

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 at COVID-19 Event: Lyme is Serious!

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

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

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

[Remarks by President Trump in a Meeting with Recovered COVID-19 Patients](#)

[Excerpts of Lyme Disease Discussion During Meeting \(below video\)](#)

EXCERPTS OF LYME DISEASE DISCUSSION DURING MEETING

STATE REPRESENTATIVE WHITSETT: The shortenings of – the shortening of breath is what really got me afraid because I do have Lyme disease. And thank you for always mentioning about Lyme disease.

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

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

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

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

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

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

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

STATE REPRESENTATIVE WHITSETT: It is brutal.

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

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

THE PRESIDENT: Incredible.

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

(Later In Discussion)

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

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

STATE REPRESENTATIVE WHITSETT: And with Lyme disease.

THE PRESIDENT: Huh?

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

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

(Later In Discussion)

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

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

THE PRESIDENT: Yeah. Well, but –

STATE REPRESENTATIVE WHITSETT: I need you on that.

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

PARTICIPANT: (Inaudible.)

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

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

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

STATE REPRESENTATIVE WHITSETT: Well, there are –

THE PRESIDENT: The Democrats might not like that.

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

THE PRESIDENT: Very good. Do it.

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

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

STATE REPRESENTATIVE WHITSETT: It's horrible.

THE PRESIDENT: – very bad thing. And it –

STATE REPRESENTATIVE WHITSETT: So it is something I'm working

on.

THE PRESIDENT: But it is something, over a period of time, you can treat generally. It also can kill you. Lyme disease – if you –

STATE REPRESENTATIVE WHITSETT: Yes.

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

STATE REPRESENTATIVE WHITSETT: Yes.

THE PRESIDENT: – it's over.

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

THE PRESIDENT: It's literally over.

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

THE PRESIDENT: I think type 0 – type 0 blood is not too good. If you have type 0 blood, stay out of the woods. Right?

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

THE PRESIDENT: You got it at home?

STATE REPRESENTATIVE WHITSETT: In Detroit.

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

STATE REPRESENTATIVE WHITSETT: It is a deer tick.

THE PRESIDENT: So where did the tick come from?

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

THE PRESIDENT: So it comes somehow, right?

STATE REPRESENTATIVE WHITSETT: Yes. A squirrel, a bug, a bird

– anything. It doesn't discriminate.

THE PRESIDENT: Well, it's like when I hit a ball into the rough in golf. (Laughter.) You know what I say? "Enjoy yourself. I'm not going in there." (Laughter.) That Lyme disease is pretty tough, right?

STATE REPRESENTATIVE WHITSETT: It is.

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

STATE REPRESENTATIVE WHITSETT: Thank you.

(Last Statements on Lyme)

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

Q We can't advise you on that, sir.

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

Q I can't advise you on that, sir. But I – I certainly hope that she –

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

Rep. Smith Questions COVID-19's Impact on Lyme Patients

On April 9th, Rep. Chris Smith sent [a letter](#) to Health and Human Services (HHS) Secretary Alex Azar and the National Institute for Allergies and Infectious Disease (NIAID) Director, Dr. Anthony Fauci, thanking them for their tireless efforts to address the



Coronavirus outbreak as well as expressing his concerns about Lyme disease sufferers and their potential to be especially vulnerable to COVID-19.

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

The letter highlighted a 2018 HHS Tick-Borne Disease Working Group (TBDWG) [report to Congress](#) indicating that there are approximately 300,000 new cases of tick-borne disease annually

in the US. Smith warned this number is likely higher and a [press release](#) from his office states that an estimated 40,000 of these cases originate in New Jersey.

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

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

Read [Congressman Smith’s letter](#) to NIH and HHS.

Read a [Press Release](#) about Congressman Smith’s letter.

TBDWG Mtg 12: Training, Education, Patient Access to Care (Video)

The Lyme Disease Association Inc. (LDA) feels it is imperative that the Lyme Community and the public understand the continued resistance by government agencies to provide information pertaining to chronic Lyme disease on their websites and in their programs despite Lyme disease being

around 45 years. LDA has provided video clips from the HHS Tick-Borne Disease Working Group meeting in Philadelphia which portray that resistance. Decades long advocate, LDA President, Pat Smith, the WG patient rep, rebuts these entrenched positions. Please note, however, that the federal government WG representatives are required by FACA WG rules to espouse and vote their agency's position, which may not necessarily be their own personal position.

[TBD Working Group Committee Members](#) / [Meeting #12 Agenda](#) / [LDA Written Summary of Meeting](#)

Full Video: [March 3rd – Day 1](#) / [March 4th – Day 2](#)

Other Video Clips: [Sam Donta, MD and Other](#) / [Public Comment \(9 speakers\)](#)

Working Group (WG) Discussion on Training, Education, Access to Care, and Reimbursement Subcommittee Recommendations

Co-Chairs: Pat Smith, President; LDA / Captain Scott Cooper, PA; CMS

1-Govt. Website Disclosures	10-B. Beard: Not Acknowledging Both Sets of Guidelines on Website	19-B. Beard: Raises Issue With Curriculum Recommendation – FACA Violation
2-CDC Surveillance Revisions	11-LA Soltysiak WG Co-Chair / D.Dixon NIH Response on Guidelines	20-P. Smith: Responds to Ben Beard FACA Violation Concern
3-Nationwide Lyme Clinical Training	12-P. Smith: Federal Agencies have not done their Job!	21-S. Cooper & WG Continue Curriculum Discussion

<p><u>4-Govt. Website Disclosure Discussion</u></p>	<p><u>13-S. Donta: Agencies Must Revisit Failures/Limitations for Chronic/Persistent Disease</u></p>	<p><u>22-P. Smith: Rebuttal to CDC Curriculum Comments</u></p>
<p><u>5-P. Smith Defends Chronic Lyme Patients</u></p>	<p><u>14-B. Beard: Addresses what Chronic Lyme Patients have had to Endure and Complexity of Moving Policy Forward Within a Large Agency</u></p>	<p><u>23-WG Continues Curriculum Discussion & Votes</u></p>
<p><u>6-P. Smith Questions WG Process/FACA</u></p>	<p><u>15-Committee Edits/Votes on Government Website Disclosure Wording</u></p>	<p><u>24-P. Smith: Legal for D. Walker To Vote In Place of E. Shapiro / Answered by J. Berger, HHS</u></p>
<p><u>7-P. Smith Questions Communication Betwn. WG & the Non Transparent WG</u></p>	<p><u>16-P. Smith: Surveillance Revisions</u></p>	
<p><u>8-P. Smith: FDA Position on Guidance vs. Guidelines, Why Chronic Cannot be Acknowledged</u></p>	<p><u>17-Committee Discussion on Surveillance Revision / Vote: P. Smith, No!</u></p>	<p><u>25-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 1</u></p>

9-P. Smith: NIH/CDC Agency Guidelines/Positions – why is chronic Lyme completely ignored?	18-S. Cooper & WG Discuss Nationwide Curriculum	26-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 2
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1 – P. Smith: Govt. Website Disclosures (5 + min)

9:59:06 to 10:04:38

35946 to 36278

2- P. Smith: CDC Surveillance Revisions (5+ min)

10:04:39 to 10:10:37

36279 to 36637

3- S. Cooper: Nationwide Lyme Clinical Training (4+ min)

10:10:38 to 10:15:35

36638 to 36935

4- Govt. Website Disclosure Discussion (10 min)

10:16:15 to 10:36:14

36975 to 38174

5- P. Smith Defends Chronic Lyme Patients (4+ min)

10:36:14 to 10:40:18

38174 to 38418

DAY 2

6-P. Smith Questions WG Process/FACA (1+ min)

2:18:37 to 2:20:12

8317 to 8412

7-P. Smith Questions Communication Betwn. WG & the Non Transparent WG (1+ min)

2:20:12 to 2:22:02

8412 to 8522

8-P. Smith: FDA Position on Guidance vs. Guidelines, Why Chronic Cannot be Acknowledged (3+ min)

2:22:02 to 2:25:15

8522 to 8715

9-P. Smith: NIH/CDC Agency Guidelines/Positions – why is chronic Lyme completely ignored? (9+ min)

2:25:15 to 2:34:30

8715 to 9270

10-B. Beard: Not Acknowledging Both Sets of Guidelines on Website (11+ min)

2:34:30 to 2:35:41

9270 to 9341

11-LA Soltysiak WG Co-Chair / D.Dixon NIH Response on Guidelines (4+ min)

2:35:42 to 2:39:45

9342 to 9585

12-P. Smith: Federal Agencies have not done their Job! (3+ min)

2:39:45 to 2:43:13

9585 to 9793

13-S. Donta: Agencies Must Revisit Failures/Limitations for Chronic/Persistent Disease (6+ min)

2:43:14 to 2:49:17

9794 to 10157

14-B. Beard: Addresses what Chronic Lyme Patients have had to Endure and Complexity of Moving Policy Forward Within a Large Agency (2+ min)

2:49:27 to 2:52:00

10167 to 10320

15-Committee Edits/Votes on Government Website Disclosure

Wording (26+ min)

2:52:00 to 3:18:38

10320 to 11918

16-P. Smith: Surveillance Revisions (1+ min)

3:18:56 to 3:20:20

11936 to 12020

17-Committee Discussion on Surveillance Revision / Vote: P. Smith, No! (15+ min)

3:20:23 to 3:36:16

12023 to 12976

18-S. Cooper & WG Discuss Nationwide Curriculum (9+ min)

3:36:29 to 3:46:10

12989 to 13570

19-B. Beard: Raises Issue With Curriculum Recommendation – FACA Violation (11+ min)

3:46:12 to 3:47:25

13572 to 13645

20-P. Smith: Responds to Ben Beard FACA Violation Concern (1+ min)

3:47:27 to 3:48:54

13647 to 13734

21-S. Cooper & WG Continue Curriculum Discussion (4+ min)

3:48:54 to 3:53:42

13734 to 14022

22-P. Smith: Rebuttal to CDC Curriculum Comments (1+ min)

3:53:42 to 3:54:51

14022 to 14091

23-WG Continues Curriculum Discussion & Votes (27+ min)

3:54:51 to 4:22:34

14091 to 15754

24-P. Smith: Legal for D. Walker To Vote In Place of E.

Shapiro / Answered by J. Berger, HHS (50 sec)

4:22:34 to 4:23:25

15754 to 15805

25-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 1 (43+ min)

9:57:06 to 10:40:26

35826 to 38426

26-Entire Discussion on Training, Education, Access to Care and Reimbursement: Day 2 (2 hr 4 min)

2:18:37 to 4:23:27

8317 to 15807

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

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

<u>1-S. Donta: Pathogenesis, Physiology of Lyme</u>	<u>4-S. Donta: Clinical Aspects of Lyme Including Potential Sexual Transmission</u>	<u>7-Use of Doxy for RMSF</u>
<u>2-P. Smith: Comments on Lyme Carditis, Tissue Testing Prob.</u>	<u>5-S. Donta: Maternal Fetal Transmission / Congenital Lyme Vote</u>	<u>8-Rickettsial CME Education</u>
<u>3-S. Donta: Comm. Discussion/Vote on Lyme Issues</u>	<u>6-Diagnostics Discussion</u>	<u>9-Alpha Gal & Data Mining</u>

Sam Donta, MD: Discussion of Pathogenesis and Physiology of Lyme Disease Subcommittee Recommendations (Day 2)

Co-Chairs: Sam Donta, MD; Prof. of Medicine (Ret) and Leith Jason States, MD, MPH; HHS

This section includes determining the mechanisms underlying the persistence of *B burgdorferi* in the host; determining the role of persistence of *B. Burgdorferi* or its components in the pathogenesis of Lyme arthritis and persistent Lyme disease; and determining the pathogenesis, pathophysiology, and effective treatment of Lyme carditis.

1-S. Donta: Pathogenesis, Physiology of Lyme

4:40:19 to 5:28:12
16819 to 19692

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

5:28:13 to 5:30:07
19693 to 19807

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.

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

Public Comments: Day 2, March 4th

<u>Lonnie Markham, LD0-Tick Attachment Time</u>	<u>Phyllis Mervine, Pres LD0- 2 Standards of Care</u>	<u>Mira Shapiro, LD0-Big Data Research</u>
<u>Dorothy Leland, VP LD0-Process Integrity</u>	<u>Melissa Potter, LD0- Patient Registry-MyLymeData</u>	<u>Jennifer Platt,TBC United-Alpha-gal & lesser known conditions</u>
<u>Mark Liberto-Patient Story</u>	<u>Dr. Betty Maloney-CDC Treatment Recommendations</u>	<u>Jill Auerbach-Prevention Emergency</u>

Lonnie Markham, LD0: Tick Attachment Time

1:41:57 to 1:44:42

6117 to 6282

Dorothy Leland, VP LD0: 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 heartfelt comments on both personal experience as well as recommended research needs. ([click here for public comments](#))
- Each of the eight Subcommittee chairs brought forward their top three recommendations which were developed from the [reports each of the TBDWG subcommittees](#). The TBDWG discussed and modified each of the three recommendations from each subcommittee and then voted to accept the recommendations to include in the report.
- Writing co-leads were determined for each section of the report. And next TBDWG meeting dates were discussed for May/April and July, 2020, though not yet set.



LDA President, Pat Smith, at 12th meeting of the TBDWG, Philadelphia, PA

Though the TBDWG worked through many of the subcommittee recommendations with good consensus, discussions regarding the recommendations brought forth by LDA President, Pat Smith for the “Training, Education, Access to Care and Reimbursement” subcommittee became heated ([click here for video](#)) as Pat asked the Federal agency representatives for agreement on website disclosures to increase public awareness for the two divergent diagnostic and treatment and approaches reflected in guidelines for Lyme disease. ([video clips: Training, Education, Access to Care and Reimbursement](#))

Ben Beard, CDC, commented after reading an excerpt from a 1990’s report, that the situation patients face today is very much unchanged from what they faced back then and that this is a “heartbreaking, tragic, failure of Public Health.” However, 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](#)

Update: US House Lyme Disease Caucus Letters

In February 2020, the Lyme Disease Association, Inc. (LDA) [asked you to contact your Congress Member](#) and request that he/she sign on to two important letters from the US House Lyme Disease Caucus. The language in the bipartisan letters was developed with input from the LDA and other TBD advocates.



Below are links to the final letters sent by House Lyme Caucus Co-Chairs Rep. Chris Smith and Rep. Collin Peterson to the Appropriations Committees last week. The letters request fund increases and provide directions for the monies for Labor HHS Appropriations and the DoD CDMRP appropriations for FY2021.

The [letter to the Subcommittee on Labor, HHS, Education and Related Agencies](#) requests significant increases for CDC Lyme disease programs. The request includes \$20 million for a new program that would allow CDC to enter into cooperative agreements with State and Tribal health departments to improve data collection and analysis of Lyme and other TBD. The letter also requests a funding increase for the Office of the Secretary of HHS, enabling the agency to enter agreements and enhance resources to accelerate breakthroughs/solutions for Lyme disease. The Caucus also outlined a number of important language specifications to be made to the Committee report.

The [letter to the Subcommittee on Defense](#) requested that the Committee provide an increase from \$7 million to \$10 million in the Congressionally Directed Medical Research Program (CDMRP) for research on Lyme and TBD. The Caucus clarifies that the goal is to make enhancements and meet the demand of an increasing number of (underreported) Lyme disease cases. The letter suggests important language specifications for the Committee report and calls attention to the increased risk and impact of TBD on military members and military readiness.

LDA thanks everyone who provided input on the letters, those who contacted their Congress Member, and the members who signed on.

Click [here](#) to view the letter to the Subcommittee on Labor, HHS, Education and Related Agencies/House Committee on Appropriations.

Click [here](#) to view the letter to the Subcommittee on Defense/House Committee on Appropriations.

Visit Congressman Chris Smith's [Leadership on Lyme webpage](#).

Researchers! CDMRP Funding Opportunities for Fiscal Year 2020

The FY20 Tick-Borne Disease Research Program (TBDRP) Program Announcements managed by the Department of Defense (DOD) office of Congressionally Directed Medical Research Programs (CDMRP) are now posted to the [grants.gov](#) (search grants by CFDA Number 12.420) and on the [CDMRP website](#).



FY20 funding opportunities include the following:

- [Career Development Award](#)
- [Idea Development Award](#)

Pre-Applications are due May 27, 2020 and invited Applications due August 27, 2020.

Click [here](#) to view the Synopsis of FY20 TBDRP Award Mechanisms

Click [here](#) to view the CDMRP TBD flyer with program highlights.

Descriptions of each of the funding opportunities, eligibility, key mechanism elements, and funding can be found in the Program pre-announcement. FY20 pre-announcements can be found on the [CDMRP home page](#).

Point of Contact:

CDMRP Public Affairs

301-619-9783

usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil

NOTE from Lyme Disease Association: Please do not contact us for information. Contact the CDMRP TBDRP directly. Thank you!

**Lyme Disease Needs Your
Congressmen to Sign Onto
Letters NOW!**



Rep. Chris Smith



Rep. Collin Peterson

ISSUE

At this time the Lyme Disease Association, Inc. is asking you to contact your Congress Member to ask him/her to sign on to 2 important letters from the US House Lyme Disease Caucus.

These bipartisan letters provide details that the Lyme Caucus is asking the 2 Appropriations Committees to include in their reports on FY 2021 Appropriations. This language will help provide direction for the monies and was developed with input from Lyme/TBD advocates.

[LETTER](#) LHHS Appropriations Committee (sign-on deadline 3/10)

[LETTER](#) DoD Appropriations Committee Lyme/CDMRP (sign-on deadline 3/13)

INSTRUCTIONS

1. Determine Who Your Congress Member Is

Click on “Find Your Rep” box below

Type in zip code (your Member or a Member who serves your group's area, your work area, etc.)

[FIND YOUR REP](#)

2. Congress Members Already Signed on Letter as of March 6, 2020/ Do Not Contact

Christopher H. Smith (NJ), Caucus Co-Chair

Collin Peterson (MN), Caucus Co-Chair

Antonio R. Delgado (NY)

Brian Fitzpatrick (PA)

Tom Malinowski (NJ)

Chellie Pingree (ME)

Bill Posey (FL)

Max Rose (NY)

Elise M. Stefanik (NY)

Jennifer Wexton (VA)

Vicky Hartzler (MO)

3. Email or Call Your Congress Member's DC office.

A. Below is an example of what you need to say to your Congress Member. Here are some examples of how you can identify yourself: I am a Lyme patient, family member, friend of, person concerned about Lyme, doctor, Lyme group leader, etc.

B. Cut & paste the red text below into an email to your Congress Member OR call and say the following verbally over the phone to your Congress Member:

Dear Congress Member,

I ask that you please sign onto the two letters from the bipartisan House of Representatives Lyme Disease Caucus – co-chairs Christopher Smith (NJ) and Collin Peterson (MN) – to the LHHS Appropriations Committee and to the DoD Appropriations Committee (Lyme/CDMRP). The important language

in these letters will help Lyme patients across the country. Here are links to the draft letters:

- LHHS bit.ly/2Vk21vt signatures due March 10
- DoD (Lyme/CDMRP) bit.ly/3bQGz77 signatures due March 13

Please call or email Kelsey Griswold Kelsey.Griswold@mail.house.gov at the Office of Christopher Smith for information or to have your signature added. Thank you so much for your support on this important issue affecting hundreds of thousands of people in the US.

Sincerely, INSERT YOUR NAME, HERE

C. PLEASE NOTE: You are NOT supposed to email Kelsey Griswold. You are to instruct your Congress Person to email her directly.

