

**LYME DISEASE: A DIAGNOSTIC AND TREATMENT
DILEMMA**

4. L 11/4: S. HRG. 103-265

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HEARING
OF THE
COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

**EXAMINING THE ADEQUACY OF CURRENT DIAGNOSTIC MEASURES AND
RESEARCH ACTIVITIES IN THE PREVENTION AND TREATMENT OF
LYME DISEASE**

AUGUST 5, 1993

Printed for the use of the Committee on Labor and Human Resources



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LYME DISEASE: A DIAGNOSTIC AND TREATMENT DILEMMA

THURSDAY, AUGUST 5, 1993

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:55 a.m., in room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Metzenbaum, Dodd, Wellstone, Kassebaum, Thurmond, and Durenberger.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

At the outset of the hearing, I want to express very sincere appreciation to the witnesses and to the families who are joining us here today. This hearing was scheduled a week ago and then, because of the Senate schedule, it was necessary to reschedule it to today. So we are grateful to all of those who have made the special effort to come back again and be with us on this subject of enormous importance and significance from a public health point of view and most importantly from the point of view of the health needs of thousands of families, children, older people, all.

So we are grateful to all of our witnesses and to the families who are so interested and concerned about this matter and whose interests we want to pursue.

Last week, we instructed the staff to conduct personal interviews with many of those who were here, and there is just a remarkable collection of stories, and we have communicated back to the particular families and indicated that we wanted to make those part of the record. They will be made a part of today's record. It was an enormously valuable and useful exercise.

I have in my hand and we have distributed the statements of the diseased patients, family members, and other experts, and it is really a remarkable collection of information and knowledge and will be very, very helpful to us on this committee, and I am personally grateful to all of those who spent the time to reveal some very difficult and painful experiences with us, and I am grateful to all of them for making it possible to include those comments as part of the record.

[The prepared statements follow:]

STATEMENTS OF LYME DISEASE PATIENTS, FAMILY MEMBERS, AND EXPERTS

AS REPORTED TO STAFF MEMBERS OF THE LABOR AND HUMAN RESOURCES COMMITTEE

STATEMENT OF MICHELE AIELLO, R.N., 2325 LOSEE CT., MERRICK, NY 11566

Mrs. Aniello testified on behalf of her daughter, Beth, who has been infected with Lyme disease for 3 years. Mrs. Aniello is on the Board of Directors of the Long Island Lyme Association, one of the 20 Lyme disease support groups within the New York State Coalition of Lyme Disease, of which she is also a board member.

In 1990, Beth Aniello came down with symptoms similar to those of meningitis. Since then she has seen at least 30 doctors, and she has been misdiagnosed with juvenile rheumatoid arthritis, lupus erythematosus, familial Mediterranean fever, osteomyelitis, and spondyloarthropathy.

Beth had suffered from multiple arthritis episodes when, in November of 1990, Mrs. Aniello read in a National Geographic article that Lyme disease can often be mistaken for other diseases. Beth's doctors took four tests for Lyme disease, all of which came back positive. However, the positive diagnosis was too late.

Mrs. Aniello is a medical professional and has taken Beth to all the best doctors. When she was first diagnosed with Lyme, Beth was treated with Doxycycline for 30 days. However, she relapsed repeatedly with arthritis episodes and bone and joint infections. In 1993, Beth was diagnosed with fibromyalgia, which is secondary to Lyme disease. Currently, she suffers from frequent fevers, sore throats, swollen glands, headaches, rashes, ringing in her ears, and muscle and joint pains. Beth misses school frequently, and occasionally, she must be tutored at home.

Mrs. Aniello feels that doctors should be able to identify possible cases of Lyme disease right away when they see patients. This means that doctors in various areas of specialty should all be familiar with the symptoms of Lyme disease; thus, more education is needed for clinical recognition.

Mrs. Aniello also claims that the tests for Lyme are unreliable, and that many produce false negatives as well as false positives. Further, there is currently no test that denotes cure.

STATEMENT OF LINDA ARDINGER-MATEO 430 SIMPSON PLACE

PEEKSKILL, NY 10566 (914)737-4331

Mrs. Ardinger-Mateo has been infected with Lyme disease since 1981. That year, she suffered from back problems, and an orthopedic doctor prescribed exercises for her that turned her condition into severe sciatica. Over the next few years, all her muscles were tight, painful, and weak. The pain was often so great that it made her cry. She visited many doctors and neurologists over the period, but did not receive diagnosis or help.

Gradually, Mrs. Ardinger-Mateo became more fatigued, and by 1987 she suffered from constant sore throats, headaches, severe fatigue, and some depression. Being a therapist herself, she thought her symptoms could be psychological, although her life was going well, and she could not imagine why she should be depressed. A therapist she visited told her that she had no psychological problems. Another doctor tested her and diagnosed her with nonspecific hepatitis. She dropped her work hours, and after 6 weeks in bed the hepatitis had cleared up.

She continued to see the same doctor over the next year as she suffered from the same flu-like symptoms. A Lyme test he gave her came back negative. Finally, he diagnosed her with Chronic Fatigue Syndrome and told her to find another doctor who could help her.

Mrs. Ardinger-Mateo found a doctor who specialized in Chronic Fatigue Syndrome, who put her on and off of ten-day doses of antibiotics. Although she felt better during these periods, she was told that her improvement was unrelated to the antibiotics because she had no bacterial infection.

At this point she began to suffer from neurological problems; she felt "zoned out", had difficulty understanding conversations, and had shortness of breath and heart palpitations. Her doctor then told her that she had hypoglycemia, even though her blood sugar tests were negative for the condition.

After a year of constant health problems, Mrs. Ardinger-Mateo demanded that she be tested for Lyme, and the test was positive. Her doctor consulted Dr. Wormser, an expert at the New York Lyme Clinic in Valhalla. Dr. Wormser instructed Mrs. Ardinger-Mateo's doctor not to treat her for Lyme because her Lyme titer was not

high enough. However, her doctor decided to treat her anyway and put her on oral medication for 6 weeks, during which time her health declined and she was given additional tests. After her doctor switched her to 2 weeks on an IV, she felt somewhat better.

Mrs. Ardinger-Mateo's doctor discontinued treatment, and a year later she suffered from severe neurological problems. She had little balance, severe headaches, difficulty with reading and speech comprehension, dizziness, and trembling. A neurologist told her that she probably did not have Lyme disease, gave her more tests, and put her on the IV for 3 weeks. When she felt some improvement, she requested another week of IV but was denied due to the AMA protocol on the treatment.

In 1989, Mrs. Ardinger-Mateo became too weak to work at all, and she discontinued her private psychotherapy practice and her work as a school social worker. She was bedridden and slept for 2 weeks straight, during which time her husband woke her to feed her. She felt abandoned by her doctor, who told her to wait 6 weeks before any additional treatment. Although she had no history of psychological problems, she began to suffer from panic attacks and clinical depression due to the Lyme germ.

Mrs. Ardinger-Mateo consulted the Lyme disease support group and was referred to an internist who saw Lyme patients. She was diagnosed with late Lyme disease and for the next several months she was administered either oral medication or IV, with only slight improvement.

Finally, she visited Dr. Burrascano, who has given Mrs. Ardinger-Mateo IV medication for the past 2 years. She experienced significant improvement during the first year, with relapses when she was taken off the medication. She is now beginning to work again and do some socializing. She is starting to feel like a family member again.

Mrs. Ardinger-Mateo has had difficulty receiving payment from her private disability company, and was finally forced to accept a lump sum settlement which canceled her policy. Her absence from work has had a serious impact on her family's finances, as she had previously earned 60 percent of the household income. Eventually, her husband's union insurance was responsible for her coverage. However, the company refused to pay for what she was told was "willy-nilly treatment."

Mrs. Ardinger-Mateo urges that legislation be passed to mandate that insurance companies pay for Lyme treatment as prescribed by the patient's doctor. She feels that there needs to be stricter enforcement for Disability Companies and Insurance Companies to honor their contracts, with penalties imposed on those companies who fail to honor them.

She also urges that money be invested in research on curing late Lyme disease as well as early-detected cases. She claims that the so-called experts at Yale, New York Medical College, and Stonybrook are years behind the doctors that have been treating Lyme patients in their understanding of Lyme disease. Doctors with practical experience with Lyme disease, as well as their patients, need to be heard.

STATEMENT OF JANICE T. BEERS, J.D.

268 N. DIAMOND HILL ROAD, CLAYTON, OHIO 45315

Mrs. Beers strongly criticized the pamphlet published by Pfizer Central Research in 1990: "Lyme Disease: what it is—how it is transmitted—what it does to you—how to detect it—how to treat it—how to prevent it. The pamphlet was being distributed to those in the room and was going to be given to Senators. It is outdated and contains misleading and incorrect information about Lyme disease.

This is a complicated multisystemic bacterial disease. The symptoms listed in the pamphlet barely begin to describe the symptoms and combinations of symptoms that a patient with Lyme disease can present to a physician. The symptoms can go into remission and the patient can present different combinations of symptoms from time to time. And different patients present differently, often very differently, depending upon what parts of the body are attacked by the bacteria at that time.

The pamphlet says nothing about the overwhelming fatigue and malaise which usually are part of Lyme disease along with other symptoms such as eye symptoms. Nothing is said to indicate how devastating and debilitating and disabling the combined symptoms of disseminated Lyme disease can be.

Mrs. Beers objected on page 1 to the statement that "It can start out as a skin rash and can progress through stages to arthritic, cardiac, or neurologic disease." The stages of Lyme disease have been abandoned and now the disease is described as localized (undisseminated) disease or disseminated disease. Statements that disseminated disease may have arthritic, cardiac, or neurologic symptoms are true, but the way they are here and in a myriad of other publications makes it appear, incor-

rectly, that these are the only symptoms of disseminated disease. It is such statements that make the disease unrecognizable to the public and physicians alike.

Mrs. Beers criticized the section "Later disease symptoms" on pages 9 to 11. Many patients seem to recover from early disease if treated fast enough and aggressively enough, but that is not made clear in the pamphlet. It is impossible to say that most patients do not develop later symptoms of Lyme disease; nobody knows, and enormous numbers develop such symptoms. Also, to say on page 9 that later symptoms "include complications of the heart, nervous system, or joints" reduces what happens in the late stage disease essentially to a triad of symptoms which misleads and which makes Lyme disease unrecognizable to the average person and physician.

It is the emphasis on Lyme arthritis and on pictures of big swollen knees as on pages 10 and 11 that causes many to be unable to recognize that a person without these may have Lyme disease. Pain in the knees and multiple other joints does not have to be accompanied by swelling for a person to have Lyme disease, and not all Lyme disease patients have joint pain, at least not all the time. The only "heart symptoms" listed are dizziness, weakness, and an irregular heartbeat' nothing is said about heart palpitations or severe and serious heart complications. More nervous system symptoms are listed, but nothing said about meningitis or stroke or other frightening and/or serious nervous system complications.

Mrs. Beers criticized page 12 on treatment. It is badly out of date. It is true that Lyme disease is "treatable." But to say it can be "handled" fails to give the slightest clue to how difficult it can be to treat disseminated, entrenched disease. The pamphlet does not disclose what tens of thousands of Lyme disease patients know from personal experience: frequently disseminated disease responds to some extent to antibiotics, but relapses occur with distressing frequency and for many the disease is intractable to present treatments, even long-term treatments with newer antibiotics.

Mrs. Beers' criticism is not limited to this pamphlet on Lyme Disease. The Centers for Disease Control produced "Lyme Disease: a public information guide" which erroneously states that "Most patients who are treated in later stages of the disease also respond well to antibiotics, and full recovery is the rule." Full recovery is not the rule as those with disseminated disease can attest. The National Institutes of Health produced a pamphlet "Lyme Disease, The Facts, The Challenge" in 1992 which also said that of patients with neurological symptoms, "Most experience full recovery." This is not true, either. There is no attempt here to point out all the deficiencies of these CDC and NIH publications.

None of these three pamphlets describe Lyme disease so the multisystemic symptoms and protean manifestations of disseminated Lyme disease are recognizable to the public or physicians. This is particularly unfortunate because Lyme disease is a clinical diagnosis and there are so many inaccuracies in the usual laboratory serology tests—as all three pamphlets point out. All three pamphlets fail to tell about the great difficulties in the treatment of disseminated disease, and they fail to tell that for many, Lyme disease is a disabling and intractable to treatment.

The sum total of information about Lyme disease symptoms, diagnosis and treatment that is going to the public and physicians alike is deplorable.

A better pamphlet needs to be written with emphasis on symptoms, diagnosis, and treatment—that is, a pamphlet which describes Lyme disease symptoms so the disease is recognizable to the public and physicians and so the realities of treatment and the difficulties of treatment are accurately described.

STATEMENT OF J. J. BURRASCANO, MD

139 SPRING ROAD, EAST HAMPTON, NY 11937

RECOMMENDATIONS

1. Require that more realistic reporting criteria be developed and be adopted by all states.
2. Require states to report all cases of Lyme, even if it must include active case detection.
3. Fund fully the Rocky Mountain Laboratory and support its research on better testing and studies on vaccine research and pathogenesis.
4. If standardized protocols for diagnosis and treatment are to be developed, then they should be devised in conjunction with practicing physicians and exclude the current inner circle of biased individuals, many of whom have their own private agendas.

5. Press for in-depth, multidisciplinary study of chronic Lyme, perhaps with an inpatient unit at NIH, but not under the direction of the arthritis branch (NIAMS), but under the branch designated to study infectious diseases.

6. Prevent third party payers from arbitrarily cutting patients off from needed therapy, as prescribed by their own attending physicians, and not allow some unseen clerk or consultant who never cared for the patient to make decisions of utmost importance to the patient's health and future.

7. Investigate and curtail the secret connection between insurance companies and those so-called Lyme experts who oppose long-term therapy yet who are being paid by these same companies to perpetuate and publicize this view.

8. Stop harassment by individual State health departments of physicians who manage Lyme aggressively, and when these physicians' practices come under criticism, ensure that judgment is made by their clinical peers, experienced in the clinical management of this illness, and not by non practicing individuals of lesser experience and knowledge.

9. Develop a forum for afflicted patients and their physicians to relate their experiences to the scientific community so research will be directed more appropriately.

STATEMENT OF EVELYN CONKLIN

311 UNION AVE., PEEKSKILL, NY 10666

Evelyn Conklin is a practical nurse who has friends and neighbors suffering from Lyme Disease. Ms. Conklin came to the forum, in her words, "for the children. I also want to talk about insurance and treatment. We will be paying for Lyme Disease for a long time unless we spend more time and energy on early treatment. If we catch the disease early, we can prevent many of the problems associated with the long-term illness."

Ms. Conklin stated that Lyme Disease patients become completely isolated and affected children can not go to school. Ms. Conklin said, "I just think they all need help."

Ms. Conklin also stated, "After hearing these stories, I don't want to get the disease. I am single, I live alone and I don't know how I could manage if I got the disease. I have been to many support group meetings and I see what they go through."

STATEMENT OF KEITH DAMA, 5 MOHINGSON CT., HOLMDEL, NJ 07733

Mr. Dama's son, Jonathan, first evidenced symptoms of Lyme disease in September of 1991. He was unable to stand up and could not even lift his head due to the severe headaches he suffered. However, the first doctor that Mr. Dama took his son to see did not know what was wrong with the child and put him on medication for 10 days. The medicine, however, only relieved the symptoms temporarily, and 2 weeks later, Jonathan suffered these same symptoms again. He was put on Amoxycylin for another week, but once off the medication he became sick once more.

By the third time, however, Amoxycylin had no effect. For 3 weeks, Jonathan could not even stand up. When they took him to the hospital, his doctor could find nothing wrong with him. The doctor suggested that Jonathan's ailment was psychological and that he was faking sickness in order to get out of school. Jonathan, though, began to suffer from dementia. He began screaming in the middle of the night and said he was seeing things. When Mr. Dama and his wife called the doctor in the middle of the night, he told them that there was nothing to worry about, and when they requested more help, the doctor told them that he would not provide anymore help unless Jonathan first saw a psychiatrist. The Dama's then stopped taking Jonathan to this doctor and sought a second opinion.

The second doctor diagnosed Jonathan's illness as Lyme Meningitis after Jonathan tested positive to a mild Lyme test. The doctor began Claforan treatment, among the best available. Within 3 days, Jonathan could sit up and within 5 days he could walk again. Jonathan remained on I.V. treatment for 6 weeks until most of the symptoms were relieved. Two weeks after I.V. treatment was stopped, he relapsed. The doctor tried oral antibiotics, but these were ineffective. Jonathan finally went back to the hospital to have an I.V. line surgically installed in his chest.

This time it took 7 months, until September 10, 1992, until the symptoms were relieved and the I.V. line was removed. This time the Dama's thought that their son was cured, but 6 weeks later he relapsed. He tried all kinds of oral antibiotics for 10 weeks, but Jonathan only got worse, and in January 1993 he developed Tachycardia, a life threatening heart disorder. He was given a heart exam, but the doctors could find no heart disease and concluded that the Tachycardia was a result of

Lyme disease. Jonathan had surgery again to install another I.V. line, and 2 months later the heart condition was resolved and his symptoms had improved, but he was still not well.

The doctor then decided to try another medication. In order to do so, however, he had to stop all other medication for a few days to let Jonathan's system clear out. In those few days he had a severe relapse. In a gradual procession over 5 days, Jonathan got worse and worse. By the fourth day he became extremely tired, and by the fifth day, the headaches had returned and he was completely debilitated. After 2 weeks of the new medication, he was able to walk again, but had neurological deficits. He lost the ability to do simple mathematical computations, even though he is a gifted math student studying algebra. He also began to mix up words and letters and lost his ability to concentrate. His severe headaches also remained. It has taken until now for his mental faculties to improve, and he remains on I.V. therapy.

Jonathan's treatment costs are roughly \$2,500 per week, and until this year, the Damas' medical insurance has covered the charge. Their insurance companies, however, have not yet agreed to cover the 1993 medical bills.

STATEMENT OF WILLIAM J. DIDONATO

4425TH STREET, ATCO, NJ 08004, PHONE: (609) 767-0018

Mr. DiDonato is the father, brother-in-law, and friend of patients with Lyme Disease and he is also the coordinator of a Lyme Disease support group.

Mr. DiDonato is concerned with the lack of understanding by some educators as to the complications and neurological effects of the disease. Some of its effects on the ability of young people in school are test-taking problems, memory loss, headache, lack of concentration.

Mr. DiDonato said, "My daughter has been evaluated by a child study team because she had to have home-study tutoring due to Lyme Disease. It has been concluded that she has a learning impairment that may or may not affect her for the rest of her life. Another major concern of mine is that there is no pharmaceutical company in the United States that has developed an intravenous antibiotic for treatment of Lyme Disease."

Mr. DiDonato also said, "I'm very fortunate to be employed with Philadelphia Electric Company whose excellent benefits make it possible for my daughter's treatment. The total cost of treatment since was first diagnosed twenty months ago has exceeded \$30,000. My insurance company disputes the treatment prescribed by our doctor. In addition after all the money that has been spent on my daughter, her condition is only 25 percent improved."

Mr. DiDonato stated, "I feel that the Centers for Disease Control and the National Institutes for Health are doing an injustice to all Lyme patients by not accepting the on-the-job diagnosis and first hand experience of those stricken with the disease. I would hope that the real life experiences and physical data from doctors in the field would be included in CDC and NIH criteria for dealing with the disease. We need a concerted effort to find a cure."

Mr. DiDonato concluded, "I have brought with me today a petition signed by twenty-two other concerned citizens and would like it entered into the record."

STATEMENT OF BEVERLY G. DYER

1863 KALORAMA ROAD, WASHINGTON, DC. 20006

I was bitten by a tick in June of 1989—not hiking in the woods—but at a Yale Law School graduation party, in a fellow student's back yard. I developed a rash, but a dermatologist was unable to diagnose Lyme disease or any other basis for the rash. After 6 months, I began experiencing severe joint pains, wooziness, fatigue, and pain behind the eyes.

I visited at least seven doctors, including a neurologist and a rheumatologist. I discussed the possibility of Lyme Disease with each of them, but the each said unequivocally that I did not have Lyme Disease. None of them knew what was wrong, nor were they particularly concerned. One doctor laughed at me when I suggested trying antibiotic treatment to see if it would help. One doctor refused to listen to my symptoms, immediately diagnosed anxiety and depression, and prescribed Prozac. I was ready to give up on the medical profession.

Eventually, through a string of references, I went to see Dr. Joseph Burrascano. I travel hundreds of miles to visit him every month or two. This is not unusual, in fact, most of the Lyme Disease patients I know of in the DC. area travel hun-

dreds of miles for treatment—none have found a doctor here with expertise in long-term treatment. One doctor in northern Virginia is treating several patients, but his patients know more than he does, and are telling him what to do.

Despite more than a year of treatment, my symptoms have only marginally improved, although, when I have stopped taking antibiotics my symptoms worsened. The only time my symptoms improved was following my first 7 week course of IV treatment. I still experience joint and muscle pain, wooziness, loss of balance, numbness in the right side of the body, fatigue, and pain and pressure in the eyes, amongst many other symptoms. Overall, I often feel like I have been run over by a truck.

Lyme disease has had a serious impact on my life. I can only work half time in my job as a lawyer, and have cut back on almost all family and social activities. At times, I have difficulty walking due to stiffness, and find it hard to be out of bed for more than a few hours a day. Sometimes the pain and pressure in my eyes makes it difficult to drive, read, or even watch T.V. The disease has also had a financial impact: I am on half salary, my long-term disability insurer has not yet agreed that I am partially disabled, and I incur between five and ten thousand dollars in uncovered annual health expenses.

I am only willing to describe my private, personal medical history on the record because of my growing frustration at the failure of the CDC and NIH to acknowledge the serious public health threat of this disease, and because I believe patients can contribute to educating the Senate and the public. Virtually every Lyme disease patient with whom I have spoken visited between five and ten doctors before being diagnosed, and received dismissive and condescending treatment by many of those doctors. Virtually every patient I have spoken with is still suffering from debilitating symptoms, despite treatment, some after years of treatment. Out of their difficult experiences, patients have developed a strong voice, through national patient networks formed to trade information and expertise. In addition, no one but patients can describe the scope and severity of the symptoms of the disease. I have spoken with patients who have suffered strokes, paralysis and loss of sight.

I believe the reason that doctors (with the exception of a handful of dedicated practitioners, such as Dr. Burraacano) have largely been dismissive of patients' is due to the lack of reliable diagnostic tests, and to the fact that doctors cannot independently or objectively confirm patients' debilitating but mostly invisible symptoms. Faced with uncertainty and the extremely difficult problems of diagnosis and treatment of Lyme Disease, many doctors have jumped to premature conclusions. For example, Dr. Allen Steere has concluded that many patients do not have Lyme Disease, but his results—in which patients with active Lyme Disease have positive blood tests, while those who never had Lyme have negative blood tests—are inherently inconsistent with his own acknowledgement that the blood tests are unreliable.

Patients are desperate for more support from the CDC and NIH for research into diagnosis and treatment, particularly into developing better diagnostic tests for the disease, discovering how the bacteria spreads through the body, reproduces, undergoes chemical changes, and cause the numerous and varied symptoms, as well as into finding both a human vaccine and antibiotics that can have more of an impact on curing the disease.

More immediately, national organizations should improve the collection of data in the incidence of the disease, and on the frequency, severity, and progression of the various symptoms. That data could assist doctors in their difficult task of clinical diagnosis. In addition, the CDC should establish a more flexible range of criteria for reporting the diseases that permits reporting of definite, probable, and possible cases of Lyme Disease. Finally, the CDC, NIH, and the AMA should work toward educating more doctors around the country in what is currently known about diagnosis and treatment. I implore the Senate to spur the CDC and NIH into more aggressive action.

STATEMENT OF ANN EBERT, 20 BEACON DRIVE, HOWELL, NJ 07731

Mrs. Ebert is afflicted with Lyme Disease and confined to a wheelchair. She has three afflicted children, two of whom are in remission.

She holds physicians responsible for this tragedy, claiming that their twenty-8 day therapy does not work. The CDC is avoiding the facts, and lives are being lost; when will something be done, she asks? The establishment is putting its head in the sand by denying Medicare patients intravenous treatment for Lyme. Mrs. Ebert demands the government put more money into Lyme research, because, unlike AIDS, Lyme is not a disease of choice—it can victimize anyone. Early treatment can be effective in putting the bacteria in remission so their victims can resume their

roles as working members of society. Unfortunately, these people are forced to be shut up in closets because the government avoids addressing the problem.

Mrs. Ebert demands Medicare extension to intravenous treatment. The problem must be addressed now, not 10 years from now.

Ann Ebert represents a group called New Jersey Voice, which proposed State legislation with an ultimate goal of national legislation.

STATEMENT OF MARYLOU EISENHARDT ON BEHALF OF HER

HUSBAND MARTIN EISENHARDT

This letter is written on behalf of my husband, Martin Eisenhardt, who died as a result of Lyme disease on July 3, 1993. He bravely fought an 8 year battle with that disease and all that it did to him.

His symptoms became medically evident March 1986. Hospitalization was necessary due to the severity of his physical symptoms many, many times during those 8 years. The first year of his illness he was hospitalized in March and after spending time in two more hospitals he was released in mid April of that year and was diagnosed with nothing more than aseptic meningitis. Continued, serious symptoms prevailed and worsened as days went by. Weekly trips to a series of doctors were necessary to treat the variety of symptoms. He was hospitalized twice again in June and was transferred to Massachusetts General Hospital where for 96 days he suffered from loss of speech and inability to eat or move. He was transferred again to Albany, NY, all the time a "puzzle to the medical profession. A shell of a once healthy person was finally sent home without a diagnosis.

Since he was a puzzle to the medical profession, I, his wife was told to put him in a nursing home and forget him. I chose not to follow the decree of the medical profession. I wanted him to find freedom at home. Unfortunately, because of his prognosis, no doctors would even come to our home to treat the severe symptoms which remained to plague his body.

My quest to find out what had caused this complete debilitation and deterioration of a "perfectly healthy" man, as he was evaluated by our family doctor in February of that year, led me on an unbelievable journey.

My husband had the classic symptoms of Lyme disease and although we asked doctors to look into that possibility, our pleas were ignored or dismissed. Watching an episode of "20/20" in 1988 led me to having an Elina test for Lyme disease at Stonybrook, NY. Results were positive even 3 years into the horror.

Medical help came only upon my insistence. He was given fourteen days of treatment of Rocephin by IM not IV. The neurological damage that had occurred prior to that antibiotic treatment needed much more help than that, but their answer was no and the death verdict continued. Martin did respond to antibiotic treatment, but unfortunately, antibiotics were only given for his pneumonia bouts and not for Lyme treatment. As soon as the various pneumonias cleared the antibiotics were stopped. The sad cycle would continue.

My husband had been diagnosed with severe Lyme disease based on a variety of tests done in 1992—and also upon his autopsy which I insisted was necessary to prove his cause of death. A brilliant, healthy man was wasted by lack of treatment for Lyme disease. Our lives and family were devastated by this event. The economic impact on our lives was also devastating.

Living with the horror of Lyme disease ignorance has led me to meet many poor, suffering people across America. These people need help desperately from a better informed medical community and proper recognition of this devious, dangerous, and devastating illness that is very real to all who suffer from its variety of symptoms. Do not ignore our plea for real treatment and research.

STATEMENT OF KAREN FORDYCE, 15 BATES RD, JACKSON, NJ 08527

"My son and I—My son was 9 at the time—got sick in 1987. We hiked together with our dog for relaxation, through woods that have been shown to be one of the most infected in New Jersey. Of course, at that time, there was no education. I knew two things, that there was a bullseye, and that you treat it with antibiotics. And I believed it."

"I think we must have been infected at that time. Our symptoms were constant headaches, fatigue, pain. I had put myself through college with two kids, and come out with a 4.0, an accomplishment I take pride in. My education had gotten me a job as a systems analyst at a major insurance company. But I started to have trouble doing my job. I started to get tired, have headaches, and have mood swings. I kept getting bronchitis. So they'd put me on antibiotics for that. I'd feel better, but

then it would all come back after I stopped anti-biotics. It got worse and worse. My son developed swollen lymph nodes. His lymph nodes were huge, he was fatigued, he was getting thin, he had dark circles under his eyes. He was literally wasting away."

"We went from doctor to doctor to doctor. I was told I was suffering from allergies or stress. I was told to seek psychiatric help. They told me that my son looked sick, but that they weren't able to confirm a diagnosis."

"Finally, in 1989 I read about Lyme, and I went to a doctor and asked for a blood test. I was positive. I was also lucky. I found a physician who was open to chronic Lyme and would treat me and my son. We went on orals, and we improved, but our condition deteriorated when we stopped. Finally, we went on 6 weeks of IV. And we got much better. Much better. We really improved."

"But my son relapsed this year. Even before the relapse, school was very difficult, because of short-term memory problems and attention deficiencies. After his relapse, his grades fell even more and he's been in and out of school all year. He's on orals, but who knows how long we can keep this up. He's been listed as chronic by the school system. I don't know what the future is for him."

"I went downhill as well. Over the last 4 years, I have been on I.V. 3 times and on orals in between. I've been on disability from my job for 3 years. I'm now dyslexic, I have brain lesions and attention deficits. I'm in constant pain. I often don't sleep until 4 in the morning. My son can't sleep either and that's one reason he's having trouble in school. I feel very strongly that there isn't a cure for this disease once it's in the central nervous system. We're still shedding the DNA of the spirochete 4 years after treatment started."

"I have another child, a 19 year old in school in Colorado. She is a biology major and teaches Aerobics. But recently she started complaining about not being able to remember things, about her feet hurting. We tested her and she's positive. I have two children with it now, and I don't know what's in store for them. I fear for my children. We've got to give help to our children."

"We need the CDC to recognize chronic Lyme disease. I know I won't be able to get coverage for IV if I try, because I fall outside the CDC definition for Lyme disease. I should be able to get insurance coverage if my doctor says I have Lyme. I have worked to educate people at the grass-roots level about this disease: We now need to educate the CDC and the NIH."

"I wish the NIH would talk to patients, to discover that we need funding for chronic Lyme. Lyme funding mainly goes to short-term research. Our small group funds Dr. Manfred at Bayer, Fox-Chase cancer center in Philadelphia. We give him \$20,000 a year. Do you know what it takes for a small group like us to raise that much? And he's done research that the NIH and the CDC can use. I know other good researchers that the NIH wouldn't fund."

"I would finally like to emphasize that we are not crazy. We are bright, articulate people stricken with a terrible disease. We deserve to be heard, we deserve to be recognized, and we deserve action on our behalf."

STATEMENT OF MARC GABRIEL

1050 LAWRENCE AVENUE, WESTFIELD, NJ 07090-3721

During the summer of 1990, I worked at the local office of the Bureau of the Census in Mountainside, NJ. The office building was located a few hundred feet from the Watchung Reserve, an area endemic for Lyme disease. We often are lunch outside.

When I returned to Lehigh University in the fall as a sophomore electrical and computer engineering student, I developed the following symptoms:

migratory foot and leg pains; temporary bouts of peripheral paralysis; headaches; extreme fatigue; and inability to concentrate.

After speaking to many people, I was told that my problem was stress. I was referred to the counseling service.

By the spring of 1991, I became convinced that the problem was not in my head but rather a medical one. I visited my primary physician at the HIP Rutgers HMO in New Jersey. He sent me to a specialist for each symptom. After several months of fruitless investigations, we came to a dead end. No one could figure out what was wrong, and I was degenerating rapidly. The migratory pains had turned into arthritis and the fatigue and headaches became much more serious.

In the late summer of 1991, an orthopedist friend of the family invited me in for a consultation. After 3 visits, he recommended that I have a Lyme titer performed. He mentioned that he had seen many "bizarre" cases of joint pain recently in Westfield, and they turned out to be Lyme disease.

HIP Rutgers performed an ELISA that was borderline, and then a second that was negative (on the Robert Wood Johnson scale). I read-up about Lyme disease and learned that a negative test does not rule out the disease, but my doctor did. He told me "Lyme disease is overdiagnosed" and sent me home.

We spent the next 9 months arguing back and forth. I met some of the most misinformed doctors in my life during this experience. They were spitting out garbage that I contradicted with medical references. They just didn't care.

In the spring of 1992, my condition worsened and I had to drop most of my courses. After a dramatic encounter with a clueless HIP Rutgers infectious disease specialist, we went to the SUNY Stony Brook Lyme Disease Clinic, where Drs. Benjamin Luft and Raymond Dattwyler diagnosed me with Lyme disease.

They prescribed 3 weeks of IV Rocephin via HIP Rutgers. My condition improved, but I relapsed after the treatment ended. I then demanded additional treatment. After the initial resistance, they conceded (probably because they were afraid I would slap them with a malpractice suit). I relapsed again after the additional 3 weeks. I left the HMO and sought the help of a Lyme specialist.

While my neurological symptoms are fully under control with the help of the specialist, I have sharp joint pain. To control this, I use:

Oral antibiotics; Non Steroidal Anti-Inflammatory Drugs (NSAIDs); Hot water therapy every morning; A TENS unit; and Frequent rest.

I am 21 year old, and I may have chronic arthritic pain for the rest of my life because I had stubborn doctors who didn't have a clue what they were doing. All they knew was "Lyme disease is overdiagnosed." They sounded like parrots.

I wish I could say that my case is rare. Unfortunately, it is not. **THE INSTITUTIONAL DENIAL IS ENTRENCHED.** Doctors refuse to believe Lyme disease is a problem UNTIL A LOVED ONE IS HIT BY IT. Then, they believe.

STATEMENT OF BARBARA GOLDKLANG

Lyme disease has attacked Barbara's family with a vengeance. Not only does she have the debilitating disease, but her two daughters also have been stricken with Lyme. Her older daughter, a good student, was forced to give up a medical career, daunted by the physical and mental strain of medical school. Debilitating fatigue caused Barbara to give up her antique interior decorating business to handle fewer clients from her home. Unable to concentrate and focus her thoughts, she eventually had to abandon her work altogether. Once an accomplished cook, Lyme has left her unable to follow a recipe.

Barbara underwent psycho-neuro testing at a Yale clinic where she was diagnosed with "deficits consistent with Lyme disease." Testers stated that active infection could not be ruled out and recommended trail antibody treatment although Barbara would not be diagnosed with Lyme if tested by the standards that Dr. Steere advocates.

Barbara received IV treatments for her illness. The first treatment had little effect. She responded well to the second treatment. However, she later relapsed and serious cognitive problems returned. The third treatment was successful, and Barbara recovered partially. While she still is unable to concentrate for an extended period of time, her cognitive problems are less severe than previously. Speaking with Barbara, one notices that she lapses between phases of extreme coherence and intelligence, utilizing a broad vocabulary and demonstrating her high intelligence, and phases of inattentiveness and inability to concentrate.

Barbara advocates:

that chronic persistent infection be addressed and researched by NIH; and the establishment of a children's facility to research the treatment of adolescents and young adults infected with the Lyme virus.

Barbara feels that the disease has been largely dismissed by academia (private university researchers) and this is a chief reason that Lyme disease has not been properly studied.

STATEMENT OF JUDI HASON

34 GILDARE DRIVE, EAST NORTHPORT, NY 11731

Judi Hason is on the Board of Directors of the Long Island Arthritis Foundation and is also the Chairperson of Education of the Lyme Disease Coalition of New York State.

Her statement is as follows:

"The Lyme Disease Coalition represents 25 support groups in New York State. We have thousands of people belonging to our coalition that are sick with Lyme Disease

and are not getting better. If Lyme Disease is an easily curable disease, why do we need 25 support groups in New York State?

We only represent one State in this country. There are hundreds of support groups in all across the country. We need money for research to help all those suffering from this disease."

Ms. Hason has been sick with Lyme Disease for 4 years. She has been treated twice with intravenous antibiotics, and still is not 100 percent well. She suffers from severe arthritis and was forced to close her business and end her career as a freelance jewelry designer.

Accompanying Ms. Hason was Ms. Karen Gustafson, a co-facilitator of the Long Island Arthritis Foundation and a strong supporter of the New York State Lyme Disease Coalition. Ms. Gustafson has tested both positive and negative for Lyme Disease and has suffered from arthritis and vertigo in the past few years which she attributes to the disease.

STATEMENT OF RAY HERNANDES

101 WEST MAIN STREET, CLINTON, NY 08809

Mr. Hernandez believes that a grassroots education is the most important element in combating Lyme disease. Specifically, a thorough education that begins in Kindergarten is needed to make children aware of the symptoms of Lyme disease and the means to prevent it.

Mr. Hernandez believes that doctors are also misinformed about the disease. He believes that:

Doctors are not familiar with the symptoms; Doctors are not familiar with effective treatment programs; and as a result doctors tend to mistreat Lyme diseases as if it were another malady.

Mr. Hernandez would encourage rigorous education to doctors. Information should be published and distributed to physicians and medical forums should be held to disseminate information about the disease and its treatment.

One other major problem that Mr. Hernandez cited was that doctors are not allowed to freely treat patients due to restrictions imposed by insurance companies. These powerful insurance companies are readily willing to treat cancer patients, for example, but will not treat those afflicted with Lyme. In the long-run, according to Mr. Hernandez, this will actually cost the insurance agencies more money due to lawsuits and other legal fees.

Mr. Hernandez then described his own affliction with Lyme disease, stating that it was a typical case of doctor misdiagnosis and mistreatment. When Mr. Hernandez first noticed the symptoms and rash typical of a Lyme tick bite, his personal physician told him to "throw the tick away" because the chances that he had Lyme disease was one in a million". Subsequent diagnoses and opinions included gout, stress, and depression. Only after seven doctors, did one ask for a medical history involving any peculiar bites or rashes.

By the time this doctor concluded that Mr. Hernandez might be afflicted with Lyme disease, he had already lost his job in construction due to a loss of equilibrium, slurred speech and impaired vision. Mr. Hernandez claimed that Lyme disease is not taken seriously enough as a affliction. Considering that it is second only to the AIDS in the number of infections, the United States should be doing much more than it currently is to educate the public as to the dangers of the disease.

STATEMENT OF MARTHA KRAMER

NEBSOX LANE, GARRISON, NY 10524, (914) 424-4051

Martha Kramer's family is chronically ill with Lyme disease—her husband, her 9 year old son and herself. She has two other children who remain in a healthy condition so far. Her family has spent 3 years on antibiotics to halt the progress and control the symptoms of the disease. In fact, her son has never known a disease-free life. She complains that there is too little research funding for those who are chronically ill, which should be committed to by the government.

She explains that her family is not an isolated case. In the township of Phillipstown, New York, many families have a similar experience in which they must live under the fear of an endemic community. Mothers and fathers are sick with the disease, their livelihood is jeopardized, and their children are invariably missing school.

Those who missed an early diagnosis are having to fight for treatment. Many insurance companies are denying benefits because long-term antibiotic treatment is

considered "unsubstantiated and experimental." She says antibiotics are the only life line until research finds a cure, which should be made the absolute priority.

She also mentions the dysfunction of the health care system—her own insurance company overcharges which gets her family in trouble financially. When the dangerous bacteria infects her children's brains, and makes them weaker day by day, she cannot turn down payments for their health.

STATEMENT OF CAROL LAYMON, 6044TH AVENUE, EAST NORTHPORT, NY 11731

"If it's not as severe as they're saying, why are there 25 support groups and two coalitions-New York and New Jersey-which don't have the funding to help? Fund-raising has been done, but it is very difficult."

One May morning in 1986, Carol Laymon awoke to find three new beauty marks on her body. After examining them closely, she found that they were caused by tiny deer ticks. In the days that followed, Carol began to feel fatigued almost daily. Movement became painful, and she developed a persistent earache and extreme neck pain.

Specialists were no help to Carol. After 4 weeks she experienced a major breakout of symptoms including neck and back pain and extreme dizziness.

As her illness continued, Carol was demoted from District Manager of the 1st Federal Savings and Loan to manager.

She underwent "thousands" of tests including nerve tests, CT's, and MRI's. She saw ten doctors, and all of her tests came back negative. All the while she felt sicker and weaker. Her muscles were weakening; her knees were troubling her; she had sever headaches and rashes. Her symptoms became so severe that she was no longer able to drive. She once lost consciousness while driving. Her illness also rendered her unable to do her job, and as a result, she had to quit.

She saw twenty doctors; each ignored her rash. In 1990 she felt psychosomatic and saw analysts for the next 10 months. Her family life was also adversely affected by her disease. Her three children and her husband of 7 years did not understand her disorder. The Laymons were forced to take a second mortgage on their home and use their savings to pay for Carol's medical bills.

Carol took IV treatments for Lyme disease for 6 months in 1990. The treatments affected her entire body, relieving some of her symptoms.

As a result of her sickness, Carol has peripheral nerve damage and muscle damage. She feels alternating periods of pain and numbness in her face and hands. She feels that her nervous disorder is getting progressively worse.

Carol is concerned that doctors are afraid to treat Lyme patients because of the threat of malpractice suits that could be brought in many Lyme cases. Doctors are also unaware of how to recognize and treat Lyme, primarily because it mimics so many other diseases.

STATEMENT OF ANTHONY L. LIONETTI, MD

630 SOUTH WHITE HORSE PIKE, SUITE A1, HAMMONTON, NJ 08037-2014

I'm a physician, licensed to practice medicine in the states of New York and New Jersey. I'm specializing in internal medicine and over the past year alone have evaluated over 500 people for the possible diagnosis and management of Lyme Disease (LD). I have felt compelled to share with this Committee some of my experiences and observations. Currently, in my private practice, I am involved in as a clinical investigator with the University of Pennsylvania in an NIH funded study of a new test for the diagnosis of LD called the Polymerase Chain Reaction (PCR) test.

I have been trained in internal medicine residencies affiliated with New York University and also with the University of Medicine and Dentistry of New Jersey. I must admit that residency training in this country is deficient in preparing the physician to go out and diagnose LD.

I have seen numerous patients with various manifestations of polyarthritis, headaches, fatigue, and focal neurological deficits that have been given other diagnoses such as rheumatoid arthritis, systemic lupus, arithmatosis, chronic fatigue syndrome, and fibromyalgia to name a few, who were in fact really suffering from LD. These patients came to my office with reams of medical data from their personal files consisting of diagnostic laboratory testing, imaging studies, and specialty consultations from University physicians. What has been most disturbing to me in my review of these files has been the inappropriate usage and interpretation of the diagnostic laboratory tests clinically available to aid in the diagnosis of LD.

There have been patients who have had negative Lyme ELISA tests who had described Erythema Chonicum Migrans (ECM) rashes after a tick bite followed by flu-

like symptoms than associated with polyarthritis, fatigue, and neurological symptoms who were told that they did not have LD. In many of these cases a Lyme Disease Western Blot was never performed. After obtaining a western blot from our office they were found to have multiple bands present for LD which would be considered positive by even the most stringent criteria for the western blot test. Of great importance has been that these patients have resolved their disease symptoms entirely or have been placed in remission by utilizing appropriate antibiotic therapy. I must emphasize again that these patients have been seen previously by leading infectious-disease and neurology experts from prestigious institutions.

I have an elderly patient who lives in an endemic area for LD and had no explanation for the development of her inability to walk after intensive investigation by her medical doctors, which included a lumbar puncture, her cerebro spinal fluid revealed six bands positive for LD. Her doctors, even though she'd never received antibiotic therapy, concluded that her LD was old and not active, and thus she was not treated. She was sent home from the hospital, and while there, fell and broke her hip. When she was re-emitted to the hospital she was finally treated for LD.

There are many more patients that I could describe case studies that would assault this Committee, however I know that there are more than enough people suffering from LD here today that will describe this problem accurately.

As a physician treating LD, I believe there are certain specific issues that this Committee must deal with completely and in a timely manner due to the amount of unnecessary suffering that is occurring in our country due to this disease.

Diagnosis and education of physicians about LD is a tremendous issue in this country. At present, the diagnosis of LD must be based on the clinical interpretations of physicians who are competent in understanding the path of physiology and clinical presentation of LD. By this I don't mean to State that LD should be its own specialty, per se, however, physicians in training need to be taught about LD by those physicians who are seeing the patients. I sincerely believe that the majority, if not all, training programs for internal medicine, family practice, and infectious diseases in this country are severely deficient in the skills needed for the understanding and management of this disease.

I have brought up a short case history to peek this Committee's interest in this problem. The greatest problem in this area is the reliance of physicians on diagnostic laboratory testing for making the diagnoses. This is fraught with error in the diagnosis of LD due to the low sensitivity and specificity of current clinically available tests (Lyme ELISA and Western Blot). The next issue I'd like to address which flows from our clinical diagnosis dilemma due to the inaccuracy of our current testing is the obvious fact that very little funding of new tests for the diagnosis of LD exist. Why is this the case? I believe an answer can be found in analyzing some of the ways funding for medical research occurs. One of the methods utilized by the NIH to determine the immediate need for funding research in medicine is an analysis of the Center for Disease Control's Surveillance of Disease reports. These reports are generated based on the incidence of disease reported to CDC. This is broken down by State and county. It would seem to be a very good system, and it generally is. With LD, however, a problem has cropped up in that the CDC has established extremely severe surveillance criteria which can tend to exclude the majority of patients who absolutely have LD. This under-reporting, of course, leads to decreased public awareness of risk of disease and thus leads to relative complacency about immediate need for funding research.

Last, I would like to address the issue of management of LD. Initially, as LD was first described, it was felt that short-term antibiotic therapy would be sufficient for the treatment of LD. This is not true. I have encountered patients who maintain positive PCR tests well after 3 months of intravenous antibiotics. Though this is anecdotal, I believe that the occurrence of this type of relative resistance to the currently used antibiotic regimens is not uncommon.

Dr. Allen Steer recently published an article in the Journal of the American Medical Association about the over-diagnosis of LD. I would request this Committee to have an independent panel of physicians and statisticians review all his conclusions in this retrospective study. I do believe they will find it is highly flawed and these inaccuracies are leading to an under-diagnosis of LD by practicing physicians who have read this article and not questioned its authority based on its merits rather than by its author.

In addition, the various insurance companies have been using this article as a basis for not paying on claims for the management of LD beyond 28 days of intravenous antibiotic therapy.

In conclusion, I would hope that this committee will be able to address these issues so that the amount of suffering that LD is causing in our country can be decreased and prevented. Thank you.

STATEMENT OF JO MCCAULLUM, P.O. BOX 3096, OAKTON, VA 22124

Mrs. McCallum contracted Lyme disease while clearing brush in Minnesota in May 1990. She noticed that, in retrospect, she and her husband had had to remove several ticks from their bodies after working in the brush. Upon her return to Virginia, she felt tired and initially thought that it was merely a bad case of jet lag.

She subsequently developed severe fatigue, headaches, muscle aches, and photophobia, which are all classic symptoms of Lyme disease. Yet she was not initially diagnosed as having Lyme. She was treated with a 10 day course of oral antibiotics which did not alleviate her problems. After asking her doctor she was put on another 14 day course of Doxycycline. Four days after she stopped the medication, her symptoms returned. She noted that she was exceptionally fatigued, so that even going to the bathroom was an arduous task.

She was then treated with I.V. antibiotics for 16 days, followed by another relapse and a 28 day I.V. treatment. None of her treatments with antibiotics made her feel "normal," though she felt much better on the drugs than off of them. She even attempted take some medications imported illegally from Europe, which she used in combination with omoxycillin. She has been off and on various medications since, and has currently gone 3 months with no antibiotics while feeling relatively well.

She stressed the difficulty of living with the disease, and the need for treatment with antibiotics for as long as the patients needs them, rather than for set treatment period. She also noted the difficulty in getting a doctor to confirm that she had Lyme disease, and fears that there are many people who have the disease, yet live with the symptoms because their doctor tells them that they are perfectly well. She wants more research to be done to find a cure for the disease, and plugged Richard Lynch from New York as a good, innovative researcher. Ms. McCallum also hopes that doctors will be better educated about the disease, in order to facilitate diagnoses.

STATEMENT OF PAT SMITH, WALL TOWNSHIP, NJ

I have two daughters, Michelle and Colleen, who suffer from Lyme disease. Colleen is a fifteen year old honor student who has been out of school for 3 years. She receives home instruction and is currently working feverishly over the summer to try and complete her freshman year. She has been experiencing seizure activity for a year and has abnormal EEG's consistent with Lyme. During the temporal lobe seizures, which can last for 2-3 days, she initially experiences speech impairment and a paralysis of her legs, and throughout the seizure, she is withdrawn from reality and experiences mental confusion, paranoia, and emotional turmoil. In addition to the seizures, she has had arthritic, ophthalmologic, dermatologic, and other neurologic and musculo-skeletal symptoms of Lyme.

Colleen has had to give up most of her childhood because of Lyme Disease. She was a very athletic and musical child who has had to forego all her activities and has experienced weight gain and dramatic changes to her life due to Lyme. In the past 3 years, she has had eye problems which have not allowed her to read for any extended period of time without violent headaches and/or distorted vision. Throughout these ordeals, she has maintained a positive attitude.

Over the past 4 years, Colleen has had approximately 5 months of IV antibiotic treatment with several different drugs. For the past 2 years, she has been on oral antibiotics. The antibiotics have helped; when she was removed from them for an extended time period, she relapsed. Her doctors include an internist, rheumatologist, ophthalmologist, neurologist, MD nutritionist, and chiropractor.

Michelle is twenty-four and has had Lyme disease since college. After oral antibiotic treatment, she suffered no symptoms for almost 3 years, then relapsed. She is chronically tired, has headaches and recurrent eye infections. Her current treatment regimen includes oral and ophthalmic antibiotics. She continues to work, since her symptoms are not as severe as Colleen's.

Last year while serving on my local board of education, I prepared a preliminary report on how Lyme has affected nine New Jersey school districts. I presented this to the Centers for Disease Control and the National Institute of Health in Washington by invitation of my Congressman. As a result of the report, CDC sent Dr. David Dennis to New Jersey to complete a more in-depth report on the effects of the disease on school children. I worked with him and the New Jersey Department of Health to expedite the data gathering. Although I do not agree with some of the conclusions drawn by the CDC in its follow-up report, I believe the data collected speaks to the seriousness of the disease.

There are a number of problems with the State and Federal public health response to Lyme that deserve Congressional scrutiny. The doctors currently

underreport the number of Lyme disease cases, primarily because the CDC definition of the disease is an epidemiological one which has been inappropriately applied to diagnosis in clinical situations. Additionally, when these agencies had obtained useful data and case studies on Lyme, they applied the information toward focusing on one treatment complication of a particular antibiotic rather than focusing on the disease itself.

The National Institute of Health (NIH) also possesses data, including tissue samples exhibiting spirochete survival after long-term antibiotic therapy, which it has failed to release to extramural researchers.

In conclusion, I urge serious consideration be given to the testimony of physicians such as Dr. Burrascano who treat hundreds of chronic Lyme patients and are knowledgeable about the variability of symptoms and the survival of the spirochete even after extensive antibiotic therapy.

Lyme has deprived children such as my daughter of their activities, friends, school and of their childhood; for others, it has taken their lives. You have the ability to stop this indiscriminate killer. Don't let our children down. Thank you.

STATEMENT OF CAROL STOLOW, 43 WINTON RD., EAST BRUNSWICK, NJ 08816

A resident of East Brunswick, NJ, Carol Stolow has been directly affected by Lyme disease since 1990, when her three children contracted the disease. Mrs. Stolow knows that had she been properly educated about the cause of Lyme disease, her children would not have suffered the incredible pain that was caused by the bacteria. As a result of her personal understanding of the trauma that debilitating diseases cause both families and individuals, Carol Stolow organized the Lyme Disease Network. Single handedly serving 1500 members, she has been able to organize approximately 200 support groups for Lyme disease victims. Fortunately, as her children have been free of symptoms for almost 1 year now, Carol Stolow is able give hope to victims whose horrible experiences with Lyme disease have left them with none.

Mrs. Stolow's three children have Lyme cases that are presently in remission, but she and her family suffered for 2 years while her daughter, Kimberly, battled Lyme disease at home. Her contact with thousands of Lyme victims has made her acutely aware that in most instances the bacteria is not easily diagnosed. In fact, most doctors are unfamiliar with the disease and it is commonly misdiagnosed. Like many other Lyme disease victims, Mrs. Stolow's children were not diagnosed immediately. She was accused of having marital problems that caused her children to act abnormally, and her daughter was accused of imagining her symptoms and "faking it" with her best friend, who also contracted the disease. Carol Stolow described an encounter with her fourth doctor who said, "I would be more likely to believe that 50 people standing at a bus stop could have the same psychosomatic disorder than I could believe that these two girls have Lyme disease." Fortunately, the fifth doctor accurately diagnosed her children with Lyme disease.

Carol Stolow administered three intravenous treatments to her daughter over the course of a year. In the months following, Kimberly received antibiotics and her condition seemed to improve. However, once she was taken off of the medication, the symptoms returned with a vengeance, and eleven year-old Kimberly suffered seizures, loss of vision, loss of appetite, rapid heart beat, loss of concentration and pain that was so unbearable she awoke screaming. After 9 months of aggressive therapy, all three children remained symptom free. Yet, Carol Stolow would be in constant fear of her children suffering relapses if she allowed the disease to control her. While forming the Lyme Disease Network has given her the opportunity to help others find proper health care, it has also given her the strength to regain control of her life.

Recently, Carol Stolow has received an increasing number of calls that she feels unqualified to handle due the severity of the callers' problems. She has discovered that on the average, a Lyme disease victim sees nine doctors before they are properly diagnosed. By the time they come into contact with the Lyme Disease Network, they are often out of work, out of money and are receiving no moral support. This is often a result of insurance agencies throughout the country that are finding loop holes in their policies which leave patients without coverage. Mrs. Stolow has found that while insurance agencies refuse their patients coverage because of "above reasonable and customary prices", these patients are in many cases receiving the most inexpensive care available. Their misdiagnosed, undiagnosed and unaddressed Lyme disease has left many victims without hope and Mrs. Stolow is, "not trained for suicide prevention."

Entire families are often infected with Lyme disease. One family that Mrs. Stolow works with has been fighting the disease for several years. A mother of three,

Donna has been working twelve hour shifts at a hospital where she is a Registered Nurse, in order to receive medicine for herself, her husband and her three children who have Lyme disease. She is able to purchase medical supplies at reduced rates, and is qualified to administer her family treatment. However, her insurance policy recently revoked her coverage because the insurance company did not feel that the treatments were medically necessary. Donna is ill herself, but nonetheless, she must work long shifts to pay for the medication. This is just one example of a family that faces financial destruction because of Lyme disease.

Carol Stolow believes that it is essential for the ignorance surrounding Lyme disease to end. Because Lyme disease manifests itself in many ways, the Center for Disease Control's criteria is completely inadequate. For this reason, hundreds of thousands of Lyme disease victims go unreported. Also, the media fails to accurately report the deaths of Lyme disease victims, and as a result, the American public is unaware of its devastating results. Through The Lyme Disease Network, Carol Stolow organizes lectures, provides a phone service, and writes a newsletter. She tells her callers of her own success with the disease, but Carol Stolow feels that until the serious issue of Lyme disease, second only to AIDS in its number of infections, is addressed people will continue to suffer.

Carol is testifying about Lyme disease as a victim of Lyme disease and as mother of a family afflicted with the disease, not as the director of the Lyme Disease Network.

STATEMENT OF RICHARD AND CAROLE TEGNANDER, 59 SOBRO AVENUE

VALLEY STREAM, NY 11580, PHONE AND FAX: (516) 285-7075

Richard and Carole Tegnander have had their normal, average American lives disrupted and nearly destroyed by Lyme disease; a ravishing disease that has irrevocably altered the normal lives of thousands of Americans like the Tegnanders. The attached letter chronicles the Tegnanders' travails with doctors and misdiagnoses to a final realization and acceptance that they both suffer from Lyme disease. Hopefully, the letter also captures the desperation of the Tegnanders and the extreme weariness they feel from years of combating inertia and ignorance.

Carole Tegnander was subjected to a slew of false diagnoses by doctors ignorant of Lyme disease. She and her husband were subjected to an emotional rollercoaster with each misdiagnosis. The diseases Carole was told she had were serious and in many cases deadly. When Carole was diagnosed with M.S., Richard was devastated to learn that this disease would eventually kill his wife. With the realization that this was a misdiagnosis, Richard and Carole were mildly relieved but also daunted by the prospect of some other unknown disease that might be attacking Carole.

The degree of incompetence about Lyme disease that the Tegnanders faced is best illustrated by the story of Carole's misdiagnoses. When she was diagnosed with Lupus, she and her husband joined a Lupus support group only to be told by support group members that Carole didn't have the symptoms of Lupus. After being diagnosed with epilepsy, Carole's doctor prescribed a common epilepsy drug which caused her to lose consciousness repeatedly. After being diagnosed with severe arthritis, Richard and Carole joined an arthritis support group. In this group, they found others who had experiences similar to their own. This group began to meet separately from the arthritis group and eventually grew into the Long Island Lyme Association (LILA), the first support group for Lyme patients on Long Island.

Richard is co-founder and vice-president of LILA. He is also an administrator with the Nassau County Parole Commission. In addition, he works as a part-time night teacher, teaching English and history to foreigners. Carole works in a nursing home. They have kept their jobs and continue to lead productive lives. However, Lyme disease is a continual drain on their energy and financial resources. In addition to the painful fatigue that the disease brings, Lyme not only drains the Tegnanders physically, but their financial resources are also strenuously taxed by their medical cost. Their financial plight was exacerbated when, during the very early stages of their respective treatments, the Tegnanders insurance company stopped covering the cost of their Lyme treatments.

According to the Tegnanders, they are not the only Lyme patients to be abandoned by their insurance companies. The Tegnanders stated that the CDC has established narrow criteria for reporting Lyme cases. These criteria require an individual to have an "E.M." rash (bullseye rash) or a positive blood test in addition to multiple physical symptoms to be considered a "reportable" case. Unfortunately, insurance companies often rely on these criteria for the basis of their coverage. If a case does not meet the criteria, the company may deny insurance reimbursement.

The Tegnanders feel that this is not fair, and it is not what the CDC intended when they established the criteria.

Beyond financial concerns, a larger specter looms on the horizon for the Tegnanders. There is a constant fear that the disease will suddenly take Carole or Richard without warning. "This thing is killing us," Richard states simply. "One day we will die from this."

The Tegnanders are not only concerned with themselves. They are troubled that people know so little about this disease, the second fastest spreading disease in the country. They are concerned that the common hiding place for the tick that spreads this disease is grassy wooded areas. "Places where children play," Richard says.

European doctors are much more informed and knowledgeable about Lyme disease than their American counterparts, according to the Tegnanders. Europeans are actively engaged in research and public awareness campaigns against the disease.

The Tegnanders' primary concerns about the disease are as follows:

there is no test for Lyme; there is little research being conducted; the rash that indicates a Lyme infection occurs in only 40% of those infected and typically occurs in places where it may go unnoticed; there is a lack of education about the disease; and doctors are afraid to diagnose Lyme patients due to fears about malpractice as well as the absence of an FDA approved drug for treatment and of a approved method of treatment.

LETTER FROM RICHARD AND CAROLE TEGNANDER

My name is Richard Tegnander. I reside in New York, and I am a "victim" of Lyme "misdiagnosis."

In the early 1980's I was living the American dream. I owned my own home. I had a beautiful wife, a handsome son, a good job, but most of all, I had my health. Then in 1985, my dream became a nightmare.

It began so subtly that I did not see it at first. It began with my coming home from work and finding my wife lying on our sofa, crying uncontrollably. I immediately thought of all possible tragedies. How ironic that it should turn out to be worse than I could have imagined. My wife, Carole had been working as a secretary at a local high school. She related to me that of late she had been coming home so exhausted that she hurt all over. She spoke of vague aches and pains. A stiff neck, a ringing in her ear, a sore throat, headaches, blurry vision, spots before her eyes, dizziness, loss of memory, slurred speech, loss of sensation on the side of her face. She began to experience knee swelling and pain. She suffered from lower back pain. She experienced "heart flutters," difficulty sleeping, uncontrollable muscle twitches.

It was at this point, early in 1986 that our odyssey of visiting doctors began. There were dentists, oral surgeons, allergists, neurologists, orthopedists, cardiologists, endocrinologists, chiropractors, internists, rheumatologists, and more. Each "specialist" had his or her own ideas as to what was causing the problems. Each had their own battery of tests. Each had their own diagnosis.

My wife had Lupus, M.S., epilepsy, Sjogrens Syndrome, TMJ, rheumatoid arthritis, allergies, was suffering from some form of psychological disorder, stress, PMS, to name but a few. It was not until a Rheumatologist, upon reexamining her, decided to test for Lyme disease. Two tests later, he said she did in fact have Lyme disease. He treated her initially with oral antibiotics. She felt better, and he said she was cured.

During the 5 years it took for my wife to be diagnosed, I'd followed her from doctor to doctor, test to test. I was experiencing fatigue, heart "flutters" and occasional headache and dizziness. Our family doctor said it was stress from my wife's condition. At my wife's urging I agreed to be tested for Lyme. Sure enough my tests came back positive, also. Like my wife, oral antibiotics did not work, and I too underwent I.V. treatment. Like my wife, I felt better also. A few weeks passed, and my wife began to experience a recurrence of her symptoms. The doctor who had treated her refused to put her back on antibiotics. You see 3 weeks of antibiotics was all that was called for Lyme disease.

The search for answers continued. Again, doctors tested and doctors prescribed, but my wife and later myself did not get better. You see, I too relapsed. It just took & little longer.

Finally, we came upon a doctor who gathered together all our records, all our tests, did his own testing and determined that there was still active Lyme infection. He treated us with various antibiotics, and in time, we responded favorably. I have been in remission for the past year. My wife, unfortunately, continues to be treated with antibiotics.

As I stated in the beginning, ours is a story of the American dream becoming the American nightmare. We have suffered physically, emotionally, and financially. Our health had deteriorated, our friends, family, even co-workers shun us. They do not understand what the hell we are going through. But you look great," they say. Little do they realize the struggle it has been to continue working, trying to keep up some semblance of normality.

Doctors who have not been blessed with infallibility, try to justify their own shortcomings by stating that they don't understand. We, after all, are not doctors and should not presume to be doctors. Nothing could be further from the truth. The truth is that we trusted our doctors. We listened to their every word. We believed they knew what they were doing. But time and time again, these doctors did not diagnose us; they misdiagnosed us. These doctors did not treat us; they mistreated us.

To say Lyme disease is over-diagnosed is to say that Lupus, M.S., epilepsy, and arthritis are over-diagnosed; for these were all attributed to my wife and later to myself. A day does not go by that I do not hear of another unfortunate individual who has had to run the gauntlet of doctors and diseases before being diagnosed with Lyme. These people did not go out and seek Lyme disease. Lyme disease found them.

Much of the rationale for saying Lyme is over-diagnosed is based upon negative blood tests. Are we to believe that only Dr. Steere's blood tests are valid, while all others are either "false-positive" or "false-negative." It's the test, stupid! There is no valid test.

Until a reliable test is developed how can any one say when Lyme disease begins and when Lyme disease ends? If someone tests positive and has symptoms but has already received the prescribed 3 weeks of treatment, then it must be a false-positive test. Why couldn't it also be chronic, persistent infection?

How can anyone be so positive about a disease that was unknown until approximately twenty years ago? It's interesting to note that Dr. Steere didn't get up one morning and say, "I think I'll drive down to Lyme, Connecticut and discover a new disease." It was a group of mothers who would not dismiss their children's problems as just arthritis. They demanded more from our medical profession. Further, Dr. Steere might have put together the evidence and found a new disease that was transmitted by a tick, but he did not know it was a spirochetal bacterium that caused the symptoms. That took another 10 years.

We are not asking for miracles, although we might silently pray for one each night. What we do want is honesty, open discussions, exchanges of information. Is that too much to ask? Polarization of views must stop. People are suffering. People are dying. We are sick and tired of being sick and tired. The time for posturing must end.

Won't help us wipe out Lyme in our lifetime? Thank You.

STATEMENT OF SALLIE FLORENCE TIMPONE

My name is Sallie Florence Timpone. I reside at One Austin Place, Hasbrouck Heights, NJ. I am married and mother of three children ages eleven, seven and five.

I have been suffering with Lyme Disease for twelve years. When infected in 1981, I had all of the classic symptoms. My torso was covered with a very large, expanding bull's eye rash. I had Acrodermatitis Chronica Atrophicans (ACA) on both legs. This is a classic sign of a spirochetal infection. My legs, from my knees to my ankles, tripled in size, became very black and blue and were covered with large hard lumps. Three dermatologists and my trio of doctors were mystified. All they could do was prescribe cortisone cream. My symptoms for the next 7 years varied greatly. They included (but were not limited to) severe headaches, disorientation, blackouts, shooting pains down arms and legs, eight "kidney stones" (diagnosed but never found), light sensitivity, and PAIN. .. migrating pain, stabbing pain, muscle pain, neck pain, you name it—it hurt!

I visited no less than sixteen different doctors. I was told I could have everything from multiple sclerosis to Bored Housewife Syndrome. I was asked questions like, "How is your sex life?, Do you love your kids?". I was sent to a psychiatrist. I was given every test known to man (CAT Scan, MRI, etc.) and was told there was nothing wrong with me. I begged doctors to explain my pain. They all wrote me off as "nuts". In 1988 I watched a television show about Lyme. It showed the rash and explained the symptoms. I talked it over with my husband and other family members that remembered the rash. We all agreed it was too much of a coincidence. I went for a test. My first test was "equivocal" so I was sent to an infectious disease doctor. This guy was actually excited about my history. He said I was a classic case. My Lyme tests showed up positive—both blood and spinal fluid. I was told by new

ID doctor, "If you have to have an infectious disease—Lyme is the one to have. I'll have you cured in 2 weeks!". Needless to say I was overjoyed. After 7 years of searching for something—anything—I had found the answer. I wasn't crazy after all.

It has been 5 years since I got that initial promise of a cure. Not much has changed—except that I'm a little poorer, a little sicker and very, very frustrated. I have tried just about everything I could possibly try to get myself better. I've found that three to 6 months on strong IV antibiotics seem to help keep me on my feet. I am not wealthy—I have already lost my insurance once. I may lose it again. Lyme Disease has made my life very difficult. The medical and insurance industries and the State and Federal governments have made it almost impossible! I am forced to fight every day for my rights as a patient.

I don't think Lyme patients are asking too much. We simply want to be believed, we want to be treated with respect. We want our government (state and federal) to fund research for a CURE for CHRONIC Lyme Disease. We want someone to put the insurance companies in their places and insist they stop practicing medicine and simply pay for it like their contracts promise!

Thank you for the opportunity to share my thoughts with you. I sincerely hope you can make a difference.

As a matter of record: I sit on the New Jersey Governor's Lyme Disease Advisory Council, I am Vice President of the Lyme Disease Association of New Jersey and am a founding member and past president of the Lyme Disease Coalition of New Jersey.

Contact number (201)288-3463.

STATEMENT OF EILEEN WADE, 474 PEMBURN DR.

FAIRFIELD, CT 06430, PHONE NUMBER: (203)336-4280

Eileen Wade of Fairfield, Connecticut contracted Lyme Disease when she was a teenager, but went undiagnosed for years. During her illness, Eileen has visited thirty physicians in search of diagnosis and treatment. Wade has been hospitalized at various times during her illness, and she adds, "the past 10 years have been devastating."

Ms. Wade suffers from a number of medical problems due to Lyme Disease. Wade has been left sterile. Wade has also had many neurological problems and seizures during the past 10 years. She has experienced temporary blindness, and at other times has been totally unable to walk.

Ms. Wade, who is a single parent of a daughter with no child support, has been unable to work for 4 years. Before the disease left her unable to work, Wade was a regional manager for a large corporation with, in her words, "a good salary and a company car." Now she and her daughter have moved back in with her parents to try save money because the costs of treating Wade and her daughter Heather total close to \$ 1 million.

Heather Wade was also diagnosed with Lyme Disease 4 years ago and she is severely ill today. Heather has not attended school in 3 years and has been hospitalized often in that span. Wade said, "Heather is bed-bound today and in the care of her grandparents, which is why she is not here today. She wrote a report about Lyme Disease that I would like included if I may."

Wade also said, "We will reach the lifetime maximum on our health insurance soon. Because of Lyme Disease, I am uninsurable. I don't know what we'll do."

Ms. Wade added, "We desperately need help. We have to leave our State to be treated." In fact, Ms. Wade travels three hours to a hospital on Long Island for treatment, while her daughter Heather goes to a hospital in New Jersey for treatment. Heather has undergone 6 weeks of treatment since January, and Eileen has to relocate to New Jersey each time to care for her.

Ms. Wade stated, "There is no question that Lyme Disease is a chronic persistent infection. Long-term antibiotics are required. New antibiotics must be developed for those of us who are treatment failures. The disease has devastated our lives. I have had to move back in with my parents in an attempt to save money."

Ms. Wade said, "My daughter was a dancer before Lyme Disease struck. She used to be a gymnast and a cheerleader—now she can't do anything at all. Her memory loss is so severe that she can't tell the difference between a nickel, a dime and a quarter."

Ms. Wade concluded, "The diagnosis took so long, that I took for granted the fact that I was going to die. When I did not know what I was afflicted with, I tried to separate myself from my daughter as much as possible to protect her. Finally, even though we have problems, I wish that you could see the other Lyme Disease pa-

tients in the Jersey Shore Hospitals who are worse off than us and see their suffering."

WRITTEN REPORT SUBMITTED AS TESTIMONY BY EILEEN WADE ON BEHALF OF
HER DAUGHTER, HEATHER WADE

474 PEMBURN DRIVE, FAIRFIELD, CT 06430

PHONE #: (203) 336-4280

BEING ALONE BY HEATHER WADE

When I was born they gave me my last rites and told my mother there was a good chance that I could die. With that, I was kept in the hospital, on and off, throughout the first 2 years of my life. I was very sick, and I stopped breathing at my house twice. Then I was admitted into Yale/New Haven Hospital, where I was diagnosed as having pneumonia and another rare disease. After the first couple of years being ill, the medicine seemed to have taken effect and everything was going alright. I was alive, kicking, and healthy or, at least, that's what the doctors thought.

Then, about 4 years later, when I was around six, I started feeling sick again, but they never related it to my illness as an infant. I was told I had pneumonia several times, that I had strep throat, bronchitis and scarlet fever. Yet, still there was something wrong and I just wasn't [sic] feeling right. This lasted about 2 months and then all the sickness disappeared.

Again, when I was ten I went away to camp for about 3 weeks. During the entire time that I was at camp I had a terrible rash that developed in the first couple of days. It spread across my whole hip, but I didn't mention it to any of the counselors. When I got home from camp, I showed my mother this awful breakout. She brought me to the doctor and he said I had impetigo.

After this experience I became very sick with severe migraine headaches, joint pain and arthritis so badly that they had to put my leg in a brace. I also suffered with dizziness, heart palpitations, tiredness, and inability to sleep.

We never thought that all of these things were related to each other and life a went on. Even though about 50 percent of the time I was sick, I still led a normal life by taking dancing, which I had been taking since I was three, and by taking gymnastics and violin lessons. One night after a violin concert, when I was about twelve, I was changing into my pajamas and I noticed something on my neck. I called my mother to my room and she said it was a tick. She was a wreck, so she asked my grandparents to take me to the hospital. She, at that time, was too sick to take me to the hospital, because she was suffering from an illness, but no one knew why she was so sick.

Anyway, when I went to the hospital my mom gave strict instructions to my grandparents to ask about Lyme Disease, a new disease she had been reading about. At the time she was reading about many diseases, because she was so sick.

When my grandparents and I arrived at the hospital, the doctors removed my tick. As my grandparents were told, they asked the doctor if it could be a Lyme tick and he said, "Oh, no, there are no ticks like that around here."

So we went home and didn't think about it again. I was often sick through sixth and seventh grades. I was hardly ever in school and my grades were increasingly dropping. Finally, when I reached the eighth grade, I was out of school more than I was in school. I knew something was wrong with me. I couldn't sleep for days; then when I did sleep, it would be for at least eighteen hours a day. I had such awful headaches that I would end up throwing up everywhere. Sometimes I would wake up in the morning unable to move for hours, either because there was excruciating pain, or my joints would lock up. Sometimes I just couldn't [sic] move at all and would literally become paralyzed. I was dizzy and blacking out, which would sometimes make me fall or faint. I had heart palpitations, which meant my heart would beat erratically. For example, 1 minute my heart would pump out of the blue as if it just jogged a mile, then a while later, it would barely be circulating.

I often lost feeling in certain parts of my body, and there were times that with my 20/20 vision I couldn't see anything. I often got sick to my stomach and had awful cramps. I developed back and neck problems that landed me in physical therapy. Sometimes I'd [sic] get ringing in my ears so loud that I couldn't [sic] hear a thing.

By the time all this happened I was convinced that I was chronically ill. I told my mother and she also knew something was wrong with me. I was at the doctor's

office about three times a week and the doctor kept saying that I had ear infections, mono, and every other virus. But, I knew it was more than that.

My mother had just undergone major surgery and had been very sick. After seeing many doctors in many states, she was diagnosed as having Lyme Disease. She insisted that I be tested for it also, but my doctors kept telling her that she just had a phobia about it because she had the disease. They told her that she was paranoid and that I had nothing serious.

Months went by where 80 percent of the time I was unexplainably ill. To everyone it was a mystery because 1 day I could be completely healthy and the next day I would be incapable of moving my own body.

Incidentally, at this point in time, which was the eighth grade, my mother was rushed to the hospital. She was extremely sick and the doctors told my grandparents that there was no way my Mom could make it through the night and that she didn't have much longer to live. But, somehow, my mother pulled through and she had to seek other help. She came across a doctor in Long Island, Dr. Burroscano, whose son also had Lyme Disease and who, at the time, was one of the only doctors who was aware of the effects of Lyme Disease, which was probably due to his contact with it.

My mother was put on I.V. antibiotics and after a few months came home where she had a nurse taking care of her and remained on I.V. She kept in touch with Dr. Burroscano and continued to have regular visits to his office.

She was doing a little better, but I on the other hand, was not. She knew something had to be done, so she mentioned it to Dr. Burroscano. He had me go in for testing. This was at the beginning of my freshman year in high school. By December of the ninth grade they had discovered that I also had Lyme Disease which I must have contracted during birth. This explained why I was so sick when I was a baby, but I still didn't understand why it didn't show up again until years later. I was told that the disease can remain dormant for years. I also got bitten by ticks on several occasions which may have made things worse, and the rash when I was younger, which had been described as impetigo, was a tick rash, which meant that I had also caught Lyme Disease then. Finally, everything was fitting together.

As a result of my getting sicker and sicker, I was taken out of school by the beginning of January in my ninth grade year. The doctor immediately put me on I.V. antibiotics (Roseprin), and several oral medications. Yet, I remained sick, and nothing was helping. I had fevers almost every day, and on the days that I didn't, my temperature was too low. I almost completely stopped breathing on three occasions before passing out. I developed seizures, arthritis, hypoglycemia, thyroid, and respiratory problems among medical problems. As a result of my heart problems, they had to put me on a heart monitor.

One day I awoke and found that I was swollen. Each part of my body was at least twice its size. My knees were so swollen that I could barely bend them, let alone walk. My feet were so swollen that slippers wouldn't fit on them. The head-to-toe hives were unbearable; they were itchy, burned and they stung. I had to go to the hospital in New York because my doctor practiced there. He also recommended a neurologist, Dr. Petruica, to see me because of all my neurological problems. She also specializes in Lyme Disease. Both of these doctors are top doctors in this country for this. They are both also on the Medical Advisory Committee on the Lyme Borreliosis Foundation, which consists of sixteen world-wide doctors. In each of the doctor's offices I have met people from Canada, California, Michigan, etc.

Anyway, while I was in the hospital they were afraid that because of all the swelling that my throat would close. During my stay at the hospital I also lost the ability to see. Because of all the seizures I was having, the swelling in my brain (encephalitis) put so much pressure on my eyes that it blinded me. I fainted once and had continual problems moving. But, worst of all were the headaches; they are always the worst. The encephalitis makes my brain too swollen for my skull. The pain in my head actually makes me vomit and cry. I can't describe such pain. I could no longer urinate because my brain could not send the message which is necessary.

Thinking is an every day problem for me. That is why my grades and intellectual status dropped so quickly. I have lots of neurological problems that make it impossible to think straight. Even left from right becomes confusing for me. Also, on many occasions I'd go for a walk down the street and wouldn't be able to find my way home. As a result of the confusion this disease causes, I cannot attend school.

While at the hospital I get inflammation of the ribs and I also become paralyzed from my left shoulder all the way down to my hand. I've had several stays at the hospital. My last one was November/December of tenth grade. The last time I was there they feared that I could actually have a stroke.

I've been doing much better since the last time I was at the hospital, but I am still very ill, although I don't act it. My main problem is getting my thoughts

straight from the confusion this sickness causes. My mother is also very sick at the moment. The saddest part of all this is the fact that both my mother and I almost died because of a bug about the size of a freckle.

But there is a bright side to all of this, and that is the fact that I am back in school and I've met many nice people through support groups and trips to the doctor. Because this disease has had such a permanent effect on my life, like the fact that I may never be able to have children, I decided to write about it and try to make people more aware.

Ms. Wade adds, "My daughter wrote this one and a half years ago. She was only able to attend school part time for 2 months in the past 3 years. Heather is still very ill. She will gladly speak to anyone who would like to know about Lyme Disease."

STATEMENT FROM EVAN WHITE AND HIS MOTHER RUCHANA

60 TRANQUILITY ROAD, SUFFERN, NY 10901

"Everybody helps when everybody knows everybody can get together and help. I want help now." Evan White—July 30, 1993

Until September 1990, Evan was the most popular boy in his class, an outstanding athlete, and an excellent student.

All of this changed, however, when Evan came down with flu-like symptoms. Because his area is endemic to Lyme disease, his doctor ordered that he be tested; the results came back positive. He was then referred to a pediatrician who specialized in infectious diseases and was started on a treatment of oral antibiotics.

Evan did not respond well to the medication. He had severe headaches and was unable to raise his head off the pillow. He was given the drug rosephin intravenously and as a result developed gallbladder sludge. During this period, Evan never had a blood test, nor did he receive treatment for the side effects he was suffering.

Evan was referred to a pediatric neurologist who said that he was not medically ill. The pediatrician declared Evan's sickness psychological, despite the fact that the original blood tests showed that he did, indeed, have antibodies to Lyme disease. His parents, obviously, were confused: "You don't want to be sick when you're eleven, on the travelling soccer team, an excellent lacrosse player, and have many girl friends." However, they had placed their faith in the doctors and found it difficult to question their prognosis. As a result, medication was stopped, and Evan began seeing a psychologist.

During the third month of psychological treatment, Evan's parents finally convinced the doctors that his illness was not "psychological": his head would fall to his shoulder, he was beginning to atrophy from head to toe, and his hearing had become so sensitive that the slightest noise was deafening.

The Whites went back to their original pediatrician who ran a complete battery of tests. It was then that they discovered that Evan's Lyme disease had "skyrocketed". Because there had been no treatment during the crucial part of his illness the disease had ravaged his body. The doctors were forced to admit that they did not know what to do.

In April 1991, the doctors placed Evan in a hospital and prescribed the drug Clafrin intravenously. He could not walk, would scream due to the severe pain of his headaches, and his speech was beginning to become unclear. Evan spent 2 weeks in intensive care during his two-month stay in the hospital. During this time, he also became desensitized to the Clafrin.

That summer, Evan made many trips to the hospital. He was dehydrated and had to receive naso-gastric feedings. He was then sent to a children's specialist hospital in New Jersey. His great pain caused him to scream day and night. At this point, his parents described him as being "completely gone in body and mind"; he could only recognize his mother and father—sometimes.

Evan has begun the slow road to recovery. He has attended the Helen Hayes Day Hospital for the past year and a half where he receives intensive rehabilitation 5 days a week. He has received multiple types of therapy: occupational, physical, speech, and acupuncture. The results of these painful treatments were evident by February 1992: he had strength in his hands.

His progress has been very slow but steady. His legs, arms, and head are much stronger now. He is able to get around with the use of a walker. Although he can only speak a few words, his vocal chords have not been damaged, nor has any other part of his body. He is much more aware of his surroundings. He has feelings and desires, and he wants very much to let the government know how catastrophic this

disease has been to his life. He feels that there is a way out of everything and that there must be a way out of this as well.

Obviously, Lyme disease has had a devastating impact on Evan's life. Although he was one of the most popular boys in his class, he no longer has any friends. Classmates continue to call and to send post cards, but Evan refuses to see them until he is well. The trauma of watching Evan suffer has taken a toll on his older brother, who is in college, and his sister, who is currently applying to medical school as well as researching Lyme Disease. Fortunately, Evan's family has health insurance—his illness has cost over \$2 million so far.

He has lost his education. He can no longer read or write and has not attended school in over 2 years. School is difficult; he cannot identify words but sometimes something in a newspaper will jump out at him. He knows everything is locked away in the back of his head, but he is unable to find a way of accessing his knowledge: "Sometimes I feel like I am in a bubble, but just can't get out."

Evan communicates through hand gestures. Frustrated with his situation, he is often angry and irritable. He has no appetite; although he is five foot four inches, he weighs only eighty pounds. He suffers from insomnia. He enjoys watching television, but without any sound—any noise is deafening, even though he wears earplugs and headphones. His voice has changed and matured. "Help" is the word that he repeats most often.

Evan has many questions: "Why me? Why did this happen to me to make me so sick? Why is no one helping me?" He is aware that he is losing his childhood. He is now fourteen and wants to be a teenager and to play lacrosse and soccer and to have friends and to socialize. One day he would like to be a psychiatrist and a stand-up comic—he feels that he has plenty of experiences upon which to draw. He wonders how this is possible when he is chronically ill. He desperately wants others to hear his story so that no more time will be wasted and that a cure will be discovered.

FAXES AND LETTERS

July 25, 1993

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(908) 949-5928

To whom it may concern:

I am writing to you as the father of a 12 year old boy who was diagnosed with Lyme Disease in November of 1991. He has suffered from severe symptoms of Lyme Disease on a nearly continuous basis for 2 years, even though he has received intravenous or oral antibiotic for the last 20 months. His symptoms have included severe and continuous headaches, joint pains, shooting pains, light and sound phobia, fatigue, tachyarrhythmia, neurological deficits in memory, reading, math, ability to concentrate and other mental faculties, an abnormal EEG, fatigue, disrupted sleep patterns, tremors, and many others symptoms of illness. He has been unable to participate in normal activities, including school, for all of this time except brief periods when the antibiotic treatment appeared to resolve the illness or at least reduce its worst effects. Only long-term intravenous antibiotic treatment has been able to resolve his symptoms. We have attempted to translate this treatment several times, but each time he has relapsed, oral antibiotics were tried to restore his health but they were not sufficiently effective and intravenous antibiotic treatment had to be restarted to avert potentially life-threatening declines in his neurological and cardiac systems. In every case, the intravenous treatment was effective in gradually relieving his symptoms and restoring his health.

My son's illness has been chronic because he was not diagnosed on a timely basis in 1991. In the fall of 1991 he suffered with significant pain and neurological complications for three months, including Lyme Meningitis, before he was diagnosed. During this period of his illness, he remained prone for weeks because the pressure and pain in his head and neck were so severe he could not raise his head.

The failure to diagnose my son's illness in 1991 occurred even though his symptoms were extreme and associated with Lyme Disease and even though my family lives in Monmouth County, New Jersey where deer ticks are prevalent and Lyme Disease has one of the highest rates of incidence in the State of New Jersey and in the country. One could reasonably believe that the publicity about Lyme Disease in New Jersey was sufficient to alert all doctors to the symptoms of this illness, but that is not the case. There is a health problem occurring across our country which is striking innocent children and adults. Action is required to address this situation.

I am a technical supervisor at AT&T Bell laboratories where I work on highspeed computer communication projects. I have worked at AT&T for 20 years. My wife is an educator with a Masters Degree from Rutgers University. She has nearly 20 years of teaching experience as a Reading Specialist. We have learned about Lyme Disease firsthand by its impact on our son and by our encounters with many other children, friends, and acquaintances who are also victims of Lyme Disease. Based on our scientific and educational backgrounds, our professional experience, and our personal experiences, we believe that there has been a significant breakdown in maintaining appropriate responses to Lyme Disease by the medical community, by government agencies, and by state and federal legislatures. It is for this reason that I am writing to you.

I hope that letters such as mine will help you understand the true nature and negative impact of Lyme Disease on the children and adults of our nation. Lyme

will take my son's life for the last 24 months. And that's the exact story you will hear from hundreds of others. If you get into the real world in the hospital wards and doctors' offices where the victims of chronic Lyme Disease seek medical treatment. This is not the story you will hear from the CDC or from certain "Eastern Establishment" medical researchers.

This doesn't quite coincide with the notion that Lyme Disease only requires four weeks of antibiotic treatment. It is true that many victims of Lyme Disease do recover after short-term antibiotics and others never develop symptoms at all. But if Lyme Disease were really that simple to cure, then what is happening? In there some other mysterious, unidentified illnesses in the other causing children and adults all over the nation to suffer from the same symptoms. Not people who develop chronic and severe Lyme Disease usually do so because their physician failed to recognize and treat the early symptoms of Lyme Disease. Lyme Disease is a complicated, multi-systemic disease with highly variable impacts on different people. Only further research and knowledge will unfold the mysteries of Lyme Disease.

Physicians do not properly diagnose Lyme Disease for many reasons. First, they rarely consider the possibility of Lyme Disease, and when they do, many doctors disregard the well documented fact that all generally available Lyme Disease tests yield false negatives and false positives, they completely ignore the symptomatology of their patients, and they fail to deliver medical treatment, even when confronted with a patient with a cluster of symptoms, unexplained by any other detectable illness, and clearly associated with Lyme Disease. In 1993 people have presented themselves to a doctor with erythema migrans rash with the information that they observed the tick bite, and that the tick was treated at a health center and found to be a positive carrier of the bacteria that causes Lyme Disease. They were sent away with no diagnosis and no preventative treatment. That's outrageous. Imagine how you would feel if this happened to you.

Imagine if you also suffered from Lyme Meningitis or seizures like some Lyme Disease victims, and your doctor says "you are just crazy" or "stop faking those behaviours or I will request a psychiatric exam." Imagine as you lie in a doctor's office with severe headaches, neuralgia, tachycardia, shooting pains in muscles and joints, and other symptoms and your doctor proclaims you are not sick because all tests are negative. Imagine your doctor won't prescribe medical services because of intimidation from other physicians or government agencies. All of this and more is happening all over our nation, now in 1993, even though we know that most chronic Lyme Disease can be prevented by early detection and treatment.

The CDC itself is not controlling disease but itself is causing disease. By using circular logic to dictate where Lyme Disease may occur and how it may be diagnosed, many people across our nation are being underdiagnosed and undertreated for Lyme Disease. Just this last Wednesday, I met a teenage girl from Corning, New York who has chronic Lyme Disease, even though she has been treated with medication for many months. The CDC has declared that Lyme Disease is not endemic in Corning, New York, so you better not acquire Lyme Disease near there because -- it can't be Lyme Disease. Well, this young woman had the nerve to catch Lyme Disease in Corning, New York. She had all the symptoms of Lyme Disease for many months. She even had three positive serological tests for Lyme Disease, but still her doctor did not treat her. Can't get Lyme Disease in Corning, NY. Well, they finally did a spinal tap and guess what, it was positive for Lyme Disease. "Well, I'll be damned," said Laurel to Hardy. "She really does have Lyme Disease." Now, sadly, the young woman has chronic Lyme Disease because she was not properly diagnosed and treated because of disinformation promoted by the CDC. But, really this person was lucky. At least she was eventually diagnosed and is receiving treatment, and maybe someday she will be healthy. God help the person who companies who do not wish to recognize Lyme Disease as a potentially severe and chronic disease because they wish to curtail insurance benefits, and the CDC has protected the interests of property over human life because of the potential economic consequences that may derive from the knowledge that people are at risk to encounter a sometimes untreatable illness such as Lyme Disease while enjoying normal outdoor activities in their yards, at the park, or at the beach.

If you listen to the victims of Lyme Disease, you will hear a message that there is a tragedy echoing from every corner of the nation. When the same so called anecdotal stories occur hundreds of times, an open minded person must take note that perhaps there is something serious going on. The innocent victims of Lyme Disease desperately need support from our government to properly attack Lyme Disease.

Lyme Disease is a poorly understood, insidious illness creeping across the backyards of our communities, striking innocent victims of all ages, wreaking havoc in the lives of victims and families, being undiagnosed by physicians who rely too heavily on poorly controlled, unstandardized and unreliable diagnostic tests, being untreated by physicians who deny its very existence. In far too many cases, doctors fail to understand, diagnose, and treat the illness, and they "copout" with assertions of patient psychosis, hypochondria, premenstrual syndrome, menopausal syndrome, fibromyalgia and other diagnoses that have far less substantiation than a diagnosis of Lyme Disease (which if treated correctly and long enough with antibiotics will respond).

If you can, contemplate the life of a chronic Lyme Disease victim. Look at the world from their point of view. Imagine for yourself.

"There are atomic bombs exploding in my head, and I have bad pains in my knees. I need some ice packs, and then I need some hugs." It's late at night and my son should be asleep, but he has severe headaches that last for 24 hours a day for weeks and even months at a time. Headaches are a very personal feeling. Rather hard to express to another. One can't say they have a headache that is four feet long. But imagine if you may your worst headache, now imagine the headache is significantly worse, and then imagine it lasting for weeks or months. Imagine your head is going to explode. Imagine that your head hurts so bad that you can't lift it at all so that you must lay flat always, except to crawl on your stomach to the bathroom. Maybe you are imagining a Lyme Disease headache.

It would be bad enough if a headache were the only affect of Lyme Disease. But it's only one of many symptoms. Imagine that all of your joints ache and that your neck is so stiff you don't want to move your body. Imagine shooting pains moving all over your body. Imagine your eyes are so sensitive to light that you must sit in a darkened room. Imagine you have neurological complications that impair your thinking, your concentration, and your memory. Imagine you were young and healthy but now you randomly forget simple facts such as how to add 2 + 2, and you forget names, words, places, directions. Imagine your cardiac system gone awry such that your heart rate is 140 when resting and 180 after mild activities. Imagine you can't ride your bike or participate in any normal life activities (school, work, and play) because you feel so poorly. Imagine you used to wake at the crack of dawn every day eager for activities, but now you sleep late and still feel fatigued all of the time.

Imagine you recover when you receive extended IV antibiotic treatment, and you cheer your recovery and stop IV treatment. And then imagine your crushing disappointment when the symptoms return again, whether from relapse or reinfection, with the same debilitating and life threatening impacts. Imagine how you would feel after this happened several times.

Disease poses a significant health danger to innocent participants of outdoor activities. I request your total and undivided commitment to truly address the health needs of the victims of this illness. I believe Congress must take firm and decisive action to:

- (1) Increase research funds for Lyme Disease;
- (2) Promote prevention of Lyme Disease;
- (3) Promote better methods of diagnosis and treatment; and
- (4) Protect the insurance rights of the innocent victims of chronic and severe Lyme Disease.

As you read the remainder of this letter, ask yourself what you would reasonably expect from your physician, from the medical community at large, from government agencies such as the state legislature, and from insurance companies. Things that come to my mind are:

- (1) Concern for the pain and suffering that victims and families experience when Lyme Disease becomes chronic;
- (2) Recognition of the severe limitations in the diagnosis and treatment of Lyme Disease based on present medical knowledge, thereby precluding fixed solutions mandated by government bureaucrats or by physicians with closed minds about the nature of Lyme Disease and its treatment;
- (3) Recognition of the need to increase research to identify more reliable methods of diagnosis and treatment;
- (4) Recognition of the need to increase education in the public and especially in the medical community to be aware of Lyme Disease, to implement preventive measures, and to promote early and effective diagnosis and treatment so as to reduce the frequency of this illness and to prevent chronic Lyme Disease; and
- (5) Compassion for the victims of chronic and severe Lyme Disease who most need our help, including access to the best possible treatments, even if required for extended periods, with the right to obtain benefits from their medical insurance for this treatment.

There are some medical researchers who have adopted the dogma that Lyme Disease is always easily treatable with a short regimen of antibiotics. This position is significantly incompatible with the real world experiences of real people who have suffered greatly for extensive periods of time due to chronic and persistent Lyme Disease. The experience of people across the entire country is unequivocal: For a certain percentage of people, Lyme Disease is chronic, persistent, debilitating, and even life-threatening. Lyme Disease has multiple manifestations, including cardiac and neurological impacts. The diverse aspects of Lyme Disease go far beyond the expertise of rheumatoid arthritis or infectious disease specialists. Any researcher or medical doctor who claims to know the definitive answers for Lyme Disease detection and treatment, simply are not being open-minded to the diversity of facts and findings about Lyme Disease. Far too little is known about Lyme Disease. The resolution of the mysteries of Lyme Disease will require collaboration across many fields of medical expertise.

There are some government agencies, such as the Center for Disease Control, which have not done enough to set the proper tone for an adequate response to Lyme Disease. In fact, certain members of this agency seem more interested in suppressing honest debate and disclosure about the true extent and nature of Lyme Disease. The CDC has itself promoted outmoded and erroneous perspectives about Lyme Disease, the CDC has systematically suppressed input from the primary physicians who are caring for chronic Lyme Disease victims on the front lines of this illness, the CDC has attacked the professional integrity of certain physicians who prefer to treat their patients based on their needs rather than be suppressed by the CDC, the CDC has practiced favoritism and bias toward a small set of medical researchers who are doing the bidding of large insurance livers in Cerning, NY or some other so called Non-endemic area, or even somebody in an endemic area such as anywhere in New Jersey, who contracts Lyme Disease, has the symptoms of Lyme Disease, has no other identifiable cause for such symptoms, but whose immune system has the audacity to not elicit a positive reaction to serological antibody tests for Lyme Disease. Never mind that many medical studies have demonstrated that immunocomplexes are created by Lyme Disease so that antibodies are not detectable or that Lyme Disease sequesters itself in brain cells and in human fibroblast cells so that it is outside the realm of immune system response. If a person has Lyme Disease symptoms but outmoded and problematic serological tests are not positive, then it can't be Lyme Disease. It must be Disease XXX, which can't be treated because it's XXX. Well what should we expect from the Center for Disease Causation?

On top of all this, insurance companies are now misusing the CDC's surveillance definition as the definitive clinical definition for Lyme Disease. For surveillance purposes the CDC definition is absolutely horrible. And because under-reporting is at epidemic proportions, the CDC surveillance numbers are totally unreliable. Ten economists can predict the direction of GNP better than the CDC can determine how many cases of Lyme Disease may be occurring with what rate of increase or decrease.

When the CDC surveillance definition is misused as a clinical definition by insurance companies, a medical travesty is put into motion. The practice of the art of Medicine is rendered inoperative and medicine by bureaucratic definition is put into practice. Doctors are no longer doctors. Cookbooks for medicine is all that is needed. Insurance company bureaucrats in charge of profit and loss use the Cookbook for Disease Causation to practice medicine along with insurance. (I wouldn't want to be a chicken inside a chicken coop in times like this.)

Imagine how you would feel when your insurance company refuses to pay medical claims for treatments for chronic Lyme Disease because you had the audacity to be sick longer than the Cookbook for Disease Caustion says is possible. This is a misguided approach to control medical costs and if this is the direction of health care reform in this country, then Canadians will stop buying U.S. medical insurance and we can all seek medical treatment in Rumania.

Medical costs for Lyme Disease should be controlled by:

- (1) Better research to develop more effective medicines;
- (2) The implementation of prevention programs through tick eradication, education, and physician awareness programs;
- (3) The development and availability of more effective diagnostic tests which can promote early detection and treatment and more effective and reliable monitoring of progress in treatment of the illness;
- (4) Negotiated volume discounts for medical supplies, medicines, and medical services for long-term treatment of Lyme Disease, via a new partnership between hospitals, doctors, and clinics, the medical supply and pharmaceutical companies, and insurance companies; and
- (5) Any other methods to prevent Lyme Disease, to promote early detection, and to provide more effective medical treatment.

Medical costs cannot and should not be controlled by a misguided effort to mandate rationing of medical services on a discriminatory and selective basis for only the victims of Lyme Disease. Insurance companies should not be permitted to sell insurance with long-term hospital or home care benefits, and then refuse coverage when a customer requires these benefits as a result of chronic Lyme Disease.

For Lyme Disease, insurance companies want to cutoff coverage simply because the treatment has an uncertain path to success. If that standard of coverage were applied to all illnesses, there would be many more victims of misguided health-care rationing. Ask us to ration healthcare for tuberculosis, diabetes, heart disease, AIDS, cancer and every other illness which has an uncertain path to resolution. That is not the way to improve healthcare in this country. That is a path to disaster.

I call upon you for your support in the following matters:

- (1) Stop the biased attacks by the CDC upon certain members of the medical community simply because they do not agree with the CDC.
- (2) Demand that the CDC redefine their surveillance definition for Lyme Disease with input from physicians most actively involved in the diagnosis and treatment of Lyme Disease.
- (3) Increase research funding for Lyme Disease and direct the CDC and the NIH to ensure that such funding is aimed at those truly seeking answers about Lyme Disease (e.g., the Fox Chase Institute near Philadelphia) rather than those who are promoting their pet theories.
- (4) Promote new ERISA guidelines for healthcare benefits such that self-insured companies may be reasonably encouraged to provide and maintain benefits for chronic illnesses such as Lyme Disease. There are children and adults who need long term treatment to resolve the impact of Lyme Disease. These people were victimized once by a medical community that failed to diagnose and treat their Lyme Disease in a timely and effective manner. Don't let insurance companies or self insured companies victimize the same people a second time by denying their medical coverage for long term treatment.
- (5) Promote better prevention, diagnosis, and treatment of Lyme Disease by supporting:
 - (a) better control of disease vectors via tick control programs such as those promoted by Dr. Terry Schulzer
 - (b) education programs for physicians to improve their ability to understand the limitations of current diagnostic tests for Lyme Disease;
 - (c) education programs for physicians to improve their ability to consider and properly diagnose Lyme Disease based on patient symptomatology;
 - (d) more research to understand the in vivo response of Lyme Disease bacteria to various antibiotic treatments; and
 - (e) more research to develop more reliable diagnostic tools and more effective medicines for Lyme Disease.

I look forward to seeing your support for legislation to accomplish the above. Please call me if you have questions about life inside a family with a young child with Lyme Disease. Thank you for your attention and your support.

Sincerely,

Keith A. Dana

Keith A. Dana

from: Mrs. Immanuel Kohn
 34 Puritan Ct.
 Princeton, NJ 08540
 609-921-2309
 to: Committee on Labor and Human Resources
 re: Research needed on Lyme Disease

Please become open-minded re Lyme disease. It affects different victims in different ways. It apes all sorts of other medical problems. Blood tests for it are very inaccurate. Doctors are too inexperienced in dealing with it and are now erring too often in NOT treating it rather than in treating it.

I am a case in point. In August, 1991, I first experienced symptoms. I live in woods full of deer. I own two dogs who have Lyme and tested positive for it. My own tests were all negative. Slowly, untreated, I became so ill I turned into an invalid unable to work. Top specialists at New York Hospital insisted that because of the blood tests, I did not have Lyme, but that I did suffer from other disease or diseases. They ran tests beginning November, 1991, searching for these other causes of my extreme neurological, muscular, skeletal etc. symptoms. All tests proved negative. Over \$20,000 was spent, of which Met Life paid over \$16,000!

Late May, 1993, a urologist found a bladder infection and gave me 1,000 mg of Cipro per day. In five days I was able to function a bit. In two weeks neurological symptoms had receded so markedly that I actually returned to life--walking around. Thereafter, I was finally given a combination of heavy duty antibiotics and am again a productive member of society. Still not what I was before August, 1991, --but functioning. As yet I have not gone off antibiotics. Who knows what will then occur?

Why wasn't I treated when I first appeared with all the clinical symptoms? ~~THINK OF THE MONEY MET LIFE WOULD HAVE SAVED!~~ Think of the pain and suffering and expense I would have saved. Think of how others can be spared a repetition of this.

PLEASE ACT!

To: Committee on Labor and Human Resources
 Re: Lyme hearing
 From: Emily Alnutz
 8 Dawn Court
 Cranbury, NJ 08512
 609-799-1882

I am a fifteen year old high school student who has had Lyme disease for six years. For five years my mother took me to doctors trying to find out what was wrong with me.

I was always a straight A student until it became very difficult to concentrate. I had memory loss, insomnia, and I was stiff in my bones every morning. Finally, in February of 1992, I was diagnosed with Lyme disease by Doctor Scotti in Little Silver, New Jersey. It was at that time I became unable to participate in sports. I had been the captain of the cheerleading team and an award-winning member of the swim team.

Dr. Scotti gave me oral antibiotics, but they did not help. I had to do IV's twice. After seven months of treatment I was so sick I was unable to attend school. I had terrible headaches, sore throats, joint pains, and extreme fatigue. Many times I wished I was dead because I could not even enjoy going out with my friends.

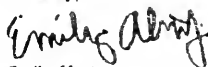
At this point I started treatment with Dr. Blewett in Trenton, NJ. Having been a patient with Lyme, he understood Lyme and how I felt. He treated me for nine months. After two and a half months I was able to return to school for half days. After two and a half months more I could go to school all day. Another two months and I was back in gym class.

Now I've been off antibiotics for three months without symptoms. I had forgotten what it felt like to have the energy to hang out with friends or wake up in the morning without stiff joints. I can now fall asleep at night because the six years of insomnia are gone. One of the worst parts of having this disease was having teachers, classmates, and even doctors minimizing my suffering.

I was lucky because my insurance paid for my treatment. I heard about a teenager in New Jersey who recently died from lack of treatment, and I thank God that I am so lucky. Please help others to have the chance I have been given to lead a normal life.

Thank you for your time. I would love to tell you my story in person.

Sincerely,



Emily Alrutz

To: Committee on Labor and Human Resources
 Re: Lyme Hearing
 From: Margaret M. Kohn R.N.
 8 Dean Court
 Cranbury, NJ 08512
 609-799-1882

Please help with research for diagnosis, treatment, and cure for Lyme disease. Granted, some people are cured of Lyme disease in thirty days. Many are not. Three members of my family have been struggling with Lyme disease for years.

My fourteen year old daughter was bedridden with severe neurological and musculoskeletal symptoms after nine months of conventional Lyme treatment including two thirty-day I.V. courses with Rocephin. I took her to a doctor who treated her with triple antibiotics including four months of Ceftriaxone IV. In two months she was able to go back to school. In four months she was symptom-free. She has been symptom-free for six months, and off antibiotics for three months.

My husband and I are up and down with symptoms constantly adjusting our antibiotics. We live in fear of not having access to antibiotics, and thus becoming unable to work. We know of several Lyme deaths in our state. Physicians who treat Lyme are being harassed by the Medical Board of Examiners. Some doctors are now afraid to treat Lyme patients because of the current atmosphere.

Please look into these matters and help us to survive!

*We believe that short term
 Lyme treatment and then
 abandonment is killing our
 children.*

Margaret Kohn

The CHAIRMAN. Disease outbreaks over the past several years have shown that old diseases such as tuberculosis remain virulent, but new diseases continue to appear on an unpredictable basis. Some, like toxic shock syndrome, are readily defined and controlled. Others, like AIDS, seem intractable, in spite of years of dedicated work by thousands of health scientists.

Today we consider Lyme disease, which afflicts thousands of Americans. Its continued spread, because of changes in our society and our lifestyle, is cause for real concern.

Lyme disease is named for the place where it was first diagnosed, in Old Lyme, CT in 1975. At that time, the disease was difficult to identify, and it was impossible to know how many Americans were afflicted. CDC counted some 500 cases in 1982, and nearly 10,000 cases in 1992, a large increase in reported cases.

Although the disease has been identified in 49 States, it is New York, Pennsylvania, and Connecticut that account for the vast majority of reported cases. Hot spots of infection occur in some counties in California, Connecticut, New Jersey, Wisconsin, New York, and Massachusetts.

Beyond these statistics, however, is the human suffering. Children may be so severely afflicted that they cannot go to school for long periods of time. One father of a 12-year-old boy wrote that his son "has suffered from severe symptoms of Lyme disease on a nearly continuous basis for 2 years. His symptoms have included severe and continuous headache, joint pains, fatigue, neurological deficits in memory, disrupted sleep patterns, and many other symptoms. He has been unable to participate in normal activities, including school, for all of this time."

Adults can be incapacitated to the point where they can no longer work. Healthy people in infected areas are afraid to be outside because of the threat of exposure to the ticks that cause the disease. People fear for their children's health and worry about the loss of insurance.

Today we will hear from patients, clinicians, epidemiologists and experts from the NIH and the CDC.

Our first panel will provide perspectives from patients and physicians, who will discuss the difficulties in diagnosing the disease, the devastating health effects, and the difficult dilemmas posed by treatment.

Our second panel consists of epidemiologists who will discuss the importance of monitoring the disease, the role of animals in spreading it, and the effectiveness of our personal protection measures.

Our final panel, from the CDC and the NIH, will review the Federal role in preventing the disease and accurately diagnosing Lyme disease and treating it.

I thank all of the witnesses for their willingness to share their experience and expertise and look forward to their testimony.

The CHAIRMAN. The first panel this morning will introduce us to the clinical aspects of Lyme disease. The witnesses include Ms. Andrea Keane-Myers, a graduate student at Johns Hopkins University, who has recovered from an acute case of Lyme disease. Mr. Carl Brenner was working as a marine geologist when he contracted Lyme disease and was forced from his job. Ms. Karen Forschner is the director of the Lyme Disease Foundation in

Tolland, CT. Evan White is a victim of Lyme disease, and his mother, Ruchana White, will tell Evan's story.

We'll start with Ms. Andrea Keane-Myers. We are grateful for your appearance here today.

STATEMENTS OF ANDREA KEANE-MYERS, RECOVERED LYME DISEASE PATIENT, BALTIMORE, MD; RUCHANA WHITE AND SON, EVAN, LYME DISEASE VICTIM, SUFFERN, NY; CARL BRENNER, LYME DISEASE VICTIM, HAWLEY, PA; AND KAREN VANDERHOOF-FORSCHNER, DIRECTOR, LYME DISEASE FOUNDATION, TOLLAND, CT

Ms. KEANE-MYERS. Thank you.

In the summer of 1989, I contracted Lyme disease. I did not realize it at the time, but this disease has had an unusual and profound impact on my life.

After enduring a summer's worth of discomfort at the mercy of a bacterium, I became interested in microbiology and immunology. This initial interest has culminated in my working on the immune response to Lyme disease for my doctoral thesis in the Department of Immunology and Infectious Diseases at Johns Hopkins School of Hygiene and Public Health.

During that summer, I was residing in Salisbury, on the Eastern Shore of Maryland. I was on summer break from the University of Richmond and was living at home with my parents. To earn money for college, I was working two jobs, one as a waitress in a local crab restaurant, and the other as a secretary in a doctor's office. By the beginning of July, I began to feel fatigued and suffered from recurrent bouts of malaise and headaches. I ascribed these ailments to a combination of allergies and to burning the candle at both ends with my jobs and busy summer social schedule.

I also noticed around that time a rather large rash on the back of my right knee, with a red center and lighter ring on the outside. It wasn't until much later that I associated the flu-like illness and the tell-tale stigmata of Lyme disease, or erythema migrans, and assumed the rash was most likely caused by a spider bite.

I left work one evening at the end of July because of feeling chilled and because my joints were so painful——

The CHAIRMAN. You might just slow down a little. It's a very moving story, and we want to make sure we all hear it. Thank you.

Ms. KEANE-MYERS. Sorry. I left work one evening at the end of July because of feeling chilled and because my joints were so painful it was becoming difficult to pick up a pitcher of beer, much less serve a whole table. I took some aspirin and went to bed and remained there for a few days, too fatigued and sore to even think about moving around.

The best description I can think of for the misery of acute Lyme disease is a combination of debilitating mononucleosis and severe arthritis in the knees and elbows. At this time, I noticed more of the strange, ring-like rash had appeared on my trunk and lower extremities and decided it was past time to visit the family physician.

Dr. Mary Fleury is our family physician and is an internist practicing in Salisbury. My symptoms suggested an almost textbook case of Lyme disease, although Dr. Fleury was aware of only one other case on the Eastern Shore at that time.

I did not remember a tick bit preceding the initial rash, but had spent some time earlier that summer on Assateague Island. A recent study done on Assateague had suggested that the majority of mammals and Ixodes ticks had contracted the bacteria that causes Lyme disease, *Borrelia burgdorferi*.

During the initial visit, Dr. Fleury suggested that I get tested for Lyme disease and prescribed 10 days of tetracycline. I was tested a week after I had begun antibiotic treatment. Not surprisingly, the blood test came back negative. Testing procedures tended to be poorly standardized at that time and often gave false negative results, especially if done after antibiotic treatment had begun. The diagnosis was then and is now primarily based upon clinical findings.

My condition began to improve with antibiotic treatment, and I finished the initial course of antibiotics. However, within a few weeks, I began to experience malaise, fever, and migratory arthritis again and returned to the doctor's office. She determined that the initial treatment was of insufficient duration and prescribed high levels of tetracycline, one gram per day, for a month. Once again, my symptoms began to recede within a few days of treatment, and I finished the course with no further relapses.

Thankfully, I have not had any further symptoms since the second treatment. However, antibiotic treatment does not always prevent further complications, so I may still be at risk. I am not pleased with the prospect of having to live with chronic Lyme disease and sincerely hope better preventive and curative measures are developed in the near future.

As a result of this experience, I have chosen a career in medical science and am currently working on my doctoral thesis at Johns Hopkins, studying the immune response to the Lyme disease agent. Such information is essential to the formulation of a vaccine. With continued funding, I hope this work will move forward and that we will soon have a cure for this perplexing and debilitating disease.

Thank you.

The CHAIRMAN. Thank you.

I think we'll hear from all the witnesses and then go to questions. Ruchana White and Evan, it's nice to see you again. Evan, we want to let you know that we're glad to have you here, and we enjoyed visiting with you last week; we had a chance to show you around the office, and we're glad to have you back.

Ruchana, if you'd like to, we'd be glad to hear from you next, make what comments you might—and I know the lights and so on can be bothersome—and then if you and Evan want to remain at the table afterward, we'd be glad to have you, but if you feel that you'd like to be excused, we'd be more than glad to accommodate that.

Ms. White. I know that Evan has some things to say, but I will speak first.

The CHAIRMAN. Fine.

Ms. White. Thank you, Senator.

My name is Ruchana White, and I am the mother of Evan White, who is suffering from chronic Lyme disease.

Last week when we were here, and he spoke, he said: "Everybody can help when everybody knows. Everybody can get together and

help. I want help now." Evan can barely speak. He is trying very hard. He lost his power of speaking.

Until September of 1990, Evan was a very popular boy in his class, an outstanding athlete, and an excellent student. All of this changed, however, when Evan came down with flu-like symptoms. Because his area is endemic to Lyme disease, his doctor, among many other blood tests, ordered a Lyme test be done. The results came back positive.

Evan was then referred to a pediatrician who specialized in infectious disease and was started on a treatment of oral antibiotics. Evan did not respond well to the medication. He had severe headaches and was unable to raise his head off the pillow. He was given the drug Rosephin intravenously for 21 days and as a result, at the end, developed gall bladder sludge.

Evan was referred to a pediatric neurologist, who said that he was not medically ill; that his sickness was psychological, despite the fact that the original blood tests which showed that he indeed had antibodies to Lyme disease. We obviously were very confused. You don't want to be sick when you are 11 years old, on the traveling soccer team, an excellent lacrosse player, and have many girlfriends—who called all the time.

Evan loved to talk—I have to add this. He never stopped talking in all of his 11 years. We would sit in the car, and he would go on and on and on. He had so much to say because he had fabulous insights into people and life.

However, we had placed our faith in the doctors and found it difficult to question their prognosis. We knew that children don't want to be sick, and we knew they don't lie, but we were brought up in a time when doctors were like gods, and we really felt that they were showing us the proper way.

As a result, they stopped the medication, and Evan began to see a psychologist. During the third month of psychological treatment, we his parents finally convinced the doctors that his illness was not psychological—that his head would fall to his shoulder, and he couldn't lift it, it was in such pain. He was beginning to atrophy from head to toe, and his hearing had become so sensitive that the slightest noise was deafening. A cracker would bother him, or just walking into the room.

We went back to the infectious disease specialist who ran a complete battery of tests. It was then discovered that Evan's Lyme disease had skyrocketed. The doctor said to us: "Oh, my God, he has Lyme disease. I don't know what to do." Because there had been no treatment during the crucial part of his illness, the disease had ravaged his body. The doctors were forced to admit that they did not know what to do. The neurologist said he had nothing to say.

In April of 1991, the doctors placed Evan in a hospital, and he was given the drug Clafrin intravenously. He could not walk at that time. He would scream due to the severe pain of his headaches, and his speech was beginning to become unclear. His words were leaving him; they were broken and shattered, and he couldn't get them out. Even spent 2 weeks in intensive care during his 2-month stay in the hospital.

That summer, Evan made many trips to the hospital. He was dehydrated; he couldn't eat anymore, and he had to receive

nasogastric feedings. He was then sent to a children's specialist hospital in Mountainside, NJ. He spent 7 months there. His great pain caused him to scream day and night. At this point, we described him as being "completely gone in body and mind." He could only recognize his mother and father. His head pain was constant.

Evan has begun the slow road to recovery. He has attended the Helen Hayes Day Hospital for the past year and a half, which is very close to our home, and he is able to be with us at 4 o'clock. He goes in the morning and comes home at 4 o'clock and is able to be with his mother and father, and his brother and sister sometimes. He receives intensive rehabilitation 5 days a week. He has received multiple types of therapy—occupational, physical, speech, etc. Whatever can be done for Evan is done at the hospital. We are so thankful for Helen Hayes Hospital.

The results of these painful treatments were evident by February 1992—he had strength in his hands again. He had not been able to lift a pencil.

His progress has been very slow, but steady. His legs, arms and head are much stronger now. He is able to get around for a few moments with the use of a walker. Although he can only speak a few words—and this testimony is helping him to get out some more, which I am so happy about—his vocal chords have not been damaged, nor has any other part of his body—we hope. He is much more aware of his surroundings. He has feelings and desires, and he wants very much to let the Government know how catastrophic this disease has been to his life. He feels that there is a way out of everything and that there must be a way out of this as well.

Obviously, Lyme disease has had a devastating impact on Evan's life. Although he was a very popular boy in his class, he no longer sees his friends. Classmates continue to call and to send postcards, but Evan refuses to see them until he is well and looks good again. The trauma of watching Evan suffer has taken a toll on his older brother, Daniel, who is in college and who has written a wonderful paper about him; and his sister, Nicole, who is currently applying to medical school as well as researching Lyme disease herself.

Fortunately, we have health insurance, because Evan's illness has cost us \$1 million so far.

In May of 1993, several months ago, Evan had a brain spec scan that showed Lyme encephalopathy throughout, low perfusion. It was done at Columbia Presbyterian Hospital. The difficulty of diagnosis and treatment is grave, and this is a very big problem that we face.

Evan has lost his education. He can no longer read or write and has not attended school in over 3 years. He cannot identify words, but sometimes something in a newspaper will jump out at him, and he will know what that word says. He knows that everything is locked away in the back of his head, but as of yet, he is unable to find a way of accessing his knowledge. He says: "Sometimes I feel like I am in a bubble, but I can't get out."

Evan communicates through hand gestures. Frustrated with his situation, he is often angry and irritable. He has no appetite. Although he is 5-foot-4-inches, he weighs only 80 pounds now. He suffers from insomnia. He enjoys watching television, but without any sound; any noise is deafening, even though he wear earplugs and

headphones. His voice has changed and matured, and "Help" is the word he repeats most often.

Evan is in constant head pain still, and basketball cards are the only thing that keep his mind off of his pain. Evan has many questions: Why me? Why did this happen to me to make me so sick? Why is no one helping me? He is aware that he is losing his childhood. He is now 14 and wants to be a teenager and to play lacrosse and soccer and to have friends and to socialize.

One day, Evan would like to be a psychiatrist and stand-up comic—maybe one and the same. He feels that he has plenty of experiences upon which to draw. He wonders how this is possible when he is chronically ill. He desperately wants others to know his story so that no more time will be wasted and that a cure will be discovered—now.

My son Daniel says that health is wealth. And all the Lyme disease people would like to achieve it. This disease can be dangerous and lethal. It is real. It is here. It will strike someone you know.

Physicians, I plead with you, be open to understanding it, and treat your desperately ailing patients. Do not give up on them. There are many people across this country like Evan. I hear the same story over and over again.

I thank you. I think you all have this tape, "Kids Speak Out on Lyme Disease." Evan speaks for all the children in the United States, for the thousands and thousands of children. Please help them.

I thank you.

Evan.

The CHAIRMAN. Evan, we want you to just relax. This probably isn't as much fun as talking, riding in the car, or being at home with your family, but we are very grateful to you for being here. We had a chance to meet you last week, and we know you are a very brave young man. I think you know that your presence here is going to help us all try to do something about this.

So we are very grateful for your taking the time to come today. If you have a little something to say, we'd be glad to hear it; whatever your mom thinks is best. I remember last week, when we asked you a question or two last week, when your mom asked you some questions, you nodded and made it very clear to me what the answers were. Maybe she would like to ask the questions now.

Ms. White. He'd like to say them. He's been trying.

The CHAIRMAN. That's fine.

Mr. WHITE. We can't think. We can't sleep. We need you. We need everybody to work together to tell everybody how we feel.

The CHAIRMAN. That's very good. Thank you very much.

Senator METZENBAUM. I'm not sure he's finished.

Ms. White. If you want to say something else, you can. What would you like to say?

Mr. WHITE. We need everybody to work together to tell how we feel.

Ms. White. Thank you, Evan.

The CHAIRMAN. Evan, we'll hear a lot of testimony, I'm sure, today about Lyme disease, but I think those few words of yours will be the most powerful. I think you said it all. We all have to work together and find ways of making progress. We thank you. You are

a very brave young man, and it helped a lot to hear from you. I think the best way we can thank you is to make sure we do something about it like you have asked us to.

Senator METZENBAUM. Evan, I want to thank you also. I just want you to know that we aren't going to let you down. We are grateful to you. It takes a lot of courage to come before a Senate committee. It means a lot, and your being here is just very, very moving and makes all of us more committed to try to be helpful.

Thank you very, very much.

The CHAIRMAN. I want to thank the mom, too. Your testimony was very special.

Ms. White. Thank you for this opportunity.

The CHAIRMAN. Mr. Brenner.

Mr. BRENNER. Thank you for inviting me to appear here today.

I used to be a working scientist. In the late summer of 1989, while visiting my parents in the Poconos, I took a half-hour recreational walk through a local field, after which I removed several ticks from my arms, legs and torso.

Several weeks later, I went to Australia on a business trip. While there, I had a severe flu-like illness that involved a sore throat, ear infection, and the most intense headache and fatigue that I had ever experienced.

I remember feeling a mixture of astonishment and alarm over my condition, but I assumed that the fatigue was due at least in part to jet lag and the extremely heavy travel schedule that I had been on over the previous year. In any case, I seemed to recover gradually from the illness over a period of 2 weeks or so and returned home to Rockland County, NY to resume my normal activities.

Over the next few months, however, it became clear to me that something was terribly wrong. I was having bouts of migrating joint pain, headaches, irritability, and sleep disturbance. I was experiencing steadily increasing fatigue. Although these symptoms were quite bothersome, I was reasonably functional for a while.

The first few of the 20-plus physicians I was eventually to consult all assured me that I was perfectly healthy. None of them ever suggested Lyme disease as a possible cause for my complaints, and it certainly never occurred to me that I might have it.

The message from the physicians to me was: This is not really happening. You are not really sick. Your symptoms are all in your head.

I was referred to a psychiatrist, whom I willingly consulted, because by this time I had become quite depressed by my predicament and my rapidly diminishing tolerance for any kind of physical or mental activity. I was particularly frightened by the fact that I was having significant problems with concentration and focus at work; I was concerned that I might lose my job.

I struggled silently with my symptoms for over a year, but by the spring of 1991, I felt as if I were nearing some sort of breakdown. Sinus surgery was suggested as a possible solution to my persistent headaches; it did not work. My symptoms expanded to include crushing fatigue and periodic attacks of paralysis on my left side. It was clear to me by now that I had some sort of serious illness.

Nevertheless it was suggested to me on more than one occasion that my symptoms were hysterical in nature.

My psychiatrist, on the other hand, had become convinced that I was in fact suffering from Lyme disease and at his suggestion, I had begun to read up on it.

In July of 1991, I had a consultation with an infectious disease specialist and a rheumatologist at a major university hospital, during which I asked about the possibility of my having Lyme disease. I was told that my symptoms sounded "completely unlike" Lyme disease. I was offered antidepressants, this despite the fact that neuropsychiatric evaluation showed that I had organic deficits in memory recall tasks, a common manifestation of late Lyme disease, and no underlying personality or mood disorder. Once again, despite evidence to the contrary, the message was: This is not really happening to you. The problem is all in your head.

I was finally diagnosed with Lyme disease in August 1991, 2 years after the onset of my illness. I was treated with oral and then intravenous antibiotics for a total of almost 6 months. In August of 1992, still severely symptomatic after having been off treatment for 6 months, my urine was probed for spirochetal DNA via the polymerase chain reaction. The results came back positive, indicating active infection. Follow-up assays performed on both urine and spinal fluid were also positive.

I was hospitalized and put back on intravenous antibiotics in October of last year, during which I had a classic Jarisch-Herxheimer reaction—also an indication of active infection—marked by fevers and a radical worsening of my arthritic symptoms. The treatment was unsuccessful. Over the past winter, I was completely crippled, unable to even stand in the shower. While the arthritis later abated somewhat with further treatment, I am now unable to either work or look after my daily needs, and have been living with my parents since last autumn.

I am deeply uncomfortable with my assigned role today of "designated Lyme victim," but I have lost almost everything of value in my life to this disease—my career, my mobility, and worst of all, my autonomy. And there are many Lyme patients, as you well know by now, who are worse off than I—people cleaned out financially, uninsured, and unemployable, children in wheelchairs.

Over the last year, I have talked on the phone with a wheelchair-bound former special education teacher from Westchester who contracted Lyme disease on a class outing and who now suffers from a horrendous seizure disorder. These calls have now ceased because she can no longer speak.

Another Westchester woman, also disabled, had the Lyme spirochete cultured from her spinal fluid after many months of high-dosage antibiotic therapy. Both of these women were told repeatedly that their symptoms were psychosomatic and not attributable to borrelial infection. "This is not really happening to you. It is all in your head."

I have been asked by the committee to comment on how Lyme disease has influenced my career path. I don't know what to say, other than it has destroyed it. Before my illness, I was a marine geologist at Columbia University, involved in research and science management on an international level. I hadn't taken a sick day

for years. I had some contacts in Washington and was hoping eventually to come here as a Senate staffer on science matters—perhaps I might even have worked for one of you. And I am really glad that Senators Metzenbaum and Kassebaum came in, so I could say that and mean it, because there was only one Senator here before that.

Instead, I am now drawing disability. You ask about the experience of being a chronic Lyme patient. To be a chronic Lyme patient is to be caught in a Catch-22. There seems to be no incentive for anyone to acknowledge that we exist. The entrenched institutional denial of both the scope and intractability of chronic Lyme disease has devastating effects and shows no signs of abating. It causes delays in diagnosis, which often allow an acute illness to become chronic, as it did in my case. It limits access to antibiotic therapy at all stages of the disease.

The researchers note the persistence of symptoms after treatment, but do not admit that their treatment recommendations are often inadequate.

The insurance companies, who don't want to pay for longer-term treatment, hire these same researchers as consultants, who predictably say that we are "cured," despite ongoing symptomatology and considerable scientific literature documenting the persistence of the bacterium after treatment.

Meanwhile, NIH allocates virtually no resources at all to research on chronic Lyme.

I am a scientist by vocation and a skeptic by nature, but I am here today to tell you that this happening, that we are real, and that I am not some rare, anomalous case that slipped through the cracks. Lyme disease has already destroyed the lives of thousands of productive Americans, with untold thousands more persistently infected and standing on a precipice.

Finally, the many controversies surrounding Lyme disease and due in part, at least, to the lack of hard data that can be applied at the individual patient level. As a result, discussion on the prevalence of persistent infection has generated largely into a game of "dueling anecdotes." The existence of new direct detection techniques now gives researchers the opportunity to explore this question in a systematic fashion. Please urge NIH to focus its funding efforts on the etiology of chronic Lyme disease with an eye toward developing a permanent cure for this affliction.

Thank you.

The CHAIRMAN. Thank you very much.

Senator Bradley is here, and we'll hear from him now.

STATEMENT OF HON. BILL BRADLEY, A U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator BRADLEY. Mr. Chairman, let me say first how much I, like you, appreciate this panel's presence here today and their willingness to share some of their own personal pain with the committee, in the expectation that it will actually make a difference in the lives of thousands of other Lyme patients who are out there in our country today, struggling with this disease in ways that are hard for us to imagine.

Lyme disease is one of the fastest growing infectious diseases in America; only AIDS is faster. And some of the stories that you have heard today illustrate the problem, and that is that the patients are denied what they feel and what they know. They have doctors who tell them they are not sick; they have treatments that they are told will solve the problem, and it doesn't solve the problem; they struggle with fear. And others who experience their lives have that fear expanded and intensified.

Since 1982 in my State of New Jersey, there have been over 4,000 reported cases of Lyme disease—4,000. And those are only the cases that have been reported. I shudder to think about how many more there are that have gone unreported or undiagnosed.

I have spoken with countless constituents who have suffered from this disease, some for years, struggling each day to battle back from an affliction with the hope that maybe we'll start to do a better job with it.

At a town meeting during the July 4th recess, one woman came to that town meeting in a wheelchair, unable to move because of Lyme disease with a child who also had Lyme disease. This is an enormous national problem that we are refusing to address.

I think this hearing could be of enormous historic importance simply because at least there is now a body that is looking at this with the seriousness that it deserves.

Mr. Chairman, that is one of the reasons that I cosponsored the joint resolution establishing Lyme Disease Awareness Week. That is just the beginning. NIH has to get its act together as well.

You will later hear from the medical community. But make no mistake about it. This is where AIDS was in the mid to late seventies in awareness, and it is a much more pervasive illness.

I live in a section of New Jersey that is wooded, and when I walk in the woods I am constantly looking for the tick, thinking that the tick might have bitten me. In New Jersey, we have the highest concentration of deer anyplace in America. Nobody realizes that. Deer are suburban rats in New Jersey, and they carry the tick. Thousands of my constituents, when they walk, believe they are taking a risk, and so they don't walk.

I hope that this committee will deal with this disease with the seriousness that I think it deserves. I hope we'll double our efforts so that we will get accurate diagnosis and adequate treatment for this disease. It is an enormous problem.

Mr. Chairman, I want to thank you for allowing me to come, and thank the panel for allowing me to make my statement in the middle of their stories, which are much more moving than any politician's statement. But I think that I am speaking for literally thousands of my constituents who are afflicted and tens of thousands more who are afraid of a walk in the woods. Many of them were here at the time last week when this hearing was scheduled; they could not come back for this hearing.

But Mr. Chairman, I want to thank you for making the effort to specifically speak to the hundreds who came the last time, to reassure them of your interest in this and the committee's interest in this. That made a difference.

I believe the committee can make a difference, and the Senate must make a difference.

Thank you very much.

The CHAIRMAN. Thank you very much, Senator Bradley, for taking the time to give that very compelling statement about your strong interest and desire and support for action.

Karen Forschner, we'd be glad to hear from you now.

Senator DODD. Mr. Chairman, Karen is from Connecticut. I want to welcome her and thank her for coming to Washington twice in 1 week. I also thank the chairman very, very much for holding this hearing.

Mr. Chairman, we in Connecticut are proud of many things in our State, but the fact that this disease is named for a couple of Connecticut towns is something we are not terribly proud of.

In fact, Mr. Chairman, you may recall a few years ago when you were visiting the State, you took a beautiful ride on a road called Joshua Town Road, and you described it to me as one of the prettiest roads you had been on in New England. That road runs right through Lyme, CT, which is the town where this disease got its name.

We are one of three States that account for a majority of the cases in the country. We also have the highest reported rate of Lyme disease among all States, at 54 cases per 100,000 people. This figure is low due to under-reporting, but those are the numbers we are given. In the Lyme, CT area, the rate is more than 500 per 100,000 people. So it is a staggering problem in our State.

I am pleased, Mr. Chairman, that Dr. Matthew Cartter, Connecticut's epidemiology program coordinator in charge of Lyme disease, will also be here this morning to discuss the situation in Connecticut and our efforts to prevent and control the disease. As I have mentioned, the disease is of particular concern to me because it affects Connecticut as a whole; however, I think it is also important that we recognize and hear from individuals who suffer from the disease, and the witness you are about to hear from, Karen Forschner, of Tolland, understands this disease in a very poignant way because of what has happened to her own family; her son lost his life and she herself has suffered. Karen has been a leader on the issue, and I think you'll be moved by what she has to say.

Mr. Chairman, there are obviously many aspects of the disease that are unknown and troublesome. First, there are few answers to the health problems of people who continue to suffer from the disease even after therapy. And there is no effective test to diagnose Lyme disease.

At a time when we must worry about the safety of our children on the streets and even in the schoolyard, it is disturbing that we must also be concerned that playing in the back yard may pose a serious hazard to our children. But we must be concerned because the absence of an effective test means that some parents won't know whether their children have Lyme disease until they get sick. If we had a vaccine against Lyme disease, we would have one less worry about their health and safety.

I agree with Senator Bradley. I think this hearing is extremely important. I commend you for holding it, and my colleagues here for attending this morning.

And I am very pleased and honored, Karen, that you are here. Again, we all apologize for what happened last week, unavoidably, but we are deeply grateful to you for being here today.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Karen.

Ms. FORSCHNER. You mentioned that I chair the board of directors of the Lyme Disease Foundation, but after all my years of a career, I find that my most important role that I have ever had was as Jamie's mom, and that's the role I will speak about today.

The other thing I'd like you to remember is that the people who are here on the panel are not the people speaking because of woe is us, and an example for fundraising to get more money from the Government. We are an example of what has happened when the Government system let us fall through the cracks. And the heroes of this disease are within the Government, within Congress. But also the main heroes of this disease are the public, the people who are sitting behind me and the people across the country who have taken the message and the advocacy to everybody they can, and as I think you know, from some of your faxes and letters, they have also taken the cause to you. And we thank you for having this meeting today.

The cancellation last week indeed was a very honorable thing for you to do, Senator Kennedy, because it gave everybody a chance to have input into the process, and I thought it was very nice.

I will talk as fast as I can, because I know you are——

The CHAIRMAN. No, no. Take your time. We have the time.

Ms. FORSCHNER. I am glad, because I'm 5 months pregnant, and I'm a little bit breathless right now.

The CHAIRMAN. That's all right. Take your time.

Ms. FORSCHNER. In 1985, our only child was born. Unfortunately, I had a bug bite and the full range of Lyme disease symptoms while I was pregnant. Soon after Jamie's birth, his symptoms started. During the pregnancy and after the birth, I was seriously ill with multiple problems, including joint swelling and pain. Shortly after giving birth, a doctor told me that my crippling pain was arthritis and a permanent condition, and that he expected me to remain on crutches until I required a wheelchair.

However, there was this mystery illness called Lyme disease, and the doctor offered me 2 weeks of antibiotics, just in case. If my symptoms went away, and I was cured, I had Lyme disease; if my symptoms remained, I did not, and I would be wheelchair-bound for the rest of my life.

At the same time, all five of our beloved pets, three cats and two dogs, became seriously ill and required repeated hospitalizations. As fate would have it, all of us had contracted Lyme disease at the same location and time. Eventually, all of our pets were lost due to their Lyme disease.

Jamie was the light of our life. He had blond hair, blue eyes, and was always smiling. By the time he was 6 weeks old, his health was in question. He had repeated vomiting and eye tremors. By 6 months old, he was showing signs of brain damage, eye problems, possible deafness and had ceased to grow properly due to malnutrition.

I questioned the doctors about whether my son could get Lyme from me during pregnancy, and they guaranteed me absolutely no.

To understand this disease and how it affected our family, I would like to tell you what it did to our son's brain. The bacteria attacked the part of his brain that controlled his eye movements, causing his eyes to swing rapidly back and forth, to turn inward at times and outward at other times. And he became light-sensitive, which caused double vision, motion sickness, inability to open his eyes outside, and blindness.

Jamie's facial and tongue muscles were also involved, causing his face to be partially paralyzed and droop, which is like a Bell's palsy, resulting in excessive drooling, loss of speech, loss of the ability to eat or swallow, and allowed food or saliva to go directly into his lungs instead of into his stomach.

Children and adults started staring at him. The loss of speech frightened him. Feeding him by mouth became life-threatening as repeated lung infections set in, and eventually a partially collapsed lung resulted in multiple hospital stays. Jamie could not tell us that he was scared, that he had a headache, that he was hungry, or that he needed to go to the bathroom. Jamie became mute, malnourished and frustrated. His hearing was affected, causing the hearing test to show another blow to us, that he was profoundly deaf. It was only then when his speech started that we realized the test was wrong and had been influenced by the damage done by the Lyme disease bacteria. He indeed wasn't deaf.

Jamie's stomach was involved, causing repeated vomiting. And since he was too weak to lift his head, we had to worry that he was going to drown.

Jamie's nerve conduction was affected, which delayed the innovation to the muscles; this caused him to lose muscle tone, and he became "floppy." This meant that he could not sit, crawl, or hold his head up, and he certainly could not feed himself.

The devastating set of involvements that are known to be Lyme disease involvements made Jamie 100 percent dependent—for life.

Tests, probes, biopsies, all could not pinpoint the problem. When Jamie was 1-1/2, he had surgery to realign his stomach in an attempt to stop the life-threatening vomiting. The surgery did not work, and our son had a permanent hole cut in his stomach so that he could feed through a feed tube. Indeed, we really only needed antibiotics.

Tom's company, a CPA firm, declared that Tom no longer had that "zip" that they expected of their potential partners, and proceeded to let Tom go. Today, the family leave bill would have protected him and given him time to set his home life more in place.

As Jamie approached his 2nd birthday, we found ourselves unable to provide the medical care needed, and we were told to institutionalize him or put him up for adoption, as there are families who are set up to handle multiple-handicap children.

I turned into our son's advocate, no longer listened to what the doctors said, and started searching the medical literature. And I realized Jamie had Lyme disease, I had Lyme disease, our pets had Lyme disease—and transplacental transmission had already been published. We fell through somebody's cracks.

Then a doctor saw permanent damage in our son's eyes, damage caused by congenital infection—one just like Lyme disease. We tested positive. We were told we would be cured. We got some treatment, and my life was good.

Unfortunately, it wasn't quite true, and our son relapsed. The meningitis in his brain had caused his head to enlarge to the size of a 14-year-old. His clothes no longer fit. We had to get specially adapted clothing. As a little boy, the head still has room to grow larger when there is a lot of pressure, and the only time we had to worry was when his head stopped having that ability to enlarge.

When his relapses were in process, his throat would collapse, and he would spend time on life support. Indeed, our lives were a mess. Media people saw this child as a great example for some sort of little TV blurb and soundbite. Indeed, I think that what we saw was a child who was courageous and might indeed help other people learn a little bit about this disease—and maybe, God forbid, yes, maybe he might be able to get some funding for the Government so there would be answers before he would die.

Indeed, when I saw what was happening when Dan Rather had him on television and showed the story not of what I saw was a courageous story, like the courageous stories here, but all of a sudden a story of what was termed “every parent's worst nightmare.” Indeed, he wasn't the worst nightmare, and we hadn't gone through the worst nightmare yet.

Those words will always haunt me. And then, the nightmare began. Indeed, over time, he was on life support many times, and when he received treatment, he would recover. His vision returned. His speech started. He started to feed by mouth. The vomiting stopped. He gained weight. His lips could kiss, and his arms could hug. But despite the dramatic and documented improvements, over the years, local doctors and health officials would interfere repeatedly with our son's retreatment. Indeed, it was an obsession to make sure that our little boy did not get treated because it was curable, and you didn't need to treat more than 4 weeks.

After attending a medical conference, I realized much information about Lyme disease was not reaching the medical community nor the public. Only limited information that was acceptable was reaching them. And with the help of researchers, business people, lay people across the country, we established the first organization dedicated to Lyme disease.

Our mission was to provide an area where scientific information could be discussed—all areas, all avenues, not just one or the status quo, but what exactly is out there, known, that we can get to the truth with?

I gave up my career and spent 70 hours a week for the last 5 years to volunteer at this organization. The sacrifices were great, as many people in the audience know. We used up our life savings in the process. We had no money left. Our parents provided us with food and clothing; Santa Claus didn't come unless my mom and dad bought the presents. We were in a race against time. Within 2 years, we had reached 210 million people across the country, and Lyme disease had become a household word—not because of two or three of us, or because the Lyme Disease Foundation, but indeed because of the public.

Much of this effort was due to this massive grassroots education. And indeed, I must say Senator Lieberman helped greatly, as did other Senators and Congressmen who then decided to set up Lyme Awareness Week.

In 1990, NIH's new test that they had developed, which is not available to the public yet, photographed the bacteria in my son despite his repeated treatment, and not only him, but other people across the country, showing that short-term treatment for a few people may not ever work and may not work at all. I was dismayed. When I showed this to the pediatricians, they said if we retreated our son, based on what they got from our local health department and our local people in the State, they would cancel us, and they canceled my son as a patient. We had no physician in the State, so we took our son to New Jersey.

Once he was retreated, all his speech came back again, and for the third time, he learned how to speak. Muscle tone came back, vision came back; indeed, they were able to show his intelligence was very high. He was mainstreamed into kindergarten. He developed girlfriends, went to birthday parties, and we finally found a little boy inside the diseased body.

We waited over 1 year for NIH's test to be released. We were hoping we could use it to check on our son's progress so that he would not have a relapse and die. As my son started to relapse, I waited and waited, and I waited too long.

Our son's last relapse came on, and he started having seizures and brain infections. Within 24 hours, he was dead. His brain had swelled up so much it had killed itself. There was no tissue bank in the country to send his autopsy remains to, so before I went down to see him and make arrangements, I picked up the phone and called around the country and found some places that could take the tissue and study it. One of those places was indeed the same place where we couldn't find the test, at Rocky Mountain Lab at NIH. And indeed, please remember that name, because those people are wonderful, and they need your funding more than any other area.

They took his tissue, as well as some other places in the country, and were able to document that when he died, he was still infected with Lyme disease bacteria. And at some point, his report, combined with other deaths due to Lyme disease, combined with other children with transplacental information, may indeed at some time in the future have enough peer review publications that the CDC may indeed accept transplacental transmission or death due to Lyme, in which case public health policy can be improved.

Insurance limits for us were used up at \$2 million. The final total cost to society for our son was that amount. We all paid the price through insurance premiums, Government, policy, and the like.

If public policy were prevention-oriented instead of antibiotic-hysterical, trying to prevent people from getting treated, my son would have been treated much sooner, and I would have been treated, and so would the people here have been treated. A society that waits for disease to happen and hopes like hell we can catch up is not the type of society we want for the future. Our public policy must dictate strong prevention programs.

Thousands of us have worked toward finding the truth about this disease. We are hoping that the Government will move forward, past its status quo-seeking behavior. We are not asking what the country can do for us; we are asking what the country can do with us, and what you will stop preventing us from trying to do with you.

We have worked for over 5 years, we and people in the audience, all together, most of the time, and find it is now time for a change. We are asking for your leadership. I hope that by the time the baby I am carrying is born, there will be some effective, coordinated program in the Government that can help prevent any other children or adults from getting this disease.

Remember, all of your States have the tick now, and all of your constituents can get this, and your grandchildren, and your uncles and aunts and nieces could get this disease.

I would like to close by saying one thing, to let you know that we received a grant as of 2 years ago from the CDC for public education, and wound up producing a bilingual educational video that went out to 9,000 schools. As of this spring, over 3.5 million children have directly seen this video on Lyme disease and remember it, because of the partnership between ourselves—I am pointing to Duane Gubler—and the CDC.

I thank you for this chance to talk, and I hope that you will take this into consideration. Thank you.

[The prepared statement of Ms. Forscher follows:]

PREPARED STATEMENT OF KAREN VANDERHOOF-FORSCHNER, BS, MBA, CPCU, CLU

In 1985 our only child, Jamie, was born. Unfortunately, I had a bug-bite and the full range of Lyme disease symptoms while I was pregnant and soon after my James birth, his symptoms started. During the pregnancy and after the birth I was seriously ill with multiple problems including serious joint swelling & pain. Shortly after giving birth, a doctor told me my crippling arthritis was a permanent condition and I would remain on crutches until I required a wheelchair. However, there was this mystery illness called Lyme arthritis and the doctor offered me 2 weeks of antibiotics—just in case. If my symptoms went away, had Lyme. My symptoms temporarily improved and once off treatment the symptoms came back—in full force.

At the same time all 5 of our beloved pets, 3 cats & 2 show dogs became seriously ill after multiple tick bites and required repeated hospitalizations. As fate would have it, all of us contracted Lyme Disease. Eventually all my pets were lost due to Lyme Disease.

Jamie was the light of our life, blond haired, blue eyed and smiling. By the time he was 6 weeks old his health was in question. He had repeated vomiting and eye tremors. By 6 months old he was showing signs of brain damage, eye problems, possible deafness and had ceased to grow properly due to malnutrition. I questioned the doctors about whether my son could get Lyme from me during pregnancy. I was guaranteed he couldn't. Our son was never exposed to ticks and never had a tick bite.

To understand this disease I would like to explain what it did to our son's brain. The bacteria attacked the part of his brain that controlled:

—Jamie's eye movements, causing his eyes to swing back & forth, turn inward & outward, and become light sensitive. This caused him to have double vision, motion sickness, inability to open his eyes outdoors, and blindness.

—Jamie's facial & tongue muscles, causing his face to be partially & sometimes fully paralyzed & droop resulting in drooling, loss of speech, loss of the ability to eat or swallow, and allowed food or saliva to go directly to his lungs. Children & adults started staring at him, loss of speech frightened him, feeding him by mouth became life threatening as repeated lung infections started & eventually a partially collapsed lung resulted in multiple hospital stays. Jamie could not tell us he was scared, had a headache, or even that he needed the bathroom. Jamie became mute, malnourished, and frustrated.

—Jamie's hearing, causing his hearing test to show he was totally deaf. Then Jamie started talking. The Lyme Disease nerve involvement had affected the test. Unfortunately, we were unable to tell how it affected Jamie's hearing.

—Jamie's stomach, causing repeated vomiting and since he was too weak to lift his head and we had to worry about his drowning during times he was laying down.

—Jamie's nerve conduction causing loss of muscle tone. Jamie was "floppy", and couldn't sit, crawl, feed himself or even hold his head up.

This devastating set of involvements made Jamie 100 percent dependent— for life.

Tests, probes, biopsies, all could not pinpoint the problem. When Jamie was 1½ he had surgery to realign his stomach in an attempt to stop his life threatening vomiting. The surgery didn't work and our son had a permanent hole cut into his stomach so he could have a feeding tube installed to help keep him alive.

Tom's company, a CPA firm, declared Tom (my husband) didn't have that "zip" that potential partners needed and proceeded to let Tom go. Today, family leave would have given him some time to take care of his devastating family life.

As Jamie approached his second birthday we found ourselves unable to provide the medical care Jamie needed and were told to institutionalize him. I turned into my sons advocate and spent several months researching the medical literature. I realized Jamie had Lyme Disease contracted through placental transmission. Transmission of infection during pregnancy and adverse outcome had been already documented in medical literature.

Then, a doctor saw permanent damage in our son's eyes—damage caused by of a congenital spirochetal infection. Indeed, we discovered Lyme Disease was caused by a spirochetal bacterium. Then, I found a test for Lyme Disease resulting in Jamie and I testing positive! All of my sons symptoms were explained by the medical literature on Lyme Disease. Life was good. I was told my son would get treated and the disease process would stop. Lyme was easily curable. Not true. Jamie was treated and relapsed—several times. The meningitis in his brain had caused his head to enlarge to the size of a 14 year old. Clothes didn't fit unless adapted "for the multihandicapped". Howl learned to hate that word. When Jamie's relapses were in process even his throat would collapse and he spent time on life support. Media people were rushing out to see this child. I thought Jamie's story was of courageous struggle, but, Dan Rather termed it the way the media saw the story as "every parents worst nightmare". Those words will always haunt me. And, then the nightmare started.

Indeed, over time he was on life support many times. When Jamie received treatment he would recover. His vision returned. His speech started. He started to feed by mouth, his vomiting stopped. He gained weight. His lips could kiss and his arms could hug. But, despite the dramatic & documented improvements, over the years local doctors and health officials would interfere repeatedly with our son's retreatment—as Lyme was easily curable. Despite the proved cause & effect of treatment, evaluated by many independent professionals, the label of "Lyme Disease" caused a paranoid behavior to withhold life-saving treatment. When we asked the pediatrician for Amoxicillin to give to our son over a 3 month period to prevent a relapse we were told that Amoxicillin was dangerous and there was no proof the Lyme bacteria can survive the short-term intravenous medicine he had while on life support. Two weeks later we were back to the pediatrician for a potential ear Infection. The same pediatrician prescribed the now "safe" antibiotic Amoxicillin to prevent an ear infection that had not yet started. And, the prescription was issued in the same dose we had requested for a total of 4 months.

After attending a medical conference, I realized much information about Lyme Disease was not reaching the medical community nor the public. And, with the help of many researchers, business, & laypeople established the first organization dedicated to Lyme Disease—the Lyme Disease Foundation. Our mission was to provide an area where all of the scientific information could be discussed, not just the U.S. version of "status quo". I gave up my career and spent 70 hours a week for the last 5 years as a volunteer. The sacrifices were great. We used up our life's savings in the process. Family provided us with food, clothing, holiday gifts for our son, and much support. We were in a race against time. Within 2 years we had reached 210 million people and Lyme Disease became a household word. Yet, there were no answers for our son.

Doctors started fighting about whether or not my son should be retreated—even doctors not involved in my sons care! Yet, there was proof that Jamie's persistent infection continued to ravage his body. Electron microscope pictures of the Lyme bacterium proving current infection were not enough "proof" for the pediatricians. After all, they had talked to the State health department and even an academic who recommend no retreatment.

In 1990, NIH's new test photographed the bacteria still in my son, despite repeated treatment, I was dismayed. When showed this to his pediatricians the doctors canceled my handicapped son as a patient since I planned to have him re-treated because he was heading into another serious relapse. Once Jamie was re-treated he gained back speech, muscle tone, vision, eating and many other little boy skills. He was finally mainstreamed, after 2 years of "advocating", into kindergarten. You see, once you are ill there are many battles to wage. Jamie developed girlfriends, learned to operate an electric wheelchair, became "potty trained" and we finally found the little boy inside the diseased body.

We waited over 1 year for the NIH test to be released and available to check our son's progress. As my son started to relapse again, I waited for the NIH test, it was always close to being run. It never came and we waited too long.

Our son's last relapse came on and he started having seizures from the brain inflammation. Within 24 hours he was put on life support. The day he was declared "out of the woods", he died. His brain swelled up so much it killed itself. There was no tissue bank to send his autopsy remains to, so I had the unpleasant task of calling researchers around the country and dividing up my son's body to sent to different researchers. I loved this little boy and would have died for him and, here was forced to arrange an autopsy. You see the CDC has been denying congenital Lyme and death due to Lyme, despite numerous publications to the contrary and I hoped this would prove it in order to help other children.

Insurance limits were used up, Jamie's medical bills totaled about 2 million dollars. The final total cost to society for our son was around 2 1/2 million dollars. The majority of the cost was in disability care and excessive nonLyme Disease testing. A minor amount was in treatment with antibiotics.

And, yes, the autopsy proved Lyme Disease bacteria were still in his brain. Our lifetime of savings were gone. Our pets were gone. Our jobs were gone. Our baby was gone.

If public policy was prevention oriented instead of anti-antibiotic hysteria oriented my son would be alive today. I am not alone. Other mothers have also lost their children.

Thousands of us have worked toward finding the truth about this disease. Unfortunately, some parts of the government have an obsession with keeping the status quo. The true heroes of Lyme Disease have been a wide mixture of public, support groups, researchers, some academics, front-line physicians and some members of congress. HHS has proved to be a failure in coping with emerging epidemics and Lyme disease patients are one more casualty from the current ineffective health care system.

We have not asked what the country can do for us, we have always tried working with the government. We are now demanding the government become responsive to the public's needs. I think this disease may not be easy to diagnose, easy to treat, nor easy to cure. And, sometimes permanent damage may occur. There may even be deaths due to Lyme Disease. We have tried the old ways for over 5 years, it is now time for a change!

The CHAIRMAN. Ms. Forschner, we thank you, not just for your words, but for your real life commitment and what you have been doing and what you continue to do. It is an extraordinary example of a mother's love for a child, going to the extent that you did under the most extraordinarily difficult and trying circumstances. You have demonstrated that and clearly extended it not just to your own child, but to others, and that's really the ultimate act of both faith and love, and I think you are a real inspiration, as are the others who have testified here, for us here today.

You mentioned the family leave legislation, and we have our good friend Senator Dodd to thank for that. This is the first day of its implementation, and I think you gave us a very good example of why that legislation is important, as just a sidelight on this.

This panel really reminds us of the importance of diagnosis. I had a son who had a tumor inside his spinal column, and we went for a number of months where they said it was psychosomatic. They examined x-rays and blood and couldn't find it, and then finally moved the MRI up two notches after he had lost all balance

and found it. And the first thing he said after 12 hours of surgery was: "I'm so glad people don't think I'm a faker."

The indignity that you had to endure over all this time when people said it's something in your mindset—not that in and of itself is wrong; people have mental challenges and needs and difficulties, but just the sense that you have that you know that it is something else and the frustrations that you had in not being able to get attention is something that I think is so powerful in terms of diagnosis and what we have to do to be able to come to grips with it. That is a challenge of education in the medical profession; it is trying to work with scientists and researchers to find the best way to be able to do that and ensure that it is quality and realistic.

We have heard about vaccinations, and Lord only knows, we want the research to go on. I think we could probably make our first progress in the diagnosis—I would hope. Vaccine, yes, but that's going to take some time.

Ms. FORSCHNER. Vaccines are in human trial right now.

The CHAIRMAN. Well, we can only hope that the trials are successful.

The challenges you face in terms of being dropped by your insurance, bankruptcy of families, is another reason out there for national health insurance. We are constantly reminded about it, but this just underlines it one more time.

And the importance of research—I know we can't wave a magic wand and resolve all of these issues in terms of research, but it is a pretty good indication of our priorities in terms of what we as a society are prepared to do in terms of research. One of the really sad aspects, even in terms of this budget reconciliation, is the freeze that we are putting on in terms of research in domestic spending. This is tough stuff that we're talking about in terms of belt-tightening out there, and that is something that is difficult, but there is no reason that we can't find within our resources the kinds of resources that are necessary in this area, and we are certainly committed to doing that and will work very closely with all of you—and the researchers, NIH, CDC, whom we'll hear from later on this morning—to see how that can be effectively done.

I just want to express enormous appreciation for the testimony. We know it is very, very difficult to talk about these personal matters.

I might just take another moment to ask Ms. Keane-Myers, do you feel that you are cured now? What is your own assessment?

Ms. KEANE-MYERS. I think that since I was treated early on in the disease—I did have recurrent conjunctivitis for a long period of time, which is one of the symptoms of chronic Lyme disease, and was treated later on for another symptom, with a month-long dose of tetracycline. So I think that I probably am cured of the disease. But that was because I was aware of the symptoms, and I was able to get treatment very quickly.

If I had not been aware of the symptoms, if I didn't know that I was in an endemic area, and I didn't go to the physician and say, "I think I have Lyme disease," I don't think that I would feel the same way.

The CHAIRMAN. I am going to recognize Senator Kassebaum. I am the floor manager for the nomination of Dr. Joycelyn Elders for

Surgeon General, who will be responsible for all public health policies. People can ask why public health issues and questions are important, and we've got one more example about what sensitive and compassionate policy can really be all about.

My colleagues will continue through the course of the hearing, and I will read through all the testimony. I am enormously grateful to all of you.

I have asked Senator Wellstone if he would chair the remainder of the hearing, and he has agreed to, and I will now yield to Senator Kassebaum.

Senator KASSEBAUM. Thank you, Mr. Chairman.

Just briefly, I was so impressed with the eloquent testimony and want to express my appreciation for your coming and the leadership you are providing in what really is a wake-up call. I must say, coming from Kansas, where it isn't something that we think about that much, I have read about it—and you can read about it, but until you hear someone like each of you and what you have gone through, it really doesn't make the impact. I can only say how grateful I am to you, Evan, and to everybody, for taking the time to come today and share with us and with the rest of the country the problems of Lyme disease.

As I said, I think it is something that most of us don't understand or don't realize unless we have been in areas where it has been prevalent. So my appreciation and thanks to all of you.

We will now receive a statement by Senator Durenberger.

[The prepared statement of Senator Durenberger follows:]

PREPARED STATEMENT OF SENATOR DURENBERGER

Mr. Chairman, I am grateful that you have called this hearing for today. Lyme disease is an important health concern to Minnesotans, and therefore important to me.

In 1992, the Minnesota Department of Health reported 196 cases of Lyme disease, a 139 percent increase from 1991. One hundred six cases were reported in the Twin Cities and 72 in 10 counties north of the Twin Cities—the most endemic counties in Minnesota. Of the one hundred six cases, most of the individuals were exposed to ticks in the counties just north of the Twin Cities and contiguous to Wisconsin. The Metropolitan Mosquito Control District has confirmed that several counties in the metropolitan area are endemic for deer ticks—the carriers of the disease.

And these figures may only tell part of the story. The numbers are from reported cases only. There are many Minnesotans who believe that the number of people with Lyme disease is higher.

In response to the incidence and spread of Lyme, in 1991, concerned Minnesotans formed a nonprofit organization, the Lyme Disease Coalition of Minnesota, to help coordinate and elevate public awareness of the disease. Lyme disease support groups also have formed to respond to the concerns of the growing number of Lyme patients. According to Barb Jones, the Coordinator for Lyme Disease Support Groups in Minnesota, there are 18 of these groups in the State today.

So we know that Lyme disease is a problem, and a serious one. However, there is a great deal of uncertainty about diagnosis and treatment. And that has led to frustration, particularly among

those who have suffered or who have loved ones who have experienced its ravages.

The uncertainty stems from the vagueness of the symptoms—which can include fatigue, weakness, numbness and stiff joints—and the need for more physician and patient education about the disease. Also, there is no standardized diagnostic test and there are reported disparities in test outcomes from different laboratories. All this makes it difficult for physicians to confirm suspicions of Lyme disease, and has led to accusations of under and over diagnosis of the disease.

I remember some years back when the daughter of two good friends, one of whom works on my staff in Minnesota, contracted Lyme disease. As a young girl and teenager Ashley Holderness was extremely athletic—a champion swimmer and figure skater in Minnesota. She was one of those people who rarely got sick. She was always on the go. Unfortunately, it was partly due to her incredible stamina that left Lyme undiagnosed for a year. But it was also due to the obvious change in her athletic ability that finally brought attention to the disease.

On and off for about a year Ashley seemed to be sick with the flu. She also tired easily, experienced agonizing headaches, dizziness and shakiness. Ashley forced herself to try and continue her normal schedule of school and sports. Her swimming times, however, became progressively worse. When it got to the point where Ashley didn't think she could swim the length of the pool, her mother took her in to see the doctor.

A battery of tests run by an infectious disease specialist, which included tests for Leukemia, Lupus and Lyme, came up positive for Lyme. She was immediately prescribed antibiotics. For 3 years Ashley endured oral and intravenous antibiotic treatments. She recalls that especially after the IV treatment, there was a definite difference in the way she felt—she was getting better. Her mother describes it as the periods of sickness getting shorter, and the time between those periods growing longer.

Since going off the treatment, she says she feels fine and can carry on a normal life. However, she still gets headaches when years ago she never did. And she said she tires more easily than friends her age.

Like many Lyme sufferers especially in the 1980's, Ashley's disease was not diagnosed in the initial stages. If it had been diagnosed earlier, 4 years of her life may not have been consumed by continuous illness. Ashley missed out on school and her sports. Some Lyme sufferers have had to leave their jobs.

Frustration over lack of information and misdiagnoses have helped stoke the fire around the issues associated with prevention, diagnosis and treatment. And we'll hear about these issues today. As a society, we know more about Lyme now than we did in 1982. But there is still a way to go.

The Minnesotans who have called my office have asked that keep an open mind during this hearing. They asked that I listen to the information presented and learn a little more about this complex disease. And Mr. Chairman, that is exactly what I intend to do.

Senator WELLSTONE [presiding]. Senator Metzenbaum.

Senator METZENBAUM. I just can't tell you how grateful I am to each of you for being here today. I think you have sounded a clarion call that we ought to get off our butts and do something about this. Frankly, I think it is an illness that has been swept under the carpet, and not many people have paid attention to it, and have said, oh, that's some little tick that doesn't matter. I have heard of Lyme disease, but it hasn't struck me with the strength of your testimony today.

And I must confess to you that the argument will be, "Well, where are we going to get the money to do the research?" I can tell you this. When I see how much money is wasted by this Government and how many giveaways we have for special interest corporations that have well-paid lobbyists, including those who are ripping off the Government in this budget reconciliation bill, I say dammit, isn't it incredible what we could do with \$100 million, \$200 million—it's just a drop in the bucket compared to the giveaways some corporations have been able to engineer in that bill.

I will just say to you that I only expect to be here 17 months more, but before I leave here, I will work with the chairman and the ranking member, and we will somehow get research money going, put into this area, to do something about it.

You are all very strong people. This young man is particularly strong to be able to be here with us today and talk about this. And we just owe it to you. We owe it to you to see to it that we find an answer, that we do the research, and if we can't find the answer the first week, the first month, the first year, at least to keep working on it. And I promise you that with others on this committee and others in the Congress, we are going to at least make the effort. We aren't doing enough right now.

Senator WELLSTONE. Ms. Forschner, did you want to respond?

Ms. FORSCHNER. Yes. I think that's a great comment you made, and I just wanted to say, too, that I don't think everybody is overwhelmingly asking for lots and lots of money to be put into Lyme disease. I think we are asking for it to be directed toward the problems people on the front lines are having. We are talking about chronic illness and a better test. NIH has a better test. It is sitting there. We had to fund it because NIH didn't have money to fund it. So we sent \$5,000 over, and then \$30,000, to the Government.

So we are asking for a better-coordinated program, more front-line sensitivity; no lowering the indirect rate on your grant programs to 25 percent, as the GAO has suggested, instead of 70 percent—Government waste. That goes to gold toilet seats in some places. So we think that the current budget—let's say we can't get any more money—can be run much more efficiently, and we can also run it more efficiently by coordinating some of the efforts inside CDC and NIH at the top level, under Joycelyn Elders possibly, because the DoD has programs, and the Park Service has programs on Lyme disease.

Instead of a massive duplication of effort, maybe we can streamline what we do, focus the research funds, get a little bit more public-oriented attitude, and take a look at the real problem of chronic illness. It is not do you treat more than 28 days—let's prevent you from getting medicine—it is what is it that is happening to these chronic patients. And I think that is what you hear here, is that

we need a better focused program; we need a real leader in a position to say, okay, this is what we're going to do, boom, boom, boom, and let's go forward.

Senator WELLSTONE. Senator Thurmond.

OPENING STATEMENT OF SENATOR THURMOND

Senator THURMOND. Thank you, Mr. Chairman.

Mr. Chairman, it is a pleasure to be here this morning to receive testimony concerning Lyme disease. I'd like to join you and the members of this committee in welcoming our witnesses here today.

Mr. Chairman, Lyme disease is primarily spread by ticks which can be found across the country. Infected ticks can be carried by animals such as dogs, cats, deer, horses, and birds. From 1982 to 1991, over 40,000 cases of Lyme disease were reported; over 50 cases were reported in my home State of South Carolina between 1985 and 1991.

Lyme disease is difficult to diagnose. There appears to be no widely-accepted test that can directly detect when the infection is present. However, if left untreated, Lyme disease can cause severe damage to the heart, brain, eyes, lungs, liver and kidneys. It can also affect fetal development.

Mr. Chairman, if Lyme disease is detected early, oral antibiotics are generally effective. This treatment may be continued for 10 to 30 days depending on the symptoms. However, the recognition and treatment of chronic Lyme disease is controversial. Possibly the best cure for Lyme disease is prevention and public awareness.

I also believe this hearing today may help increase the awareness of this spreading disease and address the controversial issues surrounding its recognition and treatment.

Mr. Chairman, I want to welcome our witnesses again here today and look forward to receiving their testimony. I want to congratulate you for holding this hearing.

Senator WELLSTONE. Thank you, Senator Thurmond.

Senator Dodd.

Senator DODD. Thank you, Mr. Chairman. I will be brief.

I think your last point about coordinating the efforts, Karen, is a very wise and good suggestion in terms of trying to bring together resources and deal with the front-line issues that have been brought up. And I suspect we can get some broad-based support for that approach.

Let me thank all of you for being here today. As so often is the case, you put a human face on these issues. The next panel of very talented and bright people deal with these issues in numbers and statistics. But for people who are unaware of what we are dealing with, it only becomes clear to them when they can actually see and listen to people who are living with it.

I always say it takes a certain amount of courage for people to step forward and talk about personal problems, but you represent literally thousands upon thousands of people who obviously can't all be here and can't all testify. So it takes a special sort of courage to be willing to come forward and talk about very personal, very painful matters, but it is tremendously helpful.

We thank you.

Senator WELLSTONE. And I also would like to thank the panelists. I cannot say it better than Senator Dodd just said it.

Just an apology. There was another committee hearing that I had requested at the same time, so my apology for coming in later due to that conflict.

Thank you all very much. We will now move on to the second panel.

Our second panel is composed of health professionals engaged in the control and treatment of Lyme disease. Dr. Platt and Dr. Cartter will tell us about the spread of Lyme disease. Dr. Platt is a veterinary microbiologist on the faculty of Iowa State University. Dr. Cartter is the epidemiology program coordinator for the State of Connecticut.

Dr. Allen Steere is director of the Lyme Disease Program at the New England Medical Center of Tufts University, and Dr. Joseph J. Burrascano, Jr., is a private practitioner from East Hampton, NY.

We thank all of you for being here, and we will start with the introduction from the Honorable George Hochbrueckner.

Senator DODD. Mr. Chairman, I'd just like to welcome Dr. Cartter. As you pointed out, Dr. Cartter is an epidemiologist from Connecticut. He graduated from Cheshire High School and Wesleyan University as well, and I gather is highly respected and tremendously appreciated for his efforts. We are pleased you are here.

Dr. CARTTER. Thank you, Senator Dodd.

Senator WELLSTONE. Congressman, we are glad you are here.

STATEMENT OF HON. GEORGE HOCHBRUECKNER, A U.S. REPRESENTATIVE FROM THE STATE OF NEW YORK

Mr. HOCHBRUECKNER. Mr. Chairman, members of the committee, I am delighted that you are having this hearing today on Lyme disease, as this is the first congressional hearing ever held on this subject. I commend you for your recognition of how serious and debilitating this disease can be and your concern for patients who are suffering from it and turning to their Government for help.

You are also to be commended for your interest in the progress of Federal research on Lyme disease currently under way and your consideration of whether additional funds are needed in light of the seriousness of the disease and its rapid spread across our Nation.

I am pleased to advise the committee that I have introduced legislation to provide new research funding to fight Lyme disease, including the creation of five national Lyme disease centers under the direction of the Centers for Disease Control.

I am providing the committee with a copy of my bill, H. R. 2813, the Lyme Disease Prevention, Control, and Research Amendments of 1993, which I hope you will give serious consideration.

I also request that my separate formal statement be inserted in the record.

As the Member of Congress who has the unfortunate distinction of having the most reported cases of Lyme disease from his district and who has introduced many pieces of legislation to promote awareness and provide research funding to combat Lyme disease, I am delighted that you have given me the opportunity to address you today and to introduce my constituent, Dr. Joseph Burrascano,

of East Hampton, NY, who will provide the committee with his views on the medical treatment of Lyme patients.

But let me say a few words off-the-cuff, if I may. When I first started to promote Lyme disease as a problem in the Congress 7 years ago, when I first started talking to my colleagues in the House, many of the members thought that Lyme disease was a citrus disease affecting lemons and oranges and grapefruit. But we have come a long way since then, and rightly so.

Much work has been done, as you have heard and will hear, on a more effective test, since Lyme disease does mimic other diseases, certainly on a vaccine, which is now going into trial; on education both for the medical community and individuals—and certainly Karen Forschner has had a lot to do with that—and certainly, the control of deer and mice, which are the main hosts for the Lyme disease tick.

Even on the House Armed Services Committee, which I have now served on for 7 years, with the military, an appreciable amount of work has been done by the military that is applicable to the civilian population. Clearly, what they have found after millions of dollars of research is that there is a good personal protection for people, that by use of promethin-based spray for the clothing coupled with a deep-based lotion for the skin—it even comes today with a sunblock—you can provide close to 97 percent protection for individuals until we do in fact come up with the ability to stop this disease.

So there are many, many things going on out there, and there is much work going on, but it is important that we keep the pressure on and continue doing what we must do. So we have come a long way; clearly, we still have a long way to go.

At this point, I am delighted to present my constituent, Dr. Joseph Burrascano of East Hampton for his testimony.

Senator WELLSTONE. Dr. Burrascano.

STATEMENTS OF DR. JOSEPH BURRASCANO, JR., PHYSICIAN, EAST HAMPTON, NY; KENNETH B. PLATT, VETERINARY MICROBIOLOGIST, IOWA STATE UNIVERSITY, AMES, IA; DR. MATTHEW CARTTER, EPIDEMIOLOGY PROGRAM COORDINATOR, STATE OF CONNECTICUT, HARTFORD, CT, AND DR. ALLEN C. STEERE, PROFESSOR OF MEDICINE, NEW ENGLAND MEDICAL CENTER, TUFTS UNIVERSITY SCHOOL OF MEDICINE, BOSTON, MA

Dr. BURRASCANO. Thank you very much for holding this committee meeting, and again, thank you for the very nice introduction.

You have heard today that there are many problems in the field of Lyme disease, and I want to address one of the core problems that you may not be aware of. Some have called this the "Lyme disease conspiracy."

There is in this country a core group of university-based Lyme disease researchers and physicians whose opinions carry a great deal of weight. Unfortunately, many of them act unscientifically and unethically. They adhere to outdated, self-serving views and attempt to personally discredit those whose opinions differ from their own. They exert strong, ethically questionable influence on medical journals, which enables them to publish and promote articles that

are badly flawed. They work with Government agencies to bias the agenda of consensus meetings and have worked to exclude from these meetings and scientific seminars those with ultimate opinions.

They behave this way for reasons of personal or professional gain and are involved in obvious conflicts of interest. This group promotes the idea that Lyme is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with 30 days or less of antibiotics.

The truth, however, is that Lyme is the fastest-growing infectious illness in this country after AIDS, with the cost to society measured in the billions of dollars. It can be acquired by anyone who goes outdoors, and very often goes undiagnosed for months, years, or even forever in some patients, and can render the patient chronically ill and even totally disabled despite what this core group of physicians refers to as "adequate" therapy.

They feel that when the patient fails to respond to their treatment regimen, which is a common occurrence, it is not because the treatment has failed, but because they have developed a new illness, what they call the "post Lyme syndrome." They claim that this is not an infectious problem, but a rheumatologic or arthritic malady due to activation of the immune system.

The fact is, this cannot be related to any consistent abnormality, but it can be related to a persistent infection. As further proof, vaccinated animals now in the vaccine trials whose immune system has been activated by Lyme disease have never developed this post Lyme syndrome. Yet on the other hand, there is a great deal of scientific proof that persistent infection can exist in these patients because the one-month treatment did not eradicate the infection.

Indeed, many chronically ill patients whom these physicians have dismissed have gone on to respond to, positively, and even recover, when additional antibiotics are given.

It is also interesting to me that these individuals who promote this so-called "post Lyme syndrome" as a form of arthritis depend on funding from arthritis groups and agencies to earn their livelihood. Some of them are known to have received large consulting fees from insurance companies to advise the companies to curtail coverage for any additional therapy beyond the arbitrary 30-day course. And this is even though the insurance companies do not do this for other illnesses.

Following the lead of this group of physicians, a few State health departments have now begun to investigate, in a very threatening way, physicians who have more liberal views on Lyme disease diagnosis and treatment than they do. And indeed, I have to confess that today I feel that I am taking a personal risk, a large one, because I am stating these views publicly, for fear that I may suffer some repercussions despite the fact that many hundreds of physicians and many thousands of patients all over the world agree with what I am saying here today.

Because of this bias by this inner circle, Lyme disease unfortunately is both underdiagnosed and undertreated in this country to the great detriment of many of our citizens. Let me address these individually.

With underdiagnosis, the first problem is underreporting. The current reporting criteria for Lyme disease are inadequate and miss an estimated 30 to 50 percent of patients. Some States curtailed their active surveillance programs and saw an artificial drop in reported cases of nearly 40 percent, leading the uninformed to believe incorrectly that the number of new cases of Lyme is on the decline.

The reporting procedure is often so cumbersome that many physicians have never bothered to report cases at all, and some physicians who have reported a large number of cases have found themselves targets of State health department investigations. Finally, too many physicians and Government agents rely on the notoriously unreliable serologic blood test to confirm the diagnosis.

That brings me to my second point, which is the poor diagnostic testing. It is very well-known that the serologic blood test for Lyme is insensitive, inaccurate, not standardized, and misses up to 40 percent of cases; yet many physicians, including many of those referred to above, and the senior staff at CDC and NIH, insist that if the blood test is negative, then the patient could not possibly have Lyme. This view is not supported by the facts. Lyme is diagnosed clinically and can exist even when the blood test is negative.

The Rocky Mountain Lab of the NIH, which is the country's best laboratory for Lyme research, had developed an excellent diagnostic test for this illness nearly 4 years ago, but further work on it has been stalled. Incredibly, if not for private donations to the Government from the National Lyme Disease Foundation, this and other related research would have had to be abandoned. Yet many physicians believe that thousands of dollars of grant moneys already awarded by the Government to other outside researchers is poorly directed, supporting work of low relevance and low priority to those sick with Lyme. In spite of this, their funding continues, and the Rocky Mountain Lab is still underfunded.

The third point is that the university and Government-based establishment deny the existence of atypical presentations of Lyme, as some of those you have heard today, and the patients in this category are not being diagnosed or treated and have no place to go for proper care.

The result of all this is that some Lyme patients have had to see, in my experience, as many as 42 different physicians over several years before being properly diagnosed, and also at tremendous cost to themselves.

Unfortunately, the disease was left to progress during that time, and these patients were left forever ill, for by that time the illness was not able to be cured.

Under the second category of undertreatment, number one is because the diagnosis is not being made properly in many patients. Second, university-based and Government-endorsed treatment protocols are empiric, insufficient, refer to studies involving inadequate animal models, and are ignorant of basic pharmacology. They are not based on honest, systematic studies or on the results of newer information.

Third, after short courses of treatment, patients with advanced disease rarely return to normal, yet many can be proven to still be infected and can often respond to further antibiotic therapy. Unfor-

tunately, Lyme patients are being denied such therapy for political reasons and/or because insurance companies refuse to pay for these longer treatments.

Fourth, long-term studies on patients who are undertreated or untreated demonstrated the occurrence of severe illness more than a decade later, reminiscent of the findings of the notorious Tuskegee Study. We have to take this illness seriously.

Senator WELLSTONE. Dr. Burrascano, I don't want to be rude, but we're going to ask all of you to try to keep within about a 5-minute time frame.

Dr. BURRASCANO. I am on the last paragraph.

Senator WELLSTONE. OK. I apologize. We just want to make sure that everybody has a chance to testify.

Dr. BURRASCANO. I understand.

Finally, the Lyme disease bacterium spreads to areas of the body that render this organism resistant to being killed by the immune system and by antibiotics, such as in the eye, deep within tendons, and within cells. The Lyme bacterium also has a very complex life cycle that renders its resistance to simple treatment strategies. Therefore, to be effective, antibiotics must be given in generous doses over a long period of time, sometimes many months, until signs of active infection have cleared. Also, because relapses have appeared very late, decades of follow-up are required before you can say someone has been adequately treated.

I have to close by saying the very existence of hundreds of Lyme support groups in this country, and the tens of thousands of dissatisfied, mistreated, and ill patients whom these groups represent, underscores the many problems that exist out in the real world of Lyme disease. I ask and plead with the committee to hear their voices, listen to their stories, and work in an honest and unbiased way to help and protect the many Americans whose health is at risk from what has now become a political disease.

Thank you.

[The prepared statement of Dr. Burrascano follows:]

PREPARED STATEMENT OF J. J. BURRASCANO, JR., M.D.

CURRENT PROBLEMS IN THE LYME DISEASE FIELD

I began treating Lyme patients in the mid 1980's in an area said to be the highest case rate of Lyme Disease in the world. I have personally seen and managed the care of several thousand patients with this illness, and patients have come to me from thirty eight states and eight countries. Physicians from all around the world call me daily for my advice, and my copyrighted guidelines for diagnosis and treatment, currently in its eighth edition¹ has been distributed world wide, and has been translated into three languages. I have attended every major conference on this subject, and have presented original research papers at many of them. I do not receive any unreasonable personal gain for the treatments I prescribe. I do not now, and never have accepted money from pharmaceutical or home care companies in exchange for my referrals, and I manage patients as I do because I believe it is the correct approach. I came here today at my own expense because I take seriously this illness and the implications of this meeting here.

THE LYME DISEASE CONSPIRACY

There is a core group of university based Lyme Disease researchers and physicians whose opinions carry a great deal of weight. Unfortunately, many of them act unscientifically and unethically. They adhere to outdated, self serving views and attempt to personally discredit those whose opinions differ from their own. They exert strong, ethically questionable influence on medical Journals, which enables them to

publish and promote articles that are badly flawed. They work with government agencies to bias the agenda of consensus meetings, and have worked to exclude from these meetings and from scientific seminars those with alternate opinions. They behave this way for reasons of personal or professional gain, and are involved in obvious conflicts of interest.

This group promotes the idea that Lyme is a simple, rare illness that is easy to avoid, difficult to acquire, simple to diagnose, and easily treated and cured with thirty days or less of antibiotics.

The truth is that Lyme is the fastest growing infectious illness in this country after AIDS, with a cost to society measured in the millions of dollars. It can be acquired by anyone who goes outdoors, very often goes undiagnosed for months, ears, or forever in some patients, and can render a patient chronically ill and even totally disabled despite what this core group refers to as "adequate" therapy. There have been deaths from Lyme Disease.

They feel that when the patient fails to respond to their treatment regimens, it is because the patient developed what they named "the post

Lyme syndrome". They claim that this is not an infectious problem, but a rheumatologic or arthritic malady, due to activation of the immune system.

The fact is, this cannot be related to any consistent abnormality other than persistent infection. As further proof, vaccinated animals whose immune system has been activated by Lyme, have never developed this syndrome. On the other hand, there is proof that persistent infection can exist in these patients because the 1 month treatments did not eradicate the infection. Indeed, many chronically ill patients, whom these physicians dismissed, have gone on to respond positively and even recover when additional antibiotics are given.

It is interesting that these individuals who promote this so called "post Lyme syndrome" as a form of arthritis, depend on funding from arthritis groups and agencies to earn their livelihood. Some of them are known to have received large consulting fees from insurance companies to advise them to curtail coverage for any antibiotic therapy beyond this arbitrary thirty day cutoff, even if the patient will suffer. This is despite the fact that additional therapy may be beneficial, and despite the fact that such practices never occur in treating other diseases.

Following the lead of this group of physicians, a few State health departments have even begun to investigate, in a very threatening way, physicians who have more liberal views on Lyme Disease diagnosis and treatment than they do. Indeed, I must confess that I feel that I am taking a large personal risk here today by publicly stating these views, for fear that I may suffer some negative repercussions, despite the fact that many hundreds of physicians and many thousands of patients all over the world agree with what I am saying here.

Because of this bias by this inner circle, Lyme disease is both underdiagnosed and undertreated, to the great detriment to many of our citizens. Let me address these points in more detail.

UNDERDIAGNOSIS

1. Under reporting: The current reporting criteria for Lyme are inadequate and miss an estimated 30% to 50% of patients. Some states curtailed their active surveillance programs and saw an artificial drop in reported cases of nearly 40%, leading the uninformed to believe incorrectly that the number of new cases of Lyme is on the decline. The reporting procedure is often so cumbersome, many physicians never bother to report cases. Some physicians who have reported a large number of cases have found themselves the target of State health department investigators. Finally, too many physicians and government agents rely on the notoriously unreliable serologic blood test to confirm the diagnosis.

2. Poor Lyme Disease diagnostic testing: It is very well known that the serologic (blood) test for Lyme is insensitive, inaccurate, not standardized, and misses up to 40% of cases, yet many physicians, including many of those referred to above, and the senior staff at CDC and NIH, insist that if the blood test is negative, then the patient could not possibly have Lyme. This view is not supported by the facts. Lyme is diagnosed clinically, and can exist even when the blood test is negative.

The Rocky Mountain Lab of the NIH, which is the country's best government laboratory for Lyme research, had developed an excellent diagnostic test for this illness nearly 4 years ago, yet further work on it has been stalled. Incredibly, if not for private donations of just \$5,000 from the nonprofit National Lyme Disease Foundation headquartered in Connecticut, then this research would have had to be abandoned. An additional \$30,000 was donated by this organization to allow them to continue other valuable projects relating to vaccine development and disease pathogenesis. Yet, many physicians believe that thousands of dollars of grant moneys

awarded by the government to other, outside researchers is poorly directed, supporting work of low relevance and low priority to those sick with Lyme. In spite of this, their funding continues, and the Rocky Mountain Lab is still underfunded.

3. The university and government based Lyme establishment deny the existence of atypical presentations of Lyme, and patients in this category are not being diagnosed or treated, and have no place to go to for proper care.

Results: Some Lyme patients have had to see as many as forty two different doctors, often over several years, and at tremendous cost, before being properly diagnosed. Unfortunately, the disease was left to progress during that time, and patients were left forever ill, for by that time, their illness was not able to be cured. Even more disturbing, these hard line physicians have tried to dismiss these patients as having "Lyme Hysteria" and tried to claim they all were suffering from psychiatric problems!

UNDERTREATMENT

1. Because the diagnosis is not being made, for reasons partly outlined above.

2. University based and government endorsed treatment protocols are empiric, insufficient, refer to studies involving inadequate animal models, and are ignorant of basic pharmacology. They are not based on honest systematic studies or on the results of newer information.

3. After short courses of treatment, patients with advanced disease rarely return to normal, yet many can be proven to still be infected and can often respond to further antibiotic therapy. Unfortunately, Lyme patients are being denied such therapy for political reasons and/or because insurance companies refuse upon the arbitrary and uninformed advice of these physicians, who are on the insurance company's payroll.

4. Long-term studies on patients who were untreated or undertreated demonstrated the occurrence of severe illness more than a decade later, reminiscent of the findings of the notorious Tuskegee Study, in which intentionally untreated syphilis patients were allowed to suffer permanent and in some cases fatal sequelae.

5. The Lyme bacterium spreads to areas of the body that render this organism resistant to being killed by the immune system and by antibiotics, such as in the eye, deep within tendons, and within cells. The Lyme bacterium also has a very complex lifecycle that renders it resistant to simple treatment strategies. Therefore, to be effective, antibiotics must be given in generous doses over several months, until signs of active infection have cleared. Because relapses have appeared long after seemingly adequate therapy, long-term followup, measured in years or decades, is required before any treatment regimen is deemed adequate or curative.

6. When administered by skilled clinicians, the safety of long-term antibiotic therapy has been firmly established.

The very existence of hundreds of Lyme support groups in this country, and the tens of thousands of dissatisfied, mistreated, and ill patients whom these groups represent, underscores the many problems that exist out in the real world of Lyme Disease. I ask and lead with you to hear their voices, listen to their stories, and work in an honest and unbiased way to help and protect the Americans whose health has is at risk from what has now become a political disease.

Thank You.

Senator WELLSTONE. Thank you very much, Dr. Burrascano, and I do apologize again for the interruption. Your testimony is very important.

Dr. Platt.

Mr. PLATT. I am a veterinary microbiologist at the College of Veterinary Medicine, Iowa State University, and I have been actively involved in Lyme disease research since 1986.

I first became involved with Lyme disease when I organized a Lyme disease surveillance program at Fort McCoy in south central Wisconsin with U.S. Army Reserve veterinary components associated with the 330th Medical Brigade at Fort Sheridan, IL. Our primary task was to identify and characterize areas of high deer tick density and to assess the threat of Lyme disease exposure to military and civilian personnel.

Subsequently, a public awareness campaign was initiated, which we felt dramatically reduced the risk of exposure to Lyme disease.

In addition, tick abatement measures were initiated in specific areas of high public use, which also appeared to markedly reduce the risk and the tick population.

Similar surveillance studies were initiated by myself and my medical entomological personnel in Iowa, where the incidence of Lyme disease is slowly increasing. As a result of these efforts, we have been able to monitor the southern and western movement of the deer tick across the eastern third of Iowa. At the present time, the largest populations of ticks infected with the Lyme disease organism exist in the northeast corner of the State. Although infected ticks have been found occasionally in other parts of eastern Iowa, it is not clear whether or not areas of endemnicity will develop, and we are continuing to monitor this situation.

We are also concerned about the presence of large populations of the lone star tick in southern Iowa. Although this tick is not considered to be a highly effective vector for a variety of reasons, its relatively large population is a cause for some concern, especially since it is possible that the southern movement of the deer tick along the Mississippi River may result in the permanent establishment of the Lyme disease organism in this region. Our current surveillance of the region indicates that this may have already occurred.

It is our opinion that the best way to control Lyme disease is to keep the public fully informed of the relative risk of exposure in specific geographical areas. Accordingly, we are conducting controlled field and laboratory studies which we believe will lead to the eventually development of a model that will make it possible to realistically assess and predict the threat of Lyme disease to the public in the Upper Midwest.

For example, because the threat of exposure to the Lyme disease organism is directly related to the tick population, we studied and defined the life cycle of the tick in the Upper Midwest and compared it to the life cycle described in the Northeast. Our studies found that the life cycles of the ticks in these two regions were essentially the same, but in the Midwest there appeared to be an earlier and broader activity period of larval and nymph stages of the tick. We don't know at this point how this difference may affect the risk of exposure, but it needs further study.

We have also been actively involved in identifying and characterizing other factors that affect the survivability of different stages of the tick population and the efficiency by which tick populations transmit the organization.

For example, in the Fort McCoy area, we found that the tick population not only varies by year, but the infection rates of specific tick populations within the area in any given year also vary.

We have also found that the mean number of Lyme disease organisms per tick decreases from the fall to the spring. At the present time, we don't know if this lower number of organisms seen in the spring population is due to a lower survival rate of overwintering ticks infected with the organism or the effect of temperature on the survivability of the organism within the tick itself. If the latter is the case, it may follow that the ability of ticks to transmit the disease following severe winters may be less than that following a mild winter. Our studies will clarify this question.

We are also investigating the effect that the immune status of animal reservoirs may have on the establishment and maintenance of the Lyme disease organism in tick populations. These studies as well as similar studies in other laboratories will help us to better understand the complex interrelationship between the Lyme disease organism, its vector and its reservoir hosts. It is this knowledge that will enable us to more precisely and accurately assess and predict risk of Lyme disease to a concerned public without creating undue alarm.

If the problem of Lyme disease is to be satisfactorily resolved, it will require the continuation of the broadly-balanced scientific approach that Federal funding has made possible. This approach has included support for surveillance and risk assessment of affected geographical areas, vaccine development, and the improvement of diagnostic tests. The continued improvement of diagnostic tests is of particular importance because in order to assess the true importance of a disease in a population, it must be possible to diagnose it correctly. This is particularly important with respect to the chronic manifestations of Lyme disease.

Thank you, Mr. Chairman, for the opportunity to present our views.

[The prepared statement of Mr. Platt follows:]

PREPARED STATEMENT OF KENNETH B. PLATT, PHD, DVM

My name is Kenneth B. Platt. I am a veterinary microbiologist at the College of Veterinary Medicine, Iowa State University. I have been actively involved in Lyme disease research since 1986.

I first became involved with Lyme disease when I organized a Lyme disease surveillance program at Fort Mc Coy in south central Wisconsin with US Army Reserve Veterinary components of the 330th Medical Brigade located at Fort Sheridan IL. Our primary task was to identify and characterize areas of high deer tick (*Ixodes scapularis*) density and to assess the threat of Lyme disease exposure to military and civilian personnel. Subsequently a public awareness campaign was initiated which we felt dramatically reduced the risk of exposure to Lyme disease. In addition tick abatement measures were initiated in specific areas of high public use which appeared to markedly reduce the tick population.

Similar surveillance studies were initiated by veterinary and medical entomological personnel in Iowa where the incidence of Lyme disease is slowly increasing. As a result of these efforts we have been able to monitor the southern and western movement of the deer tick across the eastern third of Iowa. At the present time the largest populations of ticks infected with the Lyme disease organism, *Borrelia burgdorferi* exist in the northeast corner of the State. Although infected ticks have been found occasionally in other parts of eastern Iowa, It is not clear whether or not areas of endemnicity will develop. We are continuing to monitor this situation.

We are also concerned about the presence of large populations of the lone star tick (*Amblyomma americanum*) in southern Iowa. Although this tick is not considered to be a highly effective vector for a variety of reasons, its relatively large population is cause for some concern especially since it is possible that the southern movement of the deer tick along the Mississippi river may result in the permanent establishment of the Lyme disease organism in this region. Our current surveillance of this region indicates that this may have already occurred.

It is our opinion that the best way to control Lyme disease is to keep the public fully informed of the relative risk of exposure in specific geographical areas. Accordingly, we are conducting controlled field and laboratory studies which we believe will lead to the eventual development of a model that will make it possible to realistically assess and predict the threat of Lyme disease to the public in the upper midwest. For example, because the threat of exposure to the Lyme disease organism is directly related to the tick population, we studied and defined the life cycle of the tick in the upper midwest and compared it to the life cycle described in the northeast. Our studies found that the life cycles of the ticks were essentially the same in both regions with the exception that in the midwest, larval and nymphal activities appear to occur earlier than in the northeast. We do not know at this point how

this difference may affect the risk of exposure. This is a question that needs further study.

We have also been actively involved in identifying and characterizing factors that affect the survivability of the different stages of the tick population and the efficiency by which specific tick populations transmit the Lyme disease organism. For example, in the Fort McCoy area, we found that the tick population not only varies by year but the infection rates of specific tick populations within the area in any given year also vary. We have also found that the mean number of Lyme disease organisms per tick decreases from the fall to the spring. At the present time we do not know if the lower number of Lyme disease organisms seen in spring populations of adult ticks is due to a lower survival rate of overwintering ticks infected with the Lyme disease organism or the effect of temperature on the survivability of the Lyme disease organism within the tick itself. If the latter is the case it may follow that the ability of ticks to transmit Lyme disease following severe winters may be less than that following a relatively mild winter. Our studies will clarify this question.

We are also investigating the affect that the immune status of animal reservoirs may have on the establishment and maintenance of the Lyme disease organism in tick populations. These studies as well as similar studies in other laboratories will help us to better understand the complex interrelationship between the Lyme disease organism, its vector and its reservoir hosts. It is this knowledge that will enable us to more precisely and accurately assess and predict risk of Lyme disease to a concerned public without creating undue alarm.

If the problem of Lyme disease is to be satisfactorily resolved it will require the continuation of the broadly balanced scientific approach that Federal funding has made possible. This approach has included support for, surveillance and risk assessment of affected geographical areas, vaccine development, and improvement of diagnostic tests. The continued improvement of diagnostic tests is of particular importance because in order to assess the true importance of a disease in a population it must be possible to diagnose it correctly. This is particularly important with respect to the chronic manifestations of Lyme disease.

Thank you Mr. Chairman for the opportunity to present our view of the Lyme disease problem. I will be happy to answer any questions that you or the committee members may have.

Senator DODD [presiding]. Thank you very much. You look up and you see a new face chairing this hearing every few minutes, but Senator Wellstone has another meeting he has to attend at 11:30, so I'll be chairing.

I am pleased to be able to present you once again, Dr. Cartter. I'm going to use the lights now. That way you'll have some sense of when to start wrapping up—about 6 minutes after you begin, so we can get through our last two panelists and then get to some questions.

And by the way, every piece of written testimony, supporting data, and information you'd like us to have, I will make a part of the record.

Dr. Cartter.

Dr. CARTTER. I'd like to thank Senator Kennedy and his staff and Senator Dodd and his staff for their support of my coming to this meeting.

My name is Matthew Cartter, and I am a physician and an epidemiologist with the Connecticut Department of Public Health and Addiction Services. I have been in charge of our Lyme disease activities since 1987.

It is the job of public health to prevent new cases of Lyme disease. It is the job of clinical medicine to make sure that when people get Lyme disease, they are appropriately treated and do not go on to develop late complications from the disease.

In terms of prevention, I am going to be saying some radical things here today. We are not doing well enough. We need a national strategic plan for the control and prevention of Lyme dis-

ease, and we need additional Federal resources to back the plan up. In public health, our task is to protect the health of our population. We use surveillance and epidemiologic studies to define the public health importance of a disease. We then use this information to develop, implement and evaluate population-based control and prevention strategies.

In Connecticut, we have one of the most comprehensive Lyme disease surveillance systems in the country. We have the highest reported rate of Lyme disease of any State. More than 80 percent of our cases involve people who have erythema migrans, the characteristic skin rash of early Lyme disease. Children have the highest rate of this disease and are at special risk.

From our surveillance, we know that you can get Lyme disease in any part of Connecticut, although some parts of Connecticut have a much higher risk than others.

There are two major barriers to improved surveillance for Lyme disease. The first is physician underreporting, which has been mentioned. I'd like to point out this is not just a problem with Lyme disease, but many physicians do not report cases of any reportable disease including Lyme disease.

The second barrier is resources. As you well know, data cost money. In 1991, 16 years after Lyme disease was first studied in Connecticut, we were able to hire an epidemiologist dedicated to Lyme disease surveillance for the first time. This was done with Federal funding. Our enhanced surveillance activities were largely responsible for a 48 percent increase in the number of reported Lyme disease cases between 1991 and 1992.

I'd like to turn now to prevention. We have tried to assess the effectiveness of our Lyme disease prevention efforts in Connecticut. Unfortunately, we have found that our efforts are not doing well enough. In a telephone survey of adults in Connecticut done last year, we found that 66 percent of the respondents reported they know "a lot" or "some" about Lyme disease. Unfortunately, only half of these people reported that they had taken any precautions to prevent Lyme disease during the past year.

Recently, with the help of Federal resources, we have been able to develop Lyme disease educational videos for primary and secondary school students. Our evaluation of these materials has not yet been completed, but what I can tell you is that 6 months after the video was shown to 9th grade students, much of the knowledge gained by these students about Lyme disease was lost. Behavioral changes to prevent Lyme disease are difficult to sustain with short educational interventions.

When people ask what they can do to protect themselves from getting Lyme disease, we tell them to wear long pants, use a tick repellent, and check themselves for ticks. Last summer, we conducted a study in the Lyme, CT area to determine whether these commonly recommended personal protective measures were effective in preventing Lyme disease. We did not find any evidence to support their effectiveness.

In my opinion, the use of these personal protective measures is unlikely to lead to a decrease in the incidence of Lyme disease in the areas where Lyme disease is common, like in Connecticut. This

does not mean that we should stop urging people to take these precautions.

Senator DODD. Does that include, Dr. Cartter, the tick repellent or lotion that you talked about?

Dr. CARTTER. That's correct. There is one thing about studying it in a scientific setting. It is something else when you actually look to see whether or not people can practice these precautions well enough in the field. And in looking at Connecticut, in the Old Lyme and Lyme, CT area, we found no evidence for effectiveness of any of these measures in terms of protection from Lyme disease.

Senator DODD. And you found something different?

Mr. HOCHBRUECKNER. Yes, Senator. The Army's work in the area using the promethin-based spray and the deep-based lotion showed great effectiveness. Now, perhaps the education of the individuals in terms of using the spray for the clothing and the lotion for the skin has not gone very well.

Senator DODD. We can get back to this in a minute.

Dr. CARTTER. Well, it's one thing to ask military personnel to do something, and it's another thing to ask your 9-year-old to wear long pants and tick repellent on a 95-degree day in July.

What we do need, however, is to aggressively pursue the development of more effective preventive measures. The best way to move forward on this issue is to develop a national strategic plan for the control and prevention of Lyme disease. This plan should define the path that will lead us in a timely way to effective primary prevention measures. These measures should include tick control measures that work and an effective Lyme disease vaccine for humans.

Enhanced surveillance for Lyme disease is needed so that the effectiveness of future control measures can be assessed. This strategic plan should identify the Federal resources that are needed to get the job done.

We will need continued Federal leadership. I would like to commend the Centers for Disease Control and Prevention for taking a leadership role in the public health response to this disease. CDC's leadership in this area has been especially apparent since responsibility for this disease was transferred to the Division of Vector-Borne Infectious Diseases in Fort Collins, CO in the fall of 1989.

I am fully aware that there are other important Lyme disease issues. Many of these issues, like the diagnosis and treatment of chronic Lyme disease, can best be resolved by well-designed clinical studies, which are needed and should be funded. These issues need to be resolved by the clinical medicine community. The public health focus should and must be on preventing new cases of Lyme disease.

The public health approach and the clinical medicine approach are both needed to deal with this problem.

I'd like to thank you for the opportunity to talk about this problem with you. We in Connecticut are grateful for the Federal support of our Lyme disease activities.

I would be happy to entertain any questions.

[The prepared statement of Dr. Cartter follows.]

PREPARED STATEMENT OF MATTHEW L. CARTTER, M.D.

I am Matthew L. Cartter, M.D., Epidemiology Program Coordinator for the Connecticut Department of Public Health and Addiction Services. I have been in charge of the Department's response to Lyme disease since 1987.

In public health approach, our patient is our population. We use surveillance and epidemiologic studies to define the public health importance of a disease. We then use this information to develop, implement, and evaluate population-based control and prevention strategies.

In Connecticut, we have one of the most comprehensive Lyme disease surveillance systems in the country. We have the highest reported rate of Lyme disease (54 cases per 100,000 population in 1992) of any State. More than 80% of our cases involve persons who have erythema migrans, the characteristic skin rash of early Lyme disease. From Surveillance, we know that Lyme disease can be acquired in any county in Connecticut, that some areas of the State remain much more affected than others, and that the disease has spread inland and westward along the coast since 1977. This information has been used to guide our education efforts and to identify research and education needs for Federal funding.

There are two major barriers to improved surveillance for Lyme disease. The first is physician underreporting. Many physicians do not report cases of reportable diseases, including Lyme disease.

The second barrier to improved surveillance is resources. In 1991, with Federal assistance, we were able to hire for the first time an epidemiologist dedicated to Lyme disease Surveillance. Our enhanced surveillance activities were largely responsible for a 48% increase in the number of reported Lyme disease cases between 1991 and 1992.

In the last few years, we have tried to assess the effectiveness of our Lyme disease prevention efforts. In a telephone survey of adults done in 1992, 66% of the respondents reported they knew "a lot" or "some" about Lyme disease. Only half (56%) of these respondents reported that they had taken precautions to prevent Lyme disease during the past year.

Recently, with the assistance of Federal resources, we have been able to develop Lyme disease educational videos for primary and secondary school students. Our evaluation of these materials has not yet been completed, but what I can tell you is that 6 months after the video was shown to 9th grade students, much of the knowledge gained by these students about Lyme disease was lost. Behavioral changes to prevent Lyme disease are difficult to sustain with short stand-alone educational interventions.

When people ask what they can do to protect themselves from getting Lyme disease, we tell them to wear long pants, use a tick repellent, and check themselves for ticks. Last summer, we conducted a study in the Lyme, Connecticut area to determine whether the commonly recommended personal protective measures are effective to support the effectiveness of these measures. In my opinion, the use of these personal protective measures is unlikely to lead to a decrease in the incidence of Lyme disease in areas where Lyme disease is common. This does not mean that we should stop urging people to use these measures. But it does mean that we need to aggressively pursue the development of more effective preventive measures.

The best way to move forward on this issue is to develop a national strategic plan for the control and prevention of Lyme disease. This plan should define the path that will lead us in a timely way to effective primary prevention measures. These measures should include tick control measures that work and an effective Lyme disease vaccine for humans. Enhanced surveillance for Lyme disease is needed, so that the effectiveness of future prevention efforts can be assessed. The strategic plan should identify the Federal resources needed to get the job done.

We will need continued Federal leadership. I would like to commend the Centers for Disease Control and Prevention (CDC) for taking a leadership role in the public health response to Lyme disease. CDC's leadership in this area has been especially apparent since responsibility for this disease was transferred to the Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases in Ft. Collins, CO in the fall of 1989.

I am fully aware that there are other important Lyme disease issues. Many of these issues, like the diagnosis and treatment of chronic Lyme disease, can best be resolved by well-designed clinical studies, which are needed and should be funded. These issues need to be resolved by the clinical medicine community. The public health focus should and must be on preventing new cases of Lyme disease.

Thank you for the opportunity to discuss the public health response to Lyme disease. We in Connecticut are grateful for Federal support of our Lyme disease activi-

ties. I would be more than happy to answer any questions you or other members of the committee have.

Senator DODD. Dr. Steere.

Dr. STEERE. Thank you very much, Senator Dodd.

I am Allen Steere, a professor of medicine at New England Medical Center, Tufts University School of Medicine in Boston. I directed the investigation that led to the original description of Lyme disease in 1976.

Since that time, I have directed a Lyme disease clinic now for 17 years. During that period, I have entered over 1,000 patients into Lyme disease studies supported by the extramural program at the NIH.

I want to take this opportunity to say that I am very grateful for this support which has made possible all of my work on Lyme disease. The results of these studies have been published in the peer-reviewed medical literature, and these and other studies were reviewed in the New England Journal of Medicine in 1989. I would like to enter this review article into the record of today's testimony because it gives a thorough description of the clinical features, diagnosis, and treatment of this illness.

Senator DODD. It will be included in the files of the committee.

Dr. STEERE. For the sake of brevity, I would like to stress only several points about the clinical manifestations of the illness. Lyme disease is a complex infection. However, it typically causes characteristic clinical symptoms and objective abnormalities in the skin, nerves, heart or joints. In about 80 percent of patients, the infection begins with an expanding skin lesion called erythema migrans. Even the late neurologic involvement of the disease, which causes the most nonspecific symptoms, such as memory deficit or numbness and tingling in the hands or feet, is usually associated with abnormalities on standard neurologic tests. Thus, diagnosis can usually be based upon objective clinical criteria.

In addition to the clinical picture, it is possible to show laboratory evidence of the infection in most patients. It is difficult, however, to culture the causative spirochete except from the initial skin lesion. Therefore, the only practical laboratory test currently available is serologic testing which identifies antibody directed against the spirochete. In our studies, and in most other studies, this test has been positive in almost all patients after the first several weeks of infection.

Serologic testing for Lyme disease can be done with a high degree of accuracy even now, but the test is not yet standardized, and the performance of the test nationwide is highly variable. Research is certainly needed to improve laboratory tests for Lyme disease, particularly for the development of tests that detect the spirochete or its genes or antigens directly.

However, improved laboratory tests will not by themselves solve the problem of Lyme disease diagnosis. I believe that clinical judgment will always be necessary.

Non-neurologic manifestations of Lyme disease can usually be treated successfully with oral doxycycline or amoxicillin. These are two of the most common and least expensive antibiotics available. Nervous system involvement is more difficult to treat, and appropriate regimens are still being worked out. However, in our experi-

ence and in the experience of other investigators who have published treatment studies in the peer-reviewed medical literature, 30 days of therapy with intravenous ceftriaxone or penicillin is usually sufficient, although in a few patients, or in some patients, the 30-day course of therapy may need to be repeated.

There is no evidence that many months or even years of antibiotic therapy are necessary to eradicate the Lyme disease spirochete. Because of the success of early antibiotic therapy in acute Lyme disease, chronic, active Lyme disease has become an unusual illness. However, infection with *B. burgdorferi* may occasionally trigger several puzzling syndromes that appear to continue after apparent eradication of the spirochete. A rare syndrome is chronic arthritis, usually manifested as swelling of one or both knees, which may persist for months after eradication of the spirochete, apparently for immune-mediated reasons. In addition, we have reported, as have others, that infection with *B. burgdorferi* may trigger chronic fatigue syndrome or a chronic pain syndrome called fibromyalgia. In our experience, these patients are not helped by further antibiotic therapy.

Research efforts to understand the basic mechanisms causing these problems are of great importance in Lyme disease and may also help in understanding certain other illnesses such as rheumatoid arthritis or fibromyalgia.

Finally, it is important to point out that chronic Lyme disease has become a catch-all diagnosis for a number of confusing and difficult-to-treat conditions. Of 788 patients evaluated at our center in the last 5 years who were referred with a presumptive diagnosis of chronic Lyme disease, we thought that only 23 percent had active infection with *B. burgdorferi*. We thought that the majority had other illnesses, particularly chronic fatigue syndrome or fibromyalgia, not triggered by spirochetal infection.

Confusing active Lyme disease with other illnesses runs the risk of taking Lyme disease research efforts down the wrong track and wasting scarce resources. The fact that misdiagnosis of chronic Lyme disease has become a common problem in no way changes the fact that Lyme disease itself is a great problem. I am confident that continued research, particularly continued research in basic mechanisms of Lyme disease, will result in further improvements in our ability to prevent, diagnose and treat this infection.. Continued support from the Federal Government is vital to these research efforts.

Thank you.

[The prepared statement of Dr. Steere follows:]

PREPARED STATEMENT OF ALLEN C. STEERE, M.D.

I am Allen C. Steere, M.D., Professor of Medicine at Tufts University School of Medicine in Boston. I directed the investigation that led to the original description of Lyme disease in 1976. Since that time, I have directed a Lyme disease clinic, now for 17 years. During that period, I have entered over 1,000 patients into Lyme disease studies supported by the extramural program at the NIH. I want to take this opportunity to say that I am very grateful for this support which has made possible all of my work on Lyme disease. The results of these studies have been published in the peer-reviewed medical literature and were reviewed in the *New England Journal of Medicine* in 1989. I would like to enter this review article into the record of today's testimony because it gives a thorough description of the clinical features, diagnosis, and treatment of the illness.

For the sake of brevity, I would like to stress only several points about the clinical manifestations of the illness. Lyme disease is a complex infection. However, it typically causes characteristic clinical symptoms and objective abnormalities in the skin, nerves, heart, or joints. In about 80% of patients, the infection begins with an expanding skin lesion called erythema migrans. Even the late neurologic involvement of the disease, which causes the most nonspecific symptoms, such as memory deficit or numbness and tingling in hands or feet, is usually associated with abnormalities on standard neurologic tests. Thus, diagnosis can usually be based upon objective clinical criteria.

In addition to the clinical picture, it is possible to show laboratory evidence of the infection in more patients. It is difficult, however, to culture the causative spirochete except from the initial skin lesion. Therefore, the only practical laboratory test currently available is serologic testing which identifies antibody directed against the spirochete. In our studies, this test has been positive in almost all patients after the first several weeks of infection. It should be emphasized that serologic testing for Lyme disease can be done with a high degree of accuracy, even now; but the test is not yet standardized and the performance of the test nationwide is highly variable. Research is certainly needed to improve laboratory tests for Lyme disease, particularly for the development of tests that detect the spirochete or its genes or antigens directly. However, improved laboratory tests will not by themselves solve the problem of Lyme disease diagnosis. I believe that clinical judgment will always be necessary.

Lyme disease can usually be treated successfully with oral doxycycline or amoxicillin. These are two of the most common and least expensive antibiotics available. Ten days of therapy is generally sufficient for infection localized to the skin, but 30 days is often required for disseminated infection. Nervous system involvement is more difficult to treat and appropriate regimens are still being worked out. In our experience and in the experience of other investigators who have published treatment studies in the peer-reviewed medical literature, 30 days of therapy with intravenous ceftriaxone or penicillin is usually sufficient, although in a few patients, the 30-day course of therapy may need to be repeated once. There is no evidence that many months or even years of antibiotic therapy are necessary to eradicate the Lyme disease spirochete. Because of the success of early antibiotic therapy in acute Lyme disease, chronic Lyme disease has become an unusual illness.

However, infection with *B. burgdorferi* may trigger several puzzling syndromes that may continue after eradication of the spirochete. One is chronic swelling of the knees which may persist for months after eradication of the spirochete, apparently for immune-mediated reasons. In addition, we have reported that infection with *B. burgdorferi* may trigger chronic fatigue syndrome or a chronic pain syndrome called fibromyalgia. In our experience, these patients are not helped by further antibiotic therapy.

Finally, it is important to point out that chronic Lyme disease has become a "catchall" diagnosis for a number of confusing and difficult-to-treat conditions. Of 788 patients evaluated at our center in the last 5 years who were referred with a presumptive diagnosis of chronic Lyme disease, we thought that only 23 percent had active infection with *B. burgdorferi*. We thought that the majority had other illnesses, particularly chronic fatigue syndrome or fibromyalgia not triggered by spirochetal infection. Confusing active Lyme disease with other illnesses runs the risk of taking Lyme disease research efforts down the wrong track and wasting scarce resources.

The fact that misdiagnosis of "chronic Lyme disease" has become a common problem in no way changes the fact that Lyme disease itself is a problem. I am confident that continued research into the basic mechanisms of Lyme disease will result in improvements in our ability to prevent, diagnose, and treat this infection and may also give clues for research in several other puzzling diseases of unknown cause such as rheumatoid arthritis or fibromyalgia. Continued support from the Federal government is vital for these research efforts.

Senator DODD. Thank you very much, Dr. Steere, for that testimony.

You may have touched on this earlier, but I am struck by the fact that we have seen a number of instances, including Karen Forschner who testified earlier, of a family, including every pet, being infected. The medical evidence suggests that this is not a communicable disease. And yet there seem to be a number of cases which would run contrary to that particular notion. How do you re-

spond to that? We've got a whole panel of physicians here, so anybody who wants to answer may.

Dr. BURRASCANO. I think that by and large, case clusters are due to common exposure. But one very important point to be made today is that there is no study that I know of being funded by the Government to study person-to-person transmission.

The reason why I bring that up—even though I personally don't think that occurs based on my survey of my patients—is because when I do Lyme engagements, where I speak to lay groups, which I do quite often, one of the questions I am asked over and over and over again is: Is there sexual transmission of Lyme disease? And I have to say I don't know, because that type of research has not been done.

So that's just one example of the fact that there are many, many unanswered questions, and relevant ones, too.

Senator DODD. Let me just ask you now, based on what you know as a physician, is it warranted for us to do that kind of test?

Dr. BURRASCANO. I think it would be wise, yes.

Senator DODD. Do other members of the panel wish to comment?

Dr. CARTTER. I'd like to point out that if you are in Lyme, CT and step outside your door, not only will you find ticks, but 20 percent of them will be infected with the spirochete that causes this disease. And certainly, many people and families have had this disease as a result of a common exposure to a tick.

If you look at the epidemiology, it is quite clear that the predominant mode of transmission for those disease is through a tick bite.

Senator DODD. So you don't subscribe to the notion that this is communicable through any other form of contact?

Dr. CARTTER. The epidemiology does not support transmission from person to person.

Senator DODD. Dr. Steere.

Dr. STEERE. I have also done epidemiologic studies of this disease, including the original epidemiologic study which identified Lyme disease, and the pattern of transmission looks like arthropod-borne transmission because when one looks at a population of patients, it looks like hit-and-miss acquisition of the disease.

There are families where multiple members have had the onset at the same period, but it has been difficult to trace a pattern through the family. With a person-to-person-transmitted disease, one person gets it, then the next person gets it, and so on. There is passage that you can usually identify, and that has not been the case with Lyme disease.

Senator DODD. OK. But going back to the point of where we focus resources—and I think everybody here seems to understand and appreciate it—I'm going to ask all of you to give us specifically what you would like the Congress or the Federal Government to do, specifically where you'd like to see us focus our attention. Karen talked about marshalling resources and coordinating the various well-intentioned activities going on at various levels of Government.

Is this is an area where we ought to put some dollars? Do I hear you saying is that there doesn't seem to be enough evidence to warrant this as a high priority?

Senator DURENBERGER. Mr. Chairman, while they think about it, would you favor me with a one-minute comment?

Senator DODD. Just let me get an answer to this, and I'd be glad to.

Do you think we ought to spend money on it?

Dr. STEERE. Yes, absolutely. I think that Lyme disease is a great problem, and I think studies of it, particularly basic mechanisms of the disease, are of great importance. And I think that's what is most likely to help.

Senator DODD. Dr. Cartter.

Dr. CARTTER. I think in public health, prevention always pays off, and I think the emphasis should be on prevention of this disease.

Senator DODD. Mr. Platt.

Mr. PLATT. I would agree; I think prevention is the number one problem.

Dr. BURRASCANO. When it comes to directing funds for research, which are scarce, there are several points that should be emphasized. No. 1 is realistic and widespread required reporting criteria that are reasonable and accurate in terms of what is out there in the real world. The other is a better diagnostic test, not just for making the diagnosis, but for detecting if the spirochete is still present in someone before, during, and after treatment.

So there are two goals. No. 1 is better surveillance, and number two is better testing.

Senator DODD. Howard.

Senator METZENBAUM. Thank you, Mr. Chairman. I have a couple questions.

Dr. Steere, I gather that the diagnosis of Lyme disease is not that fully developed that the physicians around the country really know enough about it or know enough about how to make the diagnosis. Is that the thrust of what you are saying?

Dr. STEERE. I think that there are objective clinical criteria. I also think that it is possible to have laboratory tests that can help support that diagnosis. But nationwide, there is no standardization of that type of testing.

There is certainly a great need for education, including education of physicians, about what this disease is and what it is like. And certainly, further research is needed to define that even more.

Senator METZENBAUM. I remember when one of our fellow Members of Congress was diagnosed as having Lyme disease, Berkeley Bidell, a fine member of this body, and he resigned—or stepped out and didn't run for re-election; I guess he didn't actually resign—because he thought he had Lyme disease, and subsequently found he did not.

I get the feeling that across this broad United States, if you go to see Dr. Steere or one of these other gentlemen here, that you probably can get an accurate answer, but that there is a reasonable chance that if you go to many other doctors in the country—and this is not a broad-brush condemnation of them—but that it is not easily diagnosed and not easily diagnosed even after laboratory tests, unless the laboratories are particularly prepared for this kind of diagnosis.

Now, am I misinterpreting what you are saying?

Dr. STEERE. No. I think that is absolutely true and very well-stated.

Senator METZENBAUM. So therefore we have the problem of how we get the education out and how we get the diagnosis out.

Now with respect to the treatment, you mentioned two particular products that can be used—I forget what they were; I'm sure you know what they are—with oral——

Dr. STEERE. Oral therapy with doxycycline, a tetracycline type of antibiotic, and amoxicillin, a penicillin type of antibiotic.

Senator METZENBAUM. And how effective is that?

Dr. STEERE. Well, I think for nonneurologic manifestations of the disease, they are quite effective. Neurologic manifestations of the disease are harder to treat, and how best to treat them is still being worked out.

Senator METZENBAUM. Would you consider arthritis a neurologic kind of illness?

Dr. STEERE. I would consider arthritis a musculo-skeletal type of involvement. So in Lyme disease, one gets inflammation of the lining of the joint because initially, the spirochete is there; so that's the reason for it. One can kill the spirochete being there with appropriate antibiotic therapy.

Senator METZENBAUM. I get the feeling as I sit here that this is a challenging medical problem, but actually not so challenging if we just put a little bit more push behind it and help the members of the medical profession know more about it, to be able to do better diagnosis, better educate at the laboratories, and then better educate the physicians as to what kind of treatment does work and what doesn't. I get the feeling that it isn't like cancer, where we don't have any answer at all, and we don't know what to do—the cancer is there, and it just grows—and some other illnesses.

Dr. STEERE. Again, I totally agree and think that is very well-stated. Lyme disease is a disease of known cause. In contrast, most of the rheumatic diseases, most of the other types of arthritis, are not of known cause. Therefore, there is much greater possibility for doing something to help with Lyme disease.

Also, by learning more about Lyme disease and its basic mechanisms, it may indeed help us understand some of these other very puzzling illnesses where we don't know the cause, like rheumatoid arthritis, like multiple sclerosis.

So I want to emphasize very much that I believe you are absolutely right that research on Lyme disease, that education, prevention—this is something we can do something about.

Senator METZENBAUM. Let me change the thrust a little bit. Dr. Cartter, you are head of the program in the State of Connecticut. What about the possibility of developing some sort of a spray, some way of going after the basic problem at the level of the deer itself, whether that makes any sense? Is there some way we can do something to destroy the ticks?

Dr. CARTTER. Until recently, methods to control the tick were not very effective. I think the folks from the CDC will be talking about some new research that suggests that the use of pesticides for residential areas may well be effective for a season. This is relatively new information that was only recently made available. If that's the case, we may have better ways to actually control the tick.

But I would like to point out that there are often community concerns about the use of pesticides, so there is a balance that has to be made out there in the community, risk of Lyme disease versus risk of pesticides.

Senator METZENBAUM. As I understand it, the ticks that may be picked up have been infected while on the deer, but then they don't remain on the deer; they move around, or fly around, I guess—is that pretty accurate?

Dr. CARTTER. Well, the ticks are actually infected as a result of being on white-footed mice, at least in our area, not the deer. And the entomologists tell us that you virtually have to eliminate deer populations to have a marked effect on the tick population. Again, politics plays into this, and there are strong forces at work to prevent that kind of deer control strategy.

Senator METZENBAUM. Well, that's a rather drastic approach to eliminate all the deer. Do you mean to say—I guess you are saying—that there are some means of dealing with the problem without actually killing all the deer.

Dr. CARTTER. The whole thrust of my testimony was that the things that we have been recommending for 17 years do not have a marked effect on decreasing Lyme disease incidence, and we need better ways. We need better ways in terms of controlling the tick. There may be some recent breakthroughs, but we don't have them yet. And we need a human vaccine against this disease.

Senator METZENBAUM. Thank you.

Senator DODD. Thank you. I'm sorry, Dr. Burrascano, you wanted to comment.

Dr. BURRASCANO. Yes. I did want to respond to some of the questions that just came before, especially to Senator Metzenbaum.

I don't want you to get the impression that Lyme disease is very simple. It is a very difficult illness to diagnose. The blood test is not reliable enough to use as a diagnostic tool. The clinical picture is not——

Senator METZENBAUM. This gentleman says exactly the opposite of what you said. [Applause.]

Senator DODD. Please, please, let's maintain order. This is a hearing.

Go ahead, Doctor.

Dr. BURRASCANO. I'm sorry. The Lyme disease diagnostic test is known to be not 100 percent accurate. There are scientific reports in published medical journals showing patients who had confirmed Lyme disease who did not test positive on this test. Many of the patients who testified today as well as in the audience who later went on to be proven unequivocally to have the infection never tested positive on this very same type of test.

Studies where this type of test was compared from lab to lab to lab found that the agreement rate among labs was so low that the test basically did not even pass statistical significance as being accurate at all.

So simplification number one that you should avoid is that it is easy to diagnose, because it is not.

Senator DODD. Well, let me just stop you right there. Dr. Steere talked about—and I wrote down the word—serological testing.

Dr. STEERE. That's correct.

Senator DODD. And you said that it's a good test, not a perfect test, but a pretty good test. Am I paraphrasing your remarks accurately?

Dr. STEERE. Yes, I believe that's right.

Senator DODD. How do you respond to this? Do you disagree with Dr. Steere on that point?

Dr. BURRASCANO. I disagree for several reasons. First of all, my own clinical practice involves patients from 38 States and 8 different countries over the last 8 to 10 years, thousands of patients, many of whom did see 10, 20, 30, 40, 50 different doctors before they were diagnosed because the doctors said, "You have a negative blood test; you don't have Lyme disease."

So my perspective is a little bit different than Dr. Steere, who requires a positive test before being entered into his studies. So there is a statistical glitch there. If you actually look at the real world of Lyme disease, you'll find that at least 20 if not 30 percent of people who have Lyme disease do not show positive on this serologic blood test. There are many explanations for that now in the medical literature.

Senator DODD. Dr. Steere.

Dr. STEERE. I stand by the studies that I have done and the other studies that are in the medical literature. I also agree that there is an entity called "sero-negative Lyme disease," and I have published on that entity. I agree that there are patients who do not have a positive serologic test late in the illness, but I think it is rare. We see about one such patient a year. I understand at Stonybrook, which is another major center, that they see about one—

Senator DODD. Please, this is a hearing, a congressional hearing. Editorial comment from the audience is not appropriate.

Go ahead, Dr. Steere.

Dr. STEERE. I understand at Stonybrook, that it is also the case that they see about one such patient a year. It also seems to be important in that entity that the patient has received early antibiotic therapy.

So yes, I agree, sero-negative Lyme disease exists, but I think it is rare.

Senator DODD. Dr. Burrascano.

Dr. BURRASCANO. The second point I wanted to address was the simplification of the treatment of Lyme disease. Many patients who have been diagnosed after the disease has been present for more than just a short period of time, those who have had the illness for several months to several years before diagnosis, very often are not returned back to normal with antibiotic therapy as we know it today.

One of the problems is that we don't know why people remain ill. We pretty much recognize that a lot of people will remain ill after short courses of antibiotic therapy when they have late disseminated Lyme disease. The controversy which I tried to address today in my testimony is that we don't know why.

There is an establishment of physicians university-based who claim that the 30 days of treatment cures the patients; anything that is left-over has to be some arthritic phenomenon or something—they don't know what it is—and they shuffle the patients off

to a chronic fatigue clinic or to a fibromyalgia clinic. Yet there have now been many, many studies showing that these people still have the infection.

So apparently, the infection can persist and evade the effects of antibiotics, and the presence of the organism somehow drives this reaction to keep the people sick.

I have here an electron micrograph, a photograph of the spirochete, done by the NIH's lab at Rocky Mountain. This was taken from the urine of a patient who remained ill after one and a half years of antibiotics. This spirochete was identified positively as *B. burgdorferi*, the causative agent for Lyme disease. So in this one patient—and again, there are patients that you might see in the audience or who have testified today who are in a similar situation—for them, the antibiotic therapy did not work.

So what I am saying is that we need to focus our research on the real world of Lyme disease. No. 1, diagnosis is not simple or clear; the diagnostic test is not 100 percent. We need better testing. No. 2, treatment strategies as you might find in New England Journal articles are very basic minimums and do not cover the more chronic patients or those who are more seriously ill, and these chronic patients are not now being studied systematically for infection, and they should be.

Senator DODD. OK.

Senator METZENBAUM. Mr. Chairman, could I just ask Dr. Burrascano—I am not clear on something. You talked about your patients, but do I understand you to be a veterinarian?

Dr. BURRASCANO. No. I am an internist.

Senator DODD. Howard, the name plates aren't quite clear. Dr. Platt is a veterinarian.

Senator METZENBAUM. OK. Thank you.

Mr. HOCHBRUECKNER. Mr. Chairman, if I could——

Senator DODD. Very briefly, yes.

Mr. HOCHBRUECKNER. —if I could again raise the issue that we touched on before in terms of the personal protection. There is no question that we don't expect that a young child would get 97 percent protection as you would with an Army person who is following direction. But the fact of the matter is that certainly, we have to do all of these things, but anything we can do to help people not get the disease by keeping the tick off the person, whether it is a spray on the clothing or the deep-based lotion on the skin, obviously is important.

I would request, could we perhaps hear from Karen Forscher for a one-minute response to some of the things that have been said here?

Senator DODD. We have another panel to hear from, so I want to try to move along. But Karen will have a chance to submit further comments on this.

Mr. HOCHBRUECKNER. Very good. Thank you.

Senator DODD. I just want to ask about the educational efforts, if I can, and to what extent they exist. Now, in Connecticut, I think they are pretty good. On television, there seem to be a lot of announcements warning people in the summer months about what to be careful of and so forth. I don't know how extensive that is na-

tionwide, and to what extent medical journals and traditional materials inform doctors about signs to be looking for in patients.

Is there a broad enough and effective enough educational program out there dealing with prevention? Is there broad enough awareness nationwide of what people ought to be looking for, what doctors ought to be looking for, what patients ought to be looking for in the early detection of this disease?

Dr. CARTTER. I'd like to address that issue of education. In terms of education of physicians, certainly more can be done. We have done a lot in Connecticut. There needs to be more in other States where Lyme disease is much less common.

In terms of educating the public, I did not mean to imply that we should stop educating people about preventive measures. I think the important thing to point out is that in practice, the things that we have been recommending to people are probably not very effective. We have to stop pretending that they are so that we can drive toward more effective preventive measures.

Senator DODD. Is there any other comment on that particular question? Do you all agree that more needs to be done on the educational efforts?

Dr. BURRASCANO. New York State a number of years ago had a direct mailing to all licensed physicians in New York that outlined the manifestations, diagnosis, and suggestions for treatment of Lyme disease. I thought that was a very good program, but it only occurred once several years ago. And such a program, which is a single, one- or two-page brochure, I think would really be helpful to nationally distribute.

Senator DODD. Let me ask about the difference in how the disease manifests itself in adults and children. You have talked about the dangers to children because of their level of energy and activity and what they do. But from a medical standpoint, is there a difference in terms of how this disease manifests itself in children and adults?

Dr. STEERE. Our studies suggest that there are very similar manifestations, with the possible exception that in very young children age 2 to 4, the illness may be milder. In general, with a number of infectious disease—Epstein-Barr virus infection would be an example which is milder as a generalization in young children than in older children or adults.

Senator DODD. Dr. Cartter, do you agree?

Dr. CARTTER. Yes.

Senator DODD. Does anyone disagree with that last statement?

Dr. BURRASCANO. I don't disagree, but I want to make one comment which is interesting. We have noticed that when children become hormonally active—when the girls and boys become 10, 11, 12 years old—the illness, if it is not arrested properly, if they have not been diagnosed, their illness can very often take a turn for the worse. You saw one child here today who had that same thing happen.

What we physicians in the field would like to see is some type of a program for children's Lyme disease issues, perhaps run by the NIH, where these specific problems could be more carefully addressed.

Senator DODD. Thank you.

I would invite all of you—Karen, as well as other witnesses on the first panel—to comment on anything you have heard here as part of the record today. And we may submit some additional questions to you in writing from other committee members who were unavoidably absent this morning.

I thank all of you very, very much for being here. I appreciate your time.

Our third and last panel is composed of experts in the study of infectious diseases. Dr. Joseph McDade is the associate director of laboratory science at the National Center for Infectious Disease at the CDC, and Dr. John LaMontagne is director of the Division of Microbiology and Infectious Diseases at the National Institute of Allergy and Infectious Diseases at the NIH.

I thank both of you for being here, and thank you for being patient with us this morning as we went through our first two panels. Again, I won't ask you to live by this timer religiously, but if you'd try to keep an eye on it, we'll be glad to accept your complete written testimony and any supporting documentation or data you think would be worthwhile for the committee to have in its consideration of the hearing this morning.

Dr. McDade, we'll begin with you.

STATEMENTS OF DR. JOSEPH McDADE, ASSOCIATE DIRECTOR OF LABORATORY SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA; AND JOHN R. LAMONTAGNE, DIRECTOR, DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. McDADE. I am Dr. Joseph McDade, associate director for laboratory science, National Center for Infectious Diseases, Centers for Disease Control and Prevention.

I am pleased to respond to the committee's invitation to discuss national Lyme disease surveillance and CDC's role in prevention and control of Lyme disease in the United States. I will briefly highlight CDC's Lyme disease program and describe some of our research efforts to develop improved strategies for prevention and control of this important disease.

Lyme disease is an emerging infectious disease. The recent Institute of Medicine report, "Emerging Infections, Microbial Threats to Health in the United States," identifies six factors which can lead to emerging microbial threats. Two of these factors—changes in land use, and erosion of the public health infrastructure—are relevant to the continuing spread of Lyme disease in the United States.

Mr. Chairman, I would like to submit a copy of the executive summary of the IOM report for the record.

Senator DODD. Without objection.

[The report referred to is retained in the files of the committee.]

Dr. McDADE. Lyme disease is an important and preventable public health problem. More than 9,600 cases of Lyme disease were reported by 45 State health departments to CDC in 1992. The figure

is a 19-fold increase from the 497 cases reported by 11 States in 1982.

Confirming a case of Lyme disease can be difficult. Signs and symptoms of Lyme disease are often diverse, and many laboratory tests show negative results in early Lyme disease. For diagnosis of patients with untreated late Lyme disease, available laboratory tests are sometimes more accurate and more reliable. Improved laboratory tests are being developed and standardized.

CDC as the Nation's prevention agency is leading the Nation's efforts to develop a comprehensive, science-based public health program for Lyme disease prevention and control, including surveillance, epidemiologic investigations, improving methods of diagnosis, ecologic studies, and education programs. CDC has developed intramural and extramural Lyme disease programs that address these components.

The Lyme disease program at CDC has been funded by congressional appropriations of approximately \$5.5 million annually during the period 1991 through 1993. Approximately \$3 million of these appropriations have been awarded annually to State and local health departments, private nonprofit foundations, and universities through cooperative agreements and contracts. I will briefly describe five aspects of this program.

First, national surveillance of Lyme disease. In 1982, CDC began a systematic collection of numbers of cases of Lyme disease reported to State health departments. The authority to make a disease notifiable rests with the States. State health departments determine which diseases must be reported to them, and through the Council of State and Territorial Epidemiologists, or CSTE, which diseases the States will report to CDC.

In 1990, CSTE adopted a uniform surveillance case definition for Lyme disease and approved a resolution making Lyme disease nationally reportable beginning in 1991.

CDC's Lyme disease case definition was developed specifically for public health surveillance of cases and not for purposes of clinical diagnosis or determination of health insurance or medical disability benefits.

In March 1993, a meeting of outside scientific consultants was convened to review the surveillance case definition. The consultants included representatives of CSTE, other public health personnel, clinicians and laboratorians. The participants carefully reviewed all clinical and laboratory components of the current definition and assessed our experience using the case definition. As a result of these and subsequent discussions, CDC recommended to CSTE that no changes be made in the current surveillance case definition, and there are no current plans to revise the surveillance case definition.

Active surveillance has been supported in some areas by CDC cooperative agreements. In 1992, the number of reported cases in Connecticut and Rhode Island detected by active surveillance increased 48 percent and 93 percent, respectively, over 1991. In contrast, New York reported a 15 percent decrease of cases from 1991. This decrease in reported cases occurred following reductions in State and county surveillance personnel.

The need for improved surveillance for Lyme disease and many other infectious diseases cannot be overstated.

Second, epidemiologic investigations. CDC has responded to a number of State health department requests for assistance with epidemiologic investigations of Lyme disease.

Senator DODD. Doctor, you've got about 8 pages left. I am just wondering if you might be able to——

Senator METZENBAUM. Why don't you just tell us what is the thrust of what you are doing?

Senator DODD. Yes. Just talk to us up here and tell us what you think.

Senator METZENBAUM. Talk to us rather than read to us. We'll go back and read the whole statement.

Dr. MCDADE. I'd be pleased to.

Senator DODD. And by the way, I should point out that Dr. McDade has a distinguished career and is probably best-known to people who follow things like this as the individual responsible for discovering Legionnaire's disease. We commend you immensely for your efforts.

And I do apologize for interrupting you, but we want to hear what you think. You know this subject really well, and my colleague from Ohio is a lot better-informed on these matters than I. Talk to me as you would talk to someone who has just arrived here and wants to know in layman's terms what you know about this.

Dr. MCDADE. I certainly will do that. I think that the most important problem that we have is a lack of recognition of Lyme disease by the average physician. A recent CDC study in a north-eastern State showed that 82 percent of the cases of Lyme disease were reported by 7 percent of the physicians.

Now, there are different ways of interpreting this data, but this was from a State in which the disease is broadly endemic, and what that suggests is——

Senator DODD. Which State are we talking about?

Dr. MCDADE. Connecticut.

Senator DODD. I was afraid of that. [Laughter.] There are a lot of States in the Northeast, and so I was hoping——

Dr. MCDADE. It is not meant at all as an indictment of Connecticut. It probably reflects the situation nationwide, which is that either people are not reporting Lyme disease, or they aren't recognizing it. And if they are not recognizing it, and they are not treating it early—and you have heard adequate testimony to this point—we have a serious problem.

So to my mind, the physician awareness and education of the professionals is a key critical component, one that we have been working on and that needs a lot more attention.

The second problem is one of diagnosis. This has been adequately documented and today, in testimony from a number of panelists, and clearly what it amounts to is a need for increased standardization and there is a need for increased research. CDC has been working in the last several months with the Association of State and Territorial Public Health Laboratory Directors to standardize some of the existing methodology, and that is currently under evaluation.

Senator DODD. Could you just comment quickly about the disagreement we had on that particular point between Dr. Steere and Dr. Burrascano?

Dr. MCDADE. Well, again, the last thing you want to do is get into a fight between two distinguished physicians, particularly when you are not a physician. But I think the point is that everyone recognizes that there are some deficiencies in the diagnostic criteria. The point is where do we go from here. I think there are in fact two different kinds of deficiencies. One is the lack of standardization in evaluation of the existing methodologies. As I indicated, we have been working with the Association of State and Territorial Laboratory Directors to standardize what we have so that we can at least look uniformly across the States.

Clearly, there are also many other things that are on the horizon that are being studied both by CDC intramurally, our extramural program, the NIH extramural program, which offer a lot of better alternatives.

What wasn't perhaps said in some detail, without going into details of the science, is that we are dealing with a very worthy adversary in *B. burgdorferi*. There are multiple strains of this organism; it undergoes antigenic variation, and any diagnostic test that you have is going to be fraught with some difficulties. So this is not an easy problem, and everyone who is doing research on this recognizes these problems and is working toward them. But clearly, what we need to do is to employ our best efforts to try to find out which ones are there and which ones work in a real life situation.

It is a long way from the laboratory to the field, and an evaluation by the average public health microbiologist, and those are the sorts of things we have to promote.

The third area is steps toward prevention and control. I think the people who talk about walking out their doors and coming into almost direct contact with spirochete-infected ticks is absolutely true. CDC has been working in some cooperative agreements with various States to evaluate various methodologies, integrated approaches, that might perhaps be effective, and we are trying to evaluate those again in a real life setting—integrated to the extent of what is the effect of not only the regional application of insecticides, plus clearing out the brush, reducing harborage for rodents and other forms of wildlife, even the possibility of the fencing for excluding deer—are those effect, or are they not? It takes time to evaluate that, but it is a very important concept.

Also, the continued effect of active surveillance is one which we cannot overstate. It goes back to the education as well, but it is also surveillance. In those States where people have actively looked for cases of Lyme disease, the numbers of cases have doubled; and where they have not looked, the numbers have gone down. We are not interested in developing case counts. What we are interested in knowing is exactly where the disease is—not at the State level or at the county level, but at the local level—so that your education strategies and your prevention and control strategies can be specifically targeted to neighborhoods, regions, and so on because as people have indicated, while there are prospects of a vaccine and they are in study, they are on the horizon.

Finally, let me sum up——

Senator DODD. On that point, you have triggered a question.

Dr. MCDADE. Yes.

Senator DODD. In your mind, is there a direct relationship between spending more dollars here and getting to that horizon more quickly? I have come to learn in this area, not this particular case, that more dollars doesn't necessarily mean you get to an answer quicker. In this case, I'd like to know whether, in your professional capacity, you think investing more would actually get us to that point.

Dr. MCDADE. I have never known of anyone who has a program that couldn't use more. I can't say that you would get a one-to-one return on your investment, but I think there is certainly ample room for growth where you would get a very goodly return on your investment, yes.

Senator DODD. Thank you.

Senator METZENBAUM. Doctor, can I ask you, has CDC done anything about notifying the doctors of this country what to look for with respect to Lyme disease and what kind of testing is suggested in order to deal with it?

I get the feeling that some doctors know about this, but there are a hell of a lot of doctors out there who don't know anything about it and just sort of push along. Am I wrong about that? Are you providing information, or what is the fact?

Dr. MCDADE. I think education is coming from a variety of sources, as was indicated earlier. For education of children, one of our cooperative agreements with the Lyme Disease Foundation—they have reached millions of people. Also, I can provide for the record if you like a list of the extramural funding; there are some half dozen various projects that are targeted directly or indirectly toward physician education. That is not to mention the general literature, three or four articles published weekly by our Morbidity and Mortality Weekly Report, that address various issues, be they clinical, epidemiologic, prevention and control.

There are a number of different approaches that are used. But as I'm sure you well can realize, any message that you might try to deliver, be it in the commercial sector, private sector, educationally, or in medical, it is sometimes very difficult to reach 100 percent of the population, and it becomes more costly as you try to get 100 percent awareness.

Senator METZENBAUM. What I understand you to say is that doctors can find this information in a lot of places—in the journals and the medical literature—but that the Centers for Disease Control itself has really—I think all of those hit a certain portion of the doctors of the country—but it seems to me that the CDC, without spending a fantastic amount of money, could do a much more effective job of really getting to all the doctors in the country.

Dr. MCDADE. We certainly don't at all think, Senator, that what we have done is enough, and we will continue to look at other approaches and other venues in order to try to leverage resources to be able to reach the people maximally. I think that's about the most general way that I can State it.

We are very aware not only of what we have done, but more aware of what we have not done.

Senator METZENBAUM. As I sit here, I get the feeling that this is a very challenging kind of illness or disease, but the fact is there is much more that can be done about it than we can do about a number of other illnesses, whether it is cancer or some other disease of that kind. And what is bothering me is that I just have the feeling that there is a gap where the physicians in the field are really not up-to-speed as to diagnosis and treatment. And I think Dr. Steere pretty much confirmed that. And I think CDC is the agency to which we in Congress would look to ask, don't you have a greater responsibility than that which you are presently doing.

Dr. MCDADE. I can say that your statement is entirely accurate, and CDC would love to have the opportunity to meet that challenge.

Senator METZENBAUM. If you need help in doing it, I think you ought to let us know.

Senator DODD. I think he just did when asked about the money.

Senator METZENBAUM. Well, I got the feeling, if you remember his response to you——

Dr. MCDADE. I think the answer to your question is yes.

Senator METZENBAUM [continuing.] was that you can always use more; but I didn't get the feeling that they couldn't do it with that which they have. And that is——

Dr. MCDADE. Realize that our active surveillance programs with what we have done have been a pilot study, and the pilot study is conducted in order to determine whether what you are doing is effective at a nominal cost. And if it turns out that it is effective, then clearly what you want to do is expand that to other areas. That is the State that we are now.

Senator DODD. Why don't we use this opportunity to request that, in the next couple of weeks, or during this month of August, you submit to this committee a recommendation of dollar amounts and how you would like to see them spent in order to deal with the very issue that Senator Metzenbaum has raised here today so that we might have an opportunity to talk to our colleagues and look at the issue during this appropriation cycle. We'd like to have solid information from the agencies and groups we have to rely on. We turn to you guys on these kinds of questions, and I think it would be helpful. Howard, I don't know if you agree with that or not.

Senator METZENBAUM. I do. As I see it, the CDC only gets, I'm told, \$3 million a year?

Dr. MCDADE. No. I believe the appropriation last year finally became \$5.1 million, reduced by the amount that went to the States, which was just under \$3 million.

Senator DODD. So about \$3 million goes to the States.

Dr. MCDADE. CDC would be pleased to provide that additional information. We have considered it before, and I think it would take us just a short time to be able to review those documents and provide them to the committee.

Senator DODD. I don't want to put a time pressure on you, but in September, the appropriations bills are upon us. If we don't get your recommendation in time, you might wait another whole fiscal year unless you can get some kind of emergency supplemental appropriation.

Thank you, Dr. McDade.

[The prepared statement of Dr. McDade follows:]

PREPARED STATEMENT OF JOSEPH MCDADE, M.D.

I am Joseph McDade, M.D., Assoc. Dir. of Lab Science, Nat. Cntr. for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). I am accompanied by Duane J. Gubler, D.Sc., Director, Division of Vector-Borne Infectious Diseases, NCID, CDC. I am pleased to respond to the committee's invitation to discuss Lyme disease surveillance and CDC's role in prevention and control of Lyme disease in the United States. I will review the CDC's Lyme disease program and describe the research efforts to develop improved strategies for prevention and control of this important disease.

Lyme disease is an emerging infectious disease. The recent Institute of Medicine (IOM) report, "Emerging Infections, Microbial Threats to Health in the United States," identifies six factors which can lead to emerging microbial threats—changes in demographics and behavior, technologic advances, economic development and land use, international travel and trade, microbial adaptation, and a breakdown of public health measures—several of these factors have had an impact on the continuing spread of Lyme disease in the United States. Mr. Chairman, I would like to submit a copy of the executive summary of the IOM report for your consideration for printing as part of the record.

Lyme disease is an important and preventable public health problem. More than 9,600 cases of Lyme disease were reported by 45 State health departments to CDC in 1992. This figure is a 19-fold annual increase from the 497 cases reported by 11 states in 1982, the year when CDC began a systematic national surveillance of the disease. Nearly 50,000 cases were reported to CDC in the period 1982-1992.

Lyme disease is a multistage, multisystem disease caused by the spirochetal bacterium, *Borrelia burgdorferi*. It is a zoonosis, a disease of animals that can be transmitted to humans. In Lyme disease, the bacterium is transmitted by the bite of certain species of ticks.

The earliest stage of the illness is characterized by fever, flu-like symptoms, and the development of a characteristic skin rash, erythema migrans. Although the early-stage illness most often responds promptly and well to antibiotic therapy, untreated or inadequately treated Lyme disease can progress to serious conditions, such as arthritis, and neurologic and cardiac disorders, that require more intensive therapy and may not fully resolve.

Confirming a case of Lyme disease can be difficult. Signs and symptoms of Lyme disease are often diverse and nonspecific, and laboratory tests have demonstrated serious limitations in reliability and accuracy. However, laboratory testing methodologies are now being standardized.

Although Lyme disease cases have been reported by 48 states, cases are concentrated in the northeastern, north central, and Pacific coastal regions. Ten states reported 88 percent of all cases reported nationally from 1982 through 1992.

The distribution of human Lyme disease cases in the United States closely correlates with the distribution of its principal vectors: the deer tick in the northeastern and upper midwestern regions, and the western black-legged tick in the Pacific coastal region. The recent increase in numbers of cases of Lyme disease and its geographic spread in the United States are related to the apparent spread of the deer tick in the eastern United States, and probably results from the great resurgence in deer populations in the region over the past several decades. This resurgence is compounded by the growth of new suburbs, where people move into areas bordered by woodlands, favorable environments for deer, deer mice, and other mammals that are hosts for *B. burgdorferi* and ticks that transmit the bacteria.

Avoiding tick habitats and using personal protective measures are the mainstays of preventing Lyme disease. Early recognition and removal of attached ticks is especially important because it takes approximately 36 hours for the attached tick to transmit the bacterium. The transmission cycle in residential areas may be susceptible to control measures such as habitat modification to remove plant growth and litter that can harbor ticks and their mammalian hosts, constructing deer enclosures, and using pesticides targeted to particular hosts as well as applying pesticides to a wide area. Stopping transmission in residential areas should significantly reduce the numbers of Lyme disease cases.

The overall objective of prevention and control measures is to reduce the incidence of early Lyme disease cases in highly endemic states to no more than 5 cases per 100,000 people, or less, by the year 2000. Currently, incidence rates in these states range from 10 to 53 cases per 100,000.

CDC, as the Nation's prevention agency, is leading the Nation's efforts to develop a comprehensive, science-based, public health program for Lyme disease prevention

and control, including surveillance; epidemiologic investigations; improving methods of diagnosis; ecology, prevention and control; and education programs. CDC has developed an intramural and extramural Lyme disease program that addresses each of these components.

The Lyme disease program at CDC has been funded by Congressional appropriations of approximately \$5.5 million annually during the period 1991-1993. Annually approximately \$3.0 million of these appropriations have been awarded to State and local health departments, foundations and organizations, and universities through cooperative agreements and contracts to support research and education. CDC works in close partnership with these organizations and other Federal agencies, including the National Institutes of Health, the Food and Drug Administration, the Department of Defense, and the National Park Service. I would like to describe this program in more detail.

1. NATIONAL SURVEILLANCE OF LYME DISEASE

In 1982, CDC began a systematic collection of numbers of cases of Lyme disease reported to State health departments. The authority to make a disease notifiable rests with the states. State health departments determine which diseases must be reported to them by physicians and diagnostic laboratories within their borders and, through the Council of State and Territorial Epidemiologists (CSTE), which diseases the states will report to CDC. In 1990, CSTE adopted a uniform surveillance case definition for Lyme disease and approved a resolution making Lyme disease nationally reportable beginning in 1991. Forty-nine states and the District of Columbia now rehire reporting of Lyme disease.

The Lyme disease surveillance case definition was developed specifically for public health surveillance of cases and not for purposes of clinical diagnosis or determination of health insurance or medical disability benefits. The surveillance case definition was discussed during a March 1993 meeting of outside consultants, including representatives of CSTE, other public health personnel, clinicians, and laboratorians. As a result of these and subsequent discussions, CDC recommended to CSTE that no changes be made in the current surveillance case definition. No changes in the definition were made by CSTE at their annual meeting during the week of June 14, 1993. CDC has no current plans to revise the surveillance case definition for public health surveillance of Lyme disease.

Active surveillance has been supported by CDC cooperative agreement funds in six highly endemic states. During 1992, Connecticut (53.6 cases per 100,000), Wisconsin (10.7), and California (0.8) reported the highest rates in the northeast, north central, and Pacific coastal regions, respectively. Rates in some counties in California, Connecticut, Massachusetts, New York, and Wisconsin exceeded 200 cases per 100,000; the incidence was highest in Nantucket County, Massachusetts (449.1). The number of reported cases in Connecticut and Rhode Island detected by active surveillance increased 48 percent and 93 percent, respectively, over 1991. New York reported a provisional total of 3370 confirmed cases during 1992, a decrease of 574 cases from 1991. From 1991 through 1992, decreases were greatest in Westchester (from 1762 cases to 1154 cases) and Suffolk (from 860 cases to 654 cases) counties. The decrease in reported cases in Westchester and Suffolk counties, New York, probably reflects reductions in State and county surveillance personnel necessary to maintain previous levels of case detection and validation. This phenomena emphasizes the need for personnel in local and State health departments dedicated to surveillance activities and liaisons with physicians. In addition to instituting active surveillance in other parts of the country, the development of standardized, sensitive and specific serologic tests should result in improved estimates of Lyme disease.

CDC works with State and county health agencies and others to map the distribution of *B. burgdorferi* and the ticks that transmit the bacterium. This surveillance has documented an expansion of the known geographic area where the bacterium is distributed in nature. New vectors and hosts of *B. burgdorferi* have been identified which indicates that the bacterium can adapt to more diverse environments and to a wider range of mammalian hosts than was previously believed. In addition, birds can transport vector ticks and have been implicated in disseminating the disease.

Surveillance efforts will be continued to improve the accuracy of the estimates of incidence and prevalence of Lyme disease in the United States, as well as trends in its occurrence and its geographic spread.

2. EPIDEMIOLOGIC INVESTIGATIONS

CDC has responded to a number of State health department requests for assistance with epidemiologic investigations of Lyme disease. Notably, CDC collaborated with the New York Health Department to determine that the attack rate for highly endemic residential communities in Westchester County was approximately 3.0 percent over a single Lyme disease transmission season (May-September), and that the likelihood of ever having Lyme disease was approximately 17 percent for residents of these communities. Companion ecologic studies in these communities identified infected ticks on 65 percent of residential properties, and found that approximately 30 percent of vector ticks were infected with *B. burgdorferi*. Studies in New York and in Pennsylvania have identified a number of personal behaviors and property characteristics that are related to an increased risk of Lyme disease. Results of these studies can be directly applied to educational efforts on prevention.

Studies in New Jersey of school children who required home tutoring because they were receiving prolonged treatment for suspected Lyme disease with intravenous antibiotics highlighted the great social and economic impact that Lyme disease can have on patients and their families and identified the potential for serious adverse consequences of intravenous antibiotic treatment. Follow-up studies in patients hospitalized for treatment of suspected Lyme disease in New Jersey documented these risks and suggested measures for their prevention.

Studies in Missouri of suspected Lyme disease patients identified an illness accompanied by a tick-associated rash that is similar to Lyme disease but without clear evidence of infection with *B. burgdorferi* or other known infectious agents. Further studies to determine the cause of this illness are in progress.

Studies are in progress to further characterize the epidemiologic features of Lyme disease, to determine better the factors associated with risk of infection and disease, and to measure better the public health impact of Lyme disease, including the economic and social costs. Populations at high risk need to be studied to determine the costs and benefits of various intervention strategies, including the use of future vaccines and efforts directed at the control of tick vectors. Guidelines are needed on the proper use and interpretation of laboratory diagnostic methods, clinical diagnosis, and the most appropriate ways to treat Lyme disease in its various stages.

3. DEVELOPMENT OF IMPROVED DIAGNOSTIC LABORATORY TESTS

Important progress has been made in improving diagnostic laboratory tests for Lyme disease. Studies in New York and Wisconsin supported by CDC contracts and cooperative agreements have shown that it is possible to isolate *B. burgdorferi* from the skin of 70 percent of patients with the rash of early Lyme disease. Serum specimens collected from patients in this study and from other studies in states with CDC cooperative agreements (Connecticut, Massachusetts, New Jersey, New York, and Wisconsin), as well as serum from other clinically characterized and laboratory confirmed patients throughout the United States, have served as a reference panel for development, evaluation, and standardization of tests detecting antibodies to *B. burgdorferi*.

Collaboration with the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and the Food and Drug Administration (FDA) has led to the distribution of serum panels to more than 50 manufacturers and other researchers and to the development of guidelines leading to clearance of candidate test methods by FDA. CDC and ASTPHLD have developed a standardized approach to testing that is highly reliable with improved specificity and sensitivity for detection of antibodies to *a. burgdorferi*. A workshop co-sponsored by CDC and ASTPHLD was held on this standardized approach in March. In addition a pilot program to evaluate this approach has begun in selected State public health laboratories across the country.

Progress is being made by CDC and its collaborators in identifying molecular subcomponents of *B. burgdorferi* that have the potential for use in a new generation of highly sensitive and specific laboratory tests for Lyme disease. An animal model of Lyme disease developed by Tulane University, in collaboration with CDC, provides opportunities for evaluating new test methods in various stages of infection and disease before and after treatment.

Development of national guidelines, in collaboration with NIH, FDA, other Federal agencies, and State and local health departments, on the use and interpretation of standardized Lyme disease laboratory tests is anticipated.

4. ECOLOGY, PREVENTION, AND CONTROL OF LYME DISEASE

The prevention of Lyme disease is based on personal protection and environmental and ecological strategies to reduce exposure to ticks infected with *B. burgdorferi*. In some communities where the disease is endemic, the risk of exposure is present in routine daily activities and personal protective measures may be insufficient. In such circumstances, all of the following strategies may be necessary: the use of chemical pesticides, habitat modification, and management of the animals that serve as hosts for the ticks carrying the bacterium.

Studies conducted by the New York Medical College and the New Jersey State Department of Health have shown that properly timed single applications of commonly used EPA registered pesticides can reduce populations of nymphal vector ticks (the stage responsible for most transmission of disease to humans) by 90 percent or more on residential properties for a whole transmission season. Strategies that target particular hosts, such as using chemicals to control ticks on rodents and deer, are under evaluation. A promising new environmentally sound approach is to use baited tubes for the control of ticks on mice and other rodent reservoirs of *B. burgdorferi*. Animals that crawl into these tubes to reach the bait pick up lipid permethrin dust, a safe and long-lasting residual pesticide. Other innovative strategies are being developed to kill ticks on deer and to exclude deer from residential properties.

CDC funded collaborative studies of the ecology of Lyme disease have documented a much wider range of habitat and mammalian hosts that maintain *B. burgdorferi* and vector ticks than previously recognized. The Norway rat was found to be the principal reservoir host of *B. burgdorferi* on an island off the coast of Maine; cotton rats and cotton mice serve as reservoir hosts in Georgia and Florida; chipmunks may serve as principal hosts in some habitats in the north-central states; and the wood rat serves as principal reservoir host in the western region of the United States. Recent studies in Colorado and California have identified a previously unrecognized tick vector, *Ixodes spinipalpis*, that transmits *B. burgdorferi* between rodents.

There are no currently recognized means of limiting the geographic spread of Lyme disease in the United States. The disease is now established in nature in at least 20 states. Although the disease appears to spread slowly to neighboring areas due to dissemination of ticks by deer, carnivores, and other medium-sized mammals, it is possible that birds play a secondary role in dissemination, both by transporting ticks along migratory pathways as well as by serving as reservoirs of infection of *B. burgdorferi*. Studies of this and other potential factors of emergence are in progress.

5. LEE DISEASE EDUCATION

Public education is a high priority in the CDC Lyme disease program. More than 25 percent of the program's nearly \$3 million in cooperative agreement funds are spent annually for education on Lyme disease. Cooperative agreement projects with State and local health departments, universities, and private nonprofit foundations are now in the third year of funding. The types of educational materials produced include classroom modules using video and written materials, computer interactive programs, public service announcements for radio and television, brochures, posters, and videos for public service transmission. The audiences targeted by these materials range from young children to adults. With few exceptions, these materials are available without charge. CDC has collaborated with cooperative agreement recipients to distribute videotaped materials to all primary and secondary schools in targeted counties of states where Lyme disease is most highly endemic.

CDC will continue to base the national program for the prevention and control of Lyme disease on partnerships with State and local health departments, NIH, FDA and other Federal agencies; private, professional and voluntary foundations and organizations; and universities. Goals include developing comprehensive science-based, intramural and extramural public health programs. These programs include: 1) improving national surveillance for determining accurate estimates of incidence and for monitoring the geographic spread of the disease; 2) identifying populations at high risk and identifying behavioral and environmental risk factors amenable to reduction strategies; 3) improving laboratory tests for clinical and epidemiologic purposes; 4) developing methods of personal protection; 5) outlining strategies to reduce exposure to infective ticks; 6) educating the public and health care communities on relevant aspects of the disease and its prevention; and 7) determining public health impact by measuring morbidity and social and economic costs of this disease.

In conclusion, our experience with Lyme disease illustrates important lessons. As documented in the IOM report on emerging infections, we can expect new infectious diseases to continue to emerge and spread in the United States as a result of microbial evolution and technological change. Conditions with unknown etiologies can turn out to have an infectious cause. The challenges posed by Lyme disease highlight the need for improved surveillance, epidemiologic assessment of new or unusual diseases, and networks of State and national public health agencies and laboratories, as recommended in the Institute of Medicine report, to detect the emergence of pathogens. Prevention also requires close multiagency collaboration, especially for diseases with potentially devastating consequences and the ability to spread rapidly.

Thank you for the opportunity to discuss CDC's role in the prevention and control of Lyme disease. Dr. Gubler and I will be pleased to answer questions you or members of the committee have.

RESPONSES OF DR. MCDADE TO QUESTIONS ASKED BY SENATORS DODD AND METZENBAUM

Question. Senator Metzenbaum was concerned that physicians be notified of current information on Lyme Disease to raise their level of awareness. He indicated he thought there was a gap between what is known and what occurs in the field. What are CDC's activities geared toward educating physicians about Lyme Disease?

Answer. CDC has published a Lyme disease informational brochure and publishes the weekly Morbidity and Mortality Weekly Report (MMWR) featuring timely disease specific information for health care providers. A copy of the brochure and recent copies of the MMWR highlighting Lyme disease are included. CDC also maintains a telephone Voice Information system [(404) 332-45550] providing health care professionals and the public with information on specific diseases. This system is organized so that direct telephone contact with CDC's Lyme disease program staff is available. Information concerning access to this system is published in the MMWR.

Education is the key to the prevention of Lyme disease and its early detection and appropriate treatment. Congress directed that 25 percent of appropriated funds for cooperative agreement research be applied to national education efforts for health care providers and for the public. Educational project awards were made by CDC to the New York and Connecticut State Health Departments, to Pennsylvania State University, and to four private, nonprofit organizations (Lyme Borreliosis Foundation, Marshfield Clinic, American Lyme Foundation, and the Arthritis Foundation, Connecticut Chapter).

Listed below is a synopsis of cooperative agreement projects providing education and information through this extramural program.

The Marshfield Clinic (Wisconsin) has produced educational materials for health care providers, a video-taped educational program for school children, brochures for the general public, and a teacher's manual.

The American Lyme Foundation (New York) has established a telephone information hot-line service and has produced educational videos. Public service announcements have also been produced. Written material is available for the lay public, and an informational brochure for physicians and other health care workers is being produced.

Pennsylvania State University has conducted two national caller-interactive Lyme disease television presentations, dealing with the basic biology, diagnosis, treatment, prevention, and control of Lyme disease. An information service has been developed on the distribution of the tick vector of Lyme disease in Pennsylvania, and a glossary of approximately 1,000 Lyme disease terms has been constructed. Videos and written materials for school children, adults, and medical professionals have also been developed. Public service announcements on Lyme disease prevention are distributed prior to the Lyme disease transmission season.

The New York State Health Department is working with Westchester and other country health departments to produce brochures, videos, public service announcements, and has developed a system of user-interactive computer kiosks on Lyme disease that provide evaluations of information transfer to users. Many of these materials are available and in use.

The Lyme Borreliosis Foundation has developed and is distributing instructional videos aimed at school children, the general public, and workers at risk because of occupational exposures. Videos for school children based on the Muppets have been shown at the 5th International Conference on Lyme Borreliosis and the annual meeting of the American Public Health Association. These educational materials also serve Spanish-speaking and hearing-impaired audiences. Several public service

announcements have been produced and widely shown and aired through the regional media. A wide range of written materials has also been produced and distributed.

The cooperative agreement projects listed below include specific educational approaches that have been developed for other targeted audiences.

The Connecticut State Health Department has developed a Lyme disease education module for 9th grade students that includes a video, and is completing a similar product for 4-6th grade students. Connecticut is participating with CDC in a national Lyme disease behavioral risk factor survey.

The Arthritis Foundation (Connecticut Chapter) has produced bilingual posters and brochures, and is completing development of an interactive computer video program to educate elementary school children. CDC professional staff also participate in appropriate medical and scientific meetings to educate health care professionals and others.

Question. Senator Dodd asked that Dr. McDade submit for the record his professional judgment recommendation for CDC's Lyme Disease funding needs and how those funds would be spent.

Answer. Dr. McDade's professional judgment budget estimate for a Lyme disease prevention program level is \$6.4 million. In working toward the goal of prevention of Lyme disease, specific activities of CDC would include:

Initiating cooperative agreements with State and local health departments to improve and standardize active surveillance, and conduct epidemiologic and ecologic studies that better define factors of risk, and enhancement of national surveillance activities to achieve more rapidly uniform surveillance practices by States, to monitor better and analyze trends of disease distribution and frequency.

Promoting increased assistance to State and local health departments and other institutions to conduct environmental and ecologic studies that define factors in the enzootic cycle related to disease distribution and risk, and supporting pilot studies of integrated pest management for interrupting the chain of transmission.

Promoting increased laboratory research to develop and evaluate improved diagnostic methodologies, strengthening national reference capabilities, and establishing standards and guidelines for diagnostic testing; providing support to selected State public health laboratories to develop and evaluate models of standardized serologic testing and quality assurance; and conducting training of public health laboratory personnel in standardized testing and quality assurance.

Developing and distributing educational materials targeted for physicians on diagnosis, treatment and prevention, and developing and distributing educational materials specifically aimed at community and school use that provide information on risk avoidance, personal protection, and early disease detection, as well as prevention strategies for environmental management.

Initiating cooperative agreements with State and local health departments to implement and evaluate prevention and control programs.

Initiating cooperative agreements with State and local health departments and other institutions to quantify the public health burden of Lyme disease in early and late stages, including measures of morbidity and cost.

Senator DODD. Dr. LaMontagne.

Mr. LAMONTAGNE. Thank you, Mr. Chairman and members of the committee, for inviting me to appear before you to discuss ongoing and planned Lyme disease research activities of the National Institute of Allergy and Infectious Diseases, a component of the NIH.

Research advances in microbiology made during the 20th century really make life in modern society possible. Smallpox has been eradicated from the globe, and in the United States, infectious diseases such as polio, whooping cough, measles, typhoid, diphtheria and many others that were once major killers in this country are now uncommon.

This backdrop of tremendous accomplishment has supported the perception that infectious diseases are one problem that we have solved. Unfortunately, the recent emergence of new infectious diseases such as Lyme disease provides ample evidence that this perception is incorrect.

Moreover, the history of the 20th century tell us that despite the many advances we have made in the diagnosis, prevention, and treatment of infectious diseases, we continue to be vulnerable to either truly new infectious diseases or to old infectious diseases reemerging into a newfound prominence.

Lyme disease is only one example of this kind of problem. It is a newly recognized infectious disease that is also emerging. The NIH has supported research on Lyme disease since the first cluster of cases was studied by Dr. Allen Steere, whom you heard from in the earlier panel of witnesses, from his studies in Old Lyme, CT more than 15 years ago.

The causative agent for Lyme disease, *B. burgdorferi*, was isolated and identified at NIAID's Rocky Mountain Laboratories in Hamilton, MT. The NIAID has supported Lyme disease research at the Rocky Mountain Laboratories ever since.

In addition, NIAID has supported Lyme disease research in the extramural community since 1985. Other components of the NIH, such as the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the Neurology Institute, have also joined the research effort to understand Lyme disease by supporting many important research projects.

Lyme disease is now the most commonly reported arthropod-borne disease in the United States. It is certainly the most common tick-borne infection in the United States. The disease, caused by the spirochete *B. burgdorferi*, is transmitted primarily by the ticks of the genus *Ixodes*. Lyme disease may be acute or self-limited, or may develop into a chronic multisystem disease that can elicit a wide and unpredictable range of clinical manifestations.

Current diagnostic tests, which are based on the detection of antibodies to *B. burgdorferi*, are useful but far from perfect, since individuals may vary in their immunologic response to infection, thus limiting the value of blood test results in the diagnostic process.

Senator METZENBAUM. [Presiding]. Doctor, I want to ask you if you would, please—I want to hear what you have to say, and I want to get the thrust of it, and we will read your full statement. But because of the press of time that I and obviously other members of the committee have, I want to be courteous to you because I think you have something to say. I am wondering if we could get you to just talk to us and tell us where you are and what you are doing.

[The prepared statement of Mr. LaMontagne follows:]

PREPARED STATEMENT OF JOHN LAMONTAGNE

Thank you, Mr. Chairman and Members of the Committee, for inviting me to appear before you to discuss ongoing and planned Lyme disease research activities of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH). My name is John La Montagne and I am the Director of the Division of Microbiology and Infectious Diseases, an NIAID extramural research division. I also serve as the Chair of the NIH Lyme Disease Coordinating Committee.

Research advances in microbiology made during the twentieth century make life in modern society possible. Smallpox has been eradicated from the globe and in the United States, infectious diseases such as polio, whooping cough, measles, typhoid fever and diphtheria, once major killers in this country, are now uncommon. In addition, we are now able to predict with some certainty the year to year changes in the Influenza virus and design a protective flu vaccine.

This backdrop of tremendous accomplishment has supported the perception that infectious diseases are one problem that we have solved. Unfortunately, the recent emergence of new infectious diseases, such as Lyme disease, provides ample evidence that this perception is incorrect. Moreover, the history of the 20th century tells us that, despite the many advances we have made in the diagnosis, prevention, and treatment of infectious diseases, we continue to be vulnerable to either truly new infectious diseases or to old infectious diseases re-emerging into a new found prominence.

Lyme disease is only one example of this kind of problem. It is a newly recognized infectious disease that is also emerging. The NIAID has supported research on Lyme disease from the first reports of cases in the early 1980s. The etiologic agent for Lyme disease, *Borrelia burgdorferi*, was isolated and identified at the NIAID's Rocky Mountain Laboratories (RML) by researchers Willy Burgdorfer and Alan Barbour while working with New York State Health Department researchers Jorge Benach and Edward Bosler in 1981. The NIAID has supported Lyme disease research at the RML ever since. In addition, NIAID has supported Lyme disease research in the extramural community since 1985. Other research components of the NIH, such as the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and, more recently, the National Institute of Neurological Disorders and Stroke (NINDS), also support Lyme disease research.

Lyme disease is now thought to be the most commonly reported arthropod-borne disease in the United States—it is certainly the most common tick-borne infection in the United States. The disease, caused by the spirochete *B. burgdorferi*, is transmitted primarily by ticks of the genus *Ixodes*. Lyme disease may be acute or self-limited or may develop into a chronic multisystem disease that can elicit a wide and unpredictable range of clinical manifestations. Current diagnostic tests, which are based on the detection of antibodies to *B. burgdorferi*, are useful, but far from perfect since individuals may vary widely in their immunological response to infection, thus limiting the value of blood test results in the diagnostic process.

As indicated, Lyme disease does not have a predictable clinical presentation or progression of symptoms. Most persons infected with *B. burgdorferi* respond to infection with strong immune responses, whereas others show no sign of infection in their blood. The organism also is very difficult and in some cases impossible to detect in infected individuals. Many published descriptions indicate that the hallmark of Lyme disease is an expanding red rash, known as erythema migrans, that may be accompanied by various other clinical signs and symptoms. Infected individuals actually present a highly variable array of signs and symptoms, such as joint pain and nerve problems, that may be easily confused with those of other diseases. The ambiguities inherent in interpreting the results of blood tests for Lyme disease added to these nonspecific symptoms have led to problems with both over- and under-diagnosis of the disease.

NIAID currently conducts and supports several projects aimed at meeting the challenges of Lyme disease. Institute goals for this area of research include:

- Improve our understanding of the immune response of infected individuals to *B. burgdorferi*.

- Improve our understanding of the biology and surface variation of *B. burgdorferi*.

- Develop tissue culture models of Lyme disease.

- Develop animal models of Lyme disease.

- Identify and characterize virulence factors and antigenic determinants of *B. burgdorferi*.

- Develop improved diagnostic and therapeutic strategies.

- Develop an effective human vaccine.

- Study the host range of *B. burgdorferi* in potential vector (transmitter) and reservoir (carrier) species.

- Study the biology and ecology of vector and reservoir species.

- Develop strategies for the control of Lyme disease transmission among reservoir species and to humans.

I would like to take this opportunity to highlight for you recent advances made in our intramural and extramural programs and to briefly outline our research plans for the near future.

NIAID INTRAMURAL RESEARCH PROGRAM

INTRAMURAL RESEARCH ADVANCES

Several NIAID scientists conduct Lyme disease research studies at the RML. Highlights of some of their recent efforts are summarized below.

Scientists at RML have developed a highly sensitive and specific method to detect *B. burgdorferi* infection. The assay works well with samples of urine, cerebrospinal fluid, blood, and synovial fluid. Because the assay detects components of the infecting spirochetes rather than immune responses to it, if it can be developed commercially, the assay may prove useful for monitoring treatment effectiveness as well.

A major stumbling block to developing diagnostic tests or a vaccine for Lyme disease is the elusive nature of the spirochete. The organism appears to evade the immune system of the host by changing its surface proteins. NIAID scientists are studying changes in genes encoding two major outer membrane proteins of the spirochete. The studies may provide insights into the surface proteins of not only *B. burgdorferi* but also other borrelia organisms as well.

NIAID's researchers have genetically characterized samples of Lyme disease bacteria taken from many patients in Europe, Asia, and North America. Based on genetic relatedness, the scientists have identified at least three distinct groups of borreliae that can cause Lyme disease. The frequency with which different Lyme disease symptoms occurs is known to vary in different geographic areas. The scientists have begun examining how the genetic distinctions within each group relate to clinical features of Lyme disease.

NIAID research recently showed that antibodies to a specific protein of the spirochete, p39, are produced only in response to an active *B. burgdorferi* infection and therefore can serve as reliable markers for Lyme disease. Using this observation, the researchers have developed three p39-based blood test kits that can help distinguish patients with Lyme disease from those with other disorders. These kits have been approved by the Food and Drug Administration and are currently available to doctors, clinics, and hospitals nationwide.

Scientists at the RML have demonstrated a characteristic of *B. burgdorferi* that may explain its ability to cluster in low numbers at the site of infection and yet cause a variety of reactions at other sites in the body. *B. burgdorferi* cells release pouches or "blebs" from their surface that become distributed widely throughout the body, unleashing a variety of immune system and tissue responses that may result in the diverse symptoms seen in Lyme disease patients.

Coumermycin A1 is an antibiotic that inhibits the enzyme that catalyzes the coiling of DNA molecules and is required for bacterial replication and growth. Since the Lyme disease spirochete has coiled molecules, NIAID investigators tested the activity of this antibiotic on *B. burgdorferi*. They found the Lyme disease spirochete to be 100 times more sensitive than other bacteria to this compound. Although coumermycin A1 or similar drugs are not ready to be tested in humans, this research indicates that such drugs should be investigated and developed further as potential therapies for human Lyme disease.

FUTURE PLANS

The following future plans will be emphasized by NIAID intramural scientists:

- Improve the sensitivity of the blood test kits and other available diagnostic tools.
- Continue studies of the variation and biological effect of Borrelial surface proteins with the goal of developing an effective vaccine.
- Examine the attachment and penetration of spirochetes into human cells as a possible mechanism of maintaining chronic infection.
- Examine the role of ticks in the maintenance and delivery of the pathogen.

NIAID EXTRAMURAL RESEARCH PROGRAM

EXTRAMURAL RESEARCH ADVANCES

Efforts currently funded through this program represent a wide range of research related to the study of Lyme disease. Currently, NIAID supports approximately 30 grants.

In cooperation with the NIAMS, the NIAID supported a State-of-the-Art Workshop on the Diagnosis and Treatment of Lyme Disease in March 1991. A publication of a newsletter on the same topic was developed following the workshop and has been distributed to 65,000 physicians to date. The newsletter aids physicians and other health professionals in managing patients that may have contracted Lyme disease.

NIAID-supported investigators at Harvard University have reported that immunization of mice against a borrelial protein (OspA) confers resistance against infection, in part, due to inhibition of transmission of *B. burgdorferi* from feeding ticks. This observation has been confirmed by researchers at the RML and the Centers for Disease Control and Prevention (CDC). These results indicate that development of an effective vaccine is a realistic objective that should be considered a high priority.

Further results of the aforementioned study also strongly indicate that antibody ingested by infected ticks feeding upon OspA-immunized animals can kill the Lyme disease spirochete in the tick gut and actually clear the tick of infection as well. This study was conducted in collaboration with grantees at Yale University.

In studies with mice, Harvard researchers have found that doxycycline (in DMSO) may prevent *B. burgdorferi* infection if the antibiotic is applied topically to the site of tick attachment within 4 days after the tick has fallen off. These studies, although so far only conducted in mice, provide a rationale for pursuing the feasibility of testing this approach in humans.

Two NIAID-supported investigators have independently demonstrated that borrelial outer surface proteins can undergo rearrangement, allowing a small percentage of infecting organisms to escape a protective immune response by the host. This observation has important implications for vaccine development.

Another extramural scientist has developed a rabbit model that is the first animal model to exhibit the skin rash often observed in human Lyme disease. This model may be useful for improving our understanding of the early events in the infectious process of Lyme disease.

An NIAMS grantee has developed a combined approach using ELISA assays and Western blots which can determine with a high degree of sensitivity and specificity whether an individual has been exposed to *B. burgdorferi*. This advance will be particularly useful in providing a standard against which new diagnostic tests for Lyme disease can be compared.

FUTURE PLANS

The following research areas will continue to be emphasized in the NIAID extramural research program:

BIOLOGY OF BORRELLIA BURGDORFERI

- Develop a defined culture medium for growing the bacterium.
- Characterize the physiology of the organism and genetically identify its surface structures.
- Compare *B. burgdorferi* with closely related bacteria causing relapsing fever.

ECOLOGY OF LYME DISEASE

- Study potential and established vectors and reservoirs.
- Define the role of ticks and other vectors in sustaining virulence.
- Support international efforts to study strain variations.

IMMUNITY AND VACCINES

- Define how different immune mechanisms influence resistance or susceptibility to infection.
- Study the roles of the various types of immune responses in infected individuals.
- Develop better animal models.
- Assist in supporting trials of Lyme disease vaccines for humans.

DIAGNOSIS

- Improve the sensitivity and specificity of diagnostic blood tests.
- Refine polymerase chain reaction techniques to detect *B. burgdorferi*.
- Develop standardized reagents for use in evaluating diagnostics.
- Improve the ability to discriminate cases of chronic Lyme disease from similar symptoms due to other etiologies.

TREATMENT

- Determine the most appropriate dosages and time courses necessary to effectively treat the different manifestations of Lyme disease.
- Evaluate new treatment regimens for Lyme disease.

CONCLUSION

In conclusion, NIAID is firmly committed to supporting the scientific research that is an essential component of any successful strategy to address Lyme disease.

Although we cannot anticipate every emerging disease, nor forecast all public health emergencies, we can be prepared to meet the challenges posed by new and re-emerging diseases by maintaining our strong basic biomedical research infra-

structure. By doing so, we are able to move ahead as expeditiously as possible to develop vaccines and improve diagnostics and treatments.

This concludes my prepared statement, Mr. Chairman. I will be pleased to answer any questions you and the members of the committee may have.

Mr. LAMONTAGNE. That will be perfectly fine, Senator.

I think the thrust of our activities at the NIH has been basically to improve diagnostic methods. We have felt that that was our first priority if in fact we were going to pursue a strategy to improve approaches to prevent the disease. I think prevention is the goal that all of the panelists that you have heard from today would want to achieve, and prevention, of course, takes many steps. It can be prevention by vaccination, prevention by education, prevention by control—

Senator METZENBAUM. Do you think the diagnostic means that are presently available are not accurate?

Mr. LAMONTAGNE. It is a rapidly evolving field, Senator. The diagnostic test that is generally commercially available is useful, but not perfect, by a long shot. There are new tests that have been developed, such as using the technique called PCR, and other techniques which actually detect parts of the organism in specimens from patients, that may be much more useful in diagnosis. However, they are available only in very scarce locations at the moment.

Senator METZENBAUM. How does the doctor in Wapakoneta, OH, a very tiny community, learn about these procedures, and how do his patients get treated? What I am trying to do is just on a practical level, not on a textbook level.

Mr. LAMONTAGNE. We understand, Senator, and that is a concern that we have in fact tried to address. In fact, 2 years ago, we convened a meeting at the NIH on the diagnosis and treatment of Lyme disease which resulted in a publication which we distributed to 65,000 physicians throughout the United States. So we have tried to get more immediate kinds of information to physicians. That document did deal with some of the diagnostic dilemmas associated with Lyme disease and also talked about some of the newer techniques.

Senator METZENBAUM. What should I do if a woman from Wapakoneta, OH calls me and asks, "What do I do? I don't think the doctors out here know much about this. Where do I turn? I am concerned that this may be Lyme disease, and I am also aware of the fact that there are many misdiagnoses in this field." She wants to know what she should do. What would I tell her?

Mr. LAMONTAGNE. Senator, there are several things that one can do in that situation. You can notify us; the Lyme Borrelia Foundation as well has the ability to refer patients to physicians, and we would be glad to identify someone in the State of Ohio or anywhere near that person that we think might be a useful place for that patient to be seen.

We have done that in the past, and presumably would continue to do so.

Senator METZENBAUM. On a scale of one to 10, how do you think the physicians in this country are handling a) the question of diagnosis and b) the question of treatment, appropriately?

Mr. LAMONTAGNE. Well, I think Dr. McDade stated that in a way that I would as well, Senator. I think there is a lot more that we

can do to try to educate physicians, and not just physicians, but nurses and other health care professionals, in identifying and channeling these patients into the appropriate places for care.

Senator METZENBAUM. How can we help you?

Mr. LAMONTAGNE. Well, I think this hearing is helping in a way.

Senator METZENBAUM. I'm not satisfied. I think this is a good first step. But I have the feeling that these people who are sitting behind you and who are so concerned about this illness are pleased that there is a hearing convened by this committee and Senator Kennedy, but I think that I for one feel that we have touched upon the problem, we have discussed the problem, but we haven't done enough about providing the solution. And the solution in part has to do with the education of physicians, better means of testing—one doctor says that the tests that are available now are good tests, the other doctor says they aren't. You are part of our Government in this particular area, and I am just trying to find out what we can do more than what we are presently doing, or what we can ask you to do more than you are presently doing. I as a Senator cannot do anything.

Mr. LAMONTAGNE. Well, Senator, that's obviously a complex question. Let me say that a lot has been done in terms of the diagnosis of Lyme disease and improving those tests. There is a good bit of effort on the part of investigators that we support, working at the Rocky Mountain Laboratories, and we now support over 50 laboratories in the United States doing research on Lyme disease. So there is a good deal of energy in that group that has partnered, if you will, with the efforts of the CDC to better define Lyme disease diagnostic tests. And I predict that within the next year or so, that investment will begin to pay off with better approaches.

So my answer to you is I think I would defer until those kinds of results are in, before commenting further.

Senator METZENBAUM. Can you accelerate the pace a little bit? I'm only going to be here 17 months, and I want to see you get something done before I leave here. [Laughter.]

Dr. McDade and Mr. LaMontagne, unless either of you have something further that you want to put in the record, both of your statements will be included in the record in full, and the record actually will remain open for a period of 1 week for any further statements that are to be included.

We are very grateful to you, and I think the message that we'd like to have you take away from here is that we want some results; we want more action than presently has occurred. We support your efforts. We are talking about absolute pittance of dollars as far as money in this town is concerned—it's an absolutely negligible amount of money. So if you need something more, I am saying to you as strongly as I can: Tell us what it is. That doesn't mean I want you to tell us how to waste money, but I want you to tell us how much more you need and what you would do with it and why it would help solve this problem that concerns so many Americans.

If you have nothing further, there are no other members present, and I would thank you very much for your cooperation, and I thank those who are in the room who are concerned about this problem.

This meeting stands adjourned.

[Editor's note—The committee has received numerous letters and articles on Lyme disease. Because of the volume and cost, it is feasible for the committee to print only the official hearing and testimony presented at that time. However, all the letters and articles are retained in the committee files.]

[A listing of people and/or organizations who submitted testimony and articles follows:]

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[Whereupon, at 12:40 p.m., the committee was adjourned.]

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