Memorandum

Date   · JAN 6 1983

From   Commissioner of Food and Drugs

Subject   Hepatitis B Vaccine and Guillain-Barre Syndrome

To   The Surgeon General

This is in response to your note of December 9, 1982 concerning a letter you received from Mrs. Diane Schweber, whose husband, Dr. Saul Schweber developed Guillain-Barre syndrome after having been given Hepatitis B vaccine.

We have been following this matter closely and had been informed of Dr. Schweber's illness earlier by the manufacturer, Merck Sharp & Dohme, and the Centers for Disease Control. Our Office of Biologics, which is responsible for the control of biological products including this vaccine, has been in close contact both with CDC and Merck regarding the evaluation of all adverse reactions temporally associated with administration of this product.

Before licensure of the vaccine, 19,000 individuals had been vaccinated and in the period since marketing began in July, 1982, it is estimated that well in excess of 200,000 doses have been administered. No illnesses suggestive of Guillain-Barre syndrome were seen in the studies conducted before licensure. In the surveillance performaned since licensure, a total of 64 reactions of all types have been reported temporally associated with administration of the vaccine. Included among these is a single occurrence of Guillain-Barre syndrome (Dr. Schweber's illness); this is the only illness among the 64 reports that constitutes a significant health problem. The incidence of Guillain-Barre syndrome in unvaccinated persons has been estimated to be in the order of 0.7 cases per million persons per month. Thus, the occurrence of Guillain-Barre syndrome in recipients of hepatitis B vaccine does not appear to be significantly different from that which might have been expected to occur by chance alone.

We are continuing to monitor the adverse reaction reports closely for any evidence of significantly increased risk of Guillain-Barre syndrome or other serious adverse effects.

Arthur Hull Hayes, Jr., M.D.

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