

Thimerosal is a mercury-containing preservative that has been used as an additive in biologics and vaccines since the 1930s because it prevents bacterial and fungal contamination, particularly in multidose containers. Given the widely acknowledged value of reducing exposure to mercury, vaccine manufacturers, FDA, and other PHS agencies are collaborating to reduce the thimerosal content of vaccines or to replace them with formulations that do not contain thimerosal as a preservative as soon as possible without causing unnecessary disruptions in the vaccination system. FDA will expedite review of supplements to manufacturers' product license applications that present formulations for eliminating or reducing the mercury content of vaccines.

The major points in the Joint Statement of the American Academy of Pediatrics and the Public Health Service are:

1. 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. **Thimerosal contains a small amount of mercury in the form of ethyl mercury.**
2. *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.*
3. *There are no guidelines for ethyl mercury, but experts agree that methyl mercury guidelines are appropriate to use in this situation. There is a significant safety margin incorporated into all Federal guidelines on methyl mercury exposure.*
4. There is no evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule.
5. **The Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agree that the use of thimerosal as a preservative should be removed as soon as possible.**
6. Clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.
7. The recommendations remain unchanged for routine vaccination with DTaP/DTP, Hib, and for hepatitis B vaccination of infants born to hepatitis B surface antigen (HBsAg) positive mothers or mothers whose HBsAg status is unknown. **All products are acceptable including those which contain thimerosal.**
8. Clinicians and parents can take advantage of the existing flexibility in the immunization schedule to delay hepatitis B vaccination from birth until two to six months for infants born to mothers who are HBsAg negative. More details are offered below.

### **Conclusions**

**Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest. It is based on poor scientific methodology** (including studies that are too small, too short, and too limited in populations represented), which is, moreover, insulated from independent criticism. The evidence is far too poor to warrant overriding the independent judgments of patients, parents, and attending physicians, even if this were ethically or legally acceptable. Indeed, evidence is accumulating that serious adverse reactions are being ignored. Although this article has focused on hepatitis B vaccine, similar questions should be raised about others as well.