

LymeRix
Vaccine Victim's
Stories

and

Related Articles

Prepared by:

January 8, 2001

FDA Vaccine Advisory Committee

To Whom It May Concern:

I am unable to attend the January 31 FDA Vaccine Advisory Committee meeting due to a restrictive condition, Transverse Myelitis, resulting from the Lymerix vaccine. In the spring of 1999, I decided to get the series of Lymerix shots, after viewing a very convincing TV commercial touting the importance of protecting oneself from Lyme Disease. I felt this would be a good thing to take advantage of since I had had numerous bites from the ticks which cause Lyme Disease.

I was given the first shot of the series on April 20, 1999. Thirteen days later, I collapsed, completely paralyzed. Many tests at the hospital confirmed the diagnosis of Transverse Myelitis – inflammation of the myelin sheath around the spinal cord. After days in Intensive Care at the hospital, I was transferred to the Rehabilitation Center where I spent six months. After intensive physical and occupational therapy, some mobility returned, but I am in a wheelchair most of the time. My life has been drastically changed for the past 21 months. Up to the day I collapsed, I was constantly on the go with meetings of historical societies and community organizations, church activities, house tours, dinner parties, exercise classes, bus trips, theater outings, concerts, etc. I used to wear my daughters out, just telling them about all of the running around I did. I used to be a world traveler, but now because of physical limitations, I stay close to home. I am able to live at home only with support from family and friends, and a paid nighttime caregiver. For the first nine months after coming home from the Rehabilitation Center, I required round-the-clock caregivers.

Prior to the Lymerix vaccine, I was in excellent health and completely independent. I strongly urge you to take Lymerix off the market to spare others the pain and suffering it can cause.

Very truly yours,

My name is _____ and I have been asked to speak on behalf of my daughter, _____. had a pretty normal childhood and adolescence until the year 1999. Until that point in time, she had a very active life. She had a horse that she used for exercise and enjoyment. She had competed on him in various venues. They enjoyed jumping and dressage. She volunteered in a therapeutic riding barn and worked with multiply handicapped children. Her plans were to get her degree in veterinary medicine and have a small animal practice. She held down a job at a vet's office and loved going to work and facing the challenges there. In the spring of that year, I decided to get her the Lyme vaccine. She was in contact with various animals daily and spent a lot of time in the woods with horses. It seemed like a good idea at the time. She had had a simple case of unconfirmed Lyme Disease when she was around 12 years old and it seemed to respond to antibiotics, so I thought Lymerix would be a good idea. My primary doctor looked over the literature and agreed to give this series of injections. Our lives have never been the same. After the 2nd injection, _____ complained of ankle pain. I took her to an orthopedic surgeon who couldn't find anything wrong at the time. We sent her for physical therapy and gave her medication. She made the best of it and never really got much better. She had vague complaints of other joints bothering her, but again she kept plugging along. She developed flulike symptoms, a rash, and woke up on October 31st, 1999 with peripheral blindness. She was having terrible muscle aches and joint swelling and pain. We went to many specialists. Finally, we decided to test her for HLA-dr4 ad lo and behold we had a positive. We also had a positive ANA. To this day, she continues to test negative for Lyme, MS, Lupus, Crohn's Disease and all of the other autoimmune illnesses that our doctors assumed were the possible cause. There is no history of juvenile arthritis in either side of the family. Her arthritis just kept getting worse, even with treatments of anti-inflammatories and all of the arthritis medications on the market. She spent her entire senior year at home, too ill to even walk through the hallways and put in a full day at school. She missed her senior prom and any social activities that a normal senior in high school participates in. Her horse could not be exercised or jumped by her for a very long period of time. We have taken _____ to many specialists in the New York area. They have no explanations for this sudden dramatic change in her health except the probability that she had a reaction to Lymerix which somehow caused an autoimmune reaction (because of the bodies exposure to OspA). I am not as knowledgeable as this distinguished panel of experts that I speak to today, but I know one thing with all of my being. It was Lymerix which somehow had this devastating

affect on my 17 year-old child. I think you have all considered that possibility before today. Maybe after today you will think it is more than just a possibility, you will see this drug can have some longlasting,dangerous side effects. Just remember, I have been told this by many a doctor in the last year and a half, they can treat and cure Lyme Disease but they cannot cure an autoimmune arthritis. This is an 18year old who will never again be able to run to catch a bus, or jump her horse with abandon. Her life will be forever changed by Lymerix. Please consider this very carefully when making your decisions about giving this to children.

To Whom It May Concern,

January 23, 2001

In 1999 I was a very healthy 40 year old. Very active with my 10 year old son, skating, bowling and biking. My only health complaint was migraines and daily headaches. On May 21, 1999 I received the Lymerix vaccine. With 24 hours I had flu like symptoms, body aches and low grade fever. I did not think much of it being a nurse and knowing that this is a common reaction to vaccines. Two weeks after the shot I woke up and my right elbow was hurting and with a few days the body aches returned. By the time I went for my second injection I had complained to my doctor that I was hurting from head to toe and the fatigue was unbearable. He did not think it was related to the vaccine, because he had heard nothing about any adverse reactions. I had the second injection that day and my life has been a living hell since. Within 48 hours I was in severe joint and body pain, that has not stopped. I tried seeing doctors and no one knew anything about this vaccine and the reactions it was causing. I was diagnosed with CFS, fibromalagia, and was even told it could be stress from my job. I am a Hospice nurse and love what I do. For months I went through this pain without any help from the medical field. I wake up in the mornings and my husband has to help me out of bed because the pain is so severe. Four times I have been paralyzed, three from my wrist down and once from my neck down for up to 20 minutes. I am scared that I my wake up one day and not be able to move ever again.

I have since seen a doctor that told me I have an auto-immune reaction to the vaccine that is untreatable and incurable. I am presently under the care of a pain management doctor. If it was not for the pain medicine I would not be able to get through my day. I still wake in the mornings with severe, debilitating pain. I have to keep the pain medicine by my bed to get up.

I have had very odd occurrences of unexplained symptoms. I have small areas on my body that become red and feel as if they are burning, like fire, from the inside. The fatigue is unbearable at times, especially with having a 10 year old. I am unable to enjoy being active with him like before.

I have been in contact with nearly 75 people that have been harmed by this vaccine. It is destroying peoples life's. It is hurting our most healthy population. The population that goes out doors for different activities, they are now bedridden or in such severe pain they are unable to move about with daily activities without difficulty.

This reaction is not just hurting a certain age group. I have been contacted by people from the age of 17 and up. I ask the committee to recommend that this vaccine be taken off the market before more people are hurt.

As of May 8, 2000 there were 467 adverse reactions reported to VAERS, and of them 144 had complained of some sort of joint pain. Please do not let this vaccine hurt anymore people. I know SmithKline is trying to get it approved for children, PLEASE DO NOT LET THEM HURT ANYMORE KIDS.

Thank you,

Subj: Lymerix Vaccine
Date: Wednesday, October 11, 2000 9:51:04 AM
From: _____
To: stanisic@cber.fda.gov
cc: _____

I know that I am having a reaction to the lymerix vaccine. My nightmare started with the second shot which I received sometime in 8/99. I had flu like systems which turned into joint pain which has lasted around a year. I received the last shot in 7/00 and have been sick ever since. I have such joint pain that it is hard to even get out of bed some days. I have had every kind of blood work done that you can imagine. I am being treated by a Rheumatologist. I have been on prednisone for the last six weeks. In four weeks he will be starting me on Methotrexate. I was only 36 yrs old when this whole thing started I just recently turned 37 yrs old and feel like I am 80. I have to young children we live in a high tic area I will never allow them to have this vaccine. The FDA and my MD should have gave some sort of warning that is could happen. Also, the adverse reaction form that you have to fill out is almost impossible to get the information for that. I thought I was protecting myself from getting

sick I didn't realize that I was allowing the government and my doctor to make me sick. I just hope some day I will feel better. Thank you _____

My name is _____ and I am HLA-DR4 positive. Eighteen months ago I ran five miles a week and worked out at least an hour a day. I was very healthy and had no health problems at all.

Within six months of getting the lymerix vaccine, I couldn't get out of bed by myself and was in constant excruciating joint and muscle pain. My joints have started making snapping sounds. I now get muscle aches in my legs and I have a hard time walking. My feet feel like they are on fire and get swollen. There are days when I all I can do is stay in bed and cry because I am in so much pain. Every week my body goes thru some other type of pain. It moves from elbows to the knees to the hips to the leg muscles. I also get cold spots that move around on my body.

I have been tested for Lupus, Crohns Disease and MS and they are negative. Smithkline should not be able to destroy peoples lives as they have destroyed mine. The FDA let them put this on the market without fully testing it. The longer that this is left on the market, the more people are going to get hurt. Please stop this madness and take it off the market.

Thank You,

January 9, 2001

To whom it may concern,

My name is : _____ —My phone number is _____

I was diagnosed with Lyme disease on October, 1991 by Doctor _____ and was treated with oral antibiotics. In July of 1998, I was reinfected and was treated by Doctor _____ with oral antibiotics. At his suggestion, I had the LymeRex vaccine on April 23, 1999 (LY 10482 exp. 10/21/99) and the booster on May 24, 1999 (LY 123A9 exp. 2/17/00).

After several months, I was experiencing hand pains and a decrease in function. X-rays of my hands were ordered plus a blood test for HLA-DR4. I tested positive for the auto immune factor and my Doctor told me not to have the additional booster shot.

I feel that the pains in my hands, wrists, shoulders, knees, ankles and neck are directly caused by reaction to the LymeRex vaccine. My hands are affected the most, I can hardly turn faucets, jar covers, door handles, etc. Since I am a realtor, the pains in my hands and feet are interfering with my job performance.

My Doctor was never notified by Smith Kline to test for the auto immune blood factor. He also was unaware that the vaccine should not be administered to people who were already infected. Why weren't the Doctors informed by Smith Kline of these limitations? I would not be experiencing the pain and diminished use of my hands if I had been told not to take the vaccine.

Sincerely yours,

January 1, 2001

To Whom It May Concern:

I am a positive, determined 40-year old woman who has recently had an extreme medical setback. I have run three (3) marathons since 1995 and have been in excellent condition all of my life. I have played sports in high school, in college, and have continued to run and bike tremendous distances up until the Fall of 1999.

Please be advised that after receiving my initial Lymerix vaccination in April of 1999 and my second Lymerix vaccination in May of 1999, I developed the following adverse reactions.

In October of 1999 while training for my fourth marathon, I suddenly became extremely fatigue and sluggish. I could no longer physically run, as if my legs were knocked out from under me. I then developed severe joint and muscle pain throughout my entire body in January of 2000.

My autoimmune system was also greatly affected. I developed full-blown Raynaud's Disease in my hands in March of 2000. There has been a total lack of circulation in my hands and severe cracking in my finger tips. I can no longer tolerate temperatures below 50 degrees.

I then received my third Lymerix vaccination in May of 2000. I have never felt so discouraged and depressed over no longer being able to physically exercise! There has been no improvement with the fatigue and achy joints even though I have been on anti-inflammatories since May of 2000 and antibiotics since October of 2000.

This has been extremely difficult for me both physically and emotionally. I have always been healthy and active, and now I can no loner live my live with zest and the way I know how! It is totally devastating!

January 4, 2001

In April of 2000, after seeing LymeRix ads on television and a poster in my doctor's office, I decided to have the vaccine. Since my husband and I love many outdoor activities including travelling, gardening, canoeing and walking in woods with our dogs, I thought the vaccine would protect him as well. We both had LymeRix in April and May.

In July, he began to have neurological symptoms and weakness, which were diagnosed in August as Guillain-Barre Syndrome. He was hospitalized following an electromyography, nerve conduction studies and a spinal tap. Released to outpatient physical therapy 5 days later, he continued to grow weaker. In September, he was rediagnosed with Chronic Inflammatory Demyelinating Polyneuropathy and hospitalized again for 9 days. Despite continuing medical care and bi-weekly rounds of plasmapheresis treatments, his condition has continued to deteriorate. A recent repeat of the electromyography and nerve conduction studies showed "severe sensory, motor, axonal and demyelinating neuropathy....In comparison with the August 2000 study, the neuropathy has increased substantially". The neurologist has reported the disease to VAERS as a vaccine adverse event.

My husband was director of the training program at the _____

For 33 years, he has earned his living by walking 10 or more miles a day in the performance of his job responsibilities. His retirement was planned for 2001, so he could have more time to enjoy his family and hobbies, but he is so profoundly disabled that he is unable to walk independently, get into bed or the shower. Personal care is accomplished only through great effort. Our plans now revolve solely around medical appointments and physical therapy.

No one else should ever suffer such profound life changes through the administration of a "safe" vaccine. He would have been far better off to get Lyme Disease than to be incapacitated by something we counted on to protect his health!

January 15 2001

To Whom It May Concern:

My name is _____ and I live in North central Indiana. I am 55 years old and for the last 27 years I have been an _____
_____ I was always pretty healthy and very active with interests and hobbies that included hunting, fishing, and golf mainly. I am 6 foot 1 and weighed 210 lbs. I stayed in reasonably good shape from activities and

In the spring of 1999 our Department decided to give us LYMERix vaccine and told us it was safe and effective. After my second shot in August of 1999 I experienced extreme rib soreness and went for a chest X ray, then developed tennis elbow, a stiff knee, and sharp pain in my left hip, along with increasing weakness in my legs. By December my legs ached and I felt flu like sometimes and had to rest more than usual. On January 30, 2000 my health nose-dived to where I could not function at all. I did not know what was wrong with me, but did not consider lyme disease, since we were told you could not get lyme disease from the vaccine. My life fell into a black hole. I became super sensitive to light and sound and was living in a darkened bedroom with earplugs, with occasional blind folded trips to various doctors to try and get a diagnoses. I thought that I would die and many times wished that I would because I felt so bad. Finally in March the Doctors started looking at Lyme disease and I tested positive. My current health is better from the neurological problems. I am still unable to work, as I have no strength, especially in my legs. Sometimes my knees hurt and burn like there is liquid fire in them. My hips and shoulders hurt and ache every day. My right index finger is too stiff to bend and my left thumb hurts. It is obvious that I will suffer for a long time because I let them inject a foreign substance called LYMERix into my body. If I had know about the HLA-DR4 theory of arthritis or that booster shots would be needed, you would not be reading this, because I would not have consented to the vaccine!! Even though my occupation is high risk, my work area is low risk and not endemic.
Please stop this vaccine from wrecking more lives!!

Respectfully submitted

January 12, 2001

To Whom It May Concern,

This letter is to inform you of my symptoms, tests and treatments since receiving the Lymerix vaccine in 1999.

I was diagnosed with Lyme disease in October, 1998, after noticing a large red rash on my right hip in July, 1998. The rash eventually disappeared, but my hip became very sore and I developed a limp. Hip pain and fatigue were my only symptoms. A western blot in October, 1998, confirmed Lyme disease. I began taking oral Cefuroxime – 500mg/twice a day for three weeks. At the end of this period, I still had some hip pain so I was placed on IV Rocephin – 2 grams/day for four weeks. At the end of this time I was almost pain-free and after several weeks of physical therapy had no pain whatsoever. I continued symptom free until May, 1999, after the second Lymerix vaccine. The vaccine was strongly recommended by the infectious disease physician who had treated me for Lyme disease and felt I would be an excellent candidate for the vaccine.

I received the first vaccine on April 12, 1999, and the second on May 7, 1999. Due to the onset of symptoms, I did not receive the third dose. Below are the symptoms I have experienced since the second vaccine. These symptoms began within 2 weeks of the second dose.

- Sinus headache and pressure.
- Tingling in my hands, arms, legs and feet. It is worse when I am lying down and can be so severe in my arms and hands that it wakes me up. It also occurs while showering, sneezing, yawning or coughing.
- Burning in my knees, legs, feet and arms.
- Pain in my knees and hips.
- Stiffness, weakness and trembling in my right hands and arms. Pain in my right wrist. This is currently my worst symptom. I find activities such as reading, writing, etc., can cause soreness and burning to develop in my arm and wrist, and tremor as well.
- Pain in the knuckles of my hands.
- A pulsating feeling in my head and arms. A feeling similar to a tremor, but there is no visible signs of a tremor.-Small exploding burst of pain/heat all over my body. I know this sounds odd, but it feels somewhat like a bee sting from the inside and is very short-lived. I have experienced this sensation in many areas of my body.
- Lightheadedness, and an inability to focus/concentrate. It almost feels like my equilibrium is off, however I do not feel dizzy, more like I'm in a fog.
- A slight jerking movement of my body or a part of my limbs as I lay down and rest.

-Monthly menstrual migraines that began immediately after the vaccine and continued for 10 months.

-The sensation of my stomach turning over, however, it is in my head. I know this sounds unusual, but someone described it that way and it seemed perfect! This feeling happens when I am lying down and can occur several times. It seems to occur over several days and then will subside for a few weeks.

I do not experience all of these symptoms simultaneously, they seem to come and go without any pattern or predictability. They all began after the second dose of the vaccine.

Listed below are the antibiotics I have taken since receiving the second vaccine.

11/22/99 – 01/28/00	Doxycycline	200mg/day
01/28/00 – 02/10/00	Doxycycline	300mg/day – Discontinued due to GI intolerance
02/13/00 – 03/23/00	Keflex	1500 mg/day – Discontinued due to yeast infections
03/23/00 – 04/12/00	Zithromax	250 mg/day
04/12/00 – 04/23/00	Zithromax	500 mg – Twice a week
05/19/00 – 06/29/00	IV Rocephin	6 week IV therapy

At the end of the IV treatment, I still had no improvement. In September, 2000, I saw Dr. _____ . He is a physician who is treating chronic lyme disease as a neurotoxin. I completed the treatment below, with*still no improvement.

09/24/00 – 10/16/00	Cholestyramine	4 grams per scoop/4 times per day
10/17/00 – 10/30/00	Cholestyramine	4 grams per scoop/4 times per day
	Chitosan	750 mg/3 times per day

The following tests have been performed:

06/29/99 - MRI of the brain without/with contrast - result: normal

07/01/99 – Lyme, Western blot. Positive.

07/28/99 – MRI of the brain with attention to the pituitary - result: 2mm microadenoma in the right side of the pituitary gland. This is something I have been aware of for 10 years and has been followed on a regular basis by my endocrinologist. This finding does not reveal any significant change in the microadenoma since my last MRI.

08/99 - EKG – result: normal

09/20/99 – Median Nerve Evoked Potential – result: normal

09/20/99 – Posterior Tibial Evoked Response – result: normal

09/23/99 – MRI, cervical without contrast – result: normal

01/13/00 – Lumbar Puncture – result: borderline lyme serology. It has been brought to my attention that since a serum sample was not taken at the same time, this result is irrelevant. I do not know why a serum sample was not ordered.

Thank you for your attention to this matter.

Sincerely,

Hello,

12/30/00

I am a fifty-one year old woman who has survived Rheumatic Fever, Child birth complications, a hysterectomy at the age of 27, and a three year bout with Lyme Disease from 1987 to 1990. I have always been a fighter, and after each setback, I battled my way back to a useful life.

This time is different. At the prompting of my insurance company and my doctor, I received my first Lyme Vaccine shot on 5/4/99 and the second on 6/4/99. No one even thought to test me for a gene that would say I was allergic to the shots. Suffering additional and increased health problems after the first two shots, which included neuropathic pain in my legs and feet, migraines and other headaches, severe sinus problems, chronic fatigue syndrome, depression, having to double my medication (a Parkinsons drug called Mirapex) which was prescribed to me for Restless Leg Syndrome which began during my first bout with Lymes, I again took the advice of my physician and got the third Lyme Vaccine shot in June of 2000.

From this point things went very wrong extremely fast, and I was able to put it all together, placing the blame where it belonged, on the vaccine shots for Lyme disease. My emotions went crazy, causing uncontrolled crying spells while I was in school where I am learning computers. I became extremely confused (Lyme victims call it brain fog) and had to drop two of my classes. My Restless Leg Syndrome, mostly, up to this point, medication controlled jerking of the legs when I relaxed, suddenly began causing severe insomnia, jerking of my head and left hand, and muscle spasms in my legs that my medication would not stop. Fearing Parkinson's, I was evaluated by two therapists who were concerned because of a noticeable facial tic as well as a neck jerking. My doctor suspected a late sequela of late treated Lyme's disease and put me on Lorazepam to calm my nerves, which did help my nerves, but nothing else.

Although _____ denied the possibility that the vaccine shots could have caused my problems, she did agree to give me 28 days of doxycycline on the chance that it might stop the irreversible neurological damage I was suffering. I began to feel much better, and have done quite well until the past month when my left knee, my lower back, hips and neck have once again begun causing me pain. (I had been pain free for at least two years before I got these shots.) Although I was never able to recall many things from my first bout with Lymes, I have been perfectly able to relearn, as my two Scholarships and 3.868 Grade Point Average prove, but now my memory is beginning to fail me again. I am signed up for three classes this next semester, and am so afraid that I won't be able to complete them. I want so badly to be independent, to get a job that I can do over the internet where I could work around the physical limitations I already had from Lyme Disease, but the additional fatigue, physical and mental limitations inflicted upon me from these Lyme vaccination shots are the last straw. Unless I can receive some serious and immediate help, I fear I may soon be of no use to anyone. I beg you to stop these vaccines now! Don't let anyone, especially children, suffer from them ever again.

January 19, 2001

To Whom It May Concern;

I am writing concerning the use of the Lyme Disease Vaccine. I am very much against the use of this vaccine, for the following reasons:

I was diagnosed in 1998 with Lyme Disease. I have had two severe outbreaks which required IV antibiotics. After the IV therapy, my health has been reasonably good. In the fall of 1999, my family doctor decided to give me the first in the series of LD vaccines. I was fine for the first two shots, but just received the last shot on Dec. 29, 2000.

Within 3 days I was extremely sick. It started with fatigue and body aches, and progressed to total exhaustion and complete pain throughout my body. I became bedridden, although I was unable to fully lie down because of the pain in my back and neck. My skin was extremely sensitive and painful to the touch. My knees, hips and ankles were too painful to move. I could not turn my neck. I suffered from intermittent sore throats and fevers. I was sleeping for 15-16 hours a day. Breathing became so hard I was taken to the ER by my husband. The ER doctors said I had fibromyalgia and needed to see a specialist. My husband had to take emergency leave from work to take care of me and our children, and I was completely unable to do anything. I have not been able to work at all.

My doctor, an infectious disease specialist, believes my condition was brought on by the vaccine. I am scheduled to undertake an MRI in the near future, and he is performing other tests to see what kind of damage I have received.

I have gradually regained some of my health. I am able to walk around for short periods now, and my husband has been able to return to work. I am nowhere near as well as I was before the vaccine, but at least I can get around a little. I still need large amounts of rest, and am taking a lot of pain pills.

Please do not consider giving this vaccine to children. I believe it should be removed from the market, as it does much more harm than good.

Sincerely,

fri 19 jan 2001

to whom it may concern

my name is _____ had the 3 shot series of the lyme vaccine. june 13 th, 2000 was shot 3 of 3. six days later on 19 june 2000 i woke up with swollen , tender, and painfull knees and both quadracept leg muscles hurt. the night before i had no problem at all. it just came from nowhere without any warning symptoms. during the following month my legs became weak and i noticed my leg muscles getting smaller. after a quadracept biopsy and leg nerve conduction tests i was diagnosed with muscle atrophy and demyelination of the nerves.

approximately 1 aug 2000 i woke up with excruiating pain in my left hip. i was first diagnosed with hip tendonitis then avascular necrosis and then with an arthritic hip. this was all done with x-rays and mri"s. in sept. 2000 my left knee became so painfull i was told to use a cane, which is the only way i can move now.

i was using oxyconyin 20 mg twice a day with no affect on the pain. i am now on percocet 5/325 about 5 times a day, just to take the extreme pain away from my body, but it has no affect on my hip and knee pain.

my history is that in 1991 i had arthritis, scoliosis, hemochromatosis. degenerative spine ,and degenerative lumbar area with stenosis of L3/L4 vertebrea causing sciatica. all the conditions starting with 1991 have been under control and stabilized with nsaid(feldene) for arthritis,theraputic phlebotomys for hemochromatosis, and gravity lumbar traction for the sciatica. i have been on social security disability since 1995. i am currently 62 years old.

when on s.s. disability i could not work (i was an electronics teacher for 30 years),because of low back pain , sciatica, and constant gravity lumbar traction. now , i have no quality of life. i get around on the cane and my right leg with great pain. i am very depressed and fearfull of what mighth happen next to my body as i live alone. if my right leg goes, im dead in the water.

thanks —

Good afternoon, my name is _____ I am from Wenham Massachusetts, one of the most Lyme-endemic areas in the US. I am a member of ActionLyme, advocating for Lyme patient rights and the _____ Lyme information and support group in my community.

I work locally with schools, parents and Lyme patients to raise awareness of Lyme disease in our area, and I have read through much of what has been written on Lymerix, especially the material provided by the CDC and FDA.

I come before you today as a mother of two, a consumer, and a patient advocate, with issues that have occurred to others and me as we carefully review the material on this vaccine.

I pose these issues in the form of questions and hope this committee sees fit to pursue answers to these important questions and concerns *before* more aggressive marketing of the vaccine is allowed, especially to our children.

I am a layperson --not a scientist. However others and myself have read material published by the government and SmithKline Beecham and we recognize the disparity between real- world experience and the reality of the trials used to study the safety of Lymerix vaccine. I am sure my questions are those that might be asked by any mother living in a Lyme-endemic area, I pose them to you here, today with hope you will consider the answers to these troubling questions before Lymerix is marketed to our children.

1. The case definition of Lyme disease used for the vaccine is different than the definition the CDC instructs our physicians to use when diagnosing and treating Lyme. Given this disparity, how can we have confidence that the vaccine trials reflect true patient situations?
2. Many individuals I know have claimed adverse events after receiving the Lymerix vaccine, yet have been told their reports are unconnected to the vaccine. How can so many people have the same type of reaction directly after being vaccinated with Lymerix without it being vaccine related?
3. My children and I have had Lyme disease. I have read literature stating the Lyme infection may persist, possibly hidden, in human cells after a patient has been treated. What attentions have the Lymerix vaccine makers taken to assure previously infected patients will not be harmed by their vaccine?
4. The children playing in the forests and along the beaches of our Massachusetts towns have been exposed to Lyme disease since they could crawl. What of the children who have not been diagnosed with

Lyme but do indeed harbor the infection? What effect would Lymerix vaccination produce in these innocents?

With new reports of asymptomatic Lyme disease now abounding, I would like to ask SmithKline Beecham how this possibility has been accounted for in the study of safety of Lymerix for pediatric use.

I urge the committee to be prudent while reviewing the safety of this vaccine.

Thank you for allowing me this opportunity.

.....

January 21, 2001

Dear , Nancy Cherry

I'm writing this in reply to my concerns about Lymerix.

1. Doctors don't know how to handle the rash of side effects.
2. Doctors don't want to feel their at fault for the vaccine causing effects.
3. Patients are suffering because doctors don't want to deal with Lyme let alone the vaccine.

Sincerely, _____

VRBPAC 1/31/01