November 22, 1982

C. Everett Koop, M.D.
The Surgeon General
U.S. Public Health Service
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Koop:

As you are aware, the Food and Drug Administration approved the public sale of the vaccine Heptavax B produced by Merck, Sharp and Dohme last spring or summer. The clinical use of the vaccine was recommended by the Immunizations Practices Advisory Committee. My husband, Dr. Saul J. Schweber, an oral surgeon in Silver Spring, Maryland, received the first of the three innoculations of Heptavax B vaccine. Approximately three weeks later, Dr. Schweber was admitted to Holy Cross Hospital and diagnosed as having Guillian-Barre syndrome. At this writing, my husband is still in the hospital and we look forward to his release within the next few weeks as well as to his recovery through next spring at which time we hope he will be able to return to his practice.

My husband suffered no symptoms of any physical disorder before innoculation with the vaccine or after until the symptoms of GBS appeared.

I am writing to you because my husband and I are concerned that the public excitement surrounding this vaccine as a long-awaited medical breakthrough to fight the dreaded hepatitis disease may be overshadowing the possible need for additional laboratory study and safety testing. We have read medical literature promoting the vaccine for mass immunization of medical, dental and laboratory personnel (at high risk to HBV infection) in hospitals, clinics, some schools, etc. Some professional organizations are presenting the conservative position that more study may be needed on the use of this vaccine. We agree with this latter point of view.

We are in communication with the Center for Disease Control in Phoenix (the hepatitis lab). Our concern is that my husband's case with which they are familiar may not be reported to the public by them or by Merck, Sharp and Dohme. The only reaction stated in the literature to date are of a minor nature relating to tenderness in the area of innoculation. This is not the case in the incident concerning my husband and may not be fair to the public with regard to public health and safety practices.

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My husband made a conscious decision to protect himself and his patients by receiving a vaccine approved by FDA, promoted by the Department of Health and Human Services and which showed virtually no risk to the recipient in any literature which he investigated. Previously, my husband, Dr. Schweber, has not taken any influenza vaccine because medical literature clearly shows some risk to the group of susceptible recipients. In our opinion, under the circumstances, there has not been a sufficient study of all the facts surrounding the use of Heptavax B vaccine to provide a basis for a professional decision by the Immunizations Practices Advisory Commitee and FDA.

We hope that this matter will receive your serious attention.

Sincerely,

Diane L. Schweber

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