



#### **FOCUS AUTISM**

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December 17, 2013

Kathleen Sebelius Secretary of the U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Margaret A. Hamburg, M.D. Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

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RE: The Necessity of Removing Mercury (thimerosal) as a Preservative from All Vaccines

Dear Secretary Sebelius, Commissioner Hamburg and Director Frieden:

To the best of our information, it is currently the position of the United States government particularly the CDC, HHS, and FDA that mercury in the form of thimerosal is a safe component in vaccines. Unfortunately, that is not a scientifically sound position as this letter will explain and as shown by the vast majority of peer reviewed science, CDC documents and emails<sup>1</sup>. This necessitates the removal of mercury in the form of thimerosal from all vaccines as soon as possible.

George Lucier, Ph.D., one of the co-signers of this letter, is former Associate Director of the National Toxicology Program responsible for coordinating toxicology research and testing across Federal agencies including CDC, EPA, FDA, NIH, OSHA, CPSC among others. Relevant to vaccines preserved with thimerosal, which contains mercury in the ethyl form, Dr. Lucier has stated in writing:

Organic mercury is a developmental neurotoxin. There is an immense scientific literature base to support this statement. Ethylmercury, used as a preservative in vaccines, is an organomercurial compound. Logic coupled with public health concerns provide an overwhelming justification that mercury should not be deliberately given to the developing fetus, infants and children as well as adults. It is incomprehensible to us that our public health agencies still permit organic mercury to be part of our vaccine program.

Our vaccine program is an important part of our disease prevention strategies. It would be much better and safer if mercury was removed from vaccines.

There are two additional irrefutable facts which support our position that mercury needs to be removed from vaccines, particularly the flu vaccine, immediately. These are:

<sup>&</sup>lt;sup>1</sup> CDC documents and emails were obtained via Freedom of Information Act (FOIA) Requests and also from members of Congress.

1. The admission shown by internal documents of the CDC, which have never heretofore been made public, that 16 micrograms of mercury when given to a pregnant woman may cause regressive autism in her child.

Regarding the prenatal flu shot, in 2010, the CDC published a study (Price et al. 2010 Pediatrics 126:656) that stated that children exposed to just 16 micrograms of mercury prenatally were 86% more likely to receive a diagnosis of regressive autism spectrum disorder.<sup>1</sup> Because this result did not meet the CDC's standard of "statistical significance" (off by a mere 2%), it was dismissed.<sup>2</sup> Contrary to biological and toxicological plausibility, the Price paper reported that mercury, a known developmental neurotoxin, decreased autism risks. The scientific reviewers noted this and said that something is wrong here. They are right and their careful review undermines the credibility of the Price paper and its conclusions.<sup>3</sup>

However, background data obtained by the Freedom of Information Act shows that when the statistics were evaluated in the most reliable fashion, the risk of having a child with regressive autism spectrum disorder was actually 773% greater in those children exposed to 16 micrograms mercury prenatally (before birth via mother's flu vaccination). This result is highly statistically significant. The CDC was informed of these risks in a report, dated December 1, 2009 (and in preliminary data presented as early as May 29, 2008), from Abt Associates, a private consulting firm hired by the CDC to perform assessments of autism risk based on prenatal and postnatal exposures to thimerosal.

2. An eleven-fold, (1100 %) increase in spontaneous abortions (miscarriages) and stillbirths in pregnant women reported to the CDC in 2009-2010. The following year the rate of spontaneous abortions and stillbirths reverted to essentially "normal" (baseline) levels. There is a reasonable explanation for this dramatic rise in spontaneous abortions and stillbirths in 2009-2010. That was the flu season when the seasonal flu vaccine and H1N1 vaccine, each containing 25 mcg of mercury, were strongly urged for all pregnant women in order to protect them and particularly their fetuses from the flu. <sup>6</sup>

Thus, those pregnant women receiving both vaccines were injected with 50 micrograms of mercury, while the CDC already knew internally that only 16 mcg of mercury would cause regressive autism. The

<sup>&</sup>lt;sup>1</sup> Read the actual published study (Price et al. 2010) which included only the "cherry picked data" aforementioned. Go to: http://www.ashotoftruth.org/sites/default/files/attachment 3 - price 2010 thimerosal pediatrics.pdf

<sup>&</sup>lt;sup>2</sup>In Price the CDC stated: "This study revealed no increased risk of ASD associated with receipt of thimerosal-containing vaccines. \*\*\* and prenatal exposure was not associated with a risk of ASD."

<sup>&</sup>lt;sup>3</sup> The Price study was rejected by two front-line journals, the New England Journal of Medicine [NEJM] and the Journal of the American Medical Association [JAMA] prior to being published in Pediatrics a year later. In one of the documents obtained by congressional request, a JAMA reviewer questioned the obvious of how a child receiving a known neurotoxin, mercury, from thimerosal, could actually decrease the risk of autism. The JAMA reviewer's comments: "I'm concerned about this manuscript. It does not make sense that receiving thimerosal would be associated with a significantly decreased risk of autism. The authors acknowledge this fact. Something is wrong." Once the Price et al manuscript received its second rejection by the NEJM, an email exchange between the Price et al study authors ensues. In his reply email to fellow co-authors William (Bill) Thompson states about the rejection, "Well that sucks. Yes I would say Pediatrics."

<sup>&</sup>lt;sup>4</sup> For further analysis of Price et al 2010 go to <a href="http://www.ashotoftruth.org/price-et-al-2010-pediatrics-126656-study-thimerosal-and-autism-analysis-cdc-documents-obtained-rep">http://www.ashotoftruth.org/price-et-al-2010-pediatrics-126656-study-thimerosal-and-autism-analysis-cdc-documents-obtained-rep</a>

<sup>&</sup>lt;sup>5</sup> View the complete Abt Associates data analysis that the CDC could have used in the 2010 Price et al. study, but notice which dataset they picked for the study---the one that showed the least likelihood of autism with prenatal exposure to thimerosal. <a href="http://www.ashotoftruth.org/sites/default/files/attachment\_l\_-">http://www.ashotoftruth.org/sites/default/files/attachment\_l\_-</a>
abt associates report results for prenatal thimerosal exposure related to regressive asd.pdf

<sup>&</sup>lt;sup>6</sup> "Thus, a synergistic fetal toxicity likely resulted from the administration of both the pandemic (A-H1N1) and seasonal influenza vaccines during the 2009/2010 season." Goldman GS 2012 Spontaneous abortions following maternal flu vax - Human & Experm Tox

following year only the one flu shot was given (seasonal) and there was dramatic drop in spontaneous abortions and stillbirths to more "normal" levels.

It should not be concluded that the return to "normal" rates of spontaneous abortions and stillbirths means that a single flu shot with 25 mcg is safe for a pregnant woman and her fetus. The table from the VAERS database shows the number of stillbirths (>20 weeks gestation) and spontaneous abortions (at or less than 20 weeks gestation) due to seasonal influenza vaccines. The rate of those losses during pregnancy steadily climbed from 2000 to 2012. For the flu season of 2009 and 2010 the losses were higher than the other flu seasons. This was probably due to the push during the 2009-2010 flu season for pregnant women to get the seasonal flu shot and the H1N1 flu shot. A greater uptake rate during those years is the most likely reason for the higher level in spontaneous abortions and stillbirths. Overall, the uptake of the flu shot in pregnant women has increased since 2000 and one can see a corresponding increase in spontaneous abortions and still births.

Given knowledge of internal recognition in 2008 within the CDC that 16 mcg of mercury in thimerosal as a preservative in flu vaccines could cause regressive autism, it is incompre-hensible that the CDC and HHS continued to push the seasonal flu vaccine and the new H1N1 Vaccine for pregnant women in the following flu season of 2009 and 2010.

Today, these agencies still continue to strongly recommend that pregnant women receive the seasonal flu vaccine. It is only reasonable to conclude that mercury in the flu vaccine may be causing both miscarriages and autism. The result of this may be the continuation of a disaster of epic proportions not only because of the dramatic increase of autism in the youth of our country but also an excessively high rate of miscarriages in the face of clear evidence that the probable cause is the continued use of thimerosal (mercury) as a preservative in the flu vaccines. There may also be a connection between our early and high vaccine rate of infants and the position of the USA as having an exceptionally high infant death rate compared to other developed countries.

In the year 2000, it was announced that mercury was going to be voluntarily taken out of all vaccines at the request of the CDC, Public Health Service and the American Academy of Pediatrics. It is hard to understand why the vaccine manufacturers are permitted to continue to use their stockpile of mercury laden vaccines rather than requiring an immediate halt of the administration of any mercury vaccines to pregnant women and children. This malfeasance was compounded by the continued use of mercury laden flu shots and recommendations that they be given to children as young as 6 months of age.

Apparent justification for this policy was attributed to the publication of Madsen et al in the journal, *Pediatrics* in 2003 which claimed that when mercury was taken out of vaccines in Denmark the rate of autism went up rather than down, when the latter would be expected on removal of exposure to a potent neurotoxin. When this paper was published, many and perhaps most scientists found the alleged claim that mercury was somehow protective of autism unbelievable. Now, through the Freedom of Information Act, we have obtained documents which demonstrate that after being rejected by *Lancet* and *The Journal of the American Medical Association (JAMA)* because the data in the paper, as submitted, did not justify the conclusions, the data was then altered in order to justify the conclusions. With this altered data the paper was published in *Pediatrics*.<sup>7</sup>

This study Madsen et al, *Pediatrics* 2003 and the studies that supported it have been further refuted by the CDC's own recent study (Gronborg et al. 2013 JAMA Pediatrics 2259) regarding autism and autism spectrum disorder in Denmark, which shows that the prevalence of autism spectrum disorder (ASD) in Denmark dramatically decreased after thimerosal-containing vaccines were phased out starting in 1992. Also, at the time of the Madsen 2003 publication the autism rate in Denmark was reported to be less than 5 per 10,000 whereas the autism rate in the USA, according the CDC, had risen from less than 5 per 10,000 in the 1980s to 167 per 10,000 in 2003. Comparing the USA autistic population to that from Denmark was not scientifically justified.

<sup>&</sup>lt;sup>7</sup> After 3 years of Congressional Hearings on vaccines the Subcommittee on Human Rights and Wellness Committee Government Reform United States House of Representatives, the May 2003 report concluded the following: "Thimerosal used as a preservative in vaccines in likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry." (emphasis added) <a href="https://www.putchildrenfirst.org/media/5.1.pdf">https://www.putchildrenfirst.org/media/5.1.pdf</a>

Madsen 2003 was widely publicized and has formed the improper basis for the conclusion that mercury in vaccines is safe and not the cause of autism. Madsen was highly significant because it was a part of the 2004 IOM conclusions which stated:

The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.

Today, U.S. pediatricians still use this 2004 IOM conclusions to convey to parents that there is no link between autism and the vaccines. These conclusions prevented not only the complete elimination of thimerosal in vaccines, but prevented tens of thousands of innocent children from being able to receive safe and appropriate medical treatment. <sup>8</sup>

The Madsen paper has been followed by a number of other poorly designed studies, including Price et al 2010 above, which have basically echoed the conclusion that mercury as thimerosal in vaccines is not causing autism.

The NIH chose to accept this incorrect conclusion, devoting none of the \$1.6 billion allocated to research to considering mercury as a possible cause of autism. Instead that \$1.6 billion in research funding was devoted principally to trying to find a genetic cause for autism without any success. Meanwhile the international scientific community and many American scientists, without any funding from the NIH over the next decade after Madsen was published, have poured out 150 peer reviewed studies indicating that thimerosal (mercury) is probably the major factor in the explosion of autism in this country and the world. It is hard to ignore the fact that the gender susceptibility indicates that boys are more susceptible to both autism and mercury toxicity than are girls based on the increased toxicity of thimerosal in the presence of testosterone and the protection by estrogen.

There are two recent studies which have been recently added to this list, one from China and the other from Iran. The paper from China<sup>9</sup> published in the *World Journal of Pediatrics* November 15, 2013 of this year, with the following statement summarizes the dangers of continuing to use mercury (thimerosal) as a preservative in vaccines:

Conclusions: The negative adverse consequences on neurodevelopment observed in the present study are consistent with previous studies; this study raised serious concerns about adverse neurodevelopmental disorder such as autism in humans following the ongoing worldwide routine administration of thimerosal containing vaccines to infants.

The Iranian paper <sup>10</sup> states:

"To the best of our knowledge, this is the first report to demonstrate a specific role of mercury, a widespread neurotoxic heavy metal, in L1 activity in NB cells. It has been **accepted that the effect of non-toxic concentrations of Hg [Mercury] can be tolerated by neurons**. Here [in this study] we show that even these ["non toxic"] concentrations may result in structural changes in DNA by increasing the activities of mobile DNA elements. Such activities could affect the expression of genes in neurons and **make [brain and nerve] cells susceptible to degeneration over time**." (bracketed words and emphasis added for clarity)

Whenever you increase the activity of DNA "mobile elements," in cells, it makes them susceptible to DNA damage (i.e., mis-incorporation or deletion of specific DNA regions resulting in harmful mutations). The cells will then undergo apoptosis (programmed cell death) in a mechanism to suppress tumor formation. Loss of a large quantity of neurons (nerve cells) however may trigger many maladies such as dementia, autism, accelerated aging, impaired immune, cardiovascular and neuro-endocrine systems. Thus, this paper is of concern in regard to anyone of any age

<sup>&</sup>lt;sup>8</sup> These are the 2004 IOM conclusions: <a href="http://www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx">http://www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx</a>

<sup>&</sup>lt;sup>9</sup> Chen YN et al Effect of thimerosal on the neurodevelopment of premature rats World J Pediatr, Vol 9 No 4. November 15, 2013.

<sup>&</sup>lt;sup>10</sup> L. Habibi, M.A. Shokrgozar, M. Tabrizi, M.H. Modarressi, S.M. Akrami, Mercury specifically induces LINE-1 activity in a human neuroblastoma cell line, *Mutation Research/Genetic Toxicology and Environmental Mutagenesis* (2013), http://dx.doi.org/10.1016/j.mrgentox.2013.07.015

receiving a mercury laden vaccine, even if there appears to be no negative impact now. Such exposures to mercury may result in very serious previously unforeseen consequences in the long term.

Similar studies and conclusions in the last few years have come out of many other countries including Brazil, Egypt, Japan and Poland, but these apparently have been ignored by HHS and CDC to the very serious detriment of our nation and particularly our children. Despite this

lassitude on the part of his administration, President Obama, in his State of the Union Address last year, vowed:

"I will not back down from protecting our kids from mercury poisoning."

And out of the Administrative Office of this President, Nancy Sutley in 2009, then Chair of the White House Council on Environmental Quality said:

Mercury poses a serious threat to public health in communities around the world. Today, the world's environmental leaders agreed that we must take immediate action to reduce mercury emissions. The United States will play a leading role in working with other nations to craft a global, legally binding agreement that will prevent the spread of mercury into the environment and improve the health of workers, pregnant women, and children throughout the world. <sup>11</sup>

Despite this statement, HHS and its agencies CDC and FDA continue to condone and even push mercury laden flu vaccines for pregnant women and children including six month-old babies.

Mercury-free vaccines should be easily available by now especially for all pediatric vaccines given the statement in 2003 that the FDA: "supports the goal of reducing exposure to mercury from all sources." To continue to use mercury as a preservative in vaccines will eventually be considered criminal and should have been so considered by 2008 given what CDC knew at that time.

It is inexplicable that mercury has not been removed from all vaccines, but particularly from the vaccines given to children under the age of six and all women who might possibly be pregnant. This action is imperative now that we know one mercury laden flu shot can cause autism or a miscarriage or stillbirth.

The evidence that thimerosal (mercury) preservatives in vaccinations are harmful to newborn infants and adults is overwhelming. In the year 2000, it was announced that mercury was going to be voluntarily taken out of all vaccines at the request of the CDC. We know that the CDC has had abundant and clear knowledge that mercury is harmful. Nevertheless, the United States government and the following departments -- Health and Human Services (HHS), Federal Drug Administration (FDA) and Center for Disease Control (CDC) -- have all maintained that mercury in the form of thimerosal preservative is a safe component in vaccines.

Similarly, lead, asbestos, and DDT were all thought to be safe and were very widely used. In each of these examples, scientific concerns were long discounted by industries that produced and used the substances, often supported by responsible government agencies.

An editorial in the New England Journal of Medicine (April 1987) warned:

Science is a hard taskmaster, and in the light of mounting evidence that suggestions of toxicity are for the most part ultimately confirmed by painstaking scientific inquiry, perhaps it is time to re-examine whether scientific standards of proof of causality - and waiting for the bodies to fall - ought not to give way to more preventive health policies that are satisfied by more realistic conventions and that lead to action sooner.

<sup>&</sup>lt;sup>11</sup> This was originally posted online but is no longer at: <a href="http://www.whitehouse.gov/administration/eop/ceq/">http://www.whitehouse.gov/administration/eop/ceq/</a> <a href="press\_releases/february\_20\_2009/">press\_releases/february\_20\_2009/</a> It still can be found many places including <a href="http://www.state.gov/e/oes/rls/fs/2009/119961.htm">http://www.state.gov/e/oes/rls/fs/2009/119961.htm</a>

<sup>&</sup>lt;sup>12</sup> FDA letter to Congr. Dave Weldon June 18, 2003 at http://www.putchildrenfirst.org/media/2.5.pdf

The National Research Council, a part of the National Academy of Sciences, restated the above principle in a much different way in its 1992 publication Environmental Neurotoxicology (National Academy Press, Washington DC) at page 3:

After many decades of evidence as to the potential toxicity, we have finally dealt with the issues of asbestos and lead. It took approximately a century after the first questions were raised about the use of mercury in teething powders before mercury was recognized as the cause of acrodynia (pinks disease).

The National Research Council went on to state at page 4:

"Anecdotal reports of neurotoxicity in humans need to be pursued vigorously with clinical surveillance and follow-up. The incorporation in surveillance systems of the concept of sentinel health events (SHEs) specifically for neurotoxic illnesses should be encouraged."

Isn't it time we apply the above quote to the use of mercury in vaccines and mercury/silver dental fillings? 13

It is time for this travesty of medical misinformation and public harm to be brought to an end. Other countries such as Denmark, Sweden and the United Kingdom have terminated the use of thimerosal in all of their vaccinations. The United States government should not ignore the wisdom of these other countries or the existing research data.

Secretary Sebelius, Commissioner Hamburg, and Dr. Frieden, it is under your watch and leadership that the autism epidemic is growing. We would ask with deep passion and concern that you thoroughly investigate the information that has been brought to your attention. It is through your strength and power that this very dangerous storm can be brought under control. To insure this happens you must remove mercury (thimerosal) from all vaccines.

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Leonge W. Luciar (signed per authorization by RER)

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<sup>&</sup>lt;sup>13</sup> IAOMT Position Paper Against Dental Mercury Amalgam April 18, 2013 http://iaomt.org/wp-content/uploads/ IAOMT-2013-Position-Statement.pdf

#### Copy with cover letter also via email:

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