

**Additions to
LymeRix Vaccine Victims' Stories
and Related Articles**

Package compiled by Jenny Marra

**Distributed to the Advisory
Committee on
January 31, 2001**

Dear

asked me to send you this letter regarding my severe reaction to the lyme-rix vaccine, as I am unable to attend the meeting in Maryland.

I was given the injection at 4:15 p.m. on 3/15/99 & the reaction began at 4:35 p.m.

1. chills/sweats 8-10hrs.
2. body aches 24 hours.
3. 103.5 degree fever 8-10 hrs.
4. head and heart painful pounding 8-10 hrs.
5. by shaking 24-hours.
6. teeth chattering 8 to 10 hours.
7. throat tightening six hours.
8. nausea 48 hours.
9. diarrhea 72 hours.
10. Anxiety at restlessness 30 hours.

My long-term problems of are: worsening arthritis and fibromyalgia, chest pain and in 10/00 I had surgery to remove and repair several cervical discs along with a spinal fusion. My surgeon cannot pinpoint an exact cause or reason for this problem (I did not have an accident or fall causing this). Therefore, it may have been aggravated or caused by the vaccine (we do not for sure).

I registered my reactions with the Vaccine Adverse Reporting System.

I sincerely hope that something will be done to require that the manufacturer of the lyme-rix vaccine and all vaccines to not be allowed to release their products until complete and proper testing are done, so that people like myself do not have to suffer extreme, deadly, long-term, life altering problems. I am in pain everyday and it is difficult for me to work every day.

Thank you.

To whom it may concern;

I was actually getting better. I think I was in remission' or something. Then I got the first two shots of the Lymerix vaccine. In less than a year, the pain started in my wrists. Now, I have arthritis in both wrists and ankles. Poor vision comes and goes. Flourescent lights make me nauseated. Had awful, throwing-up, one-eye-crying headaches. The tachycardia is scary, there were recorded events of bradycardia, too. Crushing pain in the center of my chest terrified me.

By this Spring, (2001) I will probably have to get my waist length hair cut off short. I can't take a shower without help getting the water turned on and off; getting dressed and groomed afterward is energy-draining. It takes the rest of the day to recover. We will have to install new faucets, grab-bars in the shower, and maybe steps to get into the tub. I don't know where the money will come from.

Plan A was a career designing and creating "artwear" garments. My first one won a ribbon at the state fair. Now, I have been increasingly unable to even get down the stairs to my quilting 'studio'. And, I can rarely even make my own bed, let alone stitch a full size quilt for it.

Someone has to pour my morning coffee for me, I can't lift the pot to do it for myself. There have been bad days when I have had to use both hands to even hold my cup! I haven't been able to lift the frying pan for months. Part of my 'job description' is cooking meals. I can still make a sandwich -- if I can get the lunchmeat package open.

My memory is gone, so getting my teaching degree is out of the question. When I 'retired' from home-educating our special-needs son, I was looking forward to going to college and re-joining the workforce as a special-ed teacher.

'Plan B'. I used to be a very skilled typesetter. I thought that if all else failed, I could at least get part time temporary office work.

(Plan C). Now, I can only use a keyboard a few minutes a day, (when my brain works well enough to be able to remember what I wanted to write). I have had to buy a voice-activated typing program. I forget to turn on the spell-checker.

I am not able to help make the planned additional payments on the mortgage before my husband has to retire from his job. We had counted on being able to make those extra payments. We could lose our house.

After I finish typing this letter, I will spend a good length of time with hot packs on my wrists trying to ease the increase in the pain. The bones in my left wrist frequently slip out of place, the right one has started slipping out, too. The wrist splints are not helping much anymore. The naproxen I had used in the past was starting to damage my liver, according to the doctor. I have had to choose between wrist pain and the side pain. The ankle pain is constant now. Sometimes, for variety, one, or both, ankles will swell up, too. I had to quit driving. After cutting my hair short and installing the typing program, it will feel like nearly everything has been lost to me, the last remaining part of my 'normal' life will be gone.

I believe that Smith Kline Beecham should stop ALL manufacture and sales of this product! This awful pain should absolutely never be inflicted on innocent children! Please! make them stop this now, before anymore people's entire lives are ruined! I also ask that they be required to find a cure for the damages they have already caused, and make it right for the victims and their families.

Vaccine Victim

January 26, 2001

To Whom it may concern,

I have handed out several copies of the original story I wrote about my Lyme Disease vaccine trial study experience. There are more available for anyone interested.

I'll go back a bit to tell you that I was doing OK managing my LD (which I was unaware I had) until the study shots began. Little lumps formed on my knee caps and dark, discolored, patchy rashes were visible on the inside of both knees. Increased connective tissue pain radiated from all points along my spine in waves that migrated to different areas mostly the left side of my body. Brain fog, paranoia, anxiety, heart pounding, slurred speech, heightened sensitivity to light and sound, visual overstimulation brought on migraines, nausea, vertigo, etc., my balance was off most of the time. Grocery stores, malls, driving at night were all impossible to do without getting sick.

Meanwhile, my children now ages 8, 15 & 17, (all with diagnosed Chronic LD), are prone to waves of most all these symptoms and more. Everyone of us has symptoms seemingly dependent on location of tick bite and number of times bitten over the years.

If I were not directly aware of both sides of this vaccine issue I would likely have had all my children vaccinated with Lymerix. Thank goodness this will not be so.

My husband and I heard about the Smith Kline Beecham LD vaccine trial studies on a local radio station in 1995, offering \$350.00 to each participant. We never received any money, I do not recall why.

We unknowingly had been living with LD for years, tested Western Blot negative and received all 3 shots. The symptoms that followed from the 2nd shot on has devastated our lives. Unable to work, loss of income, physical and mental disabilities as result of this vaccine has destroyed my life.

I have brought all my symptoms to the attention of both the doctors of SKB and the investigative doctors involved with the study. They denied my symptoms and broke their own rules written within the consent form. That was not their right! When considering money and reputation, they have much to lose. I can only hope the truth will prevail.

Please acknowledge what is happening to others who have now received the FDA approved Lymerix vaccine. Before approval my complaints about the LD vaccine seemed not represent enough people. I am now sorry to say, that is no longer true.

Thank goodness I found a Lyme literate MD and more than enough up to date research on LD than I could fathom would be available. This has empowered me to go back to the fact that doctors only practice medicine. A good patient is someone who learns about the disease him or herself and then helps the doctor. The doctor must be willing to learn about the disease along with the patient. If not up on the latest information, then they're behind the times. This concerns both sides of the issue, not just the ones with the most monetary values.

I live on Cape Cod, MA, which is considered an area highly endemic for LD. I personally believe that Lyme is in epidemic proportion there.

Antibiotics have undoubtedly helped me to gain back some of my former self, but this continues to be a long, daily and painfully difficult task. I wish I were back to just living with LD. This vaccine has already harmed many lives, please do not do this to our children too!

I profoundly suggest complete termination of the Lymerix vaccine until further research can develop reliable tests and better diagnostic tools.

Thank you for listening,

January 29, 2001

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RE:

Problems with the LymeRix vaccine from VAERS LymeRix filer #127749

To Whom It May Concern:

In April, 1999 I was inoculated with SmithKline Beecham's LymeRix vaccine. Because of the many adverse health effects I have experienced since this vaccine, I am very concerned that other people who receive this vaccine may suffer ill effects from it as well. I am particularly concerned about the dangerous prospect of its being given to children. I urge the FDA reviewing panel to not extend the range of possible recipients of this product. Moreover, I personally believe that the vaccine should be banned from the list of FDA-approved products because of its potential to harm people's health.

Prior to receiving the LymeRix vaccine my health history included my being treated for a thyroid condition with Synthroid, since 1984. In 1991 I discovered what appeared to be a "bull's-eye" rash on my right thigh. I was treated with a ten-day course of doxycycline in the event that the rash evidenced Lyme disease. In 1995 I was again treated with a ten-day course of doxycycline after a new "mole" (i.e. a nymph tick) on my left arm fell off in the shower four days after I discovered it. I never became ill after the above-mentioned tick-related incidents, though I did break out in rashes the second time. In about 1992 it was discovered that I had another thyroid problem, Hashimoto's disease, (an autoimmune condition). I had a hysterectomy in 1990, a pelvic floor uplift procedure in 1993, and hemorrhoid surgeries in 1996. In the early nineties I began taking Premarin for hormone replacement therapy (HRT). In the spring of 1998 I began treatment for hypertension. In the winters of 1998 and 1999 I experienced a few, (maybe five, total, for both years combined) episodes of heart palpitations, each of which lasted only a couple of seconds.

Despite the above health issues, I always considered myself to be a healthy person. I never was what I would call "sick." My problems had always been under control and manageable. I come from a long-lived family, and I expected to be similarly so disposed. Since the LymeRix vaccine, however, my life has changed dramatically; I spend several days a month going to one doctor or another, and the costs to me personally and monetarily have been great!

In August of 1999 I sent five pages of commentary to the Vaccine Adverse Events Reporting System group at the FDA about my immediate post- vaccine health history up to August 27, 1999. I assume this information is available to you separately under my VAERS filed report re LymeRix, ID #127749.

Since the end of August, 1999, I have continued to experience more health problems.

In early September, 1999 I had more episodes of feeling dizzy and faint. In mid-September, 1999, I blacked out, fell hit my head on the floor and was taken to the emergency room in an ambulance. I saw a cardiologist for the first time in my life in October, 1999, who ran a series of tests on me. They included a special 24-hour Holter Monitor test that also checked my blood pressure every 15 minutes, which evidenced heart rhythm and blood pressure irregularities. A thallium stress test administered at the doctor's office resulted my experiencing a prolonged episode of supraventricular tachycardia and abnormally high blood pressure right there in the office. A tilt-table test administered a week after I had been put on a beta blocker to control my blood pressure and heart rhythm problems was normal. A heart telemonitor that I wore for about 30 days recorded probably between 100-200m strips of heartbeat irregularities ranging from bradycardia to PVC's to supraventricular tachycardia. Around the middle of December of 1999, I again went to the emergency room and was told I was experiencing atrial fibrillation. My treating cardiologist strongly urged me to undergo an "atrial-ventricular nodular ablation procedure." After a discussion with the electro-physiologist physician who administers this procedure, I decided to forego it because of the

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serious risks (like death, stroke or heart attack) it could pose. Instead, I continue to take the Toprol-XL to control my blood pressure and heart rhythms, and am still alive to write this report, though admittedly I do still experience episodes of heartbeat irregularities, which I've come to conclude seem to relate to fluctuations in thyroid hormone levels. When I was diagnosed with atrial fibrillation when I went to the emergency room in December, 1999 I realized that that was the same problem I had experienced in early June of 1999 (about six weeks post-vaccine), when I felt so terrible I thought I was going to die. (Foolishly, I did not go to the hospital at that time).

My heart problems pretty much subsided during the winter and spring of 2000, while I was under the care of a physician who treated me for long-standing Lyme disease (which I tested positively for on a polymerase chain reaction (PCR) test in July or August of 1999). However, in the spring of 2000, my ankles swelled up to 12 inches in circumference. Intermittently I have had other bouts of bad ankle swelling and I've even had pitting edema. When I was taken off Premarin in June of 2000 for thyroid testing my ankle swelling subsided. When I resumed the Premarin in August my ankles swelled again. I stopped taking the HRT. In the last few months I discovered that my blood tests taken over the course of the preceding year had consistently shown abnormally elevated levels of calcium in my blood. An endocrinologist I saw the end of November, 2000, told me to resume the HRT to prevent calcium leaching. I may now have a parathyroid problem. On the HRT with Premarin my ankles again swelled up badly. Now I am under the care of a wonderful internist who has switched me to a compounded estrogen Rx, and my ankles are pretty much normal.

Of interest is the fact that since the vaccine I have experienced fluctuations in my TSH level tests. I have experienced periods of hypothyroidism (when I become very tired, gain weight, swell up and lose clumps of hair) and hyperthyroidism when I sweat intensely, and experience episodes of heart palpitations and dizziness. Finding the right dosage is tricky. Prior to the vaccine, my TSH tests remained relatively constant. Regardless of my TSH levels, and despite my heavy sweating episodes, my typical body temperature is well below 98.6 degrees. (Once it was as low as 95.1 degrees).

Another comment of interest: Post-vaccine I developed swollen lymph glands in my neck and eventually under my arms. In March of 1999, a month before I was vaccinated, I had had a mammogram which was normal, and no lumps of any sort. In August or September, 1999 I discovered a raised, tender palpable lump between my right breast and armpit. I was advised to see a general surgeon who concluded that it was another swollen lymph gland. I saw her several months later; the lump never went away. She now has written me and requested that I see her again. The lump still remains, and I just discovered a second lump next to it. I have an appointment with her in the next week.

Most concerning of all are the neurological problems I have experienced since the vaccine. My mental abilities have been affected dramatically. About six weeks post-vaccine I couldn't think of the words for common nouns. For example I kept picturing a house in my mind and couldn't think of the word "house." Innumerable times I have had to replay phone menu options because I haven't been able to retain instructions in my mind even for seconds. Sometimes I haven't been able to mentally calculate a 15% tip, which had never before been a problem whatsoever. There were times, particularly the summer after the vaccine when I was unable to read a book because I couldn't remember what I had read previously on the page. I often experience tingling and "vibrating" feelings all over my body, my neurological responses have diminished (e.g. in the knee hammer test), I have constant tinnitus, and I feel burning and crawling sensations in and over my head. My feet often feel like they are burning or freezing; I have to actually hold them in my hands to

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determine whether they are hot or cold. The summer after the vaccine my hands sometimes would jerk uncontrollably as if I had Parkinson's Disease. The results of an M3MN BRAIN SPECT test taken at Columbia Presbyterian Hospital in late November, 2000, stated the following under "IMPRESSION":

MODERATE, GLOBAL, CORTICAL HYPOPERFUSION WITH HETEROGENEITY CONSISTENT WITH ENCEPHALITIS OR VASCULITIS, SUCH AS FROM INFECTION (E.G., LYME DISEASE) OR AUTOIMMUNE ETIOLOGIES

Because of the Brain Spect results I plan to have an MRI scan of my brain sometime soon.

In light of all of the problems discussed above, I tend to gloss over the arthritic and muscular problems I have experienced since the vaccine, but I have had some. My hands and fingers sometimes hurt, and various knuckles have become red, stiff and inflamed. The other day the joint below my right thumb was so painful that I couldn't hold a jar to open it. Last winter my neck and shoulder hurt so much that I eventually had to have some kind of special shot in three places there which eventually alleviated the stiffness, pain and crackling. (I had waited about six weeks first, thinking the problem would go away on its own, but it didn't. Prior to the shots I went to a Chinese accupressurist for massage and heat therapy, but the relief lasted less than a half and hour). Moreover, I am plagued with plantars' fasciitis in both my feet. I currently possess an Rx for Relaxin to use when I have pain below my right ribs that radiates around my torso. Two doctors told me that that pain emanates from my spine.

Before the vaccine, my I'd characterize my life and health as relatively normal. Now it is not.

In my opinion, the LymeRix vaccine probably activated a dormant form of the Lyme bacteria that may have been residing deep within various organs of my body unbeknownst to me; perhaps I may have been fine the rest of my life. Note that the Lyme spirochete changes form and goes into an encysted form where it can "hide out" for many years in the human body (similar to what syphilis bacteria, also spirochetes, do).

I contend that this vaccine should NOT be given to anybody with any autoimmune disorder. Since many people do not know that they have an autoimmune condition, that fact alone should preclude the vaccine's use. Though I know that there are concerns regarding the use of LymeRix by people who possess the HLA-DR4 gene, I suggest that, similarly, there may be other gene/allele-LymeRix relationships that are provoked when the vaccine is administered to people with other autoimmune conditions (such as Hashimoto's disease, in my case). The vaccine is not a safe product, period. I doubt that the physicians who are administering the vaccine are reading the product literature. (Certainly the doctor who administered the vaccine to me did not!). (The product information's print is so small I had to read it with a magnifying glass).

Speaking from my personal experiences, recipients of this vaccine risk grave and life-threatening health problems. I believe the vaccine DEFINITELY SHOULD NOT BE GIVEN TO CHILDREN. I would hate to see innocent children develop unpredictable health consequences that may shorten their lives, or that may affect them for the rest of their lives. The "FDA-approved test" of LymeRix to date has failed miserably. My life has changed dramatically since I was vaccinated, and I rue the day I ever had that shot (and I never even had the booster shots because I got sick early). Please help ensure that more people do not lose their good health; reverse your approval of this product and take LymeRix off the market.

1/28/01

In 1998 we moved to We had moved up from Maryland. We bought some land and a house in the country. My mother and father were going to put a double wide on our property and I was going to take care of them. We spend a lot of time camping and working outside on our property so when we heard about the vaccine for Lyme Disease we thought it would be a good idea. I had just got a new doctor so I got a compleat physical. I was in good health and all my test came back good. In February I received my first Lymrix shot and became sick very quickly. I had constant aches and pains everywhere in my body. When I recieved my second Lymerix shot I got even sicker. My doctor then sent me to a arthritis specalist and I was informed I have Fibromyalagia. I repeatedly told my doctor that it was the Lymerix vaccine that had made me sick and I refused to take the last shot. This year I was told I have arthritis in my neck. Every bone and muscle in my body hurts. I hurt so much I have trouble sleeping. I am tired and in pain all the time.