IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL G. KING, PH.D INDIVIDUALLY AND AS *FOUNDER*, FACILITY, AUTOMATION MANAGEMENT ENGINEERING (FAME) SYSTEMS & NEW JERSEY REPRESENTATIVE FOR,
AND
REV. LISA KAREN SYKES, INDIVIDUALLY AND AS VIRGINIA REPRESENTATIVE FOR,
AND
SABRINA KNICKELBEIN, INDIVIDUALLY AND AS A REPRESENTATIVE FOR,
AND
ALL OTHER REPRESENTATIVES FOR

Coalition for Mercury-free Drugs (CoMeD)
33A Hoffman Avenue
Lake Hiawatha, NJ 07034-1922

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.

CASE NO. 1:06CV01357
JUDGE EMMET G. SULLIVAN

AMENDED 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-1 et seq. (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 other products 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 humans.

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 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, 2007*, 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.

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

PARTIES

3. Plaintiffs seek the removal of Thimerosal and other mercury-containing compounds from all FDA-licensed products because it has not been proven safe, as required by law, and because mercury is known to cause harm to the human brain, immune system, and other systems of the body. Individual Plaintiffs listed above have received mercury in FDA-licensed products, especially vaccines, and do not wish any future exposure from FDA-licensed products they will take in the future. Individual plaintiffs [list them] are also mothers of children who have received mercury from FDA-licensed products (including through in utero exposure, breast milk, and vaccines) and desire mercury-free products for their children in the future. They have been and will be required by law to obtain mercury-containing vaccines for their children and desire that these vaccines be all mercury-free. The mercury has caused injury to the neurological and immune systems (and other bodily systems) of the individual Plaintiffs and their children and (because exposure is cumulative) will, if not eliminated from FDA-licensed products, continue to cause harm in the future. The Plaintiffs are the

fathers, grandfathers, grandmothers, and mothers of babies and young children who may have more children in the future, and will need vaccines and other products to protect and treat them and their current and future children, but may not be able to obtain such products that are Thimerosal-free and safe for them to use. Plaintiff CoMeD is a broad-based advocacy organization that seeks the removal of mercury from all FDA-licensed products. 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 as well as established Thimerosal toxicity to skin and spinal cord samples exposed to similar levels of Thimerosal in toxicity studies on human tissues.

4. 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.

5. 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.

FDA REFUSED TO ACT ON PLAINTIFFS' PETITION UNTIL AFTER THIS ACTION WAS FILED AND FAILED TO ACT ON IT AS THE INITIAL LAWSUIT REQUESTED

6. Despite the fact that Plaintiffs' Citizen Petition, filed pursuant to 21 C.F.R. 10.30 et seq., urged corrective action, the Defendants refused for more than two years from the date of filing, Wednesday, 4 August 2004, 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.

7. For more than two years since the CoMeD Plaintiffs filed their petition, the Defendants neither granted nor denied the petition, and took 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 in spite of an ever-growing body of peer-reviewed published evidence that Thimerosal is highly poisonous and toxic to humans at levels of, or below, 0.02 ppm including a study published online on 20 April 2005 by Parran *et al*. that established toxicity in developing human neurons at levels below 0.001 ppm.

8. On Thursday, 28 September 2006, Plaintiffs King and Sykes and most of the other petition signers received, by Federal Express, a 24-page response with a 2-page enclosure from Food and Drug Administration (FDA) Assistant Commissioner for Policy, Jeffery Shuren, MD, JD, that failed to address the issues raised in the citizen petition filed in Docket 200**4**P-0349. Instead, it

purportedly addressed a contention that "all licensed and approved products containing thimerosal are unsafe" while the petition requested that the Agency address the legal issue of lack of the required proof of safety on the part of both the manufacturers and the FDA for all licensed and approved products containing Thimerosal.The requisite proof is required by statute and the minimum standard for proof for biological products is clearly set forth in 21 CFR 610.15(a), a regulation that has been legally binding on the manufacturers since 1973 [**See:** 38 FR 32056, Nov. 20, 1973]. In addition, the FDA response failed to mention, much less address, their failure to comply with the clear statutory requirements set forth in 42 U.S.C. Sec. 300aa-27(a) for safer childhood vaccines with fewer adverse reactions by using any and all means available to the Secretary of Health and Human Services and the FDA to reduce adverse reactions to vaccines. Thus, the FDA's answer failed to respond to the clear issues raised in the petition and, therefore, the Agency's decision to" deny the petition for the reasons stated" in this response is "non-responsive," arbitrary, capricious, and an abuse of the FDA's limited discretionary powers.

9. Therefore, to protect public safety and prevent needless injury to children, Plaintiffs continue to seek a declaration that Defendants have acted unlawfully by failing to address the issues raised by the "CoMeD" petition and an order requiring Defendants to act thereon in a manner that fully complies with all applicable federal policies, laws and statutes.

10. As set forth in more detail below, Defendants have violated the law by failing to act on the "CoMeD" petition seeking, inter alia, 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 humans

JURISDICTION

This court has jurisdiction over this action pursuant to 28 U.S.C. §1331 and 28 USD 1361

FIRST CAUSE OF ACTION

11. Despite all the evidence of harm from the inclusion of mercury-containing compounds, including Thimersol in FDA-licensed products, the Defendants have not responded, in a manner that fully complies with all applicable policies, laws and statutes, to the underlying "proof of safety" issues raised in 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". The FDA has failed to demonstrate in its response that the inclusion of mercury-based compounds (generally optional preservatives) renders that product safe within the meaning of its applicable licensing statute. Instead, FDA has *improperly* attempted to shift the burden of proof to Petitioners to prove that mercury-containing compounds render such products unsafe.

12. The Defendants have not forced manufacturers to conduct tests to determine the safety of Thimerosal or any other mercury-based compound (e.g., phenylmercuric acetate) in any quantity in vaccines or other drug products nor, as required by 21 CFR § 6101.15(a), to prove that Thimerosal or any other mercury-based compound (e.g., phenylmercuric acetate) at a preservative level is "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient," even though there is substantial evidence coming from human exposure and animal data, that Thimerosal and related mercury-based compounds can cause neurological damage as well as damage to the immune system (e.g. allergic reactions) and other systems (e.g., heart, gut, skin, and endrocrine damage) in humans at levels more than 10,000 times

lower than the 100-ppm level of Thimerosal in most Thimerosal-preserved vaccines. 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.

13. The failure to compel the vaccine manufacturers and other drug 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.

14. 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).

15. 21 C.F.R. §610.15(a) governs "Preservatives in Biological Products," including 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 has no discretion in complying with any policy, law, or statute requiring a specified course of action (*Berkovitz v. United States*, 486 U.S. 531 (1988)). In that case, the filed opinion's FN 10 is especially pertinent here. FN 10 in *Berkovitz v. USA* states:

> FN10 Even the Government conceded at oral argument that the DBS has no discretion to issue a product license without an examination of the product and a determination that the product complies with regulatory standards.

The transcript reads:

> "QUESTION: [Supposing the DBS] did not make any examination of the application at all, or any determination other than some papers have been filed and I will now issue the license.
>
> "Would that comply with the regulation?
>
> "[COUNSEL]: No, it would not comply with the regulation.
>
> "QUESTION: It would violate a mandatory duty..., wouldn't it?
>
> "[COUNSEL]: In the extreme instance you are talking about ..., it would definitely violate that regulation." Tr. of Oral Arg. 34-35.

It is clear that the FDA has no discretion to disregard the statutory mandate for safety and the regulatory mandate that vaccine manufacturers establish the safety of any preservative.

16. Under 21 U.S.C. 355(e) the Commissioner of the FDA shall withdraw approval of any FDA-approved drug product upon finding that it has not been shown to be safe or that it has been shown to be unsafe.

17. 42 U.S.C. 262(a)(2)(A) gives the FDA the authority to revoke the license of any FDA-licensed biological product (including vaccines).

18. 42 U.S.C. 300aa-27 requires the Secretary of HHS to use his licensing and other authority to reduce adverse reactions to childhood vaccines.

19. 42 U.S.C. 262(d)(1) the FDA shall revoke the license and recall any vaccine or other biologic product that is an “imminent or substantial hazard to the public health.”

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

21. The only response to this petition prior to Tuesday, 26 September 2006, 57 days after the original suit was filed (1 August 2006) and 39 days after the government was served (15 August 2006) was 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".

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

23. 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, 21 CFR § 620.15(a), 21 CFR Part 211, 21 USC Sec. 351(a)(2)(B), and 42 U.S.C. Sec. 300aa-27, and/or compel the drug makers to comply with the applicable laws requiring proof of safety (e.g., 21 CFR § 610.15(a). See February 23, 2005 response letter by Plaintiffs annexed hereto as Exhibit "C".

24. Though the Defendants issued a letter (*see* Exhibit "D") purporting to address the issues raised in the CoMeD Plaintiffs' petition, even though said letter clearly did not address said issues, and stated: "After review and consideration, we deny the petition for the reasons stated below in this response." However, not only did this letter fail to address the underlying "lack of proof of safety" issues raised by the Plaintiffs in the CoMeD Plaintiffs' petition but also the reasons stated in the letter are simple unsupported declarative statements lacking any factual support in most cases (see CoMeD Plaintiffs' "Response to the Claims Made by the FDA in Their Letter of 26 September

2006" annexed hereto as Exhibit "E" and filed with the FDA Dockets Management on 24 October 2006 as 2004P-0349/PSA1 under 21 CFR § 10.35).

25. This action seeks an Order directing the Defendants to respond to CoMeD Plaintiffs' petition in a manner that addresses the issue of the failure of Agency to: (a) require the manufacturers to prove safety of Thimerosal as a preservative in their vaccines and other drug products before the FDA licenses or approves them and (b) only license or approve said vaccines and other drug products when they fully comply with all applicable policies, laws and statutes.

SECOND CAUSE OF ACTION

26. If the FDA's September 26, 2006, answer to the Petition is deemed sufficient under the regulations governing citizen petitions, 21 CFR 10.30, then Plaintiffs should be deemed to have exhausted administrative remedies with respect to their claim that FDA is required to revoke the licenses for and recall products containing mercury compounds unless their safety is proven because FDA has not and cannot demonstrate that they are safe as required by 21. USC 355 and 42 USC 262, the manufactures have not and cannot demonstrate the safety of mercury preservatives as required by 21 CFR 610.15(a), and because FDA has not used its licensing authority as required by 42 USC 300aa-27 to reduce the adverse reactions from vaccines.

27. *Berkovitz v. USA* was a federal lawsuit arising out of the harm caused to a child inoculated with a polio vaccine that left the child severely damaged. Acting on their son's behalf, the parents sued both the government and the manufacturer of the polio vaccine he received. The manufacturer settled with the parents but the government choose to contest the government's liability on the grounds that the government agency had acted within its allowable administrative discretion in licensing the lot of polio vaccine that had caused the harm in spite of the fact that that lot failed to meet all of the regulatory requirements in effect at the time.

28. Specifically, during testing for release, the lot in question was found to have a "wild virus" level above the limit allowed for wild virus in the first stage of a required two-stage test. Not wishing to conduct the additional testing, the manufacturer asked the government to release the lot because the level of wild virus was only slightly above the limit allowed. A government administrator agreed and sent the manufacturer a letter authorizing the release of the lot even though it failed to meet the legal requirements for its release. The District Court rejected the government's arguments and found for the plaintiffs. On appeal, the Appeal Court reversed the District Court decision asserting that the government's actions were within the limits on discretion set forth in the law. The Supreme Court agreed to hear Plaintiffs appeal and, after oral argument, unanimously found that the government had exceeded their discretion and ruled that a government administrator may not use discretion whenever there is any clear applicable policy, law or statute establishes a clear requirement.

29. In this instance, the clear requirements set forth 21 CFR 610.15(a) and 42 U.S.C. 300aa-27(a) as well as all laws and statutes that bear on these *limit* the FDA's discretion to instances where the manufacturers of vaccines have fully complied with 21 CFR 610.15(a) and the FDA has fully complied with 42 U.S.C. Sec. 300aa-27(a). The FDA also must comply with 21 USC 355 and 42 USC 262, which are also limits on their discretion.

21 CFR § 610.15(a) – PROOF OF NONTOXICITY REQUIRED

30. Since, as FDA officials have repeatedly testified before Congress and Congress has found (see: "Mercury in Medicine – Taking Unnecessary Risks," A Report Prepared by the Staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform, United States House of Representatives, Chairman Dan Burton, April 2003, page 5, "II. Findings and

Recommendations, A. Findings, Through this investigation of pediatric vaccine safety, the following findings are made: … 3. Manufacturers of vaccines and thimerosal, [an ethylmercury compound used in vaccines], have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds.") the vaccine makers have *not* complied with the clear requirements of 21 CFR 610.15(a), which, among other things states, "… Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, …" – a regulation that clearly require adequate safety testing of each Thimerosal-preserved vaccine formulation before it can, under *Berkovitz*, be licensed or continued to be licensed.

31. Further, to the extent that a clear safety requirement minimum for biological drug products is applicable to other drug products, that requirement is implicitly a safety requirement for all Thimerosal-preserved drug products. This is the case because 21 CFR § 610.15(a) is a clear minimum requirement for compliance with the current good manufacturing practice (CGMP) requirement minimums set forth in 21 CFR Part 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS. That the CGMP requirements in 21 CFR Part 211 are minimum requirements is clear because 21 CFR § 211.1(a) states, with *italicization* added for emphasis, "The regulations in this part [Part 211] contain the *minimum* current good manufacturing practice for preparation of drug products for administration to humans or animals." and that 21 CFR 610.15(a) is a part of the CGMP for finished pharmaceuticals in clear from 21 CFR § 211.1(b) which states "The current good manufacturing practice regulations in this chapter as they pertain to drug products; in parts 600 through 680 of this chapter, as they pertain to drugs that are also biological products for human use; and in part 1271 of this chapter, as they are applicable to drugs that are also human cells, tissues, and cellular and tissue-based products (HCT/Ps) and that are

drugs (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act); supplement and do not supersede the regulations in this part [Part 211] unless the regulations explicitly provide otherwise."

32. Thus, by allowing manufacturers to ignore the clear requirement that they must prove that a given Thimerosal-preserved drug product formulation is "sufficiently nontoxic," the FDA has been, and is, in effect, acting in concert with the manufacturers to manufacture and distribute drug products that are "adulterated" under the Federal, Food, and Cosmetic Act (FDC Act).

33. This is the case because 21 U.S.C. Sec. 351(a)(2)(B) clearly states: "Adulterated drugs and devices *A drug* or device *shall be deemed to be adulterated* - (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture (1) …; or (2)(A) …; or (B) *if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; …*"

34. Therefore the FDA's discretion is barred because there is a specific regulatory requirement (21 CFR § 610.15(a) that must be met and the failure of the manufacturer to meet that requirement renders the drug product adulterated (as per 21 U.S.C. 351(a)(2)(B).

35. Thus, the FDA cannot ignore the explicit requirement for biological drug products set forth in 21 CFR § 610.15(a).

42 U.S.C. Sec. 300aa-27 – MANDATE FOR SAFER CHILDHOOD VACCINES

36. Turning to the other key requirement raised by the petition, 42 U.S.C. Sec. 300aa-27(a) states, with *italicization* added for emphasis:

"*General rule*

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, *the Secretary shall* -

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) *make or assure improvements in, and otherwise use the authorities of the Secretary with respect to*, the *licensing*, manufacturing, processing, testing, *labeling*, *warning*, *use instructions*, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, *in order to reduce the risks of adverse reactions to vaccines*."

37. Thus, under 42 U.S.C. 300aa-27(a)(2), the Secretary (of Health and Human Services) and, as his subordinate, the FDA is required to use all existing authority, including licensing, to reduce adverse reactions in childhood vaccines. As a corollary, the Secretary is also required to do all he can to make certain that the adverse reactions to childhood vaccines are not increased. Based on the admissions of the FDA (that Thimerosal-containing vaccines cause adverse reactions ["hypersensitivity reactions"]), the fact that the use of Thimerosal is not a requirement but an option, and the evidence from the 1930s onward submitted in the Plaintiffs' citizen petition that vaccine formulations containing Thimerosal cause severe Thimerosal-related adverse reactions while those without Thimerosal do not produce similar severe adverse reactions, to comply with this statute,

effective on 22 December 1987, the FDA should have immediately banned the use of Thimerosal in the manufacture of childhood vaccines.

Furthermore, the Secretary and the FDA should have barred the adding of any Thimerosal-preserved vaccine to the childhood vaccination schedule. However, rather than baring the use of Thimerosal, an optional compound where there are other compounds that can be used in December of 1987 with a phase out for existing Thimerosal-preserved vaccines in favor of vaccines that contain no Thimerosal at any level, the Secretary and the FDA *knowingly* (as that term in defined in 21 U.S.C. Sec. 321(bb)) ignored this statute. Their actions were especially egregious because they could have simply mandated that all of the vaccines that use Thimerosal be reformulated and packaged in single-dose vials or syringes where no preservative is required (avoiding the need to find and qualify any preservative).

38. In 2003, the Secretary also *knowingly* disregarded this statute and permitted the Center for Disease Control and Prevention (CDC) to *illegally* add an existing Thimerosal-preserved vaccine, the Thimerosal-preserved influenza vaccine, known to cause severe adverse reactions in some children, to the childhood vaccination schedule for children 6-months to 23-months of age. This vaccine is also being promoted for use in pregnant women, despite the fact that it is known that mercury crosses the placental barrier into the fetus. It is inconceivable that we warn women not to eat fish while pregnant, yet the CDC recommends they be injected with mercury during pregnancy.

39. In further disregard of this stature, the Secretary has not only permitted this Thimerosal-preserved vaccine to remain in the childhood vaccination schedule but has allowed the CDC to increase the number of children at risk by widening the age range from 6-months to 59-months of age.

40. Thus, the FDA has ignored this statue by *knowingly* continuing to license vaccines that contain Thimerosal and the Secretary has ignored it by *knowingly* permitting the CDC to add Thimerosal-preserved influenza vaccines, which have been proven to cause severe adverse reactions (see "Some VAERS Reports of Severe Thimerosal-related Adverse Reactions" annexed hereto as Exhibit "F"), to the childhood vaccination schedule in 2002 and to continue allowing the CDC to keep it in said schedule while increasing the number of children being placed at risk of having a severe adverse reaction.

CLAIMS FOR RELIEF

41. Defendants' failure to act on CoMeD Plaintiffs' petition in a manner that complies with all applicable policies, laws and statutes constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

42. Defendants' failure to act on the lack of "proof of safety" issues raised in CoMeD Plaintiffs' petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

43. 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).

44. With respect to Plaintiffs' claims that FDA has unlawfully licensed mercury-containing products and unlawfully refused to revoke these licenses and recall the products, and their claim that FDA has unlawfully approved the preservative Thimerosal, and with respect to their claim that FDA has failed to use its authority to reduce adverse reactions to childhood vaccines, Plaintiffs have exhausted their administrative remedies.

WHEREFORE, Plaintiffs requests that this Court:

A. Declare unlawful Defendants' failure to properly act on CoMeD Plaintiffs' petition in a manner that addresses the CoMed Plaintiffs' petition's issues and also complies with all applicable policies, laws, and statutes;

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

C. Order the FDA to revoke the license for any mercury-containing licensed produces on the ground that they are not proven safe within the meaning of 21 USC 355 and 42 USC 262

D. Revoke the licenses for any childhood vaccines issued after 1998, including the flu vaccine, that do not contain a specific showing of how such licensing will reduce adverse reactions

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

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

Dated: Vienna, Virginia
October 25, 2006

SHOEMAKER & ASSOCIATES

BY:_____

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[1] **63 FR** 19799-19802, April 22, 1998.