

HISTORY OF IDSA LYME GUIDELINES INVESTIGATION			
Revised: 4/30/10			
RED = IDSA Lyme Guideline Authors			
DATE	EVENT	PARTICIPANTS	NOTES
11-1-2006	<b>IDSA 2006 Lyme Treatment Guidelines published</b>	<p>Authors:</p> <p>NYMC:  <b>Wormser</b>  (chair)  <b>Nadelman</b>  <b>Dattwyler</b></p> <p>Yale:  <b>Fish</b> (ex-NYMC)  <b>Shapiro</b>  <b>Bockenstedt</b>  <b>Krause</b></p> <p>Other:  <b>Steere</b> (ex-Yale)  <b>Halperin</b>  <b>Klempner</b>  <b>Bakken</b>  <b>Dumler</b></p> <p>European:  <b>Strle</b>  <b>Stanek</b></p>	<p>IDSA Guidelines:  <a href="http://www.idsociety.org/lymedisease.htm">http://www.idsociety.org/lymedisease.htm</a></p> <p>Summary of changes that ILADS Lyme clinicians and patient advocates would like to make to the IDSA guidelines:  <a href="http://www.lymedisease.org/news/lymepolicywonk/204.html">http://www.lymedisease.org/news/lymepolicywonk/204.html</a>  —Lab tests are too insensitive to be required for diagnosis of Lyme disease.  —Evidence of persistent Lyme infection exists in animals and humans.  —Restrictive treatment duration recommendations are inappropriate given the high failure rates of the treatment protocols in the guidelines for early, late and arthritic Lyme disease. On an intent-to-treat analysis—the treatment failures range from 5 to 40% for early Lyme and exceed 65% for late Lyme.  —The prophylactic recommendation in the guidelines is not only ineffective, but may actually harm patients by abrogating their immune response.  —There is no evidence to support the definition of Post-Lyme Disease Syndrome advanced in the guidelines or to limit treatment to patients whose health is not restored under the IDSA 21-day treatment protocols.  —Despite assertions to the contrary, treatment studies cited in the IDSA guidelines do not support its recommendation not to retreat patients who remain ill after the short term treatment. The treatment studies cited are either too statistically flawed to be relied on (Klempner) or, when properly interpreted, actually support retreatment of patients (Fallon and Klempner).  —Specific language in the guidelines is inaccurate and misleading. Examples of this include, the statements that there is no evidence of bacterial persistence, that the vast majority of patients are seropositive, or that persistent symptoms are no more than the “aches and pains of daily living.”</p>
11-16-2006	<b>CT Atty General Blumenthal launches a 1.5-year investigation into conflicts of interest of IDSA Lyme guidelines authors.</b>		<p>AG’s press release:  <a href="http://www.ct.gov/AG/cwp/view.asp?a=2795&amp;q=414284">http://www.ct.gov/AG/cwp/view.asp?a=2795&amp;q=414284</a></p> <p>Investigation summary:  <a href="http://www.lymedisease.org/news/lymepolicywonk/15.html">http://www.lymedisease.org/news/lymepolicywonk/15.html</a></p>
12-15-2006	Canada Public Health Lab publishes guidelines based on IDSA guidelines	<p>Co-Chairs:  Harvey Artsob  Kevin Forward</p> <p>Members:  Michel  Couillard  Magdy Dawood  Fran Jamieson  Robbin Lindsay  Tony Mazzulli  <b>Muhammad Morshed</b>  Jean Rochefort  Louise Trudel</p>	<p>Based on IDSA Lyme guidelines, though more tolerant of clinical judgment in diagnosis and possible persistent Lyme cases:  --Bypass of two-step testing procedure is strongly discouraged  --The role of lab assessments with persistence of symptoms has not yet been established.  <a href="http://www.aldf.com/pdf/Laboratory_Diagnosis_of_Lyme_disease_Canadian_Lab_Pub_Health.pdf">http://www.aldf.com/pdf/Laboratory_Diagnosis_of_Lyme_disease_Canadian_Lab_Pub_Health.pdf</a></p> <p><b>Wormser, Dattwyler, Johnson (CDC)</b> were presenters at the Canadian Lyme consensus conference, so it appears that the Canadian Guidelines author received an advance copy of the IDSA guidelines. Obviously no journal peer review: Received by journal Dec. 15, accepted Dec. 20.</p> <p><b>Muhammad Morshed</b>, Program Head, Zoonotic and Emerging Pathogens, British Columbia CDC, also worked on the 2006 IDSA Lyme guidelines.</p>
3-2007	Halperin writes Lyme section of <i>Dana Guide to Brain Health</i> (May 2007)	<b>Halperin</b>	<p>Excerpts:  “Although Lyme disease has taken on almost mythical proportions in the public mind, it is in fact a simple bacterial infection.”  “Lyme disease does not cause psychiatric problems any more than any other comparable chronic illness.”  “Treatment for Lyme disease is highly effective. Early in the disease, a course of oral antibiotics for three to four weeks results in a cure for about 95 percent of infected people.”  “...there are no data to indicate that routine treatment for any period longer than four weeks is either necessary or reasonable.”  <a href="http://www.dana.org/news/brainhealth/detail.aspx?id=9832">http://www.dana.org/news/brainhealth/detail.aspx?id=9832</a></p>
4-28-2007	Wormser reviews new guidelines with Univ. of Minn. and IDSA’s North Central Chapter	<b>Wormser</b>	<p>The Clinical Assessment, Treatment and Prevention of Lyme Disease  <a href="http://www.opitsourcebook.com/ncentral/2007.html">http://www.opitsourcebook.com/ncentral/2007.html</a></p> <p>IDSA’s North Central Chapter CME and speaker honoraria were underwritten by Astellas Pharma US, AstraZeneca, Boehringer-Ingelheim, Bristol-Myers Squibb, Cubist, Elan, Gilead, GlaxoSmithKline, Merck, Ortho McNeil, Pfizer, Roche, Sanofi-Aventis, Tibotec, Wyeth in 2006. (Awaiting confirmation for 2007.)</p>
5-6-2007	Krause reviews new guidelines for Infectious Disease Association of California 2007 22nd Annual Spring Symposium	<b>Krause</b>	<p>Emerging Tick-Borne Infections: Lyme Disease, Babesiosis and Human Granulocytic Anaplasmosis  <a href="http://www.med.yale.edu/eph/faculty/krausecv.pdf">http://www.med.yale.edu/eph/faculty/krausecv.pdf</a></p> <p>Infectious Disease Association of California run CME and speaker honoraria underwritten by Astellas US, Merck, and Roche Laboratories. Bio K+ International, Cubist, Enzon, Focus Diagnostics (big Lyme testing lab in CA), Ortho/McNeil Pharmaceutical, and ViroPharma.</p>
7-3-2007	Halperin is lead author of <i>Neurology</i> journal’s “Treatment of nervous system Lyme disease”	<b>Halperin</b> (chair) <b>Shapiro</b> Logigian Belman Dotevall <b>Wormser</b> Krupp Gronseth Bever Jr.	<p>Neurology. 2007 Jul 3;69(1):91-102. Epub 2007 May 23.  <a href="http://www.neurology.org/cgi/rapidpdf/01.wnl.0000265517.66976.28v1.pdf">http://www.neurology.org/cgi/rapidpdf/01.wnl.0000265517.66976.28v1.pdf</a></p> <p>A press statement from Blumenthal at the time said there were “improper links” between the Neurology panel and the IDSA panel, including the overlap of chairmen and development timelines, which he said constituted “a violation of IDSA’s conflicts of interest policy.” He said the resulting guidelines “not only reached the same conclusions regarding the non-existence of chronic Lyme disease, [but] their reasoning at times used strikingly similar language.”</p>

8-15-2007	Shapiro writes Lyme chapter of Kliegman: Nelson Textbook of Pediatrics, 18th ed.	<b>Shapiro</b>	<a href="http://www.mdconsult.com/das/book/body/181031884-5/946275948/1608/598.html#4-u1.0-B978-1-4160-2450-7..50221-8_4848">http://www.mdconsult.com/das/book/body/181031884-5/946275948/1608/598.html#4-u1.0-B978-1-4160-2450-7..50221-8_4848</a>
10-2007	Wormser, Shapiro repackage IDSA guidelines into NEJM article, <i>A critical appraisal of "chronic Lyme disease"</i>	Feder Johnson (CDC) O'Connell (UK) <b>Shapiro</b> <b>Wormser</b>	<i>A critical appraisal of "chronic Lyme disease", New Engl J Med</i> 2007;357:1422-30. This article reviews the investigation, diagnosis and management of patients with longstanding infection, patients with continuing symptoms following treated Lyme disease and the misdiagnosis of "chronic Lyme disease" in patients who have other conditions. <a href="http://content.nejm.org/cgi/content/full/357/14/1422">http://content.nejm.org/cgi/content/full/357/14/1422</a> .  IDSA author <b>Klempner</b> is a NEJM Associate Editor at the time of publication.
10-2007	Gary Wormser awarded IDSA's 2007 Society Citation.	<b>Wormser</b>	"a bold champion for rational, evidence-based medicine"
11-2007	Steere gives Grand Rounds Lyme lecture at Univ. of Michigan, televised	<b>Steere</b>	Grand Rounds: Lyme Disease and Its Treatment <a href="http://michiganchannel.org/search.php?searchVar=ying&amp;type=k">http://michiganchannel.org/search.php?searchVar=ying&amp;type=k</a>
12-13-2007	Steere gives Grand Rounds Lyme lectures at Univ. of Washington (Dec. 2007)	<b>Steere</b>	"What is Lyme Disease?" 20th Annual William M. M. Kirby Award Lecture <a href="http://mailman2.u.washington.edu/pipermail/medgrdrnds/2007-November/000016.html">http://mailman2.u.washington.edu/pipermail/medgrdrnds/2007-November/000016.html</a>
2007	Krause gives medical school lecture at Tufts Univ.	<b>Krause</b>	"Tick immunity and tick-borne infection" <a href="http://www.med.yale.edu/eph/faculty/krausecv.pdf">http://www.med.yale.edu/eph/faculty/krausecv.pdf</a>
2007	Krause gives featured talk, Eastern Society of Pediatric Research. Philadelphia.	<b>Krause</b>	"Development of a novel vaccine for prevention of tick-borne infections." <a href="http://www.med.yale.edu/eph/faculty/krausecv.pdf">http://www.med.yale.edu/eph/faculty/krausecv.pdf</a>
3-6-2008	Steere writes Lyme chapter in <i>Harrison's Principles of Internal Medicine</i>	<b>Steere</b>	<i>Harrison's Principles of Internal Medicine</i> is an American textbook of internal medicine. First published in 1950, it is presently in its seventeenth edition (published in February 2008). Although it is aimed at all members of the medical profession, it is mainly used by internists and junior doctors in this field, as well as medical students.
5-1-2008	<b>IDSA settles with CT AG: Controversial guidelines must be re-reviewed with a conflict-free panel</b>		The CT AG ruling requires IDSA to review its Lyme guidelines with conflict-free panel, and rewrite them if necessary. <a href="http://www.ct.gov/AG/cwp/view.asp?a=2795&amp;q=414284">http://www.ct.gov/AG/cwp/view.asp?a=2795&amp;q=414284</a>  <b>IDSA Settlement Agreement</b> <b>Step 1—Panel selection:</b> Establish a stringent procedure for identifying and vetting a conflict-free evidence review panel. <b>Step 2—Evidence vote:</b> Assess by voting whether each of the original 2006 guidelines' recommendations are medically and scientifically justified after an open evidence collections process and hearing. (Requires a 75% supermajority to support 2006 recommendations.) <b>Step 3—Revision vote:</b> Through a vote, determine whether to make revisions to any or all of the guidelines recommendations.
5-11-2008	Steere gives Ohio Wesleyan's graduation commencement speech	<b>Steere</b>	Speech Excerpt: "Over the past several decades, a Lyme disease counterculture has emerged that has ascribed a range of puzzling and poorly understood illnesses to this tick-borne infection... Diagnostic tests based on scientific studies fail to show evidence of Lyme disease in most of these patients. Additionally, 5 studies of pain and fatigue syndromes following Lyme disease reported that placebo treatment with a sugar pill gave similar results as long-term antibiotics. If you ignore scientific reality, if you twist it, if you wish for a particular answer, you will miss Mars and drift in space. Physicians, like myself, have said "scientific evidence does not support giving antibiotics for years for Lyme disease." They have been denounced, threatened, and harassed." <a href="http://commencement.owu.edu/pdfs/20080511-steere.pdf">http://commencement.owu.edu/pdfs/20080511-steere.pdf</a>
5-16-2008	Halperin gives talk at SUNY Buffalo	<b>Halperin</b>	"Lyme Disease: Facts and Myths." Huang Lecture <a href="http://www.buffalo.edu/ubreporter/archives/vol39/vol39n31/vol39n31.pdf">http://www.buffalo.edu/ubreporter/archives/vol39/vol39n31/vol39n31.pdf</a>
6-2008	Halperin writes Nervous System Lyme Disease chapter of <i>Infectious Disease Clinics of North America</i> available online on MDConsult	<b>Halperin</b>	Infectious Disease Clinics of North America - Volume 22, Issue 2 (June 2008) Each issue of <i>Infectious Disease Clinics</i> reviews new diagnostic and management techniques for a single clinical problem--and makes them simple to apply. Its concise, comprehensive, and its editors and authors are respected experts. <a href="http://www.mdconsult.com/das/article/body/177687694-2/jorg=clinics&amp;source=&amp;sp=20629703&amp;sid=0/N/640184/1.html?issn=0891-5520#S0891552007001262">http://www.mdconsult.com/das/article/body/177687694-2/jorg=clinics&amp;source=&amp;sp=20629703&amp;sid=0/N/640184/1.html?issn=0891-5520#S0891552007001262</a>
6-2008	Aguero-Rosenfeld writes Lyme Disease: Laboratory Issues chapter of <i>Infectious Disease Clinics of North America</i> available online on MDConsult	Aguero-Rosenfeld (works for <b>Wormser</b> )	Infectious Disease Clinics of North America - Volume 22, Issue 2 (June 2008) Each issue of <i>Infectious Disease Clinics</i> reviews new diagnostic and management techniques for a single clinical problem--and makes them simple to apply. Its concise, comprehensive, and its editors and authors are respected experts. <a href="http://www.mdconsult.com/das/article/body/177687694-2/jorg=clinics&amp;source=&amp;sp=20629699&amp;sid=0/N/640180/1.html?issn=0891-5520#h07001225010206">http://www.mdconsult.com/das/article/body/177687694-2/jorg=clinics&amp;source=&amp;sp=20629699&amp;sid=0/N/640180/1.html?issn=0891-5520#h07001225010206</a>
6-19-2008	Wormser gives Westchester Medical Primary Care Talk	<b>Wormser</b>	Westchester Medical Primary Care Talk: What's New in Tick-Borne Infections in the Lower Hudson Valley <a href="http://www.nymc.edu/fammed/08_FMConf.pdf">http://www.nymc.edu/fammed/08_FMConf.pdf</a>
9-2008	Halperin writes article in <i>Neuropathy News</i>	<b>Halperin</b>	Lyme Disease and Neuropathy "Although there is a lot of controversy about the treatment of Lyme disease, 2-4 week antibiotic regimens are highly effective, particularly in peripheral neuropathies... Like virtually every other known bacterial infection, Lyme disease can be treated with antibiotics." <a href="http://www.neuropathy.org/site/DocServer/Issue_31_Sept08_.pdf?docID=1661">http://www.neuropathy.org/site/DocServer/Issue_31_Sept08_.pdf?docID=1661</a>
9-19-2008	Wormser gives CBC Infectious Diseases Board Review Course	<b>Wormser</b>	Wormser presentations: <b>Lyme Disease: An Overview:</b> What do you need to know about pathogenesis, diagnosis, treatment, and prevention? <b>Ticks, Lice, Mites, and the Diseases:</b> They Transmit Recognition, diagnosis, and management of Rocky Mountain and other spotted fevers, human monocytic ehrlichiosis and granulocytic anaplasmosis, tularemia, relapsing fever, and babesiosis. Center for Bio-Medical Communication. (Speakers are paid expenses and an honoraria of \$1,500-\$3,000 depending on experience.) <a href="https://www.idboardreview.com/Faculty/">https://www.idboardreview.com/Faculty/</a> <a href="https://www.idboardreview.com/documents/Infectious%20Disease%20Broch08--6-20FINAL.pdf">https://www.idboardreview.com/documents/Infectious%20Disease%20Broch08--6-20FINAL.pdf</a>
10-1-2008	Fish Lyme lectures at Univ. of Florida (2008)	<b>Fish</b>	Excerpts: --No culture-confirmed cases of Lyme in the south, including Florida --Patient advocacy groups are spreading disinformation

			<p>--No Lyme cases in Montana  --No congenital transmission of Lyme (referring to activist poster)  --Lyme is a curable disease; even disseminated disease responds to 30 days of antibiotics. It's rare for the disease to persist for more than a few years.  --"There is a lot of bogus serology for Lyme in the south."  --Lyme is easy to culture  <a href="https://www.epi.ufl.edu/other/video/oct1.html">https://www.epi.ufl.edu/other/video/oct1.html</a>  <a href="http://www.oceanaheraldjournal.com/news.php?story_id=31100&amp;storysize=4">http://www.oceanaheraldjournal.com/news.php?story_id=31100&amp;storysize=4</a></p>
1-19-2009	<b>IDSA announces evidence review panel</b>		<p>The settlement agreement requires that the IDSA establish a panel of 8-12 members (including the chair) "who, as a group, reflect a balanced variety of perspectives and experience across a broad range of relevant disciplines, ranging from clinical experience in treating patients with Lyme disease to experience in investigating the best methods to diagnose and treat Lyme disease or other infectious diseases" to review the recommendations in its guidelines. A medical-ethicist, Dr. Howard Brody, was selected by the Attorney General and the IDSA to ensure that panel members were free of conflicts of interest.</p> <p><b>The IDSA panel list:</b>  Carol J. Baker Houston, TX  William A. Charina, MD Peabody, MA  Paul H. Duray, MD (retired) Westwood, MA  Paul M. Lantos, MD Duke University Medical Center Durham, NC  Gerald Medoff, MD Washington University School of Medicine St. Louis, MO  Manuel H. Moro, DVM, MPH, PhD National Institutes of Health Bethesda, MD  David M. Mushatt, MD, MPH &amp; TM Tulane University School of Medicine New Orleans, LA  Jeffrey Parsonnet, MD Dartmouth, Hitchcock Medical Center Lebanon, NH  Cmdr. John W. Sanders, MD U.S. Navy Naval Medical Research Center Detachment, Peru  Arthur Weinstein, MD Washington Hospital Center Washington, DC</p> <p>Patient advocates accuse the IDSA of "panel stacking" to achieve desired outcome:</p> <ol style="list-style-type: none"> <li>1. <b>No Lyme clinicians on the panel:</b> The ethicist excluded all physicians who treat Lyme disease and received income of more than \$10,000 per year from the panel. To put this in perspective, if a physician saw more than one Lyme patient per week, he/she would be excluded for bias. This means the panel will have no expertise on the treatment of chronic Lyme disease. Normally, a conflict of interest occurs when a competing secondary interest may interfere with the physician's ability to place the concerns of the patient paramount. While physicians are incentivized to treat patients under common fee for service arrangements, these interests are generally regarded as being aligned with those of the patient care. As a general rule, practicing clinicians participate in guidelines formulation for other conditions.</li> <li>2. <b>Only academic researchers allowed.</b> Physicians who did not exceed this \$10,000 threshold and who believe in longer term treatment were excluded on the basis that they lacked experience sitting on guideline panels, IRB boards, or the peer review boards of medical boards. All of these requirements favor academicians and specialists over community treating physicians and internists. The favored ILADS Lyme clinician candidate, who met these qualifications (Betty Malone, M.D.), was rejected for this reason. IDSA received roughly 50 applications for the Lyme disease guidelines review panel. 20 from physicians receptive to the ILADS point of view—namely that patients with persistent Lyme disease should be treated until well. Not one of them was chosen.</li> <li>3. <b>Selection of panelists with preexisting bias against chronic Lyme.</b> Violating the AG's agreement which forbid the selection of panelists who had previously written Lyme guidelines, IDSA nominated Weinstein, who was an author of IDSA's 2000 Lyme guidelines; who worked closely with IDSA guidelines chairman Wormser on studies at NYMC; who was a co-author on the controversial Klempner study; who was on the safety monitoring board for the Lyme vaccines; and who was involved in the flawed western blot Lyme testing (Dearborn Conference). Because of this obvious bias and patient advocate protests, Weinstein was eventually removed. Panel chairwoman Carol Baker was a past IDSA president and had also authored pediatric Lyme guidelines (AMERICAN ACADEMY OF PEDIATRICS: Prevention of Lyme Disease.) Even though this was a clear violation of the AG action, she was not removed from the panel.</li> </ol>
1-28-2009	Halperin medical school lecture at Columbia University	<b>Halperin</b>	<p>Department of Neurology Grand Rounds: "Why is nervous system Lyme disease such a headache?"  The Neurological Institute of New York at Columbia University</p>
2-18-2009	Shapiro Lyme lecture at UC Berkeley medical school	<b>Shapiro</b>	<p><b>Lyme Disease: The Truth about Ticks</b>  Excerpts: Substantial evidence that there is no such thing as "chronic Lyme disease."  Politicization of science (akin to creationism vs. evolution issue)  Summary Points:  --Medically unexplained symptoms are common  --Cognitive behavior therapy is an effective treatment  --Associated pathology is rare and seldom missed, whereas psychiatric diagnoses are common and often missed"  (No honorarium)  <a href="http://events.berkeley.edu/?event_ID=15791&amp;date=2009-02-18&amp;tab=lectures">http://events.berkeley.edu/?event_ID=15791&amp;date=2009-02-18&amp;tab=lectures</a></p>
2-24-2009	<b>IDSA initially limited evidence submissions to 5 pages per person</b>		<p>In response to concerns raised by patient's organizations and physicians about the document submission process--which initially tried to limit submissions to five pages per person--the IDSA has changed its document submission process. The IDSA is now requesting that submissions be 10 pages or less, with an acknowledgment that they will consider all submissions regardless of length.</p> <p>Limiting evidence submissions to 5 pages shows a lack of serious resolve to consider three years of new evidence (in addition to evidence previously ignored) on the treatment and diagnosis of Lyme disease.</p>
3-21-2009	<b>IDSA fails to provide adequate notice to hearing evidence presenters</b>		<p>The IDSA sets an evidence hearing date of April 27, 2009, but fails to notify potential presenters of participation or location a month before the hearing date. IDSA is forced to delay the hearing to July 30, 2009.</p>
3-22-2009	Steere gives medical school Lyme lecture at Univ. of Maryland	<b>Steere</b>	<p><a href="http://medschool.umaryland.edu/buzz/March_2009.pdf">http://medschool.umaryland.edu/buzz/March_2009.pdf</a></p>
3-27-2009	<b>IDSA announces that its evidence hearing is closed to the public</b>		<p>Instead, the hearing will be aired live over the IDSA website. A taped archive will be available online after the hearing.</p>
4-1-2009	IDSA publishes a free physician continuing education course on Lyme disease	<p>Authors:  <b>Halperin</b></p> <p>Working Group:</p>	<p>IDSA CME Case Study Course for the Clinical Assessment, Treatment, and Prevention of Lyme Disease.  The CDC immediately posted a highly visible link to it from their main Lyme website, along with a link to the 2006 IDSA guidelines. Of all the nationally notifiable diseases, the IDSA guidelines are the ONLY third party set of treatment guidelines that are featured on a CDC disease website.  <a href="http://lymecourse.idsociety.org/LDCSC/Default.aspx">http://lymecourse.idsociety.org/LDCSC/Default.aspx</a></p>

		<b>Wormser Steere Shapiro Fish Mead (CDC)</b>	
4-6-2009	<b>IDSA announces new hearing date, limits testimony to only 1 day, 2 patient advocates given 15 minutes to speak</b>		Normally an evidence hearing of this type requires more than a day. Again, the IDSA is not showing a desire to listen to all the evidence.
4-14-2009	Halperin writes Lyme section of MedLink	<b>Halperin</b>	<a href="http://www.medlink.com/medlinkcontent.asp">http://www.medlink.com/medlinkcontent.asp</a>
4-23-2009	<b>ILADS Lyme clinicians submit over 1600 pages of analysis and research studies. Close to 300 pages of original analysis contesting IDSA recommendations.</b>		ILADS working group: Drs. Cameron, Stricker, Liegner, Maloney, Green, Phillips, Zackrisson, Tao Liu, Ph.D., Allison DeLong, M.S., Lorraine Johnson, M.D., and Barbara Blossom, B.A.
4-24-2009	Wormser gives Grand Rounds Lyme lecture at NY Methodist Hospital (2009)	<b>Wormser</b>	<a href="http://www.nym.org/upload/document/Department%20of%20Medicine%20Grand%20Rounds.xls">http://www.nym.org/upload/document/Department%20of%20Medicine%20Grand%20Rounds.xls</a> (accessed 5-21-09)
5-21-2009	Krause gives 27th Annual Connecticut Infectious Disease Society Meeting	<b>Krause Feder Cartter</b>	<b>Krause</b> -- Babesiosis <b>Feder</b> -- Three Connecticut Critters Stories (Pediatric Lyme) <b>Cartter</b> -- Epidemiology
5-30-2009	Shapiro CME Pediatrics course on Lyme at UC San Francisco	<b>Shapiro</b>	<b>Lyme Disease: The Truth about Ticks</b> Excerpts: Substantial evidence that there is no such thing as "chronic Lyme disease." Politicization of science (akin to creationism vs. evolution issue) Summary Points: --Medically unexplained symptoms are common --Cognitive behavior therapy is an effective treatment --Associated pathology is rare and seldom missed, whereas psychiatric diagnoses are common and often missed" <a href="http://www.ucsfcmc.com/2009/slides/MPD09001/21ShapiroLyme.pdf">http://www.ucsfcmc.com/2009/slides/MPD09001/21ShapiroLyme.pdf</a>
6-1-2009	<b>IDSA announces hearing presenters</b>		The speakers representing patient advocates are Tina Garcia, of the Lyme Education and Awareness Program (LEAP) and Lorraine Johnson, CEO of CALDA. Three researchers who are not affiliated with either ILADS or IDSA will speak: Drs. Brian Fallon from Columbia, Ben Luft from Stony Brook, and David Volkman, previously from the National Institute of Health (NIH). The following members of ILADS will be presenting: Drs. Daniel Cameron, Ken Liegner, Steven Phillips and Raphael Stricker. In addition, Allison DeLong, MS, of Brown University, and Dr. Donta, a member of IDSA, will present. Those advocating for the IDSA guidelines include Drs. Phillip Baker (President of the American Lyme Disease Foundation and previously with NIH), Barbara Johnson (Centers for Disease Control), Eugene Shapiro, Sunil Sood, Allen Steere, Art Weinstein and Gary Wormser.
6-29-2009	Wormser gives Grand Rounds lecture at Bassett Healthcare in NY (2009)	<b>Wormser</b>	<a href="http://www.bassett.org/edu/weeklycalendar.cfm?weekid=325">http://www.bassett.org/edu/weeklycalendar.cfm?weekid=325</a> (accessed 5-21-09)
7-29-2009	<b>IDSA requires complex registration process to view online hearings</b>		Complaints from Lyme patients, citing violation of patient privacy and the difficulty in registration, force the IDSA to drop the filter on online viewing. Again, another attempt to limit access to these "public" hearings
7-30-2009	<b>IDSA Lyme Guidelines hearing held in D.C., press and public access restricted</b>		IDSA Hearing Summary <a href="http://underourskin.com/blog/?p=250">http://underourskin.com/blog/?p=250</a>  Only a handful of IDSA-picked journalists are allowed into the hearing.
8-3-2009	<b>IDSA President Anne Gershon implies that Lyme guidelines will not be rewritten, immediately after hearing</b>		IDSA president Anne Gershon <a href="#">denied any IDSA wrongdoing</a> , saying, "IDSA's signing the agreement was not, as [Blumenthal] alleges, an admission of guilt, but an effort to end a fruitless investigation" and "The physicians and scientists who wrote the Infectious Disease Society of America's (IDSA) guidelines thoroughly reviewed all the medical evidence and took great care to address the claims made by the small minority of physicians who advocate long-term antibiotic use." Gershon went on to say, "The notion that the authors had financial conflicts of interest is absurd to anyone who has read the guidelines, which recommend generic tests and a short course of generic drugs."
8-31-2009	Wormser teaches Infectious Disease Board Review Course (2009) Faculty, National Infectious Diseases	Faculty: <b>Wormser</b>  Co-director: David Gilbert	Wormser presentation: <b>Lyme Disease: An Overview</b> : What do you need to know about pathogenesis, diagnosis, treatment, and prevention? Disclosures: Will discuss commercial products and/or services; <b>No commercial interest or affiliation</b> ; Will discuss off-label or investigative product use. Center for Bio-Medical Communication. (ID faculty are paid expenses and an honoraria of \$1,500-\$3,000 depending on experience.) <a href="https://www.idboardreview.com/Faculty/">https://www.idboardreview.com/Faculty/</a>
9-2009	Steere is section editor of the Lyme chapter in <i>UptoDate-Wolters-Kluwer Health</i> medical advice website (2009)	<b>Steere</b>	Excerpt: The term "chronic" Lyme disease is not technically correct as there is no evidence that the bacteria can survive after appropriate antibiotic treatment. There is no evidence that antibiotics improve post-Lyme disease symptoms. <a href="http://www.uptodate.com/patients/content/topic.do?topicKey=~3gC42m88uw9_uC&amp;selectedTitle=1~139&amp;source=search_result">http://www.uptodate.com/patients/content/topic.do?topicKey=~3gC42m88uw9_uC&amp;selectedTitle=1~139&amp;source=search_result</a>
10-29-2009	IDSA Annual Conference lectures by Wormser, Dumler, Steere, Beard (CDC)	<b>Wormser Steere Dumler</b>	--What's New in Tick-Borne Infections and their Diagnosis? (Dumler, Wormser) CME credits --Why is There No Vaccine for Lyme Disease? (Plotkin: Penn, Sanofi Pasteur, Wormser) --Relationship Between OspA and Lyme Arthritis (Steere) --The CDC View on a Lyme Disease Vaccine (Beard) --New Approaches to a Lyme Disease Vaccine (Ian Livey, PhD; Baxter) --A New Lyme Disease Vaccine is a Priority (Plotkin: U of Penn, Sanofi Pasteur)  <b>Wormser</b> disclosures: <b>Baxter Vaccine</b> (Consultant on upcoming Lyme vaccine) <sup>1</sup>

			<p><b>GlaxoSmithKline Vaccine</b> (Consultant on Lyme vaccine)<sup>2</sup>  <b>Immunetics Tests</b> (Research support on vaccine-compatible C6 ELISA test)<sup>3</sup>  <b>Bio-Rad</b> (Lyme test research grant)<sup>4</sup>  <b>Biopeptides</b> (Research grant, OspA Lyme diagnostics company, possible consultant)<sup>5</sup>  <b>DiaSorin</b>: (Research grant, C6 test)<sup>6</sup>  <b>Merck</b> (Lecture fees)<sup>7</sup>  <b>AstraZeneca</b> (Lecture fees)<sup>8</sup>  <b>Pfizer</b> (Lecture fees, antibiotic research for tick-borne ehrlichia)<sup>9</sup>  <b>Connaught Vaccine</b> (Ran vaccine trials, \$1.5M for 2yrs)<sup>10, 11</sup></p> <p><b>Steere disclosures:</b>  <b>GlaxoSmithKline</b> (Consultant on European OspA vaccine)  <b>Baxter</b> (Consultant on upcoming vaccine)<sup>12</sup>  <b>Novartis</b> (Paid lecturer for mfr of Lyme arthritis painkiller, Prexige, &gt;\$10,000. honorarium for writing arthritis chapter)<sup>13, 14</sup>  <b>Viramed</b> (Research grant for Lyme test kits)<sup>15</sup>  <b>SmithKline Vaccine</b> (Lead investigator vaccine trials, represented before FDA)<sup>16</sup>  <b>Connaught</b> (Consulting on vaccine and represented before FDA)<sup>17</sup>  <b>MedImmune</b> (Consulting on vaccine, represented in front of FDA)  <b>Imugen</b> (Consultant for OspA-less western blot test, success hinges on success of OspA vaccine)</p>
12-27-2009	<b>NIH Researcher supporting chronic Lyme resigns from IDSA evidence review panel</b>		Dr. Paul Duray resigns from IDSA evidence review panel due to a family illness. Duray is the only open supporter of the existence of chronic Lyme, leaving the Lyme advocates with a serious disadvantage in the voting process.
1-5-2010	ALDF posts Canadian/European "consensus" Lyme recommendations on website	Sue O'Connell  Reviewers include <b>Wormser</b> <b>Halperin</b>	<p>This poster abstract presented at a The European Union Concerted Action on Lyme Borreliosis (EUCALB) group gives the appearance of an independent body of Lyme experts coming to the same conclusions as the IDSA guidelines, when actually EUCALB is run by IDSA author <b>Stanek and Strle</b>, and ALDF (American Lyme Disease Foundation) directors <b>Fish, Shapiro, Wormser, Krause</b>; and scientific advisors <b>Fish, Steere, and Sigal</b>.</p> <p>"Recommendations for diagnosis and treatment of Lyme borreliosis: guidelines and consensus from specialist societies and expert groups in Europe and North America" O'Connell, S</p>
1-1-2010	Weinstein writes Lyme chapter of Bope: Conn's Current Therapy 2010 on MD Consult	<b>Weinstein</b> (2000 guidelines author)	<p>Bope: Conn's Current Therapy 2010, 1st ed.  Copyright © 2009 Saunders, An Imprint of Elsevier  Conn's Current Therapy 2010 provides concise and easy-to-use guidance on the latest advances in therapeutics for common complaints and diagnoses.  <a href="http://www.mdconsult.com/book/player/book.do?method=display&amp;type=bookPage&amp;decorator=header&amp;eid=4-u1.0-B978-1-4160-6642-2..00002-8--sc0135&amp;uniq=180960713&amp;isbn=978-1-4160-6642-2">http://www.mdconsult.com/book/player/book.do?method=display&amp;type=bookPage&amp;decorator=header&amp;eid=4-u1.0-B978-1-4160-6642-2..00002-8--sc0135&amp;uniq=180960713&amp;isbn=978-1-4160-6642-2</a></p>
1-8-2010	Adriana R. Marques (NIH) publishes Lyme Disease: A Review publishes in Current Allergy and Asthma Reports	Marques  Former collaborator with IDSA authors <b>Steere, Wormser, and Krause</b>	<p>Lyme Disease: A Review</p> <p>Co-PI NIH (7/1/09-9/30/11) Persistence in Lyme Disease, (Adriana Marques PI; <b>Peter J. Krause</b>, MD, co-PI)</p> <p>"At this point, the overwhelming evidence shows that prolonged antibiotic therapy, as tested in the clinical trials, does not offer lasting or substantive benefit in treating patients who have post-Lyme disease syndrome."</p>
2-1-2009	<b>A FOIA reveals that the IDSA violated the agreement terms to the voting process to favor no change in the guidelines.</b>		<p>On Monday, February 1, 2010, the Connecticut Attorney General sent a letter to the IDSA expressing "concern" over "improper voting procedures" used by the IDSA in the Lyme guidelines review voting process. The IDSA may soon approve hearing determinations based on this improper voting procedure. The IDSA is manipulating the voting process to favor no change in the guidelines.</p> <p>Internal IDSA memos reveal a deeply divided panel (4 yes, 4 no) on whether testing should be made mandatory for a diagnosis of Lyme disease, yet the gerrymandering of the voting procedure by the IDSA would allow this requirement to stand.</p>
2-5-2009	<b>IDSA procedural violations delay a guidelines rewrite by years, allowing conflicted IDSA authors to pursue commercial interests (vaccines and tests) supported by flawed science</b>		<p>During the almost 3 years since the IDSA Lyme guidelines investigation began, IDSA leadership has shown a consistent lack of concern, remorse or urgency in correcting possible inaccuracies and biases in the 2006 Lyme guidelines. As soon as Blumenthal's investigation was announced, IDSA's conflict-riddled panel launched a far-reaching campaign to disseminate their 2006 recommendations across the U.S. medical information network through physician continuing education (CME), medical textbooks, infectious disease board certification courses, online resources, and medical school lectures. (35 known information sites known to date.) So, even if the IDSA guidelines are revised immediately, it could take a year or more to remove flawed diagnosis and treatment recommendations from the system.</p> <p><b>IDSA Evidence Obstruction Summary:</b>  — <b>Panel selection:</b> Stacked the evidence review panel with IDSA loyalists and not a single Lyme-treating clinician  — <b>Evidence vote:</b> Eliminated this vote entirely, to avoid admission of "lack of evidence" for 2006 guidelines recommendations  — <b>Revision vote:</b> Elimination of the evidence vote biased the voting outcome to keeping the guidelines 'as is' because of the 75% majority vote requirement  — <b>Hearing:</b> At every turn, the IDSA has shown bad faith in an honest evidence-based review by placing unreasonable restrictions on evidence submissions, speaker time allotments, speaker venue notification, public access to hearings, and press access to the hearing.  — <b>Suppressed the seriousness of the author conflicts and controversy from the medical community:</b> IDSA leadership has continued to deny known violations of its own guidelines process, to the detriment of patient care. Their willful violations of the AG settlement agreement, which they helped to design, have allowed the conflicted 2006 guidelines authors to pursue commercial interests (vaccines and tests) with no repercussions.</p>
02-17-2010	Shapiro speaks on Northeast Public Radio on Dr. Jones hearing	<b>Shapiro</b>	<p>Doctor Eugene Shapiro argues that, on the contrary, the studies exist and scientific research simply doesn't support treating Lyme disease with years of antibiotics  <a href="http://www.publicbroadcasting.net/wamc/news.newsmain/article/1/0/1613196/WAMC.New.York.News/Lyme.Doc.Gets.Probation.Part.1">http://www.publicbroadcasting.net/wamc/news.newsmain/article/1/0/1613196/WAMC.New.York.News/Lyme.Doc.Gets.Probation.Part.1</a></p>
04-22-2010	IDSA panel unanimously votes to keep Lyme guidelines "as is"		<p>After reviewing 3,000 pages of peer-reviewed evidence challenging advice in its 2006 Lyme disease medical guidelines, eight Infectious Diseases Society of America (IDSA) panelists vote to change nothing in the 45-page document.  <a href="http://www.idsociety.org/Content.aspx?id=16501">http://www.idsociety.org/Content.aspx?id=16501</a></p>
04-23-2010	AG Blumenthal investigates allegations of improper voting procedures		<p>"The Connecticut Attorney General is reviewing the IDSA report to determine whether the IDSA has complied with the terms of the antitrust Settlement Agreement. His initial review of IDSA voting procedures on the guideline recommendations found the IDSA violated the agreement by rigging the vote to favor no change in the guidelines."  <a href="http://www.lymedisease.org/news/lymepolicywonk/404.html">http://www.lymedisease.org/news/lymepolicywonk/404.html</a></p>

Please send corrections and additions to krisnewby@comcast.net.

<sup>1</sup> **Wormser GP** et al. Self-disclosure of potential conflicts listed in *The Clinical Assessment, Treatment, and Prevention of Lyme Disease*. IDSA Guidelines. 2006.

<sup>2</sup> **Wormser GP**. Self-disclosed conflict in article Clinical practice. *N Engl J Med*. 2006; 354(26): 2794-801.

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- <sup>3</sup> **Wormser GP** et al. Self-disclosure of potential conflicts listed in *The Clinical Assessment, Treatment, and Prevention of Lyme Disease*. IDSA Guidelines. 2006.
- <sup>4</sup> Self-disclosure. "A Critical Appraisal of Chronic Lyme Disease." *N Engl J Med* 357;14. Oct. 4, 2007. [www.NEJM.org](http://www.NEJM.org).
- <sup>5</sup> Self-disclosure. "A Critical Appraisal of Chronic Lyme Disease." *N Engl J Med* 357;14. Oct. 4, 2007. [www.NEJM.org](http://www.NEJM.org).
- <sup>6</sup> **Wormser GP**. Self disclosure. IDSA CME Case Study Course for the Clinical Assessment, Treatment, and Prevention of Lyme Disease. April 2009. [www.lymecourse.idsociety.org](http://www.lymecourse.idsociety.org)
- <sup>7</sup> Self-disclosure. "A Critical Appraisal of Chronic Lyme Disease." *N Engl J Med* 357;14. Oct. 4, 2007. [www.NEJM.org](http://www.NEJM.org).
- <sup>8</sup> Self-disclosure. "A Critical Appraisal of Chronic Lyme Disease." *N Engl J Med* 357;14. Oct. 4, 2007. [www.NEJM.org](http://www.NEJM.org).
- <sup>9</sup> **Wormser GP**. Self disclosure. **Antimicrobial susceptibility of Ehrlichia phagocytophila**. [Antimicrob Agents Chemother](http://Antimicrob Agents Chemother). 2001 Mar;45(3):786-8.
- <sup>10</sup> **Lyme Disease Association**. Conflicts of Interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines. 2001. <http://www.lymediseaseassociation.org/ConflictReport.pdf/>. Accessed 1-21-07.
- <sup>11</sup> **Wormser GP, Nowakowski J, Nadelman RB**, Schwartz I, McKenna D, Holmgren D, Aguero-Rosenfeld M. Efficacy of an OspA vaccine preparation for prevention of Lyme disease in New York State. *Infection*. 1998 Jul-Aug;26(4):208-12. **1,634 patients enrolled**.
- <sup>12</sup> **Abbott A**. Steere self-disclosure in article Uphill struggle. *Nature*. February 2, 2006, 439: 524-25
- <sup>13</sup> **Steere, AC**. Case 11-2007. A 59-year-old man with neck pain, weakness in the arms, and cranial-nerve palsies. (Diagnosis: Neuroborreliosis) [N Engl J Med](http://N Engl J Med). 2007 Apr 12;356(15):1561-70. Self-disclosure of honorarium (>\$10,000) from Novartis, mfr of arthritis painkiller, Prexige, a company that benefits from the symptoms of under-treated Lyme disease. Also, <http://www3.interscience.wiley.com/cgi-bin/abstract/114203642/ABSTRACT?CRETRY=1&SRETRY=0>. Accessed 6-26-07.
- <sup>14</sup> **Steere, AC**. Self-disclosure. 2007 IDSA Annual Meeting presentation, "Lyme Disease: When Symptoms Don't Improve."
- <sup>15</sup> Self-disclosure. "A Critical Appraisal of Chronic Lyme Disease." *N Engl J Med* 357;14. Oct. 4, 2007. [www.NEJM.org](http://www.NEJM.org).
- <sup>16</sup> **Lyme Disease Association**. Conflicts of Interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines. 2001. <http://www.lymediseaseassociation.org/ConflictReport.pdf>. Accessed
- <sup>17</sup> **Steere, AC**. Disclosure in transcript. First formal meeting of the FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC). 6-7-94. (Need to find URL.)