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STATE OF CONNECTICUT

PUBLIC HEARING ON INSURANCE COVERAGE OF
LYME DISEASE

HELD AT: Legislative Office Building
Hartford, Connecticut

DATE: February 24, 1999

Transcribed from cassette tape-recordings

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1 ATTORNEY GENERAL BLUMENTHAL:

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

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

20 We hope that this hearing really
21 will provide a full opportunity and perhaps even
22 the beginning of a discussion, conversation,
23 dialogue, statewide about what more we can and
24 should be doing to diagnose and treat Lyme

25 disease and in particular, what we can do to

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1 improve the system of insurance coverage that now
2 applies.

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

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

22 I guess what brings me here in a

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

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

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

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

22 COMMISSIONER REIDER: Thank you very
23 much, Attorney General Blumenthal, and I too
24 would add that it's a pleasure to have worked
25 with the Attorney General and his office in

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1 sponsoring this hearing this morning.

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

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

18 I might say that it's important
19 that the insurance companies respond

20 appropriately in these matters, and as an
21 Insurance Department, we in the last several
22 years have developed a market conduct of
23 utilization review companies. Those are the
24 entities that make certain determinations as far
25 as the medical necessity, and again, that's at

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1 the heart of an issue.

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

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

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

22 Two, the prevention of the disease
23 by receiving immunity shots to it, which we've
24 heard a lot about, we're seeing some
25 advertisement, so we have seen advances in one,

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1 the diagnosis, the detection, and the
2 prevention. And as I said, anything that can be
3 brought forth here today -- and in addition, I
4 think today's session is very important because
5 it highlights an area that there's a lot of
6 discussion and concern about, and it also should
7 be looked at as an education forum, which I think
8 is certainly what the Attorney General and
9 ourself would want here today so that people can
10 leave here this evening and the public can be
11 better informed. Even if we don't end all
12 differences, at least the people are well
13 informed and aware of this, because it is a
14 serious disease and one that has impacted any
15 number of people and families.

16 So today, along with the Attorney

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

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

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

4 ATTORNEY GENERAL BLUMENTHAL:

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

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

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

9

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

6 ATTORNEY GENERAL BLUMENTHAL:
7 Dr. Cartter?

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

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

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

25 ATTORNEY GENERAL BLUMENTHAL: Is

10

1 the light button on?

2 DR. CARTTER: Yes, it is.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Okay. Maybe if you could just speak into the
5 microphone. Thank you.

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

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

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

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

23 AUDIENCE: It's a little hard to
24 hear.

25 DR. CARTTER: This is being

11

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

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

7 This is a story from The New York
8 Times a couple years ago, but not only are we
9 very familiar with this disease, we're also very
10 familiar with the controversy which has

11 accompanied this disease over the last two
12 decades.

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

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1 As these scientific discoveries
2 were moving forward, it's also important to point
3 out there is another side of Lyme disease which
4 lagged somewhat behind but continued to move
5 forward. It was not until 1982, seven years
6 after the discovery of Lyme disease that the
7 first Lyme disease brochure was developed by the
8 Connecticut Chapter of the Arthritis Foundation.
9 In 1984, the serologic test became widely

10 available in the state. In 1987, Lyme disease
11 was made a reportable disease in Connecticut,
12 more than 10 years after it was first described
13 here. And in 1988, the national media attention
14 to Lyme disease began.

15 This is data from the Centers for
16 Disease Control and Prevention. The 1988 data is
17 provisional, not yet finalized. Lyme disease has
18 become the most commonly reported what's called
19 vector-borne disease in the United States. You
20 see a steady increase from the early eighties to
21 1998. This should not be interpreted as a true
22 increase in disease, however. Many states did
23 not make this reportable until the late 1980s,
24 early 1990s, and much of the increase we believe
25 is due to increase in surveillance and increased

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1 resources being put into disease surveillance.

2 Connecticut does have the
3 distinction of being the state with the highest
4 rate of Lyme disease in the population.
5 Nationally, more than almost 80 percent of all
6 the cases -- more than 80 percent of all the
7 cases come from just five states. Fortunately

8 for us, New York State is number one in that
9 category with 30 percent of all cases in this
10 country being reported from New York, but
11 Connecticut, with a much smaller population,
12 reports 20 percent of all the cases that are
13 reported to Centers for Disease and Prevention.

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

17 In Connecticut, the process of
18 Lyme disease assessment consists of a number of
19 different activities. When a public health
20 person uses the word "surveillance," it means
21 that we look for new cases of illness, and these
22 are the cases that are reported to us by
23 physicians and other healthcare providers. We
24 have a statewide system of reporting, but we also
25 actively seek out cases in the Lyme, Connecticut,

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1 area, Litchfield County, Tolland and Windham
2 Counties as part of special studies.

3 We're also tracking Lyme disease
4 using GIS techniques, and particular studies are
5 being done in a number of parts of the state as
6 well. These activities together give us a

7 picture for what's happening here.

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

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

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

4 Connecticut now has all of its

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

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

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

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

4 the western part of the state as well.

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

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

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

22 COMMISSIONER REIDER: Thank you.

23 DR. CARTTER: We are very much
24 aware that what's reported to us is only a
25 fraction of what's out there. Back in 1994, we

1 did a survey in the 12-town area around Lyme,

2 Connecticut. This was a random digit dialing
3 telephone survey, and we asked folks, the head of
4 each household, if they or a member of their
5 family had ever been diagnosed with Lyme disease;
6 whether they have been diagnosed in '94 or prior
7 to '94.

8 And I'd like to emphasize that the
9 statistics here, that 8.1 percent of all
10 households, said that they had had a member of
11 their family diagnosed by a physician to have
12 Lyme disease in that year, and that more than --
13 20 percent of all the households had had at least
14 one person diagnosed with Lyme disease so --
15 before 1994.

16 If you look at this in a little
17 more detail, and I apologize for the numbers, but
18 I think it's important to understand this. That
19 if we assume that 8.1 percent of all the
20 households in this part of the state were
21 affected in 1994, and assuming that only one
22 person in each of these households was diagnosed
23 with Lyme disease, then 2,572 persons from this
24 area may have been diagnosed with Lyme disease in
25 1994. That year, 270 cases were reported from

1 this area, almost a tenfold difference. And what
2 this means is that for every case that's
3 diagnosed and reported to us, there are many more
4 people who are being diagnosed and treated for
5 Lyme disease in our high risk communities.

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

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

22 I'd like to point out that Lyme
23 disease is much more than a biological
24 phenomenon. This is a slide that was put
25 together with data from one of the Internet

1 database sources where this is a curve, a figure
2 that shows the number of Lyme disease citations
3 in magazines and newspapers from 1984 to 1996. I
4 pointed out the peak in Lyme disease media
5 coverage occurred in 1989. This was really in
6 the late eighties, when Lyme disease became a
7 national media story, and it's steadily declined
8 since that time. Although I suspect that with
9 the new Lyme disease vaccine, there will be a
10 research and media coverage related to that in
11 '97 and '98.

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

23 When it comes to Lyme disease,
24 it's been experienced in two different ways; the
25 experience of the individual of which you will be

1 hearing considerably later on this morning, but
2 Lyme disease began as a readily diagnosable and
3 treatable acute infectious disease in the 1970s.
4 In the 1980s, it began to be redefined as a
5 difficult to diagnose and treat chronic
6 infectious disease. And these two perspectives
7 continue to persist throughout the 1990s.

8 From a public health perspective,
9 looking at Lyme disease from a population point
10 of view, Lyme disease began as an epidemic in the
11 1970s, really as a local epidemic. Over the next
12 10 years it went from being an epidemic, from
13 both a medical perspective and a cultural
14 perspective, to an endemic disease, something
15 that people would have to deal with on a
16 long-term basis.

17 We went through a process in the
18 late 1980s of redefinition of Lyme disease. In
19 the early 1990s there was a new term that came
20 into use called "emerging infections," which Lyme
21 disease is one, and now with the advent of the
22 Lyme disease vaccine, we are talking about Lyme
23 disease being defined as a vaccine, preventable
24 disease which has very different connotations

25 than either epidemic or endemic disease.

21

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

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

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

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

21 ATTORNEY GENERAL BLUMENTHAL:

22 Thank you.

23 COMMISSIONER REIDER: Thank you.

24

ATTORNEY GENERAL BLUMENTHAL:

25 Thank you, Dr. Cartter.

22

1 (Clapping.)

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

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

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

22 DR. CARTTER: Well, what we've
23 learned over time is that public health
24 surveillance in general only captures about 20 to
25 30 percent of cases for most diseases, so we're

23

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

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

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

21 For example, meningococcal disease, meningococcal
22 meningitis.

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

24

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

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

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

16 COMMISSIONER REIDER: Just one
17 question, and as a layman, it's fair to say that
18 if you had a higher reporting ratio it would be

19 helpful to you in being able to get a better
20 understanding, or is that not correct?

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

25

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

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

15 DR. CARTTER: Certainly those
16 kinds of discussions have gone on in the past.
17 If we really wanted to know, if we wanted to

18 answer that question, getting that kind of
19 information from insurance companies and managed
20 care companies would be critical. I understand
21 that there have been concerns about the sharing
22 of that kind of data in the past, but certainly
23 that would be great.

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

26

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

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

10 COMMISSIONER REIDER: Okay.

11 ATTORNEY GENERAL BLUMENTHAL:
12 Thank you very much.

13 DR. CARTTER: Thank you very
14 much.

15 ATTORNEY GENERAL BLUMENTHAL:

16 Dr. Krider.

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

22 ATTORNEY GENERAL BLUMENTHAL:
23 Whichever you'd like.

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

27

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

4 DR. KRIDER: Yes, of course.

5 ATTORNEY GENERAL BLUMENTHAL:
6 Thank you.

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

10 My name is Hallie M. Krider. I'm
11 a faculty member at the University of Connecticut
12 in Storrs, a member of the Molecular and Cell
13 Biology Department in the College of Liberal Arts
14 and Sciences. And I'd like to thank you for the

15 opportunity to comment on the progress that we've
16 made in our development of an early disease
17 detection test.

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

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

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

11 The third page basically outlines
12 our perspective on the issues of developing a

13 test; that is to say, the Catch 22. Most people
14 agree that early treatment is certainly most
15 effective and substantially less expensive than
16 prolonged later attempts to cure the disease.
17 Current tests are certainly inaccurate in many
18 different respects, often giving either false
19 positives or false negatives. But in all cases
20 the tests require waiting for some titer to rise
21 in the affected individual. This can or may not
22 occur, quite independently of whether or not an
23 individual is infected.

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

29

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

6 The next page simply provides you
7 with a picture of the tick, at least in one of
8 its adult forms, and there's really two things to
9 say here. First of all, there's a lot we don't
10 understand about how frequently ticks actually
11 have spirochetes or how long it takes for a tick

12 after it's been muted to transfer the disease.
13 It's also the case that the nymphs are very much
14 smaller, the earlier stage are very much smaller
15 than the adult stage.

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

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

30

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

8 From the other side, the symptoms
9 that the host can demonstrate can be very

10 widespread, including none whatsoever.
11 Asymptomatic individuals are certainly a source
12 of some argument, but I think it's important just
13 to suppose this is entirely likely.

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

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

31

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

3 But quite simply, we can collect a
4 very small amount of blood, certainly a finger
5 prick as opposed to, for, instance the use of
6 large volumes. There are some simple
7 manipulations that are done which create a
8 microscope slide, and any reasonably trained

9 blood worker or microscopy cytotechnician will be
10 able to evaluate the results of this very
11 straightforwardly.

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

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

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

32

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

6 And it appears that the signature

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

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

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

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

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

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

14 ATTORNEY GENERAL BLUMENTHAL:

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

25 DR. KRIDER: I've had the

1 opportunity to review some of the materials that
2 have been released on the test. The use of the
3 recombinant proteins and the use of these ending

4 in a strip format is certainly going to be a
5 significant increase in convenience with regard
6 to initial evaluation.

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

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

1 some of the other tests that are available,
2 because they use essentially the same biological

3 responses from the infected individual in their
4 measurement. So while I see this as being a
5 significant increase in preliminary screening
6 capacity, I don't know that it provides more
7 assurance as an evaluator than those tests which
8 we already have.

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

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

25 I obviously have my own axe to

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

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

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

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

25 ATTORNEY GENERAL BLUMENTHAL:

1 Thank you.

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

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

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

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

24 My test is a test that works early
25 in the infection process, and we believe perhaps

1 throughout the period, in which the spirochete is
2 present. A quick test is one which may in fact
3 not be effective until weeks into the infection,
4 but which nonetheless doesn't take very long to
5 do.

6 That being said, let me return to
7 your question.

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

14 Having said that, that's generally
15 believed -- I'm not in a position to tell you
16 that's true, I'm not a physician, and in fact all
17 of my work has been on nonhuman models up to this
18 point. I can tell you that there are different
19 mouse models that would give you a different
20 answer to that question, depending on which of
21 them you chose and how you proceeded in your
22 evaluation; the degree to which genetic factors,
23 previous disease factors, and other aspects of
24 physiology are going to influence the expression
25 of the character that you're talking about, I

1 think I will leave for others to comment on. I
2 certainly don't think I understand them.

3 COMMISSIONER REIDER: Thank you
4 very much.

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

13 REPRESENTATIVE POWERS: Thank
14 you.

15 Dr. Krider, can I get you back?

16 DR. KRIDER: Oh, I'm sorry.

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

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

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

40

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

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

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

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

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

41

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

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

8 DR. KRIDER: I --

9 REPRESENTATIVE POWERS: A couple
10 of years?

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

21 perform a clinical trial.

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

25 DR. KRIDER: In a very broad

42

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

4 REPRESENTATIVE POWERS: Right.

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

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

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

23 REPRESENTATIVE POWERS: All
24 right. Thank you very much.

25 ATTORNEY GENERAL BLUMENTHAL:

43

1 Thank you.

2 Senator Peters?

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

6 DR. KRIDER: Yes.

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

16 DR. KRIDER: Let's put it this
17 way, I don't wish to assume the position of being

18 an authority on the vaccine. I'm a researcher
19 who has some specific questions that I would like
20 to see addressed in the context of the vaccine,
21 and I have some understanding of the mode that
22 those who are developing the vaccine think this
23 particular preparation, the mechanism by which it
24 works, and it is fundamentally the Osp A protein,
25 the outer surface protein A of the bacteria. Its

44

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

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

14 SENATOR PETERS: Take
15 precautions.

16 DR. KRIDER: -- you know, take all

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

20 SENATOR PETERS: Would you take
21 the vaccine?

22 DR. KRIDER: No.

23 SENATOR PETERS: Thank you.

24 (Laughter.)

25 (Clapping.)

45

1 ATTORNEY GENERAL BLUMENTHAL:

2 Thank you very much, Dr. Krider. Thank you for
3 being with us today.

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

8 I also want to apologize in
9 advance to both the speakers and the audience. I
10 apologize very sincerely that we have, as all of
11 you know, a big subject to cover and we're trying
12 to do it in a relatively short time. A day -- a
13 full day of hearings in the legislature is a
14 somewhat unique event, but even a day of hearings

15 in the view of many of us may be inadequate to do
16 justice to this subject, so we may need to have
17 another hearing. But for now, we're going to try
18 to move fairly quickly, expeditiously through the
19 speakers that we've scheduled, especially because
20 we want to hear from members of the public who
21 have come forward. Thank you.

22 Go ahead.

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

46

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

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

14 health threat as HIV.

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

25 My own story begins with a move to

47

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

8 However, like most, I was told
9 that Lyme disease was a summer flu-like illness
10 that was curable with a couple of weeks of
11 antibiotics. Also like most, I had implicit

12 trust in the medical system of diagnostics,
13 treatment and insurance coverage, and I believed
14 what my doctor thought was best would be done for
15 me.

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

48

1 pursuits I could ever possibly have.

2 In late summer of 1987 I found a
3 tick attached to my knee while fishing in Old
4 Saybrook. I pulled the tick out, I was treated
5 within a few days with penicillin for a couple of
6 weeks. A couple of years later, I removed other
7 ticks from the back of my head and shoulder area
8 immediately after fishing in East Haddam. I had
9 no reason to believe they were attached long
10 enough to transmit Lyme disease, but now I know

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

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

25 Then sometime that fall I began to

50

1 have irrational thoughts, they were obsessive,
2 intrusive thoughts, strange and often violent,
3 homicidal. I felt as if I was possessed by
4 something that was not of myself. I not only
5 felt sick but I truly felt crazy. Again, as one
6 trained in the scientific study of the mind, in
7 my moments of sanity I knew there was something

8 not yet diagnosed by the specialists my primary
9 care had sent me to. However, I could not think
10 clearly enough to advocate for myself to the
11 level I was accustomed to providing on behalf of
12 my clients when necessary.

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

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

51

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

4 In fact, I tried to find
5 Dr. Schoen in his old place of practice in or

6 near Old Lyme, but was told he had moved on to
7 Yale, so my primary care physician did the first
8 Lyme serology, followed by an infectious disease
9 specialist in New Britain. Both serologies were
10 borderline for Lyme disease, and the doctors were
11 still not convinced that the physical and
12 emotional plight I was going through was caused
13 by Lyme disease. They did not tell me that there
14 were numerous studies proving prior steroid and
15 antibiotic treatment would aggregate the body's
16 immune's response or titer to Lyme disease, thus
17 making the positive serology nearly impossible to
18 produce.

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

1 of 1993 it was the worst day of my life. If I
2 had the means, I would have taken my own life,
3 and that was a physical phenomenon known as a
4 Garrish Hercksheimer-type reaction to the

5 antibiotics where the Lyme disease cause -- the
6 antibiotics cause the Lyme disease to break
7 apart, which makes the body try to fight off this
8 disease even harder. The effect is heightened
9 symptomology, which has been reported as even
10 fatal.

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

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

53

1 the orals topped off.

2 I was then placed on intravenous

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

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

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

1 tried to convince the insurance company of the

2 medical necessity to restart I.V. medication, but
3 his requests were again denied and even ignored,
4 when Constitution Healthcare actually refused to
5 accept his faxes.

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

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

25 His reviews of those records

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

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

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

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

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

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

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

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

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

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

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

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

24 My blood was cultured for Lyme

25 disease using the new procedure developed by

58

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

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

19 Moreover, physicians' notes from
20 hundreds if not thousands of patients with
21 chronic Lyme disease show the efficacy of
22 long-term intravenous treatment over oral

23 treatment. There is no doubt which one works
24 better and no doubt of the many individuals that
25 have been -- that have been cured with long-term

59

1 I.V. treatment. The only doubt there has been is
2 will the insurance companies pay for it.

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

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

21 Minimum time period.

22 Not a standard.

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

60

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

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

17 Let me say that as a patient with
18 active Lyme disease and many -- and many
19 documented neurocognitive manifestations I face

20 for my future, I know that unless my doctors are
21 allowed to treat me with the best possible care,
22 I will continue to get worse, much worse.

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

61

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

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

15 What we do know is that patients
16 such as myself and those in the audience are here
17 because we want our lives back. We are infected,
18 not addicted. We have entrusted our insurance

19 companies to help with the antibiotic treatment
20 that we need, and in many cases, they have failed
21 us. Now we trust the very entity which oversees
22 those companies. We beg for mandating coverage
23 of our treatment until we are either cured by
24 that treatment or until we are cured through the
25 use of new research. And we beg you, beg you for

62

1 our health.

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

5 ATTORNEY GENERAL BLUMENTHAL:

6 Thank you.

7 (Clapping.)

8 ATTORNEY GENERAL BLUMENTHAL:

9 Ms. Cramoy?

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

17 AUDIENCE: Do you have a
18 microphone?

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

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

63

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

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

10 Now, although it appears that my
11 daughter has -- may have beaten Lyme disease
12 after a four-and-a-half-year battle, I remain on
13 the front lines because of moral and intellectual
14 outrage. I am appalled by the lack of scientific
15 honesty, human compassion, and basic integrity

16 which we have encountered as we struggle to find
17 a correct diagnosis and then the right treatment
18 for this very complex disease. I hope that my
19 background as a scientist and health professional
20 will allow me to help others as they seek answers
21 to their questions about this illness which
22 destroys lives.

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

64

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

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

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

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

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

65

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

6 The end point for the last two
7 therapies was eight weeks after becoming
8 symptom-free. Our current insurance company,
9 Oxford Health Plans, has refused to cover the
10 \$40,000 cost of her last I.V. course, despite the
11 fact that it was successful and she has now been
12 symptom-free for 18 months.

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

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

66

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

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

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

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

67

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

6 I and others have brought
7 additional written accounts of patients who could
8 not be here, people from all over the country are
9 suffering because Lyme disease is being

10 misdiagnosed, mistreated, and being disallowed.

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

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

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

68

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

4 If researchers at the major
5 universities are receiving very healthy fees for
6 saying more than four weeks of I.V. antibiotics
7 is not standard medical practice, it is unlikely

8 that they will design sound research to disprove
9 that statement.

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

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

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

69

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

5 Oxford's medical director has
6 never met nor examined my daughter. He has

7 justified his decisions with the generalized
8 statements of doctors who also have never
9 examined my daughter and who are paid to consult
10 on insurance cases precisely because the opinions
11 they express save money for the insurance
12 company. This is a truly nefarious, symbiotic
13 relationship.

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

70

1 Lyme disease is just one of many
2 illnesses where insurance companies are being
3 allowed to compromise the well-being of the
4 American people in pursuit of their own bottom

5 line. Legislators must close this legal gap.

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

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

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

71

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

3 If our daughter's doctor were ever

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

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

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

1 of the healing of this young woman.

2 Thank you.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Thank you.

5

6 (Clapping.)

7

8 ATTORNEY GENERAL BLUMENTHAL:

9 Ms. Vanderhoof-Forschner?

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

13 ATTORNEY GENERAL BLUMENTHAL:

14 Nobody has to feel, by the way, bound to follow
15 the written testimony that you've submitted.

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

19

20 (Laughter.)

21

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

25 MS. VANDERHOOF-FORSCHNER: Okay.

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

7 ATTORNEY GENERAL BLUMENTHAL:

8 Thank you.

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

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

22 My career spans 25 years in the
23 insurance and allied health fields. I've
24 possessed a professional designation CLU and
25 CPCU. I have held positions with insurers and am

1 a published author. I coauthored the article
2 Lyme Disease Costs To Society. I am past
3 president of the Society of Insurance Research.
4 I have an MBA and author the book "Everything You
5 Need to Know About Lyme Disease."

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

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

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

22 In July of that year, Jamie was
23 born and in July of that year, the first article
24 of maternal fetal transmission of Lyme disease
25 was published. Jamie became multihandicapped and

1 eventually died in '91. He and I had positive
2 tests. When Jamie received antibiotics, his
3 condition dramatically improved but he was never
4 cured.

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

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

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

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

25 Lyme Disease Foundation. I chair the board of

76

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

3 The LDF's web site receives over
4 300,000 hits a month. We conduct medically
5 accredited conferences, publish a peer review
6 journal and have produced two award winning TV
7 programs. I am a full-time volunteer.

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

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

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

77

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

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

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

20 You see insurers are powerful
21 financial institutions with a fiduciary

22 responsibility to cover necessary medical care
23 for insureds. Their medical consultants are
24 often well-funded physicians. Patients with
25 serious illnesses hang by a thread, knowing one

78

1 serious medical episode can and often does
2 bankrupt them.

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

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

14 In '92, things started to rapidly
15 get worse and the LDF was swamped with insurance
16 complaints. Companies that year started hiring
17 experts and were increasingly declining
18 coverage. That was also the year that a
19 consultant went to the American Academy of
20 Insurance Medicine that has all the insurers'

21 medical directors in attendance and wound up
22 presenting on Lyme disease in a very closed
23 viewpoint.

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

79

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

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

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

16 You see not all insurers are bad
17 guys. There are some that are quietly providing
18 coverage and case management for their

19 policyholders. I do feel the need to mention
20 M.D. Health Plan. M.D. Health Plan did something
21 that I thought was exemplary. They wound up
22 saying two years ago, we want to educate our
23 insureds so that they can prevent Lyme disease,
24 and they sent out to everyone in their network a
25 brochure on Lyme disease.

80

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

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

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

17 They avoid conferences that

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

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

81

1 private matter between the doctor and the
2 patient.

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

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

16 Patients are the casualties.

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

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

82

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

9 In '93, based on secondhand
10 anecdotal reports, a local physician reported a
11 colleague to the medical licensing board because
12 he felt the colleague was overtreating patients
13 with long-term antibiotics and profiteering. The
14 accuser even volunteered to set up bogus sting

15 operations and rehearse a pretend patient.
16 Surprisingly, this resulted in a real
17 investigation of the suspected wrongdoer and cost
18 him thousands of dollars to defend himself and
19 almost cost him insurer HMO affiliations.

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

83

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

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

11 For years I didn't ever find out
12 where this information came from. I have the

13 positive tests in my hand. Why was it always
14 that I claimed he had Lyme disease? Who was it
15 out there that had better knowledge than his own
16 mom? Now I find through court documents that a
17 Dr. Gerber, who is affiliated with these
18 hospitals, has appeared to breach doctor-patient
19 confidentiality in his zeal to smear my dead
20 son's, my, and the LDF's reputation. I have
21 copies of this in the material.

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

84

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

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

12 this information.

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

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

85

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

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

9 In '95, Derlin & Fish, in an

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

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

86

1 an issue in debate that he disagrees with.

2 So he suggested to this NIH
3 employee that he or others submit a bogus article
4 in the LDF journal which would have seriously
5 harmed its reputation. Derlin never used the
6 normal channels, the scientific channels of
7 submitting a letter to the editor voicing his
8 opposition. He just slammed us. Indeed he

9 wanted to do harm behind the scenes, letting the
10 Yale affiliation give him credibility.

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

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

87

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

5 When I heard about this accusation
6 I approached Derlin and provided him with the

7 correct information, but it made no difference.

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

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

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

88

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

5 Even more telling are his comments

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

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

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

89

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

3 We even have heard that some

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

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

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

90

1 attacks on a regular basis.

2 I thank you for the opportunity to

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

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

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

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

25 ATTORNEY GENERAL BLUMENTHAL:

1 Thank you very much for being here.

2

3 (Clapping.)

4

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

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

14

15 (Recess taken.)

16

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

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

24 My name is Dr. Eisenberg. I'm a
25 medical director at Oxford Health Plans and I am

1 responsible for the infectious disease management
2 programs.

3 ATTORNEY GENERAL BLUMENTHAL: They
4 cannot hear you.

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

8 ATTORNEY GENERAL BLUMENTHAL:
9 Yes.

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

24 By the time I entered my residency
25 at Albert Einstein College of Medicine in the

1 late seventies, the diagnosis that was given to
2 many of these individuals, especially ones who
3 were having central nervous system difficulties,
4 was one of hypoglycemia; that is to say that at
5 some point during the day, possibly just before
6 or possibly just after a meal, their blood sugars
7 would sink very low and they would suffer body
8 aches, joint pain, difficulty thinking. The
9 remedies for this were changes in diet, sometimes
10 medications, and attempts were made to diagnose
11 and address this problem.

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

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

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

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

16 This diagnosis, however, did not
17 last very long because a relatively new diagnosis
18 of an illness that clearly does exist, Lyme
19 disease, is now the one that's being applied to
20 many of these individuals. And as a private
21 practitioner in a highly endemic region in New
22 Jersey, I had the opportunity from the mid-1980s
23 through the mid-1990s to see sometimes the very

24 same patients who would start out with a
25 diagnosis of chronic Epstein Barr virus infection

95

1 move through the yeast connection and then come
2 back to me in the middle nineties with a
3 diagnosis of Lyme disease.

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

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

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

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

96

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

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

19 According to these criteria,
20 confirmation of Lyme disease requires objective

21 evidence on physical examination of an
22 abnormality. For example, it's not enough simply
23 to have pain in a joint, but one must have frank
24 arthritis in order for these criteria to be met.
25 More than simply difficulty thinking or headache,

97

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

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

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

19 Patients who have a negative ELISA

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

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

25 ATTORNEY GENERAL BLUMENTHAL: I'm

98

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

10 DR. EISENBERG: Now, Oxford's
11 guidelines for diagnosis and therapy mirror the
12 guidelines that have been promulgated by these
13 governmental and as well as academic societies,
14 and I'd like to show you the results of some of
15 the patients who are our members over the year of
16 1998.

17 For those of you who would like

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

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

99

1 Connecticut.

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

8 For example, about 45 percent of
9 the members are male. You can see that only 30
10 percent of patients with this difficult to
11 diagnose in some cases disease, ever saw a
12 specialist. You can see that only 33 percent
13 ever recall having had a tick bite. You can see
14 that only 22 percent ever recorded a rash. You
15 can see that only 49 percent had any objective
16 findings on physical examination of satisfying

17 any of the criteria set by the CDC or the FDA for
18 objective signs of Lyme disease, and that only 12
19 percent in fact had the most specific -- the most
20 specific diagnostic test, which is the IGG
21 Western blot.

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

100

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

10 If you would look down at number
11 4, you can see that for some members, it's
12 because the therapy that's been recommended has
13 not been approved in therapy. I think this
14 requires a little bit of explanation.

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

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

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

101

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

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

10 If you scan further down --

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

13 DR. EISENBERG: The natural

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

18 ATTORNEY GENERAL BLUMENTHAL:

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

25 DR. EISENBERG: The insurance

102

1 companies try to look as objectively as possible
2 at the possibility that any individual patient
3 has the illness that's being diagnosed, and
4 before supporting a therapy, we'd like to see the
5 objective evidence of the illness either in
6 history or physical examination or by laboratory
7 testing. We know that many of these individuals
8 have an illness that will get worse and better
9 over time, and going back to the original studies
10 by Allen Steere done in this state from patients
11 who were in Lyme, Connecticut, we know that most

12 of those patients without any therapy, because
13 the nature of Lyme disease was not recognized in
14 the seventies and the fact that antibiotics might
15 cure it was not known, that many of those
16 patients went on to be cured of their illness
17 with no therapy.

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

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

103

1 own.

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

8 ATTORNEY GENERAL BLUMENTHAL: But
9 that comes back to the first question I asked.
10 If the treatment seems to work and there is

11 physical evidence that it is working, why not
12 cover it?

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

25 ATTORNEY GENERAL BLUMENTHAL: So

104

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

6 DR. EISENBERG: It's not so
7 much -- it's not our judgment. I don't consider
8 Oxford an expert in Lyme disease. We use the

9 expertise of the people who are experts, and
10 those are the people from academic societies, the
11 people from the governmental agencies who
12 specialize and who have developed diagnosis and
13 treatment guidelines, and we try to apply those
14 guidelines to our members.

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

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

105

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

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

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

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

106

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

4 But beyond that for each
5 individual patient, there is usually a

6 conversation that goes on between the medical
7 director and that patient's either primary care
8 doctor or prescriber of care, and I think that
9 the individual judgments that come out of those
10 conversations is another very important layer of
11 the administration of our policy, and that
12 probably does differ from individual to
13 individual patient as well as from company to
14 company.

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

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

107

1 support our members seeking outside guidance.

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

5 DR. EISENBERG: Without question.

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

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

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

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

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

1 left-hand column we have some characteristics for
2 this aggregate population in terms of the

3 decisions that we've made. And if you go down to
4 one, two, three, four, the fifth, you can see
5 that the percentage of members whose requests for
6 therapy is approved is 67 percent. That's
7 despite these problems. And that after the
8 second, third or fourth opinions and on appeal,
9 that number goes up considerably, and -- although
10 because many of our appeals are pending, the
11 number is up in the high seventies at least.

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

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

1 that have been developed by highly respected

2 academic and governmental institutions are not
3 being followed, and our members are benefiting
4 from our management program.

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

7 ATTORNEY GENERAL BLUMENTHAL:
8 Dr. Federico?

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

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

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

1 acquaintances who have been treated for this
2 condition.

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

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

23 Managed care organizations are
24 aware certainly of the diagnostic confusion and
25 treatment modalities that have potential for

1 being disadvantageous for members, and
2 Dr. Eisenberg has certainly commented on this,
3 and from the -- some of the papers that were
4 distributed today -- I'm sure the panel will be
5 hearing more about this later on after lunch --
6 Physicians Health Services supports, and as a
7 health plan, generally covers timely diagnostic
8 testing appropriately to Lyme disease and
9 treatment programs which have been proven through
10 the standard scientific methods to be efficacious
11 in treatment.

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

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

24 The starting point in the process
25 of developing managed care review programs is the

1 adoption of appropriate standards of care. The
2 guidelines and criteria used by Physicians Health
3 Services and many other managed care
4 organizations to determine appropriate testing
5 and treatment regimens for various conditions is
6 drawn from published guidelines and position
7 statements produced by widely respected
8 professional organizations.

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

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

23 Yet our case review programs
24 include more than the application of standard

25 guidelines. We often discuss cases with treating

113

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

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

12 In managed care we encounter
13 matters which unfortunately encompass contentious
14 issues, and were this not the case with respect
15 to Lyme disease, we wouldn't be here today. It's
16 expected that specific anecdotal cases would be
17 presented at this public hearing to support the
18 proposed legislation. These intended to show
19 that health plans are less than sensitive and
20 supportive of members than they should be. I
21 want to present a few brief real cases
22 representative of situations which also occur and

23 which generally don't attract attention of the
24 public since they don't make the evening news nor
25 make the print media.

114

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

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

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

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

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

116

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

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

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

18 I thank you for your attention.

19

ATTORNEY GENERAL BLUMENTHAL:

20

Thank you. Dr. Federico, let me ask you a

21

similar question to the one I asked

22

Dr. Eisenberg.

23

I understand the anecdotes that

24

you've given us, but you've heard anecdotes, I'm

25

sure numerous anecdotes, numerous stories similar

117

1

to the ones that we've heard this morning, about

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treatment that does work, that has been denied

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coverage. And in light of your emphasis in your

4

testimony on the importance of the treating

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physicians' decisions and the respect they

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deserve, does PHS make an effort in its coverage

7

decisions to demonstrate that respect?

8

DR. FEDERICO: Physicians Health

9

Services, like other managed care organizations,

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obviously reviews individual cases, will talk to

11

physicians about the treatment and will even

12

often make recommendations for and seek to direct

13

members for further evaluation and determination

14

of appropriate costs of therapy to follow.

15

In instances where a diagnosis is

16

indeed confirmed and where we have further

17 opinions expressed that additional courses of
18 therapy might be suitable, we will generally go
19 along with that type of treatment, and I cannot
20 provide you with some of these same statistical
21 information as my colleague from Oxford did, but
22 this happens fairly often.

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

118

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

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

16 Lyme disease.

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

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

119

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

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

12 ATTORNEY GENERAL BLUMENTHAL: I
13 notice that none of the anecdotes that you've

14 given here involve both a diagnostic test and a
15 treating physician's prescription as to what
16 should be done about Lyme disease that's been
17 diagnosed. Are there -- is that correct?

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

120

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

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

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

10 DR. FEDERICO: On that one, I
11 could not say for certain whether one had or had
12 not been done. I had just been told that a

13 diagnosis of Lyme disease had been made.

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

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

25 ATTORNEY GENERAL BLUMENTHAL:

121

1 Well, let me ask the question --

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

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

6 As you've gathered, there are both
7 physicians and patients who feel that there
8 hasn't been adequate coverage, and there are
9 treatments that seem to be working for which
10 coverage has been denied. Does that suggest that

11 there may be a problem?

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

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

122

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

10 standard courses of therapy.

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

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

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

123

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

4 DR. FEDERICO: Yes.

5 COMMISSIONER REIDER: Okay.

6 Second, I get to a point in time some weeks out
7 and I continue to have discomfort and pain and

8 now it's suggested that I need extended
9 antibiotic treatment, okay? I think now we're
10 getting to the crux of the issue, okay? My
11 question is: If I have a positive diagnosis at
12 that point that I have Lyme disease and the
13 doctor feels that that requires some additional
14 treatment with antibiotics, oral or otherwise,
15 what is the position of your company?

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

124

1 COMMISSIONER REIDER: And for how
2 long?

3 DR. EISENBERG: Most of the
4 applications for therapy are for four weeks. We
5 have a standing policy of approving up to six
6 without questioning, and beyond six there would

7 have to be a conversation between the prescribing
8 physician and the medical director.

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

16 DR. EISENBERG: Yes.

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

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

25 For example, if you developed

1 headache and a spinal tap was done and spinal
2 fluid was looked at and there was any evidence of
3 inflammation, the most likely possibility in that
4 situation, regardless of what any of the tests

5 show, is that your spirochete, the bacteria that
6 causes Lyme disease, in fact has disseminated and
7 that you have Lyme meningitis, and that would be
8 ample justification for continuing therapy.

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

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

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

126

1 dedicated to dealing with patients with
2 infection, and they are instructed to encourage
3 the members and the physicians to seek outside

4 consultation, which we pay for unquestioningly.

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

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

24 COMMISSIONER REIDER: And I will
25 finish with this -- these last questions. If in

1 fact you reach a point in time at six weeks or

2 eight weeks, there is not a diagnosis, there is
3 no indication that treatment by antibiotics for
4 whatever reasons is there, and so there is a
5 denial from that perspective. A patient then
6 would come to you and say that I disagree with
7 you, you have an internal appeal process?

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

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

21 COMMISSIONER REIDER: And here in
22 Connecticut with the passage of the 1997
23 legislation, there is external appeal, and that
24 external appeal applies to people that are not
25 covered under federal programs. And there are

1 people who have concerns that are under the
2 federal program, and unfortunately the State
3 can't respond to that, but where there is a
4 State-covered situation, there's external
5 appeal. And you have a responsibility to inform
6 people of that external appeal and the ability to
7 move forward, that that review, which is outside
8 of your company's area of economic or other
9 authority, so I just share -- I already asked
10 some of the other doctors as we go down the path,
11 because ultimately what the Attorney General is
12 saying and what I would say or what I think most
13 people would say, is you want to be able to give
14 people the proper treatment at the proper time in
15 order to get the resolution and the cure.

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

1 ATTORNEY GENERAL BLUMENTHAL:

2 Representative Powers?

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

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

15 The FDA has restricted its
16 guidelines to that testing.

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

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

25 DR. FEDERICO: This is the

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

6 REPRESENTATIVE POWERS: Are those
7 the same as CDC?

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

18 REPRESENTATIVE POWERS: So those
19 are more detailed?

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

22 REPRESENTATIVE POWERS: So are the
23 pediatric ones more detailed?

24 DR. FEDERICO: The -- no, they are

25 not. And they are not any more detailed than

131

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

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

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

21 The purpose of a guideline
22 specifically is not that there be 100 percent
23 conformity. There needs to be some flexibility

24 and every guideline allows for that.

25 A standard of care, which is

132

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

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

11 REPRESENTATIVE POWERS: The
12 reason -- I am not from a medical field at all,
13 I'm from the education field. The reason I'm
14 trying to understand this is because both of you
15 have referred to following the guidelines and
16 recommending and accepting and paying for
17 therapies that are within the guidelines. So
18 what I'm trying to understand is how strictly do
19 you follow these guidelines and kind of where
20 does the red flashing light appear in terms of
21 being a little bit beyond the guidelines or way

22 beyond the guidelines? And how do you respond if
23 in fact those guidelines change?

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

133

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

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

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

17 DR. EISENBERG: We do not
18 provide -- our guidelines are not any tighter
19 than the ones that have been recommended by the
20 Centers for Disease Control and the FDA. Ours

21 are looser. Had we applied their guidelines
22 strictly, we would not have the two-thirds
23 approval rating at first that I showed you.

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

134

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

10 Addressing your second question
11 about how do we become knowledgeable, it's by
12 actively keeping our ears open. We are notified
13 either through regulatory bodies or governmental
14 agencies or because as a company that has a
15 professional staff of nurses and physicians, some
16 of whom specialize in the field of infections,
17 we're always attending conferences, reading the
18 literature, and getting the E-Mail bulletins from

19 services that are better and faster than they
20 ever have been before.

21 The next question, though, was a
22 very important one. Do you react to every
23 bulletin that you get from the Internet? And
24 that really is the difficult situation to try to
25 figure out. Should every physician now be

135

1 applying radiation and chemotherapy to their
2 patients with uterine cancer or will the next
3 study demonstrate not only that it didn't help,
4 but that many more of those patients turned out
5 with radiation colitis. That's the harder part.

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

18 ahead and take into account the new developments
19 in various fields.

20 ATTORNEY GENERAL BLUMENTHAL:

21 Dr. Eisenberg, do you have -- we've been talking
22 about guidelines. You refer to them as
23 guidelines or protocols or regimens? What do you
24 call them in your company?

25 DR. EISENBERG: We call them

136

1 guidelines.

2 ATTORNEY GENERAL BLUMENTHAL:

3 Guidelines?

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

8 ATTORNEY GENERAL BLUMENTHAL: And
9 are they written?

10 DR. EISENBERG: Yes, we have
11 written guidelines.

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

15 DR. EISENBERG: Yes, by HMO

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

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

21 DR. EISENBERG: Yes.

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

137

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

7 DR. EISENBERG: The conversation
8 that goes on between myself and the prescribing
9 physician is only one of the conversations that's
10 going on around any given patient. One of the
11 things that we insist, and I think other
12 companies do this often too, we'd like to know
13 what the consultants or the other physicians --
14 it might not be a consultant; it might even be

13 patients who have joint disease, whereas the
14 prescribing physician is recommending antibiotic
15 therapy.

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

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

21 DR. EISENBERG: No.

22 ATTORNEY GENERAL BLUMENTHAL: Or
23 in fact multiple tests?

24 DR. EISENBERG: No. Generally if
25 the --

139

1 ATTORNEY GENERAL BLUMENTHAL:

2 Because that was my question to you --

3 DR. EISENBERG: Oh, I'm sorry.

4 ATTORNEY GENERAL BLUMENTHAL: --

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

11 DR. EISENBERG: The conversation

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

140

1 is considered appropriate.

2 And most of the time, the
3 physician will say, okay, let's go along with
4 treatment with antibiotic X, which is one of many
5 that has been tested and shown to be helpful. Or
6 maybe they are willing to change the treatment
7 regimen from one that they've developed on their
8 own individually to one that is more widely
9 accepted by the medical community. If those

10 things don't happen, what do we suggest to the
11 patient? We suggest that they seek consultation
12 elsewhere, and oftentimes we will supply them
13 with a list of names of individuals in their
14 community, and we will always pay for that
15 consultation.

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

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

141

1 another opinion?

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

8 ATTORNEY GENERAL BLUMENTHAL: But

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

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

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

142

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

5 And I guess what I find a little
6 disquieting is there are these references to

7 guidelines and protocols and regimens in the
8 scientific community as if there were a complete
9 consensus and a degree of knowledge that doesn't
10 seem to be there.

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

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

143

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

4 ATTORNEY GENERAL BLUMENTHAL: And
5 I guess the reason we are here today is because

6 sometimes you haven't.

7

8 (Laughter.)

9

10 ATTORNEY GENERAL BLUMENTHAL:

11 Frequently there are a lot of folks who are very
12 concerned about it who have complained to
13 government officials, to their legislators, and I
14 think that's one of the points of continuing
15 contention here.

16 Representative Powers?

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

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

25 REPRESENTATIVE POWERS: If in fact

144

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

2 All right.

3 DR. FEDERICO: I concur.

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

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

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

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

145

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

3 AUDIENCE: We can't hear you.

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

11

12 (Laughter.)

13

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

25 ATTORNEY GENERAL BLUMENTHAL:

1 Thank you very much for being here, Dr. Eisenberg
2 and Dr. Federico. We are behind our schedule. I
3 would propose if Dr. Katz and Dr. Phillips can
4 stay for a while, that we take a break now and
5 then come back at -- you can be back at 1:30 --
6 1:30 and take the next panel at that time. Thank
7 you.

8

9 (A luncheon recess was taken.)

10

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

14

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

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

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

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

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

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

22 In this study also very well
23 documented, seronegative Lyme disease, they found
24 that the people with negative blood tests were
25 actually positive by PCR. PCR is a test that

1 looks for the DNA of the Lyme bacteria. The
2 people that had antibody positive tests were
3 negative by PCR. This implies that the people
4 with negative tests had a higher bacterial burden
5 and therefore could be detected by the PCR test.

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

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

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

22 In this study out of Stony Brook,
23 which is arguably one of the premiere Lyme
24 research centers in the entire world, they
25 developed a new and relatively underused test by

1 which they confined actual specific Lyme proteins
2 in the spinal fluid.

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

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

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

23 DR. PHILLIPS: Well, just to go

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

150

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

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

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

20 Now, this is just the case report,
21 but I found it so absurd and compelling that I
22 felt I had to comment on it. This is a case of a

23 seronegative, meaning blood test negative,
24 patient, an ordinary antibody negative patient
25 who had had a total of seven courses of

151

1 intravenous antibiotics and three years of
2 continuous oral antibiotics.

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

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

21 infection.

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

152

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

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

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

17 I would hardly think that
18 insurance companies will want to make its
19 decisions of whether a patient has central

20 nervous system Lyme based on inconsistent
21 findings.

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

153

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

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

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

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

154

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

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

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

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

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

155

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

10 Well, what about human persistent
11 infection despite antibiotics, which is proven by
12 culture, because anybody can say that, you know,
13 there's DNA floating around, but it's dead
14 bacteria. And it's just the dead bacteria will

15 remain in your body for years and years and there
16 is nothing you can do about it.

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

156

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

3 And in this study of
4 antibioticly-treated patients, either ones with
5 negative tests or positive tests, they culture
6 the Lyme bacteria from these patients. And guess
7 what? It's been proved again by culture and
8 antibioticly-treated patients and again by
9 culture and antibioticly-treated patients and
10 again by culture and antibioticly-treated
11 patients. And this one --

12

13 (Clapping.)

14

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

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

157

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

7 We've had those bacteria confirmed
8 by -- by every fancy test you can imagine; by
9 electromicroscope, by PCR, we sent them out to
10 two different institutions. After this went to
11 press, we kept sending it out to other

12 universities, it came back over and over again
13 yes, it's Lyme bacteria.

14 What about treatment duration?

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

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

158

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

3 COMMISSIONER REIDER: Just a
4 question.

5 DR. PHILLIPS: Go ahead.

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

9 DR. PHILLIPS: I don't know. I
10 mean, I start out at a four-week interval. Let's

11 say -- there is many, many different strains of
12 the bacteria B. burgdorferi, and they vary in
13 their levels of antibiotic resistance and
14 sensitivity.

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

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

159

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

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

9 illness.

10 COMMISSIONER REIDER: Right.

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

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

25 COMMISSIONER REIDER: Again, just

160

1 in understanding, and this follows the questions
2 I asked this morning, I mean, over the years I go
3 to a doctor or take my children to the doctor or
4 whatever and whether it be here in Connecticut or
5 some of the other states that we live, doctors
6 will say gee, Mr. Reider, or George, we want to
7 try an antibiotic but we don't want to overuse

8 that antibiotic, that's the worst thing we can do
9 so we're going to give it a shot and we're going
10 to see.

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

15 DR. PHILLIPS: Right.

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

19 DR. PHILLIPS: Long-term
20 treatment?

21 COMMISSIONER REIDER: Yeah.

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

161

1 class antibiotic for seven years for acne, so
2 when someone tells me that I can't treat Lyme for
3 more than four weeks, I find it not only amusing,
4 I find it absurd. There are definite risks to
5 long-term antibiotic therapy. Bacteria that

6 reside in your intestines will become resistant
7 to those antibiotics.

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

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

1 injection function more than doubled with
2 treatment, that's great. Does he have some
3 resistant bacteria in him? Yes, he does, but
4 sometimes the devil that you know is better than

5 the devil that you don't know.

6 COMMISSIONER REIDER: Thank you.

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

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

163

1 They also in terms of their
2 treatment guidelines for Lyme disease, after

3 bullseye rash, 43 percent treated three months or
4 more, and for chronic Lyme, meaning late stage
5 recurrent Lyme disease, 57 percent of responders
6 treat three months or more. That is the
7 majority, and that is the standard of care that
8 exists in Lyme-endemic areas.

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

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

25 Now, the patients who did not have

1 Lyme disease, surprisingly 45 percent had had

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

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

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

25 Well, let me just say I want to

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

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

13 So in summary, I'd like to say
14 that chronic Lyme is caused by chronic infection
15 with *B. burgdorferi* with the Lyme antibody; that
16 current antibody testing is inadequate; that
17 seronegative Lyme is common; that the Center for
18 Disease Control case definition criteria should
19 not be used for clinical diagnosis but it is; and
20 that longer antibiotic treatment durations are
21 more effective than shorter; that post Lyme
22 fibromyalgia is really just persistence of the
23 initial infection; and that curative therapies
24 are desperately needed but many tertiary
25 institutions are not even willing to recognize

1 the existence and true etiology of the illness,
2 let alone fund research for its cure.

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

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

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

1 the same as these kind of obscure diagnoses.

2 Further to that, I want to the
3 talk about he mentioned multiple sclerosis.

4 Well, you know, a definite diagnosis of multiple
5 sclerosis, Lyme can cause a clinical syndrome
6 which is indistinguishable to multiple
7 sclerosis. It causes white spots on the brain.
8 It causes recurrent inflammatory central nervous
9 system lesions just like MS does in a waxing and
10 waning pattern.

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

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

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

168

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

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

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

22 Also, I want to talk about

23 Dr. Federico's unsubstantiated anecdotes about a
24 relative of a friend or a family member or
25 whatever. I mean, to present that in testimony

169

1 is -- it doesn't hold any weight. I mean none of
2 this stuff is referenced, and we don't really
3 know what these people were clearly diagnosed --
4 I mean Alzheimer's is a diagnosis of exclusion.
5 Just show me a brain biopsy that was consistent
6 with Alzheimer's, let's please not entertain
7 that.

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

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

21 And I just want to show you one

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

170

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

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

9 (Clapping.)

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

12

13 (Laughter.)

14

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

17 DR. PHILLIPS: This is a strong
18 one. This is a strong one, that of Dr. Schoen's
19 study that is included in his testimony, out of

20 the patient's -- this is a quote -- Patients with
21 no evidence of Lyme disease reported partial
22 resolution of symptoms after 50 percent -- 57
23 percent of treatments so -- of treatments, so a
24 majority of patient's treatments responded, you
25 know, and these are people with no evidence of

171

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

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

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

10 DR. PHILLIPS: Yes.

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

14 DR. PHILLIPS: Why that is so?

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

18 DR. PHILLIPS: Sure. There are

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

172

1 bacteria.

2 Surprisingly, off their list, they
3 took off bands 31 and 34. 31 and 34 are by far
4 the two most specific bands for Lyme bacteria.
5 31 is what they're making the Lyme vaccine out
6 of, it's out of service.

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

15 A lot of patients do express this
16 band, so they are kind of skewed by this western

17 blot interpretation to missing late stage Lyme.

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

173

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

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

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

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

174

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

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

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

14 reporting to us the existence --

15 DR. PHILLIPS: Right.

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

19 DR. PHILLIPS: Right.

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

25 DR. PHILLIPS: Right.

175

1 ATTORNEY GENERAL BLUMENTHAL: --
2 for clinical purposes.

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

12 ATTORNEY GENERAL BLUMENTHAL:

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

25 DR. PHILLIPS: To evaluate

176

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

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

11 treat me with some form of antibiotics?

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

18 COMMISSIONER REIDER: Right.

19 DR. PHILLIPS: I mean, I have
20 patients diagnosed by Yale with Lyme, I have
21 patients with tick bite, bullseye rash, ELISA,
22 western blot. One of my first patients, a
23 darling person, had -- they put her on I.V. right
24 away, and that's something that's very uncommon,
25 you know, they put her on I.V. right away, said

177

1 we're going to cure you. Didn't do anything.
2 Before this she was completely healthy, now she
3 is disabled. Didn't do anything.

4 I tried for months to try and help
5 this person, didn't help, nothing helped. And,
6 you know, if that's the case, I'm not treating
7 her. What else do I have to offer her? We only
8 have a few treatments for Lyme. It's not like we
9 can just make stuff up out of thin air. I mean

10 we try our best, so it depends on your clinical
11 response.

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

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

178

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

5 COMMISSIONER REIDER: Maybe I can
6 explore it a little bit later, but we hear about
7 people being treated with high potency

8 antibiotics for four or five years, and the
9 question is, how frequent does that happen?

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

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

23 The person had severe neurologic
24 dysfunction which happened after they took her
25 off -- I mean, we don't limit the treatment of

179

1 cancer and diabetes in these chronic conditions
2 just because they are chronic. I mean there are
3 certain infections we cannot cure; AIDS,
4 multidrugresistant tuberculosis, I mean
5 leshmanysis [phonetic], I mean, the list goes on
6 and on. There are things that are incurable.

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

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

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

180

1 immune system and allow the bacteria to come back
2 out.

3 So if you mean symptomatically
4 cured, even the patients that get symptomatically

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

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

24 But I have to emphasize again,
25 nobody is looking for a definite bacteriologic

181

1 cure for this illness, because they are denying
2 that the illness exists.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Thank you very much.

5

6 (Clapping.)

7

8 ATTORNEY GENERAL BLUMENTHAL:

9 Dr. Katz. Thank you.

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

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

182

1 started seeing more and more patients with Lyme.

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

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

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

24 We are doing MRI of the brain to
25 see if there are any structural abnormalities,

1 and then we are doing some more detailed testing
2 of the cognitive function and of the brain
3 function, which we can image, neuropsychologic
4 assessment and brain SPECT. Well, I don't want
5 to -- I think that the Oxford and PHS are not
6 here, so I don't want to get into it personally,
7 but those two tests are not approved by both
8 Oxford and PHS and some other insurers, the
9 neuropsychological assessment and the brain
10 SPECT, because they don't feel these are needed
11 to diagnose patients with Lyme -- with Lyme
12 disease.

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

1 something I didn't understand.

2

3 (Laughter.)

4

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

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

23 I can tell you if I study a group
24 of patients before and after treatment, I can
25 analyze the results statistically and tell you

1 yes, this patient or this group of patients got
2 improved statistically.

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

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

10 COMMISSIONER REIDER: Do companies
11 pay or deny this?

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

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

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

20 What is a brain SPECT? A brain
21 SPECT is a -- a mean to assess the brain
22 function. It measures cerebral blood flow.
23 Cerebral blood flow is proportional to the
24 glucose metabolism of the neurons. If you have

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

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

23 The MRI, to remind you, is an

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

187

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

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

15 I'm not bringing this picture as a
16 scientific argument. We need to confirm all
17 those findings with scientific studies, double
18 [unintelligible] control, good papers. But I'm
19 just telling you what I see in day-to-day
20 practice, that people with seronegative Lyme are
21 being treated and, for one reason or another,

22 they are getting better. And why are they
23 getting better if the treatment was not
24 appropriate?

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

188

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

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

14 So we are dealing with a serious
15 condition, it's the second largest epidemic after
16 HIV infection. There are currently no reliable
17 tests to diagnose the disease, and I think
18 everybody can agree with the fact that there are
19 seronegative patients. These papers were
20 published and accepted. There is only one issue

21 that the paper referenced that Dr. Phillips
22 brought in I want to reiterate.

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

189

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

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

13 Now we should also talk about the
14 treatment, and in order to achieve high brain
15 concentration, we need to achieve high blood
16 concentration. That's the entire reason for
17 using I.V. antibiotics rather than oral. I think
18 every patient will be more comfortable if he will

19 take tablets rather than have the Lyme with all
20 aggravation associated with it, but we need to
21 reach higher brain concentration and that's the
22 reason for the need for I.V. antibiotics.

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

190

1

2 (Laughter.)

3

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

15 The reason I am stressing it is
16 because no HMO ever denied oral antibiotics. Why
17 is it if it's a principle, they shouldn't allow

18 any antibiotic treatment for patients with
19 nondocumented Lyme disease. It's not a matter of
20 principle. It's a matter of money, because
21 intravenous treatment is expensive.
22 Neuropsychological examination is expensive.
23 SPECT studies are expensive. It's not a matter
24 of principle, so I don't want anybody to hide
25 behind principles.

191

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

6 We need intravenous antibiotic
7 because we need to reach higher blood
8 concentration. Good brain penetration is
9 considered 1 percent of the blood level, and this
10 is, for example, achieved with ceftriaxone, which
11 goes from 150 micrograms per [unintelligible] in
12 the serum to one and a half micrograms per
13 [unintelligible] after two gram I.V. dosage. So
14 this is considered good penetration. And other
15 medications are not penetrating the central

16 nervous system as good because they are less
17 lipid soluble.

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

192

1 anybody to talk with.

2

3 (Laughter.)

4

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

14 So it is possible that the patient

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

193

1 is the only way we can offer him help.

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

8 Almost every patient I'm putting
9 on I.V. antibiotics is getting better clinically,
10 but not only something that you should call the
11 placebo effect; patients are not coming back to
12 me and telling me I'm feeling better, no. I'm

13 using the same measurable criteria that I tried
14 to apply initially; retesting them with
15 neuropsychological testing, seeing marked
16 improvement, restudying the brain cerebral flow,
17 which there is an improvement in flow, so
18 something works here.

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

194

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

11 So what happens? What happens

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

195

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

4 So what do we need to do? We need
5 to come up with some solution, because the
6 situation is indeed grave. Of course we need to
7 continue with the research to improve the
8 diagnostic means and follow the options that were
9 mentioned here. But I think we need to accept

10 the fact that additional indirect tests might
11 help with making a therapeutic decision, and this
12 agreement and acceptance should be done by the
13 HMOs, the tests should be approved.

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

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

196

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

4 But in this committee should be
5 representatives from all HMOs, and there will be
6 a representative from the medical communities,
7 and there will be expedited discussion for any
8 appeals, and instead of taking a year or two

9 years for approving a test, we'll be able to
10 really discuss issues in two weeks, one month,
11 and to get things done and resolved, not to tell
12 me that yeah, I think we will approve this
13 treatment but nothing is going to be applied to
14 the appeal process. And although we are saying
15 it will happen, it will happen next year. This
16 is not the way that things should be amended.
17 Things should be amended immediately. We don't
18 have time to waste. These people are sick, they
19 need treatment. We need to do things fast.

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

25 So that is my conclusion, and I

197

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

4 ATTORNEY GENERAL BLUMENTHAL:

5 Thank you, Doctor.

6

7 (Clapping.)

8

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

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

198

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

3 We see less deep sleep, more
4 superficial sleep, less sleep efficiency, which
5 means more arousal in time spent in bed without

6 sleeping, but it is I think not the hallmark of
7 Lyme, but for any chronic condition.

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

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

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

199

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

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

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

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

200

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

3 DR. KATZ: Right.

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

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

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

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

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

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

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

20 DR. KATZ: There will be suit --

21 ATTORNEY GENERAL BLUMENTHAL:
22 Let's say they will say to you what is the legal
23 liability if we approve this longer-term
24 treatment which may have side effects? I assume
25 you would say well, you explain the side effects

1 to the patient and the choice is made by the
2 physician and the patient.

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

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

10 DR. KATZ: Of course.

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

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

21 Dilantin, everybody talked about
22 Dilantin with threat or fear? No, but Dilantin
23 is a terrible drug. It can cause death, and it
24 has been used since 1939 and some people have
25 been put on Dilantin in 1939 and are still taking

1 it to this very day. That's the nature of
2 prescribing medication.

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

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

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

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

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

25 And I just want to point out that

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

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

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

21 The most common serious side
22 effect -- or the most commonly prescribed I.V.
23 drug, Rocephin is gallbladder sludging and

24 gallstones, which are entirely made up of the
25 drug, Rocephin. These effects are transient and

205

1 with discontinuation of the drug it goes away.

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

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

20 So many of my patients were
21 treated with steroids for years to control some
22 of their Lyme symptoms, results in diabetes, high

23 blood pressure, cataracts, osteoporosis with bone
24 fractures throughout the spine, disabling pain,
25 you know, thinning of the skin, horrible stuff.

206

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

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

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

18 All chronic bacterial infections
19 have as part of their -- part of their etiology,
20 an intracellular phase; they hide from the immune

21 system. They hide from the drugs inside the
22 cells. The I.V. antibiotics don't get inside the
23 cells. Things like Doxycycline and macrolide
24 antibiotics do get inside cells. And often that
25 can be more effective when people have a

207

1 significant intracellular burden.

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

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

18 But I will do everything in my
19 power to get my patients better, and luckily most

20 of my patients get a hell of a lot better. If
21 you just keeping plugging at it -- away at the
22 disease, it responds eventually in most cases.

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

208

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

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

15 So the call came back positive
16 saying it's Lyme bacteria. People still don't
17 believe. We publish pictures. You know, I don't

18 know, it's like anything else, it has to be
19 duplicated, it has to be verified.

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

209

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

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

10 Currently, there are very strict
11 guidelines as to internal and external appeal,
12 time lines and so on. I say currently. The
13 State statutes and the regulations require
14 companies to have an internal process for if
15 there is a disagreement, and then to move it
16 downside if the patient so wishes, and I just

17 suggest if you're finding that you feel there is
18 undue or deliberate delay, that that's a matter
19 that should be brought to us, and we're able to
20 respond to that.

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

210

1 their written deadlines themselves, so --

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

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

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

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

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

211

1 treating.

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

9 COMMISSIONER REIDER: Sure.

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

13

14 (Laughter.)

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

19 DR. PHILLIPS: Not an answer.

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

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

212

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

7 But I'd say a good -- a good 50
8 percent get denied, and these are low numbers,
9 though, but a good 50 percent, and I write a
10 letter -- I'll write a letter to the insurance
11 company with 30 references. You know, I'll spend

12 hours on the letter, only to have them reply with
13 two lines: Nope. Sorry. I find I have limited
14 recourse. What can I do, you know?

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

19 ATTORNEY GENERAL BLUMENTHAL:
20 Representative Powers?

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

213

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

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

11 REPRESENTATIVE POWERS: Right.

12 But they are not using it that way?

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

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

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

214

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

9 So, I can't comment on the stuff
10 that I'm not directly familiar with in terms of
11 this pediatric stuff, I'm not a pediatrician, so
12 of course I wouldn't be following those
13 guidelines.

14 REPRESENTATIVE POWERS: Right. I
15 was just concerned that they were all kind of
16 copying the CDC guidelines and using them as
17 their parameters.

18 DR. KATZ: CDC guidelines are
19 diagnostic criteria, not treatment criteria, and
20 their recommendations.

21 REPRESENTATIVE POWERS: I know.

22 DR. KATZ: They are not written in
23 stone.

24 REPRESENTATIVE POWERS: Right.
25 But the HMO guy sat there and said yes, that's

215

1 what we use.

2 DR. PHILLIPS: Of course they're
3 going to say that's what they use, only because,
4 you know, it is a matter of money. It's -- the
5 CDC case surveillance criteria are very strict.
6 The HMOs will not have to cover the treatment for
7 Lyme based on -- a substantial portion of Lyme

8 based on those criteria, and they are going to
9 pick and choose whatever the shortest and least
10 expensive course of therapy, it would seem.

11 REPRESENTATIVE POWERS: Is there a
12 way to override that in terms of whether it comes
13 from the CDC or maybe from the State level, to
14 say that in fact the guidelines are not the
15 narrow ones that were used for the surveying
16 technique, but in fact are broader? And if so,
17 who would do that?

18 DR. PHILLIPS: I'm not really
19 sure. I think that's why I'm here. I'm asking
20 you guys the same thing.

21

22 (Laughter.)

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24 DR. PHILLIPS: I mean I can only
25 say that it's been said over and over again that

216

1 they are not diagnostic criteria, and the CDC
2 doesn't really give -- they are not treatment
3 guidelines to begin with. They are just --
4 that's all they are, is case surveillance
5 criteria, to say, okay, we can use this.

6 Like Dr. Katz said, if you want to
7 make sure that someone has Lyme when they are in
8 the study, so they could say, okay, this is
9 appropriate treatment or not appropriate
10 treatment, but I have no answer for that.

11 REPRESENTATIVE POWERS: Okay.
12 Thank you.

13 DR. PHILLIPS: Thanks.

14 DR. KATZ: Medicine is not an
15 exact science, and that's the reason we have
16 guidelines, to keep people in the mainstream, by
17 no means prescribes you the number of weeks and
18 the grounds that you should give for people with
19 Lyme. There is some degree of freedom that is
20 hopefully still left with the physician unless we
21 are getting into a totalitarian regime in
22 medicine.

23 So, medicine is an art, and the
24 French are saying in medicine, like in laughter,
25 is no ever and there is no never. Everything --

217

1 there are exceptions, so you cannot use
2 guidelines as treatment criteria to guide every
3 physician and to tie his hands in therapeutic or
4 diagnostic workup.

5 DR. PHILLIPS: I think that that's
6 most clearly demonstrated in the survey of the 78
7 doctors from Lyme-endemic areas. 57 percent for
8 late stage Lyme are treating three months or
9 more. Clearly they are not observing what, you
10 know, was espoused by Yale; that four weeks is
11 not a good therapy. I mean, this is the standard
12 of care, and yes, if someone is saying that
13 there's a guideline out there and a majority of
14 doctors are not following that guideline because
15 they are in the trenches trying to make their
16 patients better, then the guidelines have to be
17 changed.

18 We have to use a reasonable amount
19 of common sense. I mean, anybody -- just a very
20 reasonable level of intellectual curiosity,
21 reasonable training in the field can look at this
22 and say, there's a major problem and I don't know
23 how to go about changing it, that's why I'm
24 asking you guys to help. But someone has got to
25 do it.

218

1 ATTORNEY GENERAL BLUMENTHAL:
2 Well, if we were to respond, though, meaning if

3 the legislature and any public officials were to
4 respond by saying that these decisions about
5 diagnosis and treatment ought to be made by the
6 physician and the patient without being bound
7 categorically by either the CDC guidelines or any
8 other strict protocol or regimens right now, that
9 would be a justifiable approach, in your view,
10 wouldn't it, or not?

11 DR. PHILLIPS: Yeah. I mean, I
12 think a similar bill was proposed in New Jersey,
13 where they were -- and it almost passed -- where
14 the insurance companies have to basically listen
15 to the treating physician. You know, as much as
16 they can review medical records, and as much as
17 they can try and get a handle on it, you see the
18 patient -- there is nontangible interaction
19 between the doctor and patient, you know, to look
20 at a negative blood test, but you see the
21 patient, like 30 years old, walking with a walker
22 coming into your office and living like a little
23 old person, basically disabled, and has
24 previously responded to antibiotics, only to
25 be -- when the therapy was withdrawn, to rapidly

1 deteriorate. Like I said, common sense should

2 prevail.

3 ATTORNEY GENERAL BLUMENTHAL: And
4 your idea of an ad hoc committee, Dr. Katz, have
5 you ever discussed that with members of the
6 insurance industry?

7 DR. KATZ: Well, the rare
8 occasions that they responded to my calls --

9

10 (Laughter.)

11

12 DR. KATZ: -- they have other
13 pressing issues to discuss, but I'm sure they
14 will be receptive to it, and only because of the
15 heat that is now being generated with these
16 discussions.

17 ATTORNEY GENERAL BLUMENTHAL:
18 Again, I want to thank both you and Dr. Phillips
19 for being here today and for your patience and
20 understanding in bearing with our schedule. I
21 know you are both busy, and you both made
22 sacrifices to be here today. We thank you.

23 DR. KATZ: Thank you.

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25 (Clapping.)

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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

1 disease.

2 I agree with Dr. Katz that in
3 talking about surveillance, these things are
4 sometimes used in reporting. I also think that
5 there are patterns of abnormalities that occur in
6 Lyme disease patients that are generally
7 recognizable, that it is usually possible to --
8 in a diagnostic sense, to find objective
9 manifestations of disease. But beyond this, I
10 don't think that there are any rules that anyone
11 is wedded to at this time in making the Lyme
12 disease diagnosis.

13 I do think that it's important
14 that we distinguish, and perhaps this has been
15 done already, between early Lyme disease, which
16 is typically the stage of the illness in which
17 after the tick bite a rash is often present, and
18 late Lyme disease, in which -- particularly in
19 patients who are not treated for early disease --
20 arthritic, neuro, and neurologic and cardiac
21 problems can occur.

22 You've heard already, and I won't
23 repeat the information, about the fact that
24 there's lots of evidence that in Connecticut and
25 in other states where Lyme disease is endemic,

1 early Lyme disease is underreported. I think the
2 importance of this is that citizens in
3 Connecticut correctly recognize that early Lyme
4 disease is a very common problem, more common
5 than incidence figures give as an impression, and
6 recognize how much Lyme disease occurs in their
7 community. But most of this Lyme disease is
8 early Lyme disease, which is generally not a
9 severe illness, and is generally a curable
10 disease with oral antibiotic therapy.

11 On the other hand, when we talk
12 about late Lyme disease, many physicians,
13 including myself, believe that Lyme disease is
14 over -- late Lyme disease is overdiagnosed and
15 overtreated. Lyme disease can affect or even
16 permanently damage the joints or nervous system,
17 and not all patients treated with antibiotic
18 therapy, and in late Lyme disease it's often
19 intravenous antibiotic therapy, are cured by
20 treatment. Sometimes there is a requirement for
21 additional antibiotic therapy, although in my
22 experience, there's often a diminishing return to
23 that therapy. And in that sense I would agree
24 with Dr. Phillips.

1 desirable. For example, we've treated a group of
2 patients with refractory Lyme arthritis, with
3 arthroscopic synovectomy, in which we've removed
4 inflamed and presumably infected tissue from the
5 synovial lining of joints and had good outcomes
6 in situations where antibiotic therapy had not
7 been successful up to that point.

8 But I believe that anxiety about
9 Lyme disease exists among Connecticut residents
10 because they overestimate the likelihood of
11 developing late Lyme disease following early Lyme
12 disease if adequately treated, and also they
13 underestimate the general effectiveness of
14 antibiotic therapy given for late Lyme disease.

15 What's in dispute here is whether
16 there is a significant population of patients who
17 have chronic Lyme disease for whom one month of
18 intravenous antibiotic therapy is insufficient,
19 and whether months, or in some cases, years of
20 such therapy would provide benefit.

21 In my experience, and I think
22 Dr. Katz mentioned this also, insurance companies

23 in Connecticut and elsewhere generally do not
24 dispute oral antibiotic therapy for early Lyme
25 disease treatment. It's also been my experience

224

1 that in general, insurance companies do not
2 participate in a decision by a physician in
3 Connecticut to provide an initial course of four
4 weeks of intravenous antibiotic therapy for Lyme
5 disease. It's the decision by Connecticut
6 insurance companies to require documentation of
7 active disease for treatment beyond four to six
8 weeks with intravenous antibiotic therapy, which
9 in my opinion, is at the heart of the dispute
10 that you're hearing about today.

11 As I see patients with questions
12 about Lyme disease, a frequent concern in my
13 practice, just as in Dr. Phillips' practice, is
14 the patient has already received considerable
15 antibiotic treatment and the symptoms that they
16 are having have not resolved. In my experience,
17 the most common reason for treatment failures in
18 such patients is that they do not actually have
19 active Lyme disease, and therefore, in my
20 opinion, it's good medical practice to reassess
21 the diagnosis.

22 Obviously it's difficult to
23 generalize. Every patient is different. In the
24 10 minutes provided, I can't discuss this at
25 great length, I would refer you to the paper that

225

1 I provided to you as giving you some information
2 about what's happened in my practice in the past
3 several years.

4 But I wish to emphasize that in my
5 opinion, this is -- this dispute about
6 prolonged [tape ended and then began new tape].

7 ... what is the appropriate
8 duration of I.V. antibiotic, therapeutically
9 prolonged I.V. antibiotics. As you move forward
10 and consider all the information, much of it
11 conflicting information that you've heard this
12 afternoon, whether the patient has Lyme disease
13 or not, whether prolonged intravenous antibiotic
14 treatment is useful or not, is there any harm to
15 a government remedy to help patients receive
16 prolonged intravenous antibiotic therapy for the
17 diagnosis of chronic Lyme disease.

18 In my opinion, there would be
19 several negative outcomes to such government

20 action. At least indirectly, your action would
21 inevitably validate the medical appropriateness
22 of such treatment in the absence of new
23 scientific information of effectiveness.

24 Physicians are taught above all
25 else, do no harm. If the patient does not need a

226

1 treatment, then there is no benefit, and any
2 risks are unacceptable.

3 You asked earlier about the risks
4 of prolonged intravenous antibiotic therapy.
5 Some of these risks are minor and can include
6 such things as drug allergy, a rash, a fever,
7 et cetera, phlebitis at a catheter site. Some
8 are more serious, catheter-induced septicemia,
9 catheter-induced problems where a catheter leads
10 to chronic or major blood vessel collapse and
11 loss of part of a limb.

12 Patients can also have serious
13 allergic reactions. Patients receiving
14 beta-lactam antibiotics can have bone marrow
15 suppression, as you heard from some of the
16 speakers earlier.

17 But I think the important issue
18 here is not so much the risk but the risk-benefit

19 ratio. If there's not a benefit, we shouldn't
20 take the risk.

21 What I've talked about so far is
22 risks related to treatment. I believe that
23 there's also a diagnostic risk of prolonged
24 intravenous antibiotic therapy for chronic Lyme
25 disease. The patient -- the message the patient

227

1 inevitably receives from such treatment is that
2 they have a serious, chronic, intractable
3 illness, in which powerful, broad spectrum
4 antibiotics are required, and cure is by no means
5 certain. Beyond this, there's the diagnostic
6 risk that the actual problem causing the symptoms
7 will not be addressed.

8 I wish that this controversy did
9 not exist, and I wish every patient in whom
10 there's a question about Lyme disease gets a good
11 outcome with which they are satisfied, but I
12 don't believe the treatment of Lyme disease in
13 Connecticut is so broken today that there needs
14 to be a government remedy to fix it. Thank you.

15 ATTORNEY GENERAL BLUMENTHAL:

16 Dr. Schoen, I assume that you are agreeing with

17 the previous panel and with the CDC itself that
18 these case reporting criteria should not be used
19 as binding guidelines for clinical diagnosis?

20 DR. SCHOEN: Absolutely.

21 ATTORNEY GENERAL BLUMENTHAL: And
22 when we talk about a government remedy and about
23 the possibility of the side effects that you
24 mentioned, I assume that you'd also agree that
25 protocol for I.V. treatment for whatever the

228

1 disease is, if it took longer than four, six
2 weeks, and if it were intravenous, if a company,
3 by certain kind of testing, could at least
4 minimize or reduce the risks of those side
5 effects, do you understand my question? It's
6 sort of a convoluted question. If you'd like
7 I'll try to put it in simpler language.

8 DR. SCHOEN: That's okay. I'll
9 try not to give a convoluted answer.

10 I think that I go back to what I
11 said a minute ago, which is certainly anytime a
12 doctor treats a patient and the patient is
13 participating in that decision, you have to
14 consider the risks and the benefits. And I would
15 agree that oral tetracycline is generally a

16 well-tolerated therapy.

17 I would also say that in my
18 experience, the use of prolonged cephalosporins,
19 given intravenously, is a therapy in which
20 toxicity rises over time. But ultimately what
21 you've got to weigh is the risk against the
22 benefit. And of course you want the patient to
23 be monitored, but I think that goes without
24 saying. The risk -- you want the risk of any
25 treatment you give to be as low as you can make

229

1 it when you decide to give it, but I don't think
2 monitoring justifies the act of giving. Giving
3 has got to be based on the risk.

4 ATTORNEY GENERAL BLUMENTHAL: But
5 doesn't monitoring minimize the risk?

6 DR. SCHOEN: Certainly.

7 ATTORNEY GENERAL BLUMENTHAL: And
8 isn't monitoring an acceptable way of reducing
9 the risk?

10 DR. SCHOEN: Well, monitoring is a
11 lot better than not monitoring.

12 ATTORNEY GENERAL BLUMENTHAL: And
13 in the course of a lot of treatments, aren't

14 there risks, side effects, and some pretty
15 serious side effects?

16 DR. SCHOEN: Right.

17 ATTORNEY GENERAL BLUMENTHAL: And
18 very often a physician will say to a patient,
19 we're at the limit of what we can do with X, Y,
20 or Z treatment, and now we're going to try A, B,
21 C, which could have the following risks for you
22 and here's what they are, and here's what we'll
23 do to try to minimize them? That occurs all the
24 time, doesn't it?

25 DR. SCHOEN: Yes. I'm just giving

230

1 my opinion that the time to give treatment for
2 Lyme disease is when active Lyme disease is
3 present. If it's not present, then if you give
4 treatment that carries some risk and there's not
5 a benefit, then that risk is higher than I think
6 should be taken.

7 ATTORNEY GENERAL BLUMENTHAL: But
8 on the diagnosis side, Dr. Katz has suggested
9 that there is general agreement that the
10 diagnostic procedures now available are at best
11 not 100 percent, are at best probably unreliable
12 in large part.

13 DR. SCHOEN: Well, there's two
14 parts to that; the first part is the overall
15 activity that goes into making the diagnosis, and
16 the second part is are there tests which provide
17 a sort of a yes/no answer without imperfection,
18 and I would certainly agree that the testing
19 isn't perfect, and no single test gives reliable
20 information. It gives helpful information but it
21 doesn't give conclusive information. So that if
22 one could sit back and look at a test result and
23 say yes/no, if it was that simple, there wouldn't
24 be controversy. I think you have to take it all
25 together, but at the same time, in giving my

231

1 impression, which is that the disease is being
2 overdiagnosed and overtreated.

3 And I don't think that there's
4 evidence that giving therapy beyond a period of
5 time of four to six weeks in most instances --
6 and there certainly are some exceptions --
7 conveys benefit to the patients receiving this
8 therapy in Connecticut today such that there's a
9 problem where they are being denied necessary and
10 needed care.

11 ATTORNEY GENERAL BLUMENTHAL: But
12 if there is controversy about the effectiveness
13 of the diagnostic tests available as of this
14 date, and there's also controversy within the
15 medical community among very reputable and
16 well-trained and well-regarded people about what
17 proper treatment is, why not leave it to the
18 treating physician and the patient, principally
19 the treating physician, to make these decisions
20 about cases that, as you say, should be
21 determined on an individual basis?

22 DR. SCHOEN: I believe that it is
23 possible in most instances to make a diagnosis
24 when everything is taken together. You could
25 pick any single test or any single procedure in

232

1 isolation and say this has imperfections, that
2 has imperfections. But I believe it's possible
3 to arrive at a reasonable probability as to
4 whether or not Lyme disease exists, and I would
5 certainly agree that there may be situations in
6 which one shudders on the side of treatment if
7 one's unsure, but I think the landscape out there
8 is different. The landscape is that there's a
9 lot more treatment being given than I think

10 really benefits patients in Connecticut,
11 certainly, given the limitations of the test.

12 What you say has theoretical
13 merit, I think the danger is that too much
14 treatment can be given and carries some of this
15 risk. And by "too much," I simply mean treatment
16 if the disease isn't there in an active form,
17 there is the potential for harm.

18 ATTORNEY GENERAL BLUMENTHAL: But
19 too much treatment is really in the eye of the
20 beholder, so to speak.

21 DR. SCHOEN: That's true.

22 ATTORNEY GENERAL BLUMENTHAL: And
23 that kind of generality, when brought to the
24 level of the individual who is suffering pain and
25 symptomatology that is consistent with Lyme

233

1 disease, perhaps should be left to that
2 individual or more accurately to the treating
3 physician rather than based on a more general
4 concept of what's too much and what's too
5 little.

6 DR. SCHOEN: It's easier for me,
7 in dealing with an individual patient, to have

8 this discussion, because these generalities
9 obviously could go into different directions.
10 But I've certainly seen situations in an
11 individual patient where I've seen treatment for
12 Lyme disease because a person was in pain, and in
13 my opinion, that was not -- that treatment was in
14 a sense a dead end, and other things needed to be
15 done, other diagnoses needed to be considered.

16 So there certainly may be
17 situations in which you are right, but for the
18 purposes of this hearing, I think you've asked me
19 to paint sort of a picture of what I think is out
20 there, and that's what I've tried to do.

21 ATTORNEY GENERAL BLUMENTHAL: How
22 often have you encountered the side effects as
23 you described it, that are risks of prolonged
24 treatment with antibiotics?

25 DR. SCHOEN: Well, actually, I've

234

1 been involved in seeing patients with Lyme
2 disease issues since 1981, and the paper that
3 Dr. Phillips alluded to that I provided to you
4 was a paper that we started to write because we
5 expected to see a lot of side -- we were seeing
6 side effects in our clinic from prolonged

7 antibiotic therapy, and we started working on
8 that paper in around 1993 or so. And that, in my
9 recollection, is about the time when I began to
10 see insurance companies in Connecticut take a
11 stronger interest, not so much in my experience
12 in four weeks of I.V. antibiotic therapy, but in
13 therapy beyond four weeks.

14 And I really felt as if -- in that
15 paper, for instance, most of the problems that we
16 described were not serious side effects, they
17 were relatively minor things in the sense that,
18 you know, we had sort of the mild, moderate,
19 severe. And basically they weren't things that
20 did permanent harm to people, but I believe that
21 was somewhat of a change, which reflects the fact
22 that it is harder today to get open access to
23 prolonged I.V. antibiotic therapy than it was a
24 few years ago.

25 But certainly the examples that I

235

1 described to you of catheter-induced septicemia,
2 heart valve infection, a patient losing a limb
3 because of a catheter clotting, a patient
4 developing severe bone marrow problems, requiring

5 admission to an intensive care unit because of
6 life-threatening suppression of the bone marrow
7 from ceftriaxone. Those are all things that I've
8 seen.

9 ATTORNEY GENERAL BLUMENTHAL: But
10 those are pretty rare?

11 DR. SCHOEN: Well, they don't --
12 yes. Most -- yes, the answer is yes. Most
13 patients encountering antibiotic therapy for Lyme
14 disease are not harmed by that therapy, I would
15 agree with that. But the longer you give it the
16 more risk you take, in my opinion. So if we're
17 talking about four weeks of ceftriaxone or
18 Rocephin versus 28 weeks, we're talking about a
19 different situation.

20 And in a study we did comparing
21 two versus four weeks several years ago, there
22 was a difference even between two and four
23 weeks. So again, I think we can't just look at
24 risk. We have to look at risk and benefit
25 together. I think every doctor should do that

236

1 every time they treat any patient for anything.

2 ATTORNEY GENERAL BLUMENTHAL: Have
3 you ever seen denials of insurance coverage in

4 cases where you think it should have been
5 provided?

6 DR. SCHOEN: Yes.

7 ATTORNEY GENERAL BLUMENTHAL:

8 Could you describe a few of those?

9 DR. SCHOEN: Well, the best -- I
10 had one lady come in -- I make a distinction
11 between early and late disease. I'll give you
12 this one first.

13 In an early disease case, in my
14 opinion and experience, most of the time patients
15 can be treated with oral antibiotic therapy
16 successfully. But once or twice a summer I see
17 patients with early disease who are very sick,
18 high fever, had stiff neck, meningitis, whatever,
19 and I saw a situation where a patient who, in my
20 opinion, should have been treated with -- it
21 would have been safer to treat the patient with
22 intravenous versus oral antibiotic therapy right
23 at the outset, and that's what the doctor wanted
24 to do. And in my opinion, the insurance company
25 prevented that from happening. And instead, sent

1 the patient to me, and I said, let's review

2 things.

3 By the time the person came to me,
4 they were doing okay, and we muddled through, but
5 I think that was not right, particularly given
6 the fact that the sooner the disease is treated,
7 the less problems you are likely to have. In
8 terms of late Lyme disease treatment, I think
9 that my experience has been that there is so much
10 intense interest in Lyme disease treatment now,
11 that that almost in and of itself to some extent
12 distorts what's happening. And I think that
13 there has been an attempt to -- there has been an
14 attempt to develop guidelines that allow
15 insurance companies to know who's being treated
16 and why.

17 And occasionally I've seen
18 situations where it's been necessary for me, for
19 instance, as the treating physician, to provide
20 more documentation today than I would have had to
21 in the past. But I can't think of a recent -- I
22 can't think of an example where such treatment
23 was not allowed.

24 In terms -- now I'm talking about
25 late Lyme disease treatment. But like

1 Dr. Phillips, my requests are relatively gentle,
2 probably, relative to some.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Dr. Feder?

5 DR. FEDER: My name is Dr. Henry
6 Feder, and I do family medicine, pediatric, and
7 pediatric infectious disease at the University of
8 Connecticut Health Center and Connecticut
9 Children's Medical Center. I think my insights
10 would be more in pediatric, but I also deal with
11 adults.

12 I'd like to tell you three Lyme
13 disease stories. First I'd like to give you a
14 tiny bit of background.

15 In 1977, I came to the University
16 of Connecticut. I joined the faculty as a doctor
17 who likes to see patients. My primary work is
18 seeing patients. It's interesting that in 1977,
19 that was the year that Dr. Allen Steere published
20 his first paper, really the first paper about
21 Lyme disease. His report was prompted by visits
22 from patients from Lyme, Connecticut, where they
23 gave almost bizarre stories of fevers, rashes,
24 arthritis. One of these patients, Polly Murray,
25 told about her family getting devastated by

1 arthritis and rashes and fever but said her dog
2 was lame.

3 I think it was a credit to
4 Dr. Steere to listen to these people, take it
5 seriously, and with very careful research over
6 the past two decades, I think most of the
7 mysteries of Lyme disease have been solved.
8 There are lots of questions, but in general they
9 have been solved, and I want to give you three
10 examples that I've dealt with that each one gives
11 an important point about some of the pitfalls
12 about treating or diagnosing Lyme disease.

13 The first case is a 15-year-old
14 girl from Greenwich, Connecticut. She was in
15 perfect health until May of 1994, when she
16 developed a swollen knee. The Lyme blood test,
17 I'll say the two-step test, the ELISA and western
18 blot, were both markedly positive, and there was
19 really no question that she had Lyme disease and
20 she was started on intravenous antibiotics.

21 Four days after beginning therapy,
22 her arthritis was better, but she had joint pains
23 in her ankles, shoulders, wrists, so her
24 physician decided to treat her until these other
25 symptoms that were associated first with the

1 arthritis resolved. One month later after
2 therapy, she still had the joint pains and I.V.s
3 were continued, and in fact she was treated for a
4 total of six months intravenously, and after six
5 months, the parents, getting frustrated, came for
6 a second opinion and saw me.

7 I examined her, she was normal. I
8 redid the Lyme test, although I didn't need to.
9 It was still markedly positive, and by the way,
10 once someone has a positive two-step Lyme test,
11 it may stay positive the rest of your life. And
12 one of the frustrations of us in Lyme disease is
13 we cannot tell one who has old disease and a
14 positive blood test versus something that's now
15 active. We don't have a test like that, and
16 that's what we're talking about with some of
17 these newer experimental tests, and we're waiting
18 for them to get validated.

19 So her blood test was positive,
20 her arthritis was resolved. She still didn't
21 feel good, and I said, the Lyme is gone from your
22 body. After six months of I.V. therapy, I
23 believe it is gone. I asked that I stop therapy
24 and the family agreed. We removed the I.V., and

25 over the next four weeks, with lots of phone

241

1 calls, she did not get better, but two weeks
2 after that, she slowly improved and was fine.

3 What was a surprise was her
4 neighbor worked for The New York Times, and when
5 this little girl came to see me, the neighbor
6 thought that I would do new therapies for Lyme
7 disease, and she was really amazed at what I did
8 was I stopped therapy. And she came and visited
9 me and spent a day with me, and when I talked to
10 this New York Times reporter, and I think I gave
11 that in my packet -- someone followed me around
12 all day to take that picture, and it's not too
13 flattering -- but I basically said maybe us
14 scientists may mislead the public a little bit in
15 that you get Lyme disease and you get treated.
16 I'm a believer that when someone has Lyme
17 disease, is treated orally for the rash, three
18 weeks of therapy is fine.

19 But sometimes there are associated
20 symptoms that recur, and I think I even heard
21 Dr. Phillips say once a week some of his patients
22 get some aches and pains and think they may be
23 related to Lyme disease, but he waits them out.

24 And this example of this child was her associated
25 symptoms were, I think Lyme disease, but they

242

1 were self-limited and they did not need oral
2 antibiotics.

3 Let me go to my second case. My
4 second case is 36-six-year-old female who was
5 admitted to UConn with 105 fever and no white
6 cells, she had neutropenia. Her story is as
7 follows: For two years before she had joint
8 pains, headaches, and saw many, many doctors in
9 Connecticut, and she felt she had Lyme disease
10 but they felt she did not. They did many blood
11 tests that were negative, and then on her own she
12 sought out a physician in New York, and with this
13 physician had a urine test done for Lyme disease
14 which was positive.

15 The physician in New York says
16 yes, you have Lyme disease, I will treat you
17 intravenously and in fact started treating with
18 antibiotics and she came back to Connecticut.

19 On the 23rd day of antibiotic
20 therapy, she developed a fever of 105, was seen
21 by someone who wasn't treating her, and said she

22 had no white cells and she got admitted. And
23 when we traced the case down -- by the way, what
24 we did is we stopped antibiotics. Over the
25 course of the next month, she got better. But

243

1 what I didn't understand is what was this test
2 for Lyme disease, this urine test?

3 And I researched it as best as I
4 could, and there was no science that I could
5 find. It wasn't validated, so I published this
6 case in JAMA. I also put that in your packet.
7 And the company that made the test responded and
8 said 11,000 people have been tested and it's
9 useful.

10 Right after that paper came out,
11 that test was removed. And now there are other
12 urine tests, and they also have not been
13 validated, so I'd like to see some of these tests
14 work, but validation is very important.

15 My third case: My third case is a
16 four-year old little boy who had arthralgias and
17 a positive Lyme test. Again, ELISA and western
18 blot. He was treated with oral antibiotics for
19 Lyme disease, but his joint pains continued. He
20 was able to play but he complained frequently of

21 everything hurting him. He visited a few doctors
22 and ended up at the Children's Hospital, and
23 after a lot of discussion with the parents, it
24 was decided to treat him intravenously.

25 He was treated for one month with

244

1 intravenous antibiotics and maybe improved a
2 little bit. At the end of therapy the parents
3 insisted on further therapy. We said that four
4 months was the maximum, we wanted to stop, we
5 wanted to do physical therapy, we wanted to work
6 with him and we would wait. They refused, and
7 they went to another physician, who continued the
8 intravenous antibiotics. And on the third week
9 of the second course of antibiotics, he came to
10 our Emergency Room with severe abdominal pain.

11 He ended up having a cystitis, a
12 gallbladder attack, and had his gallbladder out.
13 Antibiotics were stopped, and over the next few
14 months, his joint pains went away, so here was
15 another complication of antibiotics, and that was
16 a gallbladder attack.

17 Let me just say a few things about
18 putting Lyme disease into perspective. I gave

19 you three cases of some problems that we were
20 seeing with Lyme disease. One may be
21 misdiagnosis on a urine test, and two are people
22 that did have Lyme disease with persistent
23 symptoms that were resolved on their own and the
24 dangers of antibiotics, we paid our price.

25 From 1988 to 1993, I saw 146

245

1 children sent to UConn for second opinions of
2 Lyme disease. I also do primary care. In fact,
3 I go down to East Lyme schools and take blood
4 from the kids to check for asymptomatic
5 seroconversion. I saw some of these kids so some
6 are primary care and some are referrals.

7 Of those 146, only one needed
8 intravenous therapy, was treated two weeks, had
9 meningitis and did fine. To me, intravenous
10 therapy for Lyme disease in kids is the
11 exception.

12 Another very interesting thing is
13 a study that, by the way, Dr. Steere was the head
14 of, where we did 10,000-plus patients, a study
15 with a vaccine for Lyme disease which is
16 moderately effective. What happened was 5,467 of
17 these patients got a placebo, meaning they got no

18 vaccine. They were followed very carefully for
19 two years.

20 106 of them developed erythema
21 migrans, they were treated orally, and as far as
22 I know they all did well, and they were treated
23 for a month or less. One developed arthritis,
24 two developed neuritis. They were also treated
25 and did well. I don't know of one patient from

246

1 these 5,000 who were followed prospectively that
2 has chronic Lyme disease develop.

3 AUDIENCE INDIVIDUAL: I do.

4 DR. FEDER: Were you in that
5 study?

6 AUDIENCE INDIVIDUAL: No.

7 DR. FEDER: Well, that's why. In
8 my experience, chronic Lyme disease is rare in
9 children. When diagnosed it should be confirmed
10 by a pediatric rheumatologist or pediatric
11 neurologist. I.V. treatment should usually -- I
12 use "usually," be limited to a maximum of four
13 weeks of therapy.

14 The last thing I want to mention
15 is something from The New York Times which is not

16 in my packet. It's the front page of the Times
17 of January 4, 1994, I have it here. What is the
18 problem with prolonged antibiotics when a patient
19 or family believes they will help? I was there
20 in her room when her family says to me after four
21 weeks, we want more, and it is terrible for us to
22 sit down and say we feel the risk outweighs the
23 benefit. Because it is very, very, tricky and
24 very difficult.

25 This is what they wrote in the

247

1 Times. And the title of it was "Prolonged Lyme
2 Treatments Posing Risks, Expert Warns.

3 Almost two decades after Lyme
4 disease was discovered in Old Lyme, Connecticut,
5 health experts and officials are warning that
6 overdiagnosis of the disease and complications
7 from long-term antibiotic treatments may pose as
8 great a danger to the public health as the
9 disease itself. In one instance, cited by the
10 CDC, 14 children had to have their gallbladders
11 removed, and 23 suffer from bloodstream
12 infections because of complications from
13 long-term treatment with intravenous antibiotics
14 at the New Jersey Shore Medical Center. Though

15 the children's doctor defends their treatment,
16 the CDC found no evidence that most of the
17 children had Lyme disease."

18 My goal, when I see a patient with
19 a problem, is to figure out what's wrong and help
20 them. And I do not want to do any harm with I.V.
21 antibiotics unless there is more data that they
22 help. Thank you.

23 ATTORNEY GENERAL BLUMENTHAL:
24 Well, let me ask you, Doctor, just to complete
25 the thought, were you -- this is an article in

248

1 The New York Times of 1994?

2 DR. FEDER: Uh-huh. Yes.

3 ATTORNEY GENERAL BLUMENTHAL: Have
4 there been articles since about the effects of
5 prolonged use of antibiotics?

6 DR. FEDER: There are papers that
7 give anecdotal case reports, but I don't know
8 that the CDC has looked into it. Again, I do not
9 know.

10 ATTORNEY GENERAL BLUMENTHAL: So
11 it isn't as if there's a rash of -- or to use
12 perhaps an overused term, "epidemic" of overuse

13 of antibiotics that's produced a wave of these
14 instances --

15 DR. FEDER: This was a unique
16 situation. This was one hospital --

17 ATTORNEY GENERAL BLUMENTHAL: The
18 need for 14 cases in one hospital in a discrete
19 period of time, somebody made a mistake?

20 DR. FEDER: I would agree with
21 that, yes.

22 ATTORNEY GENERAL BLUMENTHAL: And
23 the mistakes could have been due to all kinds of
24 factors, like not monitoring what was happening
25 to these children and so forth and so on? We

249

1 don't know much more about it than what's in that
2 article.

3 DR. FEDER: Yes. No.

4 ATTORNEY GENERAL BLUMENTHAL: And
5 you are not really offering it as a -- and your
6 only -- as an argument here that physicians who
7 are listening or who may be reading this record,
8 should not prescribe antibiotics?

9 DR. FEDER: What I'm saying, as a
10 treating doctor, I read about things like that.
11 We can't monitor them for the gallbladder problem

12 with ceftriaxone. That either happens or it
13 doesn't happen. It's not something we can
14 monitor for. At least in kids we don't monitor
15 for that.

16 And we just had a case, so that
17 case -- that experience warned me, and that's one
18 of the reasons that I'm afraid to use antibiotics
19 after four weeks of I.V.

20 Now, another thing that was
21 mentioned that I think it's important, and it's
22 interesting because I don't represent the
23 insurance companies, I think I have the same
24 problem as everyone else does, some things I want
25 to do and we try to get permission, and sometimes

250

1 it's difficult. Is there is a difference between
2 I.V. and oral, and the dangers of I.V. are much
3 greater. An I.V. in your arm or sometimes they
4 do a central line, can cause sepsis, and you can
5 get bacterial infections, that is very dangerous,
6 from that.

7 And the difference, if I see one
8 with a respiratory infection, if people come to
9 me saying, Doctor, antibiotics help me, and I try

10 not to use antibiotics unless I really have to,
11 and it's very difficult when I deal with these
12 patients like for respiratory infections, where
13 they want them and I don't believe they help, and
14 sometimes I use them. If they want it
15 intravenous, I would just say so, it's too
16 dangerous. It's not only the cost that I deal
17 with, I deal with the dangers, and I.V.,
18 antibiotics through a line that's either in your
19 arm, which goes into one of your blood vessels,
20 or what we call a Hickman or broviac [phonetic]
21 through the chest, we use this in kids with
22 cancer, there the risk is worth the benefit. I
23 think in Lyme disease for prolonged therapy, the
24 risk is not worth the benefit.

25 ATTORNEY GENERAL BLUMENTHAL: But

251

1 why not let the patient and the physician make
2 that judgment?

3 DR. FEDER: Maybe in kids, then,
4 it's different. I was thinking about that. In
5 fact, some of these patients who -- the adults
6 who have lost their gallbladders and maybe later
7 on when people speak here they are going to say
8 their lives were so terrible and that losing

9 their gallbladder with the antibiotics was well
10 worth it. So I would say with adults that
11 certainly is something I respect.

12 ATTORNEY GENERAL BLUMENTHAL: But
13 with children --

14 DR. FEDER: It's different.

15 ATTORNEY GENERAL BLUMENTHAL:
16 Adults are in the position often of being -- they
17 are guardians, they have legal responsibilities,
18 why not put, again, that decision in the hands of
19 whoever is the caretaker, the legal guardian, the
20 fiduciary, however you want to characterize it?

21 DR. FEDER: I would say that's
22 fair. That's between their doctor and the
23 family, and it's just my own bias that to me,
24 that the risk outweighs the benefit.

25 ATTORNEY GENERAL BLUMENTHAL:

252

1 You've been very frank and candid, and I think
2 your suggestion is that maybe it should be the
3 patient and the physician, the treating
4 physician, as long as that physician has all of
5 the acceptable professional credentials and
6 training and so forth to make that decision.

7 DR. FEDER: Yes.

8 ATTORNEY GENERAL BLUMENTHAL: And
9 I'm interested in -- not to prolong my own
10 questions, but your reference to insurance
11 companies sometimes not permitting you to do what
12 you think is the right thing to do, is that true
13 in Lyme disease treatment?

14 DR. FEDER: It gets interesting.
15 I have very little experience treating Lyme
16 disease I.V., but I do pediatric infectious
17 disease, and I also do primary care. But I do
18 some very unusual things in pediatric infectious
19 disease, so if you feel it's something that's
20 very unusual and you have a special way you want
21 to do it, and they look at their policies, it's
22 not part of it.

23 I have a child, for example, that
24 had meningitis a few times, it's not Lyme
25 disease, but was due to a defect in his skull.

253

1 And there was someone in Boston that's famous and
2 that could fix it, and to try to get that person
3 from Connecticut to Boston for a very complicated
4 surgery was jumping through a lot of hoops, but
5 it was well worth it to jump through those

6 hoops.

7 ATTORNEY GENERAL BLUMENTHAL: And
8 sometimes jumping through that hoops -- those
9 hoops, if the physician isn't sufficiently
10 persistent or the patient isn't persevering
11 enough, it becomes impossible.

12 DR. FEDER: It's always possible,
13 but it's difficult, I know that. It's difficult,
14 yes.

15 ATTORNEY GENERAL BLUMENTHAL:
16 Well, I can tell you that my office deals with a
17 lot of cases where it takes a lot of persistence
18 and perseverance, sometimes it's a matter of life
19 and death.

20 DR. FEDER: Yes.

21 ATTORNEY GENERAL BLUMENTHAL: And
22 I think once again, to come back to something
23 that was said earlier by one of the
24 representatives of the insurance companies, and I
25 don't know whether you were here, but he said

1 that sometimes they do reverse themselves, but
2 not always. And so it takes someone with your
3 caliber of persistence, perhaps, to have that

4 done.

5 DR. FEDER: Yes.

6 ATTORNEY GENERAL BLUMENTHAL:

7 Representative Powers.

8 REPRESENTATIVE POWERS: You both
9 represent research institutes and you've
10 referenced a '93 article and a '94 article. What
11 are research institutes in Connecticut doing in
12 terms of advancing the knowledge? There's
13 clearly a difference of opinion on how long and
14 for whom and under what circumstances different
15 therapies are recommended. Are there any kind of
16 studies going on, comparative studies, in other
17 states, anything like that?

18 ATTORNEY GENERAL BLUMENTHAL:

19 Dr. Schoen?

20 DR. SCHOEN: Sure. Two things;
21 one, 1993 was when we thought about getting
22 started on this paper. It was actually published
23 in 1998, so the information I've given you, at
24 least in terms of publication, is up-to-date.

25 I think that to answer your

1 specific question, there is currently an
2 NIH-funded study to evaluate whether additional

3 antibiotic therapy in patients with well
4 documented Lyme disease history and persistent
5 symptoms, whether antibiotic therapies are a
6 benefit. So there's such a study being
7 undertaken that was funded by the NIH and there
8 are several cooperating centers, and we are
9 participating in that study.

10 REPRESENTATIVE POWERS: Who else
11 is in it?

12 DR. SCHOEN: One group is at New
13 York Medical College, and another group is up in
14 Tufts Medical Center.

15 REPRESENTATIVE POWERS: So kind of
16 New York, New Jersey, Connecticut?

17 DR. SCHOEN: Well --

18 REPRESENTATIVE POWERS: No,
19 Massachusetts.

20 DR. SCHOEN: So --

21 REPRESENTATIVE POWERS: That's
22 it?

23 DR. SCHOEN: That's a major study
24 looking at this particular thing. I can't speak
25 to anything else that I'm personally involved

1 in. I don't know --

2 REPRESENTATIVE POWERS: Well, some
3 other things, just as a non, you know, healthcare
4 person, there's lots of concerns about the
5 tests. There's lots of concerns about the
6 vaccines, whether the vaccine is worth doing or
7 not worth doing. We've had two different
8 opinions from UConn today on the vaccine.

9 Is there any other stuff going on
10 with those particular issues which you think
11 might help resolve some of these questions?

12 DR. FEDER: You said there were
13 two different opinions on the vaccine? What was
14 that? The two are what?

15 REPRESENTATIVE POWERS: Well, we
16 had someone earlier from UConn who said they did
17 not think the vaccine was -- [background loud
18 noise] --

19 DR. FEDER: From UConn? Was
20 what? Not --

21 REPRESENTATIVE POWERS: Was not
22 worthwhile.

23 DR. FEDER: I mean it was a study
24 that was done with the hosted 11,000 people, and
25 there was no toxicity, and the instances of Lyme

1 disease after three shots went down 80 percent.
2 That's not perfect, and the nice thing about the
3 measles vaccine, because I heard that mentioned
4 --

5 REPRESENTATIVE POWERS: That was
6 my question.

7 DR. FEDER: -- measles is almost
8 gone. I deal with measles, but I haven't dealt
9 with that in five years. Polio is gone. There
10 are several things with vaccines that are great.
11 But the Lyme that decreased the problem 80
12 percent, then, to me is a choice between the
13 patient, physician, to see if it's worth it.

14 I think some people living in
15 areas where there's tick bite risk constantly
16 when they go out and there's a lot of Lyme
17 disease, this makes them happy. But we know the
18 numbers; in other words I can say if you get the
19 vaccine, that your risk is decreased by a certain
20 amount. I think that's science. It's not
21 perfect, and we admit that. But I don't know how
22 one can be against the vaccine or for the vaccine
23 except to say that if you get the vaccine it will
24 decrease your risk 80 percent, and we don't know
25 about boosters. We don't know about long-term

1 side effects, and that's one thing that I can see
2 is a concern, because it's only been a few years
3 that it's been followed.

4 But, you know, there's data that's
5 reproducible. And I think that's sometimes what
6 we discuss, is things to say; this is the odds,
7 but life is not perfect, and the tests are pretty
8 good but not perfect, and there's an art of
9 medicine and a contract between doctors and
10 patients that each case is unique.

11 And that's why I can't say things
12 about some other patients that I have -- that I
13 haven't dealt with, like when someone yelled from
14 the audience and said I have chronic Lyme disease
15 that was part of the vaccine study.

16 You know, life for each person is
17 different, and I just try to give you an overall
18 perspective that many of the mysteries of Lyme
19 disease have been solved, but there's no
20 question, it's a problem, and we're doing our
21 best now working with new problems.

22 REPRESENTATIVE POWERS: I
23 appreciate those thoughts. I was just asking if
24 our two leading research institutes in
25 Connecticut are doing anything with these other

1 questions.

2 DR. FEDER: In this policy,
3 vaccine surveillance, meaning patients who have
4 gotten vaccine, were being followed very
5 carefully for many years, and I was part of that
6 vaccine study.

7 REPRESENTATIVE POWERS: Okay,
8 thank you.

9 ATTORNEY GENERAL BLUMENTHAL: Just
10 one last question. On the diagnostic test in
11 particular, the brain SPECT scan that was
12 mentioned earlier by Dr. Katz, do you have an
13 opinion as to the advisability of using that
14 test?

15 DR. SCHOEN: I think that, you
16 know, my own impression is that the -- that first
17 of all, that test carries virtually no risk, so
18 by my strategy, I have no objection to SPECT scan
19 testing. My belief is that it's not been
20 demonstrated that that test diagnoses Lyme
21 disease.

22 The same thing can be said for
23 neuropsychiatric testing, its SPECT scan, as I

24 understand it, looks at short-term changes in
25 brain metabolism, the blood flow through the

260

1 brain, as Dr. Katz described.

2 Neuropsychiatric testing, to the
3 extent it's possible, allows us to look inside
4 the brain and determine whether there are
5 patterns of defects in cognitive function which
6 is maybe hard to get at otherwise. In my opinion
7 that's very useful, helpful information in
8 understanding a patient's overall global
9 functioning, but I don't think that that testing
10 has been shown to support or refute the diagnosis
11 of a specific infectious disease. So I would
12 disagree with the idea that you can use a SPECT
13 scan to diagnose Lyme disease.

14 I would be sympathetic if a
15 Connecticut physician wanted to obtain a SPECT
16 scan for one of their patients, since I don't
17 see, compared to the prolonged antibiotic
18 therapy, that there is any risk there.

19 I just want to follow up,
20 Mr. Blumenthal, in a comment that you made. I
21 certainly have very sympathetic to your interest
22 in making sure that wherever possible the

23 relationship between the physician, the patient
24 is not intruded upon.

25 I simply want to make the point that if

261

1 you look at what's actually happening today, I do
2 believe that there is a danger in overdiagnosis
3 and overtreatment, and I do think that, for
4 example, the article that appeared in The New
5 York Times, is obviously an extreme, but also in
6 my practice I see situations in which lots of
7 Lyme disease treatments given both orally
8 intravenously and you may disagree, that's just
9 my opinion, whether the patient actually has Lyme
10 disease.

11 ATTORNEY GENERAL BLUMENTHAL: But
12 I also understand that you're not here
13 necessarily to advocate that your --

14 DR. SCHOEN: No.

15 ATTORNEY GENERAL BLUMENTHAL: --
16 opinion be adopted as the policy of the State of
17 Connecticut.

18 DR. SCHOEN: I'm here because you
19 asked me to come.

20

21 (Laughter.)

22

23 ATTORNEY GENERAL BLUMENTHAL: And
24 we appreciate it, but I don't understand your
25 being here to advocate that your view, which may

262

1 be a somewhat more conservative one on the issue
2 of treatment, and I don't mean to use that word
3 in any way pejoratively but conservative versus
4 whatever we want to characterize the other point
5 of view, and I guess part of the reason we're
6 here today is to determine really whether it
7 shouldn't be the treating physician and the
8 patient who make these decisions rather than the
9 government, which I don't think anyone wants, or
10 the insurance companies, which now they do very
11 commonly and using -- using criteria, the CDC
12 guidelines that both of you as well as the CDC
13 have said should not be used for clinical
14 diagnosis.

15 I don't mean to put you in the
16 position of answering a rhetorical question so...

17 Anybody else have any questions?
18 You both have been very understanding and patient
19 and again, my apologies to you, as to everyone,

20 for our delays here.

21 We're going to go to the public.

22 Why don't we take a 10-minute break. We'll start
23 at 4:00.

24

25 (Recess.)

263

1

2 (Tape turned on.)

3

4 ATTORNEY GENERAL BLUMENTHAL: ...

5 for example, I know I have to leave approaching
6 6:00 because of a legislative group that I have
7 to appear before, and the representatives as
8 well, so with the help of the Assistant Attorney
9 General and whatever, this is all recorded, we
10 perhaps can get underway. And I'm going to have
11 to ask, is there a sign-up sheet that we have
12 that -- let me ask you a question.

13 Without the benefit of that, is
14 there someone -- here it is. And at my age, I
15 either have to put glasses on or I have to hold
16 it way out, but Peter McFadden is the first
17 person, and I just ask that if people, you know,

18 could come and make a statement as clear and as,
19 you know, take the necessary time but to the
20 point that it be concise, because we do have
21 quite a list of people that want to talk. So if
22 Peter could...

23 I just share with you that this is
24 the list, and we have a lot of people so we're
25 going to try to move as quick as we can. Peter?

264

1 Sit here with the mike. If you would just
2 identify yourself and your hometown would be
3 appreciated.

4 MR. MCFADDEN: Can everybody hear
5 me?

6 ATTORNEY GENERAL BLUMENTHAL:
7 Yes.

8 MR. MCFADDEN: My name is Peter
9 McFadden, I'm from Huntsville, Alabama. I'm from
10 Connecticut originally, and I'm a chronic Lyme
11 disease patient.

12 ATTORNEY GENERAL BLUMENTHAL:
13 Welcome back to Connecticut.

14 MR. MCFADDEN: Thank you.

15 And I've got some science that I
16 want to present, and I'm going to move as fast as

17 I can and be as brief as possible.

18 COMMISSIONER REIDER: Do you have
19 an idea of how long this will take?

20 MR. MCFADDEN: Well, that depends
21 on how much detail people want me to go into.

22 COMMISSIONER REIDER: I would ask
23 if you have something you can present to us and
24 you can keep it in this case to five minutes we
25 will appreciate it.

265

1 MR. MCFADDEN: The first page is
2 just a little -- I'm not going to go over it at
3 all. It's a little background on me and some of
4 my struggles. I just wanted to say that we heard
5 some stuff about there's no proof that long-term
6 antibiotics work and whatnot, and I was severely
7 affected by Lyme disease. I didn't participate
8 in a recreational activity for five years before
9 I was diagnosed.

10 For the first six months of that,
11 I never left my apartment except for three
12 doctors' appointments and I've had to work at
13 home for two years. And before antibiotics, I
14 did not have enough strength even to go like

15 that...

16 (Tape ended, then new tape.)

17

18 MR. MCFADDEN: ... that it's the
19 placebo effect or anything like that. But I've
20 gone off antibiotics four times and each time was
21 a disaster, and the last time I missed six weeks
22 of work, and I think long-term antibiotics are
23 helping me. And I'm surprised there is so much
24 controversy.

25 I'm going to page 2 right now --

266

1 I'm surprised there is so much controversy about
2 whether long-term treatment helps, because the
3 only thing that's rare are attempts to isolate
4 the spirochete after treatment. For the number
5 of times that that's attempted there are a lot of
6 cases of the spirochete being isolated from all
7 sorts of human tissues and fluids listed at the
8 top left of page 2, and points 1 and 2 provide a
9 mechanism by which the spirochete is able to
10 evade antibiotics.

11 There are companion studies that
12 Dr. Kliner [phonetic] is an author on both of
13 these. The first study shows that the Lyme

14 disease spirochete can invade fibroblasts, which
15 are connective tissue cells. These cells are
16 porterly [phonetic] vascularized in the immune
17 system and antibiotics cannot get in there well.

18 And the second study proves that.
19 The second study shows that fibroblasts protect
20 the Lyme disease spirochete from Rocephin, so
21 there really shouldn't be a lot of surprise that
22 there are people that don't get better with four
23 weeks of therapy, because the spirochete is able
24 to get in places where the antibiotics can't.

25 Points 3, 4, 5, and 6 are all

267

1 cases of the spirochete being isolated after
2 long-term, some of them many courses of therapy.

3 Case 4 is a fatal case of Lyme
4 disease, and this person received four weeks of
5 intravenous Rocephin succeeded by six weeks of
6 oral antibiotics, and this poor man died in the
7 hospital while doctors were trying to save his
8 life. And at autopsy, he had spirochetes in his
9 brain.

10 Page 7 is a very important study.
11 There's just been so little work to see why these

12 patients have continuing symptoms, and this group
13 that did the study 7 on page 2, when they treated
14 dogs infected by tick bite right away, they got
15 better. And they didn't have the spirochete in
16 their body, but when they waited 60 days before
17 treating, none of the dogs got rid of the
18 spirochete. They all remained infected.

19 Now, the antibiotics reduced the
20 disease, because they had had six untreated
21 controls and those dogs all had full-blown
22 arthritis. No, excuse me, four out of six of
23 them had full-blown arthritis, and that's about
24 the proportion we have seen in humans.

25 Of the treated dogs, one had

268

1 continuing arthritis, and if these dogs were
2 humans and they were looked at by Yale, that one
3 dog, they would say okay, that has continuing
4 Lyme disease, the rest of the cases post-Lyme
5 syndrome, even though they remain infected with
6 the spirochete. And that was shown with PCR and
7 culture testing.

8 Going to page 3, there are a lot
9 of problems with the blood testing, and we heard
10 Dr. Eisenberg say that if you have a negative

11 western blot, the chances that you have Lyme
12 disease are very small, but that just doesn't
13 square with the evidence.

14 Study 1 is the best study of the
15 performance of lab in Lyme disease testing,
16 performance of 45 participating laboratories. 55
17 percent of them could not identify a person --
18 they knew this person had Lyme disease, they knew
19 this person was seropositive, they sent them a
20 sample. The lab reported it as negative and they
21 also -- the authors state that there was a
22 striking inability of many laboratories to
23 reproduce their results and split samples from
24 the same individuals. That means draw a tube of
25 blood, split it into both -- two samples, send

269

1 them marked as if they are from two separate
2 patients, the lab reports one is positive, one is
3 negative.

4 The reasons for these problems
5 really aren't well understood, but there are so
6 many cases where the spirochete is isolated from
7 people who have negative blood tests.

8 17 patients in number 2, although

9 these patients had clinically active disease,
10 none of them had diagnostic levels of antibodies
11 on either an ELISA test or a western blot, and by
12 the rationale we heard earlier from Dr. Schoen
13 and Dr. Eisenberg, these patients would be
14 designated as not having Lyme disease yet they
15 do.

16 Case 3 are three children that had
17 the spirochete isolated from spinal fluid. None
18 of them had positive blood test or antibodies in
19 their serum.

20 And study 4 was a case of 14
21 patients with the spirochete isolated from
22 various body tissues or blood. Exactly half of
23 them had negative blood tests.

24 Now, study 5 is very important.
25 It provides an answer as to why this is

270

1 happening. Many of the patients who have Lyme
2 disease yet test negative had some kind of very
3 minimal antibiotic therapy early in the illness,
4 as did I. For the antibody response to develop,
5 the antigen, the Lyme disease spirochete proteins
6 have to be present, otherwise the T cell
7 maturation will not occur, the T cells stipulate

8 the B cells to make the antibodies, and the T
9 cells require the continued presence of antigen.
10 And if the antigen is removed by antibiotic
11 therapy, which does not cure the illness, the
12 person will be seronegative. They continue to
13 have the disease and the condition is permanent.

14 There is a window there when the
15 antigen must be present, and if it's not, the
16 person will be seronegative even though they
17 continue to have the disease.

18 COMMISSIONER REIDER:

19 Mr. McFadden, we appreciate your input and you
20 are about 10 minutes -- coming from Alabama, we
21 wanted to recognize that, but just so that --

22 MR. MCFADDEN: Can I just speak
23 about page 3 for a one-minute?

24 COMMISSIONER REIDER: What I was
25 going to say, we have about 40 people, and why

271

1 don't -- yes, that's what I was going to suggest,
2 why don't you try to conclude.

3 MR. MCFADDEN: All right. All
4 right. I'm going to hurry it up. I wanted to
5 give you a sense of what's happening in the

6 trenches out there, whether these patients are
7 being treated or not and what's going on.

8 At the upper left of page 3, we
9 have a copy of a bill for an insurance company
10 consultation. I've taken the identifying
11 information, the insurance company out because
12 that's not really important, but \$350 an hour,
13 there may be a financial motivation for the
14 insurance company consultants to accommodate the
15 financial wishes of the insurance company.

16 Now, this patient had a round rash
17 the size of a dinner plate, two positive PCR
18 tests for Lyme disease, a written diagnosis of
19 Lyme disease from three physicians, yet the
20 insurance company consultant at the left of this
21 page wrote, "I definitely do not think this
22 patient has Lyme disease even though he has
23 published that the presence of an erythema
24 migrans rash is diagnostic for Lyme disease, and
25 diagnostic means alone sufficient for

272

1 diagnosis."

2 In the letter written for the
3 insurance company, the physician said that in his
4 opinion, PCR testing cannot be used

5 diagnostically, but the physician has published
6 that PCR increases confidence in the diagnosis of
7 Lyme disease, and has other papers, the most
8 recent one, the vaccine study where they are
9 using PCRs as an integral part of assessing the
10 therapeutic nature of the vaccine. They are
11 using that study but insurance company
12 consultations, they won't allow it.

13 The bottom of this page is about a
14 patient who wanted to be in a vaccine trial but
15 she had a positive blood test, she was told you
16 probably have Lyme disease and we're not taking
17 anybody with Lyme disease in this vaccine trial.
18 She had problems with her knees and arthralgias
19 and whatnot. She got a diagnosis of Lyme
20 disease, was treated with oral antibiotics, she
21 got better, she relapsed afterwards, her doctor
22 put her on I.V., and her doctor sent her to the
23 physician at the upper left here, who does
24 consulting.

25 He said that the titer was

1 probably a false positive and he said I
2 definitely don't think this patient has Lyme

3 disease, and he said I have repeated this
4 serology today. Since I do not think she has
5 Lyme disease, I anticipate this testing will be
6 negative in our laboratory. The test was
7 borderline positive with four bands on western
8 blot. In some laboratories, that's fully
9 positive. Yale sets their standard very high,
10 that's borderline positive.

11 But as we have seen, antibiotic
12 therapy lowers the antibody response and lowers
13 the response to the blood test and four bands and
14 western blot is a pretty strong response for the
15 amount of antibiotics that she was on. Yet the
16 insurance company used this physician's letter to
17 retroactively deny payment or retroactively deny
18 reimbursement for the antibiotics already
19 administered, and it's not consistent with what
20 this physician has published in this peer review
21 literature.

22 Do you want me to continue or do
23 you want me to --

24 COMMISSIONER REIDER: I think in
25 fairness, we better move along because we do have

1 about 40 people, even at several minutes each,

2 and it's important that the main point -- but we
3 do appreciate your coming and for your input and
4 the fact you've left a document that can be
5 understood and it becomes part of the record.
6 Thank you so very much.

7 MR. MCFADDEN: Thank you for
8 letting me speak.

9 COMMISSIONER REIDER: You are
10 quite welcome.

11

12 (Clapping.)

13

14 ATTORNEY GENERAL BLUMENTHAL: Next
15 is Dr. Steven Phillips, is he still with us?
16 Yes.

17 DR. PHILLIPS: I just want to make
18 a very short rebut to Dr. Schoen's and
19 Dr. Feder's comments.

20

21 (Clapping.)

22

23 DR. PHILLIPS: Anyway, Dr. Schoen
24 has made some very broad and sweeping and
25 unsubstantiated comments. I mean, he's basically

1 agreed with the fact that CDC surveillance case
2 criteria should not be used as clinical
3 diagnosis, but if you read his articles, that's
4 what he uses. So what he said here today is in
5 direct conflict with what he's published.

6 Number two, Dr. Feder has talked
7 about that -- well, first of all he referenced a
8 New York Times article, it was hardly a
9 scientific reference.

10 Also, the CDC study that he
11 referred to about the gallbladder problems in the
12 children Pat Smith, who is president of the New
13 Jersey Lyme Disease Association can give you
14 better information on this, but essentially CDC
15 did not have permission to get those records, and
16 they were hospital records taken without the
17 benefit of office records, so they made their
18 criteria of whether the patients had Lyme or not
19 based on hospital records.

20 And very often when one is
21 admitted to the hospital, you know, the doctor
22 doesn't go get their prior Lyme serology and put
23 it into the hospital record. So they did not do
24 any follow-up on that, and they didn't get the
25 office records.

1 Number two --

2 COMMISSIONER REIDER: Doctor, just
3 let me ask a question, and again just in fairness
4 to all the people here, how long will you be?

5 DR. PHILLIPS: Five minutes.

6 COMMISSIONER REIDER: Let me say
7 you've been several minutes already, and I'm
8 trying to be responsive because we do have people
9 anxiously waiting. You had the opportunity to
10 submit written testimony and follow-up which we
11 fully would expect would come, so with every
12 courtesy, and because you've been most gracious,
13 we want to respond, but if you could wrap it up
14 very, very quickly.

15 DR. PHILLIPS: Okay. Other kids
16 in that loss of gallbladders apparently had
17 family histories of very early onset gallbladder
18 disease, and CDC failed to mention that.

19 Also, Feder published a study
20 where they did 16-month follow-up of children
21 treated for Lyme, and I forget the exact
22 percentage, but around -- but around 25 percent
23 had recurrent or new symptoms. And he had stated
24 here he has never seen chronic Lyme disease, but
25 again -- that's all.

1 COMMISSIONER REIDER: Well, thank
2 you very much.

3

4 (Clapping.)

5

6 ATTORNEY GENERAL BLUMENTHAL:

7 Dr. Phillips and anyone else who has testified
8 before, if you want to submit something
9 additional in writing, we invite you to do so.
10 Anybody who has comments based on what's been
11 said after you had testified, we'd like you to
12 submit those comments.

13 Next, Richard Mourey.

14 MR. MOUREY: Hi. I'm Richard
15 Mourey. I live in East Hartford. For the
16 balance of this session, you can also find me in
17 the bill room. I have four minutes here, which
18 I'm going to cut in half.

19 First of all, as a longtime active
20 Republican I'd like to thank you for this. I'm
21 going to talk about my daughter's experience with
22 Lyme disease, but I want to bring a couple of
23 things up here that have come to me as the day
24 went on.

1 overtreatment, overbearing crowd that we have
2 here are causing three things to happen; number
3 one, a number of these people who have ascribed
4 to that theory are bringing charges against
5 doctors who treat Lyme disease. A number of
6 those doctors have lost their licenses, and for
7 the Attorney General, there was a case in
8 Michigan where a doctor lost his license and
9 appealed. I'm not sure of the result of that,
10 but I do have an amicus [phonetic] brief that I
11 can supply to you, it's quite telling.

12 Secondly, the insurance companies
13 are using this attitude as an excuse to refuse to
14 pay for advanced problems with Lyme disease.

15 Third, there are a large number of
16 practicing physicians who are using this position
17 to refuse to treat anybody under any
18 circumstances. My daughter's case is really a
19 case in point.

20 She is a 34-year-old attorney now,
21 and ladies, keep that age in mind. She graduated
22 from UConn dean's list, graduated New York Law

23 with honors, winner of the moot court
24 competition, a dozen academic awards. She was
25 published while still in school. A former

279

1 gymnast, she was very athletic. Today it's very
2 difficult for her to take a long walk.

3 She was bitten almost two years
4 ago. Her first doctor's visit, a physician's
5 assistant saw her first and told her, based on a
6 conversation with no tests, that she had MS or
7 Lupus. On her second visit, she saw the doctor
8 and the doctor told her that women in their early
9 thirties who do not have a husband suffer from
10 anxiety and exhibit a number of false symptoms
11 and advised her to take a vacation.

12 The second doctor she saw was
13 confrontational. She gave him a copy of
14 Dr. Joseph Burrascano's fine paper on Lyme
15 disease and its treatment. And if anybody wants
16 to know where to get that, you can find it on the
17 Lyme.net. This doctor literally threw it in her
18 face and demanded why she thought she had Lyme.
19 She had 30 of the 38 symptoms listed in Dr.
20 Burrascano's paper.

21 Her next doctor, a woman,

22 identified Lyme disease from the symptoms Lynn
23 described to her, and my daughter was ecstatic.
24 Finally she thought she had a doctor who would
25 believe her and would treat. Not so. This

280

1 doctor was so afraid of being brought up on
2 charges that she would not treat my daughter.

3 Through a bit of heavy research
4 and a stroke of luck we finally did find a doctor
5 who would diagnose clinically and treat. She is
6 now on I.V. antibiotics. When she started this,
7 she had the 30 symptoms, ranged from extreme
8 head, spine pain, bone and muscle pain, memory
9 loss, disorientation, dizziness, vertigo, and a
10 range of cognitive problems.

11 Today, all those are gone, the
12 only thing that's left through this treatment is
13 she still has severe head and spine pain.

14 Now, there is one ray of hope here
15 in this new test that the FDA has come up with,
16 and I certainly hope it's as good as the news
17 reports say, because I think this is going to
18 revolutionize treatment of this disease.

19 The insurance community, I would

20 recommend very strongly, that they pressure the
21 medical community to treat people who have some
22 Lyme symptoms early with a month's worth of
23 antibiotics, will probably save a great deal of
24 money, a lot of pain, and much lost work time.

25 The country now -- by the way,

281

1 there are two bills in Congress, one is sponsored
2 by Senator Dodd, another one by Congressmen
3 Malone, Gjedenson, and Shays, which provide for
4 long-term investigation of Lyme disease. And
5 very interestingly, the education of the medical
6 community about Lyme disease.

7 We desperately need strong action
8 to bring about early aggressive treatment to stop
9 the kind of suffering my daughter and others in
10 this room have experienced and a strong
11 educational program is definitely needed to teach
12 these naysayers that this is really a disease
13 that they need to pay attention to. Thank you
14 very much.

15

16 (Clapping.)

17

18 COMMISSIONER REIDER: Thank you

19 very much. Thank you, Mr. Mourey. Serina
20 Berenson.

21 MS. BERENSON: I'll try to read
22 this quickly. My name is Serina Berenson, and I
23 live in New Canaan, Connecticut. I'm a patient
24 who has been through the death of a child, the
25 chronic debilitation of a child that I have from

282

1 Lyme disease, and I'm personally disabled and
2 impaired by this crippling disease.

3 Initially I was told by several
4 prominent physicians that I did not have Lyme,
5 and that I was stressed out, and my complaints
6 were psychosomatic. I was finally diagnosed in
7 September 1995, after seeing approximately 30
8 doctors and specialists in many fields, including
9 infectious disease, rheumatology, neurology,
10 endocrinology, psychiatry, et cetera, et cetera.

11 After two weeks of diagnostic
12 testing at the Mayo Clinic in Rochester,
13 Minnesota, in which they said that the final
14 diagnosis was memory decline and fibromyalgia, I
15 returned to Connecticut and had more extensive
16 serologic testing for Lyme. The results were

17 negative from Yale and finally positive from
18 three other independent laboratories, including
19 Stony Brook, IGENEX and BBI.

20 From 1995 to '97 I was bedridden
21 with fevers, severe pain all over, muscle
22 weakness and cognitive confusion. From running a
23 successful interior design business with graduate
24 degrees, I was unable to dress or feed myself or
25 identify the names of my children. At least I

283

1 was one of the, quote, lucky ones who tested
2 positive on the ELISAs, western blot, urine, and
3 antigen, SPECT scans, FMIs and neuropsych
4 consistent with late stage, chronic Lyme.

5 At the time, Oxford cooperated
6 with intravenous treatment of Rocephin, which
7 changed to Doxycycline over the next year.
8 Slowly I began to regain functioning, although I
9 was far from my preillness state. As I sought
10 out Lyme-literate doctors and pursued aggressive
11 antibiotic treatment, Oxford, to whom we were
12 paying premiums of \$900 a month for our family
13 insurance, denied ongoing treatment.

14 By justifying, quote, appropriate
15 treatment had been achieved. My family, my

16 doctors, and I was appalled that a medical
17 director such as Dr. Eisenberg, with no knowledge
18 of my illness directly, never had met me or taken
19 the time to speak to all the physicians involved
20 in my treatment was pronouncing a cure to a
21 disease that had just begun to respond to
22 antibiotic treatment.

23 It was at that juncture in '96
24 that we began the arduous, stressful, and
25 burdensome task of appealing to Oxford for

284

1 coverage of further treatment and went back and
2 forth with denials and appeals that only
3 terminated in December with our termination of
4 Oxford.

5 We have had to pay out-of-pocket
6 since 1996 for intravenous treatment almost a
7 quarter of a million dollars. We are now
8 pursuing legal measures to get reimbursement.

9 In addition to micronic persistent
10 infection with Lyme, our 15-year old son became
11 ill in '94 from a tick bite with a bullseye rash
12 and was treated with the standard four-week
13 protocol of antibiotics. Although he had several

14 central nervous system symptoms, he did attend
15 school until '97 and '98, his 9th grade year,
16 which was last year, when he began exhibiting
17 severe neurological symptoms, fatigue,
18 arthralgias, psychotic episodes.

19 This has been a very bright
20 student, in all honors classes with straight A's,
21 energetic, confident, and active. At this stage,
22 he became lethargic, reclusive, severely
23 compromised, and he had severe cognitive
24 confusion.

25 Our son, who took great pride in

285

1 his A average could not follow the directions on
2 a Campbell soup can to make his lunch. His
3 regular pediatrician, despite positive blood
4 work, continued to deny active Lyme disease.
5 With mounting frustration and a child who was
6 homebound and not attending 9th grade, we were
7 fortunate enough to find Dr. Charles Ray Jones,
8 who believed our diagnosis, corroborated it
9 clinically and serologically and recommended I.V.
10 antibiotic treatment for Adam.

11 Although he missed the entire year
12 of his first high school experience, without

13 Dr. Jones' regimen of daily I.V.s at home with
14 home care, he would not now be an honor student
15 once again in his sophomore year.

16 During his year at home, Adam was
17 also hospitalized at Yale-New Haven children's
18 inpatient psych unit. He was experiencing
19 psychotic episodes, depression, and anxiety, and
20 he was there for an evaluation.

21 During his week inpatient stay on
22 the unit, we and his doctors requested continued
23 treatment with his I.V.s, as he had a central
24 line portacath. At first the Yale staff were not
25 pleased with the idea, but reluctantly agreed.

286

1 However, when our son was discharged, their
2 conclusion was not Lyme disease at the present
3 time. But they could not determine any other
4 diagnosis.

5 One of the reputable Yale
6 physicians proposed that perhaps my teenage son
7 was, quote, overidentifying with my illness. Why
8 would a previously healthy achievement-oriented
9 student want to do that?

10 Looking back as that nightmare

11 came to a close with his remission -- I am
12 cautious to say cure -- how can any Oxford
13 medical director such as Dr. Eisenberg, who
14 repeatedly denied treatment for this child, now
15 look at him back in school, functioning, and say
16 treatment was not necessary?

17 In total related costs our family
18 has spent a quarter of a million dollars and
19 continues to private pay for my treatment. We
20 now are preparing appeals to our new insurance
21 company, who also has randomly decided to deny
22 further treatment.

23 In summary, my hope from sharing
24 my story with you today is that another voice is
25 heard, which in turn will convince legislators

287

1 and HMOs to put treatment protocol and duration
2 of treatment in the hands of the treating Lyme
3 physician and the patient, where it ought to be.

4

5 (Clapping.)

6

7 ATTORNEY GENERAL BLUMENTHAL:

8 Thank you, Ms. Berenson.

9 Judi Bassett?

10 Anyone, by the way, who has left
11 or who has to leave before we reach you, you are
12 welcome, as I've said before, to submit comments
13 in writing.

14 Peter DePaola?

15 MR. DEPAOLA: Thank you. My name
16 is Peter DePaola. I live in Coventry but I work
17 in Middletown, Connecticut. My son had Lyme
18 disease, and that's the story unto itself, but
19 he's one of the lucky ones. After a lot of
20 persuading and cajoling, we were able to get him
21 the services he needed to basically make him
22 disease-free.

23 The reason I'm here today is to
24 talk about it with a little bit different
25 dimension from the conversations you've had from

288

1 patients and from physicians. You see, I
2 represent a company called Chartwell Southern New
3 England. We are a home I.V. provider.

4 Many of the folks behind me are
5 patients. It's our pharmacy that prepares the
6 compound Rocephin. It's our nurses that go into
7 the home and take care of these patients. Last

8 year we took care of about 260 Lyme disease
9 patients. About 5 percent of these patients,
10 about 11, 12 or so, are chronic Lyme patients,
11 and that's where we get into a real dilemma,
12 because their physicians call up and they say
13 they need an extension of services, and the
14 standard regimen is about four weeks.

15 So when we go into that six-week,
16 eight-week, 12-week therapy regimen, we pretty
17 much know it's going to be denied by the managed
18 care company, so we go into appeals but we don't
19 stop servicing our patients, so we end up
20 incurring a lot of expenses.

21 Now, the patients, they have
22 signed financial waivers, they know that they are
23 financially responsible, but in the end what
24 happens is that debt accumulates and we end up
25 getting stuck in the middle, because our job is

289

1 to respond to the physician's requests for
2 services, and that's what we do.

3 So we're there 24 hours a day,
4 seven days a week, we provide the services. We
5 incur the costs of that, and as you know,
6 healthcare is expensive today. Profit margins in

7 this industry are pretty narrow as they are. So
8 what happens is we have a handful of patients
9 that have a lot of expenses. To date we have
10 over \$97,000 worth of unpaid bills that we have
11 to carry, and it's not fair to us as a company,
12 home healthcare as an industry, and it's not fair
13 to the patients.

14 So I guess I'm here to ask for a
15 couple of things. Yeah, we'd like to see some
16 improved treatment guidelines so we are all on
17 the same page, because payment terms vary from
18 payer to payer. I'm not going to fault any one
19 person or any one company, because they all have
20 to operate as best as they see fit, but I'd also
21 like to ask that there be an expeditious appeal
22 process. That's one area that really slows us
23 down. If it takes three, four, five weeks to get
24 an appeal through the organization, we've been
25 providing those services, and we're working with

290

1 the families and with the physician's office to
2 get that appeal reviewed.

3 So if there was a way to speed
4 that process up, we could communicate that back

5 to the patients in a much more timely manner.
6 That would help us understand where we are in the
7 process, and I think it would help the families
8 understand what their financial responsibilities
9 are as well.

10 I'll leave it at that since you
11 have a lot of other folks. Thank you very much.

12 COMMISSIONER REIDER: Thank you.

13

14 (Clapping.)

15

16 ATTORNEY GENERAL BLUMENTHAL: We
17 appreciate your spending the time with us and
18 being so patient and waiting, thank you.

19 Bonnie Friedman.

20 MS. FRIEDMAN: Bonnie Friedman,
21 Trumbull, Connecticut.

22 First of all, I'm grateful for the
23 opportunity to speak before you today. I've had
24 Lyme disease for 24 years. In 1991, I was
25 hospitalized. The doctors told me that they

291

1 ruled out Lyme with what they called the
2 state-of-the-art test called the western blot. I
3 returned home after two weeks in the hospital

4 with no diagnosis.

5 However, four years later my
6 western blot became positive.

7 When my daughter became extremely
8 ill in 1994, we proceeded on the same odyssey for
9 a diagnosis for her, and her symptoms were
10 strikingly similar. Initially my daughter's
11 pediatrician thought she may have Lyme and
12 treated her for two weeks with the antibiotics.
13 When she began to get even sicker, the doctor
14 insisted that it must be something else, because
15 according to Yale's Lyme protocol, she was over
16 Lyme. She had been treated.

17 I trusted this physician and spent
18 the following months waiting for Margot to get
19 better. But her health deteriorated even more.
20 In the months that followed, I searched, read,
21 and talked to people about what was happening to
22 her. The name of a physician who had treated a
23 lot of Lyme patients kept coming up. I was very
24 cautious and wary because I had heard that there
25 were some physicians who were known for

1 overtreating their Lyme patients with too many

2 antibiotics. I was fearful because my daughter
3 was only 18.

4 I thought, what would happen to
5 her in the future if her body got pumped with all
6 these antibiotics? What a responsibility I had
7 before me. Should I submit to this aggressive
8 treatment or should I watch her fade away? I saw
9 her curled up in the fetal position in the
10 darkness and solitude of her room. She could not
11 go anywhere or do anything.

12 Because of the brightness of day
13 to her eyes and the overwhelming exhaustion, she
14 felt prevented her from continuing her studies at
15 college. There would be no life for Margot
16 unless something was done to help her.

17 With great trepidation, we
18 approached the Lyme physician's office. I wasn't
19 sure I was prepared for what he would tell us.
20 We spent the next hour and a half with the
21 physician. He was encouraging, and God, we
22 really needed hope. He suggested that Margot may
23 in fact need to be treated more aggressively than
24 before. He urged her to try some oral
25 antibiotics and see if she would respond.

1 Unfortunately there was very
2 little response, and she continued to be
3 incapacitated.

4 It was then the doctor ordered
5 three months of intravenous Rocephin. We agreed
6 we should go ahead with this plan. At the time
7 my insurance coverage was through Bridgeport
8 Hospital. Because it was an employee-owned plan,
9 it fell into the ERISA guidelines. This means
10 that it was governed by the federal regulations
11 rather than the State regulations, but the plan
12 was administered by Medspan, a Hartford-based
13 insurance company.

14 I could not get Medspan to commit
15 to approving Margot's treatment, and after weeks
16 went by they finally agreed to covering 28 days.
17 As the 28 days were ending, it was very apparent
18 that there had not been much improvement in
19 Margot's health status. My husband and I agreed
20 that we had to find a way to continue her
21 treatment. We were able to hire an I.V. nurse to
22 work independently, she will come weekly to
23 change dressings, and the pharmacy at the
24 hospital helped by ordering Rocephin and selling
25 it to us at their cost. So every 10 days I would

1 write a check for \$600 for Rocephin.

2 The next three months cost
3 \$17,000. Repeated attempts to justify the need
4 for continued coverage through our insurance was
5 futile. Medspan refused. After four months of
6 Rocephin, Margot's condition was somewhat
7 improved. She was now enrolled as a full-time
8 student at Fairfield University.

9 By spring, however, we could see
10 the ever present signs of her illness becoming
11 worse. She was unable to sleep because of her
12 tremendous neck pain. Her joint pain caused her
13 to limp. Her muscles were wasting. She was
14 living in a world of brain fog and cognitive
15 dysfunction. She had anxiety and depression.
16 She told me she felt like life was passing her by
17 and she had dreams of becoming a school counselor
18 and she wondered in fact if she would ever
19 continue college. She was missing the best part
20 of her life.

21 Friends would call and she would
22 have to refuse their invitations. Medspan's
23 refusal was based upon lack of information, they
24 told me.

25 So in the following months Margot

1 was seen by more consulting physicians. By now
2 we had eight letters of medical necessity to
3 present to Medspan in favor of continued I.V.
4 antibiotic therapy. They still refused
5 coverage. They blamed me for the delay because I
6 had given them too much information on Lyme
7 disease and too many letters of medical
8 necessity. They were curt and they were rude.

9 We argued and even pleaded with
10 the vice president of medical affairs. Margot
11 personally spoke with Dr. Cook and he just was
12 rude and blew her off.

13 Again my husband and I continued
14 to cover the expenses for treatment and Margot
15 responded. By now she had dropped out of school,
16 missing another semester. Determined as ever,
17 she registered for fall semester, she struggled.
18 Her energy was low, and her pain high. We
19 returned to the infectious disease physician we
20 had seen earlier, he reevaluated her condition
21 and agreed that even though by now she had gotten
22 nine months of intravenous antibiotics, she
23 needed more.

24 Fortunately, by now our insurance

25 company had changed and we had no further

296

1 difficulty getting Margot treatment. And after
2 five months of Claforan, that doctor felt that
3 there had been enough improvement to stop her
4 I.V. This was in February of last year.

5 For a month or so Margot felt much
6 better than the past. She had adjusted to the
7 fact that some things will probably never go
8 away, she accepted that. If her mind could
9 remain clear and she could complete her degree,
10 she would be happy.

11 On June 14th, after spending the
12 evening out with friends, Margot came home happy
13 and bubbly, just chattering away, when suddenly
14 she began to shake, her back arched and
15 stiffened. I led her to the bed and called 911.
16 By the time the EMS appeared she seemed all
17 right. They took her vital signs and were
18 discussing whether or not she should go to the
19 hospital when she began to seize away and that
20 continued all the way to the hospital.

21 The physicians and nurses at
22 St. Vincent's Hospital in Bridgeport had no
23 understanding of what was happening, even though

24 I told them I felt that the seizures were
25 resulting from Lyme disease. A psychiatrist, two

297

1 neurologists and an infectious disease doctor
2 decided Margot was having pseudoseizures; in
3 other words, they were not real seizures, they
4 were the result of a psychiatric condition.

5 I cannot describe the feelings
6 that I had. I gave the physicians literature
7 about Lyme to educate them. They were not only
8 rude, but they treated me like I needed a psych
9 consult. And by then I can tell you I probably
10 could have used one.

11 I tried to tell them if Margot did
12 present psychically, Lyme disease can cause
13 psychiatric manifestations, and that would mean
14 she needed more treatment. Four days later I
15 took her to her own neurologist and she had an
16 EEG which revealed that she was having complex
17 partial seizures to the temporal lobes.

18 A neurologist at New York Hospital
19 concurred. So in June, in spite of three
20 previous rounds of intravenous antibiotic, my
21 daughter was having seizures from Lyme disease.

22 She was put back on I.V., this
23 time penicillin, and it was administered on a
24 24-hour pump. And within a week the seizures
25 showed remarkable improvement.

298

1 In November the line used to
2 infuse the antibiotic failed, and for two weeks
3 Margot was off I.V. and on orals, and her
4 seizures worsened. It took her months to regain
5 the same level of improvement that she had
6 already gotten after going back on I.V.
7 treatment.

8 It's now February. Margot has
9 been on penicillin for eight months. Her
10 seizures continue to improve, and there is talk
11 of discontinuing the I.V. We are afraid, but we
12 have had to learn to live one day at a time. I
13 applaud my daughter for her courage. She will
14 graduate cum laude from Fairfield U in May with
15 her BA in sociology. She plans to go to graduate
16 school for counseling and school guidance, but I
17 can tell you, if we had not found the
18 compassionate physicians who believed in us, none
19 of Margot's dreams would ever come true. And
20 doesn't she deserve a chance?

21 I am here today to tell you that
22 the drastic -- that there must be drastic changes
23 in the treatment of Lyme disease. Dr. Schoen
24 from Yale, who was here today, refused to
25 establish a balanced forum at the Yale Lyme

299

1 symposium offered every year. Last year I wrote
2 to Dr. Schoen and asked him to include testimony
3 from physicians who were treating a vast number
4 of Lyme patients, and he told me it was too late
5 to change the program, so this year I wrote to
6 Dr. Schoen in November to ask him to include
7 these physicians.

8 So -- he didn't reply, so in
9 January I wrote again. He finally replied that
10 it was too early to discuss it and -- first it
11 was too late, and now it's too early. So I don't
12 really know when the right time is for that.

13 Yale is considered
14 state-of-the-art in teaching. When physicians
15 and healthcare workers attend an accredited
16 conference they are expected to come away with
17 accurate, useful information. Yale is remissent
18 [sic] in providing both. The symposium offers

19 the same 1994 study as new information every
20 year.

21 And by the way, I think Dr. Schoen
22 would be able to tell you that he was talking
23 about the 1998 paper that was written, that's
24 about the 1994 study, it's not a new study. It's
25 a new paper about a 1994 study.

300

1 Last year there was a cry from the
2 attendees for new information that they can use
3 to help their patients. Presenters from the past
4 symposium like Dr. Leonard Siegel from New Jersey
5 charges \$560 an hour as well as Dr. Schoen
6 himself, who I have a bill from 1994 for \$450 an
7 hour.

8 There's a conflict here. How can
9 doctors who are working for insurance companies
10 present at a conference? I mean, it just doesn't
11 make any sense. It serves them to keep insisting
12 that Lyme disease is overdiagnosed and
13 overtreated. It's bottom line-driven, it puts
14 money in their pockets. I can't imagine the
15 insurance companies using these people to consult
16 if they thought that they would suggest that
17 people needed long-term I.V. treatment.

18 Two years ago Dr. Schoen opened
19 the conference by displaying a portrait of a
20 family with Lyme disease on his overhead
21 projector. He stated in a joking fashion, look
22 at this family, they are all smiling, I guess
23 they are over it now. Well, the audience
24 laughed. I can't imagine going to a conference
25 on cancer where a spokesperson would get away

301

1 with making a joke about such a tragic illness.

2 Maybe Lyme isn't cancer but many
3 live a life of suffering, both mentally and
4 physically. They are robbed of a future, and
5 yes, sometimes they die. Is that something to
6 laugh about?

7 Another thing I would like to see
8 happen is making insurance companies responsible
9 for the denial of care of Lyme patients. Last
10 month I was able to recover my costs for Margot's
11 treatment. It took four years in suing
12 Bridgeport Hospital and Medspan. They really
13 lost nothing. They got to keep my money for four
14 years and collect interest. Even if we got most
15 of our money back, they still won. There are no

16 punitive damages for them to worry about.

17 Also, aren't HMOs practicing
18 medicine? How can they make a medical
19 determination without first examining the
20 patient? In our case Medspan hired two
21 infectious disease consultants from Hartford
22 Hospital. Medspan and Hartford Hospital, by the
23 way, are jointly owned.

24 Dr. Quintilano and Matarazza
25 [phonetic] were hired to give independent

302

1 consults, and yet their consult letters reflect
2 that they shared information with one another.

3 Dr. Quintilano suggested in his
4 letter that a PCR test should be done, and yet a
5 PCR test was done and the results were in the
6 hands of Medspan, so either Medspan was negligent
7 in providing the consultants with the information
8 but they withheld this information deliberately.

9 Our biggest obstacle is the
10 future. Right now our insurance has been
11 extremely cooperative, but what will happen next
12 year, or in five years if Margot needs more
13 treatment? Must I live in fear that coverage
14 will be denied? I cannot allow her to go without

15 treatment, but it's unrealistic to believe that I
16 can afford to provide ongoing I.V. treatment.
17 I'm still suffering the consequences of Lyme
18 disease myself, and yet I have to go back to work
19 to provide for her care. No one who is sick and
20 pays insurance coverage should ever have to worry
21 about paying for needed treatment.

22 Another grave concern is
23 protecting our physicians who treat us and give
24 us hope. There are cases of physicians who have
25 been scrutinized for overtreating with

303

1 antibiotics. If patients are receiving informed
2 consent regarding the pitfalls of aggressive
3 treatment for Lyme, our physicians have done
4 their jobs. It is no one else's business when a
5 patient makes a decision in his or her own care.

6 I applaud these physicians. It
7 takes great courage to take the chance of getting
8 called on the carpet. They are risking their
9 careers for standing up for what they believe
10 in. Without them we are left without hope and in
11 suffering.

12 It's important to protect them so

13 that they can protect us and Margot.

14 MISS FRIEDMAN: I just have one
15 thing to say. I just wanted to say that it's bad
16 enough that having Lyme robs you of your health,
17 but having to fight your insurance company while
18 you are sick robs you of your sanity and your
19 dignity. I am extremely fortunate to have
20 wonderful parents who not only consistently
21 support me emotionally but financially as well.
22 What do people do if they can't afford
23 treatment? Well, they end up either on
24 disability in a nursing home, a psychiatric
25 hospital, or even worse, they die.

304

1 I can't even explain the guilt
2 that is harbored when you know your parents can
3 barely make ends meet because they have to pay
4 for antibiotics, that they cannot save for their
5 retirement or that their dream of providing me a
6 college education would be shattered if I
7 continue to need treatment that would not be paid
8 for by my insurance company.

9 I desperately worry about what my
10 future holds for me. I am 22, I have a lot of
11 living to do. Will I always be disabled with

12 chronic Lyme disease? Will I always have
13 seizures? Will I be able to have a career and
14 raise a family? These are answers God only
15 knows, but I can tell you that none of my dreams
16 will come true if I don't have access to
17 treatment.

18 Unfortunately, my fate is in my
19 insurance company's hands. Our fate is in your
20 hands. Please protect our wonderful doctors who
21 so bravely treat us for as long as they feel is
22 necessary to for us to recover. And protect us
23 from insurance denial for coverage. Thank you.

24

25 (Clapping.)

305

1

2 COMMISSIONER REIDER: Thank you
3 very much.

4 ATTORNEY GENERAL BLUMENTHAL:
5 Susan Sinclair and Andrea Sinclair.

6 MS. SUSAN SINCLAIR: Good
7 afternoon, and thank you very much for holding
8 this hearing.

9 You know, I feel as if I could say

10 ditto. Thank you.

11 My name is Susan Sinclair and my
12 17-year-old daughter, Andrea suffers from Lyme
13 disease and has for the past five years.
14 Throughout elementary school and into middle
15 school, Andrea was extremely active and an
16 involved little girl. She was a straight A
17 student who would stay up all night reading and
18 working on projects. She enjoyed the gifted and
19 talented program through the school district,
20 Girl Scouts, playing on soccer and basketball
21 teams, dance classes, gymnastic classes, art
22 classes, and in the third grade she started
23 playing the trombone, which is now the love of
24 her life.

25 Andrea maintained a near perfect

306

1 attendance record, only missing one or two days
2 of school each year through her 7th grade year,
3 and enjoyed a very full social life from a very
4 young age.

5 In the fall of Andrea's 8th grade
6 year, she awoke one morning with an extremely
7 engorged right knee. Testing of the synovial
8 fluid and subsequent blood work led to a Lyme

9 disease diagnosis. Andrea was placed on 30 days
10 of an oral antibiotic with a reassurance from our
11 pediatrician that the oral antibiotic...

12

13 (Tape ended, begin new tape.)

14

15 MS. SUSAN SINCLAIR: ... The
16 swelling in her knee went down; however, she
17 continued to complain of joint pain. She became
18 tired easily and complained of feeling nauseous
19 often. By December of 1995, Andrea complained
20 almost daily about her health. Now in her first
21 year of high school, in advanced placement
22 classes, she began to struggle to complete the
23 most simple homework tasks on a consistent
24 basis. Always organized, she now had become
25 disorganized, forgetful, and unable to finish her

307

1 through to the end of a class assignment and
2 projects.

3 Simple writing tasks became
4 painful. She was often extremely fatigued and
5 nauseous. A local rheumatologist ordered blood
6 work, which revealed a Lyme infection, and

7 ordered 30 days of I.V. antibiotic.

8 Andrea felt slightly better during
9 this 30-day round of treatment, but after the
10 treatment stopped, Andrea became significantly
11 worse. Now, in the spring of her freshman year
12 in high school, Andrea's grades dipped from A's
13 to C's and D's, and she attended school
14 erratically.

15 By May of 1996, Andrea was not
16 able to get out of bed. Her symptoms now
17 included excruciating headaches, extreme joint
18 pain, nausea, vomiting on a daily basis, extreme
19 dizziness, extreme irritability, an inability to
20 sleep, light sensitivity, and I could go on and
21 on.

22 Not only could she not go to
23 school, but she declined phone calls from
24 friends. The same bright, ambitious girl who
25 would bend my ear for hours describing the

308

1 challenges of the school project, now articulated
2 daily physical pain and frustration.

3 Her doctor was baffled, and
4 because she had received the standard forms of
5 treatment, had referred her to Yale's Lyme

6 disease clinic. And Dr. Schoen.

7 I can remember thinking, how great
8 it was that we were going to be seen at Yale's
9 Lyme clinic, and that Dr. Schoen would be able to
10 get to the bottom of this and take care of
11 everything, and that finally Andrea would be
12 fine. In fact, my exact words to Andrea was, we
13 were driving down there were, "If Yale can't help
14 you, nobody can." This was truly our great
15 medicinal hope.

16 At that time, we took Andrea to
17 Dr. Schoen, literally the previous month -- I'm
18 sorry -- at the time we took Andrea to Dr. Schoen
19 and Yale's Lyme disease clinic, Andrea was barely
20 able to get out of bed with excruciating joint
21 pain, having missed literally the previous month
22 of school, unable to hold down food, unable to
23 sleep, she had problems with her eyesight, a
24 chronic, excruciating headache, but hopeful that
25 perhaps Dr. Schoen would know or could understand

309

1 what was wrong with her, the extent of her
2 suffering, and be able to do something to provide
3 her with some sense of relief.

4 Let me remind you that Andrea had
5 attained a near perfect attendance record in
6 school up to 7th grade. Once in fourth grade
7 this girl cried because she had to stay home with
8 the flu.

9 Dr. Schoen examined Andrea and
10 ordered blood work. And on the return visit,
11 Dr. Schoen explained to us that Andrea, although
12 she was seropositive by Yale standard and with
13 active symptoms, was suffering from post-Lyme
14 fibromyalgia, and that she no longer had an
15 active Lyme disease. And in time, he explained,
16 most of her remaining symptoms would go away.

17 Andrea, for all her love of school
18 and life and friends, but who couldn't get out of
19 bed, he said had to be more active. Dr. Schoen
20 said perhaps swim every day to alleviate her
21 joint stiffness and tire her out so that she
22 could sleep nights. And then Dr. Schoen
23 suggested that perhaps Elavil would help. His
24 comments too included that Lyme disease in
25 teenagers does go away.

310

1 Well, if Dr. Schoen was still
2 here, I must say that as a school teacher in New

3 Britain, I would levy the most, the greatest
4 admonishment that I could think of. Shame on
5 you, Dr. Schoen, wherever you are now. Shame on
6 you!

7

8 (Clapping.)

9

10 MS. SUSAN SINCLAIR: By December
11 of 1997, Andrea had become barely functional, her
12 symptoms were more severe and staggered. The
13 worst part was Andrea now articulated a why
14 bother attitude. No one knew the personal,
15 physical, and emotional health she was enduring,
16 and if Yale couldn't fix her, nobody could. No
17 one could do a thing for her.

18 Every day she tried to get up and
19 go to school on time and could not. Every day
20 she tried to read and by the end of a sentence
21 she couldn't remember the beginning of the
22 sentence. If she fell asleep she was awakened by
23 violent nightmares and by her screams in the
24 middle of the night. The list of her symptoms
25 were staggering and horrific. School success and

1 an active school life were distant memories, and
2 now at 16, a part-time job and a driver's license
3 was a pipe dream.

4 Keep down food was a real
5 challenge. By luck and by chance we were blessed
6 with Dr. Jones' phone number, and although Andrea
7 clearly felt he couldn't do anything to help her,
8 she went. One year ago, March of 1998, Andrea
9 began I.V. antibiotics and has continued to this
10 day. Although she has not seen complete
11 resolution of all her symptoms, Andrea has her
12 life back, and the hope of a life back too.

13 Although Andrea is on partial
14 school day, she does attend regularly, and she's
15 planning to go away to college this fall. She
16 may need to bring her I.V. with her. Some days
17 she feels so good that she talks about getting
18 her license. And her grades are back on the
19 rise.

20 Andrea knows she needs her I.V.
21 medication. There have been a few times when she
22 has had to go off and she has relapsed
23 horrifically. I have a 17-year-old who wants to
24 give herself I.V. injections daily. In March of
25 1998, our insurance company, Anthem/Blue Cross

1 and Blue Shield, approved 28 days of her I.V.
2 therapy. They knew after 28 days that she'd be
3 cured because they approved 28 days before she
4 even started. And as I was told, they only have
5 my daughter's best interests at heart.

6 Despite clinical data and dozens
7 of studies shown that four weeks of antibiotic
8 therapy gives incomplete resolution of symptoms,
9 insurance companies are advocating with the
10 support of Yale Lyme study and inappropriate
11 standard of cure, a cure by the clock.

12 Remember, Andrea was told by
13 Dr. Schoen that she had received the standard
14 course of treatment, and her symptoms, although
15 present in seropositive blood work, would
16 eventually go away.

17 There are multitudes of patient
18 studies. Clearly Andrea's own medical history
19 provides us with the knowledge that a cure by the
20 clock is inappropriate, and that prolonged and
21 aggressive I.V. therapy is appropriate.

22 Anthem/Blue Cross and Blue Shield
23 has ignored the fact, and the documentation that
24 she continues to improve.

25 Very briefly, I'd like to address

1 costs. As I mentioned, I work for the school
2 district in New Britain. I'm a 7th grade
3 teacher. My time off to take care of my daughter
4 has cost the school district since March of 1998,
5 \$4,620. The cost to Southington School District
6 where my child goes to school for homebound
7 instruction has cost \$6,400 anticipated to the
8 end of June of this year.

9 Our personal debt for Andrea's
10 I.V. therapy since April 9th, the last day that
11 Anthem/Blue Cross and Blue Shield approved
12 payment is \$40,000. That total cost of those
13 three factors is \$50,000, to date. Anthem/Blue
14 Cross and Blue Shield has paid \$5,600.

15 In closing, the most common
16 question I get asked from well-intended friends
17 is why isn't the insurance company paying? I
18 don't know. I don't know. They pay for my mom's
19 diabetes medication. There's no hope for a cure
20 and no one would argue or even question the
21 medical necessity of her diabetes medication, nor
22 her blood pressure medication, for that matter.

23 They paid for my son's antibiotics
24 for acne when he was younger. They paid for my
25 friend's medication for MS with no hope for a

1 cure and no knowledge of the origins of this
2 horrific disease. I don't understand at all why
3 Andrea is denied treatment that clearly has
4 halted her horrific spiral down, which I
5 described to you.

6 I don't understand why Andrea's
7 treatment, which clearly prevented her from a
8 very real and near certain possibility of never
9 being able to pursue her education, live a normal
10 productive and independent life, is being
11 denied. If Andrea needed chemotherapy, as I
12 believe somebody else had mentioned, I wouldn't
13 be here.

14 Our fight is ominous. It's a
15 fight for credibility, treatment, simple
16 compassion, integrity, peace of mind, wellness,
17 until a cure is found. And it's a fight for
18 financial security too.

19 Let me reassure you, Lyme disease
20 does exist and it may become chronic. Lyme
21 disease is not always cured by the clock. Lyme
22 disease can be life-threatening, and not treating
23 Lyme disease is nothing less than criminal.

24 Thank you.

25

315

1 (Clapping.)

2

3 ATTORNEY GENERAL BLUMENTHAL:

4 Andrea.

5 MISS SINCLAIR: Good afternoon. I

6 have a bit to say but I think it's important to

7 hear from the kids who are suffering from Lyme

8 disease because there are tons of us.

9 I stood on the Capitol steps nine

10 months ago and spoke about my struggle with

11 Lyme. I shouldn't have to be here again. I've

12 lived through five years of hell, five years of

13 being diagnosed with everything under the sun and

14 being told to live with it. Five years of being

15 out with friends and passing out or getting too

16 sick and ruined the night's plans, five years of

17 being through times where I couldn't write my

18 name.

19 In 8th grade I was diagnosed with

20 Lyme. I'm now a senior in high school, and I'm

21 on the road to being better, but I still have a

22 ways to go. If insurance companies are so sure

23 that the treatment from my doctor is so
24 phenominally wrong, is somehow wrong, then what
25 do they suggest I do? What do they suggest that

316

1 my parents do when I wake up blind or when my
2 joints are swollen to the point that I could be
3 mistaken for elephantitis? When the room won't
4 stop spinning?

5 Explain to me and the colleges
6 that I apply to why I went from being a straight
7 A student until I got Lyme and then my grades
8 plummeted.

9 Dr. Jones had the answers for all
10 of these. But insurance companies say to see
11 other doctors. Trust me, I've seen my share.
12 I've seen Yale's so-called "Lyme specialist."
13 I've seen rheumatologists, I've seen
14 neurologists, and still insurance isn't paying.
15 And by the way, 28 days of oral antibiotics
16 didn't scratch the surface.

17 What should we do? I'm a high
18 school senior, and while all my classmates are
19 trying to finance their college education, I'm
20 trying to finance my medicine and going to school

21 in the fall.

22 Responding to the accusations of
23 the inappropriate treatment of Lyme disease, the
24 only inappropriate treatment I've received is
25 that of Dr. Schoen and all the other doctors who

317

1 told me I didn't have Lyme disease because I was
2 cured after 28 days of oral and I would have to
3 live with whatever I had.

4 Dr. Schoen's diagnosis, along with
5 others, left me with nothing. I would have had a
6 life full of pain and agony and I wouldn't live
7 with that. If you treat the disease, you win --
8 you lose. If you treat the patient, you win.
9 Dr. Jones has won in both respects. He has
10 successfully treated Lyme disease and he has
11 healed the parents of his patients also. I'm
12 very sorry to hear that he has cost the poor
13 insurance companies too much.

14 I love Blue Cross's motto, "Our
15 plan is to keep you healthy." They should really
16 change their motto to our plan is to keep you
17 healthy at your own expense and without your
18 doctor.

19

20 (Laughter.)

21

22 MISS SINCLAIR: I sit here today
23 among many kids infected with Lyme. It is a
24 living hell for all of us. We should only have
25 to worry about getting better. We shouldn't have

318

1 to worry about the financial strain we're putting
2 on our parents and siblings. Our parents should
3 only be worried about being our caretakers, not
4 our insurers, and we should never have to fear
5 that the only doctor who is making us better is
6 being taken away.

7 I've been on I.V. antibiotics for
8 a year now continuously, and on the way to
9 getting better. I don't enjoy giving myself
10 needles on a daily basis, but it's making me
11 better. If I wasn't undergoing this treatment,
12 who knows where I would be today. But it is this
13 extended treatment that has made it possible for
14 me to speak today.

15 The bottom line is things have to
16 change. Children and adults can no longer be
17 going without the treatment due to ignorant

18 doctors and cheap insurance companies. The
19 future of this country is being destroyed. We
20 are here, we are sick, and we need to be
21 treated.

22 Thank you for your time and
23 patience.

24

25 (Clapping.)

319

1

2 COMMISSIONER REIDER: Thank you
3 very much.

4 ATTORNEY GENERAL BLUMENTHAL: Let
5 me ask, how many more people wish to testify?
6 Can you raise your hands? So we still have a
7 considerable number. Let me suggest that we all
8 want to hear certainly from all of you and again,
9 we want to be very respectful of that, but I do
10 notice that a number of people have had to leave
11 during the time. I would just suggest if you do
12 have to leave, would you leave whatever written
13 testimony at the desk, which a number of you have
14 done?

15 Also if you want to write
16 something to the Attorney General or to the

17 Insurance Department then you certainly may do
18 that as well. I would ask, and as you hear
19 testimony, it can become something that has been
20 spoken to, if it has been spoken to already, if
21 you could acknowledge that and then move to the
22 points that you'd like to make, we'd appreciate
23 it.

24 And again, I was chair to the
25 council in Farmington, Connecticut, and conducted

320

1 a number of town meetings and you want to keep
2 the balance. So as I said, out of respect to
3 everyone here, if we can move it, we'd appreciate
4 it.

5 So with that, I would like to call
6 the next person, which I believe is Robin
7 Prewitt. Robin, are you still here? Yes.

8 MS. PREWITT: Hello. I'm Robin
9 Prewitt and I live in Milford, Connecticut, and
10 I'm going to be very, very brief. I just want to
11 address something that I'm not sure has been
12 addressed to the magnitude in which it is a
13 problem here in Connecticut, and that is the
14 issue of initially getting diagnosed.

15 It took me three years to be
16 diagnosed. I had the telltale rash, I had the
17 flu-like symptoms, and my physician, my primary
18 care physician at the time, all PHS physicians I
19 should say, I was told that it was probably a
20 spider bite or a bug bite, and that it was a
21 viral infection and that it would go away. And
22 true to Lyme disease, the symptoms wax and wane
23 and come and go, and it did go away, and from
24 that point forward, my life has been changed
25 forever.

321

1 Like I say, it took three years, I
2 was very ill. I have since lost my job.

3 Another issue that I would just
4 like to mention is problems with discrimination
5 of employers when a person gets Lyme disease and
6 has to go out on disability leave. I am since
7 not back at work and I just wanted to make those
8 points. And I am on disability now and am unable
9 to work. Thank you.

10 COMMISSIONER REIDER: Thank you
11 very much. Appreciate that.

12

13 (Clapping.)

14

15

ATTORNEY GENERAL BLUMENTHAL:

16

Joanne Sturges is next. Joanne?

17

MS. STURGES: I know you said to

18

us that you wanted to not repeat a lot of the

19

things that people have said, so I'll try not to

20

do that, but I think all our concerns are very

21

much all of ours; everyone has the same concern.

22

COMMISSIONER REIDER: May I just

23

comment there if I may? I certainly recognize

24

that fully, and as I said, that's the point we're

25

trying to allow people to express. But to the

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1

extent that as many of you can be heard as

2

possible --

3

MS. STURGES: I understand.

4

COMMISSIONER REIDER: -- it's

5

important, and that's what we are trying to get

6

to. But we appreciate it, you go right ahead.

7

MS. STURGES: First of all, I

8

really would like to thank everyone here,

9

including the doctors and the supporters that

10

came. Especially for you to even set up this

11

meeting, because I feel that it restores our

12 faith to the government, that it does represent
13 the voters and the people and not necessarily the
14 insurance companies.

15 My name is Joanne Sturges. I live
16 in East Lyme, Connecticut. I'm married, I have
17 two beautiful children. We come from a long line
18 of hard-working, trustworthy social caring
19 families. As a matter of fact, many of the
20 people in the government know my father-in-law,
21 Ralph Sturges, the Chief of the Mohegans, and
22 have worked very closely with him.

23 Five years ago I was infected with
24 Lyme disease. Prior to being diagnosed or
25 infected with Lyme disease, I was a very active

323

1 person. I was a physical therapist, I worked one
2 full-time job, one part-time job. I worked out
3 two to three times a week and ran every morning
4 seven miles. But Lyme disease changed my life.

5 My joints became swollen, there
6 were a large -- great deal of neurological
7 complications and cardiac complications. After
8 going from physician to physician prior to the
9 recommendation of having the valves of my heart
10 removed, I then found Dr. Phillips, who has been

11 a godsend. I am no longer -- after being treated
12 with long-term antibiotics -- I'm making it very
13 short but I haven't been seen in quite a while.

14 COMMISSIONER REDIER: Sure.

15 MS. STURGES: I am no longer on
16 any cardiac medications. I can do a flight of
17 stairs without passing out, without having a
18 heart attack. At age 37 you should not be having
19 heart attacks. He has been fabulous.

20 In this nightmare, also my
21 12-year-old son became very ill. He also was
22 very, very active and all of a sudden was
23 complaining of severe headaches, swollen joints,
24 light-headedness, hot flashes. I took him to the
25 pediatrician, and this -- at this time was going

324

1 on before we met Dr. Phillips. I took him to the
2 pediatrician, his titer was negative. He
3 continued to become worse. We continued to treat
4 him.

5 Within three months, he lost the
6 ability to talk, to walk, no memory whatsoever.
7 Visual impairment. He had just tunnel vision,
8 that's it. Again, the night sweats, not being

9 able to sleep, his glands along his neck were so
10 swollen shut I remember one Christmas morning
11 using a straw trying to get juice. That's not
12 how you should celebrate your holidays.

13 His physician said to us he cannot
14 have Lyme, his titer was negative. Just prior to
15 him coming down with the disease -- I just want
16 to tell you something that he surprised his
17 grandfather during the federal revolution of the
18 Indians.

19 During a celebration, he learned
20 the ancient Mohegan dance, and the purpose of the
21 wishes of this dance was to teach people that all
22 people, no matter who they are, no matter what
23 nationality, they are all one on earth and
24 everyone should live long lives of happiness and
25 health. And ironically, he was now fighting for

325

1 his life.

2 Again, many physicians, Blue
3 Cross/Blue Shield denied treatment, denied
4 further testing to be done, everything. We went
5 to Dr. Jones, Dr. Jones, we believe saved our
6 son's life. For the courage that he took to
7 fight the nonbelievers, to continue to

8 investigate what was wrong with our son and to
9 continually try to fight Blue Cross/Blue Shield.

10 Blue Cross/Blue Shield finally, after
11 hospitalization of Jess, because he was too
12 unstable cardiacally [phonetic] to be at home,
13 rented I.V. treatment, 28 days. Within 10 days
14 of being on the I.V., his symptoms were getting
15 less and less. He had regained the ability to
16 open his mouth, his glands were no longer
17 swollen. He regained the ability to walk short
18 distances. He was coming along. We finally saw
19 our son back.

20 Then Blue Cross/Blue Shield upon
21 constant requests from our physicians, from other
22 physicians we jumped through every loophole they
23 requested of us, and they denied treatment. They
24 refused to give us an explanation. If they
25 denied treatment they should never, ever not give

326

1 someone an explanation and back their explanation
2 up with facts. They are dealing with human
3 beings.

4 Because over the 20 years of
5 having Blue Cross/Blue Shield, paying my payments

6 every two weeks, never have they ever denied my
7 check. We fought them and fought them. Finally,
8 on the second denial, he was denied even though
9 he showed proof in tests that he was getting
10 better.

11 We continued the I.V. on a
12 financial burden of our own. We mortgaged our
13 home. He continued to show improvement and they
14 denied it again. They said after 28 days,
15 quote-unquote, we have it in writing, "He should
16 be cured."

17 We continued to appeal. Jessie
18 continued to get better. Finally the government
19 stepped in, the federal government, Indian Health
20 heard of our situation and came to our rescue,
21 thank God, and they started paying present
22 medical bills.

23 We still went through appeals with Blue
24 Cross/Blue Shield because we feel that not
25 everyone has that as a backfall and it's just a

327

1 grant. On the third appeal they denied Jessie
2 further treatment of I.V.s based on the fact that
3 our son did not have Lyme disease. He had
4 juvenile MS.

5 This medical information or
6 diagnosis was come up with without evaluating our
7 son, without reviewing his medical records,
8 because we were paying for them financially, so
9 they had no access to them unless they asked.
10 But they were provided with -- you can see the
11 brain SPECTs, you can see the spinal fluid. You
12 can see his evaluations. But with no medical
13 expertise per se, we felt that it was totally
14 unethical, unprofessional, as well as devastating
15 for our family to be told this without any
16 backup. That was our last denial.

17 We continued with I.V.s for Jessie
18 for months. We incurred over \$80,000 in bills,
19 not counting what Indian Health has helped us.

20 Jessie, back at school, playing,
21 playing basketball, playing baseball, is doing
22 wonderful. He was then put on, by Dr. Jones, a
23 small, a lower dose of oral antibiotics. He did
24 great for six, seven months and then a relapse.
25 We're at that relapse right now.

328

1 He is no longer able to walk, he
2 can't do stairs. He is having a hard time

3 opening his mouth, the same nightmare is
4 occurring as we speak. We have been dealing with
5 Blue Cross/Blue Shield for just a denial. We're
6 not even asking them to pay for it. We want in
7 writing at least a denial so we can now go to
8 Indian Health and provide our son with the
9 medical care that this civilization should be
10 able to provide.

11 There's nothing worse in life,
12 other than maybe losing your child, but to see
13 them slowly slip away from you when you know
14 there's a treatment and there's a way that he
15 could get better.

16 They have verbally told Indian
17 Health, a representative from Mohegan Sun, that
18 yes, they will help us. This has been nine
19 weeks, so if you would like a project,
20 Commissioner, I would love for you to take this
21 on.

22 COMMISSIONER REIDER: I was going
23 to ask you, why don't you, if you would --

24 MS. STURGES: I did submit
25 everything.

1 COMMISSIONER REIDER: Okay. And

2 if you'd -- I'll come down and I'll get your name
3 and address --

4 MS. STURGES: I would love it. I
5 would love it.

6 COMMISSIONER REIDER: -- and
7 telephone number and we'll follow that up.

8 MS. STURGES: Well, indeed, they
9 have said to Indian Health they will help us, but
10 when the I.V. company called them to verify their
11 approval, they denied it. When we called them to
12 verify it, they denied it. So we have for nine
13 weeks, including our doctor calling, including
14 Indian Health calling, they have completely
15 ignored us.

16 We have met with them in person
17 just two weeks ago, and I have that
18 representative from Blue Cross/Blue Shield and
19 they said oh, no problem, we'll -- put it in
20 writing because we need it in writing in order to
21 get help.

22 And I think what's happening is
23 they are playing a very political game. I think
24 they don't want to lose the Blue Cross/Blue
25 Shield contract with Mohegan Sun. And I think

1 that it is horrible to think that they could put
2 people's lives more ahead of the almighty
3 dollar.

4 What's more important, the benefit
5 of the treatment or the benefit of the profit
6 margin? And I feel that's exactly what is
7 happening.

8 Now, in the last four months, our
9 daughter became very ill with symptoms,
10 complaining of swollen joints, fatigue,
11 headaches. We immediately called Dr. Jones, we
12 took her up there. While waiting for the -- what
13 ended up being positive Lyme test results, she
14 awoke with complete facial paralysis, no vision,
15 no balance. So now we have two that we are
16 fighting for, and if you really want to do
17 something, you need to make these insurance
18 companies responsible.

19 Dr. Jones, before he was dropped,
20 was an in-network doctor, and they refused to
21 accept his decision. We went through the
22 neurologist they recommended, they also said our
23 son needed the treatment. They again denied it.
24 They shouldn't be able to. If you have in all
25 honesty paid for your policy, they should pay for

1 it. Is it better that we all go on welfare?
2 Would we maybe have to go through these loopholes
3 that insurance companies present us? I don't
4 think so.

5 Another thing that they have just
6 recently denied is the treatment of Nephron for
7 Lyme disease. Both my son and I are on that.
8 Nephron has worked wonderful for our type of
9 disease. When I spoke with Blue Cross/Blue
10 Shield, they have denied Nephron treatment now,
11 which is an oral antigen, it's new, and it's
12 expensive is the bottom line.

13 When I asked why was this disease
14 denied, they said once a year they audit all
15 treatments and all physicians and all tests and
16 they take what tests, treatment, or antibiotics
17 or any kind of medication, whatever is showing
18 the highest rise, and they audit. And if they
19 can show you they can supply you with another
20 type of similar medication, whether it works for
21 you or not, they can. And I don't think they
22 should be able to.

23 What I'm asking and I'm begging,
24 is that you really will take this situation
25 seriously and deal with these medical insurance

1 companies and help these people get proper care.
2 Lyme disease is here to stay and it's not a
3 fantasy as much as it's a nightmare.

4 I also feel, like I had said
5 earlier, if they deny you, they should give you
6 the right -- why have they denied you, and put it
7 in facts, back up their denials. We have to back
8 up why we are claiming we want the treatment, so
9 why shouldn't they reciprocate?

10 I also feel these insurance
11 companies should not be allowed to drop these
12 physicians who prescribe long-term antibiotics or
13 long-term care for Lyme disease. Is it another
14 obstacle so patients can't now get that?

15 I also think, as someone had
16 mentioned earlier in New Jersey, there is a law
17 for continued education in the school system for
18 Lyme disease. If a teacher has a student that
19 has neurological Lyme, they have to show that
20 they have continued education to use, course
21 hours that they can adequately teach that child
22 because of the neurological complications,
23 short-term memory, word retrieval, reversals,
24 things like that.

1 required to become knowledgeable in this? And
2 whether they ever -- a group practice, send one,
3 I don't care, but they need to be accountable for
4 the knowledge. This is out there and readily
5 available.

6 And I also feel that there are so
7 many people with a wealth of information on Lyme
8 disease, and let those people be part of the
9 decision-making on grants, who gets the grants
10 for education on Lyme and who doesn't? It would
11 save you money, and you would get to the end of
12 this cure and treatment faster.

13 And again, I really, truly want to
14 thank you very much for having us.

15 COMMISSIONER REIDER: Thank you
16 very much.

17

18 (Clapping.)

19

20 COMMISSIONER REIDER: Jennifer
21 Krasinski. I'm going to have to ask, I hate to
22 do this, but we're just not going to make it

23 through this list unless people are a little bit
24 more concise, so we appreciate all your comments,
25 and if you want to supplement them afterward, we

334

1 would welcome you to do so.

2 MS. KRASINSKI: Thank you very
3 much for allowing me to speak, and thank you so
4 much for holding this. I am Jennifer Krasinski.
5 I was born in Connecticut, but at this moment I
6 hale from Mountain Lake, New Jersey, kindly known
7 as Lyme Lakes or Mountain Lakes.

8 I'm going to be very brief. I
9 won't go into my own story, my children's
10 stories, they are very much the same as the ones
11 you've heard. But I will share a little story
12 that happened here today.

13 In 1994, there was an article in
14 The New York Times which Dr. Feder referred to
15 which I also saw, and shortly thereafter I was
16 lucky enough to meet the doctor, the pediatric
17 neurologist, that had been charged with these
18 discretions of overtreating and overdiagnosing,
19 and I began to learn some facts which horrified
20 me.

21 Number one, that the records that

22 the CDC had used to define whether or not these
23 children had Lyme were at best incomplete, they
24 were simply the hospital records.

25 Number two, several of the

335

1 children, three or four, I believe, who were
2 included in this study were in fact on I.V.
3 antibiotics but were not diagnosed, nor were they
4 being treated for Lyme. This was an egregious
5 error.

6 And so subsequently I called
7 Dr. David Dennis at the Centers for Disease
8 Control. With much persistence, I was able to
9 speak with him directly, and I asked him about
10 this situation, and he informed me that they were
11 well aware of these mistakes, and that they had
12 published a follow-up study which made a
13 correction.

14 I then called the author of The
15 New York Times -- of this article, and I talked
16 to her about what I had learned and asked her if
17 I sent her this article, which Dr. David Dennis
18 sent to me, would she publish a follow-up story?
19 Her answer to me was no, she would not, not

20 unless Dr. David Dennis contacted her and asked
21 her to.

22 I then called Dr. David Dennis
23 back and I asked if he would please do this, and
24 he said to me, I do not have time for this. And
25 that's the end of my story.

336

1 I think you'll understand that
2 there are games here that are being played.
3 Thank you so much.

4

5 (Clapping.)

6

7 ATTORNEY GENERAL BLUMENTHAL:

8 Kathleen Dickson.

9

MS. DICKSON: Hi. I first would
10 like to thank Tom and Karen Forschner for the
11 sacrifices that they have made and that have been
12 put upon them in their efforts to help other
13 people with this disease and towards its
14 prevention, and we are grateful for this
15 opportunity to explain the problems we have been
16 having getting accurate diagnosis and treatment.

17 In my opinion -- this is my
18 opinion of where we are with this disease and

19 where we should go. The nature of the problem,
20 it generally starts like flu, there is no better
21 or more accurate description, only this flu never
22 leaves. Lyme disease leaves us sick for weeks
23 and months and years. Only fellow sufferers of
24 Lyme disease and chronic fatigue syndrome
25 understand what this means. People who have not

337

1 been sick for longer than a few days with the flu
2 have difficulty understanding this concept.

3 People who have Lyme disease are
4 often misdiagnosed. The average number of
5 doctors a patient sees before diagnosis is five.
6 Without treatment, encephalopathy can become so
7 severe that the symptoms mimic Alzheimer's
8 disease. We forget why we are in the car driving
9 and not know what road we're on.

10 Extremely frequent checkbook
11 errors, kitchen fires, lost articles of every
12 kind, loss of the ability to speak fluently,
13 sudden loss of emotional stability, inability to
14 remember from one second to the next what we were
15 doing and what we had done, it is a genuine
16 mental disability and in no way subtle.

17 The extent of inflammation of the
18 brain and nervous system is well documented in
19 autopsy studies and in studies in which Rhesus
20 monkeys were infected with *Borrelia burgdorferi*.
21 The longer one goes undiagnosed, the longer it
22 takes to improve and the less likely one will
23 recover fully.

24 My personal Lyme story is I got a
25 Lyme rash, it was symptomless. I took a picture

338

1 of it because it was weird to have a rash that
2 didn't itch or yield any discomfort. It was warm
3 and red and radiated. I forgot about the
4 picture. I got a summer flu, but it never went
5 away completely.

6 I kept working and working out and
7 riding centuries [phonetic] and training for a
8 triathlon, but I just got sicker and sicker. I
9 thought I had chronic fatigue syndrome. I
10 explained this to my family doctor in Milford and
11 listed my symptoms. He told me that there was
12 nothing wrong with me, to please leave his
13 office.

14 I went to UConn Health Center and
15 saw Dr. Peter Mineo [phonetic] Who, despite my

16 presenting with fever and swollen glands and my
17 insistence that I was not depressed, concluded
18 that I was depressed. Endurance athletes are
19 generally not depressed.

20 He never ran any tests, and there
21 was a journal on his desk, psychosomatic
22 diseases, in which he published his conclusion
23 about SEFITS [phonetic]. His subjects were
24 female UConn students, and based on survey
25 interviews, he concluded that SEFITS [phonetic]

339

1 was depression, and anybody that asked college
2 students if they are tired and feeling
3 overwhelmed is, in my opinion, no genius. I did
4 not stay with Dr. Minew [phonetic].

5 I called the SEFITS [phonetic]
6 people to ask their recommendation about having a
7 baby. They told me there was no data but
8 anecdotal. It appeared to be okay. I had two
9 kids, which is brutal when you have the flu all
10 the time, but I didn't regret it. It was a
11 question of do I want to be sick the rest of my
12 life with or without kids, since there is no cure
13 for SEFITS [phonetic].

14 The SEFITS [phonetic] people told
15 me about a doctor in Glastonbury who treated
16 SEFITS [phonetic] people as if they were
17 seronegative Lyme disease. I made an appointment
18 as soon as possible, because the prospect of
19 having a treatable illness was much more
20 desirable than being sick the rest of my life.

21 When I saw this doctor, I had my
22 first western blot and the result was positive.
23 I had my children tested. I had had lingering
24 concerns about their health. One definitely
25 tended to be a sickly baby, the two-year old had

340

1 more positive bands by western blot than I did,
2 and the eight-month-old had a questionable
3 result. Later SPECT scan studies showed
4 anomalies that correlated with her cognitive and
5 speech problems.

6 I am still uncertain. They see
7 Dr. Jones. A few months later, still sick but
8 being treated with Zithromax, I became pregnant
9 again, and yes, I know how this happens. And in
10 a panic I made an appointment with the Yale Lyme
11 clinic, my doctor in Glastonbury wanted me to
12 start taking amoxicillin because it was safe in

13 pregnancy. I did not tell him I was going to
14 Yale. I was afraid I would infect a third baby,
15 I thought surely Yale physicians would know what
16 to do.

17 The Yale rheumatology experience
18 is very similar to everybody else's. I saw
19 Dr. Robert Schoen. During the exam, Dr. Schoen
20 acted like he believed and understood everything
21 I said. He seemed to ask all the right questions
22 and when he was done with the exam he left the
23 room and came back and said, so you've come here
24 as an advocate for your child. And I said yes,
25 and he said, I don't think you have Lyme

341

1 disease. I don't know what you have.

2 I was shocked but at that point
3 remembered that everybody told me not to go to
4 Yale for Lyme disease, and now I understood why I
5 had been warned. Dr. Schoen deflected all my
6 protestations but sent me down the hall to the
7 lab for a western blot. It was the only negative
8 Lyme test result I ever got.

9 The phlebotomist was a pleasant
10 woman who asked me what test I was having, as she

11 was looking at the order, and she said, Oh,
12 Dr. Schoen. I should have known it was going to
13 be a western blot.

14 And I just sat there feeling
15 really stupid, and I said, He says I don't have
16 Lyme disease. And she said, Mmm, he tells that
17 to all his patients. They come down here crying
18 and saying if I don't have Lyme disease, what do
19 I have?

20 I went back to my doctor in
21 Glastonbury and he convinced me to take part in
22 the LDF's Lyme and pregnancy study, and I took
23 amoxicillin throughout the pregnancy and my son
24 was negative by their criteria and testing and
25 he's my healthiest child.

342

1 Three years after I saw Dr. Schoen
2 I finally got better, improved significantly. I
3 don't feel sick -- I don't feel sick every minute
4 of my life like I did for the first nine years.
5 I am not the person I was intellectually and
6 energy-wise, and I have bad days, but I can talk
7 now. I can drive and I can plant things.

8 I am totally amazed to be this
9 much better, and I have never -- and I'll never

10 be able to describe how grateful I am to the
11 three doctors that helped me to get this much
12 better.

13 The immediate solution, assure
14 that insurance companies no longer attempt to
15 limit or restrict medical treatment or practice
16 medicine without a license. Insist that experts
17 practice in their realm of expertise; that is,
18 rheumatologists only perform independent medical
19 evaluations for rheumatological diseases and not
20 infectious diseases.

21 We know that the insurance
22 companies send patients to Yale because Yale is
23 going to tell everybody it's not Lyme.

24 The long-term solution, since
25 there is no cure for Lyme disease, I'd like to

343

1 recommend a long-term solution for people with
2 this, our State disease, and that would be a
3 genuine Lyme disease clinic.

4 These clinics should be staffed by
5 infectious disease specialists or doctors that
6 have been specially trained in the education to
7 treat Lyme disease patients. They should include

8 management of visiting nurse services, financial
9 advisors for assisting patients with filing for
10 disability, and handling the financial fall,
11 because people with Lyme disease do not do
12 accounting things very well.

13 Phlebotomists, nutritional
14 counseling, psychiatric counseling, which would
15 include group, individual, family and family
16 group to help prevent families from
17 disintegrating because one or more of the members
18 have this burden.

19 Meals on wheels, visiting,
20 cleaning services and grocery shopping. This is
21 just the tip of the iceberg. Many, many people
22 just would not have the strength to have come
23 today. And for people who finally have the
24 infection under control, cognitive remediation
25 and physical therapy, vocational rehabilitation,

344

1 would be necessary for some patients who have
2 permanent neurological damage and just can't
3 learn things or rather to work with what they
4 have left.

5 The State should pay for a portion
6 of these services, and where people have become

7 eligible for Social Security disability.

8

9 (Clapping.)

10

11 ATTORNEY GENERAL BLUMENTHAL:

12 Thank you very much, Ms. Dickson. I just want to
13 mention, as I said earlier in the afternoon, I
14 have a legislative hearing which I'll be
15 attending now on our budget, and then onto
16 another meeting, but Mary Ellen Roe, who's life
17 and health, and deals directly with the appeal
18 process, and also the life and health issues with
19 you, and will capture the information.

20 And I appreciate very much your
21 participation and your input and your patience as
22 well, and I think it's certainly important to
23 hear what everyone has to say, so I thank you.

24

25 (Clapping.)

345

1

2 ATTORNEY GENERAL BLUMENTHAL:

3 Next, Alison Schettini, am I getting that right?

4 Susan Tremaine?

5 Jane Devine Compton or Campton?

6 Harrison Pease?

7 Karen Ferraro?

8 MS. FERRARO: I'll be fairly
9 brief. The issue of Lyme disease treatment and
10 insurance coverage is very important. It's of
11 the utmost importance to me, my family and our
12 well-being. I have to say that I've given public
13 testimony twice before for the State legislature
14 for two separate bills proposed for laws
15 requiring coverage for Lyme disease, and our
16 testimony seemed to have fell on deaf ears.

17 The State legislature essentially
18 did nothing. The bills never moved. I hope and
19 pray that our efforts to obtain treatment are not
20 in vain. I hope for a judiciary remedy, as I
21 feel that attempts to pass along through the
22 legislature are unlikely, since they in the past
23 failed and they don't seem receptive...

24

25 (Tape ended, new tape begins.)

346

1

2 MS. FERRARO: ... our problems,

3 our concerns. I fear not only for noncoverage

4 but the inability of my physicians to treat me in
5 the future. I've had Lyme disease for over five
6 years. I've been under the care of three
7 physicians who've made the clinical diagnosis of
8 Lyme disease. In my case, Lyme disease
9 serological tests ordered by all physicians
10 returned a negative result, due to the fact that
11 I had started antibiotic treatment within weeks
12 of being bitten and infected by the Lyme disease
13 bacteria, which prevents the production of
14 detectable antibodies, therefore the tests show
15 as negative.

16 Being serological negative is like
17 the worst position you could be in on top of
18 having Lyme disease. You're kind of caught in a
19 Catch 22 where you have no proof that you have
20 the disease and to try to prove that to the
21 insurance companies is near to impossible, but I
22 didn't give up.

23 I persisted and attempted to get
24 coverage through my carrier, Blue Cross/Blue
25 Shield. They were my primary health insurance

1 company, and denied me many times. I went

2 through the appeal process, which is very
3 lengthy, and consistently each appeal was over
4 the time limit that Blue Cross/Blue Shield was
5 required to respond in. By the time I received
6 the final denial, I was in desperate need of
7 infusion therapy.

8 I then requested coverage for
9 infusion therapy from my husband's carrier,
10 Connecticut General, through his employer, being
11 my secondary coverage. After one appeal,
12 Connecticut General approved four weeks of
13 infusion therapy. At the conclusion, because
14 symptoms decreased and my well-being improved,
15 four additional weeks were requested from
16 Connecticut General and two weeks were approved.

17 Again, two additional weeks were
18 requested based on persistence, but reduced
19 symptoms, this time, being denied by Connecticut
20 General for further coverage of treatment.

21 I then had to pursue another
22 appeal back with my primary carrier, Blue
23 Cross/Blue Shield, and in that I go through the
24 information and it's documented that they
25 consistently did not provide written

1 documentation or communication within the 30-day
2 time limit stated in their appeal grievance
3 process. The only way I was able to get answers
4 were through the advocacy of United States
5 Congressional Representative Nancy Johnson and
6 her contact with Blue Cross on my behalf. And
7 also through Senator Joseph Lieberman's office
8 and their contact with Blue Cross on my behalf.

9 Their delays and lack of diligence
10 during the process resulted in obtaining a final
11 determination, denying infusion therapy coverage
12 after more than 19 months from the time the
13 initial request for the treatment was made by my
14 physician.

15 Due to my failing health condition
16 and the medical necessity for infusion therapy as
17 determined by my physician, I obtained the needed
18 treatment over an extended period of time from my
19 employer, New Britain General Hospital, rejected
20 the determination to deny infusion therapy, made
21 by the group health plan carrier, Blue Cross/Blue
22 Shield of Connecticut, and provided for my
23 treatment at the hospital facility.

24 We need to get equitable treatment
25 from insurance companies for Lyme disease.

1 Insurance companies must fulfill their
2 contractual obligations and provide treatment as
3 prescribed by the patient's treating physician.

4 I assert that any therapeutic
5 decision should be made by the patient's
6 physician, not on the determination of medical
7 consultants hired for fee by the insurance
8 company or biased and in favor of noncoverage
9 resulting in no treatment for the insured. This
10 demonstrates a conflict of interest.

11 In my opinion, the practice of
12 establishing a protocol that limits the treatment
13 for Lyme disease is corrupted if many insured
14 people are covered by companies using the same
15 consultant or medical opinion. Thank you.

16 ATTORNEY GENERAL BLUMENTHAL:

17 Thank you very much.

18 Mary Ellen Robertson.

19 Brian Carroll.

20 MR. CARROLL: Mr. Attorney
21 General, I had planned on doing a presentation
22 with a very brief videotape that I had put
23 together and despite [unintelligible] by the
24 Attorney General, we weren't able to get the
25 right machine to play it. It's a regular VCR

1 tape, so she has gracefully accepted this with my
2 written testimony that went along with it, and
3 she will be able to do that at a later time.

4 ATTORNEY GENERAL BLUMENTHAL:

5 We'll look at it later this week.

6 MR. CARROLL: I think it would be
7 helpful to underscore some of the important
8 issues that are recurring in [unintelligible]
9 today.

10 ATTORNEY GENERAL BLUMENTHAL:

11 Thank you. Thank you very much.

12 Laurie Blair.

13 MS. BLAIR: My name is Laurie
14 Blair. I live in Chester, Connecticut. I was
15 diagnosed and infected with Lyme disease 15 years
16 ago in June of 1984, when I was 28 years old.
17 This was Lyme meningitis with a severe headache,
18 stiff neck, vomiting and 104 fever along with a
19 bullseye rash.

20 Was I treated quickly? Oh, yes, I
21 was. Within days. Was I treated properly? Yes,
22 I was, I was treated with Doxycycline. Was I
23 treated long enough? Well, I was given seven
24 days of Doxycycline and I threw up the first two

25 pills. My doctor had no political or economic

351

1 agendas. The only thing he was guilty of was
2 ignorance. I don't think back in the early
3 eighties that everybody realized that there is a
4 lot more to Lyme disease than a skin rash, a
5 fever, and a couple of aches and pains. So I
6 didn't get better.

7 And then in 1987, when I tested
8 positive for Lyme, I was treated again, with 10
9 days of penicillin. Since that time, I had
10 developed problems that affect nearly every
11 portion of the body; the skin, the bones, the
12 joints, the eyes, the lungs, the heart, the
13 blood, the brain, and finally in this last stage,
14 the nervous system. But I was told that it
15 wasn't from Lyme disease, because I had been
16 treated. I don't know where anybody got that
17 idea.

18 My neurological issues are now so
19 painful and incapacitating that I have gone from
20 a full-time job with some of the best insurance
21 that money can buy to a disabled middle-aged
22 woman whom you are supporting. To a shadow of
23 who I used to be, who I could be, and who I might

24 have been.

25 There's a quote from Seneca, it

352

1 says, "A disease is also on its way to being
2 cured when it breaks forth from concealment and
3 manifests its power." Today we have seen some of
4 the shocking and awful power of Lyme disease.

5 Now, I've had three weeks of I.V.
6 Rocephin. Now I'm on six months of Doxycycline.
7 Now I'm just praying that it's not too little too
8 late.

9 So we've got new vaccines for Lyme
10 disease and we've got quicker test results. Does
11 this now mean we can treat confirmed or suspected
12 cases of Lyme as nonaggressively as I was
13 treated? How much longer and in whose name are
14 we going to go on treating our young?

15 There are as many unforgivable
16 reasons for not adequately treating Lyme disease
17 as there are patients and providers. As we
18 become a nation of people crippled financially,
19 emotionally, socially, and physically, a ravaged
20 landscape straight from a Stephen King novel, we
21 are reaping the tragic harvest of these excuses,

22 and it is pointless and it is heartbreaking,
23 because we know better now.

24

25 (Clapping.)

353

1

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you.

4 Vera DeStefano.

5 MS. DESTEFANO: My name is Vera

6 DeStefano. I'm from Westport, Connecticut.

7 Thank you for the opportunity to be heard today

8 on the matter of Lyme.

9 My main concern relates to the
10 diagnosis of Lyme and the subsequent treatment.

11 Since 1984, I had requested Lyme tests and
12 received the same diagnosis of negative for Lyme
13 disease. I realized that little was known about
14 this disease in the eighties, but the fact that I
15 was misdiagnosed until 1996 is inexcusable.

16 I experienced minor visual
17 symptoms in the eighties but they were so mild I
18 thought they were caused by my contact lenses.
19 By 1992 I was in dire straits. I won't torture
20 you with my symptoms. Suffice it to say I was

21 going blind, deaf, on anticonvulsives, and on
22 heart medications.

23 Between 1991 and 1996 I saw no
24 less than 18 physicians for my worsening
25 symptoms. I consulted with neurologists, aphemic

354

1 [phonetic] neurologists, infectious disease
2 experts, mostly in Connecticut, but also
3 Valhalla, New York, Montefiori Hospital, Willis
4 [phonetic] Eye Hospital in Pennsylvania, and
5 after relaying my medical history and symptoms to
6 each physician, they all seemed to have the same
7 expression the RCA dog has hearing his master's
8 voice over the Victrola, you know the look, head
9 tilted to the side with a perplexed expression.

10 During this time, I had countless
11 blood tests, lumbar punctures, those are spinal
12 taps, brain scans, MRIs, all indicating a
13 worsening condition, cause unknown. My life
14 became a de jour menu of diseases.

15 One day it was Lupus attacking my
16 brain. That was wrong. The other it was a brain
17 tumor, that was wrong again. Multiple sclerosis,
18 strokes, fibromyalgia, they were all wrong. One

19 neurologist went so far as to say that my MRI
20 looked exactly like Lyme in the brain, but I
21 didn't have it.

22 I may not be a physician but my
23 theory is that if it looks like a pig and it
24 smells like a pig, maybe it's a pig.

25 In October of 1996, something

355

1 remarkable happened. I was helping a friend in
2 Wilton, Connecticut, with her garden. Two days
3 later I found a deer tick on my upper arm and for
4 the first time had a rash. Two days later, I
5 began treatment for Lyme disease. Within weeks,
6 my prior symptoms began to improve. I then
7 realized it was Lyme all along.

8 I sought out a Lyme specialist and
9 found Dr. Steven Phillips, who has brought me
10 back among the living. His treatment has been
11 innovative, effective, and caring. Symptoms I
12 had in the eighties are beginning to improve. I
13 am no longer on anticonvulsives, heart
14 medications, or anything else that would suppress
15 symptoms.

16 What is truly baffling to me is
17 that I was never told that evidence of Lyme

18 appeared in all three spinal taps taken from me
19 over the years, and while I was never negative to
20 Lyme, excuse me, while I was never positive to
21 Lyme, I also was never negative. My life was
22 allowed to become unbearable because I was not
23 positive enough. They watched me dying a painful
24 death but persisted in the belief that I had to
25 be a full-blown positive to deserve treatment.

356

1 Had I not been bitten by a second
2 tick and exhibited a rash, I would not have
3 received treatment. Without a doubt, their
4 mistake would have been buried.

5 Physicians allowed faulty tests
6 and an even more flawed interpretation of the
7 results to dictate my fate. Please help pass all
8 legislation to support research, diagnosis, and
9 appropriate length of treatment for this deadly
10 disease. The next Lyme victim might not be as
11 lucky as me. Thank you.

12 ATTORNEY GENERAL BLUMENTHAL:

13 Thank you.

14

15 (Clapping.)

16

17

ATTORNEY GENERAL BLUMENTHAL:

18

Billy Clinton? Dee Clinton? Susan Clinton?

19

They were here I know earlier.

20

Donald Damoth?

21

Cherie Paranto-Warren?

22

Debbie Procaccini?

23

Debbie Siciliano?

24

Douglas Mershimer?

25

MR. MERSHIMER: So that I'm not

357

1 duplicating everything else, the differences that
2 I have to present to you today is that I've
3 challenged Dr. Schoen in his decision to deny me
4 the benefits and continued therapy only after I
5 was able to get a positive spinal tap from a test
6 from Dr. Coyle, and this proved that what he
7 considered to be ample treatment was very
8 conclusive with the Osp A protein that is done
9 with the test from Dr. Coyle that I was able --
10 I'm sorry -- that I was able to demonstrate what
11 he so continuously says to everybody is ample
12 treatment. I was able to disprove that.

13

The other thing that I don't think

14

was mentioned enough today was the fact that

15 there are several coinfections. I've also been
16 treated for early gliosis [phonetic] and
17 babesiosis. I've improved since then.

18 And the newest thing that I
19 haven't heard anybody discuss at all today was
20 about the stefires [phonetic]. All these are
21 very serious and possibly fatal coinfections that
22 do exist and are carried by the Lyme ticks.

23 We need also to investigate these
24 since they help the Lyme disease continue to
25 exist even along with the most aggressive

358

1 treatments of therapy.

2

3 (Clapping.)

4

5 ATTORNEY GENERAL BLUMENTHAL:

6 Thank you.

7 Cynthia Onorato.

8 MS. ONORATO: I'll submit my

9 testimony in writing.

10 ATTORNEY GENERAL BLUMENTHAL:

11 Thank you very much.

12 MS. ONORATO: Thank you.

13 ATTORNEY GENERAL BLUMENTHAL:

14 Nancy Berntsen.

15 MS. BERNTSEN: If anybody that
16 wants to read my statement, I have one on beige
17 paper over there. I'm not going to read it.

18 ATTORNEY GENERAL BLUMENTHAL: We
19 will.

20 MS. BERNTSEN: Good. I'm going
21 to change my focus based on a need I see here, a
22 need for something uplifting.

23 I'm from the town of Scotland.
24 I've lived in Connecticut all my life except
25 three years. I have four children who've all had

359

1 Lyme disease and I've had it myself. I still
2 have Lyme disease. But the good news is that I
3 feel great and I have good insurance coverage. I
4 think everyone should be entitled to the kind of
5 coverage I've had.

6 I was only granted four weeks of
7 I.V. treatment, which did not help me, and I had
8 to change physicians, because the physician I had
9 was doing cookbook-style treatment, and she
10 referred me to another doctor, an infectious
11 disease doctor who was spoon-feeding her. So

12 certainly I didn't want to go to him and waste my
13 time to get the same news that I was cured when I
14 wasn't.

15 I'm a registered nurse. I
16 graduated from the University of Bridgeport, and
17 I think because of my background, I've been very
18 perceptive to the symptoms. I detected it in my
19 children, I detected it in my parents. They
20 didn't listen to me until they went to a lecture
21 on Lyme disease.

22 But I just want to reiterate,
23 everyone should be entitled to good coverage, and
24 the ability to make decisions about your
25 healthcare with your physician are very

360

1 important. It's important not to you just for
2 your physical health, but your mental health and
3 your self-esteem.

4 None of us -- or almost none of us
5 wanted to be medicated for Lyme disease but it's
6 necessary, it's a necessary evil. The
7 antibiotics can make you feel sick. You can feel
8 better after you've stopped taking antibiotics
9 because the antibiotics make you feel sick. That

10 doesn't mean you didn't have Lyme disease.

11 I've come to a high level of
12 recovery. I would say with the antibiotics I was
13 about 90 percent well after an undetermined
14 amount of years with Lyme disease. That decision
15 to come off the antibiotics was not easy, but it
16 was something that my physician and I discussed
17 several times over several months. We had trials
18 of stopping antibiotics, seeing how I felt.
19 Finally I got to a point where I was about 90
20 percent well and I plateaued, so that was for me
21 an optimal time to discontinue the antibiotics.

22 Since then I took an
23 over-the-counter remedy, that is antimicrobial,
24 it's not approved by any Lyme physician at all,
25 but it has helped me, it has helped other people,

361

1 and it's kept me out of the doctor's office.
2 I've gotten my independence back. And I'm here
3 not for myself, not to boast about how good I
4 feel. I'm here to represent the people who have
5 not gotten well yet.

6 I'm very committed to not just my
7 family but all these other people who are not
8 well, and I'd like to see them all have the

9 opportunity to perhaps achieve improved health if
10 not a cure. Thank you very much.

11

12 (Clapping.)

13

14 ATTORNEY GENERAL BLUMENTHAL:

15 Could I just ask you, Ms. Berentsen, you
16 mentioned that you were satisfied with your
17 insurer. Could you tell me who it is?

18 MS. BERENTSEN: Well, actually
19 there were several changes, and I was very
20 nervous when I was learning my husband's company
21 was changing coverage, but we've had Metro Health
22 and United Healthcare. They would only cover
23 four weeks of I.V. from what I understand, but
24 with consultation they would have extended it,
25 and that was from 1994 through 1996. Most of my

362

1 treatment was oral antibiotics, and not everyone
2 responds well to orals. Thank God I did.

3 ATTORNEY GENERAL BLUMENTHAL:

4 Thank you.

5

6 (Clapping.)

7

8

ATTORNEY GENERAL BLUMENTHAL:

9

Thank you very much, Ms. Berentsen.

10

Brian and Cathy Morrissey.

11

MS. MORRISSEY: Brian and Cathy

12

Morrissey from Wilton, Connecticut. We're going

13

to let our children speak and we'll be very

14

brief, because for us this is a family illness.

15

ATTORNEY GENERAL BLUMENTHAL: By

16

the way, I have received from you as you

17

indicated, you would send to me a fair amount of

18

material which we will make part of this record

19

if you would like.

20

MS. MORRISSEY: Yes, please, thank

21

you.

22

KEVIN MORRISSEY: My name is

23

Kevin. I am in first grade. I've had Lyme since

24

I was four years old and now I am seven years

25

old. It is bad because a kid can look fine like

363

1

me. They can play and be strong but it's hard

2

for them to say their brain is sticky if they

3

were like me. Your head doesn't hurt but your

4

brain won't work. I had some problems being good

5

in kindergarten but I took lots of medication and

6 I'm doing great in first grade. I am almost all
7 better because of Dr. Phillips and Dr. Jones. I
8 know I will get all the way better if you can
9 help my -- me and my doctors. Thank you.

10

11 (Clapping.)

12

13 ATTORNEY GENERAL BLUMENTHAL:

14 Thank you, Kevin.

15 BRIAN MORRISSEY: My name is Brian

16 Morrissey, I'm 16. In my own experience with

17 Lyme, I've seen a serious effect on neurological

18 symptoms. I think the easiest things -- symptoms

19 to pick up are always physical ones, and in my

20 case I knew right away that I was experiencing

21 arthritis and fatigue. However, it was 18 months

22 after my original diagnosis that I was diagnosed

23 with a wide range of cognitive problems,

24 including memory problems, dyslexia, word

25 retrieval, and poor concentration.

364

1 I was always a bright student and
2 my grades were good and I scored well on the SAT
3 in 7th grade, but over the next three years my

4 academic performance was extremely inconsistent,
5 as my arthritis and fatigued worsened as well.

6 I had to drop many honors courses
7 and was placed in special ed. Since then I've
8 come across at least a dozen other students with
9 neurological complications of Lyme just in my
10 small high school, and many others that we've met
11 across the state. Like all aspects of Lyme
12 disease, the neurological manifestations are
13 extremely difficult to pinpoint, and despite my
14 school's accommodations, they really didn't know
15 how to help, but this is a relatively unexplored
16 disease.

17 I was treated with numerous oral,
18 I.V., and intramuscular therapies over two and a
19 half years by Dr. Jones. My condition slowly but
20 surely improved, and I have been symptom-free for
21 the past seven months. I'd like to consider
22 myself a study in the benefit of long-term
23 treatment.

24 I think this hearing today is
25 vitally important, and without the support of

365

1 people like you, it isn't possible for the
2 average patient to find a diagnosis, treatment,

3 and most importantly, answers. The importance of
4 the continuation of research and the ability of
5 physicians to treat the clinical symptoms of this
6 disease is the only possible hope that many
7 patients who have written and spoken here today
8 have.

9 I thank you all for your time and
10 effort here today.

11

12 (Clapping.)

13

14 ATTORNEY GENERAL BLUMENTHAL:

15 Thank you.

16 MISS MORRISSEY: I've had Lyme for
17 four years. I suffer from light and sound
18 sensitivity, and sometimes I have to wear two
19 pairs of sunglasses. I have dizziness, learning
20 problems, and in the past have experienced
21 paralysis, narcolepsy and movement disorders.

22 I've spent time in a wheelchair
23 and missed months of school. I, like so many
24 others, was misdiagnosed, ridiculed, and
25 abandoned by doctors who called my problem

1 psychological. Eventually long-term treatment
2 has helped me to get back to school and achieve
3 an almost normal life.

4 Just three months ago, I made
5 highest honor roll and was on the varsity swim
6 team. However, now I suffer from a serious
7 relapse. Because only a handful of doctors are
8 knowledgeable about this disease, it is very
9 difficult for me to get help from neurologists,
10 even though it is clear to anyone that I am
11 suffering from a brain infection.

12 Lyme disease is caused by a tick
13 so small it is almost invisible. It causes
14 symptoms that can be invisible. It is so
15 mystifying that it is often invisible on tests.
16 The number of cases is underreported, making it
17 more invisible. In a way I'm lucky, my disease
18 is very visible to others, it is tangible and
19 real.

20 But all of the people who suffer
21 from this are real. Pain and suffering and sense
22 of loss are devastating and very, very real. We
23 are not just numbers, but people in a real
24 family, whose way of life has died. We are
25 grieving and we need help.

1 I'm so thankful for the
2 opportunity to speak to you and hope that you
3 will help me, my family, our doctors, and all the
4 people who suffer from chronic Lyme. Thank you.

5

6 (Clapping.)

7

8 ATTORNEY GENERAL BLUMENTHAL:

9 Thank you very much.

10 MR. MORRISSEY: A ground swell of
11 people are finding themselves victims of a
12 chronic debilitating often incurable illness that
13 the most influential members of the medical
14 establishment have told them absolutely does not
15 exist. Our hometown is home to scores of
16 families going through this terrible ordeal.

17 MS. MORRISSEY: Lyme and other
18 tick-borne illnesses are mysterious and
19 potentially serious, as our family has learned
20 the hard way. Misinformation about its
21 prevalence, severity, and chronicity account for
22 the illnesses in the five out of six members of
23 our family who are present here today.

24 We all contracted Lyme within 18
25 months of moving to Wilton, which is a very

1 hyperendemic area. Our illnesses almost run the
2 whole spectrum of Lyme disease. My husband
3 developed a very classic case but was
4 undertreated and so became chronic.

5 At the other extreme, our daughter
6 Erin started out only with flu-like symptoms, was
7 eventually diagnosed, but given treatment that
8 proved inadequate. This has led to a four-year
9 nightmare of serious problems that include a
10 movement disorder, profound trouble with thinking
11 and memory, and pain throughout her body. She
12 has missed many months of school and spent time
13 in a wheelchair.

14 The rest of us fall somewhere in
15 between these extremes, and we never would have
16 connected the subtle, disturbing behavior and
17 cognitive problems our boys were experiencing had
18 we not learned about it from Erin. The nature of
19 this disease is such that it affects each person
20 differently, as evidenced here in my own family.

21 Doctors like Dr. Phillips and
22 Dr. Jones understand this, but know that
23 diagnosis, treatment, and care of Lyme disease
24 patients requires individualized time-consuming,
25 compassionate care.

1 The health insurance industry's
2 favored managed cookie cutter approach and the
3 establishment of uniform standardization of
4 treatment is simply unconscionable, especially
5 with new insights into the problem of coinfection
6 with other tick-borne illnesses, which, by the
7 way, several of our family members have.

8 Although our daughter is visibly
9 ill, we are no less concerned for her brothers,
10 who suffer from different yet serious form of
11 brain infection. There is no guarantee for cure
12 for any of our children, which is absolutely
13 unacceptable to us.

14 We are deeply troubled by the
15 harassment of our doctors who are brave enough to
16 fight the bureaucracy and treat. We believe that
17 funding for the study of tick-borne illnesses has
18 been inappropriately skewed to rheumatologists,
19 when it is clear that in later stages this is a
20 brain infection. We do not believe that
21 rheumatologists should govern the research of
22 brain injured people such as our children.

23 Ironically, we realize the only

24 way to get the help we need is to become
25 politically active to help bring about research

370

1 for an effective cure for our family.

2 MR. MORRISSEY: As parents of
3 children with Lyme disease, it is extremely
4 frustrating and discouraging to deal with the
5 politics, the lack of understanding, and
6 compassion in the medical community. Children
7 are often misdiagnosed, their symptoms dismissed
8 or belittled because they are not verbalizing
9 their symptoms or the doctors explain them away
10 as growing pains, stress, depression, anxiety, or
11 behavioral issues.

12 Many local physicians rely on
13 misinformation that comes out of Yale from
14 supposed experts on the subject. The danger here
15 is that these children often go undiagnosed or
16 misdiagnosed for months or for years and develop
17 serious neurological problems that are much more
18 difficult to cure or control. Children are at
19 the greatest risk of tick-borne illnesses, they
20 play outside at home, school, and at friends'.
21 The outdoors is a great place for children to
22 explore and have fun, yet it was in such

23 seemingly safe places that our children were
24 infected.

25 Our greatest fear is that our

371

1 three children with Lyme disease will be
2 reinfected or that our one healthy daughter will
3 become infected. The vaccine currently being
4 developed is not for children under the age of
5 15. What are parents to do? Can we risk
6 sentencing our children to a lifetime of physical
7 and neurological problems? What is being done to
8 save our nation's most precious resource, your
9 children and mine?

10 We were given permission from a
11 friend to share some of his story. He believes
12 his previously healthy seven-year-old child died
13 from a tick bite sustained in the child's scalp.
14 In two days time the child became suddenly
15 lethargic and began having seizures. Tests taken
16 for Lyme were borderline, just short of arbitrary
17 standards set by those who dictate treatment.
18 The child was placed in a medically-induced coma
19 to control the seizures. The parents were faced
20 with a maddening range of diagnosis and suggested

21 course of treatments.

22 Months later when we heard of the
23 case, we sent her to a physician knowledgeable
24 about Lyme, who prescribed an appropriate and
25 reasonable treatment, but it was already too

372

1 late.

2 Insurance was also a problem, and
3 the child died. Autopsy results failed to
4 identify any known cause of the child's illness.

5 Our friend has submitted the
6 private details of his account in the hope that
7 it will help our children. Mr. Blumenthal has
8 been given his complete story.

9 MS. MORRISSEY: We would like to
10 close by reading an excerpt from our friend's
11 letter.

12 "Connecticut is home to this
13 country's largest and most influential insurance
14 firms, and it is also the state hardest hit by
15 tick-borne illnesses. Most patients have been
16 told that their illnesses were not Lyme-related.
17 I hope you will examine the facts, acknowledge
18 the uncertainty, consider the motivations of the
19 opposition and do the right thing."

20 Thank you.

21 MR. MORRISSEY: Thank you.

22 ATTORNEY GENERAL BLUMENTHAL:

23 Thank you.

24

25 (Clapping.)

373

1

2 ATTORNEY GENERAL BLUMENTHAL:

3 Thank you very much.

4 Dolly Curtis.

5 MS. CURTIS: Thank you for your
6 patience and having spent this whole day, which
7 was long overdue.

8 My name is Dolly Curtis, I've
9 lived in Easton, Connecticut, for about 21
10 years. The town is loaded with Lyme disease
11 patients, but many of them don't know they have
12 Lyme disease. I've also lived in Norwalk,
13 Connecticut, for about 12 years, so about
14 30-some-odd years living in Connecticut.

15 I'm a New York City-born person
16 and I should have stayed there. I was diagnosed
17 in '91 and I've been battling infection ever

18 since. It has been a lot more disabling than I
19 had ever, ever dreamed. I was misdiagnosed in
20 '91 by a dozen different doctors, and I sought
21 help immediately, because I'm a very active
22 person, and I didn't let a day go by that I
23 didn't try and get to a doctor to ask for help.
24 And something happened to me that is different
25 than mostly what everyone else spoke about, so I

374

1 thought I might mention it.

2 I was born with one foot that's
3 not normal, and for most of my life I've been
4 able to get by. When the Lyme disease attacked
5 my system, it went right into my foot, and I've
6 been told that it goes to the weakest part, so I
7 never, nor did Dr. Ligner [phonetic] or any other
8 specialist put together the fact that I couldn't
9 walk on my left foot and that I had Lyme
10 disease. It was very hard to put those two
11 things together.

12 So I went naturally, eventually,
13 to the Hospital of Special Surgery in New York
14 City because I was in a wheelchair on and off,
15 and I was a mother of several children and an
16 active person and I was trying to find a way to

17 continue to live my life with mobility. And I
18 ended up at Yale. This time not in
19 rheumatology. I've been there too, but I ended
20 up with their orthopaedic people, and I just
21 thought it might be a little shocking to let you
22 know that after three years, going back three
23 times because I couldn't walk on my left foot,
24 and I had mentioned that I had been treated for
25 Lyme, they suggested that I have my left foot

375

1 amputated or part of my left foot.

2 And I told them they were crazy
3 and left, which annoyed the orthopaedic surgeon
4 greatly that I didn't listen to his advice. And
5 I had been there three other times, three years
6 in a row.

7 Actually, the person that really
8 saved my life was here today, her name is Martha
9 Accola [phonetic] And she was a physician's
10 assistant to Dr. Kenneth Ligner [phonetic], and
11 she told me not to let anybody operate on my foot
12 because my foot was coming from the Lyme disease
13 spirochete. And actually I wasn't sure that she
14 was right, but it has turned out to be that she

15 was correct.

16 So this disease, as you've heard
17 today, takes many different forms. I have lots
18 of other symptoms, I have many neurologic
19 symptoms, but it seemed at first with many
20 different relapses it comes back into that part
21 of my body, my left foot and my hands.

22 I myself produce a television show
23 in about half of Connecticut, and I do this
24 without salary, so it makes my life very
25 interesting and sort of it's a sacrifice not to

376

1 have an income, but I've been able to reach
2 thousands of people.

3 I've come from a family of very
4 socially active philanthropic backgrounds, so I
5 don't know what else to do. So what I have done
6 is, we didn't have hearings like this in the last
7 eight years, I have asked some of the top
8 specialists in this Northeast to come on
9 television, which they have, without force, and
10 I've done the best I can to try to put forward to
11 the television audience what I knew.

12 At first they were more reluctant,
13 but in the last few years they have been

14 outspoken. And so there are many of us who have
15 tried to bring public awareness, and many of them
16 sit in this room today.

17 And one of the things I wanted to
18 mention that no one has mentioned, is there has
19 almost been in the Fairfield County area, no
20 public health awareness, it's all been done
21 through volunteers like Morrissey's family or
22 myself or other people who have been running
23 support groups, Cindy Onorato. We have been
24 running these groups for years, being there for
25 people who first get infected, trying to help.

377

1 I must have at about this point
2 have answered a thousand phone calls in the last
3 eight years myself personally, just trying to
4 direct people, and I'm not a doctor, in some way
5 to give them some affirmation that there is
6 help. So I am just hoping that rather than
7 volunteers like myself and Cindy Onorato and
8 Morrisseys, that somewhere the government could
9 step into the Public Health Departments and help
10 us educate the people, because honestly,
11 Mr. Blumenthal, we have been doing it all

12 ourselves for a long time. But we have no
13 budgets, we just ask these doctors to come and
14 speak, and they have been very gracious.

15 And then we hang up flyers and we
16 publicize it and 200 people will come to an
17 address like that, so it's getting to be so many
18 people that it's very hard for us to handle that
19 type of situation.

20 I also wanted to say that I've had
21 no difficulty with insurance companies. I almost
22 didn't want to say that today for fear that they
23 might red flag me, because for eight years I
24 haven't had any real denial. I mean they have
25 denied me if I want to see someone out of

378

1 network. I know I have to pay for that
2 out-of-pocket, but I've been lucky enough that
3 I've been able to get HMO coverage.

4 I have a Lyme doctor within the
5 system, so far so good, and I've been able to get
6 all my medications paid, and I've been on oral
7 medications and that's probably why.

8 So if there's one person and then
9 another person spoke, I just wanted to say I have
10 not -- I am fearful to say that, because I mean

11 if they read my testimony and they say oops,
12 missed her, you know, go back to the computer and
13 pull me off the list, there goes my coverage.

14 I don't know if anyone mentioned
15 this either today, but there has been a lot of
16 families that have gotten divorced and broken
17 through this whole thing, and I feel that many
18 phone calls like that, where people have called
19 me and told me that they just cannot live anymore
20 with the Lyme-infected spouse, and it's just more
21 than they can handle, and I try -- nobody could
22 imagine what it's like to live with this, so I
23 try in my own way to ask people to be more
24 patient.

25 But I have seen families really

379

1 just unwind. I've seen a few people go into
2 nursing homes, and we've had one person commit
3 suicide that we know of in the lower part of
4 Fairfield County, just very sad.

5 I really think it's a suburban
6 nightmare, that's what I've always called it.
7 And it's a little bit like polio, just like a
8 polio of the nineties, but nobody is paying

9 attention. FDR, where are you? We don't have
10 anybody.

11 We have been waiting for a
12 wealthy, important celebrity to come forward.
13 Paul Newman lives about a mile and a half from
14 where we meet, support group site. I never meant
15 him any harm, but I was always hoping he would
16 get Lyme disease and stand up and be counted, but
17 the people who have gotten Lyme disease, the
18 rumor goes like Woody Allen, that famous baseball
19 player, a few other people, I think they are so
20 afraid for their career, like Governor Whitman,
21 that they just don't want having the stigma of
22 being attached to Lyme Disease. We have had no
23 spokesperson [unintelligible] and they are quite
24 -- it's a very sad and impressive story.

25 Nobody today either has mentioned

380

1 the great risks that a person who is pregnant
2 takes while they are carrying a child. I think
3 it's an incredibly sad thing to think that we
4 haven't brought an awareness to people who would
5 be carrying a child and go to a Memorial Day
6 picnic or just for going to a family picnic but
7 end up being bitten. It's just an easy thing to

8 have happen.

9 It doesn't -- I was -- it doesn't
10 hurt, you would never know, especially in May,
11 when the ticks are so small, June. It's a
12 nightmare. That parent can walk right into it
13 just by walking across their front lawn, or
14 owning a dog or a cat, which the pets -- you
15 don't have to go outside. If you have a family
16 pet, they bring the ticks inside.

17 And I think the whole country is
18 looking at us with a -- we are the heart of this
19 problem because of Polly Murray and all her
20 courageous work, her book, and the Forschners,
21 and we really have the heart of what the whole
22 country sees as Lyme Disease, because it's been
23 named after our state. And I don't know if we're
24 doing the best job in helping the rest of the
25 country.

381

1 It's in every state now other than
2 Alaska and Hawaii, that I know, and it makes you
3 wonder how. It's spread on many people by birds,
4 but it is a thought; how has this spread across
5 the whole United States?

6 I just feel that people don't
7 realize the risks that are around just walking
8 across to their mailbox, and it's a real risk,
9 and the children are at most risk because they
10 are closest to the ground and ticks don't fly,
11 they are on the ground, and they crawl up blades
12 of grass, they are in your pachysandra.

13 And I just wish everybody can give
14 a little thought to their grandchildren or their
15 children or their own health because this is not
16 something that can be prevented. There has been
17 a lot of talk about prevention, and those of us
18 that have Lyme are not so sure that -- yes, you
19 have to do tick checks, and I don't mean to make
20 light of that, but this is really not something
21 that can be 100 percent prevented.

22 A tick is so infinitesimally
23 small, it's just something that can happen to
24 you. You may not get any symptoms at all at that
25 time. It could be six months, a year later, the

382

1 symptoms come on in many, many different ways.
2 As I said, with me, I couldn't walk, and I had a
3 crippled foot to begin with, so everybody just
4 said well, you have a deformed foot, so, you

5 know, what did you expect, you are 47 years old,
6 you've just been lucky until now.

7 Then the next thing is what, major
8 surgery on your foot. And if it was coming from
9 a spirochete, any surgery on my foot wasn't going
10 to do any good.

11 So I thank you for taking --

12 ATTORNEY GENERAL BLUMENTHAL:

13 Thank you very much.

14 MS. CURTIS: -- [unintelligible]

15 hours.

16 ATTORNEY GENERAL BLUMENTHAL:

17 Thank you.

18

19 (Clapping.)

20

21 ATTORNEY GENERAL BLUMENTHAL:

22 Dr. Lionetti.

23 DR. LIONETTI: Thank you very

24 much. My name is Anthony Lionetti, I'm an

25 internist. I'm from the state of New Jersey,

1 actually from Hamilton, New Jersey. My sister is
2 a physician in the state and she lives in

3 Burlington, Connecticut.

4 I wanted to -- very quickly, I
5 wanted to submit some written report -- a written
6 comment about some of the more technical aspects
7 that were discussed today by the various
8 experts. One thing, though, I want to cut to the
9 chase, and I think is very important in terms of
10 looking at the involvement of the insurance
11 industry in development of guidelines and
12 practice parameters, which I think is the
13 greatest issue here, for diagnosis and treatment
14 of this disease and perhaps other diseases, for
15 that matter.

16 One of the things that the medical
17 profession has been looking at in this issue over
18 the past, I'd say eight to nine years, as we try
19 to focus in on healthcare and decreasing cost and
20 maximizing benefits for patients, as Dr. Feder
21 has shown and discussed to some extent, however,
22 very importantly, all of the literature that has
23 been written about this subject has stated that
24 no practice parameters or guidelines should
25 really be written unless observer bias is removed

1 from the evaluations that the parameters are

2 based on.

3 What I'm trying to say is, one of
4 the biggest issues in Lyme Disease is testing,
5 and the testing is indirect testing like the
6 ELISAs and Western blots, which can tell you you
7 may have been exposed to the disease but may not
8 prove that you have it currently are two good
9 tasks that are underutilized and had not been
10 used in any of these studies, such as ploamri's
11 [phonetic] chain reaction, PCRs, which can prove
12 the person actively has the infection. That is
13 the gold standard-type test or culture where you
14 grow the organism.

15 Studies based on the results of
16 patients who are diagnosed and treated using
17 either cultures or PCRs can't be used as a gold
18 standard, they simply do not exist. The
19 insurance companies do not have really a correct
20 basis for establishing these guidelines or
21 parameters, and that's why all these people here
22 are having so much trouble.

23 It's basically one where
24 physicians who are outsiders, they need opinions
25 but they are not basing it on any gold standard

1 where we have proven the infection, and they have
2 even worked to the point of denying the ability
3 to have access to the direct detection tests.
4 They have stated that PCRs are experimental.

5 The College of American
6 Pathologists in 1988 conducted a clinical survey
7 of 16 laboratories in the United States that do
8 PCR tests commercially. They have stated with
9 certainty that there is no problem with false
10 positivity with PCRs, therefore they are not
11 considered experimental. They are actually being
12 reimbursed by the insurance companies that if the
13 result is positive, they are not allowing
14 treatment for patients.

15 I will submit the rest in writing,
16 but I thought this was a very important point to
17 bring out now as you start to look at all the
18 data that you're getting and look and say, you
19 know, like the old story, where is the beef? The
20 beef is in the gold standard test, it's not
21 available yet.

22 The lady had asked a question in
23 Connecticut, what is being done in terms of
24 research? There is no research being done using
25 a gold standard test of any sort. It is a

1 rehashing of the observer bias of a group of
2 observers, physicians, scientists.

3

4 (Tape ends, then new tape begins.)

5

6 ATTORNEY GENERAL BLUMENTHAL:

7 Carla -- I'm sorry.

8 UNKNOWN SPEAKER: I'll keep this
9 really short because it's getting late. My son
10 is one of the unfortunates who is seronegative.
11 During the course of being diagnosed he had six
12 tests in several different labs, including Yale,
13 over a period of three years. They were all
14 negative. However, he had a history of tick
15 bites. He had physical and neurological symptoms
16 of Lyme Disease. He had exposure of living in a
17 hyperendemic area, camping in Lyme, Connecticut.
18 But we could not find a doctor in Connecticut who
19 would treat him or diagnose Lyme Disease.

20 We went to the Lyme Disease
21 Foundation and they recommended a doctor in New
22 Jersey, who is currently still his doctor.
23 Although he missed a year of school he did
24 recover, and by 1996 he was doing well, both
25 academically and in sports.

1 The doctor said well, let's stop
2 the antibiotics and see how he's doing. He'd
3 been on the antibiotics for three years at that
4 time. Things seemed okay but then his teachers
5 noticed he wasn't doing well anymore. He was
6 missing things on tests and just wasn't sharp
7 like he used to be, so we put him back on
8 antibiotics and his grades went back up. He is
9 currently in college, still on antibiotics,
10 getting a B average. He's extremely fortunate.

11 So there are two things we know
12 for sure; the lab tests aren't reliable, and
13 antibiotics are not a sure cure.

14 Why are we told that the clinical
15 diagnosis of Lyme Disease must be confirmed by
16 laboratory evidence? A cure is defined by faith
17 and 21 days of antibiotics. That's all. Thank
18 you.

19

20 (Clapping.)

21

22 ATTORNEY GENERAL BLUMENTHAL:

23 Thank you very much.

24 Carla Southwick.

1 ATTORNEY GENERAL BLUMENTHAL: Good
2 afternoon.

3 MS. SOUTHWICK: My name is Carla
4 Southwick. I'm going to submit what my testimony
5 is in writing later because my family tragedy is
6 so similar to what I've heard today. I'm so
7 emotionally distraught just seeing what we've
8 suffered and continue to suffer played out in so
9 many other families.

10 We have -- I'll just say that two
11 of my children and myself have chronic Lyme
12 disease and all that goes with it. It's just --
13 it's just been horrible and it's a huge tragedy
14 and made much worse -- the spirochetal illness
15 and the other coinfections we have would have
16 been enough to deal with, enough of a challenge
17 without all this other nonsense that goes with
18 it, our delayed treatment, our doctors have been
19 intimidated resulting in changes in doctors and
20 regimens.

21 And my children have been on
22 long-term treatment of low-dose antibiotics,

23 which my question to the conservative doctors
24 that put them on that was, I thought this was the
25 way that you -- if you wanted to develop

389

1 antibiotic immunity, what you do is give
2 low-term -- very low doses over a long period of
3 time, and that's what we've had.

4 Well, the result is my children
5 have been out of school for several years, they
6 are just now trying to get back and their lives
7 are -- I just never would have anticipated this
8 for my children, and -- but I'm too emotional to
9 go into that. I'll just submit it.

10 I just want to read one quote.
11 This is from Mark Clutner, Dr. Clutner, the
12 principal investigator of the National Institutes
13 of Health extramural chronic Lyme study which is
14 currently underway.

15 "These chronic Lyme patients are
16 in a condition worse than patients with
17 congestive heart failure. They are two and a
18 half standard deviations from normal, among the
19 most deviant of any chronic illness."

20 Thank you.

21 ATTORNEY GENERAL BLUMENTHAL:

22 Thank you very much.
23 Judy Ring or Jody Ring?
24 Amy Kalafa?
25 Dawn Stevens?

390

1 That concludes the list that we
2 have here. Is there anyone whom I've missed?
3 Yes?

4 MS. FIELD: My name is Anita
5 Field. I live in Southbury, Connecticut. I have
6 a 15-year old son who's been ill and out of the
7 school for the past two years. He became ill
8 while we were living in Wilton. He started in
9 July of '97 with a flu and a rash on his chest.
10 He needed help to get up and walk to the
11 bathroom, to the bedroom. He got over that in
12 about six or seven days, and around the end of
13 August, had such severe pain in his abdomen that
14 he was doubling over.

15 I took him to the Emergency Room
16 and the surgeon was called and they took him
17 immediately and removed his appendix, and when
18 the surgeon came out of the operating suite, he
19 said to me, if his pain continues, if I would

20 seek some other opinions, because his appendix is
21 normal but his pelvis is all inflamed. So I
22 asked him who I should see, and he said probably
23 a gastroenterologist, which we did.

24 From the end of August until the
25 beginning of October, it was simply back and

391

1 forth to the surgeon, back and forth to the
2 pediatrician, and waiting for an appointment with
3 the GI specialist. No one could give us any
4 answer.

5 Danny was repeatedly given CAT
6 scans, thinking that might be leakage from
7 surgery, there might be an abscess postop. There
8 was nothing. The night of surgery, the surgeon
9 was very concerned that Danny's appendix was
10 about to rupture so he started him on I.V.
11 antibiotics that night and continued to run them
12 until the next morning, when he was discharged.

13 Danny started having really bad
14 seizures. He was collapsing. He could not go to
15 school. By the middle of October we went to
16 Yale. We then saw someone, a pediatric
17 rheumatologist, he told us Danny had rheumatic
18 arthritis, secondary to val [phonetic]

19 inflammation, and put him on 60 milligrams of
20 Prednisone, which he stayed on.

21 Came home, he was on
22 anti-inflammatory drugs, he was seeing a GI
23 specialist. He just continued to get worse until
24 in December he was having seizures that were
25 lasting two and a half to five hours, with the

392

1 longest stretch being two hours in between and
2 then back to the seizures again. And this was
3 going on 24 hours a day.

4 We went to the Emergency Room at
5 Norwalk Hospital and they admitted him, ran some
6 more tests. Said they didn't know what was wrong
7 with him. He could not walk and they discharged
8 him because they were very concerned about what
9 the insurance company would say if they kept him
10 there, because they didn't have a diagnosis.

11 So Danny was discharged. I had to
12 call a friend to help me get him to the car and
13 out of the car into the house.

14 In December, we were at home still
15 continuing two, three, four hours of seizures,
16 now two hours in between, and he was so bad that

17 his head was flailing, his arms were flailing,
18 and all of a sudden I noticed that Danny was
19 having a lot of trouble breathing, so I called
20 the ambulance.

21 When the ambulance got there, they
22 told me he was in cardiac distress, he was in
23 respiratory distress, and they started I.V.
24 morphine in the house. He was admitted to
25 Norwalk Hospital, he was seen by the

393

1 gastroenterologist.

2 Fortunately for the first time
3 that the doctor came into the hospital, he saw
4 Danny having seizures and he stood there while
5 this child was flailing all over the bed and told
6 me this is not happening because the tests are
7 proving it couldn't be happening. And he was
8 standing watching this child literally flailing
9 all over the hospital bed.

10 There happened to have been a
11 priest who is a very good friend visiting, and
12 stayed in the room while the doctor was there and
13 I will never -- it was the one humorous thing
14 that's happened in this whole two-year
15 nightmare. When the doctor left, he said to me,

16 You know, Anita, I am so glad I had my collar
17 on. And I said, Why? He said, Because I would
18 have knocked him on his ass if I didn't. He said
19 how could anybody watch this, observe this and
20 look you straight in the eye and say it's not
21 happening?

22 So we were in Norwalk, we had
23 already made the appointment at Yale, and Danny
24 was transferred from -- he went home for one day
25 or two days, I don't remember. He went to Yale.

394

1 While he was being examined by the doctors at
2 Yale, he went into the seizures again. The
3 doctor at Yale admitted him to Yale Hospital
4 immediately, because she thought he had
5 something, probably an abscess that was about to
6 rupture. She put him into the hospital at Yale,
7 they ran some tests, they found nothing.

8 Two days later, they walked into
9 the room in the hospital and said to us that
10 Danny is crying out for help, that he has
11 emotional problems, that all tests were negative
12 and he needed psychiatric help. And I kind of
13 stood there and looked at her and I said, why do

14 you believe this is psychiatric? She said
15 because all the tests are negative. I said, have
16 you run all the tests that are possible to run?
17 And she said yes.

18 And she said Danny is -- Danny had
19 been -- Danny got sick the summer he graduated
20 from grammar school, and prior to that he had
21 been on the student council, he helped write the
22 school constitution, he was on the basketball
23 team, he was an incredibly active kid. He won
24 the president's award for maintaining a straight
25 A average from fourth grade through eighth

395

1 grade.

2 During all those years, Danny had
3 very severe asthma that required him to be in
4 intensive care repeatedly. Danny could miss
5 easily two and three months of school. When he
6 was having difficulty with asthma, which usually
7 was started in the fall and would be triggered by
8 flu and carry right through the winter, through
9 the spring season, he missed months of school.
10 He still went back to school and maintained a
11 straight A average with some B's. He graduated
12 with honors.

13 And now the doctors at Yale were
14 telling me that all of a sudden for some
15 unexplained reason this child now had psychiatric
16 problems. And I said, I don't agree with you.
17 But I'm not going to leave any stone unturned, so
18 we sought a psychiatrist.

19 The psychiatrist said, after
20 seeing Danny three or four times, he wrote a
21 report to Yale that Danny was a well adjusted,
22 articulate, very bright, goal-oriented adolescent
23 who became very depressed in direct relation to
24 the amount of pain he was suffering.

25 So I went to Yale with that and

396

1 Yale asked me to see another psychiatrist. So I
2 said okay, fine, I'll see a second psychiatrist.
3 They wanted another opinion. Before we got to
4 the second psychiatrist, Danny had gone
5 continuously -- the kid was in continuous
6 horrendous pain, and finally one Saturday
7 morning, and I believe it was like January or
8 February, after 10 admissions to the hospital he
9 had had since August of that year, he just gave
10 up. He just gave up. And he said to me, no

11 matter what I do, it gets worse, and on top of
12 that, they don't believe me. They think that it
13 is in my head.

14 And I said well, we're just going
15 to have to keep trying. He said, Mom, the
16 medicines are not helping. The doctors aren't
17 helping, and the psychiatrist said that I'm
18 emotionally stable, and that he couldn't
19 understand that I would be feeling down.

20 So he refused to take his
21 medicine. And as the days went on, he became
22 grossly depressed. I took him up to the
23 Emergency Room at Yale and the one doctor up
24 there who was seeing him, who he I really think
25 believed that Danny was physically ill, was a

397

1 fellow -- and he was the one that met Danny in
2 the Emergency Room that night. He spent from
3 8:00 at night on a Saturday night until 2:00 in
4 the morning on the phone arguing with the
5 insurance company.

6 I could hear him screaming at them
7 that this kid was having gross spasms. He was
8 having very serious seizures, he needed to be
9 admitted, and they would not allow him to be

10 admitted.

11 So finally around 1:00 in the
12 morning he came in to me and called me out in the
13 hallway and he said, Anita, Danny can't go home,
14 he's too sick. He is just too sick. He said,
15 he's already gone into cardiac distress once. He
16 needs to be nearby. I'm going to try, if you'll
17 allow me, to get him admitted to the psych ward.
18 And I asked him what that meant, and he said it
19 means he's here. If he gets into any kind of
20 serious distress, he's right here.

21 So he called the insurance company
22 back again, and after an hour of screaming, they
23 said that they would allow Danny to be admitted
24 to Yale Psychiatric Institute providing he was
25 brought in by ambulance. Danny was right in the

398

1 Emergency Room, right there, and the doctor
2 argued and argued and argued, and finally he
3 agreed, and they had to take Danny on a stretcher
4 out of the Emergency Room into an ambulance,
5 because he was incapable of walking, ride around
6 the block, and admit him in the psychiatrist
7 institute at Yale.

8 That was Saturday. He finally --
9 I left Danny there at 2:00 Sunday morning. At
10 midnight Sunday night, I got a phone call from
11 the attending psychiatrist. Danny had been
12 seizuring [sic] for 50 minutes, was not
13 responding, wasn't answering questions, and the
14 psychiatrist said to me, he does not belong on
15 the psychiatrist floor, he belongs on a medical
16 floor, what kind of a mother are you.

17 I said, I'm the kind of mother who
18 can't fight the insurance company, I can't do it,
19 they won't allow him to be admitted to a medical
20 floor. I said I just -- I couldn't afford to pay
21 for Yale without insurance, and I would rather
22 have him there where at least there are doctors
23 available than at home where there are no doctors
24 available.

25 And he said to me, if you were a

399

1 good mother, you wouldn't care about money. And
2 I said well, if you were a good doctor, you
3 wouldn't care about money either, you'd pay for
4 your patients' care. I said, you want to be a
5 really good doctor, you foot the bill. And when
6 the thousands upon thousands come in, you pay for

7 them. He said well, I can't do that. I said
8 well, neither can I. He said, well, Danny
9 doesn't belong here. That was Sunday at
10 midnight.

11 Monday morning I got a call from
12 Yale. The insurance company said that Danny had
13 to leave because he had no psychiatric problems,
14 he was physically ill, and they had requested
15 that Danny be admitted to the hospital, and the
16 insurance company said no, so he came home.

17 We continued and continued and
18 continued and Yale kept insisting that there had
19 to be a psychiatric problem, the doctors that
20 were seeing Danny.

21 We went to a third psychiatrist.
22 The third psychiatrist, same thing, articulate,
23 bright, goal-oriented, perfectly well adjusted
24 young man. I went back to Yale with that. They
25 asked for a fourth opinion. And I said no. I

400

1 said absolutely not. I said you want me to keep
2 seeing psychiatrists until finally somebody
3 agrees with you that this kid doesn't have a
4 physical problem. I said you've had three

5 opinions, one of which was right out of Yale, I'm
6 not having this kid go again.

7 It was incredibly difficult for
8 Danny to walk. He is five, nine and he weighs
9 160 pounds. I can't carry him. I said each trip
10 to a doctor is a nightmare for me and for Danny.
11 So I would not do that. I told them I wouldn't
12 do that. I told them I was going to start
13 seeking help elsewhere, because I felt we had
14 just come to a dead end with them, and they
15 decided they wanted me to have Danny tested for
16 milk allergy. And I said why? They said because
17 Danny presents with a lot of GI symptoms, milk
18 allergy can be very difficult to diagnose and
19 cause these symptoms.

20 I said okay, fine. I had him
21 tested, it was negative. I called them on the
22 phone, and I said it's negative. They said we
23 still want you to continue with our allergist,
24 and I said why, the tests are negative. And she
25 said to me, because the tests aren't valid with

401

1 milk allergy affecting the GI tract, they can
2 often be negative and it doesn't mean anything.
3 I said but if a Lyme test is negative, then it's

4 really negative, but if a milk allergy test is
5 negative, it really could be positive? I said
6 don't you see how inconsistent you are? She
7 thanked me, told me she could no longer help me.

8 One day later I got a phone call
9 from a woman who introduced herself as the social
10 worker at Yale. And she was on Danny's case and
11 consulting with the doctors. I said okay. She
12 said, I understand you're not coming to have
13 Danny checked for milk allergy, and I said no,
14 I'm not. And she said, can you give me a
15 reason? I said, because Danny has been a highly
16 asthmatic child since he was three. He has been
17 tested and retested. He has never turned up a
18 food allergy ever. It's all environmental. And
19 I said, the last test that you did said it was
20 negative. He does not have a milk allergy.

21 And she says well, I just want you
22 to be aware, Mrs. Field, that if you decide to
23 pursue other things and we feel that it's not
24 adequate treatment, we can and will take legal
25 action. And I said, what kind of legal action?

1 And she said to me, well, if we feel you are not

2 giving your child proper medical care, we have
3 every right and the obligation to go to the
4 courts and get your child proper medical care.

5 I mean I'm Irish, and you don't
6 talk that way, to this Irishman anyway, and most
7 of the Irish people I know. I flipped. And I
8 said, I'd invite you, I dare you. I absolutely
9 dare you to say you are going to take -- I said,
10 who do you think you're dealing with up there?
11 Who do you think you're dealing with? I am
12 Danny's mother. I'm Danny's advocate, so no one
13 besides my husband and I will make those
14 decisions. And she said, if you pursue this, you
15 know, your insurance company can refuse to cover
16 you, and we are in contact with the insurance
17 companies.

18 I couldn't believe she was saying
19 it. I said, I dare you. I absolutely dare you.
20 I said, I want in writing from you that you have
21 a firm diagnosis for Danny that can be proven and
22 I'm refusing it. And then I dare you to take me
23 into court. I said, I would love to go into
24 court and describe what's gone on in this place
25 called Yale up here. Danny was repeatedly told

1 he had a psychiatric problem, even though
2 psychiatrists kept telling him he didn't.

3 We left Yale. We went back to my
4 own primary care doctor, Danny's pediatrician in
5 Wilton, and he said Anita, I want Danny on
6 antibiotics, Danny has Lyme. And he said, I have
7 dozens of kids like this and Yale consistently
8 sends them back saying psychiatric problem, they
9 need counseling, overachiever, too much stress,
10 parents that are too demanding. He said all of a
11 sudden I have a ton of kids who are well
12 adjusted, healthy achievers who Yale is telling
13 me all now need psychiatric help. And then the
14 other problem is fighting the insurance companies
15 to get the treatment.

16 ATTORNEY GENERAL BLUMENTHAL: Was
17 he put on antibiotics?

18 MS. FIELD: Danny was on I.V.
19 antibiotics from June until September. He came
20 off in September.

21 ATTORNEY GENERAL BLUMENTHAL:
22 September of this year? How is he doing now?

23 MS. FIELD: September of this
24 year, and was doing pretty terrible. Horrible.
25 He did pretty well for about three weeks and then

1 he crashed again. He was all excited about going
2 back to school. I mean this kid was accepted
3 into the --

4 ATTORNEY GENERAL BLUMENTHAL:
5 Could you do me a favor? Could you put this --
6 perhaps give me a letter or -- I don't think
7 you've signed up so we don't have your name.

8 MS. FIELD: Yeah, I did sign up,
9 but I don't know.

10 ATTORNEY GENERAL BLUMENTHAL: If
11 you could just give us your name and so we can
12 get back in touch with you.

13 MS. FIELD: I'll tell you
14 honestly, I found, maybe because Danny didn't
15 stay on I.V. long enough, Danny is now on oral
16 antibiotics, that he definitely has had a brain
17 SPECT and better than half of his brain is
18 abnormal. He cannot go to school. He's gone
19 from what Wilton called their gifted student to a
20 kid who can't even write a simple sentence. He
21 can't watch a movie because he can't
22 concentrate.

23 I live in fear that somehow,
24 someday, the insurance companies are going to
25 start saying we will no longer cover Danny, but I

1 found Yale far, far intimidating --

2 ATTORNEY GENERAL BLUMENTHAL: Have
3 you been covered so far?

4 MS. FIELD: I have PHS and they
5 have covered --

6 ATTORNEY GENERAL BLUMENTHAL: You
7 have PHS?

8 MS. FIELD: Yeah. They covered
9 the antibiotic therapy, they have been wonderful
10 with me on the phone. My biggest problem was
11 Yale, because when Yale couldn't come up with an
12 answer and I started saying I'm going elsewhere,
13 they used every tactic in the book to intimidate
14 me into doing what they wanted, even though they
15 couldn't offer a valid reason. And when they saw
16 that I was furious and I would have loved to go
17 into court, which I really wouldn't have, but I
18 was really angry, they backed off and left me
19 alone.

20 ATTORNEY GENERAL BLUMENTHAL: We
21 really appreciate your being here today, we do.

22 MS. FIELD: Okay.

23 ATTORNEY GENERAL BLUMENTHAL: And
24 if you could just leave your name, we'll be back

25 in touch with you. Thank you.

406

1 Thank you all very much. We
2 appreciate your participation, your help, and you
3 have given us really an enormous service, and
4 many other people who have suffered the same kind
5 of fate that many have described here today.
6 Thank you very much.

7 AUDIENCE: Thank you for listening
8 to us.

9

10 (Clapping.)

11

12 (End of hearing.)

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16

17

18

19

20

21

22

23

24

25

407

1

INDEX

2

3

LISTING OF SPEAKERS

4

5

NAME

PAGE

6

7

Dr. Cartter

9

8

Dr. Krider

26

9

Dr. Montes

45

10

Ms. Cramoy

62

11

Ms. Vanderhoof-Forschner

72

12

Dr. Eisenberg

91

13

Dr. Federico

109

14

Dr. Phillips

146

15

Dr. Katz

181

16

Dr. Feder

238

17

Mr. McFadden

264

18

Dr. Phillips

274

19

Mr. Mourey

277

20

Ms. Berenson

281

21

Mr. DePaola

287

22	Ms. Friedman	290
23	Miss Friedman	303
24	Ms. Susan Sinclair	305
25	Miss Sinclair	315

408

1 LISTING OF SPEAKERS

2 (Continued)

3		
4	NAME	PAGE
5	Ms. Prewitt	320
6	Ms. Sturges	321
7	Ms. Procaccini	334
8	Ms. Dickson	336
9	Ms. Ferraro	345
10	Mr. Carroll	349
11	Ms. Blair	350
12	Ms. DeStefano	353
13	Mr. Mershimer	356
14	Ms. Onorato	358
15	Ms. Berntsen	358
16	Morrissey Family	362
17	Ms. Curtis	373
18	Dr. Lionetti	382
19	Ms. Southwick	387
20	Ms. Field	390

21
22
23
24
25

409

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18

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

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