibiotics (which include antibiotic resistance), or the risk of infection caused by the catheters typically used to administer the drugs intravenously. *See id.*

⁹²*Id.* “Chronic” Lyme disease is sometimes referred to as “persistent.”

⁹³ Stanek et al., *supra* note 80, at 9.

⁹⁴ Auwaerter et al., *supra* note 65, at 713.

⁹⁵ IDSA GUIDELINES, *supra* note 14. The IDSA Lyme-disease guidelines address epidemiology, diagnosis, and treatment in the clinical setting. *Id.*

⁹⁶ The IDSA Guidelines stress the need for objective evidence of infection before a diagnosis is made. For instance, the Guidelines stipulate: “In the absence of erythema migrans [i.e. the characteristic skin rash caused by *B. burgdorferi* infection], neurologic manifestations are too nonspecific to warrant a purely clinical diagnosis; laboratory support for the diagnosis is required.” *Id.* at 1107.

⁹⁷ *Id.* at Table 3.

⁹⁸ *Id.* at 1105.

regimens and a number of specific drugs.⁹⁹ The IDSA Guidelines assert that it is “highly implausible” that Lyme infections can persist after the recommended, short-term antibiotic treatment regimens, based on a number of evidence-based findings.¹⁰⁰

In addition to recommending against long-term antibiotic therapy for the treatment of Lyme disease generally, the IDSA Guidelines specifically reject the administration of such regimens in the context of “chronic” Lyme disease. For one thing, the IDSA Guidelines remark that many patients initially diagnosed with “chronic” Lyme disease fail to exhibit signs of actual infection with *B. burgdorferi*.¹⁰¹ Furthermore, IDSA’s position is based on randomized controlled trials comparing the effectiveness of long-term antibiotic therapy with a placebo; such studies indicate that long-term antibiotic therapy does not help patients with putatively “chronic” Lyme disease.¹⁰² Consequently, the IDSA Guidelines stake out a clear position on the existence and treatment of “chronic” infections:

To date, 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. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (6 months) subjective symptoms after recommended treatment regimens for Lyme disease.”¹⁰³

Internationally, mainstream infection-disease groups have echoed IDSA’s position on the use of long-term antibiotic regimens to treat Lyme disease; these include physician

⁹⁹ *Id.* The IDSA Guidelines warn against a number of non-recommended treatments. These include: “Pulsed-dosing (i.e., antibiotic therapy on some days but not on other days),” “[h]yperbaric oxygen therapy,” and “[i]ntravenous hydrogen peroxide.” IDSA GUIDELINES, *supra* note 14, Table 4.

¹⁰⁰ IDSA GUIDELINES, *supra* note 14, at 1118 (“The notion that symptomatic, chronic *B. burgdorferi* infection can exist despite recommended treatment courses of antibiotics in the absence of objective clinical signs of disease, is highly implausible as evidenced by (1) the lack of antibiotic resistance in this genus, (2) the lack of correlation of persistent symptoms with laboratory evidence of inflammation or with the eventual development of objective physical signs, and (3) the lack of precedent for such a phenomenon in other spirochetal infections.”) (citations omitted).

¹⁰¹ *Id.* at 1117 (“Unfortunately, it is apparent that the term ‘chronic Lyme disease’ is also being applied to patients with vague, undiagnosed complaints who have never had Lyme disease. When adult and pediatric patients regarded as having chronic Lyme disease have been carefully reevaluated at university-based medical centers, consistently, the majority of patients have had no convincing evidence of ever having had Lyme disease, on the basis of the absence of objective clinical, microbiologic, or serologic evidence of past or present *B. burgdorferi* infection.”) (citations omitted).

¹⁰² *See, e.g.,* Mark S. Klemperer et al., *Two Controlled Trials Of Antibiotic Treatment In Patients With Persistent Symptoms And A History Of Lyme Disease*, 345 NEW ENGL. J. MED. 85, 85 (2001) (“There is considerable impairment of health-related quality of life among patients with persistent symptoms despite previous antibiotic treatment for acute Lyme disease. However, in these two trials, treatment with intravenous and oral antibiotics for 90 days did not improve symptoms more than placebo.”).

¹⁰³ *Id.* at 1120-21 (citations omitted).

groups in the UK¹⁰⁴ and Europe.¹⁰⁵ The U.S. Centers for Disease Control and Prevention (CDC), which is not affiliated with the physician groups, takes a strong public stance against theories of persistent infection and long-term treatment.¹⁰⁶

That the IDSA Guidelines go into so much detail about the treatments that physicians are to *avoid* is a reflection of the heated debate between the evidence-based guidelines and a “counterculture”¹⁰⁷ of physicians who insist that an untreatable and irreversible form of Lyme disease exists. LLMDs, represented by their own professional association, ILADS, portray mainstream doctors and researchers as having ignored long-term, “persistent” or “chronic” cases of Lyme disease.¹⁰⁸ ILADS claims that Lyme disease causes a host of subjective symptoms¹⁰⁹ that persist or recur in spite of short-term (i.e. mainstream/IDSA) antibiotic treatment.¹¹⁰

¹⁰⁴ *The epidemiology, prevention, investigation and treatment of Lyme borreliosis in United Kingdom patients: A position statement by the British Infection Association*, 62 J. INFECTION 329, 336 (2011). (There is evidence that some treatment strategies can be harmful. These include antimicrobial combinations, pulsed-dosing and long term antimicrobials. There are few data to support the use of other treatments and evidence that they may be harmful, sometimes seriously.)

¹⁰⁵ G. Stanek et al., *Lyme borreliosis: Clinical case definitions for diagnosis and management in Europe*, 17 CLINICAL MICROBIOLOGY AND INFECTION 71, 74 (2011). (“PLS [persistent lyme disease] is sometimes equated with persistent [*B. burgdorferi*] infection and referred to as ‘chronic’ Lyme disease, but this is a misnomer and PLS does not warrant the use of expensive and potentially dangerous antibiotics. For such patients symptomatic treatment is recommended.”) (citations omitted).

¹⁰⁶ CDC, *supra* note 90. (“A few health care providers tell patients that these symptoms reflect persistent infection with *Borrelia burgdorferi*. However, there is no credible scientific evidence that PTLDS is caused by persistent infection. More importantly, studies have shown that patients treated with prolonged courses of antibiotics do not do better than patients treated with placebo.”)

¹⁰⁷ Sigal & Hassett, *supra* note 67, at 608.

¹⁰⁸ ILADS GUIDELINES, *supra* note 15, at S4 (“Lyme disease was initially investigated by CDC epidemiologists focusing on erythema migrans, heart block, meningitis and arthritis. The ELISA test and later, the western blot, were introduced for seroepidemiologic studies. Chronic, persistent, recurrent and refractory Lyme disease were not included in these studies; consequently cases of chronic Lyme disease still go unrecognized.”)

¹⁰⁹ *Id.* (“For the purpose of the ILADS guidelines, ‘chronic Lyme disease’ is inclusive of persistent symptomatology including fatigue, cognitive dysfunction, headaches, sleep disturbance and other neurologic features, such as demyelinating disease, peripheral neuropathy and sometimes motor neuron disease; neuropsychiatric presentations; cardiac presentations including electrical conduction delays and dilated cardiomyopathy; and musculoskeletal problems.”). The ILADS Guidelines further provide an extensive list of symptoms that underscores the diffuse, often subjective maladies that LLMDs ascribe to Lyme disease:

“Fatigue; Low-grade fevers ‘hot flashes’, or chills; night sweats; sore throat; stiff neck; migrating arthralgias; stiffness and, less commonly frank arthritis; myalgia; chest pain and palpitations; abdominal pain, nausea; diarrhea; sleep disturbance; poor concentration and memory loss; irritability and mood swings; depression; back pain; blurred vision and eye pain; jaw pain; testicular/pelvic pain; tinnitus; vertigo; cranial nerve disturbance (facial numbness, pain, tingling, palsy or optic neuritis); headaches; ‘Lightheadedness; Dizziness.”

Id. at S5.

¹¹⁰ ILADS GUIDELINES, *supra* note 15, at S5.

3. Antibiotic Maximalism: The Alternative (ILADS) Lyme Disease Guidelines

Whereas the IDSA Guidelines caution against using antibiotic regimens that, according to the prevailing scientific consensus, are not plausibly effective against Lyme disease, a competing set of recommendations, published by the leading group of non-standard Lyme practitioners, ILADS, takes a very different approach. The current ILADS CPG departs substantially from the mainstream IDSA CPG in substance and in spirit.¹¹¹ For instance, the mainstream IDSA Guidelines provide detailed analysis of various treatment options before providing distinct recommendations. In contrast, the ILADS Guidelines offer deliberately vague recommendations that defer to the clinical judgment—and autonomy—of the treating physician.¹¹² The ILADS CPG stresses the importance of clinical flexibility, judgment, and the “community-based” physician, and has little regard for guidelines developed in the “academic research setting[.]”¹¹³

The ILADS Guidelines deploy clinical terminology to legitimize highly permissive recommendations on antibiotic therapy. For instance, the ILADS Guidelines endorse the “empiric” treatment of Lyme disease.¹¹⁴ Generally, “empiric” therapy refers to the use of antibiotics based on the suspicion of bacterial infection, and before the presence of infection is confirmed or the infective agent is identified.¹¹⁵ Empiric treatment is necessary in some clinical circumstances. For instance, an acute, life-threatening infection may require the physician to make a treatment decision quickly, before definitive identification of the infection.¹¹⁶ However, the empiric prescription of

¹¹¹ The length of each CPG and its treatment of supporting material provide a rough indication of this contrast. Whereas the mainstream guidelines run to 47 pages, citing 405 papers and studies, IDSA GUIDELINES, *supra* note 14, the ILADS Guidelines are 13 pages long, with 63 references, ILADS GUIDELINES, *supra* note 15.

¹¹² See *infra* notes 124-125 and accompanying text.

¹¹³ ILADS GUIDELINES, *supra* note 15, at S11. (“Community-based clinicians and academic centers often have different criteria for diagnosis and divergent goals of care [8]. The guidelines and standards of practice used for diagnosis of Lyme disease in academic research settings may not be applicable or appropriate for community-based settings. Moreover, the clinical manifestations of Lyme disease are often subtle or atypical in the community.”)

¹¹⁴ *Id.* at S9.

¹¹⁵ Jeffrey A. Claridge et al., *Critical Analysis of Empiric Antibiotic Utilization: Establishing Benchmarks*, 11 SURGICAL INFECTIONS 125, 126 (2010).

¹¹⁶ Community-acquired pneumonia is an example of an illness where empiric initiation of antibiotic therapy is indicated “in light of the better outcomes with the earliest possible interventions.” Jack M. Bernstein, *Treatment of Community-Acquired Pneumonia—IDSA Guidelines*, 115 CHEST 9S, 9S (1999). Even in the case of pneumonia, however, the decision to institute various empiric therapies should be based only on precise clinical factors. See, generally, Lionell A. Mandell et al., *Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults*, 44 Clinical Infectious Diseases S27 (2007) (providing comprehensive guidelines on the selection of antibiotics, including by empiric methods, for community-acquired pneumonia).

antibiotics has been blamed for the overuse of antibiotics and the resulting proliferation of dangerous resistant pathogens.¹¹⁷

Clinical emergencies that warrant empiric antibiotic therapy contrast with the chronic, diffuse, and non-fatal symptomology of Lyme disease described by the ILADS Guidelines. Indeed, by encouraging empiric antibiotic therapy based on highly subjective and remarkably broad clinical findings, the ILADS Guidelines adopt a profoundly maximalist position on antibiotic use. In spite of the existence of reliable tests for the presence of the Lyme disease bacterium, ILADS explicitly promotes the empiric treatment of patients suspected of having Lyme disease¹¹⁸ but who do not test positive for infection by an objective measure.¹¹⁹ Further, the ILADS CPG states that the “[t]he duration of therapy should be guided by clinical response, rather than by an *arbitrary* (i.e., thirty day) treatment course.”¹²⁰ Regarding non-standard, unproven treatment regimens, the ILADS Guidelines are open-minded, if not overtly optimistic.¹²¹ Perhaps the most maximalist aspect of the ILADS approach toward antibiotic use is expressed in a section entitled “[d]ecision to stop antibiotics” which states that “the optimal time to discontinue antibiotics is unknown” and that “[p]atients must therefore be carefully evaluated for persistent infection before a decision is made to withhold therapy.”¹²² The ILADS Guidelines mention only general concerns about antibiotic overuse.¹²³

¹¹⁷ A recent Institute of Medicine report opines that the availability of a diverse array of relatively safe antibiotics “created a culture of empiricism that promoted antibiotic use, which in turn selected for resistance in targeted and nontargeted microbes...with consequences that are only now beginning to be understood.” INSTITUTE OF MEDICINE, ANTIBIOTIC RESISTANCE: IMPLICATIONS FOR GLOBAL HEALTH AND NOVEL INTERVENTION STRATEGIES: WORKSHOP SUMMARY, 79-80 (2010). Though the Food and Drug Administration (FDA) acknowledges that empiric use is sometimes necessary, 68 Fed. Reg. 6069 (2003) (“FDA recognizes that in many situations physicians must make difficult choices about the need for empiric therapy and broad-spectrum agent use”), the agency promulgated new labeling language in 2004 that warns: “Prescribing [the antibacterial drug product] in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.” 21 C.F.R. § 201.24 (2011).

¹¹⁸ ILADS GUIDELINES, *supra* note 15, at S9. (ILADS “recommends that empiric treatment be considered routine for patients with a likely diagnosis of Lyme disease.”)

¹¹⁹ *See id.* at S8 (“Antibiotic therapy may need to be initiated upon suspicion of the diagnosis, even without definitive proof”). Under the heading “Seronegative Lyme Disease” (“seronegative” refers to a negative result from a test of infection), the ILADS Guidelines may be read as supporting a *presumption* of Lyme disease in individuals who do not test positive for infection. ILADS at S7 (“A patient who has tested seronegative may have a clinical presentation consistent with Lyme disease, especially if there is no evidence to indicate another illness.”) *See also supra* note 79, and accompanying text.

¹²⁰ ILADS GUIDELINES, *supra* note 15, at S5 (“Symptoms may continue despite 30 days of treatment (persistent Lyme disease). The patient may relapse in the absence of another tickbite or erythema migrans rash (recurrent Lyme disease), or be poorly responsive to antibiotic treatment (refractory Lyme disease).”)

¹²¹ *See, e.g., id.* at S8 (“There is a paucity of data on alternative intravenous antibiotics, and their success is less predictable in chronic Lyme disease.”)

¹²² *Id.* at S10.

¹²³ *Id.* at S9 (“The importance of establishing the diagnosis of Lyme disease is heightened in light of increasing concern about antibiotic overuse.”).

The conflict between the non-standard ILADS guidelines and the mainstream IDSA guidelines demonstrates the wide separation between the clinical philosophies—particularly toward antibiotic use—in the two camps. Though CPGs can have the effect of challenging the clinical autonomy of physicians,¹²⁴ the ILADS Guidelines may be read as an endorsement of the clinical autonomy of the LLMD.¹²⁵ These differences have surfaced political and legal battles, described in the Part II, that provide context to the recent flurry of legislative activity surrounding Lyme disease, detailed in Part III.

II. THE LEGAL AND POLITICAL CONTEXT OF LLMD-PROTECTION STATUTES

The most ambitious legal goal of LLMDs and their advocates has been the enactment of statutory protections for physicians who diagnose and treat Lyme disease in contradiction to the mainstream clinical guidelines. Before analyzing examples of such laws (referred to here as “LLMD-protection” statutes) that are already in effect in several states, this Part describes the legal-political landscape that set the stage for these unprecedented legislative incursions into the oversight of physicians by medical licensing boards. Two phenomena, in particular, provide important context to the enactment of LLMD-protection statutes: (1) perceptions that authors of the mainstream IDSA CPG had conflicting economic and professional interests, thereby biasing those guidelines and (2) concerns among LLMDs and their advocates that state medical boards would discipline physicians who prescribed antibiotic regimens recommended against in the IDSA guidelines.

A. *Reactions to Perceived Conflicts-of-Interest Among IDSA Members*

A significant segment of patient advocates believes that the mainstream IDSA CPG blocks necessary treatment by rejecting certain controversial diagnoses and long-term antibiotic regimens. This movement perceives that an academic-industrial complex of infectious disease experts, pharmaceutical companies, and medical insurers has conspired to ration expensive therapies.¹²⁶ In response to this grass-roots movement, politicians have taken legislative and legal action against IDSA and its guidelines.

¹²⁴ TIMMERMANS & BERG, *supra* note 34, at 103-05 (describing the impact on clinical autonomy brought about by the use of CPGs in managed-care settings, including Medicare and Medicaid, to enforce “whether, how, and how long a patient can be treated”).

¹²⁵ See *supra* note 113 and accompanying text.

¹²⁶ Such perceptions date at least to the early 1990s. See, e.g., *Lyme Disease: A Diagnostic and Treatment Dilemma, Hearing of the Committee on Labor and Human Resources*, 103d Cong. 56-59 (1993) (Testimony and prepared statement of Joseph Burrascano, a leading LLMD) (declaring that “[t]here is a core group of university based Lyme Disease researchers and physicians whose opinions carry a great deal of weight” and noting that “Lyme patients are being denied [long-term antibiotic] therapy for political reasons and/or because insurance companies refuse to pay for these longer treatments.”)

Apart from the enactment of LLMD-protection statutes, the most notable government response to the LLMD movement was the 2006 Connecticut antitrust investigation into IDSA and its Lyme disease practice guidelines.¹²⁷ Following the release of revised IDSA Guidelines in 2006,¹²⁸ the Connecticut attorney general¹²⁹ announced the investigation, alleging that IDSA had violated state antitrust laws by excluding alternative, conflicting medical perspectives.¹³⁰ The attorney general criticized the IDSA Guidelines as being “voluntary” in name only, citing the fact that major insurers “have used the guidelines as justification to deny reimbursement for long-term antibiotic treatment.”¹³¹ No court action was taken, but the IDSA agreed to a settlement in 2008, stipulating an open review of the IDSA Guidelines by an independent board of experts.¹³² That review was completed in 2010, when the independent review panel affirmed the IDSA Guidelines and concluded that they “were medically and scientifically justified on the basis of all of the available evidence and that no changes to the guidelines were necessary.”¹³³

¹²⁷ This episode has received some attention in the legal literature, though the prior coverage has embraced both the LLMD positions on both the existence of “chronic” Lyme disease as well as the need for legislative protection for long-term antibiotic therapy. See Tammy Asher, *Unprecedented Antitrust Investigation into the Lyme Disease Treatment Guidelines Development Process*, 46 GONZ. L. REV. 117, 141 (2011) (broadly endorsing the LLMD position on Lyme disease treatment and suggesting that the IDSA Guidelines prevent patients from receiving “proven treatment options”); Johanna Ferguson, Note, *Cure Unwanted? Exploring the Chronic Lyme Disease Controversy and Why Conflicts of Interest in Practice Guidelines May Be Guiding Us Down the Wrong Path*, 38 AM. J.L. & MED. 196 (2012) (suggesting that, because of the existence of the IDSA Guidelines, many [chronic] Lyme patients today continue to find themselves suffering without access to treatment”).

¹²⁸ IDSA GUIDELINES, *supra* note 14.

¹²⁹ The Connecticut attorney general, Richard Blumenthal, was elected to the U.S. Senate from Connecticut in 2010, where he has co-sponsored legislation related to Lyme disease and antibiotics. See, e.g., Press Release, Senator Richard Blumenthal, Blumenthal, Reed, Whitehouse Introduce Legislation to Combat Lyme Disease (July 18, 2011), available at <http://blumenthal.senate.gov/newsroom/press/release/blumenthal-reed-gillibrand-whitehouse-introduce-legislation-to-combat-lyme-disease>.

¹³⁰ Susan Warner, *State official subpoenas infectious disease group*, SCIENTIST, Feb. 7, 2007, <http://classic.the-scientist.com/news/display/49605/>; Kraemer & Gostin *supra* note 74.

¹³¹ Press Release, *Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines Install Independent Arbiter*, Connecticut Attorney General's Office, May 1, 2008, available at <http://www.ct.gov/ag/cwp/view.asp?A=2795&Q=414284>.

¹³² An Agreement Between the Attorney General of the State of Connecticut and the Infectious Diseases Society of America (April 30, 2008) at 1-2, available at <http://www.ct.gov/ag/lib/ag/health/idsaagreement.pdf>.

¹³³ Paul M. Lantos et al., *Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America*, 51 CLINICAL INFECTIOUS DISEASES 1, 1 (2010). Predictably, the independent review report did not appease chronic Lyme advocates. Patricia Callahan & Trine Tsouderos, *A Dubious Diagnosis*, CHI. TRIB. Dec. 8, 2010, at 1 (calling the review a “call to arms for chronic Lyme advocates”). The response of two ILADS members demonstrates their fundamental disagreement with clinical practice guidelines: “The role of a medical society is not to ‘call the science’ according to the vote of a panel that represents one side of a debate. Every guidelines panel should acknowledge diversity of opinion, defer to

The implications of antitrust law on the IDSA guidelines and the development and use of CPGs, generally, are outside the scope of this Note.¹³⁴ Although the scientific justification for the IDSA guidelines was affirmed, LLMDs and their advocates continue to attract politicians to their cause of repudiating the mainstream Lyme disease CPG. For instance, in January 2012, three members of the U.S. House of Representatives called for the removal of the IDSA Guidelines from a federal CPG database, the National Guideline Clearinghouse.¹³⁵ The Representatives referred to the IDSA Guidelines as “highly controversial,” blaming them for “insurance company denials of Lyme disease treatments.”¹³⁶

B. Discipline of Alternative Lyme Practitioners by State Licensing Boards

In addition to allegations of collusion between mainstream Lyme experts and corporate healthcare, including health insurers, a central concern among LLMDs and their advocates is that controversial practices by LLMDs could lead to sanctions from by state medical regulators. Indeed, LLMD-protection statutes primarily respond to a perception among LLMDs and their advocates that LLMDs are subject to enhanced scrutiny by state medical licensing boards when they administer long-term antibiotic therapy.¹³⁷ In line with their perception of CPG authors, LLMDs and their advocates

clinical judgment, and respect patient autonomy. Failure to do so may produce a short-term benefit in terms of upholding the status quo and protecting the society from litigation, but the ultimate cost may be severe damage to patient care and the society’s reputation as an impartial authority on good medicine.” Lorraine Johnson & Raphael B. Stricker, *Correspondence, Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America: A Pyrrhic Victory?*, 51 *CLINICAL INFECTIOUS DISEASES* 1110, 1110-11 (2010).

¹³⁴ However, some previous coverage of the putative legality of the IDSA guidelines has been misleading. See Asher, *supra* note , at 144 (suggesting that IDSA had violated § 2 of the Sherman Act by “unlawfully monopoliz[ing] the treatment of Lyme disease”). Of relevance to the current discussion of state medical regulation, Asher suggests that IDSA unlawfully monopolized Lyme disease treatment “by allowing medical boards to investigate and sanction doctors who do not follow the IDSA Guidelines.” *Id.* Asher’s argument that the IDSA guidelines are “effectively mandatory,” *id.* at 136, apparently ignores the distinction between the private CPG authors and state medical regulators. Activity by the latter would not necessarily fall within reach of the Sherman Act, due to the of the well-established “state action” exception to that law. See *Parker v. Brown*, 317 U.S. 341, 350-51 (1943); E. THOMAS SULLIVAN, HERBERT HOVENKAMP & SHOWARD A. SHELANSKI, *ANTITRUST LAW, POLICY AND PROCEDURE*, 1024-25 (6th ed. 2009).

¹³⁵ Press Release, *Outdated Guidelines for Treating Lyme Disease Should be Removed from Government Web Site Used by Doctors as Resource for Medical Protocols*, Congressman Frank Wolf (R-VA), Jan. 20 2012, *available at* <http://wolf.house.gov/index.cfm?sectionid=34§iontree=6,34&itemid=1861>.

¹³⁶ *Id.*

¹³⁷ See Open Letter to the Connecticut Legislature from Daniel Cameron, President, ILADS, February 5, 2009, *available at* http://www.ilads.org/ilads_news/2009/call-to-protect-a-physicians-freedom-to-practice-medicine (“Physicians have been reluctant to treat LD patients based on reports that physicians who treat LD have been subject to professional misconduct proceedings.”); Press Release, Connecticut Department

view state medical boards as bastions of “organized medicine” that are professionally and politically biased against “independent” physicians (i.e. those that prescribe non-standard treatments).¹³⁸

Disciplinary actions by state medical boards against LLMDs are not unprecedented. On the fringes, some such cases involve egregious medical misconduct that is not limited to the improper diagnosis or treatment of Lyme disease.¹³⁹ However, other board actions have been directed at leading LLMDs who are well respected among advocates of the “chronic” Lyme disease paradigm. For instance, in a high-profile 2006 case, the North Carolina Medical Board disciplined Joseph Jemsek, a licensed physician and well-known LLMD, for “unprofessional conduct” because he administered long-term antibiotic therapy to patients he had diagnosed with Lyme disease.¹⁴⁰ The board found that Jemsek prescribed long-term regimens of oral or intravenous antibiotics “even though there [was] an absence of any research or clinical evidence of efficacy for such treatments.”¹⁴¹ Not only did several of Jemsek’s patients experience negative side effects related to the intravenous administration of antibiotics,¹⁴² the Board also determined that

of Public Health, Governor Rell: New Law Protects Doctors in Treatment of Lyme Disease (July 16, 2009), available at <http://www.ct.gov/dph/cwp/view.asp?A=3659&Q=443628> (noting that prior to the enactment of the protective statutes “[s]ome physicians were hesitant to treat patients outside the IDSA guidelines because of potential reprimands from medical boards and insurance companies.”)

¹³⁸ See Andrew L. Schlafly, *Medical Board Stripped of Power*, 16 J. AM. PHYSICIANS & SURGEONS 77, 79 (2011) (“In many states there is a revolving door between the state medical societies, state medical boards, and the Federation of State Medical Boards (FSMB), with the result that many leaders of state medical societies view the medical boards as their allies rather than as their adversaries. Sadly, most state medical societies no longer truly represent independent physicians, and many look to other sources for additional funding.”) Andrew Schlafly is the general counsel of AAPS. *Id.*

¹³⁹ Order of Temporary Suspension, In re James Michael Shortt, M.D., South Carolina Bd. Of Medical Examiners (April 13, 2005) (suspending the license of one physician, James Shortt, for multiple reasons: not only did Shortt diagnose Lyme disease based on results from an unaccredited laboratory, he also prescribed anabolic steroids without sufficient justification and “regularly infused patients with intravenous hydrogen peroxide.”); Findings of Fact, Conclusions of Law, and Final Order on Remand, In re Stephen L. Smith, State of Washington Dept. of Health, 05-01-A-1038MD, ¶ 1.7 (July 31, 2007) (holding that physician violated a professional conduct statute when the physician had a central line installed in a patient for “possible Lyme disease treatment” and dehydration).

¹⁴⁰ Findings of Fact, Conclusions of Law, & Order of Discipline, In re Jemsek, N.C. Med. Bd. (Aug. 21, 2006), available at <http://wwwapps.ncmedboard.org/Clients/NCBOM/Public/LicenseInformationSearch.aspx> (enter “23386” in “License of Approval Number” search field) [hereinafter “*In re Jemsek*”].

¹⁴¹ *In re Jemsek*, *supra* note 140, at 2. The Board found that “Dr. Jemsek administered a treatment that departed from acceptable and prevailing standards of practice, including prescribing a course of oral and/or intravenous antibiotics to be administered to the patients for several months, or in some cases, years, even though there is an absence of any research or clinical evidence of efficacy for such treatments. In regard to the administration of intravenous antibiotics, Dr. Jemsek inserted indwelling venous access, for which there exists an increased risk of infection. Patients did, in fact, suffer infections from their indwelling catheters, some infections becoming life-threatening.” *Id.*

¹⁴² See *id.*

Jemsek's administration of unproven treatments amounted to experimentation on patients without their informed consent.¹⁴³ The Board found these practices to be "unprofessional conduct" within the meaning of the North Carolina statute.¹⁴⁴

Jemsek is one of a number of cases in which non-standard Lyme practices have drawn medical board scrutiny.¹⁴⁵ Medical boards have sometimes sided with LLMDs, or at least have sometimes adopted a more permissive attitude toward non-standard Lyme practice.¹⁴⁶ For instance, the New York State Board for Professional Conduct explicitly avoided taking a position on Lyme disease treatment in an action against another high-profile LLMD, Joseph Burrascano, in 2001.¹⁴⁷ At the time, "thousands of patients"¹⁴⁸ had seen Burrascano for treatment of Lyme and suspected "co-infective" agents.¹⁴⁹ In its findings, the Board cited then-current IDSA recommendations on Lyme treatment as "the

¹⁴³ See *id.* at 4. ("By not properly explaining his methods of diagnosing and treating Lyme disease to Patients A through J, Dr. Jemsek breached his patients' informed consent, and therefore engaged in unprofessional conduct, including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the medical profession, irrespective of whether a patient is injured thereby, within the meaning of N.C. Gen. Stat. § 90-14(a)(6), and grounds exist under that section of the North Carolina General Statutes for the Board to annul, suspend, revoke, or limit his license to practice medicine and surgery issued by the Board or deny any application he might make in the future.")

¹⁴⁴ *Id.* (citing N.C. GEN. STAT. § 90-14(a)(6). In spite of scrutiny by the North Carolina State Medical Board, Jemsek remained in a prominent LLMD, with an office in Washington D.C and a position on the board of ILADS. Callahan & Tsouderos, *supra* note 133.

¹⁴⁵ For instance, LLMD advocates claimed that at least 50 such cases had been brought prior to 2000. Holcomb B. Noble, *Lyme Doctors Rally Behind A Colleague Under Inquiry*, N.Y. TIMES, Nov. 10, 2000, available at <http://www.nytimes.com/2000/11/10/us/lyme-doctors-rally-behind-a-colleague-under-inquiry.html> (last accessed Jan. 29, 2012).

¹⁴⁶ *In re Raxlen*, a Connecticut disciplinary case provides one example of deference by a state medical board toward LLMDs. Memorandum of Decision, Connecticut Medical Examining Board, Petition No. 980108-001-001, (2002), available at www.dir.ct.gov/dph/hcquality/Physician/.../19980108001001.pdf (last accessed Jan. 5, 2012) (holding that a physician who prescribed long-term antibiotic therapy, in spite of inconclusive laboratory testing for Lyme disease, did not "[fall] below the standard of care]" because of the "developing" standards for Lyme disease care).

¹⁴⁷ Determination and Order, *In re Burrascano*, State of New York Department of Health (April 18, 2002) [hereinafter "*In re Burrascano*"]. Burrascano is a member of the working group that devised the ILADS Guidelines, *supra* note X, as well as the author of a Lyme treatment manual that promotes the use of high-dose "pulsed" antibiotic therapy, among other strategies. See JOSEPH BURRASCANO, DIAGNOSTIC HINTS AND TREATMENT GUIDELINES FOR LYME AND OTHER TICK BORNE ILLNESSES 23 (2005, 15th ed.), (available at http://www.ilads.org/files/burrascano_0905.pdf). The Board's inquiry into Burrascano attracted substantial protest from some of his patients, supporters, and other LLMDs. Noble, *supra* note 138.

¹⁴⁸ *Id.* at 41.

¹⁴⁹ Co-infection occurs when a patient is infected with other tick-borne pathogens in addition to *Borellia burgdorferi*. See Stanek et al. *supra* note 80, at 9. ("[Ticks] can be co-infected with and transmit Lyme borrelia along with other pathogens such as *Anaplasma phagocytophilum*, *Babesia* spp, and tick-borne encephalitis virus.")

standard treatment for Lyme disease.”¹⁵⁰ The Board acknowledged that the IDSA recommendations conflicted with the longer regimens Burrascano had prescribed to his patients.¹⁵¹ Though Burrascano was condemned on other counts,¹⁵² the New York board refrained from sanctioning Burrascano for prescribing long-term antibiotic therapy, citing the “highly polarized and politicized” nature of the Lyme disease treatment debate.¹⁵³

The contrasting results in *Burrascano* and *Jemsek* demonstrate the differential weight that state medical boards may give to the IDSA Lyme disease practice guidelines. Timing may also have contributed to the contrast; *Jemsek* (the more recent case, in 2006) may represent a modern board taking a stronger stand against long-term antibiotic regimens. Regardless, with the intense publicity surrounding disciplinary cases involving leaders of the LLMD movement, such as *Jemsek* and *Burrascano*,¹⁵⁴ it is unsurprising that the chronic Lyme disease movement directed its activities toward preventing such disciplinary actions in the first place.

III. RECENT STATE LAWS PROTECTING LLMDs FROM PROFESSIONAL DISCIPLINE FOR NON-STANDARD LYME DISEASE PRACTICES

In response to perceptions that LLMDs could be disciplined for prescribing long-term antibiotic therapy,¹⁵⁵ several states have passed laws that specifically protect non-standard Lyme disease practitioners from discipline by state medical regulators. To date, such laws exist in Connecticut,¹⁵⁶ Massachusetts,¹⁵⁷ Rhode Island,¹⁵⁸ and California.¹⁵⁹

¹⁵⁰ *Id.* at 8 ¶ 19.

¹⁵¹ *E.g., id.* at 18 ¶ 61 (describing one patient who was treated by Burrascano treated with several months of antibiotics).

¹⁵² The Board found Burrascano’s conduct negligent in two instances: (1) when he diagnosed ehrlichiosis in a patient without sufficient support and (2) for prescribing antibiotics to treat Lyme after the patient had experienced seizures, allegedly induced by one prescribed antibiotic, Bicillin. *In re Burrascano* at 24-25, 31-32.

¹⁵³ *Id.* at 41 (“The Hearing Committee recognizes the existence of the current debate within the medical community over issues concerning management of patients with recurrent or long term Lyme disease. This appears to be a highly polarized and politicized conflict, as was demonstrated to this Committee by expert testimony from both sides, each supported by numerous medical journal articles, and each emphatic that the opposite position was clearly incorrect. It fact [sic], it often appeared that the testimony was framed to espouse specific viewpoints, rather than directly answer questions posed. What clearly did emerge however, was that Respondent’s approach, while certainly a minority viewpoint, is one that is shared by many other physicians. We recognize that the practice of medicine may not always be an exact science, “issued guidelines” are not regulatory, and patient care is frequently individualized. We are also acutely aware that it was not this Committee’s role to resolve this medical debate...”).

¹⁵⁴ *See Callahan & Tsouderos, supra* note 133 (describing the North Carolina disciplinary actions against *Jemsek*); *Noble, supra* note 147 (describing protests held in support of Burrascano during his New York medical board hearing).

¹⁵⁵ *See supra* note 137.

¹⁵⁶ CONN. GEN. STAT. ANN. § 20-14m (West 2011) (enacted in 2009).

¹⁵⁷ MASS. GEN. LAWS. ch. 112, § 12DD (2011) (enacted in 2010).

Of these, all but the California statute¹⁶⁰ are explicitly directed at protecting the controversial use of long-term antibiotic therapy that is championed by ILADS and LLMDs, in contradiction with the mainstream IDSA guidelines.¹⁶¹ One striking aspect of these laws is the unique oversight exception that they create for Lyme disease.¹⁶²

Legislation directed at alternative Lyme disease treatments is a recent and ongoing trend. Connecticut and Massachusetts passed statutes in 2009 and 2010, respectively.¹⁶³ Similar laws have been proposed recently in other states, including Virginia and Maryland.¹⁶⁴ Minnesota legislators withdrew a 2010 LLMD-protection bill only after the state medical board announced a five-year moratorium on investigating or disciplining physicians for treating “chronic Lyme disease” with long-term antibiotic therapy.¹⁶⁵ Advocates view further LLMD-protection statutes as the vanguard of a broader campaign to enact measures that limit state regulation of medical practice.¹⁶⁶

LLMD-protection statutes create broad exceptions to the disciplinary authority of state medical regulators. First, the statutes provide an expansive definition of “Lyme disease”—one that includes diagnoses made in the absence of objective clinical manifestations of infection. Second, the statutes provide a broad description of the therapy exempt from medical board review, namely “long-term antibiotic therapy.” In

¹⁵⁸ RI. GEN. LAWS 1956, § 5-37.5-4 (2011) (enacted in 2002).

¹⁵⁹ CAL. BUS. & PROF. CODE § 2234.1 (2011). The California LLMD-protection law originated out of a 2004 blanket provision, protecting physicians from discipline for providing “alternative or complementary medicine,” subject to certain conditions, including that the treatment “does not cause death or serious bodily injury to the patient.” 2004 CAL. LEGIS. SERV. Ch. 742 (S.B. 1691) (West). In 2005, the law was amended to include “treatment of persistent Lyme disease,” specifically, among the protective alternative practices (no other disease is mentioned by name). 2005 CAL. LEGIS. SERV. Ch. 304 (A.B. 592) (WEST). The law cited the slow pace of traditional medicine as justification for protecting alternative practitioners:

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.”

Id.

¹⁶⁰ The California LLMD provision does not specifically describe protected treatments. CAL. BUS. & PROF. CODE § 2234.1 (2011).

¹⁶¹ *See, e.g.*, CONN. GEN. STAT. ANN. § 20-14m (West 2011) (entitled “Administration of long-term antibiotic therapy upon diagnosis of Lyme disease”)

¹⁶² *See, e.g.* CONN. GEN. STAT. ANN. § 20-8 *et seq.* (West 2011) (specifying no other disease contexts in which physicians are exempt from discipline).

¹⁶³ *See supra* notes 156 and 157.

¹⁶⁴ Gerald C. Canaan and Karah L. Gunther, *The Surprising Debate in the 2010 Virginia House of Delegates*, 14 RICH. J.L. & PUB. INT. 1 (2010). In Virginia, though Lyme disease had not previously entered the legislative consciousness, in 2010 five bills were proposed. *Id.* at 1.

¹⁶⁵ Callahan & Tsouderos, *supra* note X.

¹⁶⁶ *See* Schlafly, *supra* note 138, at 79 (AAPS hopes [LLMD-protection statutes] will be passed in other states...But medical board abuse extends far beyond treatment of Lyme disease. AAPS also backs a broad withdrawal of power from medical boards, in order to help patients and physicians in nearly all fields of medical practice.”).

addition, these LLMD-protection laws are bolstered in two states by separate legislation that anticipates the use of the IDSA CPG by insurance companies to deny reimbursement for non-standard care—by mandating some insurance reimbursements for those controversial therapies.

A. Statutory Definitions of Lyme Disease

Current LLMD-protection laws limit their reach to the treatment of “Lyme disease.” Thus, the manner in which the disease is defined will necessarily determine which treatment decisions qualify for protection. In line with the loose diagnostic guidelines championed by the LLMD association, ILADS,¹⁶⁷ the statutes generally place very few restrictions on the diagnosis of Lyme disease.

Where LLMD-protection statutes explicitly define Lyme disease, that definition is broader than the disease definition provided by the mainstream (IDSA) diagnostic guidelines.¹⁶⁸ The diagnostic requirements in the most recent LLMD-protection statutes, from Connecticut and Massachusetts, are nearly identical.¹⁶⁹ Each provides ample leeway for the clinical judgment of the treating physician by describing several qualifying diagnoses:

“Lyme disease” means the clinical diagnosis by a [licensed physician] of the presence in a patient of *signs or symptoms compatible with* [1] *acute infection* with *borrelia burgdorferi*; or [2] with *late stage or persistent or chronic infection* with *borrelia burgdorferi*, or [3] with *complications related to such an infection*; or [4] *such other strains of borrelia* that, on and after July 1, 2009, are recognized by the National Centers for Disease Control and Prevention as a cause of Lyme disease.¹⁷⁰

Notably, the statute does not specifically define “signs or symptoms compatible with” the various forms of Lyme disease it describes.¹⁷¹ However, the ILADS Guidelines list over two dozen Lyme disease symptoms (not including such objective indicators as lab tests or

¹⁶⁷ See *supra* section I.B.3.

¹⁶⁸ IDSA GUIDELINES, *supra* note 14.

¹⁶⁹ CONN. GEN. STAT. ANN. § 20-14m (West 2011); MASS. GEN. LAWS. ch. 112, § 12DD (2011).

¹⁷⁰ CONN. GEN. STAT. ANN. § 20-14m(a) (West 2011) (emphasis added). Massachusetts’ definition is worded only slightly differently, providing that “Lyme disease shall also include...a clinical diagnosis of Lyme disease that does not meet the National Centers for Disease Control and Prevention surveillance criteria but presents other acute and chronic signs or symptoms of Lyme disease as determined by the treating physician.” MASS. GEN. LAWS. ch. 112, § 12DD(a) (2011).

¹⁷¹ Medical “signs” are distinct from medical “symptoms”; the former are based on the subjective description of the patient and the latter on observations of the physician. See, e.g., 20 C.F.R. § 404.1528 (providing information to applicants for federal disability benefits). “Symptoms are [the patient’s own] description of [his] physical or mental impairment.” *Id.* “Signs are anatomical, physiological, or psychological abnormalities which can be observed, apart from [the patient’s] statements (symptoms). Signs must be shown by medically acceptable clinical diagnostic techniques...[Psychiatric signs] must...be shown by observable facts that can be medically described and evaluated.” *Id.*

the *erythema migrans* rash), ranging from abdominal pain and diarrhea to back pain, jaw pain, and “poor concentration and memory loss.”¹⁷² Regardless of the qualifying symptoms, the diagnosis of “chronic” and “persistent” infections is a mainstay of non-standard/LLMD Lyme practice¹⁷³ even though these conditions are not recognized by the mainstream infectious-disease community.¹⁷⁴

Finally, the statutory reference to the CDC’s Lyme diagnosis criteria is of questionable importance, because neither the Massachusetts nor Connecticut statutes actually requires objective evidence of infection. For instance, the Connecticut Lyme disease definition provides that Lyme disease includes *both* (1) an “infection that meets the surveillance criteria set forth by the National Centers for Disease Control and Prevention”¹⁷⁵ and (2) “other acute and chronic manifestations of such an infection *as determined by a physician.*”¹⁷⁶ It is not unnatural to construe that provision as rendering the CDC diagnostic criteria unnecessary.

Further, by incorporating into the definition of “Lyme disease” those diagnoses made in the absence of objective evidence of infection, the statutes endorse the empiric use of antibiotics championed by LLMDs.¹⁷⁷ Connecticut’s statute recognizes not only diagnoses reached “in conjunction with testing that provides supportive data” for diagnosis, but also “clinical diagnosis that is based on knowledge obtained through medical history and physical examination alone.”¹⁷⁸ The Massachusetts statute contains a nearly identical provision.¹⁷⁹ By explicitly removing the requirement that infection be shown by laboratory testing, the Connecticut statutes reject IDSA recommendations, opting to endorse the maximalist, empiric use of antibiotics championed by the ILADS and leading LLMDs.¹⁸⁰

The Rhode Island and California statutes provide less detailed definitions of Lyme disease. Rhode Island requires only that a patient is “diagnosed with and ha[s] symptoms of Lyme disease” and that “this diagnosis and treatment plan has been

¹⁷² See *supra* note 108; ILADS GUIDELINES, *supra* note 15, at S4-S5.

¹⁷³ See ILADS GUIDELINES, *supra* note 15, at S4-S5.

¹⁷⁴ See Stanek et al., *supra* note 80, at 9.

¹⁷⁵ “Surveillance criteria” refers to the case definition used by the CDC in monitoring Lyme disease cases in the U.S. LYME DISEASE 2011 CASE DEFINITION, CDC, *available at* <http://www.cdc.gov/lyme/diagnosis/treatment/index.html> (last accessed Jan. 22, 2012) [hereinafter “CDC SURVEILLANCE CRITERIA”]. The criteria divides cases into “confirmed,” “probable,” and “suspected” categories, all requiring positive laboratory tests or presentation of the characteristic erythema migrans rash. *Id.*

¹⁷⁶ CONN. GEN. STAT. ANN. § 20-14m(a) (emphasis added).

¹⁷⁷ See *supra* note 115 and accompanying text.

¹⁷⁸ CONN. GEN. STAT. ANN. § 20-14m(a) (2011).

¹⁷⁹ MASS. GEN. LAWS. ch. 112, § 12DD(a) (2011) (“diagnosis [of Lyme disease] shall be based on knowledge obtained through medical history and physical examination only or in conjunction with testing that provides supportive data for such clinical diagnosis”).

¹⁸⁰ See *supra* section I.B.3.

documented in the physician's medical record for that patient.”¹⁸¹ California provides protection for treatment of “persistent” Lyme disease,¹⁸² which is the term invoked by ILADS for cases that typically require long-term antibiotic therapy.¹⁸³ California’s LLMD-protection provision is contained within a broader statute protecting alternative medical practices generally; the statute contains common requirements regarding diagnosis and information that must be provided to the patient.¹⁸⁴

B. Protected Long-Term Antibiotic Therapy

Though California and Rhode Island do not describe a particular genre of Lyme disease treatment that should be exempt from discipline, Connecticut and Massachusetts specifically provide protection for “long-term antibiotic therapy.” The Connecticut and Massachusetts statutes provide almost identical¹⁸⁵ definitions this protected class of therapy: “the administration of oral, intramuscular or intravenous antibiotics singly or in combination, for periods of time in excess of 4 weeks.”¹⁸⁶ This “4 week” time limit directly challenges the upper limit for antibiotic therapy of twenty-eight days provided in the IDSA Guidelines.¹⁸⁷ Because the term “antibiotic” is undefined, a literal reading of the statute applies even to those antibiotics that IDSA has warned against using to treat

¹⁸¹ R.I. GEN. LAWS ANN. § 5-37.5-4 (West, 2011).

¹⁸² CAL. BUS. & PROF. CODE § 2234.1 (2011).

¹⁸³ See ILADS GUIDELINES, *supra* note 15, at S5 (“The practice of stopping antibiotics to allow for delayed recovery is not recommended for persistent Lyme disease. In these cases, it is reasonable to continue treatment for several months after clinical and laboratory abnormalities have begun to resolve and symptoms have disappeared.”). For discussion, and one viewpoint, of the California LLMD-protection law, see Justin J. Simpson, Note, *Chapter 304: Broadening The Scope Of Alternative And Complementary Medicine To Include Treatment Of Persistent Lyme Disease*, 37 MCGEORGE L. REV. 157, 163-64 (2006).

¹⁸⁴ CAL. BUS. & PROF. CODE § 2234.1 (2011) (protecting complementary and alternative medical treatment and advice that meets 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.)

Id. The California statute applies a risk/benefit standard to its definition of protected therapies, defining “alternative or complementary medicine,” as “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.” *Id.* § 2234.1(b).

¹⁸⁵ The Massachusetts statute omits a comma after the word “singly.” MASS. GEN. LAWS. ch. 112, § 12DD (2011).

¹⁸⁶ See *supra* notes 156 and 157.

¹⁸⁷ See, e.g. IDSA GUIDELINES, *supra* note 14, at Table 3.

Lyme disease “because of a lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient.”¹⁸⁸

C. Specific Restrictions on the Disciplinary Discretion of State Medical Regulators

Though their disease and treatment definitions differ in specificity, LLMD-protection statutes share a goal: to restrict state licensing boards from disciplining physicians for administering long-term antibiotic therapy for Lyme disease. The Connecticut provision serves as a useful example. To grant physicians leeway to employ the controversial antibiotic regimens, the statute limits the power of the state’s Medical Examining Board¹⁸⁹ to investigate or discipline¹⁹⁰ physicians for prescribing long-term antibiotic therapy in the context of the statute’s broad definition of Lyme disease.¹⁹¹ The statute explicitly shields physicians from board investigations or discipline related to the antibiotic therapy.¹⁹²

D. Statutes Mandating Insurance Coverage for Non-Standard Lyme Disease Therapy

Disciplinary-preemption statutes are bolstered by state laws that mandate insurance coverage of long-term antibiotic therapy. The high cost of long-term intravenous (IV) antibiotic treatment can represent a significant barrier to patients wishing to pursue treatment. Health insurers may reimburse for the cost of standard antibiotics in oral form, but they typically do not reimburse for the expensive IV therapy prescribed to patients with “chronic Lyme disease” or other non-standard Lyme diagnoses.¹⁹³ As a result, patients may forgo long-term antibiotic treatment even when

¹⁸⁸ IDSA GUIDELINES, *supra* note 14, at 1094 (listing, among other therapies, a number of antibiotic drugs not recommended to treat Lyme disease: “vancomycin, metronidazole, tinidazole, amantadine, ketolides, isoniazid, trimethoprim, sulfamethoxazole, fluconazole, benzathine penicillin G”).

¹⁸⁹ The Connecticut Medical Examining Board is described in CONN. GEN. STAT. ANN. § 20-8a (West 2011).

¹⁹⁰ CONN. GEN. STAT. ANN. § 20-13c (West 2011) authorizes the Connecticut Medical Examining Board to “restrict, suspend or revoke the license or limit the right to practice of a physician” for several enumerated reasons, including “illegal, incompetent or negligent conduct in the practice of medicine.”

¹⁹¹ See *supra* section III.B.

¹⁹² CONN. GEN. STAT. ANN. § 20-14m (West 2011) (“Department of Public Health shall not initiate a disciplinary action against a licensed physician and such physician shall not be subject to disciplinary action by the Connecticut Medical Examining Board solely for prescribing, administering or dispensing long-term antibiotic therapy to a patient clinically diagnosed with Lyme disease, provided such clinical diagnosis and treatment has been documented in the patient’s medical record by such licensed physician.”).

¹⁹³ See Monica Brady-Myerov, *Lyme Disease on Rise as Mass. Seeks New Solutions*, 90.9-WBUR (BOSTON), Aug. 8, 2011, <http://www.wbur.org/2011/08/08/lyme-disease>. See Open Letter to the Connecticut Legislature from Daniel Cameron, *supra* note 137 (discussing the need for legislation to prevent health insurers from denying coverage for long-term antibiotic therapy based on “NIH-sponsored” clinical trials, including those summarized in the IDSA guidelines).

they find an LLMD to provide the prescription.¹⁹⁴ (Indeed, the mainstream IDSA Guidelines were originally cited by insurance companies who denied coverage for the controversial intensive antibiotic regimens.)¹⁹⁵ An important goal of those who seek to legitimize long-term antibiotic therapy has been recognition of and payment for such treatment by health insurers.¹⁹⁶

At present, Connecticut and Rhode Island, two states with LLMD-protection laws, also mandate coverage for Lyme disease. Connecticut adopted such a mandate several years before it passed the LLMD-protection law; it does not specifically address long-term antibiotic therapy, though it states that insurance “shall provide further treatment” beyond standard, short-term regimens, “if recommended by a [licensed,] board certified rheumatologist, infectious disease specialist or neurologist.”¹⁹⁷ In contrast, Rhode Island law contains a sweeping provision requiring “coverage for diagnostic testing and long-term antibiotic treatment of chronic lyme disease,” and stipulating that “[t]reatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature.”¹⁹⁸

The combination of LLMD-protection laws and mandated antibiotic coverage announce a definitive policy statement: evidence-based recommendations on Lyme disease treatment are to be disregarded by physicians and insurers. The next section argues that such legislative evisceration of clinical practice guidelines is highly problematic and represents a dangerous endorsement of the maximalist antibiotic treatment paradigm.

IV. THE PROBLEMATIC IMPLICATIONS OF LLMD-PROTECTION STATUTES

¹⁹⁴ *See id.* (quoting a state representative who supports mandating insurance coverage for long-term antibiotics: “The insurance companies are denying coverage for those people who are receiving the long-term antibiotic treatment and if they are not denying coverage they are making it very, very difficult for the payments to be made and sometimes the patients and their families kind of give up on it.”). Brady-Myerov’s article on the Boston NPR affiliate in 2011 sparked its own Lyme-related controversy, acknowledged in an editorial rebuke attached to the original article: “Listeners and readers of this story might conclude that the medical establishment is evenly split between those who support a diagnosis of “chronic Lyme Disease” and those who do not. In fact, there is a strong consensus against that diagnosis as an explanation for the long-lasting symptoms some patients experience, and against long-term antibiotics as treatment. The issue remains hotly debated publicly....” *Id.*

¹⁹⁵ *See supra* section II.A.

¹⁹⁶ *See* Open Letter to the Connecticut Legislature from Daniel Cameron, *supra* at note 137.

¹⁹⁷ CONN. GEN. STAT. ANN. § 38a-492h (West 2011).

¹⁹⁸ R.I. GEN. LAWS 1956, § 27-18-62 (2011) (listing certain “limited-benefit” health insurance policies, such as “[a]ccident only” policies, that are exempt from this requirement); *Id.* § 27-41-65 (applying law to health maintenance organizations). *See also* STATE OF RHODE ISLAND DEPARTMENT OF HEALTH, *supra* note 63 (“Rhode Island law protects Lyme disease patients by ensuring that they can receive proper treatment and that their insurance companies cover that treatment.”)

LLMD-protection laws are problematic expressions of public health policy on the part of state governments for a number of reasons: (1) these laws protect antibiotic therapies that are needlessly dangerous to patients; (2) they weaken the authority of state medical boards and CPGs; and (3) they are counterproductive in the fight against antibiotic resistance.

A. LLMD-Protection Statutes Protect Dangerous, Maximalist Antibiotic Therapies

LLMD-protection laws protect—and arguably legitimize—treatment that not only contradicts the best available scientific evidence, but is also potentially dangerous to patients. “Long-term antibiotic therapy” inherently conflicts with the treatment guidelines for Lyme disease.¹⁹⁹ In exempting such a broad, poorly defined class of antibiotic therapies, LLMD-protection statutes do not even attempt to distinguish between various therapeutic options that may be more or less dangerous to patients. Further, by defining “Lyme disease” so loosely, the laws ostensibly defer to the judgment of LLMD to determine when a patient qualifies for the protected antibiotic regimens.²⁰⁰ These two factors—open-ended antibiotic treatment strategies and poorly defined case definitions—are the essence of the antibiotic maximalism espoused by the LLMD community.²⁰¹

It is disingenuous for state lawmakers to declare that the new statutory protections “do not protect any doctor who provides substandard care.”²⁰² This may be technically correct; physicians will still be held to the professional standard of care in malpractice suits. Yet prescribing long-term antibiotic treatment to treat patients who are improperly diagnosed with Lyme disease is exactly the activity that has been described as potentially injurious—and even fatal—to patients.²⁰³ When interpreted narrowly, LLMD-protection statutes may not prevent medical boards from disciplining the most egregiously dangerous diagnostic and therapeutic practices by the most irresponsible LLMDs.²⁰⁴ However, politicians play a dangerous game when they sanction contraindicated and potentially dangerous therapies. Apart from their direct legal effect on physician

¹⁹⁹ See *supra* section I.B.2.

²⁰⁰ See *supra*, section III.B

²⁰¹ See *supra* section I.B.3.

²⁰² See Press Release, *supra* note 137.

²⁰³ See Stanek et al., *supra* note 80, at 9.

²⁰⁴ One recent case underscores this point. In *Jones v. Conn. Medical Examining Bd.*, a Connecticut LLMD appealed a state medical board order that found Jones had diagnosed Lyme disease in two minors and prescribed antibiotics to them, all without adequate physical examination of the patients. 2011 WL 2739448 (Conn. Super. Ct. 2011). Although the statute was not in effect at the time charges were filed against the physician, the court seemed to indicate, in dictum, that the physician’s failure to make an adequate differential diagnosis (i.e. without a physical examination of the patient) was not protected under the new LLMD statute. *Id.* n.5 (“Even if [the Connecticut LLMD-protection statute] were retroactive, this is not the sole basis for disciplinary action by the Board against Dr. Jones.”).

discipline, LLMD-protection statutes represent legislative support for antibiotic maximalism that may tend to further legitimize this risky therapeutic paradigm.²⁰⁵

B. LLMD-Protection Statutes Threaten the Authority of State Medical Boards and Clinical Practice Guidelines

LLMD-protection laws disrupt the established regulatory framework wherein medical boards enforce professional standards consistently, regardless of the disease context. These laws inject politics into professional codes, threatening the legitimacy of medical regulators. On this point, the particular political context of LLMD-protection legislation is revealing. Advocates of LLMDs and of the “chronic” Lyme disease diagnosis believe that public health officials have conspired with other interests, including insurance companies, to deny them care.²⁰⁶ Accordingly, they argue, state medical regulators are an undue restraint on patient and physician freedom.²⁰⁷ Similarly, LLMD-protection statutes are advocated by those opposed to the perceived political liberalization of “organized medicine,” including state medical boards.²⁰⁸

By repudiating the mainstream IDSA recommendations for Lyme disease treatment, LLMD-protection laws represent a political attack on evidence-based medicine itself. LLMDs and their advocates reject standardizing forces in medicine, decrying the “paternalism” of clinical practice guidelines generally.²⁰⁹ Furthermore, even if the therapeutic claims of LLMDs had scientific merit, legislation is an inherently undesirable way of incorporating evidence into medical practice.²¹⁰ LLMD-protection statutes have

²⁰⁵ In some regions with endemic Lyme disease, the belief is already widespread that that “chronic” Lyme disease persists beyond the IDSA-recommended course of antibiotics. Mark M. Macaуда et al., *Long-Term Lyme Disease Antibiotic Therapy Beliefs Among New England Residents*, 11 VECTOR-BORNE & ZOONOTIC DISEASES 857, 860 (2011) (reporting on a survey of residents in areas of Connecticut and Rhode Island indicating a majority of them “believe that the Lyme disease [bacterium] can persist following antibiotic treatment, that a standard course of treatment for 2-4 weeks is often not curative, and that long-term antibiotic therapy of >2 months is sometimes useful.”).

²⁰⁶ Auwaerter et al., *supra* note 21, at 716; *supra* section II.

²⁰⁷ For instance, in signing the Connecticut LLMD-protection bill, then-Governor Jodi Rell proclaimed that Lyme disease patients “must have the freedom to choose which treatment best meets their needs.” Press Release, Connecticut Department of Public Health, *supra* note 137.

²⁰⁸ Schlafly, *supra* note 138, at 80 (citing the “unholy alliance” of “organized medicine” groups, such as the Texas Medical Association and the American Medical Association, and Texas politicians who defeated the most radical plan, supported by the AAPS, to dismantle the regulatory oversight power of the Texas Medical Board).

²⁰⁹ See, e.g., Lorraine Johnson & Ralph Stricker, *Treatment of Lyme Disease: A Medicolegal Assessment*, 2 EXPERT REV. ANTI-INFECTIVE THERAPY 533, 548 (2004) (“Rigid guidelines that fail to consider patient preference or allow for the exercise of clinical discretion are inherently paternalistic.”).

²¹⁰ As Peter Jacobson has observed, “[L]egislative mandates tied to specific technologies or treatments are inflexible, static, and not as easily changed as science advances.” Peter D. Jacobson, *Transferring Clinical Practice Guidelines Into Legislative Mandates: Proceed with Caution*, 299 JAMA 208, 209 (2008).

been justified by what proponents describe as the still-evolving nature of Lyme research.²¹¹ Paradoxically, however, these statutes enshrine a legislative endorsement of long-term antibiotic therapy that will require state legislators, rather than physician-regulators, to monitor progress in the field and update the law accordingly. This paradox underscores the fact that LLMD-protection statutes are not an attempt to correct an evidentiary bias among medical regulators, but an assault on the standardizing influence of evidence-based guidelines more generally.

LLMD-protection statutes result from a movement that has turned to politics out of frustration with limitations in medical science. Indisputably, medicine has not been able to help those who believe Lyme disease causes their varied, often subjective maladies; medical science merely indicates that those symptoms are not, in fact, caused by Lyme disease.²¹² That dissonance has fueled the passage of LLMD-protection statutes, as LLMDs and their advocates turn to the political sphere in a frustrated attempt to delegitimize the best available evidence on Lyme disease. However, society suffers when normative, value-laden positions (e.g. the desire to alleviate symptoms ascribed to “chronic” Lyme disease) are disguised as positivist, evidence-based ones.²¹³ By invoking politics and the law in an attempt to discredit evidence-based clinical guidelines and advance dangerous and unnecessary antibiotic therapies, politicians have dismantled an important firewall between the scientific process on the one hand, and normative political decision-making on the other.²¹⁴

C. LLMD-Protection Statutes Threaten the Fight Against Antibiotic Resistance

Beyond their immediate implications for Lyme disease therapy, LLMD-protection statutes threaten the unique ability of state medical boards to address the growing threat of antibiotic resistance. Antibiotic use invokes competing individual and public-health considerations—even when antibiotic use is warranted in the case of an individual patient, such use imposes external costs on others who may become infected by resistant

²¹¹ See, e.g. Open Letter, *supra* note , (arguing “[the LLMD protection law] will enable very ill [Connecticut] residents to choose treatment options that best meet their needs while the medical community works to find consensus on LD treatment guidelines” and citing a report indicating that “evidence [used to repudiate long-term antibiotic therapy] is too heterogeneous to make strong recommendations”).

²¹² See *supra*, section I.B.

²¹³ Kraemer & Gostin, *supra* note 74, at 666-67. Writing critically of the Connecticut antitrust investigation into IDSA, Kraemer & Gostin criticize the chronic Lyme movement when their “normative views are passed off as positive assertions.” *Id.* (“The [chronic Lyme disease] advocacy community understandably seeks answers for the symptoms attributed to Lyme disease. But when high-quality research repeatedly was inconsistent with the group’s hypotheses, the community should have sought other answers.”).

²¹⁴ See *id.* (“A wall of separation is needed between science, norms, and politics.”)

bacteria.²¹⁵ Relative to other regulators of physician behavior,²¹⁶ medical boards are well placed to weigh such competing interests in antibiotics because of their duty to the public at large.²¹⁷ However, LLMD-protection statutes severely impede this potential function of medical boards by preventing them from disciplining physicians for prescribing contraindicated, maximalist antibiotic regimens.

More generally, LLMD-protection statutes legitimize an individualist perspective of the doctor-patient relationship that contradicts the role of the physician, and the wider medical profession, in promoting the public health. State legislation favoring LLMDs responds to popular perceptions that the IDSA recommendations were not grounded in medical evidence but, instead, were created as instruments of cost-cutting and medical rationing.²¹⁸ Yet, antibiotic resistance is one public health concern that will, in particular, require physicians to serve as gatekeepers.²¹⁹ In contrast, LLMD-protection statutes legitimize a medical subculture that continues to express an unbridled commitment to using more and stronger antibiotics.²²⁰

D. Is There a Better Way for Legislatures to Address the Conflict over Lyme Disease?

For the reasons outlined above, LLMD-protection statutes are an aberration from sound medical policy and should be repealed promptly. Yet, is there a way for policymakers to appease those who believe that “chronic” Lyme disease requires long-term antibiotic therapy, without explicitly condoning dangerous therapies? The answer, unfortunately, is likely to be no. Short of undesirable measures, such as LLMD-

²¹⁵ Eric Kades, *Preserving a Precious Resource: Rationalizing the Use of Antibiotics*, 99 NW. U.L. REV. 611, 627 (2005). See also *supra* notes 2-11 and accompanying text (describing the problem of antibiotic resistance).

²¹⁶ In particular, the medical malpractice liability paradigm is not fit to confront the population health problems posed by antibiotic resistance. See Saver, *supra* note 56 at 464. Apart from the issue of the standard of care (which may or may not impose sufficient limits on antibiotic use), a crucial problem is that a physician’s duty is not likely to extend to third parties injured by resistant strains of bacteria. See *id.* at 464-465.

²¹⁷ See Saver, *supra* note 56, 469 (reasoning that if medical boards imposed greater controls over antibiotic usage, “such an approach would seem to fit naturally within the licensure paradigm of evaluating individual practitioners for adherence to minimal standards of professional conduct in order to protect patients in the aggregate”). Saver adds the caveat, however, that “[t]hreats to population health due to indiscriminate antibiotic prescribing would likely be seen by medical board officials as somewhat diffuse and attenuated compared to the more tangible, immediate dangers to patients arising from other licensure violations.” *Id.* at 470.

²¹⁸ See *supra* section II.A.

²¹⁹ Saver, *supra* note 56, at 434-35.

²²⁰ In an argument that the pharmaceutical company should pay more attention to chronic Lyme disease, leading LLMDs have claimed that expanded use of long-term antibiotic therapy should be a winning proposition for both for patients and “Big pharma.” Stricker & Johnson, *Lyme disease: the next decade*, 4 INFECTION & DRUG RESISTANCE 1, 4 (2011) (“The need for more effective treatment of this chronic infection in turn supports the use of more complex (and lucrative) antibiotic regimens in Lyme disease.”).

protection laws, that legitimize the LLMD paradigm, political action is unlikely to convince advocates of non-standard Lyme disease practice that medical regulators are taking them seriously. Admittedly, several states have passed legislation that, arguably, pays lip service to the chronic Lyme movement and may be effective in diffusing concerns that “chronic” Lyme disease is ignored by the government.²²¹ Similarly, proposed federal legislation would create a Tick-Borne Diseases Advisory Committee, stipulating that members must “represent[] the broad spectrum of viewpoints held within the scientific community related to Lyme and other tick-borne diseases.”²²² However, the more steadfast opponents of medical standardization are likely to be disappointed by anything less than a comprehensive structural change to physician oversight.²²³

At its base, the Lyme disease conflict reflects the fact that scientific data is often ill-equipped to compete with compelling anecdotes.²²⁴ The controversy highlights the political weaknesses of evidence-based medicine, which relies on the “biomedical model” of disease and may thus disappoint patients whose very real symptoms arise from poorly defined factors.²²⁵ Reconciling divergent perspectives on the patient-physician relationship is absolutely vital as we move closer to the “consumer health revolution,” whose advocates see the “paternalism of the medical profession” as a major barrier to the democratization of health care.²²⁶ Yet, exempting dangerous therapy from regulatory oversight, as LLMD-protection laws do, is a blunt, inflexible, and alarmingly irresponsible response to the demands of a fringe group of physicians and their patients.

V. CONCLUSION

²²¹ See, e.g., WIS. STAT. ANN. 254.52 (West 2011) (directing the department of health to conduct research and collect data on Lyme disease); ME. REV. STAT. ANN. tit. 22, § 1645 (West 2011) (providing for an annual report on Lyme disease, including “[a] summary or bibliography of peer-reviewed medical literature and studies related to the diagnosis, medical management and treatment of Lyme disease and other tick-borne illnesses, including, but not limited to, the recognition of chronic Lyme disease and the use of long-term antibiotic treatment) (emphasis added); N.J. STAT. ANN. 36:2-111 (West 2011) (“Lyme-Disease Awareness Month”). More entertaining proposals have also been put forward. In 2011, Rhode Island legislators introduced a bill that would designate a special scratch-off lottery ticket (named “Scratch-A-Tick”) to raise funds for Lyme disease research. H.R. 5116/S. 134, 2011 Leg. Sess. (R.I.).

²²² Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2011, S. 1381, 112th Cong. (2011); H.R. 2557, 112th Cong. (2011) (“To provide for the establishment of the Tick-Borne Diseases Advisory Committee”).

²²³ See Schlafly, *supra* note 138, at 80 (2011) (“Taking power away from medical boards is the only way to guarantee improvement for freedom in medicine.”).

²²⁴ Some commentators have argued that the medical community must find a way of communicating science in a way that competes with anecdote and narrative. See Zachary F. Meisel & Jason Karlawish, Commentary, *Narrative vs. Evidence-Based Medicine—And, Not Or*, 306 JAMA 2022, 2023 (2011) (describing the need to convey medical evidence in a way that competes with compelling, but misleading, anecdote).

²²⁵ See Sigal & Hassett, *supra* note 67, at 609-10.

²²⁶ See Frank Moss, Op-ed, *Our High-Tech Health-Care Future*, N.Y. TIMES, Nov. 10, 2011, at A29 (advocating greater patient involvement in health-related decision-making).

Lyme disease, and the controversy surrounding its treatment, has precipitated an unprecedented response by state governments. LLMD-protection statutes aim to protect a broad, poorly defined class of non-standard antibiotic therapy for Lyme disease. In doing so, these laws put patients at risk by delegitimizing state medical regulators and evidence-based Lyme disease treatment guidelines. Further, by explicitly endorsing the maximalist antibiotic paradigm, LLMD-protection laws are a step backward in the struggle against antibiotic resistance. Any discussion of Lyme disease must acknowledge the suffering of those individuals who believe they suffer from “chronic” Lyme disease. Yet recent enactment of LLMD-protection statutes by several states endangers the very patients those states aim to serve.