DOI: 10.1089/act.2007.13302

Further Developments in the Battle Over Treatment Standards for Lyme Disease

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Two organizations of physicians specializing in the treatment of Lyme disease and other infectious diseases; two different views about the nature of Lyme disease, how to recognize it, and how to treat it. One view follows institutional pathways of decision making and derives narrow standards of practice that leave many patients untreated. The other hears the complaints of patients, looks at the clinical science relevant to their illness, and develops broader standards that provide relief for many of these patients.

In the free marketplace that ostensibly forms the economic cornerstone of the United States, physicians who subscribe to either of these views would be available to patients, and the marketplace would, with time, determine the proper role of the treatments based on the two viewpoints. Given the complexity of knowledge in the medical context of disease, and the inequality of such knowledge between physicians and patients, enlightened medical authorities would act to ensure that patients' choices of treatment were made on an informed basis, but choice would be allowed.

It takes little experience with modern medical practice to realize that this is not how the story plays out. The first organization, the Infectious Diseases Society of America (IDSA), declares that its view of Lyme and other tick-borne ailments constitutes the only correct standard for their management, and attempts to undercut the views of the second organization, the International Lyme and Associated Diseases Society (ILADS). IDSA excluded ILADS from its meetings and rejected its papers, refusing an opportunity to weigh the science on its merits, but rather on its source. ILADS specifically asked to contribute to IDSA's guideline-setting process, and was turned away. In late 2006, IDSA published clinical guidelines that contradicted the ILADS approach in every instance.[2] IDSA asked the prestigious Institute of Medicine (IOM) of the U.S. National Academy of Sciences to adopt its views, and IOM endorsed the IDSA's views and put a link to the latter's guidelines on its website.* ILADS formally asked IOM to list its guidelines as well as those of IDSA,[1] and asked the journal that published the IDSA guidelines, *Clinical and Infectious Diseases*, to retract the paper containing the guidelines.[3] Both the IOM and the journal refused.

The results of the IDSA and IOM rejection of ILADS practice guidelines for Lyme disease are the exposure of physicians to discipline and the erection of barriers to insurance reimbursement for patients of physicians who practice with the ILADS viewpoint: physicians who refer to themselves as "Lyme-literate." Entrenching IDSA standards not only affects the disciplinary actions of medical boards, but could also affect peer review and hospital practice, as well as malpractice risk and malpractice insurance premiums, and could increase the legal pressures on physicians who do not conform to these standards. Indeed it has even been suggested that child-protective services in some states have threatened to remove children from parents who seek long-term antibiotic therapies for their children.[1]

I have more thoroughly discussed the issues in this dispute in a previous article in *Alternative & Complementary Therapies*.[4] In brief, the dispute begins with diagnosis. IDSA believes that a diagnosis of Lyme disease requires that patients present with a history of the classic "bull's-eye" or erythema migrans (EM) rash; ILADS, on solid evidence, does not. IDSA requires evidence of immunoglobulin (Ig)G antibodies in a patient's serum as detected by specific bands on a Western blot assay that was originally developed for epidemiologic surveillance; ILADS believes that more accurate laboratory tests for Lyme disease are available for clinical use that provide broader coverage and use more accurate testing reagents.

With regard to treatment, IDSA believes that Lyme disease is an acute disease; the organization does not accept that Lyme disease and related tick-borne infections can become chronic conditions. Physicians who subscribe to the ILADS view believe that these infections can become sequestered in the body in sufficient strength to re-emerge after a course of antibiotic therapy. As a

*This link can be found at www.cdc.gov/ncidod/dvbid/lyme/

result, these physicians believe in long-term intravenous antibiotic treatment for Lyme and related infectious diseases. IDSA opposes this approach, holding the view that any long-lasting effects of such diseases are postinfectious autoimmune responses rather than manifestations of continuing infection. IDSA believes that the adverse consequences of long-term antibiotic therapy make this approach too risky. IDSA believes that ILADS physicians are making money from long-term antibiotic therapy without sufficient evidence, an argument that has brought some physicians to the unwelcome attention of their state medical boards.

The Clinical Significance of the IDSA–ILADS Conflict

The conflict between the IDSA and ILADS over the management of Lyme disease provides an excellent case study in differences in clinical thinking between conventional and integrative physicians, and legal or philosophical differences in the approach to patient management. The gulf that separates IDSA from ILADS derives in part from a difference in scientific viewpoint, in this case with the interpretation of clinical evidence for infection and the responses of infections to antibiotics.

The gulf in the two organizations' views also highlights differences in institutional decision making. Because different strains of the Lyme organism create different antibody patterns, and testing the entire range of antibody responses with the techniques available was at the time expensive, a standardized approach based upon the needs for statistical significance used in public health surveillance was selected at a multidisciplinary meeting in 1994, known for its location in Dearborn, Michigan.[5] The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recognize that the Dearborn meeting was never intended to set clinical testing standards for Lyme disease,[6–9] but protective group mechanisms in academic and institutional medicine make it hard to prevent such standards from becoming accepted as clinical standards.

This gulf between the IDSA and ILADS views of Lyme disease also emphasizes differences in the two organizations' approaches to management of patients with the disease. One would hope that a Lyme-literate physician, aware of these differences, would respond by explaining the nature of the controversy to a patient and provide for the patient to make an informed choice of treatment for the disease. (See box entitled Recognizing the IDSA Position in Lyme Consent Documents.) In this view, patients can weigh the risks and benefits of potential underdiagnosis versus potential overtreatment. The paternalistic attitude so prevalent in conventional medicine decides instead that doctors should simply make the choice for the patient.

As a further matter, IDSA guidelines provide no treatment recommendations for patients with long-term Lyme disease, other than seeking presumed other causes for their continued illness. This gulf is a common one, since integrative physicians frequently look for treatments for patients who experience unexplained fatigue or other ailments for which conventional physicians commonly offer no solutions and dismiss such patients' complaints.

The Connecticut Attorney General Weighs In

Richard Blumenthal, the Attorney General for the State of Connecticut, has long been seen as sensitive to the arguments of Lyme-disease patients who believe they need the treatment approach suggested by ILADS. In 1999, Mr. Blumenthal worked with the Connecticut state insurance commissioner to protect coverage for 30 days of intravenous antibiotic therapy and 60 days of oral antibiotic therapy for Lyme disease, and has been involved in oversight to protect the rights of patients with the disease.[1] Connecticut is a fitting battleground for the dispute over the management of Lyme disease, since the dis-

Recognizing the IDSA Position in Lyme Consent Documents

Because physicians are less likely to encounter legal difficulties if patients are informed of the Infectious Diseases Society of America (IDSA) position and then choose International Lyme and Associated Diseases Society (ILADS)–suggested treatment, physicians following the ILADS approach should consider including the following language in informed-consent documents for patients:

> This treatment is highly controversial. It is supported by the International Lyme and Associated Diseases Society (ILADS), a group of physicians who have been studying Lyme disease and related tick-borne diseases. The much larger community of established medicine, however, takes a contrary view. The Infectious Diseases Society of America (IDSA) and the Institutes of Medicine (IOM) of the U.S. National Academy of Sciences maintain that a diagnosis of Lyme disease requires that a patient develop a rash with a "bulls-eye" appearance, that only two-tier enzyme-linked immunosorbent assay (ELISA)/Western blot tests should be used for laboratory diagnosis of the disease, that infections are virtually all eliminated by a 30-day oral course of antibiotics, and that long-term antibiotic therapies, whether oral or intravenous, are not indicated for Lyme disease, and that potentially adverse consequences of such therapy make it too risky. IDSA has suggested that physicians who follow ILADS recommendations for long-term antibiotic therapy ILADS may be making money from such therapy without sufficient evidence for its efficacy. IDSA believes that any long-lasting effects of Lyme disease are instead postinfectious, autoimmune responses rather than continuing infection, or may arise from another, undiagnosed condition that should be evaluated.
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> With regard to diagnosis, many medical authorities and the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recognize that the rash that can accompany Lyme disease does not occur in a significant percentage of cases, and that the conventional approach of using ELISA and then the Western Blot technique has a high rate of falsely negative results. With regard to treatment, patients should consider their own history and experience, diagnostic efforts, and experience with antibiotic therapies, and be aware of the potentially adverse effects of antibiotics in choosing a course of action for treating the disease.

Infectious Diseases Society of America (IDSA)

Updated Guidelines for the Diagnosis and Treatment of Lyme Disease

In response to growing concern and confusion about Lyme disease, the Infectious Diseases Society of America (IDSA) updated its Clinical Practice Guidelines on the disease to provide guidance to physicians and patients based on the latest scientific evidence. Reflecting the IDSA position, the guidelines were originally published in 2000. The most significant changes in the updated version include:

- The addition of information on human granulocytic anaplasmosis (HGA) and babesiosis, two diseases transmitted by the same tick that transmits Lyme disease
- Recommendations of a single dose of an antibiotic for certain high-risk patients who have been bitten by ticks but do not have symptoms of Lyme disease
- An expanded discussion and definition of so-called "chronic" or post–Lyme disease syndromes.

The guidelines also state:

- 95% of cases of Lyme disease are cured with 10–28 days of oral antibiotics.
- Long-term antibiotic treatment is not proven to be effective and may be dangerous.
- To be certain they get the proper medical care, patients who have lingering symptoms after proper treatment (those with so-called "chronic" Lyme disease) should ask their doctors if the diagnosis was accurate or if they may have a different or new illness.

Source: Press release from Alexandria Virginia dated October 2, 2006. Online document at: www.idsociety.org/Template.cfm?Section=Home&CONTENTID=17058&TEMPLATE=/ContentManagement/ContentDisplay.cfm Accessed April 6, 2007.

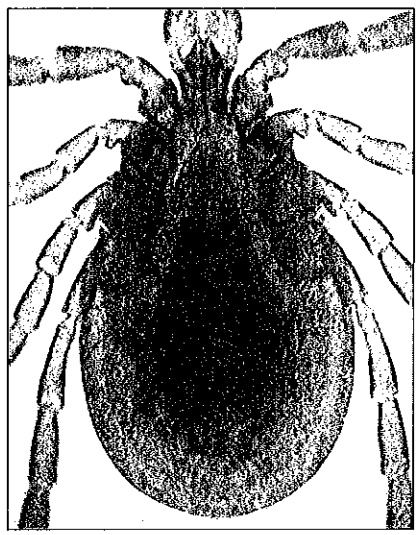
ease takes its name from the first identification, in Lyme, Connecticut, in the 1970s, of the tick-borne spirochete that causes the disease.

When IDSA began a series of efforts to undercut ILADS' viewpoint, the Connecticut Office of the Attorney General opened an investigation and filed a Civil Investigative Demand (CID) to explore possible antitrust violations by IDSA in connection with exclusionary conduct and monopolization in the development of its Lyme-disease guidelines, and potential conspiracy to unfairly restrict others' commercial activity.

The Sherman Antitrust Act (15 U.S.C. 1–7) is the best-known federal statute that limits monopolistic behavior. It provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal," and that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony."

The prohibitions found in the Sherman Act are broad and cover all commercial activities, including professional ones. As a result, antitrust has long been considered a potential legal weapon against the kind of monopolization practiced by institutional medicine. With the exception of the hard-fought and partly successful action brought by four chiropractors against the American Medical Association in Wilk v. American Medical Ass'n, 895 F.2d 352 (7th Cir. 1990), however, the Sherman Act has never been used with positive results against the medical profession.

The barriers to such suits are significant. As a threshold matter, many of the restrictive barriers erected against integrative medicine have been enforced through agencies of government or through quasigovernmental authorities. The actions of state medical boards and hospital peer-review committees, and policies of the U.S. Centers for Medicare and Medicaid Services, the Food and Drug Administration, and other government agencies, are outside the reach of antitrust statutes. Antitrust law is intended to block commercial entities, and the government's sovereign immunity protects it against actions brought under antitrust law.



Lyme disease is carried by a tick.

Individuals who act under color of state action are generally also immune from antitrust actions, with the possible exception of state medical board members who have clearly used state authority to promote anticompetitive activities. This matter is generally raised when one profession is acting against another, distinct profession, such as in the case of a board of ophthalmology trying to restrict optometrists for financial reasons. In circumstances in which physicians are setting standards of care for other physicians, it is more difficult to show distinct competitive interests.

This is true because measurable economic effects of competitors on one another, which are challenging to quantify even in the usual context of competing corporate-business entities, would be hard to determine in conflicts between two groups of physicians who simply adhere to different treatment philoso-

phies. Conflicts of the latter type are also difficult to adjudicate because in matters in which professional judgment is at issue, a plaintiff would have the burden of showing that the motivation for a standard of practice was based on competitive commercial advantage, and had no legitimate scientific basis. Because of the complexity of such issues and the deference courts have shown to institutional medicine, and because arguments exist in favor of IDSA's position, the burden of proving an anticompetitive motive on the part of IDSA could be difficult and costly. Even if a court were convinced that IDSA was wrong about the science in the conflict, an antitrust action would have to show that the organization was not only wrong, but acted with anticompetitive intent.

What makes this case intriguing, though, is not only that it was brought by the office of a state attorney general, but involves facts that could pressure the IDSA to reconsider its approach to Lyme disease. IDSA is a private association and not immune from antitrust action. A trial might show that IDSA's influence comes from the weight of its market power rather than the strength of its ideas.[1] An investigation could document, as many suspect, that IDSA is ignoring evidence, that it is barring ILADS physicians from expressing their views within the Society, and that its effort to impose its viewpoint by pressing its clinical guidelines with IOM and insurance companies as a binding standard, rather than simply as guidance, is ill-motivated. Were IDSA to be pressed into a settlement, or to lose its case in court, the consequences would be historic.

IDSA's asking IOM to support its approach is arguably protected by the First Amendment, since a widely acknowledged antitrust doctrine holds that the Sherman Antitrust Act does not prevent petitioning government under the guarantees of the First Amendment,[†] and the IOM has quasigovernmental responsibilities. The application of Pennington as a defense for IDSA in enlisting the IOM in its effort is uncertain, as is the effect of the Blumenthal investigation as a whole. It is disturbing, though, that

[†]Mine Workers v. Pennington, 381 U.S. 657 (1965). See also Eastern R. Conf. v. Noerr Motors, 365 U.S. 127 (1961)(Concerted efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition.)

The Lyme Disease Association's Response to the Infectious Diseases Society of America Guidelines

The national non-profit Lyme Disease Association (LDA), representing more Lyme disease patients than any organization in the United States, issued a press release objecting strenuously "and with great alarm to the restrictive new Clinical Practice Guidelines published this October by the Infectious Diseases Society of America (IDSA)." The LDA takes the position that the new guidelines make it far more likely that Lyme disease will be missed in its early stages, when it is easier to treat, and noted that the new guidelines "set the stage for creation of a new generation of chronic Lyme disease patients, individuals with Lyme disease diagnosed and treated so late that they may never be cured."

The LDA says that the ISDA guidelines prevent physicians from using their own clinical discretion to determine if patients have Lyme disease. The guidelines require that a characteristic rash (a "bull's eye" rash) be present although it is known to occur in only half the patients, or that patients test positive on the two tests recommended by the Centers for Disease Control and Prevention (CDC) although these tests are known to miss up to 50% of patients who have Lyme disease. Thus, notes the LDA, "at any stage of disease, as many as half the patients may remain undiagnosed."

In addition, the release made the following points:

- Lyme disease diagnosed late and allowed to disseminate for months or years without treatment causes severe disease that may never completely resolve.
- Patients with late-stage Lyme disease suffer more sequelae after treatment and are far more likely to experience treatment failures than patients who are diagnosed in a timely fashion when the disease is in an early stage.
- Patients with late-stage Lyme disease who have chronic symptoms are frequently very sick and in great pain, and are often as impaired as patients with congestive heart failure and are sicker than people with type 2 diabetes.
- Despite the basic mathematics and documented sequelae of late-diagnosed and late-treated Lyme disease, the new IDSA Guidelines state (without offering evidence or any supporting citations) that most patients with this disease are diagnosed early. This defies the experience of the LDA and the patient community. It is also flies in the face of a study, now in press at the *Journal of Evaluation in Clinical Practice*, which has found that when patients experience failure of treatment, the reason is overwhelmingly because they were diagnosed and treated late.
- The IDSA guidelines also deny that chronic persistent infection exists, arbitrarily dismissing all studies documenting persistent infection after short-term therapy and ignoring mounting evidence that more treatment is beneficial in chronic cases.
- The IDSA guidelines fail to even mention another set of diagnostic and treatment guidelines published by the International Lyme and Associated Diseases Society (ILADS) and listed with the National Guideline Clearinghouse, which offer an alternative view of Lyme disease diagnosis and treatment.

The press release then concluded:

> LDA understands that the debate over the cause of chronic Lyme disease continues to be contentious and to divide those treating and studying the disease. There continue to be two standards of care. But the need to diagnose Lyme disease early enough to obtain the best treatment outcome and most favorable prognosis has never been controversial. Despite this, the IDSA guidelines are so draconian they stand poised to let many patients slip through the cracks and elude diagnosis until they are suffering late-stage, difficult-to-treat Lyme disease. As the voice of the Lyme disease patient community, LDA challenges these guidelines on humanitarian grounds.

Source: Press release from Jackson, New Jersey, dated October 10, 2006. Online document at: www.lymediseaseassociation.org/NewsReleases/20061010.html Accessed April 6, 2007.

IOM refused a formal request by ILADS to have its guidelines listed as well as those of IDSA.[1] In any case, having a state official of Blumenthal's reach call IDSA to account for its methods is an important development.

Such a case would test the role of professional organizations in restricting the practice of the medical profession as a whole, rather than simply the members of another or competing organization. The effort of medical associations to overreach in this way is common. The ethical guidelines of the American Medical Association (AMA) suggesting that physicians should not sell dietary supplements, for example, is often pressed as a rule that AMA nonmembers should also follow.[10,11] A more recent example is the AMA's adoption in September of 2006 of a policy opposing the advancing role in diagnostics and health care practices of physician extenders and Ph.D.s. The AMA also opposed for good measure the licensure of naturopathic practitioners. AMA Resolution 904[12,‡] states that the scope of practice for such activities should remain solely in the hands of physicians. While many physicians who voted for this resolution certainly have in mind the quality of patient care, the resolution is part of a long-standing effort at building and protecting professional medical "territory" that began in the early 20th century and led to a judgment against the AMA in the Wilk matter.

The Reaction of Established Medicine

The reaction of conventional physicians to the Blumenthal investigation has, not surprisingly, been hostile. Research personnel at Yale University and the University of Connecticut met with Mr. Blumenthal in March of 2007 to dissuade him from pursuing his investigation, arguing that treatment with long-term antibiotics is an ill-advised strategy in addressing the potentially debilitating symptoms associated with tick-borne disease.[13] Durland Fish, Ph.D., a professor of epidemiology at Yale University in New Haven, Connecticut, summed up the group's feeling and at the same time demonstrated at least a lack of understanding, if not arrogance, by stating that "[t]o have good science questioned by the attorney general is very disturbing. . . ."[13] As Mr. Blumenthal notes, his concern is not with the science behind either IDSA or ILADS guidelines, but rather with investigating whether those drafting the guidelines acted in an anticompetitive manner by excluding scientific evidence that might support long-term antibiotic treatment for Lyme disease.

Conflicts of Interest?

Mr. Blumenthal has indicated that his investigation of the IDSA–ILADS matter has uncovered "conflicts of interest that are credible and powerful."[13] Conflicts of interest in medicine are widespread, and their impact on the judgment of scientific authorities has been increasingly recognized. In this case, one potential concern is that the chairman of the IDSA panel that developed the guidelines, Gary P. Wormser, M.D., of the Division of Infectious Diseases at New York Medical College, Valhalla, New York, has received consulting fees from Baxter Vaccines, of Vienna, Austria, a company that is developing a Lyme disease vaccine. The Connecticut attorney general argued that it is possible that Baxter might benefit financially from the new guidelines.

The U.S. Government Accountability Office (GAO) had examined similar issues in 2001, reviewing potential conflict-of-interest problems at the FDA, CDC, and National Institutes of Health (NIH). In a June 22, 2001 report,[14] the GAO determined that these agencies "generally" met the rules and that in those instances in which there were conflicts of interest, they had been reported and accepted because the need for expertise outweighed the potential for bias in the federal agencies' decisions. The GAO report did not examine the roles of Dr. Wormser and many other IDSA physicians' in developing the IDSA guidelines for managing Lyme disease.

Medical Board Cases

The disagreements over the diagnosis and treatment of tick-borne illness began almost simultaneously with the appearance of the disease in Connecticut in the 1970s. As a result, medical board actions against Lyme-literate physicians have placed doctors on notice that disagreements with practice guidelines can be dangerous to one's professional health.

Among physicians who have had disciplinary problems stemming from the IDSA–ILADS dispute about the management of Lyme disease is Perry Orens, M.D., of Great Neck, New York, who lost his license to practice medicine as a result of his views about Lyme disease. Dr. Orens was subjected to acrimonious hearings before the New York Office of Professional Misconduct (Albany, New York) about whether long-term antibiotic treatment was reimbursable, or was even permissible.[13] These and other physicians' struggles have been long and arduous, and have been documented by the Lyme Disease Foundation.[15] In these battles over Lyme disease, physicians who provide only short-term therapy do lose patients to Lyme-literate physicians. Equally noteworthy is that physicians who have developed Lyme disease test kits may have a vested interest in asserting the reliability of conventional enzyme-linked immunosorbent assay (ELISA)-based tests for the disease. It is reported that efforts to gain CDC or FDA approval for antibody tests that would compete with the ELISA/Western blot tests, currently standards of care for the disease, have been stymied, even though the tests' limitations and inaccuracies are well recognized.[5,13,15]

Conclusion

The struggle over standards for the management of Lyme disease illustrates the stark contrast between conventional and integrative medical approaches to the disease. It is a conflict that reflects a genuine difference in scientific understanding, in efforts to address the concerns of patients, and in philosophies about patient autonomy and choice. The scientific evidence in support of the integrative medical position in this instance is vast; the

‡See American Medical Association House of Delegates. Resolution 904. Visit www.ama-assn.org/ama1/pub/upload/mm/475/904.pdf (Accessed May 5, 2007) to obtain a pdf of this document.

argument about the management of Lyme disease is one that the ILADS should win on the merits of its case.

The willingness of a state attorney general to recognize the bad faith that might underlie IDSA's position in this matter could bring an important development for both patients and the physicians who want the freedom to treat them without the constraints of potentially self-interested private organizations.

References

1. Cohen M. Connecticut attorney general investigates restrictive Lyme guidelines. Townsend Newsletter 2006;285:53–59.
2. 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 Diseases Society of America. Clin Infect Dis 2006;43:1089–1134.
3. Stricker R. October 25, 2006 Letter, President of ILADS to Sherwood Gorbach, M.D., Editor, Clinical Infectious Diseases, Tufts University School of Medicine; Subject: Retraction of "The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: Clinical practice guidelines by the Infectious Diseases Society of America." Online document at: www.standupforlyme.org/get informed/idsa_retraction.pdf Accessed April 7, 2007.
4. Dumoff A. Diagnosing Lyme disease: A case study in complications arising in standards of care. Altern Complement Ther 2006;12:43–47.
5. [No author listed]. An Understanding of Laboratory Testing for Lyme Disease. Journal of Spirochetal and Tick-borne Diseases 1998;5,Spring/Summer. Online document at: www.igenex.com/labtest.htm
6. Food and Drug Administration (FDA). Medical Bulletin, Summer 1999. Online document at: www.fda.gov/medbull/summer99/lyme.html Accessed December 14, 2005.
7. Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Infectious Diseases. Lyme Disease Diagnosis. Online document at: www.cdc.gov/ncidod/dvbid/lyme/ld_humandisease_diagnosis.htm Accessed December 14, 2005.
8. National Institute of Autoimmune Diseases (NIAID). Diagnosis of Lyme Disease. Online document at: www.niaid.nih.gov/dmid/lyme/diagnosis.htm Accessed December 14, 2005.
9. Centers for Disease Control and Prevention (CDC). Human Ehrlichiosis in the United States: Signs and Symptoms. Online document at: www.cdc.gov/ncidod/dvrd/ehrlichia/Signs/Signs.htm Accessed December 14, 2005.
10. Dumoff, A. State medical board prohibitions on physician sale of supplements. Physician Consult Fall, 2000.
11. Dumoff A. Medical board prohibitions against physician supplement sales. Altern Complement Ther 2000;6:226–236.
12. American Medical Association. Diagnosis of Disease and Diagnostic Interpretation of Tests Constitutes Practice of Medicine to be Performed by or Under the Supervision of Licensed Physicians. Online document at: www.acnpweb.org/files/public/AMA_Resolution_904_11_06.pdf Accessed April 6, 2007.
13. Courant Staff Writers. William Hathaway, and Hilary Waldman, Lyme Disease Experts: Butt Out, Blumenthal. March 21, 2007. Online document at: www.courant.com/news/health/hc-lymewars0321.art mar21,0,1090157.story Accessed April 6, 2007.
14. General Accountability Office (GAO). Federal Agencies Generally Meet Requirements for Disclosure and Review of Financial Interests Related to Lyme Disease GAO-01-787R June 22, 2001. Online document at: www.gao.gov/docdblite/summary.php?rptno=GAO-01-787R&accno=A01242 Accessed April 7, 2007.
15. From the LymeLight Newsletter of the Lyme Disease Foundation. Online document at: www.lyme.org/lymelight/gao_investigation.html Accessed April 7, 2007.
16. Aguero-Rosenfeld ME, et al. Evolution of the serologic response to *Borrelia burgdorferi* in treated patients with culture-confirmed erythema migrans. J Clin Microbiol 1996;34:1–9.

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