

# Tick-Borne Disease Working Group



Welcome to the 4<sup>th</sup> meeting of the TBDWG



**John N. Aucott, M.D. (Chair)**

Associate Professor, Division of Rheumatology,  
Johns Hopkins University School of Medicine;  
Director, Johns Hopkins Lyme Disease Clinical Research Center



**Kristen Honey, PhD, PMP (Vice-Chair)**

Senior Policy Analyst, OMB, Executive Office of the President;  
Senior Research Scholar, Stanford University;  
Member, Stanford University Lyme Disease Working Group

# Tick-Borne Disease Working Group



## Making History

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- First report to Congress on this issue
- Bringing together many people, including patients and patient advocates, with diverse backgrounds and perspectives—many of whom had not worked together before
- Creating new tools, like the Inventory of Federal Actions, that will be useful in the future
- Co-creating a Lyme disease “reset” — a shift in focus from problems and blame to solutions and collaborations
- Moving forward, together

# Tick-Borne Disease Working Group



## Shared Vision

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A nation free of tick-borne diseases  
where new infections are prevented and  
infected patients have access  
to affordable care that restores health



# Tick-Borne Disease Working Group



## Core Values

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1. **Respect:** Everyone is valued
2. **Innovation:** Shifting the paradigm, finding a better way
3. **Honesty and Integrity:** Find the truth, tell the truth
4. **Excellence:** Quality, real-world evidence underlies decision-making
5. **Compassion:** Finding solutions to relieve suffering
6. **Collaboration:** Work with citizens and patients as partners
7. **Accountability:** The buck stops here

# Tick-Borne Disease Working Group

 What have we accomplished?

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2018 Progress

# Tick-Borne Disease Working Group



## Changes

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One Working Group and  
three subcommittee positions changed

All were filled by a patient or  
former patient





# Tick-Borne Disease Working Group



## New Working Group Member

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### Robert Sabatino

Founder and Executive Director

Lyme Society Inc.,

New York

*Public Voting Member*

*and Patient Representative*

# Tick-Borne Disease Working Group



## Recap of Meeting #3

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- 1<sup>st</sup> meeting with Working Group and all 6 subcommittee members
- Concurrent breakout groups of the 6 subcommittees
  - Volunteer introductions
  - Reviewed drafts for inventory requests from HHS/DoD/VA
  - Began identifying priorities for subcommittee reports
- Technical difficulties arose and affected amount of work done in Meeting #3, yet did not stall progress or delay schedule
  - 1<sup>st</sup> time using the software with this group
  - HHS changed online meeting platform for all future meetings



# Tick-Borne Disease Working Group



## 6 Subcommittees Composition

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- 53 additional volunteers from diverse sectors
- Mix of existing Working Group members and other individuals with TBD expertise and knowledge
- Each subcommittee is led by 2 co-chairs
  - At least 1 co-chair is a Working Group member
  - Co-chairs were originally selected from existing Working Group members by Chair and Vice-Chair with input from DFO
  - Subcommittee members were nominations through a public process and were chosen by subcommittee co-chairs



# Tick-Borne Disease Working Group



## 6 Subcommittees Composition (cont.)

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- 67 people engaged as Working Group and/or subcommittee members
- 1 in 4 Working Group members is a patient or family member
- Each subcommittee included one or more patients
- Most members had not worked together before
  - Diverse backgrounds, many different disciplines
  - Many had differing points of view
  - Understanding, trust, and respect had to be developed and continues to be developed, as this is an on-going process

# Tick-Borne Disease Working Group



## Subcommittees and Co-chairs

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1. Disease Vectors, Surveillance, and Prevention
  - C. Ben Beard, MS, PhD, CDC
  - Patricia Smith, Lyme Disease Association
2. Pathogenesis, Transmission, and Treatment
  - Wendy Adams, MBA, Bay Area Lyme Foundation
  - Captain Estella Jones, DVM, FDA
3. Testing and Diagnostics
  - Lise Nigrovic, MD, MPH, Boston Children's Hospital
  - David Roth, JD, Retired, Private Equity Firm (Blackstone)



# Tick-Borne Disease Working Group



## Subcommittees and Co-chairs (cont.)

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### 4. Access to Care Services and Support to Patients

- Commander Scott Cooper, MMSc, PA-C, CMS
- Paula Jackson Jones, Midcoast Lyme Disease Support & Education

### 5. Vaccine and Therapeutics

- Dennis Dixon, PhD, National Institute of Allergy and Infectious Diseases
- Robert Smith, MD, MPH, FACP, FIDSA, Maine Medical Center, Tufts University School of Medicine

### 6. Other Tick-Borne Disease and Co-Infections

- Richard Horowitz, MD, Hudson Valley Healing Arts Center
- Allen Richards, PhD, Naval Medical Research Center

# Tick-Borne Disease Working Group



## New Roles for 2 Subcommittee Members

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**David Roth, JD**

Co-Chair, Testing and Diagnostics



**Paula Jackson Jones**

Co-Chair, Access to Care Services  
and Patient Support

# Tick-Borne Disease Working Group



## New Subcommittee Member

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### **Sherill Franklin**

Patient Advocate and Small  
Business Owner

Pennsylvania

*Member, Access to Care Services and  
Patient Subcommittee*



# Tick-Borne Disease Working Group



## Subcommittee Progress

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- Subcommittee meeting summaries posted online
- Subcommittee reports all completed and posted online with content synthesized from diverse information sources:
  - Published studies
  - Information from patients and other experts
  - Experience/expertise of subcommittee members and invited speakers
- Subcommittees will no longer meet on weekly basis
- Subcommittees still exist to answer questions and provide input to Working Group
  - Subcommittee information given to the Working Group will be provided in writing and made available to the public through the HHS website

# Tick-Borne Disease Working Group

 What is happening today?

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Goals for Meeting 4

# Tick-Borne Disease Working Group



## Meeting 4 Overview

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- Today's focus is subcommittee reports
- Subcommittee reports were prepared to inform the Working Group and its 14 voting members
- Subcommittees offer insights into gaps, opportunities and potential actions to be considered by the Working Group for the report to Congress and HHS

Times	Session Description	Presenter
9:45 am – 10:45 am	- Subcommittee Presentation: Disease Vectors, Surveillance and Prevention	Pat Smith Ben Beard
10:45 am – 11:00 am	- Break	
11:05 am – 12:05 pm	- Subcommittee Presentation: Pathogenesis, Transmission, and Treatment	Wendy Adams Estella Jones
12:05 pm – 12:50 pm	- Lunch Break	
12:55 pm – 1:55 pm	- Subcommittee Presentation: Testing and Diagnostics	Lise Nigrovic David Roth
2:00 pm – 3:00 pm	- Subcommittee Presentation: Access to Care and Support to Patients	Scott Cooper Paula Jackson Jones
3:00 pm – 3:15 pm	- Break	
3:20 pm – 4:20 pm	- Subcommittee Presentation: Vaccine and Therapeutics	Dennis Dixon Robert Smith
4:25 pm – 5:25 pm	- Subcommittee Presentation: Other Tick-Borne Diseases and Co-infections	Richard Horowitz Allen Richards
5:30 pm – 6:30 pm	- Public Comment	John Aucott Kristen Honey
6:35 pm – 6:45 pm	- Review of Meeting Four, Next Steps - Adjournment	John Aucott Kristen Honey



# Tick-Borne Disease Working Group



## Today's Agenda

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- Six subcommittee presentations are the result of 3+ months of work
  - Enormous amount of work from a diverse group of stakeholders
- Subcommittee presentations today are:
  - Pre-decisional for consideration by the Working Group
  - **NOT** the Working Group report to Congress and the HHS Secretary

# Tick-Borne Disease Working Group

 What is next?

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Moving forward, together

# Tick-Borne Disease Working Group



## Key Logistics and Process

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- Subcommittee reports are online in their entirety, without modification to the text. Images will be posted at a later date.
- Subcommittee work and reports are inputs for the Working Group
  - Subcommittees were voluntary groups established to address a wide range of scientific and technical issues to help the Working Group deliver on 2018 schedule, given resource constraints and ambitious goals
  - Subcommittees framed issues and identified “potential actions”
  - Working Group will decide what to use, not use, and/or modify from the subcommittee reports in order to finalize recommendations
- Only the Working Group — not the subcommittees — issue the official report with recommendations to Congress and the HHS Secretary



# Tick-Borne Disease Working Group



## Report Due by December 2018

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- In this first-ever report to Congress and the HHS Secretary, the Working Group will use information from:
  - Subcommittee reports
  - Other quantitative data including surveillance, research, program monitoring and evaluation
  - Other qualitative data including case studies, patient/provider experience, public comment
  - Inventory of Federal activities
  - Public input

# Tick-Borne Disease Working Group



## Report Submission

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In December 2018, the report is submitted to:

- HHS Secretary
- House of Representatives Committee on Energy and Commerce
- Senate Committee on Health, Education, Labor, and Pensions



- Subsequent reports are due every 2 years after the first report
- Iterative updates and improvements over 6 years

# Tick-Borne Disease Working Group



## Iterative Process

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- Cannot overstate the significance of this opportunity to change old narratives and co-create new recommendations on tick-borne disease (TBD)
  - 1<sup>st</sup> report due December 2018 is more than a report; it is also establishing Federal infrastructure and procedures to **yield future value beyond 2018**
  - **2<sup>nd</sup> report due December 2020** will include systematic literature review for 20+ TBD, more time for collection and analysis of inventory data
  - **3<sup>rd</sup> report due December 2022** will further improve and update
- Working Group and subcommittees will evolve over time
  - In early 2019, HHS will issue a new public call for Working Group nominees



# Tick-Borne Disease Working Group



## Near-Term Milestones

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- Creating first-ever inventory of Federal Tick-Borne disease activities
  - Subcommittees provided input into design of inventory requests
- Took time to develop and submit inventory request to agencies
  - Differences in collecting and reporting information are anticipated and will need to be addressed
- HHS, DoD, and VA have received surveys
  - Responses due on May 11<sup>th</sup>
- Working Group will report on information received at our next meeting and establish a process for integrating inventories into the report

# Tick-Borne Disease Working Group



## Inventory of Federal Activities

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- First inventory to assess the breadth and depth of the federal response to TBDs developed and submitted to:
  - HHS, DoD, U.S. Department of Veterans Affairs (VA)
- The inventory includes:
  - Types of activities (like research, surveillance, prevention, care, and treatment)
  - Level of funding, reach, and duration
  - Number of staff devoted to tick-borne disease activities
- Responses due May 11, 2018
  - Agencies may need more time for complete reporting
  - Working Group will review available information and draw from it for the report
    - If data are incomplete or more time is needed, will seek input on case-by-case basis regarding ways to address remaining issues

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## Public Input

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- In-person public comment period is part of each Working Group meeting
  - In-person comments are limited to 3 minutes each
  - The total available time for all public comments is 30 to 60 minutes
  - Written comments are also accepted
- Comments can be sent via email at any time
  - More than 1,000 received to date
  - Personally identified information will be removed **before** it is shared with the Working Group
    - **Exception:** Names of Working Group and subcommittee members will NOT be removed





# Tick-Borne Disease Working Group



## Sharing Public Comments

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- Verbal and written comments from meetings 1-3 have been posted online
- Other public comments submitted by email required special handling due to concerns about privacy and other issues
  - Comments will be considered by the Working Group while writing the report
  - Comments will have a visible presence in the final report

# Tick-Borne Disease Working Group



## We Need You! Contact Us

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Check out the Tick-Borne Disease Working Group online:

<https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>

Reach us by email at: [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov)

Participate in public meetings on May 15 & 16<sup>th</sup>

# Tick-Borne Disease Working Group



## The Human Dimensions

Working together,  
we are advancing patient-centered medicine and next-gen solutions

**Anecdotes are not data,**

yet we must remember that behind every data point is a human life and real-world story





# Tick-Borne Disease Working Group



I'm not just Vice Chair of the Tick-Borne Disease Working Group...



I'm also a Lyme survivor!

# Tick-Borne Disease Working Group



## Join us! Together, We'll Realize Our Vision

- This work needs all of us
  - Lived experience and perspectives
  - Technical and scientific knowledge
  - Interdisciplinary and problem-solving skills
- We will not always agree, but debate is good
- We are stronger when we find the common ground that we share and, together, unite
- If we shout different things all at once, all of our voices will be lost
- If we shout the same thing all at once, our shared priorities magnify the message





# Tick-Borne Disease Working Group



## Shared Vision

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## Mission Statement

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A mission is different from a vision in that the former is the cause and the latter is the effect; a mission is something to be accomplished whereas a vision is something to be pursued for that accomplishment.

- Our core purpose and focus that normally remains unchanged over time
- Present day, given reality of today
- Volunteer(s) requested!

# Tick-Borne Disease Working Group



## Thank You



- Working Group and subcommittee members
  - Their organizations and employers for supporting their roles in this work
- Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, HHS
- Presenters and patients who have shared their knowledge with the Working Group and its subcommittees

**Special thank you to the members of the public who have shared their stories and support for this effort**