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 tickboredisease@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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**Contentious Working Group Meeting Vote on CDC Posting Lyme Guidelines**

The thirteenth meeting of the [Tick-Borne Disease Working Group](https://www.cdc.gov/ncidod/diseases/tickborne/diseases/index.htm) (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

- Adablbleto (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](http://Lymedisease.org) presented for Phyllis Mervine, President of [Lymedisease.org](http://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](https://www.cdc.gov/ncidod/eid/vol16no9/pdfs/1009-d.pdf).

- **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’s FY21 Budget Request Includes Increase for Vector-Borne Diseases

The White House released the Fiscal Year 2021 budget proposal which includes a $14 million increase compared to the 2020 enacted level that focuses on tick-borne diseases.
Excerpts from *Budget of the United States Government, Fiscal Year 2021*:

- “Prioritizes Critical Health Research and Supports Innovation” … “NIH would continue to address the opioid epidemic and emerging stimulants, make progress on developing a universal flu vaccine, prioritze vector-borne disease research, and support industries of the future.”

- “Advances Vector-Borne Disease Prevention and Control. The threat of mosquito and tickborne diseases continues to rise in the United States. Cases of tick-borne diseases, such as Lyme disease and Rocky Mountain spotted fever, affected nearly 60,000 Americans in 2017. The Budget includes $66 million for CDC’s vector-borne disease activities, a $14 million increase compared to the 2020 enacted level which focuses on tick-borne diseases. The Budget also invests in NIH research to improve the Nation’s understanding of vector-borne diseases.”

The White House also released a fact sheet titled *Protecting our Nation’s Health and Wellness* reinforcing the prioritization of critical health research and advances in vector-borne disease prevention and control. Congress will review and vote on the budget proposal within the coming weeks.
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:

James Berger, Designated Federal Officer for the TBDWG Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health, Department of Health and Human Services
Mary E Switzer Building, 330 C Street SW, Suite L600
Washington, DC 20024. Email: tickbornedisease@hhs.gov; Phone: 202-795-7608

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TBDWG Subcommittee Reports Now Accessible

The HSS-Tick-Borne Disease Working Group subcommittee reports are now accessible on the HHS-TBDWG webpage. The TBDWG established eight subcommittees in June 2019. Each subcommittee identified priorities and developed a report to the TBDWG that described current efforts, gaps in research, and potentials actions relevant to their topic. Read Subcommittee Reports

The TBDWG will discuss the subcommittee reports during the next public meeting taking place January 28-29 at Hyatt Place
In-person attendance at the meeting is limited to space available; therefore, preregistration for public members is advisable and can be accomplished by registering here. Members of the public may also attend the meeting via live webcast.

10th Meeting of TBDWG – Sept 12, 2019 Summary

Subcommittee members were announced, and the Working Group received reports from the eight subcommittees that were formed during the June 4, 2019 meeting.

Two subcommittee name changes were approved, since the Subcommittees felt names did not reflect the focus of the Subcommittees. Dr. Ben Beard, CDC, presented the change to the first committee, and Pat Smith, President LDA presented the change to the second. The two Subcommittees are now 1.) Babesiosis & Tick-Borne Pathogens and 2.) Training, Education, Access to Care & Reimbursement. Dr. Beard indicated his committee needed to include more of the tick-borne diseases and not just
viral TBD. Ms. Smith was concerned because Working Group discussion had included Access to Care & Reimbursement and that without that aspect in the title, patients needs were being removed from the focus of the Subcommittee.

- Public comments were presented by eight patients and advocates over a 30 minute time period. Issues shared included alpha-gal, 2019 TBDWG membership as it relates to patient/advocate representation, and transparency of the TBDWG process.
- Three topic development briefs were shared with the Working Group. A common theme throughout the briefs was that the most existing research that had been collected in this process is either inconclusive or indicates that further research is needed in each of the three topic areas presented. The three topic development briefs were: 1.) Cause of increase for tick-borne diseases, 2.) Cause of persistent Lyme disease, and 3.) State of current testing for tick-borne diseases.
- The Working Group created a new subcommittee, Federal Inventory, to analyze the new Federal inventory content for use in the 2020 report to congress. LDA President and TBDWG member, Pat Smith, volunteered to Chair this committee and Sam Donta volunteered to be Co-Chair.
- Pat Smith also requested the list of NIH grants be released to the public.
- Timeline for subcommittee work and dates for the next two (in-person) TBDWG meetings were announced.

The next (in-person) public meetings will be held January 28 & 29, 2020 in Washington, DC and March 3 & 4, 2020 in Philadelphia, PA

For details visit [HHS-TBDWG webpage](#)

Comments to the TBDWG may be emailed directly to [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov)
HHS Announces Sep 12 Tick-Borne Disease Working Group Meeting

The Department of Health and Human Services (HHS) gave notice that the Tick-Borne Disease Working Group (TBDWG) will hold a public meeting via webcast on September 12, 2019, from 8:30 a.m. to 5 p.m. ET (times are tentative and subject to change).

At the upcoming meeting, the TBDWG will receive updates from eight subcommittees that were formed and tasked with drafting a 2019 report for the HHS Secretary and Congress regarding activities and research related to tick-borne diseases, such as surveillance, prevention, diagnosis, diagnostics, and treatment (source, hhs.gov). The subcommittees will take into consideration the 2018 report and are expected to identify gaps in tick-borne disease research as well as offer suggestions (source, federalregister.gov).

The confirmed times and agenda items for the online meeting will be posted on the TBDWG page of the HHS website. Members of the public who wish to view this meeting online are encouraged to register. Click here to register for the September 12th TBDWG Meeting.

Article References: FederalRegister.Gov and HHS.Gov

View the announcement for the 10th meeting of the TBDWG on FederalRegister.Gov
TBD Working Group Meeting Summary/Public Comments Now Available – June 4, 2019

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

Read Meeting Summary and Written Public Comments – June 4, 2019
TBDWG Meeting

Still pending: Archived Webcast, Slide Presentation

Pat Smith Appointed to New Panel of the TBDWG

Patricia V. Smith, has been appointed as one of the public members of the new panel for Health and Human Services Tick-Borne Disease Working Group (TBDWG). Pat is in her 22 year as President of the all-volunteer run national non-profit Lyme Disease Association (LDA) and has been a leading voice and advocate for patients for over 3 decades. She was
instrumental in writing and passing the legislation that resulted in the formation of this federally mandated TBDWG. This appointment was announced publicly during the first meeting of the new TBDWG on June, 4, 2019.

Pat Smith, HHS TBDWG meeting, June 4, 2019. Photo courtesy of LymeDisease.org.

As witnessed during the meeting, Pat will continue to be the voice of the patient and the growing numbers of chronically ill. The panel convened for introductions, to hear public comment, and to develop subcommittee topics and establish subcommittee chairs to begin the work toward the next report to Congress due November of 2020. Unlike last term, nomination for subcommittee members will not be publicly solicited, but will be selected by the prospective co-chairs for each of the 7 subcommittees determined at the meeting.

Swearing in of the HHS TBDWG members, June 4, 2019. Photo
Pat served on the inaugural panel of the TBDWG, which presented it’s first report to Congress in November of 2018. She is joined for a second term by other returning members:

Charles Benjamin (Ben) Beard, Ph.D.-Deputy Director, Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention;

Dennis M. Dixon, Ph.D.-Chief, Bacteriology and Mycology Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Captain Estella Jones, DVM– Deputy Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration

Other new public and federal members and their alternates were also announced at the first meeting of the new TBDWG panel, which took place June 4, 2019 in Washington DC, and include:

Public Members

The new Working Group will be chaired by David Hughes Walker, M.D., Professor of Pathology and Executive Director, University of Texas Medical Branch Center for Biodefense and Emerging Infectious Diseases. He is an expert in Rickettsial diseases, particularly RMSF; and Leigh Ann Soltysiak, Owner, Principal, Silverleaf Consulting, LLC.


Scott Palmer Commins BS, M.D., Ph.D.– Associate Professor of
Sam T. Donta, M.D.— Infectious Disease Consultant, Falmouth Hospital; and Former Member, U.S. Department of Defense Tick Borne Disease Research Programmatic Review Panel (Falmouth, Massachusetts)

Eugene David Shapiro, M.D.— Professor of Pediatrics, Epidemiology, and Investigative Medicine, Yale University School of Medicine; Vice Chair for Research of the Department of Pediatrics; Co-Director of Education for the Yale Center for Clinical Investigation; and Deputy Director of Yale’s PhD Program in Investigative Medicine (New Haven, Connecticut)

Regular Government Employees (Federal Members)

Commander Rebecca Bunnell, MPAS, PA-C— Senior Advisor, Learning and Diffusion Group, Innovation Center, Centers for Medicare and Medicaid Services

Angel M. Davey, Ph.D.— Program Manager, Tick-Borne Disease Research Program, Congressionally Directed Medical Research Programs, U.S. Department of Defense

Leith Jason States, M.D., MPH (FMF)— Deputy Chief Medical Officer, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Adalberto (Beto) Pérez de León, M.D.— Director, Knipling-Bushland U.S. Livestock Insects Research Laboratory, Agricultural Research Service, U.S. Department of Agriculture

Alternate Government Employees (Federal Members)

Chien-Chung Chao, Ph.D.— Research Chemist, Viral and Rickettsial Diseases Department Infectious Diseases Directorate, Naval Medical Research Center, U.S. Department of Defense
Captain Scott J. Cooper, MMSc, PA-C- Senior Technical Advisor and Lead Officer for Medicare Hospital Health and Safety Regulations, Centers for Medicare and Medicaid Services

Shahla Jilani, M.D.-Deputy Chief Medical Officer, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

David A. Leiby, Ph.D.-Chief, Product Review Branch, Division of Emerging & Transfusion-Transmitted Diseases, Office of Blood Research & Review, Center for Biologics Evaluation & Research, Food and Drug Administration

Commander Todd Myers, Ph.D.-Scientist, Office of the Chief Scientist, Office of Counter Terrorism and Emerging Threats, Food and Drug Administration

Samuel S. Perdue, Ph.D.-Section Chief, Basic Sciences and Program Officer, Rickettsial and Related Diseases, Bacteriology and Mycology Branch, National Institute of Allergy and Infectious Diseases), National Institutes of Health

Susanna N. Visser, Dr.PH -Associate Director for Policy, Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

HHS TBDWG website

HHS TBDWG Members Press release
Lyme Disease Association Announces: Public Comments on Pain Management

The Pain Management Best Practices Inter-Agency Task Force (Task Force) was established to propose updates to best practices and issue recommendations that address gaps or inconsistencies for managing chronic and acute pain. The U.S. Department of Health and Human Services is overseeing this effort with the U.S. Department of Veterans Affairs and U.S. Department of Defense. The Draft Report from the Task Force on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations was issued on December 28, 2018, which calls for individualized, patient-centered pain management to improve the lives of millions of individuals who experience acute and chronic pain.

Members of the public are requested to provide comments on the draft report’s proposed recommendations by April 1, 2019. For more information about the Task Force, the report and the comment process please visit the Pain Management Best Practices Inter-Agency Task Force here.

NOTE: Please do not contact the Lyme Disease Association for information on this posting.