

the war of nature, from famine and death, the most exalted object which we are capable of conceiving, namely, the production of the higher animals, directly follows. There is grandeur in this view of life, with its several powers, having been originally breathed into a few forms or into one; and that, while this planet has gone cycling on according to the fixed law of gravity, from so simple a beginning endless forms most beautiful and most wonderful have been, and are being, evolved.³

Financial Disclosures: None reported.

REFERENCES

1. The Darwin Correspondence Project. Letter 3956—Darwin, C. R. to Trimen, Roland, 31 Jan [1863]. <http://www.darwinproject.ac.uk/darwinletters/calendar/entry-3956.html>. Accessed November 19, 2008.
2. Dobzhansky T. Nothing in biology makes sense except in the light of evolution. *Am Biol Teach*. 1973;35:125-129.
3. Darwin C. *On the Origin of Species by Means of Natural Selection, or the Preservation of Favoured Races in the Struggle for Life*. London, England: John Murray; 1859.
4. Nesse RM, Williams GC. Evolution and the origins of disease. *Sci Am*. 1998;279(5):86-93.
5. Nesse RM. What evolutionary biology offers public health. *Bull World Health Organ*. 2008;86(2):83.
6. Shubin N. *Your Inner Fish: A Journey Into the 3.5-Billion-Year History of the Human Body*. New York, NY: Random House; 2008.
7. Nesse RM, Schiffman JD. Evolutionary biology in the medical school curriculum. *Bioscience*. 2003;53(6):585-587.
8. Darwin C. *The Expression of the Emotions in Man and Animals*. London, England: John Murray; 1872.
9. Sloten R. *The Heretic in Darwin's Court: The Life of Alfred Russel Wallace*. New York, NY: Columbia University Press; 2004.

COMMENTARIES

MEDICINE AND LAW

Science, Politics, and Values

The Politicization of Professional Practice Guidelines

John D. Kraemer, JD, MPH

Lawrence O. Gostin, JD

THE INFECTIOUS DISEASES SOCIETY OF AMERICA (IDSA) issued updated clinical practice guidelines in 2006 for the diagnosis and treatment of Lyme disease.¹ Within days, the Connecticut attorney general launched an investigation, alleging IDSA had violated state antitrust law by recommending against the use of long-term antibiotics to treat “chronic Lyme disease (CLD),” a label applied by advocates to a variety of nonspecific symptoms for which frequently no evidence suggests the etiologic agent of Lyme disease is responsible. The IDSA was forced to settle the claim to avoid exorbitant litigation costs, even though the society’s guidelines were based on sound science. The case exemplifies the politicization of health policy, with elected officials advocating for health policies against the weight of scientific evidence.

The Antitrust Investigation of IDSA

Although untreated or inadequately treated Lyme disease can progress to cause neurological complications and arthritis, there is no evidence the disease has a chronic form (except perhaps as sequelae) in the absence of objective clinical or serological evidence of active infection.² Nevertheless, some patient groups and a small minority of physicians contend *Borrelia burgdorferi*, the causative agent of Lyme disease, commonly persists in patients after standard antibiotic treatments. They maintain that a constellation of

nonspecific symptoms such as fatigue, myalgia, headaches, and chest pain are evidence of chronic infection, and that standard diagnostics are inaccurate.³ Furthermore, some recommend using long-term, high-dose antibiotics—frequently administered intravenously—to treat patients with nonspecific symptoms and no objective evidence of infection.³

The IDSA treatment guidelines strongly disagreed and instead labeled the constellation of symptoms “post-Lyme syndrome”—either sequelae without ongoing infection or unrelated to *B burgdorferi*. The guidelines state, “There is no convincing biologic evidence for the existence of symptomatic chronic *B burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (≥ 6 months) subjective symptoms after recommended treatment regimens for Lyme disease.”¹ The IDSA guidelines also rejected the use of a variety of alternative diagnostic tests deemed unvalidated by the Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration.

IDSA’s guidelines were based on the biological implausibility of *B burgdorferi* persistence after proper treatment in the absence of objective indications of treatment failure; the high background rates of the subjective symptoms of-

Author Affiliations: O’Neill Institute for National and Global Health Law, Georgetown University, Washington, DC.

Corresponding Author: Lawrence O. Gostin, JD, O’Neill Institute for National and Global Health Law, Georgetown University, 600 New Jersey Ave NW, Washington, DC 20001 (gostin@law.georgetown.edu).

ten attributed to chronic Lyme infection; and the absence of benefit from, and the serious adverse effects of, long-term treatment. The CDC⁴ and National Institutes of Health⁵ concurred in the judgment that long-term antibiotic use is not justified: “despite extensive study, no clear evidence has emerged to support the contention that CLD results from a past or persistent Lyme disease infection.”⁵ American Academy of Neurology treatment guidelines for Lyme disease affecting the nervous system reached the same conclusion.⁶

The International Lyme and Associated Diseases Society (ILADS), a CLD advocacy group, immediately protested and asserted the superiority of its alternative guidelines,³ which others have suggested were based on substandard review methods.⁷ Shortly after, Connecticut Attorney General Richard Blumenthal launched an investigation of IDSA’s guideline writing process, alleging it violated state antitrust laws by excluding differing viewpoints from its guideline creation process and including members who had financial interests in, or ties to, Lyme diagnostic and treatment makers.⁸ IDSA did disclose its panel members’ potential conflicts of interest in its published guidelines, even though there is no evidence that any conflicts altered the guidelines’ content. Meanwhile, the committee that created the ILADS guidelines included the president of a company that manufactures an alternative Lyme disease diagnostic test⁹ and multiple physicians whose practices are listed with a CLD advocacy group’s patient referral service¹⁰—but ILADS did not disclose the conflicts in its guideline document.³

Antitrust laws are designed to ensure legitimate commercial competition and protect against predatory corporate practices due to inappropriate restraints on trade. Professional organizations, such as IDSA, can violate antitrust laws if their standard-setting is an unreasonable attempt to advance their members’ economic interests by suppressing competition.¹¹ Applying the antitrust “rule of reason,” a challenger must show that the professional organization both possesses substantial market power and that the anticompetitive effects of its standards outweigh patient benefits.¹² Even assuming IDSA wielded sufficient market power through its nonbinding guidelines to meet the first part (which is questionable considering that insurers and clinicians can independently choose which treatments to cover and prescribe), the second part of the rule of reason cannot be met because IDSA guidelines substantially advanced patients’ interests.

The courts should defer to professional medical associations when standards are set on the basis of valid science aimed at protecting patient health or safety. A precisely on-point federal case (though one that does not bind Connecticut courts interpreting the state antitrust law) upheld the American Academy of Ophthalmology guidelines attaching the label “experimental” to radial keratotomy, a surgical procedure for correcting nearsightedness.¹³ “Antitrust law is about consumers’ welfare,” said the court, so ultimately professional guidelines are a “medical not a legal question.”¹³ That truism should decide antitrust cases, so that

when a professional organization bases its work on the weight of science there can be no improper restraint of trade.

After spending more than a quarter of a million dollars on legal expenses, IDSA agreed to settle with the attorney general (without admitting any fault), assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines.¹⁴ While it is unlikely IDSA’s guidelines will change due to the investigation, the daunting potential for litigation by those unhappy with the outcomes of treatment guidelines may well chill the willingness of medical associations to make appropriate scientific evaluations of controversial topics—a development that would significantly threaten patient care and increase medical costs.

Science, Values, and Politics

At the heart of this controversy is the conflict between the positive nature of science and the normative function of value systems and political thought. Science is, and can only be, descriptive and explanatory. Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and whether that finding is replicable. The scientific process is not democratic—no amount of desire for different results can establish them—and inconsistent findings create true controversy only when their methods are of comparable validity.

At the same time, the sciences cannot be normative. They can establish context and a factual base for normative discourse, but scientific findings cannot entail any particular normative conclusion without reference to outside systems of thought. Science, for example, cannot resolve the never-ending debate over abortion in the United States. Medical science can describe the maternal health risks of pregnancy, elucidate fetal development, and establish risks of birth defects and complications. Nothing, however, inherently follows from any of these; rather, policy makers must look outside science, to moral, religious, ethical, and legal norms—eg, when aggregated cells become human life or what the relationship between citizens and their government should be. Medical science can, and should, inform these discussions, and in a vibrant and healthy society, such value questions will be vigorously debated.

However, all too often, the normative and positive blend into one another. Positive assertions are presented in a normative light—for example, that the cost of treating a condition surpasses a benchmark of cost-effectiveness, hence it should not be used. This really consists of 3 separate assertions: the cost of treatment equals a particular amount (a positive claim); treatments costing more than a certain amount are not cost-effective; and cost-effectiveness should guide the allocation of health care resources. All these claims may be justifiable, but only the first can be established through scientific methods.

The converse—when normative views are passed off as positive assertions—is even more problematic, such as the well-documented issue of abortion and breast cancer in the

Bush administration. Multiple adequately powered and well-designed and analyzed studies investigated the putative association between abortion and breast cancer and found no evidence of its existence. However, from 2002 to 2003, information was placed on the National Cancer Institute Web site suggesting a link between abortion and breast cancer, based largely on older epidemiologic studies that failed to sufficiently control for recall bias.¹⁵

The Connecticut attorney general's action against IDSA falls into this latter category. The CLD advocacy community understandably seeks answers for the symptoms attributed to Lyme disease. But when high-quality research repeatedly was inconsistent with the group's hypotheses, the community should have sought other answers. Instead, many advocacy organizations—and the attorney general—insisted (against the weight of evidence) on a link between the symptoms and chronic infection and continued to call for long-term antibiotic treatments. Even this was perhaps defensible—after all, medical studies cannot prove the non-existence of a phenomenon—although physicians in the CLD community should treat their patients based on the best-available evidence. But when political leaders using the force of law sued IDSA for its appropriate scientific conclusions that differed with the results they desired, they abused the public good.

A wall of separation is needed between science, norms, and politics. Science should inform normative discussions and provide the evidentiary base for political choices. Likewise, values will always be important in deciding how science is applied for human benefit. But neither should be permitted to distort the other—limits on the outer boundaries of what questions each can answer must be respected when making public policy. Medical science, and the health of patients who depend on it, are too important to be subjected to political ideologies.

Financial Disclosures: None reported.

REFERENCES

1. Wormser GP, Dattwyler RJ, Shapiro ED, et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Disease Society of America. *Clin Infect Dis*. 2006;43(9):1089-1134.
2. Feder HM Jr, Johnson BJ, O'Connell S, et al; Ad Hoc International Lyme Disease Group. A critical appraisal of "chronic Lyme disease" [correction published in *N Engl J Med*. 2008;358(10):1084]. *N Engl J Med*. 2007;357(14):1422-1430.
3. Cameron D, Gaito A, Harris N, et al; ILADS Working Group. Evidence-based guidelines for the management of Lyme disease. *Expert Rev Anti Infect Ther*. 2004;2(1)(suppl):S1-S13.
4. Lyme disease treatment and prognosis. CDC Web site. http://www.cdc.gov/ncidod/dvbid/lyme/ld_humanandisease_treatment.htm. Updated October 8, 2008. Accessed January 16, 2009.
5. Chronic Lyme disease. National Institute of Allergy and Infectious Diseases Web site. <http://www3.niaid.nih.gov/topics/lymeDisease/understanding/chronic.htm>. Updated October 23, 2008. Accessed January 16, 2009.
6. Halperin JJ, Shapiro ED, Logigian E, et al; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: treatment of nervous system Lyme disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2007;69(1):91-102.
7. Bowie WR. Guidelines for the management of Lyme disease: the controversy and the quandary. *Drugs*. 2007;67(18):2661-2666.
8. Connecticut Attorney General's Office. Attorney General's investigation reveals flawed Lyme disease guideline process, IDSA agrees to reassess guidelines, install independent arbiter. <http://www.ct.gov/AG/cwp/view.asp?A=2795&Q=414284>. Updated May 14, 2008. Accessed January 16, 2009.
9. iGenix Inc Web site. <http://igenex.com/Website>. Accessed January 16, 2009.
10. LDA automated doctor referral system. Lyme Disease Association. <http://www.lymediseaseassociation.org/referral/index.php>. Accessed January 16, 2009.
11. *Wilk v American Medical Association*, 895 F2d 352 (7th Cir 1990).
12. Harris JL. Connecticut attorney general investigating possible anticompetitive impact of practice guidelines. *ReedSmith Health Law Monitor*. 2007;11(1):2-4. http://www.reedsmith.com/_db/_documents/0704hlm.pdf. Accessed January 16, 2009.
13. *Schachar v American Academy of Ophthalmology, Inc*, 870 F2d 397 (7th Cir 1989).
14. Klein JO. Danger ahead: politics intrude in Infectious Diseases Society of America guideline for Lyme disease. *Clin Infect Dis*. 2008;47(9):1197-1199.
15. United States House of Representatives Committee on Government Reform—Minority Staff. *Politics and Science in the Bush Administration*. 2003. http://oversight.house.gov/features/politics_and_science/pdfs/pdf_politics_and_science_rep.pdf. Posted November 13, 2003. Accessed January 16, 2009.