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**Key Stakeholder Presentation**

HHS’s Tick-Borne Diseases Working Group

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**Comprehensive Version**

**INTRODUCTION**

Good afternoon. My name is Gregg Skall and I am the legal counsel for the National Capital Lyme Disease Association, also known as NatCapLyme. My wife Monte has suffered terribly from tick-borne diseases for more than 30 years. As a result, I have seen the devastation that these diseases have had on hundreds, if not thousands of people.

I am both honored and grateful to speak here today to the newly formed HHS Tick-Borne Disease Working Group and truly hope we can, as a community, come together to bring about significant changes to the state of medicine associated with Lyme and tick-borne diseases.

However, past experience demonstrates the serious challenge of achieving significant change. Seven years ago I had the privilege of participating in the Institute of Medicine’s (IOM) workshop *Critical Needs and Gaps in Understanding Tick-Borne Diseases.* Despite earnest efforts from workshop participants, there has been little progress with respect to tick-borne illnesses.

Perhaps what is most distressing about the current state of affairs regarding Lyme and tick-borne diseases is that the medical community is still so strongly divided. Since each faction seems so certain of the integrity of its position, the lack of communication and collaboration among them impedes real progress and the bitterness of this debate serves neither science nor patient.

At the October 2010 IOM workshop, we identified important research and key ideas, similar to what this group is charged to do, but unfortunately, very little came of such work. We believe that the pertinent advances that have been made since then have not been as a result of the recommendations of the IOM workshop, but instead, have been more of a process by which self-directed and self-motivated researchers have decided to study this complex medical conundrum on their own.

Another aspect of these diseases that have not changed is that tick-borne illnesses continue to be discounted by the vast majority of physicians, other medical professionals, government policy makers and researchers who cling to the inaccurate belief that Lyme disease is hard to catch and easy to treat. And while patients are being denied treatment and are being misdiagnosed, the incidence of tick-borne diseases is surging. It is now old news that the Centers for Disease Control (CDC) currently estimates more than 300,000 new cases of Lyme disease each year. This number does not include any other tick-borne diseases, only Lyme.

Not only are we seeing an explosion in the number of reported cases in the U.S., but we are also dealing with a pandemic. In the spring of this year I presented at an international tick-borne disease conference in Paris, France, and it was clear that we are seeing a corresponding outbreak in the number of cases worldwide.

Therefore, I would venture to say that we not only have a poor understanding of the true incidence and geographical distribution of Lyme and other tick-borne diseases, but it also means that we really do not have an accurate assessment of the magnitude of the effect of these diseases on the general population. We must discard the often-heard regional biases about the existence and extent of tick-borne diseases. It is no longer solely a Northeastern phenomenon, if it ever were one. Our national consciousness must be expanded to include the study and treatment of all tick-borne diseases throughout the United States.

No matter where I go or whom I meet, I am constantly being told during these exchanges that they know someone – a relative, friend, coworker or acquaintance – who is suffering terribly from Lyme and/or its coinfections. Further, many members of Congress are keenly aware of Lyme and tick-borne diseases. Visits to Congressional offices to distribute the IOM report revealed that, just as in the population as a whole, nearly every Congressional office had been touched by tick-borne diseases, again either directly or through a friend or family member.

It is crucial that Congress as well as the medical and research communities recognize the complexity of these diseases and the burdens they impose on individuals, families, and society at large. The long-term effects of persistent Lyme disease can last a lifetime, so it is incumbent upon us all to find answers so that generations to come will not be afflicted by them.

In preparing for this presentation, we were asked to provide information on:

* + what can offer the greatest impact on the greatest number of people;
  + methods to improve the lives and health of people living with tick-borne diseases; and
  + methods to prevent new tick-borne infections.

**WHAT OFFERS THE GREATEST IMPACT TO THE GREATEST NUMBER OF PEOPLE**

In response to ***what offers the greatest impact***, we believe the key to any future advancement lies in the development of better diagnostic tools***.*** We need to abandon the two-tier testing approach. The problem with tests like the ELISA is its dependence on identifiable antibodies, which, as we learned from Dr. Aucott, may not develop until weeks or months after infection – well *after* the optimum time to treat a tick-borne disease. Public education and patient informed consent require accurate patient notification of testing reliability, including the potential for a false negative result, and this should be recognized in every state, as Maryland and Virginia have done legislatively.

Therefore, we desperately need accurate tests for the detection of all tick-borne diseases. Development of accurate tests is the key to finding the most effective method for treating these diseases as well as to advancing research. The lack of an early diagnostic test for tick-borne diseases has caused untold pain and suffering as delayed diagnosis and treatment often leads to a lifetime of illness and misery. Further, medical science needs to develop a diagnostic tool that is capable of identifying all stages of these diseases as well as one that confirms eradication of the pathogens. Being armed with an arsenal of such tests may allow us to better characterize both acute and persistent manifestations of Lyme and associated co-infections. What we like to say is, “treat the patient, not the test.”

Given the current state of research, creating these tests, as well as pioneering research in the field of tick-borne diseases, may seem like a tall order. Instead of recognizing and supporting the same old cast of researchers who repeatedly test the same old ideas, it is vital to reach out to new players who offer innovative and creative ideas and look for real solutions.

Therefore, we urge HHS to expand its funding for the emerging and promising research that comes from fresh and new perspectives. We have been told that HHS’ approach to preventing waste, fraud and abuse in research funding prevents support for creative research. HHS must find a way to reach beyond the known and safe research that has been funded in the past and which has added little to solving the tick-borne disease problems.

The following are examples of research for which NatCapLyme has contributed funding:

1. **Dr. Neil Spector** of Duke University has a novel approach to Lyme research. He speculates that the process of developing immune therapies used for cancer research and treatment may provide a paradigm shift in the treatment of Lyme disease.
2. **Dr. Ying Zhang** of Johns Hopkins University has done significant work in the area of antibiotic resistance, bacterial persistence, and the development of more effective treatments for persistent Lyme disease infections that include unconventional antibiotic cocktails.
3. **Dr. Kim Lewis** of Northeastern University studies persister cells and focuses on developing new antibiotics to treat tick-borne diseases.
4. **Dr. John Aucott** of Johns Hopkins University, this Group’s chair, has been instrumental in leading a study, commonly known as the SLICE study, with the goal of understanding why some patients develop what he calls “post-treatment Lyme disease syndrome,”or persistent Lyme, lasting months, years or a lifetime, while others do not.

Bringing together the best minds and best theories of ALL parties, and requiring that ALL theories be examined and considered, can facilitate the development of such important steps forward. We must always bear in mind that “The medical elite thought they knew what caused ulcers and stomach cancer,” until an internist named Barry Marshall drank H. pylori. So, we want to examine all useful possibilities and observations gathered from both empirical observation and clinical experience, and then design science that will satisfy the skeptics as well as the believers in the integrity of the outcome. Moreover, what has been dismissed as anecdotal patient information may in fact be a treasure trove of research data that may shine a new light on a possible cure for Lyme and other tick-borne diseases.

We believe that in research for the 21st century we need to take a look at how the Alzheimer’s Disease Neuro-Imaging (ADNI) initiative was able to come up with new biomarkers and the sharing of data. Their project leader said that the three-point program they used was extremely important in moving their research agenda forward. Specifically, they agreed to share all their data. They agreed that every finding would be made public immediately and they agreed to renounce ownership and patent rights.

We need to examine the issues of ownership and patent rights and whether or not it inhibits rather than fosters research. Research that captures the characterization of Borrelia genotypes and informatics that creates national databases which capture every aspect of the disease in the ecosystem, the vectors, and the patients, should be included in future research endeavors. To encourage collaborative research, we hope that this Working Group recommends bringing university and private sector scientists and practicing medical professionals from different viewpoints together to collaborate on solving the problems of treatment failures and persistent illness. NatCapLyme believes that true solutions to the dilemma of Lyme and tick-borne infections may be found only when all parties are willing to consider the views that each party holds.

**METHODS TO IMPROVE THE LIVES AND HEALTH OF PEOPLE LIVING WITH TICK-BORNE DISEASES**

In response to the ***methods to improve the lives and health of people living with tick-borne diseases***, we have many suggestions. First and foremost, the CDC case definition of Lyme disease must be discarded for diagnosing patients. That definition designed specifically and only for surveillance, is consistently misused as the “definitive diagnostic criteria” in the clinical setting, so its use is misunderstood in the general medical community. Though presently accepted as the “gold standard,” the current case definition has dramatically failed to serve the patient population and medical community. Patients, medical providers and scientists must have a better case definition, expanded to include the entire emerging spectrum of Lyme disease and tick-borne coinfections.

If we are to stem the epidemic, persistent as well as acute Lyme disease must be taken seriously. Physicians are not updated on the existence of Lyme disease in their state or provided with the expanded list of symptoms presented by patients. Continuing medical education needs to recognize and include critical information. It is essential that medical professionals be taught to include a potential tick-borne disease in their differential diagnosis. A national education course for medical providers needs to be developed to reflect the diverse approaches to treatment and diagnosis so that family practitioners, ER practitioners and all medical providers are competent to recognize, diagnose, and treat tick-borne diseases. For example, a person bitten by a tick is at risk for multiple infections, which many front line professionals are not aware of.

In 2010, NatCapLyme conducted a 10-day on-line survey. A total of 1,438 subjects, from across the country participated. The survey found that 46% of the respondents had been diagnosed with two or more tick-borne infections. Coinfections are often overlooked by medical professionals when testing for Lyme, which can hamper an accurate diagnosis.

Today, it is essential that every medical provider be aware, through continuing education and in medical schools, of the importance of testing for coinfections as they are developing their differential diagnosis.

While we wait for current research to advance our knowledge of tick-borne diseases and for continuing education and medical schools to keep health care providers current on the latest information, it is imperative that we continue to support the providers who practice on the front lines of these diseases. State medical boards routinely penalize doctors for deviating from the Infectious Disease Society of America (IDSA) guidelines for treatment of Lyme disease by subjecting them to investigations and disciplinary procedures, rarely done to physicians treating other diseases.

Consequently, a growing number of patients lose their providers who stop treating tick-borne diseases for fear of losing their medical license. Providers are reluctant to treat Lyme and other tick-borne infections in a manner that contradicts the IDSA guidelines. This government sanctioned medical society, favoring one treatment over another, places an unnecessary burden on patients who are left to fend for themselves. This is unconscionable and must stop. Medical professionals must be allowed to treat as they deem appropriate and to practice the “true art of medicine.” The patient should have the right to choose the treatment of their choice. Medical guidelines are designed to provide recommendations and not mandates.

**METHODS TO PREVENT NEW TICK-BORNE INFECTIONS**

Finally, we were asked to discuss ***methods to prevent new tick-borne infections***.

Mass media campaigns are widely used to expose large populations to messages which deal with various health risk behaviors, and in this case it would be the exposure to ticks and the additional serious diseases they can carry. We recognize that mass media campaigns may be an efficient way to get the message out to protect the general population from getting tick-borne illnesses. NatCapLyme believes that a national media campaign on prevention and awareness of tick-borne diseases would be effective at curbing the current Lyme and tick-borne epidemic.

Specifically, NatCapLyme would like to see the CDC mount a mass media campaign similar to the response associated with the Zika virus. A comparative review of the CDC’s website for Lyme and Zika clearly shows a significant difference, or a bias towards Zika, between the two infectious diseases in terms of the amount of important content available on-line. Let’s not also forget that in 2016, Congress provided for $1.1 billion in funding to combat the Zika crisis, and millions of dollars were also allocated in 2017.

As you know, federal dollars associated with tick-borne diseases receive only a minute fraction of that in research and program funding. To add insult to injury, according to the CDC, there were only 373 cases of Zika in the United States between January 1, 2017 and December 6, 2017, compared to the more than 300,000 estimated cases of Lyme.

A research study published in 2015 by the Johns Hopkins Bloomberg School of Public Health found that Lyme disease costs the U.S. health care system between $712 million to $1.3 billion to treat each year. Again we are only talking about Lyme disease, and not other coinfections. However, if you include the indirect costs, such as lost wages or lost taxes, for example, the total cost of Lyme disease is in the billions of dollars each year.

So in the long run, a mass media campaign on prevention and awareness may be the most cost effective solution given the extreme economic burden persistent Lyme costs society.

Actually, in many aspects one must be rich or financially affluent to continue treatment for tick-borne diseases. For those with the persistent form of these diseases, often only those who can pay for out-of-pocket expenses can afford the protracted treatment period beyond mainstream’s 28-day protocol. As we see and hear on the national news daily, paying for health care is a big problem for many American families. Left behind to suffer are the tens of thousands of patients who do not have the financial means to pay for extended treatment. Many families must drain their life savings and retirement accounts to cover the cost of therapy. Think of the outdoor workers or lawn service employees who are exposed daily to tick infested habitats. In many cases, they are not even aware of the life altering risk they are assuming during their workday. The Tick-Borne Disease Working Group needs to consider such inequities and mainstream medicine must rectify this deplorable situation – **for this is a global human rights issue that can no longer be ignored!**

Next, we strongly advocate establishing a national educational curriculum for school age children. In fact children, ages 5 through 14, face the highest risk of tick infections that can affect their entire lives. This risk is likely due to the amount of time children spend outdoors as well as their lack of awareness of the importance of finding and removing ticks. Children need to be made aware and taught how to protect themselves from ticks and the serious diseases they carry. We believe that “education is your best defense” against getting a tick-borne disease. We implore HHS to encourage funding designated to provide every student with the tools they need to achieve this important goal.

Though controversial, mainstream medicine supports the belief that vaccines, in general, play an important role in preventing many diseases. While NatCapLyme would like to see a “safe and effective” vaccine, a narrow-focus of a few strains of Borrelia, and a rush to certify a vaccine, offers only a limited public-health benefit and harbors a serious potential health risk.

Given the cost of vaccine development and testing, and the perception of protection, any candidate vaccine must have demonstrable effectiveness against the full range of Borrelia strains and coinfections endemic in the U.S., at least, or in the world. Furthermore, given the history of vaccine development associated with Lyme disease, the less-than-perfect knowledge regarding Borrelia diversity and coinfections, the symptom variations due to genetic and other factors, plus the difficulty of accurately screening patients in any clinical trial as well as during eventual distribution, safety assessment of a human vaccine must be particularly stringent in this case. In simpler terms, the perception of protection from a vaccine can be dangerous if it is not effective against the full range of Borrelia or coinfections. Therefore, it is NatCapLyme’s opinion that it is premature to inoculate the general public with a tick-borne disease vaccine. We do hold out hope that these obstacles can be overcome and that such a “safe and affective” vaccine can be developed in the future.

Lastly, we must make certain that tick-borne diseases, such as Babesia, are not transmitted though the national blood supply and that proper screening techniques are in place to ensure public health safety. According to the CDC, no tests have been licensed yet for screening blood donors for Babesia. The American Red Cross is participating in an investigational study to test the blood supply for this tick-borne parasite in donated blood. The problem lies in the fact that while some individuals infected with Babesia may become seriously ill, other individuals may be asymptomatic. It is this latter group that may become blood donors, and there have been at least 100 cases of transfusion-transmitted Babesiosis to date Again, as discussed earlier in this paper, NatCapLyme wholeheartedly believes that developing better diagnostic tools, i.e., accurate tests for the detection of all tick-borne diseases, will provide the greatest impact for the greatest number of people.

**CONCLUDING REMARKS**

As I begin my concluding remarks, I would like to emphasize that my comments are not intended to be negative or to dwell on the past. NatCapLyme is extremely hopeful that we are at a critical juncture in medical history and that this Working Group offers great opportunity to advance the understanding of Lyme and tick-borne diseases beyond anything we have seen in the past.  We believe that we are now at a game-changing moment, which has the potential not only to impact tens of thousands of lives in the U.S., but millions of lives around the world. That perhaps when we look back 10 or 20 years from now we will know that we did contribute to the greater good for society. That we may, in fact, hold the power to forever end this terrible pandemic.

Lyme and other tick diseases erode every facet of an individual’s life, decimate marriages and livelihoods, cause children to leave school and lose their childhoods and for some, lead to death. For many patients, life never returns to normal, as they must accommodate activity restrictions and ongoing health concerns into their everyday routines. It is shameful that so many people suffer for lack of an accurate diagnoses or effective treatment.

Therefore, we believe that the Working Group should focus on finding answers for people who are sick but are not currently being served by the medical establishment. The patient community is extremely angry about the lack of scientific and medical progress with respect to the current Lyme and tick-borne disease epidemic, as well as the inadequate response from the medical community and the governmental agencies responsible for the health and welfare of the general public.

This anger propels us to insist that our government, medical professionals, insurers and healthcare system meet our needs as we hold these entities and individuals accountable for the delivery of the results upon which our lives depend and for which we have paid as taxpayers.

Unfortunately, our masses are growing by the tens-of-thousands each year so this problem is not going away until all parties are invested in creating real solutions that benefit all patients, and society as well. And despite being sick, in pain, exhausted, frustrated, and financially drained, we are committed to this cause and will not stop until we regain our health, halt this epidemic, and ensure that these terrible tick-borne diseases do not burden future generations.