STATE OF CONNECTICUT

PUBLIC HEARING ON INSURANCE COVERAGE OF LYME DISEASE

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ATTORNEY GENERAL BLUMENTHAL: Guests, legislators who are in attendance, and members of our staff who are here today, we will be here for I think a very full day, and I want to assure you that -- particularly members of the public, that the cafeteria is open downstairs if you want to make use of it. It's open to the public.

And those of you who will be here for the balance of the day, our schedule will be that we have scheduled some speakers for the beginning of this session going through the break for lunch, and then at 2:30 we plan to have public comment. And I would invite you to sign up for that as soon as you wish to do so, as soon as you've decided that you'd like to offer us your views and comments on what has -- what you've heard or anything else that you wish to say.

We hope that this hearing really will provide a full opportunity and perhaps even the beginning of a discussion, conversation, dialogue, statewide about what more we can and should be doing to diagnose and treat Lyme disease and in particular, what we can do to

improve the system of insurance coverage that now applies.

Being the birthplace of Lyme disease and the state with the highest incidence of the disease, we ought to be really at the forefront of treating and curing it, and our insurance industry ought to be especially sensitive to the lasting damage of this extraordinarily insidious disease, the damage that it does not only to adults but most particularly, as I have seen personally, children and young adults who may become victims of it.

Different people at various stages of the disease may need different treatments, and my own basic philosophy is that decisions about diagnosis and treatment ought to be made by the treating physician and the patient, and those decisions ought to be respected by insurance companies, by government officials and ought not to be governed by arbitrary artificial dictates or regulations.

I guess what brings me here in a

very personal sense is the numerous complaints that I've received from people suffering from Lyme disease who have tremendously moving,

incisive, and graphic complaints about the denial of insurance coverage benefits for treatment and the rejection of diagnoses and treatment prescriptions from their own doctors. And their stories attest to their own profound personal courage and fortitude in the face of the powerful physical and emotional pain that they have experienced.

Lyme disease can be very difficult to diagnose and even more difficult to treat, but the number and severity of complaints, some of them extraordinary horror stories, suggest that there must be a complete review so as to assure acceptable diagnosis, treatment, and insurance coverage.

We've organized this forum along with the -- it's really been a joint task, the Insurance Commissioner and myself, we're happy to have the participation of legislators. And with that, perhaps, Commissioner Reider, if you have a few remarks by way of introduction?

COMMISSIONER REIDER: Thank you very much, Attorney General Blumenthal, and I too would add that it's a pleasure to have worked with the Attorney General and his office in sponsoring this hearing this morning.

I think we'd all agree it's an important matter, a health matter to the people in the country and certainly as the Attorney General mentioned, here in Connecticut for the reasons cited.

Several years ago, I held a forum where we had people from different perspectives and concerns present. It's a -- it's -- the issue is one that is -- I think we should note is there is some controversy and certainly differences of opinion when it comes to the extent of treatment of Lyme disease, and there is no standardization of medical treatment by a board or any countrywide accepted approach, and I think it would be important to hear that aspect of it here this morning.

I might say that it's important that the insurance companies respond appropriately in these matters, and as an Insurance Department, we in the last several years have developed a market conduct of utilization review companies. Those are the entities that make certain determinations as far as the medical necessity, and again, that's at the heart of an issue.

They are required to have an internal review where people differ, that they have to make certain determinations within a certain time frame, and also then there's the external appeal. And there has been some internal appeals done by entities outside of the economic realm of the company that covers the patient, and so it's going to be important from that perspective, I think, as the Attorney General noted, that we understand the insurance part of the equation.

There is some good news, I think, that certainly all of you who would have some interest from one perspective or other would know or whatever, but one, there has been advances in the detection of the disease which we just received recently that the Attorney General's

Office has provided, and we'll have to learn more about that, but people are aware that it would be interesting to hear from you today.

Two, the prevention of the disease by receiving immunity shots to it, which we've heard a lot about, we're seeing some advertisement, so we have seen advances in one, the diagnosis, the detection, and the prevention. And as I said, anything that can be brought forth here today -- and in addition, I think today's session is very important because it highlights an area that there's a lot of discussion and concern about, and it also should be looked at as an education forum, which I think is certainly what the Attorney General and ourself would want here today so that people can leave here this evening and the public can be better informed. Even if we don't end all differences, at least the people are well informed and aware of this, because it is a serious disease and one that has impacted any number of people and families.

So today, along with the Attorney

General, the Insurance Department is most anxious to be here to participate, but most importantly, to listen and to understand everything that can be learned today and then to try to work in a proactive and a positive fashion to address the concerns.

I might just mention for identity, Mary Ellen Rowe is the head director of our life and health division, and she has joined me. So

occasionally I will have to turn to her for a little bit of insight and help but we're again delighted to be here. Thank you so much.

ATTORNEY GENERAL BLUMENTHAL: Before we begin with Dr. Matthew Cartter, we'll call her our first witness, let me just introduce for the record Representative Mary Magratten, Representative Dolly Powers, Representative Gary Orfice who have joined us. I understand we may be joined by other legislators later in the day. The legislature is in session today I think, isn't it, so they will have to be dividing their time as they frequently do between different committee meetings and the legislative session itself.

And Jennifer Jaff, who is an Assistant Attorney General in our office, if you could just raise your hand, Jennifer? A lot of you have probably talked to her on the phone, and she is the principal staff person in my office who has been working, as many of you know, laboring very, very hard on this issue.

COMMISSIONER REIDER: I was just going to say that several legislators have indicated this morning that they couldn't be

here, but as you may know, they do have a television and sound and will be following this from their offices as they move back and forth and vote on other things, so we are pleased with their participation.

ATTORNEY GENERAL BLUMENTHAL: Dr. Cartter?

DR. CARTTER: Good morning, Commissioner and Attorney Blumenthal. Thank you for the invitation to share with you a public health perspective on Lyme disease. My name again, for the record, is Dr. Matthew Cartter. I'm the epidemiology program coordinator for the

Connecticut Department of Public Health. I have been in charge of the department's Lyme disease activities for -- at least since 1987. And I would like to share some of the things that we have learned about the occurrence of Lyme disease in Connecticut from a public health perspective.

Just to start off, I will not be going over all the details I have provided in the written testimony in the packet. If people are interested in more detailed statistics, those are available there.

ATTORNEY GENERAL BLUMENTHAL: Is

the light button on?

DR. CARTTER: Yes, it is.

ATTORNEY GENERAL BLUMENTHAL: Okay. Maybe if you could just speak into the microphone. Thank you.

DR. CARTTER: It is the job of public health to prevent new cases of Lyme disease. It is the job of clinical medicine to make sure that when people get Lyme disease, they are treated appropriately and do not go on to develop late complications. In public health our task is to protect the health of the population.

We use surveillance and epidemiological studies to identify risk factors for disease and then we use these kind of data to develop prevention strategies.

In Connecticut, we have one of the most comprehensive Lyme disease surveillance systems in the country.

Just take a break here and turn these on. Is that any better for you folks in the back?

AUDIENCE: It's a little hard to hear.

DR. CARTTER: This is being

recorded, I take it, so I need to talk into this?

In Connecticut, we've had more than 20 years of experience with Lyme disease, and there is no state in the country that has more experience with this disease than we do.

This is a story from The New York Times a couple years ago, but not only are we very familiar with this disease, we're also very familiar with the controversy which has accompanied this disease over the last two decades.

I'd like to give you a little Connecticut perspective. Certainly the history of Lyme disease goes back more than almost 100 years in Europe, but in Connecticut the story started here in 1975, when an unusual cluster of arthritis cases was reported in Lyme, Connecticut. In 1977 we have the first publication describing the first 51 cases of Lyme arthritis in Connecticut. In 1977, the deer tick, then called exiliary stamini, was linked to the transmission of Lyme disease. And in 1982, Borrelia burgdorferi, the bacteria that causes Lyme disease, was discovered.

As these scientific discoveries were moving forward, it's also important to point out there is another side of Lyme disease which lagged somewhat behind but continued to move forward. It was not until 1982, seven years after the discovery of Lyme disease that the first Lyme disease brochure was developed by the Connecticut Chapter of the Arthritis Foundation. In 1984, the serologic test became widely available in the state. In 1987, Lyme disease was made a reportable disease in Connecticut, more than 10 years after it was first described here. And in 1988, the national media attention to Lyme disease began.

This is data from the Centers for Disease Control and Prevention. The 1988 data is provisional, not yet finalized. Lyme disease has become the most commonly reported what's called vector-borne disease in the United States. You see a steady increase from the early eighties to 1998. This should not be interpreted as a true increase in disease, however. Many states did not make this reportable until the late 1980s, early 1990s, and much of the increase we believe is due to increase in surveillance and increased

resources being put into disease surveillance.

Connecticut does have the distinction of being the state with the highest rate of Lyme disease in the population. Nationally, more than almost 80 percent of all the cases -- more than 80 percent of all the cases come from just five states. Fortunately for us, New York State is number one in that category with 30 percent of all cases in this country being reported from New York, but Connecticut, with a much smaller population, reports 20 percent of all the cases that are reported to Centers for Disease and Prevention.

Pennsylvania, New Jersey, and Massachusetts, all other states combined report only 16 percent of all the cases in the country.

In Connecticut, the process of Lyme disease assessment consists of a number of different activities. When a public health person uses the word "surveillance," it means that we look for new cases of illness, and these are the cases that are reported to us by physicians and other healthcare providers. We have a statewide system of reporting, but we also actively seek out cases in the Lyme, Connecticut, area, Litchfield County, Tolland and Windham Counties as part of special studies.

We're also tracking Lyme disease using GIS techniques, and particular studies are being done in a number of parts of the state as well. These activities together give us a picture for what's happening here.

This is a look at the Connecticut cases that have been reported since 1984, and we've been doing surveillance since 1984. 1986, there was a period that we did not collect statistics because the disease was not made officially reportable until '87. As you can see, there has been a dramatic increase, but I'd also like to put out that in 1991, we received federal funding for the first time to hire a full-time person to do Lyme disease surveillance. So in part, this increase is due to enhanced surveillance activities at the State Health Department.

Lyme disease in Connecticut over the years, it's very clear that those who are at greatest risk are the very young and the very old. This is what we call incidence rate by age group. The highest rates are in children less

than 10 years of age, the lowest rates are those who are teenagers and in their early twenties, but certainly no age group is without risk.

Connecticut now has all of its

counties affected by Lyme disease, some counties more than others. The initial epicenter, if you want to call it that, was in the Lyme, Connecticut, area, which is Middlesex County bordering on New London County. But as you can see, we now have cases being reported throughout the state. The highest rate -- I'm sorry, it's a little out of focus -- is Windham County now, with 370 cases being reported last year.

Let me show you a different view of this because I think it's important in understanding what's happening in Connecticut. If you think of the state in regions and the central region being Hartford and New Haven Counties, which consistently year after year have the lowest rates, and then there's the western, northeastern, and southeastern.

What I'd like to point out is that in the southeast, if you look at the red line, the Lyme disease case rates have been fairly stable over time, although there is this cycle

every two years which reflect particular populations. But we've had dramatic increases in the northeastern part of the state as well as in the western part of the state as well.

The Hartford and New Haven counties continue to have very low levels of Lyme disease activity compared to other parts of Connecticut.

COMMISSIONER REIDER: Let me ask a question. Maybe it's the obvious, but why is there that difference in the different regions?

DR. CARTTER: The reason for that is over the last 20 years the particular populations have spread northward and westward in the state and have moved into this area. Lyme disease does not progress rapidly year by year, but we've really seen this over 20 years, the slow progression into these areas. And this is also consistent with what's being seen in Rhode Island, in bordering states, and also in New York State as well.

COMMISSIONER REIDER: Thank you.

DR. CARTTER: We are very much aware that what's reported to us is only a fraction of what's out there. Back in 1994, we did a survey in the 12-town area around Lyme, Connecticut. This was a random digit dialing telephone survey, and we asked folks, the head of each household, if they or a member of their family had ever been diagnosed with Lyme disease; whether they have been diagnosed in '94 or prior to '94.

And I'd like to emphasize that the statistics here, that 8.1 percent of all households, said that they had had a member of their family diagnosed by a physician to have Lyme disease in that year, and that more than -- 20 percent of all the households had had at least one person diagnosed with Lyme disease so -- before 1994.

If you look at this in a little more detail, and I apologize for the numbers, but I think it's important to understand this. That if we assume that 8.1 percent of all the households in this part of the state were affected in 1994, and assuming that only one person in each of these households was diagnosed with Lyme disease, then 2,572 persons from this area may have been diagnosed with Lyme disease in 1994. That year, 270 cases were reported from this area, almost a tenfold difference. And what this means is that for every case that's diagnosed and reported to us, there are many more people who are being diagnosed and treated for Lyme disease in our high risk communities.

We estimate that the number of cases that are reported to us and meet the surveillance case definition are probably only 10 to 25 percent of all the cases that occur.

I'd like to emphasize this slide as well, because many times that we think what we do is in regards to Lyme disease has a tremendous effect, but Dr. Kirby Stafford at Connecticut Agricultural experiment station has shown that these annual differences in Lyme disease really reflect the annual differences in the particular populations. That when the ticks are up, our case numbers go up; and when the tick numbers are down, our case numbers go down. And at least right now, after 20 years, we're still at the mercy of ticks in various parts of Connecticut.

I'd like to point out that Lyme disease is much more than a biological phenomenon. This is a slide that was put together with data from one of the Internet database sources where this is a curve, a figure that shows the number of Lyme disease citations in magazines and newspapers from 1984 to 1996. I pointed out the peak in Lyme disease media coverage occurred in 1989. This was really in the late eighties, when Lyme disease became a national media story, and it's steadily declined since that time. Although I suspect that with the new Lyme disease vaccine, there will be a research and media coverage related to that in '97 and '98.

But this is to emphasize that Lyme disease is much more than a biological phenomenon. It's also a social and cultural phenomenon. I'm an amateur medical historian, and one of the things I've learned about Lyme disease and other diseases is that our understanding of Lyme disease has been framed by a succession of what historians call constructions or paradigms of disease. These are ways that people think about disease, and our attempts to explain the experience of illness.

When it comes to Lyme disease, it's been experienced in two different ways; the experience of the individual of which you will be hearing considerably later on this morning, but Lyme disease began as a readily diagnosable and treatable acute infectious disease in the 1970s. In the 1980s, it began to be redefined as a difficult to diagnose and treat chronic infectious disease. And these two perspectives continue to persist throughout the 1990s.

From a public health perspective, looking at Lyme disease from a population point of view, Lyme disease began as an epidemic in the 1970s, really as a local epidemic. Over the next 10 years it went from being an epidemic, from both a medical perspective and a cultural perspective, to an endemic disease, something that people would have to deal with on a long-term basis.

We went through a process in the late 1980s of redefinition of Lyme disease. In the early 1990s there was a new term that came into use called "emerging infections," which Lyme disease is one, and now with the advent of the Lyme disease vaccine, we are talking about Lyme disease being defined as a vaccine, preventable disease which has very different connotations than either epidemic or endemic disease.

And finally, this is a quote from Sylvia Tesh from a book she wrote on the development of public health policy called "Hidden Arguments" in 1988.

"It does give me some understanding of what all of this is about -- what Lyme disease has been about in the last 20 years; what is the legitimate source of knowledge; what is the nature of human beings, and what is the ideal structure of society.

Firmly but often unconsciously held answers to these questions got scientists, policymakers, and ordinary citizens alike to different constellations of facts about the causes of disease and hence the different preferences for prevention policy."

With that, I'd like to thank you for appearing for a public health perspective on this disease, and I'd welcome any questions that you might have.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

COMMISSIONER REIDER: Thank you.

ATTORNEY GENERAL BLUMENTHAL:
Thank you, Dr. Cartter.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: As I understand one point that you made, Dr. Cartter, it may well be -- in fact, it's likely based on what you've presented here, that the numbers of cases reported to the State of Connecticut Department of Public Health may be only 10 to 15 percent of the number of cases that actually exist; is that correct?

DR. CARTTER: That's correct. We estimate that for every case that's reported to us that meets the national surveillance case definition, there's probably another nine or 10 people out there who are diagnosed by a physician to have Lyme disease and treated for that disease.

ATTORNEY GENERAL BLUMENTHAL:
Isn't that a rather searing comment on the whole system of reporting and the accuracy of all our public health statistics, especially relating to Lyme disease?

DR. CARTTER: Well, what we've learned over time is that public health surveillance in general only captures about 20 to 30 percent of cases for most diseases, so we're

very much used to the limitations of our data. This data is most useful for looking at trends through time. It's not a good measure of total disease burden, and that's why we need to do other studies like we've done here in the state where we do surveys and other ways to try to estimate how big that iceberg is underneath the tip of reported cases.

ATTORNEY GENERAL BLUMENTHAL: And if the normal range of reporting might be only 30 percent of other diseases, reporting for Lyme disease is even lower than it is for other diseases; is that a correct understanding?

DR. CARTTER: Yes. The reason for that is that diseases that require hospitalization are usually reported much more completely than diseases that are largely seen in an outpatient setting. So if somebody is hospitalized -- many of the diseases that we have result in a high percentage of hospitalizations.

For example, meningococcal disease, meningococcal meningitis.

So I mean, probably almost 100 percent of those cases are hospitalized, and we hear about almost all of those through the

hospital system. But because most people who are seen with Lyme disease are seen as outpatients, and there are many busy physicians in the state who honestly told me, I saw 100 patients with Lyme disease this week but I really just didn't have time to fill out 100 forms to send to the Health Department, very understandable.

And so in general for outpatient diseases, the reporting is much less complete than for patients seen in hospitals.

ATTORNEY GENERAL BLUMENTHAL: I may have other questions that I'd like to follow up later, but because of the time constraints that we're operating under I'm going to yield to Commissioner Reider.

COMMISSIONER REIDER: Just one question, and as a layman, it's fair to say that if you had a higher reporting ratio it would be helpful to you in being able to get a better understanding, or is that not correct?

DR. CARTTER: Well, certainly we would love to see increased reporting of any disease, whether it's Lyme disease or any other. I think in Connecticut we have finally had the resources to do surveillance in a way that we're

able to look at, finally identify these increasing trends that spread in other parts of the state. So our surveillance system is answering many of the questions that we have. It will not answer questions like what are the total number of people being diagnosed with Lyme disease, and probably can't. We need to do other kinds of studies to answer that question.

COMMISSIONER REIDER: And one of the thoughts I had was, and I don't know just how practical, but is it possible that perhaps the insurance companies might lend support in being able to use their data to report more through the system?

DR. CARTTER: Certainly those kinds of discussions have gone on in the past. If we really wanted to know, if we wanted to answer that question, getting that kind of information from insurance companies and managed care companies would be critical. I understand that there have been concerns about the sharing of that kind of data in the past, but certainly that would be great.

COMMISSIONER REIDER: We get back to the confidentiality. But it's something

perhaps we could work with the Attorney General and see if there is something that we proactively could encourage that or support it.

DR. CARTTER: What has not been done in Connecticut and should be done and requires the cooperation of insurance companies, is an attempt to try to determine what are the annual costs of Lyme disease treatment in the state.

COMMISSIONER REIDER: Okay.

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

DR. CARTTER: Thank you very much.

ATTORNEY GENERAL BLUMENTHAL:

Dr. Krider.

DR. KRIDER: Yes. I have overheads but they may be sufficiently inconvenient that the substance of my testimony is also included in this. So I could just use this for its useful purpose.

ATTORNEY GENERAL BLUMENTHAL: Whichever you'd like.

DR. KRIDER: Does everyone have a copy of this?

ATTORNEY GENERAL BLUMENTHAL: It should be in the packet. You know, Doctor, if we all have it maybe you can just work from that.

DR. KRIDER: Yes, of course.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

DR. KRIDER: My apologies. I chose the low-tech solution that would be something that would be the easiest.

My name is Hallie M. Krider. I'm a faculty member at the University of Connecticut in Storrs, a member of the Molecular and Cell Biology Department in the College of Liberal Arts and Sciences. And I'd like to thank you for the opportunity to comment on the progress that we've made in our development of an early disease detection test.

On the second page of what were to be the overheads, I've listed the collaborators who were involved in helping me to make progress with all of this. They include members of the University of Connecticut technology transfer group, and researchers at the University of Connecticut including myself, my research associate, Claudia Curdins and Dr. Sandra

Bushmick, who is an associate professor and doctor of veterinarian medicine in the College of Agricultural and Natural Resources Department of Pathobiology.

They also include Bioinvestigations, Limited, whose president is Stuart Rosenberg and Pasteur Murrow, a major vaccine developer and one of the players in the development of the current vaccines that are available.

The third page basically outlines our perspective on the issues of developing a test; that is to say, the Catch 22. Most people agree that early treatment is certainly most effective and substantially less expensive than prolonged later attempts to cure the disease. Current tests are certainly inaccurate in many different respects, often giving either false positives or false negatives. But in all cases the tests require waiting for some titer to rise in the affected individual. This can or may not occur, quite independently of whether or not an individual is infected.

So that while early treatment is certainly preferred, long waits are often

required in order to get reasonable data about the status of the infection. So we basically began to try to think about ways in which we might approach the issue of evaluation of whether or not someone has Lyme disease.

The next page simply provides you with a picture of the tick, at least in one of its adult forms, and there's really two things to say here. First of all, there's a lot we don't understand about how frequently ticks actually have spirochetes or how long it takes for a tick after it's been muted to transfer the disease. It's also the case that the nymphs are very much smaller, the earlier stage are very much smaller than the adult stage.

So that I think the lesson that I would leave you with is twofold; one is that finding a tick doesn't mean you've got Lyme disease, and not finding a tick doesn't mean you don't have Lyme disease. In other words, the tick is not a very good way to approach the issue of whether or not someone has Lyme disease.

The next page basically shows you a picture of the organism. And there are two issues that relate to the organism. One is with

regard to the organism itself. We don't know much about where it distributes in the body. We don't know much about the forms that it takes after infection over long periods of time. And we don't know much about how or if it changes composition and how that influences all of the various tests that we might perform.

From the other side, the symptoms that the host can demonstrate can be very widespread, including none whatsoever. Asymptomatic individuals are certainly a source of some argument, but I think it's important just to suppose this is entirely likely.

And secondly, there are issues of whether or not there can be such things as chronic infections and whether chronic infections can persist after the initiation of treatment, so a test would certainly need to be able to address these issues or to consider the problems that these two sides of the host and bacteria present.

We essentially have developed a test that we think responds to many of these issues. I will talk about the test in a very nontechnical way in the hopes of being as clear

as possible, but certainly if there are issues or questions I'd be happy to answer them.

But quite simply, we can collect a very small amount of blood, certainly a finger prick as opposed to, for, instance the use of large volumes. There are some simple manipulations that are done which create a microscope slide, and any reasonably trained blood worker or microscopy cytotechnician will be able to evaluate the results of this very straightforwardly.

The result is what we refer to as a unique and quantifiable signature; that is, something appears on the slide which clearly indicates whether or not the host is having a response that suggests that they have Lyme disease. And some people have big responses and others small, so we can actually differentiate.

On the next page we point out that the signature does not show a cross-reaction with other pathogens. Unlike many tests, this one is quite specific.

Secondly, the signature appears many days prior to the onset of immune response. Many of the tests depend upon the rise of titers

that relate to the immune response. Because our organism, our test platform as it were, is a mouse, we can tell you whether or not your mouse has Lyme disease within several days after the initiation of the infection.

And it appears that the signature

is created even when the immune response does not occur. So that one of the cases in which tests often fail is that the individual that's infected just doesn't bring up a high titer and therefore can't test positive. This test apparently functions differently if not independently from the immune responses that other tests might measure.

On the last -- next page we basically point out that there are certainly many different organisms that are capable of showing the signature; cattle, dogs, horses, sheep, goats are also included. And in fact, we've also examined humans, used ourselves essentially as test objects, to determine whether or not we have reason to believe this test would be effective in humans.

Finally, we've managed to create what we consider to be the usable platform for

the test; that is to say we have created stable reagents and ways of doing this that are straightforward and that can be done in a doctor's office or certainly in a medical technician's lab.

We have the major elements of patent protection essentially in place with regard to the technology, and we're awaiting the opportunity to do -- essentially advance this for clinical trials and the appropriate approvals.

That is in fact the status of the test as we've gotten to it, and I thank you very much for the opportunity to comment.

ATTORNEY GENERAL BLUMENTHAL: Thank you. I don't mean to ask you unfairly about another test which seems to be relatively new, but we received word literally within the last few days about the new test that the FDA has just approved apparently made by the Chembio Diagnostic Systems in Medford, New York, using antigenic proteins developed by recombinant DNA technique rather than the whole cell, and I wonder perhaps if you could comment on that test if you know something about that.

DR. KRIDER: I've had the

opportunity to review some of the materials that have been released on the test. The use of the recombinant proteins and the use of these ending in a strip format is certainly going to be a significant increase in convenience with regard to initial evaluation.

The form of the test, however, mimics that of other tests that are already available. I do not anticipate from anything that I've seen that this particular test platform will be more accurate or more definitive than any of the tests which are currently available, and I do not anticipate -- indeed the literature suggests that it would be inappropriate to actually use this test as a single evaluation device; in other words, people who are indicating a positive on this test should certainly be examined again with another one of the tests, the ones that take longer and that have to be sent elsewhere for evaluation. But as a preliminary screening tool this certainly might be an useful device.

I don't know what the rate of false negatives are for this particular test, but I would assume that they must be comparable to

some of the other tests that are available, because they use essentially the same biological responses from the infected individual in their measurement. So while I see this as being a significant increase in preliminary screening capacity, I don't know that it provides more assurance as an evaluator than those tests which we already have.

ATTORNEY GENERAL BLUMENTHAL: My understanding is that the FDA approved it with the understanding that it would be used or confirmed by the Western blot test or some other diagnostic procedure, but it does offer a quicker early detection means, as I have been informed from the FDA. All of our information really comes from the FDA release and the paper that it issued when it issued its release.

DR. KRIDER: I have no more information than you have. My perspective is that all of the tests currently, regardless of how long they take, are very much able to make a mistake, and increasing the rate at which you can make a mistake is very possibly a significant improvement.

I obviously have my own axe to

grind as you might say. I believe that the tests in which we're working can substantially address all of the issues that I've raised so far. But again, that's on the basis of tests that relate almost exclusively to mouse models, and we await the clinical trials and the obvious scientific evaluation of the data that the proper tests would require.

ATTORNEY GENERAL BLUMENTHAL: The new test may be quicker but perhaps not more reliable, and in any event doesn't portend a magic bullet in terms of diagnosis?

DR. KRIDER: Let's say your question certainly reflects my concerns. I have no knowledge beyond what you've been provided, and my own experience.

I would be very happy to continue on with the development of my test, because we feel that it's unrelated in its mechanism or not directly related in its mechanisms to those which already exist. So it provides a clear alternative evaluator and thereby increases our sense of assurance about our ability to decide whether or not you are an infected individual.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

COMMISSIONER REIDER: Anticipating what we may hear, as we go through the course of the day, just to try to build a picture, the longer the delay in detecting the disease, does that relate to the amount and the extent of treatment that has to follow? In other words, if you find that -- if you detect it immediately, are you much more likely to be able to cure it quickly than if you --

DR. KRIDER: Yeah. My colleague, Stuart Rosenberg, has suggested that I distinguish between the issues of quick versus early.

A test which is quick is one which may take you a long time to be able to produce titers, but which in an office you can perform in an hour, as opposed to sending it off and waiting for three days.

An early test is one which says that you are bitten with a tick and within several days we can actually productively evaluate whether or not you have Lyme disease.

My test is a test that works early in the infection process, and we believe perhaps throughout the period, in which the spirochete is present. A quick test is one which may in fact not be effective until weeks into the infection, but which nonetheless doesn't take very long to do.

That being said, let me return to your question.

It is generally argued that the earlier you catch the infection, the more readily it can be treated, the broader the spectrum of antibiotics that can be used, the shorter the period over which the treatment is necessary, and therefore the lower the cost.

Having said that, that's generally believed -- I'm not in a position to tell you that's true, I'm not a physician, and in fact all of my work has been on nonhuman models up to this point. I can tell you that there are different mouse models that would give you a different answer to that question, depending on which of them you chose and how you proceeded in your evaluation; the degree to which genetic factors, previous disease factors, and other aspects of physiology are going to influence the expression of the character that you're talking about, I think I will leave for others to comment on. I certainly don't think I understand them.

COMMISSIONER REIDER: Thank you very much.

ATTORNEY GENERAL BLUMENTHAL: Thank you very much. We've been joined by Senator Melodie Peters, who is seated in the front row. Let me also introduce Assistant Attorney General Tom Ryan, in my office. Tom, do you want to raise your hand, who has been working on this issue as well. Do any of the legislators have any questions? Representative Powers.

REPRESENTATIVE POWERS: Thank you.

Dr. Krider, can I get you back?

DR. KRIDER: Oh, I'm sorry.

REPRESENTATIVE POWERS: I just wanted to follow up. So you've done the animals. You are now in the process of setting up human trials; is that right?

DR. KRIDER: The next steps essentially fall to two groups; one, the technology transfer infrastructure of the

University of Connecticut, and the other is the people who hold licenses on the technology.

Basically the commercial partners in this case, Stuart Rosenberg and Pasteur Murrow. As researchers, we can't proceed until such time as the technology transfer and capitalization and funding issues are settled, so I don't have an answer as much as I would like to be able to provide you with one.

REPRESENTATIVE POWERS: Okay. Then to go back to that step, how long do you anticipate that would take?

DR. KRIDER: I'm simply unable to comment. The technology transfer office of the University of Connecticut is most certainly aware of and has been interacting with the people -- but I have no sense whatsoever of that process. I am the researcher and the faculty member and not the administrator in this particular case.

REPRESENTATIVE POWERS: Okay. Once you could start the human trials, how long does the FDA set up a time frame for you, or do you set up your own time frame or how does that work?

DR. KRIDER: Well, basically, it's done in two steps. The first step is one which I would design -- or we would have an early trial,

and then the group that would be managing the trials, which would be outside of my direct control, would submit a design for approval to the FDA. That process is not one which I control or about which I know very much.

REPRESENTATIVE POWERS: So this sounds like this is a fairly long process?

DR. KRIDER: I --

REPRESENTATIVE POWERS: A couple of years?

DR. KRIDER: I think it can be completed in a relatively short time. Once it's initiated, in other words, I don't think a year, for instance, is an unreasonable period over which to anticipate the trials. The approval process might take longer, but the actual trials themselves wouldn't go on forever, we would hope. The real issues right now are the rate at which we can organize and actually begin to implement all of the steps that are necessary to perform a clinical trial.

REPRESENTATIVE POWERS: How does this work with something I've seen in the print media lately, something about a vaccine?

DR. KRIDER: In a very broad

sense, let's put it this way: I think that first of all, we will need a very good test, no matter whether there's a vaccine or not.

REPRESENTATIVE POWERS: Right.

DR. KRIDER: And secondly, let me state that I think that we will need a vaccine. The product that is currently available is essentially a way of sterilizing a tick, not removing or protecting the individual from infection, and I would suggest that the vaccine is essentially a first stage or first generation attempt to provide some protective capacity to the potential host, in this case the potential host is humans, but comparable kinds of vaccines, for instance, to be developed for dogs and for use in various veterinary environments.

REPRESENTATIVE POWERS: So it's not the level of like our measles vaccine or anything like that?

DR. KRIDER: It's my feeling that it's not at that level at all. It's not of that character.

REPRESENTATIVE POWERS: All right. Thank you very much.

ATTORNEY GENERAL BLUMENTHAL:

Thank you.

Senator Peters?

SENATOR PETERS: Thank you, Attorney General. Just to -- can you hear me all right?

DR. KRIDER: Yes.

SENATOR PETERS: Just to follow up on the vaccine question, because there are many of us that thought that this was going to come in and save the day, particularly on the coast, and I, who have had Lyme disease at least twice, thought this would be great, I'm signing up for the vaccine, and you're saying that this isn't the end all to be all that some of us may hope that it would be?

DR. KRIDER: Let's put it this way, I don't wish to assume the position of being an authority on the vaccine. I'm a researcher who has some specific questions that I would like to see addressed in the context of the vaccine, and I have some understanding of the mode that those who are developing the vaccine think this particular preparation, the mechanism by which it works, and it is fundamentally the Osp A protein, the outer surface protein A of the bacteria. Its

high titers to that protein are presumed to enter into the tick when the tick bites you, and to interact with bacteria which are in the gut of the tick, and thereby essentially eliminating or inactivating those bacteria, and perhaps also doing something to the tick.

But it is not anticipated this will be significant in its capacity to protect you once the bacteria enters your system. I have questions in that context about the durability of the vaccine as protection, and I would argue that even if you are vaccinated you should continue to --

SENATOR PETERS: Take precautions.

DR. KRIDER: -- you know, take all

precautions that you've been taking that these are probably important, effective prophylactic approaches to keeping yourself well also.

SENATOR PETERS: Would you take the vaccine?

DR. KRIDER: No.

SENATOR PETERS: Thank you.

(Laughter.)

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you very much, Dr. Krider. Thank you for being with us today.

We're going to hear from a panel of Christopher Montes, Caroline Cramoy, and Karen Vanderhoof-Forschner. Would you come forward, please?

I also want to apologize in advance to both the speakers and the audience. I apologize very sincerely that we have, as all of you know, a big subject to cover and we're trying to do it in a relatively short time. A day -- a full day of hearings in the legislature is a somewhat unique event, but even a day of hearings in the view of many of us may be inadequate to do justice to this subject, so we may need to have another hearing. But for now, we're going to try to move fairly quickly, expeditiously through the speakers that we've scheduled, especially because we want to hear from members of the public who have come forward. Thank you.

Go ahead.

DR. MONTES: For the record I am Christopher Montes of the Unionville section of Farmington. I'm a nationally certified

psychologist, and I'm employed by the City of New Britain and the Connecticut State University system.

Attorney General Blumenthal, Commissioner Reider, fellow panel members, legislators, and patients stricken with Lyme disease, thank you for giving me the opportunity to share my story of infection with Connecticut's namesake illness. My hope is that by enlightening you with the facts of my personal tragedy, you'll be more able to fully understand the necessity for taking this disease as seriously as cancer and as much as a public health threat as HIV.

Moreover, it's my sincere desire that Connecticut, as a leader in academic research, most affluent state in the union, and insurance capital of the world, might set a course of study and investment to cure this insidiously chronic infection while at the same time assure its residents and those out of state who are insured by Connecticut companies that they will never again be denied the antibiotic treatments that their doctors prescribe.

My own story begins with a move to

pursue further education in Connecticut some 19 years ago. As an avid outdoorsman, backpacker, rock climber and fisherman, I was aware that ticks could be a problem and were known to carry Rocky Mountain spotted fever as well as the newly named Lyme disease, mistakenly thought to be only endemic to shoreline communities.

However, like most, I was told that Lyme disease was a summer flu-like illness that was curable with a couple of weeks of antibiotics. Also like most, I had implicit trust in the medical system of diagnostics, treatment and insurance coverage, and I believed what my doctor thought was best would be done for me.

I was wrong on all counts. I was wrong to think that Lyme disease was benign, wrong to think it was easily diagnosed and treated, and especially wrong that my health insurance company would pay for the medically necessary care that this disease required. All of the misconceptions, and primarily the last that led to ongoing infection which racked my body, scrambled my mind, and strained every domain of work relationships and professional

pursuits I could ever possibly have.

In late summer of 1987 I found a tick attached to my knee while fishing in Old Saybrook. I pulled the tick out, I was treated within a few days with penicillin for a couple of weeks. A couple of years later, I removed other ticks from the back of my head and shoulder area immediately after fishing in East Haddam. I had no reason to believe they were attached long enough to transmit Lyme disease, but now I know that improper removal can cause transmission once the tick is attached, even after a short time.

In the meantime thereafter, I had often picked ticks off of my clothing while recreating outdoors in Connecticut and the nearby islands of Massachusetts and Rhode Island. After a few years of strange knee soreness, unexplained heart palpitations, in August of 1993 I had a very bad sore throat, sore left jaw, facial pain, debilitating fatigue, night sweats, fever, swollen glands, vision problems, forgetfulness, cognitive difficulties, violent body twitches and profound dizziness.

This lasted many months and progressed into a terrible depression and panic

disorder that rendered me unable to work regularly. I felt physically sick, as if I was losing my mind. As a psychologist, I knew that there was no rational explanation for the psychoemotional problems, but thought that the physical difficulties might somehow be connected.

All along from that August of 1993

until November, I sought medical attention and was initially given the following possible diagnoses: Ear infection, sinus infection, allergies, strep throat, deviated septum, benign positional vertigo, TMJ, postconcussion syndrome, brain tumor, depression. I had numerous CAT scans and an MRI and serologies, all of which came up with nothing specific other than continuously positive strep tests and a sinus thickening that was not seen as causal of all the discomfort and emotional trauma I was experiencing.

I was however placed on some short-term antibiotics as well as Prednisone and a steroid nasal inhaler, yet nothing seemed to work.

Then sometime that fall I began to

have irrational thoughts, they were obsessive, intrusive thoughts, strange and often violent, homicidal. I felt as if I was possessed by something that was not of myself. I not only felt sick but I truly felt crazy. Again, as one trained in the scientific study of the mind, in my moments of sanity I knew there was something not yet diagnosed by the specialists my primary care had sent me to. However, I could not think clearly enough to advocate for myself to the level I was accustomed to providing on behalf of my clients when necessary.

The violent obsessions and depression continued, and I cannot render the true nature of the homicidal tendencies as I wish to keep the privacy of my family intact. Suffice it to say I was crazy and I knew I was. I thank God I never acted upon any of the voices in my head that played over and over. Instead I would try to calm my head, drive in anguish and pray to die. It seemed as if I would never get out of the hell that I was experiencing.

In November, I was given two Lyme disease serologies at the suggestion of an acquaintance who I had rather serendipitously

met. He said he was diagnosed by a Dr. Schoen as having Lyme disease, and I had many of the same symptoms, though not to the same extent.

In fact, I tried to find Dr. Schoen in his old place of practice in or near Old Lyme, but was told he had moved on to Yale, so my primary care physician did the first Lyme serology, followed by an infectious disease specialist in New Britain. Both serologies were borderline for Lyme disease, and the doctors were still not convinced that the physical and emotional plight I was going through was caused by Lyme disease. They did not tell me that there were numerous studies proving prior steroid and antibiotic treatment would aggregate the body's immune's response or titer to Lyme disease, thus making the positive serology nearly impossible to produce.

Nonetheless, the infectious disease doctor decided to treat me with high doses of oral antibiotics. The next two weeks were amongst the worst I had ever experienced, all of the symptoms I had ever had and even more were at the height that was totally unbearable. I remember on the particular day of Thanksgiving

of 1993 it was the worst day of my life. If I had the means, I would have taken my own life, and that was a physical phenomenon known as a Garrish Hercksheimer-type reaction to the antibiotics where the Lyme disease cause -- the antibiotics cause the Lyme disease to break apart, which makes the body try to fight off this disease even harder. The effect is heightened symptomology, which has been reported as even fatal.

Yet I now know this response was proof of bacterial infection and its partial die-off. Proof of this reaction is found in several medical articles and physician descriptions.

After a few more weeks I sought out a physician who was recognized as one competent in treating Lyme disease. I saw him and was advised to stay on the protocol I was currently receiving. However, except for a few hours of relief now and then, I really wasn't getting a whole lot better, so after a month or so, I switched types of oral antibiotics and went through the same type of Garrish Herchsheimer [phonetic] reaction again, and then after a month

the orals topped off.

I was then placed on intravenous

antibiotics, where I experienced another Hercksheimer [phonetic] reaction, this time many of the neurocognitive, neuropsychiatric symptoms abated. After a couple weeks I began to feel somewhat better and even planned a vacation once the disease was over. However, that was cut short by my insurer, Constitution Healthcare, an affiliate of Blue Cross and Blue Shield of Connecticut.

An ambiguous policy of four weeks of I.V. therapy was put into effect, and despite my doctor's numerous calls, letters, faxes, et cetera, the policy was upheld. However, at the last minute an extension of two more weeks was granted due to political pressures exerted by my U.S. Congresswoman and by a State Senator, both of which I happen to have prior relationships with. That final two weeks of antibiotics would be the best I would feel for some time to come.

After going back on oral antibiotics, I deteriorated rapidly, and after a few weeks I was back to the point prior to beginning I.V. treatment. My doctor desperately

tried to convince the insurance company of the medical necessity to restart I.V. medication, but his requests were again denied and even ignored, when Constitution Healthcare actually refused to accept his faxes.

I was left with having to spend my savings and borrowing money to get back on I.V. treatment that my doctor prescribed. Friends even organized a fund-raiser to help defray the costs and extend the treatment until I could switch insurance companies. And when I did switch, Blue Cross and Blue Shield of Connecticut became my employment-provided insurer, promising beforehand that the criteria they used to overview my case would be different.

This was untrue, and it's the same medical team of nurses and medical director of Blue Cross/Blue Shield that reviewed my case and continued the denial of treatment benefits. In fact in a strange twist of events, in time some of my medical records were sent out by Blue Cross/Blue Shield for third-party consultant review -- or rather numerous reviews by the same physician I had once sought out, Dr. Schoen.

His reviews of those records

culminated with his opinion that if I did ever have Lyme disease I was no longer infected and no longer in need of any antibiotic treatment, I.V. or otherwise. This opinion was in direct opposition to a third-party consultation and full physical examination I had had by Dr. Sam Donta, a professor of molecular medicine and infectious disease at Boston University.

He agreed with the Lyme disease diagnosis, stating the antigen therapy was still needed. Dr. Donta was not however a consultant of Blue Cross, and thus his diagnostic opinion was ignored.

Fortunately there was a backup major medical insurer, Prudential, which paid for some more I.V. treatment. But after several denials and appeals, I was denied. It got substantially worse.

Oddly, during the whole insurance nightmare, I had applied to Blue Cross and Blue Shield subsidiary, Connecticut American Life Insurance Company, and I was denied life insurance by that Blue Cross/Blue Shield affiliate due to, quote, "a history of Lyme disease," end quote.

Thereby I was unable to access medical coverage for a disease I supposedly didn't have, yet could not obtain life insurance from that same company because of the disease.

Please keep in mind that Lyme disease is described as a treatable illness, quote, "rarely if ever fatal," end quote, according to the CDC's new guidelines for the new LYMErix vaccine which you heard about a few moments ago and certainly not able to withstand the antibiotic regimen I've already received, according to insurance consultants.

After once again switching insurers that my employer provided, I was once again able to receive and benefited from intravenous antibiotic therapy. However, that insurance carrier, ConnectiCare, ultimately even denied oral antibiotics with no appeal allowed. Its medical director doubted that I even had Lyme disease, and called me personally to tell me my treatment was no longer going to be paid for. He followed up with a letter stating that I had no appeal and that his decision was final.

This broke ConnectiCare's own policy and those set forth by the Connecticut

State Department of Insurance. There was nothing the Insurance Department could do, however. At least that's what I was told.

Most recently, two new physical findings have emerged in my case. Recently I was given a test for babesiosis. Babesiosis is a tick-borne disease caused by a parasite that is similar to malaria. The organism quite often travels in the gut of a deer tick, along with a Lyme bacterium and other microorganisms.

I tested strongly positive for babesiosis, in fact my immune system shows evidence of a long-term infection. It, like Lyme disease, can be deadly. I was treated for the disease, and it will take some time to determine if I still carry that organism.

This is absolute proof of a tick bite, and is even more rare than Lyme disease itself. The question is how can I have the secondary disease, yet according to insurance companies, not have the Lyme disease? The answer I propose is a financial one, especially considering the next finding.

My blood was cultured for Lyme

disease using the new procedure developed by

Dr. Steven Phillips and his research colleagues. This research already had been published in Infection, a prestigious international peer review medical journal. The culture of my blood revealed live Lyme disease spirochetes despite the oral antibiotics I was on at the time of the culture. More proof of ongoing infection, especially as I was highly symptomatic at the time, and not on antibiotic -- intravenous antibiotic for several months.

So what's the point? Intravenous antibiotics quite often are the only hope for some patients with chronic Lyme disease. There have been only a few studies involving long-term intravenous antibiotic treatment juxtaposed to oral treatment. However, if their conclusions had favored the intravenous -- their conclusions had favored the intravenous treatment.

Moreover, physicians' notes from hundreds if not thousands of patients with chronic Lyme disease show the efficacy of long-term intravenous treatment over oral treatment. There is no doubt which one works better and no doubt of the many individuals that have been -- that have been cured with long-term I.V. treatment. The only doubt there has been is will the insurance companies pay for it.

In closing, I wish to read a letter written four years ago by Dr. Sam Donta to Dr. Martina Ziska, and its message is quite poignant.

"I've been investigating and treating cases of Lyme disease since 1988. As chief of infectious diseases at the University of Connecticut Health Center, I set up a Lyme disease clinic there. After moving to Boston University in 1993, I have continued to evaluate and treat patients for Lyme disease. My resultant experience has shown that courses of treatment of one month for treatment for chronic or late Lyme disease is insufficient to eradicate or significantly improve symptoms. Three months of treatment appears to be a minimum time period needed to improve patient symptoms and prevent relapses."

Minimum time period.

Not a standard.

And it's my own -- "It is my opinion that patients have been denied therapy beyond the first month because of concerns of

third-party payers for the cost of such therapy. Blue Cross/Blue Shield of Connecticut has been especially rigid in their view, especially as there are no data that can support their view. I have tried to enjoin them in supporting clinical trials to prove or disprove the hypothesis that longer courses of therapy are more beneficial than is a one-month course of treatment, but they have shown no interest in these studies.

In the interim, they have denied therapy to at least four of my patients and I have heard of numerous other cases in which therapy was denied. I believe that until it is established that longer term therapy is not beneficial, physicians should be allowed to use their best judgment in treating patients."

Let me say that as a patient with active Lyme disease and many -- and many documented neurocognitive manifestations I face for my future, I know that unless my doctors are allowed to treat me with the best possible care, I will continue to get worse, much worse.

With thanks to the Attorney General and his staff, as well as my employer, the City of New Britain, I just started

antibiotics intravenously about three weeks ago, and this is after being on orals alone for a year and a half. I've already experienced a difference. The symptoms that come and go have lessened in intensity, and I'm able to work somewhat more productively, and without this care I may have never been able to beat Lyme disease.

My plea is to let my doctor be my doctor. My insurance company exists to pay for necessary treatment that will make me better, not to call arbitrary shots of overruling sound medical decisions solely based on profit. Lyme disease is too new a discovery to pretend that we know all the answers.

What we do know is that patients such as myself and those in the audience are here because we want our lives back. We are infected, not addicted. We have entrusted our insurance companies to help with the antibiotic treatment that we need, and in many cases, they have failed us. Now we trust the very entity which oversees those companies. We beg for mandating coverage of our treatment until we are either cured by that treatment or until we are cured through the use of new research. And we beg you, beg you for

our health.

I want to thank you again for the opportunity to speak and make myself available for your questions.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Ms. Cramoy?

MS. CRAMOY: My name is Caroline Cramoy. I'm a nutritionist by profession. I received my Master's degree from the Human Nutrition Institute at Columbia's College of Physicians and Surgeons and a Bachelor's degree in zoology from San Diego State. I am the mother of a Lyme patient, not a patient myself.

AUDIENCE: Do you have a microphone?

MS. CRAMOY: It's there. I need to be louder. Sorry.

I'd like to thank Attorney General Blumenthal and Commissioner Reider and their staffs for the effort to understand and resolve this very difficult issue that has developed around Lyme disease and the health insurance

coverage. I hope that today's hearings can prove to be a forum for breaking down barriers rather than an exercise in building higher ones.

I'm a Lyme disease advocate not by choice but by necessity. Only by arming myself with accurate in-depth knowledge was I able to identify the doctors who also had accurate in-depth knowledge of the disease or who were willing to learn.

Now, although it appears that my daughter has -- may have beaten Lyme disease after a four-and-a-half-year battle, I remain on the front lines because of moral and intellectual outrage. I am appalled by the lack of scientific honesty, human compassion, and basic integrity which we have encountered as we struggle to find a correct diagnosis and then the right treatment for this very complex disease. I hope that my background as a scientist and health professional will allow me to help others as they seek answers to their questions about this illness which destroys lives.

My daughter Samantha is one of the lucky ones, one who has been able to move on with her life and can look back on her Lyme disease

ordeal as an experience that robbed her of her teen years, caused her much pain, both physically and emotionally, but in the process honed her to be a truly strong and empathetic person.

Though we are fully prepared for the possibility of a relapse of this dreadful disease, we are nonetheless hopeful that Samantha has really been cured.

My testimony, written testimony, contains a concise description of the development, diagnosis, and treatment of Samantha's disease. It's not unlike the stories of hundreds of other Lyme disease sufferers.

Samantha was treated early with two short doses of antibiotics, therefore never tested positively on the standard immunological test. She was then not properly diagnosed or treated for a period of months. Her symptoms fit Lyme disease and were very severe and disabling. She had laboratory confirmation of Lyme disease from Stony Brook, her disease was unresponsive to oral antibiotics due to her failure to attain therapeutic serum levels with oral medication.

It was strongly responsive to I.V. antibiotics, and then would relapse within days

when I.V. antibiotics were stopped too soon. She eventually became well with successive courses of long-term antibiotics carefully picked and monitored by her primary care physician and a Lyme disease specialist.

The end point for the last two therapies was eight weeks after becoming symptom-free. Our current insurance company, Oxford Health Plans, has refused to cover the $40,000 cost of her last I.V. course, despite the fact that it was successful and she has now been symptom-free for 18 months.

The appeals process for this has been long, frustrating, and totally controlled by the insurance company. Each stage of denial has brought new reasons for the denial, many reasons blatantly inaccurate, including the infamous not medically necessary. This is a child who was about to drop out of college because she was so sick again on relapse. She had missed a year and a half of high school when she initially had the disease.

We are trying to get reimbursement for successful medical treatment which we were fortunate enough to be able to afford. For most,

the option is never there to go ahead with treatment without promise of repayment. For some the option is available only if they are willing and able to mortgage everything they own. People are being permanently disabled, losing their capacity to earn a living, made to suffer constant pain because insurance companies are refusing to allow physicians to treat patients with therapies that could allow them to live normal lives.

Whether Lyme disease can be cured with long-term antigen treatment has not been proven in the scientific literature, but it has been done in case after case in actual practice that long-term antibiotic treatment can allow many people to live normal lives with no Lyme symptoms.

Until science develops a test that can incontrovertibly prove the presence or absence of the Lyme bacteria in all the nooks and crannies of the body, the determination of whether or not these people are cured will have to wait.

A majority of patients who have made the effort to attend this hearing are those

that have not yet found a cure. They are people begging for the medical and insurance communities to help them in their battle with their disease, rather than to deny its existence or pronounce it as incurable.

I and others have brought additional written accounts of patients who could not be here, people from all over the country are suffering because Lyme disease is being misdiagnosed, mistreated, and being disallowed.

As one of my favorite T-shirts declares, Lyme is a political illness.

Clearly scientific egos, struggles for grant money, and lucrative consultation fees paid by insurance companies who benefit for the continued dissemination of the overdiagnosis, overtreatment party line, have blocked speedy progress and understanding in many twists and turns in diagnosing and treating Lyme disease.

The financial and legal environment of the health insurance industry today has encouraged automatic delays and denials and the active seeking of experts willing to legitimize withholding of coverage. The relationship between academic Lyme disease

researchers and the HMOs must be carefully assessed to determine if it has made it difficult for open, honest research to flourish.

If researchers at the major universities are receiving very healthy fees for saying more than four weeks of I.V. antibiotics is not standard medical practice, it is unlikely that they will design sound research to disprove that statement.

I am amazed by the shortsightedness of the insurance companies in their dealings with Lyme disease. It has been stated by all the experts on both sides of the Lyme fence that early, effective treatment is the best way of preventing chronic Lyme disease with all its costly and crippling complications.

One of the primary principles behind HMOs is supposed to be that properly delivered preventive healthcare and properly managed early and effective treatment of illnesses can save healthcare dollars.

I also find it outrageous that our insurance company can arbitrarily disallow the considered opinions of two well-respected board certified doctors who spent four years evaluating

every aspect of our daughter's case and declare that the treatment prescribed by these intelligent caring doctors was not medically necessary.

Oxford's medical director has never met nor examined my daughter. He has justified his decisions with the generalized statements of doctors who also have never examined my daughter and who are paid to consult on insurance cases precisely because the opinions they express save money for the insurance company. This is a truly nefarious, symbiotic relationship.

Insurance companies have also taken advantage of the federal ERISA laws which make them immune from lawsuits for failure to grant benefits and allows them to delay payment for medically appropriate claims and use the float on such withheld funds without any penalty. It's a true no lose situation for the insurance companies. They have taken a law designed to protect consumers from excessive healthcare costs and have turned it into a federal license to steal from people in their time of greatest need.

Lyme disease is just one of many illnesses where insurance companies are being allowed to compromise the well-being of the American people in pursuit of their own bottom line. Legislators must close this legal gap.

Though I support reasonable control of the number, type, and size of lawsuits which can be brought, there must be some way of assuring that it is not so economically lucrative for HMOs to delay coverage decisions and to routinely deny coverage and wait for appeals.

A mandatory 1 1/2 percentage requirement such as we all pay on credit card debt, for any delayed claim payments and a set percentage penalty in cases of denied coverage which the courts later rule should have been honored, might be a place to start.

Our insurance company has sought to dictate the type of antibiotic used, the method of delivery, the duration of treatment, and even the need for treatment without ever seeing our daughter in person. They have refused to respect and support the judgment of one of their own network's primary care physicians, proving they see the primary care physician

system as just one more way to force money to their bottom line.

If our daughter's doctor were ever

to recommend I.V. therapy again, we would find a way to pay for it. We have seen the downside of this disease. We have seen the pain, the physical disability, cognitive disability, and the psychological devastation. We would do anything we could to protect our daughter from that suffering and the permanent physical and neurological damage that can accompany it.

But health insurance is designed to protect families from financial devastation. Our insurance company has certainly fallen down on that count. Because we were able to find the right doctors and afford the right treatment, Samantha is living a normal life. She will graduate in May from one of the most demanding colleges in the country. She is skiing, jogging, working on an ambulance crew and just passed the medical college division test with flying colors. These treatments were definitely effective, medically necessary, and successful.

Oxford Health Plans, the health and healing company, should be proud to be part

of the healing of this young woman.

Thank you.

ATTORNEY GENERAL BLUMENTHAL:
Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Ms. Vanderhoof-Forschner?

MS. VANDERHOOF-FORSCHNER: Yes. I have the written documents that go along with my testimony.

ATTORNEY GENERAL BLUMENTHAL:
Nobody has to feel, by the way, bound to follow the written testimony that you've submitted.

MS. VANDERHOOF-FORSCHNER: I cut my down like really significantly so I can get to the end.

(Laughter.)

ATTORNEY GENERAL BLUMENTHAL: We don't want to discourage anyone from following their written testimony. It's your show.

MS. VANDERHOOF-FORSCHNER: Okay.

I will try to be brief. I also want you to know that I have taken the liberty of providing documents to support everything I've said and in the testimony, in the testimony it has references to all the documents, and you all have a copy of this.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

MS. VANDERHOOF-FORSCHNER: I'd like to thank you all and the good people here today and the people who have sent in material. Good morning. I am Karen Vanderhoof-Forschner.

I have always appreciated the vital role insurance plays in providing financial security to millions of people, I grew up in an insurance family. My dad was an actuary and cofounded an insurance company and after a distinguished career has retired as senior vice president at Equitable Life. He is now a professor of finance at NYU. I am proud to follow in his footsteps.

My career spans 25 years in the insurance and allied health fields. I've possessed a professional designation CLU and CPCU. I have held positions with insurers and am a published author. I coauthored the article Lyme Disease Costs To Society. I am past president of the Society of Insurance Research. I have an MBA and author the book "Everything You Need to Know About Lyme Disease."

The history of Lyme spans over 100 years and several continents. What we call Lyme disease was first described in 1883, joint involvement was described in 1921, and the research debate has been ongoing ever since.

In 1970, the first U.S. case was published by a Wisconsin physician. The first clustering of cases occurred in '76 by doctors at the Groton sub base. In 1982, LDF, founding board member and NI researcher Dr. Willy Burgdorfer, discovered the causative agent of Lyme disease.

In '85 I contracted Lyme disease while pregnant and transmitted the infection to my unborn child Jamie. My life was forever changed.

In July of that year, Jamie was born and in July of that year, the first article of maternal fetal transmission of Lyme disease was published. Jamie became multihandicapped and eventually died in '91. He and I had positive tests. When Jamie received antibiotics, his condition dramatically improved but he was never cured.

On autopsy, pathologists found the Lyme bacteria in his eyes.

I will skip over our issues with insurance coverage and medical care.

In '87, I attended a Lyme conference. I was surprised to discover a polarized scientific community. The lack of camaraderie, clash of egos, and competition for limited research funds was disturbing. However, I did find a core of compassionate, cooperative researchers who wanted to start a nonprofit organization dedicated to Lyme disease. They were seeking a scientific forum to present a range of differing research results, conduct vigorous debate, maintain friendships and support colleagues' research.

These people believe Lyme disease was serious and pervasive and have the research to back up their assertions, so in '88, my husband and many others worked to establish the

Lyme Disease Foundation. I chair the board of

directors. Our focus is education, research, and advocacy.

The LDF's web site receives over 300,000 hits a month. We conduct medically accredited conferences, publish a peer review journal and have produced two award winning TV programs. I am a full-time volunteer.

In '97, LDF received an award from the National Institutes of Health for outstanding education. The LDF is a realist. We keep the door open to the differing viewpoints, not something that everybody wants.

There have been over 120,000 cases of Lyme disease reported today by the 49 states. In 1990, the LDF Society of Actuaries and Stern School of Business conducted the most extensive survey of chronic patients. We now have 2,000 patient questionnaires in our database. This study showed that Lyme disease caused society over $1 billion per year. This is the cost of misdiagnosis, not overdiagnosis, and patients take an average of five physicians to be diagnosed.

Patients lucky enough with the telltale EM rash that you hear about with Lyme

take an average of five physicians to be diagnosed. The hallmark rash doesn't help in the diagnosis. 20 percent of newly diagnosed cases are serious enough to need intravenous antibiotics, and this study also provided other information. Early diagnosis and adequate treatment decreases insurer costs dramatically.

Insureds' experienced both lost income and medical expenses, and significant noncash losses are common. We are a society that plays catch-up with diseases. In this and all other diseases we need to play prevention, early diagnosis, and treatment.

In 1995, I met with the Insurance Department and the Blues to find a middle ground to insurance denials. The meeting turned from a negotiation, which never occurred, into a simple one-sided Blues consultant presentation. The meeting ended and nothing changed.

You see insurers are powerful financial institutions with a fiduciary responsibility to cover necessary medical care for insureds. Their medical consultants are often well-funded physicians. Patients with serious illnesses hang by a thread, knowing one

serious medical episode can and often does bankrupt them.

The LDF has even witnessed cases where medical treatment is approved, continues for weeks, and then the insured declines reimbursement, forcing both lawsuits and bankruptcy.

You see, if insurers had to pay for all of Lyme disease diagnoses and treatment and told there was a perfect test, I suspect economic finances would be shifted towards funding research to find a perfect test. Maybe we would have one by next year.

In '92, things started to rapidly get worse and the LDF was swamped with insurance complaints. Companies that year started hiring experts and were increasingly declining coverage. That was also the year that a consultant went to the American Academy of Insurance Medicine that has all the insurers' medical directors in attendance and wound up presenting on Lyme disease in a very closed viewpoint.

You see, shifting costs from one disease code to another doesn't decrease total

costs. What it does is decrease costs coded to Lyme disease.

What it still does, is patients still suffer and they still doctor shop, they still incur expenses trying to find someone who can make them better. There are medical protocols and published articles to prove that short-term treatment doesn't cure everyone, and they prove that the tests are not perfect.

I would consider a variety of questions, and most of them concentrate on financial and practice disclosures in terms of what insurers should do. I've listed them down, I'll go to them at the end. I'm afraid I'm going to run out of time.

You see not all insurers are bad guys. There are some that are quietly providing coverage and case management for their policyholders. I do feel the need to mention M.D. Health Plan. M.D. Health Plan did something that I thought was exemplary. They wound up saying two years ago, we want to educate our insureds so that they can prevent Lyme disease, and they sent out to everyone in their network a brochure on Lyme disease.

The following year, they came to us and said, we'd like to produce a brochure on tick-borne disorders. We want to do prevention, we want to get ahead of this.

You see the debate is really between two schools; the gatekeepers and the realists.

The first is a dogmatic, gatekeeping belief that only certain researchers know the truth. These elitists feel an obligation to stop those with opposing views in order to protect the public. Gatekeepers believe that Lyme disease is easy to diagnose and treat. They have a my-test-is-perfect mind-set and claim overdiagnosis when patients with positive test just negative in their labs.

They avoid conferences that

challenge their views and can honestly say in court they are unaware of information stating otherwise.

The realists now accept there is no perfect test that can prove infection and then prove a patient bacteria-free. Because of that, science doesn't have all the answers, therefore diagnostic and treatment decisions are a complex, private matter between the doctor and the patient.

Realists know persisting infection despite treatment does occur. But it's not always the explanation of persisting manifestations. This is a viewpoint of the LDF. This is the reason why the LDF has never adopted a diagnosis or treatment protocol, but we believe the door, the gatekeeping, should be open.

Intellectual differences are to be expected as our understanding evolves. However, some gatekeepers have made it their mission to ruthlessly go after individuals who think outside the box. For some gatekeeping -- for some keeping the gate closed is their personal war.

Patients are the casualties.

Gatekeepers not only block individual access to medical care, they also block doctors' right to treat and better yet, to cut out a problem doctor who incurs expenses than to cancel them with the insurer's plan, or better yet, haul them in front of the medical licensing board.

Even more disturbing is that some researchers resort to personal, professional,

behind-the-scenes smear campaigns, mocking patients even at medical conferences, accusing colleagues of overdiagnosing or overtreating for personal profit or spreading rumors about patients' confidential medical records. It is this type of action that proves this is not a debate about science. This is a debate about power, and I have some examples.

In '93, based on secondhand anecdotal reports, a local physician reported a colleague to the medical licensing board because he felt the colleague was overtreating patients with long-term antibiotics and profiteering. The accuser even volunteered to set up bogus sting operations and rehearse a pretend patient. Surprisingly, this resulted in a real investigation of the suspected wrongdoer and cost him thousands of dollars to defend himself and almost cost him insurer HMO affiliations.

Despite being found completely innocent, he closed his practice to new patients and shifted those Lyme patients to others. The atmosphere was just too nasty. Why the licensing board took this seriously I don't know, but I can tell you this, if I was a doctor, I would not

report a case of Lyme or let others know I was treating them.

I too have been the recipient of attack by gatekeepers. My son, who had Lyme disease, was in several hospitals, at Hartford Hospital and at UConn. They had copies of his positive test. However, I kept hearing rumors from media that some doctors felt my dead son didn't have Lyme disease, and that these anonymous sources had reasons to know.

For years I didn't ever find out where this information came from. I have the positive tests in my hand. Why was it always that I claimed he had Lyme disease? Who was it out there that had better knowledge than his own mom? Now I find through court documents that a Dr. Gerber, who is affiliated with these hospitals, has appeared to breach doctor-patient confidentiality in his zeal to smear my dead son's, my, and the LDF's reputation. I have copies of this in the material.

He maliciously misrepresented Jamie's condition and his last days alive. Jamie died in a hospital in another state seeking care from an out-of-state doctor. But this particular

doctor felt qualified enough to present a long-distance expert opinion on the cause of Jamie's death at the National Institutes of Health.

But the smear campaign continues. In January, just a couple weeks ago, he presented a talk on Lyme disease to the American Academy of Pediatricians. Through a combination of speech and slides -- and I have the documents from the people who were there -- he then again portrayed the LDF as a noncredible source disseminating this information.

This is not the way scientists should behave. If he has intellectual differences in science, he should come to us. He should write a letter to the editor of the journal or something.

His hostility dates back to '89 and '90 when our son was on life support at Hartford Hospital, and Dr. Gerber insisted that the intensive care unit doctor arrange a meeting with Tom and me. Dr. Gerber insisted he needed to break into our grief to talk about something urgent. What he wanted was for help from us to get him an NIH grant to experiment on congenital

Lyme disease babies. He wanted to treat -- not treat the other half, find out the difference in outcome for the two groups.

We were horrified and we refused to listen any further. We offended him greatly by telling him how outraged we were, but the big surprise came from a Yale researcher, part of their dream team.

In '95, Derlin & Fish, in an

E-Mail to NIH expressed concern that LDF's journal, quote, is not going away and it cannot be ignored. He was concerned he would have to cite articles published in this journal, articles he didn't like because he was on the opposing side.

Lyme disease in Australia had been under investigation for years but in '94, two articles were issued and distributed at the same conference in Italy. However, these two articles were opposing viewpoints from competing Australian research groups. Derlin assisted with one of the articles. The LDF published the other saying that Lyme was in Australia, and he was mad. He was also concerned with an article on short-term transmission of Lyme disease, which is

an issue in debate that he disagrees with.

So he suggested to this NIH employee that he or others submit a bogus article in the LDF journal which would have seriously harmed its reputation. Derlin never used the normal channels, the scientific channels of submitting a letter to the editor voicing his opposition. He just slammed us. Indeed he wanted to do harm behind the scenes, letting the Yale affiliation give him credibility.

The same year Derlin suggested that Yale should set me up to fail by inviting me to speak and then letting me, quote, expose myself. He says he is planning an approach to discredit me and then arrogantly says, quote, let her sue Yale and the concept of academic freedom. This proves that it is not about science, it is about gatekeeping and power.

In late '94, Derlin's second Lyme disease nonprofit -- his first Lyme disease nonprofit competing with us had failed. His second Lyme nonprofit that was established to him primarily to counter the LDF's science is now -- was now failing. And apparently Fish resorted to smearing the LDF by saying in medical meetings,

and we have these documents, that our son didn't have Lyme. If Karen is lying, her son doesn't have Lyme, the foundation is no good, and they are presenting misinformation.

When I heard about this accusation I approached Derlin and provided him with the correct information, but it made no difference.

The most appalling document smearing the LDF which is in here is now part of court documents. This document, on Yale letterhead, indicates the vicious nature and arrogance of the author. It accuses the LDF of many things, none of which are true and he knows it. But they managed to inflame the scientific community.

Amongst other things he blamed me for was organizing a Yale protest. We didn't. He knew it, the organizers took credit. Controlling science in the journal, we didn't and we haven't. We're not scientists. And he claims to be keeping a file on me that he would happily share with others but he hasn't shared it with me and he hasn't come to me for information.

These are the people in Lyme disease. What kind of scientist is this? How

does Yale operate? Well, there are many good, wonderful doctors at Yale that we deal with. This just happens to be a representation of what these patients and what I am facing.

Even more telling are his comments

about being the opposing expert witness in a court case where he lost, where the attorney was our board member. He has never contacted us about these issues. This is the political situation that is driving. These are the dirty little secrets we and others haven't told you.

But back to insurance, what is the solution? I'm told there is a perfect test. Insurers should take a balanced approach with patients. Patients should be allowed to seek a second opinion. The insurer should then honor the recommendations, especially if there is support for it in the medical literature.

Medical licensing boards should let physicians know they will no longer be subjected to attack because of the way they diagnose or treat. Insurers should disclose who their expert consultants are, how much they are paid and how many times these consultants have ruled one way or another on a particular issue.

And that's a rule not only with them but with the other places they consult.

We even have heard that some

consultants make six figures on the side from the regular job just by consulting to insurance companies.

Since education about prevention and early diagnosis is critical, we would welcome any of these insurers to come forward with us. They could get brochures out. They could get posters on -- they could get posters and send them out to doctors in the state to help encourage early diagnosis and treatment, because the EM rashes are no longer what they used to be.

We will always stand. There needs to be a clear message sent by the Insurance Commissioner and Attorney General that patient rights and access to care should be protected. Abuses should be vigorously investigated. Companies that are doing good should somehow be rewarded other than by saving money. We will always stand tall with those that want to find solutions to Lyme. It just shouldn't hurt so bad, and we, I, should not be subjected to such

attacks on a regular basis.

I thank you for the opportunity to

speak here today. If you have questions on the preview test, on the vaccines, if you have questions on -- we helped this test find funding at the very beginning. We helped Donta get involved, the doctor here, get involved in Lyme disease.

We've helped protect the doctors that were under attack. We think it should be a live and let live situation.

And I'd like to say on the cases of Lyme and the rise of it, what you see in 1988 on the graph earlier where Lyme disease really took off, that was when we started. The first thing we did was go on 20/20, Nightline, Geraldo, which was our highest doctor education program.

We had more doctors contact us because of that than any other effort we have ever had, doctor rounds during that time. I would welcome working with anyone at any time, even the people who have attacked us, to find solutions, and thank you for being patient enough for me to get through this.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much for being here.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: I would like to thank all three members of this panel for sharing with us your experience and your insight, which has been extraordinarily valuable and we will be back in touch with you.

For now we are going to take a brief break and then come back with the next panel after we're done. Thank you. We'll be back in about 10 minutes. Thank you.

(Recess taken.)

ATTORNEY GENERAL BLUMENTHAL: Our next panel will be Dr. Eisenberg, Edward Eisenberg, and Dr. Federico, John Federico, welcome. Thank you for being here.

DR. EISENBERG: Thank you very much for inviting me and for providing this forum for this discussion.

My name is Dr. Eisenberg. I'm a medical director at Oxford Health Plans and I am responsible for the infectious disease management programs.

ATTORNEY GENERAL BLUMENTHAL: They cannot hear you.

DR. EISENBERG: I will speak up and -- is this better? Are you able to hear me better?

ATTORNEY GENERAL BLUMENTHAL: Yes.

DR. EISENBERG: I attended medical school at NYU in New York City, and while there, I learned that among other diseases and disease processes that there were some people who suffered from chronic debilitating illnesses which were characterized by difficulty thinking, general body ache, muscle ache, joint pains, occasional fever, and lymph node swelling. And that many of these individuals could not be diagnosed as having any particular illness, but that the diagnosis that was attached to many of them was infection with another bacteria called grucella, and the diagnosis of chronic grucalosis was made and treated with little success.

By the time I entered my residency at Albert Einstein College of Medicine in the late seventies, the diagnosis that was given to many of these individuals, especially ones who were having central nervous system difficulties, was one of hypoglycemia; that is to say that at some point during the day, possibly just before or possibly just after a meal, their blood sugars would sink very low and they would suffer body aches, joint pain, difficulty thinking. The remedies for this were changes in diet, sometimes medications, and attempts were made to diagnose and address this problem.

By the time I entered my fellowship and then during my academic years as an attending at Einstein, this diagnosis was largely disbanded. It had been discredited and researchers announced that the diagnosis for many of these patients was infection due to a virus called the Epstein Barr virus.

The Epstein Barr virus is clearly a very prevalent virus in the world and in our community. It causes acute mononucleosis, and there was some evidence that prolonged infection with Epstein Barr virus in fact was responsible for the illness that I've described in some patients.

Diagnostic tests were developed. Therapies -- varying therapies were administered and some success again was claimed. However, by the early nineties, this diagnosis too was abandoned and again, people, mostly with fatigue and central nervous findings with sometimes joint ache and fever and lymph node swelling, were now thought to have infection with a yeast called Candida.

The diagnosis of chronic candidemia was made in the lay press. This was popularized as the yeast connection. Diagnostic tests were developed, diet therapies and antibiotic therapies were administered, and again claims of success were made.

This diagnosis, however, did not last very long because a relatively new diagnosis of an illness that clearly does exist, Lyme disease, is now the one that's being applied to many of these individuals. And as a private practitioner in a highly endemic region in New Jersey, I had the opportunity from the mid-1980s through the mid-1990s to see sometimes the very same patients who would start out with a diagnosis of chronic Epstein Barr virus infection move through the yeast connection and then come back to me in the middle nineties with a diagnosis of Lyme disease.

Now, the most unfortunate part of this is in fact it isn't clear for many of these patients what the illness that's causing their very severe, very real symptoms is. The clinical manifestations of Lyme disease, though, are by this time, pretty well understood. It is not a mimic of all diseases and syndromes.

The tests that we have to diagnose Lyme disease, though not perfect, are about as good as the tests that we have to diagnose most of the infectious diseases. They need to be used appropriately in the right setting for the right patients, and interpretation of the results of these tests requires some sophistication to be done accurately.

Antibiotic therapy using standard doses of appropriate antibiotic for a standard duration of time leads to cure in the majority of individuals.

Now, despite what I've said, there is clearly confusion about this disease. Partly this is due to remaining important gaps in our

knowledge, but it's partly due to dissemination of incorrect information and partly due to a flow of misinformation and misinterpretation of factual information. The results of this has been that some practitioners diagnose many patients who come to their offices with diseases of unclear etiology, such as Lyme disease, and they institute therapies that are inappropriate in terms of which drugs are used or how long or the course of therapy that's administered.

Oxford supports the diagnosis and treatment guidelines that have been developed by the Centers for Disease Control, the Food and Drug Administration, and the American College of Physicians. The CDC has developed a set of diagnostic criteria for Lyme disease which were initially developed for surveillance needs, but which in fact were very useful clinically.

According to these criteria, confirmation of Lyme disease requires objective evidence on physical examination of an abnormality. For example, it's not enough simply to have pain in a joint, but one must have frank arthritis in order for these criteria to be met. More than simply difficulty thinking or headache,

one must have a recognized, objectively defined abnormality of the central nervous system, either by a trained neurologist or found on testing to qualify.

Similarly, these guidelines, and especially the ones promulgated by the Food and Drug Administration, specify a certain test that should be used, and these tests should be used in a certain sequence.

The first test is the ELISA test, which is a very sensitive screening test, so sensitive in fact, that the FDA recommends if it is negative and the patient is strongly suspected of having Lyme disease, that this same test should be used again about a month later. If this test is positive or equivocal, it's recommended that it be followed up by a Western blot.

Patients who have a negative ELISA

and a negative Western blot have a very, very low likelihood of having the later stages of Lyme disease.

AUDIENCE: (Vocal reaction.) Oh, oh, oh, oh.

ATTORNEY GENERAL BLUMENTHAL: I'm

going to ask, you know, I know there are strong feelings on both sides of this issue, but normally in these legislative hearings we really try to contain both approval and disapproval until we have a chance to talk outside. So just in deference to the speakers who have been kind enough to give us the benefit of their views, I'm going to ask that we withhold those reactions. Thank you.

DR. EISENBERG: Now, Oxford's guidelines for diagnosis and therapy mirror the guidelines that have been promulgated by these governmental and as well as academic societies, and I'd like to show you the results of some of the patients who are our members over the year of 1998.

For those of you who would like

to, these tables are included in the package of information that's in your folder. You'll see them in the right side of your folder right behind the first three pages of my statement.

The first table is objective findings, and I should add, by the way, that all of these tables are for members of ours throughout our region, they are not specific to

Connecticut.

What you can see if you look down the left side of the table, you'll see various characteristics of patients who may have Lyme disease, and in the very far right column you'll see the percentage that in fact meet that parameter and in some cases criteria.

For example, about 45 percent of the members are male. You can see that only 30 percent of patients with this difficult to diagnose in some cases disease, ever saw a specialist. You can see that only 33 percent ever recall having had a tick bite. You can see that only 22 percent ever recorded a rash. You can see that only 49 percent had any objective findings on physical examination of satisfying any of the criteria set by the CDC or the FDA for objective signs of Lyme disease, and that only 12 percent in fact had the most specific -- the most specific diagnostic test, which is the IGG Western blot.

So that in fact the majority of patients that apply to us for treatment for late stages of Lyme disease have little in the way of objective supportive evidence of that diagnosis.

If you would please turn to the following table, requested therapies for Lyme disease, this one-quarter's worth of data that I just reviewed for you is folded in with the next three-quarters of data for 1998. And if you would be kind enough to look down the page to denial reasons, you can see the reasons that we have not supported therapy in some of our patients.

If you would look down at number 4, you can see that for some members, it's because the therapy that's been recommended has not been approved in therapy. I think this requires a little bit of explanation.

In the absence of really any clinically reported data that is verifiable, certain physicians are using medications for which there is little evidence that there is any activity against the bacteria causing Lyme disease, that is, Borrelia burgdorferi.

Others are using drugs which are perfectly well absorbed orally, and administering them intravenously.

Others are inventing new regimens for administering these antibiotics. The most

common one that we see is five days of therapy during the week and then the weekend off. Presumably during the Sabbath the bacteria does not replicate and require treatment.

Some of them go on with therapy forever. We frankly get requests for therapy with no end in sight, so that part of the problem that we're seeing is that the therapies are completely inappropriate.

If you scan further down --

ATTORNEY GENERAL BLUMENTHAL: But some of them seem to work, Doctor, don't they?

DR. EISENBERG: The natural

history of the illness, regardless of what it's due to, is one of waxing and waning, and there clearly are certain people who do better over time and some of those people receive therapy.

ATTORNEY GENERAL BLUMENTHAL: But -- and I don't mean to interrupt the flow of your argument, but if some of the treatment seems to work and there is physical evidence that the symptomatology goes away and the regimens, whatever their novelty, seem to have effect, why won't the insurance companies cover them?

DR. EISENBERG: The insurance

companies try to look as objectively as possible at the possibility that any individual patient has the illness that's being diagnosed, and before supporting a therapy, we'd like to see the objective evidence of the illness either in history or physical examination or by laboratory testing. We know that many of these individuals have an illness that will get worse and better over time, and going back to the original studies by Allen Steere done in this state from patients who were in Lyme, Connecticut, we know that most of those patients without any therapy, because the nature of Lyme disease was not recognized in the seventies and the fact that antibiotics might cure it was not known, that many of those patients went on to be cured of their illness with no therapy.

So the correlation between treatment and response is not always as clear as we would like it to be.

ATTORNEY GENERAL BLUMENTHAL: Maybe I don't fully understand, but what I hear you saying is that the kinds of treatment that you regard as unfounded shouldn't be covered because these diseases will go away on their

own.

DR. EISENBERG: No. The answer to that specific question about treating -- about treatments that we think are unfounded is that there's no reason to support a therapy for which there is insufficient evidence that it should work.

ATTORNEY GENERAL BLUMENTHAL: But that comes back to the first question I asked. If the treatment seems to work and there is physical evidence that it is working, why not cover it?

DR. EISENBERG: Because we look -- we try to look not only at the individual patient, who clearly is very important, and we deal with each individual patient as an individual. However, to administer any therapy to that patient without really good evidence that that therapy should work would not make sense for the great majority of our patients who would be more likely to be at least wasting their time and possibly suffering the adverse outcomes that are sometimes associated with administering these therapies.

ATTORNEY GENERAL BLUMENTHAL: So

these judgments are then made -- again, I don't want to characterize, explain your view, but the judgment really is made based on your view of what works in the majority of circumstances, not what may work in that individual case?

DR. EISENBERG: It's not so much -- it's not our judgment. I don't consider Oxford an expert in Lyme disease. We use the expertise of the people who are experts, and those are the people from academic societies, the people from the governmental agencies who specialize and who have developed diagnosis and treatment guidelines, and we try to apply those guidelines to our members.

ATTORNEY GENERAL BLUMENTHAL: And you don't regard as equally worthy of respect, the judgment of the treating physician who believes, based on his or her experience with that individual, that this treatment will work?

DR. EISENBERG: Well, that gets back to the whole notion of whether medicine is an art founded in science or not. In the past, if we were having this meeting 10 years ago, we could be having the same conversation about treating Candida in the blood. If it were

longer, it could be about whether we should be treating the Epstein Barr virus in the blood, because at that time there were individual practitioners, and in fact there were societies for the treatment of chronic Epstein Barr virus using high doses of antiviral drugs or high doses of vitamins, all of which I've seen.

ATTORNEY GENERAL BLUMENTHAL: Let me ask the question a different way. Why is it that -- and I don't mean to single out Oxford because again, I want to thank you for being here today -- I should say that we invited some other insurance companies that declined the invitation, so I respect your willingness to come forward today. Thank you.

But why is it that the different insurance companies have different approaches or practices so that the complaints seem to be about one group and not about others? And as you've heard if you were here earlier, some of them have actually been commended by people who have had firsthand experience with them.

DR. EISENBERG: I don't know the other companies' policies so I can't address that as specifically as you would like. But I do know

from talking to my counterparts in our companies that we all are generally using the same set of criteria developed by the CDC and the FDA.

But beyond that for each individual patient, there is usually a conversation that goes on between the medical director and that patient's either primary care doctor or prescriber of care, and I think that the individual judgments that come out of those conversations is another very important layer of the administration of our policy, and that probably does differ from individual to individual patient as well as from company to company.

ATTORNEY GENERAL BLUMENTHAL: And what would you -- what would you say to a patient who has been diagnosed with Lyme disease who has been prescribed treatment and is denied coverage?

DR. EISENBERG: We encourage them to seek consultation with other physicians, and that could be other people who specialize in Lyme, or it could be a specialist who is expert in the care and diagnosis of the primary symptom that they are complaining of. And we entirely

support our members seeking outside guidance.

ATTORNEY GENERAL BLUMENTHAL: And you pay for those second or third or fourth opinions?

DR. EISENBERG: Without question.

ATTORNEY GENERAL BLUMENTHAL: And what if those opinions confirm a need for that treatment?

DR. EISENBERG: In that case, we pay for the treatment.

If you would please look down at the bottom of that page and see reasons for adverse outcomes, you'll see another aspect of the treatment, and that is the number of people that suffer from medication reactions; elevated liver functions, which means hepatitis, low white counts or clotting or infection of their Lyme.

You'll see another reason for care and caution in the administration of high dose intravenous therapy.

Now, despite the issues that we've discussed and despite the fact that clearly there are some patients whose care we do not support, if you'll look on the next page, which is Lyme summary all regions, 1998, you'll see that in the

left-hand column we have some characteristics for this aggregate population in terms of the decisions that we've made. And if you go down to one, two, three, four, the fifth, you can see that the percentage of members whose requests for therapy is approved is 67 percent. That's despite these problems. And that after the second, third or fourth opinions and on appeal, that number goes up considerably, and -- although because many of our appeals are pending, the number is up in the high seventies at least.

Now, that -- one of the important factors that needs to be realized is that this approval rating is often after a chain, after a discussion that had gone on with the physician, after other diagnostic tests are obtained, after other consultations are obtained, after the therapy is discussed so that appropriate therapies are used for appropriate periods of time.

In summary, Lyme disease is a very important issue in this region. It is highly endemic. It can lead to serious problems, but clearly it is overdiagnosed, it's overtreated and it's mistreated in this region. The guidelines

that have been developed by highly respected academic and governmental institutions are not being followed, and our members are benefiting from our management program.

I thank you very much for inviting me to speak today.

ATTORNEY GENERAL BLUMENTHAL: Dr. Federico?

DR. FEDERICO: Thank you. I better lean forward here.

I'm Dr. John Federico, and I appreciate the chance to appear at this hearing today. In this, I represent Physicians Health Services, which is a managed care organization brought about through a recent merger of M.D. Health Plan with Physicians Health Services.

We have a membership of some 524,000 members in the state of Connecticut at this time. I would also tell you that as a physician who trained and later practiced pediatrics and adolescent medicine here in Connecticut for 18 years, I had occasion to diagnose and manage the clinical care of patients with Lyme disease, and I further bring the perspective of one who has had friends and other acquaintances who have been treated for this condition.

Lyme disease, which given its present distinction, is the most common vector-borne disease reported in the United States, has been receiving increasing attention in recent years from the medical and scientific communities, from health insurers, managed care companies, and of course the public. The interest is the result of a dramatic increase in cases, particularly in the Northeast, where most of these cases are clustered and where the condition is endemic.

Health plans, including managed care organizations, have for some time recognized that Lyme disease is a major cause of morbidity and disability, and managed care organizations in particular, through various care management programs and other educational efforts undertaken by the plans, are aware of complexities and of course controversies that are attended to the diagnosis of the condition and to its treatment.

Managed care organizations are aware certainly of the diagnostic confusion and treatment modalities that have potential for being disadvantageous for members, and Dr. Eisenberg has certainly commented on this, and from the -- some of the papers that were distributed today -- I'm sure the panel will be hearing more about this later on after lunch -- Physicians Health Services supports, and as a health plan, generally covers timely diagnostic testing appropriately to Lyme disease and treatment programs which have been proven through the standard scientific methods to be efficacious in treatment.

The expectation of course being that the great majority of individuals with diagnosed Lyme disease will have complete recovery with the usual and customary therapy and free of untoward complications.

The controversies arise when there's lack -- a reported lack of responsiveness to prescribed regimens, particularly where there's unclear diagnosis or use of treatment regimens which are not either broadly accepted by the medical profession or considered to be the standard of practice.

The starting point in the process of developing managed care review programs is the adoption of appropriate standards of care. The guidelines and criteria used by Physicians Health Services and many other managed care organizations to determine appropriate testing and treatment regimens for various conditions is drawn from published guidelines and position statements produced by widely respected professional organizations.

With respect to the diagnosis and treatment of Lyme disease, these come from organizations such as American College of Physicians, American Academy of Neurology, American College of Rheumatology, the American Academy of Pediatrics, of which I am a member, and the Centers for Disease Control and Prevention, among others.

The guidelines represent standards of care that are developed through consensus are those with significant medical research and practice expertise on the subjects, the standards against which diagnostic practices and treatment programs are compared.

Yet our case review programs include more than the application of standard guidelines. We often discuss cases with treating

physicians in instances where the treatment of a member with a given condition such as Lyme disease has not brought about the desired result. In this, we certainly recognize the need for flexibility, and the appropriate place, indeed support, of individualized care plans, including home care programs, where indicated.

At Physicians Health Services, we have care management programs which involve nurse case managers for members with various chronic health conditions.

In managed care we encounter matters which unfortunately encompass contentious issues, and were this not the case with respect to Lyme disease, we wouldn't be here today. It's expected that specific anecdotal cases would be presented at this public hearing to support the proposed legislation. These intended to show that health plans are less than sensitive and supportive of members than they should be. I want to present a few brief real cases representative of situations which also occur and which generally don't attract attention of the public since they don't make the evening news nor make the print media.

Several years ago, I was at a public event and I met an elderly relative of a workplace acquaintance who was receiving long-term intravenous antibiotic therapy for progressive neurologic manifestations of Lyme disease. She was confused, she was very unsteady and quite disoriented. I had a sense she didn't know where she was or why she was where she had gone to.

Some months later, I learned that she had received further evaluation by a neurologist, had undergone appropriate neurologic testing and was receiving treatment for a correct diagnosis of Alzheimer's disease or dementia.

In another instance, a community acquaintance of mine had been given a diagnosis of Lyme disease without appropriate laboratory testing and was being treated for a protracted period of time with oral antibiotics without relief of his joint pains. A suggested second medical opinion at a local medical center led to a diagnosis and treatment of osteoarthritis.

And yet in a third instance, this involving a family member, the suggestion of Lyme disease as a diagnosis was made in spite of

negative serologic testing, this on the basis of reported symptoms of fatigue, headaches, muscle aches, and joint discomfiture. No antibiotic therapy was undertaken, and the illness which was viral in nature, subsided over the course of several weeks.

It is not at all uncommon for there to occur in instances such as these mentioned, as in others I've learned of through my work as a managed care medical director, of misdiagnosis or misdirected medical treatment of individuals diagnosed as having or presumed to have Lyme disease. Alternative diagnostic possibilities are often not adequately investigated. Serological and other laboratory test results are misinterpreted and courses of treatment undertaken for protracted periods at great patient inconvenience.

Managed care programs seek to

assure that appropriate evaluations are indeed completed and suitable treatment regimens undertaken as indicated.

I don't argue with a statement you made, Mr. Attorney General, in your testimony of February 9 before the insurance and real estate

committee, where it refers to there being undiagnosed and inadequately treated Lyme disease, although I have not seen the data to accept a notion that these are epidemic in scale, in that of course, Lyme disease is essentially endemic in Connecticut.

But through my own personal clinical experiences and awareness of range of practice patterns with respect to the diagnosis and treatment of the condition, I would also submit that there is inappropriate treatment which needs to be recognized and considered as well.

I think House Bill 5694 does not accomplish this. It rather perpetuates inappropriate treatment, often at great individual discomfiture and inconvenience.

I thank you for your attention.

ATTORNEY GENERAL BLUMENTHAL: Thank you. Dr. Federico, let me ask you a similar question to the one I asked Dr. Eisenberg.

I understand the anecdotes that you've given us, but you've heard anecdotes, I'm sure numerous anecdotes, numerous stories similar

to the ones that we've heard this morning, about treatment that does work, that has been denied coverage. And in light of your emphasis in your testimony on the importance of the treating physicians' decisions and the respect they deserve, does PHS make an effort in its coverage decisions to demonstrate that respect?

DR. FEDERICO: Physicians Health Services, like other managed care organizations, obviously reviews individual cases, will talk to physicians about the treatment and will even often make recommendations for and seek to direct members for further evaluation and determination of appropriate costs of therapy to follow.

In instances where a diagnosis is indeed confirmed and where we have further opinions expressed that additional courses of therapy might be suitable, we will generally go along with that type of treatment, and I cannot provide you with some of these same statistical information as my colleague from Oxford did, but this happens fairly often.

I would also comment further that certain therapies that are undertaken that are thought to bring about results are called into

question at times, in instances where we might not know what the natural course of the illness may have been. To say a physician stating that, well, we've given this type of treatment, it seems -- it works, we should do more, the patient is certainly improved, the hard part becomes determining whether it's related to the treatment that's been given or whether the natural course of therapy -- of the disease led to that improvement.

One of the examples that I cited of a family member, you see there was no treatment at all, there was improvement because that's the natural course of a viral illness. Same thing of course can occur in the face of

Lyme disease.

ATTORNEY GENERAL BLUMENTHAL: You think that PHS's procedures or approach are different from other insurance companies?

DR. FEDERICO: Well, I think in general, you know, many of the elements of the approach taken are similar. I can't comment fully on some facets of the approach taken by other companies, not knowing all, but I mean we certainly place a lot of emphasis on

individualized case management -- we like to call individual care management. We certainly make great efforts to get into patient education -- member education, excuse me. In the managed care side, we say members. I still think of these individuals as patients, so I say patient education.

And we certainly try to work with individuals to maximize the outcomes to all of our members who are of course patients of others.

ATTORNEY GENERAL BLUMENTHAL: I notice that none of the anecdotes that you've given here involve both a diagnostic test and a treating physician's prescription as to what should be done about Lyme disease that's been diagnosed. Are there -- is that correct?

DR. FEDERICO: Well, see the first one, right. The individual was said to have had Lyme disease and would have been treated for a lengthy period of time and without any real benefits, and indeed turned out did not have, you know, Lyme disease. And same with the second case is, well, it was something entirely different.

ATTORNEY GENERAL BLUMENTHAL: But was that after there was a diagnostic test, a multiple test?

DR. FEDERICO: I know at least in the second case that no testing had ever been done.

ATTORNEY GENERAL BLUMENTHAL: And your first anecdote mentioned, your first story, doesn't mention any diagnostic test either?

DR. FEDERICO: On that one, I could not say for certain whether one had or had not been done. I had just been told that a diagnosis of Lyme disease had been made.

ATTORNEY GENERAL BLUMENTHAL: Is there -- would you recommend, Doctor, that as a matter of public policy, that anything be done to improve insurance coverage?

DR. FEDERICO: You know, follow it and prove it in terms of what? I mean, I think we've stated, as I did -- I mean, we certainly cover the appropriate diagnostic testing and therapies that are generally accepted by the full practicing community and the experts as being suitable and appropriate for the diagnosis.

ATTORNEY GENERAL BLUMENTHAL:

Well, let me ask the question --

DR. FEDERICO: That I think is a fairly broad type of coverage.

ATTORNEY GENERAL BLUMENTHAL: Let me ask the question a different way.

As you've gathered, there are both physicians and patients who feel that there hasn't been adequate coverage, and there are treatments that seem to be working for which coverage has been denied. Does that suggest that there may be a problem?

DR. FEDERICO: Well, I think as I tried to comment a little earlier, the treatments that seem to be working, we don't know are they really working or that the improvement may be related to the natural course of the disease or illness or the problem, be it Lyme disease or some other condition unrelated to Lyme disease.

As to the duration of a therapy and whether or not it should be [unintelligible], that's an entirely different matter, and I think all of the organizations that have reviewed this, including the professional societies and the experts, feel that there is seemingly a defined limit. If somebody has had, for example, several

courses of therapy and still appears to, you know, be symptomatic, have symptoms associated with the condition of Lyme disease, could be related just to either the treatment itself or could be, you know, related to factors that are caused by the condition of Lyme disease, where further treatment to eradicate the illness is not going to provide any additional benefits from what has been already achieved through one or two standard courses of therapy.

It could be that the further treatment, be it of a rehabilitative nature, et cetera, certainly would need to be addressed and dealt with, and we do this all the time and we cover this type of therapy.

COMMISSIONER REIDER: Do either or both of the doctors, and again, I'm not an attorney but I go on notice of being basic in my questioning.

I'm a patient and I'm insured by a company and I have evidence that there's a tick that's been on my neck and I have a concern and I develop some redness and so I go to my primary care physician, and the primary care physician looks at it and says, gee, you know, it's there,

you have some symptoms and I'm going to treat you with antibiotic, and they do that for a period of time. Question one, is that paid for?

DR. FEDERICO: Yes.

COMMISSIONER REIDER: Okay. Second, I get to a point in time some weeks out and I continue to have discomfort and pain and now it's suggested that I need extended antibiotic treatment, okay? I think now we're getting to the crux of the issue, okay? My question is: If I have a positive diagnosis at that point that I have Lyme disease and the doctor feels that that requires some additional treatment with antibiotics, oral or otherwise, what is the position of your company?

DR. EISENBERG: The way you've described this, I don't think anyone knowledgeable about this disease would doubt that what you had was Lyme disease. You have one such objective characteristic that meet the criteria, that is, the tick bite and the rash, that's actually two separate criteria, and your therapy would be approved routinely. In fact, it wouldn't even go to a medical director at Oxford, it would be approved by the case managers.

COMMISSIONER REIDER: And for how long?

DR. EISENBERG: Most of the applications for therapy are for four weeks. We have a standing policy of approving up to six without questioning, and beyond six there would have to be a conversation between the prescribing physician and the medical director.

COMMISSIONER REIDER: Now it's six weeks. I've been diagnosed with Lyme disease, your company is satisfied that I have Lyme disease but I'm not cured at this point or there's not evidence of cure. You're saying you'd have to have a discussion with that doctor?

DR. EISENBERG: Yes.

COMMISSIONER REIDER: And is there a possibility or probability that you would continue some type of treatment from that point forward?

DR. EISENBERG: Yes. The possibility would depend upon what your continuing symptoms are, as well as what the [unintelligible] of continuing disease are.

For example, if you developed

headache and a spinal tap was done and spinal fluid was looked at and there was any evidence of inflammation, the most likely possibility in that situation, regardless of what any of the tests show, is that your spirochete, the bacteria that causes Lyme disease, in fact has disseminated and that you have Lyme meningitis, and that would be ample justification for continuing therapy.

COMMISSIONER REIDER: And we can continue that entire line but I want to go back.

It's now six weeks I've been treated. You've allowed for two additional weeks, but there is no positive diagnosis of Lyme disease, and yet as a patient, I'm very -- having difficulty, I'm having pain and discomfort for whatever reason, and my doctor may be saying I think it's Lyme but nobody is quite sure. You've looked at it as the managed care company, and you're suggesting there is no evidence of this. Do you allow for further diagnosis of other possible causes for this and pay for that, or would you just simply cease payment at that point?

DR. EISENBERG: We not only allow for it, we encourage it. Our case managers are

dedicated to dealing with patients with infection, and they are instructed to encourage the members and the physicians to seek outside consultation, which we pay for unquestioningly.

COMMISSIONER REIDER: I have one other question and I'll ask this of the other doctors as well. I read an article recently in The Hartford Courant where an extended treatment of -- antibiotic treatment can be counterproductive in the sense that there's immunibility [sic] and whatever, whether it be penicillin or some of the other drugs. Is that a risk or is that not a risk?

DR. EISENBERG: It's a theoretical risk. There's always the possibility that this bacteria, like many others, could develop resistance to the antibiotic that's being used or it could change in some way that makes it less susceptible to the drug. So yes, that's a risk, but I don't think it's a well enough understood risk for it to enter into the thinking on whether therapy should be continued or not, so it would not be cited as a reason to stop therapy.

COMMISSIONER REIDER: And I will finish with this -- these last questions. If in fact you reach a point in time at six weeks or eight weeks, there is not a diagnosis, there is no indication that treatment by antibiotics for whatever reasons is there, and so there is a denial from that perspective. A patient then would come to you and say that I disagree with you, you have an internal appeal process?

DR. EISENBERG: Yes. Every denial of care, every notification of denial is accompanied by verbal, through our case managers, as well as a written notification of the appeals process with a complete explanation of how to accomplish that.

And in addition, we also have expedited appeals and then, depending upon the state and what that state's regulations are, we might have mandated physician conversations or other procedures that we would have to go through in order to satisfy that appropriate decisions were being made in a timely manner.

COMMISSIONER REIDER: And here in Connecticut with the passage of the 1997 legislation, there is external appeal, and that external appeal applies to people that are not covered under federal programs. And there are people who have concerns that are under the federal program, and unfortunately the State can't respond to that, but where there is a State-covered situation, there's external appeal. And you have a responsibility to inform people of that external appeal and the ability to move forward, that that review, which is outside of your company's area of economic or other authority, so I just share -- I already asked some of the other doctors as we go down the path, because ultimately what the Attorney General is saying and what I would say or what I think most people would say, is you want to be able to give people the proper treatment at the proper time in order to get the resolution and the cure.

And as I said, we're going to hear different viewpoints, but I just think it's important that there be a system in place where people certainly have every right to be heard, and for their physician to be heard. But I was interested most particularly on this point of diagnosis of confirmed or not, so I appreciate your input. And as the Attorney General said, we appreciate the fact that you would join us here today.

ATTORNEY GENERAL BLUMENTHAL: Representative Powers?

REPRESENTATIVE POWERS: Thank you. I'd like to go back to what you both discussed with acceptable protocols, and you referred to the CDC and the FDA. Are their protocols identical?

DR. EISENBERG: The CDC's guidelines address mostly how a clinical diagnosis is made from a history and physical point of view. It also addresses the laboratory testing and makes specific mention of the two-step testing that has been advised by the FDA.

The FDA has restricted its guidelines to that testing.

DR. FEDERICO: I just would add, you mentioned the FDA, and the FDA doesn't really have a role in this. Any of the specialty societies have treatment protocols. They are fairly --

REPRESENTATIVE POWERS: You are referring to these societies? Could you give me names?

DR. FEDERICO: This is the

American Academy of Pediatrics, which has -- this is from its committee on infectious diseases, which sets forth standards for diagnosis and treatment approaches for any number of infectious conditions in children.

REPRESENTATIVE POWERS: Are those the same as CDC?

DR. FEDERICO: They are very -- I would have to say that -- I cannot fully answer that. I think that any differences would be rather minor, and the CDC's more deals with the laboratory diagnosis and the laboratory testing that is done to make the diagnosis. The CDC certainly was a party to the development of the guidelines that were put out by the American Academy of Pediatrics, and if there is any differences at all, I think --

REPRESENTATIVE POWERS: So those are more detailed?

DR. FEDERICO: -- they would be very, very minor.

REPRESENTATIVE POWERS: So are the pediatric ones more detailed?

DR. FEDERICO: The -- no, they are

not. And they are not any more detailed than

those of the American College of Physicians or any other specialty society.

REPRESENTATIVE POWERS: So when you referred to these other associations and generally accepted protocols, you know, the way the treatment is supposed to go, there is a uniformity, a uniformity on this?

DR. EISENBERG: The purpose of guidelines is not to establish 100 percent uniformity. Guidelines are useful in reducing variation. When you are talking about diagnosing and treating an illness, you'd like to, with as great certainty as possible, make sure that all of your practitioners are using the same framework within which they are making a diagnosis; they are using tests that have shown themselves to be helpful; they are applying therapies that have been tested. And the guideline tries to encourage this kind of thinking.

The purpose of a guideline specifically is not that there be 100 percent conformity. There needs to be some flexibility and every guideline allows for that.

A standard of care, which is

usually developed by a governmental agency, is much more rigid.

DR. FEDERICO: Just one further point to give as an example. The Academy of Pediatrics's Guidelines obviously is more focused on the treatment protocols for children, setting forth the antibiotics that are appropriately used in children and the dosages, et cetera, as opposed to those obviously coming from American College of Physicians and other organizations.

REPRESENTATIVE POWERS: The reason -- I am not from a medical field at all, I'm from the education field. The reason I'm trying to understand this is because both of you have referred to following the guidelines and recommending and accepting and paying for therapies that are within the guidelines. So what I'm trying to understand is how strictly do you follow these guidelines and kind of where does the red flashing light appear in terms of being a little bit beyond the guidelines or way beyond the guidelines? And how do you respond if in fact those guidelines change?

Just listening to you talk I was thinking about I think in the last three or four

days, they've announced that they've discovered a group of physicians was working I think with uterine cancer, and they found that adding chemotherapy to the radiation jacked their survival numbers dramatically, and that was not the CDC guideline. And that was not the CDC recommendation.

However, they've now said well, these numbers are so dramatic that without further checking, which we will do eventually, we would like other physicians to step in and do this immediately.

So what I'm trying to understand is, how tightly are you holding to these? Where is the red light and how responsive are you to any changes?

DR. EISENBERG: We do not provide -- our guidelines are not any tighter than the ones that have been recommended by the Centers for Disease Control and the FDA. Ours are looser. Had we applied their guidelines strictly, we would not have the two-thirds approval rating at first that I showed you.

An example of how our guidelines are less strict is in the six-week treatment

regimen that we routinely approve, because the physicians in this community have spoken to us and we've had a dialogue with them and it's their belief that although the various academic societies and governmental agencies recommend pretty much uniformly that three weeks of therapy is adequate, there has been such a ground swell of discontent with that regimen that we have made a decision uniformly to go with six weeks.

Addressing your second question about how do we become knowledgeable, it's by actively keeping our ears open. We are notified either through regulatory bodies or governmental agencies or because as a company that has a professional staff of nurses and physicians, some of whom specialize in the field of infections, we're always attending conferences, reading the literature, and getting the E-Mail bulletins from services that are better and faster than they ever have been before.

The next question, though, was a very important one. Do you react to every bulletin that you get from the Internet? And that really is the difficult situation to try to figure out. Should every physician now be applying radiation and chemotherapy to their patients with uterine cancer or will the next study demonstrate not only that it didn't help, but that many more of those patients turned out with radiation colitis. That's the harder part.

DR. FEDERICO: You do raise a good question. I would tell you that often, you know, we become aware of a lot of the new developments in the field before the practicing physicians do because of the services that we avail ourselves of. I know at PHS we also have a clinical practices committee, which includes in its membership practicing physicians, and we also invite imports from our consultants who often may be aware of new developments before these find their way into the scientific literature. So -- and we do because we are really trying to stay ahead and take into account the new developments in various fields.

ATTORNEY GENERAL BLUMENTHAL: Dr. Eisenberg, do you have -- we've been talking about guidelines. You refer to them as guidelines or protocols or regimens? What do you call them in your company?

DR. EISENBERG: We call them

guidelines.

ATTORNEY GENERAL BLUMENTHAL: Guidelines?

DR. EISENBERG: And I think that's a very good term, because while it provides an overall framework within which to work, it's not so rigid that it doesn't allow --

ATTORNEY GENERAL BLUMENTHAL: And are they written?

DR. EISENBERG: Yes, we have written guidelines.

ATTORNEY GENERAL BLUMENTHAL: And if somebody asks for them, do you, for example, a physician or a patient, do you provide them?

DR. EISENBERG: Yes, by HMO

regulation in one state and perhaps all states, we must supply those guidelines to physicians or members if they ask for them.

ATTORNEY GENERAL BLUMENTHAL: In all cases when they are requested?

DR. EISENBERG: Yes.

ATTORNEY GENERAL BLUMENTHAL: And I guess what I continue to find troubling is that there are those cases where there is a diagnosis contrary to your explanation of the way the

guidelines work, a diagnosis that is a second or third diagnosis and a recommendation from a treating physician and you've heard those stories this morning, and I'm sure you've heard others, where coverage is denied. What do you suggest that a patient should do in those cases?

DR. EISENBERG: The conversation that goes on between myself and the prescribing physician is only one of the conversations that's going on around any given patient. One of the things that we insist, and I think other companies do this often too, we'd like to know what the consultants or the other physicians -- it might not be a consultant; it might even be the primary care doctor, and oftentimes, the notes from these other physicians or the conversations that I have with them is very different than the conversation that I'm having with the prescribing physician, in that these other physicians claim that either they don't know what the diagnosis is in this patient or they do know and it is not Lyme disease. That other diagnosis for a neurologic condition is most often multiple sclerosis.

And I've spoken to many

neurologists and seen many reports of MRI scans and spinal fluids that make a definitive diagnosis of multiple sclerosis in a patient whose other doctor, the prescribing doctor, wants to treat them with prolonged high dose intravenous therapy for Lyme disease rather than applying therapies that are now known to make important differences in patients with multiple sclerosis.

When I talk to rheumatologists, they tell me that they have made a definitive diagnosis of rheumatoid arthritis in some patients who have joint disease, whereas the prescribing physician is recommending antibiotic therapy.

The conversation that I have with the prescribing physician is one of many pieces of evidence that we use in making our decision.

ATTORNEY GENERAL BLUMENTHAL: Even where there is a test that shows Lyme disease?

DR. EISENBERG: No.

ATTORNEY GENERAL BLUMENTHAL: Or in fact multiple tests?

DR. EISENBERG: No. Generally if the --

ATTORNEY GENERAL BLUMENTHAL: Because that was my question to you --

DR. EISENBERG: Oh, I'm sorry.

ATTORNEY GENERAL BLUMENTHAL: -- where there are tests, diagnostic tests, maybe more than one, that show Lyme disease, a treating physician who wants to use a form of treatment that he believes will work, and in fact may work, it has worked, and then coverage is denied, what does a patient do?

DR. EISENBERG: The conversation

that then goes on -- you know, I want to emphasize that there are many steps to this process, and I don't simply mean the appeal, denial, appeals, grievance. I'm talking about conversations, whether they be through the mail, the fax or the phone. The first conversation that would go on in this particular case where a patient has not only symptoms or signs but a laboratory test that confirms a late stage of Lyme disease, but the therapy that's being applied is one that we think is inappropriate and we think it's inappropriate because of these other well-respected agencies, how about changing the therapy, Doctor, to one -- to a therapy that

is considered appropriate.

And most of the time, the physician will say, okay, let's go along with treatment with antibiotic X, which is one of many that has been tested and shown to be helpful. Or maybe they are willing to change the treatment regimen from one that they've developed on their own individually to one that is more widely accepted by the medical community. If those things don't happen, what do we suggest to the patient? We suggest that they seek consultation elsewhere, and oftentimes we will supply them with a list of names of individuals in their community, and we will always pay for that consultation.

And if that second opinion, especially if it's one that we've suggested, advises treatment, we treat. It goes through no other layers.

ATTORNEY GENERAL BLUMENTHAL: But if the form of treatment that the physician has used in the past, is using, and is working and coverage is denied, what does a patient do that will -- in other words, you are saying go to someone else, go to another consultant, get

another opinion?

DR. EISENBERG: Yes. I think the treatment regimen is a critical part of the evaluation and treatment, and to support the use of a drug for which there is little reason to believe that it would treat Lyme disease effectively is a mistake.

ATTORNEY GENERAL BLUMENTHAL: But

isn't the dispute not necessarily about the kind of drug or the specific prescription but about how long it's used and whether in fact it works for that individual? And how can you send someone to another physician simply because you don't like the treatment that's been prescribed by that physician?

DR. EISENBERG: It's not really a matter of what we like. It's a matter of what has been tested, what therapies and scientific approach has been used. What evidence has been generated that is believable and accepted by the community of scientists in this field that is worthy of our support and is appropriate for our members, our patients to receive.

ATTORNEY GENERAL BLUMENTHAL: But you would agree, wouldn't you, that -- and I

thought that was consensus on this point -- that there are a lot of unknowns and a lot still to be verified to be established, to be proved when it comes to Lyme disease?

And I guess what I find a little disquieting is there are these references to guidelines and protocols and regimens in the scientific community as if there were a complete consensus and a degree of knowledge that doesn't seem to be there.

DR. EISENBERG: Certainly there are gaps in our knowledge and there are patients who respond to therapies that you wouldn't expect them to, and when faced with a situation like that, we have in the past reversed our decision and supported the therapy, but I wouldn't advise that as an approach for developing any aspect of medical care. And I think one of the reasons that we're having this conversation is because my emphasis is on how does one approach this from up front, and the question is what to do at the back end, when perhaps everything has gone wrong except the patient is feeling better.

And in a situation like that, have we supported care that either because of the drug

or the duration or the dose or some other aspect of the treatment regimen does not fit a guideline? And the answer is yes, we have.

ATTORNEY GENERAL BLUMENTHAL: And I guess the reason we are here today is because sometimes you haven't.

(Laughter.)

ATTORNEY GENERAL BLUMENTHAL: Frequently there are a lot of folks who are very concerned about it who have complained to government officials, to their legislators, and I think that's one of the points of continuing contention here.

Representative Powers?

REPRESENTATIVE POWERS: Just real quick because I know we are over lunch here. The physicians in your network, you have a physician that maybe just because of where he is practicing diagnoses Lyme disease frequently, does that man have a flag on his dossier?

DR. EISENBERG: No. We do not single out physicians.

REPRESENTATIVE POWERS: If in fact

you have a physician -- oh, you didn't answer. All right.

DR. FEDERICO: I concur.

REPRESENTATIVE POWERS: If you have a physician who has a fair number of Lyme disease diagnoses and continually advocates with your corporation for his patients for extended therapies, different therapies, that kind of thing, what happens to a physician like that?

DR. EISENBERG: Nothing. We keep a lot of statistics but we don't keep track of the individual physicians who diagnose or treat Lyme disease.

DR. FEDERICO: A physician who treats a lot of patients with a bona fide Lyme disease, who is someone we'd be talking to on a regular basis, we would often look to as a -- someone to provide us with additional, you know, information that really helps us as we look at our guidelines and we look to that type of a person as having additional knowledge which could be useful to us.

REPRESENTATIVE POWERS: Okay. The reason I asked those questions was because I have gotten about 180 degrees from that from doctors.

And I'm not going to pick out a particular HMO coverage --

AUDIENCE: We can't hear you.

REPRESENTATIVE POWERS: -- that doctors have contacted me with the exact opposite experience, and some of them have been dropped, and their perception was it was because they advocated beyond the guideline and beyond the protocol. I'm glad to hear your companies don't do that.

(Laughter.)

COMMISSIONER REIDER: I might mention that as part again of the '97 legislation, there was a requirement that the -- each of the HMOs or managed care organizations provide the turnover rate of their physicians and that is available and is published by the Insurance Department. So it might be helpful for those of you who have that particular concern with a given company or companies to look at that document, which we'll be more than prepared to send to you if you request it.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much for being here, Dr. Eisenberg and Dr. Federico. We are behind our schedule. I would propose if Dr. Katz and Dr. Phillips can stay for a while, that we take a break now and then come back at -- you can be back at 1:30 -- 1:30 and take the next panel at that time. Thank you.

(A luncheon recess was taken.)

(Tape recorder not activated immediately. Hearing is already in progress and tape recorder picks up here.)

DR. PHILLIPS: ... we look for the body's reaction to the bacteria rather than the presence of the bacteria itself. However, many people do not react to the bacteria or only react in part.

What about the CDC? These people from the insurance companies reference the CDC guidelines over and over. Well, this is a direct quote from the CDC's Web site as of two days ago and I quote, "This surveillance case definition was developed for national reporting purposes of

Lyme disease and is not appropriate for clinical diagnosis." That word "not" was actually capitalized by the CDC. I did not capitalize that word "not."

This is a direct quote, yet many insurance companies and tertiary care centers such as Yale have adopted this case definition criteria for their clinical diagnostic purposes of Lyme, and it's incorrect.

What about Lyme that does not meet a CDC criteria? This is called seronegative Lyme and it's not uncommon. In this large study by Dr. Donta, he used to be head of infectious diseases at UConn, is now up in Boston, very well known and well respected, 71 percent of the patients were seronegative by CDC criteria. Not only is it common but potentially these people with negative blood tests can be worse off.

It's often the observation that patients with negative Lyme tests are actually sicker than the ones with positive Lyme tests.

In this study also very well documented, seronegative Lyme disease, they found that the people with negative blood tests were actually positive by PCR. PCR is a test that looks for the DNA of the Lyme bacteria. The people that had antibody positive tests were negative by PCR. This implies that the people with negative tests had a higher bacterial burden and therefore could be detected by the PCR test.

Therefore, supporting the observation that people with seronegative Lyme can be sicker than people with zero positive.

What about diagnosing and differentiating central nervous system Lyme from Lyme that has not invaded the central nervous system? Well, culturing Lyme bacteria from spinal fluid has been just as hard as growing it from blood, so just like in blood, most tests rely on the body's reaction to the bacteria in the spinal fluid rather than the presence of the bacteria in the spinal fluid itself.

Unfortunately, just like in blood, many patients don't react to the Lyme bacteria in the spinal fluid and indeed can have no abnormalities of spinal fluid at all.

In this study out of Stony Brook, which is arguably one of the premiere Lyme research centers in the entire world, they developed a new and relatively underused test by which they confined actual specific Lyme proteins in the spinal fluid.

Now, 35 patients with the specific Lyme protein in their spinal fluid a full 43 percent had completely antibody negative spinal fluid. Further to that, 47 of these patients had otherwise completely normal spinal fluid such as cell counts, which is where we look for white blood cells and such and chemistries, things like ordinary proteins. And to make matters worse, 60 percent of these patients also had negative blood tests.

So just to recap, 60 percent of these patients had negative blood tests, they had negative antibody tests in their spinal fluid, and they had very clearly documented Lyme proteins in their spinal fluid.

COMMISSIONER REIDER: Let me ask a question there. If that were the case, so now you have negative tests every which direction, I think, do you ever know if they have Lyme disease or not?

DR. PHILLIPS: Well, just to go

back to the study, they isolated Lyme-specific proteins. When I say a negative test I mean

every test is different. The test that I'm saying is negative is a test for the antibody to the Lyme bacteria. That's the body's reaction to the Lyme bacteria. The bacteria undergoes certain changes when they enter the body, which can decrease the amount of antibody production made toward the bacteria. And these patients, they have specific proteins, the protein that they are making the Lyme vaccine out of is called Osp A, it's the most specific protein on the surface of the Lyme bacteria.

That's what they found in these patients' spinal fluid, despite the fact that their antibody tests were negative and despite the fact that every other test of their spinal fluid was negative. And that's a fact.

Other researchers will notice it's pretty much the same thing. It's not just Stony Brook.

Now, this is just the case report, but I found it so absurd and compelling that I felt I had to comment on it. This is a case of a seronegative, meaning blood test negative, patient, an ordinary antibody negative patient who had had a total of seven courses of

intravenous antibiotics and three years of continuous oral antibiotics.

This patient never had detectable free antibodies to B. burgdorferi in her blood or spinal fluid but the spinal fluid was positive on multiple occasions for complex anti-B. burgdorferi antibodies, nucleic acids and free antigen. This basically means that she had antibodies but the routine test didn't pick it up.

You had to disassociate these bound up antibodies and then you could pick it up. She also had the DNA and she had the free antigen. She was treated -- in this article here she was treated for six courses of intravenous antibiotics over a period of five years. With every course of antibiotics she improved. After every course of antibiotics was discontinued, her neurologic status declined dramatically, and multiple spinal taps revealed persistent infection.

In a follow-up letter which was also published in the medical literature, it was told that she was then put on three years of continuous oral antibiotics which effectively

suppressed her symptoms for three years. Then she relapsed on that and ended up being treated with a seventh course of I.V. antibiotics and then the authors concluded they were going to keep this person on chronic antibiotics and alternate between oral and I.V.

Clearly, this is not an acceptable condition, but there's nothing better that they can do. This patient is very ill and that was their decision.

Even Allen Steere, a very conservative gentleman by any stretch of the imagination, has said, and I quote, "That local antibody production in the spinal fluid is an inconsistent finding in American patients with late neurologic manifestations of the disorder."

I would hardly think that insurance companies will want to make its decisions of whether a patient has central nervous system Lyme based on inconsistent findings.

What about treatment controversies? Well, many patients are treated for Lyme relapse. Like I said, some people call this post Lyme syndrome or post Lyme

fibromyalgia. Critics call this nonsense. Post Lyme syndrome and post Lyme fibromyalgia are the same symptoms of Lyme that come on after you are, quote-unquote, "cured of Lyme."

Well, a couple of studies have looked at post Lyme fibromyalgia. I guess they had good intentions and they had got data but the conclusions they came up with were entirely surprising.

The results basically show that they took these two subsets of patients that had post Lyme fibromyalgia, post Lyme syndrome, and treated them with antibiotics. And guess what, they got better. Then when they went off antibiotics, they relapsed. The conclusion by the authors was that this improvement was due to placebo effect.

However, this conclusion was fully unsubstantiated, it was made without the benefit of placebo-controlled studies. It should be noted that every one of the primary symptoms associated with this, quote, fibromyalgia or chronic fatigue syndrome i.e. persistent headache, fatigue, muscle aches, joint pain, sleep disturbance, et cetera, are common in

active Lyme disease and cannot be used for the differential diagnosis.

So it should come as no surprise to anybody that the Lyme bacterial DNA has been detected in the muscles of patients diagnosed with post Lyme fibromyalgia.

Woops. What about animal models? We can get some information from looking at the animals because we can dissect them and find things that we couldn't find from people. In this study, they injected dogs with Lyme bacteria and treated them with four weeks of amoxycillin or four weeks of Doxycycline, both commonly used, and, quote-unquote, curative therapies for Lyme.

Well, guess what? It didn't get rid of the Lyme bacteria. No surprise.

What about human data? Again, PCRs, you remember, is the DNA test where they can isolate bacterial DNA from the patients. Out of these patients who were treated, multiply with, quote-unquote "adequate antibiotic therapy," a full 30 percent remained positive despite multiple courses of adequate antibiotic therapy. This is a study by Steere and colleagues.

In this study, a whopping 74 percent were still PCR positive despite extensive and prolonged therapy. The reason that this study has a higher yield than the other study is postulated because it used three different PCR primers whereas the other study didn't. PCR is a very specific test. The more primer that is used, the greater the yield, but that's a little bit technical.

Well, what about human persistent infection despite antibiotics, which is proven by culture, because anybody can say that, you know, there's DNA floating around, but it's dead bacteria. And it's just the dead bacteria will remain in your body for years and years and there is nothing you can do about it.

Well, as hard as it is to culture spirochetes, and believe me it is hard, because the syphilis spirochete which is a close cousin to Lyme, they have tried to culture from the blood for 100 years and it's been unsuccessful. And Lyme bacteria they have been trying to find a way to successfully culture it for about 20 years with a high yield from patients with late stage disease. It's been mostly unsuccessful before or

after treatment. Despite the fact that it's so hard to do, it's been done.

And in this study of antibiotically-treated patients, either ones with negative tests or positive tests, they culture the Lyme bacteria from these patients. And guess what? It's been proved again by culture and antibiotically-treated patients and again by culture and antibiotically-treated patients and again by culture and antibiotically-treated patients. And this one --

(Clapping.)

DR. PHILLIPS: And this one -- this one is from recurrent bullseye rash. This isn't even from late stage Lyme. They took bullseye rash because they couldn't get rid of bullseye rash, kept getting cultures of bullseye rash, positive.

And yet again, by culture from antibiotic-treated patients and yes again, by culture from antibiotic-treated patients. And I put my own two cents in my research that was recently published in an infectious disease

journal, we found a way to culture Lyme bacteria from patient's blood with a significantly higher yield than has been done previously, and the patients had an average of three months of I.V. antibiotics and they didn't get better. 91 percent of them cultured Lyme bacteria.

We've had those bacteria confirmed by -- by every fancy test you can imagine; by electromicroscope, by PCR, we sent them out to two different institutions. After this went to press, we kept sending it out to other universities, it came back over and over again yes, it's Lyme bacteria.

What about treatment duration? You know, the area of treatment duration longer than four weeks has not been studied because a lot of people that control these studies have not elected to study longer-term treatment, but still studies have been done.

In this study by Dr. Donta, he found that after two months of treatment, 33 percent of the patients improved significantly. After three months, 61 percent of the patients improved significantly. And his conclusion is that these results support the use of longer

courses of treatment in the majority of patients with chronic Lyme disease.

COMMISSIONER REIDER: Just a question.

DR. PHILLIPS: Go ahead.

COMMISSIONER REIDER: How long would you suggest it may be needed to treat a patient with antibiotic?

DR. PHILLIPS: I don't know. I mean, I start out at a four-week interval. Let's say -- there is many, many different strains of the bacteria B. burgdorferi, and they vary in their levels of antibiotic resistance and sensitivity.

Let's say I give you Doxycycline for your bullseye rash. Your rash doesn't go away, you still feel terrible. In four weeks you are cured? Did I cure you? No. It's a waste of time. So you switch to something else. Maybe try a little bit of Ceftin or Biaxin or something like this. I mean you cannot cookbook medicine when it comes to Lyme. People respond differently and that's the bottom line.

COMMISSIONER REIDER: You cited up here I think at one point there is an extended

treatment of five years and the person still continued to have the Lyme disease?

DR. PHILLIPS: Yeah. I mean, there are people that are not curable. I mean you cannot define the fact -- you can't define cure by the fact that even unbelievable amounts of treatment have been given. The bottom line is we need a definite curative therapy for this illness.

COMMISSIONER REIDER: Right.

DR. PHILLIPS: I have multiple family members with chronic Lyme disease. They are not cured. My father almost died of dilated cardiomyopathy from Lyme. I can't cure him. I can't even cure my own family. So just because someone is taking the antibiotic doesn't mean they are going to respond.

You know, a lot of people do. Most people do. I'm not trying to press any panic buttons. Most people do get better and it's wonderful. But for people who don't get better, they are not crazy and they don't have post Lyme syndrome, they are still infected and they are still sick.

COMMISSIONER REIDER: Again, just

in understanding, and this follows the questions I asked this morning, I mean, over the years I go to a doctor or take my children to the doctor or whatever and whether it be here in Connecticut or some of the other states that we live, doctors will say gee, Mr. Reider, or George, we want to try an antibiotic but we don't want to overuse that antibiotic, that's the worst thing we can do so we're going to give it a shot and we're going to see.

Back in the fifties I remember as a young fellow they gave me the wonder drugs at that time, but clearly you can only do this so long.

DR. PHILLIPS: Right.

COMMISSIONER REIDER: So my question to you and the other doctors and the doctors who come is, what is the risk of --

DR. PHILLIPS: Long-term treatment?

COMMISSIONER REIDER: Yeah.

DR. PHILLIPS: There are certainly risks to long-term treatment. You know what? I was on Doxycycline for zits for a year and a half. I had patients treated with tetracycline

class antibiotic for seven years for acne, so when someone tells me that I can't treat Lyme for more than four weeks, I find it not only amusing, I find it absurd. There are definite risks to long-term antibiotic therapy. Bacteria that reside in your intestines will become resistant to those antibiotics.

When I treat Lyme, I limit the class to three different classes of antibiotics and that's it, and I don't go outside those classes. Therefore, the patients will not develop a resistance to multiple classes of antibiotics. If, God forbid, they have a life-threatening infection, they could be treated with something else.

Also, it's a risk/benefit ratio. If someone let's say has a positive test and they don't feel sick or have a little elbow twinge, whatever, certainly I wouldn't treat them, but if someone is rapidly losing their cognitive abilities, is disabled and whatever, sometimes you don't have a choice. If someone is a cardiac cripple like my father, you don't have a choice. So the fact that my dad has been treated for two and a half years, no choice. The fact that his

injection function more than doubled with treatment, that's great. Does he have some resistant bacteria in him? Yes, he does, but sometimes the devil that you know is better than the devil that you don't know.

COMMISSIONER REIDER: Thank you.

DR. PHILLIPS: So in this study, another group agreed with Dr. Donta and they illustrate several aspects of late Borreliosis, meaning a late Lyme disease with false negative serology, meaning negative blood tests, exist, and that there's a need for prolonged antibiotic treatment in chronic or recurring forms.

Well, what we really have to talk about is the standard of care, because what is the standard of care? Although I have been doing research on Lyme for some time, although I've done microbiology and immunology research at Yale, I've heard back to me that I'm kind of on-the-fringe of treating Lyme. Well, they have done a study of 78 physicians from Lyme-endemic areas surveyed, and surprisingly to some but not to myself, 50 percent of the respondents believe that 25 percent or more patients who have had Lyme were seronegative.

They also in terms of their treatment guidelines for Lyme disease, after bullseye rash, 43 percent treated three months or more, and for chronic Lyme, meaning late stage recurrent Lyme disease, 57 percent of responders treat three months or more. That is the majority, and that is the standard of care that exists in Lyme-endemic areas.

Now, there are articles out there that widely proclaim the overdiagnosis and overtreatment of Lyme disease. Certainly I don't have time to address all of them, however I'd like to address a couple.

This one by Dr. Steere and colleagues shows that of 788 patients with the diagnosis of Lyme, only 23 percent had active Lyme disease. 20 percent had previous Lyme but now somehow had magically developed chronic fatigue syndrome or fibromyalgia. And we know that chronic fatigue syndrome and fibromyalgia have very similar symptoms to Lyme. 57 percent did not have Lyme disease ever. Most of them just coincidentally having chronic fatigue syndrome or fibromyalgia.

Now, the patients who did not have

Lyme disease, surprisingly 45 percent had had positive blood tests and in other laboratories, but all were negative in Dr. Steere's laboratory. Remember this? This is from the CDC's Web site. It says that the surveillance case definition was developed for national reporting of Lyme disease. It is not capitalized appropriate for clinical diagnosis, yet Dr. Steere has used those clinical criteria for his diagnosis.

In addition to this I have to ask a question. Since 45 percent had had positive blood tests in other laboratories but were all negative in Steere's laboratory, who says that Dr. Steere's Lyme testing is better than anyone else's? I mean the authors offer no independent evaluations or persuasive arguments to distinguish their tests from others in current use.

Further to that, they don't use any of the more advanced tests. They don't use any culture. They don't use any PCR, which is the DNA tests, and they use no antigen capture, which is Stony Brook's test.

Well, let me just say I want to

just repeat the question. Who says that Steere's Lyme testing is better than anyone else's? Well, certainly not this patient, because this is a published report of a 24-year-old woman who gave birth to a stillborn infant. Both the Center for Disease Control and the New York State Department of Health found strongly positive Lyme antibody testing of her blood, yet Dr. Steere's lab at Yale found negative results.

Fetal autopsy unfortunately showed spirochetes in the liver, adrenal, brain, heart and placenta of this dead infant.

So in summary, I'd like to say that chronic Lyme is caused by chronic infection with B. burgdorferi with the Lyme antibody; that current antibody testing is inadequate; that seronegative Lyme is common; that the Center for Disease Control case definition criteria should not be used for clinical diagnosis but it is; and that longer antibiotic treatment durations are more effective than shorter; that post Lyme fibromyalgia is really just persistence of the initial infection; and that curative therapies are desperately needed but many tertiary institutions are not even willing to recognize the existence and true etiology of the illness, let alone fund research for its cure.

And at this time I'd just like to comment on a couple of testimonies done by the insurance representatives and Dr. Schoen's written testimony.

First, with Dr. Eisenberg, he compares Lyme disease and chronic Lyme disease to yeast, Candidasis, and hypoglycemia, and all these vague disorders from years ago. But you know, you can compare it to anything from 60 years ago and it would sound even more absurd than the stuff that came out 20 years ago. I mean, medicine is a science that is in evolution.

When Lyme disease first came out they didn't recommend any antibiotic therapy at all. The treatment was aspirin. And then all of a sudden, they said 10 days of antibiotics. Now the current adequate treatment is four weeks of antibiotics, and now you hear from Oxford that they are going six weeks. So it doesn't make much sense to compare something from 30 years ago that was obviously obsolete and outdated medicine and say that these patients with Lyme are really the same as these kind of obscure diagnoses.

Further to that, I want to the talk about he mentioned multiple sclerosis. Well, you know, a definite diagnosis of multiple sclerosis, Lyme can cause a clinical syndrome which is indistinguishable to multiple sclerosis. If causes white spots on the brain. It causes recurrent inflammatory central nervous system lesions just like MS does in a waxing and waning pattern.

I mean, I hate to present anecdotes like the doctor from PHS did, but I have seen over and over where patients, they give out diagnosis multiple sclerosis like they are giving out tickets to the policeman's ball, but to get a diagnosis of Lyme disease is like pulling teeth. I have had patients with frankly reactive ELISAs.

I had a patient -- just let me give you a reference to an anecdote. I have a patient with hundreds of tick bites, four huge bullseye rashes, a positive ELISA, nine band positive Western blot treated with two weeks of Doxycycline, each time, for each case of the

Lyme. She comes to me -- this was five years

ago. Then she came a couple years ago, did the exam. Looked like MS. Sent her for an MRI. There was lesions everywhere.

I said well, you have demyelination but because of your prior history of Lyme, I would suspect that this could be related to Lyme. Let's treat you. I got a lot of flak on that. I gave her I.V. for six weeks, she improved dramatically. I did an MRI before and after. The lesions went, completely went away afterwards. That's great. She went home. Everybody was happy.

Six months later, she relapsed. They said well, you know, Phillips was right, you had Lyme mimicking MS that first time, but now since we do another MRI and all your lesions are back, and you had the cure, you had that six weeks Rocephin and you are cured. Now it's real MS and you are just going to have to live with that. Go on, buena sera, do whatever. And that just kind of hammers home what I'm saying.

Also, I want to talk about

Dr. Federico's unsubstantiated anecdotes about a relative of a friend or a family member or whatever. I mean, to present that in testimony is -- it doesn't hold any weight. I mean none of this stuff is referenced, and we don't really know what these people were clearly diagnosed -- I mean Alzheimer's is a diagnosis of exclusion. Just show me a brain biopsy that was consistent with Alzheimer's, let's please not entertain that.

In terms of Dr. Schoen, they clearly didn't reference his included testimony on the paper entitled The Consequences of Overdiagnosis and Overtreatment of Lyme Disease in Observational Studies. Since I can't just attack every paper that was ever written that doesn't have unsubstantiated findings, but I just want to point out a couple of things.

Out of his 125 patients, of the polled 60 percent of the patients he evaluated, they lacked evidence of Lyme disease according to him. However, 61 percent of those had previously had a positive Lyme test result by other places.

And I just want to show you one

more time and I ask the same question: Who says that Yale's Lyme testing is any better than anybody else's? So he's basically saying these people had a positive test elsewhere but negative

through us, therefore they don't have Lyme. Not only is he assuming his test is superior, which clearly it's not, he's also assuming, and incorrectly so, and per the Center for Disease Control, that the CDC case definition for Lyme should be used for clinical purposes.

I think that's about all I have to say. Thank you.

(Clapping.)

DR. PHILLIPS: I'm sorry. Thank you very much. I have one more comment.

(Laughter.)

AUDIENCE INDIVIDUAL: You should have quit while you were ahead.

DR. PHILLIPS: This is a strong one. This is a strong one, that of Dr. Schoen's study that is included in his testimony, out of the patient's -- this is a quote -- Patients with no evidence of Lyme disease reported partial resolution of symptoms after 50 percent -- 57 percent of treatments so -- of treatments, so a majority of patient's treatments responded, you know, and these are people with no evidence of

Lyme disease but greater than half of them got better. So I just wanted to add that.

ATTORNEY GENERAL BLUMENTHAL: I have to stop. One question before we go to Dr. Katz, if you'll permit me, Dr. Katz.

You know, you've referenced a couple of times the CDC guidelines, saying that the case definition criteria are not appropriate for clinical diagnosis.

DR. PHILLIPS: Yes.

ATTORNEY GENERAL BLUMENTHAL: For the laymen among us, could you explain why that is so; in other words --

DR. PHILLIPS: Why that is so?

ATTORNEY GENERAL BLUMENTHAL: Why would the CDC itself say these criteria for case definition are not appropriate for --

DR. PHILLIPS: Sure. There are

many flaws in the CDC case definition criteria. Where can I start? Number one, the CDC requires the ELISA be positive and the western blot to be positive, and for western blot positivity, five bands IGG or two bands IGM, surprisingly, from the CDC's list of each band corresponds to a protein on the [unintelligible] of Lyme

bacteria.

Surprisingly, off their list, they took off bands 31 and 34. 31 and 34 are by far the two most specific bands for Lyme bacteria. 31 is what they're making the Lyme vaccine out of, it's out of service.

Protein A and 34 is out of service protein B, and why would anybody take these off their list? As was explained to me, they were numbers 11 and 12 of the most commonly seen bands with Lyme, but they established these western blot criteria for early Lyme, and later on in the illness, there is recurrent activity to -- out of service protein A and B.

A lot of patients do express this band, so they are kind of skewed by this western blot interpretation to missing late stage Lyme.

The other thing is that the bottom line is that many people do not meet the CDC criteria in Donta's study. 71 percent were seronegative, yet the vast majority responded to oral antibiotic therapy, longer term than four weeks. They had classic symptoms of Lyme, but everyone has a different idea of what a classic symptom of Lyme is.

I mean, yes, there's a subset that has Lyme arthritis, but that's the minority of patients. Lyme is primarily a neurologic illness. In Europe, the strains are primarily neurologic. There is very little arthritis in Europe. I mean, there is strain variation, and when it was discovered in Old Lyme, that was a group of patients that had primarily arthritis and that kind of just stuck, it turned into dogma, and that's the way it was.

And that's the way it was, so when you talk about objective clinical criteria for CDC case definition, they look for Bell's palsy, they look for, these things, like frank arthritis.

In my experience, most people do not develop frank arthritis, rather, they get joint pain without swelling. Don't get me wrong, I have a lot of patients that have joint swelling. Most people don't develop Bell's palsy. Some people do.

The CDC surveillance case definition was designed for reporting purposes; meaning that everybody that meets that case definition has Lyme. I mean without a doubt they

have Lyme. To get a false positive by CDC case definition criteria would be extremely rare. So they want this to compare the numbers of cases of Lyme between the state of Connecticut and New York and Iowa or wherever so they can compare apples to oranges.

This doesn't mean they should be diagnosing Lyme based on this. That's pretty much --

ATTORNEY GENERAL BLUMENTHAL: If I can put it in, again, layman's language, if you'll excuse me, the CDC is saying we're going to apply certain criteria for the purpose of your reporting to us the existence --

DR. PHILLIPS: Right.

ATTORNEY GENERAL BLUMENTHAL: -- of disease, and we don't want any gray area, any sort of uncertainty --

DR. PHILLIPS: Right.

ATTORNEY GENERAL BLUMENTHAL: -- about the reporting you do as a government agency, but don't use these criteria to decide whether or not to treat people; that is, whether or not to diagnose the disease --

DR. PHILLIPS: Right.

ATTORNEY GENERAL BLUMENTHAL: -- for clinical purposes.

DR. PHILLIPS: That's exactly right. That's exactly right, I mean, you know, it's hard to reference every bit -- this is a -- just a small snippet of what's out there. I can talk about it for hours. I mean, there's a lot of controversy about CDC criteria in the medical literature. It's -- as a clinical diagnostic criteria, it's very, very stringent and very narrow.

ATTORNEY GENERAL BLUMENTHAL:

Thank you. Let me add to this. If we are supposed to do a scientific study that would be accepted by all medical physicians including people who are hardliners that don't accept these [unintelligible], we need to use solid criteria. These will be the CDC criteria, because if I want to make a study to prove that something works rather than the other, I will need to convince everybody in the -- a peer review accepted journal, and I will use the CDC criteria for patients [unintelligible] for example. That's another reason why we need those criteria.

DR. PHILLIPS: To evaluate

[unintelligible] therapies, you want to make sure that everybody has Lyme disease, certainly.

COMMISSIONER REIDER: Doctor, in asking a similar question that I asked this morning, if I am a patient and I've been referred to you or come to you and I have the symptoms of Lyme disease and you treat me with antibiotics but you are not able to confirm a diagnosis of Lyme disease but I continue to have the symptoms, the discomfort, the concern, how long would you treat me with some form of antibiotics?

DR. PHILLIPS: Well, it depends if you are responding. Certainly if we go through several different courses of antibiotics of different antibiotic subtypes and you haven't responded to any of it, if you have Lyme, what's the sense of treating, you know?

COMMISSIONER REIDER: Right.

DR. PHILLIPS: I mean, I have patients diagnosed by Yale with Lyme, I have patients with tick bite, bullseye rash, ELISA, western blot. One of my first patients, a darling person, had -- they put her on I.V. right away, and that's something that's very uncommon, you know, they put her on I.V. right away, said we're going to cure you. Didn't do anything. Before this she was completely healthy, now she is disabled. Didn't do anything.

I tried for months to try and help this person, didn't help, nothing helped. And, you know, if that's the case, I'm not treating her. What else do I have to offer her? We only have a few treatments for Lyme. It's not like we can just make stuff up out of thin air. I mean we try our best, so it depends on your clinical response.

If you come back to me and you say, I'm feeling so much better after four weeks, I almost feel normal, I feel great, I'll say, okay, well, you feel so great, maybe in another couple weeks, just to give a little cushion, then let's stop and see how you do. Or if you say, I think I'm about halfway there, you know, like only halfway there, that slow? Okay, well, maybe we'll give it another four weeks, see how you do.

I mean, you have to use a little common sense. I mean, you cannot start out from the get-go and say we're going to follow these guidelines. I mean guidelines -- especially when

they are not really treatment guidelines. And let's face facts, CDC guidelines are not treatment guidelines. These are surveillance criteria. Anybody that says otherwise --

COMMISSIONER REIDER: Maybe I can explore it a little bit later, but we hear about people being treated with high potency antibiotics for four or five years, and the question is, how frequent does that happen?

DR. PHILLIPS: I don't know. I mean, I don't know how frequently that does happen, but I know that it's been reported in the medical literature and, you know, these patients are very well documented. There are recurrent, persistent infections despite all treatments.

That woman that I referenced, she had clear-cut infection. But let's say you have a person who had no clear-cut infection, I certainly would not encourage treating for years and years of antibiotics but, you know, I can provide you with the article and you can read it yourself.

The person had severe neurologic dysfunction which happened after they took her off -- I mean, we don't limit the treatment of cancer and diabetes in these chronic conditions just because they are chronic. I mean there are certain infections we cannot cure; AIDS, multidrugresistant tuberculosis, I mean leshmanysis [phonetic], I mean, the list goes on and on. There are things that are incurable.

It doesn't mean that these people are crazy. I'm happy that most people with Lyme get better, and I tell people right away, I'm like, your chances are very good. Most people do get better. Most people stay -- get better -- stay better, but if you don't happen to be lucky like that doesn't mean you're nuts.

COMMISSIONER REIDER: Just one question. Would you say the majority of your patients you find are cured within the four- to six-week period?

DR. PHILLIPS: Well, there's a very big difference between bacteriologic and symptomatic cure with Lyme. I mean, the animal studies, when they've injected dogs with Lyme bacteria, they treated them for four weeks and the dogs were healthy. They followed the dogs for a whole year and they gave the dogs high dose steroids and they were able to suppress the

immune system and allow the bacteria to come back out.

So if you mean symptomatically cured, even the patients that get symptomatically cured, I follow up with them on a regular basis. Most of them say every so often they get a flare-up of their old symptoms, it's not as bad as they used to be. Certainly they live their lives and they are fine, but maybe a few days out of the month they feel like they have chills and sweats and they have some joint pain, and then it goes away. And they say, should I be treated, and I say no. And I say, if you find that over a period of several weeks you are getting progressively worse, maybe we'll reevaluate it, but I can't guarantee that I'm going to get rid of every last symptom anyway, because I don't think the bacteria will go away.

And there is ample data over and over showing that they don't, but as long as you get people functional and able to -- to live their life again, that's my goal. Until the absence of a real cure.

But I have to emphasize again, nobody is looking for a definite bacteriologic cure for this illness, because they are denying that the illness exists.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Dr. Katz. Thank you.

DR. KATZ: Well, thank you for giving me the opportunity to bring my input to this very complicated and painful subject, and I'm especially happy to speak here as a neurologist, because chronic Lyme is mostly a neurologic disease, and unfortunately, not many neurologists are seeing or are actively involved in the treatment of Lyme or taking the position about treatment of Lyme. I guess that's the most appropriate statement.

Well, I am not a Lyme, quote-unquote, doctor. I'm a general neurologist with subspecialty training in epilepsy, hyperbaric medicine, sleep disorders, and most of my scientific work was done in these areas. It's only when I moved to private practice in '93 I

started seeing more and more patients with Lyme.

And in order to try and put some sense for myself in this problematic issue, I tried to build some approach that will help me and help my patients with treatment so before we treat we need to diagnose.

The clinical history of course is very important, as we heard before, that there is a detailed neurologic examination where we do a small, kind of higher cognitive function evaluation which is called the mini mentauk [phonetic] test. Well, the mini mentauk [phonetic] test cannot really detect subtle or even more than subtle finding, it's a 20-point question, and you need to be really affected cognitively to come up normal on this test.

We go of course with the blood and cerebral spinal fluid analysis, and we heard it more than once in Dr. Phillips' presentation and other people's, that these tests are not definite. You can have a patient who is seronegative and you can -- so what are you doing next? So we apply other tests.

We are doing MRI of the brain to see if there are any structural abnormalities, and then we are doing some more detailed testing of the cognitive function and of the brain function, which we can image, neuropsychologic assessment and brain SPECT. Well, I don't want to -- I think that the Oxford and PHS are not here, so I don't want to get into it personally, but those two tests are not approved by both Oxford and PHS and some other insurers, the neuropsychological assessment and the brain SPECT, because they don't feel these are needed to diagnose patients with Lyme -- with Lyme disease.

And I had a lot of discussions, written exchange, have sent them papers, documentation of -- the help of these studies has been shown in order to approve means of diagnosis in order to help us find those patients, identify those patients, which the main problem is the brain function, and we are not allowed to test them for brain function. And the reason -- the argument is circular, the argument is we allow only this testing in patients who have documented Lyme by the CDC criteria. So in order to be tested, in order to find out if you have Lyme, you need first to be proven to have Lyme. That's something I didn't understand.

(Laughter.)

DR. KATZ: What is the neuropsychologic evaluation? It's an expanded IQ that takes a lot of time and costs some money to insure. It checks the language, the comprehension, the memory. It gives you IQ in measurable numbers for every function of memory, concentration, it gives you very detailed information where you can find all those minute problems that people will complain of before they are coming to you totally unable to do any mental task.

So in order to diagnose CNS, central nervous system, involvement of Lyme, we need to use those tests, not only as diagnostic help, but also to follow up the help of the treatment. Are we moving in the right direction? And this is a quantifiable test that can be statistically analyzed.

I can tell you if I study a group of patients before and after treatment, I can analyze the results statistically and tell you yes, this patient or this group of patients got improved statistically.

COMMISSIONER REIDER: That will make a determination to a reasonable degree whether somebody has Lyme or not?

DR. KATZ: No. This is an additional test that can give you documentation of a deficiency which we see in Lyme, among other tests. We'll go over this --

COMMISSIONER REIDER: Do companies pay or deny this?

DR. KATZ: They deny -- they don't approve ordering the test, performing the test.

COMMISSIONER REIDER: Right. What about the cost of that series of tests?

DR. KATZ: The cost ranges anywhere from 1200 to $2,000. We'll get to the cost issue, which was not mentioned earlier today, but I think this is the bottom line.

What is a brain SPECT? A brain SPECT is a -- a mean to assess the brain function. It measures cerebral blood flow. Cerebral blood flow is proportional to the glucose metabolism of the neurons. If you have ailing neurons, that's what we have in Lyme

disease, then we see areas of hypoprofusion, less blood flow, less metabolism in those regions of the brain, and we see again and again in patients with Lyme and it was documented in a scientific paper, but unfortunately neither Oxford or other HMOs would approve ordering these tests, and some of the people from the academic community don't believe that these tests can help us in assessing the patient.

And I'm not telling -- again, this is a diagnostic test for Lyme, but with lack of availability of diagnostic test, we need to collect every bit of information that will document that the patient has a problem and no other explanation for the problem was found in the setting of Lyme disease symptoms. It might help us diagnose, help us make a therapeutic decision. This is an image of a SPECT scan, and I hope everybody -- we need to dim the light in order to appreciate the test, but this is not something that can be easily interpreted or read.

The MRI, to remind you, is an

image of anatomy. It gives you a picture of the brain. It doesn't give you a picture of a

functioning brain. This gives you a picture of the brain, and in this particular case we see that the thickness of the cortico mental [phonetic] is different from left to right, and this is a very subtle difference but this is something that we see with Lyme.

And the reason for this assymetry is because there is high profusion of blood in this area. There are less functioning neurons in this area, and this is something we see in patients with central nervous system Lyme. And after three months of antibiotic treatment, we see that this area regained asymmetry, regained a good blood flow.

I'm not bringing this picture as a scientific argument. We need to confirm all those findings with scientific studies, double [unintelligible] control, good papers. But I'm just telling you what I see in day-to-day practice, that people with seronegative Lyme are being treated and, for one reason or another, they are getting better. And why are they getting better if the treatment was not appropriate?

So, let's, you know, we are trying

to get -- I hope that we are trying to get some issues that we can all agree about this day and to come up with some productive conclusions, and in order to do so, I would like to state some things that I feel everybody is in agreement with.

Endemic or epidemic, I think it's a matter of semantics. The truth of the matter is there is about 1 percent of the population of Connecticut annually is being diagnosed with Lyme, and we heard about the area of one to 10 of reported and real cases, so it brings about 1 percent is the incidence of Lyme in Connecticut.

So we are dealing with a serious condition, it's the second largest epidemic after HIV infection. There are currently no reliable tests to diagnose the disease, and I think everybody can agree with the fact that there are seronegative patients. These papers were published and accepted. There is only one issue that the paper referenced that Dr. Phillips brought in I want to reiterate.

If somebody is having an active immunologic reaction against the Lyme, all his antibodies will be busy fighting those

spirochetes and you won't detect them. And this has been reported by Schutzer and Coyle and Delanset [phonetic]. I think Delanset [phonetic] is a pretty respectable journal, and these things are documented, so we are seronegative Lyme.

There are patients with chronic Lyme disease -- significant numbers of patients with chronic Lyme disease have central nervous system involvement, and there are patients with chronic central nervous system Lyme who are serologically negative. So everybody agrees so far, I believe.

Now we should also talk about the treatment, and in order to achieve high brain concentration, we need to achieve high blood concentration. That's the entire reason for using I.V. antibiotics rather than oral. I think every patient will be more comfortable if he will take tablets rather than have the Lyme with all aggravation associated with it, but we need to reach higher brain concentration and that's the reason for the need for I.V. antibiotics.

And the CDC criteria, I think we have talked about CDC today more than they expected.

(Laughter.)

DR. KATZ: So how do we treat Lyme? The -- we treat -- the treatment of choice CNS Lyme is intravenous antibiotics because we can reach concentrations, 10 to 100 more than we reach with oral medication. Theoretically we can get the same amount of antibiotics to the patient orally, but they will be either vomiting or having diarrhea the entire day. It's intolerable. You cannot get those high doses of antibiotics orally, and that's the reason to give intravenous antibiotic.

The reason I am stressing it is because no HMO ever denied oral antibiotics. Why is it if it's a principle, they shouldn't allow any antibiotic treatment for patients with nondocumented Lyme disease. It's not a matter of principle. It's a matter of money, because intravenous treatment is expensive. Neuropsychological examination is expensive. SPECT studies are expensive. It's not a matter of principle, so I don't want anybody to hide behind principles.

The only principles I see, there is expense. And it's understandable because they need to survive financially, but let's call a spade a spade, because if it was a principle they wouldn't allow oral antibiotics as well.

We need intravenous antibiotic because we need to reach higher blood concentration. Good brain penetration is considered 1 percent of the blood level, and this is, for example, achieved with ceftriaxone, which goes from 150 micrograms per [unintelligible] in the serum to one and a half micrograms per [unintelligible] after two gram I.V. dosage. So this is considered good penetration. And other medications are not penetrating the central nervous system as good because they are less lipid soluble.

What are we doing with patients who, according to the CDC criteria, don't meet -- are not having chronic Lyme so we don't treat them, right? So we will wait and see what happens. Perhaps they will have relapsing, rebutting occurs, like was suggested earlier by Dr. Eisenberg. Perhaps they will continue to get dementia and then eventually there won't be

anybody to talk with.

(Laughter.)

DR. KATZ: So my -- I am using a very practical approach. We have studied the patient thoroughly. There is a clinical setting that might be compatible with Lyme. There is no other disease that can explain the patient course that we have checked and very thoroughly, altering immune diseases, other sources of infection, other degenerative neurologic condition.

So it is possible that the patient

is having Lyme. It's not definite that he's having Lyme. It is possible. So why -- what are we going to offer to this patient? Let's see if serology will become positive next year. I think that we need to offer the patient a treatment, because that's their only chance of getting better. I think that's their only chance of getting better, should be an informed consent. The patient should be aware of the fact that antibiotics are carrying a lot of risks, and that it might not be the definite treatment, but this

is the only way we can offer him help.

And many of the patients -- and I'm the doctor, I would agree with this approach, if I will take my chances, I will take the chances of getting better and getting some of the I.V. antibiotic complications. And lo and behold, there is a lot of success stories.

Almost every patient I'm putting on I.V. antibiotics is getting better clinically, but not only something that you should call the placebo effect; patients are not coming back to me and telling me I'm feeling better, no. I'm using the same measurable criteria that I tried to apply initially; retesting them with neuropsychological testing, seeing marked improvement, restudying the brain cerebral flow, which there is an improvement in flow, so something works here.

We've talked a lot about it and I think that one of the most frustrating things for me was not being able to order tests that will help me reach a therapeutic decision because they are not approved HMO. And even though I was promised verbally that every patient that I'm referring as a neurologist for neuropsychologic

testing will be approved, this was not respected. The patients are still rebutting their approval from one committee, to the second, to the third, to the fourth. I don't know how many committees, we haven't reached the 10th yet, but it's being dragged in correspondence for months, and the tests are not being approved. It's vital, that verbal promise, that they will be approved. And the neuropsychologic testing as well.

So what happens? What happens

usually in this situation is when patients are frustrated and they are not getting what they need to get, proper medical treatment, they are trying to spend out-of-pocket, start to spend out-of-pocket all kinds of expenses. Initially it's for the I.V. antibiotics, which at least make some sense, but they are going to all kinds of not mainstream treatment options, the hyperbaric oxygen, which we don't know whether it works or not, but we know that it is expensive. And all kinds of other bizarre treatments, which I really don't know what they are doing, but the patients, I think -- the fact that the patients are not backed up by either doctors, main doctors

or by their HMOs, is pushing them aside from mainstream medicine and might progress their damage.

So what do we need to do? We need to come up with some solution, because the situation is indeed grave. Of course we need to continue with the research to improve the diagnostic means and follow the options that were mentioned here. But I think we need to accept the fact that additional indirect tests might help with making a therapeutic decision, and this agreement and acceptance should be done by the HMOs, the tests should be approved.

We need also to accept the fact that some of the patients, and I won't give you any numbers because it's not scientific presentation, I don't know what the numbers are, but some patients have chronic central nervous system Lyme who are seronegative and will benefit from I.V. antibiotics.

So as a final slide, I think we should come to some productive conclusion. This conclusion is to form an immediate committee, will have all representatives, should be sponsored by the State Department of Health, by

the Attorney General, and by the Commissioner of Insurance, which have been kind enough to ask us to come here and to talk.

But in this committee should be representatives from all HMOs, and there will be a representative from the medical communities, and there will be expedited discussion for any appeals, and instead of taking a year or two years for approving a test, we'll be able to really discuss issues in two weeks, one month, and to get things done and resolved, not to tell me that yeah, I think we will approve this treatment but nothing is going to be applied to the appeal process. And although we are saying it will happen, it will happen next year. This is not the way that things should be amended. Things should be amended immediately. We don't have time to waste. These people are sick, they need treatment. We need to do things fast.

So I think that would help not only for the Lyme patients but for any other situations where there are unapproved treatments and the patient wants a quick review by sound professionals in addition to the HMOs.

So that is my conclusion, and I

hope that we reach some positive response to this suggestion which might give some immediate results to the problem. Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you, Doctor.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Just a couple of questions, in part to anticipate some of what may be said after you finish by other members of the -- of other panels. I know that you, Dr. Katz, have done a lot of work in sleep disorders and problems relating to sleep. Is there possible confusion between the symptomatology associated with Lyme disease and sleep disorders?

DR. KATZ: Well, I don't think there should be any confusion, Lyme disease causes sleep disorders. It interferes with sleep, and like was reported a few years ago, chronic fatigue. It causes insomnia, and it goes in a special pattern on the EEG we call an alpha delta sleep intrusion. The fact that somebody is sick and the central nervous system is involved

and suffering from chronic pain definitely affects the quality of sleep.

We see less deep sleep, more superficial sleep, less sleep efficiency, which means more arousal in time spent in bed without sleeping, but it is I think not the hallmark of Lyme, but for any chronic condition.

ATTORNEY GENERAL BLUMENTHAL: And by using the kinds of tests you've described here, you can distinguish between sleep disorders that may be due to one kind of pain or some other kind of problem as opposed to Lyme disease?

DR. KATZ: Yeah. We document -- they match to the central nervous system. This is not something that we should think is an easy subject. This is a definitely -- a deficit which [unintelligible] with other conditions.

ATTORNEY GENERAL BLUMENTHAL: Again, to anticipate, I think some of what I've heard and maybe mentioned later on, the subject of risks associated with longer term use of antibiotics, there have been I think issues raised so far as damage to kidneys and side effects that are associated with longer-range use of antibiotics. And it actually was not

mentioned by the panel of insurance representatives, but I've heard that raised as a possible risk. Do you have any opinion on that?

DR. KATZ: Well, there are risks, and that's the reason we have a very thorough discussion with the patient before we start him on I.V. antibiotic, and we follow the kidney functions and the liver functions, and we don't treat patients unless they are getting better. We are not putting somebody on I.V. antibiotics unless they are getting better.

There are all kinds of practical guidelines that each physician adopts, but we are very aware of the potential risks, and we follow the patients closely with laboratory tests to catch them on time. Most of the risks are the idiosyncratic, the allergies are reversible and usually dose-dependent. So if we follow closely, we can prevent the progression of those complications, and we explain all those risks to the patient before we start the treatment.

ATTORNEY GENERAL BLUMENTHAL: So there are two ways to seek to take account of those risks; one is to explain to the patient what they are, and the other is to do testing

while the treatment is ongoing to detect and deal with the risks if they in fact materialize.

DR. KATZ: Right.

ATTORNEY GENERAL BLUMENTHAL: What are the risks that may be irreversible?

DR. KATZ: You can get an idiosyncratic reaction, which means sort of allergic; you can get liver failure, which is fatal, liver failure.

Let me just put -- the risks of -- the idiosyncratic risks are usually not dose-dependent, so somebody taking oral antibiotics, they are exposed to the same risks. So the difference between oral antibiotic in terms of the idiosyncratic reaction is usually not dose-dependent, so severe allergic reaction can be acquired if you take a tablet or an I.V. dosage, so those are fatal risks.

The Stevens Johnson syndrome, you get a severe allergic reaction but they are occurring with any medication, not only with antibiotics. Some of them are dose-dependent, so if you stop the treatment you get a reversal of the bone marrow suppression or the increase in liver functions.

ATTORNEY GENERAL BLUMENTHAL: Are there studies that show certain kind of risks are more likely with extended time of antibiotic treatment?

DR. KATZ: I think the dose-dependent reaction will be more likely to occur on chronic treatment. We see that the liver function derangements are not occurring on the first day, they might pop up in the fourth week, so this might be happening with longer treatment.

ATTORNEY GENERAL BLUMENTHAL: And what would you say to the insurance company that might say to you, well, Dr. Katz, you know, the reason we don't approve this kind of six-week or eight or longer term antibiotic treatment is that we're afraid we'll be sued because we have sanctioned this treatment and we incur the risk of the side effects?

DR. KATZ: There will be suit --

ATTORNEY GENERAL BLUMENTHAL: Let's say they will say to you what is the legal liability if we approve this longer-term treatment which may have side effects? I assume you would say well, you explain the side effects to the patient and the choice is made by the physician and the patient.

DR. KATZ: Yes. I think the HMOs are not liable at all. The physician is liable. The physician orders the medication. They are not liable professionally.

ATTORNEY GENERAL BLUMENTHAL: But you would take -- as the physician, you would take precautions in terms of --

DR. KATZ: Of course.

ATTORNEY GENERAL BLUMENTHAL: -- testing and so forth, keeping track of what symptoms are and what they are not?

DR. KATZ: That's the nature of medicine these days. We prescribe many medications, many of them have a lot of serious side effects. The epileptic drug, for example, which is my main specialty, I mean, terrible side effects, but we put people on these medications for life.

Dilantin, everybody talked about Dilantin with threat or fear? No, but Dilantin is a terrible drug. It can cause death, and it has been used since 1939 and some people have been put on Dilantin in 1939 and are still taking it to this very day. That's the nature of prescribing medication.

DR. PHILLIPS: Can I comment on some of that?

ATTORNEY GENERAL BLUMENTHAL: Yeah, sure. Thank you, Dr. Phillips.

DR. PHILLIPS: I wanted to comment first on the sleep disorder. Sleep disorders is very commonly seen with Lyme. The particular pattern is the patient can fall asleep and then wake up multiple times at night feeling very hyper and pop wide awake, like they should be vacuuming the bedroom or something like that.

With Lyme encephalopathy, which really means sick brain, there is a reversal of sleep-wake cycle, so you feel like you should be sleeping during the day and awake at night.

There has actually been published medical literature by some of the more conservative researchers in this field postulating that fibromyalgia is as a result of anxiety over Lyme, therefore causing sleep disturbance, therefore causing chronic muscle aches.

And I just want to point out that

several -- there are other diseases like AIDS and cancer and diabetes, a whole host of other serious illnesses that cause more anxiety than Lyme does, that do not cause sleep disturbance, and do not cause, quote-unquote, fibromyalgia.

As for long-term antibiotic toxicities, well, in terms of the HMOs getting sued for agreeing with long-term therapy, I don't see anybody putting up a stink for long-term tetracycline therapy for acne, and I have to make that point clear.

And secondly, these antibiotics in general are -- have been around for a long time. They are, as drugs go, a very nontoxic class, they are nontoxic classes of drugs. Certainly you can see some liver function abnormalities with any class of drugs. I personally have not heard or seen of any acute cases of renal failure associated with any of the beta-lactam antibiotics commonly prescribed for Lyme.

The most common serious side effect -- or the most commonly prescribed I.V. drug, Rocephin is gallbladder sludging and gallstones, which are entirely made up of the drug, Rocephin. These effects are transient and

with discontinuation of the drug it goes away.

Some patients have -- none of my patients, but then again, I don't treat frequently with I.V. antibiotics, and it's not because I think it's wrong. I think I.V. antibiotics are good and accepted therapy, it's just that most of my patients have been referred to me by other doctors because they have failed I.V. therapy, so they have already failed the cure. Now what?

So why would I go and re-treat with something that failed? But they have never -- you know, very rare to develop toxicities related to the treatment. Much more common that my patients I've seen with seizure disorder develop liver function abnormalities from Tegretol or Dilantin or any of these antiepileptic drugs that they were put on or worse yet, chronic steroid use.

So many of my patients were treated with steroids for years to control some of their Lyme symptoms, results in diabetes, high blood pressure, cataracts, osteoporosis with bone fractures throughout the spine, disabling pain, you know, thinning of the skin, horrible stuff.

And from what is in the medical literature, these are nontoxic classes of medicines. That's all.

ATTORNEY GENERAL BLUMENTHAL: What would you typically do if a patient is referred to you after a period of treatment with antibiotics, I.V. antibiotics, that didn't produce --

DR. PHILLIPS: I mean, the I.V. antibiotics are, like I said, a good and standard therapy, but there's a lot of data showing that Lyme bacteria go inside cells. They have been reported inside five cell types, and in unpublished data, myself and my research colleagues have found them in another cell type. Guess what? The antibiotics, I.V. antibiotics, Rocephin, beta-lactams in general don't get inside cells.

All chronic bacterial infections have as part of their -- part of their etiology, an intracellular phase; they hide from the immune system. They hide from the drugs inside the cells. The I.V. antibiotics don't get inside the cells. Things like Doxycycline and macrolide antibiotics do get inside cells. And often that can be more effective when people have a

significant intracellular burden.

But again, these drugs are limited because they don't have high concentrations in the spinal fluid.

Like Dr. Katz mentioned, Doxycycline in higher doses orally can cross the blood brain barrier, but the other ones not so much. So sometimes you are forced to do it. I mean, I don't like to advise a patient to put a line in their arm very much at all. On occasion I've done it, my dad had four weeks of I.V. I didn't advise the neurologist to treat him longer, but I have on occasion treated longer than four weeks. I've treated a little bit longer, but I don't treat very, very long because I figure if it's going to cure it's going to cure, and if it's not, it's not going to.

But I will do everything in my power to get my patients better, and luckily most of my patients get a hell of a lot better. If you just keeping plugging at it -- away at the disease, it responds eventually in most cases.

ATTORNEY GENERAL BLUMENTHAL: And just one -- one other question from me. Your most recent article describing your culturing of

the bacteria, I wonder if you could describe what you see as the longer-range implications of that.

DR. PHILLIPS: Well, it's clearly in its infancy. I mean, it took us six years to get this far. When I first presented it at Lyme Disease Foundation conferences and Institutes of Health, not many people believed that what we were growing was really Lyme bacteria. Then I sent it out to a couple of different universities and it came back, yes, it's Lyme bacteria. They did the DNA testing, they did the electromicroscopy, they did another fancy test called immunoelectromicroscopy.

So the call came back positive saying it's Lyme bacteria. People still don't believe. We publish pictures. You know, I don't know, it's like anything else, it has to be duplicated, it has to be verified.

Just as often as we have astounding results, we have miserable results. It's very, very hard to grow spirochetes. And that's an understatement. It's nearly -- I mean it took months and months for these things to repeat at trials to get them to grow. There were

greater than a thousand experiments involved in finding a way to grow them that actually worked, and that's the way it is. So it's at the beginning stages. I hope to make some progress soon.

COMMISSIONER REIDER: The Attorney General asked the questions regarding the antibiotic, and I was interested in a response. Just an observation, Dr. Katz.

Currently, there are very strict guidelines as to internal and external appeal, time lines and so on. I say currently. The State statutes and the regulations require companies to have an internal process for if there is a disagreement, and then to move it downside if the patient so wishes, and I just suggest if you're finding that you feel there is undue or deliberate delay, that that's a matter that should be brought to us, and we're able to respond to that.

DR. KATZ: Well, the patient -- I think you will receive a lot of patients' complaints in this, and I believe that it takes months to get a test approved. Needless to say, it goes back and forth, and HMOs are not keeping

their written deadlines themselves, so --

COMMISSIONER REIDER: Well, like I said, as the Insurance Department, we'd be interested in, you know, knowing of that and following it and, you know, we'd advise you as to what we did come up with.

And, Dr. Phillips, just a question. We were talking about the treatments. What percentage of the patients that have come to you do you get denials from an HMO?

DR. PHILLIPS: Well, because, like I said, most of my patients have been referred because of their failure to be cured with a cure, I don't treat -- it's nothing against I.V.

antibiotics. If someone has never been treated with antibiotics and they have persistent symptoms, definitely go for it, I mean, try it. What do you have to lose?

Yeah, there's some risks but when you are disabled, you can't work, you just imagine, you can't work, you can't think straight, you are forgetting where things are in the house, you go back to sleep after being up for two hours, heart palpitations. I mean, there is no risk, benefit is very much in favor of

treating.

But when it doesn't work, and a lot of the patients that have come to see me have been on for several months, antibiotics, there were doctors that treated for very long-term with antibiotics, and I hear anecdotes that the patients do get better, and I'm happy and support that. It's just a difference in personal style.

COMMISSIONER REIDER: Sure.

DR. PHILLIPS: But in terms of treating, I mean, what was your original question?

(Laughter.)

COMMISSIONER REIDER: Well, everything you said was interesting, but the question was --

DR. PHILLIPS: Not an answer.

COMMISSIONER REIDER: -- what percentage of the cases that come to you and you suggest treatment are denied by the HMOs?

DR. PHILLIPS: Oh. Put it this way: Out of the cases I suggest I.V. treatment, a significant number. Oxford is probably the

worst offender. I don't think I've ever had an Oxford case approved ever. I do not think ever. Actually no, excuse me, there was one. There was one, only because of the EMG, and she had good serology. If it wasn't because of that, it wouldn't have gotten approved.

But I'd say a good -- a good 50 percent get denied, and these are low numbers, though, but a good 50 percent, and I write a letter -- I'll write a letter to the insurance company with 30 references. You know, I'll spend hours on the letter, only to have them reply with two lines: Nope. Sorry. I find I have limited recourse. What can I do, you know?

So I try to do the best for my patients. I give them some more Doxycycline. You know? But no, something has to be done about this insurance situation.

ATTORNEY GENERAL BLUMENTHAL: Representative Powers?

REPRESENTATIVE POWERS: Thank you. I'm going to ask you the same -- sort of the same questions I asked the HMOs. They kept talking about using the CDC guidelines, and then in response to my questions, they indicated that

I guess he took out the book on pediatricians and he said they are less detailed, but it's all the same stuff. Is it in fact the same stuff across these different organizations that he's referring to, professional organizations?

DR. PHILLIPS: Every professional organization has their own, you know, opinion. It doesn't mean that it's correct or not correct. But the CDC case definition is just the case definition of surveillance.

REPRESENTATIVE POWERS: Right. But they are not using it that way?

DR. PHILLIPS: They are using it for clinical purposes, and I can't emphasize this enough. This has been, from the CDC's earliest involvement with Lyme, they said don't use the case definition for clinical diagnosis.

REPRESENTATIVE POWERS: But they are using it that way, and obviously Physician's Health nodded and said yes, he was doing it the same way, and yet they went on to say, but the professional organizations are saying the same thing.

DR. PHILLIPS: Saying the same thing, not to use it or saying the same thing

yes, you should use it? I haven't looked in depth at every professional organization's recommendations on Lyme, unfortunately, but, you know, I go -- there's a comment of the FDA as well that I'm aware of that I have to get my hands on also saying not to use some of these definitions as clinical -- for clinical purposes.

DR. KATZ: So, I can't comment on the stuff that I'm not directly familiar with in terms of this pediatric stuff, I'm not a pediatrician, so of course I wouldn't be following those guidelines.

REPRESENTATIVE POWERS: Right. I was just concerned that they were all kind of copying the CDC guidelines and using them as their parameters.

DR. KATZ: CDC guidelines are diagnostic criteria, not treatment criteria, and their recommendations.

REPRESENTATIVE POWERS: I know.

DR. KATZ: They are not written in stone.

REPRESENTATIVE POWERS: Right. But the HMO guy sat there and said yes, that's

what we use.

DR. PHILLIPS: Of course they're going to say that's what they use, only because, you know, it is a matter of money. It's -- the CDC case surveillance criteria are very strict. The HMOs will not have to cover the treatment for Lyme based on -- a substantial portion of Lyme based on those criteria, and they are going to pick and choose whatever the shortest and least expensive course of therapy, it would seem.

REPRESENTATIVE POWERS: Is there a way to override that in terms of whether it comes from the CDC or maybe from the State level, to say that in fact the guidelines are not the narrow ones that were used for the surveying technique, but in fact are broader? And if so, who would do that?

DR. PHILLIPS: I'm not really sure. I think that's why I'm here. I'm asking you guys the same thing.

(Laughter.)

DR. PHILLIPS: I mean I can only say that it's been said over and over again that

they are not diagnostic criteria, and the CDC doesn't really give -- they are not treatment guidelines to begin with. They are just -- that's all they are, is case surveillance criteria, to say, okay, we can use this.

Like Dr. Katz said, if you want to make sure that someone has Lyme when they are in the study, so they could say, okay, this is appropriate treatment or not appropriate treatment, but I have no answer for that.

REPRESENTATIVE POWERS: Okay. Thank you.

DR. PHILLIPS: Thanks.

DR. KATZ: Medicine is not an exact science, and that's the reason we have guidelines, to keep people in the mainstream, by no means prescribes you the number of weeks and the grounds that you should give for people with Lyme. There is some degree of freedom that is hopefully still left with the physician unless we are getting into a totalitarian regime in medicine.

So, medicine is an art, and the French are saying in medicine, like in laughter, is no ever and there is no never. Everything -- there are exceptions, so you cannot use guidelines as treatment criteria to guide every physician and to tie his hands in therapeutic or diagnostic workup.

DR. PHILLIPS: I think that that's most clearly demonstrated in the survey of the 78 doctors from Lyme-endemic areas. 57 percent for late stage Lyme are treating three months or more. Clearly they are not observing what, you know, was espoused by Yale; that four weeks is not a good therapy. I mean, this is the standard of care, and yes, if someone is saying that there's a guideline out there and a majority of doctors are not following that guideline because they are in the trenches trying to make their patients better, then the guidelines have to be changed.

We have to use a reasonable amount of common sense. I mean, anybody -- just a very reasonable level of intellectual curiosity, reasonable training in the field can look at this and say, there's a major problem and I don't know how to go about changing it, that's why I'm asking you guys to help. But someone has got to do it.

ATTORNEY GENERAL BLUMENTHAL: Well, if we were to respond, though, meaning if the legislature and any public officials were to respond by saying that these decisions about diagnosis and treatment ought to be made by the physician and the patient without being bound categorically by either the CDC guidelines or any other strict protocol or regimens right now, that would be a justifiable approach, in your view, wouldn't it, or not?

DR. PHILLIPS: Yeah. I mean, I think a similar bill was proposed in New Jersey, where they were -- and it almost passed -- where the insurance companies have to basically listen to the treating physician. You know, as much as they can review medical records, and as much as they can try and get a handle on it, you see the patient -- there is nontangible interaction between the doctor and patient, you know, to look at a negative blood test, but you see the patient, like 30 years old, walking with a walker coming into your office and living like a little old person, basically disabled, and has previously responded to antibiotics, only to be -- when the therapy was withdrawn, to rapidly

deteriorate. Like I said, common sense should prevail.

ATTORNEY GENERAL BLUMENTHAL: And your idea of an ad hoc committee, Dr. Katz, have you ever discussed that with members of the insurance industry?

DR. KATZ: Well, the rare occasions that they responded to my calls --

(Laughter.)

DR. KATZ: -- they have other pressing issues to discuss, but I'm sure they will be receptive to it, and only because of the heat that is now being generated with these discussions.

ATTORNEY GENERAL BLUMENTHAL: Again, I want to thank both you and Dr. Phillips for being here today and for your patience and understanding in bearing with our schedule. I know you are both busy, and you both made sacrifices to be here today. We thank you.

DR. KATZ: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Dr. Schoen and Dr. Feder, speaking of patience and understanding, we want to thank you as well and apologize for the delays in your testifying today.

DR. SCHOEN: Mr. Attorney General, Mr. Commissioner, ladies and gentlemen, as I sat over in the wings, it was quite clear to me as I was listening to some of the applause for Dr. Phillips what it means to have the home court advantage. But let me press on and talk about the issues about the diagnosis and treatment of Lyme disease, and also issues relating to the treatment of Lyme disease as I see it in Connecticut today.

Lyme disease is a complex illness in that it can affect multiple parts of the body. I believe, however, that correct diagnosis is usually possible. There has been a lot of discussion, this afternoon at least, about Center for Disease Control guidelines for diagnosis, and I don't think anybody in the medical community feels that Center for Disease Control guidelines are required to make the diagnosis of Lyme disease.

I agree with Dr. Katz that in talking about surveillance, these things are sometimes used in reporting. I also think that there are patterns of abnormalities that occur in Lyme disease patients that are generally recognizable, that it is usually possible to -- in a diagnostic sense, to find objective manifestations of disease. But beyond this, I don't think that there are any rules that anyone is wedded to at this time in making the Lyme disease diagnosis.

I do think that it's important that we distinguish, and perhaps this has been done already, between early Lyme disease, which is typically the stage of the illness in which after the tick bite a rash is often present, and late Lyme disease, in which -- particularly in patients who are not treated for early disease -- arthritic, neuro, and neurologic and cardiac problems can occur.

You've heard already, and I won't repeat the information, about the fact that there's lots of evidence that in Connecticut and in other states where Lyme disease is endemic, early Lyme disease is underreported. I think the importance of this is that citizens in Connecticut correctly recognize that early Lyme disease is a very common problem, more common than incidence figures give as an impression, and recognize how much Lyme disease occurs in their community. But most of this Lyme disease is early Lyme disease, which is generally not a severe illness, and is generally a curable disease with oral antibiotic therapy.

On the other hand, when we talk about late Lyme disease, many physicians, including myself, believe that Lyme disease is over -- late Lyme disease is overdiagnosed and overtreated. Lyme disease can affect or even permanently damage the joints or nervous system, and not all patients treated with antibiotic therapy, and in late Lyme disease it's often intravenous antibiotic therapy, are cured by treatment. Sometimes there is a requirement for additional antibiotic therapy, although in my experience, there's often a diminishing return to that therapy. And in that sense I would agree with Dr. Phillips.

And sometimes other modalities are

desirable. For example, we've treated a group of patients with refractory Lyme arthritis, with arthroscopic synovectomy, in which we've removed inflamed and presumably infected tissue from the synovial lining of joints and had good outcomes in situations where antibiotic therapy had not been successful up to that point.

But I believe that anxiety about Lyme disease exists among Connecticut residents because they overestimate the likelihood of developing late Lyme disease following early Lyme disease if adequately treated, and also they underestimate the general effectiveness of antibiotic therapy given for late Lyme disease.

What's in dispute here is whether there is a significant population of patients who have chronic Lyme disease for whom one month of intravenous antibiotic therapy is insufficient, and whether months, or in some cases, years of such therapy would provide benefit.

In my experience, and I think Dr. Katz mentioned this also, insurance companies in Connecticut and elsewhere generally do not dispute oral antibiotic therapy for early Lyme disease treatment. It's also been my experience

that in general, insurance companies do not participate in a decision by a physician in Connecticut to provide an initial course of four weeks of intravenous antibiotic therapy for Lyme disease. It's the decision by Connecticut insurance companies to require documentation of active disease for treatment beyond four to six weeks with intravenous antibiotic therapy, which in my opinion, is at the heart of the dispute that you're hearing about today.

As I see patients with questions about Lyme disease, a frequent concern in my practice, just as in Dr. Phillips' practice, is the patient has already received considerable antibiotic treatment and the symptoms that they are having have not resolved. In my experience, the most common reason for treatment failures in such patients is that they do not actually have active Lyme disease, and therefore, in my opinion, it's good medical practice to reassess the diagnosis.

Obviously it's difficult to generalize. Every patient is different. In the 10 minutes provided, I can't discuss this at great length, I would refer you to the paper that

I provided to you as giving you some information about what's happened in my practice in the past several years.

But I wish to emphasize that in my opinion, this is -- this dispute about prolonged [tape ended and then began new tape].

... what is the appropriate duration of I.V. antibiotic, therapeutically prolonged I.V. antibiotics. As you move forward and consider all the information, much of it conflicting information that you've heard this afternoon, whether the patient has Lyme disease or not, whether prolonged intravenous antibiotic treatment is useful or not, is there any harm to a government remedy to help patients receive prolonged intravenous antibiotic therapy for the diagnosis of chronic Lyme disease.

In my opinion, there would be several negative outcomes to such government action. At least indirectly, your action would inevitably validate the medical appropriateness of such treatment in the absence of new scientific information of effectiveness.

Physicians are taught above all else, do no harm. If the patient does not need a

treatment, then there is no benefit, and any risks are unacceptable.

You asked earlier about the risks of prolonged intravenous antibiotic therapy. Some of these risks are minor and can include such things as drug allergy, a rash, a fever, et cetera, phlebitis at a catheter site. Some are more serious, catheter-induced septicemia, catheter-induced problems where a catheter leads to chronic or major blood vessel collapse and loss of part of a limb.

Patients can also have serious allergic reactions. Patients receiving beta-lactam antibiotics can have bone marrow suppression, as you heard from some of the speakers earlier.

But I think the important issue here is not so much the risk but the risk-benefit ratio. If there's not a benefit, we shouldn't take the risk.

What I've talked about so far is risks related to treatment. I believe that there's also a diagnostic risk of prolonged intravenous antibiotic therapy for chronic Lyme disease. The patient -- the message the patient inevitably receives from such treatment is that they have a serious, chronic, intractable illness, in which powerful, broad spectrum antibiotics are required, and cure is by no means certain. Beyond this, there's the diagnostic risk that the actual problem causing the symptoms will not be addressed.

I wish that this controversy did not exist, and I wish every patient in whom there's a question about Lyme disease gets a good outcome with which they are satisfied, but I don't believe the treatment of Lyme disease in Connecticut is so broken today that there needs to be a government remedy to fix it. Thank you.

ATTORNEY GENERAL BLUMENTHAL: Dr. Schoen, I assume that you are agreeing with the previous panel and with the CDC itself that these case reporting criteria should not be used as binding guidelines for clinical diagnosis?

DR. SCHOEN: Absolutely.

ATTORNEY GENERAL BLUMENTHAL: And when we talk about a government remedy and about the possibility of the side effects that you mentioned, I assume that you'd also agree that protocol for I.V. treatment for whatever the

disease is, if it took longer than four, six weeks, and if it were intravenous, if a company, by certain kind of testing, could at least minimize or reduce the risks of those side effects, do you understand my question? It's sort of a convoluted question. If you'd like I'll try to put it in simpler language.

DR. SCHOEN: That's okay. I'll try not to give a convoluted answer.

I think that I go back to what I said a minute ago, which is certainly anytime a doctor treats a patient and the patient is participating in that decision, you have to consider the risks and the benefits. And I would agree that oral tetracycline is generally a well-tolerated therapy.

I would also say that in my experience, the use of prolonged cephalosporins, given intravenously, is a therapy in which toxicity rises over time. But ultimately what you've got to weigh is the risk against the benefit. And of course you want the patient to be monitored, but I think that goes without saying. The risk -- you want the risk of any treatment you give to be as low as you can make

it when you decide to give it, but I don't think monitoring justifies the act of giving. Giving has got to be based on the risk.

ATTORNEY GENERAL BLUMENTHAL: But doesn't monitoring minimize the risk?

DR. SCHOEN: Certainly.

ATTORNEY GENERAL BLUMENTHAL: And isn't monitoring an acceptable way of reducing the risk?

DR. SCHOEN: Well, monitoring is a lot better than not monitoring.

ATTORNEY GENERAL BLUMENTHAL: And in the course of a lot of treatments, aren't there risks, side effects, and some pretty serious side effects?

DR. SCHOEN: Right.

ATTORNEY GENERAL BLUMENTHAL: And very often a physician will say to a patient, we're at the limit of what we can do with X, Y, or Z treatment, and now we're going to try A, B, C, which could have the following risks for you and here's what they are, and here's what we'll do to try to minimize them? That occurs all the time, doesn't it?

DR. SCHOEN: Yes. I'm just giving

my opinion that the time to give treatment for Lyme disease is when active Lyme disease is present. If it's not present, then if you give treatment that carries some risk and there's not a benefit, then that risk is higher than I think should be taken.

ATTORNEY GENERAL BLUMENTHAL: But on the diagnosis side, Dr. Katz has suggested that there is general agreement that the diagnostic procedures now available are at best not 100 percent, are at best probably unreliable in large part.

DR. SCHOEN: Well, there's two parts to that; the first part is the overall activity that goes into making the diagnosis, and the second part is are there tests which provide a sort of a yes/no answer without imperfection, and I would certainly agree that the testing isn't perfect, and no single test gives reliable information. It gives helpful information but it doesn't give conclusive information. So that if one could sit back and look at a test result and say yes/no, if it was that simple, there wouldn't be controversy. I think you have to take it all together, but at the same time, in giving my

impression, which is that the disease is being overdiagnosed and overtreated.

And I don't think that there's evidence that giving therapy beyond a period of time of four to six weeks in most instances -- and there certainly are some exceptions -- conveys benefit to the patients receiving this therapy in Connecticut today such that there's a problem where they are being denied necessary and needed care.

ATTORNEY GENERAL BLUMENTHAL: But if there is controversy about the effectiveness of the diagnostic tests available as of this date, and there's also controversy within the medical community among very reputable and well-trained and well-regarded people about what proper treatment is, why not leave it to the treating physician and the patient, principally the treating physician, to make these decisions about cases that, as you say, should be determined on an individual basis?

DR. SCHOEN: I believe that it is possible in most instances to make a diagnosis when everything is taken together. You could pick any single test or any single procedure in

isolation and say this has imperfections, that has imperfections. But I believe it's possible to arrive at a reasonable probability as to whether or not Lyme disease exists, and I would certainly agree that there may be situations in which one shudders on the side of treatment if one's unsure, but I think the landscape out there is different. The landscape is that there's a lot more treatment being given than I think really benefits patients in Connecticut, certainly, given the limitations of the test.

What you say has theoretical merit, I think the danger is that too much treatment can be given and carries some of this risk. And by "too much," I simply mean treatment if the disease isn't there in an active form, there is the potential for harm.

ATTORNEY GENERAL BLUMENTHAL: But too much treatment is really in the eye of the beholder, so to speak.

DR. SCHOEN: That's true.

ATTORNEY GENERAL BLUMENTHAL: And that kind of generality, when brought to the level of the individual who is suffering pain and symptomatology that is consistent with Lyme

disease, perhaps should be left to that individual or more accurately to the treating physician rather than based on a more general concept of what's too much and what's too little.

DR. SCHOEN: It's easier for me, in dealing with an individual patient, to have this discussion, because these generalities obviously could go into different directions. But I've certainly seen situations in an individual patient where I've seen treatment for Lyme disease because a person was in pain, and in my opinion, that was not -- that treatment was in a sense a dead end, and other things needed to be done, other diagnoses needed to be considered.

So there certainly may be situations in which you are right, but for the purposes of this hearing, I think you've asked me to paint sort of a picture of what I think is out there, and that's what I've tried to do.

ATTORNEY GENERAL BLUMENTHAL: How often have you encountered the side effects as you described it, that are risks of prolonged treatment with antibiotics?

DR. SCHOEN: Well, actually, I've

been involved in seeing patients with Lyme disease issues since 1981, and the paper that Dr. Phillips alluded to that I provided to you was a paper that we started to write because we expected to see a lot of side -- we were seeing side effects in our clinic from prolonged antibiotic therapy, and we started working on that paper in around 1993 or so. And that, in my recollection, is about the time when I began to see insurance companies in Connecticut take a stronger interest, not so much in my experience in four weeks of I.V. antibiotic therapy, but in therapy beyond four weeks.

And I really felt as if -- in that paper, for instance, most of the problems that we described were not serious side effects, they were relatively minor things in the sense that, you know, we had sort of the mild, moderate, severe. And basically they weren't things that did permanent harm to people, but I believe that was somewhat of a change, which reflects the fact that it is harder today to get open access to prolonged I.V. antibiotic therapy than it was a few years ago.

But certainly the examples that I

described to you of catheter-induced septicemia, heart valve infection, a patient losing a limb because of a catheter clotting, a patient developing severe bone marrow problems, requiring admission to an intensive care unit because of life-threatening suppression of the bone marrow from ceftriaxone. Those are all things that I've seen.

ATTORNEY GENERAL BLUMENTHAL: But those are pretty rare?

DR. SCHOEN: Well, they don't -- yes. Most -- yes, the answer is yes. Most patients encountering antibiotic therapy for Lyme disease are not harmed by that therapy, I would agree with that. But the longer you give it the more risk you take, in my opinion. So if we're talking about four weeks of ceftriaxone or Rocephin versus 28 weeks, we're talking about a different situation.

And in a study we did comparing two versus four weeks several years ago, there was a difference even between two and four weeks. So again, I think we can't just look at risk. We have to look at risk and benefit together. I think every doctor should do that

every time they treat any patient for anything.

ATTORNEY GENERAL BLUMENTHAL: Have you ever seen denials of insurance coverage in cases where you think it should have been provided?

DR. SCHOEN: Yes.

ATTORNEY GENERAL BLUMENTHAL: Could you describe a few of those?

DR. SCHOEN: Well, the best -- I had one lady come in -- I make a distinction between early and late disease. I'll give you this one first.

In an early disease case, in my opinion and experience, most of the time patients can be treated with oral antibiotic therapy successfully. But once or twice a summer I see patients with early disease who are very sick, high fever, had stiff neck, meningitis, whatever, and I saw a situation where a patient who, in my opinion, should have been treated with -- it would have been safer to treat the patient with intravenous versus oral antibiotic therapy right at the outset, and that's what the doctor wanted to do. And in my opinion, the insurance company prevented that from happening. And instead, sent

the patient to me, and I said, let's review things.

By the time the person came to me, they were doing okay, and we muddled through, but I think that was not right, particularly given the fact that the sooner the disease is treated, the less problems you are likely to have. In terms of late Lyme disease treatment, I think that my experience has been that there is so much intense interest in Lyme disease treatment now, that that almost in and of itself to some extent distorts what's happening. And I think that there has been an attempt to -- there has been an attempt to develop guidelines that allow insurance companies to know who's being treated and why.

And occasionally I've seen situations where it's been necessary for me, for instance, as the treating physician, to provide more documentation today than I would have had to in the past. But I can't think of a recent -- I can't think of an example where such treatment was not allowed.

In terms -- now I'm talking about late Lyme disease treatment. But like

Dr. Phillips, my requests are relatively gentle, probably, relative to some.

ATTORNEY GENERAL BLUMENTHAL: Dr. Feder?

DR. FEDER: My name is Dr. Henry Feder, and I do family medicine, pediatric, and pediatric infectious disease at the University of Connecticut Health Center and Connecticut Children's Medical Center. I think my insights would be more in pediatric, but I also deal with adults.

I'd like to tell you three Lyme disease stories. First I'd like to give you a tiny bit of background.

In 1977, I came to the University of Connecticut. I joined the faculty as a doctor who likes to see patients. My primary work is seeing patients. It's interesting that in 1977, that was the year that Dr. Allen Steere published his first paper, really the first paper about Lyme disease. His report was prompted by visits from patients from Lyme, Connecticut, where they gave almost bizarre stories of fevers, rashes, arthritis. One of these patients, Polly Murray, told about her family getting devastated by arthritis and rashes and fever but said her dog was lame.

I think it was a credit to Dr. Steere to listen to these people, take it seriously, and with very careful research over the past two decades, I think most of the mysteries of Lyme disease have been solved. There are lots of questions, but in general they have been solved, and I want to give you three examples that I've dealt with that each one gives an important point about some of the pitfalls about treating or diagnosing Lyme disease.

The first case is a 15-year-old girl from Greenwich, Connecticut. She was in perfect health until May of 1994, when she developed a swollen knee. The Lyme blood test, I'll say the two-step test, the ELISA and western blot, were both markedly positive, and there was really no question that she had Lyme disease and she was started on intravenous antibiotics.

Four days after beginning therapy, her arthritis was better, but she had joint pains in her ankles, shoulders, wrists, so her physician decided to treat her until these other symptoms that were associated first with the arthritis resolved. One month later after therapy, she still had the joint pains and I.V.s were continued, and in fact she was treated for a total of six months intravenously, and after six months, the parents, getting frustrated, came for a second opinion and saw me.

I examined her, she was normal. I redid the Lyme test, although I didn't need to. It was still markedly positive, and by the way, once someone has a positive two-step Lyme test, it may stay positive the rest of your life. And one of the frustrations of us in Lyme disease is we cannot tell one who has old disease and a positive blood test versus something that's now active. We don't have a test like that, and that's what we're talking about with some of these newer experimental tests, and we're waiting for them to get validated.

So her blood test was positive, her arthritis was resolved. She still didn't feel good, and I said, the Lyme is gone from your body. After six months of I.V. therapy, I believe it is gone. I asked that I stop therapy and the family agreed. We removed the I.V., and over the next four weeks, with lots of phone

calls, she did not get better, but two weeks after that, she slowly improved and was fine.

What was a surprise was her neighbor worked for The New York Times, and when this little girl came to see me, the neighbor thought that I would do new therapies for Lyme disease, and she was really amazed at what I did was I stopped therapy. And she came and visited me and spent a day with me, and when I talked to this New York Times reporter, and I think I gave that in my packet -- someone followed me around all day to take that picture, and it's not too flattering -- but I basically said maybe us scientists may mislead the public a little bit in that you get Lyme disease and you get treated. I'm a believer that when someone has Lyme disease, is treated orally for the rash, three weeks of therapy is fine.

But sometimes there are associated symptoms that recur, and I think I even heard Dr. Phillips say once a week some of his patients get some aches and pains and think they may be related to Lyme disease, but he waits them out.

And this example of this child was her associated symptoms were, I think Lyme disease, but they

were self-limited and they did not need oral antibiotics.

Let me go to my second case. My second case is 36-six-year-old female who was admitted to UConn with 105 fever and no white cells, she had neutropenia. Her story is as follows: For two years before she had joint pains, headaches, and saw many, many doctors in Connecticut, and she felt she had Lyme disease but they felt she did not. They did many blood tests that were negative, and then on her own she sought out a physician in New York, and with this physician had a urine test done for Lyme disease which was positive.

The physician in New York says yes, you have Lyme disease, I will treat you intravenously and in fact started treating with antibiotics and she came back to Connecticut.

On the 23rd day of antibiotic therapy, she developed a fever of 105, was seen by someone who wasn't treating her, and said she had no white cells and she got admitted. And when we traced the case down -- by the way, what we did is we stopped antibiotics. Over the course of the next month, she got better. But

what I didn't understand is what was this test for Lyme disease, this urine test?

And I researched it as best as I could, and there was no science that I could find. It wasn't validated, so I published this case in JAMA. I also put that in your packet. And the company that made the test responded and said 11,000 people have been tested and it's useful.

Right after that paper came out, that test was removed. And now there are other urine tests, and they also have not been validated, so I'd like to see some of these tests work, but validation is very important.

My third case: My third case is a four-year old little boy who had arthralgias and a positive Lyme test. Again, ELISA and western blot. He was treated with oral antibiotics for Lyme disease, but his joint pains continued. He was able to play but he complained frequently of everything hurting him. He visited a few doctors and ended up at the Children's Hospital, and after a lot of discussion with the parents, it was decided to treat him intravenously.

He was treated for one month with

intravenous antibiotics and maybe improved a little bit. At the end of therapy the parents insisted on further therapy. We said that four months was the maximum, we wanted to stop, we wanted to do physical therapy, we wanted to work with him and we would wait. They refused, and they went to another physician, who continued the intravenous antibiotics. And on the third week of the second course of antibiotics, he came to our Emergency Room with severe abdominal pain.

He ended up having a cystitis, a gallbladder attack, and had his gallbladder out. Antibiotics were stopped, and over the next few months, his joint pains went away, so here was another complication of antibiotics, and that was a gallbladder attack.

Let me just say a few things about putting Lyme disease into perspective. I gave you three cases of some problems that we were seeing with Lyme disease. One may be misdiagnosis on a urine test, and two are people that did have Lyme disease with persistent symptoms that were resolved on their own and the dangers of antibiotics, we paid our price.

From 1988 to 1993, I saw 146

children sent to UConn for second opinions of Lyme disease. I also do primary care. In fact, I go down to East Lyme schools and take blood from the kids to check for asymptomatic seroconversion. I saw some of these kids so some are primary care and some are referrals.

Of those 146, only one needed intravenous therapy, was treated two weeks, had meningitis and did fine. To me, intravenous therapy for Lyme disease in kids is the exception.

Another very interesting thing is a study that, by the way, Dr. Steere was the head of, where we did 10,000-plus patients, a study with a vaccine for Lyme disease which is moderately effective. What happened was 5,467 of these patients got a placebo, meaning they got no vaccine. They were followed very carefully for two years.

106 of them developed erythema migrans, they were treated orally, and as far as I know they all did well, and they were treated for a month or less. One developed arthritis, two developed neuritis. They were also treated and did well. I don't know of one patient from

these 5,000 who were followed prospectively that has chronic Lyme disease develop.

AUDIENCE INDIVIDUAL: I do.

DR. FEDER: Were you in that study?

AUDIENCE INDIVIDUAL: No.

DR. FEDER: Well, that's why. In my experience, chronic Lyme disease is rare in children. When diagnosed it should be confirmed by a pediatric rheumatologist or pediatric neurologist. I.V. treatment should usually -- I use "usually," be limited to a maximum of four weeks of therapy.

The last thing I want to mention is something from The New York Times which is not in my packet. It's the front page of the Times of January 4, 1994, I have it here. What is the problem with prolonged antibiotics when a patient or family believes they will help? I was there in her room when her family says to me after four weeks, we want more, and it is terrible for us to sit down and say we feel the risk outweighs the benefit. Because it is very, very, tricky and very difficult.

This is what they wrote in the

Times. And the title of it was "Prolonged Lyme Treatments Posing Risks, Expert Warns.

Almost two decades after Lyme disease was discovered in Old Lyme, Connecticut, health experts and officials are warning that overdiagnosis of the disease and complications from long-term antibiotic treatments may pose as great a danger to the public health as the disease itself. In one instance, cited by the CDC, 14 children had to have their gallbladders removed, and 23 suffer from bloodstream infections because of complications from long-term treatment with intravenous antibiotics at the New Jersey Shore Medical Center. Though the children's doctor defends their treatment, the CDC found no evidence that most of the children had Lyme disease."

My goal, when I see a patient with a problem, is to figure out what's wrong and help them. And I do not want to do any harm with I.V. antibiotics unless there is more data that they help. Thank you.

ATTORNEY GENERAL BLUMENTHAL: Well, let me ask you, Doctor, just to complete the thought, were you -- this is an article in

The New York Times of 1994?

DR. FEDER: Uh-huh. Yes.

ATTORNEY GENERAL BLUMENTHAL: Have there been articles since about the effects of prolonged use of antibiotics?

DR. FEDER: There are papers that give anecdotal case reports, but I don't know that the CDC has looked into it. Again, I do not know.

ATTORNEY GENERAL BLUMENTHAL: So it isn't as if there's a rash of -- or to use perhaps an overused term, "epidemic" of overuse of antibiotics that's produced a wave of these instances --

DR. FEDER: This was a unique situation. This was one hospital --

ATTORNEY GENERAL BLUMENTHAL: The need for 14 cases in one hospital in a discrete period of time, somebody made a mistake?

DR. FEDER: I would agree with that, yes.

ATTORNEY GENERAL BLUMENTHAL: And the mistakes could have been due to all kinds of factors, like not monitoring what was happening to these children and so forth and so on? We

don't know much more about it than what's in that article.

DR. FEDER: Yes. No.

ATTORNEY GENERAL BLUMENTHAL: And you are not really offering it as a -- and your only -- as an argument here that physicians who are listening or who may be reading this record, should not prescribe antibiotics?

DR. FEDER: What I'm saying, as a treating doctor, I read about things like that. We can't monitor them for the gallbladder problem with ceftriaxone. That either happens or it doesn't happen. It's not something we can monitor for. At least in kids we don't monitor for that.

And we just had a case, so that case -- that experience warned me, and that's one of the reasons that I'm afraid to use antibiotics after four weeks of I.V.

Now, another thing that was mentioned that I think it's important, and it's interesting because I don't represent the insurance companies, I think I have the same problem as everyone else does, some things I want to do and we try to get permission, and sometimes

it's difficult. Is there is a difference between I.V. and oral, and the dangers of I.V. are much greater. An I.V. in your arm or sometimes they do a central line, can cause sepsis, and you can get bacterial infections, that is very dangerous, from that.

And the difference, if I see one with a respiratory infection, if people come to me saying, Doctor, antibiotics help me, and I try not to use antibiotics unless I really have to, and it's very difficult when I deal with these patients like for respiratory infections, where they want them and I don't believe they help, and sometimes I use them. If they want it intravenous, I would just say so, it's too dangerous. It's not only the cost that I deal with, I deal with the dangers, and I.V., antibiotics through a line that's either in your arm, which goes into one of your blood vessels, or what we call a Hickman or broviac [phonetic] through the chest, we use this in kids with cancer, there the risk is worth the benefit. I think in Lyme disease for prolonged therapy, the risk is not worth the benefit.

ATTORNEY GENERAL BLUMENTHAL: But

why not let the patient and the physician make that judgment?

DR. FEDER: Maybe in kids, then, it's different. I was thinking about that. In fact, some of these patients who -- the adults who have lost their gallbladders and maybe later on when people speak here they are going to say their lives were so terrible and that losing their gallbladder with the antibiotics was well worth it. So I would say with adults that certainly is something I respect.

ATTORNEY GENERAL BLUMENTHAL: But with children --

DR. FEDER: It's different.

ATTORNEY GENERAL BLUMENTHAL: Adults are in the position often of being -- they are guardians, they have legal responsibilities, why not put, again, that decision in the hands of whoever is the caretaker, the legal guardian, the fiduciary, however you want to characterize it?

DR. FEDER: I would say that's fair. That's between their doctor and the family, and it's just my own bias that to me, that the risk outweighs the benefit.

ATTORNEY GENERAL BLUMENTHAL:

You've been very frank and candid, and I think your suggestion is that maybe it should be the patient and the physician, the treating physician, as long as that physician has all of the acceptable professional credentials and training and so forth to make that decision.

DR. FEDER: Yes.

ATTORNEY GENERAL BLUMENTHAL: And I'm interested in -- not to prolong my own questions, but your reference to insurance companies sometimes not permitting you to do what you think is the right thing to do, is that true in Lyme disease treatment?

DR. FEDER: It gets interesting. I have very little experience treating Lyme disease I.V., but I do pediatric infectious disease, and I also do primary care. But I do some very unusual things in pediatric infectious disease, so if you feel it's something that's very unusual and you have a special way you want to do it, and they look at their policies, it's not part of it.

I have a child, for example, that had meningitis a few times, it's not Lyme disease, but was due to a defect in his skull.

And there was someone in Boston that's famous and that could fix it, and to try to get that person from Connecticut to Boston for a very complicated surgery was jumping through a lot of hoops, but it was well worth it to jump through those hoops.

ATTORNEY GENERAL BLUMENTHAL: And sometimes jumping through that hoops -- those hoops, if the physician isn't sufficiently persistent or the patient isn't persevering enough, it becomes impossible.

DR. FEDER: It's always possible, but it's difficult, I know that. It's difficult, yes.

ATTORNEY GENERAL BLUMENTHAL: Well, I can tell you that my office deals with a lot of cases where it takes a lot of persistence and perseverance, sometimes it's a matter of life and death.

DR. FEDER: Yes.

ATTORNEY GENERAL BLUMENTHAL: And I think once again, to come back to something that was said earlier by one of the representatives of the insurance companies, and I don't know whether you were here, but he said that sometimes they do reverse themselves, but not always. And so it takes someone with your caliber of persistence, perhaps, to have that done.

DR. FEDER: Yes.

ATTORNEY GENERAL BLUMENTHAL: Representative Powers.

REPRESENTATIVE POWERS: You both represent research institutes and you've referenced a '93 article and a '94 article. What are research institutes in Connecticut doing in terms of advancing the knowledge? There's clearly a difference of opinion on how long and for whom and under what circumstances different therapies are recommended. Are there any kind of studies going on, comparative studies, in other states, anything like that?

ATTORNEY GENERAL BLUMENTHAL: Dr. Schoen?

DR. SCHOEN: Sure. Two things; one, 1993 was when we thought about getting started on this paper. It was actually published in 1998, so the information I've given you, at least in terms of publication, is up-to-date.

I think that to answer your

specific question, there is currently an NIH-funded study to evaluate whether additional antibiotic therapy in patients with well documented Lyme disease history and persistent symptoms, whether antibiotic therapies are a benefit. So there's such a study being undertaken that was funded by the NIH and there are several cooperating centers, and we are participating in that study.

REPRESENTATIVE POWERS: Who else is in it?

DR. SCHOEN: One group is at New York Medical College, and another group is up in Tufts Medical Center.

REPRESENTATIVE POWERS: So kind of New York, New Jersey, Connecticut?

DR. SCHOEN: Well --

REPRESENTATIVE POWERS: No, Massachusetts.

DR. SCHOEN: So --

REPRESENTATIVE POWERS: That's it?

DR. SCHOEN: That's a major study looking at this particular thing. I can't speak to anything else that I'm personally involved in. I don't know --

REPRESENTATIVE POWERS: Well, some other things, just as a non, you know, healthcare person, there's lots of concerns about the tests. There's lots of concerns about the vaccines, whether the vaccine is worth doing or not worth doing. We've had two different opinions from UConn today on the vaccine.

Is there any other stuff going on with those particular issues which you think might help resolve some of these questions?

DR. FEDER: You said there were two different opinions on the vaccine? What was that? The two are what?

REPRESENTATIVE POWERS: Well, we had someone earlier from UConn who said they did not think the vaccine was -- [background loud noise] --

DR. FEDER: From UConn? Was what? Not --

REPRESENTATIVE POWERS: Was not worthwhile.

DR. FEDER: I mean it was a study that was done with the hosted 11,000 people, and there was no toxicity, and the instances of Lyme disease after three shots went down 80 percent. That's not perfect, and the nice thing about the measles vaccine, because I heard that mentioned --

REPRESENTATIVE POWERS: That was my question.

DR. FEDER: -- measles is almost gone. I deal with measles, but I haven't dealt with that in five years. Polio is gone. There are several things with vaccines that are great. But the Lyme that decreased the problem 80 percent, then, to me is a choice between the patient, physician, to see if it's worth it.

I think some people living in areas where there's tick bite risk constantly when they go out and there's a lot of Lyme disease, this makes them happy. But we know the numbers; in other words I can say if you get the vaccine, that your risk is decreased by a certain amount. I think that's science. It's not perfect, and we admit that. But I don't know how one can be against the vaccine or for the vaccine except to say that if you get the vaccine it will decrease your risk 80 percent, and we don't know about boosters. We don't know about long-term side effects, and that's one thing that I can see is a concern, because it's only been a few years that it's been followed.

But, you know, there's data that's reproducible. And I think that's sometimes what we discuss, is things to say; this is the odds, but life is not perfect, and the tests are pretty good but not perfect, and there's an art of medicine and a contract between doctors and patients that each case is unique.

And that's why I can't say things about some other patients that I have -- that I haven't dealt with, like when someone yelled from the audience and said I have chronic Lyme disease that was part of the vaccine study.

You know, life for each person is different, and I just try to give you an overall perspective that many of the mysteries of Lyme disease have been solved, but there's no question, it's a problem, and we're doing our best now working with new problems.

REPRESENTATIVE POWERS: I appreciate those thoughts. I was just asking if our two leading research institutes in Connecticut are doing anything with these other questions.

DR. FEDER: In this policy, vaccine surveillance, meaning patients who have gotten vaccine, were being followed very carefully for many years, and I was part of that vaccine study.

REPRESENTATIVE POWERS: Okay, thank you.

ATTORNEY GENERAL BLUMENTHAL: Just one last question. On the diagnostic test in particular, the brain SPECT scan that was mentioned earlier by Dr. Katz, do you have an opinion as to the advisability of using that test?

DR. SCHOEN: I think that, you know, my own impression is that the -- that first of all, that test carries virtually no risk, so by my strategy, I have no objection to SPECT scan testing. My belief is that it's not been demonstrated that that test diagnoses Lyme disease.

The same thing can be said for neuropsychiatric testing, its SPECT scan, as I understand it, looks at short-term changes in brain metabolism, the blood flow through the

brain, as Dr. Katz described.

Neuropsychiatric testing, to the extent it's possible, allows us to look inside the brain and determine whether there are patterns of defects in cognitive function which is maybe hard to get at otherwise. In my opinion that's very useful, helpful information in understanding a patient's overall global functioning, but I don't think that that testing has been shown to support or refute the diagnosis of a specific infectious disease. So I would disagree with the idea that you can use a SPECT scan to diagnose Lyme disease.

I would be sympathetic if a Connecticut physician wanted to obtain a SPECT scan for one of their patients, since I don't see, compared to the prolonged antibiotic therapy, that there is any risk there.

I just want to follow up, Mr. Blumenthal, in a comment that you made. I certainly have very sympathetic to your interest in making sure that wherever possible the relationship between the physician, the patient is not intruded upon.

I simply want to make the point that if

you look at what's actually happening today, I do believe that there is a danger in overdiagnosis and overtreatment, and I do think that, for example, the article that appeared in The New York Times, is obviously an extreme, but also in my practice I see situations in which lots of Lyme disease treatments given both orally intravenously and you may disagree, that's just my opinion, whether the patient actually has Lyme disease.

ATTORNEY GENERAL BLUMENTHAL: But I also understand that you're not here necessarily to advocate that your --

DR. SCHOEN: No.

ATTORNEY GENERAL BLUMENTHAL: -- opinion be adopted as the policy of the State of Connecticut.

DR. SCHOEN: I'm here because you asked me to come.

(Laughter.)

ATTORNEY GENERAL BLUMENTHAL: And we appreciate it, but I don't understand your being here to advocate that your view, which may

be a somewhat more conservative one on the issue of treatment, and I don't mean to use that word in any way prejoratively but conservative versus whatever we want to characterize the other point of view, and I guess part of the reason we're here today is to determine really whether it shouldn't be the treating physician and the patient who make these decisions rather than the government, which I don't think anyone wants, or the insurance companies, which now they do very commonly and using -- using criteria, the CDC guidelines that both of you as well as the CDC have said should not be used for clinical diagnosis.

I don't mean to put you in the position of answering a rhetorical question so...

Anybody else have any questions? You both have been very understanding and patient and again, my apologies to you, as to everyone, for our delays here.

We're going to go to the public. Why don't we take a 10-minute break. We'll start at 4:00.

(Recess.)

(Tape turned on.)

ATTORNEY GENERAL BLUMENTHAL: ... for example, I know I have to leave approaching 6:00 because of a legislative group that I have to appear before, and the representatives as well, so with the help of the Assistant Attorney General and whatever, this is all recorded, we perhaps can get underway. And I'm going to have to ask, is there a sign-up sheet that we have that -- let me ask you a question.

Without the benefit of that, is there someone -- here it is. And at my age, I either have to put glasses on or I have to hold it way out, but Peter McFadden is the first person, and I just ask that if people, you know, could come and make a statement as clear and as, you know, take the necessary time but to the point that it be concise, because we do have quite a list of people that want to talk. So if Peter could...

I just share with you that this is the list, and we have a lot of people so we're going to try to move as quick as we can. Peter?

Sit here with the mike. If you would just identify yourself and your hometown would be appreciated.

MR. MCFADDEN: Can everybody hear me?

ATTORNEY GENERAL BLUMENTHAL: Yes.

MR. MCFADDEN: My name is Peter McFadden, I'm from Huntsville, Alabama. I'm from Connecticut originally, and I'm a chronic Lyme disease patient.

ATTORNEY GENERAL BLUMENTHAL: Welcome back to Connecticut.

MR. MCFADDEN: Thank you.

And I've got some science that I want to present, and I'm going to move as fast as

I can and be as brief as possible.

COMMISSIONER REIDER: Do you have an idea of how long this will take?

MR. MCFADDEN: Well, that depends on how much detail people want me to go into.

COMMISSIONER REIDER: I would ask if you have something you can present to us and you can keep it in this case to five minutes we will appreciate it.

MR. MCFADDEN: The first page is just a little -- I'm not going to go over it at all. It's a little background on me and some of my struggles. I just wanted to say that we heard some stuff about there's no proof that long-term antibiotics work and whatnot, and I was severely affected by Lyme disease. I didn't participate in a recreational activity for five years before I was diagnosed.

For the first six months of that, I never left my apartment except for three doctors' appointments and I've had to work at home for two years. And before antibiotics, I did not have enough strength even to go like that...

(Tape ended, then new tape.)

MR. MCFADDEN: ... that it's the placebo effect or anything like that. But I've gone off antibiotics four times and each time was a disaster, and the last time I missed six weeks of work, and I think long-term antibiotics are helping me. And I'm surprised there is so much controversy.

I'm going to page 2 right now --

I'm surprised there is so much controversy about whether long-term treatment helps, because the only thing that's rare are attempts to isolate the spirochete after treatment. For the number of times that that's attempted there are a lot of cases of the spirochete being isolated from all sorts of human tissues and fluids listed at the top left of page 2, and points 1 and 2 provide a mechanism by which the spirochete is able to evade antibiotics.

There are companion studies that Dr. Kliner [phonetic] Is an author on both of these. The first study shows that the Lyme disease spirochete can invade fibroblasts, which are connective tissue cells. These cells are porterly [phonetic] vascularized in the immune system and antibiotics cannot get in there well.

And the second study proves that. The second study shows that fibroblasts protect the Lyme disease spirochete from Rocephin, so there really shouldn't be a lot of surprise that there are people that don't get better with four weeks of therapy, because the spirochete is able to get in places where the antibiotics can't.

Points 3, 4, 5, and 6 are all

cases of the spirochete being isolated after long-term, some of them many courses of therapy.

Case 4 is a fatal case of Lyme disease, and this person received four weeks of intravenous Rocephin succeeded by six weeks of oral antibiotics, and this poor man died in the hospital while doctors were trying to save his life. And at autopsy, he had spirochetes in his brain.

Page 7 is a very important study. There's just been so little work to see why these patients have continuing symptoms, and this group that did the study 7 on page 2, when they treated dogs infected by tick bite right away, they got better. And they didn't have the spirochete in their body, but when they waited 60 days before treating, none of the dogs got rid of the spirochete. They all remained infected.

Now, the antibiotics reduced the disease, because they had had six untreated controls and those dogs all had full-blown arthritis. No, excuse me, four out of six of them had full-blown arthritis, and that's about the proportion we have seen in humans.

Of the treated dogs, one had

continuing arthritis, and if these dogs were humans and they were looked at by Yale, that one dog, they would say okay, that has continuing Lyme disease, the rest of the cases post-Lyme syndrome, even though they remain infected with the spirochete. And that was shown with PCR and culture testing.

Going to page 3, there are a lot of problems with the blood testing, and we heard Dr. Eisenberg say that if you have a negative western blot, the chances that you have Lyme disease are very small, but that just doesn't square with the evidence.

Study 1 is the best study of the performance of lab in Lyme disease testing, performance of 45 participating laboratories. 55 percent of them could not identify a person -- they knew this person had Lyme disease, they knew this person was seropositive, they sent them a sample. The lab reported it as negative and they also -- the authors state that there was a striking inability of many laboratories to reproduce their results and split samples from the same individuals. That means draw a tube of blood, split it into both -- two samples, send them marked as if they are from two separate patients, the lab reports one is positive, one is negative.

The reasons for these problems really aren't well understood, but there are so many cases where the spirochete is isolated from people who have negative blood tests.

17 patients in number 2, although

these patients had clinically active disease, none of them had diagnostic levels of antibodies on either an ELISA test or a western blot, and by the rationale we heard earlier from Dr. Schoen and Dr. Eisenberg, these patients would be designated as not having Lyme disease yet they do.

Case 3 are three children that had the spirochete isolated from spinal fluid. None of them had positive blood test or antibodies in their serum.

And study 4 was a case of 14 patients with the spirochete isolated from various body tissues or blood. Exactly half of them had negative blood tests.

Now, study 5 is very important. It provides an answer as to why this is

happening. Many of the patients who have Lyme disease yet test negative had some kind of very minimal antibiotic therapy early in the illness, as did I. For the antibody response to develop, the antigen, the Lyme disease spirochete proteins have to be present, otherwise the T cell maturation will not occur, the T cells stipulate the B cells to make the antibodies, and the T cells require the continued presence of antigen. And if the antigen is removed by antibiotic therapy, which does not cure the illness, the person will be seronegative. They continue to have the disease and the condition is permanent.

There is a window there when the antigen must be present, and if it's not, the person will be seronegative even though they continue to have the disease.

COMMISSIONER REIDER: Mr. McFadden, we appreciate your input and you are about 10 minutes -- coming from Alabama, we wanted to recognize that, but just so that --

MR. MCFADDEN: Can I just speak about page 3 for a one-minute?

COMMISSIONER REIDER: What I was going to say, we have about 40 people, and why

don't -- yes, that's what I was going to suggest, why don't you try to conclude.

MR. MCFADDEN: All right. All right. I'm going to hurry it up. I wanted to give you a sense of what's happening in the trenches out there, whether these patients are being treated or not and what's going on.

At the upper left of page 3, we have a copy of a bill for an insurance company consultation. I've taken the identifying information, the insurance company out because that's not really important, but $350 an hour, there may be a financial motivation for the insurance company consultants to accommodate the financial wishes of the insurance company.

Now, this patient had a round rash the size of a dinner plate, two positive PCR tests for Lyme disease, a written diagnosis of Lyme disease from three physicians, yet the insurance company consultant at the left of this page wrote, "I definitely do not think this patient has Lyme disease even though he has published that the presence of an erythema migrans rash is diagnostic for Lyme disease, and diagnostic means alone sufficient for

diagnosis."

In the letter written for the insurance company, the physician said that in his opinion, PCR testing cannot be used diagnostically, but the physician has published that PCR increases confidence in the diagnosis of Lyme disease, and has other papers, the most recent one, the vaccine study where they are using PCRs as an integral part of assessing the therapeutic nature of the vaccine. They are using that study but insurance company consultations, they won't allow it.

The bottom of this page is about a patient who wanted to be in a vaccine trial but she had a positive blood test, she was told you probably have Lyme disease and we're not taking anybody with Lyme disease in this vaccine trial. She had problems with her knees and arthralgias and whatnot. She got a diagnosis of Lyme disease, was treated with oral antibiotics, she got better, she relapsed afterwards, her doctor put her on I.V., and her doctor sent her to the physician at the upper left here, who does consulting.

He said that the titer was

probably a false positive and he said I definitely don't think this patient has Lyme disease, and he said I have repeated this serology today. Since I do not think she has Lyme disease, I anticipate this testing will be negative in our laboratory. The test was borderline positive with four bands on western blot. In some laboratories, that's fully positive. Yale sets their standard very high, that's borderline positive.

But as we have seen, antibiotic therapy lowers the antibody response and lowers the response to the blood test and four bands and western blot is a pretty strong response for the amount of antibiotics that she was on. Yet the insurance company used this physician's letter to retroactively deny payment or retroactively deny reimbursement for the antibiotics already administered, and it's not consistent with what this physician has published in this peer review literature.

Do you want me to continue or do you want me to --

COMMISSIONER REIDER: I think in fairness, we better move along because we do have

about 40 people, even at several minutes each, and it's important that the main point -- but we do appreciate your coming and for your input and the fact you've left a document that can be understood and it becomes part of the record. Thank you so very much.

MR. MCFADDEN: Thank you for letting me speak.

COMMISSIONER REIDER: You are quite welcome.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Next is Dr. Steven Phillips, is he still with us? Yes.

DR. PHILLIPS: I just want to make a very short rebut to Dr. Schoen's and Dr. Feder's comments.

(Clapping.)

DR. PHILLIPS: Anyway, Dr. Schoen has made some very broad and sweeping and unsubstantiated comments. I mean, he's basically agreed with the fact that CDC surveillance case criteria should not be used as clinical diagnosis, but if you read his articles, that's what he uses. So what he said here today is in direct conflict with what he's published.

Number two, Dr. Feder has talked about that -- well, first of all he referenced a New York Times article, it was hardly a scientific reference.

Also, the CDC study that he referred to about the gallbladder problems in the children Pat Smith, who is president of the New Jersey Lyme Disease Association can give you better information on this, but essentially CDC did not have permission to get those records, and they were hospital records taken without the benefit of office records, so they made their criteria of whether the patients had Lyme or not based on hospital records.

And very often when one is admitted to the hospital, you know, the doctor doesn't go get their prior Lyme serology and put it into the hospital record. So they did not do any follow-up on that, and they didn't get the office records.

Number two --

COMMISSIONER REIDER: Doctor, just let me ask a question, and again just in fairness to all the people here, how long will you be?

DR. PHILLIPS: Five minutes.

COMMISSIONER REIDER: Let me say you've been several minutes already, and I'm trying to be responsive because we do have people anxiously waiting. You had the opportunity to submit written testimony and follow-up which we fully would expect would come, so with every courtesy, and because you've been most gracious, we want to respond, but if you could wrap it up very, very quickly.

DR. PHILLIPS: Okay. Other kids in that loss of gallbladders apparently had family histories of very early onset gallbladder disease, and CDC failed to mention that.

Also, Feder published a study where they did 16-month follow-up of children treated for Lyme, and I forget the exact percentage, but around -- but around 25 percent had recurrent or new symptoms. And he had stated here he has never seen chronic Lyme disease, but again -- that's all.

COMMISSIONER REIDER: Well, thank you very much.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Dr. Phillips and anyone else who has testified before, if you want to submit something additional in writing, we invite you to do so. Anybody who has comments based on what's been said after you had testified, we'd like you to submit those comments.

Next, Richard Mourey.

MR. MOUREY: Hi. I'm Richard Mourey. I live in East Hartford. For the balance of this session, you can also find me in the bill room. I have four minutes here, which I'm going to cut in half.

First of all, as a longtime active Republican I'd like to thank you for this. I'm going to talk about my daughter's experience with Lyme disease, but I want to bring a couple of things up here that have come to me as the day went on.

First of all, the overdiagnosis,

overtreatment, overbearing crowd that we have here are causing three things to happen; number one, a number of these people who have ascribed to that theory are bringing charges against doctors who treat Lyme disease. A number of those doctors have lost their licenses, and for the Attorney General, there was a case in Michigan where a doctor lost his license and appealed. I'm not sure of the result of that, but I do have an amicus [phonetic] brief that I can supply to you, it's quite telling.

Secondly, the insurance companies are using this attitude as an excuse to refuse to pay for advanced problems with Lyme disease.

Third, there are a large number of practicing physicians who are using this position to refuse to treat anybody under any circumstances. My daughter's case is really a case in point.

She is a 34-year-old attorney now, and ladies, keep that age in mind. She graduated from UConn dean's list, graduated New York Law with honors, winner of the moot court competition, a dozen academic awards. She was published while still in school. A former

gymnast, she was very athletic. Today it's very difficult for her to take a long walk.

She was bitten almost two years ago. Her first doctor's visit, a physician's assistant saw her first and told her, based on a conversation with no tests, that she had MS or Lupus. On her second visit, she saw the doctor and the doctor told her that women in their early thirties who do not have a husband suffer from anxiety and exhibit a number of false symptoms and advised her to take a vacation.

The second doctor she saw was confrontational. She gave him a copy of Dr. Joseph Burrascano's fine paper on Lyme disease and its treatment. And if anybody wants to know where to get that, you can find it on the Lyme.net. This doctor literally threw it in her face and demanded why she thought she had Lyme. She had 30 of the 38 symptoms listed in Dr. Burrascano's paper.

Her next doctor, a woman,

identified Lyme disease from the symptoms Lynn described to her, and my daughter was ecstatic. Finally she thought she had a doctor who would believe her and would treat. Not so. This

doctor was so afraid of being brought up on charges that she would not treat my daughter.

Through a bit of heavy research and a stroke of luck we finally did find a doctor who would diagnose clinically and treat. She is now on I.V. antibiotics. When she started this, she had the 30 symptoms, ranged from extreme head, spine pain, bone and muscle pain, memory loss, disorientation, dizziness, vertigo, and a range of cognitive problems.

Today, all those are gone, the only thing that's left through this treatment is she still has severe head and spine pain.

Now, there is one ray of hope here in this new test that the FDA has come up with, and I certainly hope it's as good as the news reports say, because I think this is going to revolutionize treatment of this disease.

The insurance community, I would

recommend very strongly, that they pressure the medical community to treat people who have some Lyme symptoms early with a month's worth of antibiotics, will probably save a great deal of money, a lot of pain, and much lost work time.

The country now -- by the way,

there are two bills in Congress, one is sponsored by Senator Dodd, another one by Congressmen Malone, Gjedenson, and Shays, which provide for long-term investigation of Lyme disease. And very interestingly, the education of the medical community about Lyme disease.

We desperately need strong action to bring about early aggressive treatment to stop the kind of suffering my daughter and others in this room have experienced and a strong educational program is definitely needed to teach these naysayers that this is really a disease that they need to pay attention to. Thank you very much.

(Clapping.)

COMMISSIONER REIDER: Thank you

very much. Thank you, Mr. Mourey. Serina Berenson.

MS. BERENSON: I'll try to read this quickly. My name is Serina Berenson, and I live in New Canaan, Connecticut. I'm a patient who has been through the death of a child, the chronic debilitation of a child that I have from

Lyme disease, and I'm personally disabled and impaired by this crippling disease.

Initially I was told by several prominent physicians that I did not have Lyme, and that I was stressed out, and my complaints were psychosomatic. I was finally diagnosed in September 1995, after seeing approximately 30 doctors and specialists in many fields, including infectious disease, rheumatology, neurology, endocrinology, psychiatry, et cetera, et cetera.

After two weeks of diagnostic testing at the Mayo Clinic in Rochester, Minnesota, in which they said that the final diagnosis was memory decline and fibromyalgia, I returned to Connecticut and had more extensive serologic testing for Lyme. The results were negative from Yale and finally positive from three other independent laboratories, including Stony Brook, IGENEX and BBI.

From 1995 to '97 I was bedridden with fevers, severe pain all over, muscle weakness and cognitive confusion. From running a successful interior design business with graduate degrees, I was unable to dress or feed myself or identify the names of my children. At least I

was one of the, quote, lucky ones who tested positive on the ELISAs, western blot, urine, and antigen, SPECT scans, FMIs and neuropsych consistent with late stage, chronic Lyme.

At the time, Oxford cooperated with intravenous treatment of Rocephin, which changed to Doxycycline over the next year. Slowly I began to regain functioning, although I was far from my preillness state. As I sought out Lyme-literate doctors and pursued aggressive antibiotic treatment, Oxford, to whom we were paying premiums of $900 a month for our family insurance, denied ongoing treatment.

By justifying, quote, appropriate treatment had been achieved. My family, my doctors, and I was appalled that a medical director such as Dr. Eisenberg, with no knowledge of my illness directly, never had met me or taken the time to speak to all the physicians involved in my treatment was pronouncing a cure to a disease that had just begun to respond to antibiotic treatment.

It was at that juncture in '96 that we began the arduous, stressful, and burdensome task of appealing to Oxford for coverage of further treatment and went back and forth with denials and appeals that only terminated in December with our termination of Oxford.

We have had to pay out-of-pocket since 1996 for intravenous treatment almost a quarter of a million dollars. We are now pursuing legal measures to get reimbursement.

In addition to micronic persistent infection with Lyme, our 15-year old son became ill in '94 from a tick bite with a bullseye rash and was treated with the standard four-week protocol of antibiotics. Although he had several central nervous system symptoms, he did attend school until '97 and '98, his 9th grade year, which was last year, when he began exhibiting severe neurological symptoms, fatigue, arthralgias, psychotic episodes.

This has been a very bright student, in all honors classes with straight A's, energetic, confident, and active. At this stage, he became lethargic, reclusive, severely compromised, and he had severe cognitive confusion.

Our son, who took great pride in

his A average could not follow the directions on a Campbell soup can to make his lunch. His regular pediatrician, despite positive blood work, continued to deny active Lyme disease. With mounting frustration and a child who was homebound and not attending 9th grade, we were fortunate enough to find Dr. Charles Ray Jones, who believed our diagnosis, corroborated it clinically and serologically and recommended I.V. antibiotic treatment for Adam.

Although he missed the entire year of his first high school experience, without

Dr. Jones' regimen of daily I.V.s at home with home care, he would not now be an honor student once again in his sophomore year.

During his year at home, Adam was also hospitalized at Yale-New Haven children's inpatient psych unit. He was experiencing psychotic episodes, depression, and anxiety, and he was there for an evaluation.

During his week inpatient stay on the unit, we and his doctors requested continued treatment with his I.V.s, as he had a central line portacath. At first the Yale staff were not pleased with the idea, but reluctantly agreed.

However, when our son was discharged, their conclusion was not Lyme disease at the present time. But they could not determine any other diagnosis.

One of the reputable Yale physicians proposed that perhaps my teenage son was, quote, overidentifying with my illness. Why would a previously healthy achievement-oriented student want to do that?

Looking back as that nightmare

came to a close with his remission -- I am cautious to say cure -- how can any Oxford medical director such as Dr. Eisenberg, who repeatedly denied treatment for this child, now look at him back in school, functioning, and say treatment was not necessary?

In total related costs our family has spent a quarter of a million dollars and continues to private pay for my treatment. We now are preparing appeals to our new insurance company, who also has randomly decided to deny further treatment.

In summary, my hope from sharing my story with you today is that another voice is heard, which in turn will convince legislators

and HMOs to put treatment protocol and duration of treatment in the hands of the treating Lyme physician and the patient, where it ought to be.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Thank you, Ms. Berenson.

Judi Bassett?

Anyone, by the way, who has left or who has to leave before we reach you, you are welcome, as I've said before, to submit comments in writing.

Peter DePaola?

MR. DEPAOLA: Thank you. My name is Peter DePaola. I live in Coventry but I work in Middletown, Connecticut. My son had Lyme disease, and that's the story unto itself, but he's one of the lucky ones. After a lot of persuading and cajoling, we were able to get him the services he needed to basically make him disease-free.

The reason I'm here today is to talk about it with a little bit different dimension from the conversations you've had from

patients and from physicians. You see, I represent a company called Chartwell Southern New England. We are a home I.V. provider.

Many of the folks behind me are patients. It's our pharmacy that prepares the compound Rocephin. It's our nurses that go into the home and take care of these patients. Last year we took care of about 260 Lyme disease patients. About 5 percent of these patients, about 11, 12 or so, are chronic Lyme patients, and that's where we get into a real dilemma, because their physicians call up and they say they need an extension of services, and the standard regimen is about four weeks.

So when we go into that six-week, eight-week, 12-week therapy regimen, we pretty much know it's going to be denied by the managed care company, so we go into appeals but we don't stop servicing our patients, so we end up incurring a lot of expenses.

Now, the patients, they have signed financial waivers, they know that they are financially responsible, but in the end what happens is that debt accumulates and we end up getting stuck in the middle, because our job is

to respond to the physician's requests for services, and that's what we do.

So we're there 24 hours a day, seven days a week, we provide the services. We incur the costs of that, and as you know, healthcare is expensive today. Profit margins in this industry are pretty narrow as they are. So what happens is we have a handful of patients that have a lot of expenses. To date we have over $97,000 worth of unpaid bills that we have to carry, and it's not fair to us as a company, home healthcare as an industry, and it's not fair to the patients.

So I guess I'm here to ask for a couple of things. Yeah, we'd like to see some improved treatment guidelines so we are all on the same page, because payment terms vary from payer to payer. I'm not going to fault any one person or any one company, because they all have to operate as best as they see fit, but I'd also like to ask that there be an expeditious appeal process. That's one area that really slows us down. If it takes three, four, five weeks to get an appeal through the organization, we've been providing those services, and we're working with

the families and with the physician's office to get that appeal reviewed.

So if there was a way to speed that process up, we could communicate that back to the patients in a much more timely manner. That would help us understand where we are in the process, and I think it would help the families understand what their financial responsibilities are as well.

I'll leave it at that since you have a lot of other folks. Thank you very much.

COMMISSIONER REIDER: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: We appreciate your spending the time with us and being so patient and waiting, thank you.

Bonnie Friedman.

MS. FRIEDMAN: Bonnie Friedman, Trumbull, Connecticut.

First of all, I'm grateful for the opportunity to speak before you today. I've had Lyme disease for 24 years. In 1991, I was hospitalized. The doctors told me that they

ruled out Lyme with what they called the state-of-the-art test called the western blot. I returned home after two weeks in the hospital with no diagnosis.

However, four years later my western blot became positive.

When my daughter became extremely ill in 1994, we proceeded on the same odyssey for a diagnosis for her, and her symptoms were strikingly similar. Initially my daughter's pediatrician thought she may have Lyme and treated her for two weeks with the antibiotics. When she began to get even sicker, the doctor insisted that it must be something else, because according to Yale's Lyme protocol, she was over Lyme. She had been treated.

I trusted this physician and spent the following months waiting for Margot to get better. But her health deteriorated even more. In the months that followed, I searched, read, and talked to people about what was happening to her. The name of a physician who had treated a lot of Lyme patients kept coming up. I was very cautious and wary because I had heard that there were some physicians who were known for

overtreating their Lyme patients with too many antibiotics. I was fearful because my daughter was only 18.

I thought, what would happen to her in the future if her body got pumped with all these antibiotics? What a responsibility I had before me. Should I submit to this aggressive treatment or should I watch her fade away? I saw her curled up in the fetal position in the darkness and solitude of her room. She could not go anywhere or do anything.

Because of the brightness of day to her eyes and the overwhelming exhaustion, she felt prevented her from continuing her studies at college. There would be no life for Margot unless something was done to help her.

With great trepidation, we approached the Lyme physician's office. I wasn't sure I was prepared for what he would tell us. We spent the next hour and a half with the physician. He was encouraging, and God, we really needed hope. He suggested that Margot may in fact need to be treated more aggressively than before. He urged her to try some oral antibiotics and see if she would respond.

Unfortunately there was very little response, and she continued to be incapacitated.

It was then the doctor ordered three months of intravenous Rocephin. We agreed we should go ahead with this plan. At the time my insurance coverage was through Bridgeport Hospital. Because it was an employee-owned plan, it fell into the ERISA guidelines. This means that it was governed by the federal regulations rather than the State regulations, but the plan was administered by Medspan, a Hartford-based insurance company.

I could not get Medspan to commit to approving Margot's treatment, and after weeks went by they finally agreed to covering 28 days. As the 28 days were ending, it was very apparent that there had not been much improvement in Margot's health status. My husband and I agreed that we had to find a way to continue her treatment. We were able to hire an I.V. nurse to work independently, she will come weekly to change dressings, and the pharmacy at the hospital helped by ordering Rocephin and selling it to us at their cost. So every 10 days I would write a check for $600 for Rocephin.

The next three months cost $17,000. Repeated attempts to justify the need for continued coverage through our insurance was futile. Medspan refused. After four months of Rocephin, Margot's condition was somewhat improved. She was now enrolled as a full-time student at Fairfield University.

By spring, however, we could see the ever present signs of her illness becoming worse. She was unable to sleep because of her tremendous neck pain. Her joint pain caused her to limp. Her muscles were wasting. She was living in a world of brain fog and cognitive dysfunction. She had anxiety and depression. She told me she felt like life was passing her by and she had dreams of becoming a school counselor and she wondered in fact if she would ever continue college. She was missing the best part of her life.

Friends would call and she would have to refuse their invitations. Medspan's refusal was based upon lack of information, they told me.

So in the following months Margot

was seen by more consulting physicians. By now we had eight letters of medical necessity to present to Medspan in favor of continued I.V. antibiotic therapy. They still refused coverage. They blamed me for the delay because I had given them too much information on Lyme disease and too many letters of medical necessity. They were curt and they were rude.

We argued and even pleaded with the vice president of medical affairs. Margot personally spoke with Dr. Cook and he just was rude and blew her off.

Again my husband and I continued to cover the expenses for treatment and Margot responded. By now she had dropped out of school, missing another semester. Determined as ever, she registered for fall semester, she struggled. Her energy was low, and her pain high. We returned to the infectious disease physician we had seen earlier, he reevaluated her condition and agreed that even though by now she had gotten nine months of intravenous antibiotics, she needed more.

Fortunately, by now our insurance

company had changed and we had no further

difficulty getting Margot treatment. And after five months of Claforan, that doctor felt that there had been enough improvement to stop her I.V. This was in February of last year.

For a month or so Margot felt much better than the past. She had adjusted to the fact that some things will probably never go away, she accepted that. If her mind could remain clear and she could complete her degree, she would be happy.

On June 14th, after spending the evening out with friends, Margot came home happy and bubbly, just chattering away, when suddenly she began to shake, her back arched and stiffened. I led her to the bed and called 911. By the time the EMS appeared she seemed all right. They took her vital signs and were discussing whether or not she should go to the hospital when she began to seize away and that continued all the way to the hospital.

The physicians and nurses at St. Vincent's Hospital in Bridgeport had no understanding of what was happening, even though

I told them I felt that the seizures were resulting from Lyme disease. A psychiatrist, two

neurologists and an infectious disease doctor decided Margot was having pseudoseizures; in other words, they were not real seizures, they were the result of a psychiatric condition.

I cannot describe the feelings that I had. I gave the physicians literature about Lyme to educate them. They were not only rude, but they treated me like I needed a psych consult. And by then I can tell you I probably could have used one.

I tried to tell them if Margot did present psychically, Lyme disease can cause psychiatric manifestations, and that would mean she needed more treatment. Four days later I took her to her own neurologist and she had an EEG which revealed that she was having complex partial seizures to the temporal lobes.

A neurologist at New York Hospital concurred. So in June, in spite of three previous rounds of intravenous antibiotic, my daughter was having seizures from Lyme disease.

She was put back on I.V., this time penicillin, and it was administered on a 24-hour pump. And within a week the seizures showed remarkable improvement.

In November the line used to infuse the antibiotic failed, and for two weeks Margot was off I.V. and on orals, and her seizures worsened. It took her months to regain the same level of improvement that she had already gotten after going back on I.V. treatment.

It's now February. Margot has been on penicillin for eight months. Her seizures continue to improve, and there is talk of discontinuing the I.V. We are afraid, but we have had to learn to live one day at a time. I applaud my daughter for her courage. She will graduate cum laude from Fairfield U in May with her BA in sociology. She plans to go to graduate school for counseling and school guidance, but I can tell you, if we had not found the compassionate physicians who believed in us, none of Margot's dreams would ever come true. And doesn't she deserve a chance?

I am here today to tell you that the drastic -- that there must be drastic changes in the treatment of Lyme disease. Dr. Schoen from Yale, who was here today, refused to establish a balanced forum at the Yale Lyme

symposium offered every year. Last year I wrote to Dr. Schoen and asked him to include testimony from physicians who were treating a vast number of Lyme patients, and he told me it was too late to change the program, so this year I wrote to Dr. Schoen in November to ask him to include these physicians.

So -- he didn't reply, so in January I wrote again. He finally replied that it was too early to discuss it and -- first it was too late, and now it's too early. So I don't really know when the right time is for that.

Yale is considered state-of-the-art in teaching. When physicians and healthcare workers attend an accredited conference they are expected to come away with accurate, useful information. Yale is remissent [sic] in providing both. The symposium offers the same 1994 study as new information every year.

And by the way, I think Dr. Schoen would be able to tell you that he was talking about the 1998 paper that was written, that's about the 1994 study, it's not a new study. It's a new paper about a 1994 study.

Last year there was a cry from the attendees for new information that they can use to help their patients. Presenters from the past symposium like Dr. Leonard Siegel from New Jersey charges $560 an hour as well as Dr. Schoen himself, who I have a bill from 1994 for $450 an hour.

There's a conflict here. How can doctors who are working for insurance companies present at a conference? I mean, it just doesn't make any sense. It serves them to keep insisting that Lyme disease is overdiagnosed and overtreated. It's bottom line-driven, it puts money in their pockets. I can't imagine the insurance companies using these people to consult if they thought that they would suggest that people needed long-term I.V. treatment.

Two years ago Dr. Schoen opened the conference by displaying a portrait of a family with Lyme disease on his overhead projector. He stated in a joking fashion, look at this family, they are all smiling, I guess they are over it now. Well, the audience laughed. I can't imagine going to a conference on cancer where a spokesperson would get away

with making a joke about such a tragic illness.

Maybe Lyme isn't cancer but many live a life of suffering, both mentally and physically. They are robbed of a future, and yes, sometimes they die. Is that something to laugh about?

Another thing I would like to see happen is making insurance companies responsible for the denial of care of Lyme patients. Last month I was able to recover my costs for Margot's treatment. It took four years in suing Bridgeport Hospital and Medspan. They really lost nothing. They got to keep my money for four years and collect interest. Even if we got most of our money back, they still won. There are no punitive damages for them to worry about.

Also, aren't HMOs practicing medicine? How can they make a medical determination without first examining the patient? In our case Medspan hired two infectious disease consultants from Hartford Hospital. Medspan and Hartford Hospital, by the way, are jointly owned.

Dr. Quintilano and Matarazza [phonetic] were hired to give independent

consults, and yet their consult letters reflect that they shared information with one another.

Dr. Quintilano suggested in his letter that a PCR test should be done, and yet a PCR test was done and the results were in the hands of Medspan, so either Medspan was negligent in providing the consultants with the information but they withheld this information deliberately.

Our biggest obstacle is the future. Right now our insurance has been extremely cooperative, but what will happen next year, or in five years if Margot needs more treatment? Must I live in fear that coverage will be denied? I cannot allow her to go without treatment, but it's unrealistic to believe that I can afford to provide ongoing I.V. treatment. I'm still suffering the consequences of Lyme disease myself, and yet I have to go back to work to provide for her care. No one who is sick and pays insurance coverage should ever have to worry about paying for needed treatment.

Another grave concern is protecting our physicians who treat us and give us hope. There are cases of physicians who have been scrutinized for overtreating with

antibiotics. If patients are receiving informed consent regarding the pitfalls of aggressive treatment for Lyme, our physicians have done their jobs. It is no one else's business when a patient makes a decision in his or her own care.

I applaud these physicians. It takes great courage to take the chance of getting called on the carpet. They are risking their careers for standing up for what they believe in. Without them we are left without hope and in suffering.

It's important to protect them so

that they can protect us and Margot.

MISS FRIEDMAN: I just have one thing to say. I just wanted to say that it's bad enough that having Lyme robs you of your health, but having to fight your insurance company while you are sick robs you of your sanity and your dignity. I am extremely fortunate to have wonderful parents who not only consistently support me emotionally but financially as well. What do people do if they can't afford treatment? Well, they end up either on disability in a nursing home, a psychiatric hospital, or even worse, they die.

I can't even explain the guilt that is harbored when you know your parents can barely make ends meet because they have to pay for antibiotics, that they cannot save for their retirement or that their dream of providing me a college education would be shattered if I continue to need treatment that would not be paid for by my insurance company.

I desperately worry about what my future holds for me. I am 22, I have a lot of living to do. Will I always be disabled with chronic Lyme disease? Will I always have seizures? Will I be able to have a career and raise a family? These are answers God only knows, but I can tell you that none of my dreams will come true if I don't have access to treatment.

Unfortunately, my fate is in my insurance company's hands. Our fate is in your hands. Please protect our wonderful doctors who so bravely treat us for as long as they feel is necessary to for us to recover. And protect us from insurance denial for coverage. Thank you.

(Clapping.)

COMMISSIONER REIDER: Thank you very much.

ATTORNEY GENERAL BLUMENTHAL: Susan Sinclair and Andrea Sinclair.

MS. SUSAN SINCLAIR: Good afternoon, and thank you very much for holding this hearing.

You know, I feel as if I could say

ditto. Thank you.

My name is Susan Sinclair and my 17-year-old daughter, Andrea suffers from Lyme disease and has for the past five years. Throughout elementary school and into middle school, Andrea was extremely active and an involved little girl. She was a straight A student who would stay up all night reading and working on projects. She enjoyed the gifted and talented program through the school district, Girl Scouts, playing on soccer and basketball teams, dance classes, gymnastic classes, art classes, and in the third grade she started playing the trombone, which is now the love of her life.

Andrea maintained a near perfect

attendance record, only missing one or two days of school each year through her 7th grade year, and enjoyed a very full social life from a very young age.

In the fall of Andrea's 8th grade year, she awoke one morning with an extremely engorged right knee. Testing of the synovial fluid and subsequent blood work led to a Lyme disease diagnosis. Andrea was placed on 30 days of an oral antibiotic with a reassurance from our pediatrician that the oral antibiotic...

(Tape ended, begin new tape.)

MS. SUSAN SINCLAIR: ... The swelling in her knee went down; however, she continued to complain of joint pain. She became tired easily and complained of feeling nauseous often. By December of 1995, Andrea complained almost daily about her health. Now in her first year of high school, in advanced placement classes, she began to struggle to complete the most simple homework tasks on a consistent basis. Always organized, she now had become disorganized, forgetful, and unable to finish her

through to the end of a class assignment and projects.

Simple writing tasks became painful. She was often extremely fatigued and nauseous. A local rheumatologist ordered blood work, which revealed a Lyme infection, and ordered 30 days of I.V. antibiotic.

Andrea felt slightly better during this 30-day round of treatment, but after the treatment stopped, Andrea became significantly worse. Now, in the spring of her freshman year in high school, Andrea's grades dipped from A's to C's and D's, and she attended school erratically.

By May of 1996, Andrea was not able to get out of bed. Her symptoms now included excruciating headaches, extreme joint pain, nausea, vomiting on a daily basis, extreme dizziness, extreme irritability, an inability to sleep, light sensitivity, and I could go on and on.

Not only could she not go to school, but she declined phone calls from friends. The same bright, ambitious girl who would bend my ear for hours describing the

challenges of the school project, now articulated daily physical pain and frustration.

Her doctor was baffled, and because she had received the standard forms of treatment, had referred her to Yale's Lyme disease clinic. And Dr. Schoen.

I can remember thinking, how great it was that we were going to be seen at Yale's Lyme clinic, and that Dr. Schoen would be able to get to the bottom of this and take care of everything, and that finally Andrea would be fine. In fact, my exact words to Andrea was, we were driving down there were, "If Yale can't help you, nobody can." This was truly our great medicinal hope.

At that time, we took Andrea to Dr. Schoen, literally the previous month -- I'm sorry -- at the time we took Andrea to Dr. Schoen and Yale's Lyme disease clinic, Andrea was barely able to get out of bed with excruciating joint pain, having missed literally the previous month of school, unable to hold down food, unable to sleep, she had problems with her eyesight, a chronic, excruciating headache, but hopeful that perhaps Dr. Schoen would know or could understand

what was wrong with her, the extent of her suffering, and be able to do something to provide her with some sense of relief.

Let me remind you that Andrea had attained a near perfect attendance record in school up to 7th grade. Once in fourth grade this girl cried because she had to stay home with the flu.

Dr. Schoen examined Andrea and ordered blood work. And on the return visit, Dr. Schoen explained to us that Andrea, although she was seropositive by Yale standard and with active symptoms, was suffering from post-Lyme fibromyalgia, and that she no longer had an active Lyme disease. And in time, he explained, most of her remaining symptoms would go away.

Andrea, for all her love of school and life and friends, but who couldn't get out of bed, he said had to be more active. Dr. Schoen said perhaps swim every day to alleviate her joint stiffness and tire her out so that she could sleep nights. And then Dr. Schoen suggested that perhaps Elavil would help. His comments too included that Lyme disease in teenagers does go away.

Well, if Dr. Schoen was still here, I must say that as a school teacher in New

Britain, I would levy the most, the greatest admonishment that I could think of. Shame on you, Dr. Schoen, wherever you are now. Shame on you!

(Clapping.)

MS. SUSAN SINCLAIR: By December of 1997, Andrea had become barely functional, her symptoms were more severe and staggered. The worst part was Andrea now articulated a why bother attitude. No one knew the personal, physical, and emotional health she was enduring, and if Yale couldn't fix her, nobody could. No one could do a thing for her.

Every day she tried to get up and go to school on time and could not. Every day she tried to read and by the end of a sentence she couldn't remember the beginning of the sentence. If she fell asleep she was awakened by violent nightmares and by her screams in the middle of the night. The list of her symptoms were staggering and horrific. School success and an active school life were distant memories, and now at 16, a part-time job and a driver's license was a pipe dream.

Keep down food was a real challenge. By luck and by chance we were blessed with Dr. Jones' phone number, and although Andrea clearly felt he couldn't do anything to help her, she went. One year ago, March of 1998, Andrea began I.V. antibiotics and has continued to this day. Although she has not seen complete resolution of all her symptoms, Andrea has her life back, and the hope of a life back too.

Although Andrea is on partial school day, she does attend regularly, and she's planning to go away to college this fall. She may need to bring her I.V. with her. Some days she feels so good that she talks about getting her license. And her grades are back on the rise.

Andrea knows she needs her I.V. medication. There have been a few times when she has had to go off and she has relapsed horrifically. I have a 17-year-old who wants to give herself I.V. injections daily. In March of 1998, our insurance company, Anthem/Blue Cross and Blue Shield, approved 28 days of her I.V. therapy. They knew after 28 days that she'd be cured because they approved 28 days before she even started. And as I was told, they only have my daughter's best interests at heart.

Despite clinical data and dozens of studies shown that four weeks of antibiotic therapy gives incomplete resolution of symptoms, insurance companies are advocating with the support of Yale Lyme study and inappropriate standard of cure, a cure by the clock.

Remember, Andrea was told by Dr. Schoen that she had received the standard course of treatment, and her symptoms, although present in seropositive blood work, would eventually go away.

There are multitudes of patient studies. Clearly Andrea's own medical history provides us with the knowledge that a cure by the clock is inappropriate, and that prolonged and aggressive I.V. therapy is appropriate.

Anthem/Blue Cross and Blue Shield has ignored the fact, and the documentation that she continues to improve.

Very briefly, I'd like to address

costs. As I mentioned, I work for the school district in New Britain. I'm a 7th grade teacher. My time off to take care of my daughter has cost the school district since March of 1998, $4,620. The cost to Southington School District where my child goes to school for homebound instruction has cost $6,400 anticipated to the end of June of this year.

Our personal debt for Andrea's I.V. therapy since April 9th, the last day that Anthem/Blue Cross and Blue Shield approved payment is $40,000. That total cost of those three factors is $50,000, to date. Anthem/Blue Cross and Blue Shield has paid $5,600.

In closing, the most common question I get asked from well-intended friends is why isn't the insurance company paying? I don't know. I don't know. They pay for my mom's diabetes medication. There's no hope for a cure and no one would argue or even question the medical necessity of her diabetes medication, nor her blood pressure medication, for that matter.

They paid for my son's antibiotics for acne when he was younger. They paid for my friend's medication for MS with no hope for a cure and no knowledge of the origins of this horrific disease. I don't understand at all why Andrea is denied treatment that clearly has halted her horrific spiral down, which I described to you.

I don't understand why Andrea's treatment, which clearly prevented her from a very real and near certain possibility of never being able to pursue her education, live a normal productive and independent life, is being denied. If Andrea needed chemotherapy, as I believe somebody else had mentioned, I wouldn't be here.

Our fight is ominous. It's a fight for credibility, treatment, simple compassion, integrity, peace of mind, wellness, until a cure is found. And it's a fight for financial security too.

Let me reassure you, Lyme disease does exist and it may become chronic. Lyme disease is not always cured by the clock. Lyme disease can be life-threatening, and not treating Lyme disease is nothing less than criminal.

Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Andrea.

MISS SINCLAIR: Good afternoon. I have a bit to say but I think it's important to hear from the kids who are suffering from Lyme disease because there are tons of us.

I stood on the Capitol steps nine months ago and spoke about my struggle with Lyme. I shouldn't have to be here again. I've lived through five years of hell, five years of being diagnosed with everything under the sun and being told to live with it. Five years of being out with friends and passing out or getting too sick and ruined the night's plans, five years of being through times where I couldn't write my name.

In 8th grade I was diagnosed with Lyme. I'm now a senior in high school, and I'm on the road to being better, but I still have a ways to go. If insurance companies are so sure that the treatment from my doctor is so phenominally wrong, is somehow wrong, then what do they suggest I do? What do they suggest that

my parents do when I wake up blind or when my joints are swollen to the point that I could be mistaken for elephantitis? When the room won't stop spinning?

Explain to me and the colleges that I apply to why I went from being a straight A student until I got Lyme and then my grades plummeted.

Dr. Jones had the answers for all of these. But insurance companies say to see other doctors. Trust me, I've seen my share. I've seen Yale's so-called "Lyme specialist." I've seen rheumatologists, I've seen neurologists, and still insurance isn't paying. And by the way, 28 days of oral antibiotics didn't scratch the surface.

What should we do? I'm a high school senior, and while all my classmates are trying to finance their college education, I'm trying to finance my medicine and going to school in the fall.

Responding to the accusations of the inappropriate treatment of Lyme disease, the only inappropriate treatment I've received is that of Dr. Schoen and all the other doctors who

told me I didn't have Lyme disease because I was cured after 28 days of oral and I would have to live with whatever I had.

Dr. Schoen's diagnosis, along with others, left me with nothing. I would have had a life full of pain and agony and I wouldn't live with that. If you treat the disease, you win -- you lose. If you treat the patient, you win. Dr. Jones has won in both respects. He has successfully treated Lyme disease and he has healed the parents of his patients also. I'm very sorry to hear that he has cost the poor insurance companies too much.

I love Blue Cross's motto, "Our plan is to keep you healthy." They should really change their motto to our plan is to keep you healthy at your own expense and without your doctor.

(Laughter.)

MISS SINCLAIR: I sit here today among many kids infected with Lyme. It is a living hell for all of us. We should only have to worry about getting better. We shouldn't have

to worry about the financial strain we're putting on our parents and siblings. Our parents should only be worried about being our caretakers, not our insurers, and we should never have to fear that the only doctor who is making us better is being taken away.

I've been on I.V. antibiotics for a year now continuously, and on the way to getting better. I don't enjoy giving myself needles on a daily basis, but it's making me better. If I wasn't undergoing this treatment, who knows where I would be today. But it is this extended treatment that has made it possible for me to speak today.

The bottom line is things have to change. Children and adults can no longer be going without the treatment due to ignorant doctors and cheap insurance companies. The future of this country is being destroyed. We are here, we are sick, and we need to be treated.

Thank you for your time and patience.

(Clapping.)

COMMISSIONER REIDER: Thank you very much.

ATTORNEY GENERAL BLUMENTHAL: Let me ask, how many more people wish to testify? Can you raise your hands? So we still have a considerable number. Let me suggest that we all want to hear certainly from all of you and again, we want to be very respectful of that, but I do notice that a number of people have had to leave during the time. I would just suggest if you do have to leave, would you leave whatever written testimony at the desk, which a number of you have done?

Also if you want to write something to the Attorney General or to the

Insurance Department then you certainly may do that as well. I would ask, and as you hear testimony, it can become something that has been spoken to, if it has been spoken to already, if you could acknowledge that and then move to the points that you'd like to make, we'd appreciate it.

And again, I was chair to the council in Farmington, Connecticut, and conducted a number of town meetings and you want to keep the balance. So as I said, out of respect to everyone here, if we can move it, we'd appreciate it.

So with that, I would like to call the next person, which I believe is Robin Prewitt. Robin, are you still here? Yes.

MS. PREWITT: Hello. I'm Robin Prewitt and I live in Milford, Connecticut, and I'm going to be very, very brief. I just want to address something that I'm not sure has been addressed to the magnitude in which it is a problem here in Connecticut, and that is the issue of initially getting diagnosed.

It took me three years to be diagnosed. I had the telltale rash, I had the flu-like symptoms, and my physician, my primary care physician at the time, all PHS physicians I should say, I was told that it was probably a spider bite or a bug bite, and that it was a viral infection and that it would go away. And true to Lyme disease, the symptoms wax and wane and come and go, and it did go away, and from that point forward, my life has been changed forever.

Like I say, it took three years, I was very ill. I have since lost my job.

Another issue that I would just like to mention is problems with discrimination of employers when a person gets Lyme disease and has to go out on disability leave. I am since not back at work and I just wanted to make those points. And I am on disability now and am unable to work. Thank you.

COMMISSIONER REIDER: Thank you very much. Appreciate that.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Joanne Sturges is next. Joanne?

MS. STURGES: I know you said to us that you wanted to not repeat a lot of the things that people have said, so I'll try not to do that, but I think all our concerns are very much all of ours; everyone has the same concern.

COMMISSIONER REIDER: May I just comment there if I may? I certainly recognize that fully, and as I said, that's the point we're trying to allow people to express. But to the

extent that as many of you can be heard as possible --

MS. STURGES: I understand.

COMMISSIONER REIDER: -- it's important, and that's what we are trying to get to. But we appreciate it, you go right ahead.

MS. STURGES: First of all, I really would like to thank everyone here, including the doctors and the supporters that came. Especially for you to even set up this meeting, because I feel that it restores our faith to the government, that it does represent the voters and the people and not necessarily the insurance companies.

My name is Joanne Sturges. I live in East Lyme, Connecticut. I'm married, I have two beautiful children. We come from a long line of hard-working, trustworthy social caring families. As a matter of fact, many of the people in the government know my father-in-law, Ralph Sturges, the Chief of the Mohegans, and have worked very closely with him.

Five years ago I was infected with Lyme disease. Prior to being diagnosed or infected with Lyme disease, I was a very active

person. I was a physical therapist, I worked one full-time job, one part-time job. I worked out two to three times a week and ran every morning seven miles. But Lyme disease changed my life.

My joints became swollen, there were a large -- great deal of neurological complications and cardiac complications. After going from physician to physician prior to the recommendation of having the valves of my heart removed, I then found Dr. Phillips, who has been a godsend. I am no longer -- after being treated with long-term antibiotics -- I'm making it very short but I haven't been seen in quite a while.

COMMISSIONER REDIER: Sure.

MS. STURGES: I am no longer on any cardiac medications. I can do a flight of stairs without passing out, without having a heart attack. At age 37 you should not be having heart attacks. He has been fabulous.

In this nightmare, also my 12-year-old son became very ill. He also was very, very active and all of a sudden was complaining of severe headaches, swollen joints, light-headedness, hot flashes. I took him to the pediatrician, and this -- at this time was going

on before we met Dr. Phillips. I took him to the pediatrician, his titer was negative. He continued to become worse. We continued to treat him.

Within three months, he lost the ability to talk, to walk, no memory whatsoever. Visual impairment. He had just tunnel vision, that's it. Again, the night sweats, not being able to sleep, his glands along his neck were so swollen shut I remember one Christmas morning using a straw trying to get juice. That's not how you should celebrate your holidays.

His physician said to us he cannot have Lyme, his titer was negative. Just prior to him coming down with the disease -- I just want to tell you something that he surprised his grandfather during the federal revolution of the Indians.

During a celebration, he learned the ancient Mohegan dance, and the purpose of the wishes of this dance was to teach people that all people, no matter who they are, no matter what nationality, they are all one on earth and everyone should live long lives of happiness and health. And ironically, he was now fighting for

his life.

Again, many physicians, Blue Cross/Blue Shield denied treatment, denied further testing to be done, everything. We went to Dr. Jones, Dr. Jones, we believe saved our son's life. For the courage that he took to fight the nonbelievers, to continue to investigate what was wrong with our son and to continually try to fight Blue Cross/Blue Shield.

Blue Cross/Blue Shield finally, after hospitalization of Jess, because he was too unstable cardiacally [phonetic] to be at home, rented I.V. treatment, 28 days. Within 10 days of being on the I.V., his symptoms were getting less and less. He had regained the ability to open his mouth, his glands were no longer swollen. He regained the ability to walk short distances. He was coming along. We finally saw our son back.

Then Blue Cross/Blue Shield upon constant requests from our physicians, from other physicians we jumped through every loophole they requested of us, and they denied treatment. They refused to give us an explanation. If they denied treatment they should never, ever not give

someone an explanation and back their explanation up with facts. They are dealing with human beings.

Because over the 20 years of having Blue Cross/Blue Shield, paying my payments every two weeks, never have they ever denied my check. We fought them and fought them. Finally, on the second denial, he was denied even though he showed proof in tests that he was getting better.

We continued the I.V. on a financial burden of our own. We mortgaged our home. He continued to show improvement and they denied it again. They said after 28 days, quote-unquote, we have it in writing, "He should be cured."

We continued to appeal. Jessie continued to get better. Finally the government stepped in, the federal government, Indian Health heard of our situation and came to our rescue, thank God, and they started paying present medical bills.

We still went through appeals with Blue Cross/Blue Shield because we feel that not everyone has that as a backfall and it's just a grant. On the third appeal they denied Jessie further treatment of I.V.s based on the fact that our son did not have Lyme disease. He had juvenile MS.

This medical information or diagnosis was come up with without evaluating our son, without reviewing his medical records, because we were paying for them financially, so they had no access to them unless they asked. But they were provided with -- you can see the brain SPECTs, you can see the spinal fluid. You can see his evaluations. But with no medical expertise per se, we felt that it was totally unethical, unprofessional, as well as devastating for our family to be told this without any backup. That was our last denial.

We continued with I.V.s for Jessie for months. We incurred over $80,000 in bills, not counting what Indian Health has helped us.

Jessie, back at school, playing, playing basketball, playing baseball, is doing wonderful. He was then put on, by Dr. Jones, a small, a lower dose of oral antibiotics. He did great for six, seven months and then a relapse. We're at that relapse right now.

He is no longer able to walk, he can't do stairs. He is having a hard time opening his mouth, the same nightmare is occurring as we speak. We have been dealing with Blue Cross/Blue Shield for just a denial. We're not even asking them to pay for it. We want in writing at least a denial so we can now go to Indian Health and provide our son with the medical care that this civilization should be able to provide.

There's nothing worse in life, other than maybe losing your child, but to see them slowly slip away from you when you know there's a treatment and there's a way that he could get better.

They have verbally told Indian Health, a representative from Mohegan Sun, that yes, they will help us. This has been nine weeks, so if you would like a project, Commissioner, I would love for you to take this on.

COMMISSIONER REIDER: I was going to ask you, why don't you, if you would --

MS. STURGES: I did submit everything.

COMMISSIONER REIDER: Okay. And

if you'd -- I'll come down and I'll get your name and address --

MS. STURGES: I would love it. I would love it.

COMMISSIONER REIDER: -- and telephone number and we'll follow that up.

MS. STURGES: Well, indeed, they have said to Indian Health they will help us, but when the I.V. company called them to verify their approval, they denied it. When we called them to verify it, they denied it. So we have for nine weeks, including our doctor calling, including Indian Health calling, they have completely ignored us.

We have met with them in person just two weeks ago, and I have that representative from Blue Cross/Blue Shield and they said oh, no problem, we'll -- put it in writing because we need it in writing in order to get help.

And I think what's happening is they are playing a very political game. I think they don't want to lose the Blue Cross/Blue Shield contract with Mohegan Sun. And I think that it is horrible to think that they could put people's lives more ahead of the almighty dollar.

What's more important, the benefit of the treatment or the benefit of the profit margin? And I feel that's exactly what is happening.

Now, in the last four months, our daughter became very ill with symptoms, complaining of swollen joints, fatigue, headaches. We immediately called Dr. Jones, we took her up there. While waiting for the -- what ended up being positive Lyme test results, she awoke with complete facial paralysis, no vision, no balance. So now we have two that we are fighting for, and if you really want to do something, you need to make these insurance companies responsible.

Dr. Jones, before he was dropped, was an in-network doctor, and they refused to accept his decision. We went through the neurologist they recommended, they also said our son needed the treatment. They again denied it. They shouldn't be able to. If you have in all honesty paid for your policy, they should pay for it. Is it better that we all go on welfare? Would we maybe have to go through these loopholes that insurance companies present us? I don't think so.

Another thing that they have just recently denied is the treatment of Nephron for Lyme disease. Both my son and I are on that. Nephron has worked wonderful for our type of disease. When I spoke with Blue Cross/Blue Shield, they have denied Nephron treatment now, which is an oral antigen, it's new, and it's expensive is the bottom line.

When I asked why was this disease denied, they said once a year they audit all treatments and all physicians and all tests and they take what tests, treatment, or antibiotics or any kind of medication, whatever is showing the highest rise, and they audit. And if they can show you they can supply you with another type of similar medication, whether it works for you or not, they can. And I don't think they should be able to.

What I'm asking and I'm begging, is that you really will take this situation seriously and deal with these medical insurance companies and help these people get proper care. Lyme disease is here to stay and it's not a fantasy as much as it's a nightmare.

I also feel, like I had said earlier, if they deny you, they should give you the right -- why have they denied you, and put it in facts, back up their denials. We have to back up why we are claiming we want the treatment, so why shouldn't they reciprocate?

I also feel these insurance companies should not be allowed to drop these physicians who prescribe long-term antibiotics or long-term care for Lyme disease. Is it another obstacle so patients can't now get that?

I also think, as someone had mentioned earlier in New Jersey, there is a law for continued education in the school system for Lyme disease. If a teacher has a student that has neurological Lyme, they have to show that they have continued education to use, course hours that they can adequately teach that child because of the neurological complications, short-term memory, word retrieval, reversals, things like that.

Why can't physicians have to be

required to become knowledgeable in this? And whether they ever -- a group practice, send one, I don't care, but they need to be accountable for the knowledge. This is out there and readily available.

And I also feel that there are so many people with a wealth of information on Lyme disease, and let those people be part of the decision-making on grants, who gets the grants for education on Lyme and who doesn't? It would save you money, and you would get to the end of this cure and treatment faster.

And again, I really, truly want to thank you very much for having us.

COMMISSIONER REIDER: Thank you very much.

(Clapping.)

COMMISSIONER REIDER: Jennifer Krasinski. I'm going to have to ask, I hate to do this, but we're just not going to make it through this list unless people are a little bit more concise, so we appreciate all your comments, and if you want to supplement them afterward, we

would welcome you to do so.

MS. KRASINSKI: Thank you very much for allowing me to speak, and thank you so much for holding this. I am Jennifer Krasinski. I was born in Connecticut, but at this moment I hale from Mountain Lake, New Jersey, kindly known as Lyme Lakes or Mountain Lakes.

I'm going to be very brief. I won't go into my own story, my children's stories, they are very much the same as the ones you've heard. But I will share a little story that happened here today.

In 1994, there was an article in The New York Times which Dr. Feder referred to which I also saw, and shortly thereafter I was lucky enough to meet the doctor, the pediatric neurologist, that had been charged with these discretions of overtreating and overdiagnosing, and I began to learn some facts which horrified me.

Number one, that the records that

the CDC had used to define whether or not these children had Lyme were at best incomplete, they were simply the hospital records.

Number two, several of the

children, three or four, I believe, who were included in this study were in fact on I.V. antibiotics but were not diagnosed, nor were they being treated for Lyme. This was an egregious error.

And so subsequently I called Dr. David Dennis at the Centers for Disease Control. With much persistence, I was able to speak with him directly, and I asked him about this situation, and he informed me that they were well aware of these mistakes, and that they had published a follow-up study which made a correction.

I then called the author of The New York Times -- of this article, and I talked to her about what I had learned and asked her if I sent her this article, which Dr. David Dennis sent to me, would she publish a follow-up story? Her answer to me was no, she would not, not unless Dr. David Dennis contacted her and asked her to.

I then called Dr. David Dennis back and I asked if he would please do this, and he said to me, I do not have time for this. And that's the end of my story.

I think you'll understand that there are games here that are being played. Thank you so much.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Kathleen Dickson.

MS. DICKSON: Hi. I first would like to thank Tom and Karen Forschner for the sacrifices that they have made and that have been put upon them in their efforts to help other people with this disease and towards its prevention, and we are grateful for this opportunity to explain the problems we have been having getting accurate diagnosis and treatment.

In my opinion -- this is my opinion of where we are with this disease and where we should go. The nature of the problem, it generally starts like flu, there is no better or more accurate description, only this flu never leaves. Lyme disease leaves us sick for weeks and months and years. Only fellow sufferers of Lyme disease and chronic fatigue syndrome understand what this means. People who have not

been sick for longer than a few days with the flu have difficulty understanding this concept.

People who have Lyme disease are often misdiagnosed. The average number of doctors a patient sees before diagnosis is five. Without treatment, encephalopathy can become so severe that the symptoms mimic Alzheimer's disease. We forget why we are in the car driving and not know what road we're on.

Extremely frequent checkbook errors, kitchen fires, lost articles of every kind, loss of the ability to speak fluently, sudden loss of emotional stability, inability to remember from one second to the next what we were doing and what we had done, it is a genuine mental disability and in no way subtle.

The extent of inflammation of the brain and nervous system is well documented in autopsy studies and in studies in which Rhesus monkeys were infected with Borrelia burgdorferi. The longer one goes undiagnosed, the longer it takes to improve and the less likely one will recover fully.

My personal Lyme story is I got a Lyme rash, it was symptomless. I took a picture

of it because it was weird to have a rash that didn't itch or yield any discomfort. It was warm and red and radiated. I forgot about the picture. I got a summer flu, but it never went away completely.

I kept working and working out and riding centuries [phonetic] and training for a triathalon, but I just got sicker and sicker. I thought I had chronic fatigue syndrome. I explained this to my family doctor in Milford and listed my symptoms. He told me that there was nothing wrong with me, to please leave his office.

I went to UConn Health Center and saw Dr. Peter Minew [phonetic] Who, despite my presenting with fever and swollen glands and my insistence that I was not depressed, concluded that I was depressed. Endurance athletes are generally not depressed.

He never ran any tests, and there was a journal on his desk, psychosomatic diseases, in which he published his conclusion about SEFITS [phonetic]. His subjects were female UConn students, and based on survey interviews, he concluded that SEFITS [phonetic]

was depression, and anybody that asked college students if they are tired and feeling overwhelmed is, in my opinion, no genius. I did not stay with Dr. Minew [phonetic].

I called the SEFITS [phonetic] people to ask their recommendation about having a baby. They told me there was no data but anecdotal. It appeared to be okay. I had two kids, which is brutal when you have the flu all the time, but I didn't regret it. It was a question of do I want to be sick the rest of my life with or without kids, since there is no cure for SEFITS [phonetic].

The SEFITS [phonetic] people told me about a doctor in Glastonbury who treated SEFITS [phonetic] people as if they were seronegative Lyme disease. I made an appointment as soon as possible, because the prospect of having a treatable illness was much more desirable than being sick the rest of my life.

When I saw this doctor, I had my first western blot and the result was positive. I had my children tested. I had had lingering concerns about their health. One definitely tended to be a sickly baby, the two-year old had

more positive bands by western blot than I did, and the eight-month-old had a questionable result. Later SPECT scan studies showed anomalies that correlated with her cognitive and speech problems.

I am still uncertain. They see Dr. Jones. A few months later, still sick but being treated with Zithromax, I became pregnant again, and yes, I know how this happens. And in a panic I made an appointment with the Yale Lyme clinic, my doctor in Glastonbury wanted me to start taking amoxycillin because it was safe in pregnancy. I did not tell him I was going to Yale. I was afraid I would infect a third baby, I thought surely Yale physicians would know what to do.

The Yale rheumatology experience is very similar to everybody else's. I saw Dr. Robert Schoen. During the exam, Dr. Schoen acted like he believed and understood everything I said. He seemed to ask all the right questions and when he was done with the exam he left the room and came back and said, so you've come here as an advocate for your child. And I said yes, and he said, I don't think you have Lyme

disease. I don't know what you have.

I was shocked but at that point remembered that everybody told me not to go to Yale for Lyme disease, and now I understood why I had been warned. Dr. Schoen deflected all my protestations but sent me down the hall to the lab for a western blot. It was the only negative Lyme test result I ever got.

The phlebotomist was a pleasant woman who asked me what test I was having, as she was looking at the order, and she said, Oh, Dr. Schoen. I should have known it was going to be a western blot.

And I just sat there feeling really stupid, and I said, He says I don't have Lyme disease. And she said, Mmm, he tells that to all his patients. They come down here crying and saying if I don't have Lyme disease, what do I have?

I went back to my doctor in Glastonbury and he convinced me to take part in the LDF's Lyme and pregnancy study, and I took amoxycillin throughout the pregnancy and my son was negative by their criteria and testing and he's my healthiest child.

Three years after I saw Dr. Schoen I finally got better, improved significantly. I don't feel sick -- I don't feel sick every minute of my life like I did for the first nine years. I am not the person I was intellectually and energy-wise, and I have bad days, but I can talk now. I can drive and I can plant things.

I am totally amazed to be this much better, and I have never -- and I'll never be able to describe how grateful I am to the three doctors that helped me to get this much better.

The immediate solution, assure that insurance companies no longer attempt to limit or restrict medical treatment or practice medicine without a license. Insist that experts practice in their realm of expertise; that is, rheumatologists only perform independent medical evaluations for rhematilogical diseases and not infectious diseases.

We know that the insurance companies send patients to Yale because Yale is going to tell everybody it's not Lyme.

The long-term solution, since there is no cure for Lyme disease, I'd like to

recommend a long-term solution for people with this, our State disease, and that would be a genuine Lyme disease clinic.

These clinics should be staffed by infectious disease specialists or doctors that have been specially trained in the education to treat Lyme disease patients. They should include management of visiting nurse services, financial advisors for assisting patients with filing for disability, and handling the financial fall, because people with Lyme disease do not do accounting things very well.

Phlebotomists, nutritional counseling, psychiatric counseling, which would include group, individual, family and family group to help prevent families from disintegrating because one or more of the members have this burden.

Meals on wheels, visiting, cleaning services and grocery shopping. This is just the tip of the iceberg. Many, many people just would not have the strength to have come today. And for people who finally have the infection under control, cognitive remediation and physical therapy, vocational rehabilitation,

would be necessary for some patients who have permanent neurological damage and just can't learn things or rather to work with what they have left.

The State should pay for a portion of these services, and where people have become eligible for Social Security disability.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Thank you very much, Ms. Dickson. I just want to mention, as I said earlier in the afternoon, I have a legislative hearing which I'll be attending now on our budget, and then onto another meeting, but Mary Ellen Roe, who's life and health, and deals directly with the appeal process, and also the life and health issues with you, and will capture the information.

And I appreciate very much your participation and your input and your patience as well, and I think it's certainly important to hear what everyone has to say, so I thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Next, Alison Schettini, am I getting that right?

Susan Tremaine?

Jane Devine Compton or Campton?

Harrison Pease?

Karen Ferraro?

MS. FERRARO: I'll be fairly brief. The issue of Lyme disease treatment and insurance coverage is very important. It's of the utmost importance to me, my family and our well-being. I have to say that I've given public testimony twice before for the State legislature for two separate bills proposed for laws requiring coverage for Lyme disease, and our testimony seemed to have fell on deaf ears.

The State legislature essentially did nothing. The bills never moved. I hope and pray that our efforts to obtain treatment are not in vain. I hope for a judiciary remedy, as I feel that attempts to pass along through the legislature are unlikely, since they in the past failed and they don't seem receptive...

(Tape ended, new tape begins.)

MS. FERRARO: ... our problems, our concerns. I fear not only for noncoverage but the inability of my physicians to treat me in the future. I've had Lyme disease for over five years. I've been under the care of three physicians who've made the clinical diagnosis of Lyme disease. In my case, Lyme disease serological tests ordered by all physicians returned a negative result, due to the fact that I had started antibiotic treatment within weeks of being bitten and infected by the Lyme disease bacteria, which prevents the production of detectable antibodies, therefore the tests show as negative.

Being serological negative is like the worst position you could be in on top of having Lyme disease. You're kind of caught in a Catch 22 where you have no proof that you have the disease and to try to prove that to the insurance companies is near to impossible, but I didn't give up.

I persisted and attempted to get coverage through my carrier, Blue Cross/Blue Shield. They were my primary health insurance

company, and denied me many times. I went through the appeal process, which is very lengthy, and consistently each appeal was over the time limit that Blue Cross/Blue Shield was required to respond in. By the time I received the final denial, I was in desperate need of infusion therapy.

I then requested coverage for infusion therapy from my husband's carrier, Connecticut General, through his employer, being my secondary coverage. After one appeal, Connecticut General approved four weeks of infusion therapy. At the conclusion, because symptoms decreased and my well-being improved, four additional weeks were requested from Connecticut General and two weeks were approved.

Again, two additional weeks were requested based on persistence, but reduced symptoms, this time, being denied by Connecticut General for further coverage of treatment.

I then had to pursue another appeal back with my primary carrier, Blue Cross/Blue Shield, and in that I go through the information and it's documented that they consistently did not provide written documentation or communication within the 30-day time limit stated in their appeal grievance process. The only way I was able to get answers were through the advocacy of United States Congressional Representative Nancy Johnson and her contact with Blue Cross on my behalf. And also through Senator Joseph Lieberman's office and their contact with Blue Cross on my behalf.

Their delays and lack of diligence during the process resulted in obtaining a final determination, denying infusion therapy coverage after more than 19 months from the time the initial request for the treatment was made by my physician.

Due to my failing health condition and the medical necessity for infusion therapy as determined by my physician, I obtained the needed treatment over an extended period of time from my employer, New Britain General Hospital, rejected the determination to deny infusion therapy, made by the group health plan carrier, Blue Cross/Blue Shield of Connecticut, and provided for my treatment at the hospital facility.

We need to get equitable treatment from insurance companies for Lyme disease.

Insurance companies must fulfill their contractual obligations and provide treatment as prescribed by the patient's treating physician.

I assert that any therapeutic decision should be made by the patient's physician, not on the determination of medical consultants hired for fee by the insurance company or biased and in favor of noncoverage resulting in no treatment for the insured. This demonstrates a conflict of interest.

In my opinion, the practice of establishing a protocol that limits the treatment for Lyme disease is corrupted if many insured people are covered by companies using the same consultant or medical opinion. Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

Mary Ellen Robertson.

Brian Carroll.

MR. CARROLL: Mr. Attorney General, I had planned on doing a presentation with a very brief videotape that I had put together and despite [unintelligible] by the Attorney General, we weren't able to get the right machine to play it. It's a regular VCR tape, so she has gracefully accepted this with my written testimony that went along with it, and she will be able to do that at a later time.

ATTORNEY GENERAL BLUMENTHAL: We'll look at it later this week.

MR. CARROLL: I think it would be helpful to underscore some of the important issues that are recurring in [unintelligible] today.

ATTORNEY GENERAL BLUMENTHAL: Thank you. Thank you very much.

Laurie Blair.

MS. BLAIR: My name is Laurie Blair. I live in Chester, Connecticut. I was diagnosed and infected with Lyme disease 15 years ago in June of 1984, when I was 28 years old. This was Lyme meningitis with a severe headache, stiff neck, vomiting and 104 fever along with a bullseye rash.

Was I treated quickly? Oh, yes, I was. Within days. Was I treated properly? Yes, I was, I was treated with Doxycycline. Was I treated long enough? Well, I was given seven days of Doxycycline and I threw up the first two pills. My doctor had no political or economic

agendas. The only thing he was guilty of was ignorance. I don't think back in the early eighties that everybody realized that there is a lot more to Lyme disease than a skin rash, a fever, and a couple of aches and pains. So I didn't get better.

And then in 1987, when I tested positive for Lyme, I was treated again, with 10 days of penicillin. Since that time, I had developed problems that affect nearly every portion of the body; the skin, the bones, the joints, the eyes, the lungs, the heart, the blood, the brain, and finally in this last stage, the nervous system. But I was told that it wasn't from Lyme disease, because I had been treated. I don't know where anybody got that idea.

My neurological issues are now so painful and incapacitating that I have gone from a full-time job with some of the best insurance that money can buy to a disabled middle-aged woman whom you are supporting. To a shadow of who I used to be, who I could be, and who I might have been.

There's a quote from Seneca, it

says, "A disease is also on its way to being cured when it breaks forth from concealment and manifests its power." Today we have seen some of the shocking and awful power of Lyme disease.

Now, I've had three weeks of I.V. Rocephin. Now I'm on six months of Doxycycline. Now I'm just praying that it's not too little too late.

So we've got new vaccines for Lyme disease and we've got quicker test results. Does this now mean we can treat confirmed or suspected cases of Lyme as nonaggressively as I was treated? How much longer and in whose name are we going to go on treating our young?

There are as many unforgivable reasons for not adequately treating Lyme disease as there are patients and providers. As we become a nation of people crippled financially, emotionally, socially, and physically, a ravaged landscape straight from a Stephen King novel, we are reaping the tragic harvest of these excuses, and it is pointless and it is heartbreaking, because we know better now.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you.

Vera DeStefano.

MS. DESTEFANO: My name is Vera DeStefano. I'm from Westport, Connecticut. Thank you for the opportunity to be heard today on the matter of Lyme.

My main concern relates to the diagnosis of Lyme and the subsequent treatment. Since 1984, I had requested Lyme tests and received the same diagnosis of negative for Lyme disease. I realized that little was known about this disease in the eighties, but the fact that I was misdiagnosed until 1996 is inexcusable.

I experienced minor visual symptoms in the eighties but they were so mild I thought they were caused by my contact lenses. By 1992 I was in dire straits. I won't torture you with my symptoms. Suffice it to say I was going blind, deaf, on anticonvulsives, and on heart medications.

Between 1991 and 1996 I saw no less than 18 physicians for my worsening symptoms. I consulted with neurologists, aphemic

[phonetic] neurologists, infectious disease experts, mostly in Connecticut, but also Valhalla, New York, Montefiori Hospital, Willis [phonetic] Eye Hospital in Pennsylvania, and after relaying my medical history and symptoms to each physician, they all seemed to have the same expression the RCA dog has hearing his master's voice over the Victrola, you know the look, head tilted to the side with a perplexed expression.

During this time, I had countless blood tests, lumbar punctures, those are spinal taps, brain scans, MRIs, all indicating a worsening condition, cause unknown. My life became a de jour menu of diseases.

One day it was Lupus attacking my brain. That was wrong. The other it was a brain tumor, that was wrong again. Multiple sclerosis, strokes, fibromyalgia, they were all wrong. One neurologist went so far as to say that my MRI looked exactly like Lyme in the brain, but I didn't have it.

I may not be a physician but my theory is that if it looks like a pig and it smells like a pig, maybe it's a pig.

In October of 1996, something

remarkable happened. I was helping a friend in Wilton, Connecticut, with her garden. Two days later I found a deer tick on my upper arm and for the first time had a rash. Two days later, I began treatment for Lyme disease. Within weeks, my prior symptoms began to improve. I then realized it was Lyme all along.

I sought out a Lyme specialist and found Dr. Steven Phillips, who has brought me back among the living. His treatment has been innovative, effective, and caring. Symptoms I had in the eighties are beginning to improve. I am no longer on anticonvulsives, heart medications, or anything else that would suppress symptoms.

What is truly baffling to me is that I was never told that evidence of Lyme appeared in all three spinal taps taken from me over the years, and while I was never negative to Lyme, excuse me, while I was never positive to Lyme, I also was never negative. My life was allowed to become unbearable because I was not positive enough. They watched me dying a painful death but persisted in the belief that I had to be a full-blown positive to deserve treatment.

Had I not been bitten by a second tick and exhibited a rash, I would not have received treatment. Without a doubt, their mistake would have been buried.

Physicians allowed faulty tests and an even more flawed interpretation of the results to dictate my fate. Please help pass all legislation to support research, diagnosis, and appropriate length of treatment for this deadly disease. The next Lyme victim might not be as lucky as me. Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Billy Clinton? Dee Clinton? Susan Clinton? They were here I know earlier.

Donald Damoth?

Cherie Paranto-Warren?

Debbie Procaccini?

Debbie Siciliano?

Douglas Mershimer?

MR. MERSHIMER: So that I'm not

duplicating everything else, the differences that I have to present to you today is that I've challenged Dr. Schoen in his decision to deny me the benefits and continued therapy only after I was able to get a positive spinal tap from a test from Dr. Coyle, and this proved that what he considered to be ample treatment was very conclusive with the Osp A protein that is done with the test from Dr. Coyle that I was able -- I'm sorry -- that I was able to demonstrate what he so continuously says to everybody is ample treatment. I was able to disprove that.

The other thing that I don't think was mentioned enough today was the fact that there are several coinfections. I've also been treated for early gliosis [phonetic] and babesiosis. I've improved since then.

And the newest thing that I haven't heard anybody discuss at all today was about the stefires [phonetic]. All these are very serious and possibly fatal coinfections that do exist and are carried by the Lyme ticks.

We need also to investigate these since they help the Lyme disease continue to exist even along with the most aggressive

treatments of therapy.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you.

Cynthia Onorato.

MS. ONORATO: I'll submit my testimony in writing.

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

MS. ONORATO: Thank you.

ATTORNEY GENERAL BLUMENTHAL:
Nancy Berntsen.

MS. BERNTSEN: If anybody that wants to read my statement, I have one on beige paper over there. I'm not going to read it.

ATTORNEY GENERAL BLUMENTHAL: We will.

MS. BERENTSEN: Good. I'm going to change my focus based on a need I see here, a need for something uplifting.

I'm from the town of Scotland. I've lived in Connecticut all my life except three years. I have four children who've all had

Lyme disease and I've had it myself. I still have Lyme disease. But the good news is that I feel great and I have good insurance coverage. I think everyone should be entitled to the kind of coverage I've had.

I was only granted four weeks of I.V. treatment, which did not help me, and I had to change physicians, because the physician I had was doing cookbook-style treatment, and she referred me to another doctor, an infectious disease doctor who was spoon-feeding her. So certainly I didn't want to go to him and waste my time to get the same news that I was cured when I wasn't.

I'm a registered nurse. I graduated from the University of Bridgeport, and I think because of my background, I've been very perceptive to the symptoms. I detected it in my children, I detected it in my parents. They didn't listen to me until they went to a lecture on Lyme disease.

But I just want to reiterate, everyone should be entitled to good coverage, and the ability to make decisions about your healthcare with your physician are very

important. It's important not to you just for your physical health, but your mental health and your self-esteem.

None of us -- or almost none of us wanted to be medicated for Lyme disease but it's necessary, it's a necessary evil. The antibiotics can make you feel sick. You can feel better after you've stopped taking antibiotics because the antibiotics make you feel sick. That doesn't mean you didn't have Lyme disease.

I've come to a high level of recovery. I would say with the antibiotics I was about 90 percent well after an undetermined amount of years with Lyme disease. That decision to come off the antibiotics was not easy, but it was something that my physician and I discussed several times over several months. We had trials of stopping antibiotics, seeing how I felt. Finally I got to a point where I was about 90 percent well and I plateaued, so that was for me an optimal time to discontinue the antibiotics.

Since then I took an over-the-counter remedy, that is antimicrobial, it's not approved by any Lyme physician at all, but it has helped me, it has helped other people,

and it's kept me out of the doctor's office. I've gotten my independence back. And I'm here not for myself, not to boast about how good I feel. I'm here to represent the people who have not gotten well yet.

I'm very committed to not just my family but all these other people who are not well, and I'd like to see them all have the opportunity to perhaps achieve improved health if not a cure. Thank you very much.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Could I just ask you, Ms. Berentsen, you mentioned that you were satisfied with your insurer. Could you tell me who it is?

MS. BERENTSEN: Well, actually there were several changes, and I was very nervous when I was learning my husband's company was changing coverage, but we've had Metro Health and United Healthcare. They would only cover four weeks of I.V. from what I understand, but with consultation they would have extended it, and that was from 1994 through 1996. Most of my

treatment was oral antibiotics, and not everyone responds well to orals. Thank God I did.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL:
Thank you very much, Ms. Berentsen.

Brian and Cathy Morrissey.

MS. MORRISSEY: Brian and Cathy Morrissey from Wilton, Connecticut. We're going to let our children speak and we'll be very brief, because for us this is a family illness.

ATTORNEY GENERAL BLUMENTHAL: By the way, I have received from you as you indicated, you would send to me a fair amount of material which we will make part of this record if you would like.

MS. MORRISSEY: Yes, please, thank you.

KEVIN MORRISSEY: My name is Kevin. I am in first grade. I've had Lyme since I was four years old and now I am seven years old. It is bad because a kid can look fine like

me. They can play and be strong but it's hard for them to say their brain is sticky if they were like me. Your head doesn't hurt but your brain won't work. I had some problems being good in kindergarten but I took lots of medication and

I'm doing great in first grade. I am almost all better because of Dr. Phillips and Dr. Jones. I know I will get all the way better if you can help my -- me and my doctors. Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you, Kevin.

BRIAN MORRISSEY: My name is Brian Morrissey, I'm 16. In my own experience with Lyme, I've seen a serious effect on neurological symptoms. I think the easiest things -- symptoms to pick up are always physical ones, and in my case I knew right away that I was experiencing arthritis and fatigue. However, it was 18 months after my original diagnosis that I was diagnosed with a wide range of cognitive problems, including memory problems, dyslexia, word retrieval, and poor concentration.

I was always a bright student and my grades were good and I scored well on the SAT in 7th grade, but over the next three years my academic performance was extremely inconsistent, as my arthritis and fatigued worsened as well.

I had to drop many honors courses and was placed in special ed. Since then I've come across at least a dozen other students with neurological complications of Lyme just in my small high school, and many others that we've met across the state. Like all aspects of Lyme disease, the neurological manifestations are extremely difficult to pinpoint, and despite my school's accommodations, they really didn't know how to help, but this is a relatively unexplored disease.

I was treated with numerous oral, I.V., and intramuscular therapies over two and a half years by Dr. Jones. My condition slowly but surely improved, and I have been symptom-free for the past seven months. I'd like to consider myself a study in the benefit of long-term treatment.

I think this hearing today is vitally important, and without the support of

people like you, it isn't possible for the average patient to find a diagnosis, treatment, and most importantly, answers. The importance of the continuation of research and the ability of physicians to treat the clinical symptoms of this disease is the only possible hope that many patients who have written and spoken here today have.

I thank you all for your time and effort here today.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you.

MISS MORRISSEY: I've had Lyme for four years. I suffer from light and sound sensitivity, and sometimes I have to wear two pairs of sunglasses. I have dizziness, learning problems, and in the past have experienced paralysis, narcolepsy and movement disorders.

I've spent time in a wheelchair and missed months of school. I, like so many others, was misdiagnosed, ridiculed, and abandoned by doctors who called my problem psychological. Eventually long-term treatment has helped me to get back to school and achieve an almost normal life.

Just three months ago, I made highest honor roll and was on the varsity swim team. However, now I suffer from a serious relapse. Because only a handful of doctors are knowledgeable about this disease, it is very difficult for me to get help from neurologists, even though it is clear to anyone that I am suffering from a brain infection.

Lyme disease is caused by a tick so small it is almost invisible. It causes symptoms that can be invisible. It is so mystifying that it is often invisible on tests. The number of cases is underreported, making it more invisible. In a way I'm lucky, my disease is very visible to others, it is tangible and real.

But all of the people who suffer from this are real. Pain and suffering and sense of loss are devastating and very, very real. We are not just numbers, but people in a real family, whose way of life has died. We are grieving and we need help.

I'm so thankful for the opportunity to speak to you and hope that you will help me, my family, our doctors, and all the people who suffer from chronic Lyme. Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

MR. MORRISSEY: A ground swell of people are finding themselves victims of a chronic debilitating often incurable illness that the most influential members of the medical establishment have told them absolutely does not exist. Our hometown is home to scores of families going through this terrible ordeal.

MS. MORRISSEY: Lyme and other tick-borne illnesses are mysterious and potentially serious, as our family has learned the hard way. Misinformation about its prevalence, severity, and chronicity account for the illnesses in the five out of six members of our family who are present here today.

We all contracted Lyme within 18 months of moving to Wilton, which is a very hyperendemic area. Our illnesses almost run the whole spectrum of Lyme disease. My husband developed a very classic case but was undertreated and so became chronic.

At the other extreme, our daughter Erin started out only with flu-like symptoms, was eventually diagnosed, but given treatment that proved inadequate. This has led to a four-year nightmare of serious problems that include a movement disorder, profound trouble with thinking and memory, and pain throughout her body. She has missed many months of school and spent time in a wheelchair.

The rest of us fall somewhere in between these extremes, and we never would have connected the subtle, disturbing behavior and cognitive problems our boys were experiencing had we not learned about it from Erin. The nature of this disease is such that it affects each person differently, as evidenced here in my own family.

Doctors like Dr. Phillips and Dr. Jones understand this, but know that diagnosis, treatment, and care of Lyme disease patients requires individualized time-consuming, compassionate care.

The health insurance industry's favored managed cookie cutter approach and the establishment of uniform standardization of treatment is simply unconscionable, especially with new insights into the problem of coinfection with other tick-borne illnesses, which, by the way, several of our family members have.

Although our daughter is visibly ill, we are no less concerned for her brothers, who suffer from different yet serious form of brain infection. There is no guarantee for cure for any of our children, which is absolutely unacceptable to us.

We are deeply troubled by the harassment of our doctors who are brave enough to fight the bureaucracy and treat. We believe that funding for the study of tick-borne illnesses has been inappropriately skewed to rheumatologists, when it is clear that in later stages this is a brain infection. We do not believe that rheumatologists should govern the research of brain injured people such as our children.

Ironically, we realize the only

way to get the help we need is to become politically active to help bring about research

for an effective cure for our family.

MR. MORRISSEY: As parents of children with Lyme disease, it is extremely frustrating and discouraging to deal with the politics, the lack of understanding, and compassion in the medical community. Children are often misdiagnosed, their symptoms dismissed or belittled because they are not verbalizing their symptoms or the doctors explain them away as growing pains, stress, depression, anxiety, or behavioral issues.

Many local physicians rely on misinformation that comes out of Yale from supposed experts on the subject. The danger here is that these children often go undiagnosed or misdiagnosed for months or for years and develop serious neurological problems that are much more difficult to cure or control. Children are at the greatest risk of tick-borne illnesses, they play outside at home, school, and at friends'. The outdoors is a great place for children to explore and have fun, yet it was in such seemingly safe places that our children were infected.

Our greatest fear is that our

three children with Lyme disease will be reinfected or that our one healthy daughter will become infected. The vaccine currently being developed is not for children under the age of 15. What are parents to do? Can we risk sentencing our children to a lifetime of physical and neurological problems? What is being done to save our nation's most precious resource, your children and mine?

We were given permission from a friend to share some of his story. He believes his previously healthy seven-year-old child died from a tick bite sustained in the child's scalp. In two days time the child became suddenly lethargic and began having seizures. Tests taken for Lyme were borderline, just short of arbitrary standards set by those who dictate treatment. The child was placed in a medically-induced coma to control the seizures. The parents were faced with a maddening range of diagnosis and suggested course of treatments.

Months later when we heard of the case, we sent her to a physician knowledgeable about Lyme, who prescribed an appropriate and reasonable treatment, but it was already too

late.

Insurance was also a problem, and the child died. Autopsy results failed to identify any known cause of the child's illness.

Our friend has submitted the private details of his account in the hope that it will help our children. Mr. Blumenthal has been given his complete story.

MS. MORRISSEY: We would like to close by reading an excerpt from our friend's letter.

"Connecticut is home to this country's largest and most influential insurance firms, and it is also the state hardest hit by tick-borne illnesses. Most patients have been told that their illnesses were not Lyme-related. I hope you will examine the facts, acknowledge the uncertainty, consider the motivations of the opposition and do the right thing."

Thank you.

MR. MORRISSEY: Thank you.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

Dolly Curtis.

MS. CURTIS: Thank you for your patience and having spent this whole day, which was long overdue.

My name is Dolly Curtis, I've lived in Easton, Connecticut, for about 21 years. The town is loaded with Lyme disease patients, but many of them don't know they have Lyme disease. I've also lived in Norwalk, Connecticut, for about 12 years, so about 30-some-odd years living in Connecticut.

I'm a New York City-born person and I should have stayed there. I was diagnosed in '91 and I've been battling infection ever since. It has been a lot more disabling than I had ever, ever dreamed. I was misdiagnosed in '91 by a dozen different doctors, and I sought help immediately, because I'm a very active person, and I didn't let a day go by that I didn't try and get to a doctor to ask for help. And something happened to me that is different than mostly what everyone else spoke about, so I

thought I might mention it.

I was born with one foot that's not normal, and for most of my life I've been able to get by. When the Lyme disease attacked my system, it went right into my foot, and I've been told that it goes to the weakest part, so I never, nor did Dr. Ligner [phonetic] or any other specialist put together the fact that I couldn't walk on my left foot and that I had Lyme disease. It was very hard to put those two things together.

So I went naturally, eventually, to the Hospital of Special Surgery in New York City because I was in a wheelchair on and off, and I was a mother of several children and an active person and I was trying to find a way to continue to live my life with mobility. And I ended up at Yale. This time not in rheumatology. I've been there too, but I ended up with their orthopaedic people, and I just thought it might be a little shocking to let you know that after three years, going back three times because I couldn't walk on my left foot, and I had mentioned that I had been treated for Lyme, they suggested that I have my left foot

amputated or part of my left foot.

And I told them they were crazy and left, which annoyed the orthopaedic surgeon greatly that I didn't listen to his advice. And I had been there three other times, three years in a row.

Actually, the person that really saved my life was here today, her name is Martha Accola [phonetic] And she was a physician's assistant to Dr. Kenneth Ligner [phonetic], and she told me not to let anybody operate on my foot because my foot was coming from the Lyme disease spirochete. And actually I wasn't sure that she was right, but it has turned out to be that she was correct.

So this disease, as you've heard today, takes many different forms. I have lots of other symptoms, I have many neurologic symptoms, but it seemed at first with many different relapses it comes back into that part of my body, my left foot and my hands.

I myself produce a television show in about half of Connecticut, and I do this without salary, so it makes my life very interesting and sort of it's a sacrifice not to

have an income, but I've been able to reach thousands of people.

I've come from a family of very socially active philanthropic backgrounds, so I don't know what else to do. So what I have done is, we didn't have hearings like this in the last eight years, I have asked some of the top specialists in this Northeast to come on television, which they have, without force, and I've done the best I can to try to put forward to the television audience what I knew.

At first they were more reluctant, but in the last few years they have been outspoken. And so there are many of us who have tried to bring public awareness, and many of them sit in this room today.

And one of the things I wanted to mention that no one has mentioned, is there has almost been in the Fairfield County area, no public health awareness, it's all been done through volunteers like Morrissey's family or myself or other people who have been running support groups, Cindy Onorato. We have been running these groups for years, being there for people who first get infected, trying to help.

I must have at about this point have answered a thousand phone calls in the last eight years myself personally, just trying to direct people, and I'm not a doctor, in some way to give them some affirmation that there is help. So I am just hoping that rather than volunteers like myself and Cindy Onorato and Morrisseys, that somewhere the government could step into the Public Health Departments and help us educate the people, because honestly, Mr. Blumenthal, we have been doing it all ourselves for a long time. But we have no budgets, we just ask these doctors to come and speak, and they have been very gracious.

And then we hang up flyers and we publicize it and 200 people will come to an address like that, so it's getting to be so many people that it's very hard for us to handle that type of situation.

I also wanted to say that I've had no difficulty with insurance companies. I almost didn't want to say that today for fear that they might red flag me, because for eight years I haven't had any real denial. I mean they have denied me if I want to see someone out of

network. I know I have to pay for that out-of-pocket, but I've been lucky enough that I've been able to get HMO coverage.

I have a Lyme doctor within the system, so far so good, and I've been able to get all my medications paid, and I've been on oral medications and that's probably why.

So if there's one person and then another person spoke, I just wanted to say I have not -- I am fearful to say that, because I mean if they read my testimony and they say oops, missed her, you know, go back to the computer and pull me off the list, there goes my coverage.

I don't know if anyone mentioned this either today, but there has been a lot of families that have gotten divorced and broken through this whole thing, and I feel that many phone calls like that, where people have called me and told me that they just cannot live anymore with the Lyme-infected spouse, and it's just more than they can handle, and I try -- nobody could imagine what it's like to live with this, so I try in my own way to ask people to be more patient.

But I have seen families really

just unwind. I've seen a few people go into nursing homes, and we've had one person commit suicide that we know of in the lower part of Fairfield County, just very sad.

I really think it's a suburban nightmare, that's what I've always called it. And it's a little bit like polio, just like a polio of the nineties, but nobody is paying attention. FDR, where are you? We don't have anybody.

We have been waiting for a wealthy, important celebrity to come forward. Paul Newman lives about a mile and a half from where we meet, support group site. I never meant him any harm, but I was always hoping he would get Lyme disease and stand up and be counted, but the people who have gotten Lyme disease, the rumor goes like Woody Allen, that famous baseball player, a few other people, I think they are so afraid for their career, like Governor Whitman, that they just don't want having the stigma of being attached to Lyme Disease. We have had no spokesperson [unintelligible] and they are quite -- it's a very sad and impressive story.

Nobody today either has mentioned

the great risks that a person who is pregnant takes while they are carrying a child. I think it's an incredibly sad thing to think that we haven't brought an awareness to people who would be carrying a child and go to a Memorial Day picnic or just for going to a family picnic but end up being bitten. It's just an easy thing to have happen.

It doesn't -- I was -- it doesn't hurt, you would never know, especially in May, when the ticks are so small, June. It's a nightmare. That parent can walk right into it just by walking across their front lawn, or owning a dog or a cat, which the pets -- you don't have to go outside. If you have a family pet, they bring the ticks inside.

And I think the whole country is looking at us with a -- we are the heart of this problem because of Polly Murray and all her courageous work, her book, and the Forschners, and we really have the heart of what the whole country sees as Lyme Disease, because it's been named after our state. And I don't know if we're doing the best job in helping the rest of the country.

It's in every state now other than Alaska and Hawaii, that I know, and it makes you wonder how. It's spread on many people by birds, but it is a thought; how has this spread across the whole United States?

I just feel that people don't realize the risks that are around just walking across to their mailbox, and it's a real risk, and the children are at most risk because they are closest to the ground and ticks don't fly, they are on the ground, and they crawl up blades of grass, they are in your pachysandra.

And I just wish everybody can give a little thought to their grandchildren or their children or their own health because this is not something that can be prevented. There has been a lot of talk about prevention, and those of us that have Lyme are not so sure that -- yes, you have to do tick checks, and I don't mean to make light of that, but this is really not something that can be 100 percent prevented.

A tick is so infinitesimally small, it's just something that can happen to you. You may not get any symptoms at all at that time. It could be six months, a year later, the symptoms come on in many, many different ways. As I said, with me, I couldn't walk, and I had a crippled foot to begin with, so everybody just said well, you have a deformed foot, so, you know, what did you expect, you are 47 years old, you've just been lucky until now.

Then the next thing is what, major surgery on your foot. And if it was coming from a spirochete, any surgery on my foot wasn't going to do any good.

So I thank you for taking --

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

MS. CURTIS: -- [unintelligible] hours.

ATTORNEY GENERAL BLUMENTHAL: Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Dr. Lionetti.

DR. LIONETTI: Thank you very much. My name is Anthony Lionetti, I'm an internist. I'm from the state of New Jersey,

actually from Hamilton, New Jersey. My sister is a physician in the state and she lives in

Burlington, Connecticut.

I wanted to -- very quickly, I wanted to submit some written report -- a written comment about some of the more technical aspects that were discussed today by the various experts. One thing, though, I want to cut to the chase, and I think is very important in terms of looking at the involvement of the insurance industry in development of guidelines and practice parameters, which I think is the greatest issue here, for diagnosis and treatment of this disease and perhaps other diseases, for that matter.

One of the things that the medical profession has been looking at in this issue over the past, I'd say eight to nine years, as we try to focus in on healthcare and decreasing cost and maximizing benefits for patients, as Dr. Feder has shown and discussed to some extent, however, very importantly, all of the literature that has been written about this subject has stated that no practice parameters or guidelines should really be written unless observer bias is removed

from the evaluations that the parameters are based on.

What I'm trying to say is, one of the biggest issues in Lyme Disease is testing, and the testing is indirect testing like the ELISAs and Western blots, which can tell you you may have been exposed to the disease but may not prove that you have it currently are two good tasks that are underutilized and had not been used in any of these studies, such as ploamri's [phonetic] chain reaction, PCRs, which can prove the person actively has the infection. That is the gold standard-type test or culture where you grow the organism.

Studies based on the results of patients who are diagnosed and treated using either cultures or PCRs can't be used as a gold standard, they simply do not exist. The insurance companies do not have really a correct basis for establishing these guidelines or parameters, and that's why all these people here are having so much trouble.

It's basically one where physicians who are outsiders, they need opinions but they are not basing it on any gold standard where we have proven the infection, and they have even worked to the point of denying the ability to have access to the direct detection tests. They have stated that PCRs are experimental.

The College of American Pathologists in 1988 conducted a clinical survey of 16 laboratories in the United States that do PCR tests commercially. They have stated with certainty that there is no problem with false positivity with PCRs, therefore they are not considered experimental. They are actually being reimbursed by the insurance companies that if the result is positive, they are not allowing treatment for patients.

I will submit the rest in writing, but I thought this was a very important point to bring out now as you start to look at all the data that you're getting and look and say, you know, like the old story, where is the beef? The beef is in the gold standard test, it's not available yet.

The lady had asked a question in Connecticut, what is being done in terms of research? There is no research being done using a gold standard test of any sort. It is a rehashing of the observer bias of a group of observers, physicians, scientists.

(Tape ends, then new tape begins.)

ATTORNEY GENERAL BLUMENTHAL: Carla -- I'm sorry.

UNKNOWN SPEAKER: I'll keep this really short because it's getting late. My son is one of the unfortunates who is seronegative. During the course of being diagnosed he had six tests in several different labs, including Yale, over a period of three years. They were all negative. However, he had a history of tick bites. He had physical and neurological symptoms of Lyme Disease. He had exposure of living in a hyperendemic area, camping in Lyme, Connecticut. But we could not find a doctor in Connecticut who would treat him or diagnose Lyme Disease.

We went to the Lyme Disease Foundation and they recommended a doctor in New Jersey, who is currently still his doctor. Although he missed a year of school he did recover, and by 1996 he was doing well, both academically and in sports.

The doctor said well, let's stop the antibiotics and see how he's doing. He'd been on the antibiotics for three years at that time. Things seemed okay but then his teachers noticed he wasn't doing well anymore. He was missing things on tests and just wasn't sharp like he used to be, so we put him back on antibiotics and his grades went back up. He is currently in college, still on antibiotics, getting a B average. He's extremely fortunate.

So there are two things we know for sure; the lab tests aren't reliable, and antibiotics are not a sure cure.

Why are we told that the clinical diagnosis of Lyme Disease must be confirmed by laboratory evidence? A cure is defined by faith and 21 days of antibiotics. That's all. Thank you.

(Clapping.)

ATTORNEY GENERAL BLUMENTHAL: Thank you very much.

Carla Southwick.

MS. SOUTHWICK: Hi.

ATTORNEY GENERAL BLUMENTHAL: Good afternoon.

MS. SOUTHWICK: My name is Carla Southwick. I'm going to submit what my testimony is in writing later because my family tragedy is so similar to what I've heard today. I'm so emotionally distraught just seeing what we've suffered and continue to suffer played out in so many other families.

We have -- I'll just say that two of my children and myself have chronic Lyme disease and all that goes with it. It's just -- it's just been horrible and it's a huge tragedy and made much worse -- the spirochetal illness and the other coinfections we have would have been enough to deal with, enough of a challenge without all this other nonsense that goes with it, our delayed treatment, our doctors have been intimidated resulting in changes in doctors and regimens.

And my children have been on long-term treatment of low-dose antibiotics, which my question to the conservative doctors that put them on that was, I thought this was the way that you -- if you wanted to develop

antibiotic immunity, what you do is give low-term -- very low doses over a long period of time, and that's what we've had.

Well, the result is my children have been out of school for several years, they are just now trying to get back and their lives are -- I just never would have anticipated this for my children, and -- but I'm too emotional to go into that. I'll just submit it.

I just want to read one quote. This is from Mark Clutner, Dr. Clutner, the principal investigator of the National Institutes of Health extramural chronic Lyme study which is currently underway.

"These chronic Lyme patients are in a condition worse than patients with congestive heart failure. They are two and a half standard deviations from normal, among the most deviant of any chronic illness."

Thank you.

ATTORNEY GENERAL BLUMENTHAL:

Thank you very much.

Judy Ring or Jody Ring?

Amy Kalafa?

Dawn Stevens?

That concludes the list that we have here. Is there anyone whom I've missed? Yes?

MS. FIELD: My name is Anita Field. I live in Southbury, Connecticut. I have a 15-year old son who's been ill and out of the school for the past two years. He became ill while we were living in Wilton. He started in July of '97 with a flu and a rash on his chest. He needed help to get up and walk to the bathroom, to the bedroom. He got over that in about six or seven days, and around the end of August, had such severe pain in his abdomen that he was doubling over.

I took him to the Emergency Room and the surgeon was called and they took him immediately and removed his appendix, and when the surgeon came out of the operating suite, he said to me, if his pain continues, if I would seek some other opinions, because his appendix is normal but his pelvis is all inflamed. So I asked him who I should see, and he said probably a gastroenterologist, which we did.

From the end of August until the beginning of October, it was simply back and

forth to the surgeon, back and forth to the pediatrician, and waiting for an appointment with the GI specialist. No one could give us any answer.

Danny was repeatedly given CAT scans, thinking that might be leakage from surgery, there might be an abscess postop. There was nothing. The night of surgery, the surgeon was very concerned that Danny's appendix was about to rupture so he started him on I.V. antibiotics that night and continued to run them until the next morning, when he was discharged.

Danny started having really bad seizures. He was collapsing. He could not go to school. By the middle of October we went to Yale. We then saw someone, a pediatric rheumatologist, he told us Danny had rheumatic arthritis, secondary to val [phonetic] inflammation, and put him on 60 milligrams of Prednisone, which he stayed on.

Came home, he was on anti-inflammatory drugs, he was seeing a GI specialist. He just continued to get worse until in December he was having seizures that were lasting two and a half to five hours, with the

longest stretch being two hours in between and then back to the seizures again. And this was going on 24 hours a day.

We went to the Emergency Room at Norwalk Hospital and they admitted him, ran some more tests. Said they didn't know what was wrong with him. He could not walk and they discharged him because they were very concerned about what the insurance company would say if they kept him there, because they didn't have a diagnosis.

So Danny was discharged. I had to call a friend to help me get him to the car and out of the car into the house.

In December, we were at home still continuing two, three, four hours of seizures, now two hours in between, and he was so bad that his head was flailing, his arms were flailing, and all of a sudden I noticed that Danny was having a lot of trouble breathing, so I called the ambulance.

When the ambulance got there, they told me he was in cardiac distress, he was in respiratory distress, and they started I.V. morphine in the house. He was admitted to Norwalk Hospital, he was seen by the

gastroenterologist.

Fortunately for the first time that the doctor came into the hospital, he saw Danny having seizures and he stood there while this child was flailing all over the bed and told me this is not happening because the tests are proving it couldn't be happening. And he was standing watching this child literally flailing all over the hospital bed.

There happened to have been a priest who is a very good friend visiting, and stayed in the room while the doctor was there and I will never -- it was the one humorous thing that's happened in this whole two-year nightmare. When the doctor left, he said to me, You know, Anita, I am so glad I had my collar on. And I said, Why? He said, Because I would have knocked him on his ass if I didn't. He said how could anybody watch this, observe this and look you straight in the eye and say it's not happening?

So we were in Norwalk, we had already made the appointment at Yale, and Danny was transferred from -- he went home for one day or two days, I don't remember. He went to Yale.

While he was being examined by the doctors at Yale, he went into the seizures again. The doctor at Yale admitted him to Yale Hospital immediately, because she thought he had something, probably an abscess that was about to rupture. She put him into the hospital at Yale, they ran some tests, they found nothing.

Two days later, they walked into the room in the hospital and said to us that Danny is crying out for help, that he has emotional problems, that all tests were negative and he needed psychiatric help. And I kind of stood there and looked at her and I said, why do you believe this is psychiatric? She said because all the tests are negative. I said, have you run all the tests that are possible to run? And she said yes.

And she said Danny is -- Danny had been -- Danny got sick the summer he graduated from grammar school, and prior to that he had been on the student council, he helped write the school constitution, he was on the basketball team, he was an incredibly active kid. He won the president's award for maintaining a straight A average from fourth grade through eighth grade.

During all those years, Danny had very severe asthma that required him to be in intensive care repeatedly. Danny could miss easily two and three months of school. When he was having difficulty with asthma, which usually was started in the fall and would be triggered by flu and carry right through the winter, through the spring season, he missed months of school. He still went back to school and maintained a straight A average with some B's. He graduated with honors.

And now the doctors at Yale were telling me that all of a sudden for some unexplained reason this child now had psychiatric problems. And I said, I don't agree with you. But I'm not going to leave any stone unturned, so we sought a psychiatrist.

The psychiatrist said, after seeing Danny three or four times, he wrote a report to Yale that Danny was a well adjusted, articulate, very bright, goal-oriented adolescent who became very depressed in direct relation to the amount of pain he was suffering.

So I went to Yale with that and Yale asked me to see another psychiatrist. So I said okay, fine, I'll see a second psychiatrist. They wanted another opinion. Before we got to the second psychiatrist, Danny had gone continuously -- the kid was in continuous horrendous pain, and finally one Saturday morning, and I believe it was like January or February, after 10 admissions to the hospital he had had since August of that year, he just gave up. He just gave up. And he said to me, no matter what I do, it gets worse, and on top of that, they don't believe me. They think that it is in my head.

And I said well, we're just going to have to keep trying. He said, Mom, the medicines are not helping. The doctors aren't helping, and the psychiatrist said that I'm emotionally stable, and that he couldn't understand that I would be feeling down.

So he refused to take his medicine. And as the days went on, he became grossly depressed. I took him up to the Emergency Room at Yale and the one doctor up there who was seeing him, who he I really think believed that Danny was physically ill, was a

fellow -- and he was the one that met Danny in the Emergency Room that night. He spent from 8:00 at night on a Saturday night until 2:00 in the morning on the phone arguing with the insurance company.

I could hear him screaming at them that this kid was having gross spasms. He was having very serious seizures, he needed to be admitted, and they would not allow him to be admitted.

So finally around 1:00 in the morning he came in to me and called me out in the hallway and he said, Anita, Danny can't go home, he's too sick. He is just too sick. He said, he's already gone into cardiac distress once. He needs to be nearby. I'm going to try, if you'll allow me, to get him admitted to the psych ward. And I asked him what that meant, and he said it means he's here. If he gets into any kind of serious distress, he's right here.

So he called the insurance company back again, and after an hour of screaming, they said that they would allow Danny to be admitted to Yale Psychiatric Institute providing he was brought in by ambulance. Danny was right in the

Emergency Room, right there, and the doctor argued and argued and argued, and finally he agreed, and they had to take Danny on a stretcher out of the Emergency Room into an ambulance, because he was incapable of walking, ride around the block, and admit him in the psychiatrist institute at Yale.

That was Saturday. He finally -- I left Danny there at 2:00 Sunday morning. At midnight Sunday night, I got a phone call from the attending psychiatrist. Danny had been seizuring [sic] for 50 minutes, was not responding, wasn't answering questions, and the psychiatrist said to me, he does not belong on the psychiatrist floor, he belongs on a medical floor, what kind of a mother are you.

I said, I'm the kind of mother who can't fight the insurance company, I can't do it, they won't allow him to be admitted to a medical floor. I said I just -- I couldn't afford to pay for Yale without insurance, and I would rather have him there where at least there are doctors available than at home where there are no doctors available.

And he said to me, if you were a

good mother, you wouldn't care about money. And I said well, if you were a good doctor, you wouldn't care about money either, you'd pay for your patients' care. I said, you want to be a really good doctor, you foot the bill. And when the thousands upon thousands come in, you pay for them. He said well, I can't do that. I said well, neither can I. He said, well, Danny doesn't belong here. That was Sunday at midnight.

Monday morning I got a call from Yale. The insurance company said that Danny had to leave because he had no psychiatric problems, he was physically ill, and they had requested that Danny be admitted to the hospital, and the insurance company said no, so he came home.

We continued and continued and continued and Yale kept insisting that there had to be a psychiatric problem, the doctors that were seeing Danny.

We went to a third psychiatrist. The third psychiatrist, same thing, articulate, bright, goal-oriented, perfectly well adjusted young man. I went back to Yale with that. They asked for a fourth opinion. And I said no. I

said absolutely not. I said you want me to keep seeing psychiatrists until finally somebody agrees with you that this kid doesn't have a physical problem. I said you've had three opinions, one of which was right out of Yale, I'm not having this kid go again.

It was incredibly difficult for Danny to walk. He is five, nine and he weighs 160 pounds. I can't carry him. I said each trip to a doctor is a nightmare for me and for Danny. So I would not do that. I told them I wouldn't do that. I told them I was going to start seeking help elsewhere, because I felt we had just come to a dead end with them, and they decided they wanted me to have Danny tested for milk allergy. And I said why? They said because Danny presents with a lot of GI symptoms, milk allergy can be very difficult to diagnose and cause these symptoms.

I said okay, fine. I had him tested, it was negative. I called them on the phone, and I said it's negative. They said we still want you to continue with our allergist, and I said why, the tests are negative. And she said to me, because the tests aren't valid with

milk allergy affecting the GI tract, they can often be negative and it doesn't mean anything. I said but if a Lyme test is negative, then it's really negative, but if a milk allergy test is negative, it really could be positive? I said don't you see how inconsistent you are? She thanked me, told me she could no longer help me.

One day later I got a phone call from a woman who introduced herself as the social worker at Yale. And she was on Danny's case and consulting with the doctors. I said okay. She said, I understand you're not coming to have Danny checked for milk allergy, and I said no, I'm not. And she said, can you give me a reason? I said, because Danny has been a highly asthmatic child since he was three. He has been tested and retested. He has never turned up a food allergy ever. It's all environmental. And I said, the last test that you did said it was negative. He does not have a milk allergy.

And she says well, I just want you to be aware, Mrs. Field, that if you decide to pursue other things and we feel that it's not adequate treatment, we can and will take legal action. And I said, what kind of legal action?

And she said to me, well, if we feel you are not giving your child proper medical care, we have every right and the obligation to go to the courts and get your child proper medical care.

I mean I'm Irish, and you don't talk that way, to this Irishman anyway, and most of the Irish people I know. I flipped. And I said, I'd invite you, I dare you. I absolutely dare you to say you are going to take -- I said, who do you think you're dealing with up there? Who do you think you're dealing with? I am Danny's mother. I'm Danny's advocate, so no one besides my husband and I will make those decisions. And she said, if you pursue this, you know, your insurance company can refuse to cover you, and we are in contact with the insurance companies.

I couldn't believe she was saying it. I said, I dare you. I absolutely dare you. I said, I want in writing from you that you have a firm diagnosis for Danny that can be proven and I'm refusing it. And then I dare you to take me into court. I said, I would love to go into court and describe what's gone on in this place called Yale up here. Danny was repeatedly told he had a psychiatric problem, even though psychiatrists kept telling him he didn't.

We left Yale. We went back to my own primary care doctor, Danny's pediatrician in Wilton, and he said Anita, I want Danny on antibiotics, Danny has Lyme. And he said, I have dozens of kids like this and Yale consistently sends them back saying psychiatric problem, they need counseling, overachiever, too much stress, parents that are too demanding. He said all of a sudden I have a ton of kids who are well adjusted, healthy achievers who Yale is telling me all now need psychiatric help. And then the other problem is fighting the insurance companies to get the treatment.

ATTORNEY GENERAL BLUMENTHAL: Was he put on antibiotics?

MS. FIELD: Danny was on I.V. antibiotics from June until September. He came off in September.

ATTORNEY GENERAL BLUMENTHAL: September of this year? How is he doing now?

MS. FIELD: September of this year, and was doing pretty terrible. Horrible. He did pretty well for about three weeks and then he crashed again. He was all excited about going back to school. I mean this kid was accepted into the --

ATTORNEY GENERAL BLUMENTHAL: Could you do me a favor? Could you put this -- perhaps give me a letter or -- I don't think you've signed up so we don't have your name.

MS. FIELD: Yeah, I did sign up, but I don't know.

ATTORNEY GENERAL BLUMENTHAL: If you could just give us your name and so we can get back in touch with you.

MS. FIELD: I'll tell you honestly, I found, maybe because Danny didn't stay on I.V. long enough, Danny is now on oral antibiotics, that he definitely has had a brain SPECT and better than half of his brain is abnormal. He cannot go to school. He's gone from what Wilton called their gifted student to a kid who can't even write a simple sentence. He can't watch a movie because he can't concentrate.

I live in fear that somehow, someday, the insurance companies are going to start saying we will no longer cover Danny, but I found Yale far, far intimidating --

ATTORNEY GENERAL BLUMENTHAL: Have you been covered so far?

MS. FIELD: I have PHS and they have covered --

ATTORNEY GENERAL BLUMENTHAL: You have PHS?

MS. FIELD: Yeah. They covered the antibiotic therapy, they have been wonderful with me on the phone. My biggest problem was Yale, because when Yale couldn't come up with an answer and I started saying I'm going elsewhere, they used every tactic in the book to intimidate me into doing what they wanted, even though they couldn't offer a valid reason. And when they saw that I was furious and I would have loved to go into court, which I really wouldn't have, but I was really angry, they backed off and left me alone.

ATTORNEY GENERAL BLUMENTHAL: We really appreciate your being here today, we do.

MS. FIELD: Okay.

ATTORNEY GENERAL BLUMENTHAL: And if you could just leave your name, we'll be back in touch with you. Thank you.

Thank you all very much. We appreciate your participation, your help, and you have given us really an enormous service, and many other people who have suffered the same kind of fate that many have described here today. Thank you very much.

AUDIENCE: Thank you for listening to us.

(Clapping.)

(End of hearing.)

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C E R T I F I C A T E

I, LEE ANN BIANCUCCI, LSR 224, RPR, do hereby certify that the foregoing 408 pages of a Public Hearing on Insurance Coverage of Lyme Disease, which was held at the Legislative Office Building in Hartford, Connecticut, on February 24, 1999, is a true and accurate transcription of the cassette tape-recordings provided to me, to the best of my knowledge and ability.

Lee Ann Biancucci, LSR 224, RPR