

**Interim Recommendations for the Use of Haemophilus influenzae Type b (Hib) Conjugate Vaccines Related to the Recall of Certain Lots of Hib-Containing Vaccines (PedvaxHIB® and Comvax®)
December 2007**

On December 13, 2007, Merck, the manufacturer of Haemophilus influenzae type b (Hib) vaccine announced a voluntary recall of certain lots of two Hib products, PedvaxHIB (monovalent Hib Vaccine) and Comvax (Hib/hepatitis B vaccine) which is expected to result in short-term disruption to the vaccine supply in the United States. Additional information regarding the affected lots is available from the Food and Drug Administration (FDA) at <http://www.fda.gov/consumer/updates/hib121307.html>. The following describes the interim recommendations for the use of Hib-containing vaccines.

The Centers for Disease Control and Prevention (CDC), in consultation with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians, and the American Academy of Pediatrics, **recommends that providers temporarily defer administering the routine Hib vaccine booster dose administered at age 12-15 months except to children in specific high risk groups.**

Children at increased risk for Hib disease, include those with asplenia, sickle cell disease, human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms. American Indian/Alaska Native (AI/AN) children also are at increased risk for Hib disease, particularly in the first 6 months of life. CDC recommends that providers continue to vaccinate these children with available Hib conjugate vaccines according to the routinely recommended schedules, including the 12-15 month booster dose.

All Hib products are equally effective after completion of the primary series. However, the administration of PedvaxHIB vaccine leads to a more rapid seroconversion to protective antibody concentrations within the first 6 months of life. CDC recommends that providers who currently use PedvaxHIB containing vaccines (PedvaxHIB and Comvax) to serve predominantly AI/AN children in AI/AN communities continue to use only PedvaxHIB containing vaccines not affected by the recall and vaccinate according to the routinely recommended schedules, including the 12-15 month booster dose. PedvaxHIB (if available), ActHIB, and TriHIBit may be used for the booster doses for these children during this shortage.

Short-term deferral of the booster dose among children aged 12-15 months is not likely to result in an increased risk for Hib disease because of continued protection of children with the primary series and the low level of nasopharyngeal carriage and transmission achieved in the United States by the Hib immunization program. Providers should register and track children for whom the booster dose is deferred to facilitate recalling them for vaccination when supply improves.

Iowa Department of Public Health
Division of Acute Disease Prevention & Emergency Response

PedvaxHIB and Comvax are recommended as a 2-dose primary series (at ages 2 and 4 months), whereas ActHIB is recommended as a 3-dose primary series (at ages 2, 4, and 6 months). If brands of vaccine are changed during the primary series, a 3 dose primary series is required (2, 4 and 6 month of age).

To maximize the amount of available vaccine, providers should only order the number of doses of vaccine required to meet immediate needs (i.e., a supply for up to 4 weeks) and should refrain from attempting to build an inventory of Hib vaccine.

The full Morbidity and Mortality Weekly Report (MMWR) is available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d1219a1.htm?s_cid=mm56d1219a1_e

If you have question regarding these recommendations please contact the Iowa Immunization Program at 1-800-831-6293.