CoMeD Inc.

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Federal Judge Considers Protecting Pregnant Women from Mercury-preserved Flu Shots

Press Release
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Washington, DC – In their lawsuit against the defendants, the Secretary of Health and Human Services (the Secretary) and Commissioner of the U.S. Food and Drug Administration (FDA), the Court has granted the Coalition for Mercury-free Drugs (CoMeD, Inc.) plaintiffs a hearing on their motion for a preliminary injunction to stop pregnant women from being given mercury-preserved flu shots. The Women's Division of the United Methodist Church, ***Mothering Magazine*** and individual people, *from as far away as India*, have submitted sworn declarations in support of CoMeD plaintiffs' lawsuit.

Thimerosal (49.6-wt% mercury) is used as a preservative in most flu shot doses (mercury-preserved flu shots). It has been confirmed as the preservative component for "preserved" or "multi-dose" "swine flu" vaccine formulations. Currently, Thimerosal-preserved flu shots may legally be given to pregnant women in most States. Pregnant women are presently one of the primary targets for the upcoming "swine-flu" campaign. In response to the CoMeD plaintiffs' legal challenge, the FDA has, as of August 17, 2009, failed to produce the vaccine maker's clinical and/or toxicological proofs that the level of mercury contained in their Thimerosal-preserved flu vaccine is safe to the required standard, "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient,".[1]

Based on statements by the producers of Thimerosal, exposure *in utero* can produce fetal death, mild to severe mental retardation, and impaired fertility. According to the package inserts for all inactivated-flu shots, the vaccines producers have not proved their safety to pregnant women and their unborn children. One government study reviewed more than 50,000 pregnancy-outcome instances and found links between both low-level topical and single-vaccine-dose Thimerosal exposures during pregnancy and significant increased risks for serious birth defects (e.g., cleft palate and microcephaly) in the child. Many published toxicological papers and several recent multi-case studies in children have linked low-level Thimerosal exposure to adverse developmental outcomes in children.

The Court has granted the CoMeD plaintiffs a hearing on their motion for a preliminary injunction to prevent these injuries to the next generation of our children. This injunction asks the Court to stop:

- The vaccination of pregnant women with any mercury-preserved flu vaccine, and
- The Secretary and the Centers for Disease Control and Prevention (CDC) from recommending the vaccination of pregnant women with mercury-preserved flu shots.

The Court has scheduled a hearing on the CoMeD plaintiffs' motion on August 26, 2009.

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[1] This prerequisite is a ***minimum*** safety requirement in the current good manufacturing practice (CGMP) regulations set forth in 21 CFR § 610.15(a) for preserved biological drug products that the vaccine makers of preserved vaccines are required to: **a)** meet, and **b)** submit proof of safety to this CGMP ***minimum*** in their Biological License Application (BLA) (by 21 CFR § 601.2(a)) **before** the FDA can legally approve the vaccine maker's BLA (as per 21 CFR § 601.4, governing the FDA's conduct with respect to proof of safety and BLA approval).