CoMeD

Coalition for Mercury-Free Drugs

CITIZEN PETITION TO BAN USE OF MERCURY IN MEDICINE, UNLESS PROVEN TOXICOLOGICALLY SAFE TO THE CGMP STANDARD "SUFFICIENTLY NONTOXIC ..."

2007P-0331

August 2007

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August 2007

FDA Original

CoMeD
Coalition for Mercury-Free Drugs
http://www.mercury-freedrugs.org
33A Hoffman Avenue, Lake Hiawatha, NJ 07034-1922

Friday, August 10, 2007

Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dr. Andrew von Eschenbach
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Filed At:
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Secretary Leavitt and Commissioner von Eschenbach:

We the undersigned [collectively, representatives for the Coalition for Mercury-free Drugs] hereby petition the United States Department of Health and Human Services (HHS) and the HHS' Food and Drug Administration (FDA), pursuant to the United States Constitution, the Public Health and Welfare (codified in Title 42 of the United States Code [**42 U.S.C.**]) at, but not limited to, **42 U.S.C. Section 262(a)(2)(A), 42 U.S.C. Section 262(d)(1), 42 U.S.C. 262(j)** and **42 U.S.C. Section 300aa-10 et seq.** [added by the National Childhood Vaccine Injury Act {1988 & 1998 Supp}]), the Federal Food, Drug, and Cosmetic Act (FDC Act, codified in Chapter 9 of Title 21 of the United States Code [**21 U.S.C. Chapter 9**]) at, but not limited to, **21 U.S.C. Section 351(a)(2)(B)** and **21 U.S.C. Section 355(e)(3)**, and Title 21 of the Code of Federal Regulations (**21 C.F.R.**) including, but not limited to, **21 C.F.R. Section 10.30**, requesting the Secretary of Health and Human Services or the Commissioner of Food and Drugs, as appropriate, to:

1. IMMEDIATELY issue an order barring the administering of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than 0.05-micrograms-per-dose levels of Thimerosal to pregnant women and children under the age of 60 months, on the grounds that higher levels are **now** (as of 1 May 2007) a ***proven*** health hazard to susceptible fetuses, newborns and young children,

2. 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*** 0.05 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, ***not more than*** 0.01 micrograms of mercury per day, on the grounds that doing so will significantly reduce the risks of adverse reactions in susceptible children under the authority conferred upon you by the National Childhood Vaccine Injury Act of 1986, **42 U.S.C. Section 300aa-10 et seq.**, under **42 U.S.C. Section 300aa-27(a)(2)** for vaccines and, *for other drugs*, the general "public safety" authority granted in the Federal Food, Drug, and Cosmetic Act (**21 U.S.C. Chapter 9**),

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3. Issue a Class I or, *failing that*, a Class II recall of all batches of multi-dose vaccines that contain a Thimerosal level of more than 0.001 % on the grounds that:

   a. All such multi-dose vaccine formulations are **now** a proven health hazard to susceptible individuals of all ages **and**

   b. Therefore, a recall will reduce the risk of adverse reactions that, *under the authority conferred upon you by the National Childhood Vaccine Injury Act of 1986*, you are directed to minimize, **and**

4. *To protect public health and safety*, issue orders:

   a. Banning vaccines and other infrequently administered biological drug products providing ***more than*** 0.05 microgram (μg) of mercury per dose of product from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after **1 January 2008**,

   b. Banning other drug products providing ***more than*** 0.01 μg of mercury per day from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after **1 June 2009**, **and**

   c. Requiring, ***after 1 January 2008***, the recall and destruction of ALL:

      i. Vaccines remaining in commerce that contain ***more than*** 0.05 μg of mercury per dose, **and**

      ii. Other drug products remaining in commerce that contain ***more than*** 0.1 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.

Respectfully,

Paul G. King, PhD, *Founder*
Facilities Automation Management Engineering (FAME) Systems,
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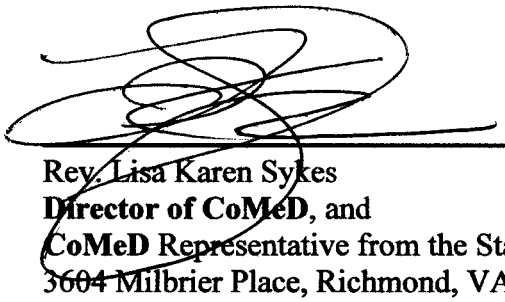
and the following persons:



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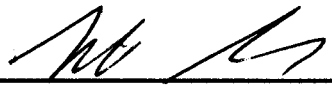

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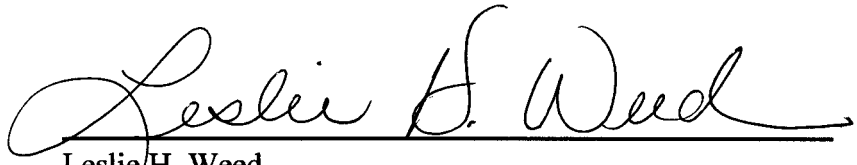

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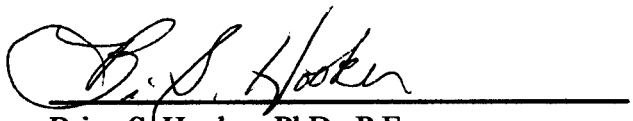

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SUPPORTING ORGANIZATIONS

In addition, the organizations listed below declare their strong support for this citizen petition:

Advocates for Children's Health Affected by Mercury Poisoning (A-CHAMP)

Alan D. Clark, MD; Memorial Research Fund

Autism One

Generation Rescue

Healing Every Autistic Life (HEAL)

Moms Against Mercury (MAM)

Mothering Magazine

National Autism Association (NAA)

NoMercury

Sensible Action For Ending Mercury-Induced Neurological Disorders (SafeMinds)

Schafer Autism Report (SAR)

Talk About Curing Autism (TACA)

OUTLINE OF CITIZEN PETITION

OVERALL CITIZEN PETITION TEXT [1 – 25; P-1 – P-447]

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[1] **Abbreviations:** Fn-nnn is used for footnote nnn with a following parenthesized letter when a footnote cites multiple articles. S-nn.mmm is used for articles cited in various sections of the petition outside of footnotes with appropriate added modifiers for subsection, paragraph and subparagraph.

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[1] **Abbreviations:** Fn-nnn is used for footnote nnn with a following parenthesized letter when a footnote cites multiple articles. S-nn.mmm is used for articles cited in various sections of the petition outside of footnotes with appropriate added modifiers for subsection, paragraph and subparagraph.

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[1] **Abbreviations:** Fn-nnn is used for footnote nnn with a following parenthesized letter when a footnote cites multiple articles. S-nn.mm is used for articles cited in various sections of the petition outside of footnotes with appropriate added modifiers for subsection, paragraph and subparagraph.

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In addition, this citizen petition references all documents submitted to, or referenced in, FDA Docket 2004P-0349 that are either: **a)** not referenced in the current petition or **b)** referenced in the current citizen petition but not provided with the filing documents at the time of filing of this citizen petition. **[Note:** For articles published in a foreign language, the petitioners have relied on the English-language abstracts in this citizen petition, except where an English-language translation has been provided.**]**