DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date FEB 04 1983

From Director
Centers for Disease Control

Subject Association of Guillain-Barre Syndrome with Heptavax B Vaccine--Dr. Saul J. Schweber

To The Surgeon General
Through: ES/PHS_____

Among the approximately 200,000 recipients of at least one dose of Hepatitis B virus vaccine (HBVV), two cases of Guillain-Barre Syndrome (GBS) have been reported to the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and the manufacturer. One of these is Dr. Schweber, who had no antecedent illness. The second had hepatitis 1 week before onset of GBS. Laboratory tests indicate cytomegalovirus as the possible cause.

Incidence rates of GBS reported in the literature vary from about 6 to 19 cases per million population per year. These rates include all ages and are subject to various degrees of underreporting. The incidence rate of 17 per million population per year published by the Mayo Clinic for Olmsted County is considered to be based on nearly complete case ascertainment. If this rate is adjusted for adults 25 to 65 years of age, representing the age range of health care personnel who are currently receiving HBVV, the rate becomes 23 cases per million persons in this age group per year. Assuming a 6-week "at-risk" period after vaccination, we would expect 0.54 cases of GBS among the 200,000 vaccine recipients. The probability of 1 case would be .312 and the probability of at least 2 cases would be 0.10. The probability of at least 2 cases remains above the .05 level, even if the nonage adjusted Olmsted County rate is used in comparable calculations.

These data do not suggest a direct association of GBS and HBVV. The Advisory Committee for Immunization Practices has recently reviewed reports of adverse reactions to HBVV and also concluded that a direct relationship has not been demonstrated.

Close surveillance is underway. We have requested that State and Territorial Epidemiologists and immunization representatives assigned to States forward any reports of adverse reactions to CDC. Information on adverse reactions is openly shared among FDA, the manufacturer, and CDC. In addition, about 40,000 vaccine recipients in the Veterans Administration Hospital system are being closely monitored.

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