Citizen Petition To Ban Use of Mercury in Medicine

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WASHINGTON, DC – On August 24, 2007, a grassroots group of parents and scientists, known as CoMeD (Coalition for Mercury-free Drugs), filed a comprehensive 447-plus-page "Citizen Petition" with the U.S. Food and Drug Administration (FDA).

CoMeD filed this petition as a part of its efforts to protect the public from unnecessary mercury poisoning.

This petition seeks to ban the addition of any mercury compound to any medicine <u>unless</u> that use is proven toxicologically safe.

Specifically, this petition asks the FDA and/or the Department of Health and Human Services to:

- 1. IMMEDIATELY issue an order barring the administering of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than 0.05-micrograms-per-dose levels of Thimerosal to pregnant women and children under the age of 60 months,
- 2. 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 <u>unless</u> the total level of said compounds is *not more than* 0.05 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, *not more than* 0.01 micrograms of mercury per day,
- **3.** Issue a Class I or, *failing that*, a Class II recall of all batches of multi-dose vaccines that contain a Thimerosal level of more than 0.001 %, and
- **4.** *To protect public health and safety*, issue orders:
 - a. Banning vaccines and other infrequently administered biological drug products providing *more than* 0.05 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 2008,
 - **b.** Banning other drug products providing *more than* 0.01 μg of mercury per day from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after 1 June 2009, and
 - **c.** Requiring, after 1 January 2008, the recall and destruction of ALL:
 - i. Vaccines remaining in commerce that contain *more than* 0.05 µg of mercury per dose, and
 - ii. Other drug products remaining in commerce that contain *more than* 0.1 μg of mercury per mL (or g) of drug,

<u>unless</u> 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.

Our "Citizen Petition" petition has been assigned the FDA Public Docket identifier, "2007P-0331" 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, we urge all interested in protecting their children from unnecessary mercury exposure 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). For instructions on how to comment to the docket, please visit: www.mercury-freedrugs.org after Labor Day.

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.