H.R. # 6140 92 31

Pt. Name: Miguel A. Perez-Lizano

PATIENT REBUTTAL for inclusion in patient's medical record.

Date of Document: 4/16/2001

Type of Document: Staff message from Joseph Kane, M.D.

Rebuttal:

Joseph Kane, M.D. has added the following comment to my medical record as a response to a physician's inquiry;

"See Steve Spindel's 6/5/2000 I.D. consultation. In view of Steve's consultation and repeated negative EIA testing, I do not believe that the equivocal result on Western Blot test which we reviewed together increases the probability that he has active chronic Lyme disease in any organ system. Thanks JK"

Selected comments:

1) **Dr. Kane is offering a second opinion. Protocols issued by the National Institutes of Health state that the diagnosis of Lyme disease is a clinical diagnosis. Dr. Kane has never met me, examined me, or spoken to me. Dr. Kane is in not in compliance with NIH protocols.**

2) **Dr. Kane relies on a report by Dr. Spindel to validate his opinion. Dr. Spindel's report is false, incompetent, and biased. A separate complaint and rebuttal has been filed against Dr. Spindel.**

3) **In March 2001, I ordered and paid for a Western Blot IgG blood test specific for Lyme disease. The CDC developed highly restrictive criteria for the surveillance reporting of Lyme disease. The criteria were meant to be definitive. Ten antibodies reactive to Lyme (arthritis) disease were defined. (Dressler F, Whalen JA, Reinhardt BN, Steere AC. Western Blotting in the serodiagnosis of Lyme disease). The CDC considers the presence of five bands definitive. My results were four positive bands and one band of equivocal band intensity. Equivocal is a measure of band intensity, not an indication of probable presence or absence of a band. An equivocal designation means the band is present.**

   The CDC gives the following description concerning antigenic identity. "B. burgdorferi is made up of at least 30 different immunogenic proteins including three major outer-surface proteins, Osp-A (30 kDa), Osp-B (34 kDa), and Osp-C (23 kDa). The 41 kDa antigen, similar to that of other spirochetes, is located on the flagellum. Other prominent antigens include the 18, 28, 35, 37, 39,

45, 58, 66, and 93 kDa antigens". My results showed the presence of the 30, 41, 45, 58, and 66 kDa antigens. Band 30 kDa was positive.

In the SmithKline Beecham clinical trials involving 11,000 patients, only 22% of those with culture-proven Lyme disease (the "gold standard") were able to show the presence of five or more significant bands.

4) **For Dr. Kane to state that, in his opinion, the results of this test do not increase the probability that I have active Lyme disease is not correct. Lyme Western Blot IgG cannot distinguish between active and past infection. The American Red Cross has issued guidelines that potential donors with past or active Lyme disease or certain other tick borne diseases are prohibited from donating blood. Dr. Kane's statement strongly implying that I do not have or have never had Lyme disease without ever having seen me or ordering additional testing for tick borne diseases, for which many tests are available, is a public health concern.**

5) **Dr. Kane bases his opinion on the EIA (ELISA) test results. It is extensively published in peer-reviewed literature that the ELISA is seriously flawed as a diagnostic test for Lyme disease. In the Lyme vaccine clinical trials, SmithKline Beecham demonstrated that 36% of the participants were culture positive but seronegative. The Centers for Disease Control (CDC) gives the ELISA a sensitivity of 64% using highly positive CDC banked blood speciments (Johnson BJ, Robbins KE, Bailey RE, Cao BL, Suiat SL, Craven RB, Mayer RW, Dennis DT; "Serodiagnosis of Lyme Disease: Accuracy of a two-step approach using a flagella-based ELISA and immunoblotting"). A very large-scale study by the American Pathologists Proficiency Testing Program showed that only 55% of Lyme disease patients were correctly identified using CDC criteria for seropositivity. Using these measures, the ELISA is 35% to 40% accurate at best.**

According to Dr. Alan Barbour of the University of California at Irvine, formerly of the NIH and regarded as a leading Lyme disease researcher, the ELISA has a sensitivity of 20% to 60%. In addition, it is known that the ELISA is a particularly poor test for late-stage Lyme disease. Knowledgeable clinicians and researchers are aware of the limitations of ELISA as a test for Lyme disease.

The accuracy of Lyme ELISA testing by Kaiser's contracted laboratory, American Medical Laboratories (AML) in Chantilly, Virginia, could be questionable. Reference criteria for West Coast strains differ from East Coast and European strains. The West Coast tick is the *Ixodes pacificus*. The East Coast tick is the *Ixodes dammini*. Comparing one against the other increases the probability of a false negative. There is also a question whether Kaiser's handling of blood samples from West Coast facilities meet AML's speciment requirements for handling and shipping. An internal Kaiser study showed that of 117 samples sent from a California facility, only one had a positive result.

6) **Dr. Kane uses the two-tier serodiagnosis surveillance criteria as diagnostic criteria. This is also not compliant with NIH guidelines. The guidelines state, "This (two-tier serodiagnostic) surveillance criteria was developed for the national reporting of Lyme disease; it is NOT appropriate for clinical diagnosis." (The capital letters are directly from the NIH statement for diagnosis).**

7) **The results of my Western Blot IgG test are completely opposed to and do not support Dr. Kane's opinion. While the Western Blot can be used to rule out false ELISA positives, it is never used to rule out false ELISA negatives.**

Patient Signature:

Miguel A. Perez-Lizano

Date:

Attachment:

Centers for Disease Control; Lyme Disease: The Bacterium

Cc:

David M. Lawrence, M.D.