



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.  
*Commissioner*

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November 4, 2008

Ari Nave, PhD  
15 Broad Street, Unit 1830  
New York, New York 10005

Dear Dr. Nave,

I am writing in response to your letter regarding concerns about immunization, conflicts of interest among members of the Advisory Committee on Immunization Practices (ACIP), the purpose of the hepatitis B vaccine given at birth, the inclusion of aluminum in hepatitis B vaccine, and the public health need for immunization requirements.

As was stated in my previous response, ACIP is comprised of nationally recognized experts who are carefully selected based on their credentials and knowledge of immunizations. There are no employees of pharmaceutical companies among the members of ACIP and any conflicts of interest are fully vetted. Any member with a conflict of interest regarding any issue is required to recuse him or herself. Dr. Dale Morse, the chair of ACIP, has no pharmaceutical supported grants. Meetings are held in a public setting and all procedures and presentations are made public on the website of the Centers for Disease Control and Prevention (CDC). A tremendous amount of scientific material is presented at their meetings and the results are debated in public. Votes are taken only after sufficient data is available regarding the safety and efficacy, cost effectiveness, and the public health merit of a vaccine, and all these factors are considered in depth. In short, the process is exhaustive, public, and iterative.

A dose of hepatitis B vaccine is recommended within 12 hours of birth in order to prevent the devastating effects that hepatitis B infection can have on newborns and young infants. The most common means of transmission to newborns is through perinatal transmission from an infected mother to her infant, though transmission has been documented in the first few months of life through household contact and medical encounters. Infants that become infected with hepatitis B have a 90% chance of becoming chronically infected with the virus, leading to all its sequelae including liver failure and liver cancer. This is compared with a 5% chance of becoming a chronic hepatitis carrier when an adult is infected with the virus. In New York State, the standard of care is for every infant to receive hepatitis B vaccine within 12 hours of birth. However, there is no law that requires that the vaccine be given to newborn infants.

The hospital stay after delivery is one of the few dependable medical encounters in a child's life, and the birth dose of hepatitis B is safe, highly effective and provides a safety net for all infants. Passing up the opportunity to provide a preventive health service in the hospital

leaves infants unprotected for the first several weeks of life and possibly longer. Due to the errors inherent in medical testing and documentation, we have seen many instances in New York State where the absence of the birth dose has placed infants unnecessarily at risk. Unfortunately, we have also seen a few cases where this has led to perinatal transmission of hepatitis B. These cases could have been prevented with universal birth dose administration.

Aluminum is used in vaccines, including hepatitis B vaccines, as a component that boosts the immune response to the vaccine. The effects of aluminum in vaccines have been studied extensively, and aluminum has not been found to cause harm. The quantities that are found in vaccines are extremely low, and far lower than amounts that are found in food, infant formula, and breast milk. For an extensive discussion of aluminum in vaccines please see the webpages of the Vaccine Education Center at <http://www.chop.edu/consumer/jsp/division/generic.jsp?id=88655>.

Immunization remains one of the most successful public health measures undertaken, and has led to a tremendous reduction in lives lost and an improvement in the quality of life. It is because of immunizations that many individuals, including many physicians, have never seen the diseases that in previous generations instilled fear. However, none of these diseases, with the exception of smallpox, has been eradicated, and indeed many are merely a plane ride away.

Recently, there have been several outbreaks in the United States that have resulted from cases that were imported by unvaccinated Americans travelling abroad or were brought into the country by foreign visitors. In particular, measles outbreaks in California, Washington State, Illinois and other states originated with and were perpetuated by unvaccinated children. These outbreaks have been reported by the media and are documented in an article published in the Morbidity and Mortality Weekly Report (MMWR), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5733a1.htm>. In addition, measles transmission was previously interrupted in the United Kingdom. Recent reports indicate that transmission of measles has been reestablished there due to low immunization rates and that measles is now endemic in the United Kingdom again. The importation of measles and other vaccine preventable disease into the United States will continue to occur because they are still common in Europe and other regions of the world.

If communicable disease were only an issue of whether one child would or would not get a disease, there would not be as much of a public health concern. However, communicable diseases, by definition, can be transmitted from one person to another. A child that goes to school unvaccinated can pose a danger to those children who cannot be vaccinated for legitimate medical reasons, to those children they encounter who are too young to be vaccinated, to those who are older and whose immunity may have waned, and to an individual in those rare instances when vaccination has not produced adequate immunity. It is for this reason that medical and religious exemptions are the only exceptions permitted according to New York State law.

Thank you for expressing your concerns. Should you have any further questions, please contact David Lynch at the New York State Department of Health Immunization Program at 518-473-4437.

Sincerely

A handwritten signature in blue ink that reads "Perry F. Smith" followed by a circled "M.D." to the right.

Perry F. Smith, M.D.

Director, Division of Epidemiology