

May 22, 2013

Editorial Board
Poughkeepsie Journal
P.O. Box 1231
Poughkeepsie, NY 12602

Dear Editors,

In response to Mary Beth Peiffer's article on Lyme disease, which appeared in the May 19th issue of the Poughkeepsie Journal, I respectfully offer the following response to counter-balance some of the distorted notions conveyed by that article. It is a perfect example of how one, unfamiliar with the complexities of the science and the actual events involved can "connect the dots" from about 7,000 old -- and often disconnected -- e-mails to construct the illusion of a conspiracy. What's even worse is how many people believe such "fiction" and embellish it with their delusions.

In 2006, I was invited by the Agency for Healthcare Research and Quality (AHRQ), the agency that posts clinical guidelines on its clearing house website, to discuss the results of NIH-sponsored clinical trials showing no benefit of extended antibiotic therapy for the treatment of "chronic Lyme disease" and their implications with respect to the International Lyme and Associated Diseases Society's (ILADS) guidelines, advocating an opposing point of view. The meeting was chaired by the Assistant Secretary of Health, Department of Health and Human Services (DHHS). At that meeting, I stated that the ILADS guidelines were deficient in that they: (a) did not provide a precise definition of "chronic Lyme disease" as a clinical entity, so that it could be distinguished from other non-infectious medical conditions (e.g., chronic fatigue syndrome, fibromyalgia, etc.) with similar symptoms; (b) failed to provide unequivocal clinical evidence to indicate that patients suspected of having "chronic Lyme disease" actually have a persistent borrelial infection that justifies antibiotic therapy; and, (c) failed to demonstrate, from the results of published, peer-reviewed, randomized, placebo-controlled trials, that extended antibiotic therapy is not only beneficial but also safe for the treatment of "chronic Lyme disease". The views that I expressed were later confirmed independently in much greater detail in a full report issued by the U.K. Health Protection Agency (see http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1294739293177). It should be noted that the obviously flawed ILADS guidelines were

removed from the guidelines clearing house, not as a result of any of the testimony presented at this meeting; rather, they were removed because ILADS failed to submit an updated version of their guidelines after they were posted for the allotted 5 year period of time. Obviously, the credibility of guidelines proposed by ILADS, a pseudoscientific organization with an undistinguished membership of about 300, as well as the similar views of those often referred to as Lyme Literate Physicians (LLMDs), should no longer be given credence and serious consideration.

The Infectious Diseases Society of America (IDSA), an organization composed of more than 8,000 outstanding scientists and physicians, independently developed and published their own guidelines on the prevention, diagnosis and treatment of Lyme disease; they were published in 2006. In contrast to the flawed ILADS guidelines, the IDSA guidelines do not recognize the poorly defined condition called "chronic Lyme disease" as a distinct clinical entity, and do not recommended prolonged antibiotic therapy. It should be noted that the recommendations of the IDSA Guidelines are almost universally accepted by experts engaged in basic and clinical research on Lyme disease and are in agreement with those of the European Federation of Neurological Societies, the European Union of Concerted Action on Lyme Borreliosis, the American Academy of Neurology, the Canadian Public Health Network, and the German Society for Hygiene and Microbiology, as well as with recommendations by expert panels from 10 European countries including The Czech Republic, Denmark, Finland, France, The Netherlands, Norway, Poland, Slovenia, Sweden, and Switzerland. None of these organizations or expert panels, as well as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) recommend the extended antibiotic therapy advocated by ILADS for the treatment of "chronic Lyme disease". Such unanimous support is precisely what one would expect to find when ones views are evidence-based and firmly supported by the facts; indeed, it would be ludicrous to suggest this represents collusion or favoritism, thereby challenging the integrity of outstanding scientists and the prestigious institutions that they represent. I am dismayed that The Poughkeepsie Journal would publish articles conveying such a distorted anti-science message. If patients can no longer believe and trust our very best research scientists, clinicians, and public health institutions, who have contributed significantly to the public health for the past many years, where should they go to get the advice and treatment they need? Obviously, not to ILADS or its disciples.

There is controversy about the existence of seronegative Lyme disease and the validity of the two-tiered diagnostic test that has been approved by the Food and Drug Administration (FDA) and recommended by the CDC for the laboratory diagnosis of Lyme disease. Much of the controversy is due to the failure to acknowledge two key observations. First, serological tests are not recommended for infections of less than 4 weeks, largely because detectable amounts of antibody are not likely to be present in the blood at that time, not because the tests being used are insensitive; this is the case, not only for Lyme disease, but also for other infectious diseases. It is an inherent limitation of virtually all serological tests, no matter how sensitive or specific they may be. At such times, the presence of a bull eye (EM) rash and/or clinical symptoms in patients living in Lyme disease endemic areas, where the risk of exposure to infected ticks is high, is considered to be sufficiently diagnostic and justifies the recommended course of oral, antibiotic therapy. There is nothing to prohibit a physician from prescribing antibiotic under such circumstances and confirming the presence of an infection later by tests conducted on convalescent serum; that is usually done. Second, there is ample published evidence -- based on well-characterized patient populations-- to indicate that, beyond 4-5 weeks of infection, practically all patients are seropositive by two-tiered testing which by then has a sensitivity and specificity of almost 100%. So, if a patient is seronegative under such circumstances, it makes good sense to consider the possibility that their very real symptoms might be due, not to Lyme disease, but to other causes that certainly merit proper medical attention and care. Most competent physicians would do that.

About 2-3 years before I became Program Officer for the National Institute of Allergy and Infectious Diseases's (NIAID) Lyme Disease Basic Research Program, the U.S. Congress mandated that NIH establish an NIH Lyme Disease Advisory Panel to facilitate the exchange of information and the development of co-operative interactions between those institutes of the NIH that support clinical studies and basic research on Lyme disease; representatives from the CDC and the FDA also were invited to serve on this panel which is required to meet at least once per year and more often if needed. The minutes of all past meetings of the panel are on file and are available from the NIAID who took the lead in chairing the panel, simply because NIAID supports most of the research conducted on Lyme disease. Therefore, it should not be surprising to discover that the NIH, CDC, and FDA work closely together on Lyme disease; not only have they been encouraged by the Congress to do so in this and other areas of scientific research (to avoid duplication of effort), but also it

makes good sense for scientists and clinicians to share the results of their studies with others working on the same or related issues to accelerate progress. That's just the way good science is done. This hardly constitutes collusion -- or a conspiracy-- as some naïve individuals believe to be the case. As a result of such close interactions, many of us have become better acquainted not only with each other, but also with scientists who actually do the research that is funded by grants from the NIH and other government agencies. As Program Officer for NIAID's Lyme Disease Basic Research Program, I managed the grants and therefore had personal contact and direct interactions with almost every well-known and accomplished scientist doing research on Lyme disease; that was an integral part of my job and is considered to be entirely appropriate and ethical.

One reason why I have not been supportive of some of the Lyme disease bills that have been proposed almost annually by Congress is not that I don't want to see more money spent on Lyme disease research; it is simply because what is being proposed in all of these bills duplicates work that is already being done by the NIH Lyme Disease Advisory Panel as part of its mandate. Because Congress seldom provides new money to implement the provisions of these Lyme disease bills, they then become essentially unfunded mandates; thus, if the NIH is mandated to create a Tick-Borne Diseases Advisory Panel, it must fund such a redundant activity from its current budget for research on Lyme disease. This would result in fewer grants to support much needed and important basic and clinical research on Lyme disease at a time when only the top 6-8% of grant applications are now being funded.

Lastly, with respect to the Banbury Conferences on the Laboratory Diagnosis of Lyme Disease, only individuals with well-documented experience (peer reviewed publications) in the development of diagnostic procedures and/or in assessing their strengths and limitations (specificity and sensitivity) were invited to participate. This was essential since these conferences were intended to focus specifically on diagnosis, rather than on a wide range of other clinical issues related to Lyme disease. I have no doubts that all of the right people were invited, and that these conferences were indeed "an in-depth and critical examination of the strengths and weaknesses of currently used diagnostic procedures and latest advances in the field". Although the proceedings were not published, the executive summaries of all past Banbury Conferences are on file with the NIAID as part of the public record. The recommendation and recent implementation of a reference specimen repository, funded by the NIH

and managed by the CDC in collaboration with the FDA, is now in operation and will surely accelerate the development of new and more sensitive FDA-approved diagnostic procedures for the early detection of Lyme disease. These panels of reference specimens will be made available to all working on the development of new diagnostic methods so that they can compare the results they obtain with their new assays to those obtained using existing conventional procedures. This is clearly a long awaited -- and much needed -- advance, and one that can help resolve many of the conflicts that have plagued the diagnosis of Lyme disease for so many years. It should be noted that the Banbury Conferences on the Laboratory Diagnosis of Lyme Disease were established in response to Lyme disease activists who falsely claimed that the NIH and CDC were doing nothing to improve diagnosis. The work presented at these conferences attests to the fact that the NIH and CDC have made -- and will continue to make -- significant efforts to develop and implement new, more sensitive and specific procedures for the diagnosis of Lyme disease, especially during its early stages.

Dr. Dattwyler whose work is funded by a Small Business Innovative Research (SBIR) research grant, has a long-standing interest in the identification and use of specific and well-defined *Borrelia* peptides for the diagnosis of early Lyme disease. He has recently published a paper on the successful use of one such peptide for the diagnosis of early Lyme disease in an ELISA test; the results obtained compare well with those of the existing two-tiered procedure, as well as the C6-ELISA. He is now examining the possibility of combining 5 or more such peptides in a single one-step assay for the better detection of early Lyme disease. No doubt, the specimens in the reference repository will enable him to compare the results obtained with his peptides to those obtained using other assays to determine superiority. This is truly exciting, cutting edge research. I am indeed proud to have assisted Dr. Dattwyler, as well as many other NIH grantees, in getting support for the outstanding work that they are doing. Clearly, positive efforts such as these will provide the knowledge we need to solve these and other problems related to Lyme disease.

Finally, I can't tell you how many vile, vicious, and profane telephone calls I received -- when I was Program Officer-- from various individuals who blame me, as well as the NIH and CDC, for all of the problems they've experienced over the past several years, including the enormous costs incurred from unproven therapies recommended by LLMDs. Although I always attempted to be as polite and responsive as possible, the same courtesies were not always extended to me. No

public servant deserves to be treated in such an abusive manner, and there is no justification for such aberrant behavior. To characterize such individuals as "loonies" might be too kind a description.

During my long scientific career, I have had the privilege of knowing many outstanding and dedicated scientists who do excellent work and really care about the public health. I am extremely proud to have been associated with all of them. Your biased article does them and all that they have accomplished a great disservice.

Sincerely,

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