Thimerosal in vaccines: inconvenient reality

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Abstract

Thimerosal has <u>not</u> been removed from all vaccines licensed by the US Food and Drug Administration (FDA) and currently available in the USA. At present, 17 of these vaccine formulations contains some level of Thimerosal and 10 of these contain a preservative level of Thimerosal (33 to 100 micrograms of Thimerosal per milliliter (mL) of vaccine. Moreover, the FDA neither revoked the licenses for all of the previous Thimerosal-containing formulations nor rescinded there approvals so that vaccine makers are free to make and market these vaccines where, currently outside of the USA, and whenever they chose to do so. Finally, the CDC continues to refuse to state a preference for "no Thimerosal" vaccines where such are available.

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Keywords: Thimerosal, vaccines,

INTRODUCTION

Thimerosal has <u>not</u> been removed from all vaccines licensed by the US Food and Drug Administration (FDA).

Further, Thimerosal remains in some FDA-licensed vaccines approved for administration to children and to pregnant women.

Moreover, to replace the mercury doses lost from the reduction in/removal of Thimerosal from some formerly Thimerosal-preserved childhood vaccines, in 2002 the US Centers for Disease Control and Prevention (CDC) cravenly added Thimerosal-preserved influenza vaccines to the vaccination recommendations for pregnant women and children from 6 to 23 months of age.

Also, the CDC has increased its recommended age range until it is now: "6 months to 18 years of age".

Finally, the CDC currently recommends two closely spaced doses the first time the child is vaccinated.

Yet, most mainstream publications ignore these inconvenient realities.

In article after article, the writers, usually vaccine apologists, misrepresent the removal of Thimerosal from vaccines as occurring in 2001 or 2002 – or, in some cases, as late as 2004.

They do this even though Thimerosal is still in FDA-approved vaccines including some of those vaccines approved for children as well as flu shots recommended for pregnant women.

Given the preceding, why do 'they' lie about the on-going presence of Thimerosal in vaccines?

Perhaps 'they' lie because:

- The American public was promised in 1999 that Thimerosal would be removed from vaccines as soon as possible.
- These writers do <u>not</u> want to admit that 'they' know that those who made the promise had no intention of keeping it.
- The writers are too lazy to do their own research to find the vaccines that still contain Thimerosal, including those that are Thimerosal preserved.

Whatever the reason, vaccine apologists continue to misrepresent: **a**) the presence of Thimerosal in FDA-approved vaccines, **b**) the magnitude of mercury bolus doses that may be given to pregnant women, developing children, adults and the elderly, and **c**) the cumulative harm that these Thimerosal-containing vaccines inflict on many in each group.

REALITIES ABOUT FDA-APPROVED THIMEROSAL-CONTAINING VACCINES [As of August 2008]

The Current FDA-licensed Thimerosal-containing Vaccines

As of Sunday, 3 August 2008, after visiting: http://www.fda.gov/cber/vaccine/thimerosal.htm#t3, "**Table 3: Thimerosal and Expanded List of Vaccines** - (updated 3/14/2008) Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines" located on the Food and Drug Administration (FDA) webpage: http://www.fda.gov/cber/vaccine/thimerosal.htm, last updated June 3, 2008, and searching the Center for Biologics Evaluation and Research (CBER) web site (http://www.fda.gov/cber/), the author found that, including the "avian flu" vaccine, there are still at least seventeen (17) FDA-approved vaccines that: a) are apparently available in the USA and b) contain some level of Thimerosal (as shown in **Table 1**).

Key realities about FDA-licensed Thimerosal-containing vaccines

- **1.** Ten (10) of these seventeen (17) vaccines are Thimerosal-preserved vaccines.
- **2.** There is no federal prohibition against giving pregnant women and developing children a Thimerosal-preserved flu shot.
- 3. Though several states (California, Delaware, Illinois, Iowa, Missouri, New York, and Washington) have enacted restrictions prohibiting giving Thimerosal-preserved flu shots to young children and pregnant women, their laws do not provide any civil penalties for any violation of the law and, in some cases (e.g., New York), are not effective until 2009.
- 4. The state's health departments in those states with restrictions on giving Thimerosal-containing vaccines to pregnant women and young children are <u>not</u> required to purchase and dispense Sanofi Pasteur's "no Thimerosal" Fluzone for pregnant women and young children, or, *for older children*, Sanofi Pasteur's "no Thimerosal" Fluzone and/or Novartis Vaccines and Diagnostics' "Preservative free" Fluviron.
- 5. Illinois state health department officials have acted to thwart the law by, *among other things*, <u>not</u> informing the doctors when the Illinois statute became effective and by claiming an influenza vaccines' shortage when there was <u>none</u>.
- **6.** In spite of joining in the 1999 resolution calling for the removal of Thimerosal from vaccines as soon as possible, the FDA has continued to license new Thimerosal-preserved influenza vaccine formulations (human and avian).

Table 1. March 2008 FDA-licensed Thimerosal-containing Vaccines

[Taken From: **FDA's "Table 3:** Thimerosal and Expanded List of Vaccines - (*updated 3/14/2008*) Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines" & Recent approvals]

No./					
Thimerosal ⁶	Vaccine	Trade Name	Manufacturer	Thimerosal Conc. ¹	Mercury per dose
1	DTaP	Tripedia ²	Sanofi Pasteur, Inc	≤ 0.00012%	$\leq 0.3 \mu g/0.5 \text{ mL}$ (young children)
2	DTaPH (Tripedia + ActHIB ²)	TriHIBit	Sanofi Pasteur, Inc/SA	≤ 0.00012%	$\leq 0.3 \ \mu g/0.5 \ mL$ (young children)
3	DT	No Trade Name	Sanofi Pasteur, Inc	< 0.00012% (single ds)	< 0.3 µg/0.5 mL (older children & adults)
4/1	DT (available but not marketed ³)	No Trade Name	Sanofi Pasteur, Ltd ³	0.01%	25 μg/0.5 mL (older children & adults)
5/2	Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL (older children & adults)
6	Td	Decavac	Sanofi Pasteur, Inc	≤ 0.00012%	$\leq 0.3 \mu\text{g} / 0.5 \text{mL}$ (older children & adults)
7/3	TT	No Trade Name	Sanofi Pasteur, Inc	0.01%	25 μg/0.5 mL (older children & adults)
8	HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002%	< 1.0 μg/1.0 mL
9/4	Influenza	Afluria	CSL Limited	0.01% (multidose)	24.5 µg /0.5 mL (adults including pregnant women)
10/5	Influenza	Fluzone ⁴	Sanofi Pasteur, Inc	0.01%	25 μg/0.5 mL (3 yrs & up, including pregnant. women) 12.5 μg/0.25 mL (6- 35- months olds)-
11/6	Influenza	Fluvirin	Novartis Vaccines and Diagnostics Ltd	0.01%	25 µg/0.5 mL (4 yrs & up, including pregnant women)
12	Influenza	Fluvirin (Preservative Free)	Novartis Vaccines and Diagnostics Ltd	< 0.0004%	< 1 μg/0.5 mL (4 yrs & up, including pregnant women)
13	Influenza	Fluarix	GlaxoSmithKline Biologicals	< 0.0004%	< 1 μg/0.5 mL (adults including pregnant women)
14/7	Influenza	FluLaval	ID Biomedical Corporation of Quebec	0.01%	25 μg/0.5 mL (adults including pregnant women)
15/8	Japanese Encephalitis ⁵	JE-VAX	Research Foundation for Microbial Diseases of Osaka University (distributed by Sanofi- Pasteur, Inc in USA)	0.007%	35 μg/1.0mL (>3 years of age 17.5 μg/0.5 mL (1 to 3 yrs of age)
16/9	Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc	0.01% (multidose)	25 µg/0.5 mL ("2"yrs and up; though the other meningococcal vaccine, Sanofi's Menactra is now being recom- mended)
17/10	Avian Influenza ⁷	Influenza Virus Vaccine, H5N1	Sanofi Pasteur Inc.	0.0098% (multi-dose with doses at 0 & 2 months)	49 μg/1.0 mL (98 μg in 2-dose regimen; 18 to 64 yrs of age)

 $^{^1\}text{Thimerosal is approximately 50\% mercury (Hg) by weight. A 0.01\% solution (1 part per 10,000) of Thimerosal contains 50 \,\mu\text{g} of Hg per 1 \,ml dose or 25 \,\mu\text{g} of Hg per 0.5 \,ml dose. Vaccines with a nominal "preservative" level of mercury have$ **bolded** $mercury values.}$

²Sanofi Pasteur's Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.

³This vaccine is not marketed in the US but it is available.

⁴Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)

⁵Aventis Pasteur distributes JE-VAX. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 μg mercury/dose).

 $^{^6}$ The numbers are the count for the current Thimerosal-preserved vaccine formulations that have FDA approval.

⁷Approved April, 17 but <u>not</u> in "Table 3" as it is currently only licensed for use in a pandemic outbreak; approvals for children are pending or deferred.

Key realities about the chronic-disease harm Thimerosal may

Though the Establishment continually:

- Directs the discussion to "anything but Thimerosal/mercury",
- Frames the harm caused as if it were limited to neurodevelopmental disorders, and
- Limits the discussion to the role of Thimerosal in "autism", the reality is that Thimerosal has been found to be:
- A systemic "all systems" poison in humans at levels below 0.1 ppm (< 0.00001 %)
- A human teratogen, mutagen and carcinogen at levels below 1 ppm (< 0.0001%),
- A strong immune-system poison at levels below 0.01 ppm (0.000001%), and
- Implicated in diseases of the central nervous system, cardiac (e.g., IDCM) and vascular (e.g., arterial plaque, and inflammation, hardening and blockage of the arteries) systems, kidney, liver, pancreas, pituitary, and pineal gland.

In addition, Thimerosal:

- Appears to be a causal factor in the epidemic increases in many chronic childhood diseases/disorders, which were either rare or unknown, before the 1970s, in children, and
- Is obviously contributing, as these children age, to the epidemic increases in chronic diseases, including "dementias" in adults and the elderly.

In children, these severe chronic conditions include, *but are not limited to*, asthma, COPD, type 2 diabetes, inflammatory bowel disease, celiac disease, certain types of leukemia, severe refractory obesity, neurodevelopmental and behavioral disorders, and severe allergies to common food ingredients (e.g., peanuts, gluten, casein, gelatin).

In spite of all these findings, the government has continued to permit Thimerosal and other mercury-containing compounds to be used as process sterilants and preservatives in vaccines and other drugs.

Moreover, rather than keeping the 1999 promise to remove Thimerosal from vaccines as soon as possible, the government (Department of Health and Human Services [DHHS], CDC, FDA and National Institutes of Health [NIH]), the American Academy of Pediatrics (AAP), the American Medical Association (AMA), healthcare providers, and the vaccine manufacturers have acted together to continue the use of Thimerosal while continually telling the public that it was removed.

For vaccines, they colluded to do this by:

- Continuing to seek the licensing of existing and new Thimerosal-preserved vaccines in the US after 2000 (the vaccine makers).
- Continuing to license new Thimerosal-preserved vaccines (FDA), failing to revoke the licenses of Thimerosalpreserved vaccines after "reduced Thimerosal" vaccines were licensed (Secretary of DHHS), and failing to revoke the licenses of "reduced Thimerosal" vaccines after "no Thimerosal" formulations were licensed (Secretary of DHHS [under 42 U.S.C. § 300aa-27(a)(2)]),

- Failing to recommend the restriction of the Thimerosalcontaining vaccines and drugs to non-pregnant adults (CDC and FDA),
- Adding, in 2002, ineffective vaccines (e.g., the human influenza vaccines), which were Thimerosal-preserved and still, *in terms of doses*, are Thimerosal-preserved, to the recommended vaccination schedules for pregnant women and children from 6 months to now 18 years of age (CDC),
- Failing to establish that the level of Thimerosal in a Thimerosal-preserved vaccine was sufficiently nontoxic as required by 21 C.F.R. § 610.15(a) (vaccine makers, FDA and NIH), and
- Continuing to recommend (AAP, AAFP, and AMA) and to give Thimerosal-preserved vaccines when the "reduced Thimerosal" and/or "no Thimerosal" alternatives were available (all pediatricians and healthcare providers who did this failed to: a) observe the precautionary principle and b) refuse to give a less safe vaccine after a safer vaccine was licensed and available).

HANNAH POLING V. SEC. HHS – A CHANCE TO DIVERT ATTENTION FROM THIMEROSAL

Seizing on the opportunity provided by the Poling case, where mitochondrial disorder/dysfunction was implicated as a factor in Hannah Poling's autism, the Establishment took action to change the focus from:

- The vaccines, several of which were Thimerosal preserved, and
- The fact that the Poling case was a "Thimerosal causes autism" case

to:

• "Mitochondrial disease/dysfunction" – portrayed as "an unpredicted rare vaccine reaction".

Moreover, to make this diversion easier, the government has refused to release the medical records and filed expert reports that probably contain the evidence that Hannah Poling was mercury poisoned by the Thimerosal in the vaccines she received at 19 months as well as the evidence that Hannah's case was properly a "Thimerosal causes autism" test case in the Omnibus Autism Proceeding <u>before</u> the medical professionals of the DHHS stepped in and conceded the case.

Moreover, *like lemmings*, many on the "Environment of Harm" side of reality have apparently followed the government's lead and veered from the pursuit of the environmental casual factors toward the newest "genetic" diversion, mitochondrial mutation, fueled by the newly reported [1] finding that 1 in 200 have a mitochondrial mutation.

In contrast, since the evidence is that Hannah Poling does <u>not</u> have any known "mitochondrial disease" and, *based on the available evidence*, her "mitochondrial dysfunction" developed <u>after</u> she received multiple vaccinations at about 19-months of age and <u>not before</u>, we should be focusing on answering the following:

 Was the primary cause of her mitochondrial dysfunction/autism simply the number of vaccines?

- Was the primary cause the Thimerosal boluses in some of the vaccines?
 - Was/is Hannah Poling mercury poisoned (as indicated by a valid urine porphyrin profile analysis (UPPA) test or other means) after her 19-month vaccinations?
- Was the primary cause the live viruses that she received at that time?
 - Does Hannah's records have evidence of viral infection of the brain (in spinal fluid) and/or the gut?
- Was the primary cause the combination of Thimerosal and the live viruses Hannah received?

Why is it that the government continues to pursue their apparent "anything but mercury" agenda while refusing to require or produce proof that Thimerosal cannot cause the harm observed?

Based on the results seen for the vaccinated hamsters in the recent Peruvian studyⁱ, the answer is: Thimerosal (49.55-wt% mercury) in preserved vaccines is <u>not</u>, and has <u>never</u> been, safe to inject into developing or, for that matter, adult humans.

Why is it that, despite scheduling the appropriate toxicity studies of Thimerosal in vaccines in 1999, the NIH has never conducted the requisite studies?

Again, one need only look at the outcomes observed in the vaccinated hamsters [2] to understand the causal role of mercury in developmental disorders.

CONCLUDING REMARKS ON THIMEROSAL IN VACCINES AND OTHER DRUGS

In spite of the 1999 promise to remove Thimerosal from vaccines and the continual disinformation that Thimerosal has been removed/reduced, the following realities remain:

- The Thimerosal removal promise has not only <u>not</u> been kept but it has also been knowingly ignored by the vaccine makers and the FDA.
- Given the current vaccines and vaccination recommendations, the maximum dose of Thimerosal (49.55-wt% mercury) a child may be exposed to from before birth to 18 years of age can now exceed 1000 micrograms (> 496 micrograms of mercury) an upper limit (maximum dose) that exceeds the upper limit under the 1999 vaccine schedule by almost a factor of two.
- Since:
 - **a.** Impurities that are less than 0.1 % (10 times higher than the maximum allowable level of Thimerosal in drug formulations [0.01%]) are <u>not</u> generally required to be disclosed to the FDA, and
 - **b.** there is <u>no</u> requirement to disclose the level of mercury and its source in all drugs,
 - who knows what other drugs produced by biotechnology-based processes (e.g., monoclonal antibody drugs) contain significant levels (> 0.000001%; > 0.01ppm) of Thimerosal.
- Although the general permitted level of known toxins (e.g., cyanide) in drugs is usually set below 1 % of the "minimum level where general toxicity is observed", it is clear that the permitted maximum preservative level of Thimerosal (0.01% [100 ppm]), the only highly toxic bioaccumulative mercury compound in Thimerosal-preserved vaccines, ex-

ceeds Thimerosal's "minimum level where general toxicity is observed" by at least a factor of 10,000.

Though there may be other ingredients that, in the absence of any harm caused by Thimerosal, may be toxic to the extent that they need to be banned from any use in medicine, until the use of Thimerosal in the manufacture of any medicine is banned and all vaccines and other drugs that contain any level of added Thimerosal or other mercury-containing compound are recalled and destroyed, Thimerosal remains the one highly toxic bioaccumulative drug ingredient whose presence the Establishment continues hide from, or misrepresent to, the public, and whose human and animal toxicity continues not to be rigorously determined.

Moreover, though the verses are continually changing, the Establishment's refrain remains: "Anything but Mercury!"

Until all use of Thimerosal and any other mercury compound is banned from medicine and all doses containing any amount of added Thimerosal or other added mercury compound are recalled and destroyed, this researcher will continue to demand "no Thimerosal" and "safer" vaccines until:

- All US-licensed vaccine formulations are "no Thimerosal" formulations.
- The US licenses for all vaccine formulations that contain any level of Thimerosal are revoked by the US Secretary of HHS (under the statutory authority granted in 42 U.S.C. Sec. 300aa-27),
- All US-licensed formulations are <u>preservative-free single-dose preparations</u>, and
- In countries that are unable to provide single-dose vaccines to their public, when a preservative must be used in some vaccine formulation, some non-bioaccumulative poison (e.g., 2-phenoxyethanol) is used in place of Thimerosal.

In conclusion, this reviewer's simple answer to the question:

"Why do 'they' lie about the on-going presence of Thimerosal in some FDA-licensed vaccines?"

is:

"Because 'they' have something 'they' *desperately* want to hide – 'their' on-going participation in the knowing mercury-poisoning of our children!"

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