Lyme Disease Association, Inc.

PO Box 1438, Jackson, New Jersey 08527
888-366-6611 Lymeliter@aol.com 732-938-7215 (Fax)
LymeDiseaseAssociation.org

Judge Jacqueline Carroll Cody
Two High Street Suite 424
PO Box 2748
West Chester PA 19380

RE: Ray Cassidy vs. SmithKline

April 25, 2002

Dear Judge Cody,

I am writing on behalf of the Lyme Disease Association (LDA), an **all-volunteer** national non-profit dedicated to raising money for Lyme disease research, education, and prevention. This past year, the LDA and its Connecticut affiliate partnered with Columbia University to establish an endowed Lyme disease research center to be housed at Columbia.

The FDA panel that recommended approval of the Lyme disease vaccine did so with many provisos. The LDA and many other Lyme groups had serious concerns about its safety and efficacy. These concerns were partly based upon already published animal studies indicating an OspA (the basis of the vaccine) sensitivity, producing a crippling autoimmune arthritis.

LDA had other concerns about whether patients who had a history of Lyme disease should receive the vaccine. There did not appear to be clear answers to that question. In addition, it was very unclear whether three shots would be enough to confer lifetime immunity or whether boosters were required. If they were to be required, safety and efficacy as well as total numbers of the boosters necessary had yet to be demonstrated.

Several months after the vaccine was released, LDA started receiving inquiries relating to any problems we knew about the vaccine. The numbers of inquiries increased as time went on, and all we could really do was tell people to let their physicians know what was happening and to make sure they reported any adverse event(s) to Vaccine Adverse Events Reporting System, VAERS. Many of these people said their physicians denied any of their problems were associated with the vaccine. In some cases, people said they called the manufacturer to report problems and were told by the manufacturer that their problems were unrelated to the vaccine.

LDA then heard about the filing of the class action suit. The filing raised awareness levels among physicians and the public, and more questions were asked by people prior to receiving the vaccine. Questions and concerns about the vaccine proliferated. Sadly, LDA had few answers. We testified before the FDA's vaccine Advisory Committee asking for a moratorium on vaccine distribution until further studies were done to

determine if the events were related. Despite the riveting testimonies of people in motorized wheel chairs, a mother, other formerly healthy individuals, and two major Lyme disease organizations testifying to the problems with the vaccine, the FDA took no action, although some panel members did call for some action. Subsequently, the LDA held a private meeting with the FDA and presented data on the vaccine. Still, the FDA took no action.

Individuals need to be informed consumers, but with this vaccine, consumers were really on their own. Information about the vaccine was confusing and/or incomplete. Despite compelling testimonies, the FDA did not act to protect consumer interests. The lawsuit was initiated to help consumers by addressing the issues of what the label should contain to protect the consumers. The suit does not address personal injury claims, which of course, consumers can still file.

The FDA never took further action on the vaccine. SmithKline (now GSK) acted. Citing poor sales of the vaccine, they withdrew it from the market. The class action was instrumental in achieving this result. Its filing caused people to rethink their intent to get the vaccine. SKB agreed not to remarket it without a label change. Consumers are now protected from further harm while the vaccine is not being distributed, and if SKB decides to redistribute, they will have to provide labels which fully inform consumers about the associated risks of the vaccine.

The attorneys who were involved with this suit did a significant amount of research on a very complex issue. By filing the suit, they have caused an awareness of problems associated with the vaccine, an awareness which did not exist and which contributed significantly to the withdrawal of the vaccine. This withdrawal was a victory for consumers. The settlement with the accompanying legal fees seems a small price to pay when weighed against the price those who could have become crippled and maimed from the vaccine would have paid in human suffering and in dollars. Therefore, we support the settlement and the legal fees.

Sincerely,

Patricia V. Smith
President

.