

# FACILITY AUTOMATION MANAGEMENT ENGINEERING (FAME) SYSTEMS

33 Hoffman Avenue Lake Hiawatha, NJ 07034-1922

Thursday, 30 September 2004

Documents Management Branch [HFA-305]  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Docket No. 04N-0214**

## FORMAL COMMENTS TO:

**A Citizen Petition Submitted by the National Vaccine Information Center (NVIC) in December of 2001 and Posted To The FDA's Public Docket As "02P-0025 Immediate suspension all vacciness containing Thimerosal \*"  
On 15 January 2002.**

## BACKGROUND

After:

- ❖ Finding this 2002 petition at the end of June of 2004,
- ❖ Checking with Docket's personnel in early July of 2004,
- ❖ Verifying with the current head of Dockets that the appropriate FDA division, the Center for Biologics Evaluation and Research (CBER), had been properly notified,
- ❖ Following up and finding, *as this commenter's searches had established*, that CBER personnel had failed to respond, *as required*, within 180 days of the filing date,
- ❖ Establishing that, *when this commenter notified CBER of the problem*, there was NO ongoing effort in CBER to address this petition, and,
- ❖ *In spite of assurances by a responsible CBER official that this apparently deliberate and knowing failure upon their part would be immediately addressed*, finding more than 81 days later that no response, *not even a notice that CBER's failure to respond had been noticed and a preliminary response would be available by a defined date (within some stated number of days of this FDA division's being made aware, on 7 July 2004, of their ongoing violation of a binding regulation governing their conduct)*, had been posted,

this commenter feels compelled to:

- a. Respond to NVIC's Citizen Petition (**2002P-0025**) and
- b. Address CBER's documented lack of response, *and apparent indifference*, to the clear issues raised in the NVIC's "Citizen Petition."

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After an initial reading and a rereading of NVIC's "Citizen Petition" and the FDA's posted acknowledgement letter, labeled "ACK 1 HFA 305 # 1," in the electronic Public Docket's database (the "e-Docket"), FAME Systems offers the following pages of comment to Public Docket: **2002P-0025**.

To clearly separate **FAME Systems'** review statements from the FDA's statements and the petition's text, **FAME Systems'** comments are in an **Arial** or **italicized Arial** font and the basis statements are in a **Times New Roman** or other font like that used by the FDA or the NVIC.

To further separate the remarks being reviewed from this commenter's remarks, this commenter has indented his commentary on both margins

When either a binding regulation or a statute is quoted, the text is in a **Lydian** font.

When other recognized sources are quoted, a **Perpetua** font is used.

Should anyone who reads these comments find that their substance is at odds with sound science or the applicable statutes and/or regulations, or that additional clarification is needed in a given area, then, in addition to providing the sound science or rationale that refutes the comment text provided, or his or her clarifying comments to the public docket, he or she is asked to e-mail [drking@dr-king.com](mailto:drking@dr-king.com) a copy of that sound science, rationale, and/or commentary.

Respectfully,

*Dr. King*

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## CBER's Apparent Knowing Failure To Respond To This "Citizen Petition"

To date, the FDA's handling of this Citizen Petition consists of an acknowledgement letter signed by Jennie C. Butler, on Department of Health and Human Services letterhead, that states:

"January 15, 2002

Kathryn M. Williams  
National Vaccine Information Center  
422-E Church Street  
Vienna, VA 22280

Dear Ms. Williams:

Your petition requesting the Food and Drug Administration to withdrawal from the market, Thimerosal-containing vaccines for which there is an existing Thimerosal-free formulation, was received by this office on 01/15/02. It was assigned docket number 02P-0025/ CP1 and it was filed on 01/15/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition."

Reviewing Title 21 of the United States Code of Regulations (**21 C.F.R.**), this commenter finds (**bolding** added to highlight critical issues):

"PART 5 DELEGATIONS OF AUTHORITY AND ORGANIZATION--Table of Contents, Subpart B General Redelegations of Authority, Sec. 5.20 **General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.**

- (f)(1) **The Senior Associate Commissioner for Policy, Planning, and Legislation (SACPPL) and the Associate Commissioner for Policy (ACP) are authorized to perform any of the functions of the Commissioner with respect to the issuance of Federal Register notices and proposed and final regulations of the Food and Drug Administration. These officials may not further redelegate this authority.**
- (2) **The SACPPL and the ACP are authorized to issue responses to the following matters under part 10 of this chapter as follows and these officials may not further redelegate this authority:**
- (i) Requests for waiver, suspension, or modification of procedural requirements under Sec. 10.19 of this chapter;
  - (ii) **Citizen petitions under Sec. 10.30 of this chapter;**
  - (iii) Petitions for reconsideration under Sec. 10.33 of this chapter;
  - (iv) Petitions for stay under Sec. 10.35 of this chapter; or
  - (v) Requests for advisory opinions under Sec. 10.85 of this chapter."

Since the "Citizen Petition" filed by the National Vaccine Information Center (NVIC) falls under **21 C.F.R. 5.20(f)(2)(ii)**, it would seem that the "SACPPL" and the "ACP" share the non-delegable responsibility to ensure that the "Commissioner" of the FDA responds to a "Citizen Petition" within the time periods allowed by law.

Returning to the regulations, this commenter notes that it seems that the "SACPPL" and/or the "ACP" must ensure that the "Commissioner" of the FDA issues a formal

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written response to a “Citizen Petition” within 180 days of that petition’s filing date, unless that petition addresses a matter covered under section **505(j)(2)(C)** of the act (in such cases, the “SACPPL” and/or the “ACP” is responsible for ensuring a written response is provided within 90 days).

This commenter’s position is derived from the controlling sections of the regulations set forth in **21 C.F.R. 10.30** (**bolding** added for emphasis):

“§ 10.30 Citizen petition.

(a) ...

(b) ...

(c) **A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number.** The docket number identifies the file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) **Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition.** The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. **The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Division of Dockets Management and may also be in the form of a notice published in the Federal Register.**

(4) **The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act.** The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.”

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Though: **a)** the law is crystal clear as to the requirements, and **b)** petitioners apparently complied with the submission requirements, *as of 30 September 2004*, more than 807 days (about 2 years, 2 months and 3 weeks) after the mandated response cutoff date and more than two and a half (2.5) months after this commenter brought this matter to the attention of both the FDA and the NVIC, the FDA has continued to knowingly violate the Agency's own legally binding rule.

Apparently, the Agency is acting outside of the law in this manner because, *as with several other of the Agency's ongoing knowing "compliance with the law" failures*, the Agency remains confident that: **a)** our Congress, their own Inspector General (IG) and Criminal Investigation Division (CID) groups, and the Justice Department will continue to ignore their unlawful conduct and **b)** the American people have no power over the FDA.

Furthermore, this commenter had to correct the FDA CBER official who contacted him because, *though this official admitted that CBER was the responsible FDA division and that the response had **not** been made in a timely fashion*, this official repeatedly said CBER had "never missed a (petition response) deadline."

Moreover, in spite of having had more than two and a half years to address this petition at the time of this commenter's contacting the FDA and promising a rapid response, the FDA has **not** yet (more than 81 days later) either: **a)** issued a decision or **b)** issued an apology for their failure and set a firm deadline by which the FDA will respond to the simple request made by the NVIC in their petition – a request that, under **42 U.S.C. 300aa-27** (bolding added for emphasis), "Sec. 300aa-27. **Mandate for safer childhood vaccines**

### (a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, **the Secretary** (of Health and Human Services and his delegates [the FDA in this case]) **shall**

- (1) **promote the development of childhood vaccines that result in fewer and less serious adverse reactions** than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
- (2) **make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.**

### (b) Task force

- (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
- (2) The Director of the National Institutes of Health shall serve as chairman of the task force.
- (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.

### (c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report

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describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.”

should have been simple to evaluate and grant in part, if **not** in full.

The petition should have been quickly granted because, in essence, **all that the NVIC petition requests is for the Agency to: a) revoke the FDA’s licensing of, and/or b) prohibit the distribution in the U.S., its territories and possessions of, any FDA-licensed vaccine that contains organomercury levels of 50 µg (micrograms) per mL (milliliter) (identified in the petition as a “Thimerosal-containing” vaccine) a when the FDA has licensed a “reduced-Thimerosal” version (< 2 µg of mercury per mL), euphemistically called a “Thimerosal-free formulation” by the Agency at that time, of that same vaccine and said vaccine is available in the marketplace.**

Given the clear language of **42 U.S.C. 300aa-27(a)(2)** and the U.S. Supreme Court’s 1988 finding (**Berkovitz, Plaintiff v. United States [486 US 531, 100 L Ed 2d 531, 108 S Ct 1954]**) that no FDA administrator can **legally** fail to comply with any clear legally binding law (as this law clearly is), **all that the petitioners are asking for is that the FDA, delegated with the responsibility to administer this portion of the law, comply with the law!**

Given the Agency’s ongoing actions and inactions, including **not** responding to this petition and, as a result, **not** complying with at least two (2) laws – one of which is a clear statutory mandate, it appears that the FDA is operating as if it is above the law – a seeming subversion of the regulatory process that, if true, is itself criminal in nature.

With the preceding in mind, this commenter will proceed to discuss the NVIC’s “Citizen Petition” in some detail.

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## Commentary On The “Citizen Petition” Filed By NVIC

### Introduction

The petition, titled, “PETITION FOR THE IMMEDIATE SUSPENSION AND EXPEDITED REVOCATION OF ALL VACCINES CONTAINING THIMEROSAL FOR WHICH THERE IS AN EXISTING THIMEROSAL-FREE FORMULATION” and assigned and posted to Public Docket “2002P-0025” on “1/15” and linked on “1/21” in 2002 with a short title of “**Immediate suspension all vacciness (sic) containing Thimerosal \***” is prefaced by a cover letter on “NATIONAL VACCINE INFORMATION CENTER” letterhead dated “December 18, 2001,” hand-labeled “*Rec'd 1. 15. 02,*” and addressed to “Bernard Schwetz, DVM, PhD, Acting Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.”

### Comments On The Cover Letter

In that cover letter, the petitioner, “Kathyrn M. Williams, Co-founder and Vice President,” states:

“Enclosed is a petition to the Department of Health and Human Services and the Food and Drug Administration asking you to use your authority to remove from the market, Thimerosal-containing vaccines for which there is an existing Thimerosal-free formulation.

Under the National Childhood Vaccine Injury Act of 1986, you have the authority to recall vaccines in order to reduce the risk of adverse reactions.”

The petitioner’s request, “... remove from the market, Thimerosal-containing vaccines for which there is an existing Thimerosal-free formulation,” is clear.

Though the petitioner cites the enabling act, “National Childhood Vaccine Injury Act of 1986” and not the statute, **42 U.S.C. § 300aa-27**, “Mandate for safer childhood vaccines,” the petitioner’s request clearly falls within the scope of **42 U.S.C. 300aa-27** which states (**bolding** added for emphasis):

“Sec. 300aa-27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall –

- (1) **promote the development of childhood vaccines that result in fewer and less serious adverse reactions** than those vaccines on the market on December 22, 1987, and **promote the refinement of such vaccines**, and
- (2) **make or assure improvements in**, and otherwise use the authorities of the Secretary with respect to, the licensing, **manufacturing**, processing, testing, labeling, warning, use instructions, **distribution**, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, **in order to reduce the risks of adverse reactions to vaccines**.

(b) Task force

- (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
- (2) The Director of the National Institutes of Health shall serve as chairman of the task force.

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- (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

SOURCE-

(July 1, 1944, ch. 373, title XXI, Sec. 2127, as added Pub. L. 99-660, title III, Sec. 311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100-203, title IV, Sec. 4302(b)(1), Dec. 22, 1987, 101 Stat. 1330-221; Pub. L. 101-239, title VI, Sec. 6601(q), Dec. 19, 1989, 103 Stat. 2292.)”

Based on the applicable statute, **42 U.S.C. § 300aa-27**, it is clear that the Secretary of Health and Human Services who heads the Department of Health and Human Services (DHHS) and the Secretary’s delegate, the Food and Drug Administration, does have the authority to recall Thimerosal-containing vaccines for which a safer licensed Thimerosal-free vaccine formulation exists (**42 U.S.C. § 300aa-27(a)(2)**) but, the statute’s wording in (**42 U.S.C. § 300aa-27(a)(2)**), “in order to reduce the risks of adverse reactions to vaccines,” clearly extends that authority to all vaccines since it does not preface the word “vaccines” with the word “childhood.”

This commenter wonders, given the fact that the licensed so-called “Thimerosal-free” vaccines are recognized by all to cause much less reactions and less severe reactions than their “Thimerosal-containing” counterparts, how the Agency could have ignored this legal mandate when the Agency elected to permit the ongoing use of the *Thimerosal-preserved* vaccines (*the term the FDA has elected to use for vaccines containing levels of typically 100 micrograms of Thimerosal per milliliter*) years after the Agency licensed their so-called “Thimerosal-free” counterparts that:

- a. Instead of having no Thimerosal, contain not more than ( $\leq$ ) 2 micrograms ( $\mu\text{g}$ ) of Thimerosal per milliliter (mL) of vaccine (at the time this petition was filed, this was the Agency’s *de facto* definition of the term “Thimerosal-free”) and
- b. The Agency and the industry now choose to use the even less informative term “Preservative-free” to describe vaccines that **today** contain not more than ( $\leq$ ) 4  $\mu\text{g}$  of Thimerosal [2  $\mu\text{g}$  of mercury] per mL.

Based on the law and the petitioner’s request, it would seem that the Agency should have honored the petitioner’s request and, at a minimum, formally proscribed the marketing all such “*Thimerosal-preserved*” vaccines in the United States, its territories, possessions, and commonwealths within a reasonable time frame (for example, 180 days of the date the petition was filed).

Instead, it seems clear that the FDA has knowingly elected to ignore the clear mandate of the statute cited.

In addition, the Agency has ignored and is today knowingly ignoring its own legally binding regulations (laws) governing a “Citizen Petition.”

The Agency has apparently done this to ensure the public continues to be exposed to vaccines that are **not** safer, contrary to the statutory mandate in **42 U.S.C. 300aa-27(a)(2)**.

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## Comments On The Petition

### *General Comments*

In general, the petitioners have filed a petition that: **a)** is presented in a format typical for legal documents and **b)** conforms to the requirements for filing a “Citizen Petition” as set forth in **21 C.F.R. § 10.30**.

The petition’s section headings are: “**PETITION**,” “**I. Petitioners**,” “**II. The Need for Action**,” “**A. Background**,” “**B. Professional Committees Recommend Use of Thimerosal-Free Vaccines**,” “**C. Thimerosal Removed from Over the Counter Products**,” “**D. Risks of Exposure in Pregnant Women**,” “**E. Influenza Vaccine**,” “**F. Europe Changes Protocol**,” “**G. Federal Advisory Committee Makes New Recommendation**,” “**H. Chairman of Government Reform Committee Asks for a Recall**,” “**NOTICE UNDER SECTION 2131**,” “**Conclusion**,” “**Certification Under 21 U.S.C. 10.30(b)(E)**,” and “**Environmental Impact Statement Under 21 U.S.C. 10.30(b)(C)**.”

The headings are, in general, clear, and appropriately label the topic presented under them except that the citation of “**21 U.S.C. ...**” in the last two headings should have been “**21 C.F.R. ...**,” and the allusion to “**... SECTION 2131**” in the heading, “**NOTICE UNDER SECTION 2131**,” that does not seem to identify any applicable section of **42 U.S.C.**, **42 C.F.R.**, or the “National Childhood Vaccine Injury Act of 1986” as far as this commenter could ascertain.

Since, in general, the petition conforms to the presentation guidelines provided and contains the required certifications, this petition was properly accepted and filed by the then Dockets Management Branch of the FDA on Tuesday, January 15, 2002 and should, *for the legal reasons cited previously by this commenter*, have been favorably acted upon by the Agency in whole on, or before, Monday, July 15, 2002.

However, as of Thursday, 30 September 2004, the FDA has knowingly failed to respond to this “Citizen Petition.”

Thereby, the Secretary of HHS and the Secretary’s delegates from 15 July 2002, *at the latest*, onwards, have effectively become not only responsible for but also, *as the responsible persons*, are, *as both government officials and individuals*, seemingly culpable for, the excess adverse reactions and damage inflicted upon the millions of children and the tens of millions of others who have been vaccinated by an FDA-licensed Thimerosal-preserved vaccine whenever there was, or is, an FDA-licensed “Thimerosal-free” or “Preservative-free” alternative vaccine that: **a)** could have been made available by the manufacturer but, for whatever reasons, was **not** available or **b)**, if available to the public, was **not** used to vaccinate all Americans who were vaccinated with said Thimerosal-preserved vaccines – including, *but not limited to*, those vaccinated for influenza with any Thimerosal-preserved vaccines from 15 July 2002 through the upcoming 2004 – 2005 “flu” season, and, *if the use of the “Thimerosal-preserved” influenza vaccines continues*, beyond..

Their personal culpability arises because, in defiance of the Congress and the statute enacted by Congress, they knowingly failed to discharge a clear binding statutory “shall” requirement imposed upon them by Congress. [Note: This is the case because no rationale person can deny that the single-dose “reduced-Thimerosal” vaccines that meet the minimum standards established under “**current good manufacturing practice**” (**CGMP**) as set forth in the applicable sections of Title 21 of the Code of Federal Regulations (C.F.R.) have lower “**risks of adverse reactions**” than their “Thimerosal-preserved” counterparts.]

### *Section-Specific Comments*

Under the “**PETITION**” heading, the petitioner states:

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“Petitioners request that the Secretary of the Department of Health and Human Services and the Commissioner of the Food and Drug Administration take action to order the immediate suspension and expedited revocation of all vaccines containing Thimerosal, now that Thimerosal-free vaccines are available.

The United States should immediately remove from the market any vaccine that contains the mercury based preservative, Thimerosal.”

Were the preceding to be what the petitioners were truly seeking, then the FDA should have denied the petitioner’s request since the reality is that the “Thimerosal-preserved” vaccines (containing, in general, more than 30 micrograms of Thimerosal per milliliter of vaccine and, with a few exceptions, 100 micrograms of Thimerosal per milliliter) that seem to be the vaccines the petitioner is requesting be removed from distribution have, in general, ONLY been replaced by vaccine formulations that contain a reduced level of Thimerosal (factually, not more than 4.0 micrograms of Thimerosal per milliliter and, typically, less than 0.5 micrograms of Thimerosal per dose.

Thus, these Thimerosal-reduced” vaccines, typically, labeled today as “Preservative-Free” are **not** truly free of Thimerosal.

However, from the text in the rest of the petition, it is clear that the petitioner is requesting that the “Thimerosal-preserved” vaccine have its license revoked and the doses in distribution be recalled on some defined schedule whenever the Agency has licensed a corresponding reduced-Thimerosal (“preservative-free”) vaccine and the licensed firm has begun to ship that vaccine.

Moreover, it is clear that the petitioner’s request is being made on the **indisputable basis** that the reduced-Thimerosal vaccines produce fewer and, in general, less-severe adverse reactions than their “Thimerosal-preserved” counterparts.

Under the “**I. Petitioners**” heading, the petitioner states:

“This petition is brought by Kathi Williams, co-founder and Vice-President of the National Vaccine Information Center (NVIC), on behalf of members of NVIC who support the withdrawal of mercury-containing vaccines from vaccine stocks. NVIC is a non-profit nationwide organization dedicated to preventing vaccine injuries and deaths through public education, improving the safety of vaccines. oversight of vaccine policies, and protecting the informed consent rights of citizens. NVIC, formerly known as Dissatisfied Parents Together (DPT) participated prominently in the development of the National Childhood Injury Act, 42 U.S.C. Sec. 300aa-10 et seq. (1988 & 1998 Supp), and has remained deeply involved in monitoring the implementation of the National Vaccine Injury Compensation Program created by the Act. NVIC has member parents whose children have received vaccines containing Thimerosal and have been diagnosed with mercury toxicity and brain damage.”

The petitioner clearly outlines the nature and background of NVIC.

Under the “**II. The Need for Action**” heading, the petitioner states:

“On October 1, 2001, the Institute of Medicine’s Immunization Safety Review Committee released a report entitled ***Thimerosal Containing Vaccines and Neurodevelopment Outcomes***. The report stated, ‘...**the committee recommends the use of Thimerosal-free DTaP, HIB, hepatitis B vaccines in the United States, despite the fact there might be supplies of Thimerosal-containing vaccine available. The committee could not explore mechanisms by which this could be accomplished.**’”

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Provided, with respect to vaccines, the report's term, "Thimerosal-free" is properly defined as "< 4 µg/mL" as the FDA had, de facto, done before the Institute of Medicine (IOM) began its deliberations and "Thimerosal-containing" is properly defined as being equivalent to "Thimerosal-preserved" (i.e., containing Thimerosal at a level high enough that can be considered as a preservative of the vaccine (> 30 µg/mL and, typically, 100 µg/mL), this commenter fully agrees with the IOM's recommendations here.

**"However, the committee is concerned that, because of meeting schedules and other requirements- for example the development of official statements on this issue by advisory groups such as the Red Book Committee of the AAP or the ACIP – might delay action. The removal of Thimerosal as a preservative from vaccines on the recommended childhood immunization schedule does not eliminate exposure to Thimerosal from other vaccines such as DT or influenza, that some infants, children and pregnant women receive. Therefore, the committee recommends full consideration be given by appropriate professional societies and government agencies to removing Thimerosal from vaccines administered to infants, or pregnant women in the United States.'<sup>1</sup>**

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<sup>1</sup> The Institute of Medicine October 1, 2001, Immunization Safety Review Thimerosal Containing Vaccines and Neurodevelopmental Outcomes"

This commenter fully supports the IOM report's recommendation here and, beyond that, *since the fundamental toxin is the 50% mercury contained in Thimerosal*, extends it to the cessation of the use of mercury or mercury compound in the manufacture of any drug, including, but not limited to, vaccines, other biologics, ophthalmics, otics, and other drug products.

"Currently every vaccine recommended for children is available without the preservative Thimerosal. Allowing Thimerosal-containing vaccines to remain in use, when Thimerosal-free versions are currently available, unnecessarily exposes American children to a heightened risk of serious adverse reactions. For these reasons, and as set forth below, Thimerosal-containing vaccines should be delicensed and removed from the market immediately."

Provided the petitioner's "Thimerosal-containing vaccines" is interpreted as "*Thimerosal-preserved vaccines*" and the petitioner's "without the preservative Thimerosal" is currently interpreted as "*vaccines containing less than 4 µg/mL of Thimerosal*," this commenter fully agrees that the petitioner's request should have been granted within 180 days of the posting of this petition to the Public Docket.

Under the "**A. Background**" heading, the petitioner states:

"Thimerosal has been used as a preservative since the 1930's. Thimerosal is effective in killing bacteria in opened multi-dose bottles. The Food and Drug Administration Modernization Act of 1997 called for an FDA review of all mercury containing food and drugs which included a review of vaccines that contain Thimerosal. This review was completed in 1999. The FDA recognized that could be exposed to a cumulative level of mercury over the first 6 months of life that exceeded the federal guidelines on methyl mercury. Thimerosal contains 49.6% mercury by weight and is metabolized to ethyl mercury and thiosalicylate. All guidelines for safe mercury intake are related to methyl-mercury, not ethyl-mercury. Methyl mercury is associated with neurotoxicity in high doses. The Center for Biologic Evaluation and Research (CBER) at the FDA had to assume the toxicity of the two compounds were equivalent. CBER realized that Thimerosal was present in over 30 licensed

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vaccines in the United States. According to CBER calculations a 6-month old baby that received all vaccines on schedule would receive 75 micrograms of mercury from three doses of DTaP, 75 micrograms of mercury from three doses of Hib and 37.5 micrograms from three doses of hepatitis B vaccine. The total of 187.5 micrograms exceeds the suggested safe limits published by the EPA.<sup>2</sup>

<sup>2</sup> Centers for Disease Control, Summer 1999, The Hepatitis Control Report "

This commenter concurs with the petitioner's "Background" statements.

In addition, this commenter notes that the absence of a proven safety level for both the known highly toxic compounds, Thimerosal (and, Thimerosal's metabolite, ethyl mercury) in drugs, including vaccines, clearly points to a glaring and knowing dereliction of duty upon the part of the manufacturers using Thimerosal in their products.

This is the case because these manufacturers have an **absolute** duty to prove that their products are safe.

In addition, this absence points to as an equally egregious abrogation by the FDA of its duty to only approve or license drugs administered to humans and animals that have been proven to be safe.

Without having an established/proven safety limit, how can any reasonable person be expected to accept that these knew, *as they are required to by law*, that the level of Thimerosal (or, for that matter, any other mercury compound) in their drugs, including vaccines, was safe?

Obviously, no reasonable person would.

Factually, as history has clearly shown the public, the level of Thimerosal allowed in "Thimerosal-preserved" drugs is **not** safe.

In addition, the level of Thimerosal in the "Preservative-free" drugs that still contain Thimerosal, while apparently safer, have themselves **not** been proven to be safe!

Moreover, to this commenter's knowledge, there is no recognized concerted effort upon the part of the industry or the American government to find those answers as quickly as possible.

Thus, *until the reduced levels can be proven to be safe*, the FDA should again direct the industry to remove Thimerosal (and any other mercury compound) from their products and drug production processes UNTIL and UNLESS the nature and level of said mercury compound can be proven to be safe at a level 100 times higher (the traditional safety factor for diverse populations) than the maximum level permitted in the drug products administered to the public using risk-relevant animal testing, including scientifically sound and appropriate chronic toxicological testing on developing primates [e.g., monkeys, apes, and orangutans]!

Under the "**B. Professional Committees Recommend Use of Thimerosal-Free Vaccines**" heading, the petitioner states:

"Due to any potential risk, the Public Health Service and the American Academy of Pediatrics and the vaccine companies that produce vaccines agreed that Thimerosal-containing vaccines should be removed as quickly as possible. A recommendation was made to forgo the infant dose of hepatitis vaccine at birth if the mother tested negative for hepatitis B disease, in an effort to provide a wider margin of safety. Pre-term babies were not to be vaccinated with hepatitis B until they reached term gestational age and the weight of at least 5.5 pounds.<sup>3</sup>

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<sup>3</sup> Center for Disease Control, July 9, 1999, Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service, Morbidity and Mortality Weekly Report."

The commenter again concurs with the petitioner's remarks and attests to their relevance at the time the petitioner filed this petition and today.

If, *as this commenter has been advised*, an at-birth dose of "some" vaccine is needed to "condition" the human immune system to vaccine components so that subsequent vaccinations **will not more than triple the risk of the vaccinated individual's developing Type II diabetes**, then:

- ❖ That fact should be revealed to the American public and
- ❖ An appropriate conditioning vaccine developed since, *based on follow-up studies*, the initial hepatitis B dose provide little, if any, persisting immunity to hepatitis B.

Under the "**C. Thimerosal Removed from Over the Counter Products**" heading, the petitioner states:

"Thimerosal is found in over-the counter products such as ophthalmic solutions and skin ointments. The FDA has already evaluated the safety and effectiveness of many of the over the counter (OTC) uses of mercury compounds as part of its OTC drug review. Many have been found to be not generally recognized as safe and effective.<sup>4</sup> For many years Thimerosal was used in latex paint to prevent mold from growing in the can. Thimerosal has been eliminated from latex paints, and Merthiolate, a concentrated form of Thimerosal used as an antiseptic, is no longer used because of serious toxic effects from these products in infants.<sup>5</sup> The American Academy of Pediatrics state: 'Mercury in all forms is toxic to the fetus and children, and efforts should be made to reduce exposure to the extent possible to pregnant women and children as well as to the general population.'<sup>6</sup>

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<sup>4</sup> Food and Drug Administration. December 14, 1998, Mercury Compounds in Drugs and Food, Request for Data and Information.

<sup>5</sup> Halsey, Neal A. November 10, 1999, Vol 282, No 18, **Journal of the American Medical Association.**

<sup>6</sup> Goldman, Lynn. July, 2001, Technical Report: Mercury in the Environment: Implications for Pediatricians, **Pediatrics.**"

The commenter again concurs with the petitioner's remarks and attests to their relevance at the time the petitioner filed this petition and today.

Under the "**D. Risks of Mercury Exposure in Pregnant Women**" heading, the petitioner states:

"In March 2001, the FDA issued a Consumer Advisory to pregnant women regarding eating fish that contain high levels of methyl mercury. The Advisory stated, 'While the primary danger from methyl mercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young mothers not to eat these fish as well.'<sup>7</sup> Unborn babies are more sensitive to the effects of mercury. Premature babies are also more vulnerable because the brain is not developed as in a full-term baby. Very young children are more sensitive to mercury than adults. Mercury in the mother's body passes to the fetus and can pass to the nursing infant through breastfeeding. If a pregnant woman ingests mercury at high levels, harmful effects that may be passed on from the mother to the developing fetus include brain damage, mental retardation, lack of coordination, blindness, seizures, and an inability to speak. Children poisoned by mercury may develop nervous and digestive system problems and kidney damage.<sup>8</sup>

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<sup>7</sup> Food and Drug Administration. March 2001, An Important Message for Pregnant Women and Women of Childbearing Age who May Become Pregnant, About the Risks of Mercury in Fish. Consumer Advisory.

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<sup>8</sup> The Centers for Disease Control – National Immunization Program. July 7, 2001. Mercury and Thimerosal FAQ <http://www.cdc.gov/nip/vacsafe/concerns.thimerosal/faqs-mercury>”

*As far as the petitioner’s statements go*, this commenter concurs with the petitioner’s remarks.

However, the human brain continues to rapidly develop after full-term birth — rapidly for about the first two (2) years and, in spurts, all through childhood and adolescence into early adulthood. [Note: Just like other developing human systems, growth is not a gradual linear phenomenon but occurs in spurts.]

Based on the reality that the human brain continues to develop, this commenter would not that the incidence rate for “pre-natal” autistics seems to be have remained at some constant level, while the rate for “post natal” developmental autism has reached epidemic levels.

“While the above information refers to mercury poisoning by ingestion or inhalation of methyl-mercury, the information causes concern for vaccines that contain Thimerosal which is 49.6% ethyl-mercury. All guidelines for safe mercury intake relate to methyl-mercury. No guideline exists for ethyl-mercury.”<sup>2</sup>

This commenter was under the impression that the above information principally refers to poisoning by ingestion since one would **not** expect the children in America to be exposed to a risk of inhaling vaporous methyl mercury or a powdered methyl mercury compound like methyl mercury chloride or powdered fish.

Perhaps the petitioner meant that the inhalation risk was from the elemental mercury present in the plumes from coal-fired power plants that has **not** yet been removed though the technology to cost-effectively do so has existed for more than a decade.

Moreover, the petitioner is **not** correct concerning the weight percentage of ethyl mercury (formula wt of 229.55 g/mole) in Thimerosal.

Thimerosal is about 57% by weight ethyl mercury; 49.6% by weight is the percentage of mercury (atomic wt. of 200.59 g/mole) in Thimerosal (formula wt of 404.82 g/mole).

Further, based on the work<sup>1</sup> of Leong *et al.*, where neurotoxicity was seen in developing neurons (neurites) at levels lower than 0.1 µg (where 2 µL of a 10<sup>-7</sup> M ionic mercury solution was diffused into 2-mL wells containing growing neurons -- an apparent 10<sup>+1</sup> to 10<sup>+3</sup> dilution depending upon the proximity of the developing neurites to the infusing mercury solution – and “neurite die back” was observed in 77% of the developing neurons [in contrast equimolar solutions of aluminum, cadmium, lead and manganese produced no similar “die back”]) and the observed level of mercury in supposedly “mercury-free” vaccines (<0.002 µg of **mercury per** 0.5-mL dose), this commenter is compelled to recommend a default level of “< 0.003 µg of **mercury per** dose” and, *if scientifically sound and appropriate safety studies in primates paralleling the dosing of humans support a higher level*, not more than “0.01 times the upper safety limit established in such studies” or “< 0.03 µg of **mercury per** dose,” *whichever is lower*, to ensure that an adequate safety margin is being provided for known “susceptible” individuals. [Note: The limit should be a

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<sup>1</sup> Christopher C. W. Leong, Naweed I. Syed and Fritz L. Lorscheider, “Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury,” **NeuroReport**, **12(4)** pages 733-737 (2001)

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**mercury** limit so that it covers any and all forms of mercury including all mercury compounds.]

This commenter thinks that preceding limit-setting rationale should be adopted because there is no absolute requirement that any form of the poison mercury be used in the manufacture of any drug.

Under the “**E. Influenza Vaccine**” heading, the petitioner states:

“The only vaccine licensed in the United States is made from killed influenza viruses. The vaccine contains 1:10,000 Thimerosal.<sup>9</sup> The Flu Vaccine is licensed for children 6 months and older. The current recommendation for influenza vaccine includes children in many categories, including those that have chronic disorders, including asthma, have required regular medical follow-up or hospitalization during the preceding year because of chronic disease, children on long-term aspirin therapy and women who will be in the second or third trimester of pregnancy during the influenza season.

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<sup>9</sup> Wyeth Laboratories. May 16, 1996, Product Insert, Flu Shield.”

This commenter only notes that the picture on the “flu” vaccine has changed significantly since December 2001 when the petitioner submitted this petition.

In addition to five inactivated “flu” vaccine formulations made by three manufacturers, the FDA has approved a weakened “flu” vaccine formulation.

Two of the inactivated “flu” vaccine formulations contain a reduced “trace” level of Thimerosal, the other three inactivated “flu” formulations have the standard 0.01% (50 µg of mercury per mL) level of Thimerosal, and the weakened “flu” is claimed to be “preservative free” and listed as containing “0” µg of mercury per dose.

Moreover, as of December 13, 2003, the CDC changed the vaccine schedule not only to recommend that all children 6-months-old and older and pregnant women be vaccinated but also that children under 9 initially be given two (2) doses a month apart (apparently in an attempt to ensure “efficacy,” if that term can be used for a vaccine that is often less than 50 % effective).

Under the “**F. Professional Committees Recommend Use of Thimerosal-Free Vaccines**” heading, the petitioner states:

“In June 1999, the Agency of the Evaluation of Medicinal Products (EMEA) completed an 18-month investigation into the risks of Thimerosal containing vaccines. EMEA concluded that even though there was no evidence of harm caused at the level of exposure (less than in the United States), it would be prudent to promote the general use of vaccines without Thimerosal.<sup>2</sup>”

This commenter concurs with the petitioner’s statements here.

Further, as of 24 March 2004,<sup>2</sup> the EMEA’s “current” position vis-à-vis mercury is stated as (**note:** in Europe, the trade name for Thimerosal is “thiomersal” and such trade names, though proper nouns, are not capitalized by the EMEA):

“▪ In line with the global goal of reducing exposure to mercury, the development of vaccines without thiomersal or with the lowest possible levels of thiomersal and other mercury containing preservatives should continue to be promoted.”

In addition, the EMEA’s position on labeling was:

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<sup>2</sup> **Document Reference:** EMEA/CPMP/VEG/1194/04/Adopted

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- The presence of thiomersal (and other preservatives) in the composition of vaccines will be stated on the label and a warning regarding the risk of sensitization in relation to thiomersal and other preservatives will be included in the Summary of Product Characteristics and Package Leaflet of such products.”

However, this commenter must note that the EMEA’s view:

- ❖ Is based on epidemiological data from a population that not only receives a much lower total dose of mercury from their “childhood” vaccines but also vaccinates their children later in their life when the neurodevelopmental disorder risk is lower **and**
- ❖ Does **not** yet factor in the recent *in vivo* work<sup>3</sup> of Hornig *et al.* or the 2001 *in vitro* studies by Leong *et al.* (**see commenter’s footnote 1**) as well as other studies completed after March of 2004.

Under the “**G. Federal Advisory Panel Makes New Recommendation**” heading, the petitioner states:

“Inspections of 225 clinics, pediatrician’s offices and family practice offices in mid-September 2001, showed approximately 5.5% of all doses of DTaP, Hib and hepatitis B vaccines still contain Thimerosal. The Advisory Commission on Immunization Practices (ACIP) will issue a recommendation in January 2002 to remove all Thimerosal-containing vaccines from the shelves by March 31, 2002.”<sup>10</sup>

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<sup>10</sup> American Academy of Pediatrics. November 2001, Vaccines with Thimerosal: Out of Offices by March 31, **Pediatric News**”

This commenter notes that, *while the petitioner appears to be repeating what was disseminated by the AAP in the November 2001 issue of their publication **Pediatric News***, the information being presented is materially incorrect.

Factually, the statement should have been revised to state, “Inspections of 225 clinics, pediatrician’s offices and family practice offices in mid-September 2001, showed approximately 5.5% of all doses of DTaP, Hib and hepatitis B vaccines still contain Thimerosal **at the preservative level (0.01% Thimerosal); the rest of the doses of those vaccines contained a reduced level that, though not “zero,” is not more than 1/50<sup>th</sup> the preservative level in the preserved DTaP, Hib and hepatitis B vaccines.**”

Similarly, to be factually correct, the AAP’s second statement should have been worded, “The Advisory Commission on Immunization Practices (ACIP) will issue a recommendation in January 2002 to remove all Thimerosal-**preserved** vaccines from the shelves by March 31, 2002.”

The misleading statements that were actually made appear, *to this informed commenter*, to be a conscious attempt on the part of the AAP to conceal the presence of lower levels of Thimerosal in approximately 95.5% “of all doses of DTaP, Hib and hepatitis B vaccines” in the clinics and offices inspected.

This commenter would strongly recommend that the Agency stop allowing anyone from continuing to misrepresent vaccines that contain as much as 4 µg of Thimerosal (2 µg of mercury) per mL, *as at least one influenza vaccine does, as*

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<sup>3</sup> Mady Hornig, David Chian, and W. Ian Lipkin, **IMMEDIATE COMMUNICATION**, “Neurotoxic effects of postnatal thimerosal are mouse strain dependent,” *Molecular Psychiatry*, pages 1-13, (Jun 8, 2004)

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“trace” Thimerosal, “Thimerosal-free,” or “preservative free” vaccines and, instead, adopt open labeling that, at a minimum, clearly:

- Discloses both: a) the maximum level of Thimerosal or other mercury compound, in nanograms per mL, permitted in each vaccine formulation and b) the actual level of mercury, in nanograms per mL in each particular batch of vaccine and
- Requires that mercury level to be on the primary container’s label.

This commenter recommends reporting the mercury level in nanograms of mercury because *in vitro* (see commenter’s footnote 1) studies have clearly established that indeterminate dilutions (that are somewhere between 10X and 1000X dilutions based on the diffusion of 2 microliter aliquots of a mercury compound solution at the 20-microgram of mercury-per-mL level ( $10^{-7}$  M) into wells containing cultured neurons growing in 2-mL of nutrient media), or somewhere between 2,000 nanograms per mL and 20 nanograms per mL with a most probable average level at or below 200 nanograms of mercury per mL, are lethal to 77 % of the neurites growing in those 2-mL cultured-neuron wells.

In addition, vaccines that are truly “Thimerosal” free have been found to contain mercury at levels of 1 ng to 3 ng per mL.

Given the FDA policy of setting a 100X safety factor and a 10-fold dilution of the mercury compound in the neuron, a prudent ***interim maximum level for mercury*** would be < 200 ng of mercury per mL (or g) of drug [0.2 microgram ( $\mu$ g) of mercury per mL of vaccine] UNTIL or UNLESS appropriate neurotoxicity studies in developing primates (at least 2 disparate species) prove that a higher level is projected to have a 100-fold safety margin in humans.

Under the “**H. Chairman of Government Reform Committee Asks for a Recall**” heading, the petitioner states:

“On July 18,2000, The Government Reform Committee of the House of Representatives held a hearing on the risks of mercury in medicine. Following that hearing, the chairman of the committee, Congressman Dan Burton wrote a letter to Dona Shalala, Secretary of Health and Human Services and said, ‘Our children are the future of this country. As a Government we have a responsibility to do everything within our power to protect them from harm, including ensuring that vaccines are safe and effective. Every day that mercury-containing vaccines remain on the market is another day HHS is putting 8,000 children at risk. Given that Thimerosal-free vaccines are available and the known risk of mercury toxicity, to leave Thimerosal-containing vaccines on the market is unconscionable.’<sup>11</sup>

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<sup>11</sup> Congressman Dan Burton’s Office. October 25, 2000,Chairman Burton Requests Vaccine Recall,”

Provided: a) the term, “mercury-containing,” is replaced with “mercury-preserved” to indicate the typical 50  $\mu$ g of mercury per mL in such vaccines, b) the term, “Thimerosal-free,” is replaced with “Thimerosal-reduced” to reveal the presence of low levels of mercury in the vaccines that the industry is allowed to euphemistically label as “preservative-free,” and the term “Thimerosal-containing” is replaced with “Thimerosal-preserved” to reveal the approximate level of Thimerosal that is equivalent to 50  $\mu$ g of mercury per mL, this commenter agrees with Congressman Burton’s observation but notes that the average 1  $\mu$ g of mercury per mL may only reduce, ***but not eliminate***, the exposure risk for those “8,000 children” of which Congressman Burton speaks.

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[**Note:** If we use the CDC's 2004 **Autism A.L.A.R.M.**<sup>4</sup> which reports, "1 in 166 children are diagnosed with an autism spectrum disorder" (or about 60 children in 10,000), presume a background level (based on the European [Scandinavian data] of 5 in 10,000 and a linear relation between mercury exposure and "autism" risk, the 55 in 10,000 **excess** "autism spectrum" cases in the United States could be reduced to about 1.1 in 10,000, IF AND ONLY IF no child under 5 years of age is given even one "Thimerosal-preserved" flu shot. If the government's recommended two-shot flu regimen is followed and half of those who are eligible are vaccinated at 6 and 7 months with a "Thimerosal-preserved vaccine," the number of **excess** "autism spectrum" (US-vaccine-practices-related) cases will probably be on the order of 10 children per 10,000.]

"Approximately one year later Congressman Burton renewed his request to HHS to recall all childhood vaccines containing Thimerosal stating that we could not leave these products on the shelves until they were used up. 'If there is even the slightest chance that a vaccine with mercury could contribute to autism spectrum disorders, learning disabilities, attention deficit disorders or any other neurological condition, then we should act quickly to stop all potential exposure to Thimerosal.'<sup>12</sup>

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<sup>12</sup> The committee on Government Reform. October 3, 2001, Press Release"

This commenter agrees with Congressman's position on mercury in vaccines that the petitioner elected to include here.

Since developing mouse studies using timing and amount scaled preservative-level Thimerosal solutions conducted by Hornig et al (**see commenter's footnote 3**) have clearly established that Thimerosal in vaccines does induce all of the autism-like symptoms of damage in one strain of immune-system deficient mouse (SJL/J) and immune system abnormalities are associated with human autism, the reality is that experimental science has given us strong evidence of harm. **Given that evidence** that clearly links the planned poisoning induced by mercury to all of the observed symptoms of full-spectrum autism, this commenter finds, *in the absence of any real proof of safety* in humans, **it is criminal to allow any level of Thimerosal, or by analogy, other mercury compound, above background (< 10 ng of mercury / mL or g) to remain in any drug administered to any human but especially in any drug, including vaccines, administered to developing children.**

Under the "NOTICE UNDER SECTION 2131" heading, the petitioner states:

"Petitioners hereby give notice of intent to commence suit under Section 21341 of the Public Health Service Act against the Secretary of HHS, the Commissioner of the FDA, and other government officials to compel the actions requested above if there is a failure or refusal within the next 60 days to take the proposed actions or otherwise to act more effectively to protect the health of America's children."

This commenter has been unable to find "Section 21341 of the Public Health Service Act" and as far as this commenter can ascertain, the petitioner's "SECTION 2131" refers to a section of the Public Health Service Act that is not applicable to vaccines unless they are radioactive.

Further, this commenter notes that, to date, the petitioner has, as far as this commenter could ascertain, not filed any lawsuit.

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<sup>4</sup> AUTISM A.L.A.R.M., issued by the HHS, CDC, American Academy of Pediatrics, and others in January of 2004 and available through <http://www.aap.org/healthtopics/autism.cfm>

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This is the case even though, *given the FDA's failure to respond for more than two years beyond the binding regulatory limit of 180 days*, it would seem that the petitioner has ample grounds to undertake a suit. [Note: Even after this commenter brought this matter to the Agency's attention in early-July of 2004 and having been contacted by an Agency official who promised an expedited review, the Agency has not yet (81+ days later) contacted either this commenter or the petitioner with even an estimate of a response date.]

Under the "**Conclusion**" heading, the petitioner states:

"The Secretary of the Department of Health and Human Services and the Commissioner of the Food and Drug Administration should take action to order immediate suspension and the expedited revocation of all vaccines containing Thimerosal, for which there is a Thimerosal-free replacement available."

Provided the petitioners phrasing of "... the immediate suspension and the expedited revocation of all vaccines containing Thimerosal, for which there is a Thimerosal-free replacement available" is changed to "... the immediate suspension **all shipments of** and the expedited ~~revocation~~ **recall** of all vaccines containing **a preservative level of** Thimerosal, for which there is ~~a~~ **an available reduced-Thimerosal-free** replacement ~~available~~," this commenter would support the actions that the petitioner seemed to be requesting.

Under the "**Certification Under 21 U.S.C. Sec. 10.30(b)(E)**" heading, the petitioner states:

"The undersigned certifies 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 the petitioners which are adverse to the petition."

This commenter first notes the citation "21 U.S.C. Sec. 10.30(b)(E)" is incorrect as "Certification" is a matter addressed in the Code of Federal Regulations (C.F.R.).

Consulting **21 C.F.R. 10.30**, this commenter finds that the appropriate reference would seem to be "21 **C.F.R.** Sec. 10.30(b)**E**."

Under the "**Environmental Impact Statement Under 21 U.S.C. Sec. 10.30(b)(C)**" heading, the petitioner states:

"The petitioners herby state that the relief requested in this petition will have no environmental impact and that, therefore, an environmental assessment is not required under 21 U.S.C. Sec. 25.24."

This commenter first notes the citation "21 U.S.C. Sec. 10.30(b)(C)" is incorrect because the "Environmental Impact Statement" is a matter addressed in the Code of Federal Regulations (C.F.R.).

Consulting 21 C.F.R. 10.30, this commenter finds that the appropriate reference would seem to be "21 **C.F.R.** Sec. 10.30(b)**C**."

Finally, neither the cited "21 U.S.C. Sec. 25.24" nor "21 C.F.R. Sec. 25.24" exist.

Based on this commenter's review of **21 C.F.R. §. 25**, the appropriate section to reference for general relief from having to file an environmental impact seems to be "21 **C.F.R.** Sec. 25.**30**."

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## Commenter's Concluding Remarks

Overall, this commenter finds that the petitioner and the applicable statutes and regulations combine to form a compelling argument that, **at a minimum**, all childhood vaccines containing a mercury-containing compound, including Thimerosal, at a level that corresponds to more than 2 micrograms of Thimerosal per mL should be recalled from commerce at the physician level in 2002, the FDA licenses for vaccines containing 100 µg/mL ("Thimerosal-preserved") should be immediately revoked, and the maximum level of mercury permitted in any vaccine should immediately be restricted to not more than 0.5 µg/dose for vaccines where the time between doses is years and not more than 0.1 µg/dose when the between-dose interval is less than 0.6 months, **unless** the manufacturer of that vaccine submits scientifically sound and appropriate toxicological proof that there is no evidence of harm in susceptible mouse or primate studies on test subjects studied from birth through full maturation using the a formulation of the vaccine that contains 100 times the level of mercury as the maximum level in the formulation that the manufacturer is seeking to license.

Moreover, if any vaccines that meet the petitioner's criteria remain in commerce, then, at a minimum, these "Thimerosal preserved" vaccines should immediately be recalled at the pharmacy level.

In addition, given the 2001 *in vitro* findings of Leong et al. (**see commenter's reference 1**) and the recent *in vivo* findings of Hornig et al. (**see commenter's reference 3**) as well as other recent experimental findings and the revelation that the epidemiological studies published under the auspices of the Centers for Disease Control and Prevention were knowingly biased to conceal significant relative risk indications between Thimerosal (mercury) exposure and neurodevelopmental delays, there is still no evidence that establishes a safe level of mercury, in any form, in a vaccine or other drug.

### *Commenter's Proposed Limits For Mercury In Drug Products*

Until and unless a manufacturer can, *in appropriate chronic and acute toxicology studies conducted on developing primates using some defined higher level of a mercury compound that has no adverse health effect at levels 100 times that found in those vaccines and other drug products that have measurable levels of said mercury compound*, prove such components in such drugs do **not** contribute to the neurodevelopmental disorders that currently afflict one child in six, this commenter can only recommend that the approval or licensing of the current drugs, including vaccines, that contain mercury levels of no more than 2 micrograms per mL or gram be maintained on an interim basis until either:

- ❑ Such drugs, including vaccines, can be replaced with formulations that contain less than 0.01 micrograms of mercury per mL or g (a level higher than that found in vaccines and other drugs which purport, or are represented to, use no *metallic mercury* or *mercury compounds* at any stage in their manufacture), or
- ❑ *With at least a 100-fold safety margin*, the drug's current mercury-containing formulation can be proven to be safe with respect to neurotoxicity in fetuses, babies, children, adolescents and adults in studies that mimic the drug's pattern of use (e.g., the worst-case vaccination schedules for vaccines, or, for other drugs, the maximum dosing at the minimum interval between doses for the longest time or, for drugs used to create chronic conditions, an appropriate intensified dosing for not less than 3 years).

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### Commenter's "Plain English" Labeling Recommendations For Mercury In Drug Products

In addition, like the recent law passed that mandates plain labeling for food allergens, the labeling regulations for drug products containing mercury should require the mercury content to be plainly disclosed on the primary container's label and in the package insert.

The word mercury should be placed on the drug product's label so that the public can readily identify the risk rather than being obscured by using a compound's trade name, Thimerosal, or concealed in phrases such as "preservative-free" as it is today.

If, *for no other reason*, this should be done to stop the public's growing perception that the government and the industry is knowingly, *as its actions seem to indicate*, minimizing or concealing the risk.

In general, so that the labeled level reflects the highly toxic nature of mercury and is easily linked to the population's numerical perception of risk level as some whole number, the units used to describe the level of mercury in a drug product should be "nanograms per dose (ng/dose)" with an actual batch value for formulations containing not less than 5 ng/dose – or, using the current reduced-mercury vaccines as examples and coding the manufacturers as "A" through "M" and the vaccines as "V-001" through "V-999," for example:

**Coded Table For Mercury Levels In Vaccines**

Manufacturer	Vaccine Code	Mercury level in ng/dose	Perceived Risk Level
A	V-051	<5ng/0.5mL	Low/No
B	V-015	<5ng/0.5mL	Low/No
C	V-060	10ng/0.5mL	Slight
C	V-024	165ng/0.5mL	Some
D	V-042	480ng/0.5mL	Moderate
E	V-043	1950ng/0.5mL	Significant

Hopefully, the commenter's remarks have clearly addressed not only the issues raised by the petitioner but also important issues associated with the petitioner's requests.

Further, this commenter supports the revocation of any manufacturer's prior and current vaccine license for a given use two (2) years after the licensing of a seeming materially safer formulation of that vaccine is granted to that manufacturer **unless** the public's experience with the replacement vaccine fails to prove the replacement formulation is materially safer than the prior formulation.

Finally, this commenter recommends:

- ❖ No new vaccine or other drug formulation containing Thimerosal or, *for that matter*, any other mercury compound should be approved until the safety of Thimerosal or that other mercury compound is established in that formulation at levels 100 times that of the maximum level permitted in the proposed drug's finished product doses.
- ❖ *Since the risks associated with mercury poisoning are related to the total burden of mercury being loaded into an individual and there are many sources*, the Agency should require all drug product manufacturers to report the maximum level of mercury in the drugs that they are currently marketing or developing, including those drug makers who manufacturer drug component materials because any component of a drug is, by statute, a drug (**21 U.S.C. 321(g)(1)**).