

# Responding to a New England Journal of Medicine Critical Appraisal of “Chronic Lyme Disease”

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*This is an opinion piece by Dr. Joseph Jemsek, in consulting collaboration with other experienced colleagues. It is not intended to reflect an exhaustive critique of the many shortcomings of the “Feder” paper, but rather an attempt to highlight the most glaring incongruities and perplexing logic flows contained within what is considered a shameful and politically-motivated article. The purpose of this critique is to place disparaging opinion about persistent disease associated with Lyme Borreliosis on full exhibit.*

The subject of “Chronic Lyme Disease” was once again presented in a prominent journal setting in a recently published “review” in the October 4 NEJM article by Feder et al. As seen in several previously published reviews, opinions, and guidelines, the tenor of the publication is dismissive to physicians who feel that *Borrelia burgdorferi*, the causative agent of Lyme disease, may be responsible for persistent illness which requires long-term antibiotics and a myriad of other treatment considerations and measures. It seems to patronize the opinions of these physicians, opinions which are backed by hundreds of scientific publications and galvanized by countless clinical encounters with desperate and marginalized patients.

Published “reviews” on Lyme disease, similar to the Feder article, seldom offer any new or credible insight into clinical or scientific issues, and therefore their purpose and timing must be questioned. This article clearly echoes the stilted logic and highly suspect content promoted by the portion of the 2006 IDSA Guidelines which dealt with this subject matter and whose authors may come under anti-trust investigation. The repetitive arguments promoted by a select group of researchers and/or self-proclaimed “ad hoc” committee members – “the Lyme Cabal”, as we will refer to them, includes the high-ranking members of the CDC’s Vector Borne Branch, Johnson and Mead, and do nothing to further our understanding of what is making our population chronically ill.

In the absence of new ideas and with a history of rejecting meaningful dialogue with those who may disagree with them, Feder and associates appear to simply reshuffle authors and rearrange their template of imperial arguments for this most recent article. Again they employ the same indecipherable, distorted, and circular logic which they have displayed in the past, and appear to play favorites with their facts. Many of the authors cited are known to have ties to patented business ventures dealing with, among other things, future testing and vaccine development in Borreliosis-related ventures. We have serious concerns about propriety and integrity issues for both the Lyme Cabal constituents and for the NEJM, which has a heretofore irreproachable standard of excellence in publishing medical science. We also express serious concerns about the health of our population in terms of the continuing scientific “ambiguity” surrounding this disease complex, which we term *Lyme Borreliosis Complex* (LBC).

The review begins by indicating an **important fact** – that Lyme disease is a *serious public health problem* which is “complex”, but the tone of the article immediately thereafter becomes and remains, dismissive. LBC is trivialized through consistent application of journalistic phrasing techniques designed to give the reader a sense that the authors are annoyed that there is a fuss about this issue, and that their views have not been accepted without reservation.

Examples of these methods of literary intimidation and the abusive misuse of factual material are scattered throughout the text and are briefly portrayed as follows:

- a) This “serious public health threat” which is “complex” will “usually respond well to conventional antibiotic therapy.” The committee fails to provide evidence of what response is measured and by what methods.
- b) They further state that a “minority of patients” have symptoms which remain after “resolution...after antibiotic treatment.” Again, this assumes that all patients are diagnosed and treated, which is simply not fact, and again this statement defaults to the committee’s inflexible criteria for diagnosis and treatment.
- c) The committee further considers symptomatic illness as “usually mild and self-limiting”, and defines these patients as having “post-Lyme disease syndrome”, an arbitrary term adopted by the Feder camp years ago and thoroughly associated with ill-defined, non-organic illness through repetitive indoctrination with this brand of pseudo-scientific jargon on the unsuspecting medical community. “Mild and self-limited” is counter to the characterization of numerous other reports, and contradicts the authors’ opening remarks of a “serious and complex” illness. The terms “mild and self-limited” are subjective, and craftily inserted to prejudice the biased opinions which follow.
- d) After the initial paragraph, the word “complex” is no longer mentioned, as if the authors feel readers will forget the reference as it is plowed under by subsequent disparaging remarks.
- e) The committee stated that their review is “*not the objective manifestations of late Lyme disease but rather the imprecisely defined condition referred to as ‘chronic Lyme disease.’*”
  - i. ‘Objectivity is in the eye of the beholder. The more skilled and experienced the observer becomes, the better the tools available with which to measure; the better the understanding of the elements which comprise the universe of the subject matter at hand, the more “objective” the manifestations of the illness complex will become.
  - ii. The committee is derelict in not being more forthright about issues of objectivity; if objective measures are wanting, why not make efforts to improve them? The practice of medicine is suffering mightily as our practitioners increasingly rely upon guidelines and “cookbook” medicine, and not on what the patient communicates. We physicians are becoming more robotic, and why is that so? The physician must constantly listen to, and learn from the patient, especially when “testing” fails both provider and patient.
  - iii. The committee stumbles over the precise definition of an illness they initially state is “complex” and proceeds to wantonly blur the debate further by talking about, “not the objective manifestations of Lyme disease”, but rather “chronic Lyme disease”. This is classic double-speak on their part.
- f) The committee targets a “small number of practitioners”, not a subtle reference, the terminology of which is assuredly designed to reduce the number and significance of those with opposing viewpoints. The committee appears to mock physicians who “suggest” that persistent *B. burgdorferi* may require long-term antibiotic treatment, or that it may be “incurable”. They do so in such manner that suggests a whimsical allusion to futility, and implies in parallel analogy that patients who embrace this view are equally futile in their thinking.
- g) Declarative and unsubstantiated statements dominate the “review” as in “*the opinion of the committee is that Lyme disease includes a broad array of illnesses or symptom complexes for*

*which there is no reproducible or convincing scientific evidence of any relationship to B. burgdorferi infection*". First, note that this is an *opinion* but, in the setting of the Lyme Cabal publishing in the NEJM, this *opinion* equates to *dictum* and also, in our collective opinion, equates to an abuse of power by those who hold power in this setting. The lack of "evidence" reference, which glides so easily on the NEJM page, is easily countered by well-documented literature references indicating that the world at large is held hostage to unreliable and stifled testing which severely limits the ability of the practitioner to provide laboratory data in support of this aforementioned "complex illness".

- h) In the very near future, we predict that many of the Lyme Cabal will find it hard to explain the more than 200 patents they hold for better testing, vaccine development, and other business interests in the expanding universe of Borreliosis-related disease. Further, it may prove exceedingly difficult for the Cabal to explain why their involvement with these patents have been largely undisclosed, when the science at hand could have benefited the untold thousands whose lives have been unalterably changed by this chronic illness.
- i) Late in the publication, the committee uses the political and inflammatory term "Chronic Lyme Disease" as the heading of a new section, instead of **their** preferred term, "late Lyme disease". We ask the obvious question of why the choice to begin a section with something the committee says does not exist.
- j) The committee further makes vague and imperial comments about those diagnosed and treated for Lyme disease, as somehow being "substantively" different than those with other "recognized" infectious diseases. We are disturbed that a NEJM editorially-approved article would accede to a reference which equates to "intellectual cement" in academic medicine. At what point did the US academic universe decide that they had a handle on the mysteries of medicine? Over 90% of the most prominent chronic illnesses, e.g. MS, RA, Crohn's, etc., have no known cause. This is hardly a position from which to exude scientific arrogance. Diagnoses are, and always will be, integrally associated with varying clinical criteria, test interpretations, and physician judgment. Testing was designed to serve the will of the clinician and now it seems that the tail wags the dog. Generational change in medicine historically shows that 50% of what we hold as fact today will change, but which 50%?
- k) A disclaimer by an organization is an attempt by the rule makers to absolve all recriminations in perpetuity. To wit, as our authors and their alter egos at the IDSA suggest, (and as some of the committee's authors who took part in the 2006 Lyme Guidelines stated): *"It is important to realize that guidelines cannot always account for individual variations among patients. They are **not intended to supplant physician judgment** with respect to particular patients or special clinical situations"*. Why then would these committee members attempt to minimize the role of physician judgment in the diagnosis of any illness, especially a disease with the devastating impact of persistent Lyme disease? Clearly the committee is de-emphasizing clinical judgment and experience because they don't fully appreciate the roots of their discipline – the patient. This is a highly disturbing and dangerous thought for the profession of medicine and for the population which it serves.
- l) The committee criticizes the "lines of reasoning" to support a diagnosis of Lyme disease in those who do not show antibodies against *B. burgdorferi* in serum, particularly given the "the well-known immunogenicity of lipoproteins". They claim these "theories" of antibody negativity with LBC are not well-supported by scientific data. They fail to acknowledge that the testing reagents used in traditional labs are limited to only one strain (B31) in a disease in

which multiple *Borrelia burgdorferi* strains may play a role. They ignore the well-documented altered life forms of *Borrelia* species, (e.g. CWD forms, cysts, and blebs), none of which manifest lipoproteins. They fail to acknowledge the intracellular habitat of both helical and cyst forms, and the disturbing ability of the B31 spirochete to penetrate a series of neuronal and glial cell lines, as described in the 2006 Livengood CDC paper published in the summer of 2006. They fail to hypothesize or consider the notion that patients with LBC may have highly dysfunctional innate and adoptive immunologic effects.

As if not satisfied with yet another highly creative and biased interpretation of the data, the authors then turn to criticize “specialty labs” as not “FDA approved”. The FDA, which by the way acknowledges that current testing is unreliable, has nothing to do with credentialing labs unless a product is marketed, a convenient oversight by the authors. This “shoot the messenger” approach ignores the highly suspect and arbitrary manipulation of data and policy which took place at the 1994 Dearborn meeting and left the world without Osp A and B bands as qualifying criteria for diagnosis. This is a particularly mystifying situation since the ill-fated and ill-conceived LYMERix vaccine promoted by several of the Lyme Cabal was based on the Osp A, or kda band 31, lipoprotein antigen.

Most significantly, the authors fail to mention that much of the research done by several of the authors of their own committee, (when closely examined), supports the opposite view of what they express. Perhaps they should go back and re-study their own, earlier research. As stated previously, many in the Lyme Cabal are involved in various side-interests which include, but are not limited to, the patenting of diagnostic tests and/or components thereof, which we have referred herein. Therefore, we and others are concerned that these individuals might have a vested interest in dismissing any diagnostic or treatment modalities contrary to their “recommendations”.

- m) The committee uses “shock value” terminology to describe a minority group who treat Lyme disease – a handful of practitioners utilizing “unconventional” or “dangerous” methods to treat Lyme, as if they are the collective majority. The mainstream of providers does not fit their characterization, so these inferences are wholly unsubstantiated, unwarranted and malicious. To this end, the committee has a history of promoting the term “medical quackery” at every opportunity because its use resonates loudly as an alarm to the public. The authors know that libelous remarks directed against specific physicians or groups are very difficult to prosecute and that their public indignation makes for good journalistic copy without fear of reprisal.
- n) Further, the committee states that “*no other spirochetal illness including...tertiary syphilis is managed in an analogous fashion.*” Syphilis, caused by *treponema pallidum*, has a formidable and sinister history for causing human illness in past centuries, and in recent times has experienced a renaissance associated with the HIV/AIDS pandemic. Unlike *Borrelia burgdorferi*, *treponema pallidum* has only one host, the human, whereas *Borrelia burgdorferi* has many hosts. For the record, we use a “tongue in cheek” byword when referring to *treponema pallidum*, which we refer to as “Lyme’s DUMB Cousin.” We use this droll term based on comparative genomic profiling among spirochetal and other bacterial species, which **makes *Borrelia burgdorferi* the clear winner in the microbial genetic lottery.**

- o) The authors compare the duration of treatment for Lyme disease to that of tuberculosis, another predominantly intracellular infection. We are amused at the implications by the authors that tuberculosis is treated successfully for a relatively limited period of 6 months, compared to LBC which “*may go on for years*”. However, in the not so distant past, tuberculosis used to require 18 months or more of antibiotics. When better drugs became available and pulsed antimicrobial programs were employed, therapy was made more efficient and shorter in duration. Of interest, pulsed therapy is precisely the treatment methodology employed by the Jemsek Specialty Clinic and other Lyme-literate physicians in treating “chronic Lyme disease”. Furthermore, as experience is gained, treatment programs using combination antimicrobials, as is the case for tuberculosis and HIV/AIDS among many other complex infections, is also allowing for more efficient therapy of shorter duration in LBC.
- p) In terms of persistence, dozens of articles support this notion, including some of the authors’ earlier works. From a purely observational basis, if *Borrelia burgdorferi* is so easily dealt with in the infectious state, why does it proliferatively persist in hard-shelled ticks, various small and large mammals, and humans (not the end host). Why is it revered by microbiologists as the most uniquely and lavishly genetically-endowed bacterium on the planet, and why is it being so heavily patented by Universities, researchers and others, including the majority of the members of the committee who performed the NEJM review?
- q) Approaching the stratosphere of arrogance, the committee goes on to summarize Lyme disease into 4 convenient categories, like shoeboxes lined up in a row for shoeless and illiterate providers, without vote or consensus via any authorized committee or organization which would consummately arrive at these “categories”; and yet these were blithely published by the NEJM. So, because they must be addressed, we will do so.
- i. They do not accurately encompass the majority of Lyme disease patients.
  - ii. They choose to ignore patients who present to their physicians with clear *erythema migrans* rashes and other clinical symptoms of Lyme disease, but who are told they “do not have Lyme”, because the physicians do not recognize its clinical manifestations, or are relying on *surveillance* criteria definitions, and inaccurate laboratory testing.
  - iii. These individuals are then not treated, and go on to develop Lyme disease in a chronic form.
  - iv. They also do not address patients who are misdiagnosed with other illnesses such as MS, ALS, RA and CFS.
  - v. The committee assumes at all points that patients are treated appropriately for their illness, and yet in fact, most patients receive little or no treatment, which is why they remain *chronic*.
  - vi. In patients with positive serology and no objective symptoms, the Bb-associated illness may be subclinical, as research proves that Bb remains dormant within the body for extended periods of time, from months to *years* after infection. Some of the committee members’ own research clearly states this.
  - vii. Category 4 disease, as newly crafted and defined by the Lyme Cabal, has had an embarrassingly small number of treatment trials upon which to draw these conclusions. Further, in eschewing the study and expansion of the scientific and clinical horizons for the innumerable issues which remain to be addressed in this illness complex, the authors make it clear that they are content to remain entrenched in their existing dogma

perhaps until it is “time to announce the Lyme epidemic” and bring out the new tests and vaccines. The most prominent of the studies mentioned above was performed by Dr. Mark Klempner, a committee member who also happens to be on the editorial board of the *New England Journal of Medicine*. If the NEJM is an *objective* medical journal, we ask why this fact was not made prominently apparent for its readership.

- r) The committee is disdainful about antibiotic therapy causing “considerable harm” to patients, but fails to mention that all medical treatments have inherent risks. This allowance by the editor of the NEJM is in and of itself, unpardonable. Further, the authors fail to present a balanced representation of the patient populations in question. They fail for example, to mention that untreated and dismissed chronic Lyme patients commit suicide at alarming rates due to the hopelessness and agony associated with this illness.
- s) The committee members claim those running clinical studies have had “difficulty” securing patients who meet the criteria of their obviously biased studies – such as the elimination of 500 people who were excluded because they lacked a “substantiated history of Lyme disease.” Substantiated by what account? Most Lyme patients have *no substantiated history* of Lyme disease because doctors are *missing the diagnosis* and *failing to treat* these patients...more circular logic. Again, the committee is myopic in arriving at its conclusions about the scarcity of patients, either those “well-documented” or who develop “clinically significant problems” after “conventional treatment.” We would like to provide the benefit of the doubt to the Lyme Cabal and pray that their glossing over and misinterpreting/ignoring or trivializing consistent and debilitating patient issues are not intentional.
- t) There are untold thousands of individuals in our country and around the world who live unfulfilled and tortuous lives due to the political situation surrounding LBC and consequent access to quality care issues. A symptom of the rudimentary state in which we find ourselves is made evident by the authors suggesting that eligibility criteria for controlled trials require symptoms be “severe enough to interfere with the patient’s ability to function”. This line of reasoning is simply astounding in its unsophistication and insensitivity. The committee’s statements about controlled trials and documented disease history is admirable and would be more so if the medical community was fully engaged in an environment in which, as in HIV research, the best minds were involved and funded in the pursuit of the study of this illness complex. Patients know what has made them better and it is highly insulting to patients who are denied care or who had irreversible adverse health consequences to themselves or their loved ones because of suspect motivations by those who now hold power.....almost certainly the patient’s interest is not the primary concern in this story.

## IN SUMMARY

Open attempts to intimidate the Connecticut Attorney General, physicians, and patients are not lending credibility to those who are perpetrating this behavior. Nevertheless, the politicization of an illness for which many people are tragically suffering, and who are afforded very little credence by the scientific community *when evidence shows their illness is real*, and who are subjected to increasingly narrow treatment options, may indeed be approaching not only anti-trust violations, but **scientific fraud** on a grand scale.

The public confusion comes not just from the myriad of symptoms or the restrictive definition of the illness itself, but also from physicians and patients who are well aware of the illness within their own bodies, and who are confounded by the unwillingness of the scientific community to embrace a medical illness of such major significance. Rather, many perceive an increasing plaintive and obvious disregard for the welfare of thousands of patients by a small number of individuals entrenched in power and trapped within their logic loops, whether these loops are genuinely believed, or contrived. Inaction is somehow justified on the basis of a lack of double-blind, randomized studies. Regrettably, there also appears to be a barrier to publication of dissenting views by the editors and reviewers of established journals. The public, including some physicians, *do* know how to read, after all, and patents and a pattern of interpretative reversal in research opinions speak volumes about the truth of LBC. So does successful resolution of symptoms through open-ended, long-term antibiotic treatment of Lyme disease. In this complex illness, therapy is most often successful, i.e. life restoring, when it is patterned on an increasingly sophisticated understanding of the many interwoven issues involved in the illness, and in the successful integration of therapies which address the immunosuppressive, multi-systemic, polymicrobial disease complex which is LBC. Most of us deeply involved in patient care don't care who takes credit for change, and realize that traditional powers must engage for this to happen. We encourage this at every opportunity. Physicians and patients are earnestly waiting for the truth to be revealed, and we hope that this truth will arise from the medical community in a proactive and vigorously engaged manner. LBC is just part of what is driving an epidemic of unwellness and chronic illness in this country. The paradigm of medicine and chronic illness must change over time.....too many of us are sick and getting sicker.

[1] Feder HM Jr, Johnson BJB, O'Connell S, Shapiro ED, Steere AC, Wormser GP, and the Ad Hoc International Lyme Disease Group\*. *NEJM*. 2007 Oct 4;357(14):1422-1430. A review article

[2] Wormser GP, Dattwyler RJ, Shapiro ED, Halperin JJ, Steere AC, Klempner MS, Krause PJ, Bakken JS, Strle F, Stanek G, Bockenstedt L, Fish D, Dumler JS, Nadelman RB. "The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America." *Clinical Infectious Diseases* 2006;43:1089-1134.