

Voluntary Recall of *Haemophilus influenzae* type B (Hib) Vaccine

RALEIGH, NC – North Carolina’s vaccine supply has been affected by the recent voluntary recall of 10 lots of *Haemophilus influenzae* type B (Hib) vaccine and two lots of a combination Hib and Hepatitis B vaccine. While the recall does affect the state’s vaccine supply, it does not have a negative effect on our children’s health, nor will it require reimmunization of children who have received the affected vaccine.

The State’s Universal Vaccine Program received and shipped 86,610 doses from the affected lots of Hib vaccine. The State program does not distribute the combination vaccine. Providers who have received recalled vaccines are in the process of being contacted and are being asked to immediately discontinue use of any of the affected lots and to return the recalled vaccine to the manufacturer.

“We want to stress that this is not a health threat for the children of North Carolina,” said Leah Devlin, State Health Director. “Children who received vaccine from affected lots do not need to be revaccinated.”

No concerns have been raised about vaccine effectiveness of the recalled vaccines. The vaccine is being recalled as a preventive measure because the manufacturing company, Merck, cannot assure sterility for the ten lots. Sterility tests of samples from the recalled lots have not found any contamination and the potential of contamination of any individual dose of vaccine is very low.

“As a precautionary measure, parents whose children have recently received a dose of the recalled vaccine should watch for any signs of infection such as redness and swelling at the injection site within seven days of receiving the vaccine,” said Dr. Devlin. “If they notice an unusual reaction, they should contact their doctor or health care provider.”

Merck & Co. initiated a voluntary recall on Wednesday in the United States for ten lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. The affected doses were distributed throughout the U.S. starting in April 2007.

As a result of this recall, providers who only use Merck Hib vaccines may have none, some or all of their vaccine recalled, and about half of the Hib vaccine in CDC’s stockpile is being recalled. North Carolina’s vaccine supply of Hib has been significantly reduced. “We do expect this nationwide Hib vaccine recall to cause a shortage in North Carolina. The extent to which this recall will impact our vaccine supply is being determined and is dependent upon the availability from the other manufacturer,” said Beth Rowe-West, Head of the North Carolina Immunization Branch.

Current immunization rates in the U.S. for Hib vaccine are high. In 2006, about 94% of U.S. children 19-35 months of age were vaccinated against Hib. For North Carolina, the immunization rate is even higher, at 99.7% for the same age group. This has resulted in a dramatic decline in transmission of this disease; however, it has not gone away completely.

Haemophilus influenzae type b vaccine prevents meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), epiglottitis (a severe throat infection), and other serious infections caused by a type of bacteria called *Haemophilus influenzae* type b. It is recommended for all children under 5 years old in the U.S., and it is usually given to infants starting at two months old.

The Hib bacterium is commonly present in the nose and throat. Bacteria are transmitted from person to person in droplets through sneezing, coughing. Infected children may carry Hib bacteria without showing any signs or symptoms of illness, but they can still infect others. The risk of disease is highest for children between six months and two years of age. Before Hib vaccine, about 20,000 children in the United States under 5 years old got severe Hib disease each year and nearly 1,000 people died.

If people have questions or concerns, please contact your physician, your local health department, or the State's Universal Vaccine Program at 919-707-5550.

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