STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

PUBLIC HEARING
IN RE:
LYME DISEASE

JANUARY 29, 2004
Verbatim proceedings of a Public Hearing of the State of Connecticut, Department of Public Health, In Re: Lyme Disease, held January 29, 2004 at 9:00 A.M., at the Legislative Office Building, 300 Capitol Avenue, Hartford, Connecticut.

ATTORNEY GENERAL RICHARD BLUMENTHAL: If I could have your attention? If I could have your attention? Welcome to everyone. Welcome to everyone in this room and I understand there are also some participants in other rooms. We're delighted to have you here, particularly so many of you. Obviously, your number demonstrates your interest and concern. And we're very, very pleased that all of you are here.

Let me begin by thanking Dr.
Galvin and the Department of Public Health for their immense help, their energy and hard work in putting together this very, very significant forum and hearing. We are also grateful to the legislature for giving us this facility and to some of the legislators who will be joining us. One is already with us. State Representative Dolly Powers is here. At least I saw her a little bit earlier. And others will be joining us. I'll try to recognize them when they arrive.

I'd also like to say that we welcome Congressional attendees. Representatives of our Congressional delegation are here from Senator Dodd's office, Anthony Householder from Senator Lieberman's office, Michelle Carpenter. Two of our other Congressmen are represented. Nancy Johnson is represented by Paul O'Sullivan and Congressman Shays by Brenda Kupchick.

And I would like to say I understand that we have with us the person who was
first diagnosed with Lyme Disease in the state of Connecticut, Polly Murray. Welcome to you. And thank you for being with us.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: That certainly is a somewhat dubious distinction. But it is a mark of courage and conviction for you to be here. And we welcome you and all of you who have the courage, bravery, fortitude, perseverance to be with us and to talk publicly about a disease that is pernicious, insidious and immensely destructive, costly to our state, society and particularly to our children.

I don't have lengthy remarks to begin this hearing. I'm going to ask Dr. Galvin a few words, if he'd like to remark. But I just want to say that we're here because even in the coldest weather, we simply cannot rest or be complacent. The ticks that carry this disease may be resting under the snow. But we have no reason to in any way rest in our efforts to educate and warn the public
and to try to improve diagnosis and reporting. So, in addition to the general concern about Lyme Disease, about improving education and awareness throughout the state, I think there are two specific objectives today. And they are to eliminate the common use of excessively restrictive Federal reporting criteria to diagnose and treat Lyme Disease and, second, to correct the under-counting of Lyme Disease cases so that we can understand how widespread and severe this disease really is. On the one hand --

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: On the one hand, under-diagnosis of Lyme Disease because of excessive reliance on restrictive criteria and under-reporting of Lyme Disease cases due to lack of funds or lack of interest on the part of relevant agencies.

And that will be the focus as we go through the day, under-diagnosis and under-counting. And, again, we will have with us
some extraordinary scientific talent, some people
who have suffered from this disease who have come
forward very bravely and articulately in the past
and now again today, and then some of the government
officials who are responsible for making policy in
these areas.

I want to thank particularly
representatives at the NIH and the CDC for making
the trip here after we very specifically asked them
to do so. Obviously, they come from farther than
many of our other guests. But we thank all of them
for joining us. And I'm very excited and
enthusiastic about the day's activities.

And having said all that, if I can
call on your, Dr. Galvin, to say a few words, if you
have some remarks?

COMMISSIONER J. ROBERT GALVIN:
Thank you, sir.

Just for those of you who don't
know me, I'm Bob Galvin. I'm a newly appointed
Commissioner of Health. I started on the 1st of
December. I come from a background of almost 40 years in clinical medicine and have been a teacher of medical students for a good part of those 40 years. I last saw patients on the 26th of November of this year. And my last patient was a gentleman who, on the 25th, sent me a small, clear plastic container with contained a tick, which I would identify as a Lyme tick, adult female. And sent me a -- accompanied it with a phone call saying he had a rash and he'd removed the tick. And, in fact, the last person I saw in my private practice was an individual who I believed had Lyme Disease but who would not be counted because he had not had enough time to develop markers in his blood for that particular disease.

I would like to tell you that one of my real heroes in the medical world is a gentleman named John Enders, who is a West Hartford native. As I'm sure many of you know, John Enders received the Nobel Prize for measles vaccine. It was -- when I was in school in Boston and later on,
it was widely known that Enders had given away
probably five or six other projects which resulted
in Nobel Prizes or the equivalent of Nobel Prizes.

And Enders, what always stuck in
my mind was that he said that the really important
ting was to be able to ask the right kind of
questions so that you could get the answers.

I would like to very briefly
introduce Dr. Randy Nelson, who is a veterinarian on
the staff of the Health Department. He also has a
Master's Degree in public health and is an expert on
diseases which are spread by contact with animals to
human beings.

Dr. Nelson and Tom Ryan, Dr. Tom
Ryan, who is a jurist doctor and on the Attorney
General's staff, Randy and Tom did a lot of the
heavy lifting on this project. I'm very pleased to
have a chance to work with the distinguished
Attorney General and to bring these issues to light.

I have no preconceived notion.

There is nothing chiseled in concrete in my
department. And I have no -- I'm not bound by any
agreements, past or present, which any of my
predecessors have made.

In case you are curious, the
distinguished gentleman to our far right is Sam
Crowley, who runs the Ledge Light Health District
down near the shoreline and has extensive experience
with Lyme surveillance within his -- the Waterford,
Groton and Ledyard areas. And he's here to help me
should I falter.

I am basically here to listen. I
have recruited a panel of physicians. Several of
them told me, "You're not going to -- you might not
like what I have to say. What would you like me to
say?" They're going to say what they think.
Particularly Dr. Sinatra, who is a fascinating
gentleman and a holistic health person and who
suffers from Lyme Disease.

So no one has been coached by me.
And I'm here to learn and to listen. And I have no
pre-formed opinions.
ATTORNEY GENERAL BLUMENTHAL:

Thank you, Dr. Galvin.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much. I might just say people ask me all the time or say to you me all the time, "You might not like what I have to say." But they usually don't say, "What would you like me to say?" after they tell me that. So I can see the medical profession is considerably more delicate in its relationships with appointed or elected officials.

And I want to thank particularly our medical group for coming today. I know how busy you are.

Let's begin with the patients group, if we may. We're going to begin with five of the ten -- five of the nine patients and their representatives that we have today. And if I can call them forward? Josh Athenios, Caroline Baisley, Mary Anne Foley, Jude Anne Jones and Donna Lake.

COMMISSIONER GALVIN: The
Reporter, Court Reporter, advises me that if, when you first speak, if you could identify yourself, then he'll be able to track the testimony.

ATTORNEY GENERAL BLUMENTHAL: Just as a matter of the ground rules today, we have a very, very extensive list of people who are going to be speaking today. And so we're going to ask each of the beginning participants on the patients panel to take about five minutes. And Tom Ryan, who is on my staff, will be letting you know if you go beyond that amount of time. And we hope that there will also be time for questions on the part of Dr. Galvin and myself.

So if we could ask Josh -- perhaps you could go first.

MR. JOSHUA ATHENIOS: Hello. My name is Joshua Athenios and I have had Lyme Disease since the summer of 2000 when my mother picked off two ticks from my body, one behind my left knee and the other behind my right ear. I never got a bull's-eye rash. I started having joint pain in the
fall of 2000 and was told by my pediatrician I was
having growing pains and fatigue due to my intense
karate training. I got physically worse and worse
as time progressed. I had extreme fatigue that was
unrelieved by rest and sleep. My joints --

COMMISSIONER GALVIN: Josh, can
you lean forward a little bit? I think some of the
folks are having problems hearing you.

MR. ATHENIOS: My joints --

COMMISSIONER GALVIN: Atta boy.

MR. ATHENIOS: -- ached. I lost
small patches of hair the size of quarters all over
my head. I had headaches, could not concentrate in
school, lost my short-term memory, could not play
sports or take karate. I was dizzy, had chest pain
and neck stiffness. For a short time, I could not
walk.

With my mother's persistence, I
had a test for Lyme Disease in the spring of 2000.
I had a positive Lyme ELISA. With my mother's
persistence, I received three weeks of Doxycycline.
My symptoms improved and I thought I was well.

In October 2001, I had a relapse of symptoms. I felt like I had the flu. I had extreme fatigue. I wanted to sleep but had a hard time doing so. I was weak and my joints, knees, hips all ached. My joint pain got to the point that I could not walk.

I came home from school one day and was in the worst pain of my life. I was unable to stand on my own two feet. My mom rushed me to the emergency room. There was no parking close to the hospital. So my mom had to park and carry me in. They gave me a wheelchair.

The doctors at the hospital diagnosed me with joint complications due to the flu. They fit me for crutches at the hospital and told me I would be better in about three days.

Three days passed and I was not better, but worse. My mom sent me to school with my crutches. I could not finish my school work or play with my friends. I was in extreme pain day and
I was on several pain pills that did not relieve my pain but only made me feel worse and gave me stomachaches. At this point, I looked as sick as I felt. Many classmates asked me what was wrong and if I had cancer. I did not know that Lyme Disease could lay dormant in the body. At recess, I was on crutches and a boy asked me what my symptoms were and I told him. And he gave me a piece of paper with a number on it and told me it sounded like I still had Lyme Disease. He told me to call his father. I went home and gave my mom the number. The next night, the boy's father ended up calling my house.

Our pediatrician told my mom that I could not have Lyme Disease because I was already treated for it for three or four weeks. I had more blood tests that came up positive for Lyme. I was sent to a rheumatologist at the Children's Hospital. He looked at me for about 60 seconds, sent me for x-rays. He ignored my positive Lyme test and
diagnosed me with arthritis. He told my mom it
would be a long time before I would walk without my
crutches. He told my mom to call the office and
schedule an appointment to have an operation in two
weeks to have my hips drained. My mother refused
the rheumatologist's diagnosis to pursue surgery.

I then went to an infectious
disease specialist. He told me that my symptoms
were all in my head. He told me to tell my mom the
truth, that I was making it up so I didn't have to
go to school. I was in the worst physical health I
had ever been in. It hurt for me to talk. And he
told me to stop pretending. He told my mom I did
not have Lyme Disease and that the antibiotics would
not work. I was misdiagnosed again and my positive
Lyme test was overlooked.

My parents could not find a doctor
to treat me for Lyme that the insurance covered. So
they took me to Dr. Charles Ray Jones, a
Lyme-knowledgeable doctor. They paid out of pocket
for my treatment. Dr. Jones took the time to listen
to me and cared enough to diagnose me properly. I was given Amoxicillin and Zithromax and was walking without crutches after three weeks.

I continued my treatment for nine months and had significant improvement in my health. I have been off all medication for over a year and a half. I am taking karate classes again and I'm studying for my black belt. I am thankful to God for my health and thankful for the responsible physicians who take the time to listen to their patients even if the patient is a kid.

I want to thank Attorney General Richard Blumenthal and Commissioner of Health Robert Galvin for this opportunity to tell my story. I would also like to thank Mr. and Mrs. Randy Sikes, Mr. Chris Montes and Sam Montes for helping me during my illness.

I hope this can shed some light on the disease so other kids and adults don't have to suffer like I did.

Thank you.
ATTORNEY GENERAL BLUMENTHAL:

Thank you very much, Josh. Very well said.

If we could now hear from Caroline Baisley?

MS. CAROLINE BAISLEY: Good morning.

ATTORNEY GENERAL BLUMENTHAL: Good morning.

MS. BAISLEY: My name is Caroline Baisley. I'm the Director of Health in Greenwich, Connecticut. I have served the Town of Greenwich as a key member of the Department of Health for 23 years. Over the past six years, I have held the title of Director of Health. I'm responsible to protect the health and well-being of the town's population.

When I received a call from the Attorney General's Office inquiring about my interest in participating today, I was honored.

After agreeing to be a part of the patient panel on
the agenda, I realized that my role would be quite
different. As a victim of LD, I would be offering
information from a patient's perspective and not
from a Public Health official's point of view.
Although I felt comfortable in sharing my story as
an LD patient, I found it difficult as I began to
assemble my experience. In addition, I found it
equally difficult to separate myself as an ailing
patient with disease and the leading health
authority that strives to protect the public's
health against the disease.

Nevertheless, my story of pain and
suffering is similar to all the other patients that
struggle in their fight against this spirochete
which causes the systemic illness.

As a woman in her early 40's, I
was grateful to have my health, a good job, close
friends and a loving family. In 1999, really
becoming ill, I came down with a bug and was out
sick from work for five days. After receiving
treatment from my primary physician, I returned to
work and never gave my illness a second thought.

Although everything seemed to be going well, my life -- my life -- oof. Is this still on? My life was not free of stress and pressure.

At work, it was the year that an unknown virus known as West Nile Virus emerged in the community. And at home, it was my failing elderly mother. It seemed that I was under much more stress than usual.

The year 2000 came in with a bang. My mother passed away in January. And health officials throughout the state were preparing for the re-emergence of West Nile Virus. I didn't notice at the time, but I began to see an array of physicians for various symptoms. An ophthalmologist I visited since my eyesight became poor. My OB-GYN and primary physician were seen for unusual constipation and severe cramps. After full examination and no diagnosis, I was sent for the MRI and a colonoscopy. Both tests proved to be negative. And in the follow-up visit to my
physician, I was encouraged to eat more foods with fiber and to exercise.

In the months to follow, I visited my dermatologist for skin blotches on my face and mild hives on my torso. After a battery of negative test results and unsuccessful attempts of prescription creams, the dermatologist suggested I see an allergist.

As I recall, this was the first time I began to think about what was happening. Being consumed by work activities, I put off seeing the allergist. I had no known allergies and the hives seemed to disappear.

In the mid-90's, I was diagnosed with a hearing impairment with an unknown cause. However, my hearing seemed to be getting much worse. In my daily activities, I was constantly requesting that a statement be repeated. My trip to the hearing doctor confirmed my suspicion. And two small hearing aids were purchased. I reluctantly wear only one in my left ear.
Without any warning, I woke up in the morning with hives from head to toe. I took over-the-counter antihistamine to get relief. The allergist conducted a complete review and prescribed medication for the hives should they return. All the tests conducted were negative. However, before long, the hives returned. But this time my face was swollen beyond belief.

Although the prescribed medication suppressed the hives, Prednisone was needed to reduce the swelling in my face. I took this many, many times.

By the end of this year, I had fallen ill once again, this time for eight days, not responding to the course of treatment set by my primary physician. I was given over-the-counter medications and was required to stay in bed until I got well. After two weeks, I returned to work.

The year 2000 seemed no brighter. I began to see the allergist more frequently. And episodes of hives and -- the episodes of hives
increased and I received higher doses of prescribed medication.

Although it seemed that I visited my primary physician less, I did begin to see a chiropractor for neck pain. Having slowed down in my physical activities, I did not know how I could have injured my neck. However, a series of x-rays identified a dislocated disk. Although I didn't feel like myself, I was much too busy with the aftermath of September 11 to think about it. I worked many long hours in the months to follow. So I became unaware of my declining condition.

In 2002, the hives began appearing more regularly, until they stayed permanently. My face would now swell more often, closing my eyes and prohibiting me from driving. The allergist continued to conduct tests, but all were coming back negative.

I began to experience chest pain and got very concerned. So I visited a cardiologist. Although not convinced that my signs
and symptoms were heart-related or that any other
symptoms could be contributory, the cardiologist
agreed to a cardio stress test. The results
indicated that I was healthy but perhaps I was under
too much stress at work.

Continuing to see the chiropractor
for neck pain for a short while longer, it seemed
that the pain subsided. And although the medication
that the allergist prescribed suppressed the hives
daily, I became very concerned about the possible
cause. It wasn’t until the morning that my face on
the right side exhibited a droopy look that I
believed that something was seriously wrong with me.

My body was obviously sending signs of its illness.

I returned to my allergist,
requesting that he look deeper into my problem. The
blood work performed isolated a C-4 deficiency that
could be associated with an autoimmune disease. I
visited my primary physician and an infectious
disease specialist. All tests that they conducted
were negative.
MR. RYAN: Time.

MS. BAISLEY: In closing, I would like to say -- actually, the most important part of this is that the hives came back. They stayed. I did take many medications to get those hives to be -- suppressed. The most important thin is that my memory started to be lost. I directed my efforts towards work. And I could not -- I was disinterested. My physical -- I was physically tired. I was depressed. I saw a psychiatrist who became a very good friend of mine. And luckily, through his perseverance, he insisted upon that I go and see a doctor who actually would treat Lyme Disease patients because he knew of the severity that -- that came with the spirochetes that -- from Syphilis. And, therefore, he realized the damage that would be done to my brain.

The bottom line is this. I would encourage all Lyme Disease patients to bear together, to give each one strength, to continue to support their doctors and their efforts to treat. I
was very, very supportive -- my family was very,
very supportive. And I'm very thankful for my
doctor, Dr. Katz, who treated me aggressively. Once
I received antibiotic intravenous treatment, which I
am currently on, my fogginess in my brain cleared
up. I became cognitively more alert. And the PhD
candidate that I once was I hope to be once again.
Because this disease -- I'll be honest with you --
it robs the brain, the brain of a very talented
person, of our children, the biggest assets in our
nation and in our state.

And I think that -- I don't know.
There's nothing more we can say, I can say. It's
that we need your support.

ATTORNEY GENERAL BLUMENTHAL:
Thank you very much.

(APPLAUSE)

COMMISSIONER GALVIN: I must say
that, Caroline, that in my work, for a long time,
ine years, I was the Medical Director for Long-Term
Disability for Aetna Life & Casualty. And I saw a
considerable number of people who were as bright and
talented as you are who had your type of
symptomatology who never worked again productively.

ATTORNEY GENERAL BLUMENTHAL: But
I'm glad that you are working productively in
Greenwich. Thank you for being here.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Mary
Anne Foley?

MS. MARY ANNE FOLEY: My name is
Mary Anne Foley and I'm from Wilton, Connecticut.
My experience with Lyme Disease is both personal and
professional. Personally, every member of my
immediate family has at one time been diagnosed for
Lyme Disease and for three members it has had
devastating impact. Professionally, I am a market
researcher by trade. And colleagues of mine at
Millard Brown in Fairfield conducted a study in 2001
looking at the household and individual incidence of
Lyme in Wilton, Ridgefield and Newtown.

The results, conducted among a
total of 1200 households, revealed four out of ten households have a member with diagnosed-by-a-physician Lyme Disease. Of those, two-thirds present with a positive blood test, two-thirds have a rash or bull's eye and virtually all were treated with antibiotics.

On an individual basis, the study found that roughly one out of five people in these areas has been diagnosed by a physician with Lyme Disease. Of these, almost one quarter saying they have lingering, persistent health problems. That equates to about five percent of the total population in this area suffering from lingering effects of Lyme Disease.

Is there convergent data? Anecdotally, my pediatrician in Wilton has told me that he has about three percent of his practice with lingering Lyme Disease. At the Cider Mill School in Wilton, when I was at one of my daughter's 504 meetings, I learned from the senior counselor there that roughly three percent of that school's study
body had some accommodation, either in 504 or IEP, due to lingering effects of Lyme Disease. We have an out-of-control school budget due to Special Education needs. I think we need to look at what Lyme is contributing to that.

On an area-wide basis, it's well known that Lyme is an issue. A survey in New Canaan in November of 2000 published that the majority of residents, 52 percent, feel that Lyme Disease is a Very Serious problem and another 34 percent suggesting it is a Somewhat Serious problem. That actually changes the way these people live. Almost nine out of ten constantly check themselves for ticks after being outdoors, 68 percent use insect repellant and over half avoid wooded or grassy areas to avoid ticks.

Living in Wilton, I am all too aware of how big a problem this is, probably more aware than most. I have three daughters. All have been diagnosed with Lyme. For my middle daughter, Kristen, all this has ever involved is a course of
antibiotics and then she returned to a normal life.

Laureen, my eldest, and Samantha, my youngest, are not nearly so lucky.

Laureen missed most of high school. She is currently a freshman at Fairfield University. While she was not diagnosed with Lyme until she was 14 years old, her medical records suggest she actually contracted it the summer she turned four. While she would be sick on and off for years -- and much like the other people here, I was told by varying doctors it was a million different things. It was not until she reached high school that she would start missing up to three months of school at a time.

Similarly, Samantha, my youngest, missed almost 70 days of sixth grade last year. My husband was one of the first employees in his business at General Electric to go out on short-term disability leave due to Lyme.

Because of my children's condition, I receive my calls from families who are
facing the same challenges, particularly for their children. While the symptoms so often include headache, fatigue, depression and joint pain, what most people don’t recognize is how alienating and lonely this disease is.

For too many children, there are extended absences from school. Having friends is so often a function of shared experience. And for the kids with Lyme Disease who are missing school and are staying home, they are sharing nothing.

Personally, I’ve seen far too many heartbreaks. Missing your surprise 16th birthday party because you spent the day in the emergency room. Losing positions on teams, in plays, at the lunch table because you’re not able to be there. Being told by your peers that you must be too stupid to attend school.

Further, school policy prohibits participation in extracurricular activity when you are not in school. For kids with Lyme who have periods of illness are interspersed with days they
are relatively well, this policy is devastating.  

For us parents, there is the emotional cost and the real cost. There are insurance battles, tutors and potential lost income from either the stigma of Lyme -- and that is real -- or from not being able to work because you are home with sick children.

At one point, my pediatrician, a wonderful man, spent over an hour with my oldest daughter, comforting her, explaining the illness was not in her head, that the taunts and the suspicions of people around her were their problem and asking her to please recognize that it was their problem and not hers. And he said to her, "Eventually, things will improve."

Things have improved because we've been diligent in getting medical help and emotional support in as many places as we can find it. This is a disease where you must be an active participant in your own health, seeking out various treatments, weighing your options and understanding how much
trust you can place in each source.

As a family, our health is improving, largely because we have reached a new level of treatment. And what I believe is equally, if not more, important, we purchased a home in Florida. Why? Sunlight. I had much anecdotal evidence from fellow Lyme combatants which I added to Internet and literature searches suggesting sunlight has a very real impact on health, more than most people realize. This was encapsulated in a Readers Digest article in June of 2003. And I quote a medical professor --

MR. RYAN: Time.

MS. FOLEY: -- from Boston University who says "There is an unrecognized epidemic of Vitamin D deficiency."

My children have improved. And while we are a small sample, there is clearly something here. Living half of each year is a pretty drastic response. But right now this has been the most lasting solution I have found for a problem
that literally plagues us. We need help on every level. And the best way to bring that about is to generate shared learning in a positive, non-threatening environment.

And I am very grateful to you for holding this hearing. Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Jude Anne Jones?

MS. JUDE ANNE JONES: Hello. My name is Jude Anne Jones. I've come here today in an attempt to share information that I've experienced and lived and that might help in the ongoing questions, research and considerations of Lyme Disease.

I am a Connecticut native. I was born and raised in Westport. I come from a large family. I am the fifth of six children. I demonstrated from early childhood an extremely strong constitution. I never got sick and it was I who always resisted the illnesses some of my
siblings contracted. My mother deliberately exposed me to sisters who might have had measles or mumps and to no avail. Although diminutive in stature, I always possessed remarkable physical strength, as well as a natural athleticism. That was my greatest gift, my constitution.

At age 5, 13, 18 or 21, one doesn't even think about one's constitution. I remember that adage I'd hear growing up, "With good health, you can do anything."

After some reflection, I realize now that I started feeling sick probably around 1979 or '80. I've always assumed that I had Lyme Disease for 15 years before I was diagnosed. But, in fact, it started earlier. Because I was treated for various infections, primarily sinus and skin, much of the symptoms were masked or tempered by short courses of Tetracycline.

By the mid-1980's, I was constantly feeling unwell, flu-ey, arthritic. I had seen a physician in New York and had shown him this
rash on my chest that looked like a spider web. I remember his comment. "You just have a case of the crazies." He gave me an antihistamine. I thought, "You might be right." I certainly was stressed, as I was managing and designing for a multi-million-dollar corporation, trying to care for a dying aunt and commuting back and forth to Westport to care for my terminally ill mother. Adrenal and determination have been very good friends of mine. I'm not here to malign an individual or an institution. What's done is done. And nothing can erase what's happened. What I can say is that I experienced what is unfortunately not that uncommon. I was not diagnosed with Lyme Disease until I went into an emergency room having a mini-stroke. I had suffered with an excruciating headache for more than a week. My blood pressure was 220 over 110. And I was walking crookedly. Prior to that trip in November of '98 to the emergency room, I had been suffering from
some form of meningitis for three years. I was told it was aseptic. I had constant fever, sore joints, sore neck and generally was very sick. This had been preceded by seizures in 1992 and '93 and abnormal MRI and CAT scans.

I didn't have health insurance in 1992 and '93. So I didn't pursue it. I had returned to Westport in 1987 to be my mother's full-time caretaker until she died. After her death, I remained in Westport.

I had always attended to my own garden and, in 1998, was asked to oversee and design other people's properties. I will never forget the day when a young woman asked me to take care of her garden, as she had explained to me she had been so sick with Lyme Disease, the tick-borne disease, that she never wanted to garden again. And I remember thinking to myself, "Tick disease, how bad could that be?" I thought she was a little over the top in her reaction. How wrong I was. How doubly ironic, as I was already infected myself.
In 1989, I had a significant bull’s eye in my right forearm, felt horrible, saw the doctor who dismissed my extremely stiff hand joints from overworking small muscles by weeding. It made sense to me. But I shouldn’t have accepted it.

This is the part for which I am responsible. As sick as I already was, I did not pursue it, didn’t go back to that doctor or seek other opinions. Had it been someone I cared for, I would have insisted, pushed them to seek additional care and viewpoints.

I’ve always been able to tough it out. After two operations, bouts of meningitis, explosive hypertension, fevers, a persistent infection, irrevocable damage to my central nervous system, the inability to work -- and I have worked since I was 14 -- the inability to drive on high-speed roads -- I cannot synchronize my brain and body. Problems with --

MR. RYAN: Time.
functions. I am here as a representative of the extraordinarily profound impact this disease can have on a human. I am here because I would like to think that my experience might help prevent it from being someone else's experience.

I am not in a wheelchair. I am not in a nursing home. I live by myself. I take care of myself. I struggle daily. I, frankly, credit my survival to date to two things; the physical constitution that I was born with, which provided me with the basic physical ability to keep fighting until it no longer could because it had been so destroyed by the insidious nature of Lyme Disease, and to one physician, my neurologist, Dr. Amiram Katz, who, through careful, professional and dedicated attention to me, diagnosed me with neurological Lyme Disease and helped champion my cause so that I could receive correct and comprehensive treatment in an attempt to get better.

I thank you for the opportunity to
ATTORNEY GENERAL BLUMENTHAL:

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Donna Lake.

MS. DONNA LAKE: Good morning. I would like to thank Attorney General Richard Blumenthal and Commissioner Galvin for holding this hearing on Lyme Disease and giving me this opportunity. My name is Donna Lake. I was born and raised in Hartford, Connecticut. I've lived in Simsbury for 12 years.

On June 6, 2003, I discovered an engorged deer tick on my abdomen. I was preparing for a pre-op physical prior to a surgery scheduled for June 20, 2003. I removed the tick, which I now know I removed improperly. I did not realize it was a tick. But I placed it in a Baggie and brought it to my appointment.

When I was seen for my physical, I
presented my tick and the bite site, which was raised and inflamed. I expressed my concerns and my knowledge of Lyme Disease because my young Lab recently had Lyme.

Living in Simsbury, a heavily wooded area, deer and bear being common to our neighborhood, I requested treatment so I could proceed with the carefully planned surgery, along with my juggling work schedule, as I am an independent contractor.

I was given 200 milligrams of Doxycycline, the standard recommendation of the CDC. I then dropped my tick off at the Farmington Valley Health Department for testing. Seven days later, I developed a slight headache, neck ache and fatigue. Eleven days later, June 17, 2003, three days prior to my surgery, I had a severe headache, redness on my neck, arms and chest, along with fever, chills, light sensitivity, sore throat, confusion, severe fatigue and complete numbness on my left side. I phoned my doctor immediately.
I fully articulated my situation, although my thought process was slow. His response was, "Donna, just because Lyme Disease is the disease of the month, it does not mean you have it."

I was shocked.

I phoned my surgeon and explained everything to him. His response was, "Donna, you are in full-blown Lyme Disease. You have an infection in your system. I cannot perform your surgery."

I was clinically diagnosed with Lyme Disease and treated on June 20, 2003. I was given a blood test. The result, three weeks later, based on recommendations by the CDC, negative. Six weeks later, I received a phone call from the Farmington Valley Health Department. They were concerned because my tick was positive and they recommended I seek medical attention immediately. Two days later, I received documentation on the tick.

I was treated for two months. I
relapsed two weeks after treatment, experiencing the
same symptoms. I was put back on medication. Each
time starting the medication, I had a Herxheimer
reaction. I had been taking medication for six
months now. I am finally feeling 93 percent better
and I have not had any Herxheimer reaction. My
recovery has been slow, but I am one of the lucky
ones.

Having this complex disease has
been a horrible learning experience at my own health
expense. My treatment proves that in some cases 200
milligrams of Doxycycline as a preventative, 21 days
of antibiotic treatment, along with standard blood
tests, is indeed ineffective.

The disease is spreading rapidly
here in Connecticut. The lack of knowledge,
education, research and understanding of this
disease is comparable to the Dark Ages. The need
for recognition and proper care is severe. To
ignore this, it would be a great travesty. After
all, this disease is in our own back yards.
Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: I have just a couple of questions and then Dr. Galvin may have some.

I want to just introduce again -- I mentioned earlier that Representative Dolly Powers is with us. She left the room earlier when I introduced her. But Representative Googins, Sonny Googins from the Hartford area, is also with us. And I don't see any other State Representatives or State Senators. But if you're here, please come forward.

You mentioned, Ms. Lake, the CDC guidelines and that those guidelines did not indicate -- the application of those guidelines did not indicate the presence of Lyme Disease. But the testing of the tick did.

Was anyone else among you told
about the CDC guidelines in the course of the
misdiagnosis or lack of diagnosis of Lyme?

MS. FOLEY: Yes.

COMMISSIONER GALVIN: I see you

noding, Ms. Foley.

MS. FOLEY: Yeah. In my husband's
case. Peter, like Laureen, it took many years and
many doctors to get diagnosed, like everyone. He's
been through two courses of IV antibiotics. And he
actually applied for Dr. Fallon's potential
research. He still does not meet CDC requirements
for Lyme Disease. This guy would be in a
wheelchair, drooling, if he hadn't been treated. I
am not exaggerating.

ATTORNEY GENERAL BLUMENTHAL: So
you were -- you were told that your husband did not
meet the CDC guidelines.

MS. FOLEY: Absolutely. That's
right.

ATTORNEY GENERAL BLUMENTHAL: I
saw someone else noding. Maybe Ms. Baisley?
MS. BAISLEY: As a Health Director, I was well aware of the CDC guideline. I didn't fully meet the guideline. However, my physician not only looked at my test results, which perhaps not enough physicians do, looked just a -- I mean he looked not just at the test results but he listened to me as a patient. He listened to what I was saying, what I was experiencing. And so, you know, that's very important to diagnose a patient.

ATTORNEY GENERAL BLUMENTHAL:

Anybody else have a comment on that aspect?

A VOICE: There's somebody over there in that corner.

ATTORNEY GENERAL BLUMENTHAL:

Yeah. You know, we can't recognize members of the audience, unfortunately. We would welcome your comments later, either written or --

A VOICE: Same thing.

ATTORNEY GENERAL BLUMENTHAL: --

oral.

A VOICE: Six years misdiagnosed.
ATTORNEY GENERAL BLUMENTHAL:

Thank you. And I apologize that we can't just open it as a kind of public forum.

None of you, if I was listening -- if I caught everything you said, none of you mentioned the classic bull's eye rash. Am I -- did I miss something there?

MS. JONES: No. I --

ATTORNEY GENERAL BLUMENTHAL: Ms. Jones?

MS. JONES: I did have it.

ATTORNEY GENERAL BLUMENTHAL: You had the rash?

MS. JONES: I had the rash in 1979 on my chest and it was not --

ATTORNEY GENERAL BLUMENTHAL: That was the -- that was what the doctor said -- how did he describe it?

MS. JONES: He referred to it as "a case of the crazies". Now, this was in New York.

And I'm not --
ATTORNEY GENERAL BLUMENTHAL: The crazies?

MS. JONES: "A case of the crazies". Then in 1989, I had it on — the classic bull's eye on my arm. But I have to say — so that was -- I probably had Lyme in all actuality from onset to formal diagnosis for 25 years. During that time, I never had a positive blood test. Never. And it was theory that when it's -- when one has it for that long a period of time, it skips over the spinal/cerebral border and lodges itself in the central nervous system, the brain. And spinal/cerebral fluid tests also were not always 100-percent positive. There were other tests, Lyme antigen capture, which is a more sophisticated test that I can't really explain to you. PCR tests done on blood work which detects the actual DNA of the spirochete. However -- and I'm sure you'll get to this later. There is inaccuracies from one laboratory to another. And I actually had blood work drawn last March as part of the -- perhaps
getting into the National Institute of Health program. Two weeks later I had it drawn separately. The one drawn from the National Institutes of Health came back negative. Two weeks later, drawn by Dr. Katz's office and sent to a laboratory in New Jersey, it came back positive. So that's part of the conundrum.

ATTORNEY GENERAL BLUMENTHAL:
Thank you. And I -- again, I was listening. I may not have caught it. But I gather none of you remember actually being bitten by a tick.

Ms. Lake, you found a tick.

MS. LAKE: I didn't -- I found it. I didn't feel it. I don't remember it.

ATTORNEY GENERAL BLUMENTHAL:
Okay.

MS. BAISLEY: I can't recall getting bit by a tick. I did not have the red -- the red bull's eye rash. I had hives instead. I had all the other classic signs, however, of Lyme Disease, the memory loss, the confusion, the
positive MRI. And I did see the inequities between
the laboratory analysis. Blood drawn is -- and even
the simple chemistries, by the way, which when I
examined the laboratory reports of my own blood
work, I saw the inequities between one lab and
another. Even the ranges of the simple chemistries.
Let's not even bother to talk about Lyme Disease.
Let's talk about simple chemistries. It really
depends on the lab that you go to.

So that's very -- it's very
important to note that when you're trying to look at
a patient, diagnose a patient for something as
serious as this, you have little inequities and you
have a negative patient. So there's a lot --
there's a whole slew of other signs and symptoms
that must be taken into account, obviously, other
than a test, a laboratory test. Certainly we want
to say that our laboratory tests play a major role
in surveillance of diseases and diagnosis for
disease. However, in this -- this one's not an easy
one, folks. You really need to look at absolutely
ATTORNEY GENERAL BLUMENTHAL: I want to thank you all.

And just to those who may have additional observations, if we have time at the end, I'd like to welcome those comments. Since we are on a schedule here, I apologize again that we can't take comments from the audience, so to speak. But I want to emphasize to you how important your experiences would be to us. If you could simply write them or convey them somehow to us?

The last time we had one of these hearings, it really made an enormous difference. We passed legislation as a result. The last hearing that I conducted with the Department of Public Health, we succeeded in changing the law to extend the guarantees for insurance coverage for treatment of Lyme Disease. Not as far as we sought or would have liked, but at least we were able to improve insurance coverage as a result of some of the testimony that we took at the time. As a matter of
fact, Tom Ryan, Assistant Attorney General, who is here today, was present then, too.

And I want to thank you for coming today, all of you, but particularly the five patients that we have before us today and the other five who will be testifying next because your being here really makes a very powerful statement and your experience is really tremendously important to us. So thank you for being here.

Dr. Galvin, did you have any questions?

COMMISSIONER GALVIN: Just one comment. Coming from primary care -- and this is simply a comment and it's not a reflection on anybody or what I think is the way things should be done. When you do primary care -- I was in Glastonbury. And there's a lot of people who have exposure to Lyme Disease. And I'm out a lot in the meadows. And I've picked Lyme ticks off myself.

We see large numbers of people beginning about late March who come in with some
sort of an insect bite. And not many of -- not all
of them have the tick. That makes it easier if the
tick is embedded or they have the tick. Some of
them simply have a circular rash and don't know
where it -- don't quite know where it came from.
Some of these are stinging insects. Some of them
are spider bites. Some of them are Lyme tick bites.
And some of them are other bites.
And the dilemma that a clinician
has is when someone shows up in your office with an
insect bite and a circular rash, what do you do? Do
you begin to treat? Do you wait for some serologic
marker to improve? Or do you try to discern exactly
from looking at the rash what bit this individual?
As one of you folks brought up,
most -- a lot of the bites are where people don't
see them. They're behind the knees, the back part
of the body, the back of the scalp. And so
sometimes the tick gets on, feeds, drops off and
just -- or gets pinched or poked off. And every one
of these patients -- it's a dilemma for people that
do primary care about do you give them three weeks
of antibiotic treatments, particularly with
Doxycycline, which is a sun sensitizer, during the
summer? Do you give them three weeks' worth of
treatment and restrict their activities? Do you
give them Penicillin? Or what do you do?

So that's -- that's what it looks
like when you look way at the end of the funnel
where people come in de novo. And I don't have an
answer for this. But it's a question that myself
and my partners dealt with almost every summer day
from March until November and sometimes during the
winter. As I told you, the last guy I saw was in
the end of November.

ATTORNEY GENERAL BLUMENTHAL:

Thank you. Thank you all.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: I'd
like to ask Elise Brady-Moe, Jennifer and Katherine
Reid, Tammy Sczepanski and Christopher Montes to
come forward please.
I'd like to say we've been joined by Representative Spallone, who is here with us, Jamie Spallone, who many of you may know.

And why don't we begin with Elise Brady-Moe please?

MS. ELISE BRADY-MOE: My name is Elise Brady-Moe. I have chronic Lyme Disease. Three years ago, I was misdiagnosed with rheumatoid arthritis by my primary care physician because I had migrating joint pain. I never saw the tick and I did not have a bull's eye rash.

Luckily, as my own health advocate, I did more research and I obtained a second opinion. Two and a half years ago, I was given a clinical diagnosis of Lyme Disease from a doctor who understands tick-borne diseases and who uses a lab that is proficient in identifying the antibodies created by the Lyme bacteria.

I was treated with seven months of oral antibiotics before I decided it was safe to try and conceive a second child. We had intentionally
postponed having a second child until we felt we had done our best to rid my body of this dangerous bacteria.

I conceived our second child in March 2002 and entered the pregnancy feeling confident that we would have a healthy child. The 15-week ultrasound showed a healthy baby with a strong heart and all its organs were functioning normally. At 16 weeks, the remaining test results were all wonderful.

At 18 weeks, I sensed something was wrong. My instinct was correct. Our baby boy was dead. While waiting for surgery the next morning, I came out of shock and I began wondering about the Lyme Disease. I had read that Lyme Disease could cause miscarriage, but there was no evidence to prove it.

I called my Lyme doctor and a lab skilled in detecting the bacteria so I could determine how to test the fetus and the placenta for the bacteria. I took the information to the
hospital. And just before the surgery, I insisted
that the OB obtain enough tissue for a separate PCR
test for the Lyme bacteria. If I had not requested
a PCR test at a specific lab, I would not know today
what took our baby's life.

Two weeks later, my OB informed us
that the baby boy was chromosomally normal and the
local lab did not find any bacterial or viral
infections that are tested for in a normal
miscarriage. He had no explanation. Only three
percent of miscarriages end at 18 weeks into a
pregnancy. I needed an answer.

I received that answer the next
Monday when the OB called me to report that the
fetus and the placenta were PCR-positive for the
Lyme bacteria. He concluded that the Lyme bacterial
infection had caused the fetal demise. He actually
thanked me for requesting the PCR test.

We grieved all over again. How
had this small bacteria survived seven months of
antibiotics and continued to destroy our lives?
When I purchased a garden stone in memory of our baby boy, I promised myself that I would do everything in my power to help others avoid this tragedy. I am here today as part of that promise.

The story continues. After the 18-week miscarriage, I began another regimen of antibiotics. I was on three different oral antibiotics for six months before conceiving our third child. I stayed on Sephtin during the pregnancy to protect the fetus. But, unfortunately, it did not survive past nine weeks due to chromosomal problems.

I requested a PCR test before the D&C. And the results were devastating. Again the placental tissue was PCR-positive for Lyme bacteria. What next? I did not want this disease to win. So I began a four-month regimen of IV antibiotics. After the IV was pulled out, I continued with oral antibiotics. And, luckily, I conceived a fourth time in November of 2003. The bad news is I have another miscarriage this month, unfortunately from
another chromosomal problem. The good news is the
PCR test was negative.
This does not mean I am rid of
this bacteria. But it is a sign there is hope.
Today I stand before you and I hope that there will
be funding for more research into the testing and
treatment of tick-borne diseases. I hope that your
wife, your daughter or your sister do not have to
deal with what we have dealt with during the past
three years. I hope that you will help the future
generations. It is time to help, not just hope.
Thank you very much for your
willingness to listen and your time today.
(APPLAUSE)
ATTORNEY GENERAL BLUMENTHAL:
Thank you.
Jennifer and Katherine Reid
please.
MS. JENNIFER REID: Thank you. My
name is Jennifer Reid. In our house, Lyme Disease
has infected four of five members, my three teenaged
daughters and me. No red circular rashes were ever present. No case was the same or easily detected. In each instance, the disease progressed to a high level of cognitive and neurological damage before a diagnosis was made. We have spent five years fighting not only the disease but also our insurance company. The strength of our family has been tested to its limits.

Lyme Disease came into our lives when our eldest daughter, Shannon, left home for college. She had been on her own just a month when she began to experience the physical and cognitive changes that would make school work impossible. She was tired, foggy, had trouble memorizing and began suffering headaches. Trips to the infirmary brought no answers nor did the testing performed when she returned home for Christmas. Despite her summer job as a riding instructor, no mention was ever made of Lyme Disease. Her symptoms were simply dismissed as those of a college freshman having too good a time.

In fact, we learned later she was
not having a good time. She was terrified. She describes that year now as watching herself slip away, becoming a completely different person whose thoughts and actions she hardly recognized. Our hard-working, happy daughter was sleeping through class, suffering from dyslexia, had short-term memory problems and was feeling angry, frightened and depressed.

During that year, I, too, did not feel right. I just wasn’t myself. I grew increasingly fatigued, foggy, impatient and disoriented. Joints began hurting until I could no longer move my neck. I felt as though my body had short-circuited. By day’s end, I could barely make dinner, often too tired to even change clothes before crawling into bed.

Trips to the doctor brought little relief, simply the diagnoses of early menopause and early arthritis, neither of which runs in my family and no tests were run to confirm either condition. I was given muscle relaxers for my neck and told to
accept the fact that we're all getting older. I was 45.

Lyme Disease was not considered for either of us until Shannon returned home from college and simply couldn't get out of bed. A full battery of blood tests finally included Lyme and it was positive. Shannon was put on one month of Doxycycline and a month of Sephtin.

When I woke a few mornings later than Shannon's diagnosis and felt my body frozen stiff, I realized I, too, might have Lyme Disease and requested testing. Once again the results were positive. I received four weeks of Doxycycline.

At the end of Shannon's course of antibiotics, both our primary doctor and a specialist confirmed that she should now stop taking antibiotics and see a psychiatrist. A second opinion -- I'm sorry. And at the end of my four weeks of oral antibiotics, I was told I had received all the antibiotics necessary. If I wanted additional treatment, I should go find a Lyme
doctor. Unbelievably, they could not provide a referral.

On the advice of a neighbor whose five family members were all suffering from Lyme, I took Shannon to see Dr. Jones, a Lyme pediatrician, and he treated her for two years. Gradually, she regained her memory, energy and personality and has now been symptom-free for another two years. She has suffered no ill effects from her antibiotic care, only relief from the horror of this disease. She is one of the fortunate ones completing college and now on to graduate school.

The search for my own cure was more daunting because I attempted to stay within the list of doctors my health care plan allowed. Months went by before I was able to restart treatment and even then it was minimal. Although I was so disoriented I could not drive myself to appointments, sat crying uncontrollably in the waiting room and was still plagued by fatigue, no mention was ever made of neurological testing or IV
antibiotics. There seemed to be no urgency in
dealing with my condition.

When I was told once more to relax
and accept that I was getting older, I chose to
change course and find a Lyme doctor. I was very
relieved to be finally under the care of Dr. Steven
Phillips and Dr. Amiram Katz and have my disease
taken seriously.

When my middle daughter, Katie,
who is with me here today, awoke in August 2002 with
a high fever, stiff neck and facial numbness, we
couldn't believe we might be facing another battle
with Lyme. Despite our recent history, doctors
assured us, based on a negative Lyme test and
negative spinal fluid, that this was a virus.

Through September, as Katie began
her senior year of high school, she developed severe
gastrointestinal and menstrual problems and, for the
first time ever, school work became a struggle.

Fatigue set in with a fogginess she could not shake.

We found ourselves caught up in addressing
individual symptoms, a time-consuming and exhausting process, that failed to address the cause of these maladies.

By November, she was close to failing her classes. We returned to doctor, convinced it was Lyme, and requested both an ELISA and a Western Blot. And the results were positive. The doctor felt it was a false positive, but was willing to treat her because we felt so strongly about it.

We sought neurological testing to help determine the extent of Katie's impairment. But, by the time our insurer approved, Katie was hospitalized with depression. In order to complete her senior year, Katie moved to Ridgefield's Alternative High School where we once again -- and we once again turned to Dr. Jones for help.

Katie began a course of IV Claforan in April 2003. We began to see progress and felt our daughter was returning to us. Four weeks later, despite the recommendations of Dr.
Jones, neurologist, Dr. Amiram Katz and neuropsychologist, Miriam Rizzenburg, who had all evaluated Katie, United Health Care denied coverage for continued IV, stating that it is an unproven treatment. As our health care plan is purchased in New York from a self-insured company, we unfortunately had no recourse. And the responsibility has fallen on us to provide peer-reviewed medical literature demonstrating the benefits of long-term antibiotic care which we had not been able to do.

The insurance company told me that they are not telling us what course of treatment is best but simply that they're not going to pay for it. Based on our doctors' recommendations, we continued Katie on IV antibiotics, paying ourselves, until she left for UConn in August 2003.

A tearful phone call home four weeks later brought the news that we had dreaded. Her symptoms had returned. And if time permits, Katie will tell you what it is like to be a college
student trying to do an IV in your dorm room.

A switch to --

MR. RYAN: Time.

MS. JENNIFER REID: --

(indiscernible) improved cognitive functions but
gall bladder problems that required surgery. Katie
has since withdrawn from college in the best
interest of her health. We have lost our tuition
and our board monies, as well as now spent
$10,000.00 on IV treatment in 2003.

Gratefully, my husband has
remained healthy, allowing us to pay for the
specialists and medications that best fight this
terrifying disease. We have seen over 20 doctors in
this five-year battle.

I am here today asking that
Connecticut take the lead for this disease is
discovered and lead our nation in eradicating this
nightmare from our lives.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.
(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Katie, we'd certainly like to hear from you.

MS. JENNIFER REID: Sure.

MS. KATHERINE REID: I don't really want to be here today. I want to be in college. I want to be attending lectures, going to libraries and even eating that notorious dining hall food. But for the past three years, nothing in my life has gone how I've planned it, especially when you think about everything I've had to compromise for this illness, but even more frustrating to think that maybe it's not over.

All I want is to wake up one day feeling like I used to. But it's hard to have hope as the months go on that that will ever happen. I don't have the time or energy to go through every symptom, doctor, medicine and experience that I've had. But I'd like to point out a few key ones that show just how devastating this illness can be on a young person's life.
As my struggle with the illness really climaxed my senior year, I went from being an athlete who easily ran six miles at a time to a person who not only didn't have the energy to participate in any sports or clubs but who could barely make it in to school before lunch. But that only meant physically making it in to the building. I couldn't handle the work any more.

I couldn't memorize, I had no concentration and felt so foggy that I often described it as living in a cloud. I went from having a 4.0 GPA to barely passing any of my classes, even the electives.

Feelings of depression mounted as the months went by. I honestly thought I was going crazy. I didn't want to be near anyone, my family, my close friends. I wanted to be alone all the time. I was paranoid, hostile and making rash, irresponsible decisions almost every day.

I never did take my mid-terms. A good thing, because I didn't remember any of the
information. But a bad thing, because I spent that week in the hospital, the results of a rash decision I've regretted ever since but honestly thought at the time was a good solution to my emotional and physical pain.

When I went back to school, we sat down with some administrators to discuss my new educational needs. This was the first time in my 13 years of being in that school system that I ever needed any assistance. The accommodations they made were to send me to the Alternative High School. I didn't get to finish my senior year or participate in any of the senior activities with my friends. Instead, I was put into a building, although filled with kind people, where I was asked to deal with situations and personalities that I had never been exposed to before.

When I spoke at that graduation, I honestly thought I was over the hardest part of my battle with Lyme Disease. I had only the most minor setbacks over the summer and began college at UConn...
very excited. My IV had just been removed because of an infection. But, regardless, I was actually feeling good.

That elation only lasted a few weeks before I found all of my old symptoms had returned despite taking my oral antibiotics religiously. I had a mid-line put in, then a pick line. I had my semester interrupted as I had to go home every weekend for various doctor appointments. Still, I worked so hard in my classes because I wanted to be there so badly. I studied all the time and was able to keep myself in the top five percent of my classes, even in the Honors Program.

The week prior to finals, terrible chest pains landed me in the hospital where I was treated with Morphine and dismissed as suffering from anxiety. It was actually my gall bladder filled with stones. I didn't get to take those finals and consequently lost all of my credits from the semester. I remember thinking to myself that it just wasn't fair. My school work had been the only
thing that was important to me there. I didn't party. I didn't drink. I didn't do drugs. I barely had time to socialize at all. I deserved those credits.

I also felt terrible that the money paid for that semester was lost. My parents have never been anything but supportive of my treatment. But I have been carrying around my own burden about the financial stress my being sick has caused my family.

I could go on forever telling you about my experience. Sometimes it overloads my own mind to look back at every area of life this illness has had an impact on. I mean not one week has gone by where I haven't been to at least two or three doctors, had some sort of procedure completed, taken three medications and been inhibited from physical and cognitive activities.

And I am only one case. There are three others in my family, ten in a group Dr. Katz has organized for teens struggling with this and
thousands more in the state. I know there are so many people who have it worse than I do. And that frightens me so much. I'm scared now dealing with this and scared about being here in the future after I've recovered. I want to move to somewhere far away from here where I can get better and never get this again. I want to move to a place where I can pet animals, go for a hike, go camping, lay down on fresh grass and not get sick from it. I want to swim without a rubber arm for my IV, read books and remember how the sentences ended and began, take walks without being instantly winded. I want my life back.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Tammy Szcepanski?

MS. TAMMY SZCEPANSKI: It pains me today when I think of how I used to be and I think of how many others really have Lyme Disease but are
being treated for Multiple Sclerosis. Think about it. No one what MS is caused from. So why treat with steroids in case it is Lyme?

In 1987, when I was pregnant with my daughter, I had a rash on my stomach. The doctor said it looked like some form of shingles. But it didn't hurt. Jacqueline was born a beautiful, healthy girl. During the next two and a half months, we noticed her eyes did not seem to focus. Her legs would turn purplish in color and one time her leg swelled three times its normal size. On June 6, 1988, she passed away from Sudden Infant Death Syndrome.

When I was pregnant with my son, I started having debilitating fatigue. But I was told this was because I was pregnant. After he was born, the fatigue was still there. But now this was due to depression because of the loss of my daughter.

In 1990, I went to the emergency room because I was vomiting, lightheaded and had pains in my stomach. I was told I had a viral
infection. I started having nausea, pain in my left ear and the fatigue was still present.

On October 31, 1992, I had to leave work because I was vomiting, had lightheadedness and I was off-balance with my walking. My mother brought me to the emergency room. When we got there, the nurse replied, "She looks like she's having a stroke." The physicians did blood work and checked me out. I was lying on a stretcher when they told me I could go home and sleep. I had my eyes closed because the light hurt my eyes. My friend had to help me get dressed because I was so sick I couldn't do it myself. My mother replied, "You're still so sick. What did they say is wrong with you?" An ear infection. I'd be better in a couple of days.

Over the next few days, my symptoms would get worse. The room felt like it was spinning and I was vomiting profusely and half my face went numb and I could barely walk. I had a CAT scan and MRI and would see a neurologist. I was
admitted to the hospital on November 4 and had blood work drawn and was started on steroids. My PCP would come in and tell me he had bad news for me. He said, "You had Lyme Disease at one time and that you do not have it any more." He proceeded to tell me that I had Multiple Sclerosis and life as I knew it before would no longer be like that.

One has to remember, I was never treated for Lyme Disease. So how did it go away?

During my stay in the hospital, I went down in the wheelchair and my neurologist said, "This girl has MS" and showed them my MRI so the class could see what a brain looks like that has MS.

When I got out of the hospital, I asked my PCP if I could have Lyme and he said no. Over the next month, I would have profuse vomiting again. Diarrhea and debilitating fatigue was still present. I would see my PCP. But I was told I had the flu now because of my weak immune system from the MS.

I saw my neurologist and asked
about Lyme and was told that Lyme does not cause lesions in your brain. It stayed as MS when we did not know what else it can be. So I believed him.

Over the years, I would question if Lyme Disease was a possibility because I was always so sick. In 1998, I started taking the ABC drugs because I was so bad. I walked like I was drunk all the time, had muscle spasms, nausea, pain that would come and go, memory problems, debilitating fatigue where getting dressed would take all my energy for the whole day. There were so many symptoms I had. I was so debilitated that I could not function. My life was an existence.

Over the years, I have had steroids intravenously eight times, been on over 50 different medications for my so many different ailments, took a shot for my secondary progressive MS, which eventually would turn into primary progressive MS, and even had Novantrone, which is a form of chemo, for my MS, just hoping it would help my symptoms get better.
Once I had the chemo, I started experiencing pain all my body. My nausea was 24/7. The light hurt my eyes. If someone hugged me, my whole body would hurt. Clothes bothered my skin. My skin felt like I had bugs crawling in it. And I had to use the walls or someone to hold onto to walk. I really believed I was dying.

There was no quality to my life at all. The fatigue was never relieved. My husband and I went through my medical records from the hospital I received care at. We found a positive test for Lyme Disease. I brought it to my PCP. He said, "Yes. The blood test was positive. And that's why we did the spinal tap." All those years I was told nothing showed for Lyme and now he tells me that something did.

My doctor thought that maybe I could have fibromyalgia now on top of my primary progressive MS. I wanted to see an infectious disease doctor in Bristol, but he said, "No, because he will say you have Lyme Disease and put you on
medication you do not need." He told me I could see a good friend of his who was an infectious disease doctor.

When we were waiting in the room, he came in and he said that he had just gotten off the phone with my doctor. I showed him my symptom list and he said, "That doesn't mean anything." I told him about all my pain and the rash when I was pregnant, that I went camping and showed him the test I found and asked if I could have Lyme Disease. He said no, that "You might have fibromyalgia on top of your Multiple Sclerosis."

I was so sick I truly believed I was dying a slow and painful death. And I was just getting worse and worse. I looked to a higher power because I believed no human could help me. Over the years, I had seen five neurologists and two infectious disease doctors and they all said it was MS.

Finally, out of desperation, I would bring my records to a doctor in New Jersey. I
wanted the pain to go away and someone to just help
me. He looked at my records, did blood work and he
was the first doctor to say, "You have chronic Lyme
disease". And I was started on antibiotics. "And I
believe you have had it for several years."

My test came back positive by the
CDC criteria. Over the next couple of months, my
family and I would notice improvement. I got a
lawyer and he would subpoena my records from all the
doctors and hospitals I saw over the years. I found
out last year from these records that my lawyer
subpoenaed that my ELISA was weakly positive,
Western Blot was equivocal and I found a Lyme
disease discharge paper, a paper that says CSF
positive and a paper the nurse wrote indicating that
I had presented with symptoms of Lyme disease way
back in '92. I never saw any of these papers until
I had a lawyer.

I have improved tremendously from
where I was two years ago. I have been off all my
MS medications for over two years now. My new
doctor in Boston was the first doctor to ever order
a brain spec scan which shows prior focal
encephalitis and lack of profusion --

MR. RYAN: Time.

MS. SZCEPANSKI: -- in certain
areas of my brain. I just had another brain spec
scan done which shows improvement.

I have started school part-time to
try to find myself. I am angry when I think of what
I have lived through and do not understand why most
doctors in the state do not realize the reality of
Lyme Disease. Lyme Disease can mimic MS and can be
treated more effectively than MS. This is not being
taught in our medical schools. I do not understand
why doctors do not realize that Lyme is a real and
complex disease that can mimic many disorders.

We really have no conception as to
the true magnitude of the Lyme Disease epidemic.

Untold numbers of Lyme patients are being labeled
with other diseases. Why are so many people being
diagnosed with Multiple Sclerosis? My story is not
unique. This is happening everywhere.

So far I've helped several others who were treated for MS only to find out that they have had Lyme all along. It appears that our state is becoming progressively disabled. This puts an enormous drain on the economy. It would seem that investigation into an accurate diagnosis and treatment of Lyme Disease should be one of Connecticut's top priorities.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Christopher Montes.

MR. CHRISTOPHER MONTES: Attorney General Blumenthal, Commissioner Galvin and esteemed elected officials, thank you for the opportunity to speak at today's hearing. Five years ago, I stood in this building with an IV shunt in my arm. And it's my fifth year of treatment for Lyme Disease. Five years ago, I was still suffering with symptoms that inundated every day of my life, making even the simplest of tasks seem insurmountable.
Five years ago, it was uncertain as to what the prognosis of my illness would be. I felt I had a death sentence. All I could do was to continue to hope and pray that one day I would be well enough to care for my wife and two children. And, in part as a result of the hearing on Lyme Disease in 1999, with your help, Mr. Attorney General, and by the grace of God, I was able to continue my antibiotic regimen without fear of my insurance company once again denying payment for treatment.

Now, two and a half years after my last antibiotic infusion, I believe I have finally beaten this disease. I must, therefore, thank my doctors not only for their willingness to treat me but for their courage to stand up for what is right in the face of controversy.

You've heard some very compelling testimonies and, no doubt, are wondering how our medical community, touted as the best in the world, could allow what has happened to occur. Indeed, the
question must be asked, "How is it that patients
could become so ill and be misdiagnosed for so long?
How is it that even after adequate antibiotic
treatment these people can still be infected to the
point that active spirochetes are found in their
bodies?"

"Why are there so few physicians
who know how to properly diagnose this disease? Why
haven't our medical schools taught students that
Lyme Disease can quite often be recalcitrant,
difficult?"

The science is there, as I believe
you will see later on today during the physicians
panel. However, we must depolarize the medical
community regarding Lyme Disease and accept the
truth of the matter.

My hope is that the State of
Connecticut will make Lyme Disease a true priority.
It is, without doubt, a major health threat that has
robbed thousands of individuals of their inherent
right to live a normal life. I believe the time has
come for our State leaders to make serious
commitments to appropriate surveillance, including
laboratory reporting, prevention, teaching its
physicians about diagnosis and treatment and even
additional promising modes of disease intervention.

Last year, in Connecticut alone,
Lyme Disease dwarfed West Nile Virus in terms of
cases by a ratio of 40,000 to 12. Yet, where were
our prevention efforts focused? Of those 40,000
cases, it is estimated that at least ten percent
remain chronic, requiring ongoing or multiple
regiments of antibiotic treatment.

Does it not make sense simply from
an epidemiological viewpoint to focus on preventing
these infections based on the rate of incidence?
True, it may be said that the State of Connecticut
has prevented the spread of West Nile Virus. And
that is admirable. However, we know for certain
that Lyme Disease and other tick-borne illnesses are
pandemic throughout our state. Yet, little has been
done to stem the tide of infection.
Moreover, from an academic standpoint, the University of Connecticut School of Medicine has a unique opportunity concerning diagnosis and treatment of Lyme Disease. Indeed, it is also -- it also has a responsibility to impart accurate information to students seeking a degree in medicine.

The proof of persistent infection has reached the tipping point in the medical community. And our state's medical teaching institution now has a choice before it. The first choice is to continue with its current methodology of teaching the diagnosis and treatment of Lyme Disease. That is using textbooks and other teaching instruments that still, for example, indicate that "The disease is, more often than not, present with a bull's eye rash." It doesn't. "It will usually be picked up through serologic testing." It isn't. "It should be diagnosed using the CDC's reporting criteria." It shouldn't. "It's mainly rheumatological." It isn't. "And requires, at most,
a three-week course of antibiotics as the cure." It doesn't, especially when the patient has been infected long-term.

Conversely, the medical school can now turn from its now-outdated stance, paying particular attention to the science of persistence, co-infections and the required treatment thereof. We have reached a place where the light has shown on Lyme Disease and revealed an insidious illness no longer to be associated with a summer flu-like benignity but, rather, much more. It is time for the UConn Medical School to embrace and teach this reality.

As a municipality official overseeing a department that provides mental health services for children and families, as well as case management and advocacy for persons with disabilities, I've witnessed patients with Lyme Disease not being able to access medical treatment. Many of these individuals often lose their jobs as a result of their result and must take State
Assistance or Medicare just to survive.

The only problem is there are no physicians I am aware of who are knowledgeable in Lyme Disease that take Title XIX or Medicare assignment. The same can also be said for our state's children on the HUSKY Program.

Concomitantly, these patients have been turned away by the mainstream physicians because Lyme Disease is, quote, too controversial. This has even happened when patients were referred to the local hospital's infectious disease specialists. This is an outrage.

MR. RYAN: Time.

MR. MONTES: Additionally, even some once-active Lyme-knowledgeable physicians have now refrained from taking new Lyme Disease patients for fear of being turned in to the Department of Public Health for over-diagnosing and over-treating the disease. However, to date, I am aware of no medical misdeeds of any physicians treating Lyme Disease. And those who have been reported as such
have been exonerated by the Department.

Still, patients have very few choices for diagnosis and treatment of the disease. All this in the country's most endemic state. There is certainly something wrong that needs to be righted.

I am, therefore, asking that a joint effort between the Office of the Attorney General and the Department of Public Health, an officially appointed committee of Lyme-knowledgeable physicians, State Agricultural Testing Station representatives, patients, lawmakers and members of advocacy groups convene to provide recommendations to the State of Connecticut regarding the status of Lyme Disease and other tick-borne infections.

Furthermore, I request that these recommendations be formalized by report and considered for action by the State of Connecticut.

Moreover, this committee would be ongoing and, thus, respondent to the changes that occur in the spread of the disease, its prevention,
diagnosis and treatment. Thereby, true progress can be made concerning this issue and, as such, ultimately benefit the citizens of Connecticut.

Thank you again for this opportunity.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Again, I gather that none of you recalls actually being bitten by a tick. And you, Ms. Szcepanski, recall a rash?

MS. SZCEPANSKI: I had a rash. They said it looked like some form of shingles. But it didn't hurt. I found out shingles hurts. I didn't know that.

ATTORNEY GENERAL BLUMENTHAL: So it was -- was it or was it not a bull's eye --

MS. SZCEPANSKI: No, it was not a bull's eye. No.

ATTORNEY GENERAL BLUMENTHAL:

Okay. So none of you had that rash that was ordinarily -- that is ordinarily associated with
diagnosing the disease.

MS. SZCEPANSKI: No.

ATTORNEY GENERAL BLUMENTHAL: And as I think was demonstrated pretty dramatically during what each of you said, you all encountered misdiagnoses in the course of your complaints and very radical delays in treatment as a result of that misdiagnosis.

We're going to move now to the scientific part of today's program --

MS. SZCEPANSKI: Okay.

ATTORNEY GENERAL BLUMENTHAL: -- for today's hearing. But let me just say --

MR. MONTES: Excuse me.

ATTORNEY GENERAL BLUMENTHAL: Let me just say, first of all, before Dr. Galvin -- before you leave and before Dr. Galvin has something to say, that I again want to thank every one of the patients, every one of the citizens who are here today. Mr. Montes mentioned again the hearing that we had five years ago. Many of you have been
working on this problem for five years or longer, as
I have been. And your perseverance, your thought, I
would say, and your help to others has made an
enormous difference. This fight is a scientific
one, but it's also a human struggle. And so the
work done by the Greater Hartford Lyme Disease
Support and Action Group has been instrumental. And
many of you on an individual basis have helped your
fellow citizens, fellow patients, in ways that I'm
sure are profoundly meaningful. So I want to thank
you for that work as well.

Dr. Galvin?

COMMISSIONER GALVIN: Yeah. I
wanted to ask Mr. Montes a couple of questions. And
then I had a comment.

If I understood your remarks
correctly, you feel that there are a group of people
with Lyme-related diseases who are unable to access
physicians because of payment issues?

MR. MONTES: Yes, sir.

COMMISSIONER GALVIN: Okay. I
would like to more about that. And I would like to
know about that as, specifically in a state of this
affluence, no one should be denied access to medical
care.

I think if I heard you correctly,
you had the opinion that most of the current tests
are not acceptable for diagnosing Lyme and we need
new testing? Is that what you're saying?

MR. MONTES: I don't believe I
said that, sir.

COMMISSIONER GALVIN: Well, I
thought you made remarks that the -- that some of
the blood tests weren't any good and -- I'm not sure
what you meant. So I probably didn't understand
your remarks. And perhaps you can say them again.

MR. MONTES: I think I said that
"It will usually be picked up through serologic
testing." And then said it isn't. Meaning that
more often than not, patients who are -- who do
have, indeed, Lyme Disease upon first being tested
do not test positive.
COMMISSIONER GALVIN: So are you saying that when they're first tested, the test is not positive because it isn't for several days or are you saying that the test is incorrect more often than not?

MR. MONTES: I can't be sure of that. But I can tell you from personal experience that I never tested positive until after I was off of antibiotics. Now I do show having an old infection. I never had an active infection show.

COMMISSIONER GALVIN: I understand that. I believe that you understand that the chap who came in my office on the 26th of November would not be -- in all likelihood, not be positive at that time because the tick hadn't been attached to him that long.

MR. MONTES: Yes.

COMMISSIONER GALVIN: And so if we take everybody who comes in with tick attached and test them at that time, most of them will be negative because the tick -- they haven't had time
enough to develop lab tests. So I think we need to
be clear about whether we're -- when we say some of
the -- a majority of the tests are negative, are we
talking about first run right after the bite or are
we talking about a long-term thing?

One of my regulators is here,

Wendy Furness, who runs the part of our Department
that investigates complaints. And I want the
audience to know that we are required to investigate
all complaints. Some of the complaints we get are
from the general public and some of them are from
other physicians who object to different types of
treatment.

We have no rule about what
treatment is correct or best in terms of the
complaints we get. I realize that there are a
variety of ways that physicians can look at cases.
So Ms. Furness I think will support me when I say
that we have no rules about how long you can treat
Lyme Disease, which antibiotics, which route or the
like. We --
But I want you to know, sir, that we are required, if somebody complains or a group of physicians complain about another physician, we have to open the complaint. We're required to do that.

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Again, I thank you for being here.

I should mention, if I didn't at the outset, that we're making a transcript. There will be a record of this hearing. And it will be made available to anyone who wants it.

In addition, we hope that perhaps we can consider the kind of suggestion you've made, Mr. Montes, about a task force or a committee that will make specific recommendations. But we'll certainly want to talk to you some more about that.

MR. MONTES: Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

Thank you very much.
I'm going to now ask the scientific panel to come forward. We're going to begin with Dr. Tilton, Dr. Kelley, Katherine Kelley, Richard Tilton. I understand Sam Donta is not here? He couldn't be here. Dr. Robert Levitz and Dr. Steven Phillips.

(Off the record)

ATTORNEY GENERAL BLUMENTHAL: If I could have your attention? If I could ask you to come to order please? Thank you. Thank you. We're going to proceed now with the scientific, the physician and laboratory panel, which consists of five -- which consists of ten individuals. We're going to divide them into groups of five.

I want to announce first that we have been joined by Representative Claire Janowski of Vernon. She's here. If you could raise your hand?

And, also, Senator McKinney of Fairfield. Where is John McKinney?

And, of course, Dolly Powers is
still here. Anyone else from the legislature still here? Representative Powers. Anyone else?

I also have been asked -- and, obviously, we have an overflow crowd. So this -- this question won't necessarily elicit an answer from everyone. But someone suggested -- I think it's a good idea -- if we could have a show of hands from everyone who has been diagnosed with Lyme Disease but did not have the bull's eye rash? If you could raise your hand? So I don't know whether we can get that on CTN or -- so we have it. Hold your hand up for just a moment.

Maybe you could pan the audience, whoever is doing CTN. Thank you.

Thank you very much. So that's a -- for the record, that is a very overwhelming show of hands, I would say. Probably about as accurate, more accurate than some of the polls we've been seeing from the primary states lately. So thank you.

I would like to introduce the
first panel that is, I believe, seated before me. And then we're going to have a second panel. And the objective here as much as anything else is to have an exchange among the docs and the experts that we have here this morning. Somebody -- I was asked, "Are you presenting only one side of this issue?" And our goal is to present as many sides as possible and produce a hearing that is truly fair and balanced. And I want to thank again our expert panel for being here this morning.

We're going to hear first from Drs. Zemel, Levitz, Phillips, Fallon and Tilton. And why don't we go in that order, if that's okay with all of you?

DR. LAWRENCE ZEMEL: Attorney General Blumenthal, Dr. Galvin and members of the audience, I am a professor of pediatrics at the University of Connecticut School of Medicine and Chief of the Division of Pediatric Rheumatology at Connecticut Children's Medical Center. I've been practicing medicine in Connecticut for nearly 27
years and have had extensive experience in
diagnosing and treating Lyme Disease in children.

I have three points to make today
at this public forum. Firstly, while I applaud
efforts to engage the public in major public health
issues, the medical and scientific aspects of this
complex disorder are best left to those forums which
traditionally discuss science, such as scientific
meetings, collaborative research and peer-reviewed
reputable journals.

My second point addresses the
diagnosis of Lyme Disease. The case definition of
Lyme Disease has been established by the CDC and
Association of State and Territorial Public Health
Laboratory Directors and forms the framework for
diagnosing Lyme Disease.

While I do not always rigidly
adhere to these criteria, I am concerned about gross
deviations which contribute to the over-diagnosis of
Lyme Disease. One of these misconceptions is the
concept of sero-negative Lyme Disease.
Sero-negative Lyme where antibodies are not detectable may be seen in early Lyme Disease. But in those patients, clinical features such as the telltale rash often allow for the diagnosis. Rarely, patients with later Lyme Disease who earlier had developed erythema migrans may be sero-negative.

There is a very slippery slope when people with non-specific complaints, such as fatigue and pain, who test negative for Lyme antibodies are nevertheless diagnosed with Lyme Disease by a small group of physicians.

I've seen many children and adolescents who were mistakenly diagnosed as having Lyme Disease and appropriate therapies for their true underlying disorder were delayed. One such child was JD, a seven-year-old who enjoyed soccer and video games. He started to complain of back and hip pain. His mother went on one of the popular Lyme websites and found that these are common Lyme symptoms.
He went to his pediatrician to be tested. And the pediatrician ran the standard ELISA and Western Blot line mass aids, which were negative, and then referred the child to me. My exam suggested that there was bone disease rather than arthritis. I repeated the Lyme tests at mother's request. These again were negative. And found that he was anemic. I ordered a bone scan, but the family cancelled that study and sought an opinion from a physician in New Haven.

He diagnosed sero-negative Lyme Disease and treated the child for the next three months with two different antibiotics. When JD deteriorated, with weight loss, pallor and increasing pain, he came back to see me. I made sure a bone scan was performed immediately. Multiple areas of bone lit up and a bone marrow aspiration confirmed the diagnosis of acute lymphocytic leukemia. Fortunately for JD, he is now doing well.

This is but one dramatic example of some of the kids I'm seeing who are misdiagnosed.
Other examples have included rheumatoid arthritis, fibromyalgia, chronic fatigue syndrome and ankylosing spondylitis and others.

Even some of the testimony heard today may be confusing.

Some of the more popular websites contribute to this misinformation by including a long list of symptoms which have nothing to do with Lyme Disease. For example, the Lyme primer on the website of the Lyme Disease Association includes constipation and weight gain as Lyme symptoms.

Diagnosis may not only be missed clinically, but different lab techniques may contribute to the confusion. A case in point is a California lab, Igenex. A few Connecticut physicians prefer this lab over such referenced labs as Yale and UConn. Igenex's urine antigen assay has
confirmed the diagnosis of Lyme Disease in a number of their patients despite negative testing elsewhere.

A 2001 report in the American Journal of Medicine concluded that this assay was useless since samples of urine submitted from healthy controls were just as likely to be abnormal as normal. In fact, samples from each control were split into five aliquots. And even these results varied.

Another report claimed to culture Borrelia from patients with chronic Lyme Disease. These patients were mostly sero-negative or had only IGM antibodies, not a reliable marker for chronic Lyme Disease, and their diagnosis was made on clinical grounds. One of the study patients was a child who I diagnosed with classic systemic juvenile rheumatoid arthritis. Needless to say, this data has never been replicated.

My last point is that as physicians we took an oath to do no harm. The New
York Times in an Editorial two years ago expressed concern about the overuse of antibiotics and the development of resistant organisms. Quote, "Drug resistance has soared because antibiotics are over-prescribed", end quote, claimed the Times.

Additionally, antibiotic use has been associated with low white blood counts, catheter infections, gall bladder surgery, colitis and even death.

There are guidelines for the duration of therapy for established Lyme Disease. And the same dangers exist for overextending this treatment. Although, I personally have had to use several courses of IV antibiotics in a few children with resistant neurologic disease.

Some of the late symptoms attributed to Lyme Disease may have immunologic mechanisms, including resistant arthritis and some encephalopathic or brain symptoms, and may no longer require antibiotic therapy.

A 2001 study in the New England
Journal of Medicine concluded that chronic Lyme symptoms were no more likely to respond to 90 days of antibiotics than placebo. For those advocating longer than standard therapy, we need more data.

In response to Mr. Montes' articulate remarks earlier, there has never been a child on Title XIX or Medicaid who was denied care at Connecticut Children's Medical Center.

I conclude with my second and third points. Let's not ignore the science. And let us do no harm.

Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Dr. Levitz?

DR. ROBERT LEVITZ: Yes. Hi. I'm Assistant Director of Infectious Disease at Hartford Hospital. And I've been in the practice of infectious disease here in Connecticut for over 20
years. I've seen hundreds of patients with Lyme Disease. And I do general practice of infectious disease, which includes AIDS, hospital infections, surgical infections, et cetera.

Actually, I think my secretary -- I don't know if we can strike words from the record after I say them. But I do take Medicaid and Medicare assignments again for patients with Lyme. But my secretary is going to kill me for mentioning that publicly, with all the phones lighting up. So there are physicians who indeed do see patients on just Medicaid or Medicare assignment.

I would like to bring up that -- we only have ten minutes allotted. But, yes, I've seen a number of patients who have misdiagnosed Lyme, including with advanced neurologic disease. I've seen patient's who had Bell's Palsy that wasn't picked up and later had cardiac arrhythmias. We haven't heard a lot about the cardiac effects from Lyme Disease.

But I'd like to talk in this
meeting when we talk about diagnosis and therapy and symptoms about one of the problems that I see in the community and the differentiating of the Lyme specialists, the infectious disease specialists and actually criticism for a lot of what we all do in our care. I also would like to bring up a few quick cases.

TK is a 16-year-old who saw me almost exactly four years ago in my office. And the reason she saw me was that in 1998, she had had difficulty concentrating at school, very similar to some of the stories you heard, missing lots of time from school, also general aches and pains in her joints.

This went on actually for several years. Finally, a Lyme serology was done which had a positive ELISA but negative Western Blot. She was begun on Amoxicillin by her physician, then Zithromax and then Sephtin, but no improvement in these symptoms. Still missing a lot of time from school. The main symptom being cognitive.
She was seen by a physician specializing in Lyme in Westchester and placed on IV Septra Zone, two grams a day. She was in her sixth week of continuing therapy with no improvement in her cognitive symptoms, still home from high school, when she was referred to see me because of a rash that developed on her body actually emanating from the IV site, most likely an allergic reaction to her Septra Zone.

When I saw her and took a history, her mom said, "Actually, she had something similar to this, difficulties in school, when she was eight years old, when she was diagnosed with profound hypothyroidism. In fact, was on Thyroid to that day. We did a fairly complete work-up. One of the things it included was a B-12 level, which was low. In fact, her whole family -- it turned out her sister and her mom were B-12 deficient. She received no further antibiotics. She did receive B-12 supplementation. I spoke to her a week ago and she's an honor student at the University of
Connecticut, has had no further symptoms, required no other antibiotics.

My partner, Dr. Brian Cooper, head of our department, had a patient sero-negative for Lyme but diffuse severe arthralgia and severe fatigue going on years, was seen by a physician for Lyme Disease and was given intramuscular shots of Penicillin on a weekly basis for treatment of perhaps sero-negative Lyme. This went on for several years before seeing my partner in consultation, who noted some elevation of liver function tests.

Serologic testing for Hepatitis C was positive, another unfortunately common disease in this state. And the antibiotics were discontinued and treatment for Hepatitis C was begun, which was does present with fatigue.

And I've had personally numerous patients who thought they might have Lyme come in with Hepatitis fatigue, with these joint pains from antigen antibody complexes. And they do respond
actually to the Interferon and Riboviron treatment.

If this sounds like there are cases I'm saying that are overdiagnosed as well, I think there's a lot of fault with the infectious disease community as well rather than just say "Well, some people with Lyme Disease -- Lyme specialists are just treating everybody as Lyme no matter what they have."

I saw a patient just a few months ago who was seen by a very prominent infectious disease physician in the Northeast here for a question of Lyme Disease, a very active, 66-year-old man who complained of cognitive deficits and joint pain, strange pains in his body, and was seen and evaluated and, as you've heard from the testimony this morning, told "You don't have anything. You don't have Lyme Disease. And basically, get out of my office." And I think this is a major problem with a lot of my colleagues, actually, in the community.

He came to see me because he still
had all the symptoms he had when he went to the
other infectious disease physician and was told he
didn't have Lyme Disease, but nothing further was
done.

Again, this 66-year-old had a
Vitamin B-12 level of 120, a normal hematocrit. We
may hear more -- I hate even commenting on this with
the neurologists here. But may talk about this more
in the future. But it's actually underdiagnosed.

It's not my field of specialty. But in my complete
work-up, I look for other diagnoses and things to
treat.

I can't say that he is all better
yet. We've just actually begun him on
supplementation. But we are seeing a lot of people
who I see all the time who come who are incompletely
worked up, not responding to antibiotics and may
have other diseases.

Several other things is what do
you do with these sero-negative patients who have
the symptoms -- and we've heard a lot about Lyme. I
actually just printed out from a website -- chronic, frequent headaches, numbness and tingling, dizziness, ringing in the ears, tremors, hands and feet, lower pain threshold, irritability, nervousness, shyness, loss of memory, inability to concentrate, mental confusion, mood changes, lack of interest, attention deficit syndrome and decline of intellect.

I printed this off the Web because a lot of my patients go to all the websites. This is not from the Lyme Disease Foundation site. This is from the Mercury Fillings Are Toxic site. The same exact list you'll find if you want to go to "The Yeast Connection", Dr. Crook's Website, and that is that yeast overgrowth in the bowel is causing these symptoms, you will find that same list.

That does not mean there isn't chronic Lyme. And I've treated advanced Lyme Disease with the mental fogginess, cognitive -- it really does exist. But you do have to be careful in
saying, "Well, this is unique to this disease"
because everybody is seizing on the same symptoms.
And, in fact, I've had referred to my office
patients seen by physicians claiming to specialize
in Lyme Disease who got no better on their IV
Rocephlan and then were told, "You know what? It's
that yeast overgrowth in your bowel. Look at all
the yeast you have in your bowel. If you look at
this site, you'll see that all your continuing
symptoms are from that." And then were on intensive
antifungal therapy. Finally coming to see me
because there hadn't been improvement when they did
that.

And another issue is -- and I
don't know if it's in existence. I haven't called
recently. Is that there are some people who take
advantage of very sick individuals. And that
includes some companies, IV companies. There was a
site, 1-800-TICK-BITE. I don't know if that number
still works. Was for an IV therapy company in New
Jersey. And if you called, you could arrange for IV
treatment for your Lyme.

I had my secretary call a few years ago and just claim chronic headaches. She was told to say nothing else. That's all she had was chronic headaches and that she had tested negative for Lyme Disease. The woman at the other end of the phone said, "It sure sounds like Lyme to me. And I can refer you to a physician for the IV therapy."

Personally -- this is over a decade ago -- I was offered -- we're in a touchy area of kickbacks and things these days in this state. But companies would offer me several hundred dollars a week per patient I referred for IV therapy. And the justification was "Well, you're going to be overseeing toxicity and any problems the patient has." This is in addition to any office visits or things of that sort.

So in the midst of all the true suffering, there are always people who are looking to profiteer or to do something about it. And, you know, I really do hope -- and I think one thing
everybody will agree with in here is that the Lyme testing has never been very good, that we do have to get better tests. It's very difficult to distinguish. And while there are false negatives, as was brought up, if you treat it very early or have early disease, there are also false positives. People come in with acute Hepatitis B, endocarditis, well-documented, who have just positive ELISAs, negative Western Blot test. It's an antibody like everything else and it cross-reacts with many things.

There was also some talk -- I'd like to point out, as was brought up, about the young child who had severe disabling disease, that the Lyme test remained positive. As I think most of the audience knows, even the most successfully treated person here were not expecting the serologic test for Lyme to turn negative. That's a body's antibody. That's a response. Just as my serologic test for measles is still positive because I got the measles antibody when I was a kid. That doesn't
mean I have measles. That we do serologic testing, most of it is antibody. The PCR tests, there are tests specifically for the bacteria, which are different.

But when you're a physician -- I get a lot of people who are worried only because their test is positive. They were successfully treated. They feel perfectly well. And they were worried because a year later they still have a positive antibody test. And I try to explain to them that it's the body's reaction. That doesn't prove that you still have Lyme Disease.

And that concludes my remarks.

Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you, Dr. Levitz.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: I appreciate those remarks. And I might just say so that everyone understands that we take action against the kind of abuse, scam, however you want to
describe it, that you just described. In fact, we
have some legal actions pending now against Internet
pharmacies that fail to require real diagnoses,
genuine diagnoses, before prescriptions are provided
through mail or other similar kinds of devices.

So I wouldn't want the record to
fail to show that we have -- that we don't take
action against those kinds of abuses. And I
encourage anyone who knows about them to let us
know.

The next person to talk to us, Dr.
Phillips? If you could go now? Thank you

DR. STEVEN PHILLIPS: Thank you

very much. I've been asked to comment specifically
on the persistence of Lyme bacteria in patients who
have been treated. Certainly, there are many
aspects of Lyme Disease which remain highly
controversial. And diagnosis and treatment are
among the top two.

The fact of the matter is that
many patients with Lyme Disease will relapse despite
antibiotic therapy. And some call this the
Post-Lyme Syndrome or post-Lyme fibromyalgia,
whereas others call this kind of nonsense and it's
just a continuation of the initial active Lyme
Disease.

A couple of very conservative
authors, including Drs. Steere and Sigal, have
evaluated patients with so-called post-Lyme
fibromyalgia. Their data was very interesting. But
their conclusions were surprising. They found that
with antibiotic therapy, the patients initially
worsened, then they improved and then, off
antibiotics, they relapsed again.

It should be noted that a
temporary worsening of symptoms with initial
antibiotic therapy is typical of active Lyme Disease
rather a post-infectious syndrome. This is
consistent with a Herxheimer reaction.

Their conclusion was that benefits
attributable to antibiotic therapy in these studies
were placebo effect. But it should also be noted
that these studies were not placebo controlled.

And, lastly, it should be noted that every one of
the primary symptoms associated with fibromyalgia is
also common in active Lyme Disease.

So it should come as no surprise
that B. Burgdorferi DNA has been detected actually
in the muscles of patients with so-called post-Lyme
fibromyalgia, demonstrating persistence of the
organism. And in animal models, despite 30 days of
Amoxicillin or Doxycycline, eradication of the
organism was not achieved. When they've expanded
these studies to include not only Amoxicillin and
Doxycycline but also Azithromycin and intravenous
Ceftriaxone at comparable human dosages for 30 days,
the same thing happened. The bacteria was not
eliminated from these animals. However, they did
note the episodes of acute arthritis or the swelling
did resolve.

In this study again by
conservative authors including Drs. Persing and
Steere, a full 30 percent of the patients remained
persistently PCR positive despite multiple courses
of, quote, unquote, adequate antibiotic therapy.

When I use the term "adequate" or "appropriate", I am specifically referring to
shorter courses of antibiotics, generally in the
four-week range.

Their conclusion was that Lyme arthritis that persists after antibiotic treatment
is due to persistence of the spirochete. In this study, a whopping 74 percent were still PCR positive
despite antibiotic therapy.

With most other infectious
diseases that I know of, PCR reactivity equates with
chronic infection. But Lyme has been held to this
higher standard, this other standard. So we'll go a step further.

Here we have human persistent
infection despite antibiotics proven by the presence
by the B. Burgdorferi. Here they found it in the
skin, despite extensive antibiotics in a
sero-negative patient. When I use the term
"extensive", I'm referring to more than four weeks of antibiotic therapy.

And here again they found it in the eye, despite intravenous antibiotics. And here found in the blood and spinal fluid of multiple patients who were both sero-negative and spinal fluid Lyme antibody negative.

Here they found it in the heart in a fatal case of Lyme Disease, from Lyme carditis, despite, quote, unquote, adequate antibiotic therapy, which was clearly inadequate in this case.

Here, despite several courses of adequate oral and intravenous antibiotics, this patient also succumbed to Lyme Disease. And her lymph nodes demonstrated B. Burgdorferi on autopsy.

Here they found it in the joints, despite, quote, adequate antibiotic therapy, both oral and intravenous, also by conservative authors, including Schoen and Steere.

Here again they found it in the spleen, despite intravenous antibiotics. And here
again in the joints, despite antibiotics. And here,
despite seven years of multiple trials of antibiotic
therapy, Lyme arthritis persisted and spirochetes
were documented in the synovium and synovial fluid.

So, with PCR data, with
histopathology specimens which demonstrate the
persistence of the organism, that should be enough
to prove chronic infection in chronic Lyme Disease
patients. But, again, Lyme has been held to this
other standard where isolation of the live bacteria
is what's been required.

And that's been accomplished, as
difficult as it has been to culture B. Burgdorferi
from patients with disseminated disease. Here they
cultured alive from the skin in early Lyme Disease,
which most people think is easily treatable. And
this was despite antibiotic therapy.

Here again cultured from the
synovial fluid, despite antibiotic therapy. Here
cultured alive from spinal fluid, despite
intravenous antibiotics, which clearly achieve high
levels of bacteriocidal antibiotic levels in the spinal fluid.

Here they have multiple cases presented whereby the bacteria was cultured alive from the eye and the spinal fluid, despite antibiotics, in sero-negative patients.

Here multiple cases were presented again. Another study. Despite antibiotic therapy, cultured alive from the skin and spinal fluid in sero-negative patients.

Here again cultured alive from the blood, despite extensive antibiotics in sero-negative patients. And here again cultured alive from the spinal fluid, despite antibiotics in sero-negative patients.

And I include this study because this patient was initially Lyme serology positive and then went negative, despite progression of the disease. And bacteria was cultured alive from the ligaments, despite oral and intravenous antibiotic therapy. And I use it as a stepping stone to say,
"Well, you know, how useful are serologies in following the progression or lack of progression of the disease?" They don't seem to be all that useful at all.

And in this study, again, conservative authors from Westchester found that 68 percent of patients became sero-negative after antibiotics, yet 62 percent of these patients were persistently symptomatic.

And here again multiple cases were presented. B. Burgdorferi cultured alive from the mitral valve of the heart, skin and joints, despite oral and intravenous antibiotics in sero-negative patients.

And here again cultured alive from 91 percent of patients, despite being sero-negative in 94 percent and despite having had six weeks minimum intravenous antibiotic therapy in all. So how does this affect, you know, treatment durations? Well, in this study, they found that after two months of treatment, roughly
one-third of the patients' conditions improved and after three months of treatment, almost two-thirds of the patients' conditions significantly improved.

The results here -- I quote. They say, "This supports the use of longer courses of treatment in the management of patients with chronic Lyme Disease."

In this study, they say that several aspects of late Borreliosis, meaning late Lyme, are false negative antibody testing and the need for prolonged antibiotic treatment in chronic or recurrent forms.

And here I present another unfortunate fatal case of Lyme Disease. And I present this one because it was expressed primarily by neuropsychiatric features with a progressive frontal lobe dementia. And here the authors stated that antibiotic treatment resulted in transient improvement but the patient relapsed after the antibiotics were stopped. And it's their conclusion that the Lyme Disease must be considered even in
cases with purely psychiatric presentation and prolonged antibiotic therapy may be necessary. So, having said all this, what's the true standard of care? In a Lyme endemic area, 78 physicians were anonymously surveyed and published in this peer-reviewed medical journal. And these were not Lyme doctors. They were general doctors. They found that 50 percent of the responders believed that 25 percent or more of patients who have Lyme Disease were sero-negative and that for post-erythema migrans Lyme Disease interpreted as acute disseminated Lyme 43 percent of the responders treat three months or more and for chronic Lyme Disease 57 percent of responders treated for three months or more. So the majority of general doctors in a Lyme endemic area in this published study were treating for more than three months for patients with chronic or refractory forms of Lyme Disease.

In summary, I'd say that there are numerous medical studies that demonstrate that
chronic Lyme is caused by chronic infection. Sero-negative Lyme Disease is common. And longer antibiotic treatment durations are more effective than shorter, although not necessarily curative. Post-Lyme Syndrome, post-Lyme fibromyalgia is really just persistence of the initial infection. It's an internally inconsistent, unscientific theory that should never have seen the light of day. And that curative therapies are needed for chronic Lyme. But this research is not really being done. And there is a denial of the high frequency and even the very existence of chronic Lyme Disease by many researchers.

And that concludes my ten-minute presentation. And if there's question-and-answer, I can address some of the other things that were said earlier.

ATTORNEY GENERAL BLUMENTHAL: I'm sure there will be.

DR. PHILLIPS: Okay.

(APPLAUSE)
COMMISSIONER GALVIN: With respect, I would like to make an observation that many of these papers are written by the same authors. And I would not like the lay people in the audience to get the impression that this is a series of perhaps two dozen papers written by two dozen different groups or individuals.

And I think you'll have to agree with me, sir, that many of the authors are the same in many of the papers.

DR. PHILLIPS: I actually would not agree. We can go over them right now. I don't agree. If you --

COMMISSIONER GALVIN: Well, I notice Dr. Danta's name is there several times. Let's -- let's go over the --

DR. PHILLIPS: Okay.

COMMISSIONER GALVIN: Perhaps I misread them.

DR. PHILLIPS: We have Nocton, Dresser, Steere, Persing. That's the first one.
Okay. Second one, we have Bayer, Zhang, Bayer.

That's the second one. Different, clearly. Here we have Liegner, Shapiro, Ramsay, Halperin. I mean -- okay. Clearly different. Meier, Blatz, Gau, Spencker, Wiedemann. All different authors.

Honegr, Hulinska, Dostal, Gebousky, Hankova, Horacek, Vysbuzil and Havlasova. Different authors.

I don't see actually one similarity yet, sir.

COMMISSIONER GALVIN: Why don't we go through the whole group?

DR. PHILLIPS: Yeah. Of course.

But you made a statement which I'm replying to.


COMMISSIONER GALVIN: I'd like to see the whole group.

DR. PHILLIPS: Okay. Hulinska --

COMMISSIONER GALVIN: Now,
Hulinska has appeared before.

DR. PHILLIPS: Yes.

COMMISSIONER GALVIN: Is that correct?

DR. PHILLIPS: She has. And so has Steere.

(APPLAUSE)

DR. PHILLIPS: And let me say Dr. Hulinska is a very well published researcher.

COMMISSIONER GALVIN: I'm not saying that. I'm just saying -- let's --

DR. PHILLIPS: It just --

COMMISSIONER GALVIN: Perhaps I misinterpreted the results.


COMMISSIONER GALVIN: I believe
Hunziger appeared someplace earlier on. But I won't argue the point.

A VOICE: What about Steere?

A VOICE: Yeah.

DR. PHILLIPS: It's not even that.

You know, there are researchers who have published multiple times in the field. It's not uncommon to see them in one or two publications. We're not quoting --

COMMISSIONER GALVIN: I'll stop --

I'll stop my --

ATTORNEY GENERAL BLUMENHAL: Do we --

(APPLAUSE)

DR. PHILLIPS: I'm responding to your comment. I mean, you know, I can go down the whole list if you want me to.

ATTORNEY GENERAL BLUMENHAL: Let me just say, since we're somewhat pressed for time, is your presentation, Dr. Phillips, in written form?

In other words, can we make it part of the record?
Because that will --

DR. PHILLIPS: Yeah. There are several things that you can make part of the record.

ATTORNEY GENERAL BLUMENTHAL:

Great.

DR. PHILLIPS: Because I was limited by time -- I will give you --

ATTORNEY GENERAL BLUMENTHAL: I appreciate that.

DR. PHILLIPS: -- something that also documents persistence of infections. Actually 71 references by many different authors. Also, I would include Dr. Zemel very accurately referred to a Klimpner study which had shown that there wasn't a demonstrable benefit to retreatment in patients with chronic Lyme. The International Lyme Association Disease Society has a position paper on that, on the lead author. It's 16 pages long. That study, in my view, is highly flawed and we critique that.

And, also, the ILADS has just been published their new treatment guidelines for the
management of Lyme Disease. It's just been
published in the peer-reviewed journal, Expert
Review of Anti-Effective Therapy. And it's hot off
the presses. And I will also include that as well.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

COMMISSIONER GALVIN: All right.

Let's -- let's move on. I just want the audience to
get an idea that they're not all --

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much.

Dr. Fallon?

DR. BRIAN FALLON: Hi. My name is
Brian Fallon. I thank the Attorney General and the
Commissioner for organizing this forum, which I
think is a great opportunity for the State of
Connecticut to openly learn more about Lyme Disease
from a variety of speakers.

I have ten minutes to talk about
the neuropsychiatric aspects of Lyme Disease. So I
will do it as quickly as I can.

I think there are a number of general aspects of Lyme Disease that cause distress and confusion. One is that symptoms fluctuate. Patients are often worse on some days, better on others. That confuses parents, school systems, employers, spouses. It's a difficult aspect of this illness.

And there's also confusion about the differences between early Lyme, late Lyme and chronic Lyme. And the symptoms, the treatment and the outcome studies of early Lyme would be very different from the symptoms, treatment and outcome of chronic Lyme. So I think that that needs to be appreciated more.

Third, neuropsychiatric aspects may be more prominent in some individuals than rheumatologic ones. And I think it's not widely appreciated that neuropsychiatric aspects are part of the Lyme Disease story.

Fourth, blood tests, we all know,
are problematic. Unless it's a culture, they don't
reveal whether you have active infection. And the
results often vary, depending on the test, the lab
and the stage of illness.

Treatment recommendations vary, as
you've heard. And science, unfortunately, honestly
has not caught up. I'm presenting one case that was
published in Biological Psychiatry in 1999 of a case
of Lyme Disease that presented as a
schizophrenia-like disorder. A 42-year-old woman
over eight months developed cognitive problems,
irritability, paranoid delusions and auditory and
visual hallucinations.

The work-up did not reveal any focal, neurologic or
arthritic signs. However, her spinal fluid showed a
lymphocytic pleocytosis and elevated protein with
antrathecal Borrelia specific antibodies. So this
was a clear case of neurologic Lyme Disease.

She was treated both with
antibiotics and antipsychotics briefly. And it led
to a complete resolution of the clinical symptoms
and her spinal fluid abnormalities. So the point that I'm emphasizing is not that psychotic symptoms are common in Lyme Disease, because they're not, but I am pointing out that they can occur and, unfortunately, they can occur in the absence of other systemic symptoms that might make you think of Lyme Disease. Now, with neurologic Lyme Disease you'll hear more about from Dr. Katz, there are the early phase, the later phase -- and I won't go through it in the interest of time. But the point I wish to make is that the neuropsychiatric symptoms may occur early or late in the illness. Common symptoms of late neuro Lyme include fatigue, headaches, sensory hyper-arousal where patients are acutely sensitive to light or sound, cognitive problems, such as slow processing speed, problems finding words, short-term memory problems, attention problems, getting lost in familiar places, peripheral neurologic symptoms, tingling, numbness, shooting or stabbing pains.
Cranial neuropathies are helpful when they occur, but they are not common. And mood problems are also common, irritability, depression, anxiety attacks, personality change and behavior change. Rarely, new-onset Lyme may manifest as mania or paranoia.

Now, with all of this, am I saying that all psychiatric problems are due to Lyme Disease? That would be absurd. I was -- obviously, most psychiatric problems are not due to Lyme Disease. But the point is that some are.

And when should one suspect that neuropsychiatric symptoms may be Lyme-related? Certainly look for multi-systemic symptoms. Certainly do the blood work and the other evaluations. If the symptoms emerge after a flu-like illness and exposure to a Lyme-endemic area, that's important. And if the psychiatric disorder is atypical, if it's manifesting at an odd age, if there are no prodromal symptoms as you might see with schizophrenia.

Is it lasting longer or not
responding to good trials of standard psychiatric medicines? Then you have to start wondering about an organic cause, such as a B-12 deficiency or Lyme Disease or thyroid abnormalities.

Are there cognitive features as well? And is there a lack of a prior personal or family history of psychiatric disorders? All these should make you wonder, is there an organic cause other than a purely psychiatric one?

Now, is there objective data indicating that chronic neuropsychiatric Lyme exists? Well, there is a great deal. I'll just present a little bit. There was a study done in Europe of psychiatric in-patients versus matched healthy subjects. And what they found was that 33 percent of the psychiatric in-patients tested positive for Borrelia on one of four tests versus only 19 percent of the community controls.

This raises the question of whether some -- in some Lyme endemic areas psychiatric symptoms may indeed be triggered or
exacerbated or worsened or caused by Borrelia Burgdorferi.

Now, what psychiatric problems do occur after getting Lyme Disease in adults? Well, we did a controlled study comparing Lyme Disease patients to patients with non-Lyme arthritis and Lupus. And although all those patient groups had a great deal of generalized anxiety, as you see on the right, in terms of major depression, on the left, the Lyme patients in the red bar had depressive symptoms three times more frequently than those patients with non-Lyme arthritis and Lupus. This surprised us and sort of started me on my interest in studying Lyme Disease further.

Now, in Dr. Steere's group up in Boston in 1998 there was a study done of neuropsychiatric problems in children after treated Lyme Disease. And this was a referral center where they referred -- where they evaluated 86 children. 12 had neuro-cognitive symptoms, such as behavior changes, forgetfulness, poor school performance,
that developed with or after the onset of classic manifestations of Lyme Disease. And two of those children have developed partial complex seizures. Five of the twelve had intrathecal antibody production and the cognitive test that showed mild to moderate auditory or visual processing deficits. Four of those five children have had prior antibiotic therapy.

So here are children who had been previously treated who had persistent cognitive problems. And two of them had partial complex seizures.

And so they're asking why this might occur. Well, one possibility certainly is a post-infectious one. The other possibility, as they say in their quote here, the other possibility, which we favor, is that the five children had hematogenous spread of Borrelia to the brain during acute infection and low-grade latent or active infection persisted, accompanied by intrathecal antibody synthesis. Now, that was their favored
hypothesis. But it certainly wasn't proven. We did a case controlled study at Columbia of chronic Lyme Disease in kids. I won't go through the symptoms in detail. But the main point was that in these children who had developed chronic cognitive problems, there was a mean delineant diagnosis of almost a year and they had to go to four different doctors until it was finally detected. And these are patients who had Western Blot positive Lyme Disease. Otherwise, they would not have entered the study.

And they, like the other study that Steere had done, they had problems with working memory and in the processing of auditory and visual input. And in 41 percent of those children during the course of their illness had had suicidal thoughts. So, obviously, we need to take the concerns of these children seriously.

This was an interesting study that came out of Sweden where they looked at 106 patients with neuro Borreliosis versus 123 patients with
erythema migrans. And they followed them up three years later. And what they found was that 50 percent of the neurologic Lyme patients had persistent neuropsychiatric symptoms, whereas only 16 percent of the erythema migrans patients did.

So what this emphasizes is that long-term follow-up may well depend on how you initially present and whether you get treated at the proper stage of infection. And these patients suffered with para-seizures, headaches, memory problems, arthralgias, depression, pain and attention problems. So there you do see a good array of neuropsychiatric symptoms.

Now, we are doing a chronic Lyme encephalopathy study at Columbia, thanks to the funding from the NIH. We have evaluated over 3400 patients who have called us because they have been diagnosed with Lyme Disease and treated with IV antibiotics. And that's over the last four years. That's a lot of patients.

The mean number of years between
symptom onset and treatment in our study was 1.2 years. So again, like the children, it shows that people are not being detected early enough. And that may be why they're developing chronic cognitive problems.

They are being treated -- they have received a fair amount of treatment in the past, 2.3 months of IV on average and 7-1/2 months of oral antibiotics on average. So -- and these came from physicians from all parts of the spectrum and all parts of the Northeast and, in fact, in the country.

The main symptoms were pain comparable to post-surgical pain, fatigue comparable to what you see with Multiple Sclerosis patients, and physical disability comparable to what has been reported in congestive heart failure. So these are patients who are, indeed, suffering.

We're also doing very sophisticated brain imaging called Pet Scan imaging, looking at the blood flow and the glucose metabolism
in these patients' brains. And all those spots on
the left and the red areas and yellow areas on the
right in the brain are areas of decreased blood flow
in the Lyme patients compared to age- and
sex-matched healthy controls.

So when someone says chronic Lyme
doesn't exist, that really belies the evidence,
which is that, in fact, chronic Lyme --

MR. RYAN: Time.

DR. FALLON: -- Disease is
associated with a good deal of abnormalities in
blood flow and metabolism. And the particular areas
affected are those that involve the
para-hippocampos, the hippocampos, the singulat,
areas that are involved in the processing of memory,
cognition, mood and sensory.

Just a word about treatment.

There have been two published control studies of
chronic Lyme Disease. Klempner's study in Boston
did not find any improvement with repeated
antibiotics. Krupner's study which focused on
post-Lyme fatigue did find that the antibiotic group
benefitted three and a half times more likely than
the placebo group at six months on their main
outcome measure of fatigue. And they're noted there
in the red bar.

There have been no published
control studies yet of chronic Lyme encephalopathy.
We are still looking for patients over the next
several months. So refer us patients. If you are a
patient, come visit us. 543-6510. Or E-mail us as
culyme@aol.com. If you're a patient, don't avoid
psychiatric treatment. Infections cause central
neuro/chemical disruptions which may require
psychiatric medications to fix. The psychiatric
medicines can also have anti-inflammatory properties
and help in the cytokine abnormalities.

Finally, I just want to emphasize
that children are suffering in the school systems.
They look like they're inattentive, unmotivated,
disorganized and confused. They fall asleep in
class. They may look good, even on bad days.
Children may function better on some days. But each
day is unpredictable. It drives parents and
teachers crazy. Children needs longer amounts of
sleep and can't make it to early classes. Normal
sound environments can be painful, disorienting and
threatening. Schools need to create flexible
programs and not penalize students for missing class
when sick. Don't give failing grades just because a
child is in on some days but not others.

A statewide required annual
educational update on Lyme Disease should be
considered for all teachers, principals and Special
Ed coordinators in Connecticut.

(APPLAUSE)

DR. FALLON: Now, this is the last
slide. What academic Lyme experts write in journals
or state from podiums may differ from what they do
with their own patients. And that's because the
practice of clinical medicine remains an art in
which medical care is individualized for each
patient. We work with uncertainty much of the time
and we learn from our patients and from the journals.

So, in the face of insufficient medical knowledge, we need to keep an open mind. Doctors need freedom to practice. And definitive practice guidelines, regardless of who publishes them, should not be made until far more research is completed.

Thank you.

(APPLAUSE)

COMMISSIONER GALVIN: I have a question for Dr. Fallon. Thank you for a very balanced and erudite presentation. I learned a lot. I wondered if, as you progressed through this, you had given some thought about are there more than one -- is there more than one kind of Lyme Disease? Is there a virulent strain or a different strain?

DR. FALLON: That's an excellent --

COMMISSIONER GALVIN: Or a fellow traveler like Babesia microti.
DR. FALLON: That's an excellent question, which is are -- do the strains have different clinical manifestations? I think that is an open question. I certainly can say in my studies even though Lyme Disease is endemic throughout the Northeast, I'm far more likely to find patients with five Western Blot bands on Cape Cod or in Old Lyme, Connecticut than I am in New Jersey or Pennsylvania or even upstate New York. And I don't think it's because Lyme Disease is -- I don't think it's because those patients don't have Lyme Disease. I think it's because perhaps the -- there are differences in the strains of the spirochete that's causing a different reactivity by the immune system among those patients. So that's one possibility.

And, in addition, you made the very important point that a number of patients may be co-infected with other organisms, some of which we know, some of which we may not know. And that also needs to be tested for and treated appropriately.
COMMISSIONER GALVIN: If you'll permit me, I'll make one -- a comment of anecdotal nature. Some years ago, a Harvard researcher was lecturing down at Yale University. And he had really a fascinating story. And what he said was that they'd had ticks up on the Cape for a long time that bothered people. 35 years ago, we used to think they had some variant of Rocky Mountain Spotted Fever. It was probably Lyme Disease. They used to -- they had a bad hurricane up in the Cape somewhere in the 60's and they had a huge enlargement in the population of ticks. So that old-timers up in the Cape, according to this individual, referred to them as hurricane ticks. And he got very interested. And I'll digress one more moment. And he went around to this little museums that all small towns have. And a lot of them had skins of rodents, particularly mice. And he got some that dated back in post-Civil War period and took them up to Harvard and was able to recover Lyme DNA from back in the 1860's and
1870's. So --

Very good talk. Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Did you have a comment, Dr. Levitz?

DR. LEVITZ: Just -- excellent presentation. One question -- comment on the Krupp study. Unfortunately, there was no cognitive improvement. You're correct that there was improvement in fatigue. And one of the things I'm glad to see at places like Columbia is that we do need to keep doing randomized studies. Whatever you believe, whoever in the panel you believe, we still don't know that Ceftriaxone is good for this. You know? That that's the best drug, that people are going to do better. What the best treatments are. And unless you do studies where you give some people one drug and some not and then look at outcomes, as they did there, you just don't know. And, you know, that's not for or against any chronic Lyme. It's just -- that's the only way we can information in
DR. FALLON: Can I make a point?

ATTORNEY GENERAL BLUMENTHAL: Sure.

DR. FALLON: I agree. I mean you need the control studies. One thing that drives me crazy about the publication about that Krupp study is that it was designed to measure post-Lyme fatigue, not cognitive problems. So patients were not entered into that study because of a certain level of cognitive severity. They were entered into the study because of a certain level of fatigue.

And although it's true cognition did not differ between the two treatment groups, you wouldn't necessarily expect it to differ because the patients didn't enter the study with a significant amount of cognitive impairment. And the way it was written, it's very misleading.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(APPLAUSE)
ATTORNEY GENERAL BLUMENTHAL:

Hopefully we'll have some more give-and-take. But I'd like to give Dr. Tilton a chance to go.

DR. RICHARD TILTON: Attorney General Blumenthal, Commissioner Galvin, distinguished members of the legislature and guests, I'm Dick Tilton. I've been a clinical microbiologist for more years than I would like to admit. I'm a former professor of laboratory medicine at UConn Health Center where much of the early testing in Lyme Disease was developed. I founded BBI Clinical Laboratories in New Britain. It was general infectious disease lab and we did a significant amount of tick-borne disease testing.

Now, rather than focus on some of the past issues of test sensitivity, specificity, accuracy, reproducibility, I would like to focus on new tests for Lyme Disease. My remarks are based on a review which I recently published.

There are essentially two types of tests, indirect tests and direct tests. Indirect
tests are usually based on the detection of antibodies and direct tests include culture, direct visualization, antigen tests and tests to detect specific DNA and/or orinite.

Now, I will be happy to respond to questions on traditional tests for Lyme such as ELISA and Western Blot, particularly as regards the use of the Western Blot.

Now, some of the new tests include Borrelia sital antibody tests. Now, the Borrelia sital antibody test is a functional antibody test which detects an antibody which kills Borrelia Burgdorferi, unlike some of the other antibodies we detect with ELISA. It is a complement mediated test. It was initially used as an immune status test when the vaccine was available. It has lost some popularity, seeing the vaccine is no longer available.

Its utility as a primary diagnostic test, however, is a problem because it is not readily available, except in a couple of
Certainly the most active field of test investigation has been in single and multiple peptide assays. And this distinguishes between single and multiple peptide assays and whole-cell assays which have been used for the last 20 years. Many papers have been published on the use of multiple and single peptides for testing. But there are really very few available. A few have become commercially available in the United States.

For example, the Wampole recombinant EIA test, ELISA test, which was recently deemed as a waived test -- I don't think a good idea -- was developed at Stoneybrook. I've had significant experience with this, unfortunately not all of it good, over the last couple of years. There have been significant problems of false positives, more than you would expect with any Lyme test, with the Wampole recombinant tests.

However, I think one of the more exciting tests available is the C-6 Lyme peptide
antibody. The outer surface of the organism Borrelia Burgdorferi has a region of outer surface proteins. There are at least six variable proteins and six invariable proteins.

Now, the most immuno-dominant of the invariable proteins was Protein No. 6. Hence, the term C-6. Now, there are two versions of the C-6 peptide. One, of course, is called the C-6 peptide. The other is the VLSE which stands for Variable Surface Protein. And it's the entire six component proteins on the outside of the cell. The C-6 is FDA-approved. The VLSE is not.

Some of the advantages of the C-6 are that it is very highly specific. In fact, there are tests going on now, some of them in my lab, to determine whether the Western Blot will be necessary for this test. This test can also function in vaccinated patients. The great majority of the tests routinely used are really not satisfactory for vaccinated patients.

This test detects antibody to a
number of Borrelia Burgdorferi strains, including European strains. And I think most significantly, it may be a test of cure, especially in early Lyme Disease. It has been seen, particularly in early Lyme Disease, that a four-fold greater decrease in C-6 titer suggests an inactive infection, even in the -- when a standard EIA is positive. That is, in early Lyme Disease, if your C-6 is negative and your ELISA is positive, it may indicate a resolved infection or no infection at all.

There is another test which I am interested in, developed in Europe. It's called the Pep-C-10. It's a measurement of an antibody to a small peptide at the end of the outer surface Protein C. We are about to test a new European product which includes all three of these new tests, the Pep-C-10, the C-6 Lyme peptide antibody and the VLSE. We are rather excited about this product.

Now, there is not a whole lot new in Western Blot except to indicate that there are still problems with the interpretation of the
Western Blot. It should come as no secret to anybody that I do not necessarily agree with the CDC criteria for interpretation, although we do use it. I have published an alternative criteria for interpretation. However, the laboratories that I direct will use both interpretive criteria.

The other problem with Western Blot is the availability of FDA-approved kits for Western Blot. The Mardex kit, which is FDA-approved, has been a standard. There's a kit available for Immunetics, although it is no longer available, unfortunately, and the kit that I developed, BBI Clinical Laboratories Western Blot Kit has recently been FDA-approved.

Now, very quickly moving on to direct tests, culture, by and large, when it's positive, is very nice. However, it is not particularly useful because of the low numbers of organisms in blood or in erythema migrans lesions.

If you look at the work of Charlie Cavia at New York State Medical College, the
incidence of blood cultures increases markedly if increased amounts of blood are used.

Now, there are some alternative direct tests available. For example, there is a direct fluorescent antibody test on blood which purports to detect Borrelia Burgdorferi directly from blood. I have a bit of a problem with this test because I've never seen a negative. Most of the tests that I've seen have been positive. And there are some significant micro-biologic problems with detecting micro-organisms, organisms directly in blood. There just aren't enough of them there to be microscopically visible.

The Lyme urinary antigen test is a fairly popular test, as is the culture of cyst forms.

COMMISSIONER GALVIN: Excuse me, sir.

(Off the record - changing tape)

COMMISSIONER GALVIN: Go ahead, Dr. Tilton.
DR. TILTON: In my opinion, there are huge specificity problems with these alternative tests.

COMMISSIONER GALVIN: Would you -- I'm sorry to interrupt you once again, sir. I'm not sure that everyone in the audience understands the difference between specificity and sensitivity and false positives and false negatives.

DR. TILTON: When you have false positives, it's specificity. When you have false negatives, it's sensitivity.

ATTORNEY GENERAL BLUMENTHAL: Well, that clears that up. Maybe for the -- I have to confess that I might claim to have an understanding. But if you could be a little more --

COMMISSIONER GALVIN: Why don't -- would you allow me to say a few words? When one develops a test, we attempt to develop a test which is very sensitive. And a test that's very sensitive doesn't miss any of the disease. So you set the test level becomes set at a level where you ideally
would like to detect 100 percent of the people who
have the disease. If you set it too low, you're
going to get false positives. False positives mean
the test says something that's there is not there.
You also want to set the -- one wants to set the
test at a level where you don't get false negative.
A false negative says that the problem is not there
when, in fact, it is there. And that's the --
that's the tension as one develops a test.

Ideally, the ideal test should
have 100 percent positives, true positives, no false
positives and all the negatives are real negatives.
And then it will have complete predictive value. In
real life, it's very hard to do that.

DR. TILTON: Thank you. I'll be
happy to deduct those two minutes from my ten.

COMMISSIONER GALVIN: You get
another 30 seconds for the tape change, sir.

ATTORNEY GENERAL BLUMENTHAL: You
don't disagree with Dr. Galvin.

DR. TILTON: No. No. Of course
ATTORNEY GENERAL BLUMENTHAL:

Okay.

DR. TILTON: I believe the most common and perhaps the best direct test is PCR. For some reason, PCR for Lyme Disease again has been held to a higher standard and stigmatized by the same people who recognize HCV, HIV, HSV PCR as a standard of care.

At least in my laboratory and many other laboratories, the yield of a single PCR is very low. For example, in whole blood only four to six percent of diagnosed patients will have a positive PCR.

The knee-jerk reaction is that it -- the PCR must be contaminated. And in some cases, the PCR is contaminated. But in spite of years of successful proficiency testing and self-sterilizing agents, the myth still goes on.

Let me very quickly tell you about some new approaches at PCR that we're using in my
laboratory. We are doing real-time PCR, which is a very rapid PCR in a machine, using multiple targets. When we amplify this DNA or RNA as the case may be, we have a sequencing machine which looks at the sequence of the nucleic acids and compares them to a large data base, such as Gene Bank. Essentially, real-time PCR using multiple targets and routine sequencing of the DNA that you amplified certainly has the ability to reduce the possibility of contaminants and false positive testing.

Now, in conclusion, a significant number of patients may have Lyme Disease or something akin to Lyme and are sero-negative and direct-test negative. It's a huge problem. And it's a problem of whether it's the initial clinical diagnosis that's in error or the laboratory test that's in error.

Let me also remind everyone that the laboratory provides only supplemental information in most any infectious disease, not only
Lyme Disease. And this supplemental information must be balanced by the clinical impressions of the physician and the signs and symptoms of the patient, however untraditional they may appear.

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Dr. Tilton, you mentioned the CDC criteria. And you indicated that you use them and that they are -- I'm not sure whether you said commonly used. But widely used. Could you expand on that point a little bit?

DR. TILTON: As a result of a conference in Deerborn, Michigan in 1995, there were a set of criteria developed for the interpretation of Western Blots. And they have become known as the CDC criteria. In fact, they are used by many laboratories. And I think most people recognize the five bands positive, less than five bands negative predictor, at least for the IgG Western Blot using the CDC criteria.

Yes, the CDC criteria are widely
used. And as I indicated, I, at least for IgG Western Blots -- and once again, I understand I am using some technical terms which may not be completely understood. But at least for IgG Western Blots I prefer a more liberal criteria.

ATTORNEY GENERAL BLUMENTHAL: And why is that, sir?

DR. TILTON: Well, there are any number of reasons. I believe the five bands positive, less than five bands negative is a particular conservative approach. And I prefer to have an indeterminate range. So that if you have two, three or four bands positive, this would be an indeterminate Western Blot. That would indicate to the physician that there may be antibodies that are indicative of Lyme Disease.

On the other hand, if a patient comes from North Dakota never having seen a tick, then the indeterminate result probably reflects a negative Western Blot.

So, once again, it must be
evaluated on the basis of the clinical presentation.

There is not time right now to discuss the science behind the CDC criteria. But, in my opinion, there are some problems with the science, particularly with the organism use.

ATTORNEY GENERAL BLUMENTHAL:

Thank you. I'm going to hold my other questions until our next panel and maybe some of those questions will be answered by the next panel.

Why don't we -- and I thank this panel. If you would perhaps move to this part of the room so that, after the next panel or during their presentation, if you have questions or comments, then you five would be able to interact with them. And I'm going to ask now Drs. Ramsby, Sinatra, Kelley and Katz to please come forward.

DR. MELINDA RAMSBY: Hello. My name is Melinda Ramsby. I am a physician/scientist and solo practitioner in rheumatology. I probably am a science geek by some estimates. I've spent way too long at the University of Connecticut in one
capacity or another. I obtained my Master's in nutritional biochemistry there, my PhD in biochemistry and cellular/molecular biology there. I did four years of post-doctoral research with a variety of sub-culture and molecular biologic techniques. I obtained my MD and then went into the sub-specialty of rheumatology. I am board certified in both internal medicine and rheumatology.

Towards the goals of today's hearing, which I consider to be a meeting of the minds, I have considered information from both the peer-reviewed literature and select publications from the International Lyme and Associated Diseases Society. I was asked to give a brief statement on my perspectives on the clinical syndromes, diagnosis and treatment of Lyme.

An overview. I believe the diagnosis of Lyme Borreliosis should be made based on historical and clinical evidence,. Laboratory tests, as noted previously, are confirmatory, are useful, but should be used with the appropriate
knowledge of their utility and their limitations.

Historical evidence should be consistent with the known epidemiology and biology of the deer tick vector and the infecting spirochete, Borrelia Burgdorferi.

Likelihood of transmission should be considered in terms of attachment time and degree of tick engorgement. Specifically, it's not thought to transfer without attachment for 48 or 72 hours and certainly not less than 24.

Borrelia infection causes early and late manifestations which can be localized or disseminated. Except for the erythema migrans rash, there is no symptom that is specific for diagnosis.

The clinical features of presenting cases should they ever be assessed relative to current understanding of stages in Lyme which include the early localized infection that may or may not have erythema migrans, although indications are that 70 to 90 percent of such cases
do, early disseminated disease, which may include multiple erythema migran lesions and a viral-like syndrome which would be hard to distinguish from a viral syndrome. Musculoskeletal, cardiac and neurologic manifestations as well.

Late disseminated disease would include the Lyme arthritis and neurologic manifestations.

In general, if there are atypical symptoms or laboratory values during base line work-up, this should prompt assessment for co-infection of other tick-borne diseases. For example, cases of Lyme -- of suspected Lyme in which a base line lab reveals thrombocytopenia, low platelets, low white cells or anemia or elevation in liver enzymes, testing for Ehrlichiosis is appropriate, especially if Doxycycline is not planned to be used or is contraindicated.

Cases with severe symptoms that do not respond to antibiotic therapy or that include GI symptoms or sponamegali or low red blood cell counts
or low platelet counts should be tested for co-infection with Babesia. Treatment would be different and it would not be eradicated by Doxycycline.

With regards to the Post-Lyme Syndrome, this seems to me less well-defined and it's often characterized by diffuse and non-specific symptoms which resemble fibromyalgia, chronic fatigue and somatization disorders. It is conceivable that a severe or prolonged bout of infectious disease could exacerbate or unmask a pre-existing sub-clinical condition or ignite a secondary form of fibromyalgia. However, like any medical condition, appropriate diagnosis fosters appropriate treatment, which in the case of fibromyalgia is multidisciplinary.

To ascribe Post-Lyme Syndrome to active antibiotic-resistant infection leads to premature closure of a differential diagnosis, potential harmful treatment, as well as an increased despair and frustration for the patient.
With regard to persistent active infection and -- the terminology is "we". This may be late manifestations of a disease or chronic Lyme Disease. Persistent infection is proposed as the basis to explain this phenomena and the rationale -- and it is also the rationale for treatment with long-term antibiotics.

Mechanisms by which persistent infection is suggested to arise have been proposed to include the localization of the spirochete in privileged or protected sites. This would include the brain, central nervous system, cerebral/spinal fluid and intracellular compartments.

Some of the data which that has been derived from are primarily case studies or reports. There are some in-vitro studies. They were limited. And other explanations are possible for some of the findings of the organisms that have been seen intracellularly which perhaps were not even intracellularly but wrapped within the membranes on the outside of the cell.
Another mechanism is surface antigen modulation as a mechanism to evade the immune system. The spirochete is a very primitive organism. It does have an outer membrane. And there are classic proteins, as mentioned before. These outer surface proteins, A through F, do change their expression under certain circumstances. This may relate to the feeding cycle. This may relate to environmental changes.

Conceivably, some of that might inhibit immune system development. But that is not clear.

Also proposed is induction to tolerance and immunosuppressive mechanisms. Most of this literature is in the research domain. Most of that is mouse studies and isolated studies with peripheral blood macrofages. This will await further testing to determine some of the validity. But certainly there are various changes in the cytokine environments and the humoral versus cell-mediated responses to an organism and, if
inappropriate, might reduce the ability to destroy invading organisms. Again, not conclusive.

Another proposal is the morphologic conversion of the spirochete into dormant cystic forms. In reviewing this work, there was one particularly scientific article. It was an in-vitro study done by Drs. Alvin, Johnson and Nelson at the Department of Biochemistry, Microbiology and Molecular Genetics in Rhode Island. It's published in Microbiology 2000, Volume 146.

In their study, they took the spirochete organism and subjected it to culture in different mediums. The BSK medium, which is the one that is usually used to try to culture these organisms and which they seem to like, as well as mediums that were deficient in serum or other nutrients.

What they observed was that there were conversions to the cystic forms in depleted mediums. Other articles have talked about hypotonic changes, PH changes, exposure to antibiotics as
being able to induce this morphologic transition.

Interestingly, in their work they were able to show a reversal phenomenon in which live spirochetes were then able to be recovered. Their study was well done in terms of the laboratory techniques used. They used two-dimensional gene electrophoresis to identify protein expression. And this is a technique that can separate proteins based on their molecular weight and their charges. And so it can identify distinct proteins.

They used S-35 methane labeling to -- and auto radiography to demonstrate which proteins --

MR. RYAN: Time.

DR. RAMSBY: -- were being newly synthesized. And they did find some specific regulation of certain proteins. These kinds of studies could go on and be tested. They do have areas of -- that you could approach with science.

If there is an outer membrane and it does change its
expression, you could make antibodies to that. You could go look for more organisms. You might be able to find techniques to test for that.

But in the absence of that or knowing whether this happens in vivo or not, it does not suffice as evidence for long-term antibiotic therapy, which can be very dangerous. And sometimes you have to wonder if some of the recurrent illness that people get from it is the consequence of the antibiotic changing the microbial floor in their gut and leading to cycles of perpetual illness when they're not on antibiotics. Certainly the evidence presented earlier today has not shown that people treated long-term recover, even in the short-term. So that is still questionable to me.

Long-term antibiotics are indicated if you have a septic joint and if Lyme Borrelia is there. But that would be an indication.

I'd like to thank Dr. Robert Galvin and Attorney General Blumenthal for inviting
me to participate. And I'm looking forward to a stimulating discussion. Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much.

(APPLAUSE)

COMMISSIONER GALVIN: Allow me to make one comment. Thank you very much for your very stimulating and erudite presentation of a lot of factors that I wasn't aware of.

For those in the audience who are non-physicians, some of what Dr. Ramsby has said dovetails with what some of Dr. Phillips has said about organisms that are recovered very late in a clinical course of disease. And Dr. Phillips' information indicated they were able to recover them from joint areas and from ligaments and the like. But Dr. Ramsby is pointing out that there seems to be a way for these organisms to become inactive and -- or put themselves in places where enough antibiotic doesn't get in to eradicate them and they come back. So there's some dovetailing of these two
presentations.

And, once again, many of the ticks have more than one organism that they can infect with. And some of the infections may be due to other things other than the classic Lyme organism. I would also have to say that our colleagues from Yale University are, even as we are meeting here, are meeting out on the West Coast and discussing some of the very topics that Dr. Ramsby brought up today.

Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Dr. Sinatra?

DR. STEPHEN SINATRA: Thank you, Dr. Galvin, Dr. Blumenthal. First of all, I want to relate to you that I'm not a Lyme specialist. I don't treat Lyme Disease on a day-to-day basis. I'm a cardiologist and a nutritionist. And my
experience with Lyme Disease is that it was placed in my path. I have it personally. My dogs have it. And I'm treating myself and my dogs.

But having said that, I've been a Director of Medical Education for 19 years. And in the course of the 19 years, I've been blessed with the fact that many healers and extremely knowledgeable physicians have been placed in my path at various conferences. They should be here speaking before you today, not me. But I'll do the best I can to relay some of their thoughts.

In the newsletter I write nationally, I have a network of what I call the 50 top physicians in the United States which I network on a day-to-day basis with. And these physicians are doing independent trials, double-blind trials, small pilot trials. But, nevertheless, a lot of the new information on Lyme Disease I could relate to you through the eyes of my colleagues.

First of all, I want to say that in relation to this disease, it's worldwide. It's
epidemic. It's in six continents. And a lot of researchers believe that a billion people are infected. It's a worldwide epidemic. And as much as 15 percent of the population right now is infected with Lyme Disease. And many of it is sero-negative.

Now, we talked about the arthropod block, the vector, being the method of transmission. There is now new research to show that Lyme Disease is spread through mosquito bite, flea bite, tick bite, and as well as sexual intercourse and as well as congenital with the newborn, and has even been transferred from breast milk to the newborn through breastfeeding.

With the compelling evidence of human-to-human transfer, it takes it away from the tick bite as being the major mode of transmission. So we have to be cognizant of the fact that there are many of us sitting in this room right now who have never been bitten by a tick that, indeed, has Lyme Disease from a different form of transmission.
The dormancy and activation have been discussed. And there are many cases on record where people have had Lyme Disease dormant for years where, when their immune system came assault from other factors, developed the full-blown illness.

The CDC -- somebody mentioned this. That we are currently under-reporting the cases of Lyme Disease. And I agree with that.

The other aspect of Lyme Disease, like Syphilis, Lyme being a spirochete -- this disease is typically a great masquerader and --

A VOICE: You took one of my slides.

DR. SINATRA: Oh, I did? I'm so sorry.

But anyway, being a cardiologist, I treat mercury intoxication. And it was brought up that similar findings of mercury intoxication is very similar to Lyme. And that is true. We have musculoskeletal symptoms and neurological symptoms.

But one thing about Lyme Disease,
like coronary artery disease -- and I can really
stand on firm ground when I speak about the heart --
is that Lyme Disease causes an acute inflammation, a
silent inflammation of the body. And like silent
inflammation, is really the root cause of multiple
illnesses, including cancer, heart, disease,
Multiple Sclerosis, ALS and any other of the
neurological or neurodegenerative diseases.

And with Lyme Disease being the
focus of chronic silent inflammation with elevation
of various cytokines, damage over time can be done.
And in my own practice of cardiology, I've seen
patients with neurological disease, with documented
Multiple Sclerosis and Parkinson's who indeed had
Lyme Disease as the hidden cause and as really the
cause of their suspected Parkinson's Disease.

Now, why is this disease so
difficult to treat? I've heard Joanne Whittaker
speak -- and, by the way, I think she's probably the
best person in the country. She's in Florida. She
has a website. I'll be happy to give it out later.
But the problem with the Lyme spirochete is that it's -- it changes direction.

First of all, it's a spirochete. It can turn into a spheroplast, which is known as the L-form, and it can also act in a cyst form.

And the problem is that when these different forms of Lyme get embedded in muscles or in tissues like the heart or in red blood cells, they hide from the eyes of the immune system. And I want to state that again. They literally hide from the eyes of the immune system. Our immune system cannot recognize it. Therefore, it can't kill it. And that's one of the reasons why this bug is so tenacious.

Now, antibiotics don't work 24/7. Antibiotics are only going to work when the bug is inside the plasma, not intracellularly like inside the muscles because it cannot be reached or even inside the CSF, cerebro/spinal fluid, unless you use an IV Rocetin.

The point I'm trying to make here
is that with standard laboratory tests, we may miss
a lot of Lyme Disease, depending on where the
spirochete is and what form it is and where it's
located in the body. So this is one of the reasons
why this is such a tenacious organism. And it's one
of the reasons why you just can't kill it.

Now, in speaking to the colleagues
that I've known who have been using an alternative
approach, as well as a conventional approach -- and
I have to say any good physician will use what
works. I mean, you know, if you look at the
discovery of insulin back in the 1920's, Bantam
treated one patient with insulin and then it became
standard of care.

A lot of these small trials that
are under way right now are using alternative forms
of therapy. And I believe that the best approach to
Lyme Disease is really an integrative approach or a
collaborative approach where you use the best that
conventional medicine has to offer and also the best
that alternative medicine has to offer.
And what a lot of these trials that are undergoing, particularly in Bulgaria, which is a wide epidemic of Lyme Disease -- Ecuador has a horrific epidemic of Lyme Disease -- is really a combined approach. And I've written this to my newsletter subscribers. But in order for a full recovery for anybody with Lyme Disease, you must detoxify and cleanse the body. And detoxification here is key. And this requires special diets, going off glutens, going off flours, avoiding sugars, taking certain nutrisudicals that can help cleanse the body, particularly from environmental poisons, insecticides, pesticides and petrochemicals and plastics. But the list goes on and on.

Following detoxification, you must -- and I have to emphasize -- must repair the overstimulated and damaged immune system caused by the Borrelia bug. And basically, following that, you need to reclaim the neurological process.

And I've spoken to a neurologist in Texas where Lyme Disease is not considered
endemic. But in Texas, one neurologist, a board
certified conventional neurologist, who was dead set
against using any alternatives in the treatment of
Lyme Disease, now uses alternatives with IV Rocetin
and other medications. And he told me that 90
percent of unexplained headache in his clinic of
2,000 patients was due to Lyme Disease.

So how do you treat this illness?

It's come out that antibiotics are good. But,
remember, antibiotics will not reach a lot of these
organisms, especially in a cyst form, especially if
they're embedded in tissues and in muscles.

So, basically, the integrative
approach to Lyme Disease, which, again, can come
under a lot of controversial discussions and
scrutinies. However, the way I'm treating myself
and the way I treat my dog and the way I treat my
patients, with the full knowledge that this again is
not considered standard of care, is with antibiotic
therapy prescribed by MD. I do believe that
antibiotics have their role and must be used in the
treatment of Lyme Disease.

The problem with this bug and the
spirochete -- and I've seen this bug under live-cell
analysis in -- actually in my own blood as well.
The problem with this bug, it has a fibrin coat
around it and it's protected from -- even from
antibiotics. And this protein coat around this bug,
you have to penetrate it. And one of the ways you
can penetrate this bug is by using enzymes or
digestive enzymes or protease enzymes that can
literally strip the fibrin coat around this bug
where antibiotics can't do its work. So we use a
combination of protialytic enzymes -- Burgin-Wolb
enzyme is an enzyme used by Olympic athletes for
years as a way of reducing inflammation in the body.

There's also a TOA-free cat's claw
which comes from the -- it's a botanical. It comes
from a vine in South America. Una Degado is the
Spanish translation. But basically TOA-free cat's
claw contains lots of alkaloids and flavenoids which
literally can have a healing process particularly on
the immune system and they're also anti-microbial.

In some of the double-blind small
trials, they've seen 85 to 100 percent reversal in
some of the most refractory patients with Lyme
disease out of Dr. Mahore's clinic in Dallas, Texas.

Another factor that we're using in
Lyme Disease is transfer factor, which really comes
from mother's milk. It's cholesterum. And
basically, some of these transfer factors can be
synthesized in the laboratory and be used in the
treatment of Lyme because they can penetrate the
cyst and penetrate other forms of the illness.
Where antibiotics only work when the bug is inside
the serum, some of these transfer factors can work
24/7, around the clock.

So, in summary, I think everything
that's been said here today has been very
meaningful. I have to say that when it comes to
Lyme Disease, having it myself and having to maybe
undergo hip replacement, I became very humble with
this illness. I think there is an enormous amount
of human suffering with this illness on the planet.
I think physicians are only scratching the surface
with this one. I truly believe that one needs to
take a more profound, integrative approach and
really choose therapies that are multidisciplinary
and can attack this bug at all stages of development
and get inside areas of the body where antibiotics
can work.

So, in the final analysis, I just
believe that more and more research will be needed
to really determine the best way of treating this
illness.

Thank you very much.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much.

Dr. Kelley?

DR. KATHERINE KELLEY: Thank you.

My name is Dr. Katie Kelley. I'm the Director for
the Connecticut Department of Public Health
Laboratory. And I've been asked to provide some information to you and the legislative representatives and your guests today about the laboratory diagnosis of Lyme Disease.

I don't want to steal any thunder away from my boss, but I do think it is important to perhaps just lay out some basic principles about laboratory testing before we get into Lyme Disease itself. So if you'll give me an opportunity, I'll do that.

The first point that I'd like to make is that laboratory tests cannot, should not be used alone. They are always used in conjunction with other information and in the investigation of a health problem. And if this is in a doctor's office, a hospital or a clinic, the investigation is -- usually involves a single patient and you're looking at the history that the patient brings to you, signs and symptoms, other physical information in order to make a diagnosis, come up with a treatment regimen and, hopefully, during the course of treatment of
the patient, determine whether you have cured the
disease in question.

In the setting that I work in,
which is primarily in public health, we're also
doing health investigations. And lab data is very
important to those. But what we're looking at,
rather than individual patients, is a population, a
community. And we're trying to investigate what is
generally considered an outbreak.

So the information that's brought
to that determination, besides laboratory test data,
would be the epidemiologic data, demographic data,
even environmental data. That's all brought
together so that we can determine what caused the
outbreak, what are the best methods to control it.
Vaccination perhaps or the use of DEET if it
involves insects or something like that. And also
to determine if those measures are effective. Have
we actually been able to control this outbreak?

That said, there's another sort of
criteria. And that is that -- and I think all of
the presenters today would agree because I sort of
heard it in what they -- in their remarks. And that
is that no test is 100 percent. It just plain
doesn't happen.

It doesn't happen because there
are errors. There are errors in the technology that
we have available. There are errors that are
related to the complexity of the agents that we're
looking at. And there are also errors that are
introduced by the patients themselves that are
generally called host factors. But we all recognize
that no group of people respond identically to an
infection. And all of those responses need to be
taken into account.

The way laboratory tests are
generally rated, if you will, is on the basis of two
criteria. And Dr. Galvin talked about those,
sensitivity and specificity. Sensitivity of a test
is related to the fact that you want that test to
identify all potential people who could have been
exposed or who are infected with the disease.
The consequence of looking so broadly is that you will have false positive results. That's just a given. It's part of the way the test is set up.

On the other hand, the test that is highly specific goes in the opposite direction and its goal is to identify all those individuals who are absolutely infected with the agent. So, in that situation, the false positive rate goes way down, but the false negative rate goes way up.

Generally speaking, and currently, with infectious diseases in particularly, a standard of lab practice that has been used very effectively is to use two tests in tandem. The first test being one that's highly sensitive that casts that wide net and catches everybody who potentially could have the disease and then following up on that population of positives with a more specific test that then identifies whether the persons actually have the specific antigens.

Sensitive tests, that first broad
net of tests, generally use antibodies. They're usually very rapid tests. They're generally pretty inexpensive. And the antigen involved may be the whole organism or a crude preparation of the organism that may -- that contains most of the key antigens.

The specific test in this day and age is generally a test that involves looking at the nucleic acids. And with Borrelia, the organism has been sequenced. And, consequently, we have a very good idea of what nucleic acids we need to look at and what segments are related directly to that organism versus others that may be in its same family.

So that's the kind of testing that we're currently doing. And with Borrelia, it gets more complicated because this organism has a lot of antigenic sites on its surface that are lipids, proteins and other chemicals. It also has some antigenic materials inside that are not related to the DNA. And that presents some problems as far as
sensitivity and specificity are concerned. The other thing that can complicate this a little bit are some other factors outside of that. One is the treatment. If treatment is done early and the antigenic process is slowed down or stopped, you may not have full expression of the antibodies. The length of time from the point of infection to the point that the patient is -- undergoes laboratory testing can also affect the results. And as other people here have said, there is good data that shows that the same tick species that carries Borrelia also carries other agents at a fairly high frequency. So we may have infections with one or more other agents at the same time that the individual is being infected with the Lyme Disease bacterium. This doesn't present a wonderful picture for laboratory testing. But I think everybody who is sitting in this room knows that there's a long way to go to improving laboratory tests. And there are -- there is some good news out
there. A lot of work that's being done now in molecular diagnostics, especially in areas that are called nanotechnology, are getting to a point where things can be seen at much lower quantitations and this will give us more rapid and better information in the future.

Right now, most of these are at the research level at universities and NIH and CDC. But the way things move in this day and age, it won't be that long before better tests will be available.

I'd like to thank you. And that concludes my remarks.

(APPLAUSE)

COMMISSIONER GALVIN: If I may make a remark and ask a question? My remark is that it is my great good fortune that Dr. Kelley and I are able to work together. I would also like to ask Dr. Kelley, should there be a very, very good, very sensitive, very specific Lyme test developed, what, in your opinion, would be a reasonable cost per
1 patient to pay for such a test?

2 DR. KELLEY: That's a loaded question.

3 COMMISSIONER GALVIN: That's why I asked you.

4 DR. KELLEY: Yeah. Given what we're looking at in terms of the move, the cost of the move to molecular diagnostics, my guess is that the cost per test will certainly exceed a couple of hundred dollars per test. Now, that may not seem like a lot to some people. But I think to some people it would. And I don't know the third-party payers will look at that. Because this is probably not going to be a single testing event. Given the course of the disease, it's likely that individuals would be tested more than once.

5 COMMISSIONER GALVIN: It's always too expensive unless it's you or your family, Dr. Kelley.

6 DR. KELLEY: Well, that's true.

7 That's true.
COMMISSIONER GALVIN: Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you, Dr. Kelley.

Dr. Katz?

DR. AMIRAM KATZ: Attorney General Blumenthal, Dr. Galvin and dear audience, patients, it's a --

VOICES: Can't hear you.

ATTORNEY GENERAL BLUMENTHAL: You know, I might ask if you and Dr. Sinatra can change chairs, that might -- thank you.

DR. KATZ: It's an honor talking about my experience with Lyme Disease, especially the neurologic aspects, in front of the audience today. I guess I'm the fortunate one to speak last. So I won't be repetitious.

I also tried to address some of the official requests in the invitation to talk about the way I diagnose and treat Lyme patients. I'm a neurologist with sub-specialty training in epilepsy, clinical neurophysiology, sleep medicine
and hyperbaric and diving medicine. And I served --
I was a faculty at Yale with the Epilepsy Center.
Then I went to Norwalk Hospital to open those
centers of epilepsy and diving medicine. And in
this capacity, I started seeing Lyme patients. And
I was intrigued by the myriad of symptoms and the
different manifestations of their illness and the
lack of improvement and started seeing more and more
patients.

I think that we are dealing with
an epidemic. I don't know if there's any other name
to call it. You know. We -- I just saw recent
reports. We have 4,000 cases reported in
Connecticut in the last -- in 2002, according to
Kirby Stafford, which I respect and consider his
opinion as valid. He claims that these are only 10
to 20 percent of the diagnosed cases. So we are
multiplying here by a factor of 10. We are getting
40,000 cases in the incidence of Lyme in
Connecticut.

And then we are left with the
cases which are not diagnosed or reported. So it's several dozens, of thousands of patients a year. And this is the incidence, not the prevalence. I think that after several presentations today, we will accept the fact that there might be chronic Lyme Disease which will carry some of the patients to the following year. So the prevalence will be 100,000 patients in Connecticut? More? Actually, if you do surveys from house to house -- and there is some information about it which was brought in the introductory letter, every household almost know about Lyme Disease. So this is a problem. It's a serious problem. And it's the reason we are sitting here trying to get further with diagnosis and treatment. Now, what about other tick-borne diseases? Babesia, the Ehrlichia, the bartonella, micoplasma, some of which are not accepted by mainstream academic medicine. But we know that there are probably other micro-organisms transmitted by the same tick. So tick-borne disease is a major
problem. Then we are talking about the rare cases of Tularemia and Rocky Mountain Spotted Fever, also. There isn't much literature about bartonella or micoplasma. And that's the reason I brought one of the references by S. Cardall. I reported a case of epilepsy aparcialis, continued in a patient with Cat Scratch Disease that was transmitted by a tick. The bartonella can cause slightly different presentation. And I hope that there will be additional literature in the future so it would be recognized by the mainstream academic community as well.

It gives central nervous system symptoms, eye symptoms, dermatologic symptoms and GI symptoms which are not typically seen with Lyme Disease.

And the micoplasma fermentins -- same author, by the way, described it in PCR in ticks in New Jersey, mainly joint symptoms.

In the acute and sub-acute presentation of Lyme Disease, there are 15 to 20
percent involvement of the nervous system. But
probably over 80 percent of late Lyme Diseases will
accept the definition of Lyme encephalopathy as part
of central nervous system involvement.

Perhaps part of the problem of the
discrepancy between mainstream academic Lyme and
what happens in the field, that the area was
researched by rheumatologists mainly. And with the
chronic disease, dermatologic problems are not that
prevalent.

This is the big masquerader of the
21st century or the end of the 20th century, as
Syphilis was the one before. We have the spirochete
that this time is much -- way more tricky, with
different evasion techniques, some of which were
mentioned. It can lose a cell wall and survive in
an L-form. And if this is the case, antibiotics
that are bactericidal, damaging the cell wall, won't
be effective. Then are the cyst forms can attack
any organ system. In the central nervous system,
Dr. Fallon reviewed some of the facets. And I won't
spend more time on this again. Start from the
muscle to the peripheral nerve to the nerve roots to
the spinal cord. The brain, any of the cranial
ers can be involved. Actually, the most
frequently involved cranial nerve is the seventh
cranial nerve. Bell's Palsy or facial paralysis.

How many of the audience had
Bell's Palsy here? I don't know. But several I
guess.

And in a state with endemic Lyme,
every patient with Bell's Palsy should be suspected
as Lyme patient unless proven otherwise. And this
dictates changes in treatment. Whereas, in the
past, every case of Bell's Palsy was given steroids,
I don't think you can safely administer steroids to
patients with Bell's Palsy in Connecticut without
giving some antibiotics if you want to do it fast.

How is the nervous affected by the
Lyme? There might be direct invasion into the cells
or extra-cell. And we know about -- at least we
have evidence that the neuroglia are invaded by the
Lyme, microscopic images. There might be injury from substances excreted by the tick. I personally don't believe that there is much evidence about neurotoxins, but some people believe and treat in this direction.

There might be change in the host function. We know that the spirochetes enter the lymphocytes and reside there. There might be change of function and injure the immune mechanism either by an innocent bystander, meaning that there is an antibody, an antigen interruption and the cell that is neighboring this interaction suffers from the pro-inflammatory substances or by autoimmune mechanism. And I believe that in the chronic Lyme scenario, autoimmune disease has a lot to say and it's the reason we need our rheumatology colleagues here. And we'll talk a little bit more.

Steere and his colleagues have several times brought into literature the fact that persistent arthritis might be mitigated by autoimmune mechanism. And they even postulated that
the OSP-A, the outer surface protein A, has a sequence of amino acid which is similar to one of our lymphocytes antigens. And this is the mechanism by -- of inducing autoimmune disease.

Well, unfortunately, it did not prevent Smith, Klein, Beecham from getting out a vaccine that is based on OSP-A, which was eventually withdrawn from the market due to higher than expected incidence of side effects. So we know that the autoimmune damage does happen.

We also know that the flagellin or the 41 kilo dalton antigen of the spirochete has a sequence of amino acid which is similar to the modern basic protein. And this might perhaps explain why Lyme can trigger --

MR. RYAN: Time.

DR. KATZ: -- (indiscernible)

disease.

Dr. Zemel mentioned very well in his succinct presentation first do no harm. And I do agree with him. And I'm working on patients
which are suffering from Lyme Disease or -- that's
the question. I always make sure we rule out other
possibilities. And from my own clinical practice, I
can stand all day here and tell you about patients
who were supposed to have chronic Lyme Disease and
were found to have other diseases. So, yes, we do
need to do a very thorough work-up to rule out other
causes of illnesses.

But, on the other hand, the
chronic Lyme cases do exist and they can be
secondary to persistent Borreliosis. They can be
secondary to other tick-borne disease which persist.
And there might -- if you are living in an endemic
area, you can always have a chance of re-infection.
So the chronic disease might be actually a
re-infection. You might have residual damage
without an infection. And then you may have
Post-Lyme Autoimmune Syndrome.

And, once again, I think that this
probably has a lot to do with the chronicity of the
disease. The HLA-DR-4 that Dr. Steere and his
colleagues talked about in their papers is actually -- the incidence is about 30 percent of the Caucasian population. So one out of three patients that was affected -- infected by Lyme Disease has at least a chance of carrying a DR-4 and developing Post-Lyme Autoimmune Disease, which is not only rheumatologic problem, neurologic as well.

A list of the work-up I'm doing as part of ruling out other problems. I won't go over it. But, indeed, B-12 was very well mentioned here as a cause for chronic neurologic disease. And the co-existence of B-12 deficiency and thyroid problem might link into the autoimmune scenario which we see in many of our Lyme patients. They have thyroid problems, might have B-12 deficiency secondary to autoimmune disease. So we are working the patients thoroughly to rule out other explanation for the condition. And then we are doing the specific tick-borne diseases, panels, sending to several labs. Some are more reputable than the other. I personally use some labs. Others use others. But
the more we send, the more likely we'll have a chance to get a positive result.

And I don't -- I can only speak for myself. I need to see some evidence of some specific bands on the Western Blot which will be indicative of exposure to Lyme before I'm convinced about or committed for treating with antibiotics.

Spinal tap has a very important role in the evaluation because if you are talking about central nervous or neurologic infectious disease, you need to tap the patient. You cannot start treating without tapping a patient. And the tap is helpful, although not many times specific for Lyme or other tick-borne diseases. But if we have a peripheral positive serology and we have elevation of protein in the cerebrospinal fluid or a few more cells than needed, then it will mean that it's very likely to be a target of involvement and will dictate certain mode of treatment.

Neuro imaging, neuro physiologic testing, neuropsychologic testing and, of course,
first and all clinical presentation. Just a little example of white matter lesions which we see in the MRI of the brain which are seen both in Lyme Disease and in Multiple Sclerosis. Sometimes you cannot distinguish between the two.

Another unfortunate case of white matter lesion in the spinal cord which causes significant neurologic morbidity. And there was positive Lyme serology, cerebrospinal fluid.

The SPEC scan which Dr. Fallon mentioned, if there is no other explanation for hypoprefusion -- and here we see this. I hope everybody can see the arrow. The arrow points on the -- in radiology, left is right and right is left. The right hemisphere, the right cortex, you see less orange, less thickness of profusion. And in this focal hypoprefusion with no other explanation, with negative MRI, would support clinical presentation and blood work. This is very characteristic but not diagnostic of Lyme.

We talked about the spinal tap.
We talked about -- a little bit about treatment. Intravenous treatment is needed when the central nervous system is involved because only several antibiotics are crossing the blood/brain barrier and reach significant concentration there. And if we need to treat with them, this is -- we always need to remember this is a dangerous treatment. It might have different problems. And we always need to make our patients aware of the side effects and complications of the treatment.

The port can cause clotting and chronic coagulation issues. The antibiotics can cause gall stones. And we need to be convinced that this is what the patient needs. And the patient needs to know about the side effects.

And we need to document the improvement with objective measures as much as possible because, otherwise, it will be an open-ended treatment.

One very important thing about Lyme Disease and other neurologic diseases -- and I
won't bore you with references. The issues of Lou
Gehrig Disease, Parkinson's Disease, dementia. Yes,
there might be a few cases where Lyme is the cause
of this illness. But in the majority of the cases,
Lyme is a co-morbidity. But if you have a patient
with Lou Gehrig Disease that has a life expectancy
of five years and he will have Lyme on top of his
Lou Gehrig's, his life expectancy will drop to a
year or a year and a half. And this is very
important to know. There is something that each
neurologist knows, but it's not written much in the
literature. It's called the recapitulation of
neurologic deficits.

You have a Parkinsonian patient
whose fine balance, gets urinary tract infection and
he cannot move. The same goes with neurologic
disease, degenerative disease on top of which you're
getting a complicating infection.

It's very important for this
particular patient with Lou Gehrig Disease to give
him his IV-Rosetin which will enable him again to
swallow for another year. And I have seen many cases with this kind of presentation. I am not saying that this is the cure. But I'm saying this will improve their quality of life.

And the same goes for dementia of various etiology and Parkinson's Disease and progressive supranuclear palsy and other degenerative neurologic diseases.

And the other thing of importance here is Lyme and MS. Multiple Sclerosis is a demalnating disease of the central nervous system, the etiology of which is unknown. Many epidemiologic studies do suggest an infectious origin, infectious trigger, some of which were tied to Herpes. But we have a very good candidate to be a trigger here in Connecticut in Lyme infection. So we can get the same demalnating lesions with Lyme alone or we can get idiopathic demalnating disease and they can co-exist.

And if we will treat aggressively the Lyme Disease in patients with demalnating
disease, we will improve the quality of life and the
course of the illness of demalnating disease in this
patient. And we also need to know that some of the
treatments, traditional treatments for Multiple
Sclerosis, would not be appropriate if we are
dealing with concurrent infection. If you're giving
high-dose steroids, if you're giving chemotherapy to
patients with a concurrent infection, you are not
doing them any good. And that's the reason we need
to pay -- be very careful in working up those
patients with typical Multiple Sclerosis before we
make treatment choices; make sure that they don't
have Lyme on top of it.

We also should make -- the State
should sponsor some epidemiologic studies and
compare the rates of Multiple Sclerosis here in
Connecticut and different counties. I tried to get
this information from the MS Society and it was
impossible. But I think we could probably have a
higher incidence, the same latitude in the West
Coast. They say that a temperate climate and
latitude are -- the incidence of MS is similar in the same latitude. So we should compare it perhaps in different parts of the country.

I don't know whether Dr. Zemel is still here. But we have another rheumatologist that perhaps will comment about this combination. I've seen several patients which had DR-4's and persistent Lyme symptoms who responded very well to this combination, which unfortunately, Dr. Donta, who started using this combination, is not able to speak with us.

But this combination has several advantages. The Plaquinil increases the bacteriastic effects of the Bioxin by changing the PH of the ELISA, enabling more efficient antibiotic treatment. We know that macrolides -- Bioxin is a macrolide -- has probably anti-inflammatory--Babesia and Plaquinil has some immune modulation.

Two more slides. This combination is also effective against Babesia. And there might be also some role of Plaquinil in cyst form. So
that's the reason it is -- might be working and
helped many of my patients.

            IVIG therapy. I won't go over
this. But probably is an option to patients who
have infection and immune disease if you don't want
to go into chemotherapy and high-dose steroids.

            And the one last thing I would
like to mention is to go along with Brian's
presentation about the role of Lyme in our kids'
development. Any change in a child's behavior,
school achievement, mood or physical state deserves
a comprehensive organic work-up. I've seen too many
cases of psychiatric presentation that were not
worked up, not for Lyme but with organic -- typical
organic work-up, with neuro imaging, et cetera. And
Lyme should be part of this work-up.

            And we should also encourage some
epidemiologic studies about the prevalence of
learning disabilities, psychiatric disorders in
children in our state as compared to other states.

            And thank you again for giving me
the opportunity to speak.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much, Dr. Katz.

We're going to, at least for a few minutes -- I think we're running a little bit over where we planned to be right now. But I think we would welcome any exchange, commentary, questions that members of the panel may have for each other.

Dr. Levitz?

DR. LEVITZ:  A comment. Several people (indiscernible - not using microphone)

A VOICE:  Can you get a little closer to the microphone, Dr. L?

A VOICE:  Turn it on.

DR. LEVITZ:  They didn't teach me that in medical school.

Many people -- I have seen patients with what I don't believe to be Lyme
Disease. And there may be disagreement. But actually totally sero-negative. But have some chronic joint pains that can't be diagnosed and will tell you -- I come into the office and they say, "You know what? I think it's Lyme because every time I'm on Doxycycline, I feel better." And I feel like the late Henny Youngman where a guy walks into the doctor's office and says, "It hurts when I do this" and the doctor says "Don't do that."

Well, if they walk into the office and say "Every time I take Doxycycline, I feel better", it's very difficult to argue with that. It's cheap. It's benign. But, as the rheumatologists will point out, in double-blind placebo-controlled studies, the Tetracycline family has been used in rheumatoid arthritis to improve people with rheumatoid arthritis. And there isn't even a disagreement. There isn't someone who is going to jump up and say, "I didn't like the study."

That all of these antibiotics actually do also have immunologic effects, as Dr.
Katz brought up. And I'd kind of add -- I'm not trying to confuse the audience. I'm just trying to bring up we don't know what each thing is doing or why it's doing it or why that happens. But I talk to my patients like that who say, "Well, the reason I'm sure I have Lyme, with every single test negative, is because I get better every time I'm on Doxycycline." Well, there are anti-inflammatory effects of these antibiotics. And it would be like when I take Advil, you know, things feel better. They do have other effects.

DR. RAMSBY: Yeah. That is a known association. And specifically, it looks like it relates to an inhibitory effect on matrix botala perdiasis (phonetic) by the Doxycycline. And those enzymes are important for the degradation of the extracellular matrix in the joint.

A VOICE: In MS studies, there is some studies about --

DR. RAMSBY: Anoratics have a lot of other effects. And so can Plaquinil. Plaquinil
can be effective here because it's inhibiting the presentation of antigens through the HLA system by its changes on the PH of the lysozone. So, yes, just because they get better on antibiotic doesn't mean that it's because of an organism. Often, the inflammatory process is involved. And especially with chronic Lyme arthritis. I mean that does, you know, appear to be a chronic inflammatory arthritis, just like rheumatoid arthritis or others. And disease-modifying agents are appropriate in those cases.

ATTORNEY GENERAL BLUMENTHAL: Dr. Phillips?

DR. PHILLIPS: I'd like to point out that although Tetracycline class antibiotics do have a measurable, but small, anti-inflammatory effect, Dr. Levitz mentioned double-blind placebo-controlled studies of Tetracycline class antibiotics and the evaluation of rheumatoid arthritis. Such studies have also been performed with intravenous Rocetin double-blinded with saline
for two weeks in patients who had weekly positive Lyme ELISAs but completely negative Western Blots. That study did not just include rheumatoid arthritis. It also included psoriatic arthritis, arthritis related to vasculitic origin and undifferentiated inflammatory arthritis. And they found, with the treatment of two weeks of Ceftriaxone, which has no notable in-vitro anti-inflammatory effects, all of these groups remarkably improved and the placebo group did not. (APPLAUSE) A VOICE: Is it a published study on -- DR. LEVITZ: Yes, it is a published study. ATTORNEY GENERAL BLUMENTHAL: Any other comments? You know, I have a question which doesn't necessarily elicit your particular expertise because I know you are experts involved in treating or diagnosing individual cases of this disease. But
the very powerful statistics that Dr. Katz gave
about the extent of the epidemic -- and we've all
used that term "epidemic". I've used it for years
and years -- raises the question on what we do about
the disease on a sort of macro level.

Obviously, you are dealing with
individual instances of symptoms and pathology and
so forth. But the spread of the disease is just
staggering. And, obviously, one explanation might
be, well, maybe we're diagnosing more cases. Going
back to the Civil War, the rodents whose skins were
found -- you know, they didn't know about Lyme
Disease. So maybe it existed then, but we're better
at diagnosing it and we're paying more attention to
it.

But I don't know that that
phenomenon can account for the exponential increase
which is astonishing and appalling. So I recognize
you're not epidemiologists or naturalists or what
the right expertise would be. Maybe there isn't one
expertise. But I just wondered if you as people who
have thought a lot about this disease might have
some observations about what should be done about it
in terms of the way we live.

You know, obviously, one -- one
thing that's been discussed a lot is there are a lot
more deer. You know. That's an obvious, much
discussed explanation. But if -- but maybe there are
other, lifestyle or similar kinds of explanations
that you might just give us the benefit of your
wisdom on.

DR. FALLON: I think we could all
move to Montana.

ATTORNEY GENERAL BLUMENTHAL: I
don't know that they'd want us all.

DR. FALLON: No. Kirby Stafford
at the excellent Connecticut Agricultural Station
gives a wonderful talk about public health problems
with Lyme Disease. And he makes the point
profoundly compellingly; that, you know, you see the
rise in the deer population, you see the rise in
Lyme Disease. We're doing nothing to control the
deer population in Connecticut. It's profoundly outrageous, I think. And I think that that needs to be paid close attention to because we're just going to have a continuing problem as the deer population expands.

In addition, there are good tick control strategies. And there isn't enough funding going into studying how to expand that, how to broaden it, how to control these ticks that are really destroying our ability to live free lives in Connecticut.

So I think your question is a super-important one, which is how do you, on a broader scale, control this disease. And I think it is true that even though very important steps have been taken in funding these efforts by the CDC, a lot more does need to be done. And there are good people out there who are willing to do it. They just need the money.

But I think deer control is not being focused on. And that would be useful.
DR. LEVITZ: I think also -- I'm probably one of the few people in the room who went -- I went to Columbia and had to work my way through. I worked summers in New York City on pest control, killing mosquitoes and ticks. The fact that Malathion had bad long-term side effects -- they should be showing up any time now.

And I think one of the keys is we heard from a lot of patients who did not recall a tick bite or perhaps didn't have a rash. But I'll bet most of them had seen ticks around, lived in areas where they've seen ticks, saw ticks on their dogs, et cetera. And if you go anywhere in Connecticut -- I'm from Glastonbury. They're -- the numbers are amazing. You just take your dog for a walk. He'll come back. He'll be a tick magnet.

And so, again, we talk -- everybody wants funding for this and funding for that, et cetera. But despite that, there was some testimony from Dr. Sinatra on other alternative ways. I think most of us still believe that ticks
are the key cause, key culprit here. And there are white-footed mice, et cetera, who they also feed on. But the idea of trying to put a lot of money and trying to control, just as the way we do mosquitoes for the West Nile, and trying to just control the tick population here is a very important one because that stops it from where it starts and we don't see all the new cases.

DR. PHILLIPS: There was actually a study in one of the barrier islands, I believe off the coast of Massachusetts, where they did that. And they eradicated the deer and the ixodes population has just plummeted.

ATTORNEY GENERAL BLUMENTHAL: We're going to be hearing from some of the government folks, like the Agricultural Station in Connecticut, later in the day.

I think we had a comment -- and if --

DR. PHILLIP BAKER: (Indiscernible - not using microphone)
COMMISSIONER GALVIN: Could you just identify yourself?

DR. BAKER: I'm Dr. Baker --

COURT REPORTER: You need to get near a microphone please. Thank you. Just give me your name?

DR. BAKER: Dr. Baker from the NIH. It's true that the --

ATTORNEY GENERAL BLUMENTHAL: From the National Institutes of Health.

DR. BAKER: National Institutes of Health. Right. We think of deer primarily when we think of Lyme Disease. And they're important because --

A VOICE: Can't hear you.

DR. BAKER: -- they have a wider range. They carry the gravid tick to areas where they drop off and lay their eggs. But I think the field mice are the most important vector because they keep the disease percolating in an endemic area.
and they multiply. And people come in contact with
ticks that develop from that vector more than the
deer. So that's -- I would have to say that's -- if
you had to choose between the two, I would focus on
that. And there are some new methods that have been
developed by the CDC that would -- are very good at
controlling rodent populations.

ATTORNEY GENERAL BLUMENTHAL:

We're going to be hearing from both the CDC, the
Center for Disease Control, and the NIH at 2:00
today.

Are there other comments or
questions that anyone might have at this point?

Yes?

MS. JILL AUERBACH: (Indiscernible
- not using microphone)

COMMISSIONER GALVIN: Excuse me.

That's not going to get on the record unless you get
to a microphone.

ATTORNEY GENERAL BLUMENTHAL: Why
don't you just come up here and you can talk into
COMMISSIONER GALVIN: And would you give your name please?

COURT REPORTER: And spell it for me.

MS. AUERBACH: My name is Jill Auerbach. I'm from Duchess County, New York. And we have a very active tick control research program ongoing. The problem is the increasing numbers of ticks. And until we do something to fund that research and stop the numbers of ticks from proliferating in our environment, our children and we will not be safe.

And there is a lot of research out there. It just has not been given the support that it's due. And I know we can make our communities, at least our communities and our residential areas, safe.

Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.
ATTORNEY GENERAL BLUMENTHAL: I think we're going to -- thank you very much for that comment, Ms. Auerbach.

I think we will take a break until probably a little before 2:00. We're going to try to start exactly at 2:00. Thank you very much.

(RECESS)

ATTORNEY GENERAL BLUMENTHAL:

Thank you. We're going to begin this afternoon's presentations with Dr. Paul Mead of the Center for Disease Control and Prevention and Dr. Phillip Baker of the National Institutes of Health.

The floor is yours, gentlemen.

Thank you for being here. We know that you've come a long way. And we really do appreciate you rearranging your schedules. I know initially you had a conflict. And we really definitively appreciate your being here this afternoon. Thank you.

COMMISSIONER GALVIN: Gentlemen,
if I could interrupt you for just one second?

I'm getting the impression that there's a degree of unrest among you folks pertaining to the Department of Health having exact ideas about what is or what isn't appropriate treatment for Lyme Disease.

One of the things I pride myself on is being a fair man. And I insist that our regulatory branch be run in a fair and above-board manner. Ms. Furness, who runs that, is exactly the type of individual to do this.

I would like to spend less than a minute to quote from a letter that was sent out in response to a complaint about a physician by some other physicians who did not agree with the first physician's methodology of treating of Lyme Disease.

"Currently, medical experts differ in their recommended treatment modalities relating to the diagnosis and management of Lyme Disease. As these groups demonstrate", the groups who have different types of treatment, "credible medical
evidence to support their differing perspectives,
the Department of Public Health is not currently
initiating investigations based solely on the
diagnosis and treatment of Lyme Disease. If you
have information indicating that standards of care
were not met in such areas as patient assessment and
monitoring, please provide this Department with the
name of the patient and a summary of the
circumstances surrounding your allegations."

And this is what we will do. We
are not in the business of advising physicians how
they should treat patients. And we have no special
criteria that we are going to use to evaluate people
who are treating Lyme Disease in a variety of ways.

And one of the reasons I wanted to
have a panel of differing practitioners here is so
we could all understand there are different ways of
trying to do the same thing. We will treat
everybody fairly. If, however, for some reason the
physician in question does other things that breach
the standard of care, then we have to act accordingly.

ATTORNEY GENERAL BLUMENTHAL: Let me just say, while we're doing announcements, I will have to leave early because I have learned that the Bureau of Indian Affairs will be announcing this afternoon, is scheduled to announce this afternoon the decision on the recognition of the Skattico petition for acknowledgement from the Federal Government. And that will be some time around 3:00. So I'm going to be leaving a little before 3:00. And Dr. Galvin and Tom Ryan of my office will be conducting the remainder of the hearing.

I want to thank Dr. Galvin for his immense contribution to this hearing. He has helped spearhead it, selecting the invitees and providing the extraordinarily meaningful advice to my staff and to me in organizing this very significant hearing.

And I just want to say in a sentence more pointedly what he has said; which is
that nothing that I've said, nothing that we've done here should be interpreted as the Attorney General or anyone from State Government really telling any doctor how to diagnose or treat a disease. We have enough to do without getting into that kind of activity. And one of our panelists said this morning -- and it is certainly a credo of the medical profession, "First do no harm." And certainly, a great deal of harm would result from State Government telling doctors how to practice. In fact, I have said repeatedly and I said at this hearing five years ago that we never would try to do so. And, in fact, our effort has been to allow the doctors and their patients to be the ones making these decisions without the interference of health insurers or HMO's or anyone else, including our State Government.

So, really, today is not intended to formulate a one fit -- one size fits all diagnosis or treatment, but simply to educate, make more aware and try to seek solutions where we can be
helpful.

Dr. Mead?

(APPLAUSE)

DR. PAUL MEAD: Good afternoon. I am Dr. Paul Mead. I'm a medical epidemiologist with the Division of Vector-Borne Infectious Diseases at the National --

A VOICE: Can't hear you.

DR. MEAD: Okay? Can you hear me now?

As I was saying, my name is Dr. Paul Mead. I'm a medical epidemiologist with the Division of Vector-borne Infectious Diseases at the National Center for Infectious Diseases at the Centers for Disease Control and Prevention, which is part of the U.S. Department of Health and Human Services. I would like to thank you both for the invitation to be here this afternoon. It is a pleasure.

I will concentrate, as requested, on two main issues within my statement, CDC funding
for states to report Lyme Disease and the
surveillance case definition for Lyme Disease.

Let me first provide a brief overview, however. Lyme Disease is the most
prevalent vector-borne infectious disease in the
United States. It is one of the nationally
notifiable diseases, with more than 23,000 cases
reported to CDC in 2002. If not diagnosed and
treated in the early stages, Lyme Disease can result
in serious complications.

Laboratory testing for Lyme Disease has improved, but greater understanding is
needed of its performance in clinical practice.

CDC's Lyme Disease prevention and
control activity is a science-based program of
education, research and service which partners with
the National Institutes of Health and other federal
agencies, state and local health departments and
other non-federal organizations.

CDC supports national
surveillance, epidemiologic response, field and
laboratory research, consultation and educational activities through intramural initiatives. CDC also funds collaborative studies on community-based prevention methods, improved diagnosis and understanding of pathogenesis, tick ecology and development and testing of new tools and methods for tick control.

CDC's budget for Lyme Disease is allocated each year by Congress. CDC received 7.1 million dollars for Lyme Disease in fiscal year 2003 and 7.4 million in 2002. CDC distributes the majority of these funds to states and universities in the form of cooperative agreements.

CDC has mapped the national distribution and risk for Lyme Disease and has defined environments, activities and behaviors that place people at high risk of infection. CDC has developed new and effective devices and methods for preventing infection and safely reducing vector ticks in the environment, such as insecticide-treated rodent bait boxes.
CDC developed and improved and standardized diagnostic tests for Lyme Disease and provided physicians standards for the use of these tests. CDC's research programs had provided an understanding of the pathogenesis of infection with Lyme Disease bacterium and of transmission with the bacterium by ticks.

Lyme Disease and other emerging tick-borne infectious diseases are cause of increasing concern with regard to public health and safety in the outdoor environment. CDC's program for 2004 and beyond emphasizes the goal of working with Lyme Disease endemic communities to develop integrated pest management approach, which includes a wide assortment of practical tick control strategies.

IPM or integrated pest management employs environmental management, biological and chemical control of ticks, and enhanced personal protection through tick avoidance and other measures to prevent Lyme Disease.
Other areas of research include the development of natural forest products for use as an environmentally acceptable alternatives in pest control, deer and rodent-targeted methods of insecticide application, further efforts to predict Lyme Disease risk on a national scale and further understanding of host immune responses to infection with the Lyme Disease bacteria.

Continued education and implementation of improved laboratory tests for early and correct diagnosis and treatment will further the trend of reducing complications of Lyme Disease.

As may be mentioned by Dr. Baker, CDC works closely with the National Institutes of Health on fundamental research related to immune responses and diagnostic development.

As previously mentioned, CDC distributes most of its Lyme Disease funds to states and universities via cooperative agreements. In accordance with federal rules and regulations,
cooperative agreements are awarded competitively based on objective review of proposals submitted by state health departments and other applicants. In general, Lyme Disease cooperative agreements are re-competed every three years.

For over a decade, the Connecticut Department of Health has competed successfully for CDC Lyme Disease funding, with the amount of funding increasing from approximately $140,000.00 in 1991 to approximately $845,000.00 per fiscal year in 2003. Connecticut universities have also competed successfully, receiving just under $490,000.00 in CDC cooperative agreements in fiscal year 2003. Overall, CDC provided approximately 1.4 million dollars to institutions in Connecticut for Lyme and tick-borne diseases in fiscal year 2003.

As a partner in the cooperative agreement process, CDC is responsible for assuring that the overall objectives of cooperative agreements are modified over time to reflect new information and changing public health goals.
In general, the overall objectives of Lyme Disease cooperative agreements have shifted over the last decade from counting cases to devising and testing methods for preventing infection.

The Connecticut Department of Health's decision to discontinue mandatory laboratory reporting reflects this increased emphasis on prevention. This particular form of surveillance for Lyme Disease as applied was costly and relatively inefficient. Money spent on mandatory laboratory reporting decreases the amount of funds available for prevention efforts.

In 2002, after five years of mandatory laboratory surveillance, Connecticut had the highest incidence of reported Lyme Disease of any state. This is precisely where the state ranked in 1997, the year before implementing mandatory laboratory surveillance.

Let me be clear. There is no question that Lyme Disease is an important public health concern in Connecticut. The question, as
emphasized by the patients we heard from today, is ultimately how to prevent it. It is towards this question that CDC cooperative agreements are focused.

Let me now say a few words about clinical diagnosis. The clinical diagnosis is made for the purpose of treating an individual patient and should consider the many details associated with that patient's illness. Surveillance case definitions are created for the purpose of standardization, not patient care. They exist so that health officials can reasonably compare the number and distribution of cases over space and time.

Whereas physicians appropriately err on the side of over-diagnosis, thereby assuring they don't miss a case, surveillance case definitions appropriately err on the side of specificity, thereby assuring they do not inadvertently capture illnesses due to other conditions.
As adopted by the Council of State and Territorial Epidemiologists, a case of Lyme Disease is defined for national surveillance purposes as physician-diagnosed erythema migrans greater than five centimeters in diameter or at least one objective manifestation of Lyme Disease, musculoskeletal, cardiovascular, neurological, with laboratory confirmation of B. Burgdorferi infection using a two-tiered assay.

Laboratory confirmation is considered critical for late-stage Lyme Disease because the symptoms mimic many other common conditions. Without firm objective evidence of the B. Burgdorferi infection, persons with other diseases would be counted erroneously as having Lyme Disease.

No surveillance case definition is 100-percent accurate. There will always be some patients with Lyme Disease whose illness does not meet the national surveillance case definition. For this reason, CDC has stated repeatedly that the
surveillance case definition is not a substitute for sound clinical judgment. Given other compelling evidence, a physician may choose to treat a patient with Lyme Disease when their condition does not meet the case surveillance definition.

In conclusion, addressing public health issues such as Lyme Disease depends on a strong public health system and sustained and coordinated efforts of many individuals and organizations. CDC will continue to work with its partners to develop and implement community-wide strategies to prevent Lyme Disease, including educational efforts, tick control and the development of improved diagnostic methods.

Thank you very much.

ATTORNEY GENERAL BLUMENTHAL:

Thank you. Thank you very much.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: Dr. Baker?

DR. BAKER: Can you hear me?
I am Dr. Phillip Baker, the Lyme Disease Program Officer and the Anthrax Basic Research Program Officer with the Division of Microbiology and Infectious Diseases, National Institutes of Allergy and Infectious Disease, NIAID, NIH, at the Department of Health.

It is a pleasure for me to be here today along with my colleagues from the CDC to tell you what we are doing about Lyme Disease.

NIH has a long-standing commitment to Lyme Disease that began more than 20 years when the cause of the disease was not yet known. In 1981, NIAID-funded scientists identified Borrelia Burgdorferi as a causative agent of Lyme Disease. Since then, basic and clinical research efforts have been expanded in scope to address a variety of issues related to this disease. These activities include both intramural and extramural research on animal models, microbial physiology, molecular and
cellular mechanisms of pathogenesis, mechanisms of protective immunity, vectors and disease transmission, efficacy of different modes of antibody therapy and the development of more sensitive and reliable diagnostic tests for both early, acute and late chronic Lyme Disease.

Other NIH institutes and centers that conduct Lyme Disease research are the National Institute on Aging, the National Institute of Arthritis, Musculoskeletal and Skin Diseases, the National Institute of Mental Health, the National Institute of Neurological Disorders and Stroke, the Fogerty International Center and the Center for Research Resources.

I might also add that we have an NIH Lyme Disease Advisory Panel that includes representation from the CDC and we meet at least once a year to discuss how we could work together to accomplish our various goals related to research on Lyme Disease.

Approximately 20 percent of
NIAID's extramural Lyme Disease grant portfolio is devoted to the development of novel and more sensitive diagnostic procedures. The NIAID also regularly re-evaluates the effectiveness of currently used diagnostic methods. In collaboration with the CDC, the Institute plays a major role in the development of new approaches for diagnosing for Lyme Borreliosis in the presence of co-infecting agents, as well as in individuals who have been immunized.

In addition, there is a strong need to develop a procedure that will enable one to distinguish those who are actively infected with B. Burgdorferi from those who have either recovered from a previous infection or have been immunized with the Lymerex vaccine.

Since the genome of B. Burgdorferi has now been completely sequenced, greater advances are anticipated as this information is used both to improve diagnosis and improve -- and provide greater and newer insights on the pathogenesis of the
disease through the application of micro-array technology and cardiometrics.

Co-infection looms as a major potential problem, mainly because the ixodes ticks that transmit B. Burgdorferi can carry and simultaneously transmit other emerging pathogens, such as Ehrlichia species, the causative agent of human granulocytic Ehrlichiosis or HE, and Babesia Micro which causes Babesiosis.

In Europe and Asia, ixodes ticks are also known to transport tick-borne encephalitis virus. Fortunately, this tick-borne viral infection has not yet been reported in the U.S. Although, co-infections with Powasson virus and deer-tick virus have been reported.

Co-infection by some or all of these infectious agents may interfere with the clinical diagnosis of Lyme Borrealiosis and/or adversely influence host defense mechanisms, thereby altering landmark characteristics of the disease and the severity of infection.
For example, studies conducted by NIAID extramural researchers have shown that co-infection with HGE increases the severity of Lyme Borreliosis.

The issue of co-infection and its potential implications also has been examined in all of NIH's clinically supported studies on Lyme Disease.

Antibiotic therapy is another aspect that we address. A clinical study on the efficacy of antibiotic therapy for the treatment of chronic Lyme Disease was completed in late 2000. It was funded through a contract awarded through the New England Medical Center in Boston. It involved randomized, double-blind, placebo-controlled, multi-center studies to examine the safety and efficacy of Ceftriaxone and Doxycycline for the treatment of patients with either sero-positive or sero-negative chronic Lyme Disease.

The clinical protocols for these studies which have been posted on the NIAID website
were developed through collaboration and extensive
discussions with Lyme Disease research experts, as
well as with NIAID Lyme Disease Advisory Panels
composed of patients with Lyme Disease, members of
patient advocacy groups, practicing physicians who
treat patients with Lyme Disease and basic research
scientists with experts in either infectious disease
or Lyme Disease.

This panel provided input on the
implementation of the protocols selected for the use
in the study, as well as on intramural clinical
studies that are also being done. In late 2001, the
Data Safety Monitoring Board, or DSMB, for the New
England Medical Center clinical trials conducted a
planned interim analysis of the data.

After its review, the DSMB
unanimously recommended that NIAID terminate the
treatment component of these studies. The
preliminary data analysis showed that after 90 days
of continuous antibiotic therapy, there were no
significant differences in the percentage of
patients who felt that their symptoms had improved, worsened or stayed the same between the antibiotic treatment and placebo groups in either trial. In other words, we had an answer to a question we were asking.

In addition, the DSMB further recommended that the investigators continue to follow the study patients to monitor their long-term safety and to obtain additional information that might have value in determining the underlying basis of chronic Lyme Disease and in suggesting more effective therapeutic approaches.

These extensive follow-up studies are still in progress. No new therapeutic studies are contemplated until these have been completed and the results analyzed. The results of New England Medical Center clinical trials were published in the New England Journal of Medicine in the year 2001.

Both the intramural and extramural studies mentioned above involve data collection as well as the maintenance of specimen repositories.
Such specimens have been made available to other investigators working on Lyme Disease and, thus, have contributed significantly to the development of improved and/or novel diagnostic procedures.

Animal models also have provided considerable information on the transmission and pathogenesis of Lyme Borreliosis as well as on the mechanisms involved in the development of protective immunity.

The NRAAID, in collaboration with the National Institute for Neurological Diseases and Stroke, has broadened these efforts to include comprehensive studies on non-human, primate animal models for experimental research on the neuro pathology associated with chronic Lyme Borreliosis. These studies will expand knowledge of those doctors that contribute to the pathology associated with persistent infection of the central nervous system by B. Burgdorferi and ultimately will enable researchers to devise more effective clinical approaches for the treatment of chronic Lyme
Borreliosis in humans.

They also will supplement and enhance the results of current clinical studies on the efficacy of antibiotic therapies for the treatment of chronic Lyme Disease and provided precedence for use in the design of future clinical studies.

Two pharmaceutical companies have devoted considerable effort towards the development of a vaccine for Lyme Disease. Double-blind, randomized, placebo-controlled clinical trials involving more than 10,000 volunteers in regions of the U.S. where Lyme Disease is highly endemic were conducted for each of two Borrelia Burgdorferi recombinant outer surface lympho protein A or OSP-A vaccines that were manufactured by Glaxo-Smith-Klein and Pastor-Marieu-Konot.

These vaccines were found to be 49 to 68 percent effective in preventing Lyme Disease after two injections and 68 to 92 percent effective in preventing Lyme Disease after three injections.
The duration of their protective immunity generated a response to the SKB vaccine which is called Lymerex, which was licensed by the FDA in December of 1998, is not known.

Although Lymerex was licensed for use in individuals from 15 to 70 years of age, the results of another study involving about 250 children from 15 to 5 to 15 years of age indicate that Lymerex is well-tolerated and highly immunogenic in children as well.

A larger pediatric study involving more than 3,000 children from 4 to 14 years of age showed that just two doses rather than the usual three given to adults were enough to provide protection. Only minor side effects were observed.

NIAID was not directly involved in the design and implementation of these particular vaccine trials. However, patents for cloning the genes used for the expression of recombinant OSP-A, as well as knowledge on the role of antibodies against OSP-A and the development of protective
immunity, were derived from basic research grants funded by the NIAID.

In April of 2003, Glaxo-Smith-Klein announced that even with the incidence of Lyme Disease on the increase, sales of Lymerex declined from about 1.5 million doses in 1999 to a projected 10,000 doses in 2002. Although studies conducted by the FDA did not reveal that any reported adverse effects were directly attributed to the vaccine, Glaxo-Smith-Klein discontinued manufacturing the vaccine for economic reasons.

The NIAID also is funding pre-clinical studies on the development and testing of other candidate vaccines. For example, Decravining Protein A which is being produced by MedImmune and Advanced Pharmaceuticals, Incorporated. These companies reported that a combination vaccine composed of Decravining Protein A and OSP-A is far more effective than either one given alone in preventing the development of Lyme
Disease in experimental animals.

On the basis of these encouraging findings, both companies have entered into agreements to develop a new, more effective second-generation vaccine to prevent Lyme Disease in humans.

In conclusion, as demonstrated above, NIAID has a comprehensive Lyme Disease research portfolio with the goal of advancing the understanding of the disease and developing ways to improve its diagnosis, treatment and prevention. These efforts highlight several specific avenues of investigation. Improving the ability to diagnose Lyme Disease in the presence of the co-infecting agents, evaluating the efficiency of antibiotic treatment for Lyme Disease and assessing candidate vaccines to replace the discontinued Lymerex vaccine.

The NIAID is fully committed to continuing to explore these and other yet-undiscovered areas of research in the hope that
future research financed will provide important
cues to better understanding this painful disease.
Lyme Disease research will continue to be a priority
for the NIAID for the foreseeable future.

Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much, Dr. Baker.

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: I

have a few questions. And I'd like to begin with
Dr. Mead, if I may. I think you very articulately
distinguished between the case surveillance
definition of the CDC guidelines, often referred to
as diagnostic criteria, and their focus on
standardization and I think you used the word
statisticity. Am I repeating that correctly or did
I mis-hear it? Anyway, statistical use. And the
clinical diagnosis that is patient care issue. And
you drew that distinction, I think, very clearly and
powerfully.

And, yet, I wonder whether it's
been your experience -- we see if from time to time.
You probably have -- I know you've sat in this room
this morning and heard the references to it in the
clinical diagnosis setting. Whether your experience
has been that the CDC surveillance definition
continue to be used in that setting as well as in
the collection of information used for surveillance.

DR. MEAD: Well, I don't know that
I can necessarily answer that question. I've
certainly heard today that there are patients who
feel that they were not given a diagnosis on the
basis of that.

I think it's important to point
out that -- first off, when we talk about CDC
criteria, there's surveillance criteria and then
there are guidelines for the interpretation of
laboratory data. The laboratory testing data
guidelines for the results of a meeting as was
discussed held in 1994 that involved various groups,
not just CDC, but also NIH, Association of State and
Territorial Public Health Laboratory Directors, et
cetera. And those -- what came out of that meeting were criteria not for laboratory diagnosis but for interpretation of laboratory tests. And that's an important distinction. And it's an important distinction because, as was also mentioned this morning, the laboratory test when it comes to diagnosis is just one bit of evidence. There are many bits of evidence that are important. The history of the patient. Had they been bitten by a tick? The nature of their symptoms. And I believe that just about any physician that has been here today will reaffirm that, as we were all taught in medical school, don't hang everything on one laboratory test or one finding. You have to consider the alternative diagnoses. Now, so one would certainly hope that physicians would look at these testing criteria as one bit of evidence when they're trying to make a clinical diagnosis. As is the case with the many
other laboratory criteria which CDC has published over the years for Hepatitis and various other diseases. So this is not unique to Lyme Disease. There are criteria for interpretation of many, many laboratory tests.

And I do not believe that it is common practice for physicians to always interpret a single laboratory test based on those guidelines and make a diagnosis solely on that basis.

Beyond that, there's the issue of the surveillance case definition and how people apply that to patients. But I'm not in a position to really say that physicians are routinely turning away patients who they believe have Lyme Disease because it doesn't meet one of these criteria. I would hope that they would not do that. If they feel that there is compelling evidence that a patient has Lyme Disease, that they would make that diagnosis. That is their responsibility for that patient.

ATTORNEY GENERAL BLUMENTHAL: I --
and I very much respect and thank you for that view, which I think is a step forward, perhaps simply articulating what CDC's position has been for some time. But as you're also aware -- and I don't mean to put you on the spot. But going back to the Appropriations Act of 2002, the Congress of the United States said at that point -- and I'm simply quoting the Appropriations Committee -- that it was distressed, to use its word, in learning of the widespread misuse of the Lyme Disease surveillance case definition as a diagnostic standard as well as the deciding factor in insurance reimbursement.

And those decisions are very much a concern to us in Connecticut. And so I guess I'm -- the question on my mind -- and I don't mean to, again, make you the spokesman for the CDC on this issue. And you may want to go back and give us a more complete answer from the agency.

The budget language recommended that CDC -- and I'm quoting -- "aggressively pursue
the correct -- pursue and correct the misuse of this definition. This includes issuing an alert to the public and physicians, as well as actively issuing letters in places -- to places misusing the definition."

And I wonder whether you could tell us whether CDC is fulfilling those recommendations and, if so, how.

DR. MEAD: Well, that -- as you say, I may need to go back to the agency and get that --

ATTORNEY GENERAL BLUMENTHAL: I would welcome your supple-- you know, we're happy to take a fuller explanation from you if you --

DR. MEAD: What I would say right now is that certainly CDC has made the statement about the surveillance case definition. It is published on our Web page along with the surveillance case definition. I've reiterated that statement here in this meeting.

We will have a mortality and
morbidity weekly report summarizing the Lyme Disease surveillance data coming out soon. And we intend to restate that issue once again to make our position once again known that there is a distinction between surveillance case definitions and clinical diagnoses.

ATTORNEY GENERAL BLUMENTHAL:

Well, I would -- I would welcome a statement that we can take to some of our insurers so that when reimbursement decisions are made about diagnoses and about treatment, we're able to use that kind of statement more widely and more persuasively. So I think you very much for clarifying it.

I wonder if you could also tell us a little bit about the tick control experiments that you mentioned earlier. I know some have been conducted in this area. And as I recall, they involved, among other things, feeding stations for deer and other methods which were in a sequenced, several-year test pattern. Maybe you could update us a little bit on those.
DR. MEAD: Well, I will try to.

There may also be -- I believe Dr. Stafford from the Connecticut Agricultural Station will be speaking later on and perhaps he will cover that in more detail than I can.

What I can tell you is that CDC has funded through the cooperative agreement process and also as part of our internal research have been working for a number of years to see if we could develop more effective methods for preventing infection.

As I think we heard today from the patients who spoke and from the physicians and their frustration in treating individual patients, this is not a benign disease and it does not always respond. And I think that underscores the tremendous importance of emphasizing efforts to actually prevent people from getting infected in the first place.

Some of the efforts have looked at deer -- what are called deer four-poster stations.
And these are essentially bait stations which have a small amount of corn in them which deer come to and they will receive around their neck as a result of trying to get the corn a dose of acaricide which can be very effective in killing the adult ticks which use the deer as essentially their source and breeding area.

And it is possible, studies have shown, that through the use of those deer feeding stations, you can greatly decrease the number of ticks in an area.

There are other studies, as were mentioned, some studies where deer were essentially excluded or eliminated from some island areas. One of the limitations on that, obviously, is that it's easier to do it on a small island than it is on the continent as a whole.

Another development which we are very excited about is the tick bait boxes which I mentioned. And these are -- the rodent bait boxes. These are small boxes which are placed around a
person's property and they have bait in them that
attracts mice and other rodents. And in the
process, they apply again a small dose of acaricide
to the fur of those mice.

And various studies have been
done. And the bottom line is that they show that
these bait boxes are extremely good at reducing the
number of ticks on these mice as well as the number
of ticks in the surrounding environment.

There are -- CDC has been working
with a company to get those bait boxes into
commercial distribution and broader use so that they
will be available not just on a research protocol
but for the general public, at which point -- you
know, one of the open questions, of course, is --
while these bait boxes clearly kill the ticks in the
area, we would ultimately like to be able to prove
that they really prevent human Lyme Disease. That's
the bottom line.

And we believe that with the
broader availability of these, we will be able to
thoroughly and scientifically evaluate that question.

ATTORNEY GENERAL BLUMENTHAL: Let me, if I may, also ask you a question about the lab reporting, mandatory lab surveillance issue. You know, I -- I suppose to ask a question -- I don't know whether the answer is obvious. But forgive me if it is. The reporting of lab results is an important indicator of the prevalence of the disease. Is it not?

DR. MEAD: There are several different forms of surveillance. And I believe that the folks from Connecticut who will be following can give a much better description of some of the issues involved in the decision to discontinue laboratory reporting or mandatory laboratory-based reporting. But there are several ways of conducting surveillance. You can rely on physicians to report. You can do active physician surveillance where you call physicians weekly and find out if they've diagnosed cases, which will capture many of
the cases, for example, with erythema migrans who
will not have a laboratory report.

And I'll let them discuss further
what's the rationale for what they're doing. But I
think it's important -- it's important to recognize
that surveillance is important, but it's not going
to prevent the illness. If we simply count cases
and if we put our resources all into simply counting
cases, we're not going to get anywhere.

And in many ways, what has evolved
in terms of CDC's philosophy over the last decade
and in the last decade of these cooperative
agreements, initially, a decade ago, we didn't
really know where the disease was and how common it
was. It was a very open question. And surveillance
was the burning issue. We needed to get
surveillance established to figure out where this
disease is and get some idea of its magnitude and
whether it was increasing or decreasing over time
and spreading.

I think our feeling is that that
question is apparent now. And what we need to do
now is not just count cases. We need to emphasize
preventing people from getting infected. And I
believe, to a certain extent, that may have been
what motivated the Department -- Connecticut
Department of Health to make that change. But I
think it's a critical issue.

Surveillance is a barometer. It
tells us current conditions. And you can buy a
fancier barometer or you can not put the springs in
it, but ultimately it's not going to change the
weather. And that really is our challenge.

ATTORNEY GENERAL BLUMENTHAL:
Well, I -- I don't disagree with you that ultimately
preventing the spread of the disease, treating it,
diagnosing it, all are what is absolutely necessary
to ending the epidemic. At the same time, we won't
know whether we're making progress unless we're
counting the cases. And --

(APPLAUSE)

ATTORNEY GENERAL BLUMENTHAL: I
just -- again, I don't mean to make you the point person or the recipient of a position that I have stated to your agency. And you were very gracious to come here. So I'm not berating you. But, in my view, we have to find the funding to do the surveillance. Otherwise, we won't know whether we're making progress. We need to count the cases. We can say, "Well, this disease now we know is so prevalent, it's off the charts." But we still need the charts to do the counting because we won't know whether we've made a dent, let alone real significant progress in fighting it. And the reason why I -- I mean I think you sort of are making the case in a way in your description of the tick control measures because, as you put it quite well, what we need to know is whether people are still getting the disease in order to know whether the tick control measures work. And we won't know that unless we're doing the counting.

DR. MEAD: Well -- and I believe
Dr. Hadler will clarify some of those issues. But Connecticut has a long and very good history of conducting surveillance for Lyme Disease, even before it instituted mandatory laboratory-based reporting. So I think it would be a mistake for people to come away with the view that Connecticut has abandoned surveillance and is not still capturing cases.

The real issue is being able to compare apples to apples and not to oranges and to be able to have a sustainable surveillance system. And that's not just an issue for Connecticut. That's an issue for all surveillance systems for all diseases in all places.

If a surveillance system is not working -- and not all surveillance systems work. They simply don't. They prove to be too costly and too inefficient to do their job. And, often, the effort is not worth the value gained. Yes, you capture a greater percentage of cases. But the truth is you still know that it's -- even without
that, you would have known that it was common in this town and not common in that town or was common in this age group and not common in that age group. And you can, even with imperfect or with active surveillance, determine trends over time. And those really are some of the key issues.

I think it's important for everyone to know that all surveillance systems undercount cases. That's true of every single national surveillance system. All surveillance systems undercount. And you can spend more on that and undercount a little bit less, but you're still be undercounting cases.

ATTORNEY GENERAL BLUMENTHAL:

Well, I -- I apologize that I'm going to have to leave a little bit early. But if you are taking a message back or any number of messages, I think one of them might well be that Connecticut would like to be a model in a sustainable, accurate surveillance system that fully captures and counts the numbers of cases in a way that enables us to make more
intelligent decisions about tick control, improved
diagnosis and more effective treatment, because
that's one of the measures of progress that we will
make. And I have contacted your agency and will
continue to do so on that score.
And, again, I want to thank you
for being here.

DR. MEAD: Thank you.

(APPLAUSE)

COMMISSIONER GALVIN: I think one
of the -- excuse me. Obviously, one of the crucial
and crucially important aspects of this meeting is
how do we treat Lyme Disease. And, really, before
that, we have to know how much of it we have. And I
think what we're all trying to look at is how do we
count this. And how about all those patients that I
saw and gave medication to and treated and never
came back? And I guessed they had Lyme Disease, but
I didn't have anything to confirm it. And mixed in
in that bunch of people with spider bites and
stinging insect bites and the like. And so we miss
all those people who have Lyme Disease. Or if we include them all, we include everybody who has any kind of a bite that gets antibiotic treatment.

And I struggle with the issue of what's the best way to count this. And it gives me pause when I heard some of our earlier experts saying that the tests we have are not so good and that they erroneously count things. And it also -- I hear that new tests are coming and new tests will be on line some time in the future that will count things better.

So I think we're at a -- nobody in -- I don't think anybody in the room, particularly the Attorney General and myself, feels that we shouldn't count this. I think we need to find what's -- what's the best way to count this? And in the Attorney General's presence, I will say the following. I used to send people for lab work and several weeks to a couple of months afterwards or longer, I get these little sheets back to fill out and I'd throw -- I would
sometimes throw them away. And I'll go public with
that much. I wouldn't fill them out. Sometimes I
threw the --

ATTORNEY GENERAL BLUMENTHAL: Let
me say you have a right to remain silent.

(LAUGHTER)

COMMISSIONER GALVIN: I hope
you'll represent me, sir.

ATTORNEY GENERAL BLUMENTHAL: I'll
be there.

COMMISSIONER GALVIN: And
sometimes I didn't do the second one. And I would
-- I'd eventually do it. But it would come in -- by
the time it came in, I couldn't remember whether
Captain Mead was the guy who had the rash on his
back or whether it -- or whether it was this
gentleman over here who didn't have the rash but had
serum positivity.

And I know that the return of
these documents was very low. And I don't know a
really good way to count this, to count this stuff.
I do know that we're hearing more and more that within the next few months, we'll have laboratory -- computerized laboratory connectivity with the -- between the labs and the Health Department. So it would be conceivable that we could have one or more labs simply send us all the positive, first -- all the Lymes that have first-time positivity, all those tests. And that would give us a way of looking at it. Or we could use the one large -- there's one lab that has the predominant number of Connecticut citizens.

And there are some other real advantages to being able to count this. I believe that my colleague, Sam Crowley, over there has a system where they can locate within the towns where the positive Lyme foci are and do some things about that.

I just don't know a really good -- it bothers me to devote a lot of time to a test that maybe isn't so reliable and that maybe we only get back seven out of ten queries on. But, you know, we
need to find a better way to do that. And that's part of the reason that we're having -- that we're having this meeting.

And the ideal thing would be to have a cheap, 100-percent effective test that was positive on day one. And then nobody would have any difficulty with that.

You should all be aware that if we cannot capture federal funding for this with the help of all our friends in Congress and our local Reps, it will come out of State of Connecticut funds. And you should all be aware that we've taken some relatively big hits in the Health Department. So if I had to fund an additional surveillance effort now, I would have to take the money away from somebody else. And I think, once again, my colleague, Sam, has 10 or 12 excellent programs operating in the Ledge Light Health Care District. And I wouldn't know which one of them I should take the money away from. Women's interests and children's, breast disease -- what?
A VOICE: (Indiscernible - not using microphone)

COMMISSIONER GALVIN: Yeah. And we've cut these guys to the bone. If I take any more money, they'll have to stop smoking in teenagers or drug abatement.

So these are very real issues. And we're looking for some solutions that are effective and that give us the kind of information we need.

Thank you.

(APPLAUSE)

COMMISSIONER GALVIN: Our next speaker is Dr. Jim Hadler from my department, the Connecticut State Department of Health, infectious disease and epidemiology expert, known to most of you in the room.

DR. JAMES HADLER: Okay. Thank you. And thanks for the opportunity for me to have an opportunity to present the State role in surveillance and prevention of Lyme Disease.
What I'd like to do is to kind of review a little background, some of which has already been mentioned by previous speakers, some of which hasn't, about the role of public health versus academic and clinical medicine. In other words, what we can and can't do. The role of the Department of Public Health, Infectious Disease Division, in which Lyme Disease Surveillance and Prevention is located. And talk about why Lyme Disease is of potential public health important. We don't do surveillance and prevention for everything. Why Lyme Disease?

Then to get down more specifically to further the discussion that was just had on surveillance for Lyme Disease, mention a little bit about prevention of Lyme Disease activities that stem from the State level and a little bit about funding issues.

Well, first just to briefly review the relative roles of public health, clinical and academic medicine. Public Health is basically
concerned with primary prevention, which means
preventing getting disease, infection or disease, in
the first place and related data collection
activities.

Public health is population-based.

Much as somebody like me who is trained in clinical
medicine would like to deal with individuals, we in
Public Health really deal with populations.

Clinical medicine, of course, is
also concerned with primary prevention, but its real
bailiwick is secondary and tertiary prevention. In
other words, people with symptoms and illnesses,
trying to keep -- trying to diagnose and keep it
from progressing further or cure disease where
possible. And the focus is really on treatment of
individuals.

Academic medicine -- and academic
medicine is funded a lot by the National Institutes
of Health -- is the best place to try to define the
natural history of disease, to do special studies to
figure out, you know, what are the various
complications of infection with Borrelia Burgdorferi or other organisms. They can conduct clinical trials, which you've heard about, for treatment. And ultimately, on the basis of evidence, academic medicine is usually the center for where guidelines for treatment come out so that that treatment is based on scientific evidence.

Turning to the role of the Department of Health, Infectious Disease Division, overall my division of the Department of Public Health has a goal to prevent the occurrence of infectious diseases. Our methods are to collect data on the occurrence of disease, describe risk groups and risk factors for those diseases and monitor trends over time. This all falls under the rubric of surveillance.

We then use the data that's collected through surveillance to implement and support targeted initiatives to prevent preventable diseases from occurring. That's the prevention function that we ultimately are working towards.
We have a variety of methods and it really depends on the disease, but we do case and outbreak investigation and control when that's appropriate. We do vaccination or support vaccination efforts when that's -- when there's a vaccine appropriate. And also prophylaxis, giving antibiotics to people who may have been exposed but don't yet have disease. And provide important information to professionals and to the public.

The scope and responsibility of my division. I oversee six programs, one of which is bioterrorism medical response. In other words, if we had to respond to smallpox or anthrax, the medical aspects of that, as well as the investigative aspects, would be in this -- in the Infectious Disease Division.

We have the acute communicable disease, emerging infections and outbreak investigation program. We call it the Epidemiology and Emerging Infections Program. This includes Lyme Disease. And it's under Dr. Matt Carter, who has
really been the coordinator of our Lyme Disease efforts for many years.

And then we have four more programs dealing with immunizations, HIV, tuberculosis and sexually transmitted diseases.

Altogether, we monitor, investigate and intervene where it's possible to intervene in 70 different infectious diseases of public health importance. 25 of them are telephone-reportable diseases any time of day or night, seven days per week. They include bioterrorism agents, outbreaks of illness in a variety of settings. SARS, tuberculosis is examples of things that are telephone-reportable and we respond to when we get information.

This is sort of our emergency room function which used to take probably one day a week of my time, now probably takes three days a week of my time. There's also 45 other diseases that are reportable by mail. That includes HIV, sexually transmitted diseases, several
food-borne -- a number of food-borne organisms, just
exemplified by campylobacter and salmonella, various
forms of Hepatitis, including Hepatitis C that was
mentioned as a major problem that's surfaced in
recent years, pneumoccocal disease, influenza, West
Nile, Lyme, so forth.

Okay. Well, turning to Lyme

Disease, in the course of -- you know, how does Lyme
Disease really fit into this big list of diseases?
And why are we interested in Lyme Disease?

Well, when it was originally
recognized in the late 70's, it was clearly an
emerging and vector-borne disease. We needed to
describe its impact, monitor trends, geographic
distribution. Who is getting it? Is it becoming an
increasing problem? Much as Dr. Mead just described
at the national level. Although, in Connecticut we
were dealing with it sort of ten years earlier than
it was really being dealt with in the same way at
the national level.

Currently, though, in 2004, it's
really an established vector-borne disease. So why
are we interested in now that at least in
Connecticut it's not really an emerging problem,
it's a well-established problem that we understand a
lot about but obviously still have a lot of
outstanding issues?

Well, from a public health
perspective, there's the potential to conduct vector
control. We always have wishful thinking about
vectors and our ability to control them. So any
vector-borne disease is of potential public health
interest.

And there's potential to limit
human exposure to the vector in this case and for
most cases of Lyme Disease -- in this case, ticks.

Important to point out that there
are questions that Public Health can't answer. But,
again, that academic medicine might be able to
answer. What is the spectrum and natural history of
illness? Is there chronic Lyme Disease? If so, how
can it best be treated? These are things again that
are really coming out of the academic medicine sector and we can't conduct surveillance that will meaningfully give answers to these questions.

One more thing before getting into Lyme Disease in more detail. Principles of surveillance. And a lot of these were actually nicely outlined by Dr. Mead and sort of supplemented by comments by Dr. Galvin.

Number one is we need to define the objectives of surveillance or collect -- or in this case, using its definition of collecting information. We need to know why we're collecting so we can make sure we can meet those objectives.

We need to determine how -- and corollary to that, we need to determine how best to accomplish these objectives.

Reporting of disease by clinicians and reporting of findings. Laboratory findings indicating possible disease is only one method. And it does have limitations. It's good for describing the epidemiology. Who is getting it? Men, women,
children, adults? In one geographic location or another? And if your system is stable, as mentioned by Dr. Mead, you can look at trends and you can compare apples with apples. This is something I'm going to focus on much more a little bit later.

It's not good for difficult-to-diagnose diseases and it's not very good for describing the magnitude of a problem, as has already been mentioned by Dr. Mead.

There are other methods of surveillance that we use. We analyze existing data sets. For example, hospital discharge data. We can examine visit data when it's computerized from health maintenance organizations or managed care organizations. We can do population surveys asking questions, like random-digit dialing. "How many -- has anybody in your house been diagnosed with Lyme Disease in the last year?" When we get actually get an answer, three to five percent say yes.

We can conduct sero-prevalent studies, go around and take blood, something we did
for West Nile in the Stamford area and Greenwich
area a few years ago.

We can also study the distribution
of disease vectors, ticks, deer and mice. And
that's something that Kirby Stafford at the Ag
Station will be talking more about.

Other principles of surveillance.
We need to keep the system simple. Complex systems
aren't sustainable without major resources. And if
physicians and labs don't understand the system,
they're not going to report. We need to have stable
systems, as mentioned by Dr. Mead. We can't measure
trends without stability in the systems.

And we need to have commitment of
our surveillance partners, as Dr. Galvin mentioned.
It takes time to report. You need to be cognizant
of unfunded mandates on the people who do reporting
to us. And the surveillance partners really need to
see the value in reporting because they're busy
treating individuals who really need care. And
filling out a piece of paper and sending it
somewhere that doesn't seem to get anything done is not something that takes a high priority compared to dealing with the individuals they're seeing.

From our perspective, if our surveillance objective is accomplished, we shouldn't continue it. And we take -- we try to take a lot of care to involve our surveillance partners in decisions about what's reportable and is it practical to report it, so forth.

Let's turn to human surveillance for Lyme Disease. So, as I mentioned, this isn't our only surveillance activity, but it's the one that's come under the most -- been given the most attention recently.

Our objectives have changed over time. In the 1970's and 80's, especially the 1980's, we were describing the magnitude of the problem, its geographic distribution, descriptive epidemiology and risk factors. In the 1990's, here in Connecticut we were describing changes in all of the above over time, further describing risk factors
and beginning to take a look at the prevalence of prevention practices, beginning to start focusing on the prevention side of things.

At the present time, 2004, I think the most important objectives for us -- and these aren't the only ones. But the most important objectives are to monitor the prevalence of prevention practices, to evaluate the benefits of individual prevention practices for the individual -- in other words, how good are those tick checks doing you? How good is it to have bait boxes in your yard? So forth. Determine population level impact of community-based prevention.

Important. There is no federal funding for states tied to case counts. Thus, unlike for HIV in which actually we get a lot of funding for treatment and support programs based on how many HIV -- how many AIDS cases we actually have, counting as many cases as possible is not a purpose of surveillance.

Our surveillance -- Lyme Disease
surveillance methods. Human case reporting. These are the ones we've been using in Connecticut. Sort of the descriptive epidemiology and trends. Important, we did a physician survey just about ten years ago. But I doubt that information will change much. Only seven percent of primary care physicians regularly report Lyme cases to us.

I don't know if, Dr. Galvin, you were in that group at that time or not.

But it's important to point out that this is reality, especially for a largely out-patient disease. We do geographic information system analysis of human cases looking at ecologic risk factors. We do population surveys based on random-digit dialing. There we can describe the magnitude of the problem and the prevalence of prevention practices.

Important. From this kind of information, we know that 20 to 25 percent of all families have had at least one person diagnosed with Lyme Disease ever and that three to five percent of
all families have had someone diagnosed with Lyme Disease in the past year. You can extrapolate that out to roughly one percent of the entire population or probably 34,000 people are getting a diagnosis of Lyme Disease in Connecticut each year. This is much more accurate data than our case counts, as you'll see.

Then we have tick-related surveillance projects. Dr. Stafford, again, will be mentioning those.

Human surveillance for Lyme Disease. Our method, basic surveillance, physician reporting to the Department of Public Health and to the local Health Department where the patient lives. That's a mandatory requirement. It's supposed to be done whenever a physician diagnoses Lyme Disease, whether it's immediately on the basis of a physical diagnosis of seeing erythema migrans or whether it's getting a laboratory report back on somebody with arthritis and saying, "I think this is Lyme arthritis."
We supplement these methods to try
to increase reporting rates, knowing that not all
physicians report very regularly. So reminders
don't hurt. In some parts of Connecticut -- and
we've been doing this from 1992 to the present. We
have active surveillance where all physicians --
we've tried to contact all physicians, primary care
physicians, in that area, get them to report to us
on a monthly basis on a Lyme list. And if we don't
get a report -- it makes it a lot easier for them.
If we don't get a report from them, we call them up
to say, "You haven't sent in a report. Did you see
any Lyme Disease cases?"

Between 1994 and 1997, we had
enhanced laboratory surveillance. Here, every
laboratory -- we asked every laboratory doing tests
whenever they had a positive test to slip in a case
report form with the test result they sent back to
the physician. We stopped that in 1998 for this
five-year period and had -- actually, we -- instead,
we required laboratories to report to us and we sent
out case report forms on every one with positive
tests, sometimes up to four efforts to try to get a
report back on individuals.

Important to point out these are
just supplementing physician reporting. These are
just reminder systems to get physicians to report.

The -- just to go back to here,
why did we do this? We did this because at that
time the Lyme Disease vaccine had just been
licensed. The CDC --

MR. RYAN: Time.

DR. HADLER: Okay. Asked us to do
a case control study or we applied for and got
funding to do a case control study to take a look at
the efficacy of vaccine. And wanted to have as
broad a spectrum of cases as possible reported to us
so that we could see if the vaccine was efficacious
against different forms of the disease. That
funding disappeared. The need for this also
disappeared.

There are issues related to each
form of surveillance. I'm not going to go over this in detail, given the time, because they all -- they basically require resources to do. And, theoretically, we shouldn't have to do them at all. Physicians are supposed to report Lyme Disease.

For laboratory reporting in particular, it requires 1.FTE for Department of Public Health, full-time equivalent position. And it's an equal burden on laboratories. We're really burning out laboratories with Lyme Disease, those that do a lot of testing.

Here's the end result to these different surveillance systems. The green one shows the result of just requiring reporting. Blue is the results of what we get back from active surveillance. This light color shows the four years of when laboratories were sending out report forms. And here's the five years when we were sending out report forms.

If you take a look at the green and the blue, you'll see our trends are not so --
are not so striking. Yes, we have -- we've had an
epidemic of Lyme Disease in Connecticut. We
actually now have an endemic, moderately stable,
with annual fluctuations in rates. That doesn't
mean they're not going to go up further. But annual
fluctuations in rates for Lyme Disease.

And you can see when we change
reporting systems, we only end up with apples and
oranges if we take a look at this line, which gives
us a very different picture than if we take a look
at the green and blue combination line.

The future of human surveillance
for Lyme Disease. Issues. Our purpose of
surveillance is to monitor trends and cases in the
era of prevention, emphasis on areas where
prevention projects are in place. We have data since
1994 that includes some reminder to report based on
laboratory reports.

We do need some degree of such a
degree, if possible, in areas where prevention
projects are funded or else we're not going to be
able to really compare current data with past data.

We need a stable, affordable, cost-effective reminder system to be able to monitor trends. As you know, our system has been changing every four to five years. And given all the competing health priorities, we can't really afford to go back to the system of the past five years. It's been too costly for what we get.

Our plan is -- and this was partly outlined by Dr. Galvin. We're going to -- laboratories have agreed to put a reminder note to report as part of all positive laboratory reports beginning some time hopefully during February. This will sort of simulate the enhanced lab surveillance that was done during this time period. We're developing an electronic reporting system that, once in place, we can then resume laboratory reporting. It won't be a burden on laboratories. Automatically, reports would be sent to us without their having to do any extra work and it will be uploaded into our system without us having to do
work. Hopefully beginning by 2005. This is what the system would look like. Maintained active surveillance. Labs including reporting reminders statewide and electronic laboratory reporting, with reminders that would still have to be sent out manually to physicians in selected areas.

From a prevention perspective, given time I'm only going to mention one or two things. We can avoid the complications and divisive controversy regarding Lyme diagnosis and treatment by preventing Lyme Disease in the first place.

Three, four main principles. Personal avoidance of ticks by various methods. Prophylactic treatment of some tick bites. Reduction of peri-domestic tick populations by a variety of means that Dr. Mead described. And still the possibility of vaccination in the future. It's kind of sad that the vaccine was taken off. But that's the way it is.

Our role in Lyme Disease
prevention is development of information. We're a source of information on how to prevent Lyme Disease. And we assist in development and evaluation of prevention efforts, passing through funding from CDC for a variety of things, for public education efforts, prevention research, community intervention, and pass them on to the Ag Station, selected local health departments at this point in time.

We also do population level assessment of prevention efforts using human and tick surveillance and population surveys. These are the three demonstration project -- prevention demonstration project areas you're going to hear from the Torrington area shortly.

From a funding perspective, all funding is -- this is my last two slides, quickly. All funding has come basically from federal sources to support our Lyme Disease surveillance and prevention efforts. Most federal funding has been competitive, as Dr. Mead pointed out. Currently,
only four states are funded for Lyme Disease
surveillance and prevention. We're one of them.
There's only one funded for tick-borne disease
prevention. That's Connecticut. Again, both of
these applications have been coordinated by Dr.
Carter.

Our partners currently include Ag
Station, three health districts and the University
of Connecticut GIS people in Storrs.

Future funding, however, for
Connecticut is uncertain. By late 2004, there will
be only two distinct cooperative -- the two distinct
cooperative agreements for the past five years will
be collapsed into one dedicated to Lyme prevention
and prevention evaluation. Only two states, instead
of four, will be funded, approximately 650,000 each,
with a range -- could be as much as 800,000.
So this is what our cumulative
funding has looked like over the years. Next year,
it may look like this, if anything. We could have
zero and we could have up to $800.00. So unknown
where our funding for prevention will be in the
future. Our application is undergoing competitive
evaluation. We hope it will be reviewed favorably.
But we don't know.

So thanks for listening. And I'm
sorry to go over.

MR. RYAN: That's okay. Thank
you, Dr. Hadler.

(APPLAUSE)

MR. RYAN: I wonder if I might ask
you a question at this point. You mentioned that --
and I think Dr. Mead had mentioned that the funding
for the state -- for state activities has gone up
considerably over the past five years. Do you
connect that in any way with the enhanced reporting
that came with the lab reports?

DR. HADLER: No. The -- as you
can see, our funding -- what happened is in 1999 --
there's a second sort of a pinkish color -- this
right here. CDC had a second cooperative agreement
for tick-borne disease that was mainly focused on
Lyme Disease but also Ehrlichiosis and Babesiosis.

So that was additional funding that was available to public health agencies. So that accounts for a lot of it.

The increase in the green part is actually, in part, related to funding for -- well, adding on -- the CDC pot got bigger and they added on some prevention activities related to Lyme Disease. And so that accounts for this.

I think as Dr. Mead said, in 1997 when this was actually -- that wasn't our case count. But in 1997, before we had any laboratory reporting, we were the number one state in the country. A number of other states -- several other states also had very high rates of Lyme Disease. We were all the -- we were obviously best positioned to get funded. Not all of us did get funded. And whether or not we had laboratory reporting -- I mean in -- we were still the number one state in 2002. So I don't think there was any -- anything there. It's really our cumulative record and trying to
conductor surveillance, meaningful surveillance, getting information and using it for prevention that's so far kept us in the funding loop. Hopefully, it will keep us in the further funding loop.

MR. RYAN: So -- but the numbers are somewhat telling? I mean the CDC needs to know some kind of count in order to tell whether --

DR. HADLER: Right. And, as you know, we do have -- we do have a count. As I said, we haven't stopped surveillance. As we change surveillance and we take off some of -- and we make it simpler, more manageable and less -- and more cost-effective, our case counts obviously went down in 2003. But we still counted more than a thousand cases. We are planning on adding back a couple of elements of surveillance that had given us higher case counts between 1994 -- let's see --

MR. RYAN: So how far did the counts drop?

DR. HADLER: Yeah. Here we are
right here. Here's 2003. Here's 2002. Obviously, a huge drop. But look at all the artifact we added by lab surveillance between this time period and over here. And the real -- and the part that doesn't depend on the laboratories at all is the green plus the blue. That hasn't changed all that much over time. It's obviously gone up and down various years. We're actually right now very similar to where we were back in 1995.

However, we're going to be adding back sort of this aspect of lab surveillance and a little bit of this in the future when we have electronic lab reporting because we think that's necessary to have as stable a system as possible in the areas where we have prevention projects.

MR. RYAN: But when Congress decides -- and Congress does decide when to allocate the monies for this. Right? I mean it's not the CDC that does this. Are they looking at numbers?

DR. HADLER: Well, Con-- it's hard to say what makes Congress decide to appropriate
funding in the first place. In terms of funding
that comes specifically to Connecticut, though,
Congress doesn't look at Connecticut. Congress
looks at the national numbers all together and other
reasons that make Lyme Disease something that has
come to of interest and appropriate funding. The
funding then goes to NIH, CDC, at least the federal
funding, as the two main agencies for dispersing
funds based on clinical research or public health
research and practice.

They have processes for
distributing funding themselves. And those are
actually outside review. Nobody at CDC or at least
the CDC people who control the money is looking at
-- they're looking at our applications only.
They're not looking at anything else. It helps to
have cases, of course. You're better off funding a
Lyme Disease prevention project probably in
Connecticut than Texas because Texas doesn't have
much Lyme Disease at this moment in time. But
whether you fund it in Connecticut or Rhode Island
or Massachusetts or New York doesn't make any
difference whether our case counts are slightly
higher or slightly lower. It's really the strength
of our proposed activities and our ability -- our
effort to present ourselves to be able to carry out
those activities that's being judged.

MR. RYAN: When the CDC gives you
the $800,000.00 that they had mentioned or I think
you had mentioned, do they tell you how to use that
money? Or do you decide how to use it?

DR. HADLER: Yeah. The -- all
this funding here -- this funding right here, it's a
combination. They put out a request for proposal
saying -- with some specific things they want to
have as part of that. They don't say, "Here's money
for Lyme Disease. Tell us how you want to use it."
It comes with "We want you to -- we want whoever
applies for this to conduct surveillance for ticks,
for human disease, for -- we want you to do a
community intervention project to see if we can
communities to do the kinds of things that might be
necessary to control deer populations and
collectively control -- do ecological things and
provide education and see if it makes a difference."

It comes with some real specific ideas attached. But how we do those is up to us.
So we propose back to them how we plan on doing it.
And they come -- and then our application is reviewed, along with the applications of all the other states that apply. And depending on how much money is available -- and in this -- for 2004, it's only going to be two grants. Two states will get an amount of money averaging this amount of money for -- starting late 2004.

We're the only state to get this pot right here. So our proposal was judged to be the best of all the proposals. And it wasn't because we had the most Lyme Disease cases because New York, Massachusetts, Rhode Island can compete with us there. They're not really very different. It was because of the strength of our proposal, having --
MR. RYAN: They don't have lab reporting?

DR. HADLER: Having the Ag Station, having --

MR. RYAN: Does New York have lab reporting? Do you know?

DR. HADLER: Some of the states around us do have lab reporting. How they use it is a question. Some attempt to do some degree of follow-up and some -- some do more follow-up. Some do less. Some give it to local health departments to follow up.

MR. RYAN: I'm sorry. I --

DR. HADLER: Some don't have it.

MR. RYAN: -- just have one more question.

DR. HADLER: Yeah.

MR. RYAN: You mentioned that you're looking to go to an electronic reporting method. Will that eliminate the extensive human follow-up that has to be done currently with the
paper-based system? Or will it still be a costly proposition?

DR. HADLER: Well, it will eliminate two out of the three costs. Currently, there's a cost to the laboratories to send all the paper to us. And it's a huge number of pieces of paper. Last year, it was 14,000 reports came to us. Those reports resulted in this many -- whoops. Wrong one. Resulted in this pink part, this many cases being reported. So it resulted in another 2,000 cases. 14,000 reports resulted in 2,000 cases being reported. We don't get responses back to everything we send out. We have to send out up to four letters to get a response back. And even then, we don't get responses back from some.

So the laboratory side is improved. Our side is improved. We don't have to enter all this data. So we don't have to take 4,000 reports and enter it into a computer. That keeps the clerical person a huge percentage of the time. And then generating letters.
But, however, the issue of then sending a letter, at least one letter, to physicians who are getting positive laboratory reports, some of that work -- that work -- that piece will still have to be done. That piece, though, what we would do is only do it in a few areas of the state where we had prevention projects going. We wouldn't do it statewide because we can't afford -- we simply can't afford to do that. And we would work in collaboration with the towns that are getting special funding to follow up on those reports. And in that way, we think it could be manageable.

But, to us, it makes -- right now it doesn't make sense to ask laboratories to every possible laboratory report and then only use a very small percentage of them because we don't have the resources and it's just not really a very practical use of our resources, given all the other responsibilities we have.

However, if the laboratory reporting is basically free for the laboratories,
they just push a button and everything that's reportable to us comes to us because it's already in their computer and gets extracted and sent to us and we don't have to spend a lot of time entering it, then we can choose to use just a fraction of it and it's not costing anybody anything except for in the areas where we decide that we want to have more intense efforts to try to count all the potentially countable cases. So that's where we see ourselves going in the future.

DR. MEAD: Excuse -- if I could just clarify or reiterate one point, two points? One of which is --

COURT REPORTER: Your name please?

DR. MEAD: This is Paul Mead for the Centers for Disease Control and Prevention.

CDC funding is not given according to the amount of cases reported. Connecticut gets more than twice as much money as New York does, but they have fewer cases. So it's not -- it's not on a case-by-case payment.
MR. RYAN: Is that population-based, though? I mean --

DR. MEAD: No. Total cases.

MR. RYAN: No? Okay.

DR. MEAD: New York, state of New York --

MR. RYAN: No. No. I meant -- I meant is it the rate of cases per person?

DR. MEAD: It has nothing to do with the rate of cases or the number of cases. New York has reported more cases than Connecticut for virtually a decade. But they get less funding. It has to do with the very competitive proposals that Connecticut has submitted and that have been ranked highly.

Secondly, CDC did not predicate any funding on Connecticut's discontinuation of laboratory-based reporting. That is a rumor which has been going around. It's not true.

MR. RYAN: Thank you.

DR. RANDALL NELSON: Before the
next panel member, I'm in the unique opportunity to both ask a question as well as offer comments since Commissioner Galvin has asked me to sit in his chair until he comes back. He'll be gone just a few minutes.

And the comment I want to make is to clarify or at least expand on one point that Dr. Hadler made. And that was when we conduct surveillance, we have to have willing partners. Those willing partners are not just the Health Department and laboratories. Those willing partners are also physicians who we contact on a regular basis to report information.

And as Dr. Hadler pointed out, they have to see the point of it. It has to be easy enough for them to do. And it has to still allow them to carry on the most important work that they do and that is treating the individual patient.

After years of surveillance, we do have in some areas exhaustion among physicians and their staff providing us with information regarding
tick-borne diseases.

So we need to take into consideration that we have many partners in conducting the surveillance. And a very important group, of course, are the clinicians who are seeing patients who are ill.

Thank you.

MR. RYAN: Can continue with James Rokos please?

DR. JAMES ROKOS: Yes. Can you hear me okay?

MR. RYAN: Yes.

DR. ROKOS: Yes. Well, first I want to thank actually both, I guess, Commissioner Galvin and Attorney General Blumenthal for inviting me here today. It's a pleasure to be here. And I know Randy Nelson quite well. Mr. Ryan.

Last time I had a chance to speak about Lyme Disease was at the semi-annual meeting of the Commissioner of Health and we had seven and a half minutes. So I've been promoted to ten minutes
today. So I'll try to do my best there.

Well, as you said, my name is Jim Rokos. I've been the Health Director for the Torrington Area Health District for the last -- I don't know -- 35 or so years. It's in a great area of Connecticut, the Northwest Corner. We cover 18 towns. Very densely wooded. I usually call it Tick Heaven. But I actually think that the entire state of Connecticut is kind of Tick Paradise because we really live in a rain forest.

And exactly why we have more ticks and why the infectivity of ticks is on the increase I think is open to some speculation. There are some reasons that maybe Kirby will talk about that later.

I'm actually here and I -- it's interesting and it's almost a little bit ironic. I used to teach kids in high school and middle school about Lyme Disease and rabies and anything else they'd sit still for for like 20 minutes.

I also had Lyme Disease back in the early 90's. And it was -- that's a whole
'nother story. So I actually have -- I'm actually a patient or victim, however you want to look at that.

I'm the Director of Health. And we were fortunate enough to be one of two sites to be chosen as to have this Lyme Disease grant, which we currently have. And we're hoping very much that it will be extended. It was for three years, over $300,000.00. And I think we've done a great job with that money.

The best thing I did with -- at the very beginning of that grant was to hire a wonderful teacher by the name of Sue Perlatto. And all the Directors of Health know Sue. She is a -- when I first hired her, she said, "Jim", she said, "I don't know anything about ticks." I said, "You don't have to." I said, "I'll teach you everything you need to know about ticks and Lyme Disease." I said, "But you have teaching skills that we're looking for." And she has never disappointed. She's just the greatest in terms of getting the message out.
We also -- people should know that we had -- the reason -- I guess one of the reasons we were successful in getting our grant is we have -- three of our towns have the highest rates of Lyme Disease, not the number of cases but the rates. And that was true a year or two ago. I'm not sure what it looks like for 2003. But that's interesting because it wasn't that long ago people in the Northwest Corner kind of thought we were not going to have much Lyme Disease. And when it was suggested that physicians start considering it, a lot of them said, "No, no. That's a shoreline problem. That's really not something we need to worry about up here." Well, obviously, we know different now.

About a third of the ticks that we submit every year -- and last year we submitted over 700 -- were positive for the spirochete. So we know we have the ticks. We have a lot of them. And we have our share of Lyme Disease.

Basically, Jim touched on some
great things that I'm going to try not to duplicate what he said. But, basically, from a local -- I'm looking at this, of course, from a local health department standpoint, as I said. This large, rural, heavily forested part of Connecticut.

The two things that we really talked about doing in our program was, number one, prevention and, number two, early diagnosis and treatment. Now, we don't diagnose and we don't treat. But as Jim indicated here, we do educate people on options that they have. We think that that's an important thing a local health department can do. And we act as a great source of information and referral.

People come to us all the time. We have this fantastic Website. There's a ton of information out there. And people are highly intelligent today and can make a lot of decisions on their own. So we kind of guide them and point them in the right directions.

So in terms of prevention, well,
obviously the very first thing when you're in public
health and you have a disease, the best thing is a
vaccine. And we were very hopeful that the vaccine
was going to be a success. And, unfortunately, it
wasn't. So we're still hoping that that will be
another -- a success story when it comes back, maybe
this second generation that someone talked about.

The second better thing that we
could do or the second best thing, I guess, is to
have a good test. And everyone's talked about that
today. I'm not going to talk much more about it.
We really don't have a reliable test. It's subject
to interpretation. And it's just -- it's something
that we think needs to be done and usually is done.
But I think both physicians and the people who are
tested just need to use that as one tool in their
box, I guess to say, because it's certainly not --
we don't think it's probably that useful for
diagnostic purposes, based on our experience.

In terms of -- the third thing in
terms of prevention that we've really excelled at, I
think, is the human education component. We
strongly talk to people about personal protection,
about wearing the right kind of clothing, about
using insecticides on themselves and their kids. We
talk about pet protection.

I had a good friend of mine, a highly intelligent woman, call me about a month ago
and she said, "I found a tick on me this morning
when I was showering." So we got to talking about
it. She was quite paranoid. Well, come to find out
they sleep with their cat every night. And I said,
"Well, is he strictly a house cat?" She said, "No,
no. He goes out all day and then he comes in at
night." So I said her name and I said, "That's not
a good idea." So I mean that was something -- I
don't know if I actually changed what they do or
not. But sleeping with your pets, if your pets are
spending time outside, is not a good idea.

We urge people to be able to
identify ticks. We identified and had tested over
700 ticks last year. I know there's controversy
about the value of having these ticks tested. But
Sue and I, Sue Perlatto and I, both feel this is an
opportunity for people when they come in to our
office. It's a very emotional thing. They've
usually already read up on Lyme Disease and about
these ticks. It gives us an opportunity to really
educate these people. We give them a lot of good
information. And whether the tick comes back
positive or negative is almost a secondary issue.
But it really gives us a chance to really interact
with these people on a one-on-one basis. So we do
think it's worthwhile doing the testing.
And we -- of course, we talk to
people about the seasonal and age distribution. We
basically do anything we can to break that cycle of
Lyme Disease. And I think we've done some pretty
good work based on some feedback that we've gotten.
We use -- and this is all to Sue's
credit. We use visual aids. And anybody that's here
today, if you look out the front window of the
Legislative Office Building, you'll see this lime
green Volkswagen with little ticks all over it.

Well, fake ticks. And this was her idea. And we --

I took her up on that immediately. And it's --

honestly, it's been the best thing. I mean

everybody knows her as either "the tick lady" or
"the tick police" and "the Lyme mobile".

And then she even went so far as
to get a kayak donated. And so on one of our trucks
that goes up into the areas where a lot of people
are at risk, we have this lime green kayak on top of
one our vehicles. And that's -- once again it's got
Lyme Disease information on it and, of course, our
Website and our phone number.

So I think that we need to do
something different. We've tried education in the
past with limited success. We need to do something
different, come up with some gimmicks to get the
message out. I mean we had this huge billboard on
the way in to the post office that so many people
talked about. And I wish I had the slides here. I
didn't realize I'd have that opportunity. Because
you would have -- everyone here would have gotten a big kick out of that.

And Sue told me, and I've never forgotten because she's told me at least seven times, that people have to hear things at least seven times to really retain time. So I do think that's probably true.

Very quickly. Environmental measures. Now, we -- in conjunction with the education part of it, we started and we're hoping to expand the environmental control measures. We talk to people about building natural barriers around their properties. We actually have a demonstration site where we have the right kinds of plants, wood chips. We tell people not to have bird feeders and wood piles close to their houses because they'll attract mice and mice, of course, are loaded with ticks.

So -- and we talk to them about using integrated pest management practices and -- which basically is using the least amount of
chemical that you can to do the job. So the first
thing, of course, is to build these natural
barriers.

Second are the rodent bait boxes. And I know Kirby is going to talk more about that.
We've given -- we probably set about a thousand of those in the ground. We need more time to evaluate their effectiveness. We think we've had some success there.

The four-poster deer feeding station we're kind of excited about. We have money in our budget for it. This will be the first year that we actually try them up in the Northwest Corner. Some people are worried that they're going to attract bears instead of deer. So we'll have to wait and see how that actually goes.

The last thing, of course, is to spray your back yard with again acaricide which kills ticks. Most people don't want chemicals sprayed in their back yards. They have kids. They have pets. We even get calls from people who are
irritated by their next-door neighbor spraying his
yard with some chemical for his lawn. So I --
that's something that's an option, but I don't think
it's ever going to be widely accepted.
The early diagnosis and treatment
part of this basically --

MR. RYAN: Time.

DR. ROKOS: -- from our standpoint
is educating the people on the early signs and
symptoms. We talk to them about rashes, fevers,
flu-like illness during the non-flu season. I had
my symptoms start in June and July and they were
just classic flu-like illness. But that's not the
time of the year we have flu.
Secondly is active surveillance.
We've already talked about that. Physicians have
never reported any diseases like they should. I
don't know what the answer is. I suggested to Sue
on the way over here, "For every report they give
us, we give them a $5.00 gift certificate to Krispy
Kreme or Dunkin' Donuts. Maybe that would do it."
So we need a simple, effective way to get physicians to report.

I do think the lab data is an important part of that. But I realize that it's an expensive thing. I'm hoping that with this new electronic surveillance system we can restore that.

And, lastly, the future. Well, number one, I was hoping Commissioner Galvin would be here because he needs to hear this. And that is that we need to have full-time health departments throughout Connecticut. We have three levels of activity right now. We have three sites, Westport/Weston, the Ledge Light Health District and ours. We're doing an intensive job with Lyme Disease. Then we have other full-time health departments that definitely have some Lyme Disease program. And then we have part-time health departments where there's no information at all. And I know that that's the case. So first we need to have full-time health departments throughout Connecticut.
I just put down here we need to restore lab reporting. We need physicians to help us. We need to continue education both for lay people and the professionals. I think just listening to all these great physicians today -- and I mean that. I think they're all well-intentioned. But we need to somehow level the playing field so everyone has an understanding, same kind of basic understanding.

I think we need to continue expanding these environmental control measures that we're going to be doing. We need to come up with a better test, a vaccine, and we need more lime green Volkswagens.

That's it.

(APPLAUSE)

MR. RYAN: I'd like to compliment you on the creative efforts that you're making. And I wonder -- you mentioned that you find that -- and you encourage people to come to you for information.

Do you find that that's mostly lay people or do you
find physicians coming to you as well?

DR. ROKOS: That's a good question. We have a Lyme Disease Committee that meets, I think, every month or six weeks. And we've had a couple of physicians come, mostly to share -- we had a rheumatologist. It is mostly lay people, actually, that come to us. But we've had calls from physicians and some of them are very interested in finding out -- they need to know what the incidence is. So we try to give them feedback. When they give us information, we try to give back to them so that they really do understand that what they're telling us does make a difference. It might not seem real clear to them right now. But --

MR. RYAN: Do you think that primary care physicians, at least in your area, are fairly knowledgeable about things to look for or do you find that, you know, they have something to learn in that area?

DR. ROKOS: They definitely need more education. They do.
MR. RYAN: Do you also -- I mean do you find that --

(APPLAUSE)

MR. RYAN: I work in our Health Care Advocacy Unit. So I hear a lot from consumers directly. And they express frustration to me when they get information from an organization like yours and they go off and they believe they have these symptoms and they'll go to their doctor, who is often primary care, and the doctor really doesn't listen to what they're saying.

Is there a way to -- is that a bad thing to begin with, to have the patient aware of this, or is there a way to get --

VOICES: No.

MR. RYAN: Is there a way to get the doctors to become more aware? I mean is that the goal?

DR. ROKOS: Well, it is. And as I said before, you know, I think the consumer -- I don't care whether it's disease or you're buying a
car today. The consumer or the patient really wants
to understand more about what's going on. And with
all the information that's out there, they should
understand it. I think they make a better patient.
I think most doctors will agree with that.

Doctors, they just need -- they
need to hear from maybe different people than their
patients that -- we had one doctor, he heard
recently -- I don't know how long ago it was -- that
Lyme Disease was no longer a reportable disease. So
he told his front office. He said, "Well, stop
reporting that. We don't have to -- because it's
not reportable." Well, he misunderstood that it's
really just the labs that don't have to report that.

So -- and we've heard many, many
stories. Children with Bell's Palsy who, it's our
understanding, it's not definitely a diagnosis for
Lyme Disease but highly indicative of that.

Physicians saying, "No, no, no. We don't think that
that's any connection between Lyme Disease and
Bell's Palsy."
So we somehow need to get the message out to these doctors. And it makes it very awkward for the patient to go there and tell the doctor, "I think you need to brush up on some of this stuff." So --

MR. RYAN: Who's job is that, would you say? I mean is it medical schools? Is it --

DR. ROKOS: We have -- I mean we have some great stuff right in our office. We have this great building. We have this room that seats 30 to 50 people and we have a satellite outside that was -- because of this whole bioterrorism stuff. So we could -- we could be -- distance-learning is a great way. Physicians are very busy today. I wouldn't put that monkey on any one back. But I think that whether we would give them CEU's to promote them to come to our office -- and these dishes are placed around Connecticut. Whether it would be a CEU or something else to get these doctors to come and sit down and listen to -- and it
can't be too long. I mean it really -- they're very
bright people. I think the message could be given
out I mean in a half a day at the most and maybe
just a brief amount of written material.

We're going over this in this
whole bioterrorism stuff. We're flooded with
written material. And we need to get back to basics,
the very simple -- maybe even when physicians --
when a person comes in, they would have a very
simple flow chart or maybe a questionnaire to ask
people. Because I think we're just inundated with
paper. And we need to simplify things.

MR. RYAN: Thanks, Jim.
DR. ROKOS: Thank you, Andy.
MR. RYAN: We'll continue with Dr. Lee.
DR. JOHNNIE LEE: Good afternoon.

First I'd like to thank Commissioner Galvin and
Attorney General Blumenthal for an opportunity to
come and address this hearing regarding Lyme
Disease. I currently serve as the Director of
Health and Social Services for the City of Stamford, Connecticut and have a 12-year history of clinical practice in internal medicine. And my training and background is in internal medicine, with a Master's Degree in public health.

The Stamford Department of Health and Social Services serves a community of approximately 117,000 residents. The primary focus of the Department of Health in Stamford is health promotion and disease prevention.

We recognize that Lyme Disease causes significant morbidity for those affected by the disease and we continue to provide services and programs to address the increasing problem of Lyme Disease in our community.

One of the ways that we try to do that is through our tick program. In 1989, Stamford, in conjunction with the Connecticut Agricultural Experiment Station, established a program to monitor the incidence of ticks infected with Borrelia Burgdorferi, the organism known to
cause Lyme Disease.

The purpose of the program is to determine the risk of contracting Lyme Disease when bitten by a deer tick. The Health Department accepts ticks submitted by residents and sends those specimens to the Agricultural Experiment Station for analysis. Those submitting ticks are given information about how to collect the ticks. They're also given information about Lyme Disease, including the need to seek medical attention if they have symptoms of Lyme Disease. They receive literature regarding the tick life cycle, tick avoidance recommendations, signs and symptoms of Lyme Disease and other tick-borne illnesses, such as Ehrlichiosis and Babesiosis.

Since 1989, there have been 8,415 specimens submitted, with 1,879 being positive for Borrelia Burgdorferi. The ticks are also assessed regarding whether or not they are engorged. And of those specimens collected to date, 358 were found to be engorged.
In 2002, there were 586 submissions for tick identification and testing. There were 178 ticks tested positive for Borrelia Burgdorferi and 32 of those were significantly engorged. In 2002, there were 55 cases of tick-borne disease reported.

In 2003, we saw a similar trend, with 673 cases -- excuse me -- submissions. And 40 of those were significantly engorged and 172 testing positively for Borrelia Burgdorferi.

It is worth noting that most of the reported cases of Lyme Disease from the positive blood results for antibodies to Lyme Disease were -- excuse me -- were -- excuse me.

It is worth noting that most of the reported cases of Lyme Disease came from positive blood results for antibodies to Lyme Disease. Many clinicians treat Lyme Disease based on symptoms and not a blood test result. So, if an individual is evaluated and treated for Lyme Disease without blood tests being ordered, no disease would
be reported, thereby leading to under-reporting, which is a significant problem.

When we receive a result back from the Agricultural Experiment Station, a letter is then sent to the person who submitted the specimen. The letter informs them whether or not there was a positive result and also tells them whether or not the tick was engorged.

If, indeed, the tick analysis was positive, we also follow up that communication with a phone call to the individual to see if, indeed, they had any symptoms and whether or not they sought medical attention.

A recent survey was conducted by our laboratory in Stamford at the Health Department of 13 individuals recently reporting or submitting specimens. Ten people actually responded and three did not. Of those ten people who responded, three had actually contacted their doctor and one had actually been treated for Lyme Disease. And seven actually had not seen a doctor. But, after the
conversation, three out of the seven decided that they would follow up and see a physician.

Our efforts in disease surveillance at the Health Department are primarily focused through the employment of two full-time epidemiologists and one full-time State epidemiologist assigned to the Stamford Health Department. The epidemiologists work with the Director of Health, the Director of Laboratory Services and a community public health nurse to evaluate the incidence and prevalence of various infectious diseases, including Lyme Disease.

The data collected is used to help direct education and prevention programs within the department. Recent data indicate that as many as 33 percent of the ticks submitted to the Health Department for analysis are, indeed, infected with Borrelia Burgdorferi.

Data collection has also allowed us to determine that young children are bitten at a higher rate than older groups. And we have also
determined that both ticks submitted and cases of Lyme Disease are fairly evenly distributed throughout all areas of Stamford, ranging from somewhat rural north Stamford to more urban and suburban Downtown and the waterfront areas.

The Stamford Department of Health and Social Services remains committed to providing resources for education and prevention initiatives, to decrease the incidence of Lyme Disease and other tick-borne illnesses in Stamford.

In an effort to decrease the incidence of Lyme Disease, we are committed to using resources to provide educational information that make people more aware of the issues related to Lyme Disease. We employ a full-time Director of Public Health Education whose primary task it is to coordinate educational initiatives related to public health matters.

In 2004, we are currently planning to use the local newspaper, public television, audio/visual and printed educational materials to
reach citizens of all ages and alert them of the
dangers of Lyme Disease. We are fortunate to have a
public health nurse from our Health Department
working in every public, private and parochial
school in Stamford. This allows us the ability to
potentially interface with every school-aged child
in Stamford, providing information on tick
avoidance.

As a public health agency, we have
an obligation to respond to the concerns of our
citizens. There appears to be an increasing --
there appears to be increase evidence that many
cases of Lyme Disease are not cured by the standard
courses of treatment we've used in the past.

There is compelling evidence that
many individuals infected with the organism that
causes Lyme Disease suffer from long-term,
debilitating symptoms. This underscores the need
for greater awareness through education and
prevention. It also underscores the need for more
research in the areas of diagnostic testing and
You mentioned that you have a full-time nurse who is basically involved with all the schools in your system?

DR. LEE: No. We have --

MR. RYAN: Oh.

DR. LEE: -- a full-time nurse assigned to each and every school.

MR. RYAN: Oh. You have more than one. Okay. Do you -- are you finding that school children are dramatically affected by this disease? And is it affecting their ability to learn within those settings?

DR. LEE: Well, you have to understand that there are many individuals who believe that undiagnosed Lyme -- undiagnosed acute Lyme Disease, which then becomes more of a chronic issue, can cause neuropsychiatric problems. That's
not what -- you know, that's not what we as a Health Department, you know, do. Certainly I've spent many years in clinical practice in internal medicine, not pediatrics. So that question is probably better addressed by a pediatrician, a pediatric neurologist, people who see children, a pediatric neuropsychologist who actually, you know, does testing on children to determine, you know, what types of problems children are having and what might be, you know, the cause for that.

Certainly, you an extrapolate, if your child lives in an area where there's a significant amount of Lyme Disease and if your child, you know, has those problems, that's one thing that you would consider in the differential. But that's just medicine. That's just the general way to sort of address, you know, patients with problems.

MR. RYAN: But your -- your office doesn't really evaluate that impact really.

DR. LEE: No. I mean -- no.
Children who have -- children who have problems in the classroom, that work is typically funneled through the Board of Ed and the Board of Ed is then responsible, in our structure in Stamford, is responsible for getting those children tested and making sure that that information is communicated to their parents to make sure that the child is evaluated. But that's not something that the Health Department would be actively involved in as far as the testing and evaluating of children with school problems.

MR. RYAN: You mentioned also that you're involved in the education process for citizens. Are you doing the same with doctors? Are you working with doctors?

DR. LEE: In Stamford, there -- we are fortunate to have, you know, an active medical community at Stamford Hospital. And there's ongoing, you know, continuing medical education. Every physician who has privileges at Stamford Hospital is required to maintain a certain amount of
continuing medical education.

And I think that there's a need to have ongoing exchange and ongoing education with regard to, you know, all disease processes. You know. And so I think that -- and certainly as the whole issue of Lyme Disease and the appropriate treatment and the appropriate testing and the appropriate evaluation, as that sort of evolves, I think that, you know, it's necessary to have continuing and ongoing dialogue and education about that, as well as about colon cancer and heart disease and -- you know, as a general rule.

MR. RYAN: But are you involved in that? I mean are you --

DR. LEE: We provide information to our citizens. We don't -- we send out information. For example, I can tell you that recently with the influenza epidemic, we sent out information from the Health Department to every pediatrician in town. We sent out information to all the family practitioners in town. We sent out
And so we would do a similar kind of thing with regard to Lyme Disease when we're doing our initiatives. I mean we do that with regard to SARS. If Avian Influenza becomes a problem, we will do that with Avian Influenza. Because as a Public Health Department, we have a responsibility to educate the public. And certainly our medical colleagues would be a part of that.

We certainly do not tell them how to practice medicine. But we make them aware that this is a problem and these are the types of things that you should be looking for and these are possibly some ways of addressing the issue.

DR. NELSON: Dr. Lee, hi.

DR. LEE: Hi.

DR. NELSON: First time I'm speaking with you. Randy Nelson at DPH. I'm sure we're going to have a long history. We provided you with some of that information to do your health
assessments. So --

DR. LEE: Yes.

DR. NELSON: I remember.

What kind of information -- or are you collecting additional information regarding the outcomes of those folks who submit ticks for testing specifically comparing people who submit ticks that ultimately test positive for Lyme Disease and among those ticks that are engorged and so had the opportunity to infect that particular patient? You had said that the people are contacted by telephone so that you're assured that they have the information that they need and that they're advised to go to see their physicians.

Do you have any follow-up information on those folks? That is, how many become ill? How many are prophylactically treated?

DR. LEE: No. The real -- you know, our -- you know, what we do is, as I say, as I stated, for every specimen that we get back, whether it's positive or negative, a letter goes out. And
for all those that are positive, that's followed up with a telephone call to verify that they got the information and to then find out if those individuals have seen a physician. If they have, great. If they have not, then that gives an opportunity to think twice about that and go on and do that.

The majority of the individuals, you know -- and this is a very small sample that -- from a recent phone survey that we did. The majority of those individuals did then say, if they had not seen a physician, they were going to go. But we do not take it a step further and then call them back later and check to see, "Did you go? And what happened when you went?" No.

DR. NELSON: Thank you.

MR. RYAN: I guess next will be Cheryl Carotenuti from the Connecticut Department of Education.

MS. CAROTENUTI: Right. Thank you.
As I was just introduced, I'm Cheryl Carotenuti, the Health Promotion Consultant from the State Department of Education. And I, too, would like to thank Commissioner Galvin and Attorney General Richard Blumenthal for inviting the department to be here today. I think it's important for us to share information on how schools and the department address the students with chronic health care needs. But it's also important for us to understand the issues that affect students with Lyme Disease.

As the Department of Education strives to attain their goal of student achievement, we recognize that an essential component is addressing the health and wellness needs of these students. Addressing the health and wellness includes health prevention, health promotion, as well as providing direct services and mental health services to students. It's also important to understand that in general the State Department of Education
doesn't provide specific interventions for all the various chronic health care needs that students have, but, rather, provides a framework for how schools can meet the needs of all the various health concerns.

And this framework includes three different areas. First, students with Lyme Disease may receive comprehensive services in their regular education program. These services and accommodations are generally identified in an individual health care plan that's developed by the school nurse, the parent, the provider and any other appropriate school personnel. Additionally, the students may receive services through school counseling programs, classroom activities or homebound instruction.

Second, students may receive services under Section 504 of the Rehabilitation Act if the chronic health needs substantially limit the major life functions, such as breathing, walking or learning. In this situation, the 504 plans may be a
combination plan for outlining classroom,
transportation or instructional accommodation as
well as an individual health care plan outlining any
health services that they may need to support their
access to an educational program.

Some school systems incorporate
504 and individual health care plans. Some schools
keep them separate.

The third avenue is that students
with Lyme Disease may be eligible for Special
Education under the Individuals with Disability
Education Act. There are several categories of
disability that may be appropriate for
consideration, including Other Health Impaired or
Learning Disabled.

It must be shown that students
meet the criteria for the category of the
disability, that the disability adversely affects
their educational performance and that, because of
this, the child needs specially designed
instruction.
In this situation, the student would have an individual educational plan that documents their educational services, as well as the health care plan that documents any health services needed.

If a student is referred for Special Education or 504, the school district must convene a Planning and Placement Team or a 504 meeting to consider the request for the evaluation. It's not appropriate for the school to refuse to schedule a meeting because the child is presenting with a medical issue.

The team is often made up of school personnel, the family, the student, when appropriate, and occasionally outside health care providers. The team is required to review any existing evaluation data, including evaluations and information provided by the parents, classroom-based observations, observations by teachers or other related staff, such as the school nurse, OT or guidance counselor.
As the information may include medical information, it's also important to have a school nurse or school medical advisor as part of the PPT or 504 meeting. If the team believes there is enough information to identify the disability, no further evaluation need be conducted. But if the team believes there is additional evaluations that are necessary to determine eligibility, the team needs to identify what additional information is needed, arrange for the evaluations and assume financial responsibilities for the evaluations.

Due to the various opinions within the medical community on Lyme Disease itself and the extent of symptoms and long-term effects, schools often don't have enough information to make accurate decisions. It's essential for schools to have this information on the disease, the symptoms, the complications and the potential educational implications.

It's also important for physicians who diagnose and treat students with Lyme Disease to
establish good communication with schools and to
provide specific student information to assist
schools in determining eligibility for services.

As a result of increased phone
calls to the department regarding Lyme Disease and a
meeting with the Lyme Disease Association and Time
For Lyme Association, the State Department of
Education also recently sent to every school
district a sample protocol and resources on Lyme
Disease based on some information from the Greenwich
public schools. The materials included an
educational video, suggested protocols, sample
criteria and a checklist for school nurses.

Other resources include serving
children with special health care needs, specialized
health care procedure guidelines and a parents guide
to Special Education through the Department of
Education.

It's important to understand the
role of the school nurse as a medical resource to
school personnel and families. As I mentioned in
the beginning and as Dr. Lee mentioned, health services includes health prevention and health promotion. And although it's not statewide, many school nurses have taken the opportunity to educate staff, students and families on Lyme Disease prevention, especially as schools engage in more outdoor activities, physical activity and science programs and field trips.

In conclusion, the Department of Education requires all schools to the health needs of students. This is effectively done through collaboration with the school staff, the family and student, the medical community and the community at large. Schools are responsible for the education of students. And in order to do so, they also need to address any barriers to learning.

Thank you.

(APPLAUSE)

MR. RYAN: Thank you.

DR. NELSON: You mentioned that the training of nursing is not a statewide thing.
Or is the out-- was that outreach or training that
you were talking about?

MS. CAROTENUTI: What I said was
that the nurses provide health prevention and
education to staff and students. And I don't know
that it's statewide. But I know that many nurses
engage in those activities in the schools because
that's part of their role to do health prevention
and health promotion.

DR. NELSON: Do you think those
nurses are universally well trained or just in
certain systems?

MS. CAROTENUTI: It's probably --
varies greatly across the state in terms of their
knowledge and comfort in educating.

DR. NELSON: Do you see any role
for your office in trying to standardize that?

MS. CAROTENUTI: Actually, in the
meeting that we did with the Lyme Disease
Association and the Time For Lyme, that was one of
the things with the -- they were going to help us
put together a packet of information that we could, in fact, distribute to school nurses.

DR. NELSON: Are you going to do follow-up with that or --

MS. CAROTENUTI: Yeah.

DR. NELSON: Sorry.

MS. CAROTENUTI: No. That's all right. We have -- twice a year I conduct a school nurse supervisors meeting. And we have a meeting in the spring. And that was when we were going to follow up on our December meeting and submit all -- distribute the material to the school nurses.

DR. NELSON: Do you see this as being a problem in our schools in particular, the Lyme Disease?

MS. CAROTENUTI: Well, because of the -- I mean there has been an increased number of phone calls to the department. And partly it's because of the information that we either don't receive or do receive from the medical communities in terms of what the specific needs of students are.
And the response of the school districts varies in terms of how they accommodate the students.

DR. NELSON: Thank you.

MR. RYAN: Well, thank you all. I guess, you know, in closing I would ask if any of you on this panel have any recommendations for --

A VOICE: We have one more.

MR. RYAN: Oh. Dr. Stafford. I'm sorry. You're -- would you like to present? Are you prepared? My apologies.

DR. STAFFORD: Okay. My name is Kirby Stafford. I'm chief scientist at Connecticut Agricultural Experiment Station. I'm an entomologist and a vector ecologist. I have been working on the ecology and control of the black-legged tick or deer tick as it's commonly known since I joined the Experiment Station in 1987.

I didn't actually realize I'd have a chance to present anything. Not only do I do research on tick control and tick ecology, but I also give a lot of public talks. And so it just so
happens earlier this week I gave a talk to the
Northeast Organic Farming Association on their
annual course on organic land care. And this
morning, I gave a talk to the Connecticut Parks and
Recreation Association, their directors, on ticks
and Lyme Disease.

What I would like to do is just
simply -- I'm going to have to race through this --
this was an hour presentation -- and just highlight
a couple of things pertaining to control that are
pertinent to this hearing.

I also want to point out that in
this whole issue of reporting, I think that one of
the things to bear in mind is that the reporting
points out trends in disease. And I did publish a
paper noting that the number of infected ticks that
I collected in Lyme and Old Lyme was highly
correlated with the reported incidence of disease,
both in those communities and statewide. So even
though Lyme Disease is under-reported, I do think it
reflects true trends and cases.
So let me go through this very quickly. Most of this is material that has been discussed. One thing I'll point out is people ask why do we have Lyme Disease and why is it a problem today. And I just quickly want to point out it's a response to our changing landscape patterns here in New England.

A Swedish naturalist back -- came through this area in the mid-1700's and in 1770, he pointed out that "To these I must add the wood lice or ticks with which the forests were so pestered it's impossible to pass through a bush or sit down. Though, the place would be ever so pleasant without having a whole swarm of them on our clothes." He was actually in New Jersey at that time. So ticks were abundant.

A century later, the State Entomologist of New York noted that "The most common tick of our country, the wood tick", as they called it then, "though formerly abundant throughout the northern and middle states, has now become nearly or
quite extinct. At this day alone on the route in pursuit, not one can be found."

During that issuing time, of course, we saw a significant change in Connecticut's forest cover, steadily declining through the 16 and 1700's. Agriculture reached its peak around the 1830's. As lands opened up out West, farms were abandoned. The Industrial Revolution began. People moved to the cities. And throughout the 20th century, our forest cover increased.

Along with that, we saw an increase in the population of white-tailed deer. These are historic estimates of the white-tailed deer in Connecticut compiled by the Department of Environmental Protection. Their latest estimates are there's around 76,000 deer in the state of Connecticut. Based on one report that the DEP has, they figure there was about 12 deer in Connecticut in 1896.

This is some records that I also pulled out. And same pattern for the Northeast.
Massachusetts in 1931 estimated there were 11,500 deer in that state. In an article in the Journal of Forestry, today the estimate is around 90,000. So it's a pattern throughout the Northeast.

But I figured this graph would be particularly interesting. This is a close-up of the deer population trends in Connecticut estimated by DEP since 1975. And what I did is I took the number of reported Lyme Disease cases and multiplied it by ten. Remember, we -- based on surveill-- other information, we figure only 10 to 13 percent of diagnosed cases are actually reported.

And you'll notice that the lines parallel each other very nicely. And this is because the deer is the primary host for the adult stage of the tick. I'm not going to dwell on the life cycle this afternoon. I don't have to time. What I want to do -- oh, I should mention -- this is a graph provided by the Department of Public Health on Lyme Disease on cases by month of onset in Connecticut from '92 to 2000. And it -- as you can
see, it peaks every summer, which corresponds with
the activity of the nymphal stage of the tick.
So a big question is how can we
prevent Lyme Disease. Obviously, there was a lot of
hope the vaccine would play a major role in that
issue. And as everyone has learned, it was
withdrawn from the market, which really brings us
back to basically preventing exposure or reducing
the tick population.
Options include personal
protection measures against tick bite, the use of
acaricides, biological control, altering the habitat
or what I call vegetative modifications. I did do
some studies in Connecticut forests on vegetative
destructive by controlled burns which were actually
for forestry generation, not for tick control.
Post-reduction or exclusion in host-targeted
acaricides.

Tick checks. Everyone knows to do
that, particularly in children. It's already been
pointed out earlier that the highest rate or
incidence of Lyme Disease is in children. This is
again data from the Department of Public Health.

I'm not going to get into how a
tick bites and the transmission. I don't have time
for that today. Usually in my talks, if I'm the only
one speaking, I'll just quickly highlight some of
the major symptoms of Lyme.

But I really want to get into the
ecology of the disease. It's primarily a
residential problem. And this is some data that was
kindly provided to me by a post-doctorate M.D. at
the Stamford Health Department and -- where, based
on questionnaires on those ticks that were submitted
to the Experiment Station for testing, they found
that 75 percent of people estimated they were picked
up outdoors at home and 21 percent were picked up
away from home. The point being it is primarily a
residential risk. And note that play, 47 percent of
those estimated it was at play.

So I think this information that
the Stamford Health Department gathered while, you
know, taking in the ticks for testing gave us some
really good insight, gave some real good insight
into, you know, where people are actually getting
their tick exposures. And, consequently, we have
focused these projects largely in a residential
setting.

Now, in a residential setting
itself, by sampling ticks, about two percent of
ticks are actually on the lawns. The majority are
in the woods. And on the lawns, 82 percent I found
were within three meters of the lawn edge. So
there's a very definite edge effect in terms of the
risk of where you're going to encounter ticks. And
this also applies to school grounds, recreational
parks, as well as the home. This is a
woodland-inhabiting tick.

Acaricides is one approach. Like
previously mentioned, a lot of people don't want to
use acaricides on their properties. I've done a lot
of trials with less toxic alternatives, including
the natural pyrethrins. As you'll see, they're not
all that effective. I did find one combination of
natural pyrethrin with the synergist propanol b
oxide mixed with insecticidal soap gave pretty good
results. The synthetic pyrethroids, regardless of
which kind you use, are fairly consistent in the
kind of control that you will get.
But I've also been conducting trials with
entomopathogenic fungi. Two products, naturalist
TNO and Botaniguard, which is the fungus babesia
dassiana, gave fairly decent control in the trials
that I conducted in homes.
And then we also tested a more
recent product containing the fungus Metarhizium
anecephaly called Tick-X. And I got decent control
with that, too, at least at the trials down in
Westport and Weston. So these hold some promise in
terms of alternative chemicals for controlling
ticks.
This is more details on those
results. I don't have time to go into the details
on those.
The one thing about the Metarhizium product is that the company has received EPA registration for their product and is seriously interested in getting this eventually commercially available for homeowners to use to control ticks.

The initial trials that we did, the products were actually shipped from England. We had spore viability with 70 percent. We had 81 to 85 percent reduction in the ticks at the homes where we sprayed this. In Old Lyme, the product that we -- the second batch that we received was -- had a 48-percent viability. Again, this was lab-produced material. And we did not get as good a control. Also, it was done late in the season, much later than you would probably ideally use a material like this.

Landscape management has been a focus of a lot of attention on tick control. And, indeed, the Westport/Weston Health Department, as part of their education efforts, has produced brochures called "Get Your Back Yard In The Zone".
There is a Spanish version as well. Which emphasizes some of these landscape measures. And they also produced a brochure on "What's Wrong With This Picture?" The particular park, working with a landscape architect, they generated a brochure to give some tips on how to design a park or recreation area, school grounds to minimize exposure to ticks.

These ticks, again, are in the woods. This is actually a home in Old Lyme. This is before. This is after. The number of ticks on the lawn at this property were reduced by 90 percent just by cleaning up the edge, opening things up and pulling that swing set out of the woods.

So what I found was just cleaning leaf litter at the edge of the property will reduce ticks approximately 49 to 70 percent. Putting in a well-maintained wood chip barrier at the lawn perimeter reduced the number of ticks in the lawn by 35 to 77 percent compared to untreated properties.

And another thing to consider possibly is cleaning up your stone walls. These are
essentially mouse hotels where you find the mice and
the chipmunks. And there is a higher rate or
association of ticks along stone walls than you
would find elsewhere. So one option, at least
adjacent to the home, is to clean those up as well.

Isolated plantings and mulch as
opposed to something like this.

Another thing I try to educate
people on is the -- you know, think about where the
children are playing. They're at high risk. A
swing set tucked back into the woods is -- in what
the Westport/Weston project called the tick zone --
is essentially asking your child to get a tick bite
and possibly acquire Lyme Disease. So you need to
pull that out, out of the risk zone, into a more
open area. And that applies to recreation and
playground areas, too, as well.

But, real quickly, in essence,
what you want to do -- you have an area of woods
behind the house. The ticks are there. You know.
They're not going away. The idea is to at least
create areas either in the park or around your home where you've created a barrier between the area where the ticks are that is safer and has a reduced risk of ticks. And that may be barrier spraying of pesticides just along the edge or landscape modifications.

A lot of our research has focused on deer and on mice. Deer are, of course, not responsible for the transmission of the disease, but they are the main host for the adult tick and, therefore, key to the reproductive success of the tick. I want to point out that each female tick that feeds on a white-tailed deer will produce a couple of thousand eggs. So how many ticks you have is linked to how many deer you have.

I did a study in the early 1990's and a similar study down in Westchester County got the same results. I looked at two properties in Lyme, Connecticut that had a seven-strand, high-tensile electric deer fence. One was about eight acres. The other was about fifteen acres.
Seventy meters inside that fence -- this is actually the outside of the fence. This is the inside of the fence. Deer will actually try to go under a fence before they try to go over it. And, of course, at some point they make contact with the electric wires and they learn to avoid the fence.

100-percent reduction in larvae.

No deer coming in. No ticks being dropped off. No eggs laid. No larvae. We had an 84-percent reduction in nymphs. We had a 74-percent reduction in adults.

To follow up on that, I did a study working with, in part, with the Department of Environmental Protection looking at the impact of deer reduction on ticks at two properties, one a privately-owned forested tract in Bridgeport, Connecticut. I called it an island in an urban sea. It had over 200 deer per square mile in that tract. And the Bluff Point Culture Preserve in Groton, which also had over 200 deer per square mile in that area.
The deer were reduced in Bridgeport initially by over half in 1992 and '93 and then more gradually. Part of this was due to some reproductive control studies on deer. But, as you can see, the population of nymphs also declined along with the deer population.

In Bluff Point, this shows you the number of deer and larval ticks. And green is the number of deer. They held the first controlled hunt in January of '96. They removed a few more animals in '97. They resumed the controlled hunts in January of 2000. Their target is about 20 deer on Bluff Point, which is what they feel that peninsula can support ecologically.

The number of larval ticks dropped. As the deer numbers started to increase, the larvae increased. There was a big peak in 2000 and then it dropped. You'll see that the nymphs started finally to drop as well. In 2001, we saw another big peak, the year after the larval peak. But then they declined. So deer numbers and tick
numbers are closely related. And I like to think if
you don't manage the deer and reverse that curve, as
the deer population steadily increases, the tick
numbers are going to increase along with it.

And I should mention that the
Experiment Station did some studies working with
deer back in 1980 when Lyme Disease was still really
relatively unknown. And we found -- Dr. Mangarelli
looked at the serology study on the deer and he
found up in Litchfield County, as you heard earlier
as some of the highest rates in the state, there
were no ticks up there and all of the deer were
sero-negative for Lyme. It hadn't gotten there yet.

By 1990, a number of the deer
starting sero-positive. And what we saw is the tick
has spread geographically and -- both in New York,
Connecticut, up the coast in Maine. The tick has
extended its range. Part of the increase in the
number of Lyme Disease cases nationally can be
attributed to the expanded geographical range of the
tick and more people being susceptible to it.
Another approach is actually treating the deer. This four-poster was developed and patented by the USDA Agricultural Research Service in Texas. It's called the four-poster. It holds about 200 pounds of corn. There's a feeding trough on either end and four paint rollers that hold a topical pesticide. The pesticide -- deer then are treated when they feed.

Now, their initial studies down in south central Texas were aimed at deer and the Lone Star tick. These are pastures and they're huge pastures. These -- it's an untreated pasture. And these are Lone Star ticks all over the ears of this animal. This is a treated pasture. No ticks.

The question was would this technology work for our tick up here in the Northeast. A regional project was begun in the fall of 1997. There was a community in Rhode Island, a community here in Connecticut, which happens to be Old Lyme, a community in Westchester County, New York, which was Bedford, Earl Weapons Station in New
Jersey and several residential communities in
Maryland were all treated with these four-posters in
about a two-square-mile area, using the pesticide
Amitraz 2% Point Guard, which is a product that was
used on hogs. It's no longer available. It was
taken off the market for economic reasons.

But you can see here from a hidden
motion detection camera the deer coming in to the
feeders, push in, as the animals put their heads up
against the rollers and are treated. We went
through a lot of corn in this study. But the main
point I want to make, we also periodically marked
the deer using marking rollers and doing
surveillance to get an idea of what proportion of
deer were actually utilizing these feeders. And
after an initial acclimation, we had all of the
observed deer were marked, indicating a high usage
rate. Unfortunately, the first -- the fall of '98,
we had a major acorn mass and the deer basically
ignored our feeders. But then you can see it
rapidly recovered. And generally through most of
the project, we had a high proportion of deer
utilizing these feeders.

We've been monitoring ticks in
that community and also as a comparison, as a
treatment, in Old Saybrook. And by 2003, we had a
70-percent reduction in the population of ticks in
Old Lyme in the treated community in comparison with
Old Saybrook. So we did have an impact.

Another study in fenced deer using
pyrethrin resulted in even better control. And
that study has been published. So that's one
approach.

Another approach is targeting the
ticks on white-footed mice. And this was -- these
are the bait boxes that were referred to earlier.
Dr. Gary Moffin at CDC, now retired, came up with
this approach. And he came to me to try and test
this technology in Connecticut, using a
Fipronel-based rodent bait box.

In the lab, Dr. Moffin found that
the Fipronel, a single application to a mouse, would
render that mouse tick-free for up to 42 days and
almost tick-free for up to over 70 days. Pyrethrin
was effective for about two weeks. And Amitraz,
which is the material we were using on the deer, you
can see didn't last very long at all.

We currently have the bait boxes
out being tested on Mason's Island, Westport and
Weston, Mumford Cove, up in Salisbury, Canaan and
Cornwall, and there's also additional test trials
being done as part of the CDC cooperative agreements
on community prevention in New Jersey, New York and
Massachusetts.

This just shows you the locations
again of the community projects. With these bait
boxes where you examine the boxes for use, we check
the mice for tick abundance and we also sample
host-seeking ticks at the residential properties.

Now, the study was begun initially
on Mason's Island by Dr. Moffin and Mark Dolan of
CDC. After I introduced them to the residents, they
went in and they put boxes in 1999 at the southern
end of the island. They expanded the number of homes treated in 2000. And by 2001, virtually every residence in the community had received the bait boxes.

Essentially, they found an 80-percent reduction in the number of ticks the first year and a 96-percent reduction during the second year. The residents of Mason's Island are extremely pleased with the outcome of this. They are no longer picking up ticks on their children or on their pets.

Based on that, Aventist Environmental Science, which is now Bayer Environmental Science, decided they would work on a commercial version of the box. The original box only held two bait boxes and had a hand-stapled wick, a yarn wick, to the lid of the box and you had to recharge them every couple of weeks.

In 2001, they tried an initial prototype which did not work very well. And in 2002 and 2003, they came up with the design that
currently exists. There had to be some
modifications to the wick and type of bait used to
get optimum use out of the box.

This shows you a magnified look at
the system. Mice and chipmunks come in on either
dend. There's a central corridor and a wick that
holds the Fipronel.

The EPA required the company to
place this in a very heavy-duty plastic,
child-resistant packaging. It is a sealed box. They
cannot be recharged. They have to be used and
thrown away.

They're placed about 30 feet
around the property. In habitat like this, you
know, near where you would expect to find mice,
stone walls, fallen trees and so on, you put a flag
by it so you can find it later. Stake it down with
a variety of stakes.

And just in the time I got in
Westport and Weston in 2003, this shows you the
number of mice that we captured in the control homes
versus bait box homes. Actually, about 70 to 74
homes were treated. We didn't, obviously, actually
sample every house. And we found a highly
significant difference in the proportion of rodents
infested with larval ticks in the bait box than
control-treated areas, 75 versus 18 percent. This
is a 64-percent reduction on the mice.

No ticks were recovered from the
chipmunks that we caught from the bait box sites in
Westport, while five of the six chipmunks that we
did capture in Westport were infested with 31 ticks.
A highly significant difference.

If you look at the number of ticks
on the mice themselves -- again, we had some
adjustment problems in the -- with the wick with the
box. 2001, there's no impact. 2002, not much of an
impact. But finally, everything's right. 2003, we
had significantly fewer larval ticks on the mice in
the bait box treated sites than in the control.
Almost 90 percent reduction. And most of the boxes
were empty.
So Bayer is planning on commercially launching this box, called the Max 4 Tick Management System. It contains .7% Fipronel. It is EPA registered. It is registered here in Connecticut. And they plan to commercialize the box this year.

Okay. Some other registrations. Brute, which is 10% pyrethrin, was approved by the EPA this past summer for restricted use on white-tailed deer. Restricted use means it is restricted-use pesticide. Only a certified applicator can purchase this material. It has received a state label now. And now we are waiting for action by the wildlife divisions in the state in terms of how this four-poster is going to be made available and managed.

You've got 10% pyrethrin on exposed rollers. So, obviously, this is something that's going to be -- have to be carefully regulated and controlled. But it is one control approach where not every residence has to take active
participation in tick reduction to have an impact on
the tick population.

If you're spraying and you want to
control it, you have to spray your property. If
you're using bait boxes, you have to put bait boxes
on your property. This approach, you can have a
handful of homeowners agree to allow access to their
property with these devices and control ticks.

Tick-X, the fungus-based material,
did receive registration from the EPA. Hopefully, I
will be able to conduct some additional trials this
summer. There are still questions on dosage,
frequency of application and things like that that
need to be answered before the company is ready to
actually commercially market this. They hope that
they might be able to do this by 2005 as an
alternative to synthetic pesticides.

We've already talked about that.

So I'll conclude with -- here's a picture of the

Volkswagen --

DR. ROKOS: Thank you.
DR. STAFFORD: -- of the Torrington Area Health District for those of you who haven't had a chance to see it yet.

I have also written a Tick Management Handbook. It is written. However, it still needs to be -- have a graphics layout done and actually printed. And that's something that's in progress.

And so, with that, I would conclude my comments on the status of tick control here in the state of Connecticut. Thank you.

(APPLAUSE)

COMMISSIONER GALVIN: Thank you very much for that last presentation. That was about as complete and succinct a report as one could do in 25 to 28 minutes. And I do admire your lapel pin.

DR. STAFFORD: Oh. Thank you.

MR. RYAN: Does anyone have any comments at this point in time as to where improvements can be made that we haven't covered? I
mean I think -- and I do appreciate what you're
telling us, Dr. Stafford, about some of the things
we have to look forward to in protecting our home
environments and actually reducing tick populations.

But do we have any other comments
from the panelists?

DR. HADLER: Yeah. Just to make a
comment; that a lot of the work -- some of the work
that Dr. Stafford was describing is funded in part
with the federal funds that the Department of Public
Health gets and shares with the Agricultural
Experiment Station. And what Jim Rokos was
describing in Torrington and also other similar
projects are happening in two other health
districts, as we mentioned, that also comes out of
the current CDC prevention funding.

I hope that people realize that we
have a very collaborative relationship.

Surveillance is -- I mean there's tick surveillance.

There's human surveillance. All these projects
together kind of interdigitate. We're hoping that
-- well, it's important to point out that none of what is happening with the way we're trying to measure Lyme Disease in Connecticut -- it's all being geared to enhance these interactive projects rather than -- rather than compete with them or potentially detract from them. So that we hope that our future will be one of continued collaboration and we can really see how well all of these activities, both the research that's led to all these ticks -- to the demonstration that tick intervention is effective in reducing the number of ticks, trying to get communities to practice them and then seeing if we can have an impact on -- overall impact on human health related to Lyme Disease. So that's kind of our collective goal in our interactive projects.

DR. STAFFORD: Yeah. I should emphasize that this collaboration goes back many years, before many people even heard of Lyme Disease. In fact, one of the first collaborations was back in 1984 and '85 when the Experiment Station
was one of the first labs to develop the early serological test for Lyme. And working through the State Health Department, free testing was offered to physicians as a pilot project in 1984 and '85. Samples were submitted to the Health Department. They came down to the Experiment Station. They were tested, sent back to the Health Department and then to the physicians.

And as a result of that collaboration, we got our first image or picture of the distribution of Lyme Disease in Connecticut at that time, which at that time was still largely in New London County and east of the Connecticut River.

Since then, you know, our agencies have continued to collaborate. Some of the early education that was done in the state was actually under the umbrella of the Arthritis Foundation, the Connecticut chapter as it was then, with a task force that was composed of Dr. Matt Carter from the Health Department, myself, Polly Murray from Old
Lyme. We produced a variety of educational brochures. And so that was some of the early education stuff that was actually done in the state. So the collaboration has been a very long one.

MR. RYAN: Thank you.

COMMISSIONER GALVIN: Well, I appreciate everybody's time and efforts today. Once again, Dr. Nelson and Tom Ryan really did, as my chief of staff says, the heavy lifting on this endeavor. I have heard a marvelous amount of expertise here from a panel that I would virtually defy anybody to put together other than somebody that had the persuasive skills that Mr. Ryan and Dr. Nelson have.

Be that as it may, what's going to happen next? I think we -- I can certainly -- I hope that I have dispelled your fears that regulators within the State Health Department are going to take issue with practitioners. That's not going to happen. Or at least, as they say, not on my watch. Unless there are other problems with --
that have to do with quality of care and are totally unrelated to diagnosis and treatment of Lyme Disease.

I have indicated that we will put a document together reviewing the findings here. That will be published hopefully in one of the local medical journals and hopefully with some input from Attorney General Blumenthal's office about suggested regulatory changes or suggested administrative changes.

Bearing in mind, as you all should, that the State Health Department -- we're basically an educational organization. We don't make the laws. And we're not the executive. We help to implement them.

It's my feeling that we still have some ways to go to resolve what's the best way to count people. And we will work on that. And I'm sure that between Dr. Nelson and my staff and the Attorney General and Mr. Ryan and his staff, we will be able to come up with a coherent solution to the
Some of the measuring of laboratory positivity will be made much easier as the various labs within the state come on line. I think, as I heard our colleagues from the CDC and the NIH indicate and as several speakers have indicated, there is no direct relationship between the numbers of cases that we count and the amount of money that the federal organizations are going to give us. However, I also heard Attorney General Blumenthal say very succinctly that -- how do we know things are better or worse unless we have some way of counting them? And we have to way of counting the cases which is not only relatively easy to do but is reproducible. We don't want to count the wrong things. We want to count the right things. So we have to have -- find a way to count these things, but to count them in a way that's reproducible and valid so that if someone else counts them, they count them pretty much the same.
way and so that we can compare them to similar-sized
states and similar venues.

That is somewhat of a daunting
process. But, once again, if we can't -- if we
don't have a correct count, how will we know if
we're affecting the disease one way or another?

We will work -- and I know that
it's been one of the Attorney General's prime
motivators, is how do you count -- how do you count
this disease appropriately? I think we'll certainly
be able, as I said a minute ago, to count them
through the use of the laboratories.

Once again I have to give you my
caveat that if we are required to put in procedures
which are not cost-effective from the standpoint of
the Department of Public Health, we will certainly
-- we are public servants. And we will do what the
public demands and what the Representatives and the
Senators think is appropriate. However, there is no
huge fund of money. And if, in their wisdom, the
Assembly decides that they want us to do additional
counting in a way which may not be effective and secondarily decide that they will not fund us for it, the money will have to come out of some other project. And the projects that we have now are -- many of them are cut to the bone and/or eliminated. And we are trying to get things back on line, particularly with immigrant health and with multicultural health, but also with a variety of programs.

So as you think about what's happening here, it's not as one would envision it a huge pot of money that we can dip into. It will be taking money from one program and putting it into another. And if we need to do those types of things, we need to do them so we get the best possible product for the least possible expenditure so we can put our money into abatement of the ticks and into research.

We will develop a product -- I believe that Randy will have something available within the next few weeks. And we can share that
with any of you folks who want to read it and look
at it.

We will do our best to spend our
money wisely and not jeopardize other programs and
yet find a way where we can count these things in a
reasonable fashion.

Thank you.

(APPLAUSE)

(Whereupon, the hearing was
concluded at 5:00 P.M.)