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 tickboredisease@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](http://www.hhs.gov). The Committee report has 16M for Lyme and 38M for vector-borne diseases.

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Congressman Christopher H. Smith (NJ-4)
(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.
GAO Investigation of Ticks/Vector-Borne Agents’ Biowarfare Experiments Passes House

Kris Newby, Stanford University Science Writer, “Bitten”

Update July 29, 2020: The Bill and passed amendments such as this one (below) has now moved to the conference committee where the House and Senate will work to decide what language goes into the final product. The LDA provided input into the amendment language and has been working to get Senators to champion the inclusion of this GAO Investigation Amendment into the final bill.

Said LDA president Pat Smith: “We thank Congressmen Smith & Peterson for championing this investigation. Lyme and tick-borne diseases (TBD) patients and the public are entitled to know the truth about what past government research may reveal not only about the documented tick releases along the Atlantic bird flyway but also about research on the mysterious ‘Swiss
agent’ which Dr. Willy Burgdorfer identified as a new Rickettsia strain in his work for the US Government— at Rocky Mountain Labs and in Switzerland. Perhaps it may uncover clues to help stop this epidemic of tick-borne diseases.”

Rep. Smith (NJ-04) NDAA FY 2021 Lyme Disease Amendment Floor Speech
Jul 21, 2020


There is information in various publications that such activities did occur, especially in the book “Bitten” by Kris Newby— a science writer at Stanford University—a book, which
explores the evidence through actual government documents and interviews with some researchers who were involved that document such experiments.

Said LDA president Pat Smith: “Lyme and tick-borne diseases (TBD) patients and the public are entitled to know the truth about what past government research may reveal not only about the documented tick releases along the Atlantic bird flyway but also about research on the mysterious ‘Swiss agent’ which Dr. Willy Burgdorfer identified as a new Rickettsia strain in his work for the US Government– at Rocky Mountain Labs and in Switzerland. The book indicates there is speculation that this pathogen, if crossed with Borrelia, might well complicate treatment and thus be a candidate for biowarfare.” She added, “There is the possibility that any uncovered information could lead to facts which could shed light on the current epidemic of Lyme and other TBD and help develop solutions. We thank Congressmen Smith and Peterson for their continued push to make the truth known and the US House of Representatives for their vote to approve the amendment.”

Some things author Newby revealed for the first time were: that ticks were developed and deployed as stealth biological weapons during the Cold War, and that Willy Burgdorfer, the scientist the Lyme bacteria, Borrelia burgdorferi, was named after, was at the center of this program. According to Newby, specific revelations she makes in book include:

- A 1962 pilot study where infected ticks were dropped on Cuba sugar workers.
- Releases of hundreds of thousands of radioactive, aggressive Lone Star ticks on the Atlantic coastal bird flyway.
- Omissions of other microbes transmitted with Lyme-carrying ticks during the original outbreak (“Swiss Agent”).
- Documentation of military studies where live disease-causing bacteria, some which can be spread by ticks,
were sprayed from planes, boats and vehicles on the unsuspecting American public.

In 2019, a similar amendment was introduced and passed the House unanimously but there was no senate support for it.

The Lyme Disease Association (LDA) has been encouraging Lyme advocates across the country to contact both of their US Senators to champion and support this amendment. It is being heard in the Senate this week. LDA thanks those leaders who have made calls and sent emails to garner support.

More Information

New Jersey Globe: House passes Chris Smith measure to probe if government turned ticks into bioweapons

Chris Smith website: Chris Smith’s Lyme Disease Amendment Passes House, Tells DOD IG to Investigate the ‘Bioweaponization’ of Ticks

NJ101.5.com: NJ Rep. Chris Smith — did our government release diseased ticks?

MoreMonmouthMusings.net: House passes Smith’s Amendment which could lead to a Lyme disease cure

Here is a very similar Smith amendment that passed the House unanimously in 2019 but did not make it through the Senate.

https://lymediseaseassociation.org/government/urgent-help-needed-for-biowarfare-investigation/

Kris Newby’s Bitten: LDA book review

All about Kris Newby, the book and access some of the documents used in book.
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 explored.)

**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
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 re-vote. That vote resulted in not overturning the original vote. The recommendation in the first bullet above stands.

Other Working Group Information:
Lyme Disease Association (LDA) Working Group Page
Health & Human Services (HHS) Working Group Page
LDo, TOUCHED BY LYME: Persistent Lyme a sticking point for TBD Working Group

Lyme Disease Association, Inc. thanks all the advocates who contributed to this page, especially Dorothy Leland.

The videos provided in the article are segments from the official Working Group meeting videos.

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.

HHS Tick-Borne Disease Working Group

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.

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**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

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**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. Dona, 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

- Adablbeta (Beto) Perez de Leon, DVM, PhD (government member) Department of Agriculture (USDA), HHS
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN  VOTE ON REVOTE: YES
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.
President at COVID-19 Event: Lyme is Serious!

President Trump hosted Michigan State Rep. Karen Whitsett – who credits his promotion of a malaria drug, hydroxychloroquine, with her recovery from coronavirus – and other COVID-19 survivors at the White House. During their informal discussions, Rep. Whitsett, who nearly lost her life to COVID-19, brought up her chronic Lyme disease as an underlying condition. Throughout the 41-minute meeting, President Trump highlighted how serious and devastating Lyme disease is, stating that it “can kill you”.

LDA President Pat Smith said, “It is a good thing for Lyme patients that the President is speaking about how serious Lyme disease really is—the message coming in an unscripted discussion on another serious disease sweeping the world, COVID-19, which preys heavily on those with chronic conditions. Lyme is often not included in that category but is looked upon by many in mainstream medicine and in government as easily cured with a few weeks of antibiotics, a myth still existing after 45 years of Lyme disease.”

Pat Smith continued, “Patients succeeded in getting an HHS Working Group formed to address the issues of Lyme and other tick-borne diseases but there is still strong resistance to Lyme getting the attention it requires—still being marginalized despite about 350,000 cases occurring annually in the US alone. The President’s open interest and willingness to discuss it publically as being serious should put all levels of government on notice that it is critical chronic Lyme disease be addressed.”

Remarks by President Trump in a Meeting with Recovered COVID-19 Patients
STATE REPRESENTATIVE WHITSETT: The shortenings of — the shortening of breath is what really got me afraid because I do have Lyme disease. And thank you for always mentioning about Lyme disease.

THE PRESIDENT: Yeah. Yeah. No, Lyme disease is a big deal.

STATE REPRESENTATIVE WHITSETT: Thank you for always bringing that to the forefront.

THE PRESIDENT: Do you think you still have Lyme disease?

STATE REPRESENTATIVE WHITSETT: I do. I have chronic Lyme disease because I was never treated in time.

THE PRESIDENT: Can that be — can you get rid of it?

STATE REPRESENTATIVE WHITSETT: I’m hoping that we’ll talk about that.

THE PRESIDENT: Lyme disease is a thing that people don’t talk about. It is brutal —

STATE REPRESENTATIVE WHITSETT: It is brutal.

THE PRESIDENT: And if you have a certain type of blood, you have no chance.

STATE REPRESENTATIVE WHITSETT: It’s brutal. It’s brutal. And then, on top of having COVID-19 with it, it is a nightmare.

THE PRESIDENT: Incredible.
STATE REPRESENTATIVE WHITSETT: But the breathing is what scared me the most. And it came — I went from 0 to 100. It was from getting tested that day on March 31st to trying to do a few things around the house, to just all of a sudden my breathing became labored.

(Later In Discussion)

THE PRESIDENT: Yeah. No, if — by the way, we have tremendous endorsements. But if it were somebody else other than President Trump that put it forward — if some other person put it forward, they’d say, “Oh, let’s go with it.” You know.

What do you have to lose? They’ve been taking it for 40 years for malaria, which — by the way, it’s an unbelievable malaria pill. Unbelievable lupus pill. Unbelievable. In fact, the problem we had is people with lupus —

STATE REPRESENTATIVE WHITSETT: And with Lyme disease.

THE PRESIDENT: Huh?

STATE REPRESENTATIVE WHITSETT: And with Lyme disease. It was (inaudible) with Lyme disease.

THE PRESIDENT: And with — I heard Lyme disease, too.

(Later In Discussion)

THE PRESIDENT: I’m a little surprised they can’t do something with your Lyme disease. The Lyme disease is really terrible.

STATE REPRESENTATIVE WHITSETT: That’s because that’s federal. I need you.

THE PRESIDENT: Yeah. Well, but —
STATE REPRESENTATIVE WHITSETT: I need you on that.

THE PRESIDENT: — I mean, I could even have you see the doctor over here, because White — White House doctor. Ask the White House doctor to come.

PARTICIPANT: (Inaudible.)

THE PRESIDENT: Seriously. Because Lyme disease can be very, very bad.

STATE REPRESENTATIVE WHITSETT: Yeah. I don’t have a doctor any longer.

THE PRESIDENT: But it also can be — it also can — is it legal for me to allow her to use the White House doctor? You know what? If it’s not, I will suffer the repercussions. (Laughter.) I don’t care.

STATE REPRESENTATIVE WHITSETT: Well, there are —

THE PRESIDENT: The Democrats might not like that.

STATE REPRESENTATIVE WHITSETT: Well, there are a lot of people in Michigan and I do have eight Lyme bills that I am putting forward for Lyme disease —

THE PRESIDENT: Very good. Do it.

STATE REPRESENTATIVE WHITSETT: — because you cannot get treated in Michigan, as a doctor sees fit, for Lyme disease.

THE PRESIDENT: People don’t know about Lyme disease. It’s a very bad —

STATE REPRESENTATIVE WHITSETT: It’s horrible.

THE PRESIDENT: — very bad thing. And it —

STATE REPRESENTATIVE WHITSETT: So it is something I’m working on.
THE PRESIDENT: But it is something, over a period of time, you can treat generally. It also can kill you. Lyme disease — if you —

STATE REPRESENTATIVE WHITSETT: Yes.

THE PRESIDENT: If you have a certain type blood, you get Lyme disease —

STATE REPRESENTATIVE WHITSETT: Yes.

THE PRESIDENT: — it’s over.

STATE REPRESENTATIVE WHITSETT: I’m glad you know that.

THE PRESIDENT: It’s literally over.

STATE REPRESENTATIVE WHITSETT: I’m glad you know that.

THE PRESIDENT: I think type O — type O blood is not too good. If you have type O blood, stay out of the woods. Right?

STATE REPRESENTATIVE WHITSETT: It’s not even the woods. I got this at home at five years old.

THE PRESIDENT: You got it at home?

STATE REPRESENTATIVE WHITSETT: In Detroit.

THE PRESIDENT: But usually it’s from a deer tick, right?

STATE REPRESENTATIVE WHITSETT: It is a deer tick.

THE PRESIDENT: So where did the tick come from?

STATE REPRESENTATIVE WHITSETT: Well, the tick does not discriminate. It will get on anything.

THE PRESIDENT: So it comes somehow, right?

STATE REPRESENTATIVE WHITSETT: Yes. A squirrel, a bug, a bird — anything. It doesn’t discriminate.
THE PRESIDENT: Well, it’s like when I hit a ball into the rough in golf. (Laughter.) You know what I say? “Enjoy yourself. I’m not going in there.” (Laughter.) That Lyme disease is pretty tough, right?

STATE REPRESENTATIVE WHITSETT: It is.

THE PRESIDENT: It’s a bad one. I’d like you to see our doctor before you leave, okay?

STATE REPRESENTATIVE WHITSETT: Thank you.

(Last Statements on Lyme)

THE PRESIDENT: But what do I know? Am I allowed to take Karen over to see the White House doctors, see if we can help her out a little bit with Lyme disease? Because Lyme disease is a problem and there are some answers. What do you think? Are you guys going to report me for being a horrible human being? For doing something illegal? Did I do something illegal?

Q We can’t advise you on that, sir.

THE PRESIDENT: And then impeach me. Then you’ll impeach me because I tried to help her out with her Lyme disease. Do you think maybe? Because I’d like to do that. What do you think? Should I do it?

Q I can’t advise you on that, sir. But I — I certainly hope that she —

THE PRESIDENT: See, they never like to take chances, but I do. So, we’ll take a chance on it. Okay?

See Also: Rep. Smith Questions COVID-19’s Impact on Lyme Patients

On April 9th, Rep. Chris Smith sent a letter to Health and Human Services (HHS) Secretary Alex Azar and the National Institute for Allergies and Infectious Disease (NIAID) Director, Dr. Anthony Fauci, thanking them for their tireless efforts to address the Coronavirus outbreak as well as expressing his concerns about Lyme disease sufferers and their potential to be especially vulnerable to COVID-19.

Smith wrote, “As you know, my home state of New Jersey has been ravaged by COVID-19—as of April 9 there have been 51,027 confirmed positive cases and 1,700 have tragically lost their lives. Thousands more have lost their lives across the entire Tri-State area which also includes New York and Connecticut. I find this outbreak especially concerning when I consider the countless individuals who live in this region who also suffer from Lyme Disease, which also considers the Tri-State Area as a ‘hotspot.’”

The letter highlighted a 2018 HHS Tick-Borne Disease Working Group (TBDWG) report to Congress indicating that there are approximately 300,000 new cases of tick-borne disease annually.
in the US. Smith warned this number is likely higher and a press release from his office states that an estimated 40,000 of these cases originate in New Jersey.

“I remain deeply concerned about what impact COVID-19 and the Coronavirus outbreak will have on the countless Americans suffering from Lyme Disease and other related coinfections,” Smith continued. “Does the National Institutes of Health believe Lyme Disease, and other tickborne diseases, are considered underlying conditions which put individuals at higher risk for COVID-19?”

Since 1993 Smith has consistently worked to address the needs of the Lyme disease community including authoring comprehensive amendments and legislation such as the Lyme Disease Initiative Act of 1998 and more recently, The Tick Act, which creates a “new whole-of-government” national strategy to combat Lyme and other tick-borne diseases.

Read Congressman Smith’s letter to NIH and HHS.

Read a Press Release about Congressman Smith’s letter.

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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 Dona, 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>1 - P. Smith: Govt. Website Disclosures (5 + min)</td>
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<td>3- S. Cooper: Nationwide Lyme Clinical Training (4+ min)</td>
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<td>5- P. Smith Defends Chronic Lyme Patients (4+ min)</td>
<td>10:36:14 to 10:40:18</td>
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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.
| 1-S. Donta: Pathogenesis, Physiology of Lyme | 4-S. Donta: Clinical Aspects of Lyme Including Potential Sexual Transmission | 7-Use of Doxy for RMSF |
| 2-P. Smith: Comments on Lyme Carditis, Tissue Testing Prob. | 5-S. Donta: Maternal Fetal Transmission / Congenital Lyme Vote | 8-Rickettsial CME Education |
| 3-S. Donta: Comm. Discussion/Vote on Lyme Issues | 6-Diagnostics Discussion | 9-Alpha Gal & Data Mining |

Sam Donta, MD: Discussion of Pathogenesis and Physiology of Lyme Disease Subcommittee Recommendations (Day 2)
Co-Chairs:  Sam Donta, MD; Prof. of Medicine (Ret) and Leith Jason States, MD, MPH; HHS

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
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
8-Rickettsial CME Education
4:06:40 to 4:12:37
14800 to 15157

9-Alpha Gal & Data Mining
8:30:00 to 9:28:01
30600 to 34081