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**Senate Health & Human Services Committee & Aging & Youth Committee - Joint Hearing
Status of Recommendations by the Task Force on Lyme Disease and Related Tick-Borne Diseases**

Testimony by:

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Member of the Task Force on Lyme Disease and Related Tick-Borne Diseases Pursuant to Act 83

I am Julia Wagner, President of PA Lyme Resource Network, a 501c3. PA Lyme Resource Network (PALRN) provides outreach, education, support and advocacy services to those concerned about and affected by Lyme and Tickborne diseases in Pennsylvania. PALRN was founded in 2012, bringing several independent support groups together. The needs from communities are accelerating every year, driving significant growth in our organization, and expanding regional support groups from 4 upon formation to 25+ regional support groups all across the state in 2017.

The Act 83 Task Force recommendations focused on several key areas, including:

- 1) Prevention
- 2) Awareness and Education – the public, schools, health care practitioners/institutions
- 3) Surveillance

In my testimony, I will address four (4) key areas relevant to these recommendations:

- 1) 2015-2017 Updates
 - 2) Actions by PALRN relevant to Act 83
 - 3) Critical Concerns and Questions
 - 4) Recommendations – immediate, short-term needs
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1) 2015-2017 Updates - What's Changed?

A. Reported cases in Pennsylvania have continued to climb:

Within the context of ongoing increases nationwide (from 320,000+ cases in 2014 to nearly 400,000 in 2016), Pennsylvania continues to increase, with no slowing in sight:

- 2013 – 5900 reported new cases, or 59,000 actual
- 2014 – 7457 reported new cases, or 74,570 actual
- 2016 - 11,443 reported new cases, or 114,430 actual

It is critical to note that **children and youth** are the most impacted age group, with youth under 20 making up approximately 25-30% of all reported cases, or 28,000 children/youth ill with Lyme in 2016. Of these approximately 20-40% (9,000), will develop persistent symptoms. In children and youth, presenting symptoms are often cognitive, behavioral, or neuro-psychiatric showing up as behavior or personality changes, difficulties at school, “acting out” behaviors (e.g. oppositional), new onset ADD/ADHD, which are unlikely to be recognized as potential tickborne disease symptoms. Illness progression can lead to autistic-like symptoms in some kids and much more.

The 2nd most prevalent age group is ages 45-54 years old, a group in the prime of their working life. When symptoms in this group present, they may be viewed as “simply aging”, and left to persist, and progress, reducing the chances of effective treatment and resolution, when and if diagnosis and appropriate treatment occurs. Recent medical literature has drawn a clear line between untreated and under-treated Lyme disease and the development of Alzheimer’s and other neurodegenerative diseases.

Public health institutions should be making EVERY effort to diagnose these diseases as EARLY as possible, and to treat these aggressively, advocating for massive improvements in testing and treatment, to identify all pathogens, and to ensure effective treatment using tools capable of tracking response to treatment and successful eradication.

B. Surveillance data has gotten worse - CDC STOPS REPORTING LYME DISEASE IN 2017!

As of January 2017, the Centers for Disease Control stopped public reporting of Lyme disease cases, even though Lyme disease is a nationally reportable disease, and as such, the CDC is required to report in a timely manner to properly inform the public, health agencies, practitioners, and institutions to ensure an appropriate response. PALRN has asked the PA Department of Health for current 2017 case data, but has been unable to obtain any 2017 data. East Stroudsburg University has anecdotally shared that they have seen a significant increase in tick populations this year. Surveillance and tracking of Lyme is absolutely critical to informing public health efforts. This lack of data, and service in the public interest requires an explanation.

C. Nations launch national plans to address tick-borne diseases

In 2016 France became the first country to release a national plan to address tick-borne diseases, including Lyme. The plan includes ramped-up surveillance of ticks and infections, prevention actions – lots of them, better diagnostic tests and better treatment protocols. What is unique about the plan is not WHAT they are doing – but the QUANTITY, NATIONAL COORDINATION, HIGH-LEVEL ATTENTION, AND BUDGET attacking the problem as a national health crisis. “If we do a good job at prevention, we’ll have fewer patients who end up seeking care and struggling in the medical system,” said Lucie Chouin, a public health official for the Greater Eastern region of France. “For me, prevention is part of a package; if we only do so much, and do not do anything upstream, the problem won’t be resolved.”

In May 2017, Canada released its first federal action plan to address Lyme.

The US has ten (10+) times the cases of these countries, but has no federal plan in place. The first step in this direction was passage of the 21st Century Cures Act in 2016, which included setting up a Lyme and Tickborne disease working group.

D. Patients are dying of Lyme and related Tickborne diseases due to ignorance/inexperience

At the time of the task force recommendations, we were aware of a 2014 death of a 2 year old (York County) from Rocky Mountain Spotted Fever, and a 38 year old (Poconos) from Lyme, Babesia and other coinfections in 2012.

Since the 2015 report was written, we are aware of more deaths from Lyme and coinfections. The Lyme community has been traumatized by several tragedies over the course of the last few months – young people being destroyed by these diseases, in one case rather suddenly, and in another after a protracted illness with roots going back to tick bites in elementary school, and high school ears that were undertreated, with the last episode in college triggering serious, chronic illness. These parents and families deserve the very best public health response we can mount:

- June 2015 – 51 year old, prior triathlon athlete (Poconos), from Lyme, Babesia, Bartonella
- July 2017 – 25 year old, Pete Smith (family here today, Quakertown), Lyme disease known, other coinfections not determined but possible from symptoms (not tested for coinfections)
- Sept 2017 – 50 year old, Jeff Naticchia (Bucks County, family/friends here today), Babesiosis
- Oct 2017 – 29 year old, Kevin Furey (Montgomery County, family here today), Lyme, Babesiosis and multiple other tickborne infections

These deaths were potentially preventable, and treatable, had up-to-date, appropriate, and knowledgeable medical care been available. Early, more effective treatment, proper evaluation for coinfections, accurate symptom recognition, diagnostic experience and appropriate treatment follow-up were all critical in these tragedies.

2) Actions by PALRN - consistent with Act 83 recommendations

PA Lyme has rapidly grown to meet the needs of communities, and has taken many actions to improve awareness and prevention, to educate, and to is providing the following services and programs, with very little funding, and only 1 paid contractor:

- **25+ Regional support groups** - providing monthly support group meetings – serving approximately 500 – 1000 constituents across the state every month, reaching approximately 7,000 annually. Includes implementation of the “Ambassador” program, with community members responsible for distributing program information, and marketing prevention and available resources through community networking.
- **Support Group in a Box** – service to help interested individuals launch a support group quickly, and effectively to provide information and resources to communities quickly. Provides standardized materials, out of the box programs, and everything you need to know to run a support group focused on Lyme and Tickborne diseases.
- **Virtual/On-Line Resources - Website and Facebook** – reaching a national audience, with posts reaching over 10,000. Online resources, including videos are being expanded in 2018.
- **Educational Programs** – launched the “Dare 2B Tick Aware” program in 2017 to improve, standardize and implement community based education across the state, funded by Health Prevention Block Grants (PA DOH). Dare 2B Tick Aware can be scheduled through requests to info@palyme.org for any location in PA. Over 100 workshops/events have been completed this year. The full program is complete, and faculty in place to support a major roll-out in 2018.

- **Event Booth** – educational booths used at community events, festivals, health fairs etc. Over 200 events have been supported this year.
- **Faculty** – 30 faculty certified in “**Dare 2B Tick Aware**” and available across the state to deliver certified primary prevention programs. Faculty include PhD Scientists, PhD Science Educators, MS Certified Health Educators, MPH Public Health Nurses, Vector Control experts and more.
- **Annual Patient Conference** – starting in 2016, both events have sold out, with waiting lists (250 total attendees). We have been unable to meet the demand. Our most recent conference was Oct 21, 2017. NOTE: Health care practitioners are registering and attending patient conferences to learn more about these diseases for their own education.
- **Annual CME Medical Conference** – 2018 will be our 5th **Annual CME Medical Conference** in Pennsylvania (Harrisburg). The event is sold out every time, and brings national experts and researchers in Lyme and Tickborne diseases to educate Pennsylvania practitioners.
- **School/School Nurse education** – PALRN has trained over 40 school district’s nurses in general awareness and prevention, providing specific peer-reviewed nurse protocol recommendations. However, without specific protocols or accountabilities, real action/change is highly variable.
- **HCP Community of Practice** – launched in 2016 a community of practice/learning community for physicians treating complex Lyme and Tickborne diseases, to support continuous education through peer to peer experience/practice sharing.
- **Health Care Practitioner referrals** – PALRN provides a HCP referral service based on geography providing the public with Lyme Literate Health Care Practitioner referrals.
- **Research partnerships** – with Drexel University and East Stroudsburg university supporting multiple research programs.

As a volunteer organization, we have 30 leaders, and hundreds (100+) of volunteers working all across the state to change the circumstances for those affected by these diseases. In 2015 we were supported with funding from the PA Department of Health Health Block Grants (\$10,000), and in 2016, we were asked to be the lead vendor coordinating community based awareness programs across the state under this same block grant, and received funding of \$40,000, with an additional \$60,000 approved. These funds have funded the identification and certification of a high quality state-wide faculty, a standardized program, and materials to drive a consistent message, “Dare 2B Tick Aware”, in a memorable way, and an Ambassador network (in process) across the state to mobilize the messages, and market the programs and resources through targeted outreach.

Coordination and outreach across the state has generated demand way beyond our capacity and funding. Pending funding, we plan to finalize “on-demand” programs that can be delivered by “Ambassadors” and can be accessed on-line at the time and point of need. Current content includes:

- Awareness of susceptibility/risk in PA
- Types of ticks and habitat
- DARE Prevention Strategies
 - o **Defend** yourself, pet and property
 - o **Avoid** tick habitat and risky areas
 - o **Remember** tick checks, and to shower after exposure
 - o **Eliminate** ticks correctly
- Recognition of potential symptoms, when to call your doctor
- Resources

3) Critical Concerns and Questions

While strides have been made, and we are anxious to hear what the other agencies and organizations have been doing, Lyme and tickborne diseases are NOT getting the level of attention that is needed.

Unfortunately, we believe this “passivity” is a trickle down from the current Federal approach to Lyme and Tickborne diseases. While Lyme disease is 6x more prevalent than AIDs, 2.5x more prevalent than Breast Cancer, there is only \$28 million being spent on Lyme R&D compared to the multi-billions being spent on HIV (\$3.5 billion), and \$46 million on West Nile Virus. WNV has had only 60 total cases reported in PA, since reporting started in 2000 (https://report.nih.gov/categorical_spending.aspx). In addition, the CDC continues to downplay the seriousness of this disease, maintaining a one-way only approach to diagnosis and treatment, and ignoring the significant shifts in evidence supporting persistence, and the complexities and seriousness of these diseases. The lack of reporting on current cases in 2017 is failure of it’s public health role and leaves the public and health organizations without the required information needed to properly respond to current data.

PALRN continues to call for a concerted, “crisis-level” approach to this epidemic in PA. With this year’s recent and tragic deaths, we cannot afford to delay and pretend that this is not a serious situation. Ignorance is not acceptable. Old dogma denying the potentially serious nature of these diseases is unacceptable and harmful. The stigmatizing and belittling of seriously ill patients is unconscionable.

A renowned Duke University oncologist, and author of “Gone in a Heartbeat: A Physician's Search for True Healing” (Neil Spector, MD) after undergoing a heart transplant as a result of his illness with complex Lyme disease, called Tickborne Diseases “**the infectious equivalent of cancer**”. He states that “I wanted to write my book, one, because I realized that there were many other people out there suffering... and two, that there is **a lot more that we don't know than we do know** about these diseases and three, that there are many people who don't fit the classic mold of a bull's-eye rash and a tick bite... and I'm an example of that somebody -- who happens to be a physician scientist. Even I was dismissed as being stressed when in fact I had a serious, life-threatening infection that almost took my life.”

Beyond the significant personal impacts these diseases may cause, TBDs also create a significant economic burden in Pennsylvania and the United States. Over \$1 billion in annual medical expenses (old study, none replicating this available) in the United States have been attributed to Lyme disease as well as up to \$10,000 per patient annually in lost productivity. Lyme disease patients required 87 percent more visits to the doctor, and 71 percent more visits to the emergency room in comparison with those without Lyme disease. Applying the above cost estimate to Pennsylvania’s 11,443 confirmed 2016 Lyme disease cases, the annual estimated cost in lost productivity alone may likely exceed \$1 billion.

These diseases are a public health crisis. The World Health Organization (WHO) has said it. Other countries experiencing a much lower burden of disease are saying it. **Pennsylvanians deserve an appropriate and serious public health response.** So far, this has not taken place in Pennsylvania. The response cannot continue to happen primarily off the backs of under-funded, under-resourced, volunteer-based patient groups. A response to this crisis, must be multi-level, adequately funded, and driven with the recognition of the high human and financial costs of further delay.

PALRN's Specific Concerns that Need to be Addressed in the Hearing:

- 1) why doesn't PA have any money in the 2017-2018 budget to address Lyme disease and the implementation of the task force recommendations?
- 2) did the PA DOH submit a budget request for Lyme?
- 3) why is \$2million being spent on tracking and spraying for West Nile Virus when there have only been 60 cases in total since the initiative of this program in 2000. \$36 million dollars spent for WNV total.
- 4) is the PA DOH reporting 2017 cases to the CDC as required (nationally notifiable, PA reportable)?
- 5) why is the CDC NOT publishing ANY Lyme disease case report data this year, in the Morbidity and Mortality Weekly Report, or any other public means?
- 6) can the PA DOH provide the current level of cases reported Year to Date in PA? and provide that data to the public, to Health Care Practitioners, and to Health Care Institutions? Have health alerts been distributed regarding the expected increase in Lyme this year (expert predictions)?
- 7) why is Babesiosis not a PA reportable disease? The CDC made it a national notifiable disease in 2010, and we are bordered by several endemic states (NY, NJ, DE). Several counties have reported enough cases to be considered endemic, AND, labs are reporting high numbers of positive cases in PA. By NOT tracking and reporting Babesiosis, we are directly harming the public, and preventing HCPs and institutions from taking the right measures to educate and respond to this serious illness, which has led to or contributed to several fatalities this year.
- 8) why do Insurance Companies continue to deny treatment prescribed by licensed physicians on the basis of medical guidelines that are so outdated they were removed from the US Health and Human Services, Agency of Health Quality's National Guidelines Clearinghouse? When such strategies are recommended in certain situations by up-to-date guidelines, in fact the only guidelines (peer reviewed) currently available on the NGC?
- 9) the CDC reported findings regarding several young adult Sudden Cardiac Death cases, that were found to be due to cardiac infection with Lyme disease. PA has had recent young adult death, with cardiac involvement. What is PA doing to ensure coroners are looking for Lyme involvement in early and sudden cardiac death in young adults?
- 10) multiple studies have reported the neuropsychiatric manifestations of Lyme disease on patients. The major cause of death in Lyme disease has been reported to be suicide. Recent studies predicted suicide rates resulting from Lyme and associated diseases. Using this model approximately 410 suicides in Pennsylvania per year could be attributed to Lyme and associated diseases. Why would this be? These complex diseases, if not diagnosed and treated early and properly, can affect the central nervous system and lead to many distressing symptoms significantly affecting quality of life, and functioning.

The combination of the disease itself, the current response from the medical system that varies from complete ignorance, to denial, to outright disparagement and belittlement ("the aches and pains of daily living"), and the toll all of this takes on family systems, relationships, and the ability to work, conspire to leave patients hopeless, and full of despair. In our support groups, we have encountered so many devastating cases, with homes lost, marriages destroyed, children's former capabilities lost (failing and dropping out of college), bedbound at home and unable to function, individuals going bankrupt and even becoming homeless. It is frankly hard to believe what is happening in the trenches, and the ongoing denial of so much human suffering.

4) Recommendations – immediate, short-term needs

It is clear there is inertia in the system, working against the urgency that is needed. The recommendations below are prioritized from the Patient's Perspective, and focus on what we think would bring most immediate impact to Prevention, Education, and Treatment. These are organized by level of effort/cost, and are based off of the original task force recommendations, with revisions due to the evolving situation:

a) **Oversight/Working Group Needed:** Act 83 recommended the formation of an "Advisory Body" that would report to the Secretary of Health and operate as an independent advisory group on Lyme disease and other TBDs. At this point, I would modify this to have this group reporting directly to the Governor's office and or other legislative bodies to drive sustained focus and accountability. The development of a comprehensive plan, including these recommendations, updated to address recent developments, and to monitor implementation and results.

b) **School Policy and Procedures:** the school re immediate and short-term actions, with low cost, that can be implemented immediately. These recommendations were in Act 83. These could be implemented rather quickly, and at low cost:

- Notifications to parents regarding risks and protective measures, especially following outdoor activities
- Encourage school staff to remind students and parents of "tick-checks" after outdoor school events
- Implement standard protocol within the school for appropriate tick removal and prompt parental notification".

The awareness and education campaign for parents/staff could leverage the "Dare 2B Tick Aware" program, but would be enabled by policy requirements that this be scheduled in spring 2018. While some funding is available, dedicated funding for school awareness sessions must be allocated.

- Implement an awareness campaign for children, parents, staff regarding risks and prevention.

c) **Standard Brochures for Physician Distribution:** immediate alerts and information about increased cases, coinfections – specifically Babesiosis, testing issues, and availability of multiple treatment approaches/guidelines for use should patients not respond to initial treatment. The recommendation stated: "develop and implement a standard brochure (based on the Virginia model) that physicians ideally should provide to patients when they are evaluated, either by clinical exam or lab testing, for potential Lyme and related tick-borne infections... regarding the effectiveness of testing...".

d) **Communication of ALL Available CME Medical Education opportunities by the PA Department of Health to all Health Care Practitioners and Institutions:** specifically, PA Lyme Resource Network with Drexel University College of Medicine, and ILADS (International Lyme and Associated Diseases Society) will have national speakers at our CME conference April 6-7, 2018. This is a great opportunity to bring CME education, with a broader perspective, to front-line health care practitioners quickly. Online education is available from the CDC that reflects the IDSA perspective, as it links directly to the IDSA education program. There is a CME online Lyme and Tickborne disease education program available that offers a more balanced perspective as well. There are short-term available options available – the key is to ensure that practitioners access a broad spectrum of views/information. Mechanisms are needed for this. Webcast programs could also be scheduled virtually to be low-cost/low burden.

The education gaps on the front-lines in our medical system are large. Here are just a few samples of what patients are experiencing on the front-lines regularly. Education is needed desparately.

Case 1 – Summer 2017: Multiple Practitioners cannot Recognize Classic Disseminated Rashes

2 year old (Erie County) presents with 15-20 circular, bulls-eye rashes all over her body, along with a fever, chills, lethargy, extreme mood swings, crying, sleep disturbances,. She is taken to doctor:

- “The physician's assistant and I talked about Lyme. I told her that was my concern. She acknowledged the rashes were suspicious. **The doctor took a quick look and called it hives.**
- “Then he showed absolute ignorance when I told him about photos I found showing a disseminated rash (which I didn't even fully understand at the time). He asked me incredulously if I thought she had been bit by 15 different ticks all over her body. I told him no, and he acted like the case was closed. “
- “I took her 2 days later to a children's urgent care clinic. When the onsite NP contacted the doctor (off-site) with photos, they said they still weren't convinced it was Lyme, but they would test. Test came back with a STRONG positive several days later”.
- “3rd visit and almost 2 weeks later – she is diagnosed and treated.”
- “the doctor would only prescribe 3 weeks, so I went back to my old doctor and begged that he prescribe for an additional 4 weeks, after she still had symptoms.”

Case 2 – 37 Year Old Denied Diagnosis and Treatment – Progressive Disease/Abandoned by HCPs

- 37 year old (New Brighton, PA). Significantly delayed diagnosis - 10 years of illness – starting in late 20's. Chronic muscle & joint pain, spinal pain, neck & shoulder pain, insomnia, soaking night sweats, muscle spasms, heat & cold intolerance, light & sound sensitivity, hypothyroidism, new onset diabetes, pancreatitis, fatty liver, obesity, depression & anxiety over the past 10 years or so, but I never saw a tick or got a bull's-eye rash, so I never thought to get tested for Lyme. Doctors could not come up with any diagnosis or treatment other than pain management.
- Pain doctor suggested I be tested for Lyme Disease. Reluctantly, after some convincing on my part, my PCP tested me. The ELISA was positive but Western Blot was negative. She told me I had a "false positive" & I didn't have Lyme Disease.
- Then saw an Infectious Diseases doctor and was tested for a lot of different things to rule stuff out. They did NOT include a Lyme test even though it was requested. When asked about it, I was dismissed/ignored. **Diagnosis:** Epstein Barr Virus, no treatment, “it will clear up on its own in 30 days”. That was a year ago, and I’m still sick.
- Paid out of pocket to test with specialty lab, which specializes in tick borne illnesses. Tested positive on 4 specific bands Igg & Igm , positive for Lyme.
- Local doctors do not agree that this is a positive, and will not treat her for Lyme, and will not evaluate her for other tickborne infections (she cannot afford to pay for additional out of pocket tests). As she has gone from doctor to doctor to find someone who will treat her, she was “degraded, humiliated, laughed at and dismissed at several locations”.
- Her only option left is to see a Lyme Literate Doctor who doesn't take insurance. Due to her illness she has not been able to work and she can't afford the doctor, or further testing, let alone treatment that may or may not be covered.
- “So here I am, sick as hell, unemployed, close to bankrupt, abandoned by the healthcare community, forgotten & lost. I'm 37 years old & I don't deserve this. I am afraid as this keeps progressing that I will die from this disease. “

Mid-term/more effort/cost:

e) **School Awareness/Education** - The awareness and education campaign for parents/staff could leverage the “Dare 2B Tick Aware” program easily, but it needs to be enabled by policies and communications that require scheduling in spring 2018. Dedicated funding for school awareness sessions must be specifically allocated. The Act 83 Recommendation related to this follows:

- Implement an awareness campaign for children, parents, staff regarding risks and prevention.

f) **Babesiosis – PA Reportable Disease** – Physicians in PA have been reporting Babesiosis and alerting the PA Department of Health since the 1990s that this disease is here, and requires attention. We are surrounded on 3 sides by states that are and have been endemic. Laboratories have shared data with PALRN that demonstrate well over 100 cases of positive Babesia cases in Pennsylvania, far exceeding any measure of endemicity (New Jersey only required 7 cases to be declared endemic). This is clearly an example of “you can’t deal with that which you aren’t aware of”. Physicians and healthcare institutions in PA are unacceptably unaware of Babesiosis, while it is here threatening our health. From our support groups/communities – these are examples of the lack of awareness, and experience with Babesia. This requires a CRISIS-level response, making Babesia reportable immediately:

- “Babesia is a tropical disease, there is no way you could have that...”
- Night sweats, drenching through to the clothes, in case of patient already diagnosed with Lyme disease – no consideration, testing or other clinical evaluation for Babesia (patient died)
- Classic presentation of Babesia in ER, yet after multiple visits including escalation to ICU, it was not diagnosed until a week had passed (patient died)
- “Babesia – that’s a disease cows get – you don’t need to worry about that”

In the Act 83 recommendations, focus is on transfusion-related transmission which is still very important, and addressing in awareness and education, but fundamental to both of these is the tracking and reporting of cases, to be able to establish risk, and to further inform communications/strategies.

g) **Sudden Cardiac Deaths in Youth/Young Adults:** implement a registry in Pennsylvania, and specifically charge coroners with continuing education, to investigate for Lyme and tickborne diseases as underlying cause in such cases. Lyme, Babesiosis and other tickborne illnesses have cardiac and pulmonary manifestations.

All of the remaining recommendations in Act 83 should be evaluated with the Oversight/Working Group for further refinement and prioritization to drive funding and implementation planning.

SUMMARY:

We are facing an epidemic in PA, of crisis proportions. Links continue to be established in the research between tickborne diseases and many other conditions, previously of “unknown” causation – including pediatric learning disabilities (treatable), psychiatric presentations especially in youth and young adults (study found more than 75% of bipolar patients were infected with tickborne diseases; when treated was greatly reduced or eliminated bipolar diagnosis), pain management addictions to cope with symptoms and denial, and suicide. Pennsylvania should take every opportunity to prevent, and to intervene at the EARLIEST possible juncture in these diseases, with these lenses in mind, to reduce the health burden, and to relieve the pain and suffering and impact on our communities, and state, resulting from these diseases.

Thank you for the invitation, and for the opportunity to testify on behalf of the patient community.

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