

Contentious 9 Hour WG Meeting: Persistent infection a Religious Belief? WG Co-Chair Says Yes



Pat Smith Describes Pre-Meeting Effort to Minimize Lyme.

Below in [For the Record](#) are the written comments LDA President Pat Smith, a public member of HHS TBD Working Group read (slightly compressed) into the record at the Working Group (WG) meeting on July 8 about the potential WG Chapter report for which she was responsible, the only one addressing patient issues. 89 written comments/deletions to the report had been suggested before the meeting by Working Group members. Working Group Co-Chair Dr. David Walker and Member Eugene Shapiro were responsible for moving to delete entire sections of Lyme material from the report, many of which called for the removal of much of the Lyme material and the de-emphasis of Patient Access to Care in the Chapter.

Co-Chair Says “almost religious belief that it’s a persistent infection”

https://lymediseaseassociation.org/wp-content/uploads/2020/07/TBDWG.2020-07-08_Religious.Belief.mp3



David Walker, MD,
Tick-Borne Disease
Working Group

At the meeting itself, Working Group Co-Chair, Dr. David Walker, and Member Eugene Shapiro made and seconded many motions to remove material from the proposed draft report including the two sets of guidelines, shared decision making, access to care, Lyme treatment trials, and cost of Lyme disease. There was also a discussion in which Shapiro and Walker wanted to remove Lyme mouse model studies and other animal studies that showed persistence that were included in the draft report, saying animal models were really not a good use for this infection.

Dr. Walker said there is “[emphasis on belief...almost religious belief that it's a persistent infection](#)” and at various times said they probably didn't have Lyme to start with. After many hours of this discussion, no other WG members would second the motions for removal.

For the record: The importance of today's meeting and our Chapter review can't be overstated. My Access to Care, Education & Training subcommittee including healthcare providers and patients, with expertise in the problems associated with patients' access to care including physician education, submitted a 75-page subcommittee report and additional 45 citation pages documenting these problems to get

help for a body of patients neglected especially those who develop the most serious stage of Lyme and to prevent acute patients from reaching that stage. Patients looked to this WG created through legislation initiated by, written by, and pushed through Congress by Lyme patients/advocates. In 2019 through now, 78% of comments to the online WG mailbox were about TBD/Ticks, 70% of those TBD comments were on Lyme disease and 81% of those were on chronic/persistent/PTL, not acute.

Before the January 2020 Working Group meeting, WG members were instructed to read each subcommittee report. Subcommittee co-chairs presented reports at that meeting. In my subcommittee case, since I had not had an active co-chair for a while, a subcommittee member stand-in, not permitted to vote or ask questions, was allowed to present with me a PowerPoint, including Subcommittee rationale and recommendations later discussed, modified, and voted upon.

Then, writing groups of 2 WG members each were solicited for each Chapter to be written for the WG report to Congress. The WG was definitively told that all information for the WG report had to be taken from the Subcommittee reports. I asked if newly published information, for example, could be used, was told, yes, but then the WG would have to approve that new material. Recently activated WG alternate member Captain Scott Cooper and I volunteered to write the Chapter we're presenting today.

As directed, we pulled language from the subcommittee reports, submitted our Chapter for review and was told "well organized, appropriate to audience level, and it flowed logically," but we needed to "rebalance" the chapter as there was too much information on Lyme disease and access to care than other tick-borne diseases and education. Suggested rebalancing included removing a factual table from CDC which listed TBDs for 3 years, in descending order of reported case numbers, as the table could "inadvertently diminish the importance of

other tick-borne diseases because their numbers are much lower.” It was OK that we led with burden of disease (cost, quality of life, & productivity), compelling reasons for Congress to act. However, we should remove those items from **our** Chapter report background and put them into the background for the **entire** WG report, despite the fact they were developed specifically for our patient issues. Bottom line: minimize Lyme, reduce access to care.

We incorporated additional other TBD material from subcommittee reports into the Chapter and shortened the Lyme portion. We didn’t remove the table, since it factually portrayed reported case numbers, nor did we remove our background material germane for our specific patient issues. After another review submission, we were told the Chapter was “starting to become balanced” but now it was too long. We needed to shorten it. We again shortened to include removing the redundant list of recommendations upfront, already elsewhere in the Chapter.

All WG Chapter Writers had a deadline to post draft Chapters to a WG private Share Point site. WG members had a May 22 deadline to submit comments there on all chapters. **All Chapter language was now up for grabs**, we were told, even the language we took from the already discussed Subcommittee reports, not just new language. I objected, since that seemed to contradict process discussion at the prior meeting. Significantly, I objected to the lack of process transparency, which was directing these online SharePoint discussions to be behind the scenes—not WG members in public holding transparent discussion with all WG members, embodying the intent of a FACA Working Group. Time went by with no response to my objection, so I reluctantly decided to proceed with filing for resolution through a FACA complaint, but I was subsequently informed my concerns were heard, and all discussion would now be in public, as we are doing today so I did not proceed with the complaint.

While working in the private SharePoint site, I stumbled across an unknown person who had direct access to all Chapters and material in the site. Research showed me this individual was from NIH, not either the NIH Working Group member or alternate—another NIH employee, an attorney. Upon questioning the individual's identity and purpose, I was informed NIH requested that that individual be allowed access to our SharePoint documents and was given access. It appears that government employee WG members have rights public members do not have, are not aware of, and do not have to be informed of. Since public members are considered special government employees, I requested to federal officials that I be permitted to have a patient advocate attorney in SharePoint to review for patient perspective. I was informed my request was denied by WG legal counsel.

These items coupled with others such as a WG member who did not attend being allowed to vote by proxy through the co-chair, without knowledge of the WG, and the unexplained delay in releasing these draft Chapters to the public prior to this meeting for their review and comments before the WG vote are concerning, and refusal to provide the public with government inventories as agreed to at the April meeting. I questioned those practices, which in my opinion, exhibit a disregard for the public, in particular, the patient community. History coupled with these practices reinforce the sentiments of many in the public that they are again being deceived by their own government.

As we move forward on our Chapter section now, note that our printed report has 12 pages with internal citations to address the decades-long problems of hundreds of thousands of Lyme patients plus other tick-borne diseases patients. Additionally, there are 7+ printed pages of comments from SharePoint made by WG members on our Chapter, a number of which call for removal of much of our documented material on Lyme disease— a disease under-reported by a factor of 10

according to CDC studies and CDC testimony by Lyle Peterson to a Senate Committee, (1) meaning about 350,000 cases annually. According to NIH, Lyme is a disease that makes up 82% of tick-borne diseases, (2) and there were 74 Lyme deaths in 2017. (3) Thus, our Chapter focuses on the tick-borne disease whose patients comprise the largest burden of disease, Lyme disease. That is balance. Captain Cooper, I now turn further Chapter discussion to you.

[\(1\) CDC Vector-Borne Diseases Director, CDC Lyle Peterson to the Senate Aging Committee September 5, 2019](#)

[\(2\) NIH says Lyme 82% of tick-borne disease cases](#)

[\(3\) NIH says 74 deaths in 2017.](#) NOTE: I had accessed this info prior and printed out the information. Link no longer goes to the page. NIH asked at the meeting where I got that death data as they could not find it anywhere. I have sent it to them.

TBD Working Group Meeting Summary/Public Comments Now Available – June 4, 2019

The federal Tick-Borne Disease Working Group (TBDWG) held their ninth meeting in D.C. on June 4, 2019 with a focus on developing the next report to be drafted for the HHS Secretary and Congress. The report will include an update on federal tick-borne disease activities and research findings.



Still pending: Archived Webcast, Slide Presentation

Institute of Med.: Lyme Wrkshp Rept.

The Institute of Medicine (IOM) released its Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes Workshop Report, on April 20, 2011.

In a move designed to protest the National Institutes of Health's (NIH) use of the IOM to conduct a workshop NIH was charged with organizing, the Lyme Disease Association (LDA), Time for Lyme (TFL), and the California Lyme Disease Association (CALDA), pulled out of the IOM workshop process and did not submit their commissioned scientific paper to the IOM committee. The three groups raised strong objections to the IOM process which:

1. permitted bias on the workshop committee and lack of transparency.
2. failed to satisfy the intent or objectives as delineated in Congressional Appropriations language.

On September 29, 2010, Congressman Christopher Smith (NJ) introduced for inclusion in the Congressional Record, "The Patient Perspectives on the Research Gaps in Tick Borne Diseases," which he stated was written by "three of the Nation's largest Lyme disease advocacy organizations [LDA,

CALDA, TFL], who represent tens of thousands of patients.”

Links are provided below to review the IOM workshop proceedings, Lyme group actions, the Congressional report and the IOM workshop report.

[September 20, 2010 Lyme Disease Association Press Release- Non Compliance Causes Lyme Patient Groups to Withdraw from Scientific Meeting](#)

[September 29, 2010 Congressional Record 111th Congress Report- “The Patient Perspectives on the Research Gaps in Tick Borne Diseases”.](#)

<http://thomas.loc.gov/cgi-bin/query/z?r111:E29SE0-0367:>

[October 5, 2010 Lyme Disease Association Press Release- Research Gaps in Lyme Disease Exposed in the Congressional Record](#)

[April 20, 2011 IOM Workshop Report](#)

http://www.nap.edu/catalog.php?record_id=13134

Petition: Grps’ Withdraw from IOM Forum

Sign up here! Let Congress know you support decision by LDA, TFL and CALDA to withdraw from the Institute Of Medicine’s (IOM) State-of-the-Science Lyme and Tick-Borne Disease Workshop.

Please let Congress know you support the move by LDA, TFL and

CALDA to withdraw from the NIH/IOM State-of-the-Science Lyme Disease and Other Tick Borne Diseases Workshop by reading the statement below and completing the response form. LDA will send your reply directly to Congressman Christopher H. Smith (NJ). It will not be used for any purpose other than this project. Thank you!

Lyme Groups Withdraw from Scientific Meeting

I support the move by the national Lyme Disease Association (LDA), the California Lyme Disease Association (CALDA), and Time For Lyme (TFL) to withdraw from the National Institutes of Health (NIH) sponsored workshop. I agree that the above groups should not participate in nor submit the Institutes of Medicine's (IOM) commissioned scientific paper to the Panel in protest of the IOM's workshop about the state of the science regarding Lyme and tick-borne diseases. Despite the 3 groups' repeated requests for transparency and a balance of scientific viewpoints, as delineated in Congressional Appropriations language, neither the hearing panel nor the speakers selected by the IOM satisfy the Congressional intent or objectives.

The IOM's mission was to provide an "independent, objective and non-partisan" program and there are no scheduled speakers with opposing viewpoints of similar scientific weight to balance Infectious Diseases Society of America (IDSA) presentations about the research gaps in Lyme disease. Many state-of-the-art scientific researchers, experienced clinicians and patient advocates have been relegated by the IOM and NIH to spectator positions. I believe that this amount of bias undermines the integrity of the scientific workshop and that its final report will reflect this lack of objectivity.

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[For more information](#)

[Lyme Groups Press Release](#)

[Institute of Medicine \(IOM\) Lyme and other tick-borne diseases workshop meeting description](#)

Non Compliance Causes Lyme Patient Groups to Withdraw from Scientific Meeting

In a move designed to protest the Institute of Medicine's upcoming Lyme disease workshop, three of the nation's largest and most influential Lyme groups have pulled out of the process.

**NIH Does Not Comply with Congressional Appropriations Language
Lyme Patient Groups Compelled to Withdraw from Scientific Meeting**

September 20, 2010 – In a move designed to protest the Institute of Medicine's upcoming Lyme disease workshop, three of the nation's largest and most influential Lyme groups have pulled out of the process. After much deliberation, speaker Diane Blanchard, co-president of the Time for Lyme (TFL- CT) has withdrawn from the panel. The national Lyme Disease Association (LDA- NJ) and the California Lyme Disease Association (CALDA), along with TFL, will not participate in the workshop and their IOM commissioned scientific paper will not be submitted.

The scientific workshop was promoted by the Institute of Medicine (IOM) to be a

conference about the state of the science regarding Lyme and tick-borne diseases. Despite the groups request for transparency and a balance of scientific viewpoints, as delineated in Congressional Appropriations language, neither the hearing panel nor the speakers selected by the IOM satisfy the Congressional intent or objectives.

The IOM's mission was to provide "independent, objective and non-partisan" advice to policy makers, yet the majority of the participants sitting on its Lyme disease panel belong to the Infectious Diseases Society of America (IDSA), a medical society with a known bias. Many key speaker roles were given to physicians who are IDSA members and supporters, a number of whom were involved with the IDSA's controversial guidelines for Lyme. IDSA's Lyme guideline development process was investigated by the Connecticut Attorney General which resulted in exposing the guideline panel as being riddled with undisclosed conflicts of interest.

In spite of the recommendations to NIH by Congress, the conference opens with perhaps the most polarizing figure in the chronic Lyme debate— Dr. Gary Wormser of Westchester Medical Center – who chaired the IDSA Lyme guideline panel and whose highly controversial biased views are well known. There are no scheduled speakers with opposing viewpoints of similar scientific weight to balance his presentation about the research gaps in Lyme disease. Many state-of-the-art scientific researchers and experienced clinicians have been relegated by the IOM and NIH to simply spectator positions.

The patient-oriented Lyme groups believe that this amount of bias undermines the integrity of the scientific workshop and that its final report will reflect this lack of objectivity. "We believe the entire process has the potential to cause additional harm to patients. After much deliberation our only recourse is to withdraw our support for this seriously flawed process. From the inception, TFL, LDA and CALDA have communicated our concerns, which were ignored. We remain hopeful that NIH/IOM will revamp the program to comply with the Congressional language which was responsible for initiating the workshop," the groups said in a joint statement.

Time for Lyme, www.timeforlyme.org, the national Lyme Disease Association, www.LymeDiseaseAssocation.org, and California Lyme Disease Association, www.lymedisease.org, are non-profit organizations that were founded by individuals who had personal experience with Lyme disease, in order to address the lack of research, education and support services available for this emerging infection.

Institute of Medicine Review of Lyme