House Lyme Disease Caucus 2020

The House Lyme Disease Caucus is a bi-partisan group working together in Congress to take action on Lyme & tick-borne diseases. Under the leadership of Congressmen Chris Smith (NJ) and co-chair Colin Peterson (MN), it has initiated letters and actions to benefit Lyme patients, such as the inclusion of the monies for Lyme & tick-borne diseases into the Congressionally Directed Medical Research Program (CDMRP) and language and Lyme monies into Appropriations over the years and initiated favorable legislation. Additionally, it has queried government agencies over policies not favorable to patients. This has reminded the agencies that someone is looking over their shoulder. Many meetings have been held and educational sessions in DC for Congress.

If Representatives are interested in signing up they can contact the offices of Congressman Christopher Smith (NJ) or Colin Peterson (MN).

Pat Smith, President & Rich Smith, Vice President of the LDA met in Wall, NJ, with Congressman Chris Smith, Co-Chair of the House Lyme Caucus, to

discuss what actions can be taken in DC to help those with Lyme and to stop the spread of Lyme & other tick-borne diseases, 4/19/2017

List of Current House Lyme Disease Caucus

Smith, Christopher H. (R-NJ-04), Co-chair
Peterson, Collin C. (D-MN-7), Co-chair
Cohen, Steve (D-TN-9)
Connolly, Gerald E. (D-VA-11)
Courtney, Joe (D-CT-2)
DeGette, Diana (D-CO-1)
Delgado, Antonio (D-NY-19)
Hartzler, Vicky (R-MO-04)
Higgins, Brian (D-NY-26)
Holmes Norton, Eleanor (D-DC)
Keating, William R. (D-MA-9)
Kennedy, Joseph P. (D-MA-4)
King, Pete (R-NY-02)
Krishnamoorthi, Raja (D-IL-08)
Langevin, James R. (D- RI-02)
Lofgren, Zoe (D-CA-19)
Malinowski, Tom (D-NJ-7)
Maloney, Sean Patrick (D-NY-18)
McGovern, James P. (D-MA-02)
Moulton, Seth (D-MA-06)
Peters, Scott (D-CA-52)
Pingree, Chellie (D-ME-01)
Pocan, Mark (D-WI-02)
Posey, Bill (R-FL-8)
Reed, Tom (R-NY)
Rose, Max (D-NY-11)
Stefanik, Elise (R-NY-21)
Steil, Bryan (R-WI-01)

Thompson, Glenn (R-PA-15)
Tonko, Paul (D-NY-20)
Wexton, Jennifer (R-VA-10)
Wittman, Robert J. (R-VA-01)

More about the Caucus

The bipartisan Congressional Lyme Disease Task Force, co-chaired by Rep. Chris Smith (R-NJ) and Rep. Collin Peterson (D-MN), is dedicated to educating Members of Congress and staff about Lyme and other tick-borne diseases, as well as advancing initiatives that are designed to help the estimated 400,000 Americans who develop Lyme disease each year and all of those living with the disease.

As co-chairs of the bipartisan Task Force, Rep. Smith and Rep. Peterson lead annual appropriations requests in support of Lyme disease research through the Department of Health and Human Services and for research funding at the Department of Defense. In 2015, the caucus secured for the first time ever, $5 million in funding in the House Appropriations Committee annual military spending legislation, which was adopted in the Fiscal Year 2016 funding bill which was signed into law, and will provide resources for Lyme disease research through DOD's innovative, high-risk, high-reward program. Subsequently, the CDMRP continued to be funded, and $7 million was secured for 2020.

The caucus helped advocates secure another major win for Lyme disease. In December of 2016, the United States House of Representatives passed, and former-President Obama signed, the 21st Century Cures Act. The Cures Act included language – similar to a bill that Rep. Smith introduced previously – which created the interagency Tick-Borne Disease Working Group. Specifically, the Working Group (WG) under the auspices of HHS, is comprised of federal and non-federal members tasked

with reporting to Congress on scientific advances, research questions, surveillance activities and emerging strains in species of pathogenic organisms. Patients, advocates and treating physicians sit at the same table with government officials. In 2018, the WG sent a report to Congress with recommendations on Lyme and other tick-borne diseases.

Sentinel Canine and Human Seroprevalence Data Provide Insight to Number of Lyme Infections

A new study published in *Infectious Disease Modelling* examines the relationships between incidence, prevalence, and total infection burden for Lyme borreliosis (LB) using sentinel canine and human seroprevalence data.

The researchers developed two models to estimate LB cases. One analyzed seroprevalence of *Borrelia* infections in human samples, applying corrections for false negative and false positive results from published test sensitivity and specificity measures. The second modeled *Borrelia* infections in sentinel dogs to quantify the prevalence of LB infections in humans. For this model, the researchers referenced human and canine infections in Germany as a baseline.

Both models were conservative and referenced published data based on medical insurance records coded for *erythema migrans*. The researchers used linear model growth rates rather than the common exponential growth models. The mean of the two models was applied to create estimates for various countries and continents.

For the year 2018, examples from the analysis for estimated LB include: incidence – USA 473,000/year, Germany 471,000/year, France 434,000/year and UK 132,000/year; prevalence – USA 2.4 million, Germany 2.4 million, France 2.2 million and UK 667,000; total infections – USA 10.1 million, Germany 10.0 million, France 9.3 million and UK 2.8 million. World estimates for 2018 are: incidence 12.3 million/year; prevalence 62.1 million; and total infection burden 262.0 million (Cook & Puri 2020).

The researchers conclude that, "These figures are considerably higher than officially published data and reflect not only the underestimation of diagnosed cases, which is acknowledged by health agencies, but also undiagnosed and misdiagnosed cases."

Read the study, "Estimates for Lyme borreliosis infections based on models using sentinel canine and human seroprevalence data" in *Infectious Disease Modelling.*

11th Hour Attempt to Commandeer & Rewrite Patient Chapter Fails

LDA Pres. Pat Smith, Capt. Scott Cooper, Chpt 7 Co-writers, at prior mtg.

BACKGROUND: The 17th Working Group Meeting turned out to be a referendum on the Patient Chapter of the upcoming 2020 Working Group report. The previous 9 months of the WG had seen that chapter content consistently eroded by comments from just a few WG members which forced shortening of chapter, removal of material, rewriting of material, and moving around of material. The terms “chronic Lyme” and “persistent Lyme” could not be used and had already been removed. Now, more changes and even a complete chapter rewrite were called for. Differences in IDSA Guidelines, LDo’s patient registry information, shared decision making permitting doctors to tell patients about different treatments, and peer review that questioned conclusions of the NIH studies were all under attack and subject to removal/more revisions after 9 months of scrutiny and changes made to accommodate numerous objections each meeting.

Chapter Co-Writers Pat Smith & Scott Cooper refused to do any more changes. A Donta/Smith motion was made to accept the

Chapter as written (with one clarification). It was voted on after about an hour of often contentious discussion including a rebuttal to the NIH objections (already previously addressed) to the chapter by Smith"…**"the 11th hour and what is (a) surprise, you want to deep-six the report. The only report that addresses what happens with patients. I'm sorry that you think the NIH is sacrosanct.** So much that the bodies of people that were charged with doing research and talking about what research should be done were not even willing to take in chronic Lyme disease research. That's why we couldn't get it done or published. That's happened for years. … **I happen to think that we have to do something for the hundreds and thousands of people over the years that have been affected. The government doesn't want to do anything about it, so I don't know why you're sitting at this table if you don't want to do something.** We have compromised plenty and removed tons of stuff…. Compromising on the fact that Lyme disease is the most prevalent tick-borne disease affecting the most people, and it's more people who aren't able to get treated because the government doesn't want to recognize they are sick. You want to send them all to psychiatrist."

TECHNICAL DIFFICULTIES WITH TRANSCRIPT BELOW: *The following article provides quotes from the automatically produced transcript downloaded during the WG meeting. The transcript often contains inaudible/ garbled material due to HHS meeting software/phone connections. Where possible, LDA has listened to the audio recording and supplied the actual word(s) in parenthesis. So that the dialogue presented makes sense, sometimes a sentence between quotes in italics is provided by LDA, indicating other WG discussion took place. The bolding in quotes has been done by the LDA to emphasize the most significant lines. You can listen to the actual audio transcript of Pat's Smith Rebuttal at the bottom of this article. (click here)*

Actual Dialogue of Pat Smith's Rebuttal to Attempt to Rewrite/Remove More Material From the Chapter 7 Patient

Report: The following section is from the audio/written transcripts downloaded from the Working Group meeting.

WALKER: You've taken advantage of being office (AUTHOR) of a chapter to launch into topics that have nothing to do with the chapter that you don't want to put into the report. It has nothing to do with supporting the recommendations of the chapter.

COOPER: They do support it, plus as Jim noted with the charter of the working group, one of the things is affordable access for patients to care that stores health.

WALKER: You need to get that into recommendations. And I hope to do it because you have not done it effectively at all, anything to do with access to care for the recommendations of this chapter.

SMITH: I don't think so David. We've done this for many hours. Hours and hours. More than probably the rest of the working group reports put together. We addressed these comments that don't have any real specific asks, it doesn't support, it's been all the way through. I don't think we need to go any further. I think we have done our part, and we are willing to move along because we don't feel that we need to discuss this any longer.

WALKER: You took two and half hours to delay moving to the meeting and that is what took all the time from the last meeting.

SMITH: Excuse me, that was not my issue. Because you work behind the scenes to change protocols, and then you did not want that brought up in public. I brought it up, and I'm very happy that I did.

DIXON: Further discussion of individual comments is not going to get us any further. I think we have had ample communication and differences of opinion have been expressed, but we have

not come to consensus, so we need to vote on the overall chapter, because it's not the individual comments of the overall some of the balance of the chapter. I feel there's not an overall balance of the chapter and I'm uncomfortable on the lack of balance and the misrepresentation or the depiction of the clinical trials overall. They are listed as preempts there is trials done and two additional trials done under grant it's the overall focus on the minority finding of those studies rather than the overall preponderance of evidence adding to that the overall depiction I think that's a good way to characterize. I think what we need to do is call to a vote and see how many people feel that way and how far apart we are before wasting additional time on individual comments that really aren't the point.

SMITH: I would say Dennis, thank you for your honesty and I know you're espousing what the party line is. **The party line for 46 years has been let's bury the patient's. I've worked for 36 years and (AS) an advocate for those with chronic Lyme disease and I have never in my life seen the hatred that I've heard from some people in this group over providing information that is totally verifiable.** We have sources coming up but you don't want to accept them. David doesn't want to accept the (THEM) or Schapiro. I don't know who else want to accept them. Nobody else gets the same scrutiny.

This group was willing to accept a 1904 piece of citation in this report. But we have citations coming up in the best institutions over many years, and you don't want to accept it.

…you can't say chronic or persistent Lyme (EXISTS). I think the community is tired of it.

So now we get to the 11th hour and what is (a) surprise you want to deep-six the report. The only report that addresses what happens with patients. I'm sorry that you think the NIH is sacrosanct. So much, that the bodies of people that were charged with doing research and talking about what research

should be done, were not even willing to take in chronic Lyme disease research. That's why we couldn't get it done or published. That's happened for years…The NIH is not sacrosanct.

I happen to think that we have to do something for the hundreds and thousands of people over the years that have been affected. The government doesn't want to do anything about it, so I don't know why you're sitting at this table if you don't want to do something. We have compromised plenty and removed tons of stuff.

Compromising on the fact that Lyme disease is the most prevalent tick-borne disease affecting the most people, and **it's more people who aren't able to get treated because the government doesn't want to recognize they are sick. You want to send them all to psychiatrist.** I've had people who I know personally that have been put into institutions and weren't able to be treated (for Lyme disease)…This includes children. I'm sick of it. I saw children seizing in the 90s from Lyme disease and hospitals…**It's a tragedy that's gone on too long. Somebody has to do something.**

I had higher hope that this group was going to be able to do something and I am disappointed. I shouldn't be, because my hopes should not have been that high…I agree that **we need to do something for these people who are suffering.**

DIXON: That's why I'm so committed to the resource section on how we need to explore and understand better the pathogenesis and suffering of the individuals, so that we can intervene with the most appropriate methods (in a scientifically rigorous fashion.)

MISSING TEXT

SMITH: (You had 46 years to do the pathogenesis and get it solved. Let's look at COVID. Let's see what was done) in the 9 months time. (….Look what has been done just in that time

period.) **You had 46 years. And what did you do. You covered up a disease.** I remember it from the 80s, from the 90s, you tried to cover it up as a disease you try to cover it up as a (IT) spread, then you went and covered up (Babesia) where it was. **And it isn't just CDC, it's the NIH, too. It's about time somebody stood up and said we have to do something that directly impacts getting help for these people.**

MISSING TEXT

DIXON: We are trying to uncover, not cover the mechanisms (of pathogenesis and understand the basic transmission) and clinical means to address that.

SMITH: And you didn't have time enough or money enough. I saw the inventories. I know what you did. I know what you should've done. But no, that was not done. I only saw a couple of years of those inventories and so you're never getting to the bottom line. **People said it this morning. Where's the help for the patient. There is none and now you want to remove their chapter? Well go ahead.**

I'm going to tell you what – we're going to do things with Congress that this group cannot do. Because it's obvious that some of you don't want to do it. And again please, the other people in the group, and you know you are, I'm not speaking to you right now. I'm speaking to these people who have prevented this from moving forward. **It's just unbelievable to me how a few pages of the chapter have been so attacked.**

LDA comment: The below references MyLymeData registry…

WALKER: I believe the survey you did and there really is exemplary of a group of people, **thousands of people that you've surveyed who are suffering and they definitely need to be helped and we don't really know what's wrong with them. The problem is they are self-reported saying that they believe they have persistent Lyme disease.**

SMITH: If you would have listened to the prior meeting, (David you would have heard)

WALKER: They really don't… they just say they've had Lyme disease, and the high rates of co-infection with respiratory illnesses like mycoplasma and (Bartonellosis)…These people definitely do need help but the help may not be Lyme disease. And if it is Lyme disease we need to understand how.

SMITH: We discussed this patient registry… The people in that registry were asked if they had the doctor diagnoses, and if they did not they were removed from the registry. **There's tons of patient registries and you just want to pick on this one because it doesn't meet your needs. This is typical…**But the rest of the patient registries of the world that the NIH have or that the CDC have or other agencies or other respected institutions have. You don't come out and say anything about those. Those registries are used everywhere. You only care because this one shows the true extent of problems across the United States and across the world. **You've had 46 years to do the research about what's wrong with these people if this isn't what they have. Not only have that (HAVEN'T YOU) done it, you've relied on mainstream medicine, which means they can't get more treatment in any way shape or form. They are not permitted.** They are told to go to a psychiatrist, even alternative medicines, (Nope, forget it you can't.) That's unconscionable, unconscionable.

DONTA: I move that this chapter be accepted with possible minor revisions.

WALKER: Sam would you be willing to break that into two sections on the recommendation and the content of the chapter?

SMITH: He cannot, because we've already voted on the recommendations.

DONTA: That is a part of the chapter David. So unless we want to hear from other members of the working group, my motion

stands that we move to accept Chapter 7 into the report.

SMITH: I second that.

SOLTYSIAK:…So now is (AS) a working group at this 11th hour. We are supposed to compromise and decide (WHAT) we want to represent. And guess what. We have that opportunity for the minority report. If we voted something down, we can choose to still put them in our (MINORITY) report (GOING) forward. I think we just have to agree to the process…

SMITH: That's correct. I would certainly be very happy that we proceed on this boat (VOTE). **And if it goes down, I'd love to be able to present to Congress how this working group voted against a chapter, the one for the patient's.** And the one that the patient had that (THE) input into, and had it well-crafted and well done, and spent hours of discussion on, then I'd be very happy to do that, and we will do that (IF THAT HAPPENS). So let's move on and get the boat (VOTE) going.

Some more procedural comments made by Donta, Soltysiak, Dixon, Berger

SMITH: I would like to say something about the fact that these comments that are put in here, were put in here by David. They are the same, (COMMENTS THAT HAVE BEEN) in there before, in the last meeting. And he didn't put these comments in there (TODAY). So therefore, he cannot go back now and put these comments in and expect that we need to address them. **We have addressed these 1000 times over and there was no reason for them to be put in here.** It was on last time's agenda, and it was pushed, in my opinion, to the end as it always was, so that we can be sacrificed and moved again and again until now we are at a critical point. And [MUSIC] about this chapter and whether it will stand or not. I mean, this is ludicrous to me and I would like, and at this point, I call the vote.

SOLTYSIAK: …let's pay attention to our tone and it also is about respect…. When the processes (PROCESS IS) we have had

months to come to agreement on this chapter and we don't agree. It's a chapter that presents many opportunities for disagreement. Therefore, the solution is, if you don't agree, present in your vote as a minority on either the hold (WHOLE) chapter or your vote on certain sections and provide a minority report.

SMITH: That's (NOT) what we have on the floor. The motion on the floor is to accept the chapter. We will fix the first comment because it was legitimate, it was confusing and we will fix that comment. These are the (OTHER) comments should've been done at the last (MEETING).

[Indiscernible – overlapping speakers]

SMITH: Wait a minute, excuse me. **As far as tone and respect, you have got to be kidding. Let me tell you. You've got to be getting (KIDDING). After all the things I have heard and seen how some people have reacted to patients, to our sick patients, they are the ones that deserve to have the respect. And they have not gotten it.** And so, therefore, we have a motion on the floor. I called the vote.

SHAPIRO: First of all, the motion hasn't been seconded. Secondly, I have a question. Could somebody please clarify what the requirement is for a minority report? Is one half (DOES ONE HAVE) to reject the chapter, can one accept the chapter but object to specific content, and how does that happen because it sounds like we have only had motions to accept or reject the chapter. So Jim, can you clarify what needs to happen to have a minority report included, please?

BERGER: Okay. It's my understanding that for a minority response there can be either a rejection of the chapter or a rejection of comments.

SMITH: That (MINORITY REPORT) has to be in response to a vote. That has to be a vote on one particular sections and that has not been done. And therefore right now we have a motion on the

floor to accept or reject the chapter. If someone – states not to accept the chapter they can do a minority report, but there's nothing right now about any kinds of sections. And so, we have a motion, Sam, motion denies seconded it. (Sam motioned it and I seconded it)

COOPER: And I would add to what Pat is saying and what Jim said. When it comes down to a vote on an entire chapter, then the dissenting opinion that's written everything in the chapter is fair game…

– [Inaudible – static] (COOPER COMES BACK ON)

COOPER: What I was saying is in this case where we are voting on the entire chapter, whatever way the vote comes out if you or someone who has dissented…from the majority for the entire chapter, your opinion that's written can cover that entire chapter. If we were voting on a specific section that would be different. The opinion would have to stick to that if you were in the minority. But in this case, that's not relevant because the motion by salmon (SAM) seconded by Pat was…the entire (CHAPTER) as is, other than the first one (CHAPTER COMMENT) we talked about with the numbers and percentages, which we [Indiscernible] (WILL) correct.

Below, Beard is addressing a number of Working Group Members' comments from above…

BEARD: You know, this has been – **I couldn't agree with Dennis More.** Certainly CDC is clearly supportive of recommendations, and honestly, I'm not so much against what's written here. I think it's what's not here, and I think it's the whole idea of showing the balance. I mean, I am fine with registry data. But I think David makes a good point and **we should point out limitations of registry data**. You know, there's truly a point and counterpoint to this and this is a dilemma in which we live and we need to work out a way to answer these questions and resolve it. But I think the way the chapter is written and

LeeAnn (LEIGH ANN), to your point, **I don't think that it's there (FAIR) to say these were 11th hour comments. It was something brought up very, very, very early on and I think can support those who have been outspoken about this, that the balance just is not been put in there and in that sense the comments have never adequately been addressed.**

Again, I'm supportive. I think was (WHAT'S) in here is good, and this is (AN) incredibly important chapter. And it doesn't need to be deleted or even rewritten. It just needs to be balanced with the other side of some of these issues. That, to me, is really the issue of debate here.

COOPER: Thank you, Sam and thank you, Ben. I will say in defense of **what Pat and I have done throughout this process, I feel like we have acted in good faith to address the comments that we have gotten, all of them, unless they were just criticisms without any constructive part to it.** As Sam was saying, there was nothing offered and I will say this last round, the preponderance here is just to comment this is irrelevant. And with nothing to offer, so if that needs to be pointed out, particularly to the public listening in, because they might not be able to see these comments, and since we will not go through each one, a lot of them are just that… We have addressed even those in the past. You know, to explain why it's not irrelevant. So I think we are at really a point here. With (WE'VE) acted in good faith. We have tried to respond and work together. I think we are at a point where Sam put the motion and Pat seconded it. To either accept the chapter as it is other than that one area or, you know, to not accept it and then we will proceed from there.

DIXON: …The overall tone of an entire page is hard to fix with one or two comments, so if you just focus on the text about the NIH trials and include the European trials, which are even bigger and did the same thing, you see such things as comments about the poor design, you see inconsistencies in result, you see controversies. The results are rather consistent. I think

the disparity is in the to interpretation of the results. So if you look at the very fine European trial done by [Name indiscernible] Goldberg and colleagues I have known Bob since the early 90s when he came into the (INFECTIOUS DISEASES ???) effect it is the them the clinical trial network that I went for 15 years. He took on the challenge of Lyme because he noted previous randomized trials have not shown convincingly that prolonged antibody treatment has been beneficial to patients. Which is true. **The trials are showing that additional drugs are not beneficial and yet there's controversy over interpreting that…**

SMITH: Excuse me, Dennis, but I believe you were most meetings and if you weren't present Sam Perdue was, and to give you both credit, you made the meetings. However, **we discussed that issue very clearly and in response to those comments many, many, months ago and we said, no, we are not talking here. We are talking about U.S. trials. We are not talking about trials in other countries. We were very clear about it.** We said it, we stated it, we made changes to that whole section. Many, many rounds of changes throughout that whole section and no one ever put (BROUGHT) it up again. And now, now that you guys have pushed this till the 11th and a half hour and you want it rewritten again and you want to bring up all that old stuff again, well, sorry, Dennis, but we're not going to do that. We are not going to bring this up again. That was already discussed. You can go back and find it in the transcripts and if that's the case but it's there and we are not going to do this again. And I call the question, we have a motion and a second on the floor.

DIXON: Another interpretation of that is the changes that were made did not have significant impact on the concerns that were registered.

SMITH: That is not true because no other concerns were registered on that aspect after that. The only concerns that have been continuously registered are concern(s) that don't

provide anything and just say that doesn't belong in the chapter. And so, we've addressed everything and then some…**I know we went above and beyond the call of duty to get this to a consensus state and, you know, and then to see now, here you are, and you're going to shoot it down. Well, please be my guest. Shoot it down, because I'm going to tell you it's about time that this nation understood where it's government stands online (ON LYME) disease, in particular, chronic and persistent, and those patients. I think they need to see it clearly, and believe me, this will drive it home. I'm perfectly fine to go with this and we have a motion and a second on the floor. Let's do it.**

WALKER: I have a question for you. **Does the (SHARED) decision making inception (OPTION), trying to force physicians to offer (IN)effective, dangerous options to the patients?**

DONTA: I disagree. David **you cannot make that kind of statement without more experience. And, Dennis, you know, we have talked about the European trial, and it had a big fatal flaw which was duration of treatment.** A couple of others. Let's not presume that appropriate duration of treatment, which is the key to the critique of all of the existing trials and whether that's correct or not remains to be seen but needs to be supportive. We can't be dancing around that there is another cause when it's staring us in the face…

SMITH:… David, here's my response. First of all, it's not my judgment. I am not a physician. I have never pretended to be one. However, I can read and I can also assess information that is provided by the tens and tens of thousands of patients and physicians across the country. And **I can look at [Indiscernible] (ILADS) guidelines which were the IOM approved the way the [Indiscernible] (ILADS) were developed. They were the last ones on the national guidelines clearinghouse as a matter of fact before the government defunded the clearinghouse. Those guidelines stand up. They give the doctor the right to make a clinical decision based on what they see**

and also based on the kinds of testing that they do and considerations of the background and the patient's history and the differential diagnoses etc. etc.

WALKER: I agree with that, Pat.

SMITH: And that is what our chapter talks about, basically is that there are two sets of guidelines and that… clinical judgment shall (SHOULD BE) permitted, because for heaven sakes, otherwise let's not bother sending those guys to med school because what good is it if they are not allowed to use the (THEIR) clinical judgment, and they are basing that on guidelines that were on the national guidelines clearinghouse approved by AHRQ.

WALKER: What if the decision is dangerous and ineffective? To (DO) they had (HAVE) to present the alternative treatment?

DONTA: David, you are telling me I have been giving dangerous medications for years excessively treating those patients. Sorry to hear you say that. Please, let's vote.

BEARD: I just wish we could address sections of this and not the whole thing, because it's just throwing the baby out with the bathwater.

SMITH: I think that, no offense, Ben, but **the government longtime (AGO) through(THREW) out the baby in the bathwater, and those were our patients. You threw them out, you left them there, and this to me just stomping all over them, so I don't think it could get much worse. I have never spoken this way at anything I have sat on before in this manner, but I just feel like this is – it's so ludicrous, I can (CAN'T) imagine what the people are thinking out there, but I can be pretty sure of it and it's disgraceful. It's absolutely disgraceful, so let's get it over with. If you're going to cut us out, then (CUT US) out.**

The Chapter 7 vote on the motion to approve the chapter, as

written with one change, was as follows:

Yes (8)
Scott Copper*, Patricia Smith, Beto Perez de Leon*, Angel Davey*, Scott Commins, Sam Donta, Leigh Ann Soltysiak, Leith States*

No (6)
Ben Beard*, Dennis Dixon*, Kevin Macaluso, Todd Myers*, Eugene Shapiro, David Walker

LDA NOTE: *There are 7 federal members* and 7 non-federal public members on the working group. Members wishing to write a minority report must vote NO to the chapter. The vote was taken and some individuals also made comments while they were voting. See official transcript. View list of TBDWG members present at meeting HERE.*

OTHER WG REPORT BUSINESS CONDUCTED:

Report Chapters:
Chapter 1: Background
Chapter 2: Methods
Chapter 3: Tick Biology, Ecology, and Control
Chapter 4: Clinical Manifestations, Diagnosis, and Diagnostics
Chapter 5: Causes, Pathogenesis, and Pathophysiology
Chapter 6: Treatment review
Chapter 7: Clinician and Public Education, Patient Access to Care
Chapter 8: Epidemiology and Surveillance
Chapter 9: Federal Inventory
Chapter 10: Public Input review
Chapter 11: Looking Forward
Chapter 12: Conclusion

Review of: Executive Summary
The section on RMSF and Ehrlichiosis states they are managed

by antibiotic therapy to prevent patient debilitation, disability and death. No mention of death was made in the Lyme reference; therefore, Pat requested that the word death be included in the section for Lyme disease. Vote to approve Executive Summary with the changes agreed to, passed unanimously. **Note:** Shapiro left the meeting (as he has done during several past meetings) once again, delegating his proxy vote to Walker.

Chapter 4: *Clinical Manifestations, Diagnosis, and Diagnostics*
Vote to approve chapter 4 passed, with Leigh Ann abstaining. Shapiro was again absent for this vote.

Chapter 6: *Treatment*
After discussions regarding Powassan Virus references, vote to approve chapter 6 passed unanimously.

Chapter 8: *Epidemiology and Surveillance*
Vote to approve chapter 8 with the changes discussed, passed unanimously.

Chapter 11: *Looking Forward*
This chapter was previously approved with minor editorial changes however, a minority report will be written by Pat Smith and Captain Scott Cooper, on the strong suggestion in here to include industry in the next WG process– concerns on conflicts of interest and legislative categories which do not include industry.

Chapters 1: *Background*; **2: *Methods***; **5: *Causes, Pathogenesis, and Pathophysiology***; **9: *Federal Inventory–*** Pat requested addition of the link to access the Federal Inventory Questions be inserted in this section, this was approved without contest. All of these chapters were approved previously at the 16th meeting with minor editorial changes.

Chapters 3: *Tick Biology, Ecology, and Control*; **10: *Public Input***; and **12: *Conclusion*** were voted on after minor editorial

changes. All passed unanimously.

Appendices: The 21st Century Cures Act delineates categories that WG members must be appointed to. Pat requested that the category of each WG member is to be listed in the report. The WG agreed to add to Appendix A. Report cover and back photos were discussed and decided upon. Smith discussed the need to promote the proper messaging in regard to tick repellent use. The front cover primary image will depict a family outdoors…the real "picture" of how Lyme and other tick-borne diseases are affecting patients across the country.

PUBLIC COMMENTS:
Verbal public comments were delivered by ten people, many of whom had presented at the previous meeting. Critical care nurse and mother of a child with Lyme, Janice Sutton; Lorraine Johnson, CEO of Lyme disease.org; Dorothy Leland, VP of Lymedisease.org and mother of a child with Lyme disease; Phyllis Mervine, President of Lymedisease.org; Patient advocate, Carl Tuttle; Patient advocate, Lucy Barnes.

View Dorothy Leland's, Touched by Lyme, blog posts on LDo's website HERE.
View LDo's Opinion and Features posts for public commenters HERE.

Public Comments Subcommittee:
Subcommittee Co-chair, Angel Davey, presented tables from the Public Comments Subcommittee, which summarizes incoming written public comments: priority areas/key themes through October 2020. November comments were too numerous to publish publicly prior to the meeting. New comments as well as recurrent themes received in October 2020 included:

- "Concern about expedited timing/deadline for call for new public WG members"
- "Inquiry as to whether anyone was establishing labeling

requirements for mammalian-containing products”

- “Obstacles to medical care for LD while living abroad in Australia”
- “Reference and supporting information submitted for a new, effective PTLDS treatment protocol”

Horowitz, R.; R. Freeman, P. Efficacy of Double-Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-infections: A Report of Three Cases and Retrospective Chart Review. Antibiotics 2020, 9, 725. https://doi.org/10.3390/antibiotics9110725

- “Reference provided for an in vitro culture study of dapsone combined with antibiotics effectively disrupting Bb biofilms and killing the bacteria”

Horowitz, R.I., Murali, K., Gaur, G. et al. Effect of dapsone alone and in combination with intracellular antibiotics against the biofilm form of B. burgdorferi. BMC Res Notes 13, 455 (2020). https://doi.org/10.1186/s13104-020-05298-6

DISCUSSION OF MINORITY REPORT: The meeting ended with discussion by those who voted against Chapter 7 of how minority reporting will be submitted in response to the large number of dissenting votes in the approval of Chapter 7. There seemed to be ongoing confusion regarding the process and requirement for minority reporting. It was decided that each minority voter for Chapter 7 may submit an individual minority report or there can be a collective report, and the writers will provide input on how to proceed once they have reviewed. View the discussion of minority reporting transcript HERE.

FINAL WG MEETING DATE: The next and final public meeting of the TBDWG for the 2020 report to Congress will take place on December 2nd. Pat requested an HHS presentation of the LymeX partnership, which Jim Berger agreed to provide at that time. Public comments on the meeting must be received by 11:59 p.m.,

ET, Tuesday, November 24.

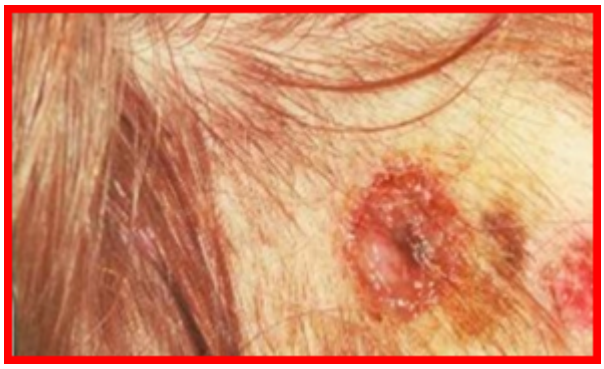
LINKS TO OFFICIAL MEETING TRANSCRIPTS:

Registration and public comment instructions may be found on the HHS website HERE.

Click downloaded official written transcript of the complete Chapter 7 discussion HERE.

Watch/Listen to the actual recording of Pat’s Smith rebuttal by clicking below:

Tularemia



Tularemia is caused by a bacterium, *Francisella tularensis,* transmitted by ticks. It can also be transmitted by deer fly bite, contact with infected animal, contaminated water, contaminated aerosols or agricultural dust, bioterrorism.

Symptoms can include headache, chilliness, vomiting, aching pains, fever, swollen glands, sweating, weight loss, debility, infection site developing into an ulcer.

Treatment can include streptomycin or gentamicin.

Ticks that transmit tularemia include *Amblyomma americanum* (lone star), *Dermacentor variabilis* (American dog) and *Dermacentor andersoni* (wood).

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New Publication: Ticks and Tick-Borne Diseases of Colorado

A review article has just been published by the Journal of Medical Entomology describing the ticks and tick-borne diseases of Colorado which includes tick-host associations, geographic distributions and medical/veterinary importance. In this article, 28 species of endemic ticks in Colorado are described as well as an additional 5 species that are occasionally detected, 13 exotic species that have been intercepted and 2 new state records: *Argas radiatus* and *Ixodes brunneus*.

This review creates a baseline for Colorado endemic ticks and tick-borne diseases, ticks that have been classified as visitors to the state via travel related introductions that may not have established populations, as well as identifying potential invasive species and human and veterinary health risks.

In review of available research and records of tick collections in Colorado, it was found that some information was outdated, incomplete or inaccurate. Authors have recommended that increased surveillance for ticks in Colorado would likely be beneficial to add to the knowledge base on resident tick species and potential new species as ticks continue to expand in geographic range in association with migrating birds, habitat modifications and other changing environmental factors.

Monica White, President/Co-founder of COTBDAA

The review article was co-authored by advocate and LDAnet member, Monica White. Monica is President and Co-Founder of Colorado Tick-Borne Disease Awareness Association, an affiliate of the national Lyme Disease Association, Inc..

Access to article: H Joel Hutcheson, James W Mertins, Boris C Kondratieff, Monica M White, Ticks and Tick-Borne Diseases of Colorado, Including New State Records for *Argas radiatus* (Ixodida: Argasidae) and *Ixodes brunneus* (Ixodida: Ixodidae), *Journal of Medical Entomology*, tjaa232, https://doi.org/10.1093/jme/tjaa232

New Direct Detection Test for Lyme

A new direct test for Lyme disease was announced by Galaxy Diagnostics Inc., the Nanotrap® Urine Test for Lyme Borreliosis. This is a urine-based Lyme antigen test, that Galaxy states "provides the most sensitive direct detection of *Borrelia burgdorferi* infection at all stages of the disease." The test is easily administered through collection of urine; and identifies positive cases missed by

CDC-recommended two-tiered testing, reducing concern for false positive results via direct detection of OspA proteins.

Published data shows that the Nanotrap® Urine Test is very effective for confirmation of early stage Lyme borreliosis in patients with EM rashes. Galaxy states that their unpublished validation data shows that the Nanotrap® Urine Test often confirms active infection in patients with negative CDC recommended Two-Tiered Testing results.

Clinical utility of this test for other presentations of Lyme, including Lyme arthritis, Lyme carditis, and neuroborreliosis, needs further research.

This information is provided by LDA for informational purposes only. The LDA does not recommend or endorse this test but provides it for informational purposes only. Contact your health care provider for medical advice.

Galaxy Diagnostics News Release: November 10, 2020

Application of Nanotrap technology for high sensitivity measurement of urinary outer surface protein A carboxyl-terminus domain in early stage Lyme borreliosis

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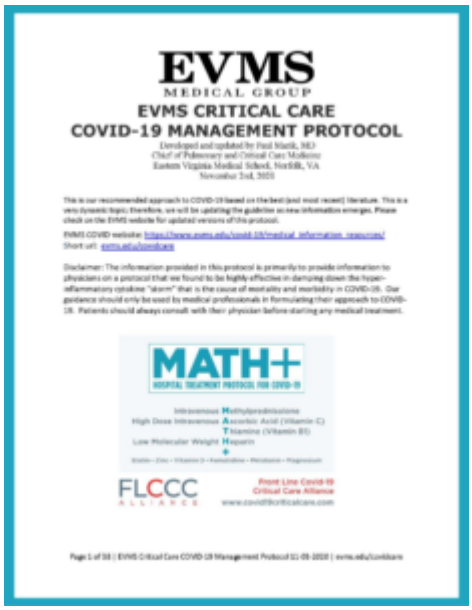
Eastern VA Medical School (EVMS) Updated COVID19 Protocol

The Lyme Disease Association (LDA) is providing you with this updated November 2, 2020, COVID-19 protocol developed by the Chief of Pulmonary and Critical Care Medicine, EVMS. The EVMS Medical continually updates this guideline as new information emerges, primarily to provide new information to physicians.


EVMS
MEDICAL GROUP
EVMS CRITICAL CARE
COVID-19 MANAGEMENT PROTOCOL
MATH+
FLCCC

This information is provided by LDA for informational purposes only. The LDA does not recommend or endorse this protocol but provides it for informational purposes only. Contact your health care provider for medical advice.

For further information
https://www.evms.edu/covid-19/covid_care_for_clinicians/

Working Group Fight Continues/Horowitz Treatment Study/PA Tick Infection Rates/MyLymeData/COVID-19 & TBD/LymeX

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 16th 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.

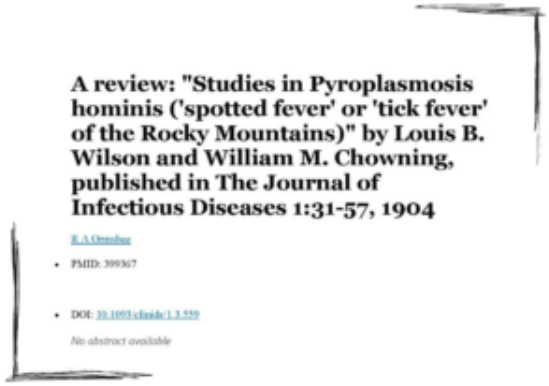
Surveillance: Captain Scott Cooper provided a comment regarding Bayes Theorem and "prior probability that the patient has Lyme disease." His comment, "All of Bayes Theorem depends on prior knowledge and assumptions, when there is not sufficient information to form these assumptions, the premise that 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

R A Ormsbee

- PMID: 399367
- DOI: 10.1093/clinids/1.3.559

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 3rd 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.

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.

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 then 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.

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’”

The 17th meeting of the WG will take place on November 17th, 2020 from 9:00 am- 5:3o 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.

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

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MyLymeData Analysis: Long-Term Antibiotic Treatment Supports CLD Recovery

Lorraine Johnson, JD, CEO, LymeDisease.org; Principle Investigator, MyLymeData

A new study lead by researchers from the University of California Los Angeles (UCLA) analyzed data from the MyLymeData patient registry. The Registry, with over 13,000 enrolled patients, is a project of the non-profit LymeDisease.org.

The researchers used machine learning techniques and analyzed more than 2,000 patients with chronic Lyme disease (CLD) from the database to identify key features associated with improved patient response. They found that the extended use of antibiotics was an important element of improved health.

“As many as 3 million people have chronic Lyme disease in the US, and nobody knows the best way to treat them,” said Lorraine Johnson, CEO of LymeDisease.org. “The key finding here is that patients who are now well or who report substantial improvement have taken longer courses of antibiotics.”

Antibiotic Use Associated with High Treatment Response

This study compared patients who became well or substantially

improved to patients who did not show improvement. High treatment response was most strongly associated with the use of antibiotics as contrasted with alternative treatments alone, or going without treatment altogether. The research team found that more “well” patients (76%) and “high responders” (59%) were treated with antibiotics compared to patients who showed no response (38%).

Offering Insight to Long-Term Antibiotic Controversy
To date, the use of extended antibiotics to treat patients with persistent symptoms of Lyme disease has been a topic of controversy. Testing for Lyme disease is lacking and therefore, no option exists that has demonstrated the ability to accurately determine whether the Lyme bacteria, *Borrelia burgdorferi (Bb),* has been effectively eradicated.

“This study confirms what many clinicians who treat chronic Lyme disease already know,” said Raphael Stricker, MD, Union Square Medical Associates, San Francisco. “Individualized patient care provided by Lyme-literate practitioners is essential to identify those patients who require longer antibiotic treatment to get better.”

Read the study press release on *WebWire.*

Learn more about MyLymeData.org.

Visit LymeDisease.org.