

Brockner Ryan, Beth



From: Patriarca, Peter
Sent: Tuesday, June 29, 1999 12:39 PM
To: 'rhb2@cdc.gov'; 'jfc1@cdc.gov'
Subject: FW: "vaccine preservative WG"

Roger/Jose: have not yet received Roger's "position paper" by e-mail, but wanted to get some comments to you quickly. Draft we heard on the call is really excellent. However, (1) would add some of the elements of my "pros and cons" listing below (especially related to the BENEFITS of having thimerosal in the first place); and (2) try to avoid suggesting that the "interim plan" would be effective "immediately". The fact of the matter is that an "interim plan" (for potential removal of thimerosal) has ALREADY been in place for MANY YEARS ... we just need to "speed up" the EXISTING plan ... not create a "new" interim plan". We are proactive ... not reactive. Thanks. Peter P.

-----Original Message-----

From: Patriarca, Peter
Sent: Tuesday, June 29, 1999 9:42 AM
To: 'Myers, Martin G.'; 'mjs2@cdc.gov'; 'tazp0@cdc.gov'
Subject: RE: "vaccine preservative WG"

PLEASE GIVE TO MARTY MYERS ASAP.

Marty: I have developed a "quick-and-dirty" pros and cons analysis for the AAP policy statement

The AAP should release its policy statement in more-or-less current form:

PROS

Will demonstrate that the AAP reacted urgently to recently uncovered information, and to disclose this information to practitioners and consumers.

Will demonstrate that the AAP adopts the most conservative position possible when it comes to protecting American children.

Will force manufacturers to develop "crash" programs for removal of all thimerosal from all vaccines.

CONS

Will raise questions about FDA being "asleep at the switch" for decades, by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products. Will also raise questions about various advisory bodies about aggressive recommendations for use. [We must keep in mind that the dose of ethyl mercury was not generated by "rocket science": conversion of the % thimerosal to actual ug of mercury involves 5th grade algebra. What took the FDA so long to do the calculations? Why didn't CDC and the advisory bodies do these calculations while rapidly expanding the childhood immunization schedule?]

Will precipitate a vaccine shortage, leaving many children unimmunized. Removal of thimerosal could delay the availability of sufficient supplies of vaccines for at least 2 years, pending proper studies.

Thimerosal has benefits: it is there for a reason. Precipitous removal may generate problems in vaccine stability (affecting efficacy), and component inactivation (affecting safety). Proper studies must be done before it can be removed from products without a thimerosal-free presentation.

Will precipitate a worldwide crisis in confidence in vaccines. This is especially true for whole-cell DTP vaccines, which are still being used throughout much of the world. Thimerosal is used in these vaccines as an inactivating agent for pertussis cells.

ALTERNATE APPROACH: LOW KEY, SYSTEMATIC, DELIBERATE PRIVATE-PUBLIC APPROACH

PROS

Already going on for quite some time.

Shows careful consideration to all benefits and risks (as enumerated above) with rational and deliberate plan of action.

Consistent with European position.

DNS