

**Tick-Borne Disease Working Group
2:02 PM TO 2:43 PM**

>> John Aucott: So in a moment we're going to start the afternoon program. I'm going to give a moment to Pat Smith for a comment before then.

>> Patricia Smith: Yes, thank you. I just wanted to -- based on what I had brought up earlier about the other federal working group and the fact that we are bringing in stake holders from various places to report and since that issue apparently has been unsettled, if no one has an objection here, I'd like to see that we put that on the agenda somewhere for discussion at maybe the next meeting or tomorrow's meeting or whatever. To invite them in to make a presentation.

>> John Aucott: Excellent idea, thank you. All right, Kristen

>> Kristen Honey: Sure. Welcome to the next session where we want to listen and learn from your perspectives. And to facilitate this portion, we thought it was important to have a third party neutral facilitator. So, Dázon Dixon Dialo is going to be our awesome facilitator.

[laughter]

She is the founder and president of Sister Love Incorporated established in 1989. The first women's HIV and AIDS and sexual reproductive justice organization in the southeastern United States. She is a recognized visionary and advocate in the struggle for human rights, sexual and reproductive rights, and the fight against HIV/AIDS. And now the fight against Lyme disease and tick-borne illness.

> Dázon Dixon Dialo: Yes.

> Kristen Honey: She has great expertise not just in the United States but in South Africa and internationally, and putting the patient voice and people first is her specialty.

> Dázon Dixon Dialo: Thank you so much, Kristen. Good afternoon.

> Multiple Speakers: Good Afternoon.

> Dázon Dixon Dialo: Yeah, you all didn't even eat a really big lunch. You can do better. Good afternoon, family.

> Multiple Speakers: Good Afternoon.

> Dázon Dixon Dialo: Welcome, welcome to your inaugural meeting. It is my distinct pleasure and privilege right now to call up to this podium, Mr. Gregg Skall. This is how we're going to start. We're going to have a couple of key speakers, informed folks, to share some perspective with you and then we'll open up for public comment soon after. So we're going to let Gregg Skall come and share with us the work of the National Capital Lyme and Tick-Borne Disease Association. Gregg is counsel to Nat Cap Lyme -- I love that. Gregg is counsel to Nat

Cap Lyme and is based here in Washington D.C. The Nat Cap Lyme is an all-volunteer, non-profit organization dedicated to improving the lives of those suffering from Lyme and other tick-borne illnesses. It was founded in 2001. And the organization has chapters throughout Virginia, Maryland, the District, North Carolina, and South Carolina. The members including the board members have either experienced the disease personally or have loved-ones suffering from a tick-borne illness. They promote prevention through education and awareness as well as encourage doctor training and research for timely diagnosis and treatment of these illnesses. Now in his other life -- in his mainstay, Gregg is a communications lawyer. He says for over 45 years which I assume he started when he was about 5 years old.

[laughter]

Gregg, please welcome to the podium.

[applause]

> Gregg Skall: Thank you very much.

> Female Speaker: Hi, Loraine, this is Selena.

> Female Speaker: Hi, can you hear me clearly?

> Gregg Skall: Thank you for that nice introduction.

> Female Speaker: I can hear you clearly.

> Gregg Skall: In addition to being legal counsel to the National Capital Lyme Disease Association, I am also here because my wife, Monte, has been struggling with tick-borne disease for more than two decades. And I have seen the devastation that these diseases have had on hundreds if not thousands of people. We've been asked by HHS to comment on three important questions and to answer these questions we must first acknowledge that tick-borne diseases are a significant problem. Because frankly it has been denied for so long by so many respected professionals.

Hopefully in convening this working group we will finally gain recognition that tick-borne disease is not simply a medical anecdote, but in fact represents a national health epidemic that must be seriously addressed and conquered. Seven years ago, I was privileged to participate in the Institute of Medicine's workshop, Critical Needs and Gaps in Understanding Tick Borne Diseases. While that workshop provided important insights, unfortunately it produced little progress. Even with respect to awareness let alone treatment of tick-borne diseases. Disturbingly, tick-borne illness continues to be discounted by the vast majority of medical professionals. Government policy makers and researchers who claim to the inaccurate belief that Lyme disease is hard to catch and easy to treat. In this regard please see the cited Holly Ahearn's presentation.

Accordingly, patients are still being misdiagnosed and denied treatment, and the incidence of

tick-borne diseases is surging. It is now old news that the CDC currently estimates that more than 300,000 new cases of Lyme disease occur each year. And that number does not include all the other tick-borne disease, only Lyme. The first question posed was, what would offer the greatest impact on the greatest number of people? The key to any future advancement lies in the development of better diagnostic tools. We desperately need accurate tests for the detection of all tick-borne diseases, tests that are capable of identifying all their stages.

Equally important, we must be able to confirm eradication of the pathogens. Such tests will be -- will enable us to better characterize both acute and persistent manifestations. 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 have learned from Dr. Aucott, may not develop until weeks or months after infection, well after the optimum time to treat tick-borne disease. Public education and patient informed consent require accurate patient notification of testing reliability including the potential for a false negative. And this should be recognized in every state as Maryland and Virginia have done legislatively.

Given the current state of research, creating these tests as well as pioneering research in the field of tick-borne disease may seem like a tall order. To do this, we have to reach out to new players who offer innovative and creative ideas and look for real solutions. We would like HHS to expand its funding criteria, to reach a merging and promising research that comes from fresh and new perspectives. Indeed, instead of these studies that only confirm old results. Here are some examples that offer promise to which Nat Cap Lyme has contributed, Dr. Neil Specter of Duke University researching immune therapy. Dr. Xin Xang of Johns Hopkins focusing on antibiotic resistance and bacterial persistence. Dr. Kim Lewis of North Eastern University researching new antibiotics for persistent bacteria cells. And Dr. John Aucott of Johns Hopkins, this groups chair with his slice study to understand what he calls post treatment Lyme disease syndrome. Most distressing is the fact that the medical community is so strongly divided and the establishment medicine, so entrenched in the belief that Lyme is not a problem. You must find ways to bring together all the best minds and theories. Examining empirical observation and clinical anecdotal experience as well as controlled studies.

We must never forget the medical elite thought they knew what caused ulcers and stomach cancer until Barry Marshall drank *H. pylori* lighting a better path. Look to the model created by the Alzheimer's disease neural imaging initiative. Their three-point program was extremely important in moving their research agenda forward, specifically, their researchers agreed to share all their data. That every finding would made publicly available immediately and to renounce ownership and patent rights. Dr. John Trojanowski, a member of that research team said, we all realize that we would never get by on markers unless all of us parked our egos and intellectual property noses outside the door.

Nat Cap Lyme believes that true solutions to the dilemma of Lyme and tick-borne infections may only be found when all parties are willing to consider the views that each seeks to contribute. We would like to see clinical trials broadened to include patients with persistent Lyme borreliosis as well as the entrance criteria for clinical trials to include entire classes of Lyme patients whose disease expression and treatment response is poorly understood. We would also like to see treatment trials conducted that better mirror the variety of treatment regimens actually

used by treating physicians. The second question posed was, how to improve the lives and health of people living with tick-borne diseases?

First and foremost, this card the CDC case definition of Lyme disease for diagnosing patients. That definition defines specifically and only for surveillance is consistently misused as the definitive diagnostic criteria in the clinical setting. The CDC needs to clarify to all health service providers and health departments, that the surveillance case definition was never intended to be used in clinical diagnosis. Patients, medical professionals, and scientists need a better case definition expanded to include the entire emerging spectrum of Lyme disease and tick-borne coinfections.

Stemming the epidemic requires physicians to be competent to recognize diagnose and treat tick-borne diseases. Thus, a national education course for medical providers should be developed that reflects the diverse approaches to treatment and diagnosis of tick-borne disease, as well as CME courses. It is critical to support medical providers who practice on the front lines. State medical boards routinely penalize doctors who deviate from the IDSA guidelines by subjecting them to investigations and disciplinary procedures. Many patients lose their doctors who stop treating out of fear of that costly gauntlet or even of losing their license.

When multiple protocols meet the new riggers for publication by the national guideline clearing house, government favoring one over another place an unnecessary burden on patients needed the disfavored protocol. Physicians must be allowed to treat the patient and the symptoms they present to practice the true art of medicine. And the patient should have the right to accept that treatment with informed consent. Medical guidelines were designed to provide recommendations, not mandates. Paraphrasing Dr. Wolitzski, last year at USCA, treat the patient not the healthcare system. Nat Cap Lyme says, "treat the patient, not the test."

Finally, we were asked to discuss methods to prevent new tick-borne infections. Mass media campaigns effectively exposed large populations to messages about challenging health risk behaviors. A CDC mass media campaign on awareness, similar to that of the Zika response which significantly reduced the rate of infection and could relieve society from the extreme economic burden of persistent incapacitating diseases. A 2015 Johns Hopkins Study found that Lyme alone cost the U.S. healthcare system as much as 1.3 billion dollars a year. With indirect costs such as lost wages that number jumps to many billions.

Children ages five through 14 face the highest risk of exposure to tick-borne infections. But tick awareness and prevention curriculum should be designed as a learning tool for public, private, and home schools, as well as for educational settings including camps and youth organizations. We know the importance of vaccines. While Nat Cap Lyme would like to see the development of a safe and effective vaccine, a narrow focus on a few strains of borrelia and a rush to certify a vaccine only offers a limited public health benefit and harbors a serious potential health risk. The perception of protection can be dangerous. If the vaccine is not effective against the full range of borrelia strains and coinfections.

In Nat Cap Lyme's opinion, it is premature to inoculate the general public with a tick-borne disease vaccine. We do hold out hope for a safe and effective vaccine in the future. Lastly, we

must make certain that tick-borne diseases such as babesia are not transmitted through the national blood supply and that proper screening techniques are in place to ensure public health safety.

In conclusion, tick-borne diseases erode every facet of an individual's life, decimate marriages and livelihoods and cause children to leave school and even lose their childhoods. For many, life never returns to normal, the patient community is extremely angry. And a lack of -- about the lack of scientific medical progress and the inadequate response from the agencies responsible for the health and welfare of the general public. This anger propels us to insist that our government, medical professionals, insurers, and health care system address 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. Finally, a quote from the paper we delivered to the IOM, courage is what it takes to stand up and speak. "Courage is what it takes to sit down and listen." Winston Churchill. Thank you.

[applause]

>> Dázon Dixon Dialo: Let's give him another round, thank you. Greg Skall, Nat Cap Lyme.

[applause]

>> Dázon Dixon Dialo:

So next we're going to hear from Lorraine Johnson. She's the CEO of lymedisease.org, the largest communications network for individuals with Lyme disease. It was founded in 1989 as a grassroots organization. [Lymedisease.org](http://lymedisease.org) seeks to empower individual patients by giving them the tools they need to understand their disease, amplify their voices and pool health care data to help find a cure through its big data project, MyLymeData. Please welcome, Lorraine Johnson is joining us via the web, and so she has a beautiful, I've seen it, lovely power point presentation and her voice. So please give her your kind and undivided attention, Lorraine, you have the floor.

>> Lorraine Johnson: Thank you. Good afternoon, I'm Lorraine Johnson the CEO of lymedisease.org and I want to thank you for the opportunity to speak today. I also want to thank those that are sitting on the panel. I know from experience that these groups require a lot of time and hard work, so your willingness to serve is appreciated by all. Like many involved in Lyme disease, I become involved when I contracted Lyme disease and became what is known as a reluctant volunteer about 15 years ago.

I'm going to talk to you today about where Lyme disease research is, the role of big data and helping advance research, our big data project MyLymeData, finally some of the top research priorities identified by the Lyme community. Next slide, please.

There are a lot of Lyme disease advocacy groups doing important work for the community focusing on different areas. The focus of lymedisease.org is on empowering individual patients. We were founded in 1989 as a grassroots organization in a small endemic area of California, today we are a virtual nationwide internet based grassroots organization reaching over four

million unique visitors on our website each year. We engage extremely large numbers of individual patients on the issues that matter to them by providing them with tools. Tools that educate like our website, tools that give patients voice like our large-scale surveys which have drawn thousands of responses and have been published in medical journals. Tools that allow patients to contact their legislatures, for example, over 14,000 patients used our voter voice to contact legislatures to form this working group and tools that allow patients to crowd source and pool their health care data to help find a cure. Like our big data project, MyLymeData.

So, let me talk for just a minute about the state of research in Lyme disease and why we ultimately launched our patient registry, MyLymeData. Next slide, please. I'm sure a lot of you know that Lyme disease, particularly chronic Lyme disease is a research disadvantaged disease. But this chart from article by Goswami compared the number of infectious disease trials listed on clinicaltrials.gov, and shows just how large the research gap is between Lyme and other infectious diseases. Only three small clinical trials on the treatment of chronic Lyme have been funded by the NIH, the largest trial enrolled just 129 people. And the last was funded over 15 years ago.

So, we have a deferred maintenance, but, you know, today we have a lot of tools available that were not available before. And this chart, by the way, looks a lot like what you see in rare disease research and at 30,000 cases a year, Lyme was pretty much considered rare. That all changed in 2013 when the CDC revived the estimate of cases to 300,000 a year. But even though we now know it is a common disease, it still has the research legacy of a rare disease and the like rare diseases, Lyme disease has lacked the research incentives essential to make progress. Next slide, please.

One of the tools that the rare disease communities have pioneered to advance research is patient led registries. Of course, patient generated data has its own limitations. It's a self-selected population, the data is not independently verified, and it relies on access to the internet. But despite these limitations, it is increasingly recognized as a valuable source of health care data, and this slide shows some of the bigger organizations involved. In addition to groups like USC and Stanford recently joining forces for a patient generated data project cancer. And other vanguards like patients like me who have been doing this for years. There is extensive government involvement in patient led registries.

The NIH just launched PregSource to study pregnancy and of course the NIH has a long history of using patient generated data in the rare disease community through the National Association of Rare Diseases. The CDC's ALS registry has a patient generated research component and the biggest government's under in the arena is the patient centered Outcomes Research Institutes. Its big data project, PCORnet, funded 18 patient powered research networks. I was privileged to serve on both their steering and executive committee. And this is where MyLymeData was conceived of and born. In a recent NEJM article, Dr. Thomas Frieden, who until recently headed the CDC, talked about the need to use all available research evidence and says for the several thousand rare diseases, and I would add research orphan diseases like Lyme, randomized controlled trials are unlikely to be conducted and detailed case studies and registries play a critical role to advance our understanding of the disease.

He goes on to say that there will always be argument for more research and for better data. But waiting for more data is often an implicit decision not to act or to act on the basis of past practice rather than on the best available evidence. Glorifying randomized control trials above other approaches, even when these other approaches may be either superior or the only practical way to get an answer relegates patients to receiving treatments that aren't based on the best available evidence, so I think he put that well. Next slide, please.

So, this is why when I was sitting on the executive committee of PCORnet, we decided to launch MyLymeData, which is a fully consented registry that patients opt in to participate. Today MyLymeData is one of the largest and fastest growing patient led registries in the nation with over 9,700 patients. We're currently in the top five percent of patient led registries and by this point we've amassed millions of data points and are just beginning to do descriptive specifics. Next slide please.

We have also partnered with academic researchers at UCLA and Claremont McKenna to explore big data analytics using artificial intelligence. Along the same vein as IBM's Watson. I am -- and we are extremely excited that the national science foundation recently granted this research team an \$800,000, three-year award to support their predictive analytic work using MyLymeData. This work will begin to answer questions such as, what factors can help us predict which patients are more likely to remain ill. Next slide, please.

Most but not all patients in MyLymeData report that the current stage of their Lyme disease is either late stage untreated Lyme disease or chronic Lyme. That is treated Lyme disease that remains symptomatic for at least six months after treatment. So, this is a very different population from those used in acute studies and some of the arguments about Lyme disease and chronic Lyme disease may be the result of comparing apples to oranges. What I am saying is that chronic Lyme patients may be chronic because they are a different subgroup than those used in acute studies because they were not diagnosed until they had late stage when treatment response is poor. Or because a higher percentage, 60 percent have coinfections. This subgroup of patients may respond differently to treatment and require novel treatment approaches. To my knowledge, there has not been a study of the optimal treatment of untreated late stage Lyme disease, but we clearly need this. Next slide, please.

Now I'm going to change topics for a minute and talk about the top 10 research priorities for Lyme disease which were developed in a three-step process. Just around the time we launched MyLymeData, we came together with a number of other groups, researchers, and physicians, including people who are on this panel. Including Wendy Adams and Pat Smith or Christin Honey, who actually organized the event which was hosted at the American Association for the Advancement of Science. Over two days the group put together a preliminary list of important research questions. Lymedisease.org then submitted this list to patients enrolled in MyLymeData which by that time had thousands of patients enrolled and asked them to rank the importance of those questions and to submit new questions that might not have been on the list. Finally, lymedisease.org took this combined list of research questions and sent them out to the broader Lyme community at large. Over 7,000 patient's researchers, physicians, and advocacy groups participate in this survey.

So, this was a very broad and inclusive process we used to determine the top 10 research priorities. Next slide, please. I'm going to conclude by talking about the results of this research setting priority. But first, I just want to point out that a lot of the end points used in research studies are not patient centered. For example, patients do not care whether a rash goes away on treatment, they want to know whether they are restored to baseline health, can they function? Anything else is treatment failure as far as the patient is concerned. Not surprisingly, the questions that patients cared about most were better direct detection diagnostic tests. Which treatments are most effective to restore health, and what impact delayed diagnosis plays on the course of disease. Big data tools like MyLymeData can help us answer these questions and can also help recruit patients for clinical trials when a randomized control trial is conducted. Next slide, please.

In closing, I would urge everyone on the working group to think about innovative patient centered approaches to research for Lyme disease. I want to thank you for your time.

[applause]

>> Dázon Dixon Dialo: Thank you so much. Both for Lorraine and for Greg for getting us started with our public comment as our key stakeholder presenters this afternoon. So now it's your time, are you ready?

>> Multiple Speakers: Yeah.

>> Dázon Dixon Dialo: Yes. Well let me tell you a little about Dázon before we get there and then you'll understand why I'm getting ready to have you do what I'm having you do. Okay. So, I didn't introduce myself before your key stakeholders on purpose because everyone has a story and I have a little one. And I'll try and make sure it's very little.

So, I'm an old act upper. AIDS Coalition to Unleash Power, if you don't know who we are, we are that really radical rowdy bunch back in the very early days of the AIDS epidemic who used the anger and the fear, the isolation, the neglect of a community of folks who felt already less than because of who they were, who were now being treated differently because of what they had. And as an act upper there are a few things, there are a few principles that were very important to us. One is exactly what I've heard you share today from the leadership of your working group. That the lived experience is power, and powerful, and that it matters.

I call that indigenous expertise which brings us as much information and data to the table as all the empirical science that our partners in the research community bring to the table. In addition to that, it was important for us to learn as much as we could learn about the disease, about the science, about the epidemiology, as much as about the numbers, as much -- I remember that I said I never had a reason to remember my chemistry and my calculus and now I do. Because we had to teach ourselves what the researchers were also learning.

What's important about that part of the story is that when I got married to my very beautiful and young, handsome, husband from West Africa and he moved to the United States, within the first year of our marriage he was eventually diagnosed with Hodgkin's Lymphoma. Now, I bring that

up because Hodgkin's isn't rare. Hodgkin's is something that a lot of people know and experience and that there's a whole world of cancer research and cancer treatment available. But I'd never heard of it. I didn't know what it was about. He certainly had not. English was his sixth language. It's still my only so that's my embarrassment.

But here was a young man coming from South Africa, born and raised in West Africa, for whom the physicians, the clinicians could not figure out for more than four and a half months what was wrong with him. Lost 40 pounds, lost 25 pounds in about 40 days, was running fevers of 104 and 105 almost 106 every day. Had been sent to infectious disease specialist because it must be AIDS especially once they learned what my work was -- it wasn't. Gastroenterologist -- it wasn't a gut problem. Urologist -- it wasn't a kidney problem.

It was when he was finally -- when we finally took him to emergency and they did a biopsy on his lymph. When he was really almost dead was when they came back with the diagnosis of Hodgkin's. A year and a half later, he was cancer free and he lived a long life of 13 more years until he passed just four years ago. That's a whole another story around heart disease undiagnosed. I'm saying all of this is because it's not unusual to have and know the feelings that you have in this newly reenergized, revised, and revitalized tick-borne disease movement because that's who you are, and what you are, and I'm really honored that you've asked me to be a part of this conversation today. Bravo to you.

[applause]

So, I believe in what I call resilience to revolution of the 300,000 plus or minus people who are affected by Lyme disease, there's a handful of you who are willing to stand up, speak out, and advocate, and activate on behalf of an entire community of people who don't even know how grateful they are for you. And so, let's give some voice to that resilience and let's hear what it sounds like in revolution because we're about to change some things with this group and today.

So, we have an open mic here in the middle of the room. And we have folks who have submitted to us for their public comment, you will know who you are, I will call you up in the order that we have designated and organized for you. There's just a few teeny tiny manageable all age ground rules or group agreements for us today. One, we have one meeting. One meeting after the exercise. We have one meeting which will be one voice. Each person who is giving public comment will have three minutes give or take.

When I call your time, finish your sentence. It just can't be run-on with ellipses and commas, and semicolons, and colons, and dot dots, and more dots. But finish your sentence and finish your thought. This is a listening session so there should not be dialogue back and forth. Or even what I like sometimes, call and response. It's okay to just be in the position of hearing what's being said. Now having said that, before we call everybody up, I have a little exercise for you.

I am a true believer that no matter how many voices you hear in the public space, everybody has something that they're thinking, and everybody has something to say. Not everybody wants to say it to everybody else. I get that. But I need you to take a few minutes to just process a little bit of what you came here with today or what you've heard today and talk with each other. So

just for two minutes is what we're going to take time to do. And right now, I need you to pair up. So, I need you to get yourselves in pairs. Everybody's got to have a partner. It's helpful. I just did this in Abidjan. So, it's very important -- in Côte d'Ivoire. It's very important that you speak the same language --

[laughter]

It can be a little awkward. It's important in age groups because that might -- yeah, you might not be able to figure that all out. But if you are 14 and you are 50, you might want to find another partner. And I want you to do is decide who is the A partner and who is the B. You have three seconds. Do I have my A's? Do I have my A's? Let me see my A's. Do I have my B's? Let me see my B's.

Okay, so, this is a practice in active listening. I'm going to ask you a question, and one at a time, and if you are tripled up that's going to be a little weird for my time, but we'll work it out. I'm going to ask you a question and whichever letter I call, you are the person who is speaking. It is your time. This is about equal time. Everybody gets equal time. You have one minute to expound -- 60 seconds worth of expounding, I don't know how that works. But you have one minute to answer the question. If you are not the person speaking, you are actively listening. That means you're not thinking about what you're having for dinner, you're not thinking about whether your plane is going to leave on time, you're not thinking about the last thing you said to your kids before you left home, you are absolutely emptying yourself to be the vessel, and hear what's being said. There's not even that [affirmative] girl, I know exactly what you mean, I've been there. None of that. None of that. It is quiet absorption of your partner's expression and story. Are we together on that?

>> Multiple Speakers: Yes.

>> Dázon Dixon Dialo: So you will do that for the full minute of that person's conversation and then we'll switch. All right? So, you will have one minute. The question is given all that you know and all that you've experienced around this work with Lyme and other tick-borne diseases, what is your best hope for the work of this group? What is your best hope for the work of this group? Based on your own experience and what you've known, what you've lived with, what you've work through. Are we together? What is your best hope? I'll set my clock here because I'm serious about this one minute. B's you may begin.

[inaudible commentary]

Time. You all did that very well. Are you ready? A's you may begin.

[inaudible commentary]

Time. Time. Now, with not -- charge it to my head and not my heart, I did not acknowledge the folks who may be online and what you just did with your two minutes. It was a commercial break.

[laughter]

But as I take my place on the floor and leave the stage. What I want to recommend in the next one minute is that for those of you who are online, if you are alone, journal your thought for one minute. Journal your thought for one minute. And if you are in a room with others then you too can pair up for your one minute as I head to the floor. And just share your best hope for the outcome of the work of this group. I'm heading down to the floor now.

[applause]

Does this turn itself on? Oh, okay. We're giving them their equal time online. So, while they're doing that, take a deep breath. Because that was not long enough, of course, but it was enough to get a little bit out. Right? So just take a deep breath and let it go. Be mindful about what we're expressing with each other and how we're doing it. As my Nana would say "it's not what you say but how you say it that matters." So, let's talk a little bit about that today.

>> Male Speaker: U.S. Department of Health and Human Services produced at tax payer expense.

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