

Greg Wallace
Script for April 8th Netconference

[Slide 1]

Thank you, Andrew. I will provide an overview of the current Pneumococcal Conjugate Vaccine shortage.

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The topics covered will be:

- 1) The timeline of the shortage
- 2) The reasons for the shortage
- 3) Production estimates during the shortage, and
- 4) The response to the shortage

This will be followed by further discussion of the response to the shortage by Dr. Moran.

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First, I will cover the timeline of the shortage. On December 19th, 2003, the Centers for Disease Control and Prevention announced that production constraints could cause delays in shipments of PCV in the first or second quarters of 2004. On February 13th, 2004, the CDC recommended temporary suspension of routine use of the 4th dose of PCV. On March 2nd, 2004, CDC recommended temporary suspension of routine use of the 3rd and 4th dose of PCV. These temporary recommendations were put in place to conserve vaccine that is in limited supply.

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What are the reasons for the current vaccine shortage? The production shortages are due to delays in the fill line process. These delays include scheduled maintenance on the fill line taking longer than expected and delays in increasing capacity to meet increasing demand for the vaccine. The shortage is NOT due to any problems with the final product that is produced.

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What is the magnitude of the shortage? For the period of January through April 2004, the total shipments of PCV are estimated to be less than or equal to 55% of the amount needed for a 4-dose schedule. This is why the recommendation was made to temporarily go to a 2-dose schedule. The period from mid-April to mid-May is projected to be the period of most limited supply. However, the duration and magnitude of this more limited supply may be less severe than previously expected based on the most recent projections. Improvements in supply are expected beginning in late May 2004, but this is not guaranteed. Updates will be provided as they become available.

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As an introduction to our response to the vaccine shortage, I will give a summary of what is being done. As I stated earlier, CDC has recommended limiting healthy children to 2 doses to conserve vaccine so more children receive at least 2 doses. CDC has implemented an allocation plan to ensure the equitable distribution of available vaccine to the public sector. The manufacturer, Wyeth, has implemented a similar allocation plan for the private sector. We are conducting weekly conference calls with CDC, the Food and Drug Administration, the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the manufacturer Wyeth, to update supply

projections and consider revisions to our response to the shortage. Up to date information can be found on our web site, www.cdc.gov/nip.

I will now turn it over to Dr. John Moran to further discuss our response to the shortage.
John.