

**“Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis”
Key Messages (Sept. 14, 2004)**

- ***CDC takes vaccine safety very seriously and is committed to monitoring the safety of all recommended vaccines.*** To assure a high standard of safety with vaccines, CDC works with other federal agencies and outside experts, including the Institute of Medicine, to continually assess and research possible or potential health effects that could be associated with vaccines.
- ***CDC is aware of the recent study*** in the September issue of *Neurology* that looks at whether there is an association between (recombinant) hepatitis B vaccine and multiple sclerosis in adults.
- ***CDC agrees with the conclusion of the Neurology editorial*** accompanying the article that ***"the data presented do not provide proof of an association sufficient to implement policy changes with regard to immunization programs."***
- ***This study did not involve children or childhood vaccinations.*** There is no evidence from this study or other studies of an increased risk of MS among children after hepatitis B vaccination.
- ***The benefits of hepatitis B vaccine are well documented.*** As many recent published studies and extensive reviews indicate, hepatitis B vaccine is safe and effective. Hundreds of millions of persons worldwide have received hepatitis B vaccine without developing MS (or any other autoimmune disease).
- ***Hepatitis B vaccine provides proven protection*** against a virus that, before routine childhood immunization programs, was estimated to infect 200,000-300,000 people each year in the U.S. Of these, about 11,000 were hospitalized and 20,000 remained chronically infected. Overall, an estimated 1.2 million people in the United States have chronic HBV infection, and 4,000 to 5,000 people die each year from hepatitis B related chronic liver disease or liver cancer. About one-third of those patients were infected in childhood.

Recently published study in Neurology:

- The recently published study in *Neurology* looks at the potential link between hepatitis B vaccine and an increased risk of multiple sclerosis (MS). The authors conclude that the findings of the study are consistent with the hypothesis that immunization with hepatitis B vaccine is associated with an increased risk of MS.
- This study only looked at adults – and as noted in the editorial accompanying the article, "the present study stands in contrast to multiple studies and expert panels that have concluded that there is no link between hepatitis B vaccine and MS." There have been at least seven scientific studies and four expert panels that have failed to identify an association between hepatitis B vaccine and MS. In particular the Immunization Safety Review Committee of the U.S. Institute of Medicine reviewed all available data on this issue in 2002 and concluded that “epidemiological evidence (i.e., from studies of vaccine-exposed populations and their control groups of patients with these diseases and

their control groups) favors rejection of a causal relationship between the hepatitis B vaccine in adults and multiple sclerosis.”

- As an accompanying editorial in *Neurology* states, this study has a number of important weaknesses that greatly limit its ability to make sound conclusions. For example, the main finding of the study is based on 11 people. In the study, only 11 of the 163 people who had MS had ever received hepatitis B vaccine—the other 152 people with MS had never received hepatitis B vaccine. As such, the sample size is too small to draw definitive conclusions. In addition, the researchers did not verify the vaccination histories of the people in the study.

Putting the study into perspective:

- Hepatitis B vaccine programs have been highly successful in decreasing the incidence of hepatitis B during the past decade.
- In light of all of the recently published research and reviews that have concluded there is not an association between hepatitis B vaccine and MS, this study’s findings do not provide a basis for any changes in CDC’s hepatitis B vaccination recommendations.
- Vaccine safety studies such as this are routinely reviewed by CDC and are also provided to the Advisory Committee on Immunization Practices (ACIP). The ACIP advises CDC and the Department of Health and Human Services on vaccination recommendations.
- Additional background information on hepatitis B vaccine and multiple sclerosis is available at: <http://www.cdc.gov/nip/vacsafe/concerns/ms/default.htm>