SB
SmithKline Beecham
Pharmaceuticals

July 31,1999

Dr. Jeffrey Koplan, Director
Centers for Disease Control and Prevention
1600 Clifton Rd., NE
Atlanta, GA 30333
(404) 639-7111 (fax)

Dear Dr. Koplan,

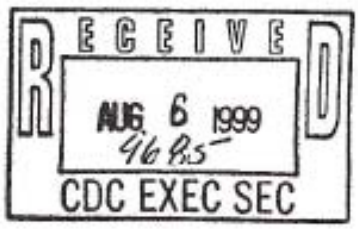
SmithKline Beecham Pharmaceuticals (SB) as a manufacturer of vaccines has been involved in discussions recently surrounding thimerosal in vaccines, and is aware of and sensitive to the related statements issued by the American Academy of Pediatrics (AAP), U.S. Surgeon General, the Department of Health and Human Services, and the Centers for Disease Control and Prevention (CDC). As a manufacturer, we agree that, despite the absence of any scientific data that thimerosal causes adverse effects, whenever possible "thimerosal-containing vaccines should be removed as soon as possible", as is recommended in the July 7 Joint Statement of the AAP and the U.S. Public Health Service (PHS). For this reason we wish to inform you that SB is in a position to supply Infanrix (Diptheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed), the only U.S. licensed DTPa vaccine that does not use thimerasol as a preservative, in enough quantities to supply the estimated U.S. market needs for at least the remainder of 1999 and the first half of 2000. By that time, other thimerosal free DTPa products, including SB's pentavalent DTPa/HB/IPV, will likely be available, pending FDA approval.

We have significantly increased our inventories of Infanrix in light of the fact that DTPa vaccines are currently a major contributor to the amount of thimerosal which may be given in the pediatric recommended vaccination schedule. Not only are there cumulatively five doses of DTPa vaccine administered to children under 7 years of age, but also three of those doses are recommended in the first 6 months of life. Furthermore, thimerosal-containing DTPa vaccines have the highest concentration of thimerosal among currently recommended vaccines with 25mcg of mercury per dose, more than twice the amount of hepatitis B vaccines. Consequently, infants who receive the first three doses of DTPa vaccine during the first six months of life are exposed cumulatively to 75mcg of mercury, nearing the threshold established by the U.S Environmental Protection Agency (EPA) of 80mcg of mercury. By contrast, infants receiving Infanrix for the primary series (and a non-thimerosal containing Hib vaccine), can receive all other recommended vaccines, irrespective of manufacturer, and still not exceed the cumulative levels of mercury under the EPA reference guidelines.

Several weeks ago, SmithKline Beecham was approached by the vaccine contracting department at the CDC inquiring about our ability to supply the entire U.S. DTPa market with Infanrix and the potential for an exclusive DTPa contract, until other non-thimerosal DTPa vaccines were licensed. In reviewing our inventory levels, SmithKline Beecham is now in the position to move forward with such a contract. We believe the exclusive availability of Infanrix DTPa moves the AAP, CDC and PHS much closer to their stated objectives of thimerosal free vaccines in the U.S. We look forward to discussing this possibility with you further in the days to come

Sincerely,

John Jabara, Vice President and Director
Vaccines Business Unit, U.S.



• Rob
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