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# Unprecedented Antitrust Investigation into the Lyme Disease Treatment Guidelines Development Process

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## TABLE OF CONTENTS

I. INTRODUCTION .....	118
II. LYME DISEASE—A BRIEF HISTORY .....	119
III. INFECTIOUS DISEASES SOCIETY OF AMERICA GUIDELINES .....	122
IV. APPLYING ANTITRUST PRINCIPLES TO THE IDSA’S GUIDELINE- DEVELOPMENT PROCESS.....	127
A. <i>The Chronic Lyme Disease Controversy</i> .....	127
B. <i>Is the Development of Medical Guidelines Analogous to         Commercial Standard-Setting?</i> .....	130
C. <i>The Sherman Act</i> .....	132
1. Could the IDSA Be Subject to Antitrust Laws? .....	133
2. Applying a Rule of Reason Analysis to the IDSA’s Guideline Development Process.....	137
(a) Did the IDSA Panel Members Engage in a Conspiracy that Restrained Trade in the Relevant Market? .....	137
(b) Do the 2006 Guidelines Have a Legitimate Purpose? .....	141
(c) Did the IDSA Guideline Development Process Have Procedural Safeguards? .....	143
3. Did the IDSA Monopolize or Attempt to Monopolize the Lyme Treatment Market? .....	144
V. CONCLUSIONS.....	145

Imagine waking up one morning with numbness and tingling in your legs and arms and an excruciating pain that migrates throughout your joints and muscles, settling primarily in your hips and back. Your doctor takes a basic blood panel and orders a Magnetic Resonance Imaging (MRI) of the brain, yet the results indicate that there is nothing wrong with you. The doctor suggests that it must be stress. The neurologist tells you that the symptoms point to multiple sclerosis or other equally frightening neurological diseases. An agonizing four weeks pass as you undergo an electroencephalogram, an electromyogram, and an MRI of the cervical spine. These tests are all negative. The rheumatologists are also puzzled and subject you to another round of twenty to thirty blood tests. Hinting at hypochondria, these doctors suggest fibromyalgia, but further inquiry reveals that this is a “catch-all” disease with

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no specific symptoms, no cause, and no cure. Three years have passed, and there appears to be no other choice but to live with the pain.<sup>1</sup>

## I. INTRODUCTION

Unfortunately, this is the life of thousands of Americans.<sup>2</sup> “Lyme disease is the most common tickborne infection in both North America and Europe,”<sup>3</sup> and according to the International Lyme and Associated Diseases Society (ILADS),<sup>4</sup> Lyme disease is the fastest-growing infectious disease in America, and it may be “occur[ing] at a rate five times higher than the number of new AIDS cases.”<sup>5</sup> Lyme disease is everywhere: if you take a walk in a field or the woods, you can encounter a tick carrying Lyme disease.<sup>6</sup> One estimate is that 300,000 Americans are infected with Lyme each year.<sup>7</sup> “And a lot of researchers believe that a billion people are

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1. Interview with Lyme Disease Sufferer, in Auburn Hills, Mich. (Mar. 2, 2009).

2. See *Examining the Adequacy of Current Diagnostic Measures and Research Activities in the Prevention and Treatment of Lyme Disease: Hearing Before the S. Comm. on Labor & Human Res.*, 103d Cong. 54, 56 (1993) [hereinafter *1993 Hearing*] (statement of Dr. Joseph Burrascano, Jr., Physician) (stating that some patients have seen more than 40 “different physicians over several years before being properly diagnosed”); Stephen Smith, *Diagnosis: Controversy More Than Two Decades Since the Threat of Lyme Disease was Recognized, Doctors and Patients are Still Warring over how to Identify and Treat it*, BOS. GLOBE, June 25, 2007, [http://www.boston.com/news/globe/health\\_science/articles/2007/06/25/diagnosis\\_controversy/](http://www.boston.com/news/globe/health_science/articles/2007/06/25/diagnosis_controversy/). Dr. Raphael Stricker, past-president of the International Lyme and Associated Diseases Society (ILADS), states that most patients have “been to 10 to 20 doctors who can’t diagnose them.” *Id.*

3. GARY P. WORMSER, ET. AL., INFECTIOUS DISEASES SOC’Y AM., THE CLINICAL ASSESSMENT, TREATMENT, AND PREVENTION OF LYME DISEASE, HUMAN GRANULOCYTIC ANAPLASMOSIS, AND BABESIOSIS: CLINICAL PRACTICE GUIDELINES BY THE INFECTIOUS DISEASES SOCIETY OF AMERICA, 1089 (2006) [hereinafter 2006 IDSA GUIDELINES].

4. “ILADS is a nonprofit, international, multi-disciplinary medical society dedicated to the diagnosis and appropriate treatment of Lyme and its associated diseases.” ILADS, *About ILADS*, INT’L LYME & ASSOCIATED DISEASES SOC’Y, [http://www.ilads.org/about\\_ILADS/about\\_us.html](http://www.ilads.org/about_ILADS/about_us.html) (last visited Oct. 10, 2010).

5. ILADS, *ILADS Lyme Disease Treatment Guidelines Summary*, INT’L LYME & ASSOCIATED DISEASES SOC’Y, [http://www.ilads.org/lyme\\_disease/treatment\\_guidelines\\_summary.html](http://www.ilads.org/lyme_disease/treatment_guidelines_summary.html) (last visited Oct. 10, 2010).

6. See *1993 Hearing*, *supra* note 2, at 54-55.

7. Press Release, Int’l Lyme & Associated Diseases Soc’y, Historic Hearings on Most Controversial Disease in U.S. (July 26, 2009), available at [http://www.ilads.org/news/lyme\\_press\\_releases/60.html](http://www.ilads.org/news/lyme_press_releases/60.html); see also KENNETH B. SINGLETON, THE LYME DISEASE SOLUTION, at xxi (2008) (stating that each year, the CDC “reports more than 20,000 diagnosed cases of Lyme disease in the United States, but . . . [s]ome estimates place the actual number of cases at 10 times or more higher than reported cases”).

infected.”<sup>8</sup> But in reality, no one knows the actual number of infected people with Lyme disease.

This article will explain what Lyme disease is, provide a brief history of Lyme disease, and explain why there is a controversy surrounding chronic Lyme disease. In addition, this article will explain how the chronic Lyme controversy led to Connecticut’s Attorney General filing “the first-ever antitrust investigation against a medical society’s guidelines development process.”<sup>9</sup> Although Connecticut’s Attorney General entered into a settlement agreement with the medical society,<sup>10</sup> this article will examine whether antitrust laws could be applied to a medical guideline development process. This examination is worthwhile because there are more than 2,300 clinical practice guidelines currently listed on the National Guideline Clearinghouse web site,<sup>11</sup> and some of these guideline development processes could face antitrust investigations in the future.

## II. LYME DISEASE—A BRIEF HISTORY

Lyme disease got its name in the late 1970s, when a cluster of children and adults living in Lyme, Connecticut, began experiencing unusual arthritic symptoms.<sup>12</sup> Consequently, many people are under the misconception that Lyme disease is a new disease that was discovered in the 1970s.<sup>13</sup> But the first known condition associated

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8. *In Re Lyme Disease: Public Hearing Before the Conn. Dep’t of Pub. Health*, 177, 179 (Conn. Jan. 29, 2004) (statement of Dr. Stephen Sinatra, Cardiologist), *available at* <http://www.ct.gov/ag/lib/ag/health/0129lyme.pdf>.

9. Press Release, Lyme Disease Ass’n, Settlement Announced in Landmark Investigation of Lyme Disease Diagnosis and Treatment Guidelines (May 1, 2008), *available at* [http://www.lymediseaseassociation.org/index.php?option=com\\_content&view=article&id=308](http://www.lymediseaseassociation.org/index.php?option=com_content&view=article&id=308).

10. See AN AGREEMENT BETWEEN THE ATTORNEY GENERAL OF THE STATE OF CONNECTICUT AND THE INFECTIOUS DISEASES SOCIETY OF AMERICA (2008) [hereinafter 2008 SETTLEMENT AGREEMENT], *available at* <http://www.ct.gov/ag/lib/ag/health/idsaagreement.pdf>. Connecticut’s Attorney General, Richard Blumenthal, investigated the Infectious Diseases Society of America (IDSA), for anti-trust violations. Press Release, Lyme Disease Ass’n, *supra* note 9.

11. *Guidelines by Topic*, NAT’L GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/browse/by-topic.aspx> (last visited Oct. 10, 2010). Interestingly, the 2006 IDSA Lyme Guidelines are listed on the National Guideline Clearinghouse Website, but the ILDSA Guidelines are not listed on the Website. See *Guideline Summary*, NAT’L GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/content.aspx?id=9537&search=lyme+guidelines> (last visited Oct. 10, 2010).

12. *A Brief History of Lyme Disease in Connecticut*, CONN. DEP’T OF PUB. HEALTH, <http://www.ct.gov/dph/cwp/view.asp?a=3136&q=388506> (last modified June 2, 2010); SINGLETON, *supra* note 7, at 13.

13. *Where did Lyme Disease Come From? Is it New?*, LYME DISEASE FOUND., [http://www.lyme.org/ld\\_history.html](http://www.lyme.org/ld_history.html) (last visited Oct. 10, 2010).

with Lyme disease was recorded in Germany in 1883.<sup>14</sup> Although the disease has been around for more than a century, the bacterium that causes Lyme disease, *Borrelia burgdorferi* (*Bb* bacteria), was not discovered until 1982.<sup>15</sup>

The black-legged deer tick<sup>16</sup> is the primary vector responsible for transmitting Lyme disease,<sup>17</sup> but research suggests that flies, gnats, mice, and mosquitoes can also transmit the *Bb* bacterium.<sup>18</sup> All vectors become infected when they bite an animal, usually a small mammal, bird, or deer,<sup>19</sup> which is already infected with the *Bb* bacteria.<sup>20</sup> The *Bb* bacteria “travels to local nerves and lymphatic channels, penetrates the blood stream, and can rapidly invade the brain without the host even knowing.”<sup>21</sup> There is also evidence that the *Bb* bacteria can also infect unborn children by crossing the placenta.<sup>22</sup> For example, in one case, a doctor concluded that a former Lyme patient’s eighteen-week-old fetus, which unexpectedly died in utero, died from Lyme disease because lab tests established that the baby was chromosomally normal, but “the fetus and placenta were PCR-positive<sup>23</sup> for Lyme bacteria.”<sup>24</sup>

The early stage of Lyme disease is generally characterized by a fever and flu-like symptoms, including fatigue, headache, and a mild stiff neck, and some patients develop a bull’s-eyed shaped skin rash known as erythema migrans (EM rash).<sup>25</sup> But

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14. *Id.*; see also SINGLETON, *supra* note 7, at 14.

15. *A Brief History of Lyme Disease in Connecticut*, *supra* note 12; see also SINGLETON, *supra* note 7, at 4, 13.

16. The scientific name for the black-legged deer tick is *Ixodescapularis*. Press Release, Infectious Diseases Soc’y Am., Updated Guidelines on Diagnosis, Treatment of Lyme Disease (Oct. 2, 2006) [hereinafter Press Release, IDSA], available at <http://www.idsociety.org/Content.aspx?id=3744>.

17. *See id.*

18. SINGLETON, *supra* note 7, at 6.

19. *See* Press Release, IDSA, *supra* note 16.

20. *See* CONSTANCE A. BEAN WITH LESLEY ANN FEIN, BEATING LYME: UNDERSTANDING AND TREATING THIS COMPLEX AND OFTEN MISDIAGNOSED DISEASE, at xii (2008); SINGLETON, *supra* note 7, at 5.

21. BEAN, *supra* note 20.

22. *See id.* at 174.

23. PCR is an acronym for polymerase chain reaction.

24. *In Re Lyme Disease*, *supra* note 8, at 57 (statement of Elise Brady, Lyme Disease Patient).

25. 1993 Hearing, *supra* note 2, at 76, 82 (statement of Dr. Joseph McDade, Associate Director of Laboratory Science, National Center for Infectious Diseases); Rendi Murphee Bacon, et al., Dep’t of Health & Human Servs., Ctrs. for Disease Control & Prevention, *Surveillance for Lyme Disease – United States, 1992-2006*, 57 MORBIDITY & MORTALITY WKLY. REP. 1, 1 (2008), available at <http://www.cdc.gov/mmwr/PDF/ss/ss5710.pdf>.

every case is different, and many patients never develop the characteristic rash.<sup>26</sup> If the early stage of Lyme disease is left untreated or inadequately treated, it can progress and cause patients to suffer persistent health problems, such as crippling muscle and joint pain, disabling fatigue, arthritis, neurological disorders, and cardiac disorders,<sup>27</sup> leading to one of the biggest controversies surrounding Lyme disease—chronic Lyme disease.<sup>28</sup>

The actual number of Lyme-infected people is unknown for many reasons. First, many cases are never diagnosed because “laboratory tests have demonstrated serious limitations in reliability and accuracy.”<sup>29</sup> Moreover, many patients never know that an infected tick has bitten them because, unless engorged with blood, the deer tick is about “the size of a period at the end of [a] sentence.”<sup>30</sup> Second, the signs and symptoms of Lyme disease can be diverse, nonspecific, and often mimic those of many other diseases because the bacteria appear to activate the entire immune system, “resulting in a clinical presentation that looks exactly like lupus or rheumatoid arthritis (RA), and many other autoimmune diseases, including sarcoidosis, multiple sclerosis, Parkinson’s, ALS,<sup>31</sup> and lupus.”<sup>32</sup> Third, physicians have been reluctant to treat or diagnose patients suffering from Lyme disease because many physicians who have reported a large number of Lyme cases or who have treated patients with long-term antibiotics have been the “targets of State health department investigations.”<sup>33</sup> For example, in 2001, only eleven doctors in New York State were willing to use long-term antibiotics to treat patients with chronic Lyme disease. And of these eleven doctors, at least three were under investigation.<sup>34</sup>

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26. See ELIZABETH L. MALONEY, CHALLENGE TO THE RECOMMENDATION RESTRICTING THE USE OF CLINICAL JUDGMENT 2 (2009), available at [http://www.ilads.org/lyme\\_disease/written\\_testimony/4%20Maloney-Clinical%20Judgment.pdf](http://www.ilads.org/lyme_disease/written_testimony/4%20Maloney-Clinical%20Judgment.pdf).

27. 1993 Hearing, *supra* note 2, at 76, 82 (statement of Dr. Joseph McDade, Associate Director of Laboratory Science, National Center for Infectious Diseases); see also SINGLETON, *supra* note 7, at 4.

28. Chronic Lyme disease is also referred to as persistent Lyme disease. See Lorraine Johnson, *Lyme Disease: Two Standards of Care*, INT’L LYME & ASSOCIATED DISEASES SOC’Y (last updated Feb. 2005), [http://www.ilads.org/lyme\\_research/lyme\\_articles4.html](http://www.ilads.org/lyme_research/lyme_articles4.html).

29. 1993 Hearing, *supra* note 2, at 76, 82 (statement of Dr. Joseph McDade, Associate Director of Laboratory Science, National Center for Infectious Diseases); see also *id.* at 54, 56 (stating that many Lyme cases are never diagnosed); Johnson, *supra* note 28 (stating that Lyme disease can be difficult to diagnose and treat because it lacks “sufficiently sensitive and reliable biological markers”).

30. SINGLETON, *supra* note 7, at 7.

31. ALS is an acronym for amyotrophic lateral sclerosis, which is also referred to as Lou Gehrig’s disease. *About ALS*, ALS ASS’N, <http://www.alsa.org/als/what.cfm> (last visited Oct. 10, 2010).

32. BEAN, *supra* note 20; see also SINGLETON, *supra* note 7, at 8.

33. 1993 Hearing, *supra* note 2, at 54, 56.

34. Jane Gross, *In Lyme Disease Debate, Some Patients Feel Lost*, N.Y. TIMES, July 7, 2001,

Although the identity of the complainants was kept secret by law, many people, including Assemblyman Joel M. Miller of Poughkeepsie, were convinced that the complaints “c[a]me from the insurance industry.”<sup>35</sup> Fourth, many states no longer require doctors to report confirmed Lyme disease cases.<sup>36</sup> Consequently, the actual number of Lyme-infected people is unknown, but is it probably more prevalent than reported or thought.

### III. INFECTIOUS DISEASES SOCIETY OF AMERICA GUIDELINES

The Infectious Diseases Society of America (IDSA) is a nonprofit corporation<sup>37</sup> that “represents over 8,000 physicians, scientists, and other health care professionals who specialize in infectious disease.”<sup>38</sup> The IDSA panel members have always believed that Lyme disease can be easily treated, and cured, with short-term antibiotics.<sup>39</sup> And physicians who treat chronic Lyme patients have, for years, complained about members of the IDSA panel and their proposed treatment plans.<sup>40</sup> In 2000, the IDSA issued its first set of Lyme treatment guidelines,<sup>41</sup> and doctors who treat Lyme patients, the Lyme Disease Association (LDA), and two of LDA’s affiliates<sup>42</sup> spoke out against the IDSA guidelines, complaining that the guidelines were too restrictive to properly treat and diagnose chronic Lyme patients.<sup>43</sup> These complaints have had dire consequences. From 1997 to 2000, “about 50 physicians in

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<http://query.nytimes.com/gst/fullpage.html?res=9B01E4DB1238F934A35754C0A9679C8B63>.

35. *Id.* Recently, AG Blumenthal confirmed this suspicion, finding that many of the 2006 IDSA panel members had financial interests “in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies.” Press Release, Conn. Attorney Gen. Office, Attorney General’s Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guideline, Install Independent Arbiter (May 1, 2008), *available at* <http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284>.

36. *See* Press Release, Conn. Attorney Gen. Office, Attorney General Chastises DPH for Failing to Institute Electronic System for Reporting Lyme Disease Cases (June 2, 2006), *available at* <http://www.ct.gov/ag/cwp/view.asp?A=2341&Q=315406>; Marcus A. Cohen, *Connecticut Attorney General Investigates Restrictive Lyme Guidelines*, TOWNSEND LETTER FOR DOCTORS & PATIENTS, Apr. 1, 2007, at 7; SINGLETON, *supra* note 7, at 12 (“CDC states that only 5 to 10 percent of Lyme disease cases are actually reported each year . . .”).

37. *See* 2008 SETTLEMENT AGREEMENT, *supra* note 10, at 1.

38. *Id.*

39. *See* 1993 Hearing, *supra* note 2, at 54-55; *see also* 2006 IDSA GUIDELINES, *supra* note 3, at 1093, 1106, 1113, 1120-21.

40. *See, e.g.,* 1993 Hearing, *supra* note 2, at 54-55.

41. *See* Gary P. Wormser et al., *The Practice Guidelines for the Treatment of Lyme Disease*, 31 CLINICAL INFECTIOUS DISEASES S1 (Supp. 2000).

42. The two affiliates were Time for Lyme (TFL), a Connecticut group, and the California Lyme Disease Association (CLDA). Cohen, *supra* note 36, at 54.

43. *See id.*

New York, New Jersey, Connecticut, Michigan, Oregon, Rhode Island and Texas had been investigated, disciplined or had had their licenses removed”<sup>44</sup> because these physicians used long-term antibiotic therapy instead of the short course recommended by the IDSA guidelines.<sup>45</sup> One such physician, John Bleiseiss, eventually committed suicide after the New Jersey Board of Medical Examiners charged him with inappropriate diagnosis and treatment of Lyme disease.<sup>46</sup>

In 1993, Dr. Joseph Burrascano, Jr., an internationally known infectious disease specialist,<sup>47</sup> made the following statements at a hearing before the Senate Committee on Labor & Human Resources, which was the first Lyme hearing:

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

They behave this way for reasons of personal or professional gain and are involved in obvious conflicts of interest.

....

... [T]hese individuals who promote this so-called “post Lyme syndrome” as a form of arthritis depend on funding from arthritis groups and agencies to earn their livelihood. Some of them are known to have received large consulting fees from insurance companies to advise the companies to curtail coverage for any additional therapy beyond the arbitrary 30-day course.<sup>48</sup>

Two months after Dr. Burrascano’s testimony, New York’s Office of Professional Medical Conduct (OPMC) began an intensive seven-year investigation of Dr.

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44. Holcomb B. Noble, *Lyme Doctors Rally Behind A Colleague Under Inquiry*, N.Y. TIMES, Nov. 10, 2000, <http://query.nytimes.com/gst/fullpage.html?res=9C00E4DA1438F933A25752C1A9669C8B63&sec=&spo>; see also Press Release, Lyme Disease Ass’n, *supra* note 9; *supra* text accompanying notes 33-35.

45. Noble, *supra* note 44.

46. *TV Interview Notes*, W. CONN. LYME DISEASE SUPPORT WEBSITE, <http://lymesupport.net/tvinterviewnotes.htm> (last visited Feb. 5, 2010).

47. *1993 Hearing*, *supra* note 2, at 54.

48. *Id.* at 54-55.

Burrascano because he treated chronic Lyme patients with long-term antibiotics.<sup>49</sup> Eventually, the OPMC hearing panel cleared him of any wrongdoing relating to his treatment of Lyme patients.<sup>50</sup>

Because the IDSA's 2000 Guidelines were too restrictive and did not even address chronic Lyme disease, Lyme patients were unable to get properly diagnosed and treated.<sup>51</sup> Consequently, in mid 2006, the LDA and two of its affiliates<sup>52</sup> appealed to Connecticut Attorney General Richard Blumenthal (AG Blumenthal), explaining that Lyme patients were being denied insurance coverage and doctors who treated Lyme patients were being investigated and prosecuted because their treatments did not conform to the 2000 IDSA Guidelines.<sup>53</sup>

A few months after the LDA and its affiliates appealed to AG Blumenthal, the IDSA issued a new set of guidelines, the 2006 IDSA Guidelines,<sup>54</sup> which were even more restrictive.<sup>55</sup> Shortly thereafter, AG Blumenthal served the IDSA with a Civil Investigative Demand (CID) because he was concerned that the 2006 IDSA Guidelines violated antitrust laws by restraining "doctor and patient choices for treatment of the disease,"<sup>56</sup> and preventing physicians' clinical judgment.<sup>57</sup>

AG Blumenthal never filed an antitrust lawsuit against the IDSA because both parties entered into a settlement agreement on April 30, 2008.<sup>58</sup> The settlement

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49. See *GAO Investigation Called – Probe Targets DHHS Agencies*, LYME LIGHT NEWSL. (Lyme Disease Found., Tolland, Conn.), available at [http://www.lyme.org/lymelight/gao\\_investigation.html](http://www.lyme.org/lymelight/gao_investigation.html); Holcomb B. Noble, *Questioning Long-Term Lyme Cases*, N.Y. TIMES, May 23, 2000, <http://www.nytimes.com/2000/05/23/health/questioning-long-term-lyme-cases.html?pagewanted=all>.

50. Joseph Burrascano, BPMC #01-265 (N.Y. Dep't of Health Nov. 2, 2001) (determination and order), available at [http://w3.health.state.ny.us/opmc/factions.nsf/58220x%20%20%20%20a7f9ecaafab85256b180058c0327f57f08d61de929c85256a4a0047c6da/\\$FILE/ATTIDOPD/lc145623.pdf](http://w3.health.state.ny.us/opmc/factions.nsf/58220x%20%20%20%20a7f9ecaafab85256b180058c0327f57f08d61de929c85256a4a0047c6da/$FILE/ATTIDOPD/lc145623.pdf).

51. See Cohen, *supra* note 36, at 54.

52. *Id.* (stating that the two affiliates were Time for Life (TFL), a Connecticut non-profit research, education, and advocacy network and the California Lyme Disease Association (CLDA)).

53. *Id.*

54. See 2006 IDSA GUIDELINES, *supra* note 3.

55. Cohen, *supra* note 36, at 54.

56. Marcia Coyle, *Scrutiny Could Affect Lyme Guidelines; Connecticut AG is Investigating the Infectious Diseases Society of America's Rules Surrounding the Treatment and Diagnosis of the Disease*, FULTON COUNTY DAILY REP., Jan. 26, 2007, at 8, available at 2007 WLNR 28038425; see also BLACK'S LAW DICTIONARY 104 (8th ed. 2004) (providing that antitrust laws "protect trade and commerce from restraints, monopolies, price-fixing, and price discrimination"); Cohen, *supra* note 36, at 53; Smith, *supra* note 2.

57. See Press Release, Conn. Attorney Gen. Office, *supra* note 35.

58. See 2008 SETTLEMENT AGREEMENT, *supra* note 10, at 1, 5; see also Press Release, Infectious Diseases Soc'y of Am., *Agreement Ends Lyme Disease Investigation By Connecticut Attorney General* (May 1, 2008), available at <http://www.idsociety.org/PrintFriendly.aspx?id=11182>



required the IDSA to “implement an Action Plan”<sup>59</sup> and convene a new and independent panel<sup>60</sup> to assess whether its “2006 Lyme disease Guidelines should be revised or updated.”<sup>61</sup> In addition, the settlement agreement required the panel to “conduct an open scientific hearing . . . [to] hear scientific and medical presentations from interested parties”<sup>62</sup> and decide if “each recommendation in the IDSA’s 2006 Lyme disease guidelines . . . is supported by the scientific evidence.”<sup>63</sup> If seventy-five percent of the panel members do not vote to sustain a recommendation, the recommendation must be revised.<sup>64</sup> The agreement also stipulated that the 2006 IDSA Guidelines would remain in place unless the new panel determines that the guidelines should be modified or replaced.<sup>65</sup> On July 30, 2009, the new IDSA panel<sup>66</sup> held a one-day hearing in Washington, D.C., and heard testimony from eighteen speakers, including patients, physicians, and research scientists.<sup>67</sup> According to AG Blumenthal, the “hearing accomplished a key goal—compelling a fair and full discussion, free of conflicts of interest by panelists, so that all scientific facts and perspectives are considered before medical guidelines are established.”<sup>68</sup>

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(stating that the settlement agreement ended AG Blumenthal’s investigation of the IDSA “without the filing of a complaint or the entry by a court of factual or legal findings, without IDSA paying any fines or penalties, and without imposing on IDSA any restrictions on its right to promulgate guidelines for Lyme disease”).

59. 2008 SETTLEMENT AGREEMENT, *supra* note 10, at 1.

60. *Id.* at exhibit 1 at 1 (stating that the Panel must have eight to twelve members, “none of whom served on the 2006 Lyme disease guideline panel”).

61. *Id.* at 1.

62. Press Release, Conn. Attorney Gen. Office, *supra* note 35.

63. Press Release, Conn. Attorney Gen. Office, *supra* note 35; *see also* 2008 SETTLEMENT AGREEMENT, *supra* note 10, exhibit 1 at 5.

64. Press Release, Conn. Attorney Gen. Office, *supra* note 35; *see also* 2008 SETTLEMENT AGREEMENT, *supra* note 10, exhibit 1 at 5.

65. *See* Press Release, Infectious Diseases Soc’y of Am., *supra* note 58.

66. The new panelists consist of the following individuals: Carol J. Baker, MD, Chair Baylor College of Medicine; William A. Charini, MD; Paul H. Duray, MD (retired); Paul M. Lantos, MD, Duke University Medical Center; Gerald Medoff, MD, Washington University School of Medicine; Manuel H. Moro, DVM, MPH, PhD, National Institute of Health; David M. Mushatt, MD, MPH, TM, Tulane University School of Medicine; Jeffrey Parsonnet, MD, Dartmouth-Hitchcock Medical Center; Commander John W. Sanders, MD, U.S. Naval Medical Research Center Detachment. Press Release, Infectious Diseases Soc’y of Am., Statement from IDSA on Selection of Panelists for Review (Jan. 26, 2009), *available at* <http://www.idsociety.org/PrintFriendly.aspx?id=13310>.

67. *See* Press Release, Conn. Attorney Gen. Office, Attorney General Says Today’s IDSA Hearing Should Set Standard for Establishing Medical Guidelines (July 30, 2009), *available at* <http://ct.gov/AG/cwp/view.asp?A=3673&Q=444348>.

68. *Id.* (quoting Connecticut Attorney General Richard Blumenthal).

The new panel did not release its report until April 22, 2010.<sup>69</sup> According to the Review Panel, “the 2006 Lyme Guidelines were based on the highest-quality medical/scientific evidence available at the time and are supported by evidence that has been published in more recent years.”<sup>70</sup> In addition, the Review Panel found “that the authors of the 2006 Lyme Guidelines had [not] failed to consider or cite relevant data and references that would have altered the published recommendations.”<sup>71</sup> Therefore, based on the Review Panel’s findings, the 2006 IDSA Guidelines will remain in place, for now.<sup>72</sup> Although this is not the outcome that Lyme sufferers had hoped for, the Final Report’s conclusion did provide one statement that could be helpful to Lyme sufferers and the doctors who treat them:

- “Guidelines are not intended to be (and cannot be) rigid dicta, inflexible rules, or requirements of practice.”<sup>73</sup>

Because the Final Report stated that guidelines cannot be “inflexible rules or requirements of practice,” state medical boards should not be able to use the 2006 Guidelines to investigate doctors whose treatment plans do not conform to the Guidelines. As such, perhaps more doctors will be willing to use long-term antibiotics to treat patients suffering from chronic Lyme disease.

Although AG Blumenthal never filed an antitrust lawsuit against the IDSA, it is still worth examining if antitrust laws could be applied to the IDSA’s guideline development process. There are more than 2,300 clinical practice guidelines currently listed on the National Guideline Clearinghouse Website,<sup>74</sup> and if antitrust laws could be applied to the IDSA’s guideline development processes, some of these other medical societies could face antitrust investigations in the future.

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69. Review Panel, Infectious Diseases Soc’y Am., Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America (IDSA) 1 (2010) [hereinafter Final Report], available at [http://www.idsociety.org/uploadedFiles/IDSA/Resources/Lyme\\_Disease/Final\\_Report/IDSA-Lyme-Disease-Final-Report.pdf](http://www.idsociety.org/uploadedFiles/IDSA/Resources/Lyme_Disease/Final_Report/IDSA-Lyme-Disease-Final-Report.pdf).

70. *Id.* at 28.

71. *Id.*

72. On April 22, 2010, AG Blumenthal released the following statement:

My office is reviewing the IDSA’s reassessment of its 2006 Lyme disease guidelines mandated by its agreement with my office. The IDSA agreed to review its Lyme disease guidelines after my office uncovered credible evidence of undisclosed conflicts of interest and other significant flaws in the process that produced the guidelines. “We will carefully and comprehensively assess the final report and the review process leading to that report to determine whether the IDSA fulfilled the requirements of our settlement.”

Press Release, Conn. Attorney Gen. Office, Attorney General Statement on IDSA Guidelines Review Panel Report (Apr. 22, 2010), available at <http://www.ct.gov/ag/cwp/view.asp?A=2341&Q=459296>.

73. See FINAL REPORT, *supra* note 69, at 28.

74. See *supra* text accompanying note 11.

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IV. APPLYING ANTITRUST PRINCIPLES TO THE IDSA'S GUIDELINE-  
DEVELOPMENT PROCESS

A. *The Chronic Lyme Disease Controversy*

As stated earlier, the IDSA developed two sets of Lyme treatment guidelines—the 2000 and the 2006 IDSA Guidelines.<sup>75</sup> Before one can understand whether antitrust principles could be applied to the IDSA's Lyme guideline development process, it is important to understand the chronic Lyme disease controversy and why the 2006 IDSA Guidelines are problematic for Lyme sufferers and the doctors who treat them. Although both guidelines have had significant impacts on Lyme disease medical care and have been used to investigate and sanction doctors who fail to follow the IDSA-suggested treatment,<sup>76</sup> the remainder of this article will concentrate on the information contained in the 2006 IDSA Guidelines because it is the version that is currently endorsed by the IDSA.<sup>77</sup>

According to the National Guideline Clearinghouse, “[c]linical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>78</sup> The IDSA claims that the main objective of its 2006 IDSA Guidelines is “[t]o provide clinicians and other health care practitioners with recommendations for the management of patients in the United States with suspected or established Lyme disease.”<sup>79</sup> Because medical guidelines are intended to assist practitioners and patients about appropriate health care, they should be based on all available scientific evidence. But when the IDSA developed its Lyme treatment Guidelines, it “refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease.”<sup>80</sup>

The 2006 IDSA Guidelines are also problematic because they actually “promote the idea that Lyme is a simple, rare illness that is easy to avoid, difficult to acquire,

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75. See *supra* notes 41, 54 and accompanying text.

76. Press Release, Time for Lyme, Inc., Lyme Patients Watching IDSA Meeting with Optimism and Caution (July 30, 2009), available at <http://www.timeforlyme.org/PDF/57%20IDSA%20july%2030%20meeting%20v5%20and%20final.doc> (“The [2006] IDSA guidelines are relied upon . . . to . . . form the basis for unprofessional conduct actions, which place physicians, who continue to treat chronic Lyme disease, at risk of losing their license.”); see also Cohen, *supra* note 36, at 54; *supra* notes 44-49 and accompanying text.

77. See Press Release, Infectious Diseases Soc’y of Am., *supra* note 66.

78. *Inclusion Criteria*, NATIONAL GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/about/inclusion-criteria.aspx> (last visited Sept. 17, 2010).

79. *Guideline Summary*, NATIONAL GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/content.aspx?id=9537> (last visited Oct. 6, 2010).

80. Press Release, Conn. Attorney Gen. Office, *supra* note 35.

simple to diagnose, and easily treated and cured with 30 days of antibiotics.”<sup>81</sup> This is simply not true. Lyme disease “often goes undiagnosed for months, years, or even forever in some patients, and [it] can render the patient chronically ill and even totally disabled.”<sup>82</sup> In addition, Lyme patients are often misdiagnosed because Lyme disease can manifest itself in many different ways.<sup>83</sup> Lyme patients have been misdiagnosed with numerous conditions, including chronic fatigue syndrome, fibromyalgia, amyotrophic lateral sclerosis,<sup>84</sup> multiple sclerosis, heart disease, and numerous neurological and psychological conditions,<sup>85</sup> such as autism, strokes, and bipolar disorder.<sup>86</sup>

The IDSA and its 2006 Guidelines are emphatic that antibiotics should not be used for more than a month.<sup>87</sup> But even when Lyme patients receive the IDSA-recommended treatment, many patients do not respond to this treatment and continue to have symptoms for years,<sup>88</sup> suggesting that a chronic form of the disease exists.<sup>89</sup>

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81. 1993 Hearing, *supra* note 2, at 54-55; *see also* 2006 IDSA GUIDELINES, *supra* note 3, at 1093, 1106, 1113, 1120-21.

82. 1993 Hearing, *supra* note 2, at 54-55.

83. SINGLETON, *supra* note 7, at 8.

84. *See supra* notes 31-32 and accompanying text.

85. SINGLETON, *supra* note 7, at 8.

86. *See* BEAN, *supra* note 20, at 119.

87. *See* 2006 IDSA GUIDELINES, *supra* note 3, at 1106 tbl.3 (showing maximum dosage recommendations of twenty-eight days); *id.* at 1105 (stating that long-term antibiotic therapy is “not recommended for treatment of patients with any manifestation of Lyme disease”).

88. *See* 1993 Hearing, *supra* note 2, at 57 (explaining that as Lyme disease progresses, “the bacterium spreads to areas of the body that render this organism resistant to being killed by the immune system and by antibiotics . . . . The Lyme bacterium also has a very complex life cycle that renders is [sic] resistance to simple treatment strategies”); *In Re Lyme Disease*, *supra* note 8, at 17 (statement of Joshua Athenios, Lyme Disease Patient); *id.* at 18-26 (statement of Caroline Baisley, Lyme Disease Patient); *id.* at 27-34 (statement of Mary Anne Foley, Family Member of Lyme Disease Patients); *id.* at 34-40, 47-49 (statement of Jude Anne Jones, Lyme Disease Patient); *id.* at 40-43 (statement of Donna Lake, Lyme Disease Patient); *id.* at 55-59 (statement of Elise Brady-Moe, Lyme Disease Patient); *id.* at 59-67 (statement of Jennifer Reid, Lyme Disease Patient); *id.* at 68-73 (statement of Katherine Reid, Lyme Disease Patient); *id.* at 73-82 (statement of Tammy Szczepanski, Lyme Disease Patient); *id.* at 82-90 (statement of Christopher Montes, Lyme Disease Patient); BEAN, *supra* note 20, at 214-22; KENNETH B. LIEGNER, CHRONIC PERSISTENT INFECTION IN LYME NEUROBORRELIOSIS DESPITE PRIOR INTENSIVE ANTIBIOTIC TREATMENT—CHALLENGE TO DURATION OF TREATMENT FOR LATE NEUROLOGIC LYME DISEASE AND POST-LYME SYNDROMES 5 (2009), available at [http://www.ilads.org/lyme\\_disease/written\\_testimony/15%20Liegner-Chronic%20Persistent%20Infection.pdf](http://www.ilads.org/lyme_disease/written_testimony/15%20Liegner-Chronic%20Persistent%20Infection.pdf) (stating that there are “extensive studies in the worldwide peer-reviewed literature in both humans and animals which corroborate persistence of borreliar infection despite prior antibiotic treatment”).

89. *See supra* text accompanying notes 79-83, 88; *infra* text accompanying notes 90-94, 98, 106.

This, in turn, has led to the most controversial and problematic issue with the 2006 IDSA Guidelines—chronic Lyme disease.

Even though there are “more than 19,000 scientific studies on tick-borne diseases” that suggest chronic Lyme disease exists,<sup>90</sup> doctors and researchers who follow the IDSA guidelines dismiss the notion that a Lyme infection can persist after a thirty-day dose of oral antibiotics and condemn the use of long-term antibiotics,<sup>91</sup> claiming they are useless and potentially harmful.<sup>92</sup> But the ILADS has a divergent view: persistent and recurring symptoms demonstrate a continuing and chronic infection,<sup>93</sup> which does not always respond to the IDSA’s limited duration of two to four weeks of antibiotic treatment.<sup>94</sup> And despite all of the evidence concerning chronic Lyme disease, the 2006 IDSA Guidelines actually dismiss chronic Lyme disease as nothing more than “the aches and pains of daily living.”<sup>95</sup> The IDSA’s dismissal of the existence of chronic Lyme is problematic because the 2006 IDSA Guidelines have been “widely cited [by many doctors and insurance companies] for conclusions that chronic Lyme disease is nonexistent.”<sup>96</sup>

The opposing view, which is held by the ILADS and the doctors who treat chronic Lyme patients, is that the IDSA’s 30-day treatment course is “arbitrary.”<sup>97</sup> This opposing view is supported by a substantial body of scientific evidence that demonstrates that many chronic Lyme patients have obtained relief from their pain and suffering, and some have been cured by the use of long-term antibiotics, including intravenous antibiotics.<sup>98</sup> The doctors who treat chronic Lyme patients

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90. See Press Release, Pam Kahn, Int’l Lyme & Associated Diseases Soc’y, ILADS Members Question Motives of New England Journal of Medicine Article on Lyme Disease Treatment (Oct. 2, 2007), available at [http://www.ilads.org/news/lyme\\_press\\_releases/11.html](http://www.ilads.org/news/lyme_press_releases/11.html); STEVEN E. PHILLIPS, ACTIVE INFECTION: CLINICAL DEFINITIONS AND EVIDENCE OF PERSISTENCE IN LYME DISEASE 3, 67 (2009), available at [http://www.ilads.org/lyme\\_disease/written\\_testimony/7Phillips\\_version2.pdf](http://www.ilads.org/lyme_disease/written_testimony/7Phillips_version2.pdf).

91. See 2006 IDSA GUIDELINES, *supra* note 3, at 1105.

92. *Id.* at 1094; see also Letter from Donald M. Poretz, President, Infectious Diseases Soc’y of Am., to Edward Kennedy, U.S. Senate (Mar. 21, 2008), available at <http://www.idsociety.org/WorkArea/DownloadAsset.aspx?id=10818> (opposing S. 1708).

93. See 1993 Hearing, *supra* note 2, at 55; *In Re Lyme Disease*, *supra* note 8, at 118-20 (statement of Dr. Steven Phillips, Physician); Johnson, *supra* note 28.

94. 1993 Hearing, *supra* note 2, at 54-55; see also *id.* (stating that Lyme disease “can render the patient chronically ill and even totally disabled despite what [the Guidelines refer] to as ‘adequate’ therapy”); BEAN, *supra* note 20, at 132; Johnson, *supra* note 28 (claiming that chronic Lyme only responds to long-term antibiotics); LIEGNER, *supra* note 88.

95. 2006 IDSA GUIDELINES, *supra* note 3, at 1115.

96. Press Release, Conn. Attorney Gen. Office, *supra* note 35.

97. THE ILADS WORKING GRP., EVIDENCE-BASED GUIDELINES FOR THE MANAGEMENT OF LYME DISEASE S5 (2004), available at [http://www.ilads.org/files/ILADS\\_Guidelines.pdf](http://www.ilads.org/files/ILADS_Guidelines.pdf)

98. See *In Re Lyme Disease*, *supra* note 8, at 182 (statement of Dr. Stephen Sinatra, Cardiologist) (stating that oral antibiotics only work when the *Bb* bacteria is inside plasma; IV

have further condemned standardized guidelines, such as the 2006 IDSA Guidelines, arguing that these guidelines prevent them from using their own clinical judgment in diagnosing and treating Lyme disease.<sup>99</sup>

Besides persistent health problems, such as crippling muscle and joint pain, disabling fatigue, arthritis, neurological disorders, and cardiac disorders,<sup>100</sup> when the Lyme bacteria invade the brain, many chronic Lyme patients also suffer from depression, thoughts of suicide, “brain fog,”<sup>101</sup> “headache, . . . weakness, memory or concentration difficulties, . . . clumsiness, bladder or bowel dysfunction, . . . [and] visual loss.”<sup>102</sup> Because many antibiotics do not effectively penetrate the blood-brain barrier, these antibiotics are not transported to the brain.<sup>103</sup> Consequently, these patients must be treated with intravenous antibiotics because when the antibiotics are “delivered directly into the blood, they bypass the digestive system where some of the medication is lost.”<sup>104</sup> And even though chronic Lyme sufferers often respond to intravenous antibiotic therapy,<sup>105</sup> the 2006 IDSA Guidelines do not recommend intravenous antibiotic treatment for any Lyme patients.<sup>106</sup>

*B. Is the Development of Medical Guidelines Analogous to Commercial Standard-Setting?*

“[A]ntitrust laws . . . are designed to preserve competition by prohibiting monopolistic practices and agreements that unreasonably restrict competition.”<sup>107</sup> As stated earlier, AG Blumenthal served the IDSA with a CID because he was concerned that the 2006 IDSA Guideline development process violated antitrust laws.<sup>108</sup> AG

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antibiotics, in particular, Rocephin, are needed when the *Bb* bacteria enter the cerebral spinal fluid); BEAN, *supra* note 20, at 182-84, 214-22.

99. See, e.g., Johnson, *supra* note 28 (“[T]he legal standard of care for treating a condition is determined by the consensus of physicians who actually treat patients, not by treatment guidelines.”) (citing Brian Hurwitz, *Clinical Guidelines and the Law*, 311 BRIT. MED. J. 1517, 1517-18 (1995)); see also THE ILADS WORKING GRP., *supra* note 97, at S9.

100. See THE ILADS WORKING GRP., *supra* note 97, at S5.

101. See BEAN, *supra* note 20, at 119.

102. ELIZABETH L. MALONEY, CHALLENGE TO THE RECOMMENDATION LIMITING THE DURATION OF TREATMENT FOR LATE NEUROLOGIC LYME DISEASE 3 (2009), available at [http://www.ilads.org/lyme\\_disease/written\\_testimony/10%20Maloney-Late%20Neurologic%20Lyme.pdf?action=ViewDetails&ItemID=21](http://www.ilads.org/lyme_disease/written_testimony/10%20Maloney-Late%20Neurologic%20Lyme.pdf?action=ViewDetails&ItemID=21); see also BEAN, *supra* note 20, at 119.

103. BEAN, *supra* note 20, at 131.

104. *Id.*

105. See *id.*; 1993 Hearing, *supra* note 2, at 56.

106. 2006 IDSA GUIDELINES, *supra* note 3, at 1110-13.

107. ABA SECTION OF ANTITRUST LAW, ANTITRUST AND ASSOCIATIONS HANDBOOK 1 (2009).

108. See *supra* text accompanying notes 56-57.

Blumenthal's antitrust investigation "uncovered serious flaws"<sup>109</sup> in the IDSA's Lyme Guideline development process.

Antitrust laws have been applied to numerous commercial standard-setting cases;<sup>110</sup> therefore if the development of medical guidelines can qualify as a standard-setting process, then antitrust laws could apply if the guideline process results in exclusionary conduct.<sup>111</sup> According to Richard Wolfram, an antitrust attorney, "[t]he development of treatment guidelines is analogous to standard-setting."<sup>112</sup>

Associations that set commercial standards are known as standard-setting organizations (SSO) or standard-development organizations (SDO).<sup>113</sup> Standard-setting is important because of its pro-competitive benefits, such as quality and safety standards and the ability of products to interface with other products.<sup>114</sup> For example, without standards, consumers could not be sure that the light bulb they purchased would fit into the lamp that they had at home.<sup>115</sup>

But "a standard-setting organization . . . can be rife with opportunities for anticompetitive activity"<sup>116</sup> because the standard-setting process can exclude products or businesses that fail to meet the standard.<sup>117</sup> When analyzing an SSO's standards, fact finders must evaluate "whether the standard causes a severe economic detriment to excluded or nonqualifying firms . . . whether competitors of the injured firm participated in the standards development process,"<sup>118</sup> and "whether the

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109. Press Release, Conn. Attorney Gen. Office, *supra* note 35; *see also* Press Release, Lyme Disease Ass'n, *supra* note 9.

110. *See, e.g., Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 (1988); *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447 (1986); *Am. Soc'y of Mech. Eng'rs, Inc. v. Hydrolevel Corp.*, 456 U.S. 556 (1982); *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656 (per curiam) (1961); *Rambus Inc. v. FTC*, 522 F.3d 456 (D.C. Cir. 2008); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007).

111. *But see* Coyle, *supra* note 56 (quoting the IDSA's attorney, Alvin Dunn, who said: "Our view is this is not a matter for antitrust laws or courts generally, but this is a medical question and one that doctors and scientists should be addressing if there is an issue as to whether the guidelines are proper").

112. *Id.* (quoting Richard Wolfram, an antitrust attorney); *see also id.* (quoting Attorney Douglas A. Hastings, stating that he "could see how the guidelines could be viewed as standard-setting").

113. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 141.

114. *See Allied Tube*, 486 U.S. at 500-01; *Golden Bridge Tech., Inc. v. Motorola, Inc.*, 547 F.3d 266, 273 (5th Cir. 2008); LAWRENCE A. SULLIVAN & WARREN S. GRIMES, *THE LAW OF ANTITRUST: AN INTEGRATED HANDBOOK* 281 (2009); ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 141.

115. SULLIVAN & GRIMES, *supra* note 114, at 281.

116. *Am. Soc'y of Mech. Eng'rs, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 571 (1982).

117. *See* SULLIVAN & GRIMES, *supra* note 114, at 282; ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 142.

118. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 145 (footnote omitted).

standards are voluntary.”<sup>119</sup> Standard-setting faces intense antitrust scrutiny when the standards are not voluntary.<sup>120</sup>

### C. *The Sherman Act*

“The antitrust concerns implicated by private standard setting fall under two general headings: anticompetitive effects stemming from concerted action (arising primarily under Section 1 of the Sherman Act); and anticompetitive unilateral conduct (raising issues under Section 2 of the Sherman Act).”<sup>121</sup> Courts generally apply a rule of reason analysis to most standard-setting cases involving antitrust issues.<sup>122</sup> “Under this rule, the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”<sup>123</sup> Section 1 of the Sherman Act applies to concerted conduct by two or more entities and prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade of commerce among the several States . . . .”<sup>124</sup> Although Section 1 of the Sherman Act prohibits *every* contract or conspiracy “in restraint of trade” of commerce, the United States Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.”<sup>125</sup> But “[w]hether an agreement is ‘unreasonable’ from an antitrust standpoint is a complicated matter.”<sup>126</sup>

Section 2 of the Sherman Act supplements Section 1 and specifically prohibits monopolizing, or attempting to monopolize, any part of interstate or foreign commerce.<sup>127</sup> A legal entity can monopolize interstate or foreign commerce by excluding competitors from a market.<sup>128</sup>

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119. *Id.* at 146.

120. *Id.*

121. *Id.* at 142.

122. See, e.g., *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006); *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988); see also ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 143; SULLIVAN & GRIMES, *supra* note 114, at 220-21.

123. See *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

124. 15 U.S.C. § 1 (2006).

125. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); see also *Texaco Inc.*, 547 U.S. at 5.

126. *DM Research, Inc. v. Coll. of Am. Pathologists*, 170 F.3d 53, 56 (1st Cir. 1999).

127. 15 U.S.C. § 2 (2006); see also *Reading Int'l, Inc. v. Oaktree Capital Mgmt. LLC*, 317 F. Supp. 2d 301, 323 (S.D. N.Y. 2003).

128. *U.S. v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) (citing *U.S. v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956)).



## 1. Could the IDSA Be Subject to Antitrust Laws?

Before determining if antitrust laws could be applied the IDSA guideline development process, it must first be determined if antitrust laws could be applied to a professional association like the IDSA. Professional associations can be subject to antitrust laws if their conduct is sufficiently commercial. In *Jung v. Association of American Medical Colleges*,<sup>129</sup> medical-school graduates brought antitrust suits against various organizations, including the Accreditation Council for Graduate Medical Education (ACGME), alleging “that the ACGME aided in and enforced the conspiracy to depress the compensation of resident physicians by promulgating and enforcing accreditation standards.”<sup>130</sup> As part of its accreditation standards, the ACGME required the medical-school graduates to enter into a contract with the National Resident Matching Program (the Matching Program) before the graduate students could be placed in their medical residency.<sup>131</sup> The medical-school graduates further “alleged that the ACGME standards directly limit competition in the hiring of medical residents by, *inter alia*, requiring prospective residents to contractually commit to any offers they receive through the Match Program and by providing for the ACGME’s policing of institutional defendants’ compensation levels.”<sup>132</sup>

The ACGME moved to dismiss the claim, stating “that the creation and enforcement of accreditation standards for resident medical programs is non-commercial conduct that is beyond the reach of antitrust laws.”<sup>133</sup> Relying on *United States v. Brown University*,<sup>134</sup> the *Jung* court denied the motion, stating that antitrust “immunity . . . is narrowly circumscribed [and] . . . does not extend to commercial transactions with a ‘public service aspect.’”<sup>135</sup>

According to *Jung*, if the development of the IDSA guidelines involves commercial conduct with a “public service aspect,” it is not immune from antitrust regulations.<sup>136</sup> Unfortunately, the *Jung* court did not provide much guidance on how to determine if conduct is commercial, stating only that “[c]ourts classify a transaction as commercial or noncommercial based on the nature of the conduct in light of the totality of surrounding circumstances.”<sup>137</sup>

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129. 300 F. Supp. 2d 119 (D.C. Cir. 2004).

130. *Id.* at 170.

131. *Id.* at 125.

132. *Id.* at 171.

133. *Id.* at 169.

134. 5 F.3d 658 (3d Cir. 1993).

135. *Jung*, 300 F. Supp. 2d at 171 (quoting *Brown Univ.*, 5 F.3d at 666); *see also* Goldfarb v. Virginia State Bar, 421 U.S. 773, 787 (1975) (holding that “learned professions” are not excluded from antitrust regulation).

136. *Id.* (citing *Brown Univ.*, 5 F.3d at 666).

137. *Id.* (quoting *Brown Univ.*, 5 F.3d at 666); *see also* Allied Tube & Conduit Corp. v. Indian

Although the courts have not developed a bright-line test to determine if conduct is sufficiently commercial, the United States Supreme Court found that legal services, such as title searches, are sufficiently commercial for antitrust purposes. In *Goldfarb v. Virginia State Bar*,<sup>138</sup> after Virginia homebuyers contracted to purchase a home, they needed to obtain a title search. At the time of the lawsuit, members of the Virginia state bar were the only individuals who could legally perform a title examination.<sup>139</sup> The homebuyers were unable to find an attorney who would perform the title search for less than the amount required under the local county bar association's minimum-fee schedule, so the homeowners sued the state and county bar, alleging that the minimum-fee schedule for title insurance violated Section 1 of the Sherman Act.<sup>140</sup>

The county bar argued that its title search services were "local in nature,"<sup>141</sup> and "that any effect on interstate commerce . . . was incidental and remote,"<sup>142</sup> and, therefore, could "never substantially affect interstate commerce."<sup>143</sup> The United States Supreme Court disagreed, finding that "interstate commerce [was] sufficiently affected"<sup>144</sup> because a large portion of the loan money came from out of state,<sup>145</sup> and that title searches are inseparable "from the interstate aspects of real estate transactions."<sup>146</sup>

If an antitrust lawsuit were filed against the IDSA, a court would probably find that the IDSA guideline development process is not immune from antitrust regulation and is sufficiently commercial for Sherman Act purposes. First, the IDSA guideline development process should not be immune from antitrust regulation because it is sufficiently similar to the creation and enforcement of the accreditation standards for medical programs in *Jung*. Second, like title searches, the treatment of Lyme disease affects interstate commerce: a large portion of money spent in treating chronic Lyme patients comes from all over the United States because many patients travel great distances to locate a doctor who is willing to treat the disease.<sup>147</sup>

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Head, Inc., 486 U.S. 492, 500 (1988) ("[P]rivate standard-setting associations have traditionally been objects of antitrust scrutiny."); *Ass'n for Intercollegiate Athletics for Women v. Nat'l Collegiate Athletic Ass'n*, 735 F.2d 577, 584-85 (D.C. Cir. 1984).

138. 421 U.S. 773 (1975).

139. *Id.* at 775.

140. *Id.* at 775-76.

141. *Id.* at 783.

142. *Id.*

143. *Id.*

144. *Id.* at 785.

145. *Id.* at 783.

146. *Id.* at 785.

147. See *infra* notes 215-217 and accompanying text.

Third, according to AG Blumenthal's investigation, "several of the most powerful IDSA panelists"<sup>148</sup> had "undisclosed financial interests"<sup>149</sup> "in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies."<sup>150</sup> And the panel members' economic interests in the Lyme diagnostic tests are directly benefited by the 2006 IDSA Guidelines' requirement of a positive lab test to diagnose Lyme disease.<sup>151</sup>

According to the 2006 IDSA Guidelines, a physician can diagnose Lyme disease in two ways: (1) the patient must exhibit an EM rash<sup>152</sup> or (2) the patient must test positive with a two-tier serology test.<sup>153</sup> As stated earlier, many patients never develop the EM rash,<sup>154</sup> and the Guidelines' requirement of a positive lab test is problematic because the two-tier serology test<sup>155</sup> "fails to detect up to 90% of [Lyme] cases."<sup>156</sup> As a result, most Lyme sufferers are left undiagnosed and untreated,<sup>157</sup> and the panel members with economic interests in Lyme diagnostic tests are left richer.

As stated earlier, "[t]he development of treatment guidelines is analogous to standard-setting."<sup>158</sup> Consequently, the IDSA's Lyme treatment guidelines are similar to the ACGME's accreditation standards in *Jung*, and both were unfairly enforced and effectively mandatory. To avoid potential antitrust issues, standards should be

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148. Press Release, Conn. Attorney Gen. Office, *supra* note 35.

149. *Id.*

150. *Id.*

151. *See id.*

152. *See infra* notes 206-207 and accompanying text.

153. *See* 2006 IDSA GUIDELINES, *supra* note 3, at 1101, 1110-11. The patient must have a positive ELISA test, and if the ELISA test is positive, the patient must also test positive for a Western Blot test. *Id.* at 1101, 1110; *see also* Marcus A. Cohen, *Crucial Differences Between IDSA and ILADS Guidelines*, LYME PROJECT (May 8, 2007, 2:25 PM), [http://www.lymeproject.com/lymenews/lyme\\_disease\\_interview/15.html](http://www.lymeproject.com/lymenews/lyme_disease_interview/15.html); *see also, e.g.*, Phillips, *supra* note 90, at 3, 26, 67.

154. *See supra* note 26 and accompanying text.

155. *See* 2006 IDSA GUIDELINES, *supra* note 3, at 1101, 1110-11; *see also* Cohen, *supra* note 153; Phillips, *supra* note 90, at 3, 67.

156. THE ILADS WORKING GRP., *supra* note 97, at S7; *see also* Cohen, *supra* note 36, at 54 (stating that the two-step test is only positive in approximately fifty percent of Lyme patients). *But see* 1993 Hearing, *supra* note 2, at 66 (statement of Dr. Allen Steere, Professor, New England Medical Center) ("[T]his [serologic] test has been positive in almost all patients after the first several weeks of infection."). Allen Steere was a member of the 2006 panel. 2006 IDSA GUIDELINES, *supra* note 3, at 1089.

157. THE ILADS WORKING GRP., *supra* note 97, at S7; *see also* BEAN, *supra* note 20, at 133 ("[R]estrictive guidelines and unreliable tests obstruct the diagnosis of Lyme disease."); 2006 IDSA GUIDELINES, *supra* note 3, at 1101 (stating that despite the inaccuracies of the two-tier diagnostic test, if the blood test is negative, then the patient is unlikely to have Lyme disease); Johnson, *supra* note 28.

158. Coyle, *supra* note 56 (quoting Richard Wolfram, an antitrust attorney).

voluntary.<sup>159</sup> And if an SSO enforces its standards merely to restrict competition, the SSO will violate Section 1 of the Sherman Act.<sup>160</sup>

Although the 2006 IDSA Guidelines are not “mandatory,” they have been regarded as “mandatory” within the medical community<sup>161</sup> for many reasons. First, the IDSA has more than 8,000 members and is extremely influential in the medical world.<sup>162</sup> Second, the 2006 IDSA Guidelines are more readily available than the ILADS Guidelines.<sup>163</sup> Consequently, most physicians use the 2006 IDSA Guidelines to determine how Lyme disease should be treated. Because the Guidelines are often the only source of information available to doctors, they “strongly influence physician treatment decisions.”<sup>164</sup> Third, the “IDSA is widely recognized as the pre-eminent authority on the treatment of infectious diseases (ID) in the United States.”<sup>165</sup>

As such, the 2006 Guidelines “have the effect of becoming the standard of care in the medical community.”<sup>166</sup> Moreover, state medical boards have used the IDSA Guidelines as the appropriate standard of care when investigating and sanctioning doctors who do not conform to the Guidelines.<sup>167</sup> The enforcement of the IDSA Guidelines has further reduced the Lyme treatment market because many doctors are reluctant to diagnose or treat chronic Lyme patients because they do not want to become the subject of an investigation by their state board of medical examiners.<sup>168</sup>

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159. See *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 n.6 (1988) (stating that when members of a private standard-setting association engage in “[c]oncerted efforts to enforce (rather than just agree upon) private product standards [they will] face more rigorous antitrust scrutiny”); see also ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 147 (stating that “[p]articipation in a standards program should be voluntary”).

160. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 142-43.

161. *Medical Antitrust Actions—Does “Might Make Right”?*, CAL. LYME DISEASE ASS’N, (Jan. 30, 2009), <http://www.lymedisease.org/news/lymepolicywonk/35.html>; see also SINGLETON, *supra* note 7, at 18 (stating that the 2006 “guidelines have received general acceptance in the medical community”).

162. 2008 SETTLEMENT AGREEMENT, *supra* note 10, at 1; see also Letter from Donald M. Poretz, *supra* note 92.

163. For years, the Centers for Disease Control and Prevention (CDC) has provided a link to the 2006 Guidelines on its web page, but it has not provided a link to the ILADS Guidelines. See Redirect to the IDSA 2006 Guidelines, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/ncidod/dvbid/lyme/includes/IDSAGuidelines.html> (last visited Sept. 11, 2010); *supra* text accompanying note 11.

164. Press Release, Conn. Attorney Gen. Office, *supra* note 35; see also Press Release, Conn. Attorney Gen. Office, *supra* note 35 (stating that the 2006 IDSA “guidelines have profoundly powerful consequences for countless lives, driving doctors’ treatment decisions and insurance company coverage determinations”).

165. Letter from Donald M. Poretz, *supra* note 92; see also Coyle, *supra* note 56.

166. Coyle, *supra* note 56.

167. See *supra* text accompanying note 76.

168. See *supra* text accompanying note 76.

In fact, the restraint on the Lyme treatment market is so great that members of Congress believe that the 2006 IDSA Guidelines “have ‘the potential to effectively shut down’ all treatment of chronic Lyme disease.”<sup>169</sup>

As demonstrated above, the IDSA’s 2006 Guidelines are effectively mandatory because the IDSA enforces its 2006 IDSA Guidelines by (1) denying the existence of chronic Lyme disease, (2) condemning the use of long-term antibiotics, (3) allowing doctors who treat chronic Lyme patients to be sanctioned by medical boards, and (4) allowing insurance companies to cite the guidelines as a basis to deny coverage of chronic Lyme treatments.<sup>170</sup> Further, the facts illustrate the power of the IDSA and its panel members to restrain competition; therefore, if an antitrust lawsuit were filed against the IDSA, a court could find that the 2006 IDSA Guidelines have significantly reduced the Lyme treatment market. Similarly, a court could find that both the IDSA’s conduct in developing its Lyme Guidelines and the treatment of Lyme disease is sufficiently commercial for Sherman Act purposes.

## 2. Applying a Rule of Reason Analysis to the IDSA’s Guideline Development Process

### (a) Did the IDSA Panel Members Engage in a Conspiracy that Restrained Trade in the Relevant Market?

Under Section 1 of the Sherman Act, AG Blumenthal would have had to establish that “(1) the [IDSA, through its Lyme panel members,] engaged in a conspiracy; (2) that restrained trade; (3) in the relevant market.”<sup>171</sup> It appears that some of the IDSA panel members did use the Lyme Guideline development process to consciously agree to exclude competing doctors (doctors who use their own clinical discretion to diagnose Lyme disease and doctors who do not follow the IDSA’s 30-day recommended treatment program) from treating Lyme patients.<sup>172</sup> And this exclusion should have antitrust implications because some panel members had an economic interest in the outcome of the development process.

To establish a conspiracy, AG Blumenthal would have had to establish that the IDSA panel members “consciously committed to a common agreement of an unreasonable restraint on trade”<sup>173</sup> in the relevant market. Because courts allow

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169. Coyle, *supra* note 56 at 8.

170. *See supra* notes 35, 66, 92-93, 96-97.

171. *Golden Bridge Tech., Inc. v. Motorola, Inc.*, 547 F.3d 266, 271 (5th Cir. 2008); *see also* *Oltz v. St. Peter’s Cmty. Hosp.*, 861 F.2d 1440, 1445 (9th Cir. 1988); *Heary Bros. Lightning Prot. Co. v. Lightning Prot. Inst.*, 287 F. Supp. 2d 1038, 1047 (D. Ariz. 2003), *aff’d in part, rev’d in part*, 262 Fed. App’x 815 (9th Cir. 2008).

172. *See* discussion *infra* Part C.2.b.

173. *GTE New Media Servs. Inc. v. Ameritech Corp.*, 21 F. Supp. 2d 27, 42 (D.C. Cir. 1998)

plaintiffs to demonstrate an agreement by showing that the defendants had a tacit understanding,<sup>174</sup> courts also “allow[] ‘inferences [to be] fairly drawn from the behavior of the alleged conspirators’ to prove conspiracy.”<sup>175</sup>

When analyzing whether the conduct imposes an unreasonable restraint on competition, “the finder of fact must . . . tak[e] into account a variety of facts, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”<sup>176</sup> As part of this analysis, the fact finder balances the SSO’s “anticompetitive effect against the procompetitive justifications for the conduct.”<sup>177</sup> “Proving injury to competition in a rule of reason case almost uniformly requires a claimant to prove the relevant market and to show the effects upon competition within that market.”<sup>178</sup> More specifically, “section one claimants must plead and prove a reduction of competition in the market in general and not mere injury to their own positions as competitors in the market.”<sup>179</sup>

Under a rule of reason analysis, courts also analyze whether the standard-setting activity includes “safeguards against improper influence or bias.”<sup>180</sup> But the courts have not specified a particular procedure to follow when determining due process under a rule of reason analysis.<sup>181</sup> Instead, the courts use a “flexible concept, [and allow] the specific procedures or safeguards [to] vary with the nature and context of the particular standard setting activity.”<sup>182</sup> No matter what procedure or test is used, the “[s]tandards must be objectively related to relevant performance characteristics and administered objectively and fairly.”<sup>183</sup>

According to the United States Supreme Court, “[t]here is no doubt that the members of [private standard-setting] associations often have economic incentives to restrain competition and that the product standards set by such associations have a

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(citing *Monsanto v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984)).

174. *Jung v. Ass’n of Am. Med. Colls.*, 300 F. Supp. 2d 119, 158 (D.C. Cir. 2004) (quoting *FTC v. Mylan Labs Inc.*, 62 F. Supp. 2d 25, 55 (D.C. Cir. 1999)).

175. *Id.* (quoting *Binder v. District of Columbia*, 1991 U.S. Dist. LEXIS 7094, at \*9).

176. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *see also* *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

177. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 143; *see also* *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500-01 (1988); *Heary Bros. Lightning Prot. Co. v. Lightning Prot. Inst.*, 287 F. Supp. 2d 1038, 1047 (D. Ariz. 2003), *aff’d in part, rev’d in part*, 262 Fed. App’x 815 (9th Cir. 2008); SULLIVAN & GRIMES, *supra* note 114, at 233.

178. *Oltz v. St. Peter’s Cmty. Hosp.*, 861 F.2d 1440, 1446 (9th Cir. 1988).

179. *Les Shockley Racing, Inc. v. Nat’l Hot Rod Ass’n*, 884 F.2d 504, 508 (9th Cir. 1989).

180. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 146.

181. *Id.* at 147.

182. *Id.*

183. SULLIVAN & GRIMES, *supra* note 114, at 312.

serious potential for anticompetitive harm.”<sup>184</sup> According to AG Blumenthal, “[s]kewing medical guidelines to benefit health insurers and HMOs, drug makers and self-interested panelists is a serious and growing problem.”<sup>185</sup> For example, “[p]ress reports abound of medical companies using financial incentives—speaking and consulting fees, research support, potentially lucrative patents—to improperly influence medical professionals.”<sup>186</sup> Consequently, is it important that economically interested parties are not allowed to improperly influence or bias the standard-setting process,<sup>187</sup> “especially when the standard-setting is done by an association or other entity that is highly influential or dominant in the relevant market.”<sup>188</sup>

In an antitrust investigation against the IDSA’s guideline development process, the relevant market would be the treatment of Lyme disease. If AG Blumenthal had filed an antitrust complaint against the IDSA guideline development process, he should have been able to demonstrate that the IDSA panel members consciously agreed to reduce competition in the Lyme treatment market because AG Blumenthal’s investigation revealed the following findings:

- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interests;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by a formal approval of the IDSA’s oversight committee;
- The IDSA’s 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group’s position on chronic Lyme disease to achieve “consensus”;
- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006

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184. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 (1988); *see also* Coyle, *supra* note 56.

185. Richard Blumenthal, *Conflicts of Interest in Treatment Guidelines*, THE DAY (July 19, 2009), <http://www.theday.com/apps/pbcs.dll/article?AID=/20090719/OP05/307199960&template=printart>.

186. *Id.*

187. *See Allied Tube & Conduit Corp.*, 486 U.S. at 500.

188. Coyle, *supra* note 56.

guidelines panel by informing them that the panel was fully staffed, even though it was later expanded;

- The IDSA portrayed the [American Academy of Neurology's] Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.<sup>189</sup>

Because courts allow inferences to be drawn from the behavior of the alleged conspirators, a court could find that the IDSA panel members conspired to unreasonably restrain trade in the relevant market—the treatment of Lyme disease—when they blocked the appointment of physicians with divergent views and refused to accept or meaningfully consider the existence of chronic Lyme disease. By excluding physicians with differing opinions from participating in its panel and suppressing scientific evidence,<sup>190</sup> the 2006 IDSA Guidelines not only adversely affected IDSA competitors—physicians who treat chronic Lyme disease with long-term antibiotics—<sup>191</sup> but also unreasonably restrained the Lyme treatment market.

The 2006 IDSA Guidelines have significantly reduced the Lyme treatment market by denying the existence of chronic Lyme disease and condemning the use of long-term antibiotics.<sup>192</sup> Insurance companies have further reduced the Lyme treatment market by citing the 2006 IDSA Guidelines in their coverage plans to deny or limit treatment costs associated with chronic Lyme disease,<sup>193</sup> claiming that the

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189. Press Release, Conn. Attorney Gen. Office, *supra* note 35 (alteration added).

190. *Id.*; see also Press Release, Pat Smith, President, Lyme Disease Ass'n, Historic Move by CT Attorney General to Investigate IDSA Guidelines Process (Nov. 16, 2006), available at <http://www.lymediseaseassociation.org/NewsReleases/20061116.html> ("The IDSA . . . refused to allow patient or chronic disease-treating physician input into the guidelines process . . . although [LDA and ILADS] requested to be a part of the process."); Press Release, Conn. Attorney Gen. Office, *supra* note 35 ("IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel . . .").

191. *Medical Antitrust Actions—Does "Might Make Right"?*, *supra* note 161.

192. See *supra* text accompanying notes 87-89; Press Release, Conn. Attorney Gen. Office, *supra* note 35 (stating that the 2006 IDSA "guidelines are . . . widely cited for conclusions that chronic Lyme disease is nonexistent").

193. Dave Collins, *Doctors to Reassess Antibiotics for "Chronic Lyme" Disease*, USA TODAY, May 3, 2008, [http://www.usatoday.com/news/health/2008-05-02-2697198997\\_x.htm](http://www.usatoday.com/news/health/2008-05-02-2697198997_x.htm); see also Press Release, Conn. Attorney Gen. Office, *supra* note 35 ("United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the guidelines as justification to deny reimbursement for long-term antibiotic treatment."); *Intravenous (IV) Antibiotic Therapy for Lyme Disease*, UNITED HEALTH CARE, [https://www.oxhp.com/secure/policy/iv\\_therapy\\_lyme\\_410.html](https://www.oxhp.com/secure/policy/iv_therapy_lyme_410.html) (last visited Oct. 5, 2010) (citing the 2006 IDSA Guidelines in its coverage plan).



costly long-term treatments are “‘experimental’ or ‘not evidence-based.’”<sup>194</sup> But in reality, “the science underlying both the short-term and the longer-term treatment options is equally uncertain.”<sup>195</sup> As such, physicians who treat chronic Lyme sufferers argue that they should be allowed to use long-term antibiotics as treatment because “[e]vidence-based medicine requires only that medicine be practiced in accordance with the evidence that currently exists, not that treatment be withheld pending research.”<sup>196</sup> Moreover, in a free marketplace, both viewpoints would be available to patients.

(b) Do the 2006 Guidelines Have a Legitimate Purpose?

“In evaluating standards developed by private associations under the rule of reason, courts have [also] considered whether the standard is intended to accomplish a legitimate purpose and, if so, whether it is reasonably related to that purpose and is objective.”<sup>197</sup> Standard-setting does not have a legitimate purpose if it is used “as a predatory device”<sup>198</sup> to injure competitors.<sup>199</sup>

Arguably, the IDSA could claim that its 2006 Guidelines are intended to protect the public from the dangers of long-term antibiotic use.<sup>200</sup> In response, a claimant could make two arguments: (1) the 2006 IDSA panel used its Guidelines as a predatory device to injure competitors—physicians who treat chronic Lyme patients,<sup>201</sup> and (2) the 2006 Guidelines’ denial of chronic Lyme disease and

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194. Johnson, *supra* note 28; see also Cohen, *supra* note 36, at 54 (stating that pharmacists have also used the Guidelines as a basis to deny filling prescriptions for Lyme patients); Letter from Donald M. Poretz, *supra* note 92. Although outside the scope of this article, it should be noted that Plan Administrators have used the IDSA Guidelines to deny coverage, claiming that Lyme treatment is not medically necessary. See *Zisel v. Prudential Ins. Co.*, 845 F. Supp. 949, 950 (E.D.N.Y. 1994).

195. Johnson, *supra* note 28.

196. *Id.* “[T]he legal standard of care for treating a condition is determined by the consensus of physicians who actually treat patients, not by treatment guidelines.” *Id.* (citing Brian Hurwitz, *Clinical Guidelines and the Law*, 311 BRIT. MED. J. 1517, 1517-18 (1995)).

197. ABA SECTION OF ANTITRUST LAW, *supra* note 107, at 144 (alteration added) (footnote omitted).

198. *DM Research, Inc. v. Coll. of Am. Pathologists*, 170 F.3d 53, 56-58 (1st Cir. 1999); see also *Heary Bros. Lightning Prot. Co. v. Lightning Prot. Inst.*, 287 F. Supp. 2d 1038, 1048-49 (D. Ariz. 2003), *aff’d in part, rev’d in part*, 262 Fed. App’x 815 (9th Cir. 2008).

199. *DM Research, Inc.*, 170 F.3d at 57-58; see also *Heary Bros. Lightning Prot. Co.*, 287 F. Supp. 2d at 1048-49.

200. See *supra* note 92 and accompanying text.

201. See *DM Research, Inc.*, 170 F.3d at 57-58; *Heary Bros. Lightning Prot. Co.*, 287 F. Supp. 2d at 1048-49.

condemnation of long-term antibiotics are not the least restrictive methods available to the IDSA to protect the public.<sup>202</sup>

Evidence suggests that the 2006 IDSA panel used the Guidelines as a predatory device to injure doctors who do not follow the Guidelines. “The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care,”<sup>203</sup> which has caused the doctors who treat chronic Lyme (competitors of the IDSA panel members) and their patients to suffer severe economic harm.<sup>204</sup> Because the 2006 IDSA Guidelines provide that the EM rash “is the only manifestation of Lyme disease in the United States that is sufficiently distinctive to allow clinical diagnosis in the absence of laboratory confirmation,”<sup>205</sup> physicians are precluded from using their own clinical judgment in diagnosing Lyme disease unless the patient has an EM rash.<sup>206</sup> This is problematic because according to the ILADS Guidelines, as many as fifty percent of all Lyme patients never develop the EM rash.<sup>207</sup> Because many patients do not get a bull’s-eye rash and do not test positive with the IDSA’s recommended serological testing,<sup>208</sup> they are never diagnosed with the disease, and they never obtain appropriate treatment.<sup>209</sup>

The 2006 IDSA Guidelines also prevent physicians from providing patients with proven treatment options<sup>210</sup> because the Guidelines are extremely restrictive and provide an extensive list of prohibitive practices, such as long-term antibiotic use and intravenous antibiotics.<sup>211</sup> Physicians who treat chronic Lyme disease have successfully used both of these treatment practices on chronic Lyme patients, so the Guidelines’ restrictions “appear[] to be directly targeted at the treatment practices of physicians following the ILADS treatment Guidelines.”<sup>212</sup> Unlike the 2006 IDSA Guidelines, the ILADS guidelines are flexible and recommend that physicians should

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202. See *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656, 658-60 (1961) (per curiam) (finding that although petitioner failed to meet gas associations “seal of approval,” the gas association’s refusal to provide gas to the petitioner was unduly restrictive).

203. Press Release, Conn. Attorney Gen. Office, *supra* note 35.

204. See *infra* notes 206, 209.

205. 2006 IDSA GUIDELINES, *supra* note 3, at 1101 (emphasis omitted).

206. See LORRAINE JOHNSON, HIGHLIGHTS OF THE NEW RESTRICTIVE IDSA TREATMENT GUIDELINES WITH COMMENTARY (2006), available at [http://www.rally11-30-06.lymerights.org/g\\_2006\\_11\\_080\\_one\\_pager\\_IDSA\\_Guidelines.pdf](http://www.rally11-30-06.lymerights.org/g_2006_11_080_one_pager_IDSA_Guidelines.pdf).

207. THE ILADS WORKING GRP., *supra* note 97, at S6. But see 2006 IDSA GUIDELINES, *supra* note 3, at 1099 (stating that “[t]he great majority of persons with *B. burgdorferi* infection” get an EM rash).

208. See *supra* text accompanying notes 155-156.

209. See Johnson, *supra* note 28; BEAN, *supra* note 20, at 133 (“[R]estrictive guidelines and unreliable tests obstruct the diagnosis of Lyme disease.”).

210. See Press Release, Time for Lyme, *supra* note 76.

211. See 2006 IDSA GUIDELINES, *supra* note 3, at 1094, 1105, 1106 tbl.3, 1110.

212. Johnson, *supra* note 206.

decide how to treat their patients based “on the severity of each case, the patient’s response to therapy and the physician’s own clinical judgment.”<sup>213</sup>

The 2006 IDSA Guidelines also effectively limit patients’ ability to obtain health care and eliminate patients’ choice of medical treatment in the Lyme treatment market because many physicians refuse to treat Lyme patients, fearing sanctions or loss of their medical license,<sup>214</sup> and many insurance companies deny payment for treatments that do not conform to the 2006 IDSA Guidelines.<sup>215</sup> Consequently, many Lyme sufferers go undiagnosed and untreated, and those who can find a doctor willing to treat their disease often suffer severe economic harm because they have to travel great distances and pay for the costly treatments themselves.<sup>216</sup>

In addition, the 2006 Guidelines’ denial of chronic Lyme disease and condemnation of long-term antibiotics is not the least restrictive method available to the IDSA to protect the public. For example, instead of condemning the use of long-term antibiotics, the IDSA and its panel members could (1) inform patients that there is a disagreement among physicians as to whether chronic Lyme exists, (2) explain the nature of the controversy to patients, and (3) provide patients with a warning to address their concerns surrounding the use of long-term antibiotics. This information would allow patients to make an informed decision when deciding which treatment option to pursue.

(c) Did the IDSA Guideline Development Process  
Have Procedural Safeguards?

AG Blumenthal’s findings clearly demonstrate that “[t]he IDSA’s Lyme guideline process lacked important procedural safeguards.”<sup>217</sup> The facts demonstrate that the IDSA’s guideline development process was not fair, open, or unbiased and that the IDSA panel improperly influenced the guideline process by refusing to meaningfully consider information regarding the existence of Lyme disease, excluding scientists and physicians with divergent viewpoints, failing to conduct a conflicts of interest review on the panelists, and failing to follow its own procedures for appointing panel members.<sup>218</sup> In addition, the IDSA panel members biased the Guideline development process due to their financial interests in Lyme diagnostic tests and their consulting arrangements with insurance companies.<sup>219</sup>

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213. THE ILADS WORKING GRP., *supra* note 97, at S4.

214. See discussion *infra* Part IV.C.3.

215. See Johnson, *supra* note 28; Press Release, Conn. Attorney Gen. Office, *supra* note 35.

216. See Johnson, *supra* note 28; see also Press Release, Conn. Attorney Gen. Office, *supra* note 35.

217. See Press Release, Conn. Attorney Gen. Office, *supra* note 35.

218. See *id.*; Press Release, Pat Smith, *supra* note 190.

219. See *supra* text accompanying notes 148-150.

Because of this abuse in the guideline development process, the Guidelines deny the existence of chronic Lyme disease and condemn the use of long-term antibiotics,<sup>220</sup> which limits consumers' diagnosis and treatment options and causes economic harm to physicians who treat chronic Lyme patients. In addition, the Guidelines cause further economic harm to competing physicians because the Guidelines prevent physicians from exercising clinical discretion in diagnosing Lyme disease.<sup>221</sup> The Guidelines have also caused economic harm to chronic Lyme patients because many patients have to pay for their treatment because many insurance companies use the Guidelines to deny treatment costs.<sup>222</sup> Consequently, the IDSA development process should constitute exclusionary conduct under the Sherman Act.

### 3. Did the IDSA Monopolize or Attempt to Monopolize the Lyme Treatment Market?

Section 2 of the Sherman Act<sup>223</sup> specifically prohibits monopolizing or attempting to monopolize, any part of interstate or foreign commerce.<sup>224</sup> In *United States v. Grinnell Corp.*,<sup>225</sup> the United States Supreme Court declared that monopolization has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."<sup>226</sup> A legal entity can monopolize interstate commerce by excluding competitors from a market.<sup>227</sup> But "to be condemned as exclusionary, a monopolist's act must have 'anticompetitive effect.' That is, it must harm the competitive process and thereby harm consumers."<sup>228</sup>

An SSO can obtain monopoly power by allowing members with an economic interest in restraining competition to bias its standard-setting process.<sup>229</sup> The IDSA and its panel members biased the Lyme treatment Guideline development process,

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220. See *supra* text accompanying notes 91-95.

221. See *supra* text accompanying notes 206-207.

222. See *supra* text accompanying notes 194-195.

223. 15 U.S.C. § 2 (2006).

224. See *supra* notes 127-128 and accompanying text.

225. 384 U.S. 563 (1966).

226. *Id.* at 570-571.

227. See *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) ("Monopoly power is the power to control prices or exclude competition."); *Grinnell Corp.*, 384 U.S. at 571.

228. *Rambus Inc. v. FTC*, 522 F.3d 456, 463 (D.C. Cir. 2008) (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (2001)).

229. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988).

unlawfully monopolized the treatment of Lyme disease by excluding certain medical treatments, such as long-term antibiotic treatment,<sup>230</sup> and denied the existence of chronic Lyme disease.<sup>231</sup> This bias has allowed the IDSA and its panel members to eliminate consumer choice in the Lyme treatment market and exclude competing doctors—doctors who clinically diagnose and treat chronic Lyme disease.<sup>232</sup> The IDSA and its panel members have also unlawfully monopolized the treatment of Lyme disease by allowing medical boards to investigate and sanction doctors who do not follow the IDSA Guidelines.<sup>233</sup>

## V. CONCLUSIONS

Individuals with confirmed and suspected Lyme disease, and the physicians who have been willing to treat them, have faced great difficulties due to the 2006 IDSA Guidelines' powerful impact on the diagnosis and treatment of Lyme disease. Medical guidelines are extremely powerful because physicians and patients rely on them to determine treatment options, and insurance companies rely on them to determine treatment coverage. Consequently, it is imperative that the guideline development process be fair, open, and free of conflicts of interest. In addition, the process must be based on all available scientific evidence.

Although AG Blumenthal's investigation did not result in an antitrust lawsuit, the investigation and settlement demonstrate that other medical associations could become the subject of an antitrust investigation. To avoid an antitrust investigation or lawsuit, all medical associations should examine their guideline development processes to ensure that their process has appropriate safeguards against improper influence or bias. More specifically, medical associations should determine if they developed their guidelines through a fair, open, and accountable process that meaningfully considered all relevant scientific evidence. In addition, medical associations should conduct a conflicts of interest check on all panel members to ensure that none of the panel members have an undisclosed financial interest, which could improperly influence or bias the outcome of the guideline development process.

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230. See *supra* text accompanying notes 87, 91-92.

231. See *supra* text accompanying notes 80, 95.

232. See *supra* text accompanying notes 57, 214-216.

233. See *supra* text accompanying notes 44-49.