Working Group Meeting: Lyme Patient Access to Care Still Under Attack

The recent 2-day virtual meeting of the Federal Tick-Borne Disease Working Group (WG) on Day 1 was more subdued than prior meetings, but Day 2 again brought forth an effort to minimize the patient access to care chapter and chronic Lyme.

Day 1 September 15, 2020

Patients and patient advocates delivered verbal comments, including advocate Carl Tuttle, who asked Pat Smith “to hold Shapiro’s feet to the fire” in regard to persistent Lyme and patient advocate Lucy Barnes, who stated “patients are fighting for their lives” and “you know better.” Erin Walker, wife of PGA tour winner Jimmy Walker, a Lyme patient, emphatically expressed the need for better testing and better treatment as Lyme is a “real disease that affects real Americans.” Problems with patient access to care was a common theme in the verbal comments.

WG member Angel Davey presented a report from the Public Comments Subcommittee, which summarizes incoming public comments: priority areas/key themes. Of note were the number of comments received in June and July 2020 after the June 8th meeting of the WG. Recurrent themes of these comments included

- “Denying the existence of persistent or chronic Lyme disease…”
- “Access to care is poor…”
- “SeroLogic diagnostic testing and CDC guidelines are
inaccurate and hurting many people”
- Persistent/chronic Lyme disease symptoms cited include: musculoskeletal pain, cramps, twitches, bladder pain, severe/chronic fatigue, swollen joints, arthritis, heart arrhythmias, mental illness, insomnia, Bell’s palsy, numbness, foot drop, inflammation, food allergies, digestive issues, skin issues, light/noise/tactile sensitivities”
- “Lyme disease misdiagnosis is rampant....”
- The final July slide states:

![Tick-Borne Disease Working Group](image)

- “Patients with chronic Lyme & other TBDs are being failed by the healthcare system”
- “Patients with chronic Lyme must be heard”
- “Deniers of chronic Lyme disease need to be removed from the TBDWG”

Chapter 8: Epidemiology and Surveillance Review.
In the discussion of this chapter, Pat Smith again reiterates that recommendations posted on the CDC guidelines webpage only addresses acute Lyme, and that this is the only guidance available to physicians and patients seeking resources. This chapter contains the minority report addressing “Effect of Geographic Restrictions on Lyme Diagnosis,” which specifies why the “diagnosis by geography” proviso should not have been removed from the WG report as a recommendation to Congress. The original recommendation which was in the patient access chapter was “CDC provide input to the Council of State &
Territorial Epidemiologists, CSTE, that the Lyme disease surveillance case definition be revised such that it abandons the use of geographic parameters for the diagnosis of Lyme disease and inform clinicians and the public that Lyme disease has been reported in all states.”

On the topic of non-tick-bite transmission, Pat vehemently disagreed with Sam Donta that modes such as “other insect vectors” be dropped from discussion stating that more research is needed on possible insect-borne transmission, since research has shown mosquitoes can carry the Lyme bacteria, and that “the whole process has been subverted to begin with.”

Chapter 9: Looking Forward Review: where Eugene Shapiro continued to contest the use of “persistent Lyme disease”. Repeated comments in the side bars viewable to the public included “persistent Lyme disease is undefined and is not a scientifically defined or recognized entity.”

Day 1 concluded with reviews of Chapters 1: “Background,” Chapter 2: “Methods,” and the Table of Contents and Title Page. Further review of the suggestions will be considered at another meeting.

After a lengthy discussion, a decision was made to include a separate chapter in the report to congress on Public Comments.

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Day 2-September 22, 2020

Day 2 of meeting 15 resumed Sept. 22, beginning with reviews of Chapter 3: “Tick Biology, Ecology, and Control,” presented by CDC’s Dr. Ben Beard. Of note was that two times as many TBDs have been discovered in the past 60 years than the previous 60 years.

Chapter 4: Clinical Manifestations, Diagnosis, and Diagnostic Review: was presented by Dr. Sam Donta. Immediately, there was a replay of the June 8 meeting with further disagreement
regarding the word “likely” versus “possibly.” Dr. David Walker stated “likely as too strong a word” regarding the hypothesis that the effects of persisting organisms are the source of ongoing symptoms in patients with unresolved Lyme disease. After much discussion and disagreement regarding persistence, the WG agreed that a statement such as “Evidence continues to be gathered that supports that persistent infection plays a role” may be an acceptable solution, and wording will be revisited by the co-leads of this chapter.

Convergent views and difference of opinion continued into Chapter 5 review: “Causes, Pathogenesis, and Pathophysiological,” where disagreements arose about TBD ability to suppress, subvert or modulate immune system in humans and effects to response to treatment and increase risk of developing other infections. Dr. Walker stated that “this speculation requires a reference. I do not know of any supportive evidence.” Although Angel Davey cited references on human effects, arguments over the validity of animal studies to translate to human effects continued. It was agreed that further studies are needed.

Chapter 6: Treatment Options and Strategies Review: was presented by Dr. Sam Donta and Dennis Dixon, NIH. When discussing Rickettsial diseases, Pat Smith requested that the stated fatality rate of 20% be cited and/or updated with current numbers. Dr. Walker argued that this statement was in regard to untreated infections, however Pat argued that these numbers are being quoted from 1940’s and 1950’s studies, and that current citations are needed. Ben agreed to update with more timely and relevant data, especially bringing forth regional outbreaks in Arizona, which have higher numbers. Pat then said great, we can then include numbers from Lyme in high case areas.

Chapter 7: Clinician and Public Education, Patient Access to Care Review: was presented by Pat Smith and captain Scott Cooper, PA, the latter went down the previously addressed
(online) comments one by one explaining the changes he and Ms. Smith had made. Drs. David Walker and Eugene Shapiro surfaced on the topic of “persistent Lyme.” This chapter review was again the longest and most contentious of all chapters discussed. Walker started off by disputing the patient percentage numbers that describe chronic and often debilitating symptoms. He believes the cited 35% to be too high and inconsistent with numbers used previously in the report. Walker’s comments on the sidebar of the report continue to argue that “persistent/chronic Lyme disease is an unproven hypothesis, and accused Pat Smith of using this chapter to address “the author’s pet topics.” She explained that these numbers were generated from a study conducted by Dr. John Aucott, Johns Hopkins University. Shapiro went on to discredit the Aucott study arguing the validity of the patient cohort, to which Smith responded that the patient cohort was comprised of all EM rash patients. Ultimately, it was agreed that Captain Cooper and Ms. Smith would revise and include a range of percentages from various Lyme patient studies with chronic or persistent symptoms.

However, Shapiro continued his attack of the topic of “persistent Lyme disease” while attempting to discredit the use of the largest patient registry, MyLymeData with comments written on the sidebar of the report stating “This is mostly propaganda and typically based on self-reports with no confirmation that the patients have Lyme disease.” In regard to the data presented where “67% (of patients) report that they have postponed or avoided medical treatment due to discrimination, disrespect or difficulty obtaining care, and nearly half (47%) report that they have been denied treatment.” Shapiro argued the credibility of the patient registry responding to Pat Smith, “I don’t buy it.” She explained that NIH uses patient registries, 72 of them. Pat went on to describe that this patient registry is a rigorous one, featured in college textbooks, in collaboration with UCLA, and a registry that has resulted in citations in 4 peer
reviewed studies as well as having received $800,000 in funding from the National Science Foundation. Walker argued that “the evidence isn’t there that it really is associated with Lyme disease.” Dennis Dixon suggested a writing a preamble to this section describing what patient registries are and how they are collected. Pat responded, “we can certainly do that, but I believe that again, we are being discriminated against…our patients…and all of the information we have about them.” She further explained “every time we present something that other people use with many, many other diseases, it’s like we have to jump through hoops in order to indicate these people are sick.”

In response to erroneously reported case numbers that were discovered in the past subcommittee report on ehrlichiosis/anaplasmosis, Smith and Cooper replaced report text with quoted material from the CDC website. Walker did not like those CDC numbers. Discussion ensued regarding reported case numbers for each of the tick-borne diseases. Ben Beard suggested to just capture the big picture rather than talking about numbers in one year or another and stated “diseases are on the rise and no one disputes that,” so why not just state “cases over the past 15 years have increased significantly.” The co-leads will review that for inclusion.

The disagreements continued…In regard to Walker’s and Shapiro’s comments about NIH Lyme clinical treatment trials Cooper stated “ these are long standing professional disagreements.” Shapiro said “it could be presented in a much more balanced way”. Smith responded that they had already revised and made the changes as recommended. Shapiro stated “I’ll just write something…. a minority report I guess.” Smith said, “as long as you vote against this you certainly can do that. We indicated that there was a difference of opinion…and we did that. We felt that we addressed the huge discussion that was held last meeting…we looked back and read the summaries of the meeting…and we felt that we addressed those.”
Shapiro said “I vote no.” To which Pat responded, “you can’t vote no, there is no motion on the floor.” When asked by Dennis Dixon if there were any minor wording suggestions to take the need for minority report off the table, Shapiro stated “No, I don’t…I think it is too great a gap.”

When contrasting the differing treatment guidelines (IDSA vs ILADS), Shapiro commented, “again the authors ignore the fact that ILADS recommendations are gross outliers,” and that the authors have presented an “inaccurate, biased table” and he wants it deleted. After much discussion about the table’s contents and title, co-leads agree to revisit. Shapiro stated that he did not believe that information is being presented in a balanced way and that he will move forward with a minority report. Pat reminded Shapiro that to write the minority report, he will have to vote against the report.

On the topic of “shared decision making,” Walker proposed removal of the entire section. He stated that he “can’t see how this is relevant to this chapter.” He stated in the comments that “The authors of this chapter have departed from its intention…and that they have presented too much content on the ideas espoused by ILADS...” Walker further commented “This is an inappropriate balance. It represents a biased overemphasis on Lyme disease in the context of this chapter.” Pat Smith again championed the voice of the patients explaining why this content is not only appropriate but supports the intent of the WG.

Meeting Conclusion:

- Jim Berger announced that HHS will be seeking nominations in the next couple of weeks for TBDWG members for work on next report to Congress due in 2022. 4 of 7 public members terms expire Dec.2020 , other 3 in June 2021. Nominees will be asked to submit CV or Resume through a link in the Federal Register which will be open for 30 days.
- The next meeting of the Working Group will take place virtually on October 27, 2020. Following meeting dates were also announced for November 17 and December 2, 2020.

*Slide presentations from the September 15th and 22nd meetings may be obtained by sending your request to tickbornedisease@hhs.gov.

MyLymeData 2019 Chart Book

TOUCHED BY LYME BLOG: Walker & Shapiro fail to change report’s Chapter 7

TOUCHED BY LYME BLOG: Will Working Group acknowledge patient voices?
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 tickborendisease@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 (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
- Adablbero (Beto) Perez de Leon, DVM, PhD (government member) Department of Agriculture (USDA), HHS
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN VOTE ON REVOTE: YES
- Kevin R. Macaluso, PhD, MS (government member) University of South Alabama
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN VOTE ON REVOTE: NO
- Leigh Ann Soltysiak, MS (co-chair) (public member) Silverleaf Consulting, LLC Adjunct Professor, Stevens Institute of Technology
  VOTE ON GUIDELINES RECOMMENDATION: ABSTAIN VOTE ON REVOTE: YES
- Leith States (government member) Deputy Chief Medical
The TBDWG, received verbal comments from the public on a range of topics including:

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

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

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

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

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

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

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

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

Click here to view information about prior TBDWG meetings.

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.
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

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

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 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
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

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