

# TBDWG 16 – Fight Continues for Patient Relief: Get Patients Diagnosed & Chronic/Persistent Lyme Recognized



Photo from LDA Archives: Elizabeth Maloney, MD; Capt. Scott Cooper, PA, CMS; and Pat Smith, LDA at January 29, 2020 WG meeting

The 16<sup>th</sup> meeting of the Federal Tick-Borne Disease Working Group (WG) took place 10.27.20. Public commenters urged the WG to acknowledge and act on the changes needed for patient relief. In review of report chapters, contentious arguments continued, with Pat Smith again advocating passionately on behalf of chronic Lyme patients. (Below items are not in agenda order; quotes are from recorded transcript).

***Smith in WG meeting on geographic boundaries preventing Lyme diagnosis:*** “I lived in the world of patients for 36 years, and I can tell you that they are not getting treated in those states [low incidence states] because the government and other

*entities are telling them there is no disease. They are consistently not being diagnosed and treated, and you think this because there is a positive test they will get treated? No way. That doesn't happen. To do this is the kiss of death. You will put another nail into the coffin of people in these states and to do this without even being willing to make changes to the language, I find it totally unconscionable."*

## **Chapter 8: Epidemiology and Surveillance Review (2.5 Hours of Contentious Discussion of Diagnostic Testing)**

Pat Smith stated "Since Lyme disease has the burden of illness within TBD and testing is one of the biggest issues, why is that not discussed in this report?" Emphatically explaining position: "We have a whole section on major challenges and issues and I didn't see Lyme disease mentioned as far as diagnostics, and it's unbelievable to me that after 46 years, and after the time since 1994 at Dearborn when the test were developed, that we consistently say the tests are appropriate, and I think something is to be put in that section about Lyme disease." After further discussion Smith reiterates, "I think it [Lyme] definitely needs to be entered in, and the huge significance that it holds for Lyme patients, it is one of the major reasons that they are not getting diagnosed and they are not getting treatment." David Walker responded, "Lyme disease moves more slowly and there is ample opportunity and a much better opportunity to make diagnosis." Pat retorted, "David, you don't think there's any Lyme disease beyond a few weeks and a few Doxy pills, and I think the time has come that we have to acknowledge there is ample research out there to show it isn't true, and that diagnostic tests are not picking up our patients, and it's time we did something about it! I don't know what we are waiting for. And I'm not asking for the moon in this chapter but asking merely for something that addresses the fact that there is a need and obviously the government has to look at that need." Walker responded, "I'm aware that Lyme disease can lead to death. Cardiac arrhythmia...that can happen.

But Post Treatment Lyme Syndrome pathogenesis is unsettled." After further discussion, there was WG agreement to make changes to include Lyme.


**Surveillance:** Captain Scott Cooper provided a comment regarding Bayes Theorem and "prior probability that the patient has Lyme disease." His comment, "All of Bayes Theorem depends on prior knowledge and assumptions, when there is not sufficient information to form these assumptions, the premise that Bayes Theorem is helpful is incorrect. Instead the important thing is to develop the underlying knowledge base. This is why the CDC conducted 3 studies that increases its estimate of Lyme disease from 30,000 to 300,000 cases. Likewise we need to look at all available data (laboratory tests, insurance claims, etc.) to determine ground truth about prevalence and incidence in an area before we 'assume' we know the distribution of the disease. This is a circular argument. The assumption that pre-test probabilities are accurate depends on whether the Bayes theorem analysis is correct. As pointed out above, the accuracy of Bayes Theorem here is flawed because we do not know the ground truth about the incidence of Lyme." When asked to explain comments, he responded, "So I was saying it needs to be clarified, that I wasn't buying the base there and that analysis." Ben Beard, "You disagree with the prospect of how pretest likelihood predictive values fit into this? Or do you think that in states, the bar is fairly low for establishing Lyme disease to be, in states like Colorado? If it were common you would at a minimum see a lot of EM rash with tick bites. That constitutes probably 80% of the reported Lyme disease cases."

Discussion continued with topic of travel related reporting, with Smith using Florida as an example of endemic Lyme disease, but for years, reported cases were often deemed travel related but the State of FL had checked out those cases and many were not travel related. Ben Beard, "I think I understand what Coop and Pat are requesting is an open door to

emphasize things that pretest likelihood and probability is important and a limitation, and that we are still learning the area of risk, and it's changing and acknowledging that." Walker had made a motion to retain the paragraph as originally written. Smith again contested Beard's comments, "I would like to say first of all that it's bothersome to me and then you touched on this, that the area of risk is changing, and that is exactly what I think we are talking about. First of all, the surveillance that is done in a lot of the states that are considered 'low incidence' is not good. They hardly have any surveillance. You may be funding them now but they have not been traditionally funded to do tick surveillance and often times when they do surveillance, they do show up that they are – there are other types and perhaps those ticks may be transmitting and nobody is really looking at that issue because I don't think anyone wants to look at that issue." (Pat was referring to other proven competent tick vectors for the Lyme disease bacterium, like *Ixodes spinipalpis* and *Ixodes angustus*, known to be endemic in many deemed 'low incidence' states in which little or no tick surveillance is occurring). Surveillance definition, and the problem of positive results automatically being deemed as false positives because they are originating from states that are deemed "low incidence" is an issue that Smith continued to fight as she explained, "That is going to cause patient death.... That is what diagnostic is with Lyme disease, it IS surveillance definition, therefore in the states already considered low, so that they already cannot get diagnosed and treated, and now you are further emphasizing to their position." Walker responded, "Of course they can be treated. Signs and symptoms of Lyme disease and confirmed with laboratory tests but everyone would treat this." Smith responded to Walker, **"I lived in the world of patients for 36 years and I can tell you that they are not getting treated in those states because the government and other entities are telling them there is no disease. They are consistently not being diagnosed and treated, and you think this because there is a positive test they will get treated? No way. That doesn't**

happen. To do this is the kiss of death. You will put another nail into the coffin of people in these states and to do this without even being willing to make changes to the language, I find it totally unconscionable.” She held strong in defense of patients, “David, you don’t know what goes on with Lyme disease in patients and you don’t know the difficulty.” The motion was again brought forward to retain the original language in the paragraph, the motion failed, Smith prevailed. Suggestions for additions & changes continued. The WG group will review revisions next meeting.

**“Streamlining” CDC Reporting:** Ben explained “The problem we are having is that reporting changes constantly and the way it is right now it is unsustainable...As it is now you’ve got states, some states that are following it and some states that are not, because it is too burdensome and it changes every few years. It is comparing apples to oranges. What we want to accomplish for surveillance is to have a system where it stays the same so we can really understand burden in print and how it is changing and what is going on.” Pat Smith: “As you know, this is certainly something that we advocates have been looking for a very long time.” The WG agreed to the verbiage of a “standardized” rather than a “streamlined” reporting system.



A review: "Studies in Pyroplasmosis hominis ('spotted fever' or 'tick fever' of the Rocky Mountains)" by Louis B. Wilson and William M. Chowning, published in *The Journal of Infectious Diseases* 1:31-57, 1904

[E. A. Oroszko](#)

• PMID: 399367

• DOI: [10.1093/infdis/1.3.57](https://doi.org/10.1093/infdis/1.3.57)

No abstract available

Reference proposed by WG Co-chair, David Walker, to document fatality rates for RMSF is both dated (1904)

and inaccessible.

**Citations:** Although lack of citations sometimes happens, extended discussions occurred when Pat Smith requested that more current and relevant resources be used to cite the percentages used in the paragraph citing untreated Rocky Mountain Spotted Fever (RMSF) fatality rates. Pat specifically requested that references more current than the published review of a 1904 reference provided by Walker be inserted to represent the current, rather than historical fatality rate, especially because the 1904 information is not even accessible. Pat expressed "Our citations are supposed to be ones that someone can find and look up and that is substantiating what we put there." Walker argued, that in 1941 [another reference used by Walker], preceding the use of antibiotics, the case fatality rate was 74%. Pat responded, "It would be interesting and appropriate if it was a discussion of the history of research and the fatality rates. But that is not what we're looking for. We're looking for current fatality rates." Walker defended that untreated fatality percentage numbers are still relevant by saying "The organism hasn't changed, and people have not changed." Pat contended that "people back then did not have the same amenities, and so on to survive that we have here in our country today." The exhaustive discussion described historical percentages as well as percentages for different parts of the world where this disease occurs, (Pat cited a CDC study addressing a possible more virulent strain in Brazil that has a higher fatality rate but says US rates lower) and clarified that the issue is not that RMSF is not a serious disease that can result in mortality if left untreated. The issue is that the resources cited are extremely dated and inaccessible. Pat reiterated "We need current data, not old data." The WG agreed to revise with a more current citation provided by Ben Beard.

**Minority Reporting (Discussion to get Smith motion passed to**

**prevent removal took 1 hour):** This chapter contains the minority report, which was written by Pat Smith and submitted in April after a “no” vote, addressing “Effect of Geographic Restrictions on Lyme Diagnosis. It specifies why the “diagnosis by geography” proviso should not have been removed from the WG report as a recommendation to Congress. The original recommendation which was in the patient access chapter was *CDC provide input to the Council of State & Territorial Epidemiologists, CSTE, that the Lyme disease surveillance case definition be revised such that it abandons the use of geographic parameters for the diagnosis of Lyme disease and inform clinicians and the public that Lyme disease has been reported in all states.*

Because changes over the past two weeks in WG minority report process appeared to have occurred between meetings through a string of emails, Smith wanted to insure that her minority report remained in place, so she moved that her “..minority report shall remain in Chapter 8 where it was placed after she followed the working group procedures then in place, she having voted no to the recommendation the minority report addresses at a public working group meeting, and having submitted the minority report for Chapter placement on April 17, 2020. The minority report was placed where it has remained in Chapter 8 for all WG members to see after placement and discussion of many iterations of the Chapter. There is no requirement for her to vote against the Chapter for it to remain there, as she has voted no to the recommendation.”

Lengthy and confusing discussion ensued following the motion regarding the process and requirement for minority reporting. Smith stated, “I do not agree that we should have minority reports if you don’t vote no on some aspect.” Smith further stated, “A consensus process means you go in with the idea that you are going to work to a common goal and hopefully gets to where everybody agrees.” The WG works through a consensus process. Smith stated, “we had these values in place which is

all about collaboration where we are trying to put forward the best report." Further Smith explains, "if a person does not have to accept responsibility, they are not on the floor making a vote and expressing their dissatisfaction by voting no for a certain segment, the accountability is tremendously diminished." She goes on to say "We are allowing somebody to go off and give a proxy vote to somebody else. In my opinion that abrogates the entire process that we go through sitting at a table and having our discussions." The discussion continued until Jim Berger interceded, "This is the response that I got from legal counsel in regard to the minority responses. They stated, minority responses are included in the report when members of the working group disagree with the recommendation or agrees with the recommendation, but disagrees with the verbiage that the members add to provide their support. If there was total agreement to the verbiage that was added to the chapter supporting the recommendation, then there will be no need for minority response." Ben asked, "How do you know there is a minority if there is no vote?" After even more discussion regarding whether a vote is required or not in order to write a minority report, Smith moved the WG vote on her original motion for the 3<sup>rd</sup> time, and the vote passed unanimously. To resolve the total issue of minority reporting Smith stated, "I would like to make a motion at this time, that in order for the minority report, a person has to vote no against either the report or some portion of the report." The motion was further clarified to state "the report chapter or some portion of that chapter," and the vote again passed unanimously, putting this issue to rest.

**Shapiro pushes back:** Shapiro had left the meeting during the discussion of minority reporting and upon his return to the meeting, he was extremely disgruntled when he realized that the group had passed a motion requiring that one must vote in the minority on a chapter report or some portion of the chapter report in order to write a minority report. He was



reminded that he had left his vote with Walker during his absence from the meeting discussion...and Walker had voted yes on the motion for both of them. Because Shapiro had asked Walker to cast his proxy vote in his absence, he voted 'yes' to the motion.

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After lunch, Chapter 11: Looking Forward, Chapters 1: Background, Chapter 2: Methods, and the Table of Contents and Title Page were all reviewed and motions to accept the chapters passed. In the Looking Forward chapter, however, language suggesting that the next working group perform outreach to other stakeholders, including industry, was challenged by Pat Smith who said it needed to be restricted to preclude industry being put on the WG. The two co-chairs argued the point, but Pat Smith indicated the legislation creating the WG does not include industry category, which Jim Berger concurred with when asked. Industry could be on subcommittee or as a speaker. Co-Chair Soltysiak did not want to put on restrictors. A motion was made to keep language as is, which passed with a no vote by Smith and Cooper. The concerns expressed were conflicts of interest from industry, and changing the intended nature of the WG. Smith and Cooper also voted no to the Chapter itself.

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### **Chapter 3: Tick Biology, Ecology, and Control Review**

This chapter review and discussion was uneventful with request for added citations for data sources and maps.

### **Chapter 4: Clinical Manifestations, Diagnosis, and Diagnostic Review**

Again, Walker and Shapiro expressed issue with Donta's paragraph that describes the lack of IGG and IGM antibody response in patients with Lyme disease. Walker stated in the

comments that “this paragraph contains opinions that are not sufficiently evidence based.” After much discussion, revisions were made to this paragraph to state that “In the absence of being able to prove that there was persisting infection in patients it’s not possible to say a patient did or did not have (Lyme disease).” Additional citation changes were again requested by Smith as she has repeated throughout the review of chapters. She stated, “it’s amazing to me...for one disease we have to document 50 times over and for others we don’t have to provide citations.” Ben agreed to locate some of the references requested. A vote to accept this chapter was postponed until next meeting. Entering into Chapter 5, many WG members announced that they would have to leave the meeting before completing review of all chapters on the agenda.

### **Chapter 5: Causes, Pathogenesis and Pathophysiology Review**

Review of this Chapter was uneventful, with only a few suggestions from Smith for reference citations to be added regarding Alpha-gal Syndrome and NIH. A motion to accept this chapter passed unanimously.

### **Chapter 6: Treatment Review**

Walker asked that Donta make changes to the paragraph that discusses the success of long-term antibiotic trials between patients receiving long-term antibiotics versus placebo. Walker’s intent was to highlight that long-term antibiotics used in the studies did not show any better symptom resolution than patient’s receiving the placebo. Donta agreed to revise the paragraph. Pat again requested additional references to support the content of this chapter. A decision to hold on voting until Donta reviews the chapter.

### **Chapter 7: Clinician and Public Education, Patient Access to Care Review**

At this point in the day, WG members questioned whether there was time to get through this chapter, or to postpone until the

next meeting. Smith responded that "our chapter only has like 3 comments, or maybe 4, and some of those are reference comments I believe, so hopefully it's going to be quick." Shapiro then announced, "I have a minority report for this chapter which is why I did not make comments." Sam Donta suggested that perhaps the WG should postpone so that they could work through Shapiro's comments and edits, and Pat said "I would personally like to go through, when you set an agenda and say you will be done at 4pm, how many meetings are done at that time/ We always get put on the end, and I think we need to go through. If we have to do it then let's go through first the ones we already have, then let's see what Gene has to say." At that point more WG members stated that they would have to leave the meeting due to other commitments and that they "prefer to delay until we can have the full group discussion." Walker then said, "I too have a lot of comments...they must not have gotten recorded, but they would form the basis for a minority report." Pat retorted, "if it helps, we will make changes to what we have but I will be honest, we have made enough changes now, I don't know we will make more changes to anything we have before. We have whittled it down and removed and recited and reworded with things in all places and chapters. Now you want to push us off to the next meeting so you can spend another two hours on our chapter. I don't get it." Shapiro made a motion to adjourn. With many WG members already having left the meeting and given their proxy vote to other WG members, the motion to adjourn passed, 8 yes, 2 no, 2 abstain.

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## **National Framework**

Ben Beard provided a more detailed description of the recently published A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans that he announced at the September meeting. Of note was the statement that "there is an increasing risk of all human

vector-borne diseases... and the US is not prepared to deal with these diseases.” Key partners and stakeholders will be working together on this strategy, including public and patients. View the National Framework which Beard announced at the September meeting of the WG here: <https://www.cdc.gov/ncezid/dvbd/framework.html>

## **Public Comments**

Verbal public comments were delivered by seven people including critical care nurse and mother of a child with Lyme, Janice Sutton. Janice described the horrifying experience that she and her daughter have gone through in attempting to get both an accurate diagnosis and appropriate treatment stating, “Doctors are only as good as their toolboxes, so let’s give them the tools they need to better help people.” Dorothy Leland, VP of Lymedisease.org and mother of a child with Lyme disease, urged HHS to “choose patient representatives who actually want to represent patients.” Leland stated that Pat Smith, as the sole patient representative on the current WG panel, “has done an excellent job, but it is unfair to our constituency and individuals to expect any one person to carry such a burden.” She urged that the process must be transparent and patient representatives “should be nominated by or endorsed by patient advocacy groups.” She requested HHS select three “true advocates who are not afraid to go on the record for those that they represent” for the next WG panel. Phyllis Mervine, President of Lymedisease.org spoke to the issue of the CDC incidence maps and how they are hurting patients in California. Mervine explained, “the CDC Map downplays the incidence of Lyme disease in all but a handful of states” which is making it “more difficult for people with Lyme to be diagnosed in states not designated high risk by the CDC restrictive accounting system.” Mervine asked the WG for “a simple, quick and cost free fix,” which is “to ask the CDC to revert back to the previous style (of mapping).” She concluded that “the simple change would impact the health of all

Americans irrespective of geographic regions.” Patient advocate, Carl Tuttle had received no response to an email that he sent to the WG regarding evidence of persistent Lyme infections after antibiotic treatment. So he asked Dr. Ben Beard “what is the motivation for suppressing evidence of persistent Lyme disease after extensive antibiotic treatment and claiming there is no evidence?” He ended with a quote from Dr. Kenneth Liegner, ‘ In time the mainstream handling of chronic Lyme disease will be viewed as one of the most shameful episodes in the history of medicine because elements of academic medicine, government and virtually the entire insurance industry have colluded to deny a disease.”

### **Public Comments Subcommittee**

Co-chair Leigh Ann Soltysiak presented tables from the Public Comments Subcommittee, which summarizes incoming written public comments: priority areas/key themes through September 2020. New comments as well as recurrent themes received in August/September 2020 included:

- “Alpha gal sufferer requests 100% transparency of all food and drug ingredients and training of medical personnel”
- “EVOLVA (Company) EPA testing NOOTKATONE for insecticide and repellent development”
- “Request that Multiple chemical Sensitivities (MCS) be included in the TBDWG report to Congress”
- “Concern that CDC guidelines for Lyme management create challenges and obstacles for patient care, reimbursement and treatment”
- “Lyme disease treatments should be covered by medical insurance”
- Need for better testing, treatment and increased research funding for Lyme disease”
- “Concern that TBDWG members allegedly referred to persistent Lyme infection as a ‘religious belief’”

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The 17th meeting of the WG will take place on November 17th, 2020 from 9:00 am- 5:30 pm, ET. This online meeting is open to the public. Written comments and requests to make verbal comments must be received by midnight ET, Friday, November 6, 2020. For more information and registration visit HHS TBDWG here. Comments may be sent directly to the WG through email at [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov).

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Read LDA articles summarizing past meetings here.

Read blog by Lymedisease.org VP, Dorothy Kupcha Leland here: TOUCHED BY LYME: Shapiro and Walker tried having it both ways. It didn't work.

Read blog by Lymedisease.org VP, Dorothy Kupcha Leland here: TOUCHED BY LYME: What's true Lyme patient representation?

Read article by Lymedisease.org President and Founder, Phyllis Mervine here: A simple, quick and cost-free fix-ditch the misleading Lyme map