

## Letters to the Editor

To Whom It May Concern:

There are too many factual errors to count in Johanna Ferguson's article *Cure Unwanted? Exploring the Chronic Lyme Disease Controversy and Why Conflicts of Interest in Practice Guidelines May be Guiding Us Down the Wrong Path*<sup>1</sup>—and the author unfortunately uses these errors to support misleading assertions about Lyme disease and the Infectious Diseases Society of America (IDSA). The implication that the physicians who wrote the IDSA's Lyme disease guidelines willingly stood in the way of a cure because doing so somehow benefitted them is offensive and outrageous.

At issue is the controversy over "chronic Lyme disease." Self-described "Lyme-literate" doctors diagnose sick patients with this condition and prescribe treatment with costly long-term antibiotics, often administered intravenously for months or years. The IDSA guidelines, conversely, note that there is no medical evidence that Lyme disease bacteria remain after administration of appropriate antibiotic therapy; nor is there evidence that long-term antibiotic therapy benefits people suffering from a constellation of non-specific symptoms that some doctors attribute to chronic Lyme disease.<sup>2</sup> However, there is extensive evidence that long-term antibiotic therapy can lead to serious drug reactions and potentially fatal infections.<sup>3</sup>

Further, the author makes numerous assertions of alleged conflicts of interest among the guidelines review panel, which are sourced from the Connecticut Attorney General's press release (which is cited repeatedly through the article)<sup>4</sup> and an opinion piece written by two chronic Lyme advocates who espouse long-term

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<sup>1</sup> Johanna Ferguson, Note, *Cure Unwanted? Exploring the Chronic Lyme Disease Controversy and Why Conflicts of Interest in Practice Guidelines May Be Guiding Us Down the Wrong Path*, 38 AM. J.L. & MED. 196 (2012).

<sup>2</sup> See, e.g., Raymond J. Dattwyler et al., *A Comparison of Two Treatment Regimens of Ceftriaxone in Late Lyme Disease*, 117 WIENER KLINISCHE WOCHENSCHRIFT 393 (2005) (Austria); B.A. Fallon et al., *A Randomized Placebo-Controlled Trial of Repeated IV Antibiotic Therapy for Lyme Encephalopathy*, 70 NEUROLOGY 992 (2008); H. Feder, Jr. et al., *A Critical Appraisal of "Chronic Lyme Disease,"* 357 NEW ENG. J. MED. 1422 (2007); Mark S. Klempner et al., *Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease*, 345 NEW ENG. J. MED. 85 (2001); L.B. Krupp et al., *Study and Treatment of Post Lyme Disease (STOP-LD): A Randomized Double Masked Clinical Trial*, 60 NEUROLOGY 1923 (2003); J. Oksi et al., *Duration of Antibiotic Treatment in Disseminated Lyme Borreliosis: A Double-Blind, Randomized, Placebo-Controlled, Multi-Center Clinical Study*, 26 EUR. J. CLINICAL MICROBIOLOGY & INFECTIOUS DISEASES 571 (2007); Gary P. Wormser et al., *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America*, 43 CLINICAL INFECTIOUS DISEASES 1089 (2006) [hereinafter, Wormser et al., *The Clinical Assessment*]; Gary P. Wormser et al., *Duration of Antibiotic Therapy for Early Lyme Disease: A Randomized, Double-Blind, Placebo-Controlled Trial*, 138 ANNALS INTERNAL MED. 697 (2003).

<sup>3</sup> See Paul J. Ettestad et al., *Biliary Complications in the Treatment of Unsubstantiated Lyme Disease*, 171 J. INFECTIOUS DISEASES 356, 359 (1995); Krupp et al., *supra* note 2, at 1923; Robin Patel et al., *Death from Inappropriate Therapy for Lyme Disease*, 31 CLINICAL INFECTIOUS DISEASES 1107, 1108 (2000).

<sup>4</sup> Press Release, Conn. Att'y Gen.'s Office, *A General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guidelines, Install Independent Arbiter* (May 1, 2008), available at <http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284>.

antibiotic treatment for chronic Lyme disease patients.<sup>5</sup> The assertion that IDSA guidelines panelists stood to gain from their recommendations is ridiculous in light of the fact that the guidelines actually recommend less expensive generic drugs and against long-term antibiotic use. The fact is the majority of panelists had nothing to disclose, and those that did have disclosures do not stand to benefit financially from the recommendations.<sup>6</sup> Meanwhile, “Lyme-literate” physicians who wrote opposing Lyme disease guidelines actually do stand to profit from their recommendations to use a specific test (made by a lab with ties to one of the Lyme-literate doctors) and for repeated visits needed for expensive long-term antibiotic treatment.<sup>7</sup>

The article is rife with small but profoundly misleading or outright false verbiage. For instance, the author insists that “the Centers for Disease Control (CDC) and the IDSA, believe that Lyme disease can always be effectively treated and eradicated with fourteen to twenty-eight days of antibiotics.”<sup>8</sup> IDSA’s guidelines assert no such thing, rather stating that in cases where symptoms do not resolve, studies have shown no significant or durable benefit for taking longer courses of antibiotics.<sup>9</sup>

The author, not surprisingly, discusses the Connecticut attorney general’s antitrust investigation, which examined whether the IDSA Lyme disease guidelines authors had conflicts of interest and failed to consider divergent medical opinions.<sup>10</sup> Those assertions were unfounded, and as part of an agreement to end the investigation, IDSA voluntarily agreed to a special one-time review of the guidelines by an independent scientific review panel whose members were certified to be free from any conflicts of interest by an independent ombudsman.<sup>11</sup>

The author’s comments about this initiative, however, are misleading. For instance, she writes that “[t]he IDSA’s review board subsequently determined that the guidelines were to remain unchanged.”<sup>12</sup> There are two problems with that statement. First, it was not IDSA’s review board but an independent review panel chosen by the neutral ombudsman who was jointly selected by both the Connecticut attorney general and the IDSA.<sup>13</sup> Let us be clear that the neutral review was in fact the whole point of the settlement.

Second, by providing no other insight into the review process, Ms. Ferguson implies that IDSA took a brief look at the guidelines and quickly decided they were just fine.<sup>14</sup> In fact, the independent review panel convened sixteen times over the course of more than a year, including at an all-day public hearing in Washington, D.C. More than 150 individuals or organizations submitted evidence and other information including letters, newspaper articles, patient medical records and other

<sup>5</sup> L. Johnson & R.B. Stricker, *Attorney General Forces Infectious Disease Society of America to Redo Lyme Guidelines Due to Flawed Development Process*, 35 J. MED. ETHICS 283 (2009).

<sup>6</sup> Paul G. Auwaerter et al., *Scientific Evidence and Best Patient Care Practices Should Guide the Ethics of Lyme Disease Activism*, 37 J. MED. ETHICS 68, 71 (2011).

<sup>7</sup> See *id.*; see also Paul G. Auwaerter et al., *Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease*, 11 LANCET INFECTIOUS DISEASES 713, 715 (2011); David Whelan, *Ticks Aren’t the Only Parasites Living Off Patients in Borreliosis-Prone Areas*, FORBES (Mar. 12, 2007), <http://www.forbes.com/forbes/2007/0312/096.html>.

<sup>8</sup> Ferguson, *supra* note 1, at 198.

<sup>9</sup> See Wormser et al., *The Clinical Assessment*, *supra* note 2, at 1121.

<sup>10</sup> See Ferguson, *supra* note 1, at 215-16.

<sup>11</sup> Paul M. Lantos et al., *Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America*, 51 CLINICAL INFECTIOUS DISEASES 1 (2010).

<sup>12</sup> Ferguson, *supra* note 1, at 216.

<sup>13</sup> See Lantos et al., *supra* note 11, at 1.

<sup>14</sup> See Ferguson, *supra* note 1, at 216.

materials on Lyme disease and its treatment. The panel reviewed all of those materials, as well as hundreds of published studies, case reports and reviews. After this extensive review, the independent review panel unanimously agreed that the guidelines were medically and scientifically valid and no changes needed to be made.<sup>15</sup>

Yet the author maintains that as a result of IDSA's Lyme disease guidelines, "many Lyme patients today continue to find themselves suffering without access to treatment."<sup>16</sup>

IDSA has never said that these patients are not suffering and, in fact, that is why the Society continues to search for improved treatments.

However, there is no proof that people who are ill with a constellation of frustrating symptoms have chronic Lyme disease.<sup>17</sup> Treating them with long-term antibiotics is dangerous and unproven.<sup>18</sup> People who have been prescribed long-term antibiotics to treat "chronic" Lyme disease have died of complications of this and other unproven therapies.<sup>19</sup> Meanwhile, the true cause of "chronic" Lyme patients' suffering remains undiscovered. For instance, one young father treated for chronic Lyme eventually learned he was suffering not from chronic Lyme disease, but cancer.<sup>20</sup>

IDSA's guidelines are simply that—guidelines, not directives—and are not intended to replace physician judgment. They are intended to help conscientious physicians steer away from questionable therapies and, instead, help their patients with proven ones.

IDSA's primary concern is for the health and safety of patients and to ensure they are given treatment that is safe, effective and supported by scientific evidence. To imply otherwise, in fact to imply ill will, is beyond the pale.

Sincerely,

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President, IDSA

<sup>15</sup> Lantos et al., *supra* note 11, at 5.

<sup>16</sup> Ferguson, *supra* note 1, at 216.

<sup>17</sup> See Feder, Jr. et al., *supra* note 2, at 1427; Auwaerter et al., *supra* note 6, at 69-70.

<sup>18</sup> See *supra* note 2 and accompanying text.

<sup>19</sup> See Patel et al., *supra* note 3, at 1108-09; see also Stacy M. Holzbauer et al., *Death Due to Community-Associated Clostridium Difficile in a Woman Receiving Prolonged Antibiotic Therapy for Suspected Lyme Disease*, 51 CLINICAL INFECTIOUS DISEASES 369 (2010); Steve Fry, *Former Doctor John Toth Faces Federal Case*, CJONLINE.COM (Dec. 6, 2008), [http://cjonline.com/stories/120608/loc\\_364328990.shtml](http://cjonline.com/stories/120608/loc_364328990.shtml).

<sup>20</sup> Patricia Callahan, *A Lyme Disease Diagnosis Gone Wrong*, L.A. TIMES, Dec. 27, 2010, <http://articles.latimes.com/2010/dec/27/health/la-he-lyme-disease-side2-20101227>.