

to compare the “toxicities of ethyl mercury and methyl mercury.”

“Tryphona, et al. conclude that alkyl mercury compounds, if fed at low concentrations for long periods, were poisonous to swine. The authors were concerned with public health implications, especially when meat, liver, etc., of poisoned pigs are consumed by people.”

Reviewing the statements in 2004P-0349/CP1, your remarks, and the article cited, the current petitioners find that your narrative here is, *at best*, problematic.

Factually, the time periods in the study were short, only up to 60 days for the methyl mercury compound (“MMD”) and only up to 90 days for the ethyl mercury compound (“EMC”) tested.

[Note: Reviewing the treatment period data, we find that, at the high-dose, the treatment periods, *for those pigs not slaughtered early*, were 41 to 46 days for the “MMD” treatment and 30 days for the “EMC” treatment. At the mid-dose level, the treatment periods, *for those pigs not slaughtered early*, were 60 days for “MMD” and 75 to 90 days for “EMC.”]

Second, in the treatment groups, the dosages used were equivalent to 0.19 (group I), 0.38 (group II) and 0.76 mg Hg/kg per day (group III), or 0.19 ppm, 0.38 ppm, and 0.76 ppm, since the goal of the study was to induce clinical mercury poisoning.

Third, the investigators found that the EMC compound was more toxic than the MMD compound as their “Table 2—Mean, Minimal and Maximal Values in Days for ...” clearly showed.

Clinical Signs	Day of Onset of Clinical Symptoms
	Average (Minimum- Maximum)
Anorexia	12 (12-12)
Retarded growth rate	16 (14-18)
Incoordination	52 (49-56)
Aimless walking	52 (49-56)
Blindness	52 (49-56)
Empty mastication	51 (51-51)
Flaccid abdominal musculature	52 (49-56)
Negative weight balance	58 (53-64)
Tremor	47 (44-50)
Peddling Movements	66 (60-71)
Comatose	67 (61-73)
Death	70 (64-75)

For example, *for the group II pigs*, no visible clinical signs were seen for the pigs given the MMD compound but the EMC-treated group exhibited the preceding pattern of mercury poisoning effects from the ethylmercury chloride.

Fourth, there was considerable individual variability among the pigs, as the authors stated (with underlining added for emphasis):

“The importance of susceptibility of the individual animal to organomercurial poisoning became apparent in group II pigs in which, within the time period studied, 3 pigs developed severe lesions and clinical signs, 3 had clinically silent lesions, and 2 remained unaffected.”

Thus, petitioners find that your, *“The authors were concerned with public health implications, especially when meat, liver, etc., of poisoned pigs are consumed by people,”* is not relevant to: **a)** the petition or **b)** the issues it raises.

Thus, the petitioners find that 2004P-039-49/CP1 did not overstate this paper’s findings when 2004P-0349/CP1 stated:

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

“Magos, et al. compared the neurotoxicity and renotoxicity of alkyl mercury compounds in Parton Wistar rats. FDA acknowledges that alkyl mercury compounds, such as methyl mercury and ethyl mercury, especially when administered at high doses, are toxic; however, an extrapolation of the above data to infant exposure at far lower levels of thimerosal, and neurodevelopmental disorders, is problematic.”

The petitioners find that your statements here do not address the issues addressed by 2004P-0349/CP1, which stated:

“As early as 1985, Magos *et al.* (petition endnote 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’) 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.’”

Analyzing the data, petitioners find the issues addressed here in 2004P-0349/CP1 relate to the comparative toxicities, distributions, and nature, of the mercury species when ethylmercury chloride and methylmercury chloride are orally dosed into comparable groups of rats.

As a whole, this paper supports the previous use of the EPA “Rfd” for methyl mercury in fish as an approximate starting basis “safety” standard ceiling for Thimerosal, an ethyl mercury compound, when the required toxicological studies required to establish the “sufficiently nontoxic ...” (safe) level for Thimerosal in humans have not, as you have repeatedly admitted, been conducted.

The important findings, relative to the short-term effects of these two compounds, can be summarized as follows:

- For the equal levels of oral mercury dosed, the ethylmercury-treated rats “had

higher total or organic mercury concentrations in blood and lower concentrations in kidneys and brain than methylmercury-treated rats.” [Indicating that, *when the mode of administration is constant, ethylmercury chloride, and hence Thimerosal, clears the blood slower than methylmercury chloride.*]

- **“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.”** [Note: This finding clearly indicates that ethylmercury chloride is more rapidly metabolized in the brain and kidney to “inorganic” mercury, known to have a long half-life in the brain.]

- **“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.”**

[Note: This finding shows that the “ethyl” compound is more toxic to: **a)** the kidney and **b)**, *based on weight loss*, normal metabolism in the rat than the “methyl compound.”]

- **“There was little difference in the neurotoxicities of methylmercury and ethylmercury when effects on the dorsal root ganglia or coordination disorders were compared.”**

[Note: This finding indicates that the both compounds have comparable short-term effects on the rats’ neurological systems.]

Since the short-term neurological effects were comparable, this study supports the findings from the studies of long-term effects that have been conducted using dosing with 0.02% levels of methylmercury hydroxide as the organomercurial to estimate neurological impact of 0.01% Thimerosal (the maximum level in Thimerosal-preserved vaccines), since the truly long-term (over years) adverse neural effects of mercury are, of necessity, related to the level of sequestered “inorganic mercury.”

In addition, this article can be used to understand that the differences in inorganic

mercury levels in the baby monkey studies of Burbacher, et al. (2005), *which the FDA has cited*, are probably related more to the innate differences in the compounds studied there than to the confounding differences in their routes of administration in that baby monkey study.

Finally, we find your “...*extrapolation of the above data to infant exposure at far lower levels of thimerosal, and neurodevelopmental disorders, is problematic*” concerns are not relevant to the root issue, “**safety not proven**,” in a manner that complies with: **a) Berkovitz v. U.S.**, **b) 21 C.F.R. § 610.15(a)**, **c) 42 U.S.C. § 300aa-27(a)(2)**, and **d)** related applicable federal regulations and statutes, the first grounds raised by the **CoMeD** petition (“**III. Statement of Grounds A. Safety Not Proven**”), when there is: **1)** clear evidence of harm from Thimerosal and **2)** proven differences in the susceptibility of individual subjects to being mercury poisoned.

“For example, Tryphonas, et al., was concerned with consumption of parts of pig by humans derived from animals exposed to certain threshold levels of mercury that may pose health hazards.”

Petitioners reiterate: “The ‘concerns’ of a publication are not, *per se*, relevant to a study’s findings or the information study provides.”

“In addition, in the study by Magos, et al., the cumulative dose administered to rats was 40 mg/kg which is <13000 times the cumulative dose that an infant less than 6 months of age would be exposed to (<3 µg) through administration of vaccines containing trace amounts of mercury.

First, we find that the cumulative dose administered by “*Magos, et al.*” is not germane to the fundamental issues that 2004P-0349/CP1 raised.

This study was only offered as evidence that the neurotoxicities of Thimerosal and “methyl mercury” are similar and that individual susceptibilities are a proven reality.

“Fagan, et al., analyzed samples of fresh and fixed tissues from infants with exomphalos treated by thimerosal application for mercury content.”

Factually, petitioners find that these authors reported on 13 cases of “*exomphalos*”

treated by thimerosal” in which 10 of the 13 infants had died.

Next, we also note that the tissues were from the 10 dead infants who had received repeated (avg. 21; 9 – 48) topical applications of a “0.1-% tincture of Thimerosal (thiomersal),” where a tincture is an alcohol solution and the Thimerosal concentration was only 10X the level in a Thimerosal-preserved vaccine.

Unfortunately, the amounts of Thimerosal tincture applied were not recorded.

Moreover, there was no correlation between the number of applications and the average level of mercury found in the various tissues tested – indicating that the amount in each application was somewhat variable and/or that individual susceptibility is a reality in human infants.

“Results showed that thimerosal can induce blood and organ levels of organic mercury that were, as stated by the authors, in excess of the minimum toxic level in adults and fetuses. However, the authors note that ‘whether the levels reported are acutely toxic or capable of producing chronic neurological damage in the newborn infant exposed perinatally... is unclear.’”

Since the infants autopsied were dead, the comment you quote is an obvious one.

However, we note that you did not report the authors found one of the three survivors when he was 10 years of age, and, *with respect to his intellectual development, tellingly* reported:

“... the school reports that he is restless, easily distracted, and not interested in schoolwork.”

indicating to the current petitioners evidence of Thimerosal-induced mental impairment.

*“We note that the authors advise against the use of mercurial antiseptics for the treatment of exomphalos or for hospital use in general. We further note that the authors’ statement that equally effective and far less toxic broad spectrum antifungal and antibacterial antiseptics were available in 1977 referred to **topical** antiseptics, and not to preservatives used in vaccine products.”*

The petitioners note that, though you were quick to address the issue of “*topical antiseptics*” (which the FDA banned in 1998), you did not address the cogent issues raised in 2004P-0349/CP1’s narrative including:

- The results showed that Thimerosal applied topically induced blood and organ levels of organic mercury that are well in excess of the minimum toxic levels in adults and fetuses.
- “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.”
- Mercury and mercury-containing compounds are highly toxic.
- Alkyl mercury compounds (e.g., methyl mercury and ethyl mercury [the initial mercury-containing metabolite from Thimerosal]) penetrate intact membranes.

Petitioners must also question the judgment of any agency that would deem mercury compounds, which, *because of safety concerns*, are banned from topical drug products, to be acceptable components for injectable drugs, *especially those given to infants*, without the requisite proof of safety.

“G. The Ashwood, et al., McGinnis, and Megson Studies Cited, which Hypothesize that Thimerosal Causes Gastrointestinal Illness, Vitamin A Depletion, and other Problems, Lack Evidence to Support their Theories”

First, the petitioners note that, though the 2004P-0349/CP1 petition asked:

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

you chose only to review the articles in petition endnotes 61, 64, and 63 here.

Second, we find that your “Lack Evidence to Support their Theories,” again addresses a non-relevant issue that you have generated because the researchers in the articles in question put forward hypotheses (for which they did provide evidence) and not theories.

With these realities in mind, we will now review and address your remarks.

“FDA has also reviewed studies by Ashwood, et al., McGinnis, and Megson, which you cited (endnotes 61, 64, and 63). Ashwood, et al. (endnote 61) tested the hypothesis of a novel and characteristic enterocolitis in a subset of children with autism and gastrointestinal symptoms. The study did not examine the etiology of the enterocolitis in affected children. The authors stated that further studies are required to demonstrate potential links of these findings with disturbed cognition in autism.”

Petitioners note that you agree that the researchers in Ashwood, et al. (petition endnote 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)) *“tested the hypothesis of a novel and characteristic enterocolitis in a subset of children with autism and gastrointestinal symptoms.”*

While we do not dispute your statements, we note that this study also reported, *more importantly:*

“The data provide further evidence of a pan-enteric mucosal immunopathology in children with regressive autism that is apparently distinct from other inflammatory bowel diseases,”

indicating that there may be some linkage between the causal or triggering agent for “regressive autism” and the causal or triggering agent for “pan-enteric mucosal immunopathology.”

Since: **a)** the symptoms of “regressive autism” are the same as those for sub-acute mercury poisoning by alkylmercurials and **b)** Thimerosal is a known immune system dysregulator, the petitioners note that perhaps these comorbid conditions are both “caused”/“triggered” by Thimerosal exposure.

“McGinnis (endnote 4) suggests that toxins known to cause gut injury be considered when looking for causes of autism and that ‘some specifies about autism should heighten interest in mercury.’ He mentions that ‘ethyl mercury as a vaccine preservative may also inflict gut injury.’ No data were

presented or referred to substantiate these statements. Thus, a link between ethyl mercury and gut injury as a cause for autism is speculative.”

First, the petitioners note that this correspondence was speculative in nature and that the basis for McGinnis’ statements about “ethyl mercury” is both well known and well documented in other references, some of which have been cited elsewhere in 2004P-0349/CP1.

Second, we note that you misquoted the author – who actually observed, based on his understanding of mercury toxicity in all its forms (as established earlier in this correspondence):

“Organic forms of mercury such as methyl mercury from fish and ethyl mercury as a vaccine preservative (thimersol” [sic; Thimerosal] “) may also inflict gut injury.”

As to your statement, *“Thus, a link between ethyl mercury and gut injury as a cause for autism is speculative,”* petitioners suggest that you reread petition endnote 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),” where the link between ethyl mercury and gut injury was clearly established more than three (3) decades ago.

Based on the preceding, the petitioners find you either have a very short memory or, *more probably*, you think the FDA can make any unsupported statement the Agency wishes to make, and the reader should accept its validity simply because the FDA has written it.

“Megson, et al. (endnote 63) hypothesize that autism may be a disorder linked to the disruption of the G-alpha protein and suggests that this may be reversible by treatment with natural vitamin A. The paper mentions that pertussis toxin in the DPT vaccine leads to a G-alpha protein defect causing autism in genetically at risk children. The paper also speculates that live viral measles vaccines depletes children of their Vitamin A supply. FDA finds that the conclusions reached in this paper are speculative and do not support the theory.”

First, the current petitioners note that the appropriate reference is simply Megson,

and not your “Megson, *et al.*,” as the petition endnote 63 clearly states:

“Mary N. Megson, ‘Is autism a G-alpha protein defect reversible with natural vitamin A?,’ **Medical Hypotheses**, 54(6), pages 979-983 (2000).”

Second we agree with you that Dr. Megson hypothesizes:

“autism may be a disorder linked to the disruption of the G-alpha protein and suggests that this may be reversible by treatment with natural vitamin A.”

Third, we also agree with you that:

“The paper mentions that pertussis toxin in the DPT vaccine leads to a G-alpha protein defect causing autism in genetically at risk children. The paper also speculates that live viral measles vaccines depletes children of their Vitamin A supply.”

However, based on the preceding realities, we must reject your closing statement:

“FDA finds that the conclusions reached in this paper are speculative and do not support the theory.”

because:

- No theory³⁴⁸ was stated, as you admit, the paper only stated a hypothesis:

“... autism may be caused by inserting a G-alpha protein defect, the pertussis toxin found in the DPT vaccine, into genetically at-risk children,”

based on a “study of 60 autistic children.”

- Since the paper also states no conclusions, we are at a loss to see how you can state: *“the conclusions reached in this paper are speculative.”*

Finally, since you did *not* address the author’s:

“Recent evidence indicates that autism is a disorder of the nervous system and the immune system, affecting multiple metabolic pathways,”

petitioners find that you have apparently accepted the validity of this statement.

“III. PETITIONERS’ LEGAL ARGUMENTS LACK MERIT”

The current petitioners find that, *contrary to your assertion*, your failure to

³⁴⁸ Webster’s New Universal Unabridged Dictionary, 2001, page 1967, column 3, bottom to page 1968 column 1, “the-ory” is scientifically defined as “a coherent group of general propositions used as principles of explanation for a class of phenomena: *Einstein’s theory of relativity*. ... A THEORY in technical use is a more or less verified or established explanation accounting for known facts or phenomena: *the theory of relativity*. A hypothesis is a conjecture put forth as a possible explanation of phenomena or relations, which serves as a basis of argument or experimentation to reach the truth: *This idea is only a hypothesis*.”

directly address the 2004P-0349/CP1 petition's legal arguments in your answer implies that you found them to be valid, or that you had no legal counter argument to overcome 2004P-0349/CP1 petition's legal arguments.

As evidence of the validity of 2004P-0349/CP1's position, petitioners note that you had no problem addressing the legal arguments **CoMeD** petitioners raised in the petition's sections **III. B** and **III. C** even though 2004P-0349/CP1 did not request the FDA to make any decision based on the legal arguments in the petition's sections **III. B** and **III. C**.

"A. The Actions and Legal Remedies Requested are Unwarranted on Scientific Grounds"

Since, *as petitioners have clearly have stated*, the basis of the 2004P-0349/CP1 petition includes:

- The knowing failure of the Secretary of HHS (Secretary) and his subordinates to comply with **42 U.S.C. Sec. 300aa-27(a)(2)** for childhood vaccines since December 22, 1987, as mandated to do by statute,
- The admitted failure FDA and the Secretary to require the manufacturers of Thimerosal-preserved biological products, including vaccines, to prove their products meet the clear "sufficiently nontoxic ..." requirement *minimum* set forth in **21 C.F.R. § 610.15(a)** before you license/approve a new Thimerosal-preserved or other mercury-compound-preserved biological product or, *for Thimerosal-preserved or other mercury-compound-preserved biological products licensed before 1973*, continue to license/approve those products if and only if their manufacturer was able to provide the requisite proof ,
- Your failure, *after April 1988*, to restrict your administrative discretion to instances where the drug product manufacturer has complied with all of the

applicable requirement minimums set forth clearly in any federal policy, law (binding regulation), or statute governing drug products, as *Berkovitz v. U.S.* clearly requires you to do, and

- The CDC's knowing failure to comply with comply with **42 U.S.C. Sec. 300aa-27(a)(2)** for childhood vaccines since December 22, 1987, as mandated to do by statute, when that Agency recommended adding Thimerosal-preserved vaccines for Hib, hepatitis B, and DTap to the recommended vaccination program for children in the late 1980s and the early 1990s and, in 2002, when the CDC recommended adding Thimerosal-preserved influenza vaccines to the recommended vaccination schedules for children and pregnant women,

petitioners find that the Secretary, and the FDA should have either:

- Addressed these legal issues first or
- Addressed them at the same time as the FDA was addressing the scientific issues raised in the 2004P-0349/CP1 petition,

and note that, *in your letter*, you did not address:

- The aforementioned federal law requiring the manufacturer to unequivocally prove that Thimerosal used as a preservative for a biological product is "sufficiently nontoxic ..." or
- The aforementioned federal statute that mandates the Secretary and the subordinate agencies, including the CDC and the FDA, take whatever actions they can (and, for biological products, those actions include the direct ability to revoke a product license) to reduce adverse reactions in vaccine approved for administration to children or

- The 1988 US Supreme Court's legal decision (*Berkovitz v. U.S.*) affirming that the administrative discretion of any federal official first requires that official to act in a manner that complies with each applicable official policy, law (regulation) or statute.

Further, you have presented no valid scientific grounds that have refuted the fundamental propositions set forth in the 2004P-0349/CP1petition.

In general, you have only made unsupported declarations or, *in some cases*, made statements that are provably false.

For example, you have presented or cited no scientific proof or evidence that:

1. You or, as *directly required by 21 CFR § 610.15(a)*, the product manufacturers have proven Thimerosal-preserved biological products are “sufficiently nontoxic ...” to use as a preservative in said biological products, including vaccines, a requisite, *under Berkovitz v. U.S.*, that must be met before you can use your administrative discretion to determine the products are “safe” and license/approve such drug products.
2. That the removal of Thimerosal from each and every licensed Thimerosal-containing childhood vaccine formulation (including vaccine formulations given to pregnant women) does not reduce the inoculees' risk of adverse reactions as compared to the Thimerosal-containing childhood vaccine formulation, a statutory requirement (under **42 U.S.C. Sec. 300aa-27(a)(2)**) that, *under Berkovitz v. U.S.*, you must meet before you can license/approve, or continue to license/approve, a Thimerosal-containing childhood vaccine.

Since you have failed to provide:

- The requisite scientific proofs to address the preceding petition issues and

- Any sound science (with, at a minimum, complete references to the articles that unequivocally prove the scientific validity of the statements you make and that these proven-valid statements refute the evidence-based statements made in 2004P-0349/CP1) to refute the citation-supported assertions made in 2004P-0349/CP1,

petitioners are compelled to find that you have failed to provide any scientific grounds to:

- Support your rhetoric or
- Overcome the evidence-based statements made in 2004P-0349/CP1.

Since petitioners have demonstrated that you not only have provided no scientific grounds but also have fabricated statements and views that are at odds with the actual statements made in 2004P-0349/CP1 and the references that it cited, you have destroyed your credibility as a reliable presenter of fact.

“For the scientific reasons discussed above in Sections I and II, none of the actions and legal remedies you seek against vaccines or other products containing thimerosal are warranted.”

First, petitioners find that you have failed, *in general*, to provide any sound science, published scientifically sound toxicological studies, or references thereto, to support your statements and therefore, you have provided only your unsupported statements, which are *not* scientific reasons – but only your unsupported views.

Second, in the cases that you cited a new epidemiological study (e.g., your “*Fombonne, et al. (2006)*”) or an animal study published after 2004P-0349/CP1 was submitted (e.g., your “*Burbacher, et al. (2005)*”) to address a contention made on 2004P-0349/CP1, petitioners were able to show:

- That study had significant flaws,

- Your presentation of the facts was either incomplete, knowingly misleading, or simply at odds with the apparently sound data supported, and/or
- The valid data in these papers actually supported one or more of the contentions in 2004P-0349/CP1.

Based on the preceding realities, petitioners find that your responses have failed to prove that *“none of the actions and legal remedies you seek against vaccines or other products containing thimerosal are warranted.”*

Furthermore, petitioners find you cannot avoid the legal mandates set forth in **42 U.S.C. Sec. 300aa-27**, “Mandate for safer childhood vaccines” in December of 1987, unless you have proven, *what is contrary to factual reality*, that the formulation of a vaccine, which is free of all Thimerosal or other added mercury compound, has the same adverse risk incidence and severity as the same formulation with Thimerosal at the nominal level declared in its formula.

Since: **a)** you have provided no evidence that this is the case and **b)** 2004P-0349/CP1 includes a peer-reviewed published report that a Thimerosal-containing formulation has a significantly higher risk of adverse reactions than the same formulation without Thimerosal (e.g., Nelson and Gottshall [petition endnote 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)”]), then you are legally bound to comply with this mandate.

Thus, the petitioners are compelled to find that the Secretary and his subordinate agencies, *including the CDC and the FDA*, have, *since it became law in December of 1987*, knowingly failed to comply with this explicit “Mandate for safer childhood vaccines” for all childhood vaccines, including vaccines given to pregnant women that are, *in effect*, also given to the *in utero* child.

For example, the FDA failed to comply with **42 U.S.C. § 300aa-27(a)(2)** when it approved the Thimerosal-preserved Hib, hepatitis b, and DTaP vaccines in the late 1980s and early 1990s when the FDA could have refused to license them unless the adverse-reaction Thimerosal was removed from the formulations, since the FDA knew (as that term is defined in **21 U.S.C. Sec. 321(bb)**) that approving a Thimerosal-preserved vaccine would increase adverse reaction more than approving the same vaccine formulation without the Thimerosal.

Thus, after December 22, 1987, if the FDA had wished to comply with the letter and the spirit of **42 U.S.C. § 300aa-27(a)(2)**, the FDA would have only approved Thimerosal-free vaccines since it is known that adding a mercury-based increases the risk of adverse reactions and does not safen the vaccine doses as compared to the same formulation manufactured without the use of Thimerosal and packaged in single-dose containers.

Similarly, after December 22, 1987, if the CDC had wished to comply with the letter of **42 U.S.C. § 300aa-27(a)(2)**, a mandate that limits the legal actions of the CDC with respect to recommending vaccines for children, the CDC would not have added any new Thimerosal-preserved vaccines to the recommended vaccination schedule for children (e.g., the Thimerosal-preserved Hib and hepatitis B vaccines) after 1987.

Obviously, the historical record clearly demonstrates that both the FDA and the CDC have repeatedly ignored the law and failed to act, as the statute mandates, “to reduce the risks of adverse reactions to vaccines” and not, as the facts show the CDC and the FDA have done:

- Significantly increasing the “adverse reaction” risks on the late 1980s and 1990s,
- Starting to reduce them in 2000 and

- Again starting to increase them in 2002.

In addition, while claiming since 1999 to be reducing the cumulative exposure level to Thimerosal in childhood vaccines, *amongst other actions*, you:

- Added both Thimerosal-preserved and reduced-Thimerosal influenza vaccines to the national immunization for children and pregnant women in 2002, thereby increasing the maximum level of Thimerosal-derived mercury exposure for a seven-month-old routine-vaccination-schedule-inoculated child from “< 3” µg Hg, when all Thimerosal-containing vaccines are reduced-Thimerosal vaccines, to a maximum of about 53 µg after the influenza vaccines were added, without proof of safety, to the recommended vaccination schedule for pregnant women (thus exposing the fetus to 25 µg of mercury) and children 6-months to 23-months of age, directly adding a 37.5-µg of mercury.
- Licensed/approved a new Thimerosal-preserved influenza vaccine, FluLaval, which, *because it is licensed for adults*, can be given to pregnant women.

Thus, your actions clearly contradict your claim.

Further, based on the preceding realities, it is clear to the petitioners that, *in addition to being unsupported by references and consistent with your actions*, your statements cannot be relied upon to be either factual or, *in some cases*, even truthful.

“Therefore, we need not address your arguments about the scope of FDA’s authority to take particular legal actions or to pursue particular remedies.”

Given all of the preceding, your lack of legal citations supporting your statement here, and your implicit position that your actions are not bound by the law, petitioners must:

- Reject your unsupported assertion here, and

- Again demand that you address 2004P-0349/CP1's assertions about the scope of your administrative authority to:
 1. Ignore laws that mandate you take certain actions to safen vaccines,
 2. *Knowingly* license/approve drug products that do not meet the clear CGMP minimums (and **21 C.F.R. § 610.15(a)** is a clear CGMP requirement *minimum*), and
 3. Based on Point 2, collusively participate in the knowing marketing of drugs that, under **21 U.S.C. § 351(a)(2)(B)**, are "deemed to be adulterated."

"Instead, we decline your request for those actions and remedies on the substantive grounds that the few vaccines and other legally marketed products that contain thimerosal are safe and that no action against those products based on their thimerosal content is appropriate."

Based on the preceding realities concerning the applicable laws and statutes, petitioners find that, as the U.S. Supreme Court affirmed in 1988 in *Berkovitz v. U.S.*, you lack the administrative discretion to ignore said laws and statutes, and further find that your "*substantive grounds*" argument is flawed.

The preceding is factual reality because you have knowingly failed to: **a) prove** or **b) require the drug manufacturers to prove**, to the minimum "*sufficiently nontoxic ...*" standard established by **21 C.F.R. § 610.15(a)** (as the FDA has repeatedly admitted in testimony before Congress) that marketed products containing Thimerosal as a preservative are safe.

Therefore, the current petitioners again ask that you to answer 2004P-0349/CP1 in a manner that complies with all applicable policies, laws and statutes, because your answer here clearly has, as we have shown, failed to do so.

In addition, given: **a)** the scientific progress in determining levels where the toxicity of Thimerosal appears to be repeatably measurable and **b)** the failure to find a reliable level where the mercury-compounds used in medicine have no adverse

effect, the petitioners now request that the interim estimated safety guideline for a “safe” dose of Thimerosal for susceptible individuals be set at 0.01 micrograms of mercury per kg of body mass per day, and the acceptable levels for Thimerosal or other mercury compound in any drug also be, as *the current evidence suggests*, lowered by a factor of 10 to protect the identified sub-population of individuals who are susceptible to mercury-poisoning.

“B. The Constitutional and Civil Rights Claims do not Articulate any Grounds upon which FDA Should or Could Grant the Petition

At the end of the ‘Statement of Grounds’ portion of your citizen petitions, you add two legal arguments as subsections B and C: ‘Violation Of Constitutional Right To Bodily Integrity’ and ‘Violation of Other Civil Rights And Societal Tenants.’”

Before proceeding to address your response here, the petitioners offer the following outline of 2004P-0349/CP1:

CITIZEN PETITION

I. Actions Requested (P-1 to P-6)

II. Petitioners (P-6 to P-7)

III. Statement of Grounds (P-7 to P-52)

A. Safety Not Proven (P-7 to P-45)

1. **General Background** (P-7 to P-8)
2. **Removal Of Thimerosal And Other Mercury-based Compounds From OTC Drugs (P-8 to P-9)**
3. **Petitioners’ General Concerns** (P9 to P-12)
4. **FDA’s Published Call-For-Data Notices And Announcements** (P-13)
5. **Thimerosal At Multi-Dose Vaccine Or Lower Levels** (P-13 to P-34)
 - a. **Recent Comments of a US House Subcommittee and the US Office of Special Counsel (OSC)** (P-17 to P-20)
 - b. **“Confounded” and “Biased” Epidemiological Studies On Vaccinated Children?** (P-20 to P-29)
 - c. **Studies Establishing Linkages Between Thimerosal Exposure And Adverse Outcomes, Including “Neurodevelopmental Disorders” (“NDDs”)** (P-29 to P-33)
 - d. **Inconsistencies Between The Exposure Limits For: i) Thimerosal In Drugs And ii) Methyl Mercury In Food: A Regulatory Conundrum?** (P-33 to P-34)
6. **Ethyl Mercury, The Initial Thimerosal Metabolite** (P-34 to P-36)
7. **Ionic Mercury, The Final Thimerosal Metabolite** (P-36 to P-37)
8. **The Link Between Thimerosal And Neurological Disorders** (P-37 to P-39)
9. **Autism Alarm** (P-39)
10. **Clinical Evidence** (P-39 to P-42)
11. **Significant 2004 Studies** (P-42 to P-44)
12. **Summary Of “Safety Not Proven”** (P-44 to P-45)

B. Violation Of Constitutional Right To Bodily Integrity (P-45 to P-49)

C. Violation Of Other Civil Rights And Societal Tenants (P-49 to P-51)

D. Summary (P-51 to P-52)

IV. Environmental Impact (P-52)

V. Certification (P-53 to P-54)

Endnotes: (P-55 to P-59)

Based on the outline provided, the current petitioners note that petition sections “B” and “C” are integral parts of “**III. Statement of Grounds.**”

With the preceding facts in mind, the petitioners will now address your comments concerning sections “**III. B**” and “**III. C.**”

“Those two sections are not included among your Requested Actions, and you do not appear to be petitioning FDA to act on those claims. Nevertheless, FDA has the following responses to your arguments.”

Since these two sections are simply additional grounds that 2004P-0349/CP1 found supported the actions being requested, there was no need to petition you to “*act on these claims.*”

“In subsection B (page P-45 of your petition), you cite In re Cincinnati Radiation Litigation, 874 F. Supp, 796, 810-811 (S.D. Ohio, 1995), Albright v. Oliver, 510 U.S. 266 (1994), and Schmerber v. California, 384 U.S. 757, 772 (1966), to argue that the Due Process Clause of the Fourteenth Amendment creates a substantive due process right to be free of state-sponsored invasion of a persons bodily integrity.”

Factually, the petitioners note that the 2004P-0349/CP1 petition cited “*In re Cincinnati Radiation Litigation, 874 F. Supp, 796, 810-811 (S.D. Ohio, 1995), Albright v. Oliver, 510 U.S. 266 (1994), and Schmerber v. California, 384 U.S. 757, 772 (1966), to*” establish that the courts have recognized that, in your words, “*Due Process Clause of the Fourteenth Amendment creates a substantive due process right to be free of state-sponsored invasion of a persons bodily integrity.*”

“You then state that ‘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...’ the government is ‘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.’ You conclude that by doing so, the government is breaching those individuals’ “bodily integrity.” Similarly, you argue in subsection C (page P-49 of your petition) that ‘basic American civil rights and tenants (including informed consent, self determination, and personal autonomy) continue to be violated’ ... ‘because misled and coerced parents offer up their children for injection with mercury-laced pharmaceuticals...’”

The petitioners note that, in subsection **B** (page P-46 of the 2004P-0349/CP1 petition) the petition actually stated:

*“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.”*

Similarly, *“in subsection C (page P-49 of your petition),”* the petition actually asserted:

“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.”

“Regardless of the scope of the Due Process Cause of the Constitution and the ‘basic American civil rights and tenants’ on which you rely, the facts, even as you allege them, do not amount to the government violating anyone’s rights.”

If, as you state, the facts are as the 2004P-0349/CP1 petitioners “allege them,” then, since they asserted, “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,” their assertions most certainly do amount to the government’s violating “the constitutionally protected bodily integrity rights of those susceptible individuals that have been injured.”

“For example, In re Cincinnati Radiation Litigation involved doctors who were alleged to have subjected indigent cancer patients to increasing levels of radiation to determine what levels that the human body can withstand, even though the doctors knew that the radiation had no therapeutic value to patients. Allegedly the doctors never informed the patients about any of those facts, but instead told them that the radiation was to treat their cancer. In contrast, here you are not denying that the vaccines and other products have prophylactic or therapeutic value to those who take them.”

Addressing your assertions in reverse order, the petitioners note that:

- The 2004P-0349/CP1 petition did not admit, *“that the vaccines and other products have prophylactic or therapeutic value to those who take them.”*
- The 2004P-0349/CP1 petition has asserted and established that, *under law*, you have represented preservative levels of Thimerosal in vaccine formulations as “safe” without having the requisite proofs of safety and in disregard for your mandate to reduce adverse effects in childhood vaccines.
- Based on studies published subsequent to the filing of this petition, we find and have noted that the in-use history for the human influenza vaccines has established that these vaccines are not effective.³⁴⁹
- You have *knowingly* failed to fully disclose to the recipients or their legal guardians all the risks and the true risk incidences associated with each vaccine (e.g., recent smallpox vaccine case where the claimed risk of death was 1 in 1,000,000 and, for serious harm, about 1 in 100,000, but, *as about 38,000 first providers found out*, the real rates were closer to 1 in 10,000 for deaths and 1 in 100 for severe adverse reaction),
- You have been ineffective in tracking adverse reactions to vaccines by failing to

³⁴⁹ a. Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *J Am Phys Surg* 2006; 11(3): 69-74 and the supporting studies referenced therein.
b. Jefferson T. Influenza vaccination: Policy versus evidence. *BMJ (British Medical Journal)* 2006 October 28; 333: 912-915.
c. Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet* 2005; 365: 773-780.

provide monetary and other sanctions for the failure of a healthcare provider to report an adverse effect (e.g., even the government admits that less than 10% of adverse reactions are reported to the government and entered into VAERS),

- You have not assessed the long-term (beyond 6 months) risks associated with each vaccine, even though there is evidence that the adverse reactions to certain vaccines may occur years or decades after inoculation (e.g., “causal relationship between the haemophilus vaccine and the development of insulin dependent diabetes ... 3 – 4 years after four doses of Hib”³⁵⁰),
- You have understated the risks for death and serious injury from the each vaccine (e.g., Varivax®)
- You have inflated the effectiveness of vaccines (e.g., Prevnar®),
- You have *knowingly* failed to *fully* disclose the limitations on vaccines that do not cover all strains of the organism for which “protection” is claimed (e.g., the “Meningitis” vaccines for *Neisseria meningitidis* that provide no protection for the strain that causes about 50% of the cases of disease [“strain B”], but that the government permits the manufacturers to misrepresent said vaccines as generally protecting those vaccinated from contracting meningitis).

Based on the preceding facts, and the preceding petition statements and our review comments, the current petitioners are declaring:

- You have *knowingly* concealed the fact that the current human inactivated-influenza vaccines are not effective from the public and continued to recommend universal immunization for large segments of the population (i.e., young children, pregnant women, the elderly).

³⁵⁰ <http://www.vaccines.net/newpage112.htm>

- You have *knowingly* concealed and are *knowingly* concealing the toxicity of Thimerosal used in the formulation of vaccines and other drugs from those who are inoculated with Thimerosal-containing vaccines or, *in the case of children*, the guardians or parents of those who are inoculated with Thimerosal-containing vaccines.
- You are *knowingly* continuing to claim that Thimerosal-preserved and Thimerosal-containing vaccines are safe without direct toxicological proof of their safety and with a growing body of toxicological and other evidence that Thimerosal is toxic at levels approaching or exceeding 1/100,000th of the 0.01% (100 ppm) level found in Thimerosal-preserved influenza vaccines.
- While claiming to be reducing Thimerosal exposure in children since 2000, you have actually been *knowingly* increasing some children's exposure to Thimerosal by recommending that pregnant women and all children 6-months to now 59 months of age be inoculated during each year's flu season with ineffective influenza vaccines that include Thimerosal-preserved influenza vaccines.
- You have *knowingly* concealed the increased risks of allergy, asthma, type I and type 2 diabetes, certain leukemias, skin damage, neurological damage, immune system damage, endocrine system damage, digestive system damage, circulatory system damage, and organ damage to those inoculated with Thimerosal-containing vaccines as compared to those not inoculated with such vaccines.
- You have *knowingly* failed to accurately convey the risks, severity of risks, and the incidence of risks associated with all vaccines.
- You have *knowingly* overstated and/or participated in the overstating of the benefits associated with all vaccines.

Further, as a direct parallel to the *"In re Cincinnati Radiation Litigation,"* we have provided **Petitioners' Table 5**, which compares your remarks concerning the *"In re Cincinnati Radiation Litigation"* to your current recommendations for Thimerosal-preserved influenza vaccines.

To the petitioners, the parallels are clear.

Petitioners' Table 5 *"In re Cincinnati Radiation Litigation"* & US Influenza Vaccination Program

In re Cincinnati Radiation Litigation	US Recommended Thimerosal-preserved Influenza Vaccination Program
<p><i>"... involved doctors who were alleged to have subjected indigent cancer patients to increasing levels of radiation to determine what levels that the human body can withstand,"</i></p>	<p>Involves DHHS, including FDA and CDC who directly and indirectly, <i>by recommending the inoculation of their mothers when the children are fetuses</i>, recommended inoculating young children with <i>ineffective</i> influenza vaccines, including those vaccines that are Thimerosal preserved <u>without</u> proof of safety. [Factually, since 2002, you have <i>knowingly</i> subjected children to increasing cumulative doses of mercury from the Thimerosal-preserved influenza vaccines apparently to increase the level of harm. You knowingly did this by: 1) adding the influenza vaccines to the your recommended vaccination schedule for pregnant women and children 6-months to now up to 59-months of age and 2) allowing Thimerosal-preserved influenza to be used to inoculate these children and pregnant women with having proof of safety.]</p>
<p><i>"... even though the doctors knew that the radiation had no therapeutic value to patients."</i></p>	<p>You included Thimerosal-containing influenza vaccines in your immunization recommendations for young children and pregnant women even though you <i>knew</i> that these influenza vaccines were <i>not</i> effective in preventing those inoculated from getting influenza or in stopping the spread of influenza, and knew, or are responsible for knowing, that injecting Thimerosal-preserved influenza vaccines that are ineffective into pregnant women and young children mercury-poisons the children injected to varying degrees. In addition, you claimed these vaccines were safe without having proved that they were, in fact, safe.</p>
<p><i>"Allegedly the doctors never informed the patients about any of those facts, but instead told them that the radiation was to treat their cancer."</i></p>	<p>You never told the public the facts about the ineffectiveness of the human influenza vaccines, the risk of mercury-poisoning harm presented by Thimerosal-preserved vaccines, and the toxic properties of Thimerosal. Instead, you continued to claim these ineffective influenza vaccines were effective in preventing those inoculated from getting and/or spreading influenza and, <i>for the Thimerosal-containing influenza vaccines</i>, claimed they were safe without proof of safety and <i>knowingly</i> failed to warn those inoculated or, for children, their parents or guardians, that said Thimerosal-containing vaccines present clear clinical mercury-poisoning risks to themselves and/or their fetuses and children.</p>

Worse, though you have lacked scientific proof of safety since 1930 and numerous scientific articles, *published since then*, have repeatedly warned of the toxic risks of alkyl mercury compounds, including Thimerosal, including articles that found toxicity to human skin and neural tissues at the sub-ppm level that date from the 1940s, you have: **a)** *knowingly* claimed Thimerosal-preserved vaccines to be “safe” and **b)**, *since 1973*, have refused to require the manufacturers thereof to prove the Thimerosal they were using as a preservative met the clear CGMP minimum, “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,” as set forth in **21 CFR § 610.15(a)**.

In addition, since 1988, you have *knowingly* failed to act in accordance with the “Mandate for safer childhood vaccines” set forth in **42 U.S.C. Sec. 300aa-27**, which clearly required/requires you to take all possible actions to reduce the risk of adverse reactions in childhood vaccines in **42 U.S.C. Sec. 300aa-27(a)(2)**.

Thus, we find that, as agents of the government, you are even more culpable for your knowing actions than the doctors in “*In re Cincinnati Radiation Litigation*.”

“Nor have you provided any evidence to claim that FDA officials have been hired to conduct ‘uncontrolled involuntary experiments’ on people.”

Worse than being the hired agents, petitioners find, as the 2004P-0349/CP1 petition asserted, that, as the accountable order givers and overseers, the Secretary of DHHS and his accountable subordinates, and other accountable high governmental officials in the CDC and FDA are responsible.

As the 2004P-0349/CP1 petition cogently put it, “...high governmental officials, ..., 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.”

“Nor do you claim that FDA has hidden any facts from those who will use thimerosal-containing products.”

First, petitioners find that, as 2004P-0349/CP1 established, you have repeatedly *knowingly* claimed that Thimerosal-containing drugs are “safe” without the required level of proof to support your claim.

Thus, you have most certainly concealed the facts:

- From all of those who were, are, or will be, given such products
- About the risks of Thimerosal in Thimerosal-containing vaccines
- Behind:
 - Your unsupported claims of safety and
 - Your “there is no proof” mantra.

In addition, in support of this effort to conceal the risks of Thimerosal in vaccines, the FDA has permitted specific language, warning about the anaphylactic shock risk from Thimerosal, to be removed from the package inserts for Thimerosal-containing vaccines.

Thus, petitioners find that, *contrary to your protestation here*, you have, in your words, most certainly hidden the “*facts from those who will use thimerosal-containing products*” behind your unsupported claims of safety – an issue repeatedly raised in 2004P-0349/CP1, and have buttressed your claims by permitting the specific risks associated with Thimerosal to be deleted from the package inserts for Thimerosal-containing vaccines.

Therefore, we must reject your statement here because it is clearly at odds with the facts.

Second, the current petitioners note that 2004P-0349/CP1 also did not assert the affirmative – that you had revealed the facts about Thimerosal risks to those given Thimerosal-containing vaccines or other mercury-containing drugs.

Third, we find that you have not required the manufacturers of vaccines and other affected drug products to provide the requisite proofs of safety as required (under **21 CFR § 610.15(a)**) so that the facts could be known and, thus, the Agency's knowing non-actions have also very effectively hidden the *"facts from those who will use thimerosal-containing products."*

Based on all of the preceding facts, petitioners find that you have *knowingly* concealed facts about the risks from Thimerosal in Thimerosal-containing vaccines and, by analogy, in other mercury-product-containing drugs.

"You simply disagree with the conclusions that FDA draws from those facts."

Based on the current petitioners' understanding of 2004P-0349/CP1 and your letter purporting to respond to 2004P-0349/CP1, we find that your statement here is based on an unsupported premise – namely that your conclusions are drawn from the *"facts"* presented.

"As explained above, however, FDA's conclusions are based on sound scientific principles."

Again, the current petitioners find that your statement here is at odds with the facts because, as we have established, you have failed to provide or reference any body of *"sound scientific principles"* and, in most cases, have failed to provide any cogent citations supporting your views.

Thus, we are compelled to find your conclusions are simply based on your unsupported rhetoric and not *"sound scientific principles"* as, again without any supporting documents or citations, you claim.

“Moreover, as explained extensively above, studies and other evidence support FDA’s determination that vaccines and other FDA-approved products containing thimerosal are safe.”

Since your extensive explanations are mostly unsupported rhetoric and the few studies and evidence you have provided have either been shown to be flawed, refuted, or shown to support the petitioners’ assertions, the current petitioners find your claim, *“that vaccines and other FDA-approved products containing thimerosal are safe,”* is an unsupported statement that, *based on the evidence provided here and in 2004P-0349/CP1*, is at odds with:

- The body of scientific toxicity evidence presented for Thimerosal and
- In your letter and our response, the sound scientific toxicity evidence presented for phenylmercuric acetate (PMA).

“The evidence on which your petition relies either does not support your requests, or is too flawed to be considered valid scientific evidence.”

Since only scientifically sound and appropriate toxicological evidence can be used to prove the safety of highly poisonous bioaccumulative compounds, *like Thimerosal and PMA*,

- The toxicological evidence you presented for PMA does (when properly interpreted) support the petitioner’s assertion about **“Safety Not Proven,”**
- Your own admissions repeatedly affirm that the required toxicity studies for Thimerosal in each approved drug formulation have either not been conducted or, *if conducted*, not provided, submitted or published, and
- You have provided no studies that refute the scientifically sound toxicity evidence that the 2004P-0349/CP1 petition provided,

the evidence provided does support 2004P-0349/CP1’s assertion that safety has not been proven.

Thus, petitioners find, *absent any scientifically sound and appropriate refutation of 2004P-0349/CP1's cited scientific studies and their findings*, the scientific evidence upon which 2004P-0349/CP1 was based is valid science that most certainly does support the requests made in 2004P-0349/CP1.

Finally, because: **a)** 2004P-0349/CP1 rests upon laws and statutes and petitioners' understanding thereof, and **b)** you have *not* addressed, much less attempted to deny, the validity of petition's understanding thereof, the current petitioners find that your statement here is at odds with factual reality.

"Therefore, FDA has no grounds to revoke the licenses and withdraw the approvals of thimerosal-containing products, or to take any of the other actions that you seek."

First, since you have not addressed the fundamental petition issue of compliance with **21 C.F.R. § 610.15(a)**, much less proven that biological drug product manufacturers are somehow not required to comply with this binding regulation, you have this *"grounds to revoke the licenses and withdraw the approvals of thimerosal-containing products, or to take any of the other actions that"* 2004P-0349/CP1 sought and the current petition seeks, but have obviously failed to require compliance with this clear regulation and, thereby, have acted outside the law.

You also have this legal ground because, *as you have repeatedly admitted*, the manufacturers of mercury-compound-preserved vaccines and other biological products have not met this requirement.

Second, since you have not addressed the fundamental petition issue of your mandates under **42 U.S.C. Sec. 300aa-27**, much less proven that you are somehow above a statutory mandate that requires you to reduce the risk of adverse reaction in childhood vaccines (as per **42 U.S.C. Sec. 300aa-27(a)(2)**), you also have this *"grounds to revoke the licenses and withdraw the approvals of thimerosal-containing*

products, or to take any of the other actions that" the 2004P-0349/CP1 petition seeks, but have obviously failed to comply with this clear statute and, *thereby*, are declaring that you are above complying with statutes that require you to reduce the adverse reactions in childhood vaccines.

Third, given the 1988 unanimous Supreme Court ruling (*Berkovitz v. U.S.*) that affirmed you have no "administrative discretion" when there is a clear policy, law or statute that compels a given course of action, we find that you have no legal basis for:

- Your *knowing* failure to enforce the drug product manufacturers' compliance with **21 C.F.R. § 610.15(a)** or
- Failing to comply with **42 U.S.C. Sec. 300aa-27(a)(2)** yourselves.

Based on the preceding factual realities, you not only have the "*grounds to revoke the licenses and withdraw the approvals of thimerosal-containing products, or to take any of the other actions that you seek*" but also are compelled by the highest law in the land, the US Supreme Court in *Berkovitz v. U.S.*, to use those grounds to take the actions 2004P-0349/CP1 properly petitioned you to take.

"Consequently, even if constitutional or other 'civil rights' were considered to exist in this context, declining to take any action against those products does not violate anyone's constitutional or other rights."

For the cogent reasons asserted throughout this review and in 2004P-0349/CP1, petitioners must reject your unsupported statement here because, as *the 2004P-0349/CP1 petition and the current petitioners have shown*:

- This statement flies in the face of the clear protections afforded all citizens under the Fourteenth Amendment of the Constitution of the United States of America as interpreted by the courts and
- Your actions to conceal the risks from Thimerosal behind unsubstantiated claims of "safety" that are, *in part*, unsubstantiated because you have refused to act to:

a. find or

b. as **21 C.F.R. § 610.15(a)** clearly compels the manufacturers of Thimerosal-containing and/or other mercury-compound containing vaccines and other drug products to do, prove

what the real risks of these mercury-containing compounds when used as a preservative are to the most susceptible children.

“IV. AGENCY CONCLUSIONS

For the reasons discussed above, the studies and other documents on which you rely do not support your argument that FDA should take action against biologics and other drugs that contain thimerosal.”

Petitioners must reject your statement here based on:

- The evidence-supported reasons presented in this citizen petition, in the current review of your letter, and in the 2004P-0349/CP1 petition and
- Your failure to present any cogent evidence-supported rationale to refute the evidence provided, the claims made by the petitioners, or the laws, statutes, and court decisions upon which the 2004P-0349/CP1 petition is based.

“Only a small number of licensed and approved products still contain thimerosal, and the available evidence supports FDA’s conclusion that all currently licensed vaccines and other pharmaceutical drug products containing thimerosal are safe.”

The petitioners must reject your statement here because:

1. Compliance with the laws and statutes compelling certain actions or the meeting of certain standards does not depend on the fact that *“a small number of licensed and approved products still contain thimerosal,”*
2. Contrary to your unsupported statements and opinions, the body of scientific, legal, and historical evidence clearly supports the petitioners’ **“Safety Not Proven”** grounds, and

3. Since you have not denied that **21 C.F.R. § 610.15(a)** is a legally binding requirement on the manufacturers of all preserved biological products, including vaccines preserved with Thimerosal, or that the manufacturers of said products have not complied with **21 C.F.R. § 610.15(a)**, the current petitioners find all such drugs are adulterated under **21 U.S.C. § 351(a)(2)(B)**, as the 2004P-0349/CP1 petition has asserted, and, therefore, are illegal to be on the market,
4. Under *Berkovitz v. U.S.*, you lack the administrative discretion to allow these violative (adulterated) products to remain on the market, especially since you assert that only “a small number of licensed and approved products still contain thimerosal,” and
5. As the petitioners have reported, recent published studies³⁵¹ have proven that one group of these Thimerosal-containing vaccines, the influenza vaccines, are not effective.

“For these reasons, we deny your petition in its entirety.

Sincerely,

Jeffrey Shuren's signature'

Jeffrey Shuren, M.D., J.D.

Assistant Commissioner for Policy”

Because your letter, Dr. Shuren, has failed to provide any cogent evidence-based rationale that overcomes the issues raised in the 2004P-0349 petition, and you failed to mention, much less address in this letter, the legal issues:

³⁵¹ a. Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *J Am Phys Surg* 2006; 11(3): 69-74 and the supporting studies referenced therein.
b. Jefferson T. Influenza vaccination: Policy versus evidence. *BMJ (British Medical Journal)* 2006 October 28; 333: 912-915.
c. Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet* 2005; 365: 773-780.

- “**Safety Not Proven**” to the standard “sufficiently nontoxic ...” as set forth in **21 C.F.R. Sec. 610.15(a)**,
- The failure to heed the statutory “Mandate for safer childhood vaccines” as set forth in **42 U.S.C. Sec. 300aa-27(a)(2)** when it licensed the Thimerosal-preserved versions of the current Hib, hepatitis B, and DTaP vaccines in the late 1980s and early 1990s and/or added Thimerosal-preserved and/or Thimerosal-containing inactivated influenza vaccines to the recommended childhood vaccination schedule in 2002, even though the Secretary of HHS and the responsible officials in subordinate agencies, including the CDC, FDA, and NIH knew, should have known, or were responsible for knowing, that these vaccines were not effective in preventing those inoculated from contracting or spreading a human influenza viral infection,
- The limits on the administrative discretion available to federal officials that the 1998 U.S. Supreme Court clarified and affirmed in their unanimous decision *Berkovitz v. U.S.*,
- *Knowingly* licensing and approving, or continuing to license or approve, drugs that the FDA knew, should have known, and were responsible for knowing, are “adulterated” under **21 U.S.C. Sec. 351(a)(2)(b)**, and
- The FDA’s failure to take the statutorily mandated legal actions (as set forth in **21 U.S.C. Sec. 333 Penalties**) against adulterated drugs (which are illegal to market under **21 U.S.C. Sec. 331(a)**³⁵² that the FDA *knew*, should have known, or was responsible for knowing, were adulterated under **21 U.S.C. § 351(a)(2)(b)**

³⁵² **21 U.S.C. Sec. 331(a):**

“The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”

because of their manufacturer *knowingly* failed to comply with the “sufficiently nontoxic ...” CGMP *minimum* for preservative safety as set forth in **21 C.F.R. § 610.15(a)**, as well as those, *including FDA officials*, who were and/or are in any manner responsible for “causing” these adulterated drugs to be introduced into interstate commerce),

the petitioners are compelled to reject your decision because it is both lacking in substance and violates the laws governing your conduct and that of the Secretary of HHS and those other administrative officials who directly, or indirectly, report to him.

“Enclosure: Table — Thimerosal Content of Vaccines Routinely Recommended for Children 6 Years of Age and Younger.”

The petitioners note that the “Table” provided by the FDA failed to provide those Thimerosal-containing vaccines that are licensed, approved for use, and currently marketed in the United States of America for citizens over 6 years of age.³⁵³

Today, that list includes the vaccines listed below.

Vaccine	Tradename (Manufacturer)*	Thimerosal Percentage (Mercury concentration in nanograms per dose)
DT	No Trade Name (Sanofi Pasteur, Inc.)	≤ 0.00012% [single dose] (≤ 300 ng/0.5mL)
Td	No Trade Name (Mass Public Health)	0.0033% (8,300 ng/0.5mL)
	Decavac (Sanofi Pasteur Inc.)	≤ 0.00012% (≤ 300 ng/0.5mL)
TT	No Trade Name (Sanofi Pasteur, Inc.)	0.01% (25,000 ng/0.5mL)
Hepatitis B	Energix B (GlaxoSmithKline)	< 0.0002% (<500 ng/0.5mL [adolescent]) (<1,000 ng/1 mL [adult])
HepA/HepB	Twinrix (GlaxoSmithKline)	< 0.0002% (<1,000 ng/1 mL)
Influenza	Fluarix (GlaxoSmithKline)	< 0.0004% (<1,000 ng/0.5 mL)

³⁵³ See <http://www.fda.gov/cber/vaccine/thimerosal.htm#t3> -- last visited on June 22, 2007

	FluLaval (ID Biomedical Corporation of Quebec, subsidiary of GlaxoSmithKline)	0.01% (25,000 ng/0.5 mL)
Japanese Encephalitis	JE-VAX (BIKEN [distributed by "Sanofi"])	0.007% (35,000 ng/1.0mL)
Meningococcal	Menomune A, C, AC and A/C/Y/W-135 (Sanofi Pasteur, Inc.)	0.01% [multidose] (25,000 ng/0.5 mL)

In addition, the FDA failed to note:

- The worst-case total mercury-burden added by an annual Thimerosal-preserved influenza shot to a person in a "high risk" category could exceed 1,500 micrograms (1.5 mg) by age 60, or
- Coincidentally, the incidence of Alzheimer's disease (another neurological disorder that may be caused and/or worsened by the accumulation of mercury in the adult brain) has been increasing as the number of annual doses of the Thimerosal-preserved flu vaccine that a vaccinated adult gets has increased, or
- *Though known to be ineffective*, pushing annual influenza vaccine on the elderly has been mandated for nursing homes and retirement facilities as a condition of their being eligible for Medicare reimbursement and, *for children*, as a condition of their being able to attend public schools even though, *for the Thimerosal-containing vaccines (which are the overwhelming majority of the doses given)*, this amounts to the coerced mercury poisoning of the American public disguised as a measure to protect their health.

"Enclosure

Table 1. Thimerosal Content of Vaccines Routinely Recommended for Children 6 Years of Age and Younger - (updated 7/18/2005)*

**Since this update, a biologics license application was approved for Rotavirus Vaccine, Tradename - RotaTeq (Merck), that is thimerosal free and never contained thimerosal.*

Vaccine	Tradename (Manufacturer)*	Thimerosal Status Concentration** (Mercury)	Approval Date for Thimerosal Free or Thimerosal / Preservative Free (Trace Thimerosal)*** Formulation
DTaP	Infanrix (GSK)	Free	Never contained more than a trace of thimerosal, approval date for thimerosal-free formulation 9/29/00
	Daptacel (AP)	Free	Never contained Thimerosal
	Tripedia (AP)	Trace ($\leq 0.3 \mu\text{g Hg}/0.5\text{mL dose}$)	03/07/01
DTaP-HepB-IPV	Pediarix (GSK)	Trace ($< 0.0125 \mu\text{g Hg}/0.5\text{mL dose}$)	Never contained more than a Trace of Thimerosal
Pneumococcal conjugate	Prevnar (WL)	Free	Never contained Thimerosal
Inactivated Poliovirus	IPOL (AP)	Free	Never contained Thimerosal
Varicella (chicken pox)	Varivax (M)	Free	Never contained Thimerosal
Mumps, measles, and rubella	M-M-R-II (M)	Free	Never contained Thimerosal
Hepatitis B	Recombivax HB (M)	Free	08/27/99
	Engerix B (GSK)	Trace ($< 0.5 \mu\text{g Hg}/0.5\text{mL dose}$)	03/28/00
Haemophilus influenzae type b conjugate (Hib)	ActHIB (AP)/OmniHIB (GSK)	Free	Never contained Thimerosal
	PedvaxHIB (M)	Free	08/99
	HibTITER, single dose (WL) ¹	Free	Never contained Thimerosal
Hib/Hepatitis B combination	Comvax (M)	Free	Never contained Thimerosal
Influenza, inactivated	Fluzone (AP)	0.01% ($12.5 \mu\text{g}/0.25 \text{mL dose}$, $25 \mu\text{g}/0.5 \text{mL dose}$) ²	
	Fluzone (AP) ³ (no thimerosal)	Free	12/23/2004

	<i>Fluvirin (Chiron/Evans)</i>	<i>0.01% (25 µg/0.5 mL dose)</i>	
	<i>Fluvirin (Chiron/Evans) (Preservative Free)</i>	<i>Trace (<1µg Hg/0.5mL dose)</i>	<i>09/28/01</i>
<i>Influenza, live</i>	<i>FluMist⁴ (MedImmune)</i>	<i>Free</i>	<i>Never contained Thimerosal</i>

Manufacturer abbreviations:

GSK = GlaxoSmithKline; WL = Wyeth Lederle; AP = Aventis Pasteur; M = Merck.

** Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 mL dose or 25 µg of Hg per 0.5 mL dose.

*** The term "trace" has been taken in this context to mean 1 microgram of mercury per dose or less.

1 HibTITER was also manufactured in thimerosal-preservative containing multidose vials but these were no longer available after 2002.

2 Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.

3 A trace thimerosal containing formulation of Fluzone was approved on 9/14/02 and has been replaced with the formulation without thimerosal.

4 FluMist is not indicated for children less than 5 years of age.”

21. Summary Of “Safety Not Proven”

Until and unless Thimerosal and other mercury-containing compounds are conclusively demonstrated to be safe and effective at levels 100 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 other drugs 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 cited published studies 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, the petitioners find that the systematic, **uncalled for** exposure of generations of America’s children to neurotoxic levels of mercury-based “preservatives” and “antiseptics” (through Rho(D) injections, vaccines, and other drugs that contain Thimerosal and/or other mercury-based*

compounds) is an unparalleled and unnecessary iatrogenic tragedy, inflicted upon *susceptible* fetuses, newborns, and children of all ages.

With the preceding reality in mind, petitioners 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 have created.

C. 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, children and adults with 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 100X 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 not been, and cannot be, obtained from the patient or the patient's guardian [because their 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. § 1983³⁵⁴, 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.]

Thus, petitioners again beseech the Food and Drug Administration to immediately proceed as we have petitioned until and unless the U. S. 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**

³⁵⁴ 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.”

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.

D. 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*”³⁵⁵ although:

- ❖ 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.

³⁵⁵ 38 FR 32056.

- ❖ Recent studies^{356,357}, *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 to American children, which 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 150 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 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.

³⁵⁶ a. Bingham M, Copes R. Thimerosal in vaccines Balancing the risks of adverse effects with the risk of vaccine-preventable disease. *Drug Safety* 2005; **28**(2): 89-101.

b. Waly M, Olteanu H, Banerjee R, Choi S-W, Mason JB, Parker BS, Sukumar S, Shim S, Sharma A, Benzecry JM, Power-Charnitsky V-A, Deth RC, **IMMEDIATE COMMUNICATION**, Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal. *Molecular Psychiatry* 2004 January 27: 1-13.

³⁵⁷ a. Nataf R, et al. Porphyrinuria in childhood autistic disorder: implications for environmental toxicity. *Toxicol Appl Pharmacol* 2006; **214**: 99-108.

b. Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure *Neurotox Res* 2006; **10**: 57-64.

c. Geier DA, Geier MR. A case series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. *J Toxicol Environ Health A* 2007; **70**: 837-851.

Perhaps, the Secretary of HHS, the CDC, and the FDA have, 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 federal government'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 100X, 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 U.S. 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.

E. 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 adulterated³⁵⁸.

On this basis, we petition the DHHS and the FDA to comply with and/or enforce all applicable laws and statutes requiring directly, or indirectly, vaccines and other biological drug products to be proven safe to the standard “sufficiently nontoxic ...” as well as insist that the DHHS comply with the statute requiring the DHHS to reduce the adverse risks to vaccines by:

- *At a minimum, immediately recalling* all vaccines that contain any level of added-mercury where there is an alternative vaccine that is free of added mercury and
- *Ideally, requiring* all vaccines to be produced in a preservative-free formulation because preservatives are known to increase the risk of adverse reactions.

In addition, we petition the DHHS and the FDA to take actions to ensure that:

- The actual risks and incidence rates for all risks are measured and reported for all vaccines and other disease-preventive biological products,
- The true benefits and effectiveness of vaccines be reported along with the residual risks from strains outside of those covered by the vaccine,
- The per-dose level of mercury be required to be *prominently* displayed in terms of the micrograms of mercury per dose on the label of all vaccines and other drug products where any mercury compound is added in the manufacture of such drug products or any

³⁵⁸ 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; ...”

component used in the manufacture of all such and the package insert, and immediate packaging for all drugs that contain any level of added mercury, and

- Regulations be passed making it a criminal offense to administer any mercury-containing drug without fully informing the recipient or his or her guardian of all adverse risks and their incidence rates for any disease-preventive biological drug products.

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.

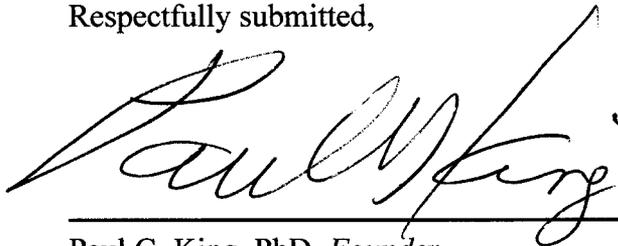
IV. ENVIRONMENTAL IMPACT

The petitioners hereby state that the relief requested in this petition will have no direct 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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