**Brockner Ryan, Beth**

**From:** Patriarca, Peter
**Sent:** Friday, July 02, 1999 10:24 AM
**To:** BACHORIK, LAWRENCE
**Cc:** Baylor, Norman; Esber, Elaine; Goldenthal, Karen; Ball, Leslie; Deal, Carolyn D.
**Subject:** RE: Q and As

**Sensitivity:** Confidential

Larry: I also have a few suggestions and some "heads-up's" which you may wish to consider ... they represent my own personal views, and, in the interest of time, have not been cleared by my superiors.

You may wish to point out that (1) FDA continuously examines safety, potency, and purity issues for all vaccines and works closely with manufacturers to improve every product wherever and whenever possible [i.e., the thimerosal issue is part of larger, global effort to make vaccines even more safe and efficacious than they currently are]; (2) FDA began the process of encouraging thimerosal-free preparations before FDAMA through the IND and pre-PLA processes [I'm not sure if we can compile specific examples rapidly ... Karen Goldenthal may know]; and (3) thimerosal has potential benefits as well as potential risks -- it's not simply a matter of "thimerosal is a totally inert, unnecessary ingredient, and is potentially bad ... so let's get rid of it". Thimerosal has been an important component in the manufacturing of certain vaccines, and the addition of thimerosal to the final (multi-dose) container provides additional assurances that the product will not become contaminated with bacteria once the vial is entered by the practitioner. In addition, removal of thimerosal -- if and whenever possible [and FDA is now actively pursuing this, as you probably know] -- could have other important "non-medical" downsides, including the potential elimination of multi-dose presentations for certain vaccines, which will (i) increased the cost of vaccines; and (ii) increase storage [space] requirements in the clinic setting. You should also be aware that if the U.S. (and perhaps the EU) adopts a position that the theoretical risk of ethyl mercury exposure outweigh its potential benefits to the point where no vaccines used in the US or Europe will contain thimerosal [which is where things appear to be headed], this could also have a severe impact on global ("third world") vaccination programs, particularly for hepatitis B and whole-cell DTP vaccines, which, for various reasons, will almost certainly have to have thimerosal as an ingredient for potentially many years to come. WHO has already made a plea to the Academy of Pediatrics to "tread lightly" and "consider the global ramifications" of their evolving policy.

Finally, in my own personal opinion -- and as a heads-up because I believe it could come up -- the greatest point of vulnerability on this issue is that the systematic review of thimerosal in vaccines by the FDA could have been done years ago and on an ongoing basis as the childhood immunization schedule became more complex. The calculations done by FDA are not complex. I'm not sure if there will be an easy way out of the potential perception that the FDA, CDC and immunization policy bodies may have been "asleep at the switch" re: thimerosal until now.

-----Original Message-----
**From:** Ball, Leslie
**Sent:** Thursday, July 01, 1999 11:08 PM
**To:** BACHORIK, LAWRENCE
**Cc:** Baylor, Norman; Esber, Elaine; Patriarca, Peter; Goldenthal, Karen
**Subject:** Q and As
**Sensitivity:** Confidential

Larry:

Attached are my suggested revisions to the Q and As. Regarding the literature review, we found several reports of acute toxicity at high doses, as well as hypersensitivity reactions at low doses, especially from topical exposure. Regarding the VAERS search, there were 45 reports in the VAERS database from 1990 to 1998 for thimerosal. Most reports involved allergic reactions (hypersensitivity), although a cause-and-effect relationship could not be established.

I hope this helps.

<< File: thimerosalQA1.doc >>