

Friday, August 6, 2004

To All Interested Physicians, Scientists and Legal Scholars,

This Wednesday, in Rockville, Maryland, at the Division of Dockets Management of the Food and Drug Administration (FDA), a small grassroots group of parents and scientists, known as CoMeD (Coalition for Mercury-free Drugs), filed a “Citizen Petition” that requests the FDA or 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 preservative level of more than 0.001 % (1 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” 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>). Because the FDA is required to consider the petition along with the comments made thereto in its review process, we urge you to add your supportive comments to this docket within the sixty-day period following its posting on the electronic edition of the Public Docket (the e-Docket).

Therefore, we have placed a copy of the petition that we filed on our web site www.mercuryfreedrugs.org to facilitate your review of this petition.

If, after reading the petition, you, or your group, have supportive information or research, bearing on the issues we raise, we urge you to submit your comments and corroborative documentation to the FDA database as soon as you can.

To facilitate having your comments linked to the e-Docket's electronically accessible documents associated with the petition, so that all may read and review them through the Internet, 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 medical practice, educational institution, advocacy group or 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
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.

Hopefully, if physicians, scientists and legal scholars who:

- o treat children with neurodevelopmental disorders and/or mercury toxicity, **and/or**
- o study the toxicity of mercury, mercury-compounds, and/or products containing any form of mercury

add their comments to this docket, then, not only will the case for a ban on the manufacture, distribution and use of 0.01%-Thimerosal-containing drugs be made stronger but also an extensive database of information regarding the dangers of Thimerosal will be generated on the Public Docket's website. [Note: If you choose to submit unpublished research or your published articles, please remember to include an explicit statement in your submission that your submission is not copyright protected so that it may be published in the e-Docket.]

As you are or should be aware, the current United States' vaccination guidelines prescribe the flu shot for pregnant women and children between 6 months and 5 years of age. 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. [Nota Bene: According to the most recent AUTISM A.L.A.R.M., 1 child in 6 is diagnosed with a developmental disorder and/or behavioral problem, 1 child in 166 is diagnosed with an autism spectrum disorder and, based on epidemiological studies, more than 80 % of the children with an “autism spectrum disorder” are male.]

In closing, we thank Paul G. King, PhD, Mark R. Geier, MD, PhD and FABGM, David A. Geier, BA, and Brian G. Hooker, PhD, for contributing their scientific and technical expertise to this project; Kelli Ann Davis, BA, and Lisa Sykes, MDiv, for their project leadership; Bobbie Manning, for contributing her expertise in interfacing with the media; and Leslie Weed, BA, 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, **2004P-0349**.

Sincerely,

Coalition for Mercury-Free Drugs (CoMeD)

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