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

Case: 1:09-cv-00015  
Assigned To : Walton, Reggie B.  
Assign. Date : 1/6/2009  
Description: Admin. Agency Review

**THE COALITION FOR MERCURY  
FREE DRUGS (CoMeD, Inc), a non-profit  
organization, Lisa Sykes,  
Mark R. Geier, M.D., Ph.D.,  
David A. Geier, B.A. and Paul King, PhD ,  
Plaintiffs,**

**COMPLAINT**

**-against-**

**Michael O. Leavitt as Secretary, Department of  
Health and Human Services and  
Andrew C. von Eschenbach as Commissioner of  
The United States Food and Drug Administration,**

**Defendant(s).**

NOW COME the Plaintiffs, by and through their attorney, John McHugh, Esq.,  
and complain of the Defendants as follows:

**JURIDICTION AND VENUE**

1. This Court has jurisdiction over this action pursuant to 28 USC §1331 and §2201, all conditions set forth in 5 U.S.C. 701 et seq. having been met.
2. The venue is proper in this district under 28 USC 1391(e).

**PARTIES**

3. Plaintiff, The Coalition for Mercury-free Drugs (CoMeD) is a 501(C)(3) not-for-profit group with its principal place of business at Silver Spring Maryland. CoMeD is dedicated to reducing the mercury-exposure risks, for the unborn, infants, children, adolescents and adults, from all mercury-containing medical products to which they are, or may be, exposed and includes numerous persons who have been exposed to such products
4. Plaintiff Lisa Sykes is a resident of Richmond, VA.
5. Plaintiff Mark R. Geier, M.D., Ph.D., FABMG is a resident of Silver Spring MD.
6. Plaintiff David A. Geier, B.A. is a resident of Silver Spring, MD.
7. Plaintiff Paul King PhD is a resident of Lake Hiawatha, NJ.
8. Defendant Michael O. Leavitt is, upon information and belief, the Secretary of the Department of Health and Human Services (“DHHS”), an agency of the United States Government. Defendant’s office and the DHHS’ principal place of business is located at 200 Independence Avenue, SW, Washington, DC 20201.
9. Defendant Andrew C. von Eschenbach is, upon information and belief, the Commissioner of the United States Food and Drug Administration (“FDA”) of the Department of Health and Human Services, an agency of the United States Government. Defendant’s office and the FDA’s principal place of business is located at 5600 Fisher’s Lane, Rockville, MD 20857.

### STATEMENT OF FACTS

10. On or about August 24, 2007, Plaintiff CoMeD submitted a Citizen's Petition with Defendant, FDA, subsequently assigned Docket No. 2007P0331/CP1, relating to the use of Thimerosal in pharmaceutical products, which is incorporated herein in its entirety.. A copy of the August 10, 2007 Citizen's Petition filed with the FDA on 24 August 2007 is available on the CoMeD website ( <http://mercury-freedrugs.org/>).
11. On or about February 8, 2008, Defendant FDA issued a 180 Letter to Plaintiffs regarding their Citizen Petition, which is incorporated herein in its entirety. A copy of the February 8, 2008, The 180-day Letter issued by Defendant is available at the CoMeD website (<http://mercury-freedrugs.org/>)
12. On or about September 21, 2008, Defendant FDA, acting on its on behalf and on behalf of Defendant DHHS, issued a letter denying the Plaintiffs' Citizen Petition, which is incorporated herein in its entirety. A copy of the "Denial Letter," 2007P-0331/PDN1 is available on the CoMeD website (<http://mercury-freedrugs.org/>)
13. The Complaint at issue reiterates the arguments presented by Plaintiffs to the FDA and the DHHS, and which the FDA declined to act upon. All citations included herein are available at <http://mercury-freedrugs.org/>
14. The compound, ethyl(2-mercaptobenzoato-S)mercury sodium salt or, more commonly named, sodium ethylmercurithiosalicylate, patented as a topical anti-infective in 1928 and known by many trade names, including Thimerosal, has been used in the United States since the 1930's.

15. Subsequently, Thimerosal came to be widely accepted as a “preservative” component in some of the vaccines and other drugs intended for use in humans.
16. 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.”
17. 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, vaccines, 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.
18. Today, a range of multi-dose vaccines and related biological products that contain levels of Thimerosal above 0.0001 % (1.0 ppm) are still produced, licensed or approved, and available for unrestricted use in humans.
19. ✓ 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.

20. ✓ 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), 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)) and effective in humans and animals.
21. 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 the manufacturer to prove 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”.
22. 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 as required by law. Scientifically sound experimental studies have proven the neurotoxicity 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.
23. 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: Address

susceptible fetuses, newborns, children, adolescents and adults, and 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” all who may receive such drug products, or 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 maximum “trace” levels (0.0004% [0.0002% mercury, 2 µg/mL]) in the “single dose” and/or “trace Thimerosal” formulations (e.g., “trace Thimerosal” influenza vaccines produced by Aventis Pasteur, CSL Limited,, GlaxoSmithKline, and Novartis) 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.

24. Today, in many cases, the level of Thimerosal has been reduced in, and, in some instances, eliminated from, pediatric “single dose” vaccine formulations.
25. 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

“preservative” (Thimerosal’s only FDA-approved use in vaccines), or 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).

26. 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. 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.
27. Moreover, there are other suitable, less neurotoxic non-bioaccumulative 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).
28. In December of 1998 and April of 1999, 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.”

29. 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") 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."
30. 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.
31. It is apparent that decades after an FDA advisory committee found, in 1982, that Thimerosal was not safe for use in topical antiseptic and 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.
32. In 2003, after a three-year investigation, a Congressional report (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":

33. “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.’
34. 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.
35. 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.”

36. 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.”
37. 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.
38. 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.
39. “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.’’

40. In 1967, Nelson and Gottshall from the Division of Biologic Products, Bureau of Laboratories, Michigan Department of Public Health published:
41. “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.”
42. In 1979, Heyworth and Truelove stated: “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.”
43. In 1980, Forstrom et al. noted: “...reactions can be expected in such a high percentage of merthiolate-sensitive persons that merthiolate in vaccines should be replaced by another antibacterial agent.”

44. In 1983, Kravchenko et al reported: “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.”
45. In 1986, Winship reported: “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.”
46. In 1988, Cox and Forsyth urged: “However, severe reactions to thiomersal demonstrate a need for vaccines with an alternative preservative.”
47. In 1991, Seal et al. 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.”
48. In 2001, van’t Veen 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.”

49. In 2002, Schumm et al. recommended: “We also recommend that safer alternatives to thimerosal (a mercury sodium salt, 50% mercury) be used to preserve all vaccines.”
50. 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.
51. In actual studies of ethyl mercury and methyl mercury, it has been demonstrated that the two compounds possess at least similar toxicities.
52. In some cases, it was even determined that ethyl mercury was more toxic than methyl mercury.
53. 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: “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.”

54. In 1977, Fagan et al. reported, 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: Mercury and mercury-containing compounds are highly toxic; and Alkyl mercury compounds (e.g., methyl mercury and ethyl mercury [the initial mercury-containing metabolite from Thimerosal]) penetrate intact membranes.
55. In 1977, equally effective and far less toxic broad-spectrum antifungal and antibacterial antiseptics were available.
56. As early as 1985, Magos et al. 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.”

57. In actual studies of ionic mercury, it has been demonstrated that sub-nanomolar concentrations (less than 0.2 nanograms [0.000000002 gram {0.0002  $\mu$ g}] per mL) of ionic mercury were able to markedly affect neuron growth and structure.
58. Specifically, in 2001, Leong et al. 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  $\mu$ l) 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.”

59. Neurological disorders, especially autism, and other developmental and behaviora; disorders are now at epidemic levels among our nation’s children.

60. 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 by the California Department of Developmental Services found: "Between 1987 and December 2002, the population of persons with autism increased by 634 percent," and The population increase was not "due to" potential confounding or bias.
61. 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."
62. 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.
63. 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.

64. Additionally, in February 2004, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (CA OEHHA) reaffirmed 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.
65. 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.<sup>56</sup> (“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.”
66. Thus, developmental/behavioral disorders, including autism, are now at epidemic levels among our nation's children.
67. 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. [Note: Based on the autism sex ratio reported by Verstraeten, more than 80 % of the diagnosed autistic children are male.]
68. 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: The mercury-based preservatives in vaccines with which they have been immunized and/or, In

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

69. Bradstreet et al. 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.
70. Similarly, in 2003, Holmes et al. 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.

71. 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.
72. By contrast, these correlations were absent in the group of autistic children. 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: “We are moving toward causality.” [Note: During his presentation, Dr. Aposhian referred to “autism” as a “Mercury Effluxor” [elimination] “Disorder.”]

73. More recently, Mady Hornig et al. 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: Support the hypothesis that the adverse outcomes observed have a genetic component, and Provide a model for investigating Thimerosal-related neurotoxicity.
74. Also, in 2004, Havarinasab et al. 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 fibrillar, 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 antifibrillar 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.”

75. 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).]

76. As the Supreme Court 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).]
77. 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”).]
78. 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.
79. 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.

80. 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.
81. 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 not been, and is not, 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: Legally culpable for their actions and 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, 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, ...”

- 82.** 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.

**AS AND FOR A FIRST CAUSE OF ACTION**

**VIOLATION OF THE National Childhood Vaccine Injury Act of 1986,**

**42 U.S.C. Section 300aa-10 et seq**

83. Plaintiffs restate and reallege all of the allegations in paragraphs 1-82 as if set forth fully herein.
84. Defendant has violated its mandate under the National childhood Vaccine Safety Act by failing to adequately test pharmaceutical products that contain Thimerosal prior to approving same for vaccinations for children.

**AS AND FOR A SECOND CAUSE OF ACTION**

**VIOATION OF 42 U.S.C. Section 300aa-27(a)(2)**

85. Plaintiffs restate and reallege all of the allegations in paragraphs 1-84 as if set forth fully herein.
86. Defendant has violated its mandate under 42 USC Sec. 300aa-27(a)(2) for the general public safety authority granted to it by Federal statute by failing to promote the welfare of the public by approving the use of Thimerosal in pharmaceutical products without adequate testing.
87. Defendant has violated its mandate under the same statute by not recalling or banning the use of Thimerosal in pharmaceutical products despite the growing body of literature and evidence that exposure to Thimerosal is harmful, even in trace amounts.

**AS AND FOR A THRID CAUSE OF ACTION**

**VIOLATION OF 21 U.S.C. 601351 (a)(2)(B)**

88. Plaintiffs restate and reallege each and every allegation contained in paragraphs 1-87 above as if set forth here in full.
89. Under 42 U.S.C. §262 the defendants were assigned the duty owed by the drug manufacturer to the plaintiffs to assure that any drug licensed for use in the United States was safe, pure, and potent and upon a determination that a batch, lot, or other quantity of a product licensed under that section presents an imminent or substantial hazard to the public health, the defendants have an

absolute duty immediately order the recall of such batch, lot, or other quantity of such product.

90. Under the applicable statutes the defendants were required to establish the drug's safety before releasing it to the public.
91. The plaintiffs relied on the government's use of due care in approving for release the particular vaccines administered to citizens.
92. Based upon the information available to the defendants as set forth above, any drug to be used on children could not have been licensed by the defendants in compliance with their duties as assigned by 42 U.S.C. §262.
93. The Citizen's petition submitted to the defendants outlined these failures in substantial detail.
94. The Citizens Petition was rejected by the defendants in derogation of their obligations to the plaintiffs and others under applicable law.

**AS AND FOR A FOURTH CAUSE OF ACTION**

95. Plaintiffs reallege and restate each and every allegation contained in paragraphs 1-94 as if set forth here in full.
96. Plaintiffs' children are compelled to receive the vaccines in issue by law.
97. Plaintiffs do not have the right to refuse medication.
98. Defendants' duty is enhanced due to the fact that these vaccinations are compulsory.
99. The defendants knew at all times that their failure to strictly comply with the law would and did injure the plaintiffs, their members and their dependants, and the defendants have been well aware of this at all times as they had an

absolute duty to appraise themselves of the information set forth above and in the Citizens Petition.

100. The refusal to remove thimerosal form drugs administered to children in compulsory vaccine programs is gross negligence and unlawful.


WHEREFORE, Plaintiffs pray that this Court provide relief to the Plaintiffs by issuing an Order as follows:

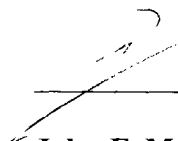
- a. Barring the administering of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than “trace” (more than 0.5 micrograms per dose) levels of Thimerosal to pregnant women and children under the age of 36 months, on the grounds that higher levels are now a *proven* health hazard to “susceptible” fetuses, newborns and young children
- b. Suspending the approval or licensing of any FDA-regulated product that contains Thimerosal or any other mercury-based compounds as a preservative, or adjuvant, in the final formulation unless the total level of 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,
- c. Recalling of all batches of multi-dose vaccines that contain a Thimerosal preservative level of more than 0.001 % on the grounds that: All such multi-dose vaccine formulations are now a proven health hazard to susceptible individuals of all ages and 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

- d. Banning vaccines, and other drugs, containing more than 0.5 microgram ( $\mu\text{g}$ ) 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 Requiring, after 1 January 2006, the recall and destruction of ALL: Vaccines remaining in commerce that contain more than 0.5  $\mu\text{g}$  of mercury per dose, and Other drug products remaining in commerce that contain more than 1.0  $\mu\text{g}$  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.

Dated: December 18, 2008  
New York, NY

  
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