

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

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

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

Other Video Clips: Training, Education, Access to Care
Discussion / Public Comment (9 speakers)

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

19619 to 19692

2-P. Smith: Comments on Lyme Carditis, Tissue Testing Prob.

5:28:13 to 5:30:07

19693 to 19807

3-S. Donta: Comm. Discussion/Vote on Lyme Issues

5:30:07 to 5:33:28

19807 to 20008

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

3:54:12 to 3:57:04

14052 to 14224

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

TBDWG Mtg 12: Public Comments (Video)

At the start of the second day of the HHS Tick-Borne Disease Working Group meeting in Philadelphia on March 4, 2020, nine Lyme disease advocates and patients who preregistered either

called in or were present at the meeting in person to provide public comments. Their input was invaluable and helped Working Group members appreciate issues of concern throughout the country.

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Public Comments: Day 2, March 4th

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

Lonnie Markham, LDO: Tick Attachment Time

1:41:57 to 1:44:42

6117 to 6282

Dorothy Leland, VP LDO: Process Integrity

1:52:05 to 1:55:17

6725 to 6917

Mark Liberto: Patient Story

1:55:18 to 1:59:11

6918 to 7151

Phyllis Mervine, President LD0: 2 Standards of Care

1:59:14 to 2:02:39

7154 to 7359

Melissa Potter, LD0: Patient Registry-MyLymeData

2:02:40 to 2:05:39

7360 to 7539

Dr. Betty Maloney: CDC Treatment Recommendations

2:05:40 to 2:08:47

7540 to 7727

Mira Shapiro, LD0: Big Data Research

2:08:49 to 2:11:55

7729 to 7915

Jennifer Platt, TBC United: Alpha-gal & lesser known conditions

2:11:55 to 2:15:04

7915 to 8104

Jill Auerbach, HVLDA: Prevention Emergency

2:15:05 to 2:18:01

8105 to 8281

12th meeting of the TBDWG- Summary



Tammy R. Beckham, Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), US Health and Human Services (HSS)

The 12th meeting of the Tick-Borne Disease Working Group (TBDWG) took place over two days, March 3rd-4th, 2020, at The College of Physicians of Philadelphia in Philadelphia, PA. A summary of this in-person public meeting is as follows:

- Opening statements were presented by Tammy R. Beckham, Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), US Health and Human Services (HSS).
- The TBDWG discussed and voted on recommendations for the format/template of the 2020 TBDWG Report to the HHS Secretary and Congress. There was full agreement by the TBDWG to use the same format/branding of the 2018 TBDWG Report for the 2020 TBDWG Report to HHS Secretary and Congress.
- Ben Beard, Deputy Director, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention (CDC) provided an update to the CDC Tick Surveillance program. CDC has increased monies and guidance being provided to States to conduct active tick surveillance activities. In addition, the CDC will provide both tick identification and testing services for States that do not have the expertise needed to conduct these activities.
- Public comment was provided by eleven patients/advocates to the TBDWG. These patients/advocates provided

he also stated that “The vast majority of Lyme disease patients are served quite well by the guidance we have on our website. The diagnostic test is reliable in terms of it telling you what you expect to hear.”

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

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

For upcoming meeting notifications please visit the HHS-TBDWG webpage here.

Public comments may be made in writing directly to the HHS-TBDWG at tickbornedisease@hhs.gov

Associated Links

[TBD Working Group Home Page](#)

[TBD Working Group Committee Members](#)

[Meeting #12 Agenda / Summary / Written Public Comment](#)

Video Clips

[Training, Education, Access to Care](#)

[Dr. Donta, MD & Misc. Other](#)

[Public Comments](#)

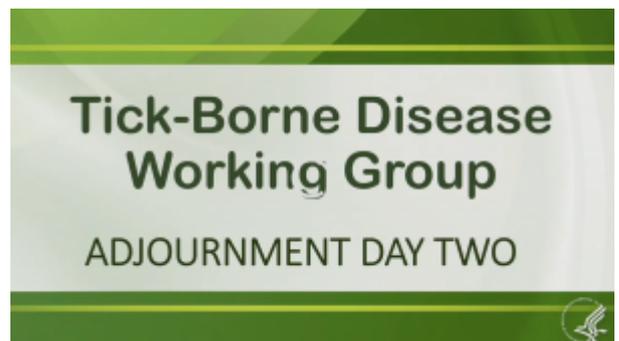
Full Video

[March 3rd – Day 1](#)

[March 4th – Day 2](#)

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](https://www.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 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.

TBDWG: Jan. 2020 Meeting in DC/In-person, Written Comments Accepted

The 11th meeting of the Tick-borne Disease Working Group (TBDWG) will be held on January 28 and 29, 2020, from 9:00 a.m. to 4:30 p.m. ET on both days

The logo for the Tick-Borne Disease Working Group features a green gradient bar at the top. Below it, the text "Tick-Borne Disease Working Group" is displayed in a dark green, sans-serif font on a light green background.

(times are tentative). The HHS.gov site has announced that, for this meeting, the eight subcommittees will present their findings and potential actions for the TBDWG to consider. The TBDWG will hear updates from Public Comments and Inventory Subcommittees as well as advance discussions regarding plans for developing the 2020 report to the HHS Secretary and Congress on federal tick-borne activities and research. Information provided via Public Comment will be summarized and provided to the subcommittees for review and possible incorporation into the next TBDWG report.

The meeting will take place at the Hyatt Place Washington DC/US Capitol located at 33 New York Avenue NE, Washington, DC 20002. In-person attendance is limited to space available. Pre-reregistration for public members is advised and can be accomplished by registering on the HHS.gov site. [Click Here](#) to register to attend the 11th TBDWG Meeting in person.

To request an opportunity for in-person Verbal comments:

- Requests for verbal (in-person) public comment must be submitted via email **by midnight Tuesday, January 17, 2020, ET** to tickbornedisease@hhs.gov. In the Subject

line please enter: **Verbal Public Comment – January 28-29 Meeting.**

- A total of 30 minutes has been set aside for verbal comments on both days. Each person will be limited to only 3 minutes so that as many speakers can be accommodated as possible. Speakers will be randomly selected if more requests are received than can be accommodated.
- In-person remarks will be heard over a live webcast will become part of the archived meeting recording and summary which will be posted on the HHS.gov website.

To submit Written comments which will be posted on the HHS.gov webpage and accessible to the public:

- Written public comments must be submitted via email **by midnight Tuesday, January 17, 2020, ET** to tickbornedisease@hhs.gov. In the Subject line please enter: **Written Public Comment – January 28-29 Meeting.**
- Please include a statement indicating how you would like to be identified with your comment. You may choose to use your name or to be anonymous. You may also list your city and/or state. If you are providing comments on behalf of an organization, please include the name of the organization. ***The TBDWG cannot post your comment until you advise how you would like to be identified.***
- Comments should either be provided in the body of your email, or in an attachment in Word format and equivalent to no more than 4 pages in Calibri or Times New Roman, 11 point font. Text that exceeds the 4 pages will be deleted.
- The TBDWG does not post graphics, images, text boxes, or tables. If included with your comment, they will not be able to retain them.
- The TBDWG can only create hyperlinks to “.gov” sites (local, state, or federal). For all other reference sites, please insert the full URL (e.g.,

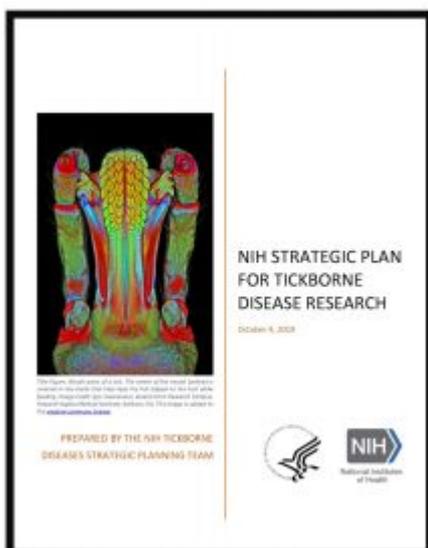
<http://learn.genetics.utah.edu/content/epigenetics>).

- The TBDWG is unable to include attachments as supporting documentation to written comments.

Members of the public who cannot attend in-person may attend the meeting via webcast. Instructions for attending via webcast will be posted approximately one week prior to the meeting.

Click [Here](#) for furthered information on the HHS.gov website, including the meeting agenda and more details on how to provide public comment.

NIH Releases Strategic Plan for Tick-Borne Disease Research



The *NIH Strategic Plan for Tickborne Disease Research*, October 9, 2019, is good news for everyone in the Lyme and tick-borne diseases community! The plan builds on the activities of the Department of Health and Human Services Tick-Borne Disease Working Group (TBDWG), which issued a 2018 report to Congress outlining research recommendations. Through inventories sent to government agencies to determine gaps in their research on tick-borne diseases (TBD), the Working Group uncovered the fact that NIH did not have a national strategy for TBD. The HHS TBDWG Report made the recommendation below in the November 2018 report:

Recommendation 8.1: NIH: Create an NIH tick-borne disease strategic plan, with public input during creation and implementation, to address tick-borne diseases, including all stages of Lyme disease. Include in the strategic plan the coordination of research funding across NIAID, NINDS, NIAMS, and NIMH to increase knowledge of pathogenesis, improve diagnosis, and develop and test new therapeutics for tick-borne diseases. Update every five years.

The LDA President, Pat Smith, served as a TBDWG member that wrote the 2018 report. She was reappointed this year for a second term as it develops the next report to Congress due December of 2020.

In developing this strategic plan, as recommended by the TBDWG Report, NIH sought input from the research and medical communities, patient advocacy groups, pharmaceutical industry, and the general public.

The Lyme Disease Association submitted input to the NIH on a strategy:

<https://lymediseaseassociation.org/news/lda-provides-input-to-national-institutes-of-health-strategic-plan-development>

The newly released NIH plan focuses on five scientific priorities important for advancing research and development

over the next five years.

1. Improving fundamental knowledge of tickborne diseases, including the biology of tickborne pathogens; how they are transmitted to humans, evade the immune system, and spread within the body. Including determining the cause of persistent symptoms in some people infected with tickborne diseases, such as Lyme disease, and furthering the understanding of how tick-derived factors contribute to the establishment and severity of disease.
2. Advance research to improve detection and diagnosis of TBDs. Improving detection and diagnosis of tickborne diseases by developing rapid diagnostic tests that can detect a pathogen both early and late in infection and distinguish between active and past infections. NIH will support the development of diagnostics capable of predicting treatment success and identifying human biomarkers of infection and persistent symptoms.
3. Accelerate research to improve prevention of TBDs. The new plan also prioritizes the acceleration of research designed to prevent tickborne disease infection, including vaccines, and immune-based treatments, as well as strategies to reduce the transmission of tickborne pathogens to animal populations that serve as hosts.
4. Focusing on research to develop new treatments for tickborne diseases and techniques to reduce disease complications.
5. Prioritizing the development of tools and resources to advance tickborne disease research by improving scientists' access to biological samples, tickborne disease genetic data, and supporting preclinical development of promising products.

NIH intends to expand collaborations across its institutes and centers to promote a multidisciplinary approach to tickborne disease research, answer complex biological questions and encourage the application of state-of-the-art technologies

used successfully in a range of scientific disciplines.

NIH Strategic Plan for Tickborne Disease Research

NIH Strategic Plan News Release

Congressman Smith praises NIH announcement (TAPinto.net)

Congressman Smith press release on NIH Strategy

Note from LDA: tick-borne disease is generally spelled with a hyphen. NIH has chosen to leave out the hyphen in its report.

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 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