

# LDA Remarks Before Vaccines & Related Biological Products Advisory Committee

I am here today because we do favor a safe and effective vaccine, but we are unsure whether an OSP A based vaccine can meet those criteria. Since the inception of OSP A vaccine trials, we heard from individuals experiencing difficulties after immunization. The information was startling, not only because of the problems described, but also because of doctors' apparent incomprehension of the problem.

## REMARKS OF PAT SMITH, PRESIDENT, LYME DISEASE ASSOCIATION, INC. BEFORE THE VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE, JANUARY 31, 2001, BETHESDA, MD

The Lyme Disease Association's mission is Lyme disease education, prevention, and research funding, so one might automatically assume we're favorable to a safe and effective vaccine for Lyme disease. That's certainly a valid assumption. The Association's board consists of patients and families of patients—all of whose lives have been personally touched by this disease, and all who are dedicated to preventing others from experiencing the physical, mental, and emotional devastation Lyme disease can produce. To that end, we fund research projects, sponsor medical conferences and continue to work with Members of Congress developing federal legislation providing \$125 million for Lyme disease research, physician education, and prevention.

I am here today because we do favor a safe and effective vaccine, but we are unsure whether an OSP A based vaccine can meet those criteria. Since the inception of OSP A vaccine trials, we heard from individuals experiencing difficulties after immunization. The information was startling, not only because of the problems described, but also because of doctors' apparent incomprehension of the problem. At a vaccine meeting sponsored by the LDF where pharmaceuticals reps were discussing how well the trials were going, I questioned, without satisfaction, the issue of these trial-patient complaints.

After vaccine approval, LDA received inquiries about the vaccine, many from individuals who had received all or some of the vaccination series. Most proceeded to talk about symptoms they developed subsequent to receiving the vaccine. When asked if they had reported this to the administering doctor, and if the doctor had reported the adverse event, the usual response was that the doctor did not take the complaint seriously or did not think the symptoms were related.

Sadly, none were aware of the HLADR4 situation, and several were in the midst of the immunization series and did not know whether to continue taking the shots. Some called to ask if they should get the shots if they had had Lyme in the past, a question which appears to have no clear answer—particularly in light of the unreliable antibody response tests used to determine who has or had Lyme disease. A few insisted they had gotten “full blown Lyme” from the shots, and after further discussion, indicated they had had Lyme disease in the past.

I want to share an email I received Monday. “I live in Wisconsin. I received your name from person X who told me you may be able to give me some direction. I received two vaccines in the spring of 2000. Couple days within the first shot my neck and higher back stiffened up severely. In a month I went back for the second shot and asked the nurse and doc to check for side effects before I took the second. They informed me there were none. I took the second dose and the problem with my neck and back worsened within a couple of days. My family doctor gave me anti-inflammatories but they did nothing. I’ve tried a chiropractor but the only relief was for a couple of hours. Never tried one before but am getting desperate. Then I went to a orthopedic and am now on anti inflammatories again but not helping. He told me that I have a disc that is somewhat smaller than the others in my neck and maybe the vaccine somehow aggravated it. Prior to the vaccine I have had 0 neck or back problems. I am looking for treatment somehow someway.” I called him. He is 39 years old. He asked me to help him. He wants treatment for what he has.

Today you are hearing about how this vaccine has physically impacted human lives. It appears that little can be done to

stop whatever process triggers some of these reactions, or if something can be done, it remains as yet undiscovered. I listen to the despair and bewilderment of those adversely impacted: How can this happen from a medicine to keep me from getting sick? Who can help me get better? I can only comfort them as I do not have any answers, and I do not know who does.

This committee has the authority to formulate recommendations that may prevent others from potentially suffering the same fate. You can revisit the original data and research which appears to show a link between OSP A and adverse reactions and view it in light of the adverse events you have now heard about. You can recommend further studies. You can find out why many doctors who treat chronic Lyme disease are not giving the vaccine.

The Advisory Committee on Immunization Practices recommends under future considerations in their report on the Lyme disease vaccine, June 4, 1999 MMWR, "establish post licensure epidemiological studies of safety, efficacy, prevention effectiveness, cost effectiveness, and patterns of use." We concur with that recommendation and would like to see a moratorium on vaccine administration until those studies are completed and the results critically analyzed.

Thank you for your time.