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Joint Statement (concerning Thimerosal) of the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (PHS)

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The Food and Drug Administration (FDA) Modernization Act of 1997 called for the FDA to review and assess the risk of all mercury containing food and drugs. In line with this review, U.S. vaccine manufacturers responded to a December 1998 and April 1999 FDA request to provide more detailed information about the thimerosal content of their preparations which include this compound as a preservative. Thimerosal has been used as an additive to biologics and vaccines since the 1930's because it is very effective in killing bacteria used in several vaccines and in preventing bacterial contamination, particularly in opened multi-dose containers. Some but not all of the vaccines recommended routinely for children in the United States contain thimerosal.

There is a significant safety margin incorporated into all the acceptable mercury exposure limits. Furthermore, there are no data or evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule. Infants and children who have received thimerosal-containing vaccines do not need to be tested for mercury exposure.

The recognition that some children could be exposed to a cumulative level of mercury over the first six months of life that exceeds one of the federal guidelines on methyl mercury now requires a weighing of two different types of risks when vaccinating infants. On the one hand, there is the known serious risk of diseases and deaths caused by failure to immunize our infants against vaccine-preventable infectious diseases; on the other, there is the unknown and probably much smaller risk, if any, of neuro-developmental effects posed by exposure to thimerosal. The large risks of not vaccinating children far outweigh the unknown and probably much smaller risk, if any, of cumulative exposure to thimerosal-containing vaccines over the first six months of life.

Nevertheless, because any potential risk is of concern, the Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by European regulatory agencies, the European vaccine manufacturers, and the US FDA which examined the use of thimerosal-containing vaccines produced or sold in European countries.

The US Public Health Service and the American Academy of Pediatrics are working collaboratively to assure that the replacement of thimerosal-containing vaccines takes place as expeditiously as possible while at the same time ensuring that our high vaccination coverage levels and their associated low disease levels throughout our entire childhood population are maintained.

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The key actions being taken are:

1. A formal request to manufacturers for a clear commitment and a plan to eliminate or reduce as expeditiously as possible the mercury content of their vaccines.
2. A review of pertinent data in a public workshop.
3. Expedited FDA review of manufacturers' supplements to their product license applications to eliminate or reduce the mercury content of a vaccine.
4. Provide information to clinicians and public health professionals to enable them to communicate effectively with parents and consumer groups.
5. Monitoring immunization practices, future immunization coverage, and vaccine-preventable disease levels.
6. Studies to better understand the risks and benefits of this safety assessment

The PHS and AAP continue to recommend that all children should be immunized against the diseases indicated in the recommended immunization schedule. Given that the risks of not vaccinating children far outweigh the unknown and much smaller risk, if any, of exposure to thimerosal-containing vaccines over the first six months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.

While there is a margin of safety with existing vaccines containing thimerosal, there are steps that can be taken to increase that margin even further. Clinicians and parents can take advantage of the flexibility within the existing schedule **for infants born to Hepatitis B surface antigen (HbsAg)- negative women** to postpone the first dose of hepatitis B vaccine from birth until two to six months of age when the infant is considerably larger. Pre-term infants born to HbsAg-negative mothers should similarly receive hepatitis B vaccine, but ideally not until they reach term gestational age and a weight of at least 2.5 kilograms. Because of the substantial risk of disease, there is no change in the recommendations for infants of HbsAg-positive mothers or of mothers whose status is not known.

Also, in populations where HbsAg screening of pregnant women is not routinely performed, vaccination of all infants at birth should be maintained, as is currently recommended.

- In addition to the key actions mentioned above, the PHS Advisory Committee on Immunization Practices (ACIP) and the AAP Committee on Infectious Diseases will be reviewing these issues and may make additional statements.

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