

January 15, 2001

Nancy Cherry
FDA Advisory Committee

Dear Ms. Cherry and FDA Committee Members:

It has been _____ And if we had known then what we know now . . .

August 1996 _____ daughter _____ had lymes disease.
She was successfully treated with antibiotics.

April 2000 _____ received the LYMERix vaccine.
She developed moderate symptoms.

May 2000 _____ received the second dose of the LYMERix vaccine.
She developed lymes-like symptoms: fatigue to the point of
taking 3-4 hour naps and having to be awakened, pain in knees
and hands, aching all over and on-and-off again headaches.
Those symptoms have continued to date.

Since _____ became ill, she has been "diagnosed" with everything from
fibromyalgia to chronic fatigue syndrome (because she did not have the tender
points for fibromyalgia) to kneecaps that slip out of place to possible depression.
Despite several tests, she basically went untreated for six months. At that time, she
became very ill, averaging three days a week at school in October and November.
For a child who would be described as a straight A athlete (participating in soccer,
tennis, skiing, swimming, golf, dance, etc.), _____ life changed dramatically.

This has been met by such phrases as:

1. "We are sorry this has happened to your family "
Why did we learn of these things months after the vaccine was injected?
2. "Sometimes bad things happen to good people."
Bad things do not have to happen to anyone if people communicate and
are made aware of dangers.
3. "This would only be reported as serious if hospitalization or death occurs "
This is not something to say to any parent whose child has been ill for
several months

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Our concern with this vaccine falls into two categories: safety for children and information concerning the vaccine. On the first issue, we were informed by the administering medical personnel that this vaccine was safe. We trusted them. What we should have questioned further was how safe was this vaccine for _____. She had previously had lymes. She was HLA-DR4 positive but this test was not performed prior to the vaccine being given. No blood tests were done to check her lymes titres.

Second, information that would have been instrumental in our decision to give both our daughters the vaccine was not disclosed to us despite questions (that would be normal for non-medical personnel) about a seven-page consent form that included every symptom from redness at the injection site to death. Most importantly, nothing was said concerning the HLA-DR4 testing—even after _____ had blood drawn for the test on August 25, 2000—four months after receiving the initial LYMERix vaccine. Nothing was mentioned about a major class action lawsuit concerning vaccine safety. It was not thoroughly explained that there were possible arthritic side effects or possible auto-immune reactions that could affect her for life, because we failed to ask the right question, properly worded.

After our daughter received the LYMERix vaccine, she became ill with lymes-like symptoms. Medical personnel believe that could be sheer coincidence but we believe it could be related to the vaccine. But had she been appropriately screened prior to receiving the vaccine and had we been thoroughly informed of all the pertinent information, especially for a child who had previously had lymes, all of the health problems and frustrations of the past year could have been averted.

Due to distance and limited presentation time, we did not feel it would be prudent to travel to Washington, D.C, however, we very much wanted to share _____ story with you. Our foremost concern is for _____ to get well. But we are also concerned that such an unnecessary travesty does not occur to other unsuspecting children and trusting parents. The need for prior testing and/or comprehensive screening for vaccine recipients and complete information disclosure by the vaccine provider (either SmithKline or the administering institution and medical personnel) seems only logical. There are simply too many unknowns concerning this vaccine to allow it to be used at this time on any child.

Sincerely,
