June 24, 2019

ADM. Brett Giroir, MD
Assistant Secretary of Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 716G
Washington, DC 20201
ASH@hhs.gov

RE: Tick-Borne Disease Working Group formed in 2019 Under the 21st Century Cures Act

Dear ADM. Giroir:

We are submitting these concerns on behalf of the 57 patient advocacy organizations who have signed onto this letter.

We are writing to express our dismay at the newly appointed Tick-Borne Disease Working Group (TBDWG). More specifically, we are concerned with

- The lack of process integrity and transparency in the selection of the members,
- The lack of balance of membership on the group,
- Conflicts of interests and extreme viewpoints of certain members, and
- Barriers imposed on patients for making comments at in person public meetings of the group.

The Centers for Disease Control (CDC) estimates that there are over 300,000 new cases of Lyme disease each year (CDC 2013). Most patients who are diagnosed and treated promptly respond well to treatment. However, the rate of treatment failures is unacceptably high and many patients are not diagnosed until the disease has advanced and is much more difficult to treat. These patients have chronic Lyme disease and suffer a severe quality of life impairment. Many are disabled and cannot work (Johnson 2011).

The treatment of patients with chronic Lyme disease is a controversial issue, which creates a heightened need for process transparency and integrity. The evidence base in chronic Lyme disease treatment is scant. Only three small studies have been funded by the NIH and these have yielded conflicting results (Klempner, 2001; Fallon, 2007; Krupp, 2008). In the face of this scientific uncertainty, two medical specialty societies, the Infectious Diseases Society of America (IDSA) and the International Lyme and Associated Diseases Society (ILADS) have produced contradictory guidelines. Very few patients report being diagnosed (11%) or treated (3%) by infectious disease clinicians (Johnson 2011). Hence, the primary physicians involved in the treatment of chronic Lyme disease are ILADS clinicians.

The Working Group is subject to the Federal Advisory Committee Act (FACA), which was adopted in response to concerns: (a) that federal advisory committees did not have adequate review, oversight, or accountability and (b) that certain special interests had too much influence over federal agency decision makers (GAO 2004). In 2008, the United States Government Accountability Office testified that advisory committees constitute the "fifth arm of government" because of their role in advising federal agencies, Congress, and the President on policy issues (GAO 2008) To be effective, advisory committees must be perceived as being balanced as a whole. This means that appointments should not favor one group of stakeholders over others.

According to the CDC, the burden of tick-borne illness is predominately borne by Lyme disease, which constitutes 82% of all tick-borne disease in the United States (CDC 2018). The legislative intent behind the working group was to address the needs of chronic Lyme patients, who have long been marginalized by government health officials and the medical establishment. Over 14,000 patients responded to LymeDisease.org's mobilization efforts to have the Working Group included in the 21st Century Cures Act. Hence, while the panel is called the Tick-Borne Disease Working Group, it was passed at the behest of patients with chronic Lyme disease to address their needs—and the voices of chronic Lyme patients, doctors who treat them, and researchers seeking to help them should be paramount. Patients pushed for the inclusion of FACA in the legislation to redress the secrecy that had previously shrouded NIH policymaking in Lyme disease and to provide representation into the advisory process that had previously excluded chronic Lyme patients and the physicians who treat them.

The formation and membership constitution of the initial 2017 Working Group was adequately balanced in terms of viewpoints, and it reflected process integrity. Moreover, it was a highly effective, well-functioning group that produced a report under an extremely condensed timetable, with committee members and subcommittee members putting in extraordinary hours to meet deadlines.

However, there has been a profound shift in both the process integrity and transparency for the newly selected 2019 Working Group. The effect is that the voices of patients and their treating physicians are being suppressed, while the interests of academic researchers who do not focus on Lyme disease are being elevated. To the Lyme community, it appears that HHS has removed patient advocates and ILADS physicians and replaced them with Rickettsia experts and other academic researchers.

The manner in which the process was conducted, the constitution of the newly selected group, the presence of conflicts of interest, and the dramatically diminished role of the patients who were responsible for passing the legislation that created the Working Group raise red flags in the community regarding the legitimacy of the working group. This jeopardizes the credibility of its work. We call upon you to investigate our concerns and reconstitute the membership of the committee and its subcommittees so that they represent a balance of viewpoints, preserve the patient voice, and eliminate conflicts of interest.

Lack of Process Integrity and Transparency

The best way to understand the sharp erosion of process integrity and transparency is to compare the 2017 Working Group process with that of the 2019 Working Group process. The 2017 process included a call for public nominations for the group. LymeDisease.org submitted nominations as did other Lyme disease advocacy organizations. Richard Henry (HHS Deputy Director, Blood Policy & Programs) was the point of contact for patients and responded to many emails regarding the submittal process and effectively shepherded patient advocacy organizations through the process.

The selection of the working group membership was announced three weeks before the first meeting of the group. This allowed patient advocacy organizations to review the membership to assess whether it was balanced and to voice any concerns. There were serious concerns regarding one appointed member, Dr. Gary Wormser, a member of the Infectious Disease Society of America, who had substantial financial conflicts of interests. Over 10,000 patients signed a petition calling for his resignation or removal from the group. Before the TBDWG actually convened, Dr. Wormser resigned and another IDSA member, Dr. Robert Smith, was appointed as his replacement.

The first public meeting of the 2017 Working Group focused heavily on the patient experience and evoked the legacy of HIV/AIDS. Richard Wolitski reviewed the charter for the Working Group and

framed the task by saying, "Our job is to make sure this is a transparent and fair process...and find solutions."

Public comments were facilitated by Dazon Dixon Diallo, president and CEO of SisterLove, Inc, a women's AIDS and reproductive justice nonprofit. Lorraine Johnson, JD, MBA and CEO of LymeDisease.org gave a remote ten-minute presentation at the beginning of the meeting about issues affecting patients. Gregg Skall, of the National Capital Lyme Disease Association, a patient advocacy nonprofit, also gave extended remarks. These were followed by many three-minute patient comments including retired Air Force Colonel Nicole Malachowski, a combat veteran and the first woman pilot on the Thunderbirds Air Demonstration Squadron, who at age 43 was deemed unfit for duty due to neurological damage from tick-borne illness. Then-13-year-old Olivia Goodreau, and patient advocate Robert Sabatino also spoke. The patient community was heavily involved in the inaugural meeting and then got the word out to patients. The room was filled with patients. Subcommittees were selected, reviewed by the working group, and posted on the TBDWG website. All subcommittees included patients.

The 2017 inaugural meeting was in the spirit of "nothing about us without us," while the 2019 working group inaugural meeting essentially kicked the patients to the curb. The 2019 Working Group membership was officially announced by the HHS less than 24 hours before the first meeting. There were no patient presentations to kick-off the meeting. Public comments were limited to three-minute blocks, with no remote participation allowed. Although it was posted in the Federal Register, few patients were even aware of the meeting. The patient community simply was not notified by email about the meeting as they had been in the past. As a result, the meeting was sparsely attended.

Although there was a public call for nominations and LymeDisease.org nominated several patients who would be qualified to represent the Lyme community, there is no evidence that these nominations were considered in the panel selection. In fact, the Lyme community has no idea whether or how the role of balance of the Working Group was determined. Nor was the community given an opportunity to comment on the panel balance. This is alarming, given the amount of controversy surrounding Lyme disease and the heightened need for transparency.

Although the 2019 Working Group members were not officially and publicly announced until the day before the meeting, the Infectious Diseases Society of America sent an email to its members and posted an announcement three weeks earlier that one of its members, Dr. Eugene Shapiro, had been selected for the group. When LymeDisease.org asked the HHS about this announcement, we were told by TBDWG staff that no members had been selected. Dr. Shapiro is a lightning rod in the patient community, well known for his flagrant conflicts of interest, disparaging comments about patients, and providing expert testimony against chronic Lyme patients and their treating physicians. LymeDisease.org launched a petition calling for his removal from the 2019 Working Group, which over 23,500 patients have signed. We advised Jim Berger, the Designated Federal Officer, about the petition and Dr. Shapiro's conflicts of interests on May 21 but have not received a response to date.

The IDSA did not remove its website posting and Dr. Shapiro was in fact listed as a member of the group by the HHS the night before the first meeting. Why did the TBDWG deny his appointment when asked, and claim that no members had been selected? What consideration was given to Dr. Shapiro's conflicts of interest and extremely biased points of view in his selection and continued membership on the 2019 Working Group? All of this reveals a staggering lack of transparency and process integrity.

At the meeting, Co-Chairman Walker provided a glimpse into a continuation of this pattern by suggesting that the chairs of the various subcommittees would select subcommittee members without public disclosure, without any opportunity for stakeholder input, transparency, or consideration for balance under FACA. This would undermine the entire purpose of a balanced Working Group and be at odds with the processes used in the 2017 Working Group.

This would allow subcommittee chairs to hand-pick their subcommittees with no oversight. These subcommittees could then be stacked with vested interests and exclude patients and their treating physicians as members. These ideas are inconsistent with the requirement of membership balance on the group and the impetus behind passing the legislation which created the Working Group. All work of the Working Group is conducted by subcommittees, with the results flowing upward to the Working Group for consolidation into a single report. If there is no balance in the subcommittees, the only content that the Working Group will be able to condense may exclude vital viewpoints such as the perspective of patients and their treating clinicians. It also allows viewpoints shaped by conflicts of interests or extreme bias in determining what information the Working Group is provided, which is a high risk in hand-picked groups that have no oversight.

Dr. Walker also announced that Bob Sabatino, one of two patient advocates on the 2019 panel, would be replaced with a Rickettsia expert at the expiration of his term in August. A patient representative cannot be replaced by a Rickettsia expert without compromising the requirement that those affected be represented on the panel. In addition, although the other subcommittee chairs were allowed to select their committee of interest, Dr. Walker announced that Bob Sabatino would serve on the tick subcommittee without choice or any rationale for singling out a patient to head a subcommittee on ticks—an area where that patient does not have expertise. This appears to be an attempt by Dr. Walker to ensure that the Rickettsia expert he selected to replace Sabatino will be chairing a subcommittee of the Rickettsia expert's choosing. This means that Sabatino will not be chairing a committee where patient subject matter expertise is most relevant. Rather, he is merely a place holder for his replacement. This is tokenism. Sabatino can have no influence in this position. He's a lame duck without a patient successor.

Finally, Dr. Walker announced that as far as he was concerned, Lyme disease had already been covered by the previous Working Group and therefore there was no need to focus on this topic any more. This is remarkable considering that 82% of the burden of tick-borne disease is borne by Lyme disease (CDC 2018), as well as the fact that the 2017 Working Group highlighted many areas for the future Working Group to address. It would be hard to imagine that a panel for HIV/AIDs would declare that they were "all done" before patient needs had been addressed.

There is a lack of balance in the committee memberships.

Under <u>FACA rules</u>, the Working Group is required to be "fairly balanced in terms of the points of view represented and the functions to be performed." In balancing committee memberships, agencies are expected to consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and function of the advisory committee. The primary people affected by the Working Group are patients with Lyme disease and the clinicians who treat them. These are the people who ensured that the 21st Century Cures Act was passed with the Working Group provision and these are the people who are denied care, denied insurance coverage, and whose treating physicians are targeted by medical boards. Yet patients and their treating clinicians are not adequately represented on the 2019 Working Group.

The 21st Century Cures Act provides that "the Working Group will consist of 14 voting members, including the Chair, who **represent** diverse scientific disciplines and views." It provides that the members will include:

NON–FEDERAL PUBLIC MEMBERS. —Seven non–Federal public members, consisting of representatives of the following categories:

- (i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.
- (ii) Scientists or researchers with expertise.
- (iii) Patients and their family members.
- (iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

When selecting committees, FACA requires that the committees include those affected and that a balance of viewpoints be represented (GAO 2004). Moreover, the FACA handbook provides that the Membership Balance plan should identify the categories (e.g., individual expertise or represented interests) that potential members would fill. The patient community does not understand how the 2019 Working Group was selected, what roles the individual members fulfill or whose interests they represent. Nor do they understand why the approach this time is vastly different than was used for the 2017 Working Group. Why the sudden change?

Excluding the co-chairs (which are addressed below), the 2017 Working Group included three patient representatives. After August, the 2019 Working Group will have one. The remaining patient slots will have been filled with academic researchers. The 2017 Working Group included a representative with clinical experience from ILADS as well as the IDSA. The 2019 group only has the IDSA perspective represented, by Dr. Shapiro. He not only has substantial conflicts of interest, but also has extreme viewpoints and biases that are reflected in articles and statements denigrating patients and in his provision of expert testimony against patients and their treating physicians as further described below.

The 2019 Working Group selected does not adequately represent the views of patients or the views of the ILADS community physicians who treat them. In addition, the committee is over-weighted with expertise in Rickettsia and with academic researchers, when the legislation was passed to address the needs of patients with chronic Lyme disease.

The Working Group does not adequately represent the interest of patients with chronic Lyme disease.

The first Working Group included three patient representatives: Karen Forschner, Pat Smith, and Wendy Adams. In addition, the vice-chair was Kristen Honey, who also has lived experience with the disease. The new Working Group has two patient representatives: Pat Smith and Bob Sabatino. However, Dr. Walker announced (without any apparent process integrity) that Bob Sabatino would be replaced with a Rickettsia expert in August. For reasons outlined below, the community does not view Soltysiak as a patient representative.

Although the patient community supports the selection of Pat Smith as a patient representative, she alone cannot effectively represent the community on a committee in which she represents a minority. Effective representation of patients on the group depends upon the number selected. Single patients cannot shoulder the weight in deliberations or in votes. As the TBDWG's new term gets underway, patients selected as public representatives will be outnumbered seven to one.

The Working Group's expertise is over weighted in Rickettsia and Academic Researchers.

The Working Group is disproportionately constituted of members with an expertise in Rickettsial illness, rather than Lyme disease. Dr. Walker, the Co-Chair, specializes in rickettsial illnesses, as do two alternative government members, Chien-Chung Chao, Ph.D, and Samuel S. Perdue, Ph.D. Dr. Walker announced at the meeting that Bob Sabatino, the patient representative, will be replaced by Dr. Kevin Macaluso, whose expertise is Rickettsia. This results in a Working Group that is unduly focused on Rickettsia.

The Working Group does not include a member of the International Lyme and Associated Diseases Society.

Last term, Dr. Richard Horowitz represented community physicians who treat chronic Lyme disease. However, this term there are no community physicians from the International Lyme and Associated Diseases Society (ILADS). Given that there is a substantial conflict between the viewpoint of the Infectious Disease Society of America (which is represented by Dr. Shapiro) and ILADS, the failure to include the ILADS perspective is a critical flaw in the constitution of the present Working Group. When the Guidelines Clearinghouse was operational, the guidelines of ILADS (which were developed under GRADE and met the high standards of the National Academy of Medicine—previously the Institute of Medicine) were posted and the IDSA guidelines were removed because they were outdated. As noted above, almost all patients with chronic Lyme disease are treated by ILADS clinicians. The appointment of an IDSA representative without appointing an ILADS representative constitutes favoritism and excludes a vital perspective on the diagnosis and treatment of Lyme disease.

Women are under-represented on the Working Group.

There is a lack of balance in representation of women on the Working Group non-federal membership. This is particularly striking when you compared the 2017 Working Group, on which four of the seven public members were women, with the 2019 Working Group, which has only two women who are public members. This should be viewed in the context that patients with chronic Lyme disease are significantly more likely to be female (Wormser, Shapiro, 2009). NIH Director Dr. Francis Collins has recently pointed out that women are too often under-represented on panels (Edwards 2019).

The Selected Co-Chairs Raise Concerns.

Leigh Ann Soltysiak is the co-chair and has lived experience with Lyme disease. However, she is not known in the Lyme community and was not nominated by any trusted patient advocacy group as being qualified to represent patient interests. In addition, she works as a consultant for the pharmaceutical and medical device industry. It is unclear whose interests she represents. The last working group, she served on the vaccine committee which issued "unanimous" recommendations that the Lyme community opposed. Hence, the Lyme community does not believe that she represents the patient perspective. Whose interests was she selected to represent?

Dr. Walker, the Co-Chair, specializes in rickettsial illnesses and is not known to have experience with Lyme disease. His first move as Co-Chair was to limit the focus on Lyme disease and shift the focus to rickettsia and other co-infections—essentially claiming there was no need to discuss Lyme disease further.

Rather than run the meeting collegially, allowing different viewpoints, Dr. Walker used his position as Co-Chair to drive his own agenda of switching the focus of the committee away from Lyme disease. Dr. Walker does not have the experience with Lyme disease essential to the Working Group and lacks the temperament to deal with a controversial illness and allow a diversity of perspectives to be heard.

His appointment as Co-Chair of this group is also troubling because he serves as Chair of the Congressionally Directed Medical Research Program (CDMRP), tick borne disease panel. The Working Group and the CDMRP are the only federal advisory committee and panel containing patient representation that focus on tick-borne diseases. Having Dr. Walker chair both bodies consolidates his power to disproportionately affect the national agenda and policy-making for Lyme disease.

Conflicts of interests and extreme viewpoints of certain members

The Lyme community does not object to the IDSA having a representative on the panel. However, we take serious exception to Dr. Shapiro, who has substantial financial conflicts of interest and has an extreme anti-patient bias. His conflicts of interest and bias are well known and wide ranging. They are exhibited in his publications, public statements, legal testimony against patients and their treating physicians, and consulting arrangements. He was a named defendant in the Connecticut Attorney General Antitrust Investigation regarding the IDSA guidelines, which he co-authored (Johnson 2009). He is currently a named defendant in a civil RICO suit alleging that he, among others, conspired with insurance companies to deny patients with Lyme disease access to care (Torrey et al vs IDSA et al).

Dr. Shapiro's most recent conflict of interest disclosure on a JAMA opinion piece reveals that he consults with Lyme vaccine manufacturer Valneva (which just announced successful results from FDA Phase 2 trials), is paid by insurers to testify against Lyme patients, receives fees for testifying against the physicians who treat patients with chronic Lyme disease, and serves as a director on the American Lyme Disease Foundation, an organization that represents the interests of IDSA researchers and disingenuously holds itself out as representing patient interests. [Its website touts "the best private organization-based site that can be recommended to patients for education on Lyme disease is that of the American Lyme Disease Foundation." Patients regard this organization as waging a war against Lyme disease. In a recent interview, its President (and former NIH Lyme program director) Dr. Phil Baker referred to patients with chronic Lyme disease as a "cult."] (Shapiro 2018, Valneva 2019, Sholtis 2019).

Dr. Shapiro also has an annual NIH grant (Clinical and Translational Science Award UL1 TR001863) of \$1.2 million, which pays a portion of his salary. His position on the Working Group, when he has received funding from the sponsoring agency, suggests further politicization of the Working Group selection and process.

His publications are polemic in nature. For example, a recent publication entitled "False and Misleading Information About Lyme Disease," disparages organizations that hold views that diverge from his and dismisses these views as "false equivalency" or fake (Shapiro 2017).

His public statements show a strong and derisive anti-patient bias. For example, a Stanford grand rounds presentation took special aim at patients, making fun of and eliciting laughs at their expense (Shapiro 2004).

"So clearly, these patients were sick. They had problems. It's just that antibiotic deficiency was not one of them. [laughter]."

"Q (Audience): How do you convince people who are committed to the diagnosis of Lyme disease, that Lyme disease is not the cause of their non-specific symptoms, especially after they have the support of their own physician, confirming this diagnosis. A (Shapiro): I have a whip! [laughter]"

Substantial barriers to participation were imposed on chronic Lyme patients, many of whom are disabled.

Unlike the 2017 meeting, which allowed a patient to provide extended comments by phone, the 2019 meeting required that patients attend in person in order to make comments. This created a geographic barrier for patients who were not in the immediate Washington DC area. Many chronic Lyme patients are unable to physically attend due to health issues or disability and others were unable to afford the airfare, time off work, and hotel to travel. Hence, this restriction effectively silenced the patient voice. It represents a significant discrimination issue against a disabled and financially constrained patient population. We have received patient complaints about this restriction. (See Attachment A.)

Conclusion.

From the perspective of the patient community, there is no reason why the 2019 Working Group should lack process integrity and membership balance. Nor should it permit strong conflicts of interest and bias into its process. After all, the 2017 Working Group was able to meet these standards. However, those processes and considerations appear to have been abandoned for the 2019 Working Group.

We call upon you to investigate our concerns and reconstitute the membership of the committee and revamp the process of selecting its subcommittees so that they represent a balance of viewpoints, preserve the patient voice, and eliminate conflicts of interest.

- 1. Dr. Shapiro should be removed from the Working Group because of his flagrant conflicts of interests, his extremely anti-patient views, and the fact that a portion of his current salary is paid under an NIH/NCATS grant.
- 2. The Working Group balance should be improved by including more representation from patients with chronic Lyme disease, women, and ILADS, so that it is more closely aligned with that of the 2017 Working Group. More specifically:
 - a. Two more patients should be selected for the Working Group. These should be patients with chronic Lyme disease (or caregivers) who have either been nominated by a trusted patient advocacy group or who are officers or directors of a patient advocacy group. Bob Sabatino's position should be filled by a Lyme disease patient representative when his term expires. For example, the 2017 panel included three patient representatives who were officers or directors of patient advocacy groups. This panel has one.
 - b. A representative of ILADS with experience either treating patients or educating clinicians in the care of patients with chronic Lyme disease should be selected for the Working Group. For example, the 2017 Working Group had an ILADS physician as a member, the 2019 Working Group has none.
 - c. The public Working Group needs more women. For example, four of the seven members of the 2017 Working Group were women, the 2019 Working Group has two. The majority of those affected by chronic Lyme disease are women.
 - d. One Co-Chair should be a patient representative. Leigh Ann Soltysiak works in the pharmaceutical field. Although she has lived experience with Lyme disease, she is not recognized as a patient representative by the Lyme community and should either be removed or at least should not serve as Co-Chair. Her dual role (pharma vs patient)

- provides opportunity for conflicts to arise or, at a minimum, for any role as a patient representative to be compromised.
- e. Dr. David Walker should not chair two federal tick-borne disease bodies (the TBDWG and the DOD CDMRP). This consolidates too much power over policy making in one individual, especially with the lack of balance of the other members on the Working Group. He should resign from one of these panels.
- 3. Each subcommittee of the TBDWG should include at least two patients/advocates and at least one ILADS clinician. They should be subject to the same balance as the Working Group and represent a diversity of viewpoints. The members should be publicly disclosed and confirmed by the Working Group in terms of balance.
- 4. Process integrity and transparency should be improved to ensure meaningful stakeholder engagement. More specifically,
 - a. Patients who have signed up for email notices should receive them far enough in advance of meetings to prepare any remarks or written submissions. There was no email notice of the June 4 Working Group meeting.
 - b. Members of the Working Group should be publicly disclosed sufficiently in advance for patients to comment on the panel's balance. Transparency about the member selection process, including who chooses the members, how nominations from patient advocacy groups were taken into consideration, other factors considered, and whose interest individual members represent should be disclosed.
 - c. Patients should be permitted to give public comments remotely by phone to avoid discrimination against those who are disabled or cannot afford the travel or the time entailed in flying to Washington, DC.

Respectfully submitted on behalf of the 57 patient organizations that have signed onto this letter. If you have any questions, please contact Lorraine Johnson at 310-365-3233 or lbjohnson@lymedisease.org.

Lorraine Johnson, CEO LymeDisease.org

Phyllis Mervine, President and Founder

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Cc:

Kaye Hayes (Deputy Director, Office of Infectious Disease and HIV/AIDS Policy) James Berger (Designated Federal Officer Tick-Borne Disease Working Group)

Rep. Christopher H. Smith (House Lyme Disease Caucus Co-Chair)

Rep. Collin Peterson (House Lyme Disease Caucus Co-Chair)

Also signed by

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References

Centers for Disease Control and Prevention. Vital Signs: Trends in Reported Vectorborne Disease Cases — United States and Territories, 2004–2016. MMWR, Mobid Mortal Wkly Rep 2018; 67((17)). Available from: https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm.

Centers for Disease Control and Prevention. CDC provides estimate of Americans diagnosed with Lyme disease each year. 2013; Available from: http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html.

Edwards E. No more 'manels,' NIH head says in call to end all-male science panels. NBC News. 2019 June 13, 2019. Available from: https://www.nbcnews.com/health/health-news/no-more-manels-nih-head-says-call-end-all-male-n1017181.

Fallon BA, Keilp JG, Corbera KM, Petkova E, Britton CB, Dwyer E, Slavov I, Cheng J, Dobkin J, Nelson DR, Sackeim HA. A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy. Neurology. 2008 Mar 25;70(13):992-1003. doi: 10.1212/01.WNL.0000284604.61160.2d. Available from: https://n.neurology.org/content/70/13/992.long#%20

Johnson L, Aylward A, Stricker RB. Healthcare access and burden of care for patients with Lyme disease: a large United States survey. Health Policy. 2011 Sep;102(1):64-71. doi: 10.1016/j.healthpol.2011.05.007 Available from: http://www.ncbi.nlm.nih.gov/pubmed/21676482

Johnson L, Stricker RB. Attorney General forces Infectious Diseases Society of America to redo Lyme guidelines due to flawed development process. J Med Ethics. 2009 May;35(5):283-8. Available from: http://jme.bmj.com/content/35/5/283.

Klempner MS, Hu LT, Evans J, Schmid CH, Johnson GM, Trevino RP, Norton D, Levy L, Wall D, McCall J, Kosinski M, Weinstein A. Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease. N Engl J Med. 2001 Jul 12;345(2):85-92. doi: 10.1056/NEJM200107123450202. Available from: https://www.nejm.org/doi/full/10.1056/NEJM200107123450202

Krupp LB, Hyman LG, Grimson R, Coyle PK, Melville P, Ahnn S, Dattwyler R, Chandler B. Study and treatment of post Lyme disease (STOP-LD): a randomized double masked clinical trial. Neurology. 2003 Jun 24;60(12):1923-30. doi: 10.1212/01.wnl.0000071227.23769.9e. Available from: https://n.neurology.org/content/60/12/1923.long

Rebman AW, Bechtold KT, Yang T, Mihm EA, Soloski MJ, Novak CB, Aucott JN. The Clinical, Symptom, and Quality-of-Life Characterization of a Well-Defined Group of Patients with Posttreatment Lyme Disease Syndrome. Front Med (Lausanne). 2017; 4: 224. doi: 10.3389/fmed.2017.00224 Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5735370/

Rosenberg R, Lindsey NP, Fischer M, Gregory CJ, Hinckley AF, Mead PS, Paz-Bailey G, Waterman SH, Drexler NA, Kersh GJ, Hooks H, Partridge SK, Visser SN, Beard CB, Petersen LR. Vital Signs: Trends in Reported Vectorborne Disease Cases - United States and Territories, 2004-2016. MMWR Morb Mortal Wkly Rep. 2018 May 4;67(17):496-501. doi: 10.15585/mmwr.mm6717e1. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933869/

Shapiro ED, Baker PJ, Wormser GP. False and Misleading Information About Lyme Disease. Am J Med. 2017 Jul;130(7):771-772. doi: 10.1016/j.amjmed.2017.01.030. Available from: https://www.amjmed.com/article/S0002-9343(17)30138-9/fulltext#back-bib19

Shapiro ED, Wormser GP. Lyme Disease in 2018: What Is New (and What Is Not). JAMA. 2018 Aug 21;320(7):635-636. doi: 10.1001/jama.2018.10974. Available from: https://jamanetwork.com/journals/jama/article-abstract/2696480

Shapiro ED. Lyme Disease: The Truth About Ticks. Grand Rounds Presentation, Lucile Packard Children's Hospital, Stanford Medical School. September 24, 2004.

Brett Sholtis, Lyme disease bill would change coverage amid controversy over 'chronic' condition. WITF News, Transforming Health. June 13, 2019

US General Accountability Office. Federal Advisory Committee Act: Issues Related to the Independence and Balance of Advisory Committees. Testimony Before the Subcommittee on Information Policy, Census, and National Archives, Committee on Oversight and Government Reform, House of Representatives. April 2, 2008. Available from: https://www.gao.gov/products/GAO-08-611T

US General Accounting Office. Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance. April 16, 2004. Available from: www.gao.gov/cgibin/getrpt?GAO-04-328.

Torrey et al vs. Infectious Diseases Society Of America, Blue Cross And Blue Shield Association, Anthem, Inc., Blue Cross And Blue Shield Of Texas, Aetna Inc., Cigna Corporation, Kaiser Permanente, Inc., United Healthcare Services, Inc., Unitedhealth Group Incorporated, Dr. Gary P. Wormser, Dr. Raymond J. Dattwyler, Dr., Eugene Shapiro, Dr. John J. Halperin, Dr. Robert B. Nadelman, Dr. Leonard Sigal, And Dr. Allen Steere. 17-cv-190 (USDC ED Texas, Texarkana) https://www.courthousenews.com/wp-content/uploads/2017/11/LymeDisease.pdf

Valneva Reports Successful Outcome of Phase 2 Run-In for its Lyme Disease Vaccine Candidate. GlobeNewswire, June 12, 2019. Available from: https://finance.yahoo.com/news/valneva-reports-successful-outcome-phase-155000494.html

Wormser GP, Shapiro ED. Implications of gender in chronic Lyme disease. J Womens Health (Larchmt). 2009 Jun;18(6):831-4. doi: 10.1089/jwh.2008.1193. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2913779/

Attachment A

June 12, 2019

Dear Mr. James Berger & TBDWG Members and Staff,

As a volunteer involved in Lyme and tick borne disease education and support for several decades, I would appreciate being able to participate in the federal TBDWG proceedings. Being one of only three people to submit tick borne disease related white papers to Congress for the 21st Century Cures Act that helped create this group, I am very interested in seeing this project through and also having meaningful input along the way.

If I could make the trip to Washington DC to share my comments with the working group, which I am unable to do because of my multiple Lyme-related disabilities, it would cost approximately \$1,200 plus meals, tips, and transportation fees to attend. That is more income than I receive for three months on disability, making the trip to speak to the group both physically and financially impossible.

Unfortunately, I am not alone in dealing with this situation. Many sick patients across the country also cannot participate due to the severity of their TBD related illnesses, their disabilities and/or the costs involved.

The current policy to not allow people to speak remotely at in-person meetings of the TBDWG is unfair to all interested parties, especially the disabled. It places an undue burden on those who are not in the DC area and it essentially silences voices across the country.

I write to you today and request that you act immediately to accommodate those who are unable to attend in person for whatever reason so they may have a chance to participate in this process. You can do this easily by allowing verbal comments to be made by phone as you do in your phone conference meetings.

Thank you very much for your consideration. I will be awaiting your reply. Sincerely,

Lucy Barnes
www.MarylandLyme.org
AfterTheBite@gmail.com