

1 VERBATIM PROCEEDINGS

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STATE OF CONNECTICUT

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DEPARTMENT OF PUBLIC HEALTH

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PUBLIC HEARING

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IN RE:

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LYME DISEASE

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23 JANUARY 29, 2004

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ATTORNEY GENERAL RICHARD

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

21

Let me begin by thanking Dr.

1 Galvin and the Department of Public Health for their
2 immense help, their energy and hard work in putting
3 together this very, very significant forum and
4 hearing.

5 We are also grateful to the
6 legislature for giving us this facility and to some
7 of the legislators who will be joining us. One is
8 already with us. State Representative Dolly Powers
9 is here. At least I saw her a little bit earlier.
10 And others will be joining us. I'll try to
11 recognize them when they arrive.

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

20 And I would like to say I
21 understand that we have with us the person who was

1 first diagnosed with Lyme Disease in the state of
2 Connecticut, Polly Murray. Welcome to you. And
3 thank you for being with us.

4 (APPLAUSE)

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

14 I don't have lengthy remarks to
15 begin this hearing. I'm going to ask Dr. Galvin a
16 few words, if he'd like to remark. But I just want
17 to say that we're here because even in the coldest
18 weather, we simply cannot rest or be complacent.
19 The ticks that carry this disease may be resting
20 under the snow. But we have no reason to in any way
21 rest in our efforts to educate and warn the public

1 and to try to improve diagnosis and reporting.

2 So, in addition to the general
3 concern about Lyme Disease, about improving
4 education and awareness throughout the state, I
5 think there are two specific objectives today. And
6 they are to eliminate the common use of excessively
7 restrictive Federal reporting criteria to diagnose
8 and treat Lyme Disease and, second, to correct the
9 under-counting of Lyme Disease cases so that we can
10 understand how widespread and severe this disease
11 really is. On the one hand --

12 (APPLAUSE)

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

19 And that will be the focus as we
20 go through the day, under-diagnosis and
21 under-counting. And, again, we will have with us

1 some extraordinary scientific talent, some people
2 who have suffered from this disease who have come
3 forward very bravely and articulately in the past
4 and now again today, and then some of the government
5 officials who are responsible for making policy in
6 these areas.

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

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

17 COMMISSIONER J. ROBERT GALVIN:
18 Thank you, sir.

19 Just for those of you who don't
20 know me, I'm Bob Galvin. I'm a newly appointed
21 Commissioner of Health. I started on the 1st of

1 December. I come from a background of almost 40
2 years in clinical medicine and have been a teacher
3 of medical students for a good part of those 40
4 years. I last saw patients on the 26th of November
5 of this year. And my last patient was a gentleman
6 who, on the 25th, sent me a small, clear plastic
7 container with contained a tick, which I would
8 identify as a Lyme tick, adult female. And sent me
9 a -- accompanied it with a phone call saying he had
10 a rash and he'd removed the tick. And, in fact, the
11 last person I saw in my private practice was an
12 individual who I believed had Lyme Disease but who
13 would not be counted because he had not had enough
14 time to develop markers in his blood for that
15 particular disease.

16 I would like to tell you that one
17 of my real heroes in the medical world is a
18 gentleman named John Enders, who is a West Hartford
19 native. As I'm sure many of you know, John Enders
20 received the Nobel Prize for measles vaccine. It
21 was -- when I was in school in Boston and later on,

1 it was widely known that Enders had given away
2 probably five or six other projects which resulted
3 in Nobel Prizes or the equivalent of Nobel Prizes.

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

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

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

20 I have no preconceived notion.
21 There is nothing chiseled in concrete in my

1 department. And I have no -- I'm not bound by any
2 agreements, past or present, which any of my
3 predecessors have made.

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

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

19 So no one has been coached by me.
20 And I'm here to learn and to listen. And I have no
21 pre-formed opinions.

1 ATTORNEY GENERAL BLUMENTHAL:

2 Thank you, Dr. Galvin.

3 (APPLAUSE)

4 ATTORNEY GENERAL BLUMENTHAL:

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

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

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

21 COMMISSIONER GALVIN: The

1 Reporter, Court Reporter, advises me that if, when
2 you first speak, if you could identify yourself,
3 then he'll be able to track the testimony.

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

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

16 MR. JOSHUA ATHENIOS: Hello. My
17 name is Joshua Athenios and I have had Lyme Disease
18 since the summer of 2000 when my mother picked off
19 two ticks from my body, one behind my left knee and
20 the other behind my right ear. I never got a
21 bull's-eye rash. I started having joint pain in the

1 fall of 2000 and was told by my pediatrician I was
2 having growing pains and fatigue due to my intense
3 karate training. I got physically worse and worse
4 as time progressed. I had extreme fatigue that was
5 unrelieved by rest and sleep. My joints --

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

9 MR. ATHENIOS: My joints --

10 COMMISSIONER GALVIN: Atta boy.

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

18 With my mother's persistence, I
19 had a test for Lyme Disease in the spring of 2000.
20 I had a positive Lyme ELISA. With my mother's
21 persistence, I received three weeks of Doxycycline.

1 My symptoms improved and I thought I was well.

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

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

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

18 Three days passed and I was not
19 better, but worse. My mom sent me to school with my
20 crutches. I could not finish my school work or play
21 with my friends. I was in extreme pain day and

1 night. I was on several pain pills that did not
2 relieve my pain but only made me feel worse and gave
3 me stomachaches.

4 At this point, I looked as sick as
5 I felt. Many classmates asked me what was wrong and
6 if I had cancer. I did not know that Lyme Disease
7 could lay dormant in the body. At recess, I was on
8 crutches and a boy asked me what my symptoms were
9 and I told him. And he gave me a piece of paper
10 with a number on it and told me it sounded like I
11 still had Lyme Disease. He told me to call his
12 father. I went home and gave my mom the number.
13 The next night, the boy's father ended up calling my
14 house.

15 Our pediatrician told my mom that
16 I could not have Lyme Disease because I was already
17 treated for it for three or four weeks. I had more
18 blood tests that came up positive for Lyme. I was
19 sent to a rheumatologist at the Children's Hospital.
20 He looked at me for about 60 seconds, sent me for
21 x-rays. He ignored my positive Lyme test and

1 diagnosed me with arthritis. He told my mom it
2 would be a long time before I would walk without my
3 crutches. He told my mom to call the office and
4 schedule an appointment to have an operation in two
5 weeks to have my hips drained. My mother refused
6 the rheumatologist's diagnosis to pursue surgery.

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

17 My parents could not find a doctor
18 to treat me for Lyme that the insurance covered. So
19 they took me to Dr. Charles Ray Jones, a
20 Lyme-knowledgeable doctor. They paid out of pocket
21 for my treatment. Dr. Jones took the time to listen

1 to me and cared enough to diagnose me properly. I
2 was given Amoxicillin and Zithromax and was walking
3 without crutches after three weeks.

4 I continued my treatment for nine
5 months and had significant improvement in my health.

6 I have been off all medication for over a year and
7 a half. I am taking karate classes again and I'm
8 studying for my black belt. I am thankful to God
9 for my health and thankful for the responsible
10 physicians who take the time to listen to their
11 patients even if the patient is a kid.

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

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

21 Thank you.

1 (APPLAUSE)

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you very much, Josh. Very well said.

4 If we could now hear from Caroline
5 Baisley?

6 MS. CAROLINE BAISLEY: Good
7 morning.

8 ATTORNEY GENERAL BLUMENTHAL: Good
9 morning.

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

18 When I received a call from the
19 Attorney General's Office inquiring about my
20 interest in participating today, I was honored.
21 After agreeing to be a part of the patient panel on

1 the agenda, I realized that my role would be quite
2 different. As a victim of LD, I would be offering
3 information from a patient's perspective and not
4 from a Public Health official's point of view.
5 Although I felt comfortable in sharing my story as
6 an LD patient, I found it difficult as I began to
7 assemble my experience. In addition, I found it
8 equally difficult to separate myself as an ailing
9 patient with disease and the leading health
10 authority that strives to protect the public's
11 health against the disease.

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

16 As a woman in her early 40's, I
17 was grateful to have my health, a good job, close
18 friends and a loving family. In 1999, really
19 becoming ill, I came down with a bug and was out
20 sick from work for five days. After receiving
21 treatment from my primary physician, I returned to

1 work and never gave my illness a second thought.
2 Although everything seemed to be going well, my life
3 -- my life -- oof. Is this still on? My life was
4 not free of stress and pressure.

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

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

1 physician, I was encouraged to eat more foods with
2 fiber and to exercise.

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

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

14 In the mid-90's, I was diagnosed
15 with a hearing impairment with an unknown cause.
16 However, my hearing seemed to be getting much worse.
17 In my daily activities, I was constantly requesting
18 that a statement be repeated. My trip to the
19 hearing doctor confirmed my suspicion. And two
20 small hearing aids were purchased. I reluctantly
21 wear only one in my left ear.

1 Without any warning, I woke up in
2 the morning with hives from head to toe. I took
3 over-the-counter antihistamine to get relief. The
4 allergist conducted a complete review and prescribed
5 medication for the hives should they return. All
6 the tests conducted were negative. However, before
7 long, the hives returned. But this time my face was
8 swollen beyond belief.

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

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

19 The year 2000 seemed no brighter.
20 I began to see the allergist more frequently. And
21 episodes of hives and -- the episodes of hives

1 increased and I received higher doses of prescribed
2 medication.

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

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

19 I began to experience chest pain
20 and got very concerned. So I visited a
21 cardiologist. Although not convinced that my signs

1 and symptoms were heart-related or that any other
2 symptoms could be contributory, the cardiologist
3 agreed to a cardio stress test. The results
4 indicated that I was healthy but perhaps I was under
5 too much stress at work.

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

14 My body was obviously sending signs of its illness.

15 I returned to my allergist,
16 requesting that he look deeper into my problem. The
17 blood work performed isolated a C-4 deficiency that
18 could be associated with an autoimmune disease. I
19 visited my primary physician and an infectious
20 disease specialist. All tests that they conducted
21 were negative.

1 MR. RYAN: Time.

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

18 The bottom line is this. I would
19 encourage all Lyme Disease patients to bear
20 together, to give each one strength, to continue to
21 support their doctors and their efforts to treat. I

1 was very, very supportive -- my family was very,
2 very supportive. And I'm very thankful for my
3 doctor, Dr. Katz, who treated me aggressively. Once
4 I received antibiotic intravenous treatment, which I
5 am currently on, my foggiess in my brain cleared
6 up. I became cognitively more alert. And the PhD
7 candidate that I once was I hope to be once again.
8 Because this disease -- I'll be honest with you --
9 it robs the brain, the brain of a very talented
10 person, of our children, the biggest assets in our
11 nation and in our state.

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

15 ATTORNEY GENERAL BLUMENTHAL:

16 Thank you very much.

17 (APPLAUSE)

18 COMMISSIONER GALVIN: I must say
19 that, Caroline, that in my work, for a long time,
20 nine years, I was the Medical Director for Long-Term
21 Disability for Aetna Life & Casualty. And I saw a

1 considerable number of people who were as bright and
2 talented as you are who had your type of
3 symptomatology who never worked again productively.

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

7 (APPLAUSE)

8 ATTORNEY GENERAL BLUMENTHAL: Mary
9 Anne Foley?

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

21 The results, conducted among a

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

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

15 Is there convergent data?
16 Anecdotally, my pediatrician in Wilton has told me
17 that he has about three percent of his practice with
18 lingering Lyme Disease. At the Cider Mill School in
19 Wilton, when I was at one of my daughter's 504
20 meetings, I learned from the senior counselor there
21 that roughly three percent of that school's study

1 body had some accommodation, either in 504 or IEP,
2 due to lingering effects of Lyme Disease. We have
3 an out-of-control school budget due to Special
4 Education needs. I think we need to look at what
5 Lyme is contributing to that.

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

17 Living in Wilton, I am all too
18 aware of how big a problem this is, probably more
19 aware than most. I have three daughters. All have
20 been diagnosed with Lyme. For my middle daughter,
21 Kristen, all this has ever involved is a course of

1 antibiotics and then she returned to a normal life.
2 Laureen, my eldest, and Samantha, my youngest, are
3 not nearly so lucky.

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

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

20 Because of my children's
21 condition, I receive my calls from families who are

1 facing the same challenges, particularly for their
2 children. While the symptoms so often include
3 headache, fatigue, depression and joint pain, what
4 most people don't recognize is how alienating and
5 lonely this disease is.

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

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

18 Further, school policy prohibits
19 participation in extracurricular activity when you
20 are not in school. For kids with Lyme who have
21 periods of illness are interspersed with days they

1 are relatively well, this policy is devastating.

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

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

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

1 trust you can place in each source.

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

13 MR. RYAN: Time.

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

17 My children have improved. And
18 while we are a small sample, there is clearly
19 something here. Living half of each year is a
20 pretty drastic response. But right now this has been
21 the most lasting solution I have found for a problem

1 that literally plagues us. We need help on every
2 level. And the best way to bring that about is to
3 generate shared learning in a positive,
4 non-threatening environment.

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

7 (APPLAUSE)

8 ATTORNEY GENERAL BLUMENTHAL: Jude
9 Anne Jones?

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

16 I am a Connecticut native. I was
17 born and raised in Westport. I come from a large
18 family. I am the fifth of six children. I
19 demonstrated from early childhood an extremely
20 strong constitution. I never got sick and it was I
21 who always resisted the illnesses some of my

1 siblings contracted. My mother deliberately exposed
2 me to sisters who might have had measles or mumps
3 and to no avail. Although diminutive in stature, I
4 always possessed remarkable physical strength, as
5 well as a natural athleticism. That was my greatest
6 gift, my constitution.

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

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

19 By the mid-1980's, I was
20 constantly feeling unwell, flu-ey, arthritic. I had
21 seen a physician in New York and had shown him this

1 rash on my chest that looked like a spider web. I
2 remember his comment. "You just have a case of the
3 crazies." He gave me an antihistamine. I thought,
4 "You might be right." I certainly was stressed, as
5 I was managing and designing for a
6 multi-million-dollar corporation, trying to care for
7 a dying aunt and commuting back and forth to
8 Westport to care for my terminally ill mother.

9 Adrenal and determination have
10 been very good friends of mine. I'm not here to
11 malign an individual or an institution. What's done
12 is done. And nothing can erase what's happened.
13 What I can say is that I experienced what is
14 unfortunately not that uncommon. I was not
15 diagnosed with Lyme Disease until I went into an
16 emergency room having a mini-stroke. I had suffered
17 with an excruciating headache for more than a week.
18 My blood pressure was 220 over 110. And I was
19 walking crookedly.

20 Prior to that trip in November of
21 '98 to the emergency room, I had been suffering from

1 some form of meningitis for three years. I was told
2 it was aseptic. I had constant fever, sore joints,
3 sore neck and generally was very sick. This had
4 been preceded by seizures in 1992 and '93 and
5 abnormal MRI and CAT scans.

6 I didn't have health insurance in
7 1992 and '93. So I didn't pursue it. I had
8 returned to Westport in 1987 to be my mother's
9 full-time caretaker until she died. After her
10 death, I remained in Westport.

11 I had always attended to my own
12 garden and, in 1998, was asked to oversee and design
13 other people's properties. I will never forget the
14 day when a young woman asked me to take care of her
15 garden, as she had explained to me she had been so
16 sick with Lyme Disease, the tick-borne disease, that
17 she never wanted to garden again. And I remember
18 thinking to myself, "Tick disease, how bad could
19 that be?" I thought she was a little over the top
20 in her reaction. How wrong I was. How doubly
21 ironic, as I was already infected myself.

1 In 1989, I had a significant
2 bull's eye in my right forearm, felt horrible, saw
3 the doctor who dismissed my extremely stiff hand
4 joints from overworking small muscles by weeding.
5 It made sense to me. But I shouldn't have accepted
6 it.

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

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

21 MR. RYAN: Time.

1 MS. JONES: -- cognitive
2 functions. I am here as a representative of the
3 extraordinarily profound impact this disease can
4 have on a human. I am here because I would like to
5 think that my experience might help prevent it from
6 being someone else's experience.

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

1 share this.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you.

4 (APPLAUSE)

5 ATTORNEY GENERAL BLUMENTHAL:

6 Donna Lake.

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

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

21 When I was seen for my physical, I

1 presented my tick and the bite site, which was
2 raised and inflamed. I expressed my concerns and my
3 knowledge of Lyme Disease because my young Lab
4 recently had Lyme.

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

11 I was given 200 milligrams of
12 Doxycycline, the standard recommendation of the CDC.

13 I then dropped my tick off at the Farmington Valley
14 Health Department for testing. Seven days later, I
15 developed a slight headache, neck ache and fatigue.
16 Eleven days later, June 17, 2003, three days prior
17 to my surgery, I had a severe headache, redness on
18 my neck, arms and chest, along with fever, chills,
19 light sensitivity, sore throat, confusion, severe
20 fatigue and complete numbness on my left side. I
21 phoned my doctor immediately.

1 I fully articulated my situation,
2 although my thought process was slow. His response
3 was, "Donna, just because Lyme Disease is the
4 disease of the month, it does not mean you have it."
5 I was shocked.

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

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

21 I was treated for two months. I

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

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

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

1 Thank you.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you.

4 (APPLAUSE)

5 ATTORNEY GENERAL BLUMENTHAL: I

6 have just a couple of questions and then Dr. Galvin
7 may have some.

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

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

21 Was anyone else among you told

1 about the CDC guidelines in the course of the
2 misdiagnosis or lack of diagnosis of Lyme?

3 MS. FOLEY: Yes.

4 COMMISSIONER GALVIN: I see you
5 nodding, Ms. Foley.

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

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

18 MS. FOLEY: Absolutely. That's
19 right.

20 ATTORNEY GENERAL BLUMENTHAL: I
21 saw someone else nodding. Maybe Ms. Baisley?

1 MS. BAISLEY: As a Health
2 Director, I was well aware of the CDC guideline. I
3 didn't fully meet the guideline. However, my
4 physician not only looked at my test results, which
5 perhaps not enough physicians do, looked just a -- I
6 mean he looked not just at the test results but he
7 listened to me as a patient. He listened to what I
8 was saying, what I was experiencing. And so, you
9 know, that's very important to diagnose a patient.

10 ATTORNEY GENERAL BLUMENTHAL:
11 Anybody else have a comment on that aspect?

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

14 ATTORNEY GENERAL BLUMENTHAL:
15 Yeah. You know, we can't recognize members of the
16 audience, unfortunately. We would welcome your
17 comments later, either written or --

18 A VOICE: Same thing.

19 ATTORNEY GENERAL BLUMENTHAL: --
20 oral.

21 A VOICE: Six years misdiagnosed.

1 ATTORNEY GENERAL BLUMENTHAL:

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

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

8 MS. JONES: No. I --

9 ATTORNEY GENERAL BLUMENTHAL: Ms.
10 Jones?

11 MS. JONES: I did have it.

12 ATTORNEY GENERAL BLUMENTHAL: You
13 had the rash?

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

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

19 MS. JONES: He referred to it as
20 "a case of the crazies". Now, this was in New York.
21 And I'm not --

1 ATTORNEY GENERAL BLUMENTHAL: The
2 crazies?

3 MS. JONES: "A case of the
4 crazies". Then in 1989, I had it on -- the classic
5 bull's eye on my arm. But I have to say -- so that
6 was -- I probably had Lyme in all actuality from
7 onset to formal diagnosis for 25 years. During that
8 time, I never had a positive blood test. Never.
9 And it was theory that when it's -- when one has it
10 for that long a period of time, it skips over the
11 spinal/cerebral border and lodges itself in the
12 central nervous system, the brain. And
13 spinal/cerebral fluid tests also were not always
14 100-percent positive. There were other tests, Lyme
15 antigen capture, which is a more sophisticated test
16 that I can't really explain to you. PCR tests done
17 on blood work which detects the actual DNA of the
18 spirochete. However -- and I'm sure you'll get to
19 this later. There is inaccuracies from one
20 laboratory to another. And I actually had blood
21 work drawn last March as part of the -- perhaps

1 getting into the National Institute of Health
2 program. Two weeks later I had it drawn separately.
3 The one drawn from the National Institutes of
4 Health came back negative. Two weeks later, drawn
5 by Dr. Katz's office and sent to a laboratory in New
6 Jersey, it came back positive. So that's part of
7 the conundrum.

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

12 MS. LAKE, you found a tick.

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

15 ATTORNEY GENERAL BLUMENTHAL:
16 Okay.

17 MS. BAISLEY: I can't recall
18 getting bit by a tick. I did not have the red --
19 the red bull's eye rash. I had hives instead. I
20 had all the other classic signs, however, of Lyme
21 Disease, the memory loss, the confusion, the

1 positive MRI. And I did see the inequities between
2 the laboratory analysis. Blood drawn is -- and even
3 the simple chemistries, by the way, which when I
4 examined the laboratory reports of my own blood
5 work, I saw the inequities between one lab and
6 another. Even the ranges of the simple chemistries.
7 Let's not even bother to talk about Lyme Disease.
8 Let's talk about simple chemistries. It really
9 depends on the lab that you go to.

10 So that's very -- it's very
11 important to note that when you're trying to look at
12 a patient, diagnose a patient for something as
13 serious as this, you have little inequities and you
14 have a negative patient. So there's a lot --
15 there's a whole slew of other signs and symptoms
16 that must be taken into account, obviously, other
17 than a test, a laboratory test. Certainly we want
18 to say that our laboratory tests play a major role
19 in surveillance of diseases and diagnosis for
20 disease. However, in this -- this one's not an easy
21 one, folks. You really need to look at absolutely

1 everything.

2 ATTORNEY GENERAL BLUMENTHAL: I
3 want to thank you all.

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

12 The last time we had one of these
13 hearings, it really made an enormous difference. We
14 passed legislation as a result. The last hearing
15 that I conducted with the Department of Public
16 Health, we succeeded in changing the law to extend
17 the guarantees for insurance coverage for treatment
18 of Lyme Disease. Not as far as we sought or would
19 have liked, but at least we were able to improve
20 insurance coverage as a result of some of the
21 testimony that we took at the time. As a matter of

1 fact, Tom Ryan, Assistant Attorney General, who is
2 here today, was present then, too.

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

10 Dr. Galvin, did you have any
11 questions?

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

20 We see large numbers of people
21 beginning about late March who come in with some

1 sort of an insect bite. And not many of -- not all
2 of them have the tick. That makes it easier if the
3 tick is embedded or they have the tick. Some of
4 them simply have a circular rash and don't know
5 where it -- don't quite know where it came from.
6 Some of these are stinging insects. Some of them
7 are spider bites. Some of them are Lyme tick bites.
8 And some of them are other bites.

9 And the dilemma that a clinician
10 has is when someone shows up in your office with an
11 insect bite and a circular rash, what do you do? Do
12 you begin to treat? Do you wait for some serologic
13 marker to improve? Or do you try to discern exactly
14 from looking at the rash what bit this individual?

15 As one of you folks brought up,
16 most -- a lot of the bites are where people don't
17 see them. They're behind the knees, the back part
18 of the body, the back of the scalp. And so
19 sometimes the tick gets on, feeds, drops off and
20 just -- or gets pinched or poked off. And every one
21 of these patients -- it's a dilemma for people that

1 do primary care about do you give them three weeks
2 of antibiotic treatments, particularly with
3 Doxycycline, which is a sun sensitizer, during the
4 summer? Do you give them three weeks' worth of
5 treatment and restrict their activities? Do you
6 give them Penicillin? Or what do you do?

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

15 ATTORNEY GENERAL BLUMENTHAL:

16 Thank you. Thank you all.

17 (APPLAUSE)

18 ATTORNEY GENERAL BLUMENTHAL: I'd
19 like to ask Elise Brady-Moe, Jennifer and Katherine
20 Reid, Tammy Szczepanski and Christopher Montes to
21 come forward please.

1 I'd like to say we've been joined by Representative
2 Spallone, who is here with us, Jamie Spallone, who
3 many of you may know.

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

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

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

19 I was treated with seven months of
20 oral antibiotics before I decided it was safe to try
21 and conceive a second child. We had intentionally

1 postponed having a second child until we felt we had
2 done our best to rid my body of this dangerous
3 bacteria.

4 I conceived our second child in
5 March 2002 and entered the pregnancy feeling
6 confident that we would have a healthy child. The
7 15-week ultrasound showed a healthy baby with a
8 strong heart and all its organs were functioning
9 normally. At 16 weeks, the remaining test results
10 were all wonderful.

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

18 I called my Lyme doctor and a lab
19 skilled in detecting the bacteria so I could
20 determine how to test the fetus and the placenta for
21 the bacteria. I took the information to the

1 hospital. And just before the surgery, I insisted
2 that the OB obtain enough tissue for a separate PCR
3 test for the Lyme bacteria. If I had not requested
4 a PCR test at a specific lab, I would not know today
5 what took our baby's life.

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

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

19 We grieved all over again. How
20 had this small bacteria survived seven months of
21 antibiotics and continued to destroy our lives?

1 When I purchased a garden stone in memory of our
2 baby boy, I promised myself that I would do
3 everything in my power to help others avoid this
4 tragedy. I am here today as part of that promise.

5 The story continues. After the
6 18-week miscarriage, I began another regimen of
7 antibiotics. I was on three different oral
8 antibiotics for six months before conceiving our
9 third child. I stayed on Septrin during the
10 pregnancy to protect the fetus. But, unfortunately,
11 it did not survive past nine weeks due to
12 chromosomal problems.

13 I requested a PCR test before the
14 D&C. And the results were devastating. Again the
15 placental tissue was PCR-positive for Lyme bacteria.

16 What next? I did not want this disease to win. So
17 I began a four-month regimen of IV antibiotics.
18 After the IV was pulled out, I continued with oral
19 antibiotics. And, luckily, I conceived a fourth
20 time in November of 2003. The bad news is I have
21 another miscarriage this month, unfortunately from

1 another chromosomal problem. The good news is the
2 PCR test was negative.

3 This does not mean I am rid of
4 this bacteria. But it is a sign there is hope.
5 Today I stand before you and I hope that there will
6 be funding for more research into the testing and
7 treatment of tick-borne diseases. I hope that your
8 wife, your daughter or your sister do not have to
9 deal with what we have dealt with during the past
10 three years. I hope that you will help the future
11 generations. It is time to help, not just hope.

12 Thank you very much for your
13 willingness to listen and your time today.

14 (APPLAUSE)

15 ATTORNEY GENERAL BLUMENTHAL:

16 Thank you.

17 Jennifer and Katherine Reid
18 please.

19 MS. JENNIFER REID: Thank you. My
20 name is Jennifer Reid. In our house, Lyme Disease
21 has infected four of five members, my three teenaged

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.

21 In fact, we learned later she was

1 not having a good time. She was terrified. She
2 describes that year now as watching herself slip
3 away, becoming a completely different person whose
4 thoughts and actions she hardly recognized. Our
5 hard-working, happy daughter was sleeping through
6 class, suffering from dyslexia, had short-term
7 memory problems and was feeling angry, frightened
8 and depressed.

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

17 Trips to the doctor brought little
18 relief, simply the diagnoses of early menopause and
19 early arthritis, neither of which runs in my family
20 and no tests were run to confirm either condition.
21 I was given muscle relaxers for my neck and told to

1 accept the fact that we're all getting older. I was
2 45.

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

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

14 At the end of Shannon's course of
15 antibiotics, both our primary doctor and a
16 specialist confirmed that she should now stop taking
17 antibiotics and see a psychiatrist. A second
18 opinion -- I'm sorry. And at the end of my four
19 weeks of oral antibiotics, I was told I had received
20 all the antibiotics necessary. If I wanted
21 additional treatment, I should go find a Lyme

1 doctor. Unbelievably, they could not provide a
2 referral.

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

13 The search for my own cure was
14 more daunting because I attempted to stay within the
15 list of doctors my health care plan allowed. Months
16 went by before I was able to restart treatment and
17 even then it was minimal. Although I was so
18 disoriented I could not drive myself to
19 appointments, sat crying uncontrollably in the
20 waiting room and was still plagued by fatigue, no
21 mention was ever made of neurological testing or IV

1 antibiotics. There seemed to be no urgency in
2 dealing with my condition.

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

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

16 Through September, as Katie began
17 her senior year of high school, she developed severe
18 gastrointestinal and menstrual problems and, for the
19 first time ever, school work became a struggle.
20 Fatigue set in with a foggiess she could not shake.
21 We found ourselves caught up in addressing

1 individual symptoms, a time-consuming and exhausting
2 process, that failed to address the cause of these
3 maladies.

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

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

18 Katie began a course of IV
19 Claforan in April 2003. We began to see progress
20 and felt our daughter was returning to us. Four
21 weeks later, despite the recommendations of Dr.

1 Jones, neurologist, Dr. Amiram Katz and
2 neuropsychologist, Miriam Rizzenburg, who had all
3 evaluated Katie, United Health Care denied coverage
4 for continued IV, stating that it is an unproven
5 treatment. As our health care plan is purchased in
6 New York from a self-insured company, we
7 unfortunately had no recourse. And the
8 responsibility has fallen on us to provide
9 peer-reviewed medical literature demonstrating the
10 benefits of long-term antibiotic care which we had
11 not been able to do.

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

18 A tearful phone call home four
19 weeks later brought the news that we had dreaded.
20 Her symptoms had returned. And if time permits,
21 Katie will tell you what it is like to be a college

1 student trying to do an IV in your dorm room.

2 A switch to --

3 MR. RYAN: Time.

4 MS. JENNIFER REID: --

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

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

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

20 ATTORNEY GENERAL BLUMENTHAL:

21 Thank you.

1 (APPLAUSE)

2 ATTORNEY GENERAL BLUMENTHAL:

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

4 MS. JENNIFER REID: Sure.

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

14 All I want is to wake up one day
15 feeling like I used to. But it's hard to have hope
16 as the months go on that that will ever happen. I
17 don't have the time or energy to go through every
18 symptom, doctor, medicine and experience that I've
19 had. But I'd like to point out a few key ones that
20 show just how devastating this illness can be on a
21 young person's life.

1 As my struggle with the illness
2 really climaxed my senior year, I went from being an
3 athlete who easily ran six miles at a time to a
4 person who not only didn't have the energy to
5 participate in any sports or clubs but who could
6 barely make it in to school before lunch. But that
7 only meant physically making it in to the building.
8 I couldn't handle the work any more.

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

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

20 I never did take my mid-terms. A
21 good thing, because I didn't remember any of the

1 information. But a bad thing, because I spent that
2 week in the hospital, the results of a rash decision
3 I've regretted ever since but honestly thought at
4 the time was a good solution to my emotional and
5 physical pain.

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

18 When I spoke at that graduation, I
19 honestly thought I was over the hardest part of my
20 battle with Lyme Disease. I had only the most minor
21 setbacks over the summer and began college at UConn

1 very excited. My IV had just been removed because of
2 an infection. But, regardless, I was actually
3 feeling good.

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

14 The week prior to finals, terrible
15 chest pains landed me in the hospital where I was
16 treated with Morphine and dismissed as suffering
17 from anxiety. It was actually my gall bladder
18 filled with stones. I didn't get to take those
19 finals and consequently lost all of my credits from
20 the semester. I remember thinking to myself that it
21 just wasn't fair. My school work had been the only

1 thing that was important to me there. I didn't
2 party. I didn't drink. I didn't do drugs. I
3 barely had time to socialize at all. I deserved
4 those credits.

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

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

19 And I am only one case. There are
20 three others in my family, ten in a group Dr. Katz
21 has organized for teens struggling with this and

1 thousands more in the state. I know there are so
2 many people who have it worse than I do. And that
3 frightens me so much. I'm scared now dealing with
4 this and scared about being here in the future after
5 I've recovered. I want to move to somewhere far
6 away from here where I can get better and never get
7 this again. I want to move to a place where I can
8 pet animals, go for a hike, go camping, lay down on
9 fresh grass and not get sick from it. I want to
10 swim without a rubber arm for my IV, read books and
11 remember how the sentences ended and began, take
12 walks without being instantly winded. I want my
13 life back.

14 ATTORNEY GENERAL BLUMENTHAL:

15 Thank you.

16 (APPLAUSE)

17 ATTORNEY GENERAL BLUMENTHAL:

18 Tammy Szcepanski?

19 MS. TAMMY SZCEPANSKI: It pains me
20 today when I think of how I used to be and I think
21 of how many others really have Lyme Disease but are

1 being treated for Multiple Sclerosis. Think about
2 it. No one what MS is caused from. So why treat
3 with steroids in case it is Lyme?

4 In 1987, when I was pregnant with
5 my daughter, I had a rash on my stomach. The doctor
6 said it looked like some form of shingles. But it
7 didn't hurt. Jacqueline was born a beautiful,
8 healthy girl. During the next two and a half
9 months, we noticed her eyes did not seem to focus.
10 Her legs would turn purplish in color and one time
11 her leg swelled three times its normal size. On June
12 6, 1988, she passed away from Sudden Infant Death
13 Syndrome.

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

19 In 1990, I went to the emergency
20 room because I was vomiting, lightheaded and had
21 pains in my stomach. I was told I had a viral

1 infection. I started having nausea, pain in my left
2 ear and the fatigue was still present.

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

17 Over the next few days, my
18 symptoms would get worse. The room felt like it was
19 spinning and I was vomiting profusely and half my
20 face went numb and I could barely walk. I had a CAT
21 scan and MRI and would see a neurologist. I was

1 admitted to the hospital on November 4 and had blood
2 work drawn and was started on steroids. My PCP would
3 come in and tell me he had bad news for me. He said,
4 "You had Lyme Disease at one time and that you do
5 not have it any more." He proceeded to tell me that
6 I had Multiple Sclerosis and life as I knew it
7 before would no longer be like that.

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

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

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

21 I saw my neurologist and asked

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

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

14 Over the years, I have had
15 steroids intravenously eight times, been on over 50
16 different medications for my so many different
17 ailments, took a shot for my secondary progressive
18 MS, which eventually would turn into primary
19 progressive MS, and even had Novantrone, which is a
20 form of chemo, for my MS, just hoping it would help
21 my symptoms get better.

1 Once I had the chemo, I started
2 experiencing pain all my body. My nausea was 24/7.
3 The light hurt my eyes. If someone hugged me, my
4 whole body would hurt. Clothes bothered my skin.
5 My skin felt like I had bugs crawling in it. And I
6 had to use the walls or someone to hold onto to
7 walk. I really believed I was dying.

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

17 My doctor thought that maybe I
18 could have fibromyalgia now on top of my primary
19 progressive MS. I wanted to see an infectious
20 disease doctor in Bristol, but he said, "No, because
21 he will say you have Lyme Disease and put you on

1 medication you do not need." He told me I could see
2 a good friend of his who was an infectious disease
3 doctor.

4 When we were waiting in the room,
5 he came in and he said that he had just gotten off
6 the phone with my doctor. I showed him my symptom
7 list and he said, "That doesn't mean anything." I
8 told him about all my pain and the rash when I was
9 pregnant, that I went camping and showed him the
10 test I found and asked if I could have Lyme Disease.

11 He said no, that "You might have fibromyalgia on
12 top of your Multiple Sclerosis."

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

20 Finally, out of desperation, I
21 would bring my records to a doctor in New Jersey. I

1 wanted the pain to go away and someone to just help
2 me. He looked at my records, did blood work and he
3 was the first doctor to say, "You have chronic Lyme
4 Disease". And I was started on antibiotics. "And I
5 believe you have had it for several years."

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

19 I have improved tremendously from
20 where I was two years ago. I have been off all my
21 MS medications for over two years now. My new

1 doctor in Boston was the first doctor to ever order
2 a brain spec scan which shows prior focal
3 encephalitis and lack of perfusion --

4 MR. RYAN: Time.

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

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

17 We really have no conception as to
18 the true magnitude of the Lyme Disease epidemic.
19 Untold numbers of Lyme patients are being labeled
20 with other diseases. Why are so many people being
21 diagnosed with Multiple Sclerosis? My story is not

1 unique. This is happening everywhere.

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

10 (APPLAUSE)

11 ATTORNEY GENERAL BLUMENTHAL:
12 Christopher Montes.

13 MR. CHRISTOPHER MONTES: Attorney
14 General Blumenthal, Commissioner Galvin and esteemed
15 elected officials, thank you for the opportunity to
16 speak at today's hearing. Five years ago, I stood
17 in this building with an IV shunt in my arm. And
18 it's my fifth year of treatment for Lyme Disease.
19 Five years ago, I was still suffering with symptoms
20 that inundated every day of my life, making even the
21 simplest of tasks seem insurmountable.

1 Five years ago, it was uncertain
2 as to what the prognosis of my illness would be. I
3 felt I had a death sentence. All I could do was to
4 continue to hope and pray that one day I would be
5 well enough to care for my wife and two children.
6 And, in part as a result of the hearing on Lyme
7 Disease in 1999, with your help, Mr. Attorney
8 General, and by the grace of God, I was able to
9 continue my antibiotic regimen without fear of my
10 insurance company once again denying payment for
11 treatment.

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

18 You've heard some very compelling
19 testimonies and, no doubt, are wondering how our
20 medical community, touted as the best in the world,
21 could allow what has happened to occur. Indeed, the

1 question must be asked, "How is it that patients
2 could become so ill and be misdiagnosed for so long?
3 How is it that even after adequate antibiotic
4 treatment these people can still be infected to the
5 point that active spirochetes are found in their
6 bodies?"

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

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

17 My hope is that the State of
18 Connecticut will make Lyme Disease a true priority.
19 It is, without doubt, a major health threat that has
20 robbed thousands of individuals of their inherent
21 right to live a normal life. I believe the time has

1 come for our State leaders to make serious
2 commitments to appropriate surveillance, including
3 laboratory reporting, prevention, teaching its
4 physicians about diagnosis and treatment and even
5 additional promising modes of disease intervention.

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

13 Does it not make sense simply from
14 an epidemiological viewpoint to focus on preventing
15 these infections based on the rate of incidence?
16 True, it may be said that the State of Connecticut
17 has prevented the spread of West Nile Virus. And
18 that is admirable. However, we know for certain
19 that Lyme Disease and other tick-borne illnesses are
20 pandemic throughout our state. Yet, little has been
21 done to stem the tide of infection.

1 Moreover, from an academic
2 standpoint, the University of Connecticut School of
3 Medicine has a unique opportunity concerning
4 diagnosis and treatment of Lyme Disease. Indeed, it
5 is also -- it also has a responsibility to impart
6 accurate information to students seeking a degree in
7 medicine.

8 The proof of persistent infection
9 has reached the tipping point in the medical
10 community. And our state's medical teaching
11 institution now has a choice before it. The first
12 choice is to continue with its current methodology
13 of teaching the diagnosis and treatment of Lyme
14 Disease. That is using textbooks and other teaching
15 instruments that still, for example, indicate that
16 "The disease is, more often than not, present with a
17 bull's eye rash." It doesn't. "It will usually be
18 picked up through serologic testing." It isn't.
19 "It should be diagnosed using the CDC's reporting
20 criteria." It shouldn't. "It's mainly
21 rheumatological." It isn't. "And requires, at most,

1 a three-week course of antibiotics as the cure." It
2 doesn't, especially when the patient has been
3 infected long-term.

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

14 As a municipality official
15 overseeing a department that provides mental health
16 services for children and families, as well as case
17 management and advocacy for persons with
18 disabilities, I've witnessed patients with Lyme
19 Disease not being able to access medical treatment.
20 Many of these individuals often lose their jobs as a
21 result of their result and must take State

1 Assistance or Medicare just to survive.

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

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

13 MR. RYAN: Time.

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

1 have been exonerated by the Department.

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

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

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

19 Moreover, this committee would be
20 ongoing and, thus, respondent to the changes that
21 occur in the spread of the disease, its prevention,

1 diagnosis and treatment. Thereby, true progress can
2 be made concerning this issue and, as such,
3 ultimately benefit the citizens of Connecticut.

4 Thank you again for this
5 opportunity.

6 (APPLAUSE)

7 ATTORNEY GENERAL BLUMENTHAL:

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

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

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

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

19 ATTORNEY GENERAL BLUMENTHAL:

20 Okay. So none of you had that rash that was
21 ordinarily -- that is ordinarily associated with

1 diagnosing the disease.

2 MS. SZCEPANSKI: No.

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

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

11 MS. SZCEPANSKI: Okay.

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

14 MR. MONTES: Excuse me.

15 ATTORNEY GENERAL BLUMENTHAL: Let
16 me just say, first of all, before Dr. Galvin --
17 before you leave and before Dr. Galvin has something
18 to say, that I again want to thank every one of the
19 patients, every one of the citizens who are here
20 today. Mr. Montes mentioned again the hearing that
21 we had five years ago. Many of you have been

12 Dr. Galvin?

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

21 COMMISSIONER GALVIN: Okay. I

1 would like to more about that. And I would like to
2 know about that as, specifically in a state of this
3 affluence, no one should be denied access to medical
4 care.

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

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

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

16 MR. MONTES: I think I said that
17 "It will usually be picked up through serologic
18 testing." And then said it isn't. Meaning that
19 more often than not, patients who are -- who do
20 have, indeed, Lyme Disease upon first being tested
21 do not test positive.

1 COMMISSIONER GALVIN: So are you
2 saying that when they're first tested, the test is
3 not positive because it isn't for several days or
4 are you saying that the test is incorrect more often
5 than not?

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

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

17 MR. MONTES: Yes.

18 COMMISSIONER GALVIN: And so if we
19 take everybody who comes in with tick attached and
20 test them at that time, most of them will be
21 negative because the tick -- they haven't had time

1 enough to develop lab tests. So I think we need to
2 be clear about whether we're -- when we say some of
3 the -- a majority of the tests are negative, are we
4 talking about first run right after the bite or are
5 we talking about a long-term thing?

6 One of my regulators is here,
7 Wendy Furness, who runs the part of our Department
8 that investigates complaints. And I want the
9 audience to know that we are required to investigate
10 all complaints. Some of the complaints we get are
11 from the general public and some of them are from
12 other physicians who object to different types of
13 treatment.

14 We have no rule about what
15 treatment is correct or best in terms of the
16 complaints we get. I realize that there are a
17 variety of ways that physicians can look at cases.
18 So Ms. Furness I think will support me when I say
19 that we have no rules about how long you can treat
20 Lyme Disease, which antibiotics, which route or the
21 like. We --

1 But I want you to know, sir, that
2 we are required, if somebody complains or a group of
3 physicians complain about another physician, we have
4 to open the complaint. We're required to do that.

5 Thank you.

6 (APPLAUSE)

7 ATTORNEY GENERAL BLUMENTHAL:

8 Again, I thank you for being here.

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

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

18 MR. MONTES: Thank you.

19 ATTORNEY GENERAL BLUMENTHAL:

20 Thank you.

21 Thank you very much.

1 I'm going to now ask the
2 scientific panel to come forward. We're going to
3 begin with Dr. Tilton, Dr. Kelley, Katherine Kelley,
4 Richard Tilton. I understand Sam Donta is not here?
5 He couldn't be here. Dr. Robert Levitz and Dr.
6 Steven Phillips.

7 (Off the record)

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

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

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

21 And, of course, Dolly Powers is

1 still here. Anyone else from the legislature still
2 here? Representative Powers. Anyone else?

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

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

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

21 I would like to introduce the

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

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

15 DR. LAWRENCE ZEMEL: Attorney
16 General Blumenthal, Dr. Galvin and members of the
17 audience, I am a professor of pediatrics at the
18 University of Connecticut School of Medicine and
19 Chief of the Division of Pediatric Rheumatology at
20 Connecticut Children's Medical Center. I've been
21 practicing medicine in Connecticut for nearly 27

1 years and have had extensive experience in
2 diagnosing and treating Lyme Disease in children.

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

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

17 While I do not always rigidly
18 adhere to these criteria, I am concerned about gross
19 deviations which contribute to the over-diagnosis of
20 Lyme Disease. One of these misconceptions is the
21 concept of sero-negative Lyme Disease.

1 Sero-negative Lyme where antibodies are not
2 detectable may be seen in early Lyme Disease. But
3 in those patients, clinical features such as the
4 telltale rash often allow for the diagnosis.

5 Rarely, patients with later Lyme
6 Disease who earlier had developed erythema migrans
7 may be sero-negative.

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

13 I've seen many children and
14 adolescents who were mistakenly diagnosed as having
15 Lyme Disease and appropriate therapies for their
16 true underlying disorder were delayed. One such
17 child was JD, a seven-year-old who enjoyed soccer
18 and video games. He started to complain of back
19 and hip pain. His mother went on one of the popular
20 Lyme websites and found that these are common Lyme
21 symptoms.

1 He went to his pediatrician to be
2 tested. And the pediatrician ran the standard ELISA
3 and Western Blot line mass aids, which were
4 negative, and then referred the child to me. My
5 exam suggested that there was bone disease rather
6 than arthritis. I repeated the Lyme tests at
7 mother's request. These again were negative. And
8 found that he was anemic. I ordered a bone scan,
9 but the family cancelled that study and sought an
10 opinion from a physician in New Haven.

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

20 This is but one dramatic example
21 of some of the kids I'm seeing who are misdiagnosed.

1 Other examples have included rheumatoid arthritis,
2 fibromyalgia, chronic fatigue syndrome and
3 ankylosing spondylitis and others.

4 Even some of the testimony heard
5 today may be confusing.

6 [Statements contained in lines 5 through 9 of this
7 page have been removed due to the presence of unconsented
8 confidential medical information.]

9

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

16 Diagnosis may not only be missed
17 clinically, but different lab techniques may
18 contribute to the confusion. A case in point is a
19 California lab, Igenex. A few Connecticut
20 physicians prefer this lab over such referenced labs
21 as Yale and UConn. Igenex's urine antigen assay has

1 confirmed the diagnosis of Lyme Disease in a number
2 of their patients despite negative testing
3 elsewhere.

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

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

20 My last point is that as
21 physicians we took an oath to do no harm. The New

1 York Times in an Editorial two years ago expressed
2 concern about the overuse of antibiotics and the
3 development of resistant organisms. Quote, "Drug
4 resistance has soared because antibiotics are
5 over-prescribed", end quote, claimed the Times.

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

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

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

21 A 2001 study in the New England

1 Journal of Medicine concluded that chronic Lyme
2 symptoms were no more likely to respond to 90 days
3 of antibiotics than placebo. For those advocating
4 longer than standard therapy, we need more data.

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

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

12 Thank you.

13 ATTORNEY GENERAL BLUMENTHAL:

14 Thank you.

15 (APPLAUSE)

16 ATTORNEY GENERAL BLUMENTHAL: Dr.
17 Levitz?

18 DR. ROBERT LEVITZ: Yes. Hi. I'm
19 Assistant Director of Infectious Disease at Hartford
20 Hospital. And I've been in the practice of
21 infectious disease here in Connecticut for over 20

1 years. I've seen hundreds of patients with Lyme
2 Disease. And I do general practice of infectious
3 disease, which includes AIDS, hospital infections,
4 surgical infections, et cetera.

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

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

21 But I'd like to talk in this

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

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

15 This went on actually for several
16 years. Finally, a Lyme serology was done which had
17 a positive ELISA but negative Western Blot. She was
18 begun on Amoxicillin by her physician, then
19 Zithromax and then Sephtin, but no improvement in
20 these symptoms. Still missing a lot of time from
21 school. The main symptom being cognitive.

1 She was seen by a physician
2 specializing in Lyme in Westchester and placed on IV
3 Septra Zone, two grams a day. She was in her sixth
4 week of continuing therapy with no improvement in
5 her cognitive symptoms, still home from high school,
6 when she was referred to see me because of a rash
7 that developed on her body actually emanating from
8 the IV site, most likely an allergic reaction to her
9 Septra Zone.

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

1 Connecticut, has had no further symptoms, required
2 no other antibiotics.

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

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

18 And I've had personally numerous
19 patients who thought they might have Lyme come in
20 with Hepatitis fatigue, with these joint pains from
21 antigen antibody complexes. And they do respond

1 actually to the Interferon and Riboviron treatment.

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

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

21 He came to see me because he still

1 had all the symptoms he had when he went to the
2 other infectious disease physician and was told he
3 didn't have Lyme Disease, but nothing further was
4 done.

5 Again, this 66-year-old had a
6 Vitamin B-12 level of 120, a normal hematocrit. We
7 may hear more -- I hate even commenting on this with
8 the neurologists here. But may talk about this more
9 in the future. But it's actually underdiagnosed.
10 It's not my field of specialty. But in my complete
11 work-up, I look for other diagnoses and things to
12 treat.

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

19 Several other things is what do
20 you do with these sero-negative patients who have
21 the symptoms -- and we've heard a lot about Lyme. I

1 actually just printed out from a website -- chronic,
2 frequent headaches, numbness and tingling,
3 dizziness, ringing in the ears, tremors, hands and
4 feet, lower pain threshold, irritability,
5 nervousness, shyness, loss of memory, inability to
6 concentrate, mental confusion, mood changes, lack of
7 interest, attention deficit syndrome and decline of
8 intellect.

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

18 That does not mean there isn't
19 chronic Lyme. And I've treated advanced Lyme
20 Disease with the mental foggiess, cognitive -- it
21 really does exist. But you do have to be careful in

1 saying, "Well, this is unique to this disease"
2 because everybody is seizing on the same symptoms.
3 And, in fact, I've had referred to my office
4 patients seen by physicians claiming to specialize
5 in Lyme Disease who got no better on their IV
6 Rocephan and then were told, "You know what? It's
7 that yeast overgrowth in your bowel. Look at all
8 the yeast you have in your bowel. If you look at
9 this site, you'll see that all your continuing
10 symptoms are from that." And then were on intensive
11 antifungal therapy. Finally coming to see me
12 because there hadn't been improvement when they did
13 that.

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

1 treatment for your Lyme.

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

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

18 So in the midst of all the true
19 suffering, there are always people who are looking
20 to profiteer or to do something about it. And, you
21 know, I really do hope -- and I think one thing

1 everybody will agree with in here is that the Lyme
2 testing has never been very good, that we do have to
3 get better tests. It's very difficult to
4 distinguish. And while there are false negatives,
5 as was brought up, if you treat it very early or
6 have early disease, there are also false positives.
7 People come in with acute Hepatitis B, endocarditis,
8 well-documented, who have just positive ELISAs,
9 negative Western Blot test. It's an antibody like
10 everything else and it cross-reacts with many
11 things.

12 There was also some talk -- I'd
13 like to point out, as was brought up, about the
14 young child who had severe disabling disease, that
15 the Lyme test remained positive. As I think most of
16 the audience knows, even the most successfully
17 treated person here were not expecting the serologic
18 test for Lyme to turn negative. That's a body's
19 antibody. That's a response. Just as my serologic
20 test for measles is still positive because I got the
21 measles antibody when I was a kid. That doesn't

1 mean I have measles. That we do serologic testing,
2 most of it is antibody. The PCR tests, there are
3 tests specifically for the bacteria, which are
4 different.

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

13 And that concludes my remarks.
14 Thank you.

15 ATTORNEY GENERAL BLUMENTHAL:

16 Thank you, Dr. Levitz.

17 (APPLAUSE)

18 ATTORNEY GENERAL BLUMENTHAL: I
19 appreciate those remarks. And I might just say so
20 that everyone understands that we take action
21 against the kind of abuse, scam, however you want to

1 describe it, that you just described. In fact, we
2 have some legal actions pending now against Internet
3 pharmacies that fail to require real diagnoses,
4 genuine diagnoses, before prescriptions are provided
5 through mail or other similar kinds of devices.

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

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

13 DR. STEVEN PHILLIPS: Thank you
14 very much. I've been asked to comment specifically
15 on the persistence of Lyme bacteria in patients who
16 have been treated. Certainly, there are many
17 aspects of Lyme Disease which remain highly
18 controversial. And diagnosis and treatment are
19 among the top two.

20 The fact of the matter is that
21 many patients with Lyme Disease will relapse despite

1 antibiotic therapy. And some call this the
2 Post-Lyme Syndrome or post-Lyme fibromyalgia,
3 whereas others call this kind of nonsense and it's
4 just a continuation of the initial active Lyme
5 Disease.

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

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

19 Their conclusion was that benefits
20 attributable to antibiotic therapy in these studies
21 were placebo effect. But it should also be noted

1 that these studies were not placebo controlled.
2 And, lastly, it should be noted that every one of
3 the primary symptoms associated with fibromyalgia is
4 also common in active Lyme Disease.

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

19 In this study again by
20 conservative authors including Drs. Persing and
21 Steere, a full 30 percent of the patients remained

1 persistently PCR positive despite multiple courses
2 of, quote, unquote, adequate antibiotic therapy.

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

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

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

17 Here we have human persistent
18 infection despite antibiotics proven by the presence
19 by the B. Burgdorferi. Here they found it in the
20 skin, despite extensive antibiotics in a
21 sero-negative patient. When I use the term

1 "extensive", I'm referring to more than four weeks
2 of antibiotic therapy.

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

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

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

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

20 Here again they found it in the
21 spleen, despite intravenous antibiotics. And here

1 again in the joints, despite antibiotics. And here,
2 despite seven years of multiple trials of antibiotic
3 therapy, Lyme arthritis persisted and spirochetes
4 were documented in the synovium and synovial fluid.

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

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

18 Here again cultured from the
19 synovial fluid, despite antibiotic therapy. Here
20 cultured alive from spinal fluid, despite
21 intravenous antibiotics, which clearly achieve high

1 levels of bacteriocidal antiobiotic levels in the
2 spinal fluid.

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

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

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

16 And I include this study because
17 this patient was initially Lyme serology positive
18 and then went negative, despite progression of the
19 disease. And bacteria was cultured alive from the
20 ligaments, despite oral and intravenous antibiotic
21 therapy. And I use it as a stepping stone to say,

1 "Well, you know, how useful are serologies in
2 following the progression or lack of progression of
3 the disease?" They don't seem to be all that useful
4 at all.

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

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

15 And here again cultured alive from
16 91 percent of patients, despite being sero-negative
17 in 94 percent and despite having had six weeks
18 minimum intravenous antibiotic therapy in all.

19 So how does this affect, you know,
20 treatment durations? Well, in this study, they
21 found that after two months of treatment, roughly

1 one-third of the patients' conditions improved and
2 after three months of treatment, almost two-thirds
3 of the patients' conditions significantly improved.

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

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

13 And here I present another
14 unfortunate fatal case of Lyme Disease. And I
15 present this one because it was expressed primarily
16 by neuropsychiatric features with a progressive
17 frontal lobe dementia. And here the authors stated
18 that antibiotic treatment resulted in transient
19 improvement but the patient relapsed after the
20 antibiotics were stopped. And it's their conclusion
21 that the Lyme Disease must be considered even in

1 cases with purely psychiatric presentation and
2 prolonged antibiotic therapy may be necessary.

3 So, having said all this, what's
4 the true standard of care? In a Lyme endemic area,
5 78 physicians were anonymously surveyed and
6 published in this peer-reviewed medical journal.
7 And these were not Lyme doctors. They were general
8 doctors. They found that 50 percent of the
9 responders believed that 25 percent or more of
10 patients who have Lyme Disease were sero-negative
11 and that for post-erythema migrans Lyme Disease
12 interpreted as acute disseminated Lyme 43 percent of
13 the responders treat three months or more and for
14 chronic Lyme Disease 57 percent of responders
15 treated for three months or more. So the majority
16 of general doctors in a Lyme endemic area in this
17 published study were treating for more than three
18 months for patients with chronic or refractory forms
19 of Lyme Disease.

20 In summary, I'd say that there are
21 numerous medical studies that demonstrate that

1 chronic Lyme is caused by chronic infection.
2 Sero-negative Lyme Disease is common. And longer
3 antibiotic treatment durations are more effective
4 than shorter, although not necessarily curative.
5 Post-Lyme Syndrome, post-Lyme fibromyalgia is really
6 just persistence of the initial infection. It's an
7 internally inconsistent, unscientific theory that
8 should never have seen the light of day. And that
9 curative therapies are needed for chronic Lyme. But
10 this research is not really being done. And there
11 is a denial of the high frequency and even the very
12 existence of chronic Lyme Disease by many
13 researchers.

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

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

20 DR. PHILLIPS: Okay.

21 (APPLAUSE)

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

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

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

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

17 DR. PHILLIPS: Okay.

18 COMMISSIONER GALVIN: Perhaps I
19 misread them.

20 DR. PHILLIPS: We have Nocton,
21 Dresser, Steere, Persing. That's the first one.

1 Okay. Second one, we have Bayer, Zhang, Bayer.
2 That's the second one. Different, clearly. Here we
3 have Liegner, Shapiro, Ramsay, Halperin. I mean --
4 okay. Clearly different. Meier, Blatz, Gau,
5 Spencer, Wiedemann. All different authors.
6 Honegr, Hulinska, Dostal, Gebousky, Hankova,
7 Horacek, Vysbuzil and Havlasova. Different authors.
8 I don't see actually one similarity yet, sir.
9 COMMISSIONER GALVIN: Why don't we
10 go through the whole group?
11 DR. PHILLIPS: Yeah. Of course.
12 But you made a statement which I'm replying to.
13 Reimers, deKoning, Neubert, Preac Mursic, Koster,
14 Muller, Felber, Pongratz and Duray. Kirsch, Ruben,
15 Steere, Duray. Winkelstein and Norden. Schoen,
16 Aversa, Rahn and Steere. Cimmino, Azzolini, Tobia,
17 Pesche. How many do you want me to go through?
18 COMMISSIONER GALVIN: I'd like to
19 see the whole group.
20 DR. PHILLIPS: Okay. Hulinska --
21 COMMISSIONER GALVIN: Now,

1 Hulinska has appeared before.

2 DR. PHILLIPS: Yes.

3 COMMISSIONER GALVIN: Is that

4 correct?

5 DR. PHILLIPS: She has. And so

6 has Steere.

7 (APPLAUSE)

8 DR. PHILLIPS: And let me say Dr.

9 Hulinska is a very well published researcher.

10 COMMISSIONER GALVIN: I'm not

11 saying that. I'm just saying -- let's --

12 DR. PHILLIPS: It just --

13 COMMISSIONER GALVIN: Perhaps I

14 misinterpreted the results.

15 DR. PHILLIPS: Okay. Battafarano,

16 Combes, Enzenauer, Fitzpatrick. I don't remember

17 those names before. Strle, Preac Mursic, who had

18 appeared before, Cimperman, Ruzic and Marasan and

19 Jereb. I don't recall those. Schmidli, Hunziker,

20 Muesli and Schaad.

21 COMMISSIONER GALVIN: I believe

1 Hunziger appeared someplace earlier on. But I won't
2 argue the point.

3 A VOICE: What about Steere?

4 A VOICE: Yeah.

5 DR. PHILLIPS: It's not even that.

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

10 COMMISSIONER GALVIN: I'll stop --
11 I'll stop my --

12 ATTORNEY GENERAL BLUMENTHAL: Do
13 we --

14 (APPLAUSE)

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

18 ATTORNEY GENERAL BLUMENTHAL: Let
19 me just say, since we're somewhat pressed for time,
20 is your presentation, Dr. Phillips, in written form?
21 In other words, can we make it part of the record?

1 Because that will --

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

4 ATTORNEY GENERAL BLUMENTHAL:
5 Great.

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

8 ATTORNEY GENERAL BLUMENTHAL: I
9 appreciate that.

10 DR. PHILLIPS: -- something that
11 also documents persistence of infections. Actually
12 71 references by many different authors. Also, I
13 would include Dr. Zemel very accurately referred to
14 a Klimpner study which had shown that there wasn't a
15 demonstrable benefit to retreatment in patients with
16 chronic Lyme. The International Lyme Association
17 Disease Society has a position paper on that, on the
18 lead author. It's 16 pages long. That study, in my
19 view, is highly flawed and we critique that.

20 And, also, the ILADS has just been
21 published their new treatment guidelines for the

1 management of Lyme Disease. It's just been
2 published in the peer-reviewed journal, Expert
3 Review of Anti-Effective Therapy. And it's hot off
4 the presses. And I will also include that as well.

5 ATTORNEY GENERAL BLUMENTHAL:

6 Thank you.

7 COMMISSIONER GALVIN: All right.

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

10 (APPLAUSE)

11 ATTORNEY GENERAL BLUMENTHAL:

12 Thank you very much.

13 Dr. Fallon?

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

20 I have ten minutes to talk about
21 the neuropsychiatric aspects of Lyme Disease. So I

1 will do it as quickly as I can.

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

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

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

21 Fourth, blood tests, we all know,

1 are problematic. Unless it's a culture, they don't
2 reveal whether you have active infection. And the
3 results often vary, depending on the test, the lab
4 and the stage of illness.

5 Treatment recommendations vary, as
6 you've heard. And science, unfortunately, honestly
7 has not caught up. I'm presenting one case that was
8 published in Biological Psychiatry in 1999 of a case
9 of Lyme Disease that presented as a
10 schizophrenia-like disorder. A 42-year-old woman
11 over eight months developed cognitive problems,
12 irritability, paranoid delusions and auditory and
13 visual hallucinations.
14 The work-up did not reveal any focal, neurologic or
15 arthritic signs. However, her spinal fluid showed a
16 lymphocytic pleocytosis and elevated protein with
17 antrathecal Borrelia specific antibodies. So this
18 was a clear case of neurologic Lyme Disease.

19 She was treated both with
20 antibiotics and antipsychotics briefly. And it led
21 to a complete resolution of the clinical symptoms

1 and her spinal fluid abnormalities.

2 So the point that I'm emphasizing
3 is not that psychotic symptoms are common in Lyme
4 Disease, because they're not, but I am pointing out
5 that they can occur and, unfortunately, they can
6 occur in the absence of other systemic symptoms that
7 might make you think of Lyme Disease.

8 Now, with neurologic Lyme Disease
9 you'll hear more about from Dr. Katz, there are the
10 early phase, the later phase -- and I won't go
11 through it in the interest of time. But the point I
12 wish to make is that the neuropsychiatric symptoms
13 may occur early or late in the illness.

14 Common symptoms of late neuro Lyme
15 include fatigue, headaches, sensory hyper-arousal
16 where patients are acutely sensitive to light or
17 sound, cognitive problems, such as slow processing
18 speed, problems finding words, short-term memory
19 problems, attention problems, getting lost in
20 familiar places, peripheral neurologic symptoms,
21 tingling, numbness, shooting or stabbing pains.

1 Cranial neuropathies are helpful when they occur,
2 but they are not common. And mood problems are also
3 common, irritability, depression, anxiety attacks,
4 personality change and behavior change. Rarely,
5 new-onset Lyme may manifest as mania or paranoia.

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

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

21 Is it lasting longer or not

1 responding to good trials of standard psychiatric
2 medicines? Then you have to start wondering about
3 an organic cause, such as a B-12 deficiency or Lyme
4 Disease or thyroid abnormalities.

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

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

19 This raises the question of
20 whether some -- in some Lyme endemic areas
21 psychiatric symptoms may indeed be triggered or

1 exacerbated or worsened or caused by *Borrelia*
2 *Burgdorferi*.

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

15 Now, in Dr. Steere's group up in
16 Boston in 1998 there was a study done of
17 neuropsychiatric problems in children after treated
18 Lyme Disease. And this was a referral center where
19 they referred -- where they evaluated 86 children.
20 12 had neuro-cognitive symptoms, such as behavior
21 changes, forgetfulness, poor school performance,

1 that developed with or after the onset of classic
2 manifestations of Lyme Disease. And two of those
3 children have developed partial complex seizures.
4 Five of the twelve had intrathecal antibody
5 production and the cognitive test that showed mild
6 to moderate auditory or visual processing deficits.
7 Four of those five children have had prior
8 antibiotic therapy.

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

13 And so they're asking why this
14 might occur. Well, one possibility certainly is a
15 post-infectious one. The other possibility, as they
16 say in their quote here, the other possibility,
17 which we favor, is that the five children had
18 hematogenous spread of *Borrelia* to the brain during
19 acute infection and low-grade latent or active
20 infection persisted, accompanied by intrathecal
21 antibody synthesis. Now, that was their favored

1 hypothesis. But it certainly wasn't proven.

2 We did a case controlled study at
3 Columbia of chronic Lyme Disease in kids. I won't
4 go through the symptoms in detail. But the main
5 point was that in these children who had developed
6 chronic cognitive problems, there was a mean
7 delineant diagnosis of almost a year and they had to
8 go to four different doctors until it was finally
9 detected. And these are patients who had Western
10 Blot positive Lyme Disease. Otherwise, they would
11 not have entered the study.

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

19 This was an interesting study that
20 came out of Sweden where they looked at 106 patients
21 with neuro Borreliosis versus 123 patients with

1 erythema migrans. And they followed them up three
2 years later. And what they found was that 50
3 percent of the neurologic Lyme patients had
4 persistent neuropsychiatric symptoms, whereas only
5 16 percent of the erythema migrans patients did.

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

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

21 The mean number of years between

1 symptom onset and treatment in our study was 1.2
2 years. So again, like the children, it shows that
3 people are not being detected early enough. And
4 that may be why they're developing chronic cognitive
5 problems.

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

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

19 We're also doing very
20 sophisticated brain imaging called Pet Scan imaging,
21 looking at the blood flow and the glucose metabolism

1 in these patients' brains. And all those spots on
2 the left and the red areas and yellow areas on the
3 right in the brain are areas of decreased blood flow
4 in the Lyme patients compared to age- and
5 sex-matched healthy controls.

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

9 MR. RYAN: Time.

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

17 Just a word about treatment.
18 There have been two published control studies of
19 chronic Lyme Disease. Klempner's study in Boston
20 did not find any improvement with repeated
21 antibiotics. Krupner's study which focused on

1 post-Lyme fatigue did find that the antibiotic group
2 benefitted three and a half times more likely than
3 the placebo group at six months on their main
4 outcome measure of fatigue. And they're noted there
5 in the red bar.

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

17 Finally, I just want to emphasize
18 that children are suffering in the school systems.
19 They look like they're inattentive, unmotivated,
20 disorganized and confused. They fall asleep in
21 class. They may look good, even on bad days.

1 Children may function better on some days. But each
2 day is unpredictable. It drives parents and
3 teachers crazy. Children needs longer amounts of
4 sleep and can't make it to early classes. Normal
5 sound environments can be painful, disorienting and
6 threatening. Schools need to create flexible
7 programs and not penalize students for missing class
8 when sick. Don't give failing grades just because a
9 child is in on some days but not others.

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

14 (APPLAUSE)

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

1 and we learn from our patients and from the
2 journals.

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

9 Thank you.

10 (APPLAUSE)

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

18 DR. FALLON: That's an excellent
19 --

20 COMMISSIONER GALVIN: Or a fellow traveler like
21 Babesia microti.

1 DR. FALLON: That's an excellent
2 question, which is are -- do the strains have
3 different clinical manifestations? I think that is
4 an open question. I certainly can say in my studies
5 even though Lyme Disease is endemic throughout the
6 Northeast, I'm far more likely to find patients with
7 five Western Blot bands on Cape Cod or in Old Lyme,
8 Connecticut than I am in New Jersey or Pennsylvania
9 or even upstate New York. And I don't think it's
10 because Lyme Disease is -- I don't think it's
11 because those patients don't have Lyme Disease. I
12 think it's because perhaps the -- there are
13 differences in the strains of the spirochete that's
14 causing a different reactivity by the immune system
15 among those patients. So that's one possibility.

16 And, in addition, you made the
17 very important point that a number of patients may
18 be co-infected with other organisms, some of which
19 we know, some of which we may not know. And that
20 also needs to be tested for and treated
21 appropriately.

1 COMMISSIONER GALVIN: If you'll
2 permit me, I'll make one -- a comment of anecdotal
3 nature. Some years ago, a Harvard researcher was
4 lecturing down at Yale University. And he had
5 really a fascinating story. And what he said was
6 that they'd had ticks up on the Cape for a long time
7 that bothered people. 35 years ago, we used to
8 think they had some variant of Rocky Mountain
9 Spotted Fever. It was probably Lyme Disease. They
10 used to -- they had a bad hurricane up in the Cape
11 somewhere in the 60's and they had a huge
12 enlargement in the population of ticks. So that
13 old-timers up in the Cape, according to this
14 individual, referred to them as hurricane ticks.

15 And he got very interested. And
16 I'll digress one more moment. And he went around to
17 this little museums that all small towns have. And
18 a lot of them had skins of rodents, particularly
19 mice. And he got some that dated back in post-Civil
20 War period and took them up to Harvard and was able
21 to recover Lyme DNA from back in the 1860's and

1 1870's. So --

2 Very good talk. Thank you.

3 (APPLAUSE)

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

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

1 this field.

2 DR. FALLON: Can I make a point?

3 ATTORNEY GENERAL BLUMENTHAL:

4 Sure.

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

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

19 ATTORNEY GENERAL BLUMENTHAL:

20 Thank you.

21 (APPLAUSE)

1 ATTORNEY GENERAL BLUMENTHAL:
2 Hopefully we'll have some more give-and-take. But
3 I'd like to give Dr. Tilton a chance to go.

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

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

20 There are essentially two types of
21 tests, indirect tests and direct tests. Indirect

1 tests are usually based on the detection of
2 antibodies and direct tests include culture, direct
3 visualization, antigen tests and tests to detect
4 specific DNA and/or orinite.

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

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

19 Its utility as a primary
20 diagnostic test, however, is a problem because it is
21 not readily available, except in a couple of

1 laboratories.

2 Certainly the most active field of
3 test investigation has been in single and multiple
4 peptide assays. And this distinguishes between
5 single and multiple peptide assays and whole-cell
6 assays which have been used for the last 20 years.
7 Many papers have been published on the use of
8 multiple and single peptides for testing. But there
9 are really very few available. A few have become
10 commercially available in the United States.

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

20 However, I think one of the more
21 exciting tests available is the C-6 Lyme peptide

1 antibody. The outer surface of the organism
2 Borrelia Burgdorferi has a region of outer surface
3 proteins. There are at least six variable proteins
4 and six invariable proteins.

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

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

21 This test detects antibody to a

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

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

19 Now, there is not a whole lot new
20 in Western Blot except to indicate that there are
21 still problems with the interpretation of the

1 Western Blot. It should come as no secret to
2 anybody that I do not necessarily agree with the CDC
3 criteria for interpretation, although we do use it.
4 I have published an alternative criteria for
5 interpretation. However, the laboratories that I
6 direct will use both interpretive criteria.

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

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

20 If you look at the work of Charlie
21 Cavia at New York State Medical College, the

1 incidence of blood cultures increases markedly if
2 increased amounts of blood are used.

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

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

17 COMMISSIONER GALVIN: Excuse me,
18 sir.

19 (Off the record - changing tape)

20 COMMISSIONER GALVIN: Go ahead,
21 Dr. Tilton.

1 DR. TILTON: In my opinion, there
2 are huge specificity problems with these alternative
3 tests.

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

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

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

16 COMMISSIONER GALVIN: Why don't --
17 would you allow me to say a few words? When one
18 develops a test, we attempt to develop a test which
19 is very sensitive. And a test that's very sensitive
20 doesn't miss any of the disease. So you set the
21 test level becomes set at a level where you ideally

1 would like to detect 100 percent of the people who
2 have the disease. If you set it too low, you're
3 going to get false positives. False positives mean
4 the test says something that's there is not there.
5 You also want to set the -- one wants to set the
6 test at a level where you don't get false negative.
7 A false negative says that the problem is not there
8 when, in fact, it is there. And that's the --
9 that's the tension as one develops a test.

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

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

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

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

21 DR. TILTON: No. No. Of course

1 not.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Okay.

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

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

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

20 Let me very quickly tell you about
21 some new approaches at PCR that we're using in my

1 laboratory. We are doing real-time PCR, which is a
2 very rapid PCR in a machine, using multiple targets.

3 When we amplify this DNA or RNA as the case may be,
4 we have a sequencing machine which looks at the
5 sequence of the nucleic acids and compares them to a
6 large data base, such as Gene Bank.

7 Essentially, real-time PCR using
8 multiple targets and routine sequencing of the DNA
9 that you amplified certainly has the ability to
10 reduce the possibility of contaminants and false
11 positive testing.

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

19 Let me also remind everyone that
20 the laboratory provides only supplemental
21 information in most any infectious disease, not only

5 Thank you.

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

21 Yes, the CDC criteria are widely

1 used. And as I indicated, I, at least for IgG
2 Western Blots -- and once again, I understand I am
3 using some technical terms which may not be
4 completely understood. But at least for IgG Western
5 Blots I prefer a more liberal criteria.

6 ATTORNEY GENERAL BLUMENTHAL: And
7 why is that, sir?

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

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

21 So, once again, it must be

1 evaluated on the basis of the clinical presentation.

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

6 ATTORNEY GENERAL BLUMENTHAL:

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

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

17 DR. MELINDA RAMSBY: Hello. My
18 name is Melinda Ramsby. I am a physician/scientist
19 and solo practitioner in rheumatology. I probably
20 am a science geek by some estimates. I've spent way
21 too long at the University of Connecticut in one

1 capacity or another. I obtained my Master's in
2 nutritional biochemistry there, my PhD in
3 biochemistry and cellular/molecular biology there.
4 I did four years of post-doctoral research with a
5 variety of sub-culture and molecular biologic
6 techniques. I obtained my MD and then went into the
7 sub-specialty of rheumatology. I am board certified
8 in both internal medicine and rheumatology.

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

17 An overview. I believe the
18 diagnosis of Lyme Borreliosis should be made based
19 on historical and clinical evidence,. Laboratory
20 tests, as noted previously, are confirmatory, are
21 useful, but should be used with the appropriate

1 knowledge of their utility and their limitations.

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

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

11 *Borrelia* infection causes early
12 and late manifestations which can be localized or
13 disseminated. Except for the erythema migrans rash,
14 there is no symptom that is specific for diagnosis.
15

16 The clinical features of
17 presenting cases should they ever be assessed
18 relative to current understanding of stages in Lyme
19 which include the early localized infection that may
20 or may not have erythema migrans, although
21 indications are that 70 to 90 percent of such cases

1 do, early disseminated disease, which may include
2 multiple erythema migrans lesions and a viral-like
3 syndrome which would be hard to distinguish from a
4 viral syndrome. Musculoskeletal, cardiac and
5 neurologic manifestations as well.

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

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

19 Cases with severe symptoms that do
20 not respond to antibiotic therapy or that include GI
21 symptoms or splenomegaly or low red blood cell counts

1 or low platelet counts should be tested for
2 co-infection with Babesia. Treatment would be
3 different and it would not be eradicated by
4 Doxycycline.

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

17 To ascribe Post-Lyme Syndrome to
18 active antibiotic-resistant infection leads to
19 premature closure of a differential diagnosis,
20 potential harmful treatment, as well as an increased
21 despair and frustration for the patient.

1 With regard to persistent active
2 infection and -- the terminology is "we". This may
3 be late manifestations of a disease or chronic Lyme
4 Disease. Persistent infection is proposed as the
5 basis to explain this phenomena and the rationale --
6 and it is also the rationale for treatment with
7 long-term antibiotics.

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

14 Some of the data which that has
15 been derived from are primarily case studies or
16 reports. There are some in-vitro studies. They
17 were limited. And other explanations are possible
18 for some of the findings of the organisms that have
19 been seen intracellularly which perhaps were not
20 even intracellularly but wrapped within the
21 membranes on the outside of the cell.

1 Another mechanism is surface
2 antigen modulation as a mechanism to evade the
3 immune system. The spirochete is a very primitive
4 organism. It does have an outer membrane. And
5 there are classic proteins, as mentioned before.
6 These outer surface proteins, A through F, do change
7 their expression under certain circumstances. This
8 may relate to the feeding cycle. This may relate to
9 environmental changes.

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

13 Also proposed is induction to
14 tolerance and immunosuppressive mechanisms. Most of
15 this literature is in the research domain. Most of
16 that is mouse studies and isolated studies with
17 peripheral blood macrophages. This will await
18 further testing to determine some of the validity.
19 But certainly there are various changes in the
20 cytokine environments and the humoral versus
21 cell-mediated responses to an organism and, if

1 inappropriate, might reduce the ability to destroy
2 invading organisms. Again, not conclusive.

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

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

18 What they observed was that there
19 were conversions to the cystic forms in depleted
20 mediums. Other articles have talked about hypotonic
21 changes, PH changes, exposure to antibiotics as

1 being able to induce this morphologic transition.

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

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

14 MR. RYAN: Time.

15

16 DR. RAMSBY: -- were being newly
17 synthesized. And they did find some specific
18 regulation of certain proteins. These kinds of
19 studies could go on and be tested. They do have
20 areas of -- that you could approach with science.
21 If there is an outer membrane and it does change its

1 expression, you could make antibodies to that. You
2 could go look for more organisms. You might be able
3 to find techniques to test for that.

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

16 Long-term antibiotics are
17 indicated if you have a septic joint and if Lyme
18 Borreliosis is there. But that would be an
19 indication.

20 I'd like to thank Dr. Robert
21 Galvin and Attorney General Blumenthal for inviting

1 me to participate. And I'm looking forward to a
2 stimulating discussion. Thank you.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Thank you very much.

5 (APPLAUSE)

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

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

1 presentations.

2 And, once again, many of the ticks
3 have more than one organism that they can infect
4 with. And some of the infections may be due to
5 other things other than the classic Lyme organism.

6 I would also have to say that our
7 colleagues from Yale University are, even as we are
8 meeting here, are meeting out on the West Coast and
9 discussing some of the very topics that Dr. Ramsby
10 brought up today.

11 Thank you.

12 ATTORNEY GENERAL BLUMENTHAL:

13 Thank you.

14 (APPLAUSE)

15 ATTORNEY GENERAL BLUMENTHAL: Dr.
16 Sinatra?

17 DR. STEPHEN SINATRA: Thank you,
18 Dr. Galvin, Dr. Blumenthal. First of all, I want to
19 relate to you that I'm not a Lyme specialist. I
20 don't treat Lyme Disease on a day-to-day basis. I'm
21 a cardiologist and a nutritionist. And my

1 experience with Lyme Disease is that it was placed
2 in my path. I have it personally. My dogs have it.
3 And I'm treating myself and my dogs.

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

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

20 First of all, I want to say that
21 in relation to this disease, it's worldwide. It's

1 epidemic. It's in six continents. And a lot of
2 researchers believe that a billion people are
3 infected. It's a worldwide epidemic. And as much
4 as 15 percent of the population right now is
5 infected with Lyme Disease. And many of it is
6 sero-negative.

7 Now, we talked about the arthropod
8 block, the vector, being the method of transmission.

9 There is now new research to show that Lyme Disease
10 is spread through mosquito bite, flea bite, tick
11 bite, and as well as sexual intercourse and as well
12 as congenital with the newborn, and has even been
13 transferred from breast milk to the newborn through
14 breastfeeding.

15 With the compelling evidence of
16 human-to-human transfer, it takes it away from the
17 tick bite as being the major mode of transmission.
18 So we have to be cognizant of the fact that there
19 are many of us sitting in this room right now who
20 have never been bitten by a tick that, indeed, has
21 Lyme Disease from a different form of transmission.

1 The dormancy and activation have
2 been discussed. And there are many cases on record
3 where people have had Lyme Disease dormant for years
4 where, when their immune system came assault from
5 other factors, developed the full-blown illness.

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

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

12 A VOICE: You took one of my
13 slides.

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

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

21 But one thing about Lyme Disease,

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

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

17 Now, why is this disease so
18 difficult to treat? I've heard Joanne Whittaker
19 speak -- and, by the way, I think she's probably the
20 best person in the country. She's in Florida. She
21 has a website. I'll be happy to give it out later.

1 But the problem with the Lyme
2 spirochete is that it's -- it changes direction.
3 First of all, it's a spirochete. It can turn into a
4 sphaerosplast, which is known as the L-form, and it
5 can also act in a cyst form.

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

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

21 The point I'm trying to make here

1 is that with standard laboratory tests, we may miss
2 a lot of Lyme Disease, depending on where the
3 spirochete is and what form it is and where it's
4 located in the body. So this is one of the reasons
5 why this is such a tenacious organism. And it's one
6 of the reasons why you just can't kill it.

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

15 A lot of these small trials that
16 are under way right now are using alternative forms
17 of therapy. And I believe that the best approach to
18 Lyme Disease is really an integrative approach or a
19 collaborative approach where you use the best that
20 conventional medicine has to offer and also the best
21 that alternative medicine has to offer.

1 And what a lot of these trials
2 that are undergoing, particularly in Bulgaria, which
3 is a wide epidemic of Lyme Disease -- Ecuador has an
4 horrific epidemic of Lyme Disease -- is really a
5 combined approach. And I've written this to my
6 newsletter subscribers. But in order for a full
7 recovery for anybody with Lyme Disease, you must
8 detoxify and cleanse the body. And detoxification
9 here is key. And this requires special diets, going
10 off glutens, going off flours, avoiding sugars,
11 taking certain nutraceuticals that can help cleanse
12 the body, particularly from environmental poisons,
13 insecticides, pesticides and petrochemicals and
14 plastics. But the list goes on and on.

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

20 And I've spoken to a neurologist
21 in Texas where Lyme Disease is not considered

1 endemic. But in Texas, one neurologist, a board
2 certified conventional neurologist, who was dead set
3 against using any alternatives in the treatment of
4 Lyme Disease, now uses alternatives with IV Rocetin
5 and other medications. And he told me that 90
6 percent of unexplained headache in his clinic of
7 2,000 patients was due to Lyme Disease.

8 So how do you treat this illness?
9 It's come out that antibiotics are good. But,
10 remember, antibiotics will not reach a lot of these
11 organisms, especially in a cyst form, especially if
12 they're embedded in tissues and in muscles.

13
14 So, basically, the integrative
15 approach to Lyme Disease, which, again, can come
16 under a lot of controversial discussions and
17 scrutinies. However, the way I'm treating myself
18 and the way I treat my dog and the way I treat my
19 patients, with the full knowledge that this again is
20 not considered standard of care, is with antibiotic
21 therapy prescribed by MD. I do believe that

1 antibiotics have their role and must be used in the
2 treatment of Lyme Disease.

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

17 There's also a TOA-free cat's claw
18 which comes from the -- it's a botanical. It comes
19 from a vine in South America. Una Degado is the
20 Spanish translation. But basically TOA-free cat's
21 claw contains lots of alkaloids and flavenoids which

1 literally can have a healing process particularly on
2 the immune system and they're also anti-microbial.

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

7 Another factor that we're using in
8 Lyme Disease is transfer factor, which really comes
9 from mother's milk. It's cholosterum. And
10 basically, some of these transfer factors can be
11 synthesized in the laboratory and be used in the
12 treatment of Lyme because they can penetrate the
13 cyst and penetrate other forms of the illness.
14 Where antibiotics only work when the bug is inside
15 the serum, some of these transfer factors can work
16 24/7, around the clock.

17 So, in summary, I think everything
18 that's been said here today has been very
19 meaningful. I have to say that when it comes to
20 Lyme Disease, having it myself and having to maybe
21 undergo hip replacement, I became very humble with

1 this illness. I think there is an enormous amount
2 of human suffering with this illness on the planet.
3 I think physicians are only scratching the surface
4 with this one. I truly believe that one needs to
5 take a more profound, integrative approach and
6 really choose therapies that are multidisciplinary
7 and can attack this bug at all stages of development
8 and get inside areas of the body where antibiotics
9 can work.

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

14 Thank you very much.

15 (APPLAUSE)

16 ATTORNEY GENERAL BLUMENTHAL:

17 Thank you very much.

18 Dr. Kelley?

19 DR. KATHERINE KELLEY: Thank you.

20 My name is Dr. Katie Kelley. I'm the Director for
21 the Connecticut Department of Public Health

1 Laboratory. And I've been asked to provide some
2 information to you and the legislative
3 representatives and your guests today about the
4 laboratory diagnosis of Lyme Disease.

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

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

1 the patient, determine whether you have cured the
2 disease in question.

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

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

20 That said, there's another sort of
21 criteria. And that is that -- and I think all of

1 the presenters today would agree because I sort of
2 heard it in what they -- in their remarks. And that
3 is that no test is 100 percent. It just plain
4 doesn't happen.

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

15 The way laboratory tests are
16 generally rated, if you will, is on the basis of two
17 criteria. And Dr. Galvin talked about those,
18 sensitivity and specificity. Sensitivity of a test
19 is related to the fact that you want that test to
20 identify all potential people who could have been
21 exposed or who are infected with the disease.

1 The consequence of looking so
2 broadly is that you will have false positive
3 results. That's just a given. It's part of the way
4 the test is set up.

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

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

21 Sensitive tests, that first broad

1 net of tests, generally use antibodies. They're
2 usually very rapid tests. They're generally pretty
3 inexpensive. And the antigen involved may be the
4 whole organism or a crude preparation of the
5 organism that may -- that contains most of the key
6 antigens.

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

15 So that's the kind of testing that
16 we're currently doing. And with *Borrelia*, it gets
17 more complicated because this organism has a lot of
18 antigenic sites on its surface that are lipids,
19 proteins and other chemicals. It also has some
20 antigenic materials inside that are not related to
21 the DNA. And that presents some problems as far as

1 sensitivity and specificity are concerned.

2 The other thing that can
3 complicate this a little bit are some other factors
4 outside of that. One is the treatment. If
5 treatment is done early and the antigenic process is
6 slowed down or stopped, you may not have full
7 expression of the antibodies. The length of time
8 from the point of infection to the point that the
9 patient is -- undergoes laboratory testing can also
10 affect the results. And as other people here have
11 said, there is good data that shows that the same
12 tick species that carries *Borrelia* also carries
13 other agents at a fairly high frequency. So we may
14 have infections with one or more other agents at the
15 same time that the individual is being infected with
16 the Lyme Disease bacterium.

17 This doesn't present a wonderful
18 picture for laboratory testing. But I think
19 everybody who is sitting in this room knows that
20 there's a long way to go to improving laboratory
21 tests. And there are -- there is some good news out

1 there. A lot of work that's being done now in
2 molecular diagnostics, especially in areas that are
3 called nanotechnology, are getting to a point where
4 things can be seen at much lower quantitations and
5 this will give us more rapid and better information
6 in the future.

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

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

14 (APPLAUSE)

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

1 patient to pay for such a test?

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

4 COMMISSIONER GALVIN: That's why I
5 asked you.

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

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

20 DR. KELLEY: Well, that's true.
21 That's true.

1 COMMISSIONER GALVIN: Thank you.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you, Dr. Kelley.

4 Dr. Katz?

5 DR. AMIRAM KATZ: Attorney General

6 Blumenthal, Dr. Galvin and dear audience, patients,

7 it's a --

8 VOICES: Can't hear you.

9 ATTORNEY GENERAL BLUMENTHAL: You

10 know, I might ask if you and Dr. Sinatra can change

11 chairs, that might -- thank you.

12 DR. KATZ: It's an honor talking
13 about my experience with Lyme Disease, especially
14 the neurologic aspects, in front of the audience
15 today. I guess I'm the fortunate one to speak last.

16 So I won't be repetitious.

17 I also tried to address some of
18 the official requests in the invitation to talk
19 about the way I diagnose and treat Lyme patients.
20 I'm a neurologist with sub-specialty training in
21 epilepsy, clinical neurophysiology, sleep medicine

1 and hyperbaric and diving medicine. And I served --
2 I was a faculty at Yale with the Epilepsy Center.
3 Then I went to Norwalk Hospital to open those
4 centers of epilepsy and diving medicine. And in
5 this capacity, I started seeing Lyme patients. And
6 I was intrigued by the myriad of symptoms and the
7 different manifestations of their illness and the
8 lack of improvement and started seeing more and more
9 patients.

10 I think that we are dealing with
11 an epidemic. I don't know if there's any other name
12 to call it. You know. We -- I just saw recent
13 reports. We have 4,000 cases reported in
14 Connecticut in the last -- in 2002, according to
15 Kirby Stafford, which I respect and consider his
16 opinion as valid. He claims that these are only 10
17 to 20 percent of the diagnosed cases. So we are
18 multiplying here by a factor of 10. We are getting
19 40,000 cases in the incidence of Lyme in
20 Connecticut.

21 And then we are left with the

1 cases which are not diagnosed or reported. So it's
2 several dozens, of thousands of patients a year.
3 And this is the incidence, not the prevalence. I
4 think that after several presentations today, we
5 will accept the fact that there might be chronic
6 Lyme Disease which will carry some of the patients
7 to the following year. So the prevalence will be
8 100,000 patients in Connecticut? More?

9 Actually, if you do surveys from
10 house to house -- and there is some information
11 about it which was brought in the introductory
12 letter, every household almost know about Lyme
13 Disease. So this is a problem. It's a serious
14 problem. And it's the reason we are sitting here
15 trying to get further with diagnosis and treatment.

16 Now, what about other tick-borne
17 diseases? Babesia, the Ehrlichia, the bartonella,
18 micoplasma, some of which are not accepted by
19 mainstream academic medicine. But we know that
20 there are probably other micro-organisms transmitted
21 by the same tick. So tick-borne disease is a major

1 problem. Then we are talking about the rare cases
2 of Tularemia and Rocky Mountain Spotted Fever, also.

3 There isn't much literature about
4 bartonella or micoplasma. And that's the reason I
5 brought one of the references by S. Cardall. I
6 reported a case of epilepsy aparcialis, continued in
7 a patient with Cat Scratch Disease that was
8 transmitted by a tick. The bartonella can cause
9 slightly different presentation. And I hope that
10 there will be additional literature in the future so
11 it would be recognized by the mainstream academic
12 community as well.

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

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

20 In the acute and sub-acute
21 presentation of Lyme Disease, there are 15 to 20

1 percent involvement of the nervous system. But
2 probably over 80 percent of late Lyme Diseases will
3 accept the definition of Lyme encephalopathy as part
4 of central nervous system involvement.

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

11 This is the big masquerader of the
12 21st century or the end of the 20th century, as
13 Syphilis was the one before. We have the spirochete
14 that this time is much -- way more tricky, with
15 different evasion techniques, some of which were
16 mentioned. It can lose a cell wall and survive in
17 an L-form. And if this is the case, antibiotics
18 that are bactericidal, damaging the cell wall, won't
19 be effective. Then are the cyst forms can attack
20 any organ system. In the central nervous system,
21 Dr. Fallon reviewed some of the facets. And I won't

1 spend more time on this again. Start from the
2 muscle to the peripheral nerve to the nerve roots to
3 the spinal cord. The brain, any of the cranial
4 nerves can be involved. Actually, the most
5 frequently involved cranial nerve is the seventh
6 cranial nerve. Bell's Palsy or facial paralysis.

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

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

18 How is the nervous affected by the
19 Lyme? There might be direct invasion into the cells
20 or extra-cell. And we know about -- at least we
21 have evidence that the neuroglia are invaded by the

1 Lyme, microscopic images. There might be injury
2 from substances excreted by the tick. I personally
3 don't believe that there is much evidence about
4 neurotoxins, but some people believe and treat in
5 this direction.

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

18 Steere and his colleagues have
19 several times brought into literature the fact that
20 persistent arthritis might be mitigated by
21 autoimmune mechanism. And they even postulated that

1 the OSP-A, the outer surface protein A, has a
2 sequence of amino acid which is similar to one of
3 our lymphocytes antigens. And this is the mechanism
4 by -- of inducing autoimmune disease.

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

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

16 MR. RYAN: Time.

17 DR. KATZ: -- (indiscernible)
18 disease.

19 Dr. Zemel mentioned very well in
20 his succinct presentation first do no harm. And I
21 do agree with him. And I'm working on patients

1 which are suffering from Lyme Disease or -- that's
2 the question. I always make sure we rule out other
3 possibilities. And from my own clinical practice, I
4 can stand all day here and tell you about patients
5 who were supposed to have chronic Lyme Disease and
6 were found to have other diseases. So, yes, we do
7 need to do a very thorough work-up to rule out other
8 causes of illnesses.

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

19 And, once again, I think that this
20 probably has a lot to do with the chronicity of the
21 disease. The HLA-DR-4 that Dr. Steere and his

1 colleagues talked about in their papers is actually
2 -- the incidence is about 30 percent of the
3 Caucasian population. So one out of three patients
4 that was affected -- infected by Lyme Disease has at
5 least a chance of carrying a DR-4 and developing
6 Post-Lyme Autoimmune Disease, which is not only
7 rheumatologic problem, neurologic as well.

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

1 the more we send, the more likely we'll have a
2 chance to get a positive result.

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

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

20 Neuro imaging, neuro physiologic
21 testing, neuropsychologic testing and, of course,

1 first and all clinical presentation. Just a little
2 example of white matter lesions which we see in the
3 MRI of the brain which are seen both in Lyme Disease
4 and in Multiple Sclerosis. Sometimes you cannot
5 distinguish between the two.

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

10 The SPEC scan which Dr. Fallon
11 mentioned, if there is no other explanation for
12 hypoperfusion -- and here we see this. I hope
13 everybody can see the arrow. The arrow points on
14 the -- in radiology, left is right and right is
15 left. The right hemisphere, the right cortex, you
16 see less orange, less thickness of perfusion. And in
17 this focal hypoperfusion with no other explanation,
18 with negative MRI, would support clinical
19 presentation and blood work. This is very
20 characteristic but not diagnostic of Lyme.

21 We talked about the spinal tap.

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

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

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

20 One very important thing about
21 Lyme Disease and other neurologic diseases -- and I

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

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

19 It's very important for this
20 particular patient with Lou Gehrig Disease to give
21 him his IV-Rosetin which will enable him again to

1 swallow for another year. And I have seen many
2 cases with this kind of presentation. I am not
3 saying that this is the cure. But I'm saying this
4 will improve their quality of life.

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

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

20 And if we will treat aggressively
21 the Lyme Disease in patients with demalinating

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

14 We also should make -- the State
15 should sponsor some epidemiologic studies and
16 compare the rates of Multiple Sclerosis here in
17 Connecticut and different counties. I tried to get
18 this information from the MS Society and it was
19 impossible. But I think we could probably have a
20 higher incidence, the same latitude in the West
21 Coast. They say that a temperate climate and

1 latitude are -- the incidence of MS is similar in
2 the same latitude. So we should compare it perhaps
3 in different parts of the country.

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

12 But this combination has several
13 advantages. The Plaquenil increases the
14 bacteriastatic effects of the Bioxin by changing the
15 PH of the ELISA, enabling more efficient antibiotic
16 treatment. We know that macrolides -- Bioxin is a
17 macrolide -- has probably anti-inflammatory--Babesia
18 and Plaquenil has some immune modulation.

19 Two more slides. This combination
20 is also effective against Babesia. And there might
21 be also some role of Plaquenil in cyst form. So

1 that's the reason it is -- might be working and
2 helped many of my patients.

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

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

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

21 And thank you again for giving me

1 the opportunity to speak.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you.

4 (APPLAUSE)

5 ATTORNEY GENERAL BLUMENTHAL:

6 Thank you very much, Dr. Katz.

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

12 Dr. Levitz?

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

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

17 A VOICE: Turn it on.

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

20 Many people -- I have seen
21 patients with what I don't believe to be Lyme

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

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

20 That all of these antibiotics
21 actually do also have immunologic effects, as Dr.

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

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

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

20 DR. RAMSBY: Anoratics have a lot
21 of other effects. And so can Plaquenil. Plaquenil

1 can be effective here because it's inhibiting the
2 presentation of antigens through the HLA system by
3 its changes on the PH of the lysozone. So, yes,
4 just because they get better on antibiotic doesn't
5 mean that it's because of an organism. Often, the
6 inflammatory process is involved. And especially
7 with chronic Lyme arthritis. I mean that does, you
8 know, appear to be a chronic inflammatory arthritis,
9 just like rheumatoid arthritis or others. And
10 disease-modifying agents are appropriate in those
11 cases.

12 ATTORNEY GENERAL BLUMENTHAL: Dr.
13 Phillips?

14 DR. PHILLIPS: I'd like to point
15 out that although Tetracycline class antibiotics do
16 have a measurable, but small, anti-inflammatory
17 effect, Dr. Levitz mentioned double-blind
18 placebo-controlled studies of Tetracycline class
19 antibiotics and the evaluation of rheumatoid
20 arthritis. Such studies have also been performed
21 with intravenous Rocetin double-blinded with saline

1 for two weeks in patients who had weekly positive
2 Lyme ELISAs but completely negative Western Blots.

3 That study did not just include
4 rheumatoid arthritis. It also included psoriatic
5 arthritis, arthritis related to vasculitic origin
6 and undifferentiated inflammatory arthritis. And
7 they found, with the treatment of two weeks of
8 Ceftriaxone, which has no notable in-vitro
9 anti-inflammatory effects, all of these groups
10 remarkably improved and the placebo group did not.

11 (APPLAUSE)

12 A VOICE: Is it a published study
13 on --

14 DR. LEVITZ: Yes, it is a
15 published study.

16 ATTORNEY GENERAL BLUMENTHAL: Any
17 other comments?

18 You know, I have a question which
19 doesn't necessarily elicit your particular expertise
20 because I know you are experts involved in treating
21 or diagnosing individual cases of this disease. But

1 the very powerful statistics that Dr. Katz gave
2 about the extent of the epidemic -- and we've all
3 used that term "epidemic". I've used it for years
4 and years -- raises the question on what we do about
5 the disease on a sort of macro level.

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

16 But I don't know that that
17 phenomenon can account for the exponential increase
18 which is astonishing and appalling. So I recognize
19 you're not epidemiologists or naturalists or what
20 the right expertise would be. Maybe there isn't one
21 expertise. But I just wondered if you as people who

1 have thought a lot about this disease might have
2 some observations about what should be done about it
3 in terms of the way we live.

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

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

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

15 DR. FALLON: No. Kirby Stafford
16 at the excellent Connecticut Agricultural Station
17 gives a wonderful talk about public health problems
18 with Lyme Disease. And he makes the point
19 profoundly compellingly; that, you know, you see the
20 rise in the deer population, you see the rise in
21 Lyme Disease. We're doing nothing to control the

1 deer population in Connecticut. It's profoundly
2 outrageous, I think. And I think that that needs to
3 be paid close attention to because we're just going
4 to have a continuing problem as the deer population
5 expands.

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

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

20 But I think deer control is not
21 being focused on. And that would be useful.

1 DR. LEVITZ: I think also -- I'm
2 probably one of the few people in the room who went
3 -- I went to Columbia and had to work my way
4 through. I worked summers in New York City on pest
5 control, killing mosquitoes and ticks. The fact
6 that Malathion had bad long-term side effects --
7 they should be showing up any time now.

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

17 And so, again, we talk --
18 everybody wants funding for this and funding for
19 that, et cetera. But despite that, there was some
20 testimony from Dr. Sinatra on other alternative
21 ways. I think most of us still believe that ticks

1 are the key cause, key culprit here. And there are
2 white-footed mice, et cetera, who they also feed on.

3 But the idea of trying to put a lot of money and
4 trying to control, just as the way we do mosquitoes
5 for the West Nile, and trying to just control the
6 tick population here is a very important one because
7 that stops it from where it starts and we don't see
8 all the new cases.

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

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

18 I think we had a comment -- and if
19 --

20 DR. PHILLIP BAKER: (Indiscernible
21 - not using microphone)

1 COMMISSIONER GALVIN: Could you
2 just identify yourself?

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

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

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

9 ATTORNEY GENERAL BLUMENTHAL: From
10 the National Institutes of Health.

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

15 A VOICE: Can't hear you.

16

17 DR. BAKER: -- they have a wider
18 range. They carry the gravid tick to areas where
19 they drop off and lay their eggs. But I think the
20 field mice are the most important vector because
21 they keep the disease percolating in an endemic area

1 and they multiply. And people come in contact with
2 ticks that develop from that vector more than the
3 deer. So that's -- I would have to say that's -- if
4 you had to choose between the two, I would focus on
5 that. And there are some new methods that have been
6 developed by the CDC that would -- are very good at
7 controlling rodent populations.

8 ATTORNEY GENERAL BLUMENTHAL:
9 We're going to be hearing from both the CDC, the
10 Center for Disease Control, and the NIH at 2:00
11 today.

12 Are there other comments or
13 questions that anyone might have at this point?
14 Yes?

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

17 COMMISSIONER GALVIN: Excuse me.
18 That's not going to get on the record unless you get
19 to a microphone.

20 ATTORNEY GENERAL BLUMENTHAL: Why
21 don't you just come up here and you can talk into

1 one of these microphones?

2 COMMISSIONER GALVIN: And would
3 you give your name please?

4 COURT REPORTER: And spell it for
5 me.

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

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

19 Thank you.

20 ATTORNEY GENERAL BLUMENTHAL:

21 Thank you.

1 (APPLAUSE)

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

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

8 (RECESS)

9 ATTORNEY GENERAL BLUMENTHAL:
10 Thank you. We're going to begin this afternoon's
11 presentations with Dr. Paul Mead of the Center for
12 Disease Control and Prevention and Dr. Phillip Baker
13 of the National Institutes of Health.

14 The floor is yours, gentlemen.
15 Thank you for being here. We know that you've come
16 a long way. And we really do appreciate you
17 rearranging your schedules. I know initially you
18 had a conflict. And we really definitively
19 appreciate your being here this afternoon. Thank
20 you.

21 COMMISSIONER GALVIN: Gentlemen,

1 if I could interrupt you for just one second?

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

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

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

17 "Currently, medical experts differ
18 in their recommended treatment modalities relating
19 to the diagnosis and management of Lyme Disease. As
20 these groups demonstrate", the groups who have
21 different types of treatment, "credible medical

1 evidence to support their differing perspectives,
2 the Department of Public Health is not currently
3 initiating investigations based solely on the
4 diagnosis and treatment of Lyme Disease. If you
5 have information indicating that standards of care
6 were not met in such areas as patient assessment and
7 monitoring, please provide this Department with the
8 name of the patient and a summary of the
9 circumstances surrounding your allegations."

10 And this is what we will do. We
11 are not in the business of advising physicians how
12 they should treat patients. And we have no special
13 criteria that we are going to use to evaluate people
14 who are treating Lyme Disease in a variety of ways.
15

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

1 the standard of care, then we have to act
2 accordingly.

3 ATTORNEY GENERAL BLUMENTHAL: Let
4 me just say, while we're doing announcements, I will
5 have to leave early because I have learned that the
6 Bureau of Indian Affairs will be announcing this
7 afternoon, is scheduled to announce this afternoon
8 the decision on the recognition of the Skattico
9 petition for acknowledgement from the Federal
10 Government. And that will be some time around 3:00.

11 So I'm going to going to be leaving a little before
12 3:00. And Dr. Galvin and Tom Ryan of my office will
13 be conducting the remainder of the hearing.

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

20 And I just want to say in a
21 sentence more pointedly what he has said; which is

1 that nothing that I've said, nothing that we've done
2 here should be interpreted as the Attorney General
3 or anyone from State Government really telling any
4 doctor how to diagnose or treat a disease. We have
5 enough to do without getting into that kind of
6 activity. And one of our panelists said this
7 morning -- and it is certainly a credo of the
8 medical profession, "First do no harm." And
9 certainly, a great deal of harm would result from
10 State Government telling doctors how to practice.
11 In fact, I have said repeatedly and I said at this
12 hearing five years ago that we never would try to do
13 so. And, in fact, our effort has been to allow the
14 doctors and their patients to be the ones making
15 these decisions without the interference of health
16 insurers or HMO's or anyone else, including our
17 State Government.

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

1 helpful.

2 Dr. Mead?

3 (APPLAUSE)

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

8 A VOICE: Can't hear you.

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

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

20 I will concentrate, as requested,
21 on two main issues within my statement, CDC funding

1 for states to report Lyme Disease and the
2 surveillance case definition for Lyme Disease.

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

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

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

20 CDC supports national
21 surveillance, epidemiologic response, field and

1 laboratory research, consultation and educational
2 activities through intramural initiatives. CDC also
3 funds collaborative studies on community-based
4 prevention methods, improved diagnosis and
5 understanding of pathogenesis, tick ecology and
6 development and testing of new tools and methods for
7 tick control.

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

14 CDC has mapped the national
15 distribution and risk for Lyme Disease and has
16 defined environments, activities and behaviors that
17 place people at high risk of infection. CDC has
18 developed new and effective devices and methods for
19 preventing infection and safely reducing vector
20 ticks in the environment, such as
21 insecticide-treated rodent bait boxes.

1 CDC developed and improved and
2 standardized diagnostic tests for Lyme Disease and
3 provided physicians standards for the use of these
4 tests. CDC's research programs had provided an
5 understanding of the pathogenesis of infection with
6 Lyme Disease bacterium and of transmission with the
7 bacterium by ticks.

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

17 IPM or integrated pest management
18 employs environmental management, biological and
19 chemical control of ticks, and enhanced personal
20 protection through tick avoidance and other measures
21 to prevent Lyme Disease.

1 Other areas of research include
2 the development of natural forest products for use
3 as an environmentally acceptable alternatives in
4 pest control, deer and rodent-targeted methods of
5 insecticide application, further efforts to predict
6 Lyme Disease risk on a national scale and further
7 understanding of host immune responses to infection
8 with the Lyme Disease bacteria.

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

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

18 As previously mentioned, CDC
19 distributes most of its Lyme Disease funds to states
20 and universities via cooperative agreements. In
21 accordance with federal rules and regulations,

1 cooperative agreements are awarded competitively
2 based on objective review of proposals submitted by
3 state health departments and other applicants. In
4 general, Lyme Disease cooperative agreements are
5 re-competed every three years.

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

17 As a partner in the cooperative
18 agreement process, CDC is responsible for assuring
19 that the overall objectives of cooperative
20 agreements are modified over time to reflect new
21 information and changing public health goals.

1 In general, the overall objectives
2 of Lyme Disease cooperative agreements have shifted
3 over the last decade from counting cases to devising
4 and testing methods for preventing infection.

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

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

19 Let me be clear. There is no
20 question that Lyme Disease is an important public
21 health concern in Connecticut. The question, as

1 emphasized by the patients we heard from today, is
2 ultimately how to prevent it. It is towards this
3 question that CDC cooperative agreements are
4 focused.

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

15 Whereas physicians appropriately
16 err on the side of over-diagnosis, thereby assuring
17 they don't miss a case, surveillance case
18 definitions appropriately err on the side of
19 specificity, thereby assuring they do not
20 inadvertently capture illnesses due to other
21 conditions.

1 As adopted by the Council of State
2 and Territorial Epidemiologists, a case of Lyme
3 Disease is defined for national surveillance
4 purposes as physician-diagnosed erythema migrans
5 greater than five centimeters in diameter or at
6 least one objective manifestation of Lyme Disease,
7 musculoskeletal, cardiovascular, neurological, with
8 laboratory confirmation of B. Burgdorferi infection
9 using a two-tiered assay.

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

17 No surveillance case definition is
18 100-percent accurate. There will always be some
19 patients with Lyme Disease whose illness does not
20 meet the national surveillance case definition. For
21 this reason, CDC has stated repeatedly that the

1 surveillance case definition is not a substitute for
2 sound clinical judgment. Given other compelling
3 evidence, a physician may choose to treat a patient
4 with Lyme Disease when their condition does not meet
5 the case surveillance definition.

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

15 Thank you very much.

16 ATTORNEY GENERAL BLUMENTHAL:

17 Thank you. Thank you very much.

18 (APPLAUSE)

19 ATTORNEY GENERAL BLUMENTHAL: Dr.

20 Baker?

21 DR. BAKER: Can you hear me?

1 ATTORNEY GENERAL BLUMENTHAL: yes.

2 DR. BAKER: Okay. Good afternoon.

3 I am Dr. Phillip Baker, the NI-- the Lyme Disease
4 Program Officer and the Anthrax Basic Research
5 Program Officer with the Division of Microbiology
6 and Infectious Diseases, National Institutes of
7 Allergy and Infectious Disease, NIAID, NIH, at the
8 Department of Health.

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

12 NIH has a long-standing commitment
13 to Lyme Disease that began more than 20 years when
14 the cause of the disease was not yet known. In
15 1981, NIAID-funded scientists identified *Borrelia*
16 *Burgdorferi* as a causative agent of Lyme Disease.
17 Since then, basic and clinical research efforts have
18 been expanded in scope to address a variety of
19 issues related to this disease. These activities
20 include both intramural and extramural research on
21 animal models, microbial physiology, molecular and

1 cellular mechanisms of pathogenesis, mechanisms of
2 protective immunity, vectors and disease
3 transmission, efficacy of different modes of
4 antibody therapy and the development of more
5 sensitive and reliable diagnostic tests for both
6 early, acute and late chronic Lyme Disease.

7 Other NIH institutes and centers
8 that conduct Lyme Disease research are the National
9 Institute on Aging, the National Institute of
10 Arthritis, Musculoskeletal and Skin Diseases, the
11 National Institute of Mental Health, the National
12 Institute of Neurological Disorders and Stroke, the
13 Fogarty International Center and the Center for
14 Research Resources.

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

21 Approximately 20 percent of

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

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

17 Since the genome of B. Burgdorferi
18 has now been completely sequenced, greater advances
19 are anticipated as this information is used both to
20 improve diagnosis and improve -- and provide greater
21 and newer insights on the pathogenesis of the

1 disease through the application of micro-array
2 technology and cardiometrics.
3 Co-infection looms as a major potential problem,
4 mainly because the ixodes ticks that transmit B.
5 Burgdorferi can carry and simultaneously transmit
6 other emerging pathogens, such as Ehrlichia species,
7 the causative agent of human granulocytic
8 Ehrlichiosis or HE, and Babesia Micro which causes
9 Babesiosis.

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

16 Co-infection by some or all of
17 these infectious agents may interfere with the
18 clinical diagnosis of Lyme Borreliosis and/or
19 adversely influence host defense mechanisms, thereby
20 altering landmark characteristics of the disease and
21 the severity of infection.

1 For example, studies conducted by
2 NIAID extramural researchers have shown that
3 co-infection with HGE increases the severity of Lyme
4 Borreliosis.

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

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

20 The clinical protocols for these
21 studies which have been posted on the NIAID website

1 were developed through collaboration and extensive
2 discussions with Lyme Disease research experts, as
3 well as with NIAID Lyme Disease Advisory Panels
4 composed of patients with Lyme Disease, members of
5 patient advocacy groups, practicing physicians who
6 treat patients with Lyme Disease and basic research
7 scientists with experts in either infectious disease
8 or Lyme Disease.

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

16 After its review, the DSMB
17 unanimously recommended that NIAID terminate the
18 treatment component of these studies. The
19 preliminary data analysis showed that after 90 days
20 of continuous antibiotic therapy, there were no
21 significant differences in the percentage of

1 patients who felt that their symptoms had improved,
2 worsened or stayed the same between the antibiotic
3 treatment and placebo groups in either trial. In
4 other words, we had an answer to a question we were
5 asking.

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

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

19 Both the intramural and extramural
20 studies mentioned above involve data collection as
21 well as the maintenance of specimen repositories.

1 Such specimens have been made available to other
2 investigators working on Lyme Disease and, thus,
3 have contributed significantly to the development of
4 improved and/or novel diagnostic procedures.

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

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

1 Borreliosis in humans.

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

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

18 These vaccines were found to be 49
19 to 68 percent effective in preventing Lyme Disease
20 after two injections and 68 to 92 percent effective
21 in preventing Lyme Disease after three injections.

1 The duration of their protective immunity generated
2 a response to the SKB vaccine which is called
3 LymereX, which was licensed by the FDA in December
4 of 1998, is not known.

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

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

16 NIAID was not directly involved in
17 the design and implementation of these particular
18 vaccine trials. However, patents for cloning the
19 genes used for the expression of recombinant OSP-A,
20 as well as knowledge on the role of antibodies
21 against OSP-A and the development of protective

1 immunity, were derived from basic research grants
2 funded by the NIAID.

3 In April of 2003,
4 Glaxo-Smith-Klein announced that even with the
5 incidence of Lyme Disease on the increase, sales of
6 Lymerex declined from about 1.5 million doses in
7 1999 to a projected 10,000 doses in 2002.

8 Although studies conducted by the
9 FDA did not reveal that any reported adverse effects
10 were directly attributed to the vaccine,
11 Glaxo-Smith-Klein discontinued manufacturing the
12 vaccine for economic reasons.

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

1 Disease in experimental animals.

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

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

19 The NIAID is fully committed to
20 continuing to explore these and other
21 yet-undiscovered areas of research in the hope that

1 future research financed will provide important
2 clues to better understanding this painful disease.
3 Lyme Disease research will continue to be a priority
4 for the NIAID for the foreseeable future.

5 Thank you.

6 ATTORNEY GENERAL BLUMENTHAL:

7 Thank you very much, Dr. Baker.

8 (APPLAUSE)

9 ATTORNEY GENERAL BLUMENTHAL: I

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

21 And, yet, I wonder whether it's

1 been your experience -- we see if from time to time.

2 You probably have -- I know you've sat in this room
3 this morning and heard the references to it in the
4 clinical diagnosis setting. Whether your experience
5 has been that the CDC surveillance definition
6 continue to be used in that setting as well as in
7 the collection of information used for surveillance.

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

13 I think it's important to point
14 out that -- first off, when we talk about CDC
15 criteria, there's surveillance criteria and then
16 there are guidelines for the interpretation of
17 laboratory data. The laboratory testing data
18 guidelines for the results of a meeting as was
19 discussed held in 1994 that involved various groups,
20 not just CDC, but also NIH, Association of State and
21 Territorial Public Health Laboratory Directors, et

1 cetera. And those -- what came out of that meeting
2 were criteria not for laboratory diagnosis but for
3 interpretation of laboratory tests. And that's an
4 important distinction.

5 And it's an important distinction
6 because, as was also mentioned this morning, the
7 laboratory test when it comes to diagnosis is just
8 one bit of evidence. There are many bits of
9 evidence that are important. The history of the
10 patient. Had they been bitten by a tick? The nature
11 of their symptoms.

12 And I believe that just about any
13 physician that has been here today will reaffirm
14 that, as we were all taught in medical school, don't
15 hang everything on one laboratory test or one
16 finding. You have to consider the alternative
17 diagnoses.

18 Now, so one would certainly hope
19 that physicians would look at these testing criteria
20 as one bit of evidence when they're trying to make a
21 clinical diagnosis. As is the case with the many

1 other laboratory criteria which CDC has published
2 over the years for Hepatitis and various other
3 diseases. So this is not unique to Lyme Disease.
4 There are criteria for interpretation of many, many
5 laboratory tests.

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

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

21 ATTORNEY GENERAL BLUMENTHAL: I --

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

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

19

20 The budget language recommended
21 that CDC -- and I'm quoting -- "aggressively pursue

1 the correct -- pursue and correct the misuse of this
2 definition. This includes issuing an alert to the
3 public and physicians, as well as actively issuing
4 letters in places -- to places misusing the
5 definition."

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

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

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

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

21 We will have a mortality and

1 morbidity weekly report summarizing the Lyme Disease
2 surveillance data coming out soon. And we intend to
3 restate that issue once again to make our position
4 once again known that there is a distinction between
5 surveillance case definitions and clinical
6 diagnoses.

7 ATTORNEY GENERAL BLUMENTHAL:

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

14 I wonder if you could also tell us
15 a little bit about the tick control experiments that
16 you mentioned earlier. I know some have been
17 conducted in this area. And as I recall, they
18 involved, among other things, feeding stations for
19 deer and other methods which were in a sequenced,
20 several-year test pattern. Maybe you could update
21 us a little bit on those.

1 DR. MEAD: Well, I will try to.
2 There may also be -- I believe Dr. Stafford from the
3 Connecticut Agricultural Station will be speaking
4 later on and perhaps he will cover that in more
5 detail than I can.

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

12 As I think we heard today from the
13 patients who spoke and from the physicians and their
14 frustration in treating individual patients, this is
15 not a benign disease and it does not always respond.

16 And I think that underscores the tremendous
17 importance of emphasizing efforts to actually
18 prevent people from getting infected in the first
19 place.

20 Some of the efforts have looked at
21 deer -- what are called deer four-poster stations.

1 And these are essentially bait stations which have a
2 small amount of corn in them which deer come to and
3 they will receive around their neck as a result of
4 trying to get the corn a dose of acaricide which can
5 be very effective in killing the adult ticks which
6 use the deer as essentially their source and
7 breeding area.

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

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

18 Another development which we are
19 very excited about is the tick bait boxes which I
20 mentioned. And these are -- the rodent bait boxes.
21 These are small boxes which are placed around a

1 person's property and they have bait in them that
2 attracts mice and other rodents. And in the
3 process, they apply again a small dose of acaricide
4 to the fur of those mice.

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

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

20 And we believe that with the
21 broader availability of these, we will be able to

1 thoroughly and scientifically evaluate that
2 question.

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

11 DR. MEAD: There are several
12 different forms of surveillance. And I believe that
13 the folks from Connecticut who will be following can
14 give a much better description of some of the issues
15 involved in the decision to discontinue laboratory
16 reporting or mandatory laboratory-based reporting.

17 But there are several ways of
18 conducting surveillance. You can rely on physicians
19 to report. You can do active physician surveillance
20 where you call physicians weekly and find out if
21 they've diagnosed cases, which will capture many of

1 the cases, for example, with erythema migrans who
2 will not have a laboratory report.

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

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

21 I think our feeling is that that

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

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

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

20 (APPLAUSE)

21 ATTORNEY GENERAL BLUMENTHAL: I

1 just -- again, I don't mean to make you the point
2 person or the recipient of a position that I have
3 stated to your agency. And you were very gracious
4 to come here. So I'm not berating you.

5 But, in my view, we have to find
6 the funding to do the surveillance. Otherwise, we
7 won't know whether we're making progress. We need
8 to count the cases. We can say, "Well, this disease
9 now we know is so prevalent, it's off the charts."
10 But we still need the charts to do the counting
11 because we won't know whether we've made a dent, let
12 alone real significant progress in fighting it.

13 And the reason why I -- I mean I
14 think you sort of are making the case in a way in
15 your description of the tick control measures
16 because, as you put it quite well, what we need to
17 know is whether people are still getting the disease
18 in order to know whether the tick control measures
19 work. And we won't know that unless we're doing the
20 counting.

21 DR. MEAD: Well -- and I believe

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

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

15 If a surveillance system is not
16 working -- and not all surveillance systems work.
17 They simply don't. They prove to be too costly and
18 too inefficient to do their job. And, often, the
19 effort is not worth the value gained. Yes, you
20 capture a greater percentage of cases. But the
21 truth is you still know that it's -- even without

1 that, you would have known that it was common in
2 this town and not common in that town or was common
3 in this age group and not common in that age group.
4 And you can, even with imperfect or with active
5 surveillance, determine trends over time. And those
6 really are some of the key issues.

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

14 ATTORNEY GENERAL BLUMENTHAL:
15 Well, I -- I apologize that I'm going to have to
16 leave a little bit early. But if you are taking a
17 message back or any number of messages, I think one
18 of them might well be that Connecticut would like to
19 be a model in a sustainable, accurate surveillance
20 system that fully captures and counts the numbers of
21 cases in a way that enables us to make more

1 intelligent decisions about tick control, improved
2 diagnosis and more effective treatment, because
3 that's one of the measures of progress that we will
4 make. And I have contacted your agency and will
5 continue to do so on that score.

6 And, again, I want to thank you
7 for being here.

8 DR. MEAD: Thank you.

9 (APPLAUSE)

10 COMMISSIONER GALVIN: I think one
11 of the -- excuse me. Obviously, one of the crucial
12 and crucially important aspects of this meeting is
13 how do we treat Lyme Disease. And, really, before
14 that, we have to know how much of it we have. And I
15 think what we're all trying to look at is how do we
16 count this. And how about all those patients that I
17 saw and gave medication to and treated and never
18 came back? And I guessed they had Lyme Disease, but
19 I didn't have anything to confirm it. And mixed in
20 in that bunch of people with spider bites and
21 stinging insect bites and the like. And so we miss

1 all those people who have Lyme Disease. Or if we
2 include them all, we include everybody who has any
3 kind of a bite that gets antibiotic treatment.

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

12 So I think we're at a -- nobody in
13 -- I don't think anybody in the room, particularly
14 the Attorney General and myself, feels that we
15 shouldn't count this. I think we need to find
16 what's -- what's the best way to count this?

17 And in the Attorney General's
18 presence, I will say the following. I used to send
19 people for lab work and several weeks to a couple of
20 months afterwards or longer, I get these little
21 sheets back to fill out and I'd throw -- I would

1 sometimes throw them away. And I'll go public with
2 that much. I wouldn't fill them out. Sometimes I
3 threw the --

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

6 (LAUGHTER)

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

9 ATTORNEY GENERAL BLUMENTHAL: I'll
10 be there.

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

19 And I know that the return of
20 these documents was very low. And I don't know a
21 really good way to count this, to count this stuff.

1 I do know that we're hearing more and more that
2 within the next few months, we'll have laboratory --
3 computerized laboratory connectivity with the --
4 between the labs and the Health Department. So it
5 would be conceivable that we could have one or more
6 labs simply send us all the positive, first -- all
7 the Lymes that have first-time positivity, all those
8 tests. And that would give us a way of looking at
9 it. Or we could use the one large -- there's one
10 lab that has the predominant number of Connecticut
11 citizens.

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

18 I just don't know a really good --
19 it bothers me to devote a lot of time to a test that
20 maybe isn't so reliable and that maybe we only get
21 back seven out of ten queries on. But, you know, we

1 need to find a better way to do that. And that's
2 part of the reason that we're having -- that we're
3 having this meeting.

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

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

1 A VOICE: (Indiscernible - not
2 using microphone)

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

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

11 Thank you.

12 (APPLAUSE)

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

18 DR. JAMES HADLER: Okay. Thank
19 you. And thanks for the opportunity for me to have
20 an opportunity to present the State role in
21 surveillance and prevention of Lyme Disease.

1 What I'd like to do is to kind of
2 review a little background, some of which has
3 already been mentioned by previous speakers, some of
4 which hasn't, about the role of public health versus
5 academic and clinical medicine. In other words,
6 what we can and can't do. The role of the
7 Department of Public Health, Infectious Disease
8 Division, in which Lyme Disease Surveillance and
9 Prevention is located. And talk about why Lyme
10 Disease is of potential public health important. We
11 don't do surveillance and prevention for everything.

12 Why Lyme Disease?

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

19 Well, first just to briefly review
20 the relative roles of public health, clinical and
21 academic medicine. Public Health is basically

1 concerned with primary prevention, which means
2 preventing getting disease, infection or disease, in
3 the first place and related data collection
4 activities.

5 Public health is population-based.

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

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

17 Academic medicine -- and academic
18 medicine is funded a lot by the National Institutes
19 of Health -- is the best place to try to define the
20 natural history of disease, to do special studies to
21 figure out, you know, what are the various

1 complications of infection with *Borrelia Burgdorferi*
2 or other organisms. They can conduct clinical
3 trials, which you've heard about, for treatment.
4 And ultimately, on the basis of evidence, academic
5 medicine is usually the center for where guidelines
6 for treatment come out so that that treatment is
7 based on scientific evidence.

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

17 We then use the data that's
18 collected through surveillance to implement and
19 support targeted initiatives to prevent preventable
20 diseases from occurring. That's the prevention
21 function that we ultimately are working towards.

1 We have a variety of methods and
2 it really depends on the disease, but we do case and
3 outbreak investigation and control when that's
4 appropriate. We do vaccination or support
5 vaccination efforts when that's -- when there's a
6 vaccine appropriate. And also prophylaxis, giving
7 antibiotics to people who may have been exposed but
8 don't yet have disease. And provide important
9 information to professionals and to the public.

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

17 We have the acute communicable
18 disease, emerging infections and outbreak
19 investigation program. We call it the Epidemiology
20 and Emerging Infections Program. This includes Lyme
21 Disease. And it's under Dr. Matt Carter, who has

1 really been the coordinator of our Lyme Disease
2 efforts for many years.

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

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

16 This is sort of our emergency room
17 function which used to take probably one day a week
18 of my time, now probably takes three days a week of
19 my time. There's also 45 other
20 diseases that are reportable by mail. That includes
21 HIV, sexually transmitted diseases, several

7 Okay. Well, turning to Lyme
8 Disease, in the course of -- you know, how does Lyme
9 Disease really fit into this big list of diseases?
10 And why are we interested in Lyme Disease?

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

21 Currently, though, in 2004, it's

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

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

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

16 Important to point out that there
17 are questions that Public Health can't answer. But,
18 again, that academic medicine might be able to
19 answer. What is the spectrum and natural history of
20 illness? Is there chronic Lyme Disease? If so, how
21 can it best be treated? These are things again that

1 are really coming out of the academic medicine
2 sector and we can't conduct surveillance that will
3 meaningfully give answers to these questions.

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

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

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

17 Reporting of disease by clinicians
18 and reporting of findings. Laboratory findings
19 indicating possible disease is only one method. And
20 it does have limitations. It's good for describing
21 the epidemiology. Who is getting it? Men, women,

1 children, adults? In one geographic location or
2 another? And if your system is stable, as mentioned
3 by Dr. Mead, you can look at trends and you can
4 compare apples with apples. This is something I'm
5 going to focus on much more a little bit later.

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

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

20 We can conduct sero-prevalent
21 studies, go around and take blood, something we did

1 for West Nile in the Stamford area and Greenwich
2 area a few years ago.

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

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

14 And we need to have commitment of
15 our surveillance partners, as Dr. Galvin mentioned.
16 It takes time to report. You need to be cognizant
17 of unfunded mandates on the people who do reporting
18 to us. And the surveillance partners really need to
19 see the value in reporting because they're busy
20 treating individuals who really need care. And
21 filling out a piece of paper and sending it

1 somewhere that doesn't seem to get anything done is
2 not something that takes a high priority compared to
3 dealing with the individuals they're seeing.

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

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

15 Our objectives have changed over
16 time. In the 1970's and 80's, especially the
17 1980's, we were describing the magnitude of the
18 problem, its geographic distribution, descriptive
19 epidemiology and risk factors. In the 1990's, here
20 in Connecticut we were describing changes in all of
21 the above over time, further describing risk factors

1 and beginning to take a look at the prevalence of
2 prevention practices, beginning to start focusing on
3 the prevention side of things.

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

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

21 Our surveillance -- Lyme Disease

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

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

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

18 Important. From this kind of
19 information, we know that 20 to 25 percent of all
20 families have had at least one person diagnosed with
21 Lyme Disease ever and that three to five percent of

1 all families have had someone diagnosed with Lyme
2 Disease in the past year. You can extrapolate that
3 out to roughly one percent of the entire population
4 or probably 34,000 people are getting a diagnosis of
5 Lyme Disease in Connecticut each year. This is much
6 more accurate data than our case counts, as you'll
7 see.

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

11 Human surveillance for Lyme
12 Disease. Our method, basic surveillance, physician
13 reporting to the Department of Public Health and to
14 the local Health Department where the patient lives.
15 That's a mandatory requirement. It's supposed to
16 be done whenever a physician diagnoses Lyme Disease,
17 whether it's immediately on the basis of a physical
18 diagnosis of seeing erythema migrans or whether it's
19 getting a laboratory report back on somebody with
20 arthritis and saying, "I think this is Lyme
21 arthritis."

1 We supplement these methods to try
2 to increase reporting rates, knowing that not all
3 physicians report very regularly. So reminders
4 don't hurt. In some parts of Connecticut -- and
5 we've been doing this from 1992 to the present. We
6 have active surveillance where all physicians --
7 we've tried to contact all physicians, primary care
8 physicians, in that area, get them to report to us
9 on a monthly basis on a Lyme list. And if we don't
10 get a report -- it makes it a lot easier for them.
11 If we don't get a report from them, we call them up
12 to say, "You haven't sent in a report. Did you see
13 any Lyme Disease cases?"

14 Between 1994 and 1997, we had
15 enhanced laboratory surveillance. Here, every
16 laboratory -- we asked every laboratory doing tests
17 whenever they had a positive test to slip in a case
18 report form with the test result they sent back to
19 the physician. We stopped that in 1998 for this
20 five-year period and had -- actually, we -- instead,
21 we required laboratories to report to us and we sent

1 out case report forms on every one with positive
2 tests, sometimes up to four efforts to try to get a
3 report back on individuals.

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

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

11 MR. RYAN: Time.

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

21 There are issues related to each

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

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

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

20 If you take a look at the green
21 and the blue, you'll see our trends are not so --

1 are not so striking. Yes, we have -- we've had an
2 epidemic of Lyme Disease in Connecticut. We
3 actually now have an endemic, moderately stable,
4 with annual fluctuations in rates. That doesn't
5 mean they're not going to go up further. But annual
6 fluctuations in rates for Lyme Disease.

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

12 The future of human surveillance
13 for Lyme Disease. Issues. Our purpose of
14 surveillance is to monitor trends and cases in the
15 era of prevention, emphasis on areas where
16 prevention projects are in place. We have data since
17 1994 that includes some reminder to report based on
18 laboratory reports.

19 We do need some degree of such a
20 degree, if possible, in areas where prevention
21 projects are funded or else we're not going to be

1 able to really compare current data with past data.

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

9 Our plan is -- and this was partly
10 outlined by Dr. Galvin. We're going to --
11 laboratories have agreed to put a reminder note to
12 report as part of all positive laboratory reports
13 beginning some time hopefully during February. This
14 will sort of simulate the enhanced lab surveillance
15 that was done during this time period. We're
16 developing an electronic reporting system that, once
17 in place, we can then resume laboratory reporting.
18 It won't be a burden on laboratories.
19 Automatically, reports would be sent to us without
20 their having to do any extra work and it will be
21 uploaded into our system without us having to do

1 work. Hopefully beginning by 2005.

2 This is what the system would look
3 like. Maintained active surveillance. Labs
4 including reporting reminders statewide and
5 electronic laboratory reporting, with reminders that
6 would still have to be sent out manually to
7 physicians in selected areas.

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

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

21 Our role in Lyme Disease

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

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

16 From a funding perspective, all
17 funding is -- this is my last two slides, quickly.
18 All funding has come basically from federal sources
19 to support our Lyme Disease surveillance and
20 prevention efforts. Most federal funding has been
21 competitive, as Dr. Mead pointed out. Currently,

1 only four states are funded for Lyme Disease
2 surveillance and prevention. We're one of them.
3 There's only one funded for tick-borne disease
4 prevention. That's Connecticut. Again, both of
5 these applications have been coordinated by Dr.
6 Carter.

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

10 Future funding, however, for
11 Connecticut is uncertain. By late 2004, there will
12 be only two distinct cooperative -- the two distinct
13 cooperative agreements for the past five years will
14 be collapsed into one dedicated to Lyme prevention
15 and prevention evaluation. Only two states, instead
16 of four, will be funded, approximately 650,000 each,
17 with a range -- could be as much as 800,000.

18 So this is what our cumulative
19 funding has looked like over the years. Next year,
20 it may look like this, if anything. We could have
21 zero and we could have up to \$800.00. So unknown

1 where our funding for prevention will be in the
2 future. Our application is undergoing competitive
3 evaluation. We hope it will be reviewed favorably.
4 But we don't know.

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

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

9 (APPLAUSE)

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

17 DR. HADLER: No. The -- as you
18 can see, our funding -- what happened is in 1999 --
19 there's a second sort of a pinkish color -- this
20 right here. CDC had a second cooperative agreement
21 for tick-borne disease that was mainly focused on

1 Lyme Disease but also Ehrlichiosis and Babesiosis.
2 So that was additional funding that was available to
3 public health agencies. So that accounts for a lot
4 of it.

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

10 I think as Dr. Mead said, in 1997
11 when this was actually -- that wasn't our case
12 count. But in 1997, before we had any laboratory
13 reporting, we were the number one state in the
14 country. A number of other states -- several other
15 states also had very high rates of Lyme Disease. We
16 were all the -- we were obviously best positioned to
17 get funded. Not all of us did get funded. And
18 whether or not we had laboratory reporting -- I mean
19 in -- we were still the number one state in 2002.
20 So I don't think there was any -- anything there.
21 It's really our cumulative record and trying to

1 conduct surveillance, meaningful surveillance,
2 getting information and using it for prevention
3 that's so far kept us in the funding loop.
4 Hopefully, it will keep us in the further funding
5 loop.

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

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

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

21 DR. HADLER: Yeah. Here we are

1 right here. Here's 2003. Here's 2002. Obviously,
2 a huge drop. But look at all the artifact we added
3 by lab surveillance between this time period and
4 over here. And the real -- and the part that
5 doesn't depend on the laboratories at all is the
6 green plus the blue. That hasn't changed all that
7 much over time. It's obviously gone up and down
8 various years. We're actually right now very
9 similar to where we were back in 1995.

10 However, we're going to be adding
11 back sort of this aspect of lab surveillance and a
12 little bit of this in the future when we have
13 electronic lab reporting because we think that's
14 necessary to have as stable a system as possible in
15 the areas where we have prevention projects.

16 MR. RYAN: But when Congress
17 decides -- and Congress does decide when to allocate
18 the monies for this. Right? I mean it's not the
19 CDC that does this. Are they looking at numbers?

20 DR. HADLER: Well, Con-- it's hard
21 to say what makes Congress decide to appropriate

1 funding in the first place. In terms of funding
2 that comes specifically to Connecticut, though,
3 Congress doesn't look at Connecticut. Congress
4 looks at the national numbers all together and other
5 reasons that make Lyme Disease something that has
6 come to of interest and appropriate funding. The
7 funding then goes to NIH, CDC, at least the federal
8 funding, as the two main agencies for dispersing
9 funds based on clinical research or public health
10 research and practice.

11 They have processes for
12 distributing funding themselves. And those are
13 actually outside review. Nobody at CDC or at least
14 the CDC people who control the money is looking at
15 -- they're looking at our applications only.
16 They're not looking at anything else. It helps to
17 have cases, of course. You're better off funding a
18 Lyme Disease prevention project probably in
19 Connecticut than Texas because Texas doesn't have
20 much Lyme Disease at this moment in time. But
21 whether you fund it in Connecticut or Rhode Island

1 or Massachusetts or New York doesn't make any
2 difference whether our case counts are slightly
3 higher or slightly lower. It's really the strength
4 of our proposed activities and our ability -- our
5 effort to present ourselves to be able to carry out
6 those activities that's being judged.

7 MR. RYAN: When the CDC gives you
8 the \$800,000.00 that they had mentioned or I think
9 you had mentioned, do they tell you how to use that
10 money? Or do you decide how to use it?

11 DR. HADLER: Yeah. The -- all
12 this funding here -- this funding right here, it's a
13 combination. They put out a request for proposal
14 saying -- with some specific things they want to
15 have as part of that. They don't say, "Here's money
16 for Lyme Disease. Tell us how you want to use it."
17 It comes with "We want you to -- we want whoever
18 applies for this to conduct surveillance for ticks,
19 for human disease, for -- we want you to do a
20 community intervention project to see if we can
21 communities to do the kinds of things that might be

1 necessary to control deer populations and
2 collectively control -- do ecological things and
3 provide education and see if it makes a difference."

4 It comes with some real specific
5 ideas attached. But how we do those is up to us.
6 So we propose back to them how we plan on doing it.
7 And they come -- and then our application is
8 reviewed, along with the applications of all the
9 other states that apply. And depending on how much
10 money is available -- and in this -- for 2004, it's
11 only going to be two grants. Two states will get an
12 amount of money averaging this amount of money for
13 -- starting late 2004.

14 We're the only state to get this
15 pot right here. So our proposal was judged to be
16 the best of all the proposals. And it wasn't
17 because we had the most Lyme Disease cases because
18 New York, Massachusetts, Rhode Island can compete
19 with us there. They're not really very different.
20 It was because of the strength of our proposal,
21 having --

1 MR. RYAN: They don't have lab
2 reporting?

3 DR. HADLER: Having the Ag
4 Station, having --

5 MR. RYAN: Does New York have lab
6 reporting? Do you know?

7 DR. HADLER: Some of the states
8 around us do have lab reporting. How they use it is
9 a question. Some attempt to do some degree of
10 follow-up and some -- some do more follow-up. Some
11 do less. Some give it to local health departments
12 to follow up.

13 MR. RYAN: I'm sorry. I --

14 DR. HADLER: Some don't have it.

15 MR. RYAN: -- just have one more
16 question.

17 DR. HADLER: Yeah.

18 MR. RYAN: You mentioned that
19 you're looking to go to an electronic reporting
20 method. Will that eliminate the extensive human
21 follow-up that has to be done currently with the

1 paper-based system? Or will it still be a costly
2 proposition?

3 DR. HADLER: Well, it will
4 eliminate two out of the three costs. Currently,
5 there's a cost to the laboratories to send all the
6 paper to us. And it's a huge number of pieces of
7 paper. Last year, it was 14,000 reports came to us.
8 Those reports resulted in this many -- whoops.
9 Wrong one. Resulted in this pink part, this many
10 cases being reported. So it resulted in another
11 2,000 cases. 14,000 reports resulted in 2,000 cases
12 being reported. We don't get responses back to
13 everything we send out. We have to send out up to
14 four letters to get a response back. And even then,
15 we don't get responses back from some.

16 So the laboratory side is
17 improved. Our side is improved. We don't have to
18 enter all this data. So we don't have to take 4,000
19 reports and enter it into a computer. That keeps
20 the clerical person a huge percentage of the time.
21 And then generating letters.

1 But, however, the issue of then
2 sending a letter, at least one letter, to physicians
3 who are getting positive laboratory reports, some of
4 that work -- that work -- that piece will still have
5 to be done. That piece, though, what we would do is
6 only do it in a few areas of the state where we had
7 prevention projects going. We wouldn't do it
8 statewide because we can't afford -- we simply can't
9 afford to do that. And we would work in
10 collaboration with the towns that are getting
11 special funding to follow up on those reports. And
12 in that way, we think it could be manageable.

13 But, to us, it makes -- right now
14 it doesn't make sense to ask laboratories to every
15 possible laboratory report and then only use a very
16 small percentage of them because we don't have the
17 resources and it's just not really a very practical
18 use of our resources, given all the other
19 responsibilities we have.

20 However, if the laboratory
21 reporting is basically free for the laboratories,

1 they just push a button and everything that's
2 reportable to us comes to us because it's already in
3 their computer and gets extracted and sent to us and
4 we don't have to spend a lot of time entering it,
5 then we can choose to use just a fraction of it and
6 it's not costing anybody anything except for in the
7 areas where we decide that we want to have more
8 intense efforts to try to count all the potentially
9 countable cases. So that's where we see ourselves
10 going in the future.

11 DR. MEAD: Excuse -- if I
12 could just clarify or reiterate one point, two
13 points? One of which is --

14 COURT REPORTER: Your name please?

15 DR. MEAD: This is Paul Mead for
16 the Centers for Disease Control and Prevention.

17 CDC funding is not given according
18 to the amount of cases reported. Connecticut gets
19 more than twice as much money as New York does, but
20 they have fewer cases. So it's not -- it's not on a
21 case-by-case payment.

1 MR. RYAN: Is that
2 population-based, though? I mean --

3 DR. MEAD: No. Total cases.

4 MR. RYAN: No? Okay.

5 DR. MEAD: New York, state of New
6 York --

7 MR. RYAN: No. No. I meant -- I
8 meant is it the rate of cases per person?

9 DR. MEAD: It has nothing to do
10 with the rate of cases or the number of cases. New
11 York has reported more cases than Connecticut for
12 virtually a decade. But they get less funding. It
13 has to do with the very competitive proposals that
14 Connecticut has submitted and that have been ranked
15 highly.

16 Secondly, CDC did not predicate
17 any funding on Connecticut's discontinuation of
18 laboratory-based reporting. That is a rumor which
19 has been going around. It's not true.

20 MR. RYAN: Thank you.

21 DR. RANDALL NELSON: Before the

1 next panel member, I'm in the unique opportunity to
2 both ask a question as well as offer comments since
3 Commissioner Galvin has asked me to sit in his chair
4 until he comes back. He'll be gone just a few
5 minutes.

6 And the comment I want to make is
7 to clarify or at least expand on one point that Dr.
8 Hadler made. And that was when we conduct
9 surveillance, we have to have willing partners.
10 Those willing partners are not just the Health
11 Department and laboratories. Those willing partners
12 are also physicians who we contact on a regular
13 basis to report information.

14 And as Dr. Hadler pointed out,
15 they have to see the point of it. It has to be easy
16 enough for them to do. And it has to still allow
17 them to carry on the most important work that they
18 do and that is treating the individual patient.

19 After years of surveillance, we do
20 have in some areas exhaustion among physicians and
21 their staff providing us with information regarding

1 tick-borne diseases.

2 So we need to take into
3 consideration that we have many partners in
4 conducting the surveillance. And a very important
5 group, of course, are the clinicians who are seeing
6 patients who are ill.

7 Thank you.

8 MR. RYAN: Can continue with James
9 Rokos please?

10 DR. JAMES ROKOS: Yes. Can you
11 hear me okay?

12 MR. RYAN: Yes.

13 DR. ROKOS: Yes. Well, first I
14 want to thank actually both, I guess, Commissioner
15 Galvin and Attorney General Blumenthal for inviting
16 me here today. It's a pleasure to be here. And I
17 know Randy Nelson quite well. Mr. Ryan.

18 Last time I had a chance to speak
19 about Lyme Disease was at the semi-annual meeting of
20 the Commissioner of Health and we had seven and a
21 half minutes. So I've been promoted to ten minutes

1 today. So I'll try to do my best there.

2 Well, as you said, my name is Jim
3 Rokos. I've been the Health Director for the
4 Torrington Area Health District for the last -- I
5 don't know -- 35 or so years. It's in a great area
6 of Connecticut, the Northwest Corner. We cover 18
7 towns. Very densely wooded. I usually call it Tick
8 Heaven. But I actually think that the entire state
9 of Connecticut is kind of Tick Paradise because we
10 really live in a rain forest.

11 And exactly why we have more ticks
12 and why the infectivity of ticks is on the increase
13 I think is open to some speculation. There are some
14 reasons that maybe Kirby will talk about that later.

15 I'm actually here and I -- it's
16 interesting and it's almost a little bit ironic. I
17 used to teach kids in high school and middle school
18 about Lyme Disease and rabies and anything else
19 they'd sit still for for like 20 minutes.

20 I also had Lyme Disease back in
21 the early 90's. And it was -- that's a whole

1 'nother story. So I actually have -- I'm actually a
2 patient or victim, however you want to look at that.

3 I'm the Director of Health. And
4 we were fortunate enough to be one of two sites to
5 be chosen as to have this Lyme Disease grant, which
6 we currently have. And we're hoping very much that
7 it will be extended. It was for three years, over
8 \$300,000.00. And I think we've done a great job
9 with that money.

10 The best thing I did with -- at
11 the very beginning of that grant was to hire a
12 wonderful teacher by the name of Sue Perlatto. And
13 all the Directors of Health know Sue. She is a --
14 when I first hired her, she said, "Jim", she said,
15 "I don't know anything about ticks." I said, "You
16 don't have to." I said, "I'll teach you everything
17 you need to know about ticks and Lyme Disease." I
18 said, "But you have teaching skills that we're
19 looking for." And she has never disappointed. She's
20 just the greatest in terms of getting the message
21 out.

1 We also -- people should know that
2 we had -- the reason -- I guess one of the reasons
3 we were successful in getting our grant is we have
4 -- three of our towns have the highest rates of Lyme
5 Disease, not the number of cases but the rates. And
6 that was true a year or two ago. I'm not sure what
7 it looks like for 2003. But that's interesting
8 because it wasn't that long ago people in the
9 Northwest Corner kind of thought we were not going
10 to have much Lyme Disease. And when it was
11 suggested that physicians start considering it, a
12 lot of them said, "No, no. That's a shoreline
13 problem. That's really not something we need to
14 worry about up here." Well, obviously, we know
15 different now.

16 About a third of the ticks that we
17 submit every year -- and last year we submitted over
18 700 -- were positive for the spirochete. So we know
19 we have the ticks. We have a lot of them. And we
20 have our share of Lyme Disease.

21 Basically, Jim touched on some

1 great things that I'm going to try not to duplicate
2 what he said. But, basically, from a local -- I'm
3 looking at this, of course, from a local health
4 department standpoint, as I said. This large,
5 rural, heavily forested part of Connecticut.

6 The two things that we really
7 talked about doing in our program was, number one,
8 prevention and, number two, early diagnosis and
9 treatment. Now, we don't diagnose and we don't
10 treat. But as Jim indicated here, we do educate
11 people on options that they have. We think that
12 that's an important thing a local health department
13 can do. And we act as a great source of information
14 and referral.

15 People come to us all the time.
16 We have this fantastic Website. There's a ton of
17 information out there. And people are highly
18 intelligent today and can make a lot of decisions on
19 their own. So we kind of guide them and point them
20 in the right directions.

21 So in terms of prevention, well,

1 obviously the very first thing when you're in public
2 health and you have a disease, the best thing is a
3 vaccine. And we were very hopeful that the vaccine
4 was going to be a success. And, unfortunately, it
5 wasn't. So we're still hoping that that will be
6 another -- a success story when it comes back, maybe
7 this second generation that someone talked about.

8 The second better thing that we
9 could do or the second best thing, I guess, is to
10 have a good test. And everyone's talked about that
11 today. I'm not going to talk much more about it.
12 We really don't have a reliable test. It's subject
13 to interpretation. And it's just -- it's something
14 that we think needs to be done and usually is done.
15 But I think both physicians and the people who are
16 tested just need to use that as one tool in their
17 box, I guess to say, because it's certainly not --
18 we don't think it's probably that useful for
19 diagnostic purposes, based on our experience.

20 In terms of -- the third thing in
21 terms of prevention that we've really excelled at, I

1 think, is the human education component. We
2 strongly talk to people about personal protection,
3 about wearing the right kind of clothing, about
4 using insecticides on themselves and their kids. We
5 talk about pet protection.

6 I had a good friend of mine,
7 highly intelligent woman, call me about a month ago
8 and she said, "I found a tick on me this morning
9 when I was showering." So we got to talking about
10 it. She was quite paranoid. Well, come to find out
11 they sleep with their cat every night. And I said,
12 "Well, is he strictly a house cat?" She said, "No,
13 no. He goes out all day and then he comes in at
14 night." So I said her name and I said, "That's not
15 a good idea." So I mean that was something -- I
16 don't know if I actually changed what they do or
17 not. But sleeping with your pets, if your pets are
18 spending time outside, is not a good idea.

19 We urge people to be able to
20 identify ticks. We identified and had tested over
21 700 ticks last year. I know there's controversy

1 about the value of having these ticks tested. But
2 Sue and I, Sue Perlatto and I, both feel this is an
3 opportunity for people when they come in to our
4 office. It's a very emotional thing. They've
5 usually already read up on Lyme Disease and about
6 these ticks. It gives us an opportunity to really
7 educate these people. We give them a lot of good
8 information. And whether the tick comes back
9 positive or negative is almost a secondary issue.
10 But it really gives us a chance to really interact
11 with these people on a one-on-one basis. So we do
12 think it's worthwhile doing the testing.

13 And we -- of course, we talk to
14 people about the seasonal and age distribution. We
15 basically do anything we can to break that cycle of
16 Lyme Disease. And I think we've done some pretty
17 good work based on some feedback that we've gotten.

18 We use -- and this is all to Sue's
19 credit. We use visual aids. And anybody that's here
20 today, if you look out the front window of the
21 Legislative Office Building, you'll see this lime

1 green Volkswagen with little ticks all over it.
2 Well, fake ticks. And this was her idea. And we --
3 I took her up on that immediately. And it's --
4 honestly, it's been the best thing. I mean
5 everybody knows her as either "the tick lady" or
6 "the tick police" and "the Lyme mobile".
7 And then she even went so far as
8 to get a kayak donated. And so on one of our trucks
9 that goes up into the areas where a lot of people
10 are at risk, we have this lime green kayak on top of
11 one our vehicles. And that's -- once again it's got
12 Lyme Disease information on it and, of course, our
13 Website and our phone number.
14 So I think that we need to do
15 something different. We've tried education in the
16 past with limited success. We need to do something
17 different, come up with some gimmicks to get the
18 message out. I mean we had this huge billboard on
19 the way in to the post office that so many people
20 talked about. And I wish I had the slides here. I
21 didn't realize I'd have that opportunity. Because

1 you would have -- everyone here would have gotten a
2 big kick out of that.

3 And Sue told me, and I've never
4 forgotten because she's told me at least seven
5 times, that people have to hear things at least
6 seven times to really retain time. So I do think
7 that's probably true.

8 Very quickly. Environmental
9 measures. Now, we -- in conjunction with the
10 education part of it, we started and we're hoping to
11 expand the environmental control measures. We talk
12 to people about building natural barriers around
13 their properties. We actually have a demonstration
14 site where we have the right kinds of plants, wood
15 chips. We tell people not to have bird feeders and
16 wood piles close to their houses because they'll
17 attract mice and mice, of course, are loaded with
18 ticks.

19 So -- and we talk to them about
20 using integrated pest management practices and --
21 which basically is using the least amount of

1 chemical that you can to do the job. So the first
2 thing, of course, is to build these natural
3 barriers.

4 Second are the rodent bait boxes.
5 And I know Kirby is going to talk more about that.
6 We've given -- we probably set about a thousand of
7 those in the ground. We need more time to evaluate
8 their effectiveness. We think we've had some
9 success there.

10 The four-poster deer feeding
11 station we're kind of excited about. We have money
12 in our budget for it. This will be the first year
13 that we actually try them up in the Northwest
14 Corner. Some people are worried that they're going
15 to attract bears instead of deer. So we'll have to
16 wait and see how that actually goes.

17 The last thing, of course, is to
18 spray your back yard with again acaricide which
19 kills ticks. Most people don't want chemicals
20 sprayed in their back yards. They have kids. They
21 have pets. We even get calls from people who are

1 irritated by their next-door neighbor spraying his
2 yard with some chemical for his lawn. So I --
3 that's something that's an option, but I don't think
4 it's ever going to be widely accepted.

5 The early diagnosis and treatment
6 part of this basically --

7 MR. RYAN: Time.

8 DR. ROKOS: -- from our standpoint
9 is educating the people on the early signs and
10 symptoms. We talk to them about rashes, fevers,
11 flu-like illness during the non-flu season. I had
12 my symptoms start in June and July and they were
13 just classic flu-like illness. But that's not the
14 time of the year we have flu.

15 Secondly is active surveillance.
16 We've already talked about that. Physicians have
17 never reported any diseases like they should. I
18 don't know what the answer is. I suggested to Sue
19 on the way over here, "For every report they give
20 us, we give them a \$5.00 gift certificate to Krispy
21 Kreme or Dunkin' Donuts. Maybe that would do it."

1 So we need a simple, effective way to get physicians
2 to report.

3 I do think the lab data is an
4 important part of that. But I realize that it's an
5 expensive thing. I'm hoping that with this new
6 electronic surveillance system we can restore that.

7 And, lastly, the future. Well,
8 number one, I was hoping Commissioner Galvin would
9 be here because he needs to hear this. And that is
10 that we need to have full-time health departments
11 throughout Connecticut. We have three levels of
12 activity right now. We have three sites,
13 Westport/Weston, the Ledge Light Health District and
14 ours. We're doing an intensive job with Lyme
15 Disease. Then we have other full-time health
16 departments that definitely have some Lyme Disease
17 program. And then we have part-time health
18 departments where there's no information at all.
19 And I know that that's the case. So first we need
20 to have full-time health departments throughout
21 Connecticut.

1 I just put down here we need to
2 restore lab reporting. We need physicians to help
3 us. We need to continue education both for lay
4 people and the professionals. I think just
5 listening to all these great physicians today -- and
6 I mean that. I think they're all well-intentioned.
7 But we need to somehow level the playing field so
8 everyone has an understanding, same kind of basic
9 understanding.

10 I think we need to continue
11 expanding these environmental control measures that
12 we're going to be doing. We need to come up with a
13 better test, a vaccine, and we need more lime green
14 Volkswagens.

15 That's it.

16 (APPLAUSE)

17 MR. RYAN: I'd like to compliment
18 you on the creative efforts that you're making. And
19 I wonder -- you mentioned that you find that -- and
20 you encourage people to come to you for information.
21 Do you find that that's mostly lay people or do you

1 find physicians coming to you as well?

2 DR. ROKOS: That's a good
3 question. We have a Lyme Disease Committee that
4 meets, I think, every month or six weeks. And we've
5 had a couple of physicians come, mostly to share --
6 we had a rheumatologist. It is mostly lay people,
7 actually, that come to us. But we've had calls from
8 physicians and some of them are very interested in
9 finding out -- they need to know what the incidence
10 is. So we try to give them feedback. When they
11 give us information, we try to give back to them so
12 that they really do understand that what they're
13 telling us does make a difference. It might not
14 seem real clear to them right now. But --

15 MR. RYAN: Do you think that
16 primary care physicians, at least in your area, are
17 fairly knowledgeable about things to look for or do
18 you find that, you know, they have something to
19 learn in that area?

20 DR. ROKOS: They definitely need
21 more education. They do.

1 MR. RYAN: Do you also -- I mean
2 do you find that --

3 (APPLAUSE)

4 MR. RYAN: I work in our Health
5 Care Advocacy Unit. So I hear a lot from consumers
6 directly. And they express frustration to me when
7 they get information from an organization like yours
8 and they go off and they believe they have these
9 symptoms and they'll go to their doctor, who is
10 often primary care, and the doctor really doesn't
11 listen to what they're saying.

12 Is there a way to -- is that a bad
13 thing to begin with, to have the patient aware of
14 this, or is there a way to get --

15 VOICES: No.

16 MR. RYAN: Is there a way to get
17 the doctors to become more aware? I mean is that
18 the goal?

19 DR. ROKOS: Well, it is. And as I
20 said before, you know, I think the consumer -- I
21 don't care whether it's disease or you're buying a

1 car today. The consumer or the patient really wants
2 to understand more about what's going on. And with
3 all the information that's out there, they should
4 understand it. I think they make a better patient.
5 I think most doctors will agree with that.

6 Doctors, they just need -- they
7 need to hear from maybe different people than their
8 patients that -- we had one doctor, he heard
9 recently -- I don't know how long ago it was -- that
10 Lyme Disease was no longer a reportable disease. So
11 he told his front office. He said, "Well, stop
12 reporting that. We don't have to -- because it's
13 not reportable." Well, he misunderstood that it's
14 really just the labs that don't have to report that.

15 So -- and we've heard many, many
16 stories. Children with Bell's Palsy who, it's our
17 understanding, it's not definitely a diagnosis for
18 Lyme Disease but highly indicative of that.
19 Physicians saying, "No, no, no. We don't think that
20 that's any connection between Lyme Disease and
21 Bell's Palsy."

1 So we somehow need to get the
2 message out to these doctors. And it makes it very
3 awkward for the patient to go there and tell the
4 doctor, "I think you need to brush up on some of
5 this stuff." So --

6 MR. RYAN: Who's job is that,
7 would you say? I mean is it medical schools? Is it
8 --

9 DR. ROKOS: We have -- I mean we
10 have some great stuff right in our office. We have
11 this great building. We have this room that seats
12 30 to 50 people and we have a satellite outside that
13 was -- because of this whole bioterrorism stuff. So
14 we could -- we could be -- distance-learning is a
15 great way. Physicians are very busy today. I
16 wouldn't put that monkey on any one back. But I
17 think that whether we would give them CEU's to
18 promote them to come to our office -- and these
19 dishes are placed around Connecticut. Whether it
20 would be a CEU or something else to get these
21 doctors to come and sit down and listen to -- and it

1 can't be too long. I mean it really -- they're very
2 bright people. I think the message could be given
3 out I mean in a half a day at the most and maybe
4 just a brief amount of written material.

5 We're going over this in this
6 whole bioterrorism stuff. We're flooded with
7 written material. And we need to get back to basics,
8 the very simple -- maybe even when physicians --
9 when a person comes in, they would have a very
10 simple flow chart or maybe a questionnaire to ask
11 people. Because I think we're just inundated with
12 paper. And we need to simplify things.

13 MR. RYAN: Thanks, Jim.

14 DR. ROKOS: Thank you, Andy.

15 MR. RYAN: We'll continue with Dr.
16 Lee.

17 DR. JOHNNIE LEE: Good afternoon.
18 First I'd like to thank Commissioner Galvin and
19 Attorney General Blumenthal for an opportunity to
20 come and address this hearing regarding Lyme
21 Disease. I currently serve as the Director of

1 Health and Social Services for the City of Stamford,
2 Connecticut and have a 12-year history of clinical
3 practice in internal medicine. And my training and
4 background is in internal medicine, with a Master's
5 Degree in public health.

6 The Stamford Department of Health
7 and Social Services serves a community of
8 approximately 117,000 residents. The primary focus
9 of the Department of Health in Stamford is health
10 promotion and disease prevention.

11 We recognize that Lyme Disease
12 causes significant morbidity for those affected by
13 the disease and we continue to provide services and
14 programs to address the increasing problem of Lyme
15 Disease in our community.

16 One of the ways that we try to do
17 that is through our tick program. In 1989,
18 Stamford, in conjunction with the Connecticut
19 Agricultural Experiment Station, established a
20 program to monitor the incidence of ticks infected
21 with *Borrelia burgdorferi*, the organism known to

1 cause Lyme Disease.

2 The purpose of the program is to
3 determine the risk of contracting Lyme Disease when
4 bitten by a deer tick. The Health Department
5 accepts ticks submitted by residents and sends those
6 specimens to the Agricultural Experiment Station for
7 analysis. Those submitting ticks are given
8 information about how to collect the ticks. They're
9 also given information about Lyme Disease, including
10 the need to seek medical attention if they have
11 symptoms of Lyme Disease. They receive literature
12 regarding the tick life cycle, tick avoidance
13 recommendations, signs and symptoms of Lyme Disease
14 and other tick-borne illnesses, such as Ehrlichiosis
15 and Babesiosis.

16 Since 1989, there have been 8,415
17 specimens submitted, with 1,879 being positive for
18 Borrelia Burgdorferi. The ticks are also assessed
19 regarding whether or not they are engorged. And of
20 those specimens collected to date, 358 were found to
21 be engorged.

1 In 2002, there were 586
2 submissions for tick identification and testing.
3 There were 178 ticks tested positive for Borrelia
4 Burgdorferi and 32 of those were significantly
5 engorged. In 2002, there were 55 cases of
6 tick-borne disease reported.

7 In 2003, we saw a similar trend,
8 with 673 cases -- excuse me -- submissions. And 40
9 of those were significantly engorged and 172 testing
10 positively for Borrelia Burgdorferi.

11 It is worth noting that most of
12 the reported cases of Lyme Disease from the positive
13 blood results for antibodies to Lyme Disease were --
14 excuse me -- were -- excuse me.

15 It is worth nothing that most of
16 the reported cases of Lyme Disease came from
17 positive blood results for antibodies to Lyme
18 Disease. Many clinicians treat Lyme Disease based
19 on symptoms and not a blood test result. So, if an
20 individual is evaluated and treated for Lyme Disease
21 without blood tests being ordered, no disease would

1 be reported, thereby leading to under-reporting,
2 which is a significant problem.

3 When we receive a result back from
4 the Agricultural Experiment Station, a letter is
5 then sent to the person who submitted the specimen.
6 The letter informs them whether or not there was a
7 positive result and also tells them whether or not
8 the tick was engorged.

9 If, indeed, the tick analysis was
10 positive, we also follow up that communication with
11 a phone call to the individual to see if, indeed,
12 they had any symptoms and whether or not they sought
13 medical attention.

14 A recent survey was conducted by
15 our laboratory in Stamford at the Health Department
16 of 13 individuals recently reporting or submitting
17 specimens. Ten people actually responded and three
18 did not. Of those ten people who responded, three
19 had actually contacted their doctor and one had
20 actually been treated for Lyme Disease. And seven
21 actually had not seen a doctor. But, after the

1 conversation, three out of the seven decided that
2 they would follow up and see a physician.

3 Our efforts in disease
4 surveillance at the Health Department are primarily
5 focused through the employment of two full-time
6 epidemiologists and one full-time State
7 epidemiologist assigned to the Stamford Health
8 Department. The epidemiologists work with the
9 Director of Health, the Director of Laboratory
10 Services and a community public health nurse to
11 evaluate the incidence and prevalence of various
12 infectious diseases, including Lyme Disease.

13 The data collected is used to help
14 direct education and prevention programs within the
15 department. Recent data indicate that as many as 33
16 percent of the ticks submitted to the Health
17 Department for analysis are, indeed, infected with
18 *Borrelia Burgdorferi*.

19 Data collection has also allowed
20 us to determine that young children are bitten at a
21 higher rate than older groups. And we have also

1 determined that both ticks submitted and cases of
2 Lyme Disease are fairly evenly distributed
3 throughout all areas of Stamford, ranging from
4 somewhat rural north Stamford to more urban and
5 suburban Downtown and the waterfront areas.

6 The Stamford Department of Health
7 and Social Services remains committed to providing
8 resources for education and prevention initiatives,
9 to decrease the incidence of Lyme Disease and other
10 tick-borne illnesses in Stamford.

11 In an effort to decrease the
12 incidence of Lyme Disease, we are committed to using
13 resources to provide educational information that
14 make people more aware of the issues related to Lyme
15 Disease. We employ a full-time Director of Public
16 Health Education whose primary task it is to
17 coordinate educational initiatives related to public
18 health matters.

19 In 2004, we are currently planning
20 to use the local newspaper, public television,
21 audio/visual and printed educational materials to

1 reach citizens of all ages and alert them of the
2 dangers of Lyme Disease. We are fortunate to have a
3 public health nurse from our Health Department
4 working in every public, private and parochial
5 school in Stamford. This allows us the ability to
6 potentially interface with every school-aged child
7 in Stamford, providing information on tick
8 avoidance.

9 As a public health agency, we have
10 an obligation to respond to the concerns of our
11 citizens. There appears to be an increasing --
12 there appears to be increase evidence that many
13 cases of Lyme Disease are not cured by the standard
14 courses of treatment we've used in the past.

15 There is compelling evidence that
16 many individuals infected with the organism that
17 causes Lyme Disease suffer from long-term,
18 debilitating symptoms. This underscores the need
19 for greater awareness through education and
20 prevention. It also underscores the need for more
21 research in the areas of diagnostic testing and

1 treatment.

2 Thank you.

3 (APPLAUSE)

4 MR. RYAN: Thank you, Dr. Lee.

5 You mentioned that you have a full-time nurse who is
6 basically involved with all the schools in your
7 system?

8 DR. LEE: No. We have --

9 MR. RYAN: Oh.

10 DR. LEE: -- a full-time nurse
11 assigned to each and every school.

12 MR. RYAN: Oh. You have more than
13 one. Okay. Do you -- are you finding that school
14 children are dramatically affected by this disease?
15 And is it affecting their ability to learn within
16 those settings?

17 DR. LEE: Well, you have to
18 understand that there are many individuals who
19 believe that undiagnosed Lyme -- undiagnosed acute
20 Lyme Disease, which then becomes more of a chronic
21 issue, can cause neuropsychiatric problems. That's

1 not what -- you know, that's not what we as a Health
2 Department, you know, do. Certainly I've spent many
3 years in clinical practice in internal medicine, not
4 pediatrics. So that question is probably better
5 addressed by a pediatrician, a pediatric
6 neurologist, people who see children, a pediatric
7 neuropsychologist who actually, you know, does
8 testing on children to determine, you know, what
9 types of problems children are having and what might
10 be, you know, the cause for that.

11 Certainly, you can extrapolate, if
12 your child lives in an area where there's a
13 significant amount of Lyme Disease and if your
14 child, you know, has those problems, that's one
15 thing that you would consider in the differential.
16 But that's just medicine. That's just the general
17 way to sort of address, you know, patients with
18 problems.

19 MR. RYAN: But your -- your office
20 doesn't really evaluate that impact really.

21 DR. LEE: No. I mean -- no.

1 Children who have -- children who have problems in
2 the classroom, that work is typically funneled
3 through the Board of Ed and the Board of Ed is then
4 responsible, in our structure in Stamford, is
5 responsible for getting those children tested and
6 making sure that that information is communicated to
7 their parents to make sure that the child is
8 evaluated. But that's not something that the Health
9 Department would be actively involved in as far as
10 the testing and evaluating of children with school
11 problems.

12 MR. RYAN: You mentioned also that
13 you're involved in the education process for
14 citizens. Are you doing the same with doctors? Are
15 you working with doctors?

16 DR. LEE: In Stamford, there -- we
17 are fortunate to have, you know, an active medical
18 community at Stamford Hospital. And there's
19 ongoing, you know, continuing medical education.
20 Every physician who has privileges at Stamford
21 Hospital is required to maintain a certain amount of

1 continuing medical education.

2 And I think that there's a need to
3 have ongoing exchange and ongoing education with
4 regard to, you know, all disease processes. You
5 know. And so I think that -- and certainly as the
6 whole issue of Lyme Disease and the appropriate
7 treatment and the appropriate testing and the
8 appropriate evaluation, as that sort of evolves, I
9 think that, you know, it's necessary to have
10 continuing and ongoing dialogue and education about
11 that, as well as about colon cancer and heart
12 disease and -- you know, as a general rule.

13 MR. RYAN: But are you involved in
14 that? I mean are you --

15 DR. LEE: We provide information
16 to our citizens. We don't -- we send out
17 information. For example, I can tell you that
18 recently with the influenza epidemic, we sent out
19 information from the Health Department to every
20 pediatrician in town. We sent out information to
21 all the family practitioners in town. We sent out

1 information to every elementary school student in
2 town.

3 And so we would do a similar kind
4 of thing with regard to Lyme Disease when we're
5 doing our initiatives. I mean we do that with
6 regard to SARS. If Avian Influenza becomes a
7 problem, we will do that with Avian Influenza.
8 Because as a Public Health Department, we have a
9 responsibility to educate the public. And certainly
10 our medical colleagues would be a part of that.

11 We certainly do not tell them how
12 to practice medicine. But we make them aware that
13 this is a problem and these are the types of things
14 that you should be looking for and these are
15 possibly some ways of addressing the issue.

16 DR. NELSON: Dr. Lee, hi.

17 DR. LEE: Hi.

18 DR. NELSON: First time I'm
19 speaking with you. Randy Nelson at DPH. I'm sure
20 we're going to have a long history. We provided you
21 with some of that information to do your health

1 assessments. So --

2 DR. LEE: Yes.

3 DR. NELSON: I remember.

4 What kind of information -- or are
5 you collecting additional information regarding the
6 outcomes of those folks who submit ticks for testing
7 specifically comparing people who submit ticks that
8 ultimately test positive for Lyme Disease and among
9 those ticks that are engorged and so had the
10 opportunity to infect that particular patient? You
11 had said that the people are contacted by telephone
12 so that you're assured that they have the
13 information that they need and that they're advised
14 to go to see their physicians.

15 Do you have any follow-up
16 information on those folks? That is, how many
17 become ill? How many are prophylactically treated?

18 DR. LEE: No. The real -- you
19 know, our -- you know, what we do is, as I say, as I
20 stated, for every specimen that we get back, whether
21 it's positive or negative, a letter goes out. And

1 for all those that are positive, that's followed up
2 with a telephone call to verify that they got the
3 information and to then find out if those
4 individuals have seen a physician. If they have,
5 great. If they have not, then that gives an
6 opportunity to think twice about that and go on and
7 do that.

8 The majority of the individuals,
9 you know -- and this is a very small sample that --
10 from a recent phone survey that we did. The
11 majority of those individuals did then say, if they
12 had not seen a physician, they were going to go.
13 But we do not take it a step further and then call
14 them back later and check to see, "Did you go? And
15 what happened when you went?" No.

16 DR. NELSON: Thank you.

17 MR. RYAN: I guess next will be
18 Cheryl Carotenuti from the Connecticut Department of
19 Education.

20 MS. CAROTENUTI: Right. Thank
21 you.

1 As I was just introduced, I'm
2 Cheryl Carotenuti, the Health Promotion Consultant
3 from the State Department of Education. And I, too,
4 would like to thank Commissioner Galvin and Attorney
5 General Richard Blumenthal for inviting the
6 department to be here today. I think it's important
7 for us to share information on how schools and the
8 department address the students with chronic health
9 care needs. But it's also important for us to
10 understand the issues that affect students with Lyme
11 Disease.

12 As the Department of Education
13 strives to attain their goal of student achievement,
14 we recognize that an essential component is
15 addressing the health and wellness needs of these
16 students. Addressing the health and wellness
17 includes health prevention, health promotion, as
18 well as providing direct services and mental health
19 services to students.

20 It's also important to understand
21 that in general the State Department of Education

1 doesn't provide specific interventions for all the
2 various chronic health care needs that students
3 have, but, rather, provides a framework for how
4 schools can meet the needs of all the various health
5 concerns.

6 And this framework includes three
7 different areas. First, students with Lyme Disease
8 may receive comprehensive services in their regular
9 education program. These services and
10 accommodations are generally identified in an
11 individual health care plan that's developed by the
12 school nurse, the parent, the provider and any other
13 appropriate school personnel. Additionally, the
14 students may receive services through school
15 counseling programs, classroom activities or
16 homebound instruction.

17 Second, students may receive
18 services under Section 504 of the Rehabilitation Act
19 if the chronic health needs substantially limit the
20 major life functions, such as breathing, walking or
21 learning. In this situation, the 504 plans may be a

1 combination plan for outlining classroom,
2 transportation or instructional accommodation as
3 well as an individual health care plan outlining any
4 health services that they may need to support their
5 access to an educational program.

6 Some school systems incorporate
7 504 and individual health care plans. Some schools
8 keep them separate.

9 The third avenue is that students
10 with Lyme Disease may be eligible for Special
11 Education under the Individuals with Disability
12 Education Act. There are several categories of
13 disability that may be appropriate for
14 consideration, including Other Health Impaired or
15 Learning Disabled.

16 It must be shown that students
17 meet the criteria for the category of the
18 disability, that the disability adversely affects
19 their educational performance and that, because of
20 this, the child needs specially designed
21 instruction.

1 In this situation, the student
2 would have an individual educational plan that
3 documents their educational services, as well as the
4 health care plan that documents any health services
5 needed.

6 If a student is referred for
7 Special Education or 504, the school district must
8 convene a Planning and Placement Team or a 504
9 meeting to consider the request for the evaluation.
10 It's not appropriate for the school to refuse to
11 schedule a meeting because the child is presenting
12 with a medical issue.

13 The team is often made up of
14 school personnel, the family, the student, when
15 appropriate, and occasionally outside health care
16 providers. The team is required to review any
17 existing evaluation data, including evaluations and
18 information provided by the parents, classroom-based
19 observations, observations by teachers or other
20 related staff, such as the school nurse, OT or
21 guidance counselor.

1 As the information may include
2 medical information, it's also important to have a
3 school nurse or school medical advisor as part of
4 the PPT or 504 meeting. If the team believes there
5 is enough information to identify the disability, no
6 further evaluation need be conducted. But if the
7 team believes there is additional evaluations that
8 are necessary to determine eligibility, the team
9 needs to identify what additional information is
10 needed, arrange for the evaluations and assume
11 financial responsibilities for the evaluations.

12 Due to the various opinions within
13 the medical community on Lyme Disease itself and the
14 extent of symptoms and long-term effects, schools
15 often don't have enough information to make accurate
16 decisions. It's essential for schools to have this
17 information on the disease, the symptoms, the
18 complications and the potential educational
19 implications.

20 It's also important for physicians
21 who diagnose and treat students with Lyme Disease to

1 establish good communication with schools and to
2 provide specific student information to assist
3 schools in determining eligibility for services.

4 As a result of increased phone
5 calls to the department regarding Lyme Disease and a
6 meeting with the Lyme Disease Association and Time
7 For Lyme Association, the State Department of
8 Education also recently sent to every school
9 district a sample protocol and resources on Lyme
10 Disease based on some information from the Greenwich
11 public schools. The materials included an
12 educational video, suggested protocols, sample
13 criteria and a checklist for school nurses.

14 Other resources include serving
15 children with special health care needs, specialized
16 health care procedure guidelines and a parents guide
17 to Special Education through the Department of
18 Education.

19 It's important to understand the
20 role of the school nurse as a medical resource to
21 school personnel and families. As I mentioned in

1 the beginning and as Dr. Lee mentioned, health
2 services includes health prevention and health
3 promotion. And although it's not statewide, many
4 school nurses have taken the opportunity to educate
5 staff, students and families on Lyme Disease
6 prevention, especially as schools engage in more
7 outdoor activities, physical activity and science
8 programs and field trips.

9 In conclusion, the Department of
10 Education requires all schools to the health needs
11 of students. This is effectively done through
12 collaboration with the school staff, the family and
13 student, the medical community and the community at
14 large. Schools are responsible for the education of
15 students. And in order to do so, they also need to
16 address any barriers to learning.

17 Thank you.

18 (APPLAUSE)

19 MR. RYAN: Thank you.

20 DR. NELSON: You mentioned that
21 the training of nursing is not a statewide thing.

1 Or is the out-- was that outreach or training that
2 you were talking about?

3 MS. CAROTENUTI: What I said was
4 that the nurses provide health prevention and
5 education to staff and students. And I don't know
6 that it's statewide. But I know that many nurses
7 engage in those activities in the schools because
8 that's part of their role to do health prevention
9 and health promotion.

10 DR. NELSON: Do you think those
11 nurses are universally well trained or just in
12 certain systems?

13 MS. CAROTENUTI: It's probably --
14 varies greatly across the state in terms of their
15 knowledge and comfort in educating.

16 DR. NELSON: Do you see any role
17 for your office in trying to standardize that?

18 MS. CAROTENUTI: Actually, in the
19 meeting that we did with the Lyme Disease
20 Association and the Time For Lyme, that was one of
21 the things with the -- they were going to help us

1 put together a packet of information that we could,
2 in fact, distribute to school nurses.

3 DR. NELSON: Are you going to do
4 follow-up with that or --

5 MS. CAROTENUTI: Yeah.

6 DR. NELSON: Sorry.

7 MS. CAROTENUTI: No. That's all
8 right. We have -- twice a year I conduct a school
9 nurse supervisors meeting. And we have a meeting in
10 the spring. And that was when we were going to
11 follow up on our December meeting and submit all --
12 distribute the material to the school nurses.

13 DR. NELSON: Do you see this as
14 being a problem in our schools in particular, the
15 Lyme Disease?

16 MS. CAROTENUTI: Well, because of
17 the -- I mean there has been an increased number of
18 phone calls to the department. And partly it's
19 because of the information that we either don't
20 receive or do receive from the medical communities
21 in terms of what the specific needs of students are.

1 And the response of the school districts varies in
2 terms of how they accommodate the students.

3 DR. NELSON: Thank you.

4 MR. RYAN: Well, thank you all. I
5 guess, you know, in closing I would ask if any of
6 you on this panel have any recommendations for --

7 A VOICE: We have one more.

8 MR. RYAN: Oh. Dr. Stafford. I'm
9 sorry. You're -- would you like to present? Are you
10 prepared? My apologies.

11 DR. STAFFORD: Okay. My name is
12 Kirby Stafford. I'm chief scientist at Connecticut
13 Agricultural Experiment Station. I'm an
14 entomologist and a vector ecologist. I have been
15 working on the ecology and control of the
16 black-legged tick or deer tick as it's commonly
17 known since I joined the Experiment Station in 1987.

18 I didn't actually realize I'd have
19 a chance to present anything. Not only do I do
20 research on tick control and tick ecology, but I
21 also give a lot of public talks. And so it just so

1 happens earlier this week I gave a talk to the
2 Northeast Organic Farming Association on their
3 annual course on organic land care. And this
4 morning, I gave a talk to the Connecticut Parks and
5 Recreation Association, their directors, on ticks
6 and Lyme Disease.

7 What I would like to do is just
8 simply -- I'm going to have to race through this --
9 this was an hour presentation -- and just highlight
10 a couple of things pertaining to control that are
11 pertinent to this hearing.

12 I also want to point out that in
13 this whole issue of reporting, I think that one of
14 the things to bear in mind is that the reporting
15 points out trends in disease. And I did publish a
16 paper noting that the number of infected ticks that
17 I collected in Lyme and Old Lyme was highly
18 correlated with the reported incidence of disease,
19 both in those communities and statewide. So even
20 though Lyme Disease is under-reported, I do think it
21 reflects true trends and cases.

1 So let me go through this very
2 quickly. Most of this is material that has been
3 discussed. One thing I'll point out is people ask
4 why do we have Lyme Disease and why is it a problem
5 today. And I just quickly want to point out it's a
6 response to our changing landscape patterns here in
7 New England.

8 A Swedish naturalist back -- came
9 through this area in the mid-1700's and in 1770, he
10 pointed out that "To these I must add the wood lice
11 or ticks with which the forests were so pestered
12 it's impossible to pass through a bush or sit down.
13 Though, the place would be ever so pleasant without
14 having a whole swarm of them on our clothes." He
15 was actually in New Jersey at that time. So ticks
16 were abundant.

17 A century later, the State
18 Entomologist of New York noted that "The most common
19 tick of our country, the wood tick", as they called
20 it then, "though formerly abundant throughout the
21 northern and middle states, has now become nearly or

1 quite extinct. At this day alone on the route in
2 pursuit, not one can be found."

3 During that issuing time, of
4 course, we saw a significant change in Connecticut's
5 forest cover, steadily declining through the 16 and
6 1700's. Agriculture reached its peak around the
7 1830's. As lands opened up out West, farms were
8 abandoned. The Industrial Revolution began. People
9 moved to the cities. And throughout the 20th
10 century, our forest cover increased.

11 Along with that, we saw an
12 increase in the population of white-tailed deer.
13 These are historic estimates of the white-tailed
14 deer in Connecticut compiled by the Department of
15 Environmental Protection. Their latest estimates
16 are there's around 76,000 deer in the state of
17 Connecticut. Based on one report that the DEP has,
18 they figure there was about 12 deer in Connecticut
19 in 1896.

20 This is some records that I also
21 pulled out. And same pattern for the Northeast.

1 Massachusetts in 1931 estimated there were 11,500
2 deer in that state. In an article in the Journal of
3 Forestry, today the estimate is around 90,000. So
4 it's a pattern throughout the Northeast.

5 But I figured this graph would be
6 particularly interesting. This is a close-up of the
7 deer population trends in Connecticut estimated by
8 DEP since 1975. And what I did is I took the number
9 of reported Lyme Disease cases and multiplied it by
10 ten. Remember, we -- based on surveill-- other
11 information, we figure only 10 to 13 percent of
12 diagnosed cases are actually reported.

13 And you'll notice that the lines
14 parallel each other very nicely. And this is
15 because the deer is the primary host for the adult
16 stage of the tick. I'm not going to dwell on the
17 life cycle this afternoon. I don't have to time.
18 What I want to do -- oh, I should mention -- this is
19 a graph provided by the Department of Public Health
20 on Lyme Disease on cases by month of onset in
21 Connecticut from '92 to 2000. And it -- as you can

1 see, it peaks every summer, which corresponds with
2 the activity of the nymphal stage of the tick.

3 So a big question is how can we
4 prevent Lyme Disease. Obviously, there was a lot of
5 hope the vaccine would play a major role in that
6 issue. And as everyone has learned, it was
7 withdrawn from the market, which really brings us
8 back to basically preventing exposure or reducing
9 the tick population.

10 Options include personal
11 protection measures against tick bite, the use of
12 acaricides, biological control, altering the habitat
13 or what I call vegetative modifications. I did do
14 some studies in Connecticut forests on vegetative
15 destructive by controlled burns which were actually
16 for forestry generation, not for tick control.
17 Post-reduction or exclusion in host-targeted
18 acaricides.

19 Tick checks. Everyone knows to do
20 that, particularly in children. It's already been
21 pointed out earlier that the highest rate or

1 incidence of Lyme Disease is in children. This is
2 again data from the Department of Public Health.

3 I'm not going to get into how a
4 tick bites and the transmission. I don't have time
5 for that today. Usually in my talks, if I'm the only
6 one speaking, I'll just quickly highlight some of
7 the major symptoms of Lyme.

8 But I really want to get into the
9 ecology of the disease. It's primarily a
10 residential problem. And this is some data that was
11 kindly provided to me by a post-doctorate M.D. at
12 the Stamford Health Department and -- where, based
13 on questionnaires on those ticks that were submitted
14 to the Experiment Station for testing, they found
15 that 75 percent of people estimated they were picked
16 up outdoors at home and 21 percent were picked up
17 away from home. The point being it is primarily a
18 residential risk. And note that play, 47 percent of
19 those estimated it was at play.

20 So I think this information that
21 the Stamford Health Department gathered while, you

1 know, taking in the ticks for testing gave us some
2 really good insight, gave some real good insight
3 into, you know, where people are actually getting
4 their tick exposures. And, consequently, we have
5 focused these projects largely in a residential
6 setting.

7 Now, in a residential setting
8 itself, by sampling ticks, about two percent of
9 ticks are actually on the lawns. The majority are
10 in the woods. And on the lawns, 82 percent I found
11 were within three meters of the lawn edge. So
12 there's a very definite edge effect in terms of the
13 risk of where you're going to encounter ticks. And
14 this also applies to school grounds, recreational
15 parks, as well as the home. This is a
16 woodland-inhabiting tick.

17 Acaricides is one approach. Like
18 previously mentioned, a lot of people don't want to
19 use acaricides on their properties. I've done a lot
20 of trials with less toxic alternatives, including
21 the natural pyrethrins. As you'll see, they're not

1 all that effective. I did find one combination of
2 natural pyrethrin with the synergist propanol b
3 oxide mixed with insecticidal soap gave pretty good
4 results. The synthetic pyrethroids, regardless of
5 which kind you use, are fairly consistent in the
6 kind of control that you will get.

7 But I've also been conducting trials with
8 entomopathogenic fungi. Two products, naturalist
9 TNO and Botaniguard, which is the fungus babesia
10 bassiana, gave fairly decent control in the trials
11 that I conducted in homes.

12 And then we also tested a more
13 recent product containing the fungus Metarhizium
14 anecephaly called Tick-X. And I got decent control
15 with that, too, at least at the trials down in
16 Westport and Weston. So these hold some promise in
17 terms of alternative chemicals for controlling
18 ticks.

19 This is more details on those
20 results. I don't have time to go into the details
21 on those.

1 The one thing about the
2 Metarhizium product is that the company has received
3 EPA registration for their product and is seriously
4 interested in getting this eventually commercially
5 available for homeowners to use to control ticks.

6 The initial trials that we did,
7 the products were actually shipped from England. We
8 had spore viability with 70 percent. We had 81 to
9 85 percent reduction in the ticks at the homes where
10 we sprayed this. In Old Lyme, the product that we
11 -- the second batch that we received was -- had a
12 48-percent viability. Again, this was lab-produced
13 material. And we did not get as good a control.
14 Also, it was done late in the season, much later
15 than you would probably ideally use a material like
16 this.

17 Landscape management has been a
18 focus of a lot of attention on tick control. And,
19 indeed, the Westport/Weston Health Department, as
20 part of their education efforts, has produced
21 brochures called "Get Your Back Yard In The Zone".

1 There is a Spanish version as well. Which
2 emphasizes some of these landscape measures. And
3 they also produced a brochure on "What's Wrong With
4 This Picture?" The particular park, working with a
5 landscape architect, they generated a brochure to
6 give some tips on how to design a park or recreation
7 area, school grounds to minimize exposure to ticks.

8 These ticks, again, are in the
9 woods. This is actually a home in Old Lyme. This
10 is before. This is after. The number of ticks on
11 the lawn at this property were reduced by 90 percent
12 just by cleaning up the edge, opening things up and
13 pulling that swing set out of the woods.

14 So what I found was just cleaning
15 leaf litter at the edge of the property will reduce
16 ticks approximately 49 to 70 percent. Putting in a
17 well-maintained wood chip barrier at the lawn
18 perimeter reduced the number of ticks in the lawn by
19 35 to 77 percent compared to untreated properties.

20 And another thing to consider
21 possibly is cleaning up your stone walls. These are

1 essentially mouse hotels where you find the mice and
2 the chipmunks. And there is a higher rate or
3 association of ticks along stone walls than you
4 would find elsewhere. So one option, at least
5 adjacent to the home, is to clean those up as well.

6 Isolated plantings and mulch as
7 opposed to something like this.

8 Another thing I try to educate
9 people on is the -- you know, think about where the
10 children are playing. They're at high risk. A
11 swing set tucked back into the woods is -- in what
12 the Westport/Weston project called the tick zone --
13 is essentially asking your child to get a tick bite
14 and possibly acquire Lyme Disease. So you need to
15 pull that out, out of the risk zone, into a more
16 open area. And that applies to recreation and
17 playground areas, too, as well.

18 But, real quickly, in essence,
19 what you want to do -- you have an area of woods
20 behind the house. The ticks are there. You know.
21 They're not going away. The idea is to at least

1 create areas either in the park or around your home
2 where you've created a barrier between the area
3 where the ticks are that is safer and has a reduced
4 risk of ticks. And that may be barrier spraying of
5 pesticides just along the edge or landscape
6 modifications.

7 A lot of our research has focused
8 on deer and on mice. Deer are, of course, not
9 responsible for the transmission of the disease, but
10 they are the main host for the adult tick and,
11 therefore, key to the reproductive success of the
12 tick. I want to point out that each female tick
13 that feeds on a white-tailed deer will produce a
14 couple of thousand eggs. So how many ticks you have
15 is linked to how many deer you have.

16 I did a study in the early 1990's
17 and a similar study down in Westchester County got
18 the same results. I looked at two properties in
19 Lyme, Connecticut that had a seven-strand,
20 high-tensile electric deer fence. One was about
21 eight acres. The other was about fifteen acres.

1 Seventy meters inside that fence -- this is actually
2 the outside of the fence. This is the inside of the
3 fence. Deer will actually try to go under a fence
4 before they try to go over it. And, of course, at
5 some point they make contact with the electric wires
6 and they learn to avoid the fence.

7 100-percent reduction in larvae.
8 No deer coming in. No ticks being dropped off. No
9 eggs laid. No larvae. We had an 84-percent
10 reduction in nymphs. We had a 74-percent reduction
11 in adults.

12 To follow up on that, I did a
13 study working with, in part, with the Department of
14 Environmental Protection looking at the impact of
15 deer reduction on ticks at two properties, one a
16 privately-owned forested tract in Bridgeport,
17 Connecticut. I called it an island in an urban sea.

18 It had over 200 deer per square mile in that tract.
19 And the Bluff Point Culture Preserve in Groton,
20 which also had over 200 deer per square mile in that
21 area.

1 The deer were reduced in
2 Bridgeport initially by over half in 1992 and '93
3 and then more gradually. Part of this was due to
4 some reproductive control studies on deer. But, as
5 you can see, the population of nymphs also declined
6 along with the deer population.

7 In Bluff Point, this shows you the
8 number of deer and larval ticks. And green is the
9 number of deer. They held the first controlled hunt
10 in January of '96. They removed a few more animals
11 in '97. They resumed the controlled hunts in
12 January of 2000. Their target is about 20 deer on
13 Bluff Point, which is what they feel that peninsula
14 can support ecologically.

15 The number of larval ticks
16 dropped. As the deer numbers started to increase,
17 the larvae increased. There was a big peak in 2000
18 and then it dropped. You'll see that the nymphs
19 started finally to drop as well. In 2001, we saw
20 another big peak, the year after the larval peak.
21 But then they declined. So deer numbers and tick

1 numbers are closely related. And I like to think if
2 you don't manage the deer and reverse that curve, as
3 the deer population steadily increases, the tick
4 numbers are going to increase along with it.

5 And I should mention that the
6 Experiment Station did some studies working with
7 deer back in 1980 when Lyme Disease was still really
8 relatively unknown. And we found -- Dr. Mangarelli
9 looked at the serology study on the deer and he
10 found up in Litchfield County, as you heard earlier
11 as some of the highest rates in the state, there
12 were no ticks up there and all of the deer were
13 sero-negative for Lyme. It hadn't gotten there yet.

14 By 1990, a number of the deer
15 starting sero-positive. And what we saw is the tick
16 has spread geographically and -- both in New York,
17 Connecticut, up the coast in Maine. The tick has
18 extended its range. Part of the increase in the
19 number of Lyme Disease cases nationally can be
20 attributed to the expanded geographical range of the
21 tick and more people being susceptible to it.

1 Another approach is actually
2 treating the deer. This four-poster was developed
3 and patented by the USDA Agricultural Research
4 Service in Texas. It's called the four-poster. It
5 holds about 200 pounds of corn. There's a feeding
6 trough on either end and four paint rollers that
7 hold a topical pesticide. The pesticide -- deer
8 then are treated when they feed.

9 Now, their initial studies down in
10 south central Texas were aimed at deer and the Lone
11 Star tick. These are pastures and they're huge
12 pastures. These -- it's an untreated pasture. And
13 these are Lone Star ticks all over the ears of this
14 animal. This is a treated pasture. No ticks.

15 The question was would this
16 technology work for our tick up here in the
17 Northeast. A regional project was begun in the fall
18 of 1997. There was a community in Rhode Island, a
19 community here in Connecticut, which happens to be
20 Old Lyme, a community in Westchester County, New
21 York, which was Bedford, Earl Weapons Station in New

1 Jersey and several residential communities in
2 Maryland were all treated with these four-posters in
3 about a two-square-mile area, using the pesticide
4 Amitraz 2% Point Guard, which is a product that was
5 used on hogs. It's no longer available. It was
6 taken off the market for economic reasons.

7 But you can see here from a hidden
8 motion detection camera the deer coming in to the
9 feeders, push in, as the animals put their heads up
10 against the rollers and are treated. We went
11 through a lot of corn in this study. But the main
12 point I want to make, we also periodically marked
13 the deer using marking rollers and doing
14 surveillance to get an idea of what proportion of
15 deer were actually utilizing these feeders. And
16 after an initial acclimation, we had all of the
17 observed deer were marked, indicating a high usage
18 rate. Unfortunately, the first -- the fall of '98,
19 we had a major acorn mass and the deer basically
20 ignored our feeders. But then you can see it
21 rapidly recovered. And generally through most of

1 the project, we had a high proportion of deer
2 utilizing these feeders.

3 We've been monitoring ticks in
4 that community and also as a comparison, as a
5 control, in Old Saybrook. And by 2003, we had a
6 70-percent reduction in the population of ticks in
7 Old Lyme in the treated community in comparison with
8 Old Saybrook. So we did have an impact.

9 Another study in fenced deer using
10 pyrmethrin resulted in even better control. And
11 that study has been published. So that's one
12 approach.

13 Another approach is targeting the
14 ticks on white-footed mice. And this was -- these
15 are the bait boxes that were referred to earlier.
16 Dr. Gary Moffin at CDC, now retired, came up with
17 this approach. And he came to me to try and test
18 this technology in Connecticut, using a
19 Fipronel-based rodent bait box.

20 In the lab, Dr. Moffin found that
21 the Fipronel, a single application to a mouse, would

1 render that mouse tick-free for up to 42 days and
2 almost tick-free for up to over 70 days. Pyrethrin
3 was effective for about two weeks. And Amitraz,
4 which is the material we were using on the deer, you
5 can see didn't last very long at all.

6 We currently have the bait boxes
7 out being tested on Mason's Island, Westport and
8 Weston, Mumford Cove, up in Salisbury, Canaan and
9 Cornwall, and there's also additional test trials
10 being done as part of the CDC cooperative agreements
11 on community prevention in New Jersey, New York and
12 Massachusetts.

13 This just shows you the locations
14 again of the community projects. With these bait
15 boxes where you examine the boxes for use, we check
16 the mice for tick abundance and we also sample
17 host-seeking ticks at the residential properties.

18 Now, the study was begun initially
19 on Mason's Island by Dr. Moffin and Mark Dolan of
20 CDC. After I introduced them to the residents, they
21 went in and they put boxes in 1999 at the southern

1 end of the island. They expanded the number of
2 homes treated in 2000. And by 2001, virtually every
3 residence in the community had received the bait
4 boxes.

5 Essentially, they found an
6 80-percent reduction in the number of ticks the
7 first year and a 96-percent reduction during the
8 second year. The residents of Mason's Island are
9 extremely pleased with the outcome of this. They
10 are no longer picking up ticks on their children or
11 on their pets.

12 Based on that, Aventist
13 Environmental Science, which is now Bayer
14 Environmental Science, decided they would work on a
15 commercial version of the box. The original box
16 only held two bait boxes and had a hand-stapled
17 wick, a yarn wick, to the lid of the box and you had
18 to recharge them every couple of weeks.

19 In 2001, they tried an initial
20 prototype which did not work very well. And in 2002
21 and 2003, they came up with the design that

1 currently exists. There had to be some
2 modifications to the wick and type of bait used to
3 get optimum use out of the box.

4 This shows you a magnified look at
5 the system. Mice and chipmunks come in on either
6 end. There's a central corridor and a wick that
7 holds the Fipronel.

8 The EPA required the company to
9 place this in a very heavy-duty plastic,
10 child-resistant packaging. It is a sealed box. They
11 cannot be recharged. They have to be used and
12 thrown away.

13 They're placed about 30 feet
14 around the property. In habitat like this, you
15 know, near where you would expect to find mice,
16 stone walls, fallen trees and so on, you put a flag
17 by it so you can find it later. Stake it down with
18 a variety of stakes.

19 And just in the time I got in
20 Westport and Weston in 2003, this shows you the
21 number of mice that we captured in the control homes

1 versus bait box homes. Actually, about 70 to 74
2 homes were treated. We didn't, obviously, actually
3 sample every house. And we found a highly
4 significant difference in the proportion of rodents
5 infested with larval ticks in the bait box than
6 control-treated areas, 75 versus 18 percent. This
7 is a 64-percent reduction on the mice.

8 No ticks were recovered from the
9 chipmunks that we caught from the bait box sites in
10 Westport, while five of the six chipmunks that we
11 did capture in Westport were infested with 31 ticks.

12 A highly significant difference.

13 If you look at the number of ticks
14 on the mice themselves -- again, we had some
15 adjustment problems in the -- with the wick with the
16 box. 2001, there's no impact. 2002, not much of an
17 impact. But finally, everything's right. 2003, we
18 had significantly fewer larval ticks on the mice in
19 the bait box treated sites than in the control.
20 Almost 90 percent reduction. And most of the boxes
21 were empty.

1 So Bayer is planning on
2 commercially launching this box, called the Max 4
3 Tick Management System. It contains .7% Fipronel.
4 It is EPA registered. It is registered here in
5 Connecticut. And they plan to commercialize the box
6 this year.

7 Okay. Some other registrations.
8 Brute, which is 10% pyrethrin, was approved by the
9 EPA this past summer for restricted use on
10 white-tailed deer. Restricted use means it is
11 restricted-use pesticide. Only a certified
12 applicator can purchase this material. It has
13 received a state label now. And now we are waiting
14 for action by the wildlife divisions in the state in
15 terms of how this four-poster is going to be made
16 available and managed.

17 You've got 10% pyrethrin on
18 exposed rollers. So, obviously, this is something
19 that's going to be -- have to be carefully regulated
20 and controlled. But it is one control approach
21 where not every residence has to take active

1 participation in tick reduction to have an impact on
2 the tick population.

3 If you're spraying and you want to
4 control it, you have to spray your property. If
5 you're using bait boxes, you have to put bait boxes
6 on your property. This approach, you can have a
7 handful of homeowners agree to allow access to their
8 property with these devices and control ticks.

9 Tick-X, the fungus-based material,
10 did receive registration from the EPA. Hopefully, I
11 will be able to conduct some additional trials this
12 summer. There are still questions on dosage,
13 frequency of application and things like that that
14 need to be answered before the company is ready to
15 actually commercially market this. They hope that
16 they might be able to do this by 2005 as an
17 alternative to synthetic pesticides.

18 We've already talked about that.
19 So I'll conclude with -- here's a picture of the
20 Volkswagen --

21 DR. ROKOS: Thank you.

1 DR. STAFFORD: -- of the
2 Torrington Area Health District for those of you who
3 haven't had a chance to see it yet.

4 I have also written a Tick
5 Management Handbook. It is written. However, it
6 still needs to be -- have a graphics layout done and
7 actually printed. And that's something that's in
8 progress.

9 And so, with that, I would
10 conclude my comments on the status of tick control
11 here in the state of Connecticut. Thank you.

12 (APPLAUSE)

13 COMMISSIONER GALVIN: Thank you
14 very much for that last presentation. That was
15 about as complete and succinct a report as one could
16 do in 25 to 28 minutes. And I do admire your lapel
17 pin.

18 DR. STAFFORD: Oh. Thank you.

19 MR. RYAN: Does anyone have any
20 comments at this point in time as to where
21 improvements can be made that we haven't covered? I

1 mean I think -- and I do appreciate what you're
2 telling us, Dr. Stafford, about some of the things
3 we have to look forward to in protecting our home
4 environments and actually reducing tick populations.

5 But do we have any other comments
6 from the panelists?

7 DR. HADLER: Yeah. Just to make a
8 comment; that a lot of the work -- some of the work
9 that Dr. Stafford was describing is funded in part
10 with the federal funds that the Department of Public
11 Health gets and shares with the Agricultural
12 Experiment Station. And what Jim Rokos was
13 describing in Torrington and also other similar
14 projects are happening in two other health
15 districts, as we mentioned, that also comes out of
16 the current CDC prevention funding.

17 I hope that people realize that we
18 have a very collaborative relationship.
19 Surveillance is -- I mean there's tick surveillance.
20 There's human surveillance. All these projects
21 together kind of interdigitate. We're hoping that

1 -- well, it's important to point out that none of
2 what is happening with the way we're trying to
3 measure Lyme Disease in Connecticut -- it's all
4 being geared to enhance these interactive projects
5 rather than -- rather than compete with them or
6 potentially detract from them. So that we hope that
7 our future will be one of continued collaboration
8 and we can really see how well all of these
9 activities, both the research that's led to all
10 these ticks -- to the demonstration that tick
11 intervention is effective in reducing the number of
12 ticks, trying to get communities to practice them
13 and then seeing if we can have an impact on --
14 overall impact on human health related to Lyme
15 Disease. So that's kind of our collective goal in
16 our interactive projects.

17 DR. STAFFORD: Yeah. I should
18 emphasize that this collaboration goes back many
19 years, before many people even heard of Lyme
20 Disease. In fact, one of the first collaborations
21 was back in 1984 and '85 when the Experiment Station

1 was one of the first labs to develop the early
2 serological test for Lyme. And working through the
3 State Health Department, free testing was offered to
4 physicians as a pilot project in 1984 and '85.

5 Samples were submitted to the
6 Health Department. They came down to the Experiment
7 Station. They were tested, sent back to the Health
8 Department and then to the physicians.

9 And as a result of that
10 collaboration, we got our first image or picture of
11 the distribution of Lyme Disease in Connecticut at
12 that time, which at that time was still largely in
13 New London County and east of the Connecticut River.

14

15 Since then, you know, our agencies
16 have continued to collaborate. Some of the early
17 education that was done in the state was actually
18 under the umbrella of the Arthritis Foundation, the
19 Connecticut chapter as it was then, with a task
20 force that was composed of Dr. Matt Carter from the
21 Health Department, myself, Polly Murray from Old

1 Lyme. We produced a variety of educational
2 brochures. And so that was some of the early
3 education stuff that was actually done in the state.

4 So the collaboration has been a very long one.

5 MR. RYAN: Thank you.

6 COMMISSIONER GALVIN: Well, I
7 appreciate everybody's time and efforts today. Once
8 again, Dr. Nelson and Tom Ryan really did, as my
9 chief of staff says, the heavy lifting on this
10 endeavor. I have heard a marvelous amount of
11 expertise here from a panel that I would virtually
12 defy anybody to put together other than somebody
13 that had the persuasive skills that Mr. Ryan and Dr.
14 Nelson have.

15 Be that as it may, what's going to
16 happen next? I think we -- I can certainly -- I
17 hope that I have dispelled your fears that
18 regulators within the State Health Department are
19 going to take issue with practitioners. That's not
20 going to happen. Or at least, as they say, not on
21 my watch. Unless there are other problems with --

1 that have to do with quality of care and are totally
2 unrelated to diagnosis and treatment of Lyme
3 Disease.

4 I have indicated that we will put
5 a document together reviewing the findings here.
6 That will be published hopefully in one of the local
7 medical journals and hopefully with some input from
8 Attorney General Blumenthal's office about suggested
9 regulatory changes or suggested administrative
10 changes.

11 Bearing in mind, as you all
12 should, that the State Health Department -- we're
13 basically an educational organization. We don't
14 make the laws. And we're not the executive. We
15 help to implement them.

16 It's my feeling that we still have
17 some ways to go to resolve what's the best way to
18 count people. And we will work on that. And I'm
19 sure that between Dr. Nelson and my staff and the
20 Attorney General and Mr. Ryan and his staff, we will
21 be able to come up with a coherent solution to the

1 problem.

2 Some of the measuring of
3 laboratory positivity will be made much easier as
4 the various labs within the state come on line.

5 I think, as I heard our colleagues
6 from the CDC and the NIH indicate and as several
7 speakers have indicated, there is no direct
8 relationship between the numbers of cases that we
9 count and the amount of money that the federal
10 organizations are going to give us.

11 However, I also heard Attorney
12 General Blumenthal say very succinctly that -- how
13 do we know things are better or worse unless we have
14 some way of counting them? And we have to way of
15 counting the cases which is not only relatively easy
16 to do but is reproducible. We don't want to count
17 the wrong things. We want to count the right
18 things. So we have to have -- find a way to count
19 these things, but to count them in a way that's
20 reproducible and valid so that if someone else
21 counts them, they count them pretty much the same

1 way and so that we can compare them to similar-sized
2 states and similar venues.

3 That is somewhat of a daunting
4 process. But, once again, if we can't -- if we
5 don't have a correct count, how will we know if
6 we're affecting the disease one way or another?

7 We will work -- and I know that
8 it's been one of the Attorney General's prime
9 motivators, is how do you count -- how do you count
10 this disease appropriately? I think we'll certainly
11 be able, as I said a minute ago, to count them
12 through the use of the laboratories.

13 Once again I have to give you my
14 caveat that if we are required to put in procedures
15 which are not cost-effective from the standpoint of
16 the Department of Public Health, we will certainly
17 -- we are public servants. And we will do what the
18 public demands and what the Representatives and the
19 Senators think is appropriate. However, there is no
20 huge fund of money. And if, in their wisdom, the
21 Assembly decides that they want us to do additional

1 counting in a way which may not be effective and
2 secondarily decide that they will not fund us for
3 it, the money will have to come out of some other
4 project. And the projects that we have now are --
5 many of them are cut to the bone and/or eliminated.
6 And we are trying to get things back on line,
7 particularly with immigrant health and with
8 multicultural health, but also with a variety of
9 programs.

10 So as you think about what's
11 happening here, it's not as one would envision it a
12 huge pot of money that we can dip into. It will be
13 taking money from one program and putting it into
14 another. And if we need to do those types of
15 things, we need to do them so we get the best
16 possible product for the least possible expenditure
17 so we can put our money into abatement of the ticks
18 and into research.

19 We will develop a product -- I
20 believe that Randy will have something available
21 within the next few weeks. And we can share that

1 with any of you folks who want to read it and look
2 at it.

3 We will do our best to spend our
4 money wisely and not jeopardize other programs and
5 yet find a way where we can count these things in a
6 reasonable fashion.

7 Thank you.

8 (APPLAUSE)

9 (Whereupon, the hearing was
10 concluded at 5:00 P.M.)

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