

Brockner Ryan, Beth

From: Ball, Leslie
Sent: Tuesday, July 06, 1999 3:53 PM
To: Baylor, Norman
Cc: 'Pless, Robert'; Ball, Robert; Pratt, Douglas R.; Goldenthal, Karen; Geber, Antonia; BOLGER, PHILIP
Subject: RE: CDC Q and A's
Importance: High
Sensitivity: Confidential

Regarding the FDA calculations for Hg exposure from thimerosal, presented to the IAG on 6/28/99 and AAP on 6/30/99:

Above all, it is important to emphasize the original intent of the FDA calculations. The purpose of these calculations was to determine whether infant exposure to ethyl mercury exceeds established guidelines for exposure to methyl mercury. They were not intended to serve as maximum exposure limits, the manner in which the CDC is now using them.

These were meant to be preliminary calculations based on the most conservative assumptions (meaning maximum possible exposure to thimerosal in the first 6 months of life). We appreciated that there would be alternate (and perhaps better) approaches.

The differences between the CDC and FDA numbers appear to be based on the following:

- 1) 5% weight at 6 months (FDA: 4.1 kg; CDC 5.6 kg). Our number was based on growth curves for premature infants found in the Harriet Lane Handbook. The CDC numbers probably have a firmer basis (NHANES data?) In addition, the FDA weight was based on averaging male/female weights. CDC calculates these separately. The weight difference alone appears to allow an extra 14 ug exposure for the CDC calculations.
- 2) Time period of exposure: The FDA used 26 weeks (6 months); the CDC uses 30 weeks (7 months). This difference accounts for an extra 11 ug for the CDC calculations.
- 3) Average weight over 6 months: The CDC uses a weighted average month by month, the FDA used average weight between birth and 6 months. This different assumption does not contribute much to the difference between the CDC and FDA calculations.

If the CDC is planning to use these calculations as dosing guidelines, there are two important considerations:

1) These calculations do not account for other sources of Hg in the environment. Even infants can have additional exposures, e.g., breast milk.

2) Has the application of these calculations as exposure guidelines received the sign off by toxicologists? In prior discussions, the toxicologists seemed reluctant to state any Hg level was "safe". This approach leaves open the criticism that the PHS is arbitrarily designating a certain level as acceptable when there continues to be so much uncertainty about the science in this area.

I hope this information is helpful.

Leslie

*No Safe
Level!*



—Original Message—

From: Pless, Robert [SMTP:rkp2@cdc.gov]
Sent: Tuesday, July 06, 1999 12:25 PM
To: Ball, Leslie K. (FDA)
Subject: RE: CDC Q and A's

They were "taken over" by Barbara Reynolds et al.
Hopefully drafts are being circulated to your area as well.

By the way, I would like to touch base regarding your calculations for the maximum allowable "dose" in the first 6 months. You have a birth weight of 2.5kg and a weight of 4.1kg at 6 months. I cannot locate the 6 month weight. The text I have says 5.6

(see attached)

Rob.