Lyme Patients: Speak Up Now on Persistent/Chronic Lyme! Sept 4 Deadline

Background: The upcoming meeting of the HHS Working Group on Sept. 15 may be your last chance to influence language on persistent/chronic Lyme. At the last meeting, several members of the Working Group (WG) worked hard to have language related to patients with persistent Lyme symptoms removed from the WG report which will go to Congress at end of year. Read more about the last TBDWG meeting.

At the upcoming September meeting, the WG will vote on proposed changes in language that can affect patient access to care. Please submit verbal or written comments now, deadline to request verbal comment or to submit written comment 11:59 p.m., ET, Friday, September 4, 2020.

Meeting Details: The fifteenth meeting of the Tick-Borne Disease Working Group (TBDWG) will be held on two non-consecutive days, September 15 and 22. This is an online meeting and everyone is welcome to attend. The TBDWG will review the draft 2020 report to the HHS Secretary and Congress, as well as review and approve graphics and images for the report.

Register to Attend the Online Meeting.

View the Federal Register Meeting Notice.

View the Meeting Agenda.
How to Submit Your Request for Verbal Public Comment at September 15 meeting (heard online at meeting): Verbal remarks will be provided by the public over the phone during the live webcast and will become part of the archived recording and meeting summary that is posted afterward on the HHS website.

- **Deadline:** All sign-up requests must be received by **11:59 p.m., ET, Friday, September 4**
- Submit an email request to **tickbornedisease@hhs.gov**
- Use the email subject line: Verbal Public Comment – September 15

**Next steps:** If more requests to provide verbal public comment are received than can be accommodated during the meeting, speakers will be randomly selected. You will receive notification on the status of your request on **Wednesday, September 9**.

- If you are selected to provide verbal public comment at the meeting, you will be asked to confirm that you are still available to speak during the assigned time. Upon confirmation, you will receive a call-in number and time to provide your comment. Each person will be limited to 3 minutes in order to accommodate as many speakers as possible. If you are no longer able to provide verbal public comment, HHS will randomly select another speaker.
- If you are not selected, you are welcome to submit your name for consideration in a future meeting of the Working Group once the meeting information is posted.
- Please note: All public comment requests that were made for the postponed August meeting will be reviewed for possible speaking opportunity at the September 15 meeting. Those who did not request to speak at the August meeting may also apply to speak for the September 15 meeting.
Please note: All public comment requests that were made for the postponed August meeting will be reviewed for possible speaking opportunity at the September 15 meeting. Those who did not request to speak at the August meeting may also apply to speak for the September 15 meeting.

How to Submit Your Written Public Comment: Written public comments are shared with Working Group members and are also posted on the HHS webpage. Written public comments will be made accessible to the public in advance of the meeting.

- Submit an email to tickbornedisease@hhs.gov
- Use the email subject line: Written Public Comment – September 15
- Provide your preferred identification: Explain how you prefer to be identified with your comment. Without this information, your comment will not be posted. You may choose one or more of the following options:
  - Use your name
  - Be listed as anonymous
  - Include your city and/or state
  - Provide comments on behalf of an organization (please include the organization’s full name)
- Deadline: All written comments must be received by 11:59 p.m., ET, Friday, September 4

Writing your public comment:

- Format: Comments must be in the body of your email or in an attached Word document.
- Page Limit: Comments must not exceed four (4) pages in Calibri or Times New Roman, 11 point font (text that exceeds four pages will be deleted).
- Graphics: Do not include graphics, images, text boxes, or tables. If included, they will not be retained.
- Links: Hyperlinks will only be added for “.gov” sites
(local, state, or federal). For all other reference sites, please insert the full URL (e.g., http://learn.genetics.utah.edu/content/epigenetics).

**Attachments:** Do not include any attachments. It is not possible to include attachments as supporting documentation to written comments.

**Next steps:** Your written comment will be posted to the HHS website before the meeting. If you have any questions or concerns about submitting your comment, contact tickbornediseases@hhs.gov.

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**Series of Amendments Go Through Process to Increase Lyme/TBD CDC $$**

In a complex government process, the Tick Act—a bill that provides funding for Vector-Borne Diseases including Lyme—was not fully funded according to the Committee report on HHS. The Committee report has 16M for Lyme and 38M for vector-borne diseases.
(NOTE: as LDA has mentioned in prior information on the Tick Act, it is for Vector-Borne Diseases of which TBD are only a part).

To address the issue, Congressman Chris Smith (NJ-4) developed an amendment to raise that funding for TBD, which was co-sponsored by Congressman Collin Peterson (MN). During amendment development, the President’s budget request for 2021 was examined, which asked for $14 million increase over 2020 for vector-borne diseases. Suggested funding levels in the Tick Act for vector-borne diseases were also examined. The LDA provided input into that amendment process and concurred with an additional $11.4M to be asked for on top of the $2M increase in appropriations asked for in the report. Congressmen Smith and Peterson submitted the amendment for $11.4M, but Congressman Delgado (NY) also submitted an amendment, asking for $4M. The Congressmen agreed on $4M in an amendment Smith et al # 289.

Amendment # 289. Smith, Christopher (NJ), Peterson (MN), Stefanik (NY), Delgado (NY), Rose, Max (NY) does the following: Redirects $4 million from General Departmental Management at the Department of Health and Human Services to Emerging Zoonotic and Infectious Diseases at the Centers for Disease Control, for Lyme Disease and other Vector-Borne Diseases.

House Report 116-461, the Rules Committee Report on HR 7167, with amendments made in order, including the Chris Smith amendment. A description of the Smith amendment (289) is on page 33 of the pdf, and the actual language is on page 365 of the pdf.

Listen to the video below of Congressman Smith pitching the amendment to the committee.
Contentious 9 Hour WG Meeting: Persistent infection a Religious Belief? WG Co-Chair Says Yes

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

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

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

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

For the record: The importance of today’s meeting and our Chapter review can’t be overstated. My Access to Care, Education & Training subcommittee including healthcare providers and patients, with expertise in the problems associated with patients’ access to care including physician education, submitted a 75-page subcommittee report and additional 45 citation pages documenting these problems to get
help for a body of patients neglected especially those who develop the most serious stage of Lyme and to prevent acute patients from reaching that stage. Patients looked to this WG created through legislation initiated by, written by, and pushed through Congress by Lyme patients/advocates. In 2019 through now, 78% of comments to the online WG mailbox were about TBD/Ticks, 70% of those TBD comments were on Lyme disease and 81% of those were on chronic/persistent/PTL, not acute.

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

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

As directed, we pulled language from the subcommittee reports, submitted our Chapter for review and was told “well organized, appropriate to audience level, and it flowed logically,” but we needed to “rebalance” the chapter as there was too much information on Lyme disease and access to care than other tick-borne diseases and education. Suggested rebalancing included removing a factual table from CDC which listed TBDs for 3 years, in descending order of reported case numbers, as the table could “inadvertently diminish the importance of
other tick-borne diseases because their numbers are much lower.” It was OK that we led with burden of disease (cost, quality of life, & productivity), compelling reasons for Congress to act. However, we should remove those items from our Chapter report background and put them into the background for the entire WG report, despite the fact they were developed specifically for our patient issues. Bottom line: minimize Lyme, reduce access to care.

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

All WG Chapter Writers had a deadline to post draft Chapters to a WG private Share Point site. WG members had a May 22 deadline to submit comments there on all chapters. All Chapter language was now up for grabs, we were told, even the language we took from the already discussed Subcommittee reports, not just new language. I objected, since that seemed to contradict process discussion at the prior meeting. Significantly, I objected to the lack of process transparency, which was directing these online SharePoint discussions to be behind the scenes—not WG members in public holding transparent discussion with all WG members, embodying the intent of a FACA Working Group. Time went by with no response to my objection, so I reluctantly decided to proceed with filing for resolution through a FACA complaint, but I was subsequently informed my concerns were heard, and all discussion would now be in public, as we are doing today so I did not proceed with the complaint.
While working in the private SharePoint site, I stumbled across an unknown person who had direct access to all Chapters and material in the site. Research showed me this individual was from NIH, not either the NIH Working Group member or alternate—another NIH employee, an attorney. Upon questioning the individual’s identity and purpose, I was informed NIH requested that that individual be allowed access to our SharePoint documents and was given access. It appears that government employee WG members have rights public members do not have, are not aware of, and do not have to be informed of. Since public members are considered special government employees, I requested to federal officials that I be permitted to have a patient advocate attorney in SharePoint to review for patient perspective. I was informed my request was denied by WG legal counsel.

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

As we move forward on our Chapter section now, note that our printed report has 12 pages with internal citations to address the decades-long problems of hundreds of thousands of Lyme patients plus other tick-borne diseases patients. Additionally, there are 7+ printed pages of comments from SharePoint made by WG members on our Chapter, a number of which call for removal of much of our documented material on Lyme disease— a disease under-reported by a factor of 10
according to CDC studies and CDC testimony by Lyle Peterson to a Senate Committee, (1) meaning about 350,000 cases annually. According to NIH, Lyme is a disease that makes up 82% of tick-borne diseases, (2) and there were 74 Lyme deaths in 2017. (3) Thus, our Chapter focuses on the tick-borne disease whose patients comprise the largest burden of disease, Lyme disease. That is balance. Captain Cooper, I now turn further Chapter discussion to you.

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

(2) NIH says Lyme 82% of tick-borne disease cases

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

Govt Agencies Deny Persistent Lyme at WG: Take Action Now!

ACTION Recommended by LDA: Make Your Voices Heard on Persistent Lyme to the Working Group Now! June 24th
Deadline.

Our government denies persistent (chronic) Lyme and refuses to acknowledge and help those patients. Please submit comments, can be short, about the existence and importance of persistent (chronic) Lyme. How it affects your life, family, job, school, and your doctors. Only your action by June 24th can make them listen!

- **Submit Comments** (verbal or written) for the next meeting by Wednesday, June 24th
- **Next Meeting** held online, Wednesday July 8th
- **Register** for the online meeting
- **View Agenda**

View Lyme controversy on videos below!

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**History of Working Group (WG) Formation:**

The 21st Century Cures Act, signed into law in 2016, called for the formation of a 14-member Tick-Borne Disease Working Group, to work under the auspices of the US Department of Health and Human Services (HHS). The panel would bring together representatives of various federal agencies, medical experts, scientists, and Lyme disease patient advocates. Together, they would strategize the best ways for the government to combat the huge public health threat posed by acute Lyme, persistent Lyme, symptoms, and other tick-borne diseases. Giving patients a voice in policy decisions that deeply affect them was an issue long championed by the Lyme community.

**First Term of the Working Group – Success:**

The Working Group was set up to last six years, reporting to Congress about its progress every two years. The first iteration of the panel, named in 2017, included three representatives of Lyme patients. The Working Group’s Report to Congress was submitted at the end of 2018, with generally
good reviews from the Lyme community. It appeared progress was being made.

Current Term of the Working Group – Controversy:

Only one patient advocate chosen…. Things took a different turn in 2019, with the naming of the next panel. There was obfuscation, lack of transparency, and process irregularities from the very start. The Working Group’s membership wasn’t even publicly announced until less than a day before its first meeting on June 4. Only one patient advocate was chosen—LDA President Pat Smith. And, in a move that especially stuck in the craws of Lyme patients everywhere, the IDSA’s Dr. Eugene Shapiro was appointed as well.

Controversial IDSA doctor chosen for Working Group…. Dr. Shapiro is well-known for publicly mocking and belittling Lyme patients and their concerns, and for helping target the medical licenses of Lyme-treating doctors who don’t follow the IDSA’s Lyme guidelines, which he co-authored. He also has flagrant Lyme-related financial conflicts of interest that should have precluded him from serving on the Working Group according to the opinions of many people. (More than 38,000 people have signed a petition to remove Shapiro from the panel (see petition). Despite many inquiries, there has been no official response from HHS regarding the petition.)

Co-Chair announces enough focus on Lyme, must focus on other tick-borne diseases…. Also at that opening meeting on June 4, newly appointed co-chair David Walker MD—who is an expert in rickettsial infections, not Lyme disease—made a startling announcement. He said that the prior Working Group had spent enough effort on Lyme disease, and he thought the new group should put its energies elsewhere.

(Note: According to the CDC, 82% of the cases of tick-borne infection in the US are Lyme disease. Shouldn’t it get 82% of the group’s attention? Furthermore, the first panel was aware there were still many Lyme related issues to be further
Non-Attendee Votes by Proxy…. For example, at a two-day meeting in Philadelphia on March 3 and 4, Eugene Shapiro did not attend in person nor did he participate by telephone. However, when it came time to vote, Co-chair Walker cast votes on his behalf. Pat Smith questioned this and was basically told, “We checked. It’s allowed.” (Wait…what? Why have any debate at all if an absent panelist can pre-program his votes in advance?)

Agencies refuse to address persistent Lyme (Pat Smith strongly responds – see 2.5 min. video below)…. Also at that meeting, discussions edged closer to the controversial “elephant in the room”—the topic of persistent Lyme disease and the failure of US health agencies to adequately address it. Pat Smith pointed out that the CDC website only acknowledges acute Lyme disease. She said this leaves people who remain sick after beyond the early stages of the illness—along with their doctors—without any advice at all. In response, CDC spokesperson Ben Beard insisted, “The vast majority of Lyme disease patients are served quite well by the guidance we have on our website.” After representatives of several agencies echoed similar responses, here’s how Pat replied:

(Clip 2.5 min.)

(NOTE: Once viewed, hit your browser’s refresh button to view again)

Dennis Dixon, NIH, Ben Beard CDC, and Pat Smith responding:
The segment is about unsettled science, 2 guidelines, Lyme 2 different diseases, Lyme only in certain states…. (Clip 13 min.)

(NOTE: Once viewed, hit your browser’s refresh button to view again)
Pat Smith asking CDC are there 2 Standards of Care – CDC Replies No
(1 min.)

(NOTE: Once viewed, hit your browser’s refresh button to view again)

Controversy continues at April 27th meeting…. The following month, the contentious issue of persistent Lyme disease again reared its head during April 27’s online audio meeting.

Below shows the agencies refusal to acknowledge persistent Lyme disease and need for treatment guidelines.

- A subcommittee put forth the following recommendation for a vote: Recommend that IF the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme disease. Unexpectedly, five panelists abstained—which left five yes votes and 3 no votes. (One member was absent.)
- Remarks made after the vote seemed to indicate that the abstainers felt they had defeated the measure, because “yes” votes didn’t comprise a majority of panel members. But the Working Group found out abstentions don’t effect outcome of the yes or no total. So, the recommendation passed, 5-3.
- At that point, one of the abstainers announced that he wanted to change his vote to “no.” That request was denied. There was heated discussion about whether the panel could or should hold a re-vote on the matter. After a lot of back and forth discussion, two motions were made and seconded, one was withdrawn, and the second ended with a vote on whether to have a revote. That vote resulted in not overturning the original vote. The recommendation in the first bullet above stands.
Contentious Working Group Meeting Vote on CDC Posting Lyme Guidelines

The thirteenth meeting of the Tick-Borne Disease Working Group (Working Group) was held online on April 27, 2020, from 9:00 a.m. to 12:30 p.m., ET. This meeting was open to the public, with request to comment accepted by April 19, 2020.
The Working Group reviewed the work of the Public Comment Subcommittee followed by the Federal Inventory Subcommittee. The Working Group had sent inventories with a series of questions to the federal agencies, and the Inventory Subcommittee of David Walker (Chair), Sam Donta MD, and LDA President Pat Smith developed recommendations based on gaps in agency programs/research. The WG voted on the various recommendations for each agency to be brought forward in the Working Group Report to be submitted to Congress.

The Working Group members engaged in heated discussion regarding one recommendation “that IF the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme disease.” Pat Smith, Lyme Disease Association President, argued persuasively on behalf of the chronic Lyme patient community, in favor of this recommendation. After the vote to pass the recommendation, some members wanted to change votes. So a member moved to revote causing a long discussion on the advisability/legality of such a vote. The Working Group federal official researched the question and indicated it was a dangerous precedent. Despite that, a revote was taken to permit a revote. It failed. So the original vote accepting the recommendation stands. Ms. Smith asked when the actual inventories would be released to the public, and after a discussion, the federal official indicated they could be.
Two Votes Taken

“Recommend that IF the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme disease.” Pat Smith moved, Sam Donta, MD seconded the motion. Vote Results 6 YES, 3 NO, 5 ABSTAIN, 1 ABSENT

“Motion to have a revote on the last vote” Scott Commins, MD moved, Eugene Shiparo seconded the motion. Vote Results 5 YES, 6 NO, 0 ABSTAIN, 1 ABSENT

Roll Call Vote of Members

- Captain Scott J. Cooper, PA-C (government member) Centers for Medicare and Medicaid Services (CMS), HHS
  VOTE ON GUIDELINES RECOMMENDATION: YES VOTE ON REVOTE: NO
- Angel M. Davey, PhD (government member) Tick-Borne Disease Research Program, Congressionally Directed Medical Research Programs, U.S. Department of Defense, DoD
  VOTE ON GUIDELINES RECOMMENDATION: YES VOTE ON REVOTE: NO
- Dennis M. Dixon, PhD (government member) National Institute of Allergy and Infectious Diseases (NIAID/NIH), HHS
  VOTE ON GUIDELINES RECOMMENDATION: YES *post vote, wanted to change to Abstain VOTE ON REVOTE: NO
- Sam T. Donta, MD –Professor of Medicine (ret.) (public member)
  VOTE ON GUIDELINES RECOMMENDATION: YES VOTE ON REVOTE: NO
- Patricia V. Smith- (public member) Lyme Disease Association, Inc.
  VOTE ON GUIDELINES RECOMMENDATION: YES VOTE ON REVOTE:
NO

- Charles Benjamin (Ben) Beard, PhD (government member)
  Division of Vector-Borne Diseases, Centers for Disease
  Control and Prevention (CDC)
  VOTE ON GUIDELINES RECOMMENDATION: NO  VOTE ON REVOTE: YES

- Eugene David Sharpiro, MD  (public member) Yale
  University School of Medicine
  VOTE GUIDELINES ON RECOMMENDATION: NO  VOTE ON REVOTE: YES

- David Hughes Walker, MD, (public member) TBDWG co-chair,
  UTMB Center for Biodefense & Emerging Infectious
  Diseases
  VOTE ON GUIDELINES RECOMMENDATION: NO  VOTE ON REVOTE: NO

- Scott Palmer Commins, MD, PhD (public member) –
  University of North Carolina
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: YES

- CDR Todd Myers, PhD (government member) Food and Drug
  Administration, HHS
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: YES

- Adablbeto (Beto) Perez de Leon, DVM, PhD (government
  member) Department of Agriculture (USDA), HHS
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: YES

- Kevin R. Macaluso, PhD, MS  (government member)
  University of South Alabama
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: NO

- Leigh Ann Soltysiak, MS (co-chair) (public member)
  Silverleaf Consulting, LLC Adjunct Professor, Stevens
  Institute of Technology
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: YES

- Leith States  (government member) Deputy Chief Medical
The TBDWG, received verbal comments from the public on a range of topics including:

- Dorothy Leland, Vice-President of Lymedisease.org presented for Phyllis Mervine, President of Lymedisease.org comments on the need for Lyme disease treatment guidelines similar to COVID-19 guidelines as posted by NIH. She stated COVID-19 won’t stop tick season, and for Lyme disease treatments, ultimately the choice of what to do for an individual patient should be decided by the patient and their treating physician, just as it is recommended in the COVID-19 NIH treatment guidelines.

- Lucy Barnes, Lyme advocate, presented comments on the Infectious Diseases Society of America’s (IDSA’s) outdated Lyme treatment guidelines, which she stated has discredited anything, and anyone, that disrupts their status quo, often resulting in name calling and demeaning the character of both patients and their treating physicians.

- Beth Carrison, from TBC united, commented on the unique health challenges faced by Alpha-gal patients in light of the current COVID-19 treatments. She pleaded for an urgent Health Alert to be posted in order to help protect these at risk patients.

- Stephen Rich, professor of Microbiology at University of Mass, TickReport Lab commented on the value of tick testing and prevention messaging that accompanies their tick testing reports. He urged the CDC to review their stance against tick-testing.
The meeting concluded after updates on the status of the writing groups for each of the assigned chapters being developed for the 2020 report to Congress on federal tick-borne activities and research. The next public virtual meeting is scheduled for July 8, 2020.

LDA encourages patients, advocates, caregivers and family of Lyme disease patients to submit verbal or written comments about Lyme disease to the TBDWG for the July 8th meeting and to attend the meeting online.

Read Lymedisease.org VP, Dorothy Leland’s, Bizarre happenings at the TBD Working Group Blog here.

Read Lymedisease.org, President, Phyllis Mervine’s, NIH’s COVID-19 guidelines offer useful advice for Lyme disease, too Blog here.

Visit the HHS TBDWG webpage for more information, including how to submit verbal and written public comments.

Click here to view information about prior TBDWG meetings.

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TBDWG Mtg 12: Training, Education, Patient Access to Care (Video)

The Lyme Disease Association Inc. (LDA) feels it is imperative that the Lyme Community and the public understand the continued resistance by government agencies to provide information pertaining to chronic Lyme disease on their websites and in their programs despite Lyme disease being around 45 years. LDA has provided video clips from the HHS
Tick-Borne Disease Working Group meeting in Philadelphia which portray that resistance. Decades long advocate, LDA President, Pat Smith, the WG patient rep, rebuts these entrenched positions. Please note, however, that the federal government WG representatives are required by FACA WG rules to espouse and vote their agency’s position, which may not necessarily their own personal position.

**TBD Working Group Committee Members / Meeting #12 Agenda / LDA Written Summary of Meeting**

Full Video:  March 3rd – Day 1 / March 4th – Day 2

Other Video Clips:  Sam Donta, MD and Other / Public Comment (9 speakers)

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Working Group (WG) Discussion on Training, Education, Access to Care, and Reimbursement Subcommittee Recommendations

Co-Chairs:  Pat Smith, President; LDA / Captain Scott Cooper, PA; CMS

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<td>2-CDC Surveillance Revisions</td>
<td>11-LA Soltysiak WG Co-Chair / D.Dixon NIH Response on Guidelines</td>
<td>20-P. Smith: Responds to Ben Beard FACA Violation Concern</td>
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<td>3-Nationwide Lyme Clinical Training</td>
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<td>13-S. Donta: Agencies Must Revisit Failures/Limitations for Chronic/Persistent Disease</td>
<td>14-B. Beard: Addresses what Chronic Lyme Patients have had to Endure and Complexity of Moving Policy Forward Within a Large Agency</td>
<td>15-Committee Edits/Votes on Government Website Disclosure Wording</td>
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<td>22-P. Smith: Rebuttal to CDC Curriculum Comments</td>
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<td>25-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 1</td>
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<td>8-P. Smith: FDA Position on Guidance vs. Guidelines, Why Chronic Cannot be Acknowledged</td>
<td>17-Committee Discussion on Surveillance Revision / Vote: P. Smith, No!</td>
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1 – P. Smith: Govt. Website Disclosures (5 + min)
9:59:06 to 10:04:38
35946 to 36278

2- P. Smith: CDC Surveillance Revisions (5+ min)
10:04:39 to 10:10:37
36279 to 36637

3- S. Cooper: Nationwide Lyme Clinical Training (4+ min)
10:10:38 to 10:15:35
36638 to 36935

4- Govt. Website Disclosure Discussion (10 min)
10:16:15 to 10:36:14
36975 to 38174

5- P. Smith Defends Chronic Lyme Patients (4+ min)
10:36:14 to 10:40:18
38174 to 38418

DAY 2

6-P. Smith Questions WG Process/FACA (1+ min)
2:18:37 to 2:20:12
8317 to 8412

7-P. Smith Questions Communication Betwn. WG & the Non Transparent WG (1+ min)
2:20:12 to 2:22:02
8-P. Smith: FDA Position on Guidance vs. Guidelines, Why Chronic Cannot be Acknowledged (3+ min)
2:22:02 to 2:25:15
8522 to 8715

9-P. Smith: NIH/CDC Agency Guidelines/Positions – why is chronic Lyme completely ignored? (9+ min)
2:25:15 to 2:34:30
8715 to 9270

10-B. Beard: Not Acknowledging Both Sets of Guidelines on Website (11+ min)
2:34:30 to 2:35:41
9270 to 9341

11-LA Soltysiak WG Co-Chair / D.Dixon NIH Response on Guidelines (4+ min)
2:35:42 to 2:39:45
9342 to 9585

12-P. Smith: Federal Agencies have not done their Job! (3+ min)
2:39:45 to 2:43:13
9585 to 9793

13-S. Donta: Agencies Must Revisit Failures/Limitations for Chronic/Persistent Disease (6+ min)
2:43:14 to 2:49:17
9794 to 10157

14-B. Beard: Addresses what Chronic Lyme Patients have had to Endure and Complexity of Moving Policy Forward Within a Large Agency (2+ min)
2:49:27 to 2:52:00
10167 to 10320

15-Committee Edits/Votes on Government Website Disclosure
Wording (26+ min)
2:52:00 to 3:18:38
10320 to 11918

16-P. Smith: Surveillance Revisions (1+ min)
3:18:56 to 3:20:20
11936 to 12020

17-Committee Discussion on Surveillance Revision / Vote: P. Smith, No! (15+ min)
3:20:23 to 3:36:16
12023 to 12976

18-S. Cooper & WG Discuss Nationwide Curriculum (9+ min)
3:36:29 to 3:46:10
12989 to 13570

19-B. Beard: Raises Issue With Curriculum Recommendation – FACA Violation (11+ min)
3:46:12 to 3:47:25
13572 to 13645

20-P. Smith: Responds to Ben Beard FACA Violation Concern (1+ min)
3:47:27 to 3:48:54
13647 to 13734

21-S. Cooper & WG Continue Curriculum Discussion (4+ min)
3:48:54 to 3:53:42
13734 to 14022

22-P. Smith: Rebuttal to CDC Curriculum Comments (1+ min)
3:53:42 to 3:54:51
14022 to 14091

23-WG Continues Curriculum Discussion & Votes (27+ min)
3:54:51 to 4:22:34
14091 to 15754

24-P. Smith: Legal for D. Walker To Vote In Place of E.
Shapiro / Answered by J. Berger, HHS (50 sec)
4:22:34 to 4:23:25
15754 to 15805

25-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 1 (43+ min)
9:57:06 to 10:40:26
35826 to 38426

26-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 2 (2 hr 4 min)
2:18:37 to 4:23:27
8317 to 15807

TBDWG Mtg 12: S. Donia, MD: Lyme / Other Clips (Video)

TBD Working Group Committee Members / Meeting #12 Agenda / LDA Written Summary of Meeting

Full Video: March 3rd – Day 1 / March 4th – Day 2

Other Video Clips: Training, Education, Access to Care Discussion / Public Comment (9 speakers)
This section includes determining the mechanisms underlying the persistence of B. burgdorferi in the host; determining the role of persistence of B. Burgdorferi or its components in the pathogenesis of Lyme arthritis and persistent Lyme disease; and determining the pathogenesis, pathophysiology, and effective treatment of Lyme carditis.

1-S. Donta: Pathogenesis, Physiology of Lyme
4:40:19 to 5:28:12
16819 to 19692

2-P. Smith: Comments on Lyme Carditis, Tissue Testing Prob.
5:28:13 to 5:30:07
19693 to 19807
3-S. Donta: Comm. Discussion/Vote on Lyme Issues
5:30:07 to 5:33:28
19807 to 20008

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Sam Donta, MD: Discussion of Clinical Aspects of Lyme Disease Subcommittee Recommendations (Day 2)
Co-Chairs: Sam Donta, MD; Prof. of Medicine (Ret) and Captain Scott Cooper; CMS

This section includes conducting additional targeted controlled clinical treatment trials in patients with early and persistent Lyme disease, using different antibiotic regimens and longer durations of treatment than those used in previously conducted trials; educating clinicians as to the limitations of currently available tests in the diagnosis and in the monitoring of treatment of patients with persistent Lyme disease; further evaluating potential maternal-fetal transmission of Lyme disease and of congenital Lyme disease. (Passed); and further evaluating purported human-to-human sexual transmission of Lyme disease.

4-S. Donta: Clinical Aspects of Lyme Including Potential Sexual Transmission
5:34:09 to 6:59:48
20049 to 25188

5-S. Donta: Maternal Fetal Transmission / Congenital Lyme Vote
7:35:30 to 7:44:41
27330 to 27881

Other Video Clips:

6-Diagnostics Discussion
3:47:25 to 3:50:35
13645 to 13835

7-Use of Doxy for RMSF
At the start of the second day of the HHS Tick-Borne Disease Working Group meeting in Philadelphia on March 4, 2020, nine Lyme disease advocates and patients who preregistered either called in or were present at the meeting in person to provide public comments. Their input was invaluable and helped Working Group members appreciate issues of concern throughout the country.

**TBDWG Mtg 12: Public Comments (Video)**

TBD Working Group Committee Members / Meeting #12 Agenda / LDA Written Summary of Meeting


Other Video Clips: [Training, Education, Access to Care] / [Dr. Donta, MD & Other]
## Public Comments: Day 2, March 4th

<table>
<thead>
<tr>
<th>Lonnie Markham, LDO-Tick Attachment Time</th>
<th>Phyllis Mervine, Pres LDO-2 Standards of Care</th>
<th>Mira Shapiro, LDO-Big Data Research</th>
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<tr>
<td>Dorothy Leland, VP LDO-Process Integrity</td>
<td>Melissa Potter, LDO-Patient Registry-MyLymeData</td>
<td>Jennifer Platt, TBC United-Alpha-gal &amp; lesser known conditions</td>
</tr>
<tr>
<td>Mark Liberto, Patient Story</td>
<td>Dr. Betty Maloney- CDC Treatment Recommendations</td>
<td>Jill Auerbach- Prevention Emergency</td>
</tr>
</tbody>
</table>

**Lonnie Markham, LDO: Tick Attachment Time**
1:41:57 to 1:44:42
6117 to 6282

**Dorothy Leland, VP LDO: Process Integrity**
1:52:05 to 1:55:17
6725 to 6917

**Mark Liberto: Patient Story**
1:55:18 to 1:59:11
6918 to 7151

**Phyllis Mervine, President LDO: 2 Standards of Care**
1:59:14 to 2:02:39
7154 to 7359

**Melissa Potter, LDO: Patient Registry-MyLymeData**
2:02:40 to 2:05:39
7360 to 7539

**Dr. Betty Maloney: CDC Treatment Recommendations**
2:05:40 to 2:08:47
The 12th meeting of the Tick-Borne Disease Working Group (TBDWG) took place over two days, March 3rd-4th, 2020, at The
College of Physicians of Philadelphia in Philadelphia, PA. A summary of this in-person public meeting is as follows:

- Opening statements were presented by Tammy R. Beckham, Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), US Health and Human Services (HSS).
- The TBDWG discussed and voted on recommendations for the format/template of the 2020 TBDWG Report to the HHS Secretary and Congress. There was full agreement by the TBDWG to use the same format/branding of the 2018 TBDWG Report for the 2020 TBDWG Report to HHS Secretary and Congress.
- Ben Beard, Deputy Director, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention (CDC) provided an update to the CDC Tick Surveillance program. CDC has increased monies and guidance being provided to States to conduct active tick surveillance activities. In addition, the CDC will provide both tick identification and testing services for States that do not have the expertise needed to conduct these activities.
- Public comment was provided by eleven patients/advocates to the TBDWG. These patients/advocates provided heartfelt comments on both personal experience as well as recommended research needs. (click here for public comments)
- Each of the eight Subcommittee chairs brought forward their top three recommendations which were developed from the reports each of the TBDWG subcommittees. The TBDWG discussed and modified each of the three recommendations from each subcommittee and then voted to accept the recommendations to include in the report.
- Writing co-leads were determined for each section of the report. And next TBDWG meeting dates were discussed for May/April and July, 2020, though not yet set.
LDA President, Pat Smith, at 12th meeting of the TBDWG, Philadelphia, PA

Though the TBDWG worked through many of the subcommittee recommendations with good consensus, discussions regarding the recommendations brought forth by LDA President, Pat Smith for the “Training, Education, Access to Care and Reimbursement” subcommittee became heated (click here for video) as Pat asked the Federal agency representatives for agreement on website disclosures to increase public awareness for the two divergent diagnostic and treatment and approaches reflected in guidelines for Lyme disease. (video clips: Training, Education, Access to Care and Reimbursement)

Ben Beard, CDC, commented after reading an excerpt from a 1990’s report, that the situation patients face today is very much unchanged from what they faced back then and that this is a “heartbreaking, tragic, failure of Public Health.” However, he also stated that “The vast majority of Lyme disease patients are served quite well by the guidance we have on our website. The diagnostic test is reliable in terms of it telling you what you expect to hear."

During discussions, Pat implored to the TBDWG, “You have left out a whole entire group of people…the chronic people. These are the people that need the help.” She further stated that “it’s the chronic population that’s being neglected and marginalized.”

LymeDisease.org provides a video clip of Pat Smith’s continued strong advocacy for patient needs in Dorothy Leland’s March
5th, Touched by Lyme blog [here](#).

For upcoming meeting notifications please visit the HHS-TBDWG webpage [here](#).

Public comments may be made in writing directly to the HHS-TBDWG at [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov)

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**Associated Links**

- [TBD Working Group Home Page](#)
- [TBD Working Group Committee Members](#)
- [Meeting #12 Agenda / Summary / Written Public Comment](#)

**Video Clips**

- [Training, Education, Access to Care](#)
- [Dr. Donta, MD & Misc. Other](#)
- [Public Comments](#)

**Full Video**

- [March 3rd – Day 1](#)
- [March 4th – Day 2](#)

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**11th Meeting of TBDWG – January 28-29, 2020 Summary**
The 11th meeting of the Tick-borne Disease Working Group (TBDWG) was held at the Hyatt Place Washington DC/US Capitol, 33 New York Avenue NE, Washington, DC.

During the two-day meeting, the Working Group 1) heard presentations on findings and actions for TBDWG to consider from eight subcommittees; 2) heard updates from the Public Comment and Inventory Subcommittees; and 3) continued discussion of plans for the development of the 2020 report to Congress on federal tick-borne activities and research.

The first day’s meeting on January 28th went from 8:30 AM – 4 PM. Click here to view the meeting summary.

The second day’s meeting on January 29th went from 9 AM – 4:30 PM. Click here to view the meeting summary.

In June of 2019 the TBDWG established eight subcommittees, each identified priorities and developed a report to the TBDWG that described current efforts, gaps in research, and potential actions relevant to their topic. Click here to view the subcommittee reports.

Click here to view Public Comments from the January 28-29 meeting.

For more information visit the HHS.gov page.

Further questions or comments can be sent to:

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