



STATE OF MARYLAND

Office of Health Services  
Medical Care Programs

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary

## Memorandum

**Date:** December 27, 2007

**To:** MCO CEOs and Medical Directors

**From:** Nadine Smith, Deputy Director  
DHMH – Health Choice and Acute Care Administration

**Re:** Recall of Certain Lots of PedvaxHIB® and COMVAX®

Merck and Company, Inc. announced on December 13, 2007 the voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB® and COMVAX® because the company could not guarantee that these lots were manufactured under sterile conditions. The potency of the vaccines in these recalled lots was not affected and no contamination of these vaccines has been found. As a result, children already immunized with vaccines from the recalled lots do not need to be revaccinated.

The Vaccines for Children (VFC) sent the attached information to providers enrolled in the VFC Program. On December 14, 2007 the recall information went to providers by fax and on December 20, 2007 VFC faxed the MMWR™ "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®)" to providers.

Additional information about the affected lots is available from the Food and Drug Administration at <http://www.fda.gov/cber/index.html>. Providers should return unused vaccines from the affected lots according to procedures outlined on the Merck website at <http://www.merckvaccines.com/PCHRecall.pdf>.

Attachments



MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
John M. Colmers, Secretary

COMMUNITY HEALTH ADMINISTRATION  
Peter A. Sybinsky, Ph.D., Director  
Richard W. Stringer, Deputy Director

**Maryland Vaccine for Children's Program**  
Friday, December 14, 2007  
**Recall of Certain Lots of PedvaxHIB® and COMVAX®**

Merck & Co., Inc. ("Merck") has initiated a voluntary recall in the United States for ten lots of PedvaxHIB® and two lots of COMVAX®, due to a very slight risk of potential bacterial contamination of those lots.

The Maryland Vaccines for Children (VFC) Program distributed these lots to some VFC providers since April 2007. The lots that VFC shipped that are being recalled are:

PRODUCT DESCRIPTION	LOT #	EXP. DATE
PedvaxHIB®	0677U	11 January 2010
PedvaxHIB®	0995U	16 January 2010
PedvaxHIB®	1164U	18 January 2010
PedvaxHIB®	0259U	17 October 2009
PedvaxHIB®	0435U	18 October 2009
PedvaxHIB®	0436U	19 October 2009
PedvaxHIB®	0437U	19 October 2009
COMVAX®	0376U	05 January 2010
COMVAX®	0377U	08 January 2010

The VFC Program will replace any of the remaining Hib lots which it shipped to you, with ActHib®. In the case of Comvax®, because supplies will be severely limited, ActHib® and Recombivax® will be sent as replacement vaccines.

In the meantime, please do the following:

- **Immediately discontinue use of any of the affected lots.**
- **Remove the affected lots from your refrigerator (It does not have to remain refrigerated) and label it "Do Not Use".**
- **Merck will be contacting affected providers via mail, to arrange return of the affected vaccines. You may also contact Merck at 1-800-672-6372 or go to their website, [www.merckvaccines.com](http://www.merckvaccines.com), for information about returns. Also, Stericycle, the company handling returns for Merck, can be contacted at 1-800-668-4391.**

In addition, Merck is not recommending re-vaccination of children who may have received these lots, because the potency of the vaccines is not affected. Please contact your VFC Consultant if you have any questions.



MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
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**Maryland Vaccine for Children Program**  
**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®)**

Thursday, December 20, 2007

The following is a summary of new CDC recommendations for Hib vaccination during the current Hib vaccine shortage: Please refer to the accompanying December 19, 2007 MMWR Dispatch for detailed information.

- Children NOT at high risk for Hib disease
  - Temporarily defer administering the routine Hib vaccine booster dose administered at age 12–15 months. In these children, a total of 3 doses will complete the primary series.
- Children AT increased risk for Hib disease

These include children with asplenia, sickle cell disease, human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms.

  - CDC recommends that providers continue to vaccinate these high-risk children with available Hib conjugate vaccines 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.
- Susceptible close contacts of patients with Hib disease

Hib vaccines also are recommended for use in prophylaxis.

  - CDC recommends that providers continue to vaccinate close contacts according to published guidelines.
- American Indian/Alaska Native (AI/AN) children
  - CDC recommends that providers who currently use PedvaxHIB and Comvax to serve predominantly AI/AN children in AI/AN communities continue to stock and use only PedvaxHIB – containing Hib vaccines not affected by the recall and vaccinate according to the routinely recommended schedules, including the 12–15 month booster.

The Maryland Vaccines for Children (VFC) Program will ship only ActHIB during the shortage. VFC ActHIB shipments will be in slightly reduced amounts to accommodate the deferred booster dose in non-high risk children.

Please contact your VFC Consultant if you have any questions.





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[www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

*MMWR Dispatch*  
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## 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<sup>®</sup> and Comvax<sup>®</sup>)

On December 13, 2007, Merck & Co., Inc. (West Point, Pennsylvania) announced a voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB<sup>®</sup> (monovalent Hib vaccine) and Comvax<sup>®</sup> (Hib/hepatitis B vaccine). Providers should return unused vaccine from these recalled lots using procedures outlined on the Merck website at <http://www.merckvaccines.com/PCHRecall.pdf>. Additional information regarding the affected lots is available online from the Food and Drug Administration (FDA) at <http://www.fda.gov/consumer/updates/hib121307.html>. Merck has suspended production of its Hib conjugate vaccines and does not expect to resume distribution of these vaccines until the fourth quarter of 2008. The recall of PedvaxHIB and Comvax and suspension of production are expected to result in short-term disruption to the Hib vaccine supply in the United States.

Merck issued this voluntary recall as a precautionary measure because the company cannot assure the sterility of equipment used during manufacture of these lots. However, the potency of the vaccine in the recalled lots was not affected, and Merck reported that no contamination of vaccine has been detected. Therefore, children who received Hib conjugate vaccine from the recalled lots do not need revaccination or any special follow-up.

Two other Hib conjugate vaccines manufactured by Sanofi Pasteur (Swiftwater, Pennsylvania) and currently licensed and available for use in the United States, ActHIB<sup>®</sup> (monovalent Hib vaccine) and TriHIBit<sup>®</sup> (diphtheria and tetanus toxoids and acellular pertussis [DTaP] /Hib vaccine), are unaffected by the recall. However, Sanofi Pasteur likely will not be able to immediately provide adequate Hib vaccine to vaccinate fully all children for whom the vaccine is recommended (1).

The recommended vaccination schedule for all available Hib-containing vaccines consists of a primary series (consisting of 2 or 3 doses, depending on the formulation) administered beginning at age 2 months and a booster dose at age 12–15 months (1).

Because of the short-term reduction in available doses of Hib-containing vaccines, 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 groups at high risk, which are described in this report. Providers should register and track children for whom the booster dose is deferred to facilitate recalling them for vaccination when supply improves.

Sustained high levels of coverage with Hib conjugate vaccine have resulted in a substantial decline in the incidence of Hib disease in the United States (2). In 2006, the incidence of Hib disease in children aged <5 years was 0.21 per 100,000, representing a greater than 99% reduction in disease compared with incidence in the prevaccine era (3). Population immunity is a result of direct protection of children by vaccination with Hib vaccine and herd immunity resulting from prevention of nasopharyngeal carriage and interruption of Hib transmission (4). 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.

The vaccines affected by the recall, PedvaxHIB and Comvax, contain Hib capsular polysaccharide (i.e., polyribosylribitol phosphate [PRP]) covalently linked to a meningococcal outer membrane protein (OMP) carrier. The two unaffected vaccines, ActHIB and TriHIBit, are PRP-tetanus toxoid (PRP-TT) conjugate Hib vaccines. 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

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6 months). ActHIB and PedvaxHIB also are licensed for the 12–15 month booster dose. TriHIBit is licensed only for the 12–15 month booster dose. Children who are not at increased risk for Hib disease, as described in this report, and who received PRP-OMP vaccines for only the first or second dose of their routine primary series may be administered PRP-TT to complete the primary series. In these children, a total of 3 doses will complete the primary series. Children who are behind schedule should complete the primary series according to age-appropriate recommendations (f).

Certain children are at increased risk for Hib disease, including children with asplenia, sickle cell disease, human immunodeficiency virus infection and certain other immunodeficiency syndromes, and malignant neoplasms (5). 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. PedvaxHIB (if available), ActHIB, and TriHIBit may be used for the booster doses for these children during this shortage. Hib vaccines also are recommended for use in prophylaxis for susceptible close contacts of patients with Hib disease. CDC recommends that providers continue to vaccinate close contacts according to published guidelines (5).

American Indian/Alaska Native (AI/AN) children also are at increased risk for Hib disease, particularly in the first 6 months of life (5). Before the use of Hib conjugate vaccines, the incidence of Hib disease among young AI/AN children in AI/AN communities was approximately 10 times higher than among children of comparable age in the general population (5). Compared with PRP-TT conjugate vaccines, the administration of PRP-OMP vaccines leads to a more rapid seroconversion to protective antibody concentrations within the first 6 months of life (6,7). Failure to use PRP-OMP vaccines for the first dose is associated with excess cases of Hib disease in AI/AN infants living in communities where Hib transmission is ongoing and exposure to colonized persons is likely (8). Although PRP-OMP and PRP-TT vaccines are equally effective after completion of the primary series, availability of more than one Hib vaccine in a clinic could lead to administration of the wrong vaccine for the first dose in these populations (5). For these reasons, CDC recommends that providers who currently use PRP-OMP-containing Hib vaccines (PedvaxHIB and Comvax) to serve predominantly AI/AN children in AI/AN communities continue to stock and use only PRP-OMP-containing Hib vaccines not affected by the recall and vaccinate according to the routinely recommended schedules, including the 12–15 month booster dose. In its vaccine stockpile, CDC has PRP-OMP-containing Hib vaccines not affected by the recall and will prioritize distribution of available PRP-OMP vaccines for use in AI/AN communities. AI/AN children not in AI/AN communities or who already receive PRP-TT conjugate vaccines should continue to be vaccinated with available vaccines according to the routinely recommended schedules, including the 12–15 month booster dose.

Limitations of the vaccine supply underscore the importance of surveillance for Hib disease in children and serotyping of *H. influenzae* isolates. ACIP recommends that public health practitioners conduct thorough and timely investigations of all cases of Hib disease. To maximize the amount of available vaccine, providers should order only 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. CDC, ACIP, and other partners will continue to monitor the supply of available Hib vaccines and the epidemiology of Hib disease and provide updates when available. FDA and CDC will continue to monitor the safety of Hib vaccines. Any adverse events that are potentially vaccine-related should be reported to the Vaccine Adverse Event Reporting System (VAERS) by telephone (800-822-7967) or online (<http://www.vaers.hhs.gov>). Additional information regarding Hib vaccine is available at <http://www.cdc.gov/vaccines/vpd-vac/hib/default.htm>. Updates on vaccine supply are available at <http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm#chart>.

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