

INTRODUCTION

I am, Dr. Paul G. King, speaking on behalf of the American public and the Coalition for Mercury-free Drugs (CoMeD) [<http://www.mercuryfreedugs.org>], an advocacy group dedicated to the removal of mercury from all drugs.

I am neither affiliated with the government nor any pharmaceutical manufacturer.

My background is in the area of CGMP, regulatory compliance, and sound science.

I am a PhD Analytical Chemist with a MS in Inorganic Chemistry – I am not a “vaccinologist”!

If you are interested you can find my credentials and background on my website (<http://www.dr-king.com>).

In general, my oral presentation will discuss Aventis' proposed new vaccine, Menactra™, from the viewpoint of the reduced mercury-poisoning risk to all from this vaccine as compared to the current Menomune® meningococcal vaccine, the current Thimerosal-preserved vaccine (50 µg Hg/mL) as well as the safety concerns that the data I was given failed to address.

REMARKS

First, nowhere, either in my discussions with an Aventis representative or in the information provided was the level of mercury in Menactra™ revealed. Verbally, I was told it is “zero” but no quantitative values were supplied to support this assertion. Moreover, based on tests of two other manufacturers' vaccines that were purported to contain “no” or “zero” mercury that were found to contain low, but not “zero,” levels of mercury, this question needs to be answered BECAUSE studies by Leong¹ have found mercury neurotoxicity at levels below 1 part per billion ($\sim 4 \times 10^{-11}$ g in 2 µL applied to neurons in 2-mL preparations).

Second, though the data show that Menactra™ probably is no worse than Menomune® as a vaccine and, unlike the represented behavior of Menomune®, Menactra™ booster doses boost previous immunity, the manufacturer presented no data the vaccine candidate is, a priori, safe – just that it is no worse than the present approved vaccine (a fundamentally less-than-sound scientific practice).

Third, the data package glossed over the fact that the existing vaccine, Menomune®, seems to have shifted the relative prevalence of the strains and, because it failed to identify other than the “C” and “W-135” strains, one cannot know the extent to which vaccination may lead, at some future time, to the emergence of a virulent “now rare” strain that will trigger a major outbreak.

Moreover, no risk/benefit analysis is provided nor is any concrete data furnished that PROVES vaccination guarantees EFFECTIVE long-term protection (up to three years) to the 90 % initially vaccinated who were deemed to be effectively protected.

Nonetheless, on balance, *being forced to consider the lesser of two evils*, I would recommend that the committee approve Menactra because, *if nothing else*, it seems to reduce the poisoning risk to mercury-sensitive individuals over the current vaccine.

¹ Christopher C. W. Leong, Naweed I. Syed and Fritz L. Lorscheider, “Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury,” *NeuroReport*, 12(4) pages 733-737 (2001).

However, I would also recommend that the following actions be taken:

1. The approval requires post-approval monitoring (Phase IV trials) for a period of not less than 5 years.
2. Concomitant with the approval of Menactra™, the Center for Biologic Evaluation and Research (CBER): a) revokes the license of Menomune®² and b), within 90 days of the approval of Menactra, Aventis agrees to withdraw all stocks of Menomune® and also agree, in writing, to destroy all of the recalled doses because: i) Menomune's safety vis-à-vis mercury-sensitive persons has **never** been proven and ii) removing this vaccine will increase the safety of the approved vaccines as 42 U.S.C. 300aa-27 expects.
3. To minimize strain shift, a) the vaccine should **ONLY** be approved for the vaccination of the most seriously at-risk subpopulations (e.g., in-coming college freshman who reside in dormitory settings, military conscripts/volunteers on entry into the service, orphanage residents, nursing-home or residential communities for the elderly) and, for similar reasons, b) vaccination should be restricted to an initial dosing and one booster dose at three years – subject to a review after 5 years of experience under the post-approval surveillance program, and c) to prolong a baby's acquired maternal immunity, DHHS should strongly promote breastfeeding for not less than two years.

In closing let me assure this panel that failure to truly consider these simple science-based requests and act appropriately on them may further undermine the public's willingness to subject themselves and their children to vaccines that have real costs and real risks to them for the sake of the purported benefits to the population as a whole.

Rather than continuing to try to increase the number of vaccines and the number of doses given to the point that bad vaccines (e.g., the Lyme disease and smallpox vaccines) and worse practices are incorporated into the "vaccine schedule," the money would be better spent in: a) reemphasizing the importance of personal hygiene and b) providing clean housing for the poor and homeless!

For example, since bedbugs, and NOT direct contact, are the vector that transmits SMALLPOX and, with supportive medicines, the death rate is under 10 %, the DHHS would be better off spending money on: a) providing clean insect-free housing for the poor and homeless and b) promoting the washing of bed clothes with very hot water instead of trying to vaccinate the public and cause thousands of unnecessary cowpox reactions and hundreds of unnecessary deaths.

Finally, does the cost of one population dose (> \$ 80.00/dose X 300,000,000 people) really outweigh the "potential" maximum benefits per year? [Note: The historical data provided do NOT seem to support a significant benefit over no vaccine for other than confined diverse populations (like, college students living in dorms, military inductees, jail populations on initial intakes, nursing homes, orphanages, and group homes).]

² Given the mercury content of the Menomune® vaccine, this vaccine should, in any case, be removed from the market under the "make vaccines safer" provisions of 42 U.S.C. 300aa-27.