

Contentious Working Group Meeting Vote on CDC Posting Lyme Guidelines

Tick-Borne Disease Working Group

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.

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 ON GUIDELINES 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**

- Adablбето (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 Officer Office of the Assistant Secretary for Health, HHS

**VOTE ON GUIDELINES RECOMMENDATION: ABSENT VOTE ON
REVOTE: ABSENT**

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'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, **prioritize 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."

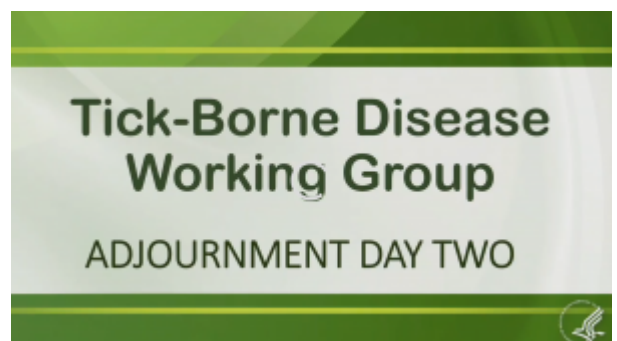
The White House also released a fact sheet titled [*Protecting our Nation's Health and Wellness*](#) reinforcing the prioritization of critical health research and advances in vector-borne disease prevention and control. Congress will review and vote on the budget proposal within the coming weeks.

Click here to view [*Budget of the United States Government, Fiscal Year 2021*](#)

Click here to view supplementary document [*Protecting our Nation's Health and Wellness*](#)

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

TBDWG Subcommittee Reports Now Accessible



Tick-Borne Disease Working Group

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 potential 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 Washington DC/US Capitol, 33 New York Avenue NE, Washington, DC 20002.

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



Tick-Borne Disease Working Group

The tenth meeting of the Tick-Borne Disease Working Group (TBDWG) was held via webcast on Sept 12, 2019 from 9:00 a.m. to 3:00 p.m. ET.

- 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 being removed from the focus of the Subcommittee.
- Public comments were presented by eight patients and avocates 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

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 courtesy of LymeDisease.org.

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.

Robert Sabatino— Founder and Executive Director, Lyme Society Inc., Staten Island, New York (Term expires in August 2019).

Scott Palmer Commins BS, M.D., Ph.D.— Associate Professor of Medicine & Pediatrics, University of North Carolina at Chapel Hill; Member, UNC Food Allergy Initiative, Thurston Research Center (Chapel Hill, North Carolina)

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.