CoMeD

Coalition for Mercury-free Drugs
NJ Representative
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Wednesday, 23 February 2005

Jesse L. Goodman, M.D., M.P.H.
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Re: Your 4 February 2005 response to Docket Number 2004P-0349/CP1

Dear Dr. Goodman:

Thank you for responding, *in accordance with the FDA regulations on citizen petitions (21 Code of Federal Regulations 10.30(e)(2))*, to **CoMeD**'s citizen petition, *dated July 30, 2004*, which was submitted to and filed with Division of Dockets Management on Wednesday, August 4, 2004.

Thank you also for informing us that CBER is "continuing to work on" the Agency's response to our petition.

However, we disagree with your assessment that we made "numerous requests" or raised "complex issues."

Factually, we only raised a few (four) issues that can be simply characterized as follows:

1. Immediately bar the administration of Thimerosal-preserved vaccines to pregnant women and children under the age of 36 months (under the statutory mandate to do so that is clearly set forth in 42 *United States Code* (U.S.C.) Section 300aa-27).
2. Suspend the approval or licensing of any FDA-regulated product that contains Thimerosal or any other mercury-based compound as a preservative, or adjuvant, in the final formulation under 42 U.S.C. Section 300aa-27(a)(2) for vaccines and the general "public safety" authority granted in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Chapter 9) for drugs other than vaccines.
3. Issue a Class I or, failing that, a Class II recall of all batches of multi-dose vaccines that contain a Thimerosal preservative level of more than 0.001 % because, *as repeatedly admitted by senior CBER personnel in Congressional testimony*, the required scientifically sound and appropriate chronic safety studies to prove that such vaccines are safe were not conducted as the laws governing such drugs require.
4. To protect public health and safety, issue orders banning vaccines and other drugs containing more than trace levels of mercury (in any form), because, *as repeatedly admitted by senior CBER personnel in Congressional testimony*, the required scientifically sound and appropriate clinical studies to prove that such are safe have apparently not been conducted as the laws governing drugs require.

Of these general issues, only Issues "3" and "4" and the concerns for drugs that are not vaccines broached in Issue "2" raise questions that could conceivably be characterized as "complex issues."

The vaccine matters, raised in Issues "1" and "2," are straightforward statutory compliance issues because 42 U.S.C. Sec. 300aa-27. Mandate for safer childhood vaccines clearly states (bolding added for emphasis):

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"(a) ...the Secretary shall –

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines. ..."

Therefore, *considering that the actions requested for Issues "1" and "2" simply request the Agency to comply with a clear statutory mandate that is plainly set forth in 42 U.S.C. Section 300aa-27 for vaccines and the fact that the Secretary clearly has the authority to suspend and revoke the license for a vaccine,* we are at a loss to find that your "interim" response apparently indicates a knowing decision by the Agency to disregard a clear statutory mandate for reducing "the risks of adverse reactions to vaccines."

Given the revelation on Tuesday, 8 February 2005 on the front page of the Los Angeles Times that Merck was aware of the problem with the mercury level in vaccines in 1991, the Agency's apparent knowing failure to address Issues "1" and "2" for vaccines in the manner requested is even more puzzling.

In addition, it seems that, *for these two issues*, the Secretary of the Department of Health and Human Services and the Acting Commissioner of the Food and Drug Administration are knowingly holding themselves above the statutory mandates set forth in 42 U.S.C. Section 300aa-27 because the adverse reactions documented for Thimerosal-preserved vaccines are significantly higher than the adverse reactions for the *corresponding* trace-Thimerosal vaccines.

Hopefully, *given the recent revelations of Merck's awareness in 1991 of the hazard posed by the organic mercury in vaccines and the Agency's admissions that the requisite acute, short-term and, most important, long-term scientific studies to prove that the inclusion of neurotoxic mercury compounds (that are known to be converted into mercury species that both accumulate in the human brain and have been proven to be toxic to the brain), have not been conducted,* the Agency will act rapidly as the petition requests for vaccines and, shortly thereafter, for those other drugs that contain added mercury.

We are only seeking to have the Agency to fulfill its obligations to protect the public health.

Should the Agency fail to so act within the next 90 days, we would call upon the Justice Department to

1. Take legal action, *at the highest level,* against those individuals in the federal government who are most responsible for the apparent knowing failure to act in accordance with the cited statute for vaccines (42 U.S.C. Section 300aa-27), and
2. Consider taking action, at the highest level, against those individuals in the federal government who are most responsible for the apparent knowing failure to require the manufacturers of drugs that contain mercury at any level to prove that the inclusion of the mercury in the drug was safe, using the rubric that the level of the mercury species present was no less toxicologically safe, and caused no additional, more frequent, or more severe adverse reactions, than the same formulation without the mercury species present.

Respectfully yours

Paul G. King 23 Feb 2005

Paul G. King, PhD, *Founder*
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