July 30, 2004

Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Lester M. Crawford, DVM, PhD,
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

In care of:
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Dear Secretary Thompson and Acting Commissioner Crawford:

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 Acting 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 "trace" (more than 0.5 micrograms per dose) levels of mercury to pregnant women and children under the age of 36 months[1,2], on the grounds that higher levels are **now** 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*** 0.5 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, not more than 0.5 micrograms of mercury per day, on the grounds that so doing will 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**),

3. Issue a Class I or, *failing that*, a Class II recall of all batches of multi-dose vaccines that contain a Thimerosal preservative 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 drugs, containing more than 0.5 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 2006, **and**

b. Requiring, *after 1 January 2006*, the recall and destruction of ALL:

i. Vaccines remaining in commerce that contain more than 0.5 μg of mercury per dose, **and**

ii. 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.

Sincerely,

Kelli Ann Davis

James R. Davis

Rev. Lisa Karen Sykes

Seth Sykes, PhD

Bobbie L. Manning

R. Michael Manning

Leslie H. Weed

Robert C. Weed

Marcia C. Hooker

Brian S. Hooker, PhD, P.E.

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Collectively, Representatives For CoMeD

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

CITIZEN PETITION REQUESTING CERTAIN ACTIONS WITH RESPECT TO VACCINES AND OTHER DRUG PRODUCTS, CONTAINING ADDED MERCURY, IN ORDER TO REDUCE THE HEALTH RISK TO SUSCEPTIBLE FETUSES, NEWBORNS, CHILDREN, ADOLESCENTS AND ADULTS	§	Docket No.: 2004P-_____

CITIZEN PETITION

I. Actions Requested

Petitioners request:

1. *Until the federal government can **prove** that any and all Thimerosal-containing products have a **10X** safety margin with respect to the risk of causing any level of neurological damage in newborns and children under 36 months of age*,[1,2] we request, under **42 U.S.C. Section 300aa-27**, the **Secretary** of the Department of Health and Human Services **or** the **Acting Commissioner** of the Food and Drug Administration **to immediately issue an order** proscribing the use of disease-preventive Thimerosal-containing vaccines or other similarly preserved medical products in newborns, children under the age of 36 months, and pregnant women unless:

a. The level of mercury in said vaccines, other pediatric drugs, and drugs administered during pregnancy is ***not more than*** 0.5 microgram (μg) per dose, **or**

b. *For other mercury-containing drugs*, ***not more than*** 1.0 μg of mercury per milliliter (mL) for liquids or gram (g) for solid, semi-solid and other drugs.

2. *Until the federal government can **establish** that any and all Thimerosal-containing products have no less than a **10X** safety margin with respect to the risk of causing any level of neurological damage to developing fetuses, newborns, children and adolescents*, we request that the Commissioner of the Food and Drug Administration move to withdraw the approval (under **21 U.S.C. 355(e)**) of any FDA-approved drug product (e.g., ophthalmic products) and revoke the license (under **42 U.S.C. 262(a)(2)(A))** of any FDA-licensed biological product (e.g., vaccines and other preserved serological preparations) that uses Thimerosal, *or any other mercury-based neurotoxic compound*, as a "preservative" or "adjuvant" unless the federal government and/or the manufacturer of said medical product can **prove, at its maximum level, its safety and efficacy as a preservative or adjuvant** in scientifically sound animal model studies using appropriate susceptible animal strains as the test subjects. [**Note:** We make this request because, *as all parties (federal government, industry, academia, and the public) know*[3,4], **all such current products lack the appropriate safety studies.** *Despite the recent report*[5] *by the Institute of Medicine (IOM)*, **there is substantial inferential evidence, and some Thimerosal and related-compounds human exposure and animal data, that have proven Thimerosal and other mercury-based compounds can cause neurological damage in *susceptible* individuals** at levels of exposure **above** 0.1 microgram (μg) of mercury per kilogram (kg)[6]. *For the other recognized hazardous alkyl mercury compound, methyl mercury*, the current EPA (United States Environmental Protection Agency) guideline[7] for methyl mercury from all sources for "infants" is *not more than* 0.1 μg/kg/day (0.093 μg of mercury/kg/day).]

3. Issue:

a. *Pursuant to the statutory authority set forth in **42 U.S.C. 262(d)(1)** and the procedures set forth in **21 C.F.R. Section 7**, governing recalls*, an immediate Class I, or Class II, recall[8] and destruction of all batches of multi-dose vaccines and other mercury-containing drug products: **i)** containing a mercury level of more than 0.5 microgram per dose or 0.0001 % (1 part per million [ppm]; 1 µg per milliliter [mL] or 1 µg per gram [g]), *whichever is higher*, **and ii)** having approved alternatives that are ***not more than*** 0.0002% mercury, **and**

b. *If the "Class II recall" option is chosen*, an open letter to all physicians advising them that they should destroy any of the drug products recalled in **Point 3.a.**

We make this request because:

- The current 0.01 % Thimerosal levels (equivalent to about 50 µg of mercury per mL or, *for 0.5-mL-dose vaccines*, 25 µg of mercury per dose) are **now** a proven health hazard to ***susceptible*** individuals of all ages,

- **For a single dose**, the current 0.01 % Thimerosal levels in multi-dose vaccine formulations (equivalent to about 50 µg mercury per 1-mL dose, 25 µg of mercury per 0.5-mL dose, or 12.5 µg of mercury per 0.25-mL dose):

  - *Obviously* exceed the total recommended mercury-equivalent daily intake level for infants and children under 13.3 kg (29.3 pounds) for the 0.25-mL dose level, 26.9 kg (59.3 pounds) for the 0.5-mL dose and 53.3 kg (117.5 pounds) for the 1-mL dose. [**Note:** We base these estimates on the daily intake limits for infants (established by the EPA for the related proven toxic mercury-containing compound, methyl mercury) of 0.093 µg of mercury per kg of body weight per day. The EPA's recommended daily intake

level for methyl mercury [which is 93 % mercury by weight] is 0.1 μg per kg of body weight per day (0.1 μg/kg/day {equivalent to 0.093 μg of mercury/kg/day}).]

- Have been **proven,** in one animal model study using "susceptible" (**autoimmune disease-sensitive) SJL/J mice** exposed to the same relative levels and at the same relative developmental times that match those factors in humans, **to:**
  - **Elicit** the same etiology as "autism spectrum disorders" **and**
  - **Alter** the brain structures in the vaccinated mice.

  [**Note:** The study did **not** find either adverse effect in the two similarly treated mouse strains, C57BL/6J and BALB/cJ, used as controls. These strains do not have autoimmune disease sensitivity.]

❖ Such 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.

4. *Until medical products containing Thimerosal and other mercury-based preservatives can be removed from the market and be replaced by a suitable non-neurotoxic alternative, or, reformulated to contain not more than 0.5 microgram of mercury per dose of vaccine or, for other drugs, not more than 1.0 microgram of mercury per milliliter or gram, or said current products can be proven to have not less than a **10X** safety margin for **susceptible individuals***, we request that the Commissioner of the Food and Drug Administration issue orders ***requiring***:

a. All such medical products, *including all OTC products*, to contain a clear "Black Box" warning of the potential risk for neurological damage to ***susceptible*** fetuses, newborns, and children on all of said medical product's labeling,

b. *For prescription medical products, including vaccines, preserved with mercury-based compounds that are administered to newborns, children, and all women of child bearing age*, informed written consent be obtained, as appropriate, from all such patients or their guardians before any such medical product is administered to any covered patient and that said consent forms: **i)** clearly state the possibility of neurological injury **and ii)** permit patients or their guardians, as appropriate, to postpone, *for any reason*, or decline, *for religious or other stated health reasons*, the administration of said medication, **and**

c. All vaccines remaining in commerce after 1 January 2006 that contain more than 0.5 micrograms of mercury per dose of drug product and all other drugs containing more than 1.0 microgram of mercury per milliliter or gram to be recalled and destroyed.

5. Finally, *on the grounds that the manufacturer must prove safety for whomever may be treated with each drug product*, we request that the Commissioner of the Food and Drug Administration issue a policy that requires any preservative or other component of a vaccine, RhoD injection, flu shot, or other FDA-regulated product administered to humans or animals must be a substance that **either:**

a. Is not mercury based, **or**

b. *When the manufacturer of such medical products **provides proof** that said preservative or other component must be mercury-based*, the level of mercury-based preservative or other mercury-containing component in the formulation must be proven (in scientifically sound repetitive acute and/or intermediate-term chronic-toxicity studies using "susceptible" animals [e.g., SJL/J mice]) to be non-neurotoxic:

i. At levels not less than ten (10) times the maximum component level of that mercury-based compound in any medical product that is intended to be administered to, or taken by, women of child-bearing age, newborns and children under the age of 15 years or, *for any person*, is intended to be taken for extended periods of time (e.g., ophthalmic eye drops approved for the treatment of a chronic eye condition), **or**

ii. At levels not less than three (3) times the maximum component level of that mercury-based compound in any medical product that is intended to be administered to or taken by adults and children 15 years of age or older, other than women of child-bearing age, at widely separated intervals (e.g., vaccines) or for short periods of time (e.g., prescription post-operative eye drops).

II. Petitioners

The undersigned representatives for the Coalition for Mercury-free Drugs (CoMeD), a group who supports the withdrawal of drug products containing added mercury-based compounds unless they have been unequivocally proven safe for **all** ***susceptible*** individuals, bring this petition.

CoMeD is a broad-based advocacy group dedicated to:

a. The immediate removal of drug products whose formulations contain more than "trace" (***not more than*** 0.5 μg per dose) levels of mercury from the medical products approved or licensed for use in the United States because of the proven harm that higher levels of mercury have now been established to cause **and**

b. *Longer term*, banning the addition of: **i)** mercury **or ii)** mercury-based materials and components to the formulation of all medical products unless, at "trace" or lower levels, the presence of said added mercury is proven to be safe for administration to susceptible individuals.

CoMeD's position on mercury is based on 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 observable harm[9].

III. Statement of Grounds

We urge you to honor our requests because:

- They arise out of our experience- and science- based concerns for the public health.
- *Based on the body of scientifically sound evidence we will cite*, these actions are required to guarantee the uncompromised neurological development of **all** children before, at, and after their birth in this generation and future generations.

Therefore, we implore you to:

- Review the issues that we herein identify.
- Carefully consider the information and documentation that we are submitting with this petition.

A. Safety Not Proven[10]

1. *General Background*

The compound, ethyl(2-mercaptobenzoato-S)mercury sodium salt or, more commonly named, sodium ethylmecurithiosalicylate, patented as a topical anti-infective in 1928 and known by many trade names, including Thimerosal, has been used since the 1930's.

Subsequently, Thimerosal came to be widely accepted as a "preservative" component in some of the vaccines and other drugs intended for use in humans.

Moreover, *though not labeled as such*, Thimerosal (at levels from 0.01 % [100 ppm] down to "0.0002 % [2 ppm]" in vaccine formulations) seems to function as an "adjuvant."

From the 1980's to present, the Centers for Disease Control and Prevention (CDC) and the FDA have allowed: **a)** the administration of Thimerosal-preserved RhoD and other biological preparations to pregnant women **and b)** the immunization of newborns and young children with Thimerosal-preserved vaccines that, *in both instances*, contain levels of Thimerosal that exceed EPA's implicit safety limits for mercury exposure.

Today, a range of multi-dose vaccines and related biological products that contain levels of Thimerosal above 0.001 % (10 ppm) are still produced, licensed or approved, and available for unrestricted use in humans.

2. *Removal Of Thimerosal And Other Mercury-based Compounds From OTC Drugs*

In 1982, a scientific panel, convened by the FDA to review the over-the-counter (OTC) use of Thimerosal, concluded,[11] "that thimerosal is not safe for [over-the-counter] topical use because of its potential for cell damage if applied to broken skin and its allergy potential." [**Note:** This FDA-sponsored panel only addressed the epidermal and dermal effects of Thimerosal**.**]

Based on the results of their review, that scientific panel recommended the removal of Thimerosal from over-the-counter products.

Sixteen years later, in 1998, the FDA finally banned[12] the use of:

a. Thimerosal and any other ingredient containing mercury in OTC "topical antimicrobial" products, **and**

b. Phenylmecuric acetate, phenylmecuric nitrate, and any other ingredient containing mercury in "vaginal contraceptive" products. [**See 21 C.F.R. Section 310.545**.]

3. ***Petitioners' General Concerns***

Of general concern to these petitioners are the facts that:

a. Today, Thimerosal's mercury-containing metabolites, ethyl mercury and ionic mercury, are known neurotoxins at levels below 0.1 part per million (0.1 ppm; 0.1 μg/mL in liquids or 0.1 μg/g in solids) **and**

b. *When Thimerosal is present at 0.01 %, as it commonly is in multi-dose vaccine formulations and other similarly preserved biological preparations*, the effective level of "mercury" added to such formulations is about 50 parts per million (50 ppm; 50 μg/mL or 50 μg/g).

In spite of the preceding facts, the manufacturers have failed**,** *as far as we have been able to ascertain***,** to establish the intrinsic safety of formulations containing added Thimerosal, a known neurotoxic compound, at the 0.01% level or, *for that matter*, at lower levels.

We find that the safety of each formulation has **not** been scientifically established in the appropriate rigorous comparative toxicology studies (comparing the acute and chronic neurotoxicity of the formulation with added Thimerosal to the neurotoxicity of the same formulation without Thimerosal) using an appropriate ***mercury-susceptible*** cellular or animal model.

Inexplicably, the preceding safety-study data is deficient or non-existent even though the regulations for drugs, *including vaccines and other biological preparations classified as drugs*, explicitly require that all drugs (as that term is defined in **21 U.S.C. Section (§) 321(g)(1)**[13], *including any component used in a drug [**21 U.S.C. § 321(g)(1)(D)**]*) must be ***safe*** (based on the definition of ***safe*** in **21 U.S.C. § 321(u)**[14]) and effective in humans and animals.

In addition, the regulations governing "Preservatives in Vaccines" (contained in Section 610.15 of the Code of Federal Regulations [**21 C.F.R. § 610.15]**) *explicitly* require that "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"[15].

Thus, *as far as we have been able to ascertain*, the maximum level of **Thimerosal present** in today's Thimerosal-preserved drug products (0.01% [100 micrograms per milliliter or gram of drug product]) has **not** been **proven safe**.

In contrast, *we now know*:

- **Scientifically sound experimental studies have <u>proven</u>** the **<u>neurotoxicity</u>** of Thimerosal and its metabolites, ethyl mercury and mercuric ion, **at "mercury" levels below 0.1 part-in-a-million** (0.1 ppm; 0.1 μg per mL or g) [**see**, *for example*, the articles in **Endnote 6**], **and**

- **There are NO properly designed experimental studies** [using today's science and animal models that, *to the best of our understanding*, mimic the early growth pattern and neuromaturational changes in humans] **that:**

  a. **Address *susceptible*** fetuses, newborns, children, adolescents and adults, **and**

  b. **Have proven** the human central-nervous-system (CNS) **safety** (no acute or chronic effect) for Thimerosal at 1000 ppm (0.1 %) in each biological product formulation so that the current 0.01 % level permitted in multi-dose formulations could be presumed, *with a 10-fold safety margin*, to be "sufficiently non-neurotoxic so that the amount present in the recommended dose of the product will not be toxic to" **<u>all</u>** who may receive such drug products, **or**

  c. *For that matter*, **have proven** the human CNS **safety** (no acute or chronic effect) for Thimerosal at 40 ppm (0.004 % [0.002 % mercury, 20 μg/mL]) in the product formulation so that the current <u>maximum</u> "trace" levels (0.0004% [0.0002% mercury, 2 μg/mL]) in the "single dose" and/or "trace Thimerosal" formulations[16] (e.g., "trace Thimerosal" influenza vaccines produced by Aventis Pasteur, Wyeth-Lederle, and Evans) could be presumed, *with a 10-fold or higher safety margin*, to be "sufficiently non-neurotoxic so that the amount present in the recommended dose of the product will

not be toxic to" **all**, *including susceptible individuals of all ages*, who may receive such drug products.

Today, *in many cases*, the level of Thimerosal has been reduced[16] in, and, *in some instances*, eliminated from, pediatric "single dose" vaccine formulations.

However, *in the case of drug products with the "trace" levels of Thimerosal (**not more than** 0.0004 % [4 ppm])*, there is no scientifically sound or regulatory permissible justification for the continued use of Thimerosal, or any other, known, "sub-ppm-level" neurotoxin or neurotoxin precursor as:

a. A "preservative" (Thimerosal's only FDA-approved use in vaccines), **or**

b. An "adjuvant" (a clearly unapproved use) or "permissible contaminant carried over from a previous processing step" (an implicit claim for the current "mercury free" vaccines that contain Thimerosal at "trace" levels).

The preceding is the case because, *at Thimerosal's current maximum "trace" level (**not more than** 2 μg of Thimerosal [1 μg of mercury] per 0.5-mL dose [**not more than** 0.0004 %]) in "trace Thimerosal" vaccine formulations*, Thimerosal does **not** meet the accepted United States Pharmacopeia's (USP's) definition of a preservative. [**Note:** The "0.01 % [100 μg per mL] Thimerosal" present in the current "multi-dose" vaccine formulations is represented to meet the USP's definition even though some studies suggest that, at 0.01%, it is a marginal preservative.]

Moreover, there are other suitable, less neurotoxic preservatives that have proven to be safe and effective for use, and are being used, in vaccines and other biological drugs (e.g., benzethonium chloride, phenol, and 2-phenoxyethanol).

4. ***FDA's Published Call-For-Data Notices And Announcements***

In December of 1998[17] and April of 1999[18], the FDA announced, *pursuant to Section 413 of the Food and Drug Modernization Act of 1997 (FDAMA)*, "a call-for-data to identify food and drug products that contain intentionally introduced mercury compounds, e.g., mercurous chloride, mercuric chloride, phenylmercuric acetate, Thimerosal. The agency is seeking both quantitative and qualitative information about the mercury compounds in these food and drug products." [**Note:** In November of 1999, the FDA posted[19] a notice of the availability of a document, entitled "**Mercury Compounds in Drugs and Food,**" that discussed drugs (including biologics) and foods that contain intentionally introduced mercury compounds.]

In July of 1999, *shortly after the FDA's second "call-for-data" notice*, the FDA issued a press release (entitled "**Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service**"[20]) that, *in part*, stated, "because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by European regulatory agencies, European vaccine manufacturers, and FDA, which examined the use of thimerosal-containing vaccines produced or sold in European countries."

5. ***Thimerosal At Multi-Dose Vaccine Or Lower Levels***

[**Note:** *Where appropriate*, **bolding** has been added to the quoted passages for emphasis.]

Consider the **1985** report in which Stetler et al.[21], *from the CDC*, evaluated the use of Thimerosal as a preservative in vaccines.

Based on their review of available data, these authors reported:

"Laboratory experiments in this investigation have shown up to 2 weeks' survival of at least one strain of group A Streptococcus in multidose DTP [Diphtheria-Tetanus-Pertussis] vials. The manufacturer's **preservative effectiveness tests**" [at 0.01 % (**100** micrograms of Thimerosal {50 micrograms of mercury} per milliliter)] "**showed** that at 4°C, **4.5% of the challenge Streptococcus survived 14 days after inoculation** into a multi-dose DTP vaccine vial. **At currently used concentrations, thimerosal is not an ideal preservative**."

Further, the authors warned:

"However, **because thimerosal is an organic mercurial compound, higher concentrations might** reduce vaccine potency or **pose a health hazard to recipients**."

Moreover, *in the limited experiments conducted on animals using Thimerosal*, the rapid metabolic conversion of the Thimerosal into ethyl mercury (an alkyl mercury compound that is a known human and animal neurotoxin) and, *in general*, the unequivocal neurotoxic effects caused by alkyl mercury compounds (and the ionic mercuric into which alkyl mercury compounds are metabolized) combine to establish that Thimerosal is a neurotoxic compound that should **not** be permitted in any drug product that is administered to humans or animals ***unless*** the manufacturer can **prove**:

a. The **proposed level** of the mercury-based compound **is safe** at 10 times its proposed maximum level, **and**

b. This medical **product cannot safely be used without** including **this compound** or another mercury-containing compound **in** the **formulation**.

For example, in **1975**, Gasset et al.[22] reported:

"…administration of thimerosal to rabbits shows that a substantial concentration of mercury was present in blood and tissues of the treated animals and their offspring. **Thimerosal was found to cross the blood-brain and placenta barriers**."

In **2001**, Redwood et al.[23] reported that infants who received multiple Thimerosal-containing vaccines probably had been exposed to cumulative mercury doses well in excess of Federal safety guidelines.

Based on the CDC's 2001 recommended immunization schedule, that study found infants could have been exposed to ***not less than*** 12.5 micrograms (μg) of mercury at birth, 62.5 μg of mercury at 2 months, 50 μg of mercury at 4 months, 62.5 μg of mercury at 6 months, and 50 μg of mercury at approximately 18 months, for a total of ***not less than*** 237.5 μg of mercury during the first 18 months of life, provided: **a)** the infants' vaccinations were all given as scheduled **and b)** the vaccines administered were Thimerosal-containing multi-dose vaccines in every instance.

The authors estimated concentrations of mercury in hair expected to result from the recommended CDC schedule utilizing a one compartment pharmacokinetic model, and found that those modeled mercury concentrations in infants immunized with Thimerosal-preserved "multi-dose" vaccines were in excess of the Environmental Protection Agency's safety guidelines.

In addition, several modeled peak concentrations within this period were in excess of 4.5 times the EPA limit.

Similarly, in **2000**, Slikker[24] from the FDA stated,

"Thimerosal (sodium ethyl mercurithiosalicylate) crosses the blood-brain and placental barriers and results in appreciable mercury content in tissues including the brain."

Additionally, Stajich et al.[25] have examined total mercury levels before and after the administration of hepatitis B vaccine in 15 pre-term and 5 term infants.

In **2000**, these authors reported that there were statistically significant increased levels of mercury in the blood 48 to 72 hours following hepatitis B immunization in both pre-term (relative increase = 13.5, $p < 0.01$) and term (relative increase = 56, $p < 0.01$) infants.

Finally, in **2004**, the summary results presented by Dr. Polly Sager[26] from the National Institutes of Health (NIH) at the February Institute of Medicine (IOM) meeting were corrected to show a half-life of mercury in the brain of more than 28 days following injections of solutions containing low levels of Thimerosal into ***infant*** monkeys. [**Note:** At a subsequent joint HHS and EPA Symposium[27], Thomas Brubacher, PhD, the researcher who actually headed the infant-monkey study, gave a presentation. When asked about the mercury present in the brain tissue, Dr. Brubacher volunteered that the predominate mercury species in the infant monkeys' brains was ionic mercury.]

In spite of the preceding realities and other studies, the FDA has, *to date*, failed to proscribe the use of Thimerosal in all prescription drugs.

It is apparent that decades after an FDA advisory committee[28] found, in 1982, that Thimerosal was **not** safe for use in topical ointments, new vaccines containing Thimerosal were, and are, being approved and added to the recommended childhood immunization schedule, including general-use vaccines (e.g., influenza) that are formulated to contain 0.01 % (100 ppm)

Thimerosal. [**Note:** We have similar concerns because these Thimerosal-preserved, general-use vaccines and other Thimerosal-preserved biological drugs are licensed for administration during pregnancy.]

a. Recent Comments of a US House Subcommittee and the US Office of Special Counsel (OSC)

In **2003**, after a three-year investigation, a Congressional report[29] (prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform of the United States' House of Representatives) had this to say regarding the FDA, Thimerosal in vaccines, and the "autism epidemic":

"The Food and Drug Administration's (FDA) mission is to 'promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.' However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, 'at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions.' This argument—that known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to thimerosal in vaccines-is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from thimerosal was theoretical: that no proof of harm existed. However, the Committee, upon a thorough review of the scientific literature and internal documents from government and industry, did find evidence that thimerosal did pose a risk. …

…

… Thimerosal used as a preservative in vaccines is likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry."

In addition, that subcommittee reviewed the CDC's epidemiological studies and concluded: "To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC's rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccines."

On May 20, 2004, *responding to public concern about the CDC's apparently flawed studies*, the United States Office of Special Counsel (OSC), an independent federal agency, issued:

a. A press release[30] **and**

b. A letter from Special Counsel Scott Bloch[31] to Congress stating, "I have recently received hundreds of disclosures from private citizens alleging a widespread danger to the public health, specifically to infants and toddlers, caused by childhood vaccines which include thimerosal, a mercury-containing preservative... The disclosures allege that thimerosal/mercury is still present in childhood vaccines, contrary to statements made by HHS agencies, HHS Office of Investigations and the American Academy of Pediatrics. According to the information provided, vaccines containing 25 micrograms of mercury and carrying expiration dates of 2005, continue to be produced and administered. In addition,

the disclosures allege, among other things, that some datasets showing a relationship between thimerosal/mercury and neurological disorders no longer exist, that independent researchers have been arbitrarily denied access to the Centers for Disease Control and Prevention (CDC) databases, and that government-sponsored studies have not assessed the genetic vulnerabilities of subpopulations. Due to their heightened concern that additional datasets may be destroyed, these citizens urge the immediate safeguarding of the Vaccine Safety Datalink database, and other relevant CDC information, so that critical data are not lost. The disclosures also allege that the CDC and the Food and Drug Administration colluded with pharmaceutical companies at a conference in Norcross, Georgia, in June 2000 [**see** this petition's **Endnotes 4** and **36**], to prevent the release of a study which showed a statistical correlation between thimerosal/mercury exposure through pediatric vaccines and neurological disorders, including autism, attention-deficit/hyperactivity disorder (ADHD), stuttering, tics, and speech and language delays. Instead of releasing the data presented at the conference, the author of the study, Dr. Thomas Verstraeten, later published a different version of the study in the November 2003 issue of ***Pediatrics***, which did not show a statistical correlation. No explanation has been provided for this discrepancy. Finally, the disclosures allege that there is an increasing body of clinical evidence on the connection of thimerosal/mercury exposure to neurological disorders which is being ignored by government public health agencies... I believe that these allegations raise serious continuing concerns about the administration of the nation's vaccine program and the government's possibly inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines. The allegations also present troubling information regarding children's cumulative exposure to mercury and the connection of

that exposure to the increase in neurological disorders such as autism and autism-related conditions among children in the US."

b. "Confounded" and "Biased" Epidemiological Studies On Vaccinated Children?

Studies Based On American Children

Among other things, Special Counsel's letter discussed a CDC-commissioned epidemiological study that troubled those who had contacted him.

In that epidemiological study, Thomas Verstraeten reported, *in a "02/29/00" draft report he authored*[32], finding a significant relationship between Thimerosal-containing childhood vaccines and some types of neurodevelopmental disorders, including autism.

By a "06/01/00" draft[33] (*the closest draft [provided under the Freedom of Information Act {FOIA} to SafeMinds in 2001] to the exact documents discussed in a closed meeting held between government and industry at the Simpsonwood Retreat Center on June 7-8, 2000 in Norcross, Georgia*[4]), the report, titled, *"***Risk of neurologic and renal impairment associated with thimerosal-containing vaccines**," concluded that there was **no** evidence of a "Thimerosal-containing vaccines" risk for renal impairment.

However, this **draft did report** "a statistically significant positive correlation" between the probable levels of Thimerosal "exposure and outcomes:

- the cumulative exposure at 2 months of age and unspecified developmental delay
- the cumulative exposure at 3 months of age and tics
- the cumulative exposure at 6 months of age and attention deficit disorder

- the cumulative exposure at 1, 3 and 6 months of age and language and speech delay
- the cumulative exposure at 1, 3 and 6 months of age and neurodevelopmental delays in general."

Nonetheless, *principally because of a change in criteria and the inclusion of additional children*, the relationships reported in this June draft were different and less significant than those reflected in the graphs shown in the February draft[32].

In the published version of that study, Verstraeten et al.[34], using further adjusted criteria and an altered dataset, no longer found a significant relationship between Thimerosal-containing childhood vaccines and some types of neurodevelopmental disorders.

In **2004**, Verstraeten, *the lead author in the cited drafts*[32,33] *and the prior publication*[34], reiterated[35] that the published findings were *epidemiologically* neutral (i.e., could ***neither*** accept ***nor*** reject) with respect to a causal relationship between Thimerosal inoculation exposure and neurodevelopmental disorders (NDDs), in general, or diagnosed autism, in specific.

A version of the June 2000 report[33] (that, *after further "adjustment"*, was used to generate the published article[34]) was the subject of robust debate in the "Simpsonwood" closed meeting.[4]

The following are some pertinent excerpts from a copy of a printed record of the "Simpsonwood" meeting[36].

This record, obtained by SafeMinds under FOIA in 2001, sheds light on the underlying issues surrounding the June draft's findings. [**Note:** *Where appropriate*, **bolding** has been added to the quoted passages for emphasis.]

Dr. Bernier (page 113): "We have asked you to keep this information confidential…So we are asking people who have done a great job protecting this information up until now, to continue to do that until the time of the ACIP meeting…That would help all of us to use the machinery that we have in place for considering these data and for arriving at policy recommendations."

Dr. Verstraeten (page 31): "It is sort of interesting that when I first came to the CDC as a NIS officer a year ago only, I didn't really know what I wanted to do, but one of the things I knew I didn't want to do was studies that had to do with toxicology or environmental health. Because I thought it was too much confounding and it's very hard to prove anything in those studies. Now it turns out that other people also thought that this study was not the right thing to do, so what I will present to you is the study that nobody thought we should do."

Dr. Verstraeten (pages 40 – 41): "...we have found statistically significant relationships between the exposures and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay, which has its own specific ICD-9 code. Exposure at three months of age, Tics. Exposure at six months of age, an attention deficit disorder. Exposure at one, three and six months of age, language and speech delays which are two separate ICD-9 codes. Exposure at one, three and six months of age, the entire category of neurodevelopmental delays, which includes all of these plus a number of other disorders."

Dr. Chen (page 151): "One of the reasons that led me personally to not be so quick to dismiss the findings was that on his own Tom independently picked three different outcomes that he did not think could be associated with mercury (conjunctivitis, diarrhea and injury) and three out of three had a different pattern across different exposure levels as compared to the ones

that again on a priority basis we picked as biologically plausible to be due to mercury exposure."

Dr. Johnston (pages 199 – 200): "This association leads me to favor a recommendation that infants up to two years old **not** be immunized with Thimerosal containing vaccines if suitable alternative preparations are available. My gut feeling? It worries me enough. **Forgive this personal comment, but I got called out at eight o'clock for an emergency call and my daughter-in-law delivered a son by C-Section. Our first male in the line of the next generation, and I do not want that grandson to get a Thimerosal containing vaccine until we know better what is going on.** It will probably take a long time. In the meantime, and I know there are probably implications for this internationally, but in the meantime I think **I want that grandson to only be given Thimerosal-free vaccines**."

Dr. Weil (page 207): "The number of dose related relationships are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant. The positive relationships are those that one might expect from the Faeroe Islands studies. They are also related to those data we do have on experimental animal data and similar to the neurodevelopmental tox data on other substances, so that I think you can't accept that this is out of the ordinary. It isn't out of the ordinary."

Dr. Brent (page 229): "**The medical legal findings in this study, causal or not, are horrendous and therefore, it is important that the suggested epidemiological, pharmacokinetic, and animal studies be performed**. If an allegation was made that a child's neurobehavioral findings were caused by Thimerosal containing vaccines, you could readily find a junk scientist who would support the claim with 'a reasonable degree of certainty'. But you will not find a scientist with any integrity who would say the reverse with

the data that is available. And that is true. So we are in a bad position from the standpoint of defending any lawsuits if they were initiated and I am concerned."

Dr. Clements (pages 247 – 248): "I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which way the boat should go at all. And I really want to risk offending everyone in the room by saying that perhaps this study should not have been done at all, because the outcome of it could have, to some extent, been predicted, and we have all reached this point now where we are left hanging, even though I hear the majority of consultants say to the Board that they are not convinced there is a causality direct link between Thimerosal and various neurological outcomes. I know how we handle it from here is extremely problematic. The ACIP is going to depend on comments from this group in order to move forward into policy, and I have been advised that whatever I say should not move into the policy area because that is not the point of this meeting. But nonetheless, we know from many experiences in history that the pure scientist has done research because of pure science. But that pure science has resulted in splitting the atom or some other process which is completely beyond the power of the scientists who did the research to control it. And what we have here is people who have, for every best reason in the world, pursued a direction of research. But there is now the point at which the research results have to be handled, and even if this committee decides that there is no association and that information gets out, the work that has been done and through the freedom of information that will be taken by others and will be used in ways beyond the control of this group. And I am very concerned about that as I suspect it is already too late to do anything regardless of any professional body and what they say …"

A Congressman's Published Views On The CDC Study

On October 31, 2003, *after reviewing the CDC-sponsored article*[34] *and the report from the 2000 closed-door meeting*[4], Congressman Dave Weldon, a concerned legislator and physician, wrote a letter to Julie Gerberding[37], Director of the CDC, stating, "I have reviewed the article and have serious reservations about the four-year evolution and conclusions of this study. …"

The Congressman then continued:

"I am a strong supporter of childhood vaccinations and know that they have saved us from considerable death suffering. A key part of our vaccination program is to ensure that we do everything possible to ensure that these vaccines, which are mandatory, are as safe as possible. We must fully disclose adverse events. Anything less than this undermines public confidence.

I have read the upcoming ***Pediatrics*** study and several earlier versions of this study dating back to February 2000. I have read various emails from Dr. Verstraeten and coauthors. I have reviewed transcripts of a discussion at Simpsonwood, GA between the author, various CDC employees and vaccine industry representatives. I have found a disturbing pattern which merits a thorough, open, timely, and independent review by researchers outside of the CDC, HHS, the vaccine industry, and others with a conflict of interest in vaccine related issues (including many in University settings who may have conflicts).

A review of these documents leaves me very concerned that rather than seeking to understand whether or not some children were exposed to harmful levels of mercury in childhood vaccines in the 1990s, there may have been a selective use of the data to make the associations in the earliest study disappear. …

Furthermore, the lead author of the article, Dr. Thomas Verstraeten, worked for the CDC until he left over two years ago to work for GlaxoSmithKline (GSK), a vaccine manufacturer facing liability over TCVs. In violation of their own standards of conduct, ***Pediatrics*** failed to disclose that Dr. Verstraeten is employed by GSK and incorrectly identifies him as an employee of the CDC. This revelation undermines this study further.

The first version of the study, produced in February 2000, found a significant association between exposure to thimerosal-containing vaccines (TCVs) and autism and neurological developmental delays (NDDs). When comparing children exposed to 62.5 µg [micrograms] of mercury by 3 months of age to those exposed to less than 37.5 µg, the study found a relative risk for autism of 2.48 for those with the higher exposure levels. (While not significant in the 95% confidence interval for autism, this meets the legal standard of proof exceeding 2.0.) For NDDs, the study found a relative risk of 1.59 and a definite upward trend as exposure levels increased.

A June 2000 version of the study applied various data manipulations to reduce the autism association to 1.69 and the authors went outside of the VSD database to secure data from a Massachusetts HMO (Havard Pilgrim, HP) in order to counter the association found between TCVs and speech delay. At the time that HP's data was brought in, HP was in receivership by the state of Massachusetts, its computer records had been in shambles for years, it had multiple computer systems that could not communicate with one another, and it used a health care coding system totally different from the one used across the VSD. There are questions relating to a significant underreporting of Autism in Massachusetts. The HP dataset is only about 15% of the HMO dataset used in the February 2000 study. There may also be significant problems with the statistical power of the dataset.

In June 2000, a meeting was held in Simpsonwood, GA, involving the authors of the study, representatives of the CDC, and the vaccine industry. I have reviewed a transcript of this meeting that was obtained through FOIA. Comments from Simpsonwood meeting include: (*summary form, not direct quotes*):

- We found a statistically significant relationship between exposures and outcomes. There is certainly an under ascertainment of adverse outcomes because some children are just simply not old enough to be diagnosed, the current incidence rates are much lower than we would expect to see (Verstraeten);
- We could exclude the lower exposure children from our database. Also suggested with removing the children that got the highest exposure levels since they represented an unusually high percentage of outcomes (Rhodes);
- The significant association with language delay is quite large (Verstraeten);
- This information should be kept confidential and considered embargoed;
- We can push and pull this data anyway we want to get the results we want;
- We can alter the exclusion criteria any way we want, give reasonable justifications for doing so, and get any result we want;
- There was really no need to do this study. We could have predicted the outcomes;
- I will not give TCVs to my grandson until I find out what is going on here.

Another version of the study – after further manipulation – finds no association between TCVs and autism, and no consistency across HMOs between TCVs and NDDs and speech delay.

The final version of the study concludes that 'No consistent significant associations were found between TCVs and neurodevelopmental outcomes,' and that the lack of consistency argues against an association. In reviewing the study there are data points where children with higher exposures to the neurotoxin mercury had fewer developmental disorders. This demonstrates to me how excessive manipulation of data can lead to absurd results. Such a conclusion is not unexpected from an author with a serious, though undisclosed, conflict of interest. This study increases speculation of an association between TCVs and neurodevelopmental outcomes."

Published Epidemiological Studies From Other Developed Countries

Other epidemiological studies using the health histories of Danish and Swedish children and purporting to show a negative relationship between Thimerosal and autism have been published[38].

Sadly, these studies have little applicability to the United States' experience with Thimerosal-containing vaccine immunizations.

This is the case *in both Denmark and Sweden* because:

- Significantly lower levels of Thimerosal were administered to their children as part of the childhood immunization schedule than to American children. [**Note:** Overall, during the study period, these countries' vaccination guidelines suggested giving approximately one-third the Thimerosal dose recommended in the United States' guidelines.]
- *When compared to the vaccination schedules in these countries*, the CDC's vaccination schedules specify more inoculations and a more compressed early childhood schedule.

Additionally, the studies in Denmark are flawed[39] because:

- *Initially*, **only** inpatient diagnosed autistics were identified; later in these studies, **both** inpatient and outpatient diagnosed autistics were identified – leading to an increase in reporting being improperly twisted into an increase in incidence. [**Note:** Based on the incidence studies noted in their Endnote 35, the incidence rate for autism in Denmark during the study period was about 5 per 10,000 children as compared to the US rate of 30 per 10,000 children – a much lower incidence and one that compares favorably to the rate of 4 per 10,000 children reported in Denmark for the 1950's.]

- Different diagnosis codes of neurodevelopmental maladies, i.e., psychosis infantilis posterior (ICD-8 299.01) versus atypical (i.e. regressive) autism (ICD-10 F84.1), were used before and during the presumed increase in autism incidence, respectively.

- Data from additional clinics, with a significant portion of the autistic children in the entire country, were added as the studies progressed.

Further, the very Danish vaccine manufacturer who obtains a significant portion of its profits from the manufacture and distribution of "Thimerosal-preserved" vaccines in Denmark, Sweden and elsewhere, authored, financed, and/or resourced these studies.

Finally, much of the information needed to validly compare these results to those found in the US was simply **not** reported.

c. Studies Establishing Linkages Between Thimerosal Exposure And Adverse Outcomes, Including "Neurodevelopmental Disorders" ("NDDs")

In stark contrast to the published epidemiological studies funded by pharmaceutical or government monies[34,38], numerous published epidemiological studies by the Geiers[40] and Holmes et al.[41] clearly establish a causal association between increasing mercury exposure from Thimerosal-containing childhood vaccines and neurodevelopmental disorders.

In these studies, both from cohort and epidemiological evaluations, the authors found a statistically significant, "2- to 6- fold overall" and "dose-response related," increased risk, in the United States, for neurodevelopmental disorders following the administration of additional doses of Thimerosal-containing vaccines in conformance to the applicable CDC-recommended childhood immunization schedules.

In addition, these studies identified children who had received doses of mercury from Thimerosal-containing childhood vaccines that were in some cases more than 100-fold in excess of the FDA's and/or the EPA's allowable safety guidelines for instantaneous exposure to orally ingested methyl mercury.

Thimerosal is a Problematic Preservative

[**Note:** *Where appropriate*, **bolding** has been added to the quoted passages for emphasis.]

Sadly, *for seven decades*, the FDA has not heeded the recommendations (made by recognized researchers from many scientific and medicinal disciplines) published in the peer-reviewed scientific and medical literature.

These researchers have repeatedly called for an end to adding any amount of Thimerosal to vaccines and related products.

The following represent but a few examples of such calls for **not** using Thimerosal (also having the trade names of Merthiolate, Merzonin, Mertorgan, Merfamin, and, *in Europe*, Thiomersal), a compound, found in some approved vaccines and other biological drug products, that rapidly "dissociates" into ethyl mercury (56.7%) and sodium thiosalicylate (43.3 %) in living systems.

"In 1935, in a letter from the Director of Biological Services, of the Pittman-Moore Company to Dr. Jamieson of Eli Lilly, **'we have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in 1 in 40,000 to 1 in 5,000** … **no connection between the lot of serum and the reaction.** In other words, **Merthiolate is unsatisfactory as a preservative for serum** intended for use on dogs ... I might say that we have tested Merthiolate on humans and find that it gives a more marked local reaction than does phenol and tricresol.**'**''[29]

In **1967**, Nelson and Gottshall from the Division of Biologic Products, Bureau of Laboratories, Michigan Department of Public Health published[42]:

"**Pertussis vaccines preserved with 0.01% Merthiolate are more toxic for mice than unpreserved vaccines prepared from the same parent concentrate and containing the same number of organisms**… An increase in mortality was observed when Merthiolate was injected separately, before or after an unpreserved saline suspension of pertussis vaccine."

In **1979**, Heyworth and Truelove stated[43]:

"For many years, merthiolate was known to have anti-microbial activity. When it was first introduced as an anti-microbial preservative, little information about the fundamental biological effects of organic mercury compounds was available. **We should like to suggest that**

merthiolate should now be regarded as an inappropriate preservative for anti-lymphocytic globulin preparations and other materials which are intended for administration to human subjects."

In **1980**, Forstrom et al. noted[44]:

"…reactions can be expected in such a high percentage of merthiolate-sensitive persons that **merthiolate in vaccines should be replaced by another antibacterial agent**."

In **1983**, Kravchenko et al reported[45]:

"Thus thimerosal, commonly used as a preservative, has been found not only to render its primary toxic effect, but also is capable of changing the properties of cells. This fact suggests that the **use of thimerosal for the preservation of medical biological preparations, especially those intended for children, is inadmissible**."

In **1986**, Winship reported[46]:

"Multi-dose vaccines and allergy-testing extracts contain a mercurial preservative, usually 0.01% thimerosal, and may present problems occasionally in practice. **It is, therefore, now accepted that multi-dose injection preparations are undesirable and that preservatives should not be present in unit-dose preparations**."

In **1988**, Cox and Forsyth urged[47]:

"However, **severe reactions to thiomersal demonstrate a need for vaccines with an alternative preservative**."

In **1991**, Seal et al.[48] commented in the *Lancet*,

"**Thiomersal is** a weak antibacterial agent that is **rapidly broken down to products, including ethyl mercury residues, which are neurotoxic**. Its role as a preservative in vaccines has been questioned, and the pharmaceutical industry considers its use as historical."

In **2001**, van't Veen[49] stated:

"The very low thiomersal concentrations in pharmacological and biological products are relatively non-toxic, but probably not *in utero* and during the first 6 months of life. **The developing brain of the fetus is most susceptible to thiomersal and, therefore, women of childbearing age, in particular, should not receive thiomersal-containing products**."

In **2002**, Schumm et al.[50] recommended:

"**We** also **recommend** that **safer alternatives to thimerosal** (a mercury sodium salt, 50% mercury) **be used to preserve all vaccines**."

d. Inconsistencies Between The Exposure Limits For: i) Thimerosal In Drugs And ii) Methyl Mercury In Food: A Regulatory Conundrum?

Ironically, this nation's federal health agencies continue to assert Thimerosal-containing drugs are safe for administration to pregnant women, unborn children, newborns and toddlers, while simultaneously advising the public to limit consumption of tuna and other large fish, because of the proven risk of non-reversible neurological damage, to developing fetuses and growing children, from the low levels of methyl mercury (*a related alkyl mercury compound*) that such fish contain.

The assertion that low levels of methyl mercury are dangerous to ingest, but that higher levels of Thimerosal (a compound that rapidly breaks down into ethyl mercury) are somehow safe to:

a) infuse into pregnant women **and**

b) repeatedly inject into newborns and children

is both incongruous and illogical.

6. ***Ethyl Mercury, The Initial Thimerosal Metabolite***

[**Note:** *Where appropriate*, **bolding** has been added to the quoted passages for emphasis.]

In actual studies of ethyl mercury and methyl mercury, it has been demonstrated that the two compounds possess *at least similar* toxicities.

In some cases, it was even determined that ethyl mercury was more toxic than methyl mercury.

For example, in the early 1970's, Tryphonas and Nielsen conducted a study supported by the Medical Research Council of Canada to evaluate chronic low-dose exposure to ethyl mercury and methyl mercury compounds in young swine.

The authors of that study found[51]:

"The resulting toxicosis was primarily related to the nervous system, in which neuronal necrosis followed by secondary gliosis, capillary endothelial proliferation, and additional neuronal necrosis due to developing degenerative arteriopathy in the blood vessels supplying injured gray matter were seen. In other systems, degeneration of hepatocytes and renal tubular cells were commonly

occurring lesions in pigs given both MMD [methyl-mercury-containing compound] and EMC [ethyl-mercury-containing compound]… The results proved that the alkyl mercurial compounds MMD and EMC, if fed at low concentrations for long periods, were highly poisonous to swine."

In **1977**, Fagan et al. reported[52], in a study funded by the National Institute of Environmental Health Sciences, that, between 1969 and 1975, there were 13 cases of exomphalos treated by thimerosal.

The authors found that 10 of the patients had died, and their tissues were analyzed for mercury content.

The results showed that Thimerosal can induce blood and organ levels of organic mercury that are well in excess of the minimum toxic levels in adults and fetuses.

The authors concluded:

"Although thiomersal is an ethyl mercury compound, it has similar toxicological properties to methyl mercury and **the long-term neurological sequelae produced by the ingestion of either methyl or ethyl mercury-based fungicides are indistinguishable**."

The authors also observed that the scientific community seems to have forgotten:

a. Mercury and mercury-containing compounds are highly toxic,

b. Alkyl mercury compounds (e.g., methyl mercury and ethyl mercury [the initial mercury-containing metabolite from Thimerosal]) penetrate intact membranes, **and**

c. In 1977, equally effective and far less toxic broad-spectrum antifungal and antibacterial antiseptics were available.

As early as **1985**, Magos et al.[53] reported:

"Neurotoxicity and renotoxicity were compared in rats given by gastric gavage five daily doses of 8.0 mg Hg/kg methyl- or ethylmercuric chloride or 9.6 mg Hg/kg ethylmercuric chloride. Three or 10 days after the last treatment day"[,] "rats treated with either 8.0 or 9.6 mg Hg/kg ethylmercury had higher total or organic mercury concentrations in blood and lower concentrations in kidneys and brain than methylmercury-treated rats. **In each of these tissues the inorganic mercury concentration was higher** [approximately twice as high in the brain] **after ethyl-**" [ethyl mercury] "**than after methylmercury**. Weight loss relative to the expected body weight and renal damage was higher in ethylmercury-treated rats than in rats given equimolar doses of methylmercury. These effects became more severe when the dose of ethylmercury was increased by 20%. Thus in renotoxicity the renal concentration of inorganic mercury seems to be more important than the concentration of organic or total mercury. In methylmercury-treated rats"[,] "damage and inorganic mercury deposits were restricted to the P2 region of the proximal tubules, while in ethylmercury-treated rats the distribution of mercury and damage was more widespread. There was little difference in the neurotoxicities of methylmercury and ethylmercury when effects on the dorsal root ganglia or coordination disorders were compared."

7. ***Ionic Mercury, The Final Thimerosal Metabolite***

In actual studies of ionic mercury, it has been demonstrated that sub-nanomolar concentrations (***less than*** 0.2 nanograms [0.0000000002 gram {0.0002 µg}] per mL) of ionic mercury were able to markedly affect neuron growth and structure.

Specifically, in **2001**, Leong et al.[9] reported:

"Therefore, the present study examined whether Hg ions could affect membrane dynamic of neurite growth cone morphology and behavior … To test this possibility, the identified, large Pedal A (PeA) neurons from the central ring ganglia of the snail *Lymnoea stagnalis* were cultured for 24 h in 2 ml brain conditioned medium (CM). Following neurite outgrowth, metal chloride solution (2 μl) of Hg, Al, Pb, Cd, or Mn (10^{-7} M) was pressure applied directly onto individual growth cones. Time-lapse images with inverted microscopy were acquired prior to, during, and after the metal ion exposure. We demonstrate that Hg ions markedly disrupted membrane structure and linear growth rates of imaged neurites in 77% of all nerve growth cones. When growth cones were stained with antibodies specific for both tubulin and actin, it was the tubulin/microtubule structure that disintegrated following Hg exposure. Moreover, some denuded neurites were also observed to form neurofibrillary aggregates. In contrast, growth cone exposure to other metal ions did not effect growth cone morphology, nor was their motility rate compromised. To determine the growth suppressive effects of Hg ions on neuronal sprouting, cells were cultured either in the presence or absence of Hg ions. We found that the presence of Hg ions, neuronal somata failed to sprout, whereas other metallic ions did not effect growth patterns of cultured PeA cells. We conclude that this visual evidence and previous biochemical data strongly implicate Hg as a potential factor in neurodegeneration."

8. ***The Link Between Thimerosal And Neurological Disorders***

Neurological disorders, especially autism, are now at epidemic levels among our nation's children.

For more than a decade, California's Department of Developmental Services has conducted a careful analysis of the apparent autism epidemic in that state.

The most recent, April 2003 report[54] by the California Department of Developmental Services found:

a. "Between 1987 and December 2002, the population of persons with autism increased by 634 percent," **and**

b. The population increase was not "due to" potential confounding or bias.

Specifically, this report states:

"(1) The cumulative prevalence of autism in California increased from 7.5 per 10,000 for the sample 1983-85 birth cohort to 20.2 per 10,000 for the 1993-95 birth cohort, an increase of 269 percent. Other studies outside of California have found similar increases in prevalence rates equal to or greater than those in the Autism in California study (Yeargin-Allsopp, et al, 2003).

(2) Families immigrating into the state for services were not a factor affecting prevalence in California.

(3) Any shift in the interpretation of diagnostic criteria could not explain the increased prevalence.

(4) The regional centers had achieved high levels of diagnostic accuracy, i.e., 89 percent of the children with autism selected for the study were accurately diagnosed by regional centers."

Interestingly, the study also concluded that 18 to 19 percent of persons in the study diagnosed with mental retardation and without full syndrome autism met the "DSM IV" criteria for autism.

Thus, the study supported the interpretation that the increased prevalence of autism in California is a valid phenomenon and is derived by factors beyond improved identification and diagnosis.

Additionally, in February 2004, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (CA OEHHA) **reaffirmed**[55] that, *under California Proposition 65*, **mercury and mercury compounds**, *including ionic mercury salts, ethyl mercury and Thimerosal*, had been and **are** properly classified as **reproductive toxins**.

9. ***Autism Alarm***

In January 2004, the Department of Health and Human Services (HHS), the CDC, and the American Academy of Pediatrics issued an AUTISM A.L.A.R.M.[56] ("**Autism is prevalent**, **Listen to parents**, **Act early**, **Refer** and **Monitor**") stating, under "**Autism is prevalent**":

"• 1 out of 6 children are diagnosed with a developmental disorder and/or behavioral problem

• 1 in 166 children are diagnosed with an autism spectrum disorder and

• Developmental disorders have subtle signs and may be easily missed."

Thus, developmental/behavioral disorders, including autism, are now at epidemic levels among our nation's children.

The best estimates are that autism in American children has increased from 1 child in each 2,500 children born in 1970 to 1 child in each 323 children born in 1997, **a 774 percent increase**.[55] [**Note:** Based on the autism sex ratio reported by Verstraeten[33], ***more than*** 80 % of the diagnosed autistic children are male.]

10. ***Clinical Evidence***

Growing clinical evidence strongly suggests that many, if **not** most, of these *damaged* children are members of a genetically vulnerable, mercury-sensitive subpopulation that have been, and are being, injured by:

a. The mercury-based preservatives in vaccines with which they have been immunized **and/or**,

b. In utero, by the mercury-based preservatives in some of the drugs prescribed to and/or used by their mothers.

Bradstreet et al.[57] have evaluated the concentration of heavy metals in the urine among children with autistic spectrum disorders against two matched control groups based upon excretion levels following a three-day treatment with DMSA.

The authors observed that the urinary mercury difference between the groups was statistically significant.

Factually, the vaccinated children with autistic spectrum disorders had, on average, an approximately 6-times greater urinary mercury concentration than the group of matched unaffected vaccinated children.

In contrast, after the treatment, the three groups of children (vaccinated affected, vaccinated unaffected, and non-vaccinated unaffected) had similar urinary cadmium and lead concentrations in their urine samples.

Moreover, the urinary mercury concentrations for the unaffected vaccinated children were comparable to those observed for the matched unaffected non-vaccinated group of children.

Similarly, in **2003**, Holmes et al.[41] reported that one possible factor underlying this rapid growth in the number of children with neurodevelopmental disorders is the increased exposure to mercury arising from an increasing number of immunizations of newborns and young children with Thimerosal-containing vaccines.

However, this researcher cautioned that vaccine exposures should be evaluated in the context of cumulative exposures during gestation and early infancy.

Differential rates of postnatal mercury elimination may explain why similar gestational and infant exposures produce variable neurological effects.

First baby haircut samples were obtained from 94 children diagnosed with autism and 45 age- and gender-matched controls.

Information on diet, dental amalgam fillings, vaccine history, RhoD immunoglobulin administration, and autism symptom severity was collected through a maternal survey questionnaire and clinical observation.

Resulting average mercury levels in hair samples from the autistic group of children were 0.47 ppm versus 3.63 ppm in the control group of children, a significant difference.

Furthermore, the mothers of the children in the autistic group had significantly higher levels of mercury exposure through RhoD immunoglobulin injections and amalgam fillings than the mothers of the children in the control groups.

Within the autistic group, the mercury levels in their hair samples varied significantly across the mildly, moderately, and severely autistic subgroups of children, with mean subgroup levels of 0.79, 0.46, and 0.21 ppm, respectively.

Among the infants in the two control groups, the mercury levels in their hair samples matched the levels expected from their historical exposures to mercury-containing materials, including exposure to mercury through pediatric vaccinations.

By contrast, these correlations were absent in the group of autistic children. [**Note:** Based on the hair results, it seems obvious that the mercury detoxification and excretion patterns among autistic infants were significantly reduced relative to those of the matched control infants.]

After a thorough review of clinical studies to date, Dr. H. Vasken Aposhian, Ph. D., Professor of Molecular and Cellular Biology, University of Arizona, *referring to the causal association between mercury exposure and the disorder we have misnamed "autism*," declared before the Institute of Medicine (IOM) at its February 9, 2004 Meeting[58]: "We are moving toward causality." [**Note:** During his presentation, Dr. Aposhian referred to "autism" as a "Mercury Effluxor" [elimination] "Disorder."]

11. ***Significant 2004 Studies***

Most recently, Mady Hornig et al.[59] **reported** (in June of 2004) that, *following exposure to Thimerosal reflecting the United States' childhood immunization schedule (i.e., the dose and stage of development)*, **autoimmune disease-sensitive SJL/J mice developed symptoms mirroring childhood autism, including:**

- ✓ Growth delay;
- ✓ Reduced locomotion;
- ✓ Decreased numbers of Purkinje cells;
- ✓ Exaggerated response to novelty;
- ✓ Significant abnormalities in brain architecture, affecting areas subserving emotion and cognition; and
- ✓ Densely packed, hyperchromic hippocampal neurons with altered glutamate receptors and transporters.

However, the same treatment regimen did **not** similarly affect two mouse strains, C57BL/6J and BALB/cJ, that are not autoimmune sensitive.

The authors concluded that their findings:

a. **Support** the hypothesis that the adverse outcomes observed have **a genetic component**, **and**

b. **Provide a model** for investigating Thimerosal-related neurotoxicity.

Also, in **2004**, Havarinasab et al.[60] reported that Thimerosal, *which was primarily present in the tissues as ethyl mercury and ionic mercury*, has caused illness and several deaths due to erroneous handling when used as a disinfectant or as a preservative in medical preparations.

The authors stated:

"We have studied if thimerosal might induce the systemic autoimmune condition observed in genetically susceptible mice after exposure to inorganic mercury. A.SW mice were exposed to 1.25-40 mg thimerosal/l drinking water for 70 days. Antinucleolar antibodies, targeting the 34-kDa protein fibrillarin, developed in a dose-related pattern and first appeared after 10 days in the two highest dose groups. The lowest observed adverse effect level (LOAEL) for antifibrillarin antibodies was 2.5 mg thimerosal/l, corresponding to an absorbed dose of 147 microg Hg/kg bw and a concentration of 21 and 1.9 microg Hg/g in the kidney and lymph nodes, respectively. The same LOAEL was found for tissue immune-complex deposits. The total serum concentration of IgE, IgG1, and IgG2a showed a significant dose-related increase in thimerosal-treated mice, with a LOAEL of 5 mg thimerosal/l for IgG1 and IgE, and 20 mg thimerosal/l for IgG2a. The polyclonal B-cell activation showed a significant dose-response relationship with a LOAEL of 10 mg thimerosal/l. Therefore, thimerosal induces in genetically susceptible mice a systemic autoimmune syndrome very similar to that seen after treatment with inorganic mercury, although a higher absorbed dose of Hg is needed using thimerosal. The autoimmune syndrome induced by thimerosal is different from the weaker and more restricted autoimmune reaction observed after treatment with an equipotent dose of methyl mercury."

We also request that you review the landmark and courageous research of: Dr. Boyd Haley[41], Dr. Richard Deth[6(A[3])], Dr. Andrew Wakefield[61], Dr. Jeff Bradstreet[58], Dr. David Baskin[62], Dr. Mary Megson[63], Dr. Woody McGinnis[64], Dr. Amy Holmes[41], Dr. Stephanie Cave[65], and Dr. William Walsh[66].

12. *Summary Of "Safety Not Proven"*

*Until and unless Thimerosal and other mercury-containing compounds are conclusively demonstrated to be safe and effective at levels 10 times higher than the current highest permissible levels (i.e., 25 micrograms per dose in vaccines and 50 micrograms per mL or g in other drug products), these compounds should be removed from the nation's supply of vaccines and injectables in accordance with the Food, Drug, and Cosmetic Act's defining all drug components as drugs (**21 U.S.C. § 321(g)(1)(D)**) that must be **proven** to be safe (**21 U.S.C. § 351(a)(2)(b)**).*

Based on a careful examination of the preceding studies and the published studies[34,38] *that purportedly document the lack of epidemiological evidence linking neurodevelopmental damage to unwarranted mercury exposure from Thimerosal-containing products licensed or approved by the FDA*, we find that the systematic, ***uncalled for*** exposure of generations of America's children to neurotoxic levels of mercury-based "preservatives" and "antiseptics" (through RhoD injections, vaccines, and other drugs that contain Thimerosal and/or other mercury-based compounds) is an unparalleled tragedy, inflicted upon ***susceptible*** fetuses, newborns, and children of all ages.

With the preceding reality in mind, we ask the Agency to urgently consider:

- The information we have provided,
- Our requests for action, and
- The following causes of action that such knowing conduct may create.

B. Violation Of Constitutional Right To Bodily Integrity

First, the right to bodily integrity is a fundamental right protected by the Constitution. "The right to be free of state-sponsored invasion of a person's bodily integrity is protected by the

[constitutional] guarantee of due process." [In re Cincinnati Radiation Litig., 874 F. Supp. 796, 810-11 (S.D. Ohio 1995).]

As the Supreme Court of the United States of America noted, "[t]he protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." [Albright v. Oliver, 510 U.S. 266, 272, 114 S. Ct. 807, 812 (1994).]

Moreover, the right to bodily integrity has long been recognized. [See Union Pac. Ry. Co. v. Botsford, 141 U.S. 250, 251, 11 S. Ct. 1000, 1001 (1891) (holding that "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law"); Schlumber v. California, 384 U.S. 757, 772, 86 S. Ct. 1826, 1836 (1966) (stating that "[t]he integrity of an individual's person is a cherished value of our society").]

Given the preceding, there should be no approval to inject, or otherwise administer to, susceptible pregnant women, newborns and children any preserved biological preparation containing Thimerosal, *a known neurotoxic drug*, that has **not** been proven to be safe at any level and, *at the levels in the current Thimerosal-containing flu vaccines and other similar vaccines*, has been clearly implicated in adverse neurological outcomes, including attention deficit disorders and autism.

Thus, high governmental officials, *by authorizing the manufacture, distribution, and, most importantly, the use of vaccines and other drug and biological products containing neurotoxic*

ingredients, including, but not limited to, Thimerosal, that have not been unequivocally proven to be safe (with at least a 10 X safety margin) to ***all*** *who may receive said products*, have been and are, *in effect*, **responsible** for performing uncontrolled involuntary experiments on susceptible pregnant women, fetuses, newborns, children, and the rest of the public under the guise of protecting them from various diseases.

By so doing, said officials are not only knowingly breaching the bodily integrity of said susceptible pregnant women, fetuses, newborns, children, and others but also violating one of the fundamental tenets for drugs – namely that such shall be proven to be safe before being approved for use.

Since the knowing conduct of these responsible high governmental officials has clearly violated, and continues to clearly violate, the constitutionally protected bodily integrity rights of those susceptible individuals that have been injured in said uncontrolled involuntary experiments (where proper informed consent has <u>not</u> been, and is <u>not</u>, obtained from the patient or the patient's guardian [because the patients or their guardians were and are not truly informed of the risk or the lack of proof of safety of the mercury-based preservative in medical products containing such] prior to exposure), these officials and the agencies they head are:

a. Legally culpable for their actions **and**

b. If, *in the face of this petition and the evidence provided*, they continue to permit this uncontrolled involuntary experimentation, said responsible governmental officials risk being sued under **42 U.S.C. § 1983**[67], a federal statute that permits legal action against "[e]very person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any

citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, …" This is the case because the States have laws that, in general, mandate the repeated injection of newborns and children with an ever increasing list of vaccines *purportedly* designed to prevent disease and/or disease outbreak. [**Note:** Since the States recognize the "bodily integrity" right, this statute by Congress seems to permit the suing of federal officials acting in their official capacity whose knowing actions consequentially lead to: **a)** the violation of the bodily integrity of all those who receive said mandated mercury-containing vaccines **and b)**, *for those who are susceptible*, irreparable bodily injury and damage.]

Therefore, we again beseech the Food and Drug Administration to immediately proceed as we have petitioned until and unless the Department of Health and Human Services and the Food and Drug Administration can prove:

a. Their previous, current, and on-going actions do **not** constitute a violation of the "bodily integrity" of:

1. Those patients who receive medical products that are preserved with neurotoxic mercury-containing compounds whose safety has **not** been proven, **or**

2. *In cases where such are infants and children*, those who are given these mercury-containing medical products based upon the uninformed and/or coerced consent of their parents or legal guardians,

and

b. Their policies and practices no longer permit the uncontrolled involuntary experiments on susceptible pregnant women, fetuses, newborns, children, and the rest of the public under the guise of protecting them from various diseases.

C. Violation Of Other Civil Rights And Societal Tenants

In addition to violating the constitutional right to bodily integrity, basic American civil rights and tenants (including informed consent, self determination, and personal autonomy) continue to be violated daily in this nation because misled and coerced parents offer up their children for injection of mercury-laced pharmaceuticals, some nominally containing 25 μg of mercury per dose with expiration dates of 2005, and, *in the case of the influenza and some other vaccines*, beyond.

Instead of being provided unequivocal proof that such mercury-containing medical products are safe for their children, pregnant women and parents are told that they must accept these medications because "*there is no direct causative link that proves that the mercury-containing preservatives in these medications cause the neurological disorders being observed*"[5] even though:

- There has been a growing body of epidemiological and animal data which suggests that, in "susceptible" (i.e., those that have been damaged) individuals, there is some linkage between the individual's exposure and the severity of the damage observed.
- Recent studies[59,60], *published after the IOM's February 2004 meeting on Thimerosal in vaccines*, have clearly established the existence of a causal link.

We do **not** understand how the federal government could, or can continue to, permit the on-going use of these neurotoxic mercury-containing compounds in drugs, given:

a. The increase in the rate of irreparable neurological damage in our children that may be vaccine-mercury-related (from about 1 child in 2,500 children in the 1970's to today's greater than 1 child in 330 children),

b. The reality that many vaccines contain no preservative nor, *for unit-dose packaging*, is a preservative required for marketed lots of vaccines or related drug products produced in the United States in a manner that fully complies with CGMP (current good manufacturing practice, as that term is used in **21 U.S.C. 351(a)(2)(B)**), **and**

c. The fact that, *in most cases*, there are other equally effective or superior mercury-free preservatives that have been, are being, and could be, used in vaccine formulations requiring a preservative.

Instead of erring on the side of safety and acting to remove mercury-based preservatives from our vaccines and other medicines when the possibility of a connection was first found, the Food and Drug Administration and other federal agencies elected, *and sadly continue*, to stonewall and obfuscate on this issue.

Perhaps, the FDA has, to date, failed to protect the citizens of our nation from Thimerosal and other mercury-containing neurotoxins because taking action to remove these mercury-based compounds from vaccines and other drug products would:

a. Be costly to the Pharmaceutical industry,

b. Reveal the Agency's on-going failure to protect the public's health, **and**

c. Expose both the Pharmaceutical industry and the federal government to lawsuits to recover for the damage done by the mercury-based "preservatives" that the governmental agencies, *though charged with protecting the public's health*, allowed to be used without requiring the Pharmaceutical industry to provide the rigorous proof that, *with a safety factor of at least 10X*, their use was safe for **all** of our children.

Thus, the rights of our children, and our children themselves, were sacrificed, and are being sacrificed daily, for the benefit (cost and profit) of the Pharmaceutical industry.

Moreover, the current systemic governmental foot dragging, equivocation, obfuscation, and worse by the agencies (CDC, HHS, IOM, NIH, HRSA and FDA) charged with protecting the public health, and similar actions by the "biologicals" segment of the pharmaceutical industry are no different than like practices observed in previous cases.

In those cases, *involving the Asbestos and Tobacco industries*, the regulating agencies and the regulated industry used similar "*there is no direct causative link that proves ...*" mantras to postpone accepting their joint responsibility for their knowing failure to protect the public health.

They did this in order to:

a. Postpone their being held accountable for their actions and inactions, **and**

b. Allow those industries to continue to profit from their less-than-safe products.

D. Summary

Based on the aforementioned realities and the fact that there is **no** unequivocal proof that the levels of mercury, *even the reduced ones in the recently reformulated vaccines*, in such added-mercury-containing drug products are safe, the Pharmaceutical industry is engaged in the knowing manufacture of vaccines and other drugs that, *because of the unproven safety of the mercury-based compounds used in their formulations*, would seem to be both unsafe and adulterated[68].

Given the preceding, we again call upon the Department of Health and Human Services and Food and Drug Administration to proceed as we have petitioned.

IV. Environmental Impact

The petitioners hereby state that the relief requested in this petition will have no environmental impact and that, therefore, an environmental assessment is **not** required under **21 C.F.R. Section 25.30**.

V. Certification

The undersigned representatives for the Coalition for Mercury-Free Drugs (**CoMeD**) certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to these petitioners that are unfavorable to the petition.

Respectfully submitted,

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Endnotes:

[1] The control level and population demographics were chosen to match those in the *pending* California statute, AB 2943, passed by the California State Assembly in May of 2004, that reads,
"*Section1. Article 9 (commencing with Section 124172) is added to Chapter 3 of Part 2 of Division 106 of the Health and Safety Code, to read:*

Article 9. Mercury-Containing Vaccines

124172. On and after January 1, 2006, a person who is pregnant or who is under three years of age may not be vaccinated with a mercury-containing vaccine or injected with a mercury-containing product that contains more than 0.5 micrograms of mercury per 0.5 milliliter dose."

[2] The control level was also selected to agree with that implicit in the Iowa statute, enacted in 2004, where "trace" is presumed to be not greater than 0.5 µg of mercury per 0.5 mL of vaccine, the typical dose, found in the current "trace Thimerosal" childhood vaccines. [**Note**: On Friday, May 14, 2004, Iowa Governor Tom Vilsack signed into law SF 2209, effective January 1, 2006. This Iowa law bans more than "trace" levels of mercury in vaccines given to children under eight (8) years of age.] Unless the California statute is amended to reflect the higher level of Thimerosal found in the "trace Thimerosal (0.0004 %)" influenza vaccines, the California statute would seem to be controlling for children 3 years of age and under.

[3] Transcript from the two-day "NATIONAL VACCINE ADVISORY COMMITTEE SPONSORED WORKSHOP ON THIMEROSAL VACCINES," held on August 11-12, 1999, at the National Institutes of Health, Lister Hill Auditorium in Bethesda, Maryland, sponsored by the United States Department of Health and Human Services, Public Health Service, and the Centers for Disease Control and Prevention.

[4] Copy of FOIA (Freedom Of Information Act) report from the day and a half meeting, "**Scientific Review of Vaccine Safety Datalink Information**," held on June 7-8, 2000 at the Simpsonwood Retreat Center in Norcross, Georgia that was chaired by then Director of the National Immunization Program at CDC, Dr. Walter Orenstein.

[5] "Immunization Safety Review: Vaccines and Autism, Immunization Safety Review Committee," National Academy Press, May 17, 2004, ISBN 0-309-09237-X.

[6] Supportive studies include, *but are not limited to*:

A. Thimerosal Effects:

1. David S. Baskin, Hop Ngo and Valdimir V. Didenko, "Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts," ***Toxicological Science***, **74**, pages 361-368 (2003). [Thimerosal Effects at Parts per Million]

2. S. Makani, Sastry Gollapudi, Leman Yel, Shubpa Chiplunkar and Sudhir Gupta, "Biochemical and molecular basis of thimerosal-induced apoptosis in T Cells: a major mole of mitochondrial pathway," ***Genes and Immunity,*** **3**(5), pages 270-278 (2002). [Thimerosal Effects at Parts per Billion]

3. Mostafa Waly, Horatiu Olteanu, Ruma Banerjee, Sang-Woon Choi, Joel B. Mason, Belinda S. Parker, Saraswati Sukumar, S. Shim, Alok Sharma, Jorge M. Benzecry, V.-A. Power-Charnitsky and Richard C. Deth, **IMMEDIATE COMMUNICATION**, "Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal," ***Molecular Psychiatry***, pages 1-13 (January 27, 2004). [Confirmation of Thimerosal Effects at Parts per Billion]

B. Ethyl Mercury Effects:

1. Eddie S-E. Chao, John F. Gierthy and Gerald D. Frenkel, "A Comparative Study Of The Effects Of Mercury Compounds On Cell Viability And Nucleic Acid Synthesis In HeLa Cells," ***Biochemical Pharmacology*****, 33**, pages 1941-1945 (1984). [Ethyl Mercury Effects at Parts per Billion]

C. Ionic Mercury Effects:

1. Christopher C. W Leong, Naweed I. Syed and Fritz L. Lorscheider, "Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury," ***NeuroReport***, **12**(4) pages 733-737 (2001). [Ionic Mercury Effects at Parts per Trillion]

[7] Based on the information provided on the estimated safety limit for *chronic toxicity effects* arising from the intake of methyl mercury at **http://www.epa.gov/ttn/atw/hlthef/mercury.html** including the following (**bolding** added for emphasis), "The RfD [oral reference dose: 'An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of a chemical to the human population (including sensitive subpopulations) that is likely to be without risk of deleterious noncancer effects during a lifetime')] for methyl mercury is **0.0001 mg/kg/d** [equivalent to 0.1 µg/kg/day] based on developmental neurologic abnormalities in human infants.(13)," and "EPA has medium confidence in the RfD due to: (1) medium confidence in the studies on which the RfD was based because the benchmark dose approach allowed use of the entire dose-response assessment, and the results of laboratory studies with nonhuman primates support the quantitative estimate of the no-observed-adverse-effect-level/lowest-observed-adverse-effect-level (NOAEL/LOAEL) range of the benchmark dose that was indicated by the human studies; and (2) medium confidence in the database.(13)," and its ***reproductive/developmental effects***, "Oral exposure to methyl mercury has been observed to produce significant developmental effects in humans. Infants born to women who ingested high concentrations of methyl mercury exhibited CNS effects, such as mental retardation, ataxia, deafness, constriction of the visual field, blindness, and cerebral palsy. At lower methyl mercury concentrations, developmental delays and abnormal

reflexes were noted. (1,2,8" [,13]) "(References: 1. Agency for Toxic Substances and Disease Registry (ATSDR). *Toxicological Profile for Mercury*. Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA. 1999; 2. U.S. Environmental Protection Agency. *Locating and Estimating Air Emissions from Sources of Mercury and Mercury Compounds*. EPA-453/R-93-023. Office of Air Quality Planning and Standards, Research Triangle Park, NC. 1993; 8. World Health Organization. *Inorganic Mercury. Volume 118*. Distribution and Sales Service, International Programme on Chemical Safety, Geneva, Switzerland. 1991; and 13. National Toxicology Program. *Toxicology and Carcinogenesis Studies of Mercuric Chloride in F344 Rats and B6C3F1 Mice (Gavage Studies)*. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD. 1991.)"

[8] The recall classes are defined in **21 C.F.R. Section 7.3 Definitions** which, in part, reads (**bolding** added for emphasis):

"(m) Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) **Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences** or death.

(2) **Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote**.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences."

[**Note**: Since 2004 animal studies have now clearly established that there is a definite link between the administration of 0.01%-Thimerosal-preserved vaccines and neurodevelopmental disorders, including autism, that are recognized "serious adverse health consequences," in susceptible individuals, the only issues remaining are whether, or not, these mercury-related "serious adverse health consequences" are "medically reversible adverse health consequences." If deemed medically reversible, then a Class II recall is indicated; if **not**, then a Class I recall should be issued. *Since the recent studies have proven causality*, it is no longer permissible for any vaccine containing more than 0.0004 % Thimerosal to be left in commerce where it can be administered.]

[9] Christopher C. W. Leong, Naweed I. Syed and Fritz L. Lorscheider, "Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury," ***NeuroReport***, **12**(4) pages 733-737 (2001).

[10] **21 C.F.R**. "Sec. 610.15 Constituent materials. [With **bolding** added for emphasis.]

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. **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**, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:

(1) 0.85 milligrams if determined by assay;

(2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or

(3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research."

[11] **47 FR** 436**,** Jan 5, 1982.

[12] **63 FR** 19799-19802, April 22, 1998.

[13] **21 U.S.C. 321(g)(1)**, "The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). …"

[14] **21 U.S.C. 321(u)**, "The term 'safe' as used in paragraph (s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal."

[15] **21 C.F.R.** "Sec. 610.15 Constituent materials. [With **bolding** added for emphasis.]

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. **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**, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying

diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:

(1) 0.85 milligrams if determined by assay;
(2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or
(3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research."

[16] As of June 2004, the vaccine information reported on http://www.fda.gov/cber/vaccine/thimerosal.htm that was last updated in October of 2003.

[17] **63 FR** 68775-68777, December 14, 1998.

[18] **64 FR** 23083-23086, April 29, 1999.

[19] **64 FR** 63323-63324, November 19, 1999.

[20] ***Morbidity And Mortality Weekly Report***, **48**(26), pages 563-565 (July 09, 1999 [original press release issued on July 7, 1999]) – can be found by searching the MMWR subsite (http://www.cdc.gov/mmwr/).

[21] Harrison C. Stetler, Paul L. Garbe, Diane M. Dwyer, Richard R. Facklam, Walter A. Orenstein, Gary R. West, K. Joyce Dudley and Alan B. Bloch, "Outbreaks of Group A Streptococcal Abscesses Following Diphtheria-Tetanus Toxoid-Pertussis Vaccination," ***Pediatrics***, **75**(2), pages 299-303 (1985).

[22] Antonio R. Gasset, Motokazu Itoi, Yasuo Ishii and Richard M. Ramer, "Teratogenicities of Ophthalmic Drugs. II. Teratogenicities and Tissue Accumulation of Thimerosal," ***Archives of Ophthalmology***, **93**, pages 52-55 (1975).

[23] Lyn Redwood, Sallie Bernard, and David Brown, "Predicted Mercury Concentrations in Hair From Infant Immunizations: Cause for Concern," ***NeuroToxicology***, **22**, pages 691-697 (2001).

[24] William Slikker, Jr., "Developmental Neurotoxicology Of Therapeutics: Survey Of Novel Recent Findings," ***NeuroToxicology***, **21**, page 250 (2000).

[25] Gregory V. Stajich, Gaylord P. Lopez, Sokei W. Harry and William R. Sexson, "Iatrogenic exposure to mercury after hepatitis B vaccination in preterm infants," ***The Journal of Pediatrics***, **136**(5), pages 679-681 (2000).

[26] Polly R. Sager (Corrected Slides), "Comparative Toxicokinetics of Methylmercury and Thimerosal in Infant *Macca fascicularis*," Institute of Medicine, National Academy of Sciences, Washington, DC, February 9, 2004.

[27] "***Mercury: Medical and Public Health Issues***," a symposium that was held at the Tampa Marriott Waterside Hotel and Marina, Tampa, Florida, on April 28-30, 2004 and sponsored by the United States Department of Health and Human Services and the United States Environmental Protection Agency.

[28] FDA, HHS, "Mercury Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph," ***Federal Register***, **47**(2), pages 436-442 (January 5 1982).

[29] Subcommittee on Human Rights and Wellness, Committee on Government Reform of the House of Representatives, "*Mercury in Medicine Report*," Washington, DC, as published in the ***Congressional Record***, pgs. E1011-E1030, May 20, 2003.

[30] U.S. Office of Special Counsel, 1730 M Street, N.W., Suite 218, Washington, D.C. 20036-4505, "**OSC Forwards Public Health Concerns on Vaccines to Congress**, …" For more information please visit our web site at *www.osc.gov* or call 1-800-872-9855.

[31] Special Counsel Scott Bloch's letter to Congress addressed to: "The Honorable Judd Gregg, United States Senate, Chairman, Committee on Health, Education, Labor and Pensions, 428 Dirksen Senate Office Building, Washington, D.C. 20510-6300 and The Honorable Joe Barton, U.S. House of Representatives, Chairman, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515" [OSC File Nos.: DI-04-1399, et al.]

[32] Thomas Verstraeten, Robert Davis and Frank DeStefano, "**Thimerosal VSD study, Phase I, Update, 02/29/00**," obtained by SafeMinds under FOIA in 2001. [**Note:** This draft ends with 5 pages, having a footer notation of "LKLK03/28/00 … Response.doc," and starting with a page heading of "**Thimerosal VSD study- Follow-up on conference call 03/02/200**0," that indicate the overall document dates to the end of March 2000.]

[33] Thomas Verstraeten, Robert Davis, Frank DeStefano and the VSD team, "**Risk of neurologic and renal impairment associated with thimerosal-containing vaccines**," obtained by SafeMinds under FOIA in 2001.

[34] Thomas Verstraeten, Robert L. Davis, Frank DeStefano, Tracy A. Lieu, Philip H. Rhodes, Steven B. Black, Henry Shinefield and Robert T. Chen; for the Vaccine Safety Datalink Team, "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," ***Pediatrics***, **112**(5), pages 1039-1048 (2003).

[35] Thomas Verstraeten, "Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline," ***Pediatrics***, **113**(4), page 932. (2004).

[36] A copy of the printed Simpsonwood-meeting record (with an appended copy of the "**Thimerosal VSD study, Phase I, Update, 02/29/00**" document that is missing page 5 of the draft) can be found in the http://www.safeminds.org/legislation/foia/ sub directory (its label is *http://www.safeminds.org/legislation/foia/simpsonwood.html*).

[37] Congressman Dr. Dave Weldon's Official Letter to Julie Gerberding, Director of the CDC, dated October 31, 2003.

[38] Specifically, the following articles:

1. Paul Stehr-Green, Peet Tull, Michael Stellfeld, Preben-Bo Mortenson and Diane Simpson, "Autism and Thimerosal-Containing Vaccines: Lack of Consistent Evidence for an Association," ***American Journal of Preventive Medicine***, **25**(2), pages 101-106 (2003).
2. Anders Hviid, Michael Stellfeld, Jan Wohlfahrt and Mads Melbye, "Association Between Thimerosal-Containing Vaccine and Autism," ***Journal of the American Medical Association*** (***JAMA***), **290**(13), pages 1763-1766 (2003).
3. Kreesten M. Madsen, Marlene B. Lauritsen, Carsten B. Pedersen, Poul Thorsen, Anne-Marie Plesner, Peter H. Andersen, and Preben B. Mortensen, "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data," ***Pediatrics***, **112**(3), pages 604-606 (2003).

[39] Mark Blaxill, Director, Safe Minds Analysis of Madsen et al.**, "Danish Thimerosal-Autism Study in *Pediatrics*: *Misleading and Uninformative on Autism-Mercury Link*"** (September 1, 2003), whose observations were determined by Dr Mark R. Geier and Mr. David A. Geier to apply to all of the studies cited.

[40] Including, *but not limited to*, the following recent publications:

1. Mark R. Geier and David A. Geier, "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication," ***Society for Experimental Biology and Medicine***, pages 660-664 (2003).
2. Mark R. Geier and David A. Geier, "Thimerosal in Childhood Vaccines, Neurodevelopmental Disorders, and Heart Disease in the United States," ***Journal of American Physicians and Surgeons***, **8**(1), pages 6-11 (2003).
3. David A. Geier and Mark R. Geier, "An assessment of the impact of thimerosal on childhood neurodevelopmental disorders," ***Pediatric Rehabilitation***, **6**(2), pages 97-102 (2003).
4. David A. Geier and Mark R. Geier, "A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism," ***Medical Science Monitor***, **10**(3), pages P133-P139 (2004).

[41] Amy S. Holmes, Mark F. Blaxill and Boyd E. Haley, "Reduced Levels of Mercury in First Baby Haircuts of Autistic Children," ***International Journal of Toxicology***, **22**, pages 277-285 (2003).

[42] E. A. Nelson and R. Y. Gottshall, "Enhanced Toxicity for Mice of Pertussis Vaccines When Preserved with Merthiolate," ***Applied Microbiology***, **15**(3), pages 590-593 (1967).

[43] Martin F. Heyworth and Sidney C. Truelove, "Problems Associated With The Use Of Merthiolate As A Preservative In Anti-Lymphocytic Globulin," **Toxicology**, **12**, pages 325-333 (1979).

[44] Lars Forstrom, M. Hannuksela, Merja Kousa and E. Lehmuskallio, "Merthiolate hypersensitivity and vaccination," ***Contact Dermatitis***, **6**, pages 241-245 (1980).

[45] Abstract of A. T. Kravchenko, S. G. Dzagurov, G. P. Chervonskaia, "Evaluation of the toxic action of prophylactic and therapeutic preparations on cell cultures. III: The detection of toxic properties in medical biological preparations by the degree of cell damage in the L-132 continuous cell line," ***Zhurnal Mikrobiologii, Epidemiologii, Immunobiologii***, **March** (3), pages 87-92 (1983).

[46] K. A. Winship, "Organic mercury compounds and their toxicity," ***Adverse Drug Reaction Acute Poisoning Review***, **3**, pages 141-180 (1986).

[47] Neil H. Cox and Angela Forsyth, "Thiomersal allergy and vaccination reactions," ***Contact Dermatitis***, **18**, pages 229-233 (1988).

[48] David Seal, Linda Ficker, Peter Wright and Victor Andrews, "The case against thiomersal," ***The Lancet***, **338**, pages 315-316 (August 3, 1991).

[49] Albert-Jan van't Veen, "Vaccines Without Thiomersal Why So Necessary, Why So Long Coming?," ***Drugs***, **61**(5), pages 565-572 (2001).

[50] Walter R. Schumm, Earl J. Reppert, Anthony P. Jurich, Stephan R. Bollman, Farrell J. Webb, Carlos S. Castelo, James C. Stever, Diane Sanders, Gabriele N. Bonjour, Janet R. Crow, Carol J. Fink, Jeanne F. Lash, Beverlyn F. Cay Brown, Carolyn A. Hall, Barbara L. Owens, Michelle Krehbiel, Liang-Yu Deng and Mark Kaufman, "Self-Reported Changes In Subjective Health And Anthrax Vaccination As Reported By Over 900 Persian Gulf War Era Veterans," ***Psychological Reports***, **90**, pages 639-653 (2002).

[51] Leander Tryphonas and N. O. Nielsen, "Pathology of Chronic Alkylmercurial Poisoning in Swine, "***American Journal of Veterinary Research***, **34**(3), pages 379-392 (1973).

[52] D. G. Fagan, J. S. Pritchard, Thomas W. Clarkson and M. R. Greenwood, "Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic," ***Archives of Disease in Childhood***, **52**, pages 962-964 (1977).

[53] Laszlo Magos, A. W. Brown, S. Sparrow, E. Bailey, R. T. Snowden and W. R. Skipp, "The comparative toxicology of ethyl- and methylmercury." ***Archives of Toxicology***, **57**, pages 260-267 (1985).

[54] California Department of Health and Human Services, Department of Developmental Services, "AUTISTIC SPECTRUM DISORDERS Changes In The California Caseload An Update: 1999 through 2002," Sacramento, CA (April 2003).

[55] The California OEHHA in a February 2004 document titled, "RESPONSE TO THE PETITION OF BAYER CORPORATION FOR CLARIFICATION OF THE PROPOSITION 65 LISTING OF "MERCURY AND MERCURY COMPOUNDS" AS CHEMICALS KNOWN TO CAUSE REPRODUCTIVE TOXICITY."

[56] AUTISM A.L.A.R.M., issued by the HHS, CDC, American Academy of Pediatrics, and others in January of 2004 and available through *http://www.aap.org/healthtopics/autism.cfm*. When that web page displays, click on the "**Autism A.L.A.R.M. (Fact Sheet)**" entry (the second reference) to load the two-page ".pdf" file.

[57] Jeff Bradstreet, David A. Geier, Jerold J. Kartzinel, James B. Adams and Mark R. Geier, "A Case-Control Study of Mercury Burden in Children with Autistic Spectrum Disorders," ***Journal of American Physicians and Surgeons***, **8**(3), pages 76-79 (2003).

[58] Institute of Medicine (IOM) meeting held at the National Academy of Sciences in Washington, DC on February 9, 2004.

[59] Mady Hornig, David Chian, and W. Ian Lipkin, **IMMEDIATE COMMUNICATION,** "Neurotoxic effects of postnatal thimerosal are mouse strain dependent," ***Molecular Psychiatry***, pages 1-13, (Jun 8, 2004).

[60] Said Havarinasab, Lars Lambertsson, J. Qvarnstrom and Per Hultman, "Dose-response study of thimerosal-induced murine systemic autoimmunity," ***Toxicology and Applied Pharmacology***, **194**, pages 169-179 (2004).

[61] Paul Ashwood, Andrew Anthony, Alicia A. Pellicer, Franco Torrente, John A. Walker-Smith and Andrew J. Wakefield, "Intestinal Lymphocyte Populations in Children with Regressive Autism: Evidence for Extensive Mucosal Immunopathology," ***Journal of Clinical Immunology***, **23**(6), pages 504-517 (2003).

[62] David S. Baskin, Hop Ngo and Vladimir V. Didenko, "Thimerosal induces DNA breaks, caspase-3 activation, membrane damage, and cell death in cultured human neurons and fibroblasts," ***ToxSci Advance Access,*** 30 pages, **published May 28, 2003**.

[63] Mary N. Megson, "Is autism a G-alpha protein defect reversible with natural vitamin A?," ***Medical Hypotheses***, **54**(6), pages 979-983 (2000).

[64] Woody R. McGinnis, "Mercury and Autistic Gut Disease," ***Environmental Health Perspectives***, **109**(7), pages A303-A304 (July 2001).

[65] "**What Your Doctor May Not Tell You About Children's Vaccinations**" by Stephanie Cave, M.D., F.A.A.F.P. and Deborah Mitchell, Warner Books (2001).

[66] "Biochemical Treatment Of Mental Illness And Behavior Disorders," William J. Walsh, Health Research Institute, Presentation at Minnesota Brain Bio Association, November 1997.

[67] **42 U.S.C. § 1983**, "Civil action for deprivation of rights.

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia."

[68] **21 U.S.C. § 351, "(a)** Poisonous, insanitary, etc., ingredients; adequate controls in manufacture **… (2)(B),** A drug or device shall be deemed to be adulterated— 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; …"