

CITING RECENT PROOF OF HARM, PARENTS AND SCIENTISTS PETITION FDA FOR A BAN ON ADDING MERCURY TO DRUGS, AND GIVING MERCURY-CONTAINING DRUGS TO PREGNANT WOMEN, NEWBORNS, AND CHILDREN

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Coalition for Mercury-Free Drugs (CoMeD), a grassroots group of parents and scientists, seeks to ban the making and dispensing of drugs that contain neurotoxic mercury components.

On Wednesday, August 4, 2004, CoMeD filed a formal “Public Citizen” petition with the Food and Drug Administration (FDA).

The petition first requests the Secretary of Health and Human Services (HHS), Tommy Thompson, or the FDA Acting Commissioner, Lester Crawford, to immediately issue an order barring the administration of any Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical products, that contains more than “trace” (sub-parts-per-million) levels of mercury to pregnant women and children under the age of 36 months.

The petition also requests the FDA to 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.”

Finally, the petition requests the FDA to issue a Class I or, *failing that*, a Class II recall of all batches of multi-dose vaccines that contain more than “trace” levels of Thimerosal.

Contrary to public perception, drug makers are adding a known neurotoxic mercury-based compound (Thimerosal) to over-the-counter (e.g., ophthalmic solutions, and ear and nasal drops) and prescribed (e.g., the influenza and other vaccines, and RhoD) drug products

Further, these drug makers are adding this mercury-containing component without adequately proving the safety of the resulting mercury-containing drug products.

For decades, in scientific and medical studies, independent researchers have consistently found that the use of Thimerosal as a “preservative” (at the 0.01% level) is **not** safe.

Moreover, safer effective preservatives (e.g., benzethonium chloride, phenol and 2-phenoxyethanol) are readily available.

In the case of preserved vaccines, some drug makers are already using these safer preservatives.

Recent studies, cited in this petition, clearly prove the causal link between mercury exposure and neurodevelopmental disorders (NDDs).

These studies also establish that, *though susceptibility to NDDs is genetically linked and mitigated by other factors*, mercury is the causative agent.

These NDDs are currently at epidemic levels.

The 2004 AUTISM A.L.A.R.M., *jointly issued by HHS, the Centers for Disease Control and Prevention and the American Academy of Pediatrics*, recognizes:

- “• 1 out of 6 children are diagnosed with a developmental disorder and/or behavioral problem” and
- “• 1 in 166 children are diagnosed with an autism spectrum disorder.”

Thus, granting CoMeD’s first request is vital because most of the available influenza vaccine doses contain 0.01 % (50 µg mercury per milliliter [mL]) of Thimerosal.

The applicable EPA implicit mercury guideline is 0.093 µg/kg/day.

Thus, a single 0.25-mL “preserved” flu shot, containing 12.5 µg of mercury, exceeds that guideline unless the recipient weighs more than 297 pounds (134.4 kg).

Based on these realities and the FDA’s duty to protect the health of all of the public, CoMeD expects the reviewers of this petition to grant CoMeD’s requests.

The quicker the Agency grants each CoMeD’s request, the sooner the FDA will begin reducing the risk of irreversible neurological harm to susceptible individuals of all ages.