## Brockner Ryan, Beth

From

Patriarca, Peter

Sent

Tuesday, June 29, 1999 12:39 PM 'thb2@cdc.gov'; "fc1@cdc.gov'

To: 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 BENEFTTS of having thirmerosal 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 thirmerosal) has ALREADY been in place for MANY YEARS ... we just need to "speed up" the EXISTING plan ... not create a "now" interim plan". We are proactive ... not reactive. Thanks. Peter P.

-Original Message

From

Patriasca, Peter

Sent

Subject

Tuesday, June 29, 1909 9:42 AM
"Myors, Martin G.", "six2@cdc.gov"; "ezg0@cdc.gov"
RE: "vaccine preservative WG"

PLEASE GIVE TO MARTY MYERS ASAP.

Marty: I have developed a "quick-end-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 "autopait 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 demand tilly instruct with instruction and the relations of the % frimerosal to actual up of mercury with a positive manufacture of the calculations? Why didn't CDC and the advisory bodies are the childhood immunication about the childhood immunication about the do these claculations 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.

Thirmerosal 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 thimerogal-free presentation.

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

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.

ONS