



Bulletin No. 6
March 30, 1979
Wyeth DPT Vaccine Recall

On Wednesday March 21 this office learned from the CDC, Atlanta that Wyeth Labs, after discussions with the CDC, had agreed to recall DPT vaccine associated with sudden unexplained infant deaths in Tennessee. The vaccine associated with these deaths was all of a single lot number - 64201. This lot number occurred only on 15-dose vials and 480,000 doses (32,000 vials) were produced. We were also informed that Alaska received 101 vials of this lot number in July, 1978. These vials were distributed **ONLY** from the Northern Regional Lab from mid-August to November 1978. We have contacted by phone all health care deliverers who we believe may have received DPT vaccine of this lot number. However, we ask that all Wyeth DPT vaccine currently stocked be checked and any of lot number 64201 be returned to your supplier in Alaska.

Single dose Wyeth DPT of lot numbers 61987, 61988, 61989, 61990, and 61991 are also being recalled. The Alaska Department of Health and Social Service **DID NOT** purchase any of these lot numbers. Anyone receiving single dose Wyeth DPT vaccine directly from the company should check this vaccine and return to the company any with these lot numbers.

To determine whether any deaths have occurred in Alaska related to this DPT vaccine lot number we have examined death certificates of infants less than 1 year dying of unexplained death between August, 1978 and January 1, 1979. Only two such cases were found and in both instances no immunization was given prior to death. However, we have also learned of a 6-week-old infant in Fairbanks with aortic stenosis who died suddenly 30 hours following a DPT immunization which may have been of the recalled lot number. In this instance it appears we will be unable to determine the exact lot number of the vaccine used. Any unexplained infant deaths or severe neurologic reactions possibly related to DPT immunization should be reported immediately to our office.

To provide more thorough and reliable information on this problem we are providing below the complete text of the CDC press release of March 22, 1979.

"Between August 1978 and March 1979, 77 infants in Tennessee died suddenly from unexpected causes - compared with 74 during the same period in 1977-78. These deaths were diagnosed as sudden infant death syndrome, or crib death. Of these 77 infants, eight died within a week of being vaccinated against diphtheria, tetanus and pertussis (whooping cough) using the same lot of DTP vaccine.

"Of these eight infants, one died in November 1978 and one in January 1979, both within 24 hours of having been vaccinated with this lot of vaccine. The Tennessee Health Department took no immediate action in either case because DTP vaccine is generally administered for the first time at two months of age - precisely the age when the risk of sudden, unexplained death is greatest in infants. Some incidence of sudden and unexplained deaths would, therefore, be expected by chance alone among infants that had received the vaccine.

"In early March CDC learned that two more infants had died within 24 hours of DTP vaccination, again from the same lot of vaccine produced by Wyeth Laboratories, Inc. That brought the total to four deaths within 24 hours of vaccination. On March 12, the Tennessee Health Department placed a hold on the use of this lot of vaccine and began an investigation of the problem. They discovered that four other infants had died within a week of having been immunized using this lot of vaccine, bringing the total to eight.

"Today at the request of the Food and Drug Administration, Wyeth Laboratories has voluntarily agreed to withdraw all unused doses of this lot of vaccine from use while Tennessee Health officials, the Center for Disease Control and the Food and Drug Administration continue the investigation of those events.

"These actions were taken out of an abundance of caution because it is far from clear the analysis of available data by CDC and FDA that there is any cause-and-effect relationship between this lot of DTP vaccine and the cluster of sudden infant deaths in Tennessee. The difficulty of demonstrating this relationship is the result of several factors.

"First, sudden infant deaths occur between the ages of one and six months, with a marked peak at two months. The initial DTP vaccination is generally administered at two months. By chance alone, therefore, some sudden infant deaths would have occurred shortly after DTP immunization using this lot of vaccine.

"The scientists were unaware of any previous association between clusters of sudden infant deaths and the administration of DTP vaccine. They agreed that the deaths gave cause for concern and deserved further study. But they did not feel that the statistical evidence established an association between the lot of DTP vaccine and the cluster of deaths.

Nevertheless, the Center For Disease Control decided that the prudent course was to err on the side of caution. Accordingly, the Food and Drug Administration asked Wyeth Laboratories to voluntarily withdraw all unused doses of this vaccine lot from further use. Both Wyeth and CDC estimate that two-thirds of the 480,000 total doses in this lot have already been administered.

"The events in Tennessee raise questions for which we have no ready answers. Even with sophisticated statistical techniques, it is extremely difficult to assess the relationship between these eight sudden deaths in Tennessee and this particular lot of DTP vaccine.

"Nonetheless, it is clear that we need more detailed analysis of the statistics that is currently available. CDC and the Tennessee Health authorities will continue to study the Data already available and those now being gathered concerning the sudden infant deaths and the lot of DTP vaccine used in Tennessee.

"Dr. William H. Foege, Director of the Center for Disease Control, praised Wyeth laboratories for their prompt and responsible action in withdrawing this lot of vaccine from use.

"It is important to emphasize, however, that this action applies only to one lot of DTP vaccine. DTP immunization can and should continue with other lots of Wyeth vaccine, as well as vaccines produced by other pharmaceutical manufacturers. The risks of serious side effects of vaccination are rare compared to the universal risk of disease, complications and death faced by the child who is not immunized against diphtheria, tetanus and pertussis."