IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL G. KING, PH.D., *FOUNDER*, FACILITY, AUTOMATION MANAGEMENT ENGINEERING (FAME) SYSTEMS, INDIVIDUALLY & AS NEW JERSEY REPRESENTATIVE FOR, AND REV. LISA KAREN SYKES, INDIVIDUALLY AND AS VIRGINIA REPRESENTATIVE FOR,	)	
Coalition for Mercury-free Drugs 33A Hoffman Avenue Lake Hiawatha, NJ 07034-1922	)	**CIVIL ACTION NO.**
Plaintiffs,	)	
vs.	)	
MICHAEL O. LEAVITT, SECRETARY	)	
Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201	)	
ANDREW C. VON ESCHENBACH, M.D., ACTING COMMISSIONER	)	
Food and Drug Administration (FDA) 5600 Fishers Lane Rockville, MD 20857	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs bring this action pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-394 (FDCA), Public Health and Welfare Act, 42 U.S.C. §§ 262 and 300aa-10 (PHWA) and the Administrative Procedure Act, 5 U.S.C. §§ 555, 702 and 706 (APA), to compel the United States

Department of Health and Human Services (HHS) and the United States Food and Drug Administration (FDA) to act on Coalition For Mercury-Free Drugs (CoMeD) Plaintiffs' petition seeking to have the Secretary of HHS and the FDA *fully* comply with the laws requiring unequivocal proof of safety for all drugs, including vaccines, and proof that any preservative is "sufficiently nontoxic," as well as the laws requiring the Secretary of HHS to reduce adverse reactions in vaccines and to prove the safety for any and all drugs containing any level of any added Thimerosal and/or any other added mercury-containing compound for administration to any mercury-poisoning-susceptible sub-populations.

2. On July 30, 2004 CoMeD Plaintiffs' petitioned HHS and the FDA, pursuant to 21 C.F.R. § 10.30, to issue an order:

a. barring the administration of any Thimerosal-containing vaccine containing more than "trace" (more than 0.5 micrograms per dose) levels of mercury to pregnant women and children under the age of 36 months;

b. suspending of 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 the compounds is **not more than** 0.5 micrograms of mercury per dose;

c. issuing a Class I or Class II recall of all batches of multi-dose vaccines that contain a Thimerosal level of more than 0.001%;

d. banning vaccines and other drugs containing more than 0.5 micrograms (µg) of mercury per dose of product from being introduced into commerce in the United States and its territories, possessions and commonwealths; and

e. requiring, *after January 1, 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 1.0µg 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.

See Plaintiffs' Citizen Petition annexed hereto as Exhibit "A".

3. Despite the fact that Plaintiffs' Citizen Petition urged corrective action, the Defendants have refused to require manufacturers to prove the safety of products containing Thimerosal or other added mercury-compounds, or in the alternative, to take the necessary steps to protect fetuses, infants and children from the dangers of mercury exposure from Thimerosal or other mercury-containing compounds present in any drug or medicine until the maximum total dose of mercury that may be legally administered for any approved or licensed drug or medicine is proven, in appropriate toxicology studies, to be safe with at least a 10-fold safety margin in susceptible individuals.

4. Although more than one year has passed since the CoMeD Plaintiffs filed their petition, the Defendants have neither granted nor denied the petition, and have taken no action to remove Thimerosal-preserved drug products, or other drug products containing a preservative level of any other mercury-based compound, from the market. Therefore, to protect public safety and prevent needless injury to children, Plaintiffs seek a declaration that Defendants have acted unlawfully by withholding action on the "CoMeD" petition and an order requiring Defendants to act thereon in a manner that fully complies with all applicable federal laws.

PARTIES

5. Plaintiffs, representatives for CoMeD, a broad based advocacy group that supports the withdrawal of all drug products containing added mercury-based compounds unless they have been unequivocally proven to be safe for all susceptible individuals, are dedicated to advocating for the removal of all mercury-containing products used in medicine and dentistry unless that medical or dental product has been proven to be safe, with a safety factor of not less than 10, for use in susceptible individuals who have impaired mercury detoxification systems. Plaintiffs' position is based on, among other scientific findings of mercury toxicity, the proven harm that ionic mercury causes at levels of approximately twenty (20) parts per billion (1,000,000,000) [0.02 ppm; 0.02 µg/mL] to growing neurological structures when comparable levels of other ionic heavy metals (i.e. cadmium, lead, and manganese) and ionic aluminum have been shown to cause no harm.

6. Defendant HHS is the federal agency responsible for administration of the FDCA, 21 U.S.C. § 301 et seq. Defendant Andrew C. von Eschenbach, M.D. is the Acting Commissioner of the FDA, an agency within the HHS. He has the responsibility for implementing the federal statutes and regulations applicable to Thimerosal-containing products, pursuant to the authority delegated to him by Defendant Michael O. Leavitt, the Secretary of HHS.

7. Defendant FDA is an agency within HHS. By delegation from HHS, FDA is responsible for administration of the FDCA. 21 C.F.R. § 5.l0. In particular, FDA is responsible for withdrawing approval or licensing of unsafe drugs.

8. As set forth in more detail below, Defendants have violated the law by failing to act on the "CoMeD" petition seeking, amongst other things, the withdrawal of marketing approval or licensing of mercury-containing drugs, including vaccines, containing more than a trace level of mercury from Thimerosal or other mercury-based compound **unless**, *in appropriate toxicological*

studies, the level of mercury in the drug formulation has been proven to be safe, with a safety factor of not less than 10, when administered to susceptible individuals who have impaired mercury detoxification systems.

JURISDICTION

9. This court has jurisdiction over this action pursuant to 28 U.S.C. §1331.

FACTS

10. Despite all the evidence of Thimerosal danger, the Defendants have not responded to Plaintiffs' Citizen Petition, dated July 30, 2004, submitted in person by Plaintiffs, and filed on the FDA's Public Docket by the FDA on August 4, 2004, requesting corrective action, although the time to respond has expired. 21 C.F.R. §10.30 (e)(2). *See* Exhibit "A".

11. The Defendants have not forced manufacturers to conduct tests to determine the safety of Thimerosal in any quantity in vaccines, even though there is substantial inferential evidence coming from human exposure and animal data, that Thimerosal and related compounds can cause neurological damage in susceptible individuals. Nor, as promised and scheduled in 1999, have the Defendants used the offices of the National Institute of Environmental Health to determine the level in a given drug formulation at which Thimerosal is safe, with a proven safety factor of not less than 10 times the lowest level at which toxicity was observed in susceptible individuals, to be injected into pregnant women and children.

12. The failure to compel the vaccine manufacturers to conduct these safety tests as required by law (21 CFR 610.15(a) and 21 U.S.C. 351(a)(2)(B)) or for these Agencies to conduct the requisite toxicological tests, or have them conducted, has undercut efforts to uncover the true danger of Thimerosal.

13. The maximum level of Thimerosal present in today's Thimerosal-preserved drug products has not been proven safe even though the regulations for drugs, including vaccines and other biological preparations classified as drugs, explicitly require that all drugs must be safe and effective in humans and animals. 21 U.S.C. § 351(a)(2)(b).

14. 21 C.F.R. §610.15 governs "Preservatives in Vaccines" and explicitly requires that "any preservative shall be sufficiently nontoxic so that the amount in the recommended dose of the product will not be toxic to the recipient". In 1988, the Supreme Court unanimously held, in a vaccine case, that FDA officials have no discretion in complying with any policy, law, or statute requiring a specified course of action (Berkovitz v. USA; 108 S.Ct. 1954, 100 L.Ed.2d 531, 56 USL W 4549 [Cite as: 486 U.S. 531, 108 S.Ct. 1954]).

15. Under 21 U.S.C. 355(e) the Commissioner of the FDA has the authority to withdraw approval of any FDA-approved drug product.

16. 42 U.S.C. 262 (a)(2)(A) gives the FDA the authority to revoke the license of any FDA-licensed biological product.

17. 42 U.S.C. 300aa-27 gives the Secretary of HHS the authority to revoke the license of any childhood vaccine and requires the Secretary to do what ever the Secretary must do to reduce the adverse reactions to childhood vaccines.

18. 42 U.S.C. 262(d)(1) governs recalls of products presenting an imminent or substantial hazard to public health.

19. On August 4, 2004, CoMeD Plaintiffs personally submitted a written Citizen Petition, dated July 30, 2004, to the Defendants. *See* Exhibit "A".

20. The only response to this petition to date is an "interim response," dated February 4, 2005, which states that the FDA is continuing to work on a response to the petition. *See* February 4, 2005 interim response annexed hereto as Exhibit "B".

21. The interim response, however, gave no indication of how long the FDA expects to delay before it makes a decision as to whether to comply with the requests in CoMeD Plaintiffs' petition.

22. In response to the FDA's interim response (*see* Exhibit "B"), on Wednesday, 23 February 2005, the Plaintiff King submitted a formal response that challenged the FDA's characterization of the issues as complex and again asked that the Defendants comply with all applicable laws, including, but not limited to, 42 U.S.C. 300aa-27, and/or compel the drug makers to comply with the applicable laws requiring proof of safety. See February 23, 2005 response letter by Plaintiffs annexed hereto as Exhibit "C".

23. To date, the Defendants have not issued their final determination on CoMeD Plaintiffs' petition.

24. This action seeks an Order directing the Defendants to respond to CoMeD Plaintiffs' petition in a manner that fully complies with all applicable statutes.

CLAIMS FOR RELIEF

25. Defendants' failure to act on CoMeD Plaintiffs' petition constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

26. Defendants' failure to act on CoMeD Plaintiffs' petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

27. Defendants' failure to reach a decision on CoMeD Plaintiffs' petition within a reasonable time, taking into account the emergency nature of the petition, has denied CoMeD Plaintiffs their right to timely action under the Administrative Procedure Act (APA) 5 U.S.C. 555(e), 706 (1).

WHEREFORE, Plaintiffs requests that this Court:

A. Declare unlawful Defendants' failure to act on CoMeD Plaintiffs' petition;

B. Order Defendants to issue a decision on CoMeD Plaintiffs' petition that *fully* complies with all applicable laws within 30 days of declaring Defendants' failure to act unlawful;

C. Award Plaintiffs their reasonable costs, disbursements, and reasonable attorney's fees under 28 U.S.C. § 2412; and

D. Grant all such other and further relief as may be just and proper.

Dated: Vienna, Virginia
July 7 , 2006

SHOEMAKER & ASSOCIATES

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