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TO: **All Users of State Supplied Vaccines**

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DATE: **July 1, 2009**

SUBJECT: **Reinstatement of the *Haemophilus influenzae* type b (Hib) Vaccine Booster Dose at Ages 12–15 Months**

The primary purpose of this communication is to notify you of the reinstatement of the *Haemophilus influenzae* type b (Hib) vaccine booster dose at ages 12–15 months. Despite the reinstatement of the Hib booster dose, as of July, we are continuing to receive a monthly allocation of Hib-containing vaccine; so depending upon the amount of vaccine requested we may still need to adjust provider orders based upon our current supply. The following information is reproduced from the Morbidity and Mortality Weekly Report available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5824a5.htm?s_cid=mm5824a15e

Hib Vaccine Supply

On December 13, 2007, certain lots of *Haemophilus influenzae* type b (Hib) vaccine marketed as PedvaxHIB (monovalent Hib vaccine) and Comvax (Hib-HepB vaccine), and manufactured by Merck & Co., Inc., were recalled voluntarily, and the company temporarily suspended production of these vaccines. To conserve the limited supply of Hib-containing vaccines, CDC, in consultation with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP), on December 18, 2007, recommended that vaccination providers temporarily defer the routine Hib vaccine booster dose administered to most healthy children at age 12–15 months (*1–5*).

Production of Merck Hib vaccine products is still suspended. However, two other Hib-containing vaccines manufactured by Sanofi Pasteur have been available for use in the United States during this shortage: monovalent Hib vaccine (ActHIB) and DTaP-IPV/Hib (Pentacel). Beginning in July 2009, the manufacturer of these two vaccines will increase the number of doses of these two products available for use in the United States, which will result in the supply being sufficient to reinstate the Hib vaccine booster dose.

Reinstatement of Hib Booster Dose

Effective immediately, CDC, in consultation with ACIP, AAFP, and AAP, is recommending reinstatement of the booster dose of Hib vaccine for children aged 12–15 months who have completed the primary 3-dose series. Infants should continue to receive the primary Hib vaccine series at ages 2, 4, and 6 months. Children aged 12–15 months should receive the booster dose on time.

Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter. **Although supply is sufficient to reinstate the booster dose and begin catch-up vaccination, supply is not yet ample enough to support a mass notification process to contact all children with deferred Hib booster doses.**

Sufficient vaccine will be available to administer the primary series at ages 2, 4, and 6 months and a booster dose on time to children aged 12–15 months. As part of delivering the booster dose to those children for whom it was deferred at the next routinely scheduled appointment or medical encounter, practices should discuss with parents the reasons for the change in recommendation and might consider 1) reviewing electronic or paper medical records or immunization information system records to identify children in need of a booster dose before physician encounters, 2) evaluating children's vaccination status during their scheduled visit, and 3) sharing immunization schedules with parents to make them aware of this plan.

Use of Combination Vaccines

During the Hib shortage, children received protection from certain vaccine preventable diseases in their primary vaccination series through various permutations of available combination vaccines (e.g., DTaP-IPV/Hib [Pentacel] and DTaP-IPV-HepB [Pediarix]) and monovalent vaccines (e.g., ActHib, HepB, and IPV). Therefore, a mismatch might exist between patient vaccination needs and the available stock of different vaccine formulations (e.g., combination products versus single-antigen vaccines) in local provider offices.

This situation presents a challenge for providers to administer vaccines to ensure appropriate coverage while minimizing extra doses of unneeded vaccine. For example, if a provider is using DTaP-IPV/Hib (Pentacel) vaccine to protect infants against Hib disease, the provider should ensure that adequate stock of monovalent HepB vaccine is available to complete the HepB vaccine series. Children who need the Hib booster and who already have received 4 doses of DTaP should receive monovalent Hib vaccine (ActHIB) as their Hib booster dose. **However, if DTaP-IPV/Hib is the only Hib-containing vaccine available, this combination product can be used to complete the series of Hib vaccination, even if the child already has received all the necessary doses of DTaP and IPV.**

Please see the attached CDC question and answer document for providers regarding the Hib booster. As always, if you have any questions please call the State Immunization Program at (860) 509-7929.

Hib Return to Booster Q & A – for Providers

1. Is there any guidance about completing the HepB vaccine series in settings where Pentacel (DTaP-IPV-Hib) is being used for the Hib series?
Providers who are using Pentacel for the Hib series should use monovalent HepB vaccine to complete the HepB vaccine series. This will minimize extra-immunization. Providers will need to plan ahead to ensure they have adequate doses of HepB vaccine on hand. For more guidance about completing the HepB vaccine series, taking into account the mother's hepatitis B surface antigen status (HBsAg) and vaccine availability, please refer to http://www.cdc.gov/vaccines/vac-gen/shortages/downloads/eohib-hepb-cov.pdf.

2. What are the different Hib vaccine products currently available and for what ages are they recommended for use?
Hib vaccine products that are available include Sanofi's monovalent Hib vaccine (ActHib) and the combination product DTaP-IPV/Hib (Pentacel). These two products are recommended for ages 2 months, 4 months, 6 months, and 12-15 months.

Note that for providers who serve predominantly American Indian/Alaska Native (AI/AN) children living in AI/AN communities, the Merck monovalent Hib vaccine, PedvaxHib, has been available through the states' immunization programs from the VFC Pediatric Vaccine Stockpile. These providers should continue to stock and use PRP-OMP – containing Hib vaccines (PedvaxHib and Comvax) and vaccinate according to the routinely recommended schedule.

3. Can the Hib "booster" dose refer to either the third or the fourth dose of Hib-containing vaccine?
Yes. If for a given child a provider has used a Sanofi product (either monovalent ActHib or combination vaccine Pentacel) for any of the doses in the series at the recommended ages, a total of 4 doses is needed (3 primary doses in the first year of life and 1 booster dose in the second year of life) If for a given child the provider has restricted use to Merck's monovalent Hib product (PedvaxHib) or the combination product HepB-Hib (Comvax) for age appropriate doses, the total number of doses in this series is three (2 primary doses and 1 booster dose). If a child has fallen behind in the series of Hib vaccine, fewer doses are required to complete the series regardless of the previous brand used. See Table 1 catch up at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm?s_cid=mm5751a5_e

4. What is the current recommendation for children at increased risk for Hib disease, and has this recommendation changed?
There has been no change in the recommendation for children at increased risk for Hib disease. Throughout the shortage—during which deferral of the booster dose was recommended for most children, those children at increased risk for Hib disease have specifically been recommended to continue to receive the complete series of Hib vaccine (including the primary series and booster). Children at increased risk for Hib disease include those with asplenia, sickle cell disease, and human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms. In addition, some groups at particular risk of invasive Hib disease (i.e., American Indians/Alaska Natives) have been recommended to receive remaining doses of Merck's Hib vaccine, which is available from the VFC Pediatric Vaccine Stockpile. This recommendation has not changed.

5. Is it anticipated that supplies of Hib–containing vaccine will be sufficient in the near future to allow for active recall of children for whom the booster dose was deferred?
CDC does not recommend active recall for children for whom the booster dose was deferred until supplies of Hib vaccine improve. CDC recommends that children older than age 15 months for whom the booster dose was deferred receive the booster dose when they are next seen in the office for a routinely scheduled or sick visit. If additional Hib-containing vaccine becomes available to support active recall, CDC will communicate this information broadly with partners and providers.

6. If a Hib-containing combination vaccine is the only product available to a practice to bring a child up-to-date for Hib, but the child is already up-to-date for the other vaccines in the combination, is it safe to administer the combination vaccine?
Providers should plan ahead so that adequate supplies of the appropriate products are available at the time of the child's visit and that extra-immunization is minimized. However, if Pentacel (that is, the Sanofi combination product DTaPIPV/Hib) is the only Hib-containing vaccine available, this product should be used to complete the Hib vaccination series, even if the child has already received all the necessary doses of DTaP and IPV. Studies suggest that extra DTaP can lead to an increase in local reactogenicity (e.g., sore arm).

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