

UNITED STATES DISTRICT COURT
District of Columbia

Paul King, et al

SUMMONS IN A CIVIL CASE

v.

Michael Leavitt, et al

CASE NUMBER 1:06CV01357

JUDGE: Emmet G. Sullivan

DECK TYPE: Administrative Agency Review

DATE STAMP: 08/01/2006

TO: (Name and address of Defendant)

Michael O. Leavitt, Secretary
Dept. of Health & Human Services
200 Independence Ave., SW
Washington, D.C. 20201

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Clifford J. Shoemaker
Shoemaker & Associates
9711 Meadowlark Rd.
Vienna, VA 22182

an answer to the complaint which is served on you with this summons, within 60 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

NANCY M. MAYER-WHITTINGTON

CLERK

AUG 01 2006

DATE

Museu Negyias
(By) DEPUTY CLERK

UNITED STATES DISTRICT COURT
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TO: (Name and address of Defendant)

U.S. ATTORNEY
501 3RD. ST. N.W.
WASHINGTON, D.C. 20001

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

*Clifford J. Shoemaker
Shoemaker & Associates
9711 Meadowlark Rd.
Vienna, VA 22182*

an answer to the complaint which is served on you with this summons, within 60 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

NANCY M. MAYER-WHITTINGTON

CLERK

AUG 01 2006

DATE

Maura Higgins
(By) DEPUTY CLERK

UNITED STATES DISTRICT COURT
District of Columbia

Paul King, et al

SUMMONS IN A CIVIL CASE

v.

Michael Leavitt, et al

CASE NUMBER 1:06CV01357

JUDGE: Emmet G. Sullivan

DECK TYPE: Administrative Agency Review

DATE STAMP: 08/01/2006

TO: (Name and address of Defendant)

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Clifford J. Shoemaker
Shoemaker & Associates
9711 Meadowlark Rd.
Vienna, VA 22182

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NANCY M. MAYER-WHITTINGTON

CLERK

AUG 01 2006

DATE

(By) DEPUTY CLERK

Marcus Higgins

UNITED STATES DISTRICT COURT
District of Columbia

Paul King, et al

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V.

Michael Leavitt, et al

CASE NUMBER 1:06CV01357

CA JUDGE: Emmet G. Sullivan

DECK TYPE: Administrative Agency Review

DATE STAMP: 08/01/2006

TO: (Name and address of Defendant)

U.S. ATTORNEY GENERAL
D.O.J.
950 PENNSYLVANIA AVE. NW
WASHINGTON, D.C. 20530

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

*Clifford J. Shoemaker
Shoemaker & Associates
9711 Meadowlark Rd.
Vienna, VA 22182*

an answer to the complaint which is served on you with this summons, within 60 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

NANCY M. MAYER-WHITTINGTON
CLERK

AUG - 1 2006
DATE

Maureen Higgins
(By) DEPUTY CLERK

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE
NAME OF SERVER (<i>PRINT</i>)	TITLE

Check one box below to indicate appropriate method of service

- Served personally upon the defendant. Place where served: _____

- Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left: _____

- Returned unexecuted: _____

- Other (specify): _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____ Date _____ Signature of Server _____

Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Nancy M. Mayer-Whittington
Clerk

**NOTICE OF RIGHT TO CONSENT TO TRIAL
BEFORE UNITED STATES MAGISTRATE JUDGE**

The substantial criminal caseload in this Court and the requirements of the criminal Speedy Trial Act frequently result in a delay in the trial of civil cases. Aware of the hardship and expense to the parties, counsel, and witnesses caused by the delays which are beyond the control of the Court, this notice is to advise you of your right to a trial of your case by a United States Magistrate Judge. By statute, 28 U.S.C. § 636(c), Fed.R.Civ.P.73 and Local Rule 502, the parties, by consent, can try their case by means of a jury trial or bench trial before a United States Magistrate Judge. Appeals from judgments and final orders are taken directly to the United States Court of Appeals for the District of Columbia Circuit, in the same manner as an appeal from a judgment of a District Judge in a civil case.

WHAT IS THE PROCEDURE?

One of the matters you are required to discuss at the meet-and-confer conference mandated by Local Rule 206 is whether the case should be assigned to a United States Magistrate Judge for all purposes, including trial.

All parties must consent before the case is assigned to a Magistrate Judge for trial. You may consent at any time prior to trial. If you expressly decline to consent or simply fail to consent early in the case, you are not foreclosed from consenting later in the case. However, a prompt election to proceed before a Magistrate Judge is encouraged because it will facilitate a more orderly scheduling of the case.

Attached is a copy of the "Consent to Proceed Before a United States Magistrate Judge for All Purposes" form. Your response should be made to the Clerk of the United States District Court only.

WHAT IS THE ADVANTAGE?

The case will be resolved sooner and less expensively. The earlier the parties consent to assigning the case to a Magistrate Judge the earlier a firm and certain trial date can be established, even if the case is to be tried to a jury.

Upon the filing of the consent form and with the approval of the District Judge, the case will be assigned for all purposes to a Magistrate Judge.

CO-942A
Rev 3/95
Rev 7/99

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)

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.)

CIVIL ACTION NO.

CASE NUMBER 1:06CV01357

JUDGE: Emmet G. Sullivan

DECK TYPE: Administrative Agency Review

DATE STAMP: 08/01/2006

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. § 5.10. 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).

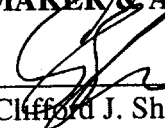
WHEREFORE, Plaintiffs requests that this Court:

- 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

BY: _____


Clifford J. Shoemaker, Esquire
Shoemaker & Associates
9711 Meadowlark Road
Vienna, VA 22182
(703) 281-6395
Fax: (703) 281-5807

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INITIAL ELECTRONIC CASE FILING
ORDER

Subsequent filings in this case must be made electronically using the Court's Electronic Case Filing System (ECF) pursuant to Local Rule 5.4.

ORDERED that counsel shall:

- Submit in paper, the original and copy of the complaint/notice of removal/petitions for habeas corpus and any accompanying papers (**not including summons and civil cover sheets**). Additionally, litigants are hereby required to provide those filings in PDF Format on a floppy disk or CD-Rom compact disk. The disk should be clearly labeled with the case number (if known) and the name of the parties. If unable to deliver the filing on a disk at the time of the new case filing, counsel should e-mail the initiating document and accompanying papers to dcd_cmecf@dcd.uscourts.gov by the close of business the day the new case was filed. Failure to supply electronic copies of the new case in a timely manner, will result in the attorney's name being added to the attorney non-compliant list and shared with the Court's ECF Judge's Committee. **Regardless of what option counsel chooses, the complaint/notice of removal and accompanying papers must come to the Court as PDF documents.** Each exhibit to the new case shall be in a separate PDF file. Failure to submit PDF versions of the complaint/notice of removal and other documents will delay the opening of the case in ECF.
- Register, if not previously registered, to become an electronic filer by completing and returning the enclosed ECF Registration Form found on the Court's Website at (www.dcd.uscourts.gov). The login and password are case specific and can be used for all cases.
- **Make all subsequent filings electronically. This is mandatory.**
- Have a PACER (Public Access to Court Electronic Records) account, in order to view dockets and documents. Call 1-800-676-6856 or visit www.pacer.psc.uscourts.gov for additional information.
- Schedule a training class at the Courthouse by going to the Court's ECF Internet Website (www.dcd.uscourts.gov/ecf.html). Also, filing instructions and an interactive tutorial can be found at this Internet Website.

SULLIVAN, J. EGS

UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**ELECTRONIC CASE FILES
Attorney/Participant Registration Form**

LIVE SYSTEM

This form shall be used to register for an account on the Court's Electronic Case Files (ECF) system and to subscribe to the ECF EMail (Listserver) notification service. Registered attorneys and other participants will have privileges both to electronically submit documents, and to view and retrieve electronic docket sheets and documents for all cases assigned to the Electronic Case Files system. Listserver subscribers receive email messages whenever the Court wishes to electronically notify ECF registrants of pertinent ECF information.

The following information is required for registration:

If you are appointed pro bono or pro hac vice, please provide the case number: _____

First Name/Middle Initial/Last Name _____

Last four digits of Social Security Number _____

DC Bar ID#: _____

Firm Name _____

Firm Address _____

Voice Phone Number _____

FAX Phone Number _____

Internet E-Mail Address _____

By submitting this registration form, the undersigned agrees to abide by the following rules:

1. This system is for use only in cases permitted by the *U.S. District Court for the District of Columbia*. It may be used to file and view electronic documents, docket sheets, and notices. Please visit the Court's ECF Internet, www.dcd.uscourts.gov, website to schedule training.
2. Pursuant to Federal Rule of Civil Procedure 11, every pleading, motion, and other paper (except list, schedules, statements or amendments thereto) shall be signed by at least one attorney of record or, if the party is not represented by an attorney, all papers shall be signed by the party. An attorney's/participant's password issued by the court combined with the user's identification, serves as and constitutes the attorney's/participant's signature. Therefore, an attorney/participant must protect and secure the password issued by the court.

If there is any reason to suspect the password has been compromised in any way, it is the duty and responsibility of the attorney/participant to immediately notify the court. This should include the resignation or reassignment of the person with authority to use the password. The Court will immediately delete that password from the electronic filing system and issue a new password.

3. An attorney's/participant's registration will not waive conventional service of a summons and complaint, subpoena, or other judicial process; submit the client to the jurisdiction of the Court; or operate as a consent to accept service of pleadings, documents, and orders in actions in which such attorney/participant has not entered an appearance. An attorney's/participant's registration will constitute a waiver in law only of conventional service of other non-process pleadings, documents, and orders in the case. The attorney/participant agrees to accept, on behalf of the client, service of notice of the electronic filing by hand, facsimile or authorized e-mail.
4. Upon receipt of your login and password, you are strongly encouraged to change your password, which may be done through the Utilities function, to a name easily recalled. **You may be subjected to a fee, should the Clerk's Office have to create a new password for you, or alternatively, you may be required to appear in person to receive your new password.**
5. Attorneys who are active members of the bar of this Court, or government attorneys who are employed or retained by the United States, or who have been permitted to proceed *pro hac vice*, must file pleadings electronically.

Please return this form to:

U.S. District Court for the District of Columbia
Attn: Attorney Admissions
333 Constitution Avenue NW, Room 1825
Washington, DC 20001

Or FAX to:

Peggy Trainum
U.S. District Court for the District of Columbia
(202) 354-3023

Applicant's Signature _____

Full Last Name

Initial of
First Name

Last 4 Digits SS#