In most every General Assembly session, there are those bills that—while on the surface appear fairly innocuous—quickly take on a life of their own, generating an audible buzz in and around the General Assembly Building. The 2010 Virginia General Assembly session was no different. Amidst hallway discussions concerning the budget, gun rights, and abortion, one could also hear the distinct murmur of a completely novel topic: Lyme disease. Often associated with a small, pesky insect known as the black-legged tick, until this year, Lyme disease had not been the subject of any controversial legislation proposed in the Commonwealth of Virginia, until this year. In 2010, five separate bills pertaining to Lyme disease were proposed, primarily by elected representatives from the Northern Virginia area, allowing the unwelcome summer guest to achieve a newfound level of notoriety. And one thing remains sure: the tick’s recent
rise to fame will not be short-lived; Lyme disease will continue to be a contested issue in the legislative sessions ahead.

BACKGROUND

A. What is Lyme Disease?

Lyme disease in humans is caused by infection with a spiral-shaped bacterium called *Borrelia burgdorferi*. The bacteria are carried and transmitted to humans by the black-legged tick (formerly known as the deer tick). Indeed, the black-legged tick is the only known carrier of the disease in the Eastern United States. Transmission of the disease typically occurs in the late spring and early summer when young, or nymph stage ticks, are active and feeding. Tick nymphs themselves become infected with the bacteria after feeding on certain rodent species.

Transmission of the disease does not usually occur until the tick has been attached and feeding on the human host for approximately 36 hours. In as little as a few days or as long as a few weeks following the infectious tick bite, many patients (approximately 80 percent) will develop a red rash called an erythema migrans, or “bull’s eye” rash, which slowly expands and clears around the center of the bite site. Other more immediate symptoms can include fatigue, general malaise, fever, headache, stiff neck, muscle aches, and joint pains. However, if left untreated, some patients can develop longer-term symptoms, including arthritis, neurological problems, and/or heart problems. Unfortunately, since black-legged ticks are small, often difficult to see, and generally cause no itch or irritation at the site of the bite, many people are not aware that they have been bitten. Thus, the disease can go unnoticed for quite some time.

The prevalence of Lyme disease has risen significantly in the United States, particularly on the East Coast. Although it is unclear whether

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4. VA. DEP’T OF HEALTH, supra note 1.
5. Id.
6. Id.
7. Id.
8. Id.
9. Id.
11. Id.
12. Id.
13. VA. DEP’T OF HEALTH, supra note 1.
increases are due to heightened recognition and education, or whether they are due to an actual jump in the incidence of the disease, the number of confirmed reported cases in the United States in 2008 was 28,921. This is an increase from 19,804 cases in 2004 and 16,273 cases in 1999. In Virginia alone, there were 886 confirmed cases reported to the Centers for Disease Control. Most of these cases were reported in Northern Virginia, which is comprised of once heavily wooded areas that are now becoming more densely populated due to the urban sprawl surrounding Washington, D.C.. Loudon County, just west of Washington, D.C. reports having an incidence rate nearly twenty times greater than that of the Virginia average.

B. "Two Schools of Thought"

The next question that logically follows is: how is Lyme disease treated? This question, and its variant answers, comprise the larger part of the Lyme disease debate in the 2010 General Assembly. Over the past several years, two separate "factions" have emerged, and each has its own view regarding how Lyme disease should be treated. First, there are the "mainstream" physicians who, along with the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Infectious Diseases Society of America (IDSA), and the American Academy of Neurology (AAN), feel that most instances of Lyme disease can be cured with a few weeks of taking oral antibiotics. This group generally concedes that in a relatively smaller number of cases, patients with persistent or recurrent symptoms may require a second four-week course of therapy. Any antibiotic treatment beyond this, however, is not seen to be beneficial and is believed to result in serious complications, including the

15. Id.
16. Id.
19. Infectious Diseases Society of America, supra note 18.
elimination of “good” bacteria from the immune system, secondary infections that are passed through intravenous lines used to administer the antibiotics, adverse reactions to the drugs themselves, and overall antimicrobial resistance.20 The mainstream group tends to doubt the existence of “chronic Lyme disease,” which has been used to describe some patients who exhibit symptoms of Lyme (such as fatigue and pain—symptoms commonly experienced in the rest of the population), but who have never actually tested positive for the bacteria.21

On the other hand, there are those who fiercely advocate for long-term antibiotic treatment, which can last for months or even years. This group, comprised of patient advocates and those physicians they consider to be forward-thinking (often referred to and identified as “Lyme-literate medical doctors”), has become increasingly vocal over the past few years.22 Both the patients and the doctors who comprise this side of the debate voice frustration with standard treatments, and they believe that many diffuse ailments, from arthritis and headaches to irritability and poor concentration, are actually symptoms of lingering, active Lyme disease.23 Specifically, they believe that an ongoing infection with the spirochetal bacterium Borrelia burgdorferi may be the cause of persistent symptoms in chronic Lyme disease.24 Thus, extended courses of antibiotics are seen as the only way to provide meaningful symptomatic relief in chronic patients.25 The “very real consequences” of untreated persistent Lyme infection are perceived to far outweigh the potential adverse side effects of long-term antibiotic therapy.26

Lyme activists, whose national lobbying arms include the Lyme Disease Association and the International Lyme and Associated Diseases Society (ILADS),27 have attacked legislation on state and federal levels, protested outside doctors’ offices, and lined up powerful allies, including the Connecticut Attorney General.28 One of the Lyme activists’ strongest

20. Centers for Disease Control, supra note 14, National Institutes of Health, supra note 18 (emphasis added).
21. Id.
23. Id.
24. Id.
26. Id.
28. Feifer, supra note 22.
fights to date has been to challenge the IDSA-developed guidelines for the treatment of Lyme disease. The IDSA guidelines, which are considered to be the “prevailing” or majority view state, “[a]ntibiotic 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 . . . .” The guidelines further advise against other therapeutic modalities, including, but not limited to, “pulsed-dosing (i.e., dosing on some days but not others),” hyperbaric oxygen, fever therapy, intravenous immunoglobulin, and specific nutritional supplements. Lyme advocates have vehemently opposed these guidelines, claiming that they are “one-sided” and prevent otherwise qualified doctors from recognizing and treating the symptoms of “chronic Lyme.” After the promulgation of the IDSA guidelines in 2006, Lyme advocates appealed to the Connecticut Attorney General to investigate what they perceived to be an inherent unfairness in the guidelines. In response, the Attorney General’s antitrust division conducted an in-depth analysis of the IDSA guidelines, searching for conflicts of interest among panelists and looking for the exclusion of differing, yet legitimate points of view. Ultimately, the IDSA voluntarily agreed to a one-time special review of its guidelines, with the proviso that the current guidelines would stay intact until a comprehensive review panel holds that they should be revised. The results of this review have not yet been published. In the meantime, Lyme activist groups have proactively developed their own guidelines for treatment of the disease. The ILADS guidelines specifically address the fact that treatment should not be withheld solely based on laboratory testing, and they also recommend both longer courses of antibiotic treatment, as well as repeat antibiotics for recurrence.

29. Id.
31. Id.
32. Feifer, supra note 22.
33. Id.
36. ILADS Lyme Disease Treatment Guidelines Summary, supra note 25.
37. Id.
Beyond challenging the traditional schools of thought, Lyme activists have exercised their political clout to successfully enact legislation in several states that will protect physicians who prescribe extended courses of antibiotics. In 2009, at the urging of vocal patient advocates, the Connecticut General Assembly passed a bill containing language that protects licensed physicians from disciplinary action by the State of Connecticut Medical Examining Board solely on the basis of a clinical diagnosis and/or treatment of chronic Lyme disease. Specifically, a Connecticut statute now provides that a "physician may prescribe, administer, or dispense long-term antibiotic therapy" to Lyme patients, provided the physician clearly documents a clinical diagnosis and treatment plan in the patient's medical record. Rhode Island passed similar legislation, where in addition to protecting doctors from medical board investigation, the law further provides that insurance companies must provide coverage for Lyme disease treatment.

Local Lyme advocacy groups have taken note of these recent successes and have quickly begun to expand legislative efforts in their home states. Bills that extend protection to Lyme literate doctors who prescribe long-term antibiotics are being proposed across the country. In Virginia, a highly organized advocacy group, known as the National Capital Lyme & Tick-Borne Disease Association ("NatCapLyme"), played a critical role in gaining support and patronage for five Lyme disease-related bills.

2010 PROPOSED VIRGINIA LEGISLATION & OUTCOMES

Of the five bills proposed this legislative session regarding Lyme disease, all but one were incorporated into Delegate Tom Rust's House Bill 512. Specifically, House Bill 897 (sponsored by Delegate Barbara Comstock), House Bill 1017 (sponsored by Delegate Tim Hugo), and

39. Id.
40. R.I. GEN. LAWS §§ 37.5-4(a) (2009)(stating that "[n]o physician is subject to disciplinary action by the board solely for prescribing, administering, or dispensing long-term antibiotic therapy for a therapeutic purpose for a patient clinically diagnosed with Lyme disease..."); R.I. GEN. LAWS §§ 37.5-5 (2010).
42. See National Capital Lyme & Tick-Borne Disease Association, http://www.natcaplyme.org/index.php (last visited March 8, 2010); infra Part II.
House Bill 1288 (sponsored by Delegate Ken Plum) were all incorporated into Delegate Tom Rust’s House Bill 512.\(^{44}\) Notably, all of the chief patrons, as well as a significant number of the co-patrons, represent districts in Northern Virginia, where the prevalence of Lyme disease is reported to be quite high.\(^{45}\) Delegate Rust’s bill addressed long-term prescribing of antibiotics for patients with chronic Lyme disease, largely mirroring the language of the Connecticut and Rhode Island legislation.\(^{46}\) In particular, the bill sought to clarify that “[a] licensed physician may prescribe, administer, or dispense long-term antibiotic therapy to a [Lyme disease] patient . . ., provided such clinical diagnosis and treatment are documented in the patient’s medical record by such licensed physician.”\(^{47}\) Similar to legislation proposed in other states, the bill also sought to prohibit the Virginia Board of Medicine from bringing disciplinary action against physicians solely for prescribing, administering, or dispensing long-term antibiotic therapy to Lyme patients.\(^{48}\)

The House of Delegates Health, Welfare and Institutions Subcommittee meeting\(^{49}\) at which the incorporated bill was heard, drew a large crowd that mostly comprised of Lyme disease patients, their families, and physician advocates. However, also on hand were members of the Virginia medical community, who primarily attended to oppose the bill. Both sides were given a limited amount of time to advance their respective arguments for or against the bill. Among those who provided testimony in support of the bill were several Lyme disease patients, a physician advocate from Northern Virginia, and the legal counsel to NatCapLyme. Additionally, a letter was read that was written by a physician who herself


\(^{46}\text{See H.B. 512, Gen. Assem., Reg. Sess. (Va. 2010), ¶ 1, § 54.1-3408.2 (as introduced Jan. 13, 2010); supra notes 38 and 40 and accompanying text.}

\(^{47}\text{H.B. 512, ¶ 1, § 54.1-3408.2(A).}

\(^{48}\text{Id.}

\(^{49}\text{The discussion that follows is based on personal attendance at the first House of Delegates Health, Welfare, and Institutions Subcommittee meeting that was held in the Virginia General Assembly building on February 1, 2010 at 5:00 p.m.}
suffers from Lyme disease and who advocates protection of those doctors who choose to prescribe long-term antibiotics. The advocates' testimony, often quite emotional, urged legislators to take notice of the growing prevalence of Lyme disease in our state and also urged them to consider the possibility that there may be more than one "right" way to treat chronic symptoms of Lyme disease.

In rebuttal, the Medical Society of Virginia ("Medical Society") took the stance that extended courses of antibiotics are often inappropriate, particularly when there is no laboratory evidence that the patient was ever infected with the bacteria. Two physicians speaking on behalf of the Medical Society, one of whom was the former president of the IDSA, pointed out the harms that can occur when a person stays on antibiotics for too long, including bloodstream infections caused by intravenous administration and the creation of "superbugs" that can become resistant to antibiotic treatment. The Medical Society also expressed concern that passing the legislation would be akin to codifying a standard of care, something physicians have traditionally cautioned against. Physicians have long advocated that whenever the legislature attempts to dictate the standard of care, it is a slippery slope whereby state legislators can begin dictating courses of care for other medical conditions. Particularly in this case, the Medical Society argued it would be dangerous to legislate a standard of care that was indeed a controversial one and over which the medical community was divided. Further, while House Bill 512 would not specifically mandate that a physician choose long-term antibiotic therapy for patients who exhibit chronic, Lyme-like symptoms, the legislation's permissive choice could open the door to challenging a physician's clinical determination to not use long-term therapy. Finally, citing anecdotal information provided by the Virginia Department of Health Professions, the Medical Society explained that physician investigations by the Board of Medicine were not an issue in the Commonwealth. According to the Department of Health Professions, only one physician had ever been investigated for improperly prescribing antibiotics to a Lyme disease patient, and that complaint had subsequently been dropped.

Ultimately, the House Subcommittee chose to carry the bill over to the 2011 regular session.\(^{50}\) There was only one dissenting vote to the Subcommittee's recommendation to carry the bill over, and Delegate Lionel Spruill of the 77th District voiced that dissent.\(^{51}\) Delegate Spruill indicated

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50. See Bill Tracking: H.B. 512, supra note 44 (stating that the "[s]ubcommittee recommends continuing to 2011 by voice vote.").
51. See Bill Tracking: Members, supra note 44.
his concern for failing to take action on the bill during the 2010 session, pointing to the large number of advocates who had traveled considerable distances to make their opinions known. In explaining the Subcommittee’s decision to carry the bill over to the next session, the chair of the subcommittee, Delegate John O’Bannon (himself a physician), gave the stakeholders a verbal command to begin working with one another towards a resolution during the interim. The Virginia Department of Health, represented by Commissioner Dr. Karen Remley, agreed to draft a letter to all physicians in the Commonwealth and underscore the increasing prevalence of Lyme disease in the state. The following day, the full House Committee of Health, Welfare, and Institutions affirmed the subcommittee’s recommendation to carry the bill over by a voice vote.\(^5\)

The one remaining bill that was not incorporated in House Bill 512, and was thus heard alone by the House Health, Welfare and Institutions Subcommittee meeting, was House Bill 36, sponsored by Delegate Robert G. Marshall of the 13th District.\(^5\) Delegate Marshall’s bill sought to require that Lyme disease be included among the Virginia Board of Health’s list of reportable diseases.\(^5\) The Medical Society opposed this bill as well, arguing that House Bill 36 was duplicative of already existing law. Specifically, the Medical Society pointed out in oral testimony that Delegate Marshall’s proposed statutory requirement was unnecessary, since the Health Board’s regulations already require that certain health care providers report Lyme disease to specified health agencies.\(^5\) The Subcommittee ultimately agreed with this conclusion and recommended tabling the bill by a voice vote.\(^5\)

**FUTURE OUTLOOK**

Although no immediate action was taken on House Bill 512 in the 2010 session, the fact that the bill has been carried over to the 2011 session signals that this issue is far from over. Large numbers of patient advocates (or in other words, large numbers of voting constituents) have made their opinions known, and legislators have taken note. Even after House Bill 512 was carried over in the Commonwealth of Virginia, the issue did not immediately fall off the General Assembly members’ radars. A newly formed joint caucus of the House and Senate known as the “Allied Health

\(^5\) Bill Tracking: H.B. 512, *supra* note 44 (stating that House Bill 512 was “[c]ontinued to 2011 in Health, Welfare, and Institutions by voice vote.”).

\(^5\) See *supra* notes 43-44 and accompanying text.


\(^5\) See 12 VA. ADMIN. CODE §5-90-80, which includes “Lyme disease” as a reportable disease.

\(^5\) Bill Tracking: H.B. 36, *supra* note 44.
Caucus” held its first meeting in February on the subject of Lyme disease. Dr. Keri Hall, Director of Epidemiology in the Commonwealth of Virginia, provided up-to-date statistics on the prevalence of Lyme disease in Virginia and helped explain the current state of scientific research from a non-politicized standpoint. Legislators responded with many questions, signaling their ongoing desire to learn more about this complex and often highly divisive topic.

Lyme advocacy groups continue to work tirelessly in surrounding states as well. At the time of this submission, there is currently an ongoing debate over proposed Lyme disease legislation in the state of Maryland. Interestingly, it seems that at least some members of the Lyme community are in fact opposed to legislation that purports to extend immunity to physicians who prescribe long-term antibiotics, claiming that the bill does not go far enough to provide Lyme literate medical doctors with the protection that they need. The Maryland bill provides that physicians may prescribe long-term antibiotics to treat Lyme disease, so long as the Centers for Disease Control do not publish additional guidance that would recommend against this form of therapy. Lyme advocates also take issue with the fact that the Maryland bill defines Lyme disease as an “acute” infection with *Borrelia burgdorferi* and that it allows the State Medical Board to investigate a physician for prescribing the incorrect long-term antibiotic.

As the debate in Maryland illustrates, Lyme advocates are not likely to bend easily. They will continue to fight for unfettered access to long-term antibiotic therapy, and they will continue to ensure that both state and national lawmakers alike hear their voices. While organized medicine will likely continue to insist on a reliable amount of evidence-based research before lending its support to long-term therapy, health care providers would be remiss to ignore the issue. Given Chairman O’Bannon’s charge during the bill hearing, all stakeholders must be prepared to work together this coming summer. The Medical Society, along with the relevant state health agencies, must stand ready to further educate both physicians and the Virginia citizenry at large about the increasing prevalence of Lyme disease. For, just as sure as humidity and warmer temperatures will begin to descend on our great Commonwealth, so too will the “tick.” But this time, he may extend his stay - at least figuratively - through February or March.

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60. Posting of Bettyg, *supra* note 58 (citing H.B. 290, ¶ 1, § 14-508(A)(4) and (E)(4)).