Monday, August 09, 2004

To ALL Who Question The Safety Of The Mercury In Their Drugs (including, but not limited to, vaccines, sera, and preserved liquids):

Last Wednesday, a small grassroots group of parents and scientists, known as **CoMeD** (**Co**alition for **Me**rcury-free **D**rugs), filed an official "Citizen Petition" with the Food and Drug Administration (FDA) that requests the FDA and the Department of Health and Human Services (HHS), as appropriate, to:

- Immediately issue an order barring the administration of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than "trace" (more than 0.5 micrograms per dose) levels of Thimerosal to pregnant women and children under the age of 36 months.
- Suspend the approval or licensing of any FDA-regulated product that contains Thimerosal or any other mercury-based compounds as a preservative, or adjuvant, in the final formulation unless the total level of said compounds is *not more than* 0.5 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, not more than 0.5 micrograms of mercury per day.
- Announce a recall of all batches of multi-dose vaccines that contain a Thimerosal level of more than 0.001 % (10 μg per mL).
- Issue orders:
  - Banning vaccines, and other drugs, containing more than 0.5 microgram (μg) of mercury per dose of product from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after 1 January 2006.
  - Requiring, *after 1 January 2006*, the recall and destruction of ALL:
    - vaccines remaining in commerce that contain more than 0.5 μg of mercury per dose and
    - other drug products remaining in commerce that contain more than 1.0 μg of mercury per mL (or g) of drug,

  unless the manufacturer thereof can prove that the mercury-based compound in said vaccine or other drug product causes no adverse neurological health outcomes in any group or subgroup of *susceptible* individuals, including, but not limited to, males, fetuses, newborns, children, and adolescents.

A "Citizen Petition" is a federally established avenue of recourse for the public to pursue a review of any aspect of the FDA's oversight of foods, drugs, medical devices, and cosmetics.

By rule, the FDA, the Agency that oversees such filings, has 180 days to respond to the petitioners' requests.

Our "Citizen Petition" petition has been assigned the FDA Public Docket identifier, "**2004P-0349**" and should soon be linked to, and available on, the electronic edition of this docket (http://www.fda.gov/ohrms/dockets/default.htm).

Since the FDA will review your submitted comments to the docket along with the petition, we urge you to submit your supportive comments to this docket by **Wednesday, 6 October 2004**.

To facilitate your commenting, we have placed a copy of the filed petition on our web site www.MercuryFreeDrugs.org.

IF you belong to an advocacy group, are registered as a business in your locality, or choose to become one for the sake of this effort, **THEN** please submit copies of your comments on behalf of

your group, so that they will then be linked to the FDA's e-Docket's electronically accessible documents, and all may read and review them through the Internet.

To do this, **please:**

1. Address your comments to:
   Dockets Management Branch
   Food and Drug Administration
   Department of Health and Human Services
   5630 Fishers Lane
   Room 1061
   Rockville, MD 20852
2. Make your comments on behalf of some group of which you are a member (e.g., a parent advocacy or support group, an educational institution, or a business)
3. Include a cover letter that: **a)** references your written remarks to "**Public Docket: 2004P-0349**" **and b)** requests your comments and any supporting information you submit be made available to the public through the FDA's e-Docket, **and c),** *if you can*, states that you are "writing in support of the petition filed by CoMeD"
4. Submit two copies of your written remarks
5. Use a transmission means that provides you with a traceable receipt to ensure you know when it arrives at the FDA's Division of Dockets Management.

As you are aware, the current vaccination guidelines prescribe the flu shot for pregnant women and children between 6 months and 5 years of age in the nation.

Most of the doses available will contain 0.01 % Thimerosal.

Even a 0.25-mL dose of such 0.01-%-Thimerosal-preserved vaccines contains 12.5 μg of mercury.

Based on the EPA's methyl mercury intake guidance, this level exceeds the implicit recommended maximum for mercury (0.093 μg/kg/day) unless the infant, child or adult weighs more than 134.4 kg (296.3 pounds).

Thus, we are seeking to protect the unborn, and the current generation of children between 6 months and 5 years of age, from the risk of the tragedy that has befallen many of our own children

In closing, we thank Paul G. King, PhD, Dr. Mark Geier, MD, PhD and FABGM, Mr. David Geier, BA, and Brian G. Hooker, PhD for contributing their scientific and technical expertise to this project; Ms. Kelli Ann Davis and the Rev. Lisa Sykes for their project leadership; Ms. Bobbie Manning for contributing her expertise in interfacing with the media; and Ms. Leslie Weed for her expertise in information and document gathering.

With a real hope for effecting meaningful change, we urgently seek your active support for our Citizen Petition, **FDA Public Docket: 2004P-0349**.

Sincerely,

Coalition for Mercury-Free Drugs (CoMeD)

[**Note:** If you have questions, please contact CoMeD through its website, http://MercuryFreeDrugs.org.]