

**From:** Paul G King <paulgkingphd@gmail.net>

**To:** Boyd E. Haley, PhD

**Cc:** ....

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**RE: The CDC's perplexing reporting of the historical incidence of "autism"<sup>1</sup> and its actions to offset the removal of Thimerosal (49.6 % mercury by weight) from the early childhood vaccines that were Thimerosal-preserved prior to 2000 by recommending flu shots<sup>2</sup> for pregnant women and developing children from 2002 onwards without proscribing the giving them Thimerosal-preserved flu shots**

Dear Dr. Boyd E. Haley,

I agree that it is important to emphasize the fact that the intermittent reports<sup>3</sup> for 8-year olds published by the U.S. Centers for Disease Control and Prevention (CDC) still are for children born in the 1990s when all of the early childhood vaccines that were Thimerosal-preserved (DTaP, DT, Hep B and Hib) were only available as Thimerosal-preserved vaccine and most of the Rh-negative mothers received a Thimerosal-preserved, Ortho Clinical Diagnostics' RhoGAM<sup>®</sup> shot at 28 weeks gestation and, in some cases, at other times as well as just after the birth of their child/children.

However, any significant decrease in the children's mercury poisoning by Thimerosal-preserved early childhood vaccines has been masked by the CDC's knowingly beginning in April of 2002 (*MMWR* 2009 April 12; **51**(RR03): 1-31) to recommend flu shots for:

- a. Pregnant women [more than replacing the mercury exposures lost when, starting in 2001, without a recall of all released in-date Thimerosal-preserve serum doses, the manufacturer of RhoGAM received approval for its no-Thimerosal formulation and committed to only shipping no-Thimerosal RhoGAM into the USA] and
- b. Children 6 months to 23 months of age during the flu season each year [partially replacing the decline in mercury exposures from the phasing out of the Thimerosal-

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<sup>1</sup> Actually, the data that the CDC reports is for the incidence of "autism spectrum disorders", which, in the USA, principally includes those with a diagnosis of "autism" (i.e., autistic disorder), "pervasive developmental disorders – not otherwise defined (PDD-NOS)" or "Asperger's disorder".

<sup>2</sup> Since no US-population-scale study has ever shown that flu vaccination in a given flu season is effective in preventing those vaccinated from subsequently contracting influenza in that same flu season or affecting the number of persons who contract influenza, the CDC's reports knowingly overestimate cases, hospitalizations and deaths by counting "flu-related" illnesses as though they were influenza cases, and the only US-population-scale study (Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *Journal of American Physicians and Surgeons* 2006 Fall; **11**(3): 69-74) has shown that the influenza vaccination program is not effective, and the CDC's own reviews of the in-use outcomes of the annual flu programs find vaccination programs to be usually less than 50% effective, it seems obvious that, *notwithstanding the CDC's "public service" announcements and its flu-related propaganda*, the CDC is not recommending flu vaccination for children and pregnant women to protect them from contracting or spreading influenza.

<sup>3</sup> The CDC's survey reports for "autism" in eight-year-old children are not only intermittent (with the data for the 2000 and 2002 reviews being published in 2007 and the data for the 2006 review being published in 2009 with an abridged report of the 2004 review in an appendix) but also inconsistent in the states surveyed in a manner that appears to bias the results lower and, though doable, lacking any correction factor for undercounting.

preserved DTaP, Hep B and Hib by the phasing in of reduced-Thimerosal replacements for these vaccines].

The CDC issued these recommendations at a time when the then FDA-approved influenza vaccines were Thimerosal-preserved inactivated-influenza vaccine formulations and, *as is still the case today*, all of the influenza vaccine formulations were “Pregnancy Category C”<sup>4</sup> drugs for which there were “no proofs” of:

- a. Safety for the developing children carried by pregnant women who are inoculated or
- b. Reproductive safety for those pregnant women who are administered a given influenza vaccine.

Moreover, the CDC's subsequent actions:

- ◆ Recommending 2 doses the first time a child of up to 9 years is vaccinated in 2004 and, in the period 2004 -- 2008,
- ◆ Expanding the age range for annual flu shots to first 35 months (2004), then 59 months (2006), then 59 - 107 (2007) and finally to 18 years in 2008 - 2009)

coupled with:

- ◆ The refusal of the U.S. Food and drug Administration (FDA) to:
  - Comply with the clear proof-of-safety requirements imposed upon the FDA by 21 CFR Sec. 601.4(a) for new vaccine approvals and/or
  - Stop the manufacture of Thimerosal-preserved vaccines lacking proof of safety to the legal minimum of "sufficiently nontoxic ..." set forth in 21 CFR Sec. 610.15(a) under the vaccine safening mandates set forth in 42 U.S.C. 300a-27(a)(2) and/or the adulterated-drug authority set forth in 21 U.S.C. 351(a)(2)(B), and
- ◆ The on-going decision of the makers of inactivated flu vaccines “approved” for use in children to make the majority of doses of their vaccines in a Thimerosal-preserved formulation without complying with both 21 CFR Sec. 610.15(a) and 21 CFR Sec. 601.2(a) — clearly rendering those vaccine doses adulterated drugs under 21 U.S.C. 351(a)(2)(B).

have combined to actually increase the maximum total drug-sourced mercury (Hg) exposure that children may receive.

Thus, a child conceived in 2002 by any flu-vaccination-compliant mother could be nominally<sup>5</sup> exposed to 25 micrograms of Thimerosal-derived Hg at some time during the later part of pregnancy versus the 15 - 18 micrograms Hg from an about 0.6- to 0.7- mL RhoGAM shot at 28 weeks gestation (7 lunar months; or 3/4ths of the “normal” human gestation period), to which, prior to 2002, only the

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<sup>4</sup> Typically, with reference to teratogenicity and safety of use in pregnancy, today’s influenza vaccines are typically labeled according to 21 CFR 201.57(c)(9)(i)(A)(3) <b>, which states:

If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: “Pregnancy Category C. Animal reproduction studies have not been conducted with ( name of drug ). It is also not known whether ( name of drug ) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ( Name of drug ) should be given to a pregnant woman only if clearly needed.” The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child. [Emphasis supplied.]

<sup>5</sup> The maximum concentration of Hg from the nominally 0.01% of Thimerosal in a releasable Thimerosal-preserved vaccine lot is not about 50 micrograms of Hg but rather 62 micrograms or 31 micrograms of Hg per 0.5-mL dose (and 15.5 micrograms of Hg per 0.25-mL dose) — thus the nominal maximum exposures reported here should be multiplied by the factor 1.25 to obtain the permissible maximum Hg exposures that a cohort member may receive from an injection of a Thimerosal-preserved inactivated-influenza vaccine.

children of most Rh-negative pregnant women (about 10% of the American women who are pregnant in any given year) were previously at risk of being exposed.

When that child was born in late 2002 or early 2003 and given the recommended “annual”/“seasonal” flu shots, he or she would most likely have nominally been exposed to 25 micrograms of Hg — 12.5 micrograms each from: **a)** a 0.25-mL flu shot at 6 months of age and **b)** a second 0.25-mL dose near his or her first birthday in late 2003 or early 2004.

Thus, these children would have a total nominal exposure of about 50 micrograms of Hg from the flu shot alone before they were two years old.

Apparently realizing that the dose was not sufficient to mask the prior Hg poisoning, in 2004, the CDC officially began recommending giving:

- a.** Two doses of the flu shot (at 6 and 7 months) and
- b.** Two doses the first time a child under 9 (or 10) years of age was inoculated with an influenza vaccine,

and extended the upper age cutoff from 23 months to 35 months.

Thus, a 2002-cohort child could not only receive another nominal 12.5-microgram Hg exposure around age 2 (in late 2004 or early 2005) but also could receive another nominal 12.5-microgram Hg exposure in late 2005 or early 2006 before turning 3 years of age.

In addition, a 2004-cohort child, getting two, 0.25-mL flu-shot doses at ages of 6 and 7 months could have a nominal maximum exposure of up to 62.5-micrograms of Hg from the flu shots alone before age 2 — with small exposures from other vaccines or, in a few cases (e.g., pertussis-vaccine-component allergy), significant exposures from the still Thimerosal-preserved DT vaccine used when a child is pertussis-vaccine allergic.

In 2006, the CDC increased the age range for annual flu shots to 6 to 59 months ensuring the majority of the vaccination-recommendation-compliant children could get a nominal additional 75 micrograms of Hg exposure from the Thimerosal-preserved flu shots alone by the time they were 5 years of age or, for the 2002 cohort and the 2003 cohort, a nominal maximum exposure from Thimerosal-preserved flu shots of about 125 micrograms of mercury.

For the 2004 and subsequent cohorts, the nominal maximum Hg exposure by 5 years of age would, had nothing changed, have been about 137.5 micrograms of Hg from flu shots alone.

To ensure that the mercury exposure risk continued:

- ◆ In 2007, the CDC issued a complicated set of recommendations for children that effectively raised the maximum age for annual flu shots to 107+ months (9 years) for most children and
- ◆ In 2008, the CDC raised the maximum age for annual childhood flu shots to 215+ months (18 years).

The CDC made the preceding recommendations even though most doses of the flu vaccines approved for children were, and still are, Thimerosal-preserved, inactivated-influenza vaccine doses.

In 2009, with the age range now at 6 months to 18 years of age and most doses approved for children and pregnant women still Thimerosal-preserved inactivated-influenza vaccine doses, the CDC, with the help of the World Health Organization’s redefinition of the term “pandemic”:

- ◆ Ginned up a "swine flu" pandemic but also recommended that pregnant women be given a 0.5-mL dose of an inactivated-influenza "swine flu" vaccine where most doses were Thimerosal-preserved and,

- ◆ More importantly for the 2002 and 2003 cohorts, recommended that all children up to age 10 receive 2 doses of a "swine flu" vaccine.

Thus, in the "2009-2010" flu season, children under the age of 3 who receive Thimerosal-preserved doses of the seasonal and swine flu vaccines will not only be exposed to a nominal dose of 37.5 micrograms of Hg or, if this is their first time to get a flu shot, 50 micrograms of Hg if they receive all Thimerosal-preserved influenza vaccine doses but also, because the swine flu and seasonal vaccines can be given at the same time, bolus doses nominally of up to 25 micrograms of Hg separated by only a month.

For children over 3 but under 10 years of age, like those in the 2002 cohort, the nominal maximum exposure in the "2009 – 2010" flu season to Hg from Thimerosal-preserved vaccines has been increased by 50 micrograms.

Thus, for children in the 2002 and 2003 cohorts, who have been exposed to Thimerosal-preserved flu shots as the CDC has recommended, the nominal maximum Hg exposure by age 7, presuming the "swine flu" campaign is a one-time occurrence, will be 225 micrograms of Hg.

For children born in 2004 and 2005 cohorts (ages 5 and 4 respectively) and vaccinated against flu under similar assumptions, the 2004 cohort will have received a nominal maximum exposure to 187.5 micrograms of Hg by age 5 and the 2005 cohort will have received a nominal maximum exposure to 162.5 micrograms of Hg by age 4 — with both group projected to maximally receive nominally 237.5 micrograms of Hg exposure from Thimerosal-preserved flu shots by age 7.

Since the preceding exposures are comparable to or exceed the total exposures children typically received from Thimerosal-preserved vaccines under the pre-2000 CDC-recommended vaccination programs and the impact of giving two, Thimerosal-preserved flu shots in pregnancy in the 2009-2010 flu season (1 seasonal and 1 "swine flu") on the children carried by these mothers will have the effect of generating a new "unique" exposure pattern in the children born in late 2009 and 2010, the complexity of identifying and separating out all of the different exposure patterns and their effects, in general, and in the population segment susceptible to mercury poisoning, in specific, will make it even more difficult to sort out the factor effects in the absence of accurate records of both:

- ◆ The actual Hg exposures and
- ◆ The specific Hg exposures<sup>6</sup>

for each child on each inoculation date.

Moreover, the preceding variabilities will make it increasingly difficult to make valid comparisons between the vaccinated and the never vaccinated populations for the effect of mercury poisoning because the actual Hg exposures will vary because:

- ◆ The children who are vaccinated have been getting:
  - No flu shots,
  - Some flu shots or
  - All recommended flu shotsat varying times and for various periods, and
- ◆ These flu shots can be
  - Thimerosal-preserved,
  - Reduced-Thimerosal or

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<sup>6</sup> The specific exposure value is the total exposure level for the Hg injected into a child on a given date divided by the weight of the child in kilograms on that day.

- No-Thimerosal

in composition —

without, in some cases, any certain means to unequivocally identify the exact FDA-approved inactivated-influenza vaccine formulation actually administered at each time point.

Therefore, even if "the CDC stays on the same timeline track" in reporting the incidence rates for the cumulative "Autism Spectrum Disorder" (ASD) category, we will not know what the effect of making no-Thimerosal early childhood vaccines available by 2007 (with a transition from Thimerosal-preserved beginning in 2001 to reduced-Thimerosal early childhood vaccines [essentially complete by 2005] and then from trace-Thimerosal early childhood vaccines to no-Thimerosal early childhood vaccines [essentially beginning in 2004 and still ongoing]).

We will not know the effects of removing Thimerosal from the Thimerosal-preserved early childhood vaccine formulations because the additions of a variable number of Thimerosal boluses from Thimerosal-preserved inactivated-influenza vaccines starting in 2002 has obscured, is obscuring, and will, *unless stopped*, continue to obscure the effects of this protracted removal of Thimerosal from the distributed early childhood vaccines.

Moreover, the CDC's recommendations<sup>7</sup> permit the administration of Thimerosal-preserved flu shots to:

- ◆ Pregnant women, currently without regard to their stage in pregnancy and
- ◆ Developing children, starting at 6 months of age, and currently up to 18 years of age, in increasingly complex patterns with significant changes in maximum exposure levels in some years (e.g., in 2004: Recommending 2 doses the first time a child under "9" or "10" is vaccinated; and, in 2009: Recommending an additional 2 doses of "swine flu" for every child under 10 years of age).

Furthermore, there are no verified, accurate, comprehensive data records for:

- ◆ The exact total level of Hg exposure from Thimerosal and
- ◆ The specific mercury exposure (total exposure divided by the child's weight in kilograms),

for the shots administered each time a child is given a flu shot<sup>8</sup>.

Given the current realities, until:

- ◆ All vaccines that are administered to pregnant women and children are required to be no-Thimerosal vaccines,
- ◆ No other vaccines are added to the recommended vaccine schedule, and
- ◆ The children in that birth cohort reach the age of 5 years — obviously in some year after 2016 given today's realities (as roughly outlined above) —

none should expect a significant population-wide ASD-incidence decline.

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<sup>7</sup> Ironically, though the CDC refuses to even state a preference for no-Thimerosal flu shots for pregnant women, it proscribes the administration of the live-virus influenza vaccines that, like all of the inactivated-influenza vaccine formulations, are Pregnancy Category C drugs, but, unlike most doses of the inactivated-influenza flu shots, contain no Thimerosal.

<sup>8</sup> In addition, for an accurate assessment, concomitant records of all medications being administered, their dose and last and next dose times as well as records of the state of the child's health (as, at a minimum, measured by his or her temperature, respiration rate, heart rate, and blood pressure) would be required.

The changes that apparently begun to appear in the younger children (i.e., those who are 3 to 5 years of age) with a clear confirmed diagnosis are:

- ◆ A lessening in the severity of the symptoms used to diagnose an ASD in those who are diagnosed with an ASD and
- ◆ An apparent, but not necessarily permanent, shift from a diagnosis of “autistic disorder” toward a lesser diagnosis (e.g., “PDD-NOS”, pervasive developmental disorder – not otherwise specified).

Hopefully, after carefully considering these remarks, you will better understand:

- ◆ The complexity of the problem and
- ◆ Why your expectations for a significant decrease in children with an ASD diagnosis in the aggregate are problematic, to say the least.

Given these population complexities, we should focus our efforts on identifying those children who have:

- a. Just received a confirmed ASD diagnosis or have a well-document diagnosis and
- b. Body-burden-related (or other body-pervasive) evidence of present(or previous) sub-acute Hg toxicity and/or other heavy-metal toxicities

so that the appropriate direct or indirect Hg and/or other heavy-metal detoxification programs may be initiated and, where appropriate, those children flagged as being susceptible to Hg and/or other heavy-metal poisoning so that we can appropriately guard them from future exposures.

Respectfully,

Paul G. King, PhD

<http://www.dr-king.com>

CoMeD Science Advisor

PS: Given the preceding realities, clearly the CDC seems to be doing its best to ensure that the "Thimerosal"/vaccine-mercury effect problem is made as difficult as possible to solve (with the complicit help of the FDA and the vaccine manufacturers).

In addition, there are other sources of mercury exposure that developing children receive, including, in some cases, direct or indirect exposures to the Hg in some other drugs, Hg exposures from dental amalgam, as well as Hg exposures from air, water and food that further complicate this picture.

For example, some studies have found that having more than about 4 “Hg-silver” amalgams in pregnancy produces a definite increased risk for mercury toxicity in the developing child and an Australian study has reported increased risk in a small number of children fed a fish mixture during weaning.

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