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Friday, 22 November 2013

On 24 October 2013, Paul G. King, PhD, downloaded an October 23, 2013 on-line article, that was titled "**Expert Q&A: Childhood Vaccine Safety**" from an Internet web site link http://newyork.cbslocal.com/2013/10/23/expert-qa-childhood-vaccine-safety/.

This article was a "WebMD Health News" item by "Kathleen Doheny", that was reviewed by "Jennifer Shu, MD", where the answers to the "**Expert Q&A**" were apparently provided by "CDC's Frank DeStefano, MD, MPH, director of its immunization safety office", who, as reported by "Kathleen Doheny", is listed as the article's "**Source**". Dr. King's response to these answers follows these introductory remarks and a table-of-contents page.

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This analytical response is titled, **"A Formal Response to the Answers in 'Expert Q&A: Childhood Vaccine Safety'"**.

Introductory Remarks

First, each portion of article's text is quoted in a grayed "Times New Roman" font.

Second, Dr. King's comments follow in a "Verdana" font and are indented.

Third, when quoting from the item's text, the quoted portions of the text are in an *italicized* "*Times New Roman*" font.

Fourth, when quoting/referencing other sources, the text is in an "Arial Narrow" font.

Finally, should anyone find any significant factual error in this response for which they have independent[a], scientifically sound, peer-reviewed-published-substantiating documents, please submit that information to Dr. King so that he can improve his understanding of factual reality and, where appropriate, revise his views and this formal response.

Respectfully,

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[To whom all responses should be directed]

[a] To qualify as an independent document, the study should be published by researchers who have no direct or indirect conflicts of interest from their ties to either those commercial entities who profit from the sale of any product or practice addressed in this response or those entities, academic, commercial or governmental, who directly or indirectly, actively promote any product or practice, the development of any product or practice, and/or programs using any product or practice covered in this response.

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A Formal Response to the Answers in "Expert Q&A: Childhood Vaccine Safety"

"For parents, childhood vaccines are a source of reassurance — protecting your child against disease naturally helps you sleep better at night — but also anxiety about side effects and reactions.

With misinformation about vaccines and health problems, it can be difficult for a parent to sort it all out.

For help, WebMD turned to the CDC's Frank DeStefano, MD, MPH, director of its immunization safety office."

Introductory Remarks

If the goal of WebMD were to address the "*misinformation about vaccines and health problems*", this reviewer finds it odd that WebMD would turn to "*Frank DeStefano, MD, MPH*".

This is the case because it seems that Dr. DeStefano's primary job is doing whatever he can to support the safety of the products promoted by the U.S. Centers for Disease Control and Prevention (CDC) for vaccination in an "*office*" that has a claimed function, "*immunization safety*", which implies that vaccination provides "disease immunity".

Unfortunately, none of the current vaccines recommended in the CDC's vaccination program provide "disease immunity"[1], some seem to provide limited-duration "disease protection"[1] to only some of those

[1] In the context of this response, "**disease immunity**" is taken to mean that a person innately has or has acquired lifetime, or near lifetime, protection from contracting a given "disease" when that person is subsequently exposed to that disease. [**Note:** If immunity is desired, in general, for the viral diseases covered by a vaccine (e.g., measles, mumps, rubella, polio, rotavirus, chickenpox, hepatitis B and hepatitis A) which people normally only naturally contract once, the person should age-appropriately contract that viral disease (e.g., measles) at a time when his or her immune system has developed to the point it can resolve the viral infection but before puberty, when the severity of the symptoms for those contracting the disease for the first time significantly increases.] When the protection from the disease itself is, for whatever reasons, *significantly less than* lifetime, the proper term to use is "**disease protection**". [For example, contracting an influenza vaccine might provide "disease protection" from contracting another related influenza virus.] Whenever the protection from disease is short-term or related to some substance that that disease organism produces, the proper term is "**disease resistance**". [**Note:** For example, being inoculated with the diphtheria toxin found in a tetanus, diphtheria and pertussis vaccine may provide "disease resistance" may provide the inoculees with diphtheria resistance but it does not provide the inoculees with either "diphtheria protection" or "diphtheria immunity". The major reason that notified cases of diphtheria infections are rare is that the causative organism, *Corynebacterium diphtheriae*, is a facultative anaerobic, Gram-positive bacterium, which only thrives in low-oxygen environments, conditions which are virtually non-existent in healthy, well fed, clean developing children.] When vaccines are considered, the best that vaccines have been proven to do is to provide limited-duration "disease protection" to some percent of those who, for whatever reasons, have been multiply inoculated (usually with 2 or more doses) with them. For vaccines that are based on providing protection against some modified toxin (e.g., tetanus toxiod for tetanus, diphtheria toxiod for diphtheria, and the isolated pertussis toxins given to protect against *Bordetella pertussis* (*B. pertussis*) infection), produced by the disease organism, the best the vaccine can do is to cause some inoculees to develop effective "disease resistance" to the disease pathogen. [**Note:** The disease resistance from the acellular pertussis components harvested from *B. pertussis* is especially problematic (see: http://dr-king.com/docs/120806_PGKDrftRevu_Anti_vaccineMovementCausesTheWorstWhoopingCoughEpidemicIn70Yrs_fnlr2b.pdf for the problematic nature of giving a vaccine containing pertussis toxins to protect against "whooping cough").] The influenza vaccines are even more problematic because they provide little, and only short-term, protection from influenza-virus infection and, *as has been recently proven*, actually increase the inoculees' risk of contracting post-vaccination non-influenza viral respiratory infections.

who are age-appropriately vaccinated with them, and some others seem to provide only some level of "disease resistance"[1] to some fraction of those inoculated with them.

Had WebMD been interested in obtaining less-biased answers to the questions to which Dr. DeStefano responded, WebMD would have also asked these same questions to a recognized expert (e.g., Dr. Sherri Tenpenny), who has science-based concerns about the current CDC-recommended vaccination programs.

Then, *at a minimum*, it would have posted both sets of answers to the questions posed in this article without editing either response.

However, what the reader sees are the less-than-accurate, misleading and biased responses that present, at best, only the Establishment's views of "***Childhood Vaccination Safety***".

Thus, this article is *little more than* a slick vaccine/vaccination propaganda piece that disingenuously continues to sell vaccine inoculation as if it can/does provide "disease immunity".

In this response, Dr. King will generally limit his remarks to the answers provided and attribute them to the "***Expert***", "*Frank DeStefano, MD, MPH*", who will be referred to as "Dr. DeStefano" in this response.

"**Are there dangerous side effects or reactions to childhood vaccines?**

Fortunately, dangerous side effects or reactions to vaccines are few and rare.

Probably the main one is anaphylaxis, a severe allergic reaction. But like I said, it's rare. It occurs on the order of one per several hundred thousand to one per million vaccinations.

The other condition is encephalopathy, and that is even more rare, primarily reported with the [old form] of pertussis [vaccine]. But that hasn't been used in the United States for more than 10 years.

In terms of reactions that have the potential to kill you or result in lasting disability, they are very rare."

Yes, there are serious post-vaccination adverse reactions, which are also "*dangerous side effects*"

When answering a straightforward question that has been asked, Dr. King expects the answerer to begin by answering the question.

Yet, Dr. DeStefano did <u>not</u> start by answering the question asked.

To ensure that this question was clearly answered, Dr. King has used his answer as the title for this response.

Further, to put Dr. DeStefano's answer into perspective, Dr. King has based his response on at least one recent instance where the CDC

made a verifiable claim about the frequency of the most dangerous reaction, death, to a vaccine that was once recommended for population-wide use.

Following the start of a "first responders" smallpox vaccination program, it appears to Dr. King that the CDC's "1 in a million" estimate for death after smallpox vaccine inoculation was actually closer to 1 in 10,000 for the "about 29,000 first responders who had been vaccinated"[2].

Thus, the actual post-inoculation death rate observed in this 21st-century "first responders" vaccination program was roughly 100 times higher than the CDC's pre-program claim.

Applying this "100 times" correction factor to the risk estimates reported by the CDC's Dr. DeStefano, Dr. King thinks that the general occurrence rate for post-vaccination "*anaphylaxis*" is probably "*on the order of one per several*" thousand "*to one per*" ten thousand.

For "*encephalophy*", Dr. DeStefano's vague "*even more rare*" actually translates to a probable post-vaccination "*encephalophy*" of one case per

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[2] This recent example is from a first-responders live-virus smallpox vaccine inoculation program for civilians where the claimed risk of post-vaccination death was "1 in a million" and the observed risk in non-military first responders was closer to 1 in 10,000 when 3 died after about 29,000 were inoculated – at which point the remaining first responders, having heard about the deaths, refused to be inoculated and the civilian program was discontinued. [See http://www.the-injury-lawyer-directory.com/article_smallpox.html, last visited on 27 October 2013,

"The Smallpox Vaccination Program launched in January 2003, with the goal of vaccinating 450,000 first responders against smallpox by the end of February 2003, to protect them in case of bio-terrorism. By the end of March 2003, only about 29,000 first responders had been vaccinated, three people had died from the vaccine and dozens more had suffered adverse reactions.

Because the smallpox vaccinations are voluntary, most first responders are not eligible for worker's compensation claims to cover injuries caused by the vaccine.

On April 16, 2003, congress passed the Smallpox Emergency Compensation Act. Compensation was made available to those who received vaccinations during the period of January 24, 2003 through February 24, 2004 and included:

- Health care workers
- Law enforcement officers
- Firefighters
- Security personnel
- Emergency medical personnel
- Other public safety personnel who have volunteered for and received the smallpox vaccination as part of a state smallpox emergency response plan
- Any individual who is accidentally injured by a smallpox vaccination given to a First Responder

The Smallpox Emergency Compensation Act provided compensation for injury, illness, disability, condition or death caused by the vaccine. Compensation included:

- All reasonable and necessary medical care to treat the injury
- Death benefits of either a lump sum payment of $262,100 or, if there are children under the age of 18, up to $50,000 per year
- Permanent and total disability benefits equal to 66 2/3 percent of wages (75 percent in the case of dependents) up to $50,000 per year for life
- Partial disability benefits of up to $262,100, payable at the same rate as permanent disability benefits and capped annually at $50,000 per year

According to the CDC, "in a recent study of adult primary vaccinees, 36% were sufficiently ill to miss work, school, or recreational activities or to have trouble sleeping."
Known adverse reactions to the smallpox vaccine include:

- Local Reactions - Lesions, inflammation, swollen and tender lymph nodes, edema
- Systemic Reactions – fever, rashes
- Inadvertent Inoculation – transfer of the virus to other parts of the body or to other people, the most common adverse reaction to the vaccine, if transferred to the eyes it can damage vision
- Generalized Vaccinia - vesicles or pustules appearing on normal skin distant from the vaccination site
- Eczema Vaccinatum – spread of the disease itself due to inoculating a person with eczema, can be fatal
- Vaccinia Keratitis – lesions on the eyes, can cause permanent vision loss
- Progressive Vaccinia – necrosis in the area of vaccination, often fatal, most commonly occurs in people with compromised immune systems
- Post-Vaccinial Encephalitis – swelling of the brain and/or membrane surrounding the brain and spinal cord, 15-25% who have this reaction die, 25% with this reaction suffer permanent neurological damage
- Fetal Vaccinia – caused by inoculating pregnant women, can result in stillbirth and infant death
- Death – usually the result of postvaccinial encephalitis or progressive vaccinia

In spite of the dangers associated with the smallpox vaccine, the risks to first responders who are not vaccinated could be catastrophic in the event of a bio-terrorism attack. The campaign to vaccinate first responders continues, and the compensation program for those injured by the vaccine has been extended.

In May 2006, the Department of Health and Human Services issued a press release stating that, 'the date by which an individual in an HHS-approved smallpox emergency response plan may receive a smallpox vaccination and still be considered for benefits under the program has been extended to Jan. 23, 2007.'"]

ten thousand to one per hundred thousand vaccine inoculations.

Moreover, in his response, Dr. DeStefano failed to mention the third highest identified cause of death in infants under one year of age in the United States of America (USA), "sudden infant death syndrome" (SIDS), which is listed as such in a 2013 CDC report that addressed infant mortality[3].

SIDS should have been mentioned because it has been shown, and, *based on reports in VAERS*[4], appears, to be associated with the initial diphtheria, tetanus and pertussis (DTP) vaccination series.

In 2010, SIDS[5] was the listed cause of death for 2,063[3] infants according to the CDC or roughly about 1 in 2,500 infants presuming that there were about 5.2 million live births that year.

Clearly, the post-vaccination-associated adverse reaction labeled SIDS occurred more frequently than Dr. DeStefano's claimed "*one per several hundred thousand to one per million vaccinations*".

To assess the likelihood that there is an association between the infant-mortality reports of SIDS in 2010 and the deaths associated with the then-marketed vaccines containing diphtheria, tetanus and acellular pertussis (DTaP), Dr. King conducted a search of the Vaccine Adverse Events Reporting System (VAERS)[6] for reports of deaths in infants listed as one year of age and younger in the VAERS records for 2010[7].

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3 In early May of 2013, the U.S. CDC published http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf, Murphy SL, Xu J, Kochanek KD. Deaths: Final Data for 2010. *National Vital Statistics Report*, 2013 May 8; 61(4), page "19" (Note: "This document will be replaced by a reformatted, typeset report in the near future"), last visited on 22 September of 2013. This publication listed SIDS as the third leading cause for infant mortality in 2010 and reported that 2063 infant deaths were SIDS deaths (see "Table E").

4 VAERS is the acronym for the Vaccine Adverse-Event Reporting System database jointly maintained by the U.S. Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA).

5 Based on Malloy MH, MacDorman M. Changes in the Classification of Sudden Unexpected Infant Deaths: United States, 1992–2001. *Pediatrics* 2005 May; 115(5): 1247 -1253. (doi: 10.1542/peds.2004-2188)

> "Before 1970 the ICD chapter listing symptoms and ill-defined conditions, which eventually was to house the diagnosis of SIDS, represented ~5% of all postneonatal mortality, whereas the ICD chapter containing diagnoses associated with external causes of injury contained ~10% of all postneonatal mortality (Fig 1). That began to change in 1970 as the ICD chapter on symptoms and ill-defined conditions grew to represent 15% of all postneonatal mortality. From that point on, the symptoms chapter continued to grow in size, peaking in 1990 and representing 41% of all postneonatal mortality, whereas the external-causes chapter dropped to 6% of all postneonatal mortality. When examined as a proportion of total sudden unexpected infant deaths (symptoms plus external-causes chapters), the symptoms chapter accounted for 31% to 36% of all sudden unexpected infant deaths in 1950–1965. This proportion then increased to a high of 87% in 1985 and 1990 and subsequently declined to 71% in 2001."

These findings indicate that, since after 1990, intentional diagnostic substitution appears to have been a factor in reducing the number of SIDS death reports because SIDS has been proven to be associated with post-vaccination adverse reactions but the other substituted diagnoses (e.g., suffocation in bed, suffocation-other, unknown, and unspecified) have not. In this paper, when all of these other applicable substituted causes were added to the SIDS deaths, the overall rate of Sudden Unidentified Infant Death remained constant – indicating that SIDS was linked to the vaccination program because the uptake of the implicated early childhood vaccines tracks with the changes in SIDS death rates over time.

6 The VAERS database is jointly maintained by the CDC and the U.S. Food and Drug Administration (FDA)

7 An October 2013 search in VAERS, using the MedAlert search engine (http://www.medalerts.org/vaersdb/index.php), for all infant deaths in those 1 year of age or less found 55 reports of death meeting the search criteria. Sixteen (16) of these deaths were reported as "SIDS" deaths. Based on these data, only (16/2063) times 100% or about 0.78% of the SIDS reports in 2010 were reported in VAERS. In addition, 81.25% (13 of 16) of the VAERS death reports listing SIDS were reports where the DTaP vaccine or DTaP components plus the *Haemophylis influenza* type b [Hib], or hepatitis B [Hep B], and/or inactivated poliovirus vaccine [IPV], as well as a pneumococcal vaccine, and/or a rotavirus vaccine were given; the remaining 18.75% (3 of 16) were deaths associated with near-birth Hep B inoculation. Presuming that the 0.78% reporting level for SIDS reports in VAERS represents roughly a 1%

That VAERS search generated 55 death reports for children one year of age or younger.

Of these reports in VAERS for vaccination in 2010, 16 were verified post-inoculation SIDS deaths, occurring shortly after vaccination.

That group of 16 VAERS-reported deaths included a "DTaP" vaccine or another "DTaP"-containing combination vaccine, along with one or more other vaccines, in 13 instances, while the remaining three (3) instances were reports for deaths occurring shortly after the administration of a near-birth dose of a hepatitis B vaccine.

Because:

- The overall vaccination-associated infant SIDS death reports found in VAERS (16) is about 0.8% of the infant-mortality deaths identified by the CDC as SIDS deaths (2063[3]) and
- The vaccination-associated SIDS deaths that were reported to VAERS were *about* 1% of their actual level[5] as reported by the CDC[3], as a 1993 study[8] led by David A. Kessler, MD, (a former Commissioner of the U.S. Food and Drug Administration [FDA]) indicated they should be for an event like death,

the infant deaths found in the VAERS search were a very small percentage of the SIDS-associated infant deaths reported in 2010, which is consistent with the findings reported in the cited Kessler-led 1993 study[8] of under-reporting of serious adverse events.

Furthermore, because the trend in the USA is to continue to:

a. Increase the number of recommended vaccines and vaccine doses given to young children and

b. Through the use of increasingly complex combination vaccines[9], administer more of the vaccine actives in the same inoculation session,

Dr. DeStefano was remiss in <u>not</u>, at least, mentioning, if <u>not</u> addressing, these factors in his answer here.

Finally, since the risks of serious injury and/or permanent disability are significantly higher than the risks of death, Dr. DeStefano's,

"*In terms of reactions that have the potential to kill you or result in lasting*

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reporting level, then, in 2010, there were about 1300 death reports for infants up to 1 year of age that were TDaP-plus-related-vaccines-vaccination-session deaths occurring between 2 months and 11 months of age, and about 300 death reports for babies in this age range that were associated with the near-birth ("0" to 0.1 month) dose of the hepatitis B vaccine".

8 Kessler, DA, the Working Group, Natanblut S, Kennedy D, Lazar E, Rheinstein P, et al. Introducing MEDWatch: a new approach to reporting medication and device adverse effects and product problems. *JAMA* 1993; 269(21): 2765.

9 Up to five-component (pentavalent) combination vaccines are approved in the USA and six-component (hexavalent) combination vaccines have been approved for use in some countries in Western Europe.

disability, they are very rare",

is factually misleading.

Were the intent to provide an accurate answer, Dr. DeStefano's answer here would have been something like,

"*In terms of post-vaccination reactions that result in lasting disability, the rates for such serious adverse reactions are several times higher than the vaccination-associated reactions that have the potential to kill you*", or simply,

"*Adverse reactions that result in lasting disability occur more often than those reactions that have the potential to kill you*".

Based on Dr. King's research into the listed mortality and disability reports for young children in VAERS, the preceding edited responses appear to be close to the post-vaccination-related realities concerning the serious post-vaccination adverse events associated with the current childhood vaccination programs.

Finally, independent studies have clearly established that:

1. Added early childhood "vaccine doses" are significant factors in infant "mortality rates" in those developed countries that were studied[10], and
2. More "vaccine doses" at once[11] are important factors in "hospitalizations and mortality among infants" who were *less than* one year of age based on the reports found in the VAERS' USA records.

"**We hear about adverse events; is that the same as a dangerous reaction?**

An adverse event following immunization can be any adverse health condition that occurs after the vaccination. It doesn't necessarily have to be caused by the vaccine."

Post-vaccination-associated serious "*adverse events*" are "*the same as a dangerous reaction*" to a vaccine

First, "*a dangerous reaction*" is the same thing as a serious post-vaccination serious adverse event.

Moreover, Dr. DeStefano's use of the word "*immunization*" is doubly inappropriate here.

This is the case because any effective antibody-titer-related *disease protection* or *disease resistance* provided by a vaccination takes

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10 Miller NZ, Goldman GS. Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity? *Hum Exp Toxicol* 2011; 30: 1420-1428.

11 Goldman GS, Miller NZ. Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990–2010 . *Hum Exp Toxicol* 2012; 31: 1012-1021.

weeks to form.

Therefore, "disease preventive" childhood vaccination does not:

a. Immediately provide any significant *disease protection/resistance* to those who are vaccinated; or

b. Provide *disease immunity* (lifetime protection) from subsequently contracting the disease(s) purportedly covered by the administered vaccine(s).

These facts are obvious because the early childhood vaccines must be administered repeatedly followed by one or more "booster" doses later in childhood and, increasingly, also into adulthood to get, and keep, their "disease preventive" status, as the CDC's recommended vaccination schedules clearly show.

Moreover, as the vaccine makers' package inserts clearly indicate, their vaccines did not even provide sufficient "antibody" protection to all of those healthy children studied in the vaccines' phase 3 clinical trials, who were age-appropriately multiply vaccinated, from being at risk for contracting the covered disease(s) if they are subsequently exposed to the causative organism(s).

The preceding realities are especially important for those serious adverse reactions that occur just after, or within a few hours or days of, the affected child's vaccination session's end.

Had Dr. DeStefano wanted to respond more candidly, his response to this question could have been,

> "*An adverse event following ~~immunization can be~~ inoculation is any adverse health condition or inoculee reaction that occurs after the vaccination*".

Moreover, his "*It doesn't necessarily have to be caused by the vaccine*" should have been stated as,

> "*Such adverse reactions should be classified as vaccination-related adverse events unless there is unequivocal evidence that there was no causal linkage between the inoculation and the subsequently observed adverse health condition or inoculee reaction*".

Finally, had Dr. DeStefano meant to furnish an accurate response, his response should have concluded with something like,

> "*In general, 'disease preventive' vaccines are only deemed to be safe to be given to healthy individuals when they are approved. Thus, a post-vaccination serious adverse reaction (hospitalization, disability or permanent disability) or death 'immediately following' vaccination, which is not proven to have been connected to some unrelated cause (e.g., intentional or accidental physical injury), should be regarded as an immediate dangerous reaction to some*

> *component(s) in one or more-than-one of the vaccines administered shortly before the dangerous reaction began*".

"**Can you give an example?**

Vaccines are given to millions of people every year. A lot of people will have adverse health events that occur just coincidentally after vaccination. An adverse event of pregnancy is miscarriage, those occur in 10% or more of pregnancies. Often if a woman has a vaccine and then within several weeks has a miscarriage, there is the temptation to say the miscarriage was caused by the vaccine."

A misleading response to "*Can you give an example?*" that ignores the concept of logical connection and the factual record

Had Dr. DeStefano wished to give a cogent example, he would have introduced the concept of the "reporting rate" in VAERS for those adverse events actually occurring in the vaccinated population and emphasized that such adverse-event reports would have had to have:

- Occurred after vaccination and, critically,
- Been thought to be possibly vaccination related,

because *more than* 90% of the reports in VAERS are submitted by health care professionals.

Moreover, when others file reports to VAERS, they generally have a strong conviction or life-based experience that causes them to file an adverse-event report to those who maintain the VAERS database.

With respect to the narrative provided,

> "*An adverse event of pregnancy is miscarriage, those occur in 10% or more of pregnancies. Often if a woman has a vaccine and then within several weeks has a miscarriage, there is the temptation to say the miscarriage was caused by the vaccine*",

while the first generalization about miscarriages in pregnancy ("*about 10% or more*") is fairly accurate, Dr. DeStefano's second statement is misleading.

His remarks are misleading because they confound what may be a "*temptation*" by the public with the reality that the person, usually a healthcare professional, reporting a "*miscarriage*" to VAERS has to think that the vaccination was associated with the subsequent "*miscarriage*" before that person reports it as a post-vaccination "*miscarriage*".

In addition, the number of reports in VAERS of fetal loss ("*miscarriage*" [also labeled "spontaneous abortion" in the medical literature] and "stillbirth" [when the fetus dies *in utero* in the 20th week of gestation or later]) historically did <u>not</u> exceed five reports annually before 2009.

Accepting the validity of Dr. DeStefano's assertions that miscarriages "*occur in 10% or more of pregnancies*" and that, after correcting for elective abortions, there are about 5 million pregnant women seeking to give birth annually, *more than* 500,000 miscarriages occur annually.

However, after correcting for the percentage of pregnant women who were vaccinated against influenza during the 2009-2010 flu sea - son, there are roughly 100,000 – 200,000-plus miscarriages for which a health care professional could have had a "*temptation*" to report an influenza-vaccine-related fetal loss.

Thus, given these facts, it would appear that those reporting a post-influenza-vaccination-related "*miscarriage*" to VAERS were, like Dr. DeStefano, significantly influenced by their knowledge of the general rate of miscarriages and, if anything, had a strong "*temptation*" not to report influenza-vaccine-related fetal loss during the flu season.

Finally, had the reporting of miscarriages been driven by "*temptation*" to submit reports to VAERS, certainly *more than* five (5) reports out of the possible 100,000 to 200,000 post-influenza-vaccination miscarriages would have been submitted to VAERS each year since 1997.

However, the reality is that, in some years into the 2000s, there were no influenza-vaccination-related "*miscarriage*" reports to VAERS.

Moreover, since adverse-event reporting to VAERS only occurs for a small percent of the actual post-inactivated-influenza-vaccination-related fetal losses that occurred[8], Dr. DeStefano and the CDC, have *incorrectly* presumed that they can validly use the reports of inactivated-influenza-vaccine-associated reports of spontaneous abortion ("*miscarriage*") and stillbirth found in VAERS over some time period as if they were valid estimates of the population-wide rate for post-influenza-vaccination-associated "fetal loss".

For example, in a study period that encompassed about 19 "flu" seasons, from 1990 through the start of 2009, the number of reports of "miscarriage", characterized in that article as "*spontaneous abortion*", in VAERS, which were associated with the prior administration of an inactivated-influenza vaccine, was relatively low.

In some years, before and even after the CDC's Advisory Committee on Immunization Practice (ACIP) first made an official recommendation in 1997 that all pregnant women in their second and third trimesters be given an inactivated-influenza vaccine, there were no ("0") post-influenza-vaccination-associated fetal-loss reports.

Based on a study[12], published in 2011, CDC researchers (emphasis added), "Moro PL, Broder K, Zheteyeva Y, Walton K, Rohan P, Sutherland A, Guh A, Haber P, DeStefano F, Vellozzi C," essentially misreported that average report-filing rate in VAERS as if it were representative of the cases of inactivated-influenza-vaccine-related "spontaneous abortion" (which accounted for most of the VAERS "fetal loss" reports) for those 19 "flu" seasons.

These researches mistakenly reported (emphasis added), "1.9 ***cases*** per million pregnant women vaccinated", when the records in VAERS were simply reports of some small percentage of a subset of influenza-vaccinated "*spontaneous abortion*" cases that actually were vaccination related.

What the researchers should have reported was "1.9 ~~cases~~ ***spontaneous-abortion reports in VAERS*** per million pregnant women vaccinated".

Thus, their error is obvious since VAERS *only* contains "reports", which are known to be *only* some small percentage of the post-vaccination-related "cases" of "spontaneous abortion" that actually occurred.

Moreover, there were only between "0" and "4" fetal-loss reports associated with inactivated-influenza inoculation in VAERS associated with any "flu" season during the "mid-1990 to mid-2009" study period.

Clearly, there was very little "*temptation to say the miscarriage was caused by the vaccine*" for the inactivated-influenza-vaccine-related fetal losses reported in VAERS.

However, the CDC's findings[12] for the general historical level and rate for "*miscarriage*" ("spontaneous abortion") reports in VAERS following the vaccination of pregnant women with an inactivated-influenza vaccine are invaluable in assessing the importance of a sudden change in the level of adverse events should such a change occur.

For example, if, *in a subsequent flu season*, there was an apparent sudden increase (spike) in fetal-loss reports to VAERS after administration of some inactivated-influenza vaccine doses, then the previously determined average reports and report rate (reports per million pregnant women vaccinated) found using VAERS can be used to estimate the magnitude of the signal being generated.

Further, when that signal[13] exceeded ten (10) times the historical average number of inactivated-influenza-vaccine-related fetal-loss reports[12] being submitted to VAERS in any flu season, as it did by mid-

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12 Moro PL, Broder K, Zheteyeva Y, Walton K, Rohan P, Sutherland A, Guh A, Haber P, DeStefano F, Vellozzi C. Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009. *Am J Obstetrics Gynecol.* 2011 February; 204(2): 146.e1-146.e7.

13 A signal in VAERS is any significant increase in a given type of adverse event report being submitted, in this instance, the fetal-loss reports following the start of inactivated-influenza vaccine administration, in excess of the historical average reporting pattern for that adverse-event type.

December of 2009, the CDC should have noticed that the signal was significantly above the historical level.

If protecting the health of the unborn were the CDC's top priority, the CDC would have reacted to that signal by notifying the public of the problem, starting a formal investigation into the causal factors, and, *at a minimum*, suspending the novel monovalent pandemic [A (H1N1) 2009] influenza vaccines from being given to pregnant women.

Stopping the administration of the pandemic (A [H1N1] 2009) flu vaccine was justified because:

- Most of the fetal-loss reports submitted were associated with the pandemic influenza vaccination and these pandemic influenza vaccines were rushed into distribution without complete safety testing.
- Additionally, the pandemic influenza vaccines were being given to pregnant women along with the seasonal influenza vaccines, which had been being given to pregnant women for *more than* a decade with only a small number ("0" to "5") of influenza-vaccine-linked fetal-loss reports being submitted to VAERS annually.

If the CDC felt medically compelled to allow pregnant women to be given the novel pandemic influenza vaccines, then the CDC should have issued an immediate ban on the administration of any Thimerosal-preserved inactivated-influenza vaccines, pandemic or seasonal, to pregnant women.

Taking this later action was medically indicated because the CDC knew, or should have known, that doubling the dose of Thimerosal administered, when two (2) Thimerosal-preserved, inactivated-influenza, vaccine doses were given to a pregnant woman, was most probably the major cause of the greatly increased number of fetal-loss reports to VAERS[14] and *more than* half of the seasonal inactivated-influenza vaccine doses as well as most of the pandemic inactivated-influenza vaccine doses, which were CDC-recommended for administration to pregnant women, were Thimerosal-preserved doses.

However, the CDC took neither of these medically indicated actions, which, if both had been taken in a timely manner, would probably have:

[14] See footnotes **24** and **25**, and **Appendix A** for some recently uncovered evidence hidden from the public until 2013 that, since 2000, the CDC knew, or should have known, that doubly injecting pregnant women with a Thimerosal-preserved influenza vaccine would cause fetal harm and increased fetal loss.

- Reduced the number of vaccination-related fetal losses, and
- Resulted in a reduction in the number of post-influenza-vaccination-related fetal loss reports submitted to VAERS.

Thus, using the "*miscarriage*" example Dr. DeStefano misleadingly presented and the very significant increase in fetal-loss reports submitted to VAERS, which occurred after the start of the CDC-recommended influenza vaccination programs for pregnant women in the 2009-2010 flu season[15], Dr. DeStefano and the CDC should have recognized that:

- There was a strong signal, a highly significant increase in adverse-event reports of fetal loss to VAERS and
- Given the magnitude of the increase that was seen, the increase observed was causally related to the pandemic influenza vaccination program and/or the recommended double dose of inactivated-influenza vaccines that many pregnant women were being given, and,

based on the "precautionary principle" that supposedly governs the decisions made by our public health agencies and medical doctors, responded to that strong signal as Dr. King has suggested.

Because the CDC failed to intervene, by the end of the 2009-2010 flu season in June of 2010, the crude signal in the VAERS reports of post-inactivated-influenza-vaccination-associated fetal loss was *more than* 44 times the number of such reports in the prior flu season[16].

Furthermore, in 2013, GS Goldman, PhD reported[17],

> "The unadjusted fetal-loss report rates for the three consecutive influenza seasons beginning 2008/2009 were 6.8 (95% CI: 0.1–13.1), 77.8 (95% CI: 66.3–89.4), and 12.6 (95% CI: 7.2–18.0) cases per million pregnant women vaccinated, respectively.
>
> …
>
> 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",

where the CDC's reported average rate for "*spontaneous abortion*" reports for the 19 "flu" seasons from August of 1990 through the June of 2009 was "1.9 ... per million pregnant women vaccinated"[18].

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15 Before mid-season, the fetal-loss adverse-event reports to VAERS exceeded the historical average level by *more than* a factor of 20 – to which the CDC should have responded by, at a minimum, suspending the pandemic [A (H1N1) 2009] influenza vaccination program for pregnant women.

16 In terms of reports to VAERS, the increase was from "4" inactivated-influenza vaccine-related reports in the 2008-2009 flu season, where only trivalent inactivated-influenza vaccines were being given, to about "178" such fetal-loss reports in the 2009-2010 season, where two (2) influenza vaccine doses, seasonal and pandemic, were administered to most of the pregnant women, who were given a flu shot.

17 GS Goldman. Comparison of VAERS fetal-loss reports during three consecutive influenza seasons Was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season? *Hum Exp Toxicol.* 2013 May; 32(5): 464-475.

Given the values reported by Goldman[17], the average vaccination-related fetal-loss signal in the 2009-2010 flu season was 11.4 to 6.2 times the bracketing years' reporting rates or, on average, 8.4 times the average post-vaccination reporting rates in the bracketing years[19].

Further, the 1.8-fold increase in the "fetal loss" rate Dr. Goldman found[17] in the 2010-2011 flu season over the 2008-2009 flu season supports the reality that:

- The pandemic inactivated-influenza vaccines' viral component "(A-H1N1)" and
- Increased reporting[20]

were secondary factors[21].

The most probable cause for the spike in fetal-loss reports in the 2009-2010 flu season was the double exposure to Thimerosal suffered by many pregnant woman and their fetuses[22].

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18 Moro PL, Broder K, MD, Zheteyeva Y, Walton K, Rohan P, Sutherland A, Guh A, Haber P, DeStefano F, Vellozzi C. Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009. *Am J Obstetrics Gynecol.* 2011 February; 204(2): 146.e1-146.e7.

19 In the 20011-2012 "flu" season, where the A (H1N1) 2009 virus was still in the trivalent seasonal influenza vaccine formulations, there were only five (5) fetal-loss reports in VAERS, four (4) miscarriage reports and one (1) stillbirth report (Dr. King, unpublished data). Given that the uptake level was comparable to that in the prior "flu" season, these findings indicate that "increased reporting" was a minor effect that accounted for *no more than* 16 additional reports in the 2010-2011 "flu" season and *no more than* 26 reports in the 2009-2010 "flu" season based on the estimated relative "Weber" effect for the 2009-2010 "flu" season (see footnote **17**). This would mean that the remaining roughly 150 fetal-loss reports should probably be attributed to the double-dose of Thimerosal (49.55% mercury by weight) that many of the pregnant women received in the 2009-2010 "flu" season. Thus, it would appear that there is a threshold for Thimerosal-related reports of fetal loss such that one nominal 50-µg Thimerosal dose does not cause a significant number of influenza-vaccine-related fetal-loss reports (0-4), while two doses (nominally 100 µg of Thimerosal) in the 2009-2010 "flu" season generated *more than* 150 additional fetal-loss reports that were thought to be post-influenza-vaccination related.

20 For the 2010-2011 flu season, Goldman (2013) [see footnote **17**], found "21" influenza-vaccine-related fetal-loss reports, in VAERS. For the 2011-2012 flu season, Dr. King (unpublished data) found "5" fetal loss (FL) reports:

Table A comparison of United States VAERS reports during six consecutive influenza seasons, 2006/2006 through 2011/2012[1]

Season and vaccine (July–June)	All VAERS reports (% change from 2006.2007)	A: All influenza reports[a] (% change from previous	B: VAERS female influenza reports[b] (% change from 2006/2007)	% of VAERS female influenza reports (100xB/A)	No. of fetal-loss [FL] reports to VAERS (1 TIV FL/female reports)
2006/2007 TIV	20,502 (—)	3,123 (—)	2,048 (—)	65.6	—[c]
2007/2008 TIV	26,117 (27.4)	4,205 (34.6)	2,654 (29.6)	63.1	4 (663.5)
2008/2009 TIV	22,579 (- 13.5)	5,707 (35.7)	3,529 (33.0)	61.8	5[d] (882.2)
2009/2010 A-H1N1	32,877 (45.6)	12,300[e]	7,734[f]	62.9	170[g] (45.5)
2009/2010 TIV		7,671[e] (NC)	4,863[f] (NC)	63.4	22[g] (221.0)
2010/2011 TIV	23,416 (- 28.8)	9,602 (25.2)	6,372 (31.0)	66.4	21 (303.4)
2011/2012 TIV[2]	21,198 (- 9.5)	8,035 (-16.3)	5,326 (-16.4)	66.3	5 (1,065.2)

Note: The bold figures show existing trends for the Trivalent Influenza Vaccine (TIV) over several years and should not be confused with the figures for the special 2-dose 2009/10 Influenza season which includes the unique, separate dose of A-H1N1. Also, linear regression analysis was run on the figures shown in bold to show statistical correlation and annual existing trends in TIV reports.
VAERS: Vaccine Adverse Event Reporting System; TIV: trivalent inactivated influenza vaccine.

[1] Derived from Table 5 in paper referenced in footnote 17.

[2] Added data for 2011/2012 TIV flu season. Obviously, a significant decrease over trend and change from the trend seen in mid-2006 — mid-2011 period.

[a] All influenza adverse reports for TIV by year demonstrate linear correlation (figures in blue), r^2 =0.99.

[b] Female influenza adverse reports for TIV by year demonstrate a linear correlation (figures in blue), r^2 = 0.97.

[c] Not Reviewed.

[d] Includes one live virus–related fetal death.

[e] For 2009/2010, the combined A-H1N1 and TIV influenza reports total 19,971; however, 1105 duplicate reports must be deducted due to patients reporting receipt of both TIV and A-H1N1, yielding 18,866.

[f] For 2009/2010, the combined A-H1N1 and TIV female influenza reports total 12,597; however, 536 duplicate reports must similarly be deducted, yielding 12,061.

[g] Figure includes 18 VAERS fetal-loss reports specifying receipt of both A-H1N1 vaccine and TIV.

21 **Appendix C** contains some additional data (Dr. King unpublished) that carries Dr. Goldman's findings (footnote "**17**") forward through the 2012-2013 flu season, and, based on this wider period of review, purposes a threshold of 36 fetal-loss reports following an inactivated-influenza vaccination beyond which that type of report to VAERS should be considered a signal for a vaccine-related problem.

Had the CDC properly responded to this signal, it would have:

a. *As a precaution*, suspended the pandemic vaccination program for pregnant women before the end of 2009;

b. Banned administering any Thimerosal-preserved inactivated-influenza vaccines to pregnant women (and developing children) by the beginning of January 2010; and, critically,

c. Admitted, as the preliminary epidemiological studies it had conducted in Vaccine Safety Datalink (VSD) database in early 2000 had found[23,24], that *in utero* Thimerosal exposure was a risk factor for autism and other neurodevelopmental damage in infants who were exposed *in utero* to Thimerosal when their mothers were administered Thimerosal-preserved immunoglobulins and/or Thimerosal-preserved vaccines when they were pregnant with these children.

Results from the first phase of the CDC's VSD study[24], reported in an internal presentation abstract submission by "Thomas Verstraeten, R. Davies" [sic; Davis?]", D Gu and Frank DeStefano" in early 2000[25], showed that infants whose cumulative Thimerosal-related exposure to organic mercury was *nominally greater than* 25 µg of mercury from a Thimerosal-preserved product by one month of age were about "7.6" times more likely to have an "autism" diagnosis than those not exposed to any organic mercury derived from Thimerosal[26].

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22 On average, *more than* half of the pregnant women, who were vaccinated for influenza, received a nominal dose of 100 µg of Thimerosal when they were given two Thimerosal-containing inactivated-influenza vaccine doses in the 2009-2010 flu season as compared to a maximum nominal dose of 50 µg of Thimerosal from one inactivated-influenza vaccine in prior and subsequent flu seasons.

23 These epidemiological studies in the VSD were completed in February 2000 prior to the CDC's illegal, clandestine "Simpsonwood" meeting in Norcross, Georgia on June 6-7, 2000.

24 These results were part of a set of documents released to a U.S. House of Representatives office in August of 2013, which included an abstract submission for an April 2000 CDC Epidemic Intelligence Service [EIS] annual conference presentation (see footnote **25**), which reported this finding and others clearly showing a link between the level of organic mercury exposure from Thimerosal-preserved vaccines to developing children up to one month of age and their risk of subsequently being diagnosed with autism as compared to babies receiving no injected-Thimerosal exposure prior to one month of age.

25 Verstraeten, T.; Davis, R.L.; Gu, D.; DeStefano, F., Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life. [Submission abstract for the Epidemic Intelligence Service (EIS) Annual Conference, Centers for Disease Control and Prevention held April of 2000 in Atlanta, Georgia].

26 A copy of this abstract submission form may be viewed by clicking on the link to it, "CDC Epidemic Intelligence Service (EIS) annual conference abstract submission for the EIS conference in April 2000, discovered in August of 2013 in a CDC response to a Congressional Request by an office in the U.S. House of Representatives - the abstract submission is titled, "Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life", which is located in the "Documents" section of the web site http://Mercury-freeDrugs.org. In addition, a copy of that document has been appended to this response (see **Appendix A**). [**Note:** Furthermore, evidence confirming that this initial-study information was presented in April of 2000 at the Epidemic Intelligence Service annual conference, which was held in Atlanta, Georgia, can be found in http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/DeStefano102004.ashx (an Adobe Acrobat®-generated encapsulation of a PowerPoint slide presentation prepared for presentation by Dr. DeStefano at an Institute of Medicine (IOM) meeting {see slide/page "18"}).]

This abstract submission also reported that the relative risks for the Thimerosal-exposed infants relative to the non-exposed infants were:

- "1.8" for "a neurologic development disorder",
- "2.1" for "speech disorders", and
- "5.0" for "non organic sleep disorder"

for the same mercury exposure level (*greater than* 25 µg of mercury) at one (1) month of age.

Further, the abstract submission form stated,

> "For the neurologic degenerative and renal disorders group we found no significantly increased risk or a decreased risk",

indicating that, *in contrast to the effects observed for the group of "*3702 with developmental neurologic disorders*" and its sub groups, which were statistically significant*, the effects observed for the "286 children with degenerative ... disorders, and 310 with renal disorders" were <u>not</u> statistically significant when all of these outcomes were compared to the corresponding outcomes in a matched <u>no-exposure</u> control group.

Thus, *based on the preceding findings*, since 2000, if <u>not</u> before, the CDC and Dr. DeStefano apparently have:

- ❑ Dishonestly claimed that there was <u>no</u> link between developing children's exposures to Thimerosal (49.55% mercury by weight) from Thimerosal-preserved drug products (vaccines and immunoglobulins) and the subsequent post-vaccination risk that some of those developing Thimerosal-exposed children will later receive a diagnosis of "autism" and,
- ❑ By dataset and study-design manipulation, knowingly twisted their published findings to support this falsehood.

"**What does the CDC do when it gets a report that a vaccine has caused a serious side effect?**

It depends on the nature of the condition. There is a routine reporting system; physicians can file reports. What we do depends on whether it is a known adverse reaction to a vaccine or whether it's not known.

We get as detailed information on the case as possible.

If it's a known adverse vaccine reaction, usually questions arise about the clinical management [for the patient]. For example, febrile seizures. This is a known adverse reaction after MMR [measles, mumps, rubella] vaccine, [occurring in] about 1 in 2,500 vaccinations.

It's known that febrile seizures following [vaccination] are known to be fairly benign with a good prognosis.

If it's an unknown reaction, often a physician will call and want to know if the vaccine caused it.

We encourage the physician or provider to file a report. We review [the database] to see if there is kind of a pattern that does indicate this particular adverse event is occurring more frequently with this vaccine than with other vaccines.

Usually the next step would be to initiate more formal epidemiological investigation. Usually that is through our program called the Vaccine Safety Datalink (VSD). That's a collaboration we have with 8 managed care organizations.

They cover about 9 million people and they have electronic records."

CDC handling of a post-vaccination "*serious side effect*" reports: A beautiful story concealing an ugly reality

First, Dr. DeStefano paints a beautiful but illusory picture of how the CDC addresses post-vaccination-associated adverse events.

However, as the reality of the detailed example described in the preceding response shows, when there was a significant confirmed vaccine-associated signal for fetal loss in pregnant women following an inactivated-influenza inoculation, rather than functioning as Dr. DeStefano claims the system does, the reality was that other vaccine-safety advocates noticed and reported the strong fetal-loss adverse-event signal in VAERS to the public.

Nonetheless, neither Dr. DeStefano nor the CDC took any action to warn about, or minimize, this increased risk of fetal loss.

In contrast to Dr. DeStefano's portrayal, after the 2009-2010 flu season was over, the CDC public health officials:

a. Claimed that they did not see any unexpected fetal outcomes although they had been repeatedly informed of the VAERS signal[27,28], and

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27 http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-oct10.pdf, page 182-183, the comments of Renee Tocco (see **Appendix B** for excerpts of the minutes and a slide shown by "Tom Shimabukuro, MD, …" [**Notes** by Dr. King].

28 http://progressiveconvergence.com/Final%20Press%20Release%20CDC%20Allegedly%20falsified.pdf, titled "CDC allegedly falsifies reports--ignoring up to 3,587 Miscarriages from H1N1 Vaccine", which was issued on 28 October 2010 and reported, among other information,

'Excerpts and adaptation from speech delivered by Eileen Dannemann, Director, National Coalition of Organized Women Friday, September 3, 2010 to the Advisory Commission on Childhood Vaccines (ACCV) meeting.

"Initially, at the beginning of the H1N1 pandemic consequence management drill there were allegedly 30 maternal deaths. It was these deaths that the CDC used as the basis to initiate a strenuous and aggressive campaign to vaccinate the pregnant population with the untested H1N1 vaccine. The CDC ascertained that there were eventually a total of 56 maternal deaths (assuming the fetuses died with them). Dr. Alicia Siston's JAMA study (CDC) acknowledged that most of these deaths were 'unconfirmed' H1N1 virus caused deaths despite the fact that the CDC had tests that could have verified, for certain, that these were H1N1 related deaths.

Vaccine-related fetal demise reports from VAERS increased 2,440%--from 7 cases in 2008/9 to 178 in 2009/10. Seventy deaths reported from another source had 7 overlapping cases with VAERS, yielding 241 unique cases. Simplistically speaking, it would have been 85 to 192 times safer not to vaccinate from the perspective of the in-utero child.

Considering that the total of 56 maternal deaths in Dr. Alicia's Siston's study, allegedly due to the H1N1 virus itself, are unverified and in light of the overwhelming adverse events reported, we emphasize that inoculating pregnant women with another untested vaccine containing a combination of components found in the offending 2009 H1N1 vaccine is insupportable. Thus, it must be argued that the CDC was grossly negligent to fail to inform their vaccine providers of the incoming VAERS data, while providers blindly followed the CDC "standard of care" guidelines to vaccinate every pregnant woman in 2009/10. Furthermore, in the face of these findings and the purposeful withholding of these findings by CDC's Dr. Marie McCormick and her vaccine risk assessment group, for the CDC's Advisory Committee on Immunization Practices (ACIP) to recommend another iteration of the same vaccine to pregnant women in 2010/11 may be argued as *more than* gross negligence -but rather- an act of willful misconduct.

b. Did not properly respond to, publicly report, and document that fetal-loss signal and the probable cause(s) for it[29].

Instead, as Dr. DeStefano persists in doing, they intentionally misdirected the public by pointing to the pregnant population's "*miscarriages*" percentage as if that percentage ***directly*** influences the number of fetal-loss reports submitted to VAERS, although Dr. DeStefano and his fellow federal health officials knew, or should have known, that it did not.

Worse, even after the strong signal in VAERS was independently reported in the literature[17], the CDC has continued to:

- Ignore that signal and
- Refuse to, *at a minimum*, ban administering Thimerosal-containing influenza vaccines to pregnant women.

However, based on the strong Thimerosal-exposure-level-linked signal observed in the 2009-2010 flu season, a ban on administering Thimerosal-containing vaccines to pregnant women should have been adopted because:

a. There was a definite Thimerosal-dose-dependent exposure effect on the risk of fetal loss in the 2009-2010 flu season, and

b. *By scientifically sound, biologically plausible inference*, there was a risk of harm to at least some of those developing fetuses, who survived that increased level of Thimerosal exposure and were born alive.

However, *as far as Dr. King can ascertain*, the CDC has not yet reported any in-depth follow-up studies comparing the developmental, behavioral, and physical health of:

- Those babies born to pregnant women who declined to get any influenza vaccine in the 2009-2010 flu season to

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We strongly recommend that the CDC withdraws their continued recommendation to pregnant women, instead, strictly adhering to the FDA/manufacturers warning on the insert packages that the flu shot not be given to pregnant women unless clearly needed. As well, we suggest that the CDC advise all Ob/Gyns, vaccine providers and the public this year, of last season's VAERS reports on H1N1 vaccine-related fetal deaths" despite the fact that it may be contrary to CDC's vaccine uptake performance goals".'

29 Moro PL, Broder K, Zheteyeva Y, Revzina N, Tepper N, Kissin D, Barash F, Arana J, Brantley MD, Ding H, Singleton JA, Walton K, Haber P, Lewis P, Yue X, DeStefano F, Vellozzi C. Adverse events following administration to pregnant women of influenza A (H1N1) 2009 monovalent vaccine reported to the Vaccine Adverse Event Reporting System. *Am J Obstet Gynecol* 2011; 205: 473.e1-9. Where, instead of reporting on the large signal observed in VAERS associated with the "influenza A (H1N1) 2009 monovalent vaccine" as compared to the historical annual "spontaneous abortion" signal that Moro PL, Broder K, MD, Zheteyeva Y, Walton K, Rohan P, Sutherland A, Guh A, Haber P, DeStefano F, Vellozzi C. Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009. *Am J Obstetrics Gynecol.* 2011 February; 204(2): 146.e1-146.e7 found, the abstract falsely reported, "CONCLUSION: Review of reports to VAERS following H1N1 vaccination in pregnant women did not identify any concerning patterns of maternal or fetal outcomes" – knowingly ignoring the *more than* 10-fold increase in fetal losses over the prior flu season and the *more than* 30-fold increase over the historical rate for "spontaneous abortions" this CDC research group had found and reported in the earlier paper.

- Those babies born to pregnant women who received two (2) doses of a Thimerosal-containing inactivated-influenza vaccine in the 2009-2010 flu season[30].

Worse, almost all of the published epidemiological studies, by the CDC and those in public health, academia and industry with whom they collaborate, seem to be intentionally misdesigned to ensure that any potential vaccination-related adverse effects will be minimized, eliminated, and/ or misrepresented in the published findings of such studies[31].

Moreover, comparative health-outcome studies of the actual children, not their routinely collected medical records, who may have been affected by the highest Thimerosal exposure to those whose mothers received no pre-natal Thimerosal-preserved vaccine or immunoglobulin are not available.

However, *to be fair*, the full effects of the aforementioned harms to those children, who were indirectly exposed *in utero* to high doses of Thimerosal in the 2009-2010 flu season may not be realized, in all instances, until 2018 at the earliest[32].

"**Do vaccines cause autism?**

The scientific evidence is clear that vaccines do not cause autism. The Institute of Medicine, IOM, issued a report in 2004. … Studies since 2004 have continued to find no increased risk of autism following vaccination, including a study we published in Pediatrics."

Scientific evidence?

Here, Dr. DeStefano begins with a statement,

"*The scientific evidence is clear that vaccines do not cause autism*",

which is, at best, knowingly false.

For a given published scientific study to be considered as "*evidence*" of any assertion, that study must meet several "quality" criteria, including being "independent"[33] and, to be "*scientific evidence*", all the origi-

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30 In addition, the infant outcomes of both groups should also be compared to those babies subsequently born to pregnant women who had received no flu shot during pregnancy in each flu season from August of 2008 through June of 2011 so that, if any, the adverse effect attributable to the monovalent A (H1N1) 2009 inactivated-influenza vaccine per se could be assessed.

31 See, for example, http://dr-king.com/docs/20120331_FalsusInUnoFalsusInOmnibusAThimerosalpreservedVaccineConundrum_b.pdf.

32 This 8-plus-year delay is caused by the slow onset of the symptoms used to diagnose the worst of these neuro-developmental harms as the CDC's surveys for autism in 8-year-old children indicate.

33 Donohoe, M. Evidence-based medicine and shaken baby syndrome; Part 1: Literature review, 1966-1998, *Am J Forensic Med Pathol.* 2003 September; 24(3): 239–242. This paper discusses general issues with determining which findings meet the quality of evidence standards needed for those studies to be legally accepted as "scientific evidence". Generally, (emphasis added),

nal anonymized raw data collected and all of the study details must be freely available for independent review and confirmation of the published findings after the study is published.

Neither the non-cited, population-statistics-based, published studies upon which Dr. DeStefano relies, "*including a study we published in Pediatrics*", nor the report about which Dr. DeStefano states, "*Institute of Medicine, IOM, issued a report in 2004*", which was derived from statistical studies that fail to even meet the quality standards for "*evidence*", are "*scientific evidence*".

If for no other reason, the "*study we published in Pediatrics*", led by Dr. Thomas Verstraeten, in which Dr. DeStefano admits participating, fails to meet the minimum standards for "*scientific evidence*" because, when asked to provide the original anonymized data sets and study details for independent review after the study was published, CDC officials claimed that all of the raw data sets and study details had been lost – irrevocably consigning that published study to the scientific dust bin reserved for studies whose validity cannot be confirmed.

Worse, those data sets and study details were "lost" even though the Congress had previously instructed the CDC to preserve all of the files that were associated with its studies assessing the associations between Thimerosal exposure and the subsequent risk of harm.

In addition, at least one of the other studies, for which the CDC provided funding and oversight, and upon which the IOM report relied, appears to be a fraudulent study[30].

Additionally, all the population-statistics-based studies upon which the IOM relied for its report were not, and are not, "*scientific evidence*".

This is the case because, as far as Dr. King has been able to ascertain, their original data sets and study details are not readily availa-

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"Genuine hypothesis testing requires use of appropriate research methodologies, including collection of relevant control data, and suitable statistical analysis. The interpretation of individual study findings may be constrained by factors such as whether the cohort examined was adequately representative of the patient population in general. Replication across studies and in independent research centers is a key factor in the reliability of evidence. Compelling evidence comes from consistent findings in 2 or more well-constructed, controlled trials or population-based epidemiologic studies (i.e., level I or level II evidence). ...
Quality of Evidence Ratings

I: Consistent evidence obtained from more than 2 independent, randomized, and controlled studies or from 2 independent, population-based epidemiologic studies. Studies included here are characterized by sufficient statistical power, rigorous methodologies, and inclusion of representative patient samples. Meta-analysis of smaller, well-characterized studies may support key findings.

II: Consistent evidence from 2 randomized controlled studies from independent centers, a single multicenter randomized controlled study, or a population-based epidemiologic study. Data included here have sufficient statistical power, rigorous methodologies, and the inclusion of representative patient samples.

III-1: Consistent evidence obtained from 2 or more well-designed and controlled studies performed by a single research group.

III-2: Consistent evidence obtained from more than 1 study but in which such studies have methodologic constraints, such as limited statistical power, or the inclusion of patient samples that may be nonrepresentative.

III-3: Evidence obtained from a single case study or a selected cohort study.

III-4: Conflicting evidence obtained from 2 or more well-designed and controlled studies.

IV: Consensus opinions of authorities according to clinical experience or descriptive reports."

***Nota bene*:** To satisfy the legal requirements for "scientific evidence", the studies must be independent and all of the anonymized raw data initially examined and the study details must be readily available for other independent experts to check and verify the validity of all of the study's designs, treatment decisions and choices, and findings.

ble for independent review even though the federal government provided funding for and directly oversaw all but one of the studies used by the IOM in fashioning its 2004 report.

Further, neither the published "Verstraeten" study nor any of the other similar statistical studies directly or indirectly overseen, commissioned and/or influenced by the CDC, any other federal agency, or a vaccine maker can rationally be characterized as "*scientific evidence*".

Similarly, the IOM report cannot be considered "*scientific evidence*" since it was not a scientific study but rather simply a review of only a few of the many pertinent studies available to IOM committee, *which was hired and given its review framework by the CDC*, for its review in 2004.

Finally, since the IOM committee was "conflicted" by the CDC, *which hired and instructed it*, this IOM report is not even "*evidence*".

"*[V]accines cause autism*"

First, based on the outcomes reported by Dr. Goldman[17], and the results of the initial studies conducted by the CDC and deliberately hidden from the public (see **Appendix A**), the CDC and Dr. DeStefano have known since 2000, if not before, that Thimerosal exposure from injected Thimerosal-preserved vaccines and serums causes developmental harm.

The currently recognized harms, include but are not limited to:

- Noticeable increases in fetal loss when the dose given to pregnant women was high enough[17]. and,
- "*[A]utism*" and other neurodevelopmental, developmental, behavioral deficits and other chronic health issues seen today in some developing children, who were vaccinated and/or are still being vaccinated with Thimerosal-preserved vaccines.

Clearly, since "autism" is diagnosed by the symptoms children exhibit and the federal administrative "vaccine court" system has: **a)** conceded that vaccines have caused the harms that ultimately led to some damaged children's exhibiting the "symptoms of autism" and **b)** awarded significant sums to care for some of these children, vaccines are, *contrary to Dr. DeStefano's answer*, a recognized causal factor for "*autism*".

Moreover, in contrast to the non-independent, non-verifiable statistics-based studies and the IOM report to which Dr. DeStefano refers, there exist other independent and verifiable statistics-based

studies and a body of independent, independently verifiable and, in some instances, verified, toxicological, case and cohort studies that have found a clear link between:

- ❖ Some specific component in a vaccine or immunoglobulin product or some vaccine (for example, respectively,
  - Thimerosal in all of the Thimerosal-preserved serum and vaccine products that have been administered to pregnant women and/or to developing children, or
  - The doses of the MMR [and MMRV] vaccine that are given to developing children), and
- ❖ The post-inoculation risk of a susceptible inoculee's subsequently being diagnosed with
  - "Autism" and/or a related neurodevelopmental disorder, and/or
  - Other medically recognized developmental or chronic medical condition issues, and/or
  - Other medically recognized behavioral abnormalities.

Although these studies exist and can be easily found using Google Scholar (http://scholar.google.com/), the federally funded searchable database PubMed (http://www.ncbi.nlm.nih.gov/pubmed/), and/or other on-line search tools that are designed to search the published medical and scientific literature, those who are vaccine apologists and/or vaccination acolytes continue to:

1. Deny that any such studies exist,
2. Attack those researchers who publish any such studies in order to discredit those papers whose findings show any evidence of:
   - **a.** Generalized harm associated with any vaccine component, vaccine, or vaccination program as well as
   - **b.** Problems with the fundamental "disease-agent exposure" basis underpinning vaccination, including but not limited to the damage caused by both single and repeated abnormal exposures to a single antigen[34],

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[34] Tsumiyama K, Miyazaki Y, Shiozawa S. Self-Organized Criticality Theory of Autoimmunity. *PLoS ONE* 2012 December 31; 4(12): e8382 (9 pages). doi:10.1371/journal.pone.0008382, http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0008382, (emphasis added),

"Abstract

Background: The cause of autoimmunity, which is unknown, is investigated from a different angle, i.e., the defect in immune 'system', to explain the cause of autoimmunity.

Methodology/Principal Findings: Repeated immunization with antigen causes systemic autoimmunity in mice otherwise not prone to spontaneous autoimmune diseases. Overstimulation of CD4+ T cells led to the development of autoantibody-inducing CD4+ T (aiCD4+ T) cell which had undergone T cell receptor (TCR) revision and was capable of inducing autoantibodies. The aiCD4+ T cell was induced by de novo TCR revision but not by cross-reaction, and subsequently overstimulated CD8+ T cells, driving them to become antigen-specific cytotoxic T lymphocytes (CTL). These CTLs could be further matured by antigen cross-presentation, after which they caused autoimmune tissue injury akin to systemic lupus erythematosus (SLE).

and

3. Attempt, often successfully, to cut off the funding to any investigator or research group whose future studies might show that, instead of making our children (and ourselves) healthier, the current CDC-recommended vaccination programs are making our children (and ourselves) increasingly less healthy.

Additionally, instead of a holistic approach to health that focuses on the American people's:

- ✓ Freedom from pollution, oppression and war;
- ✓ Improved hygiene, nutrition, and sanitation;
- ✓ Clean air and water; and
- ✓ Adequate clothing and shelter,

the *de facto* "standards of care" for what is euphemistically called "medical health care" for children in the USA today seem to mainly focus on:

- Disease treatment not cure for chronic medical conditions,
- Suppression of: **a)** holistic healing modalities and **b)** in most instances, the use of curative "dietary" interventions,
- Limited-duration disease-suppression labeled as a "cure" or a "prevention" for cancers and other diseases, and
- *Based on the growth in children with medical conditions that once were very rare or unknown before the 1940s*, ignoring the non-genetic causal factors that have created the current epidemic levels of chronic childhood medical conditions.

Furthermore, the mainstream ("Establishment") media outlets in the USA today are dependent upon the health systems' advertising dollars for a significant portion of their revenue as well as the federal government's favor to maintain their licenses.

Therefore, it is no wonder that these media outlets ignore inconvenient truths while publishing articles and touting studies that promote the industry's views and governmental recommendations; drug products, including vaccines; and the CDC's recommended childhood vaccination programs even when these programs:

a. *Like the annual influenza vaccination program*, do not really protect most who are vaccinated with any influenza vaccine

Conclusions/Significance: Systemic autoimmunity appears to be the inevitable consequence of over-stimulating the host's immune 'system' by repeated immunization with antigen, to the levels that surpass system's self-organized criticality.

from subsequently getting the "flu"[35,36] as well as actually significantly increase the vaccinees' risk of contracting other non-influenza viral respiratory infections[36];

b. *Like the current two-plus-dose chickenpox vaccination program*, are not even societally cost-effective in the USA to the tune of *more than* $700 million annually, even when the costs associated with the serious adverse reactions, including permanent disability, which some of the vaccinees suffer, are not addressed[37]; or

c. *Like those vaccines that deliver a preservative-level dose of Thimerosal-derived organic mercury and other immune-system dysregulating substances with each vaccine dose*, are a causal factor for neurodevelopmental disorders (such as, for example, autism [see footnote **25** and **Appendix A**]), other developmental disorders (e.g., bowel dysfunction), behavioral problems (e.g., hyperactivity) and chronic childhood conditions (e.g., childhood asthma and peanut allergy).

"**Is it dangerous for kids to be getting so many vaccines at once?**

The available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effects on the normal childhood immune system.

A number of studies have been conducted … and these studies have shown that recommended vaccines are as effective in combination as they are individually and that such combinations carry no greater risk for adverse side effects.

So no evidence suggests that the recommended childhood vaccines can, quote, overload the immune system."

Yes, it is "*dangerous for kids to be getting so many vaccines at once*"

First, Dr. King notices that Dr. DeStefano does not cite any studies to support his "*no*"[38] danger claims here.

Second, his unsupported assertion that,

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35 Kelly H, Jacoby P, Dixon GA, Carcione D, et al. Vaccine Effectiveness against laboratory-confirmed influenza in healthy young children: a case-control study. *Pediatr Infect Dis J* 2011; 30:107–111.

36 Cowling BJ, Fang VJ, Nishiura H, et al. Increased Risk of Noninfluenza Respiratory Virus Infections Associated with Receipt of Inactivated Influenza Vaccine. *Clin Infect Dis*. 2012 June15; 54(12): 1778-1783.

37 Goldman GS, King PG. Review of the United States universal varicella vaccination program: Herpes zoster incidence rates, cost effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data. *Vaccine* 2013 March 25; 31(13): 1680-1684 (open access) [http://www.sciencedirect.com/science/journal/0264410X/31/13, article "6"]

38 Essentially, Dr. DeStefano's "no" claims are (emphasis added), **a)** "*vaccination with multiple vaccines has no adverse effects on the normal childhood immune system*", **b)** "*such combinations carry no greater risk for adverse side effects*" and **c)** "*no evidence suggests that the recommended childhood vaccines can… overload the immune system*".

"*simultaneous vaccination with multiple vaccines has no adverse effects on the normal childhood immune system*",

is clearly at odds with the findings in a 2009 paper, by Tsumiyama K, et al.[33], that reported that repeated exposures to even a single antigen caused the once-normal adaptive immune system of the test subjects to be non-reversibly changed into an abnormal immune system with significant autoimmune reactivity.

In addition, this assertion is at odds with the findings reported in Goldman GS and Miller NZ (2012)[11], which found increasing risks of hospitalization and death as more disease-preventive vaccine components were given at once to children under one (1) year of age.

Furthermore, given the findings in Tsumiyama K, et al. (2009)[34], repeated inoculation with vaccines that contain antigenic substances in common (like adjuvants or gelatin), as some vaccines do, has been shown to cause serious immune-system damage in some children.

Moreover, based on Tsumiyama K, et al. (2009)[34], any vaccination that abnormally exposes the vaccinees to disease-related substances or disease-causing pathogens may convert some susceptible children's immune system into an *abnormal* "*childhood immune system*", which can persist.

Additionally, Dr. DeStefano's unsupported "*such combinations carry no greater risk for adverse side effects*" assertion is contradicted by the very example he cites in his answer to the next question (emphasis added),

"*There are a few exceptions. The most notable is the MMRV: measles, mumps, rubella, and varicella all in one. Febrile seizures can occur more frequently with a combination MMRV than when MMR and V are administered as separate injections*",

which plainly disproves his assertion that "... *combinations carry no greater risk for adverse side effects*".

Moreover, two previously cited studies[10,11] are independent verifiable studies that also clearly contradict his initial claim,

"*simultaneous vaccination with multiple vaccines has no adverse effects on the normal childhood immune system*".

For example, when *more than* two vaccine components for diseases were given in the same vaccination session, there was a significant increase in the inoculated child's risk for hospitalization and death in the relevant adverse-event reports in the VAERS database[11] for children *less than* one year of age.

Further, the other previously cited article[10] found a statistically significant infant-mortality-rate trend, which increases as the number of "vaccines" recommended to be given to children before the children are one year of age increases in those developed countries that were studied[39].

Additionally, another previously cited study[34], which used mice from an autoimmune-disease-resistant mouse strain as its test and control subjects, has unequivocally shown that the repeated administration of just one single antigen can overload the immune system of this "resistant" mouse strain and cause the multiply inoculated mice to "develop" damaging autoimmune reactions.

Thus, all of Dr. DeStefano's statements are at odds with the reality that most of the CDC-recommended vaccinations unbalance the human immune system by generally up-regulating the circulating immune system's activities, down-regulating the innate immune system's ability to suppress disease-agent ingress into the body, and reducing the circulating immune system's adaptability.

Based on the preceding realities, it should be obvious that the current vaccines are, *given their principal modes of action*, incapable of producing disease immunity, and can, and do, imbalance and, *in some instances*, non-reversibly overload some children's immune system.

"**Are the combination vaccines safe?**

Combination vaccines have been used since the mid-1940s. … They have been used for many years without evidence of adverse effects and just as effectively as giving them singly.

There are a few exceptions. The most notable is the MMRV: measles, mumps, rubella, and varicella all in one. Febrile seizures can occur more frequently with a combination MMRV than when MMR and V are administered as separate injections.

No proof that "*the combination vaccines*" are "*safe*"

First, as far as Dr. King can determine, there have been no scientifically sound toxicological studies[40] or true-placebo clinical trials in which a randomized double-blind study with a true placebo (e.g., for injectable vaccines, an injectable, sterile pH-balanced isotonic saline

[39] To be included in the study, the country had to be a developed country and to have a population that was large enough to generate enough infant deaths to overcome the quantization error, where one additional or one less death can affect the infant mortality rate (infant deaths per 1,000 live births) by *more than* 10%.

[40] http://dr-king.com/docs/20130501_Vaccines_The_Safest_of_Medicines_or_the_Biggest_Liequstn_e_b_r1.pdf.

solution), which is given to the randomly assigned control subjects[41], which have proven that any combination vaccine is "safe".

In addition, there even appear to be no real three-way double-blind comparative harm assessment for, for example, the MMR or DTaP vaccines, which compare the double-blind administration of the combination vaccine with a blinded single-dose true placebo control to the double-blind administration of each component in combination with three separate, blinded, true-placebo injections for the controls in that part of the study.

Moreover, Dr. DeStefano does not even attempt to answer the question posed,

"*Are the combination vaccines safe?*"

Instead, he begins by citing his view of the historical record,

"*Combination vaccines have been used since the mid-1940s. … They have been used for many years without evidence of adverse effects and just as effectively as giving them singly.*"

From Dr. King's point of view, these statements remind him of the historical justifications used for the sale of cigarettes and the non-tobacco components added to them, like, for example,

- *Cigarettes have been smoked for more than 300 years.*
- *Commercial cigarettes were sold for decades without any evidence of harm; and even medical doctors touted their "benefits".*
- *Smoking the modern paper-wrapped filtered multi-component cigarette is just as safe as smoking a comparable paper-wrapped filtered cigarette that only contains shredded, cured tobacco leaves; and it is safer than smoking cigars.*

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[41] For example, *as Dr. Andrew Wakefield reported in 1998*, there apparently have been no scientifically sound and appropriate clinical trials for the MMR vaccines that prove that the MMR vaccines are as safe as appropriately giving the individual live viruses for measles, mumps and rubella on separate dates or, at a minimum, in separate inoculations on the same day, which would establish whether giving the MMR vaccines is as safe as giving the components on different days or on the same date in different locations (relative safety).

Worse, as far as Dr. King can ascertain, the requirements to prove preclinical safety (that the MMR vaccine cannot cause cancer, mutations, or adverse effect on reproduction) have been disregarded. In addition, there have been no randomized double-blind, true-placebo clinical safety trials with at least 30,000 volunteer subjects in each trial group, vaccine and true placebo, for any of the MMR vaccines. In general, all of the "modern", post-1980, combination vaccines are tested for safety by comparing the adverse events seen for the combination vaccine to those seen for a combination of an existing multi-component vaccine containing a lesser number of vaccine actives and separately administered additional active component vaccine(s). In this manner, the only requirement seems to be that the full combination vaccine must not produce a significantly higher risk than the lesser combination vaccine plus the added active vaccine component(s) given separately. However, as the MMRV case illustrates, even when the full combination vaccine, MMRV, produced febrile-seizure adverse reactions at *more than* twice the rate in children under 2 years of age as giving the MMR vaccine and the varicella vaccine in separate locations on the same day, ignoring its statutory mandate "to reduce the risks of adverse reactions to vaccines" [42 U.S.C. Sec. 300aa-27(a)(2)], the CDC has refused to ban the giving of the MMRV vaccine to children under 2 years of age.

As with Dr. King's unsupported statements about the modern multiple-component cigarettes, none of Dr. DeStefano's unsupported remarks asserts that any of the "*combination vaccines*" are "*safe*".

Perhaps that is because Dr. DeStefano knows that none of these combination vaccines, repeatedly advertised and promoted as "*safe and effective*", have been proven to be non-carcinogenic, non-mutagenic and devoid of any and all reproductive toxicity as all drugs, including vaccines, intended to be given to healthy people for the prevention of future disease, are supposed to be[42].

Although this requirement is clearly ignored, the aforementioned toxicological studies are legally required to be conducted and the candidate vaccine proven to be non-carcinogenic, non-mutagenic and reproductively non-toxic before any "disease preventive" vaccine formula can legally be given to human subjects in a "phase 1" clinical safety trial.

Moreover, though he only mentions one example, Dr. DeStefano admits (emphasis added),

"*There are a few exceptions*".

However, he neglects to tell us what the other exceptions are.

Additionally, Dr. DeStefano does not explain why no rigorous relative safety studies have been conducted comparing the safety of, for example:

- Giving the MMR vaccine to the safety of giving each of its live-virus components separately on the same or different days; or, at a minimum,
- Giving the possible two-component live-virus vaccines (MM [measles and mumps] or an MR [measles and rubella] or an RM [rubella and mumps]) together with the other component administered separately on the same or on another day.

After all, it was Dr. Andrew Wakefield's: **a)** pointing out that the required safety tests for the MMR combination vaccines had never been conducted, **b)** calling for those safety studies to be done, and **c)** suggesting that only the single-disease vaccines should be administered until the MMR vaccines' safety could be proven that got him cashiered out of British medicine — not claims that, in 1998, he had not made concerning a causal link between some children's MMR vacci-

[42] http://dr-king.com/docs/20130501_Vaccines_The_Safest_of_Medicines_or_the_Biggest_Liequstn_e_b_r1.pdf. See Section "13" and sub section 13.1" in those package inserts that conform to the current FDA regulations for the format and content of a package insert.

nation and their later being diagnosed with autism, a seizure disorder, or some bowel disease.

"**So are they recommended as separate injections?**

That is kind of left to the physicians. A clinician should explain the risks and benefits carefully with the child's parents. If they think the parent may not understand, there is a suggestion to give the MMR and varicella separately."

Separate M-M-R® II and Varivax® injections? Strongly recommended!

While Dr. DeStefano's statements correctly reflect the CDC's position, they gloss over the fact that the CDC is more concerned about issues other than the risk of febrile seizures for the individual vaccinated child as the "summary" of the CDC's recommendations[43] clearly shows (emphasis added),

"Summary and Rationale for MMRV Vaccine Recommendations

Two postlicensure studies (11,18) and other related data support the conclusion that use of MMRV vaccine among children aged 12–23 months results in a higher risk for fever and febrile seizures during the 5–12 days after the first dose compared with the use of MMR vaccine and varicella vaccine at the same visit. The approximately twofold increased risk results in an estimated one additional febrile seizure per 2,300–2,600 children vaccinated with the first dose of MMRV vaccine compared with those who receive the first dose with MMR vaccine and varicella vaccine. Although data regarding the risk for febrile seizures after administration of the first dose of MMRV vaccine are available only for children aged 12–23 months, the increased risk for febrile seizures during the 5–12 days postvaccination is likely to be present among children aged ≤47 months because that is the biologic window of vulnerability for febrile seizures in children (approximately 97% of febrile seizures occur in children aged <4 years) (22). Compared with no vaccination, MMR vaccine is associated with one additional febrile seizure among every 3,000–4,000 children aged <7 years vaccinated with MMR vaccine (8). The risk for febrile seizures during measles illness is higher than the risk after either MMRV vaccine or MMR vaccine (between one in 40 and one in 1,000 children with measles experience a febrile seizure) (46).

Results from postlicensure studies do not suggest that children aged 4–6 years who receive the second dose of MMRV vaccine have an increased risk for febrile seizures after vaccination compared with children the same age who receive the second dose of MMR vaccine and varicella vaccine at the same visit (11,17). Prelicensure data indicated that the rate of fever after the second dose of MMRV administered to children aged 15–26 months was lower than after the first dose administered to children the same age as either MMRV vaccine or MMR vaccine and varicella vaccine at the same visit (12).

The evidence suggests that the two vaccine options (MMRV vaccine or MMR vaccine and varicella vaccine) are equivalent in terms of efficacy, effectiveness, immunogenicity, and burden of disease prevented with the first dose. Evidence to date is not sufficient to demonstrate a clear advantage of either option for the first dose in terms of an impact on program implementation. For

[43] Marin M, Broder KR, Temte JL, Snider DE, Seward JF. Use of Combination Measles, Mumps, Rubella, and Varicella Vaccine -- Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010 May 07; 59(RR-03): 1-12 [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5903a1.htm].

> the second dose, routine use of MMRV vaccine has the potential to increase second-dose varicella vaccine coverage and thus have a greater impact on controlling varicella disease than MMR vaccine and varicella vaccine, particularly in states that lack school-entry requirements for a second dose of varicella vaccine."

Thus, even though recommending MMR with a separate Varicella vaccination cuts the risk of febrile seizures in half when the first doses of these vaccines are given separately (an "approximately twofold increased risk" ... "with the first dose of MMRV vaccine compared with those who receive the first dose with MMR vaccine and varicella vaccine"), the CDC clearly refuses to only recommend that option.

Apparently not desiring to cut into Merck's MMRV sales or disclose the true nature of this increased risk, the CDC refuses to place reducing the risk to the health of the children first.

To justify this craven decision, the CDC's recommendations state,

> "the two vaccine options (MMRV vaccine or MMR vaccine and varicella vaccine) are equivalent in terms of efficacy, effectiveness, immunogenicity, and burden of disease prevented with the first dose".

This cleverly crafted statement does not even mention "safety".

Thus, *with respect to febrile seizures*, the CDC admits that giving MMRV vaccine, a combination quadrivalent live-virus vaccine, to initially healthy children as their early childhood vaccination is significantly less safe (by about a factor of two) than giving the corresponding combination trivalent live-virus MMR vaccine and a monovalent live-virus varicella vaccine, in separated injection locations on the same day, but takes no action to reduce the risk of these serious, and in some instances, life-threatening, febrile seizures.

If the safety of our children's health were the CDC's top priority, then, *at a minimum*, the CDC's position would have been to recommend separate MMR and varicella vaccinations for the first inoculation.

However, the CDC did not take the safer position probably because stating that preference could alert parents and guardians to the reality that giving the MMR and varicella vaccines separately is safer than giving the MMRV vaccine – as Dr. DeStefano's answer affirmed.

Moreover, though there is a slight elevated risk for febrile seizures during the second vaccination window, the CDC simply dismissed that risk because the "routine use of MMRV vaccine has the potential to increase second-dose varicella vaccine coverage and thus have a greater impact on controlling varicella disease than MMR vaccine and varicella vaccine, particularly in states that lack school-entry requirements for a second dose of varicella vaccine".

Further, the CDC's remarks indicates that it knows that multiple inoculations with a live varicella-containing vaccine, which, as all live-virus inoculations do, infects all of the inoculees with the desired live "vaccine strain" virus(es) [and any viral contaminant(s)] that the vaccine may contain, and spreads the vaccine strain of this virus and any contaminating virus(es) across the USA, are only "controlling varicella disease" — not eliminating it.

Moreover, based on the CDC's recommendations, it is clear that the CDC is less interested in protecting the health of our children than it is in protecting and promoting the vaccines it recommends and the vaccination programs it has devised because its recommendations are designed to obscure and justify the increased risk of "febrile seizures" associated with the MMRV vaccine as compared to separate-location, same-day MMR and varicella inoculations.

Worse, the CDC's recommendations for MMRV vaccine use also knowingly ignore this federal agency's statutory mandate, through a legal binding, unconditional mandate placed on the federal official to whom the CDC reports, the Secretary of Health and Human Services ("Secretary"), to (emphasis added):

> "make or assure improvements in ... use instructions ... of vaccines ... in order to reduce the risks of adverse reactions to vaccines."[44,45].

Hopefully, after verifying the preceding realities, the readers will demand that the CDC's priorities be changed to placing the minimization of each child's risk of febrile seizures above protecting and promoting the MMRV vaccination program.

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[44] As set forth in 42 U.S.C. Section 300aa-27(a) (emphasis added),

"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."

[45] Given the preceding mandate, with which the FDA is also legally bound to comply, it is obvious that, bound by the mandate to "make or assure improvements in ... the licensing ... of vaccines ... in order to reduce the risks of adverse reactions to vaccines, the FDA should not have licensed the MMRV vaccine because it plainly increased, rather than reduced, the "risks of adverse reactions to vaccines". Given this reality, all parents should be immediately demanding that: **1)** the license for the MMRV vaccine be revoked; **2)** those officials in the CDC and the FDA who are responsible for this ongoing violation of the law be appropriately sanctioned; **3)** the MMRV be removed from the vaccines covered by the National Vaccine Injury Compensation Program (NVICP); **4)** all doses of the MMRV vaccine be recalled by the FDA; **5)** the date for filing any civil litigation alleging post-vaccination-associated injury from an MMRV inoculation be tolled from the date the MMRV vaccine was covered by the NVICP for a period of *not less than* 25 years, and **6)** all plaintiffs alleging a vaccine injury from an MMRV inoculation be granted standing, the right of discovery in any state, and the right to pursue class-action standing for those whose injuries have a common pattern of onset and progression.

However,

- IF the CDC and the FDA cannot be convinced to put reducing our children's risk of febrile seizures above protecting and promoting vaccines and vaccination programs,
- THEN, at a minimum, all parents should unite and demand that the liability protections, afforded to the vaccine makers of, and those who administer, the MMRV vaccine and any other combination vaccine for which the combination increases rather than reduces the risks of adverse reactions, as set forth in the National Childhood Injury Protection Act of 1986 (NCIPA), as amended, should be stricken.

Moreover, the statute amending the NCIPA should contain language that allows class action lawsuits and restores the right of each apparently vaccine-injured person, who has not been compensated by an award by the administrative "vaccine court" system, to file a civil lawsuit for damages in a state court, with a tolled 45-year filing window in addition to any state's normal filing limitations, so that both those who administer such vaccines and those who market them can again be held civilly liable for the increased harm their knowing actions may have caused to any child or other person who has been or is injured by any such combination vaccine.

"**How will I know if my child is having a bad reaction?**

If it's any unusual condition such as a high fever [over 100], weakness, or behavioral changes that are particularly concerning to the parent, such as the child is unresponsive … the ones to really look out for are signs of a serious allergic reaction, and these can include difficulty breathing, hoarseness or wheezing, hives, weakness, a fast heartbeat, or dizziness.

They should call the doctor and get to the [child's] personal doctor right away."

Recognizing "*bad reactions*"

While Dr. King has no issue with the "*such as*" conditions that Dr. DeStefano lists, Dr. King is surprised that that list did not include, for example, rigidity, prolonged ear-piercing crying, loss of coordination or gait disturbances, projectile vomiting, bloody diarrhea, and syncope (fainting).

However, Dr. King would advise a parent or guardian, who sees that his or her child ***may*** be having a serious adverse reaction to a vaccination, to call "911", *when that option is available,* or, *when*

"911" is not available, arrange to transport his or her child in distress to the nearest emergency care facility.

The parent or guardian can then:

a. Call the doctor after arranging the child's transport to the nearest emergency care facility so that that child may get the emergency care, which a child, who is truly having a serious adverse reaction to a vaccine inoculation that the child has received, often requires as soon as possible, and

b. Notify the doctor about the name and location of the emergency care facility to which the child is being transported.

"**If your kid is sick, should you get vaccinated or wait?**

A child with a mild common illness such as a cold or a low-grade fever does not have to wait to be vaccinated. It is preferable to delay vaccination for a child with a more severe illness.

If they have just the sniffles or mild diarrhea, it would be OK to vaccinate."

The precautionary principle: Wait, do not vaccinate sick kids

Since vaccines should only be administered to healthy children with no illnesses and even medical healthcare practitioners cannot know for certain whether an apparently common illness or low-grade fever is a minor problem or is signaling the onset of a serious medical condition, it is generally less risky to postpone the vaccination of:

a. A young child who cannot tell you how he or she is actually feeling about what appears to be a "*mild common illness*" that the child has, or, for that matter,

b. An older child who can be asked about how he or she feels,

regardless of the practitioner's, the parent's or the older child's feelings about the prognosis of what seems to be "*the sniffles or mild diarrhea*".

Thus, as a parent who has been there and now a grandparent, Dr. King would suggest erring on the side of caution and postponing a vaccination would be preferable to vaccinating a child who is not well.

"**If my child is taking medications on a regular basis, such as for ADHD, or steroids, are there interactions with vaccines I need to be concerned about?**

The parent should consult with their health care provider before getting that vaccination. But in general the commonly used medications, including those for ADHD, are not known to have powerful interactions with vaccinations.

Short-term steroid therapy is usually not a contraindication to administer live virus vaccines. … There's no evidence of increased severity of reactions to live attenuated vaccine that's been reported among people receiving corticosteroid therapy by aerosol … so that sort of therapy is not a reason to delay.

Higher doses or longer-term treatment, someone probably being treated for a fairly chronic or severe medical condition, should consult with their health care provider before being vaccinated."

Vaccinating medicated children

When it comes to medications given to a less-than-healthy child, only the healthcare providers who are taking care of that child and that child's parent(s) or guardian(s) should be involved in making such decisions.

Even the initial safety studies in healthy children for vaccination outcomes are deficient because: **a)** the requisite preclinical testing required to establish that the candidate vaccine formulation is neither carcinogenic or mutagenic nor, for vaccines given to children and adults of reproductive age, causes any direct or, in the case of pregnant women, indirect reproductive toxicity, including loss of fertility or impaired reproductive capability, before that vaccine formulation is administered to any human; **b)** there are generally no true placebo (i.e., sterile, pH-balanced, isotonic saline containing a low level of glucose for injectable vaccines or just sterile, isotonic pH-balanced saline for vaccines that are administered orally or squirted up the nose) comparison groups included in the phase 3 studies of the vaccine; **c)** the comparative safety studies that are conducted are neither double-blind nor do the studies last for an extended period (e.g., *not less than* the period over which the vaccine is supposed to provide disease protection or 10 years, whichever is longer); and **d)** those "phase 3" clinical safety studies for vaccines to be given to children and/or adults in the USA studies are not conducted in US-population-representative subjects with *not less than* 30,000 subjects in the vaccine-test group and 30,000 subjects in a true-placebo group in the study to enable valid estimates of the incidence for rare adverse reactions (e.g., anaphylaxis and Guillain-Barré syndrome).

Further, except for short-term "phase 4" (post-approval) monitoring studies, there are few, or no, vaccination-outcome studies in less-than-healthy children.

Additionally, besides taking some medication on a "long-term" basis, such less-than-healthy children may have a variety of health is-

sues that preclude generalizations about whether a given child may or should be inoculated with a given vaccine.

Thus, all that Dr. King can agree with Dr. DeStefano is,

"*The parent should consult with their health care provider before getting any vaccination*".

Moreover, such decisions should be made in a consultation with the parent(s) or guardian(s) of the child by the healthcare provider(s) who is(are) most knowledgeable with the child's medical history and *current* medical condition.

"**My child has a weakened immune system. Is it safe to vaccinate?**

Again, it depends on the level of weakened immunity. If the child has leukemia or other types of cancer, or AIDS, they should not receive vaccines with live weakened or live attenuated vaccines. Examples of these include measles, intranasal influenza. Obviously**,** any decisions … should be made on a case-by-case basis in consultation with the child's doctor.

We are talking about live vaccine. … Most of the other vaccines are inactivated. Inactivated vaccines can be administered safely to persons with altered immunocompetence.

Vaccinating children with compromised immune systems

Again, absent an intimate knowledge of the child's current medical condition and his or her medical history and, if at all possible, the medical histories and conditions of the parents and other family members, Dr. King thinks that no medical professional other than those who care for such children and their parent(s) or guardian(s) should make any decision as to whether to administer a given vaccine to children who have "*a weakened immune system*".

Therefore, Dr. King would suggest that Dr. DeStefano should have answered this question with,

"*The parent should consult with their health care provider and, after weighing the known risks, the theoretical benefits, and the medical history of the child and the family, decide whether to permit a given vaccine to be given to the minor child who has a weakened immune system*",

and said nothing more.

"SOURCE: Frank DeStefano, MD, MPH, director, immunization safety office, CDC."

This statement confirms that Dr. DeStefano was the source for the answers presented.

Dr. King's closing remarks

Hopefully, after reading this in-depth response to Dr. DeStefano's answers and studying the supporting references that this response provides, all will, at a minimum, understand that the admonitions, propaganda, and "evidenced based" claims about vaccines, vaccination and their "benefits and theoretical risks" have little to do with the intrinsic safety, disease-prevention effectiveness, and medical cost-effectiveness of any of the current vaccination programs.

Moreover, Dr. DeStefano's answers seem to be designed to support and defend the current vaccination practices that are:

a. Continually drifting toward a growing and increasingly coercive one-size-fits-all vaccination program with more vaccines and doses of vaccines being added to that program;

b. Increasingly less concerned about the safety, effectiveness and cost-effectiveness of those vaccines; and

c. Even less concerned about protecting the health of those to whom said vaccines are being administered as well as, *for the live-virus-containing vaccines or vaccines that can create silent disease carriers*, the health of all those persons who interact with those who have recently been vaccinated.

Thus, hidden behind today's vaccine apologists' and acolytes' misleading answers, mantras, slogans, propaganda and "tobacco science" studies is the reality that the current ever-growing and enlarging childhood and, increasingly, adult vaccination programs have everything to do with, *at any cost*, growing mass vaccination programs for the profit of the Establishment at the expense of the long-term health and prosperity of the people.

Acknowledgements

For contributing valuable insights and providing their personal experience-based knowledge in various areas, Dr. King thanks Mayer Eisenstein, MD, JD, MPH; Gary S. Goldman, PhD; Boyd E. Haley, PhD; Melissa and Doug Troutman; Eileen Dannemann; Brian Hooker, PhD; Janet K. Kern, PhD; Catherine J. Frompovich; Neil Z. Miller; Mark R. Geier, MD, PhD; and David A. Geier.

In addition, Dr. King specifically thanks Catherine J. Frompovich, Melissa Troutman, Gary S. Goldman, and Eileen Dannemann for their support, suggestions, corrections and alternate wordings that helped

him to finalize this response.

About the Answer Provider, Frank DeStefano, MD, MPH

Source: http://www.medscape.com/viewarticle/812044

"Frank DeStefano, MD, MPH, is Director of the Immunization Safety Office of the Centers for Disease Control and Prevention (CDC). He is a graduate of Cornell University and the University of Pittsburgh School of Medicine. He received training in public health and preventive medicine in the Epidemic Intelligence Service and preventive medicine residency at CDC. He obtained a master of public health degree at Johns Hopkins University School of Hygiene and Public Health. He has had extensive epidemiologic research experience at CDC, the National Institutes of Health, and at nongovernmental research organizations. His areas of research have included immunizations, autism and other developmental disabilities, reproductive health, veterans' health, diabetes, cardiovascular diseases, and other chronic diseases. Dr. DeStefano is an author on over 150 publications in leading scientific and medical journals. For the past 16 years, Dr. DeStefano has had a focus on vaccine safety."

About the Responder, Paul G. King, PhD

In addition to the information that is available on his Internet web site, http://www.dr-king.com/, Dr. King is the Science Advisor to the Coalition for Mercury-Free Drugs (CoMeD, Inc., which is a 501(3)(c) not-for-profit corporation (http://www.mercury-freedrugs.org/) as well as the Science Advisor to the National Coalition of Organized Women (NCOW).

As a scientist and student of the federal regulations and statutes that govern pharmaceutical drugs, including vaccines, Dr. King has led CoMeD, on two separate occasions, in the drafting and submission of a "citizen petition" seeking to have the federal government comply with the law, and, based on the improper denial of the citizen petition submitted, a federal lawsuit seeking to have the Federal District Court for the District of Columbia compel the Secretary of the Department of Health and Human Services (DHHS) and the FDA Commissioner to comply with the statutes, laws (regulations) and policies that regulate the lawful conduct of the DHHS Secretary, the FDA Commissioner and CDC and FDA officials.

Further, Dr. King has, on several occasions, drafted legislation for submission to the Congress of the USA as well as to the legislatures of various States, submitted cogent comments in opposition to proposed changes to federal and state regulations that are not in the public interest or appear to be at odds with the law, reviewed numerous

documents, and written articles on a multiplicity of vaccine-related and other issues.

Moreover, he has provided diverse groups with his analysis of various Congressional bills, resolutions and treaty documents as well as federal and state judicial proceedings.

In addition, he has been an author of papers bearing on issues related to the toxicity of Thimerosal and other compounds and, if any, their connection to a range of chronic neurodevelopmental, other developmental and behavioral abnormalities that appear to be well-above (> 1 in 10 children; asthma and obesity), above (> 1 in 100 children; the autism spectrum disorders), at (> 1 in 1000 children; non-genetic childhood type 1 diabetes), or approaching (peanut allergy) epidemic childhood levels in the USA.

More recently, Dr. King was the co-author of a paper in the journal ***Vaccine*** with Gary S. Goldman, PhD that reviewed the United States universal varicella vaccination program[46].

This paper established that the current CDC-recommended two-dose vaccination program was neither truly effective in preventing all of those who are twice vaccinated from getting chickenpox nor, since it greatly increases the public's risk of having clinical cases of shingles, even societally cost-effective for universal use.

Finally, Dr. King was also one of the authors of a paper in the ***Int. J. Environ. Res. Public Health***, where the lead author was Janet K. Kern, PhD. This paper reviewed Thimerosal exposure and the roles of sulfation chemistry and thiol availability in autism[47].

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46 Goldman GS, King PG. Review of the United States universal varicella vaccination program: Herpes zoster incidence rates, cost effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data. *Vaccine* 2013 March 25; 31(13): 1680-1684 (open access) [http://www.sciencedirect.com/science/journal/0264410X/31/13, article "6"].

47 Kern JK, Haley BE, Geier DA,Sykes LK, King PG, Geier MR. Thimerosal Exposure and the Role of Sulfation Chemistry and Thiol Availability in Autism [Review]. *Int. J. Environ. Res. Public Health* 2013 Aug, 10, 3771-3800, which can be downloaded from http://www.mdpi.com/1660-4601/10/8/3771/pdf.

Appendix A

Copy of submitted abstract,

"Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life",

as provided to Dr. Brian S. Hooker by a U.S. House of Representatives' office from a CDC response to a Congressional Request, where the document was labeled as "**File 10 25 of 334**", indicating that this document was page 25 of 344 in "File 10"

"File 10 25 of 334

Verstraeten, Thomas M., MD, NIP, Division of Epidemiology and Surveillance, Vaccine Safety and Development Branch, Mailstop E-61, 770-639-8327.
EIS Class Year of Entry: 1999
No previous EIS Conference presentations
Mackel Award consideration: No
Number of abstracts submitted: 2, priority this abstract: **1**
Strong preference for poster presentation: No

Thomas M. Verstraeten, R. Davies, D. Gu, F DeStefano

Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.

Background: Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. We assessed the risk for neurologic and renal impairment associated with past exposure to thimerosal-containing vaccine using automated data from the Vaccine Safety Datal ink (VSD). VSD is a large linked database from four health maintenance organizations in Washington, Oregon and California, containing immunization, medical visit and demographic data on over 400,000 infants born between '91 and '97.

Methods: We categorized the cumulative ethylmercury exposure from thimerosal containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six. We applied proportional hazard models adjusting for HMO, year of birth, and gender, excluding premature babies.

Results: We identified 286 children with degenerative and 3702 with developmental neurologic disorders, and 310 with renal disorders. The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8-31.5), non organic sleep disorders (RR 5.0, 95% CI = 1.6-15.9}, and speech disorders (RR 2.1, 95% CI = 1.1-4.0). For the neurologic degenerative and renal disorders group we found no significantly increased risk or a decreased risk.

Conclusion: This analysis suggests that high exposure to ethyl mercury from thimerosal-containing vaccines in the first month of life increases the risk of subsequent development of neurologic development impairment, but not of neurologic degenerative or renal impairment. Further confirmatory studies are needed.

Word count: 271 (allowed: 275)"

Appendix B

Annotated excerpts from ACIP meeting on 27-28 October 2010,

"Influenza Vaccine"

Source: http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-oct10.pdf

Pg 175 mid-page –

"Influenza Vaccine Safety Monitoring Update
Tom Shimabukuro, MD, MPH, MBA
Immunization Safety Office
Division of Healthcare Quality Promotion,
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Dr. Shimabukuro reported that the seasonal influenza vaccine for 2010-2011 is comprised of A/California/7/2009 (H1N1)-like virus strain, A/Perth/16/2009 (H3N2)-like virus strain, and B/Brisbane/60/2008-like virus strain. There is a universal recommendation for influenza vaccine for all people ages 6 months and older. High dose inactivated influenza vaccine has been approved for people aged 65 years and older. As of October 15, 2010, approximately 139 million doses of influenza vaccine have been distributed in the US.

CDC and FDA staff recently published a paper describing 2009 H1N1 influenza vaccine safety based on the VAERS monitoring system [Vellozzi C, Broder K, Haber et al. Vaccine. doi:10.1016/j.vaccine. 2010.09.021]. VAERS received approximately 10,000 reports after 2009 H1N1 vaccine for persons vaccinated during the first 4 months of the vaccination program. Of these reports, 93% were non-serious. The reporting rate was higher after 2009 H1N1 vaccines than 2009-2010 seasonal influenza vaccines, which may be due to stimulated reporting. Death, Guillain-Barré syndrome, and anaphylaxis reports after 2009 H1N1 vaccination were rare, with each no higher than 2 per million doses administered. The adverse event reporting profile after 2009 H1N1 vaccines was consistent with that of seasonal influenza vaccines [Vellozzi C, Broder K, Haber et al. Vaccine. doi:10.1016/j.vaccine. 2010.09.021].

With respect to the Vaccine Safety Risk Assessment Work Group summary of 2009 H1N1 vaccine safety, ACIP was briefed on the NVAC report on 2009 H1N1 vaccine safety risk assessment in June 2010. There was a weak signal for Guillain–Barré Syndrome (GBS) in the Emerging Infections Program (EIP) data. A weak signal was detected for Bell's Palsy in the

VSD and the Indian Health Service (IHS) database. The signal in the VSD has since been ruled out. There was a weak signal for TP / ITP in the Defense Medical Surveillance System (DMSS), Department of Veterans Affairs (DVA), and the IHS databases. Further work is on-going and the final end-of-season analysis for 2009-2010 will be presented to the NVAC's VSRAWG in November 2010 [Source: http://www.hhs.gov/nvpo/nvac/reports/vsrawg_repot_may2010.html].

With regard to vaccine safety monitoring for the 2010-2011 influenza season, the VSD currently has sufficient power to detect a relative risk of 5-10 for seizures.

CDC Monitoring systems include the following:

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Real Time Immunization Monitoring System (RTIMS)

- Clinical Immunization Safety Assessment (CISA) Network
- Vaccine Analytic Unit (VAU)

High priority conditions, areas, and enhanced monitoring include GBS; seizures, especially in children aged < 9 years old; narcolepsy; and events associated with high dose influenza vaccine. The VAERS surveillance period for influenza vaccine began in September 2010. VSD rapid cycle analysis (RCA) is underway for influenza vaccine safety monitoring. As of October 10, 2010 there were 424,322 TIV doses and 45,843 LAIV doses in the VSD.

Events in Europe have raised concerns about a possible link between Pandemrix™ and narcolepsy. Pandemrix™ is a monovalent 2009 H1N1 influenza vaccine containing ASO3 adjuvant, which has been used widely in Europe during 2009-2010. No adjuvanted influenza vaccines have been used in the US. The European Medicines Agency recently reviewed available data and concluded that the available evidence was insufficient to confirm a link and suggested that further studies would be necessary. The European Centre for Disease Prevention and Control (ECDC) is funding the VAESCO network, which is similar to the VSD project, to conduct further research to examine the possible link between Pandemrix ™ and narcolepsy. The VAESCO network, coordinated by the Brighton Collaboration, is finalizing a case definition for narcolepsy along with partner researchers. The 2010-2011 seasonal influenza vaccines in Europe are unadjuvanted.

Comprehensive influenza vaccine safety monitoring in VAERS during the 2009-2010 influenza vaccination season yielded no signals for narcolepsy or cataplexy, which frequently accompanies narcolepsy and aids in its diagnosis. Enhanced monitoring was put in place in VAERS and VSD for the 2010-2011 influenza season. As of October 22, 2010, no reports of narcolepsy or cataplexy following 2010-2011 seasonal influenza vaccines had been submitted to VAERS.

Febrile seizures have not been associated with influenza vaccines in previous seasons. There have been no special concerns for the 2010-2011 influenza season, with the exception of CSL vaccine in children aged < 9 years. CDC implemented enhanced monitoring for seizure following receipt of 2010-2011 seasonal influenza vaccine in VAERS and VSD. The working hypothesis for CSL is that neuraminidase appears to be higher in the H1N1 strain used in the 2010 seasonal influenza vaccine used in the Southern Hemisphere (Australian Therapeutic Goods Administration, Oct 8, 2010). VAERS reports of febrile seizures for the 2010-2011 influenza season from July 1 through October 15, 2010 include 2421 total adverse event reports following influenza vaccine. Among these are 25 reports of possible seizure in children < 9

years of age, with 13 confirmed febrile seizures all in those < 5 years of age, none with CSL vaccine, 2 indeterminate, and 2 pending further review. The remainder were ruled out as febrile seizures. The take-home message thus far is that automated data review and clinical review of cases do not indicate a signal in VAERS for febrile seizures following receipt of influenza vaccine in children aged < 9 years. As of October 11, 2010 a total of 16,513 doses of TIV have been administered to children < 5 years of age, with 0 cases of seizures observed within 0-1 days of vaccine administration.

Moving to high dose Fluzone® pre-licensure data, the following is a table from the package insert reflecting a side-by-side comparison of injection site reactions and systemic adverse events for high dose Fluzone® versus regular Fluzone®:"

<Figure not included in excerpt>

"http://www.fda.gov/downloads/biologicsbloodvaccines/.../ucm195479.pdf [Note: This link is invalid.]

There is a slightly elevated risk for injection reactions and systemic adverse events for the high dose Fluzone®. As of October 15, 2010, VAERS had received 258 reports after high dose Fluzone®, of which 94% were coded as non-serious. Adverse events reported in VAERS after high dose influenza vaccine were consistent with those that are clinically expected adverse events (e.g., fever and headaches). As of October 11, 2010, approximately 700 high dose Fluzone® doses had been administered in the VSD system, with 0 anaphylaxis cases observed.

Early in the season, concern was expressed from a large vaccinator that they were observing some increase in anaphylaxis. Once those reports were submitted to VAERS and were analyzed, this concern was eliminated but continues to be monitored.

Discussion Points

With respect to vaccine safety, Dr. Katz (IDSA) asked what procedures were in place or are being planned to monitor vaccine safety in pregnant women.

Dr. Shimabukuro replied that for 2009 H1N1 vaccine, there was enhanced monitoring for vaccine adverse events in pregnant women who were considered to be a priority group. Reports of spontaneous abortion and stillbirths would be expected by change. CDC has a manuscript in clearance detailing these data, the bottom line of which is that there were roughly 344 reports, of which 149 were spontaneous abortion and 21 were stillbirths. The message is that a review of VAERS reports in pregnant women who received H1N1 vaccine revealed no unexpected patterns or unusual events. A paper was recently published by Dr. Pedro Moro that assessed adverse events in VAERS from 1990 through June 30, 2009 that found no patterns of adverse event reports in pregnant women [Moro PL, Broder K, Zheteyeva Y, et al. Adverse

events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009. Am J Obstet Gynecol 2010; 203: xx-xx]. VAERS continues to monitor for adverse events in pregnant women. There are currently VSD studies underway that are examining this issue as well.

Dr. Meissner requested that Dr. Uyeki make a statement about the current status of cell culture based influenza vaccine.

Dr. Uyeki responded that while there are tissue cell culture influenza vaccines approved for use in Europe, none are approved for use in the US. Some recent data have been published on this, and he asked that manufacturers add comments if they wished.

Dr. Lewin (Novartis) added that the Novartis cell culture vaccine is licensed in Europe and is undergoing Phase 3 trials in the US. Novartis expects to file for licensure in the first half of 2011.

Dr. Baker inquired as to whether these trials are based on serologic correlates or efficacy.

Dr. Lewin (Novartis) responded that some Phase 3 efficacy data compared to a comparator egg vaccine have been published in Europe, which was scheduled to be presented to the ACIP Influenza Vaccine Working Group the week follow this meeting.

Dr. Katz (IDSA) pointed out that each year they are told that vaccine expires by June after it has been distributed in the fall. He wondered whether there were any data to show that immunogenicity and potency have actually diminished during that timeframe.

Dr. Schuchat reminded everyone that there were several recalls for potency declines during the course of the last season, which is an example of things changing over time.

Dr. Keitel pointed out that the manufacturers should be prepared to address the issues of ongoing potency. The supposition typically is that vaccine retains potency through that period, and likely contains adequate potency for periods after that timeframe. However, they expire because usually there is at least one antigen that changes in the vaccine from year to year. The potency would still have to be checked in an on-going fashion.

Dr. Baker noted that a common question from the public pertains to how long the vaccine will protect them if they are vaccinated in August. The serology suggests that it will.

Dr. Keitel responded that serum antibody titers decline over time. There is approximately a 50% decline after an inactivated vaccine over a season if not infected; however, higher than prevaccination levels are maintained at least through a year following vaccination.

Dr. Temte said he had heard rumors of a serological survey being conducted for 2009 H1N1, and wondered whether Dr. Uyeki could comment on this.

Dr. Uyeki replied that several serologic surveys are being conducted to assess the rates of 2009 H1N1 virus infection in various populations. The results of the surveys are not yet published.

CDC's Influenza Division laboratory is continuing to work on the sera, but perhaps this information can be presented during the next ACIP meeting or during a subsequent working group meeting.

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Dr. Schaffner (NFID) inquired as to whether Dr. Uyeki could tell them anything more than what appeared in the newspapers about the H1N1 drifted strain in Australia, New Zealand, and Singapore.

Dr. Uyeki clarified that influenza viruses are dynamic and continue to evolve. The antigenic changes are unpredictable. What was reported in *Eurosurveillance* the previous week was that the strains reported in Australia, New Zealand, and Singapore do not represent significant antigenic drift. The 2009 H1N1 virus that emerged as a pandemic virus has actually not significantly changed antigenically since the emergence. This is being monitored worldwide on an on-going basis. There is an expectation that at some point there will be significant antigenic drift, but genetic changes do not necessarily equal antigenic changes. The good news is that the 2009 H1N1 strain that is included the seasonal vaccine, which is the same as last season, is a good match with what is currently circulating.

Dr. Judson asked what was known about efficacy if the same strain circulated two years in a row, but someone was vaccinated the first year and not the second.

Dr. Keitel responded that clearly there is some protection if the same strain circulates two years in a row. The data she is familiar with involves university students who were vaccinated and followed for duration of protection. During a second season and even somewhat into a third season they still had some protection. She thought there were also some data published many years ago that showed protection in children for at least three years against an influenza B strain. There can be some, but it is low. There would be no reason to tell someone not to receive another dose of vaccine for the current influenza season because H1N1 that was provide last season was monovalent. All three viruses are circulating in the US this season.

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"Public Comments", starting on middle of page 182

"…

Dr. Renee Tocco
Hope for Autism

I have no conflicts of interest. I am actually reading a brief statement today on behalf of the National Coalition of Organized Women (NCOW). They actually collected data on miscarriages and stillbirths in pregnant women that occurred after they were administered a 2009 A/H1N1 vaccine. Using the VAERS database as a second ascertainment source, capture / recapture statistical methods were used to estimate the true number of miscarriages and stillbirths following an H1N1 flu vaccination in the US.

Typically, even so-called complete studies conducted by CDC have been shown to miss between 10% to 90% of actual cases because of under-reporting. The capture / recapture estimate, while not 100% accurate, is nonetheless a very cost-effective and rapid way to get a complete count of all cases when 2 or more ascertainment sources have failed to collect all of the existing cases. Overall, this approach shows that only approximately 15% of the occurrences of a miscarriage or stillbirth were actually reported. The ascertainment corrected estimate for the total number of 2009 A/H1N1 influenza-associated miscarriages and stillbirths during the 2009-2010 flu season is 1588 with a 95% goodness of fit confidence interval, meaning that the range probability of miscarriages and stillbirths following H1N1 vaccine is as low as 946 and as high as 3487.

CDC ascertained that there were actually 56 maternal deaths from the H1N1 virus itself. It is assumed that the fetuses, of course, died with mothers. For a majority of these deaths, the actual cause of death was unconfirmed. In other words, despite the ability of CDC to confirm the H1N1 virus as the culprit, the confirming tests were not performed. NCOW has issued a request for the raw data in order to ascertain the co-morbidity factors. To date, that has not been received. Vaccine-related fetal death reports from VAERS increased 2440% from just 7 cases in the 2008-2009 flu season to 178 in the 2009-2010 season.

70 deaths reported from another source had 7 overlapping cases with VAERS, yielding 241 unique cases. According to federal data gathered over 15 years, only a mere 24 adverse events were reported for every million doses of annual flu vaccine amongst all people—men, women, and children.

About 1 million pregnant women were vaccinated in 2009-2010. If the 24 adverse events that were reported for all demographics were assigned solely to the pregnant population, the actual 178 VAERS reports would still be nearly 8 times higher. Simplistically speaking, not vaccinating would have been at the low range 85 times safer for fetus than vaccinating and at a higher range of up to 192 times safer. It may be argued that ACIP and CDC willfully withheld information from vaccine providers that the

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original maternal deaths were mostly unconfirmed and replete with co-morbidity factors. It may be argued that it was an act of gross negligence that ACIP and CDC failed to adequately track the adverse events in the pregnant population. It may be the case that CDC did track VAERS and willfully declined to inform their vaccine providers that there were numerous reports of suspected vaccine-related fetal demise.

In fact, on two occasions Dr. Murray McCormick stated that there were no adverse events reported. Today I believe is the first time that acknowledgement was made of that. Considering the evidence of harm submitted by the NCOW, it could be argued that the current recommendation by the ACIP to vaccinate pregnant women with the seasonal flu shot containing H1N1, [T]himerosal, and two other viral components has now escalated to willful misconduct.

We strongly request that during the 2010-2011 season, all vaccine providers are informed of last season's VAERS report of vaccines in pregnant women. In addition, every pregnant woman who is considering the flu vaccine should be given a CDC vaccine information statement that properly advises of the adverse events reported last year.

Furthermore, the most responsible action would be for ACIP to withdraw its recommendation for pregnant women and strictly adhere to the FDA and manufacturers' warnings. After all, as we all know, the inserts for flu vaccines say that they should not be administered to pregnant women unless they are clearly needed.

On one final note, on behalf of Hope for Autism and also on behalf of an ever growing thousands of parents and healthcare providers, we acknowledge that there is an abundance of evidence showing that our aggressive US vaccination policy is directly related not only to autism but many different chronic childhood illnesses. Despite government and pharmaceutical studies that claim otherwise, currently there are thousands of unvaccinated children in our country. It is an outrage that to date no study has ever been done on these to populations in showing the relative health outcomes. I believe that only when the results of those studies are shown to the public will everything be self-evident. Thank you.

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[Annotations, in red, added by Dr. King in November of 2013]

Slide Presentation [slide 1]

Influenza Vaccine Safety Monitoring Update Advisory Committee on Immunization Practices
October 28, 2010

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion –Immunization Safety Office

Tom Shimabukuro, MD, MPH, MBA
Immunization Safety Office
Division of Healthcare Quality Promotion,
National Center for Emerging and ZoonoticInfectious Diseases
Centers for Disease Control and Prevention (CDC)

...

Extra slides [slide 17]

...

2009 H1N1 influenza vaccine safety: Vaccine Adverse Event Reporting System (VAERS)pregnant women [slide 20]

- Pregnant women were a priority group for 2009 H1N1 vaccine
  - Expected to find reports of spontaneous abortion (SAB) and stillbirths by chance [**Note 1:** Based on review of the fetal-loss reports data in VAERS from mid 1990 to mid 2009, the expected "chance" annual reports for fetal loss associated with a prior influenza vaccination in VAERS should be 5 or fewer (see footnote **18**, Moro, et al. [2011 February]).
- During Oct 1, 2009 –Jun 30, 2010, 3% of 11,230 reports after 2009 H1N1 vaccine submitted to VAERS involved pregnant women who reported an adverse event
  - 344 reports (330 inactivated, 13 live vaccine, 1 unknown type)
  - SAB (N=149; ~43% of all pregnancy reports) [**Note 2:** This analysis left out those pregnant women who were only given an inactivated-influenza seasonal vaccine, but counted those who were reportedly given both seasonal and 2009-A(H1N1) vaccines.]
  - Stillbirths (N=21; ~6% of all pregnancy reports) [**Note 3:** See "**Note 2**".]
    [**Note 4:** As shown at the bottom of this slide, "* Moro PL, unpublished CDC data", Dr. Moro and his fellow researchers are the source of the data, indicating that Moro found a total of 170 fetal-loss reports for pregnant women given an inactivated-influenza 2009 H1N1 inoculation as opposed to a historical ("chance") level of < 6 fetal-loss reports annually.]
- Review of VAERS reports in pregnant women who received H1N1 vaccines revealed no unexpected patterns or unusual events
  [**Note 5:** Either Dr. Moro or Dr. Shimabukuro or both knew that this statement was a misrepresentation or, before the mostly Thimerosal-preserved A (H1N1) 2009 inactivated-influenza vaccines were deployed, the CDC knew that giving it to pregnant women could cause a "40- to 50-fold" increase in reported fetal losses. When the Moro et al. (2011) pandemic influenza safety paper reviewing this data was finally published in 2011, the slide's *knowing* misrepresentation was similar to the conclusion in the published paper's "Abstract": "Review of reports to VAERS following H1N1 vaccination in pregnant women did not identify any concerning patterns of maternal or fetal outcomes" – indicating that the CDC researchers were **not** concerned about the *greater than* 40-fold increase in fetal losses observed in the 2009-2010 flu season over the previous season! Otherwise, the CDC researchers were knowingly covering up these increased reports of fetal loss by inappropriately alluding the pregnant population's background rate ("10%") for "spontaneous abortions" instead of, as they should have compared the reports in the 2009-2010 flu season to the historical reporting rate for such events (1.9 per million doses distributed and not returned), or, for roughly 5,000,000 pregnancies carried to term, *less than* 10 reports per year, on average, provided all pregnant women got a flu shot during pregnancy and actually, *less than* 2.5 per year on average because, overall, *less than* 25% of the women who were pregnant during the flu season were given a flu shot in the 1990-2009 period used to estimate the average annual reports in VAERS.]
- VAERS reporting rates of stillbirths and spontaneous abortions after 2009 H1N1 vaccine were well below background rates
  [**Note 6:** Since Dr. Moro knew that the historical reporting rate in VAERS for "spontaneous abortions" (which were most all {> 80%} of the reports of fetal loss filed in period from August of 1990 through June of 2009) was 1.9 per million doses of inactivated-influenza distributed, Moro knew, or should have known that this statement was intentionally misleading. Based on the historical data, where, on average, there were 2 or fewer flu-shot-related fetal-loss reports to VAERS, the VAERS historical reporting rate was roughly 0.00005% of the average 4-plus-million pregnancies meant to be carried to term annually or 0.0005% of the "10%" of expected fetal losses. Thus, since the reports to VAERS typically reflect from 1 to 10% of all the possible reports, the population of VAERS reportable fetal-loss events must be in the range of from roughly 30 to 600 with an expectation of *no more than* about 22 reports to VAERS for the 2009-2010 flu season for an influenza vaccine based on the TIV fetal-loss reports in VAERS for the 2009-2010 flu season and the 21 similar reports in VAERS for the 2010-2011 flu season. Based on the upper estimate in Goldman (2013) of < 2,800 possible fetal-loss reports for the 2-dose 2009-2010 flu season at an uptake level of about 43% or ~ 6,500 at 100% vaccination. Thus, the population of possible VAERS-listed fetal-loss reports is certainly < 9,000. Even with the inclusion of the 22 and 21 seasonal fetal-losses for the 2009-2010 and 2010-2011 flu seasons, the historical "average" rate for TIV reports becomes about 4 fetal loss reports per year for the 21-flu-seasons' estimate for fetal losses per flu season – reducing the point-estimate for the Signal for the 2009-2010 flu season to 374 – ~ 4 ≈ 370 net fetal-loss reports. **Thus, the number of reports for influenza-vaccination-associated fetal losses in VAERS greatly exceeded the background reports level by *more than* 40-times!**

* Moro PL, unpublished CDC data

Appendix C

Overview of fetal-loss reports in VAERS — July 2006-June 2013

Updated Table Assessing Fetal Losses Following Inactivated-influenza Vaccine Inoculation – July 2006- June 2013

Flu Season [July of a given year through June of the next year]	**Fetal Loss Reports[1] and Influenza Vaccination Coverage Information[2] [For Trivalent Inactivated-influenza Vaccine Inoculation (TIV)[a]]**			
	TIV	**Pandemic** [A (H1N1) 2009]	**Total**	**Vaccine Coverage in Pregnant Women**
2006-2007	1	0	1[a]	Not Assessed
2007-2008	**4**	0	**4**	~ ----- {26%[j]}
2008-2009	**4**	0	**4**[a]	~ **11%** {35%[j]}
2009-2010	**22**[b]	**170**[b]	**174**[a,c,d]	~ **43%** [42%[h]] {38%[j]}
2010-2011 [A (H1N1) 2009 in TIV]	**21**	0	**21**[d]	~ **32%** [45%[i]] {40%[j]}
2011-2012 [A (H1N1) 2009 in TIV]	5	0	5[d]	~ 36.5[e] {42%[j]}
2012-2013 [A (H1N1) 2009 in TIV]	11[f]	0	11	~ 35.9[g]

[1] Data values in **bold** were taken from Goldman (2013); all uptake percentages are highly uncertain because sample size is generally *much less than* 0.5%, and *generally less than* 0.025%, of the population of pregnant women (~ 5 to 5.2 million per year).

[2] Until the 2010-2011 flu season, all estimates were generally for pregnant women getting influenza vaccine – not for pregnant women getting influenza vaccine during pregnancy.

[a] Excludes 1 or more reports where the live attenuated influenza vaccine was inappropriately administered.

[b] Includes 18 reports where both TIV and Pandemic were administered

[c] Only counts the 18 reports (where both TIV and Pandemic were given) once to avoid inflating actual number of reports in VAERS.

[d] Includes at least 1 report of stillbirth

[e] Uptake in pregnancy for 2011-2012 flu season: 36.5% [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6138a2.htm?s_cid=mm6138a2_w]

[f] Original 16 reports reduced to 11 by removing 1 LAIV report, 1 fetal serious chromosomal abnormality, and 3 reports with a miscarriage onset before vaccination

[g] Uptake in pregnancy for 2012-2013 flu season: 35.9% [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6238a3.htm?s_cid=mm6238a3_w]

[h] Average uptake for pregnant women during the 2009-2010 season TIV & Pandemic: 42.0% [http://www.cdc.gov/flu/fluvaxview/prams-flu-vaccination.htm]

[i] Uptake in pregnant women for 2010-2011 flu season [http://www.cdc.gov/flu/pdf/fluvaxview/dinginternetpanelsurveypregnantwomen.pdf]

[j] Survey, Behavioral Risk Factor Surveillance System (BRFSS), estimates for pregnant women getting seasonal influenza vaccination in 2007-2008, 2008-2009, 2009-2010, 2010-2011, and 2011-2012 [http://www.cdc.gov/mmwr/pdf/ss/ss6204.pdf, data values interpolated from "FIGURE 8".]

Based on the data in the preceding table, for audited reports where only those for which the vaccine given was probably an inactivated-influenza vaccine and reports where the onset of the fetal loss occurred after the vaccine was administered for which there was no definitive reason (severe genetic abnormality or acute disease in, or injury to the pregnant mother), the current "background" level for audited inactivated-influenza reports in VAERS for a given influenza "year" is about "12" fetal-loss reports [based on the integer average of the reports for the 2010-2011, 2011-2012, and 2012-2013 flu seasons].

Further, based on this background level and the fact that vaccine coverage is roughly 40% of the pregnant women, the threshold for a "fetal loss" signal in VAERS can be conservatively set at three times the current average "background level of fetal-loss reports or "36 fetal-loss reports".

Using this "36 reports" threshold, going forward, a "VAERS fetal-loss signal" will be any audited aggregate of inactivated-influenza-vaccination-associated fetal-loss reports in a given flu season in VAERS that exceeds "36" such fetal-loss reports.

In any given flu season, a count of 37-49 fetal-loss reports should be classified as a "weak signal; a count of 50-74 reports per flu season should be classified as a moderate signal; a count of 75-99 reports should be classified as a strong signal, and counts of 100 or

more fetal-loss reports in a given flu season should be an emergency signal, requiring immediate action to be taken to suspend the administration of any flu vaccine that has generated 100 or more fetal-loss reports for the season.

Since there is no direct correlation between the number of fetal-loss reports and the estimated coverage level for pregnant women who received an inactivated-influenza vaccination during pregnancy, this threshold has been set high enough that neither fluctuations in the reporting rate to VAERS, which appeared to have occurred in the July 2009 through June of 2011, nor increased coverage, which jumped from the "25% or less" level in the period from 1990 through June of 2007 to the "roughly 40%" level in the July 2009 through June of 2013, should be able to generate a false VAERS "signal" .

Finally, using the "36-reports threshold", in the 2009-2010 flu season, the signal in VAERS exceeded this inactivated-influenza-vaccination-associated-reports threshold by roughly a factor of five.

Looking at the flu seasons after the 2009-2010 flu season where the A (H1N1) 2009 influenza virus was incorporated into the seasonal influenza vaccine, clearly neither its administration nor increased reporting accounted for the increased reports to VAERS in the 2009-2010 flu season.

This leaves Thimerosal, specifically the double dosing with a Thimerosal-pre-served inactivated-influenza vaccine that *more than* half of those pregnant women who were given both a seasonal and a pandemic inactivated-influenza vaccine during the 2009-2010 flu season, as the probable causal factor in *more than* 138/174 = 79% of those fetal-loss reports filed in VAERS where the vaccines were administered in the July 2009-June 2010 period.

Since this the number found exceeds the threshold established by *more than* a factor of 2, (174/36 = 4.8333), the effect is not a direct 2x effect but rather a threshold effect.

This effect arose because, in general, pregnant women, who chose to be vaccinated during the 2009-2010 flu season first received a Thimerosal-preserved seasonal vaccine dose because the distribution of the seasonal vaccine stated ahead of the distribution pandemic [A (H1N1) 2009].

Then, in the 2009-2010 influenza season, most of the pregnant women for whom fetal loss reports were filed were subsequently administered the pandemic influenza vaccine (in about 152 instances) or, if they had not had the seasonal influenza vaccine, were given both at the same time (in about 18 instances).

Since the VAERS reports were initiated after the vaccination most closely associated with the fetal loss and are not designed to capture the patient's prior vaccination history, the filed VAERS reports only reflect the last influenza vaccination(s) given, the reports misleadingly appear to indicate that the causal factor was the pandemic influenza vaccine.

However, based on the surveys covering the 2000-2010 flu season that were conducted by various federal agencies and an independent vaccine-safety advocate others found that most pregnant women, who were given a pandemic influenza vaccination, had received both the pandemic and the influenza vaccines during their pregnancy or, by mistake, received two seasonal or two pandemic Thimerosal-preserved vaccine doses[17].

Thus, the second doses of Thimerosal increased the mercury toxicity sufficiently to cause the fetal-loss level (174) to exceed: the previous season's level (4) by *more than* a factor of 40 or the 36-reports threshold by roughly a factor of 5.

Therefore, these updated findings continue to indicate that the injection of Thimerosal-preserved influenza vaccines into pregnant women was significantly toxic to the developing child, who she was carrying, to the point that two doses were sufficient to cause fetal death in some developing fetuses, who are exposed to that double dose.