T he Tick-Borne Disease Working Group was authorized by the 21st Century Cures Act, which was passed and signed into law in 2016. The idea was to bring together a wide variety of viewpoints and subject matter experts to figure out the best federal response to Lyme and other tick-borne diseases.

The Working Group does not have the authority to pass laws. It can only recommend congressional action, which it will do in the form of reports submitted to Congress in 2018, 2020, and 2022.

Tick-Borne Disease Working Group Process

The process established for the Working Group requires process integrity and transparency under FACA and the Sunshine Act. This means that:

- a balance in points of views must be represented on the Working Group;
- meetings must be open to the public, who must be informed of meetings at least 15 days in advance;
- there must be opportunities for public comment;
- Working Group recommendations must be accessible to the public; and
- Working Group minutes, reports, expenses, and related documents must be available to the public.

The Working Group met seven times between December 11, 2017, and July 24, 2018. Some of these meetings were web-based and some were in person.

Tick-Borne Disease Working Group Subcommittees

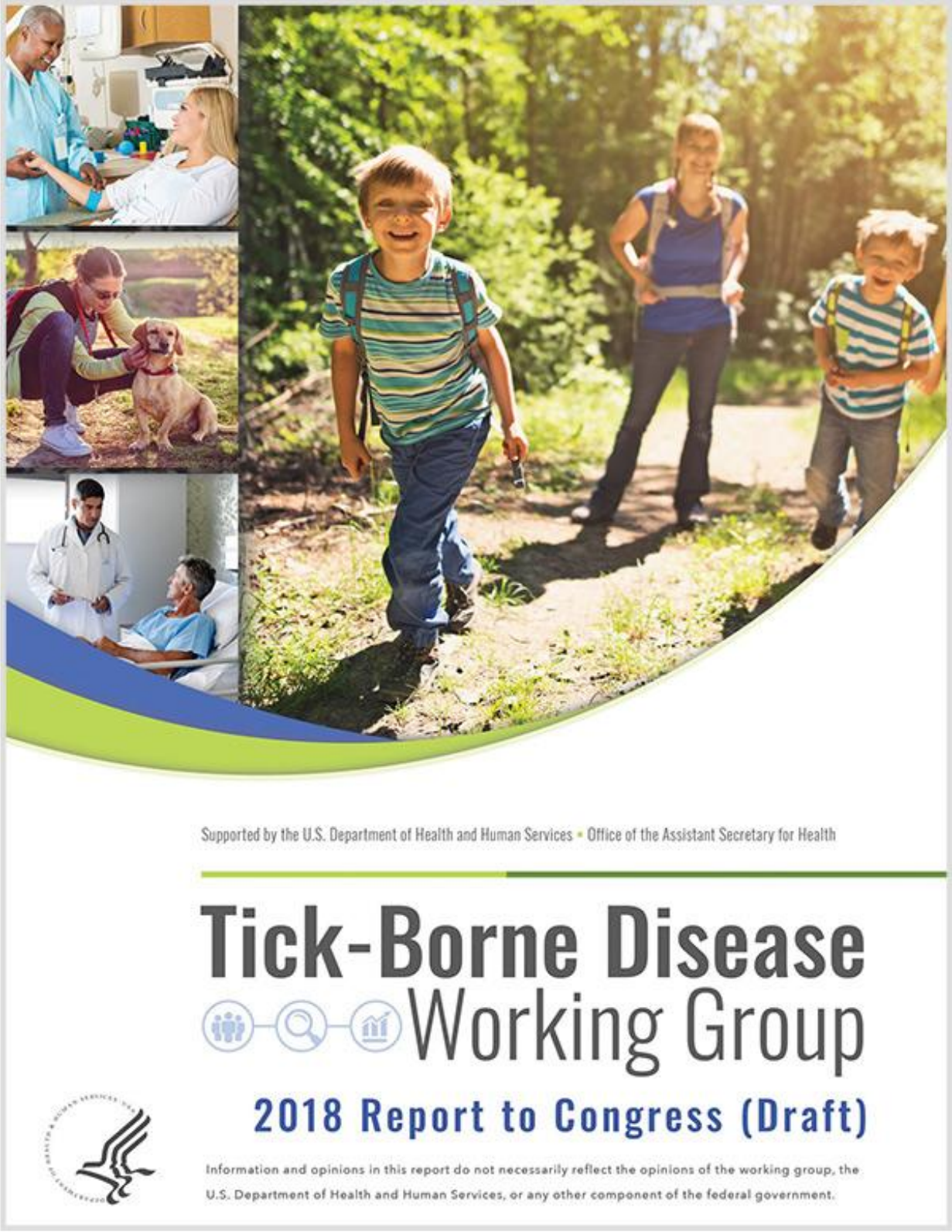
To help accomplish its goals, the Working Group established subcommittees composed of group members and other individuals with tick-borne disease expertise and knowledge. The six subcommittees were:

- Access to Care Services and Support;
- Disease Vectors, Surveillance, and Prevention;
- Tick-Borne Diseases and Co-Infections;
- Pathogenesis, Transmission, and Treatment;
- Testing and Diagnostics; and

- Vaccines and Therapeutics.

These subcommittees conducted regular meetings via telephone to consider relevant issues. For example, the subcommittee I served on—Pathogenesis, Transmission, and Treatment—met once a week by phone for an hour and a half. These meetings usually started with one or two presentations on a topic under consideration and were followed by extensive discussion.

Tick-Borne Disease Working Group's Draft Report



In between meetings, we broke our group into three sections to draft different portions of a

report to the Working Group, which our entire subcommittee voted on. We worked practically around the clock to prepare our report, which was 136 pages long. We had a little over two months to perform this Herculean task. The tight time frame was necessary for the Working Group to be able to submit its report to Congress later this year.

Processes like these do not guarantee particular outcomes, but they do provide voice, transparency, and a place for opposition. You might recall that LymeDisease.org enlisted more than 10,000 people in a matter of days to protest the naming of Dr. Gary Wormser to the Working Group. As a result, he withdrew from the panel. (We objected to Wormser's place on the panel because of his serious financial conflicts of interest.)

We were able to do this because the names of the group members were made public. This does not happen in closed processes. For example, we still do not know the identity of the two patients chosen by the Infectious Diseases Society of America (IDSA) to sit on its current Lyme guidelines panel. The IDSA says it will not disclose the names of these patients in order to "protect" them. This might be appropriate for rape victims; however, people chosen to represent the interests of patients should be known and respected by the community they represent; transparency is critically important to the Lyme community.

The Working Group's process also allows for minority reports, both from the group itself and its subcommittees. These allow members who disagree in a majority vote to draft a statement on their own viewpoint, which must be published along with the majority report.

The Working Group's current draft of its report to Congress includes three minority responses.

Transparency was also provided in the subcommittee reports, which are **published online**, and in the minutes of the subcommittees, which are part of the subcommittee reports.

What about the Balance of Members on the Subcommittees?

Each subcommittee chair and co-chair chose members from a list of people who applied in an open public process.

> Members of the Working Group included known advocates in the community and

treating physicians, such as Pat Smith of the national Lyme Disease Association, Wendy Adams from Bay Area Lyme Foundation, Robert Sabatino of Lyme Society, Inc., and Dr. Richard Horowitz from ILADS. Three members of the LymeDisease.org board, Dr. Chris Green, Phyllis Mervine, and I, applied and were selected to serve on subcommittees.

Pat Smith

Wendy Adams

Robert Sabatino

Dr. Chris Green

Phyllis Mervine

Lorraine Johnson

Other known patient advocates named to subcommittees included Holly Ahern, Jill Auerbach, Monica White, David Roth, Sherill Franklin, Holiday Goodreau, Colonel Nicole Malachowski, and Paula Jackson Jones.

Holly Ahern

Jill Auerbach

Monica White

David Roth

Sherill Franklin

Holiday Goodreau

Colonel Nicole Malachowski

Paula Jackson Jones

From ILADS, in addition to Dr. Horowitz serving on the Working Group, Dr. Chris Green, Dr. Betty Maloney, Dr. Sheila Statlender, and Dr. Robert Bransfield served on subcommittees.

Richard Horowitz, MD

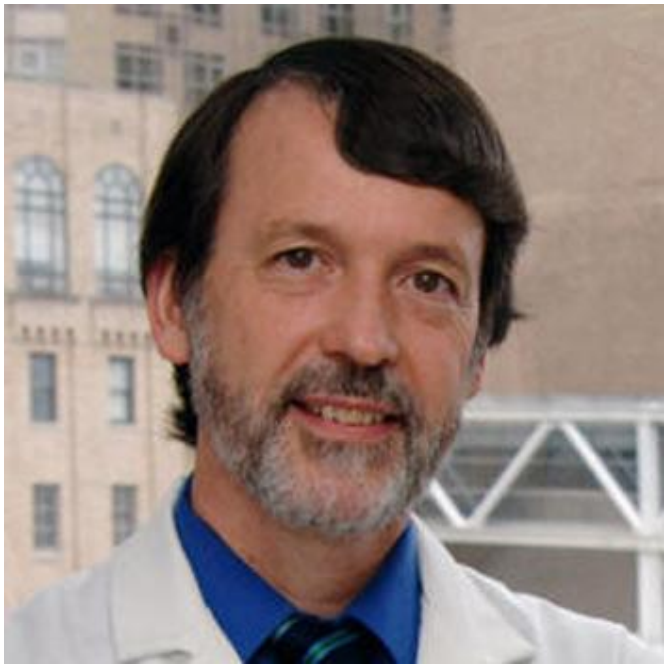
Christine Green, MD

Betty Maloney, MD

Sheila Statlender, MD

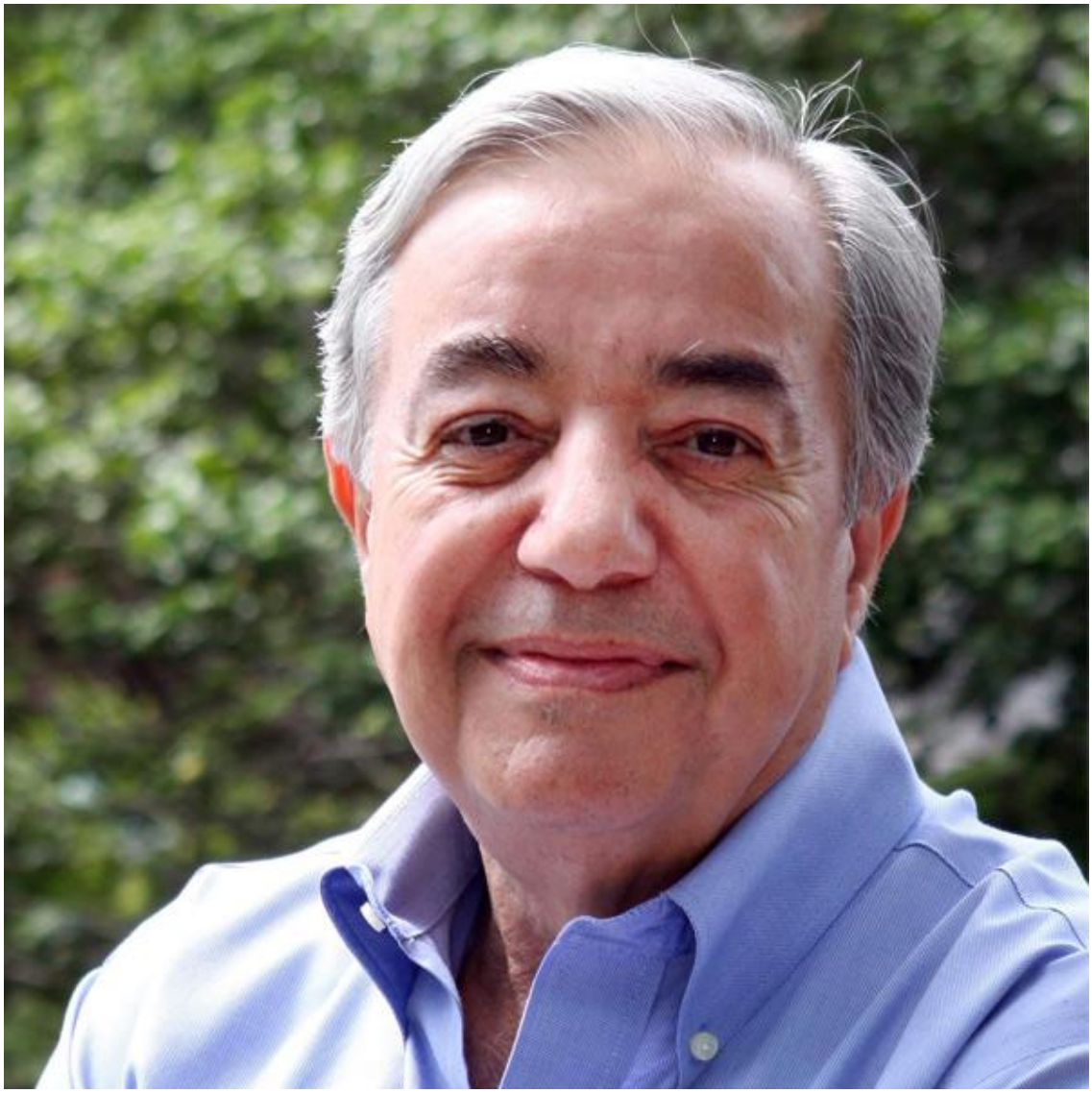
Robert Bransfield, MD

On my subcommittee (Pathogenesis, Transmission, and Treatment), we also had Dr. Brian Fallon of Columbia University, Wendy Adams, and Dr. Sam Donta, an infectious disease specialist who was kicked off a past IDSA guidelines panel when he disagreed with the viewpoint that Lyme disease was easy to diagnose and cure. I did not find the government employees on my subcommittee to be biased, but it is possible that this could have varied from subcommittee to subcommittee.



Dr. Brian Fallon

Wendy Adams



Dr. Sam Donta

Many patient groups, including LymeDisease.org, were unhappy

with the results of the vaccine subcommittee's report. Several of our board members filed written comments criticizing the failure of the subcommittee to openly discuss safety issues connected with the LYMErix vaccine, which was briefly on the market from 1998–2002.

At the May 16 meeting, Working Group members Pat Smith, Kristen Honey, and Wendy Adams pressed for a thorough examination of problems associated with the prior vaccine to be carried out before going forward with any recommendations for a new vaccine. They said that without transparency about the issues with the past vaccine, there would be no trust in the patient community for a new one.

Specifically, they were referring to the fact that the vaccine was withdrawn from the market due to safety concerns in the midst of a class action lawsuit by patients for vaccine-related adverse events and injuries against the manufacturer, SmithKline Beecham (now GlaxoSmithKline). (A copy of the settlement of the lawsuit can be downloaded here: 2003 Vaccine Judgement.)

What Really Happened with the Working Group's Decision on Diagnostic Testing?

Regarding diagnostic testing, the Working Group voted on two major issues, both of which were raised at the insistence of the patient community.

The first recommendation to Congress was to have the CDC and NIH convene a meeting of all stakeholders to examine the science and real-world evidence of the diagnosis of Lyme disease. This was passed almost unanimously (12 to 1). This is a victory for the Lyme disease community because up until now, almost all decisions about diagnostic testing have been done behind closed doors, without the participation of patients or the physicians who treat them.

The CDC requires that a positive lab test be based on the demonstration of 5 out of 10 specified bands on a Western blot test. This standard was adopted at a meeting in Dearborn, Michigan, in 1994, which excluded both patients and treating physicians. It was supposed to be a temporary standard but soon became the prevailing standard incorporated into the IDSA diagnostic guidelines.

Patients object to the CDC banding restrictions, because they miss too many cases of Lyme disease and result in misdiagnoses. Patients also view the two-tiered lab testing criteria as too insensitive. The result of these flawed testing standards is that far too many patients are not diagnosed early, when treatment is most effective. The approval of this motion by the Working Group is a big step forward because it reopens a discussion that has been closed for years.

The second motion was to empower patients to access their own data, including all of the bands on the Lyme diagnostic Western blot. Today, many labs simply say a test is positive or negative without providing any information on the specific bands that were positive for the patients. Many Lyme-literate physicians rely on individual banding information to guide their treatment and diagnostic decisions. This motion did not pass, but the vote was split (9 to 4). The dissenters subsequently drafted a minority report. *This does not change the status quo of testing and reporting on bands.* However, the minority response included in the report to Congress shines a light on this important issue.

What Other Important Issues Were Addressed?

The Pathogenesis, Transmission, and Treatment Subcommittee, on which I served, made major points about patient-centered outcomes, shared medical decision-making, patient engagement in research, and innovative research designs. I believe that unless the patients are at the center of research and the results of clinical research apply to patients seen in clinical practice and focus on outcomes that patients see as important, we will not be able to make progress.

For example, some trials consider resolution of an EM rash to be the "success" endpoint, but patients can have the rash clear up and yet still remain ill. Patients don't just want their rash to go away–they want to be well! Similarly, the trials funded by the NIH for chronic Lyme excluded up to 89–99% of the patients who tried to enroll. Restrictive entry criteria necessarily mean that the results of those trials will not apply to most patients.

My subcommittee also extensively discussed the evidence supporting persistence of the Lyme spirochete in animals and humans. The aim here was to illuminate all of the known facts, not to prevail on a viewpoint.

Finally, we objected to the use of nomenclature that is dismissive or stigmatizing to patients. We highlighted the fact that the term *post-treatment Lyme disease syndrome* (PTLDS) excludes most of the clinical population with the late or chronic Lyme disease. This issue has never been raised in a public forum before. It is critical because the research definition of PTLDS is being misapplied to clinical diagnosis.

I am quite pleased with the report that came out of our subcommittee. I believe it really moves the needle forward in terms of patient-centered research, shared medical decision-making, innovative clinical trials, persistence, and the use of stigmatizing language such as PTLDS to describe patients. I encourage people to read the actual reports of the subcommittees, which are quite extensive.

I was also pleased that the Access to Care Services and Support Subcommittee included my "Two Standards of Care" informed consent form in its report. I developed this form about 10 years ago with Ginger Savely, DNP. This informed consent form advises patients that there are two standards of care (IDSA and ILADS) and explains the risks and benefits of treating persisting Lyme disease with oral or intravenous antibiotics. It has been widely adopted by many ILADS physicians. You can download the most current version here: Informed consent for Lyme treatment.

I was selected to give verbal comments to the Working Group at its June 21 meeting. I explained about "Two Standards of Care" for Lyme disease—IDSA vs. ILADS—and urged the following:

- that government agencies provide unbiased information regarding both standards of care,
- that physicians inform patients about the risks and benefits of different treatment options in the context of shared medical decision-making and individualized care, and

- that insurance reimbursement be available for treatment under either standard of care.

I was pleased to find that many of these ideas were acknowledged in the Working Group's draft report to Congress. In part, it says:

"Despite the existence of two peer-reviewed, evidence-based treatment guidelines, there is an apparent governmental and insurance industry bias for use of the IDSA standards and guidelines exclusively. Physicians who choose to follow the ILADS guidelines are often criticized by other physicians and penalized by state medical boards, causing many providers to avoid treating chronically ill patients."

The Working Group's draft report now goes to various federal agencies for feedback. The final report will be given to Congress in December 2018.

As I noted above, process integrity alone cannot ensure outcomes. However, I appreciated the opportunity for the patient voice to be heard, the transparency of the process, and the ability of those who dissented from the group to have their views memorialized in a minority report. These are the hallmarks of process integrity.

Editor's note: Any medical information included is based on a personal experience. For questions or concerns regarding health, please consult a doctor or medical professional.