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Joint Statement Concerning Removal of Thimerosal from Vaccines

Dated: June 22, 2000 (material on this page was accurate only during this time period)

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Introduction

This statement has been prepared by the American Academy of Family Physicians, the American Academy of Pediatrics, the Advisory Committee on Immunization Practices, and the U.S. Public Health Service in response to 1) the progress being made in achieving the national goal declared in **July 1999** to remove thimerosal from vaccines, and 2) the results of studies to better assess any potential relationship between exposure to mercury in thimerosal containing vaccines and health effects.

Background

A Joint Statement issued by AAP and the PHS in July 1999 and agreed to by the AAFP **later in 1999** established the goal of removing the vaccine preservative thimerosal as soon as possible from vaccines routinely recommended for infants. Thimerosal is a

derivative of ethylmercury and has been used as an additive to biologics and vaccines since the 1930s because it is effective in killing bacteria and in preventing bacterial contamination, particularly in opened multi-dose containers. While there was no evidence of any harm caused by low levels of thimerosal in vaccines and the risk was only theoretical, this goal was established as a precautionary measure. There is public concern about the health effects of mercury exposure of any sort, and the elimination of mercury from vaccines was judged a feasible means of reducing an infant's total exposure to mercury in a world where other environmental sources of exposure are more difficult or impossible to eliminate (e.g., certain foods).

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Progress report on vaccine supply

During the year since the original statement, substantial progress has been made in removing thimerosal from vaccines. A hepatitis B vaccine without thimerosal produced by Merck Vaccine Division was released in **August 1999, and in March 2000**, a hepatitis B vaccine that does not contain thimerosal as a preservative was approved for SmithKline Beecham Biologicals. This SKBB product contains only a trace amount of mercury (less than 0.5mcg/dose), a greater than 96% reduction from the 12.5mcg in the previous SKBB vaccine and an amount considered clinically insignificant. A combination vaccine containing both hepatitis B and Haemophilus influenzae type b (Hib) vaccine produced by Merck Vaccine Division, Inc. has always been free of thimerosal. Thus, as of March 2000, all U.S children had access to hepatitis B vaccines that are free of thimerosal as a preservative.

In addition, three of the four Hib vaccines currently licensed for use in the United States do not contain thimerosal as a preservative. The fourth vaccine is produced by Wyeth Lederle which has marketed this Hib vaccine in both thimerosal free, single dose formulations and multidose, thimerosal-containing preparations. As of July 2000, Wyeth Lederle is expected to produce only the single dose, thimerosal-free formulation for the U.S. Thus, the Hib vaccine supply being produced will become entirely free of thimerosal as a preservative **beginning in July 2000**.

For DTaP vaccine, a thimerosal free vaccine produced by SKBB has been licensed and available in the United States since 1997. There are three other vaccine manufacturers whose DTaP vaccines still contain thimerosal as a preservative. Discussions are underway with these manufacturers and it is hoped that at least one additional DTaP vaccine without thimerosal as a preservative will become available in early 2001.

Based on this progress, the most likely maximum amount of ethylmercury that an infant may be exposed to from the routine immunization schedule has been reduced by 60% from 187.5mcg to 75mcg. Measles mumps rubella, varicella, inactivated polio, and pneumococcal conjugate vaccines have never contained thimerosal.

Progress report on research

Since July 1999, efforts to remove thimerosal from the US vaccine supply have been accompanied by research investigations to better assess the potential health effects of exposure to thimerosal-containing vaccines.

First, NIH scientists are collaborating with investigators from the University of Rochester and the Bethesda Naval Hospital to determine retrospectively the blood levels of mercury achieved following routine pediatric vaccination. Preliminary data from a very small number of term infants in these studies indicate that the blood levels of mercury produced by exposure to thimerosal preservative containing vaccines are less than 2mcg/L, the level many experts consider as background.

These findings differ from those recently reported by Stajich and coworkers (*J Pediatr* 2000;136:679-681) who found blood mercury levels of greater than 2.9 mcg/L in 9 of 15 premature infants who had received a hepatitis B immunization within the first week of life. However, all of these infants were very premature (birth weights < 1000 grams, mean birth weight of 748 grams). Hepatitis B immunization is not recommended for infants < 2000 grams unless their mother is HBsAg positive.

Second, CDC is using large automated databases that link vaccination and International Classification of Disease codes (ICD-9) stored in medical records in managed care organizations (the Vaccine Safety Datalink project, VSD) to rapidly screen for any possible association between exposure to thimerosal containing vaccines and a variety of neurologic, developmental, and renal outcomes.

In the preliminary screening phase of this investigation, CDC and VSD investigators observed no association between exposure to thimerosal containing vaccines and 12 of the 17 renal and neurologic ICD-9 codes examined from two of the managed care organizations studied. These 12 ICD-9 codes examined were extrapyramidal disease, autism, childhood psychosis, stammering, sleep, eating, misery disorders, mixed emotional conditions, infantile cerebral palsy, epilepsy, migraines, and unspecified renal conditions. From these preliminary data, an inconclusive correlation (i.e., one that is inadequate to support or refute a causal link) was observed between exposure to thimerosal containing vaccines and five of the 17 ICD-9 codes, including language delays, speech delays, attention deficit disorder, unspecified developmental delays and tics. There was no evidence of any increased risk for these codes among premature infants.

Reviews of these preliminary observations by expert consultants first at CDC and then from outside PHS identified many important shortcomings in the dataset and in this type of analytic approach. These consultants concluded that the correlation is very weak and

insufficient to support a causal relationship. This inconclusive information does not provide a sound scientific basis for making new policy decisions or changes in current policies. Nevertheless, because of the potential implications of this screening-phase observation, consultants urged further investigation.

In pursuit of these further studies, CDC investigators have obtained preliminary data from a third managed care organization. Analyses of these data using the same methods and having similar limitations as in the two earlier managed care organizations showed no association for two specific conditions, namely, speech delay, which in this dataset included language delay, and attention deficit disorder. The number of events was too small to examine the association with tics and the category of unspecified developmental delays was not defined clearly enough to permit reanalysis. Additional review of this dataset is planned and new studies which can test the hypotheses of interest more directly and definitively also are being considered by CDC.

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Policy

The AAFP, AAP, and the PHS in consultation with the ACIP reaffirm the goal set in July 1999 to remove or greatly reduce thimerosal from vaccines as soon as possible for the following reasons: 1) the removal or substantial reduction of thimerosal from vaccines is feasible, 2) the progress in removal which has been made to date is substantial, 3) the discussions between the Food and Drug Administration and the vaccine manufacturers in removing thimerosal are ongoing, and 4) the public concern about the use of mercury of any sort remains high. Based on information from the FDA and manufacturers, the PHS projects that the United States will complete its transition to a secure routine pediatric vaccine supply free of thimerosal as a preservative (i.e. at least two vaccine products each for Hep B, Hib, and DTaP) by the first quarter of 2001.

The use of any Hib or DTaP vaccine should continue according to the currently recommended schedule. The risk of not vaccinating children on time with DTaP to protect them against pertussis or with any remaining Hib vaccine is believed to far outweigh the risk, if any, of exposure to thimerosal containing DTaP and Hib vaccines which are still available or still being produced. Any new information from ongoing investigations will be monitored carefully by the PHS to determine if any change in this assessment and in existing recommendations is warranted.

Other vaccines such as diphtheria-tetanus, meningococcal, and influenza vaccines will still contain thimerosal after the first quarter of 2001. Diphtheria-tetanus (DT) and meningococcal vaccines are not recommended for children as part of the recommended childhood immunization schedule. Influenza vaccine is not recommended routinely for infants under 6 months of age, but should be given to infants and children 6 months of age and older

who are at high risk of morbidity and mortality from the influenza virus. Continued use of these products as indicated is recommended until thimerosal is removed or until new products without thimerosal are licensed.

The vaccination of children in much of the world will continue to require the use of multi-dose vials for reasons of cost, production, and storage capacity. Multi-dose vials require a preservative to prevent microbial contamination after the vial is opened. While thimerosal is currently the preferred preservative, manufacturers are encouraged to seek alternatives.

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Summary

In 1999, family physicians, pediatricians, federal health officials, and vaccine manufacturers stated that because any potential risk from mercury is of concern, and the elimination of exposure to mercury in the form of thimerosal from vaccines is feasible, thimerosal should be removed from vaccines as soon as possible. However, there remains no convincing evidence of harm caused by low levels of thimerosal in vaccines.

Since mid-1999, two new hepatitis B vaccine products have been introduced and one new Hib product will be produced next month to make the new supply of both hepatitis b and Hib vaccines for infants entirely free of thimerosal as a preservative. One of the four licensed DTaP vaccines is already thimerosal free, and at least one other thimerosal free DTaP vaccine is anticipated to be licensed by early 2001. Thus, the likely maximum number of micrograms of ethylmercury that an infant may be exposed to from the routine immunization schedule will have been reduced by 60%. This amount will be reduced even further in early 2001 when at least two vaccine products for hepatitis B, Hib, and DTaP are expected to be available. Meanwhile, research on the potential health effects of exposure to thimerosal is continuing, and information will be monitored closely by the PHS to determine if any changes in policy are needed.

The AAFP, AAP, ACIP, and the PHS recommend continuation of the current policy of moving rapidly to vaccines which are free of thimerosal as a preservative. Until an adequate supply of each vaccine is available, use of vaccines which contain thimerosal as a preservative is acceptable.

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