

## Summary of CDC/FDA Conference Call: Hib Vaccine Recall December 12, 2007

### Key Points

- This week, Merck initiated a voluntary, class 2 recall of two presentations of their Haemophilus influenzae type B (Hib) vaccine. The products are PedvaxHIB and COMVAX (a combination Hib + Hepatitis B vaccine).
- The recall was initiated due to a “lack of assurance of product sterility”. There is no known contamination of any of the vaccine that has been released; routine testing was performed before the lots were released and no contamination was found. This recall is a precautionary measure due to manufacturing conditions that could have allowed contamination to occur.
- CDC does not believe this situation presents a health threat to children, and no adverse events have been reported following vaccination with the recalled vaccine.
  - If a child received contaminated vaccine, adverse reactions would include localized reactions around the site of vaccination, and would likely be identified within one week after vaccination.
- At this time, CDC does not recommend that children who received the recalled vaccine be revaccinated. The situation in Merck’s facilities has not had any impact on the potency of the vaccine.
- Providers who have recalled vaccine should return their product per the instructions in the attached Merck letter.
- The potential impact of this situation is on the vaccine supply. Approximately 1 million doses of the vaccine are being recalled (the annual US usage of Hib vaccine is 14 million doses). Merck produces approximately 50% of the nation’s Hib vaccine supply, and it is not yet known when they will resume full production of the vaccine. Sanofi pasteur produces the other 50% of the national supply and is working with CDC to address the situation.
  - At this time, routine recommendations for Hib vaccine administration should continue to be followed. CDC will convene ACIP in the coming days to discuss possible prioritization of the vaccine.
  - CDC has approximately 750,000 doses of Hib vaccine in the pediatric vaccine stockpile. Priority consideration may be given to American Indian and Alaska Native children, who have a higher incidence of the disease.
- CDC does not anticipate outbreaks of disease due to an interrupted vaccine supply because of the high levels of vaccine coverage in the U.S.
- Additional information:
  - FDA website: <http://www.fda.gov/cber/recalls/merckhib121107.htm>
  - Merck website: <http://www.merck.com/>

\*\*Please also see the attached “Dear Doctor” letter to providers from Merck, and CDC’s Q&A.