

# Facility Automation Management Engineering (FAME) Systems

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Friday, 28 November 2008

To All:

The text following this page is a draft response to: “**Vaccines: Separating fact from fiction**”, by Walt Larimore, MD, which was downloaded on 8 November 2008 from:

<http://www.drwalt.com/blog/2008/11/05/vaccines-separating-fact-from-fiction/>.

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This formal response, which is titled: “**A Draft Response To: ‘Vaccines: Separating fact from fiction’**”, begins on the next page.

## Introductory Remarks

First, to “*simplify*” this response, when portions of the article being reviewed are addressed in the review, the statements in this report will be quoted in a “Times New Roman” font.

Second, remarks by this reviewer, Paul G. King, PhD, will be presented in indented text following the section of the article that is being reviewed.

In addition, this reviewer’s remarks and suggested changes will be in a **dark blue** “News Gothic MT” font except, when he quotes: **a)** from or refers to any federal statute or regulation, the text will be in a “Lydian” font or **b)** from other sources, the quotations will be in an “Arial Narrow” font.

When this reviewer quotes from statements made in the author’s article, this reviewer will use an *italicized* “Times New Roman” font; suggested corrections, *if any*, will be made in **red**.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and revise his views and the final response.

Respectfully,

<ds>

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[To whom all inquiries should be directed]

## A Draft Response To: “Vaccines: Separating fact from fiction”

### INTRODUCTION

Lest any take this reviewer's responses as those of someone who is anti-vaccine, this reviewer again reiterates that, *given the scientific information available*, he currently supports national vaccination programs for those vaccines that have truly been proven to be both generally safe and, *at least*, societally cost-effective, provided the individual parent's, guardian's, or competent citizen's constitutional right to "due process of law" is neither abridged nor ignored.

Having made clear his position as an advocate for:

- a. Banning the use of mercury compounds in medicine to safen vaccines,
- b. Vaccine safety, and
- c. Medically cost-effective vaccines,

this reviewer will now respond to the statements made in this article by “*Dr. Walt*”.

“When it comes to the arguments about the safety of vaccines, what’s a worried mom to do? Between the scary claims about shots themselves and the scary news about what can happen without them, you might feel like you need a Ph.D. in immunology, toxicology, and biostatistics to make sense of it all. Never fear, Dr. Walt is here. The bottom line: No medical intervention is 100 percent risk-free, and no one but you can choose what’s right for your child. My job is to help that decision come a little easier, so here goes:”

The author begins by stating some general concerns that a “*worried mom*” might have in the context of his view of the current situation.

Yet, he proposes to calm these moms’ fears by providing the reader with his views on vaccines (“*Never fear, Dr. Walt is here*”).

Then, the author begins with a standard medical “*bottom line*” disclaimer worthy of the Surgeon General: “*No medical intervention is 100 percent risk-free*” to which he appends a generalization, “*no one but you can choose what’s right for your child*”.

Unfortunately, his generalization glosses over the reality that, *in the area of vaccination*, your states’ public health officials, and not “*you*”, have dictated your vaccination options by mandating that your child receive certain vaccinations (while providing some sort of medical, religious [in 48 states and the military], and, *in about 18 to 20 states*, providing some form of a conscientious/philosophical exemption) by certain times as a pre-condition for your being able to send your child to school or, in some cases, even to a childcare facility.

Currently, you can fully maintain your right to “*choose what’s right for your child*” only by home schooling your children.

However, in some states, public health officials and the healthcare establishment are lobbying for laws to: **a)** restrict your right to home school your own children and/or **b)** require home schooled children to be vaccinated.

“**More Information:**

To help you out, I found an excellent article from Parenting.com that highlights four of the concerns I hear regularly. You can find out more in my book, **God's Design for the Highly Healthy Child**, but this article is a good introduction.

Parenting.com dug through the science to get the facts. So, here we go!”

In general, this reviewer finds that articles based on the information reported in some popular on-line magazine, like *“Parenting.com”* in this case, are poor sources, at best, for factual information on *“science”*, though these magazines are good sources for anecdotal accounts of the personal experiences of some individuals.

Thus, though the author purports to be separating the facts from the fictions about vaccines, this reviewer finds that many of the statements made in this article are at odds with the information provided by: **a)** U.S. Center for Disease Control and Prevention (CDC) reports, **b)** the Vaccine Adverse Events Reporting System database jointly maintained by the CDC and the U.S. Food and Drug Administration (FDA), and **c)** independently verified articles published in peer-reviewed journals where the findings are based on other than retrospective records reviews of patient-records datasets, which cannot themselves be independently reviewed.

Therefore, this reviewer must respectfully conclude that this article does not separate vaccine fact from vaccine fiction.

“When Katie Shutters’s 13-month-old daughter, Averie, was born, she followed the recommended vaccine schedule for two months. Then she did some research and decided to hold off on additional shots until Averie turned 9 months old. ‘I liked the idea of my breast milk giving her the immunities she needs and allowing her body to work for her instead of some medicine,’ says the stay-at-home mom from Indianapolis, Indiana. ‘She isn’t in daycare, and we don’t travel overseas. I had concerns about injecting her for no reason.’

Eventually Shutters found a doctor who would immunize according to her schedule: ‘We broke up the MMR [which protects against measles, mumps, and rubella] into three separate shots spread out over a year, and we’re skipping the chicken pox shot,’ she says. ‘Instead, I’d love to find a kid who has chicken pox so we could expose Averie naturally.’”

First, this reviewer finds this anecdotal story interesting but puzzlingly incomplete.

Missing are the reasons that Katie Shutters *“followed the recommended vaccine schedule for two months”* and what happened at, or after, the two-month vaccinations Averie received to cause Katie to: **a)** do some research and **b)** *“hold off on additional shots until Averie turned 9 months old”*.

Moreover, though this reviewer has no problem with the actions taken by Katie Shutters, he hopes that her splitting up the live-virus MMR vaccine and spreading it over a year gave the measles vaccine last because the measles virus in the vaccine significantly suppresses the child’s immune system for about a year.

Furthermore, since the causative virus for chickenpox, herpes varicella zoster, is the same virus that causes shingles, this reviewer is surprised that the author of this article, *a medical doctor who is board certified in family practice*, did not mention this fact so that Katie Shutters and other mothers might know that they can also expose their children to herpes varicella zoster by exposing them to a child or an adult with an early-stage shingles case.

Finally, this reviewer is surprised that the author did not disclose the fact that the childhood vaccination program for varicella is not even societally cost-effective since more than one dose of vaccine is now being recommended and, *based on the more than 30,000 annual cases observed and the need for periodic exogenous boosting after the initial chickenpox case to maintain the child's immunity to a recurrence as shingles, not* even an effective disease-control strategy for herpes varicella zoster infection.

“If Shutter’s approach to vaccination sounds familiar, that’s because it is. In fact, most moms don’t have to look far beyond their circle of friends to find a family with serious concerns. It’s not difficult to understand why. For one, it can be torture to watch your child get jabbed repeatedly with a needle. Combine that discomfort with a steady stream of negative publicity — celebrity diatribes, alarmist news and Internet reports, ripped-from-the-headline TV shows — and the wariness seems warranted.”

While the author’s narrative here begins by stating the factual “*serious concerns*” that parents have (“*a family with serious concerns*”), he attempts to attribute these “*serious concerns*” to “*wariness*” caused by external factors rather than addressing the real risks and adverse outcomes associated with the current recommended national vaccination programs in the USA.

“Yet underneath all the debate and impossibly good intentions (after all, everyone hopes to be doing the best for their child no matter how or whether they immunize), there are some solid facts about the benefits of shots that cannot be ignored. ‘We live thirty years longer now than we did a century ago, thanks to purified water — and vaccines,’ says Paul Offit, M.D., chief of infectious diseases at the Children’s Hospital of Philadelphia in Pennsylvania.”

After parenthetically stating the obvious, “*after all, everyone hopes to be doing the best for their child no matter how or whether they immunize*”, the author asserts, “*there are some solid facts about the benefits of shots that cannot be ignored*”.

Yet all this author offers to support his assertion is an unsubstantiated quotation, “*We live thirty years longer now than we did a century ago, thanks to purified water — and vaccines*” from a known vaccine apologist, “*Paul Offit*”, who simply attributes some unspecified part of the asserted 30-year increase in life span from the early 1900s to “*vaccines*”.

Having claimed that there are “*some solid facts about the benefits of shots*”, the author supports his “*benefits of shots*” claim with a single unsupported quotation, attributed to a known vaccine apologist, that only suggests a single benefit (some part of a putative 30-year increase in life span, where, as stated by this author, even Paul Offit seems to attribute the majority of the increase to “*purified water*”).

Thus, the author fails to provide any supporting evidence of “*benefits*” and the one purported benefit is an unsupported claim by an avowed vaccine apologist where it appears the “*purified water*” is the major contributor to this one benefit.

“But as soon as compliance wanes, the protection we have against many devastating, and sometimes fatal, diseases wanes right along with it. This year’s measles outbreak — the biggest in nearly a decade — may be the first warning shot, says Dr. Offit. Nearly all of the 131 people affected so far, many of them children, were purposely not vaccinated against the disease, according to a new report from the Centers for Disease Control and Prevention (CDC), in Atlanta, Georgia.”

Here, the author again begins by making vague generalizations:

“But as soon as compliance wanes, the protection we have against many devastating, and sometimes fatal, diseases wanes right along with it” ,

which fail to mention:

1. The type of waning compliance being addressed,
2. The types, and their duration, of the protections that wane, or
3. The names of the “many devastating, and sometimes fatal, diseases” for which there is guaranteed protection.

Moreover, the author fails to note that “we” do not have FDA-licensed vaccines for many other devastating, and sometimes fatal, diseases (e.g., syphilis and tuberculosis), nor has the CDC recommended national vaccination programs for some of the diseases for which there is an FDA-approved vaccine (e.g., cholera).

For example, consider some of the data from “**Table 1. Reported cases of notifiable diseases,\* by month --- United States, 2006**” and, *for deaths*, some of the 2004 data from “**Table 12. Deaths from selected notifiable infectious diseases United States 2002 --- 2004**” in the CDC’s “**Summary of Notifiable Diseases --- United States, 2006**”<sup>1</sup>:

| Disease  | Reported Cases | Reported Deaths<br>2006 (2004) |
|--|----------------|--------------------------------|
| Acquired immunodeficiency syndrome (AIDS)                            | NR             | NR (13,063)                    |
| <b>Anthrax</b> (vaccine only given to adults in military at present) | 1              | NR ( 0 of NR cases)            |
| Botulism   |                |                                |
| foodborne  | 20             | NR ( 0 of 16 cases)            |
| infant   | 97             | NR                             |
| other (wound and unspecified)  | 48             | NR                             |
| Brucellosis  | 121            | NR ( 0 of 114 cases)           |
| Chancroid  | 33             | NR ( 0 of 30 cases)            |
| <u>Chlamydia trachomatis</u> , genital infection                     | 1,030,911      | NR ( 0 of 949,462 cases)       |
| <b>Cholera</b> (vaccine only on outbreak)                            | 9              | NR ( 0 of 5 cases)             |
| <u>Coccidioidomycosis</u>  | 8,917          | NR ( 100 of 6,449 cases)       |
| Cryptosporidiosis  | 6,717          | NR ( 1 of 3,577 cases)         |
| Cyclosporiasis   | 137            | NR                             |
| <b>Diphtheria (5+ doses)</b>   | "0"            | NR ( 0 of "0" cases)           |
| Domestic arboviral diseases, neuroinvasive and nonneuroinvasive      |                |                                |
| California serogroup virus disease,                                  | 69             | NR ( 0 of 112 cases)           |
| neuroinvasive  | 65             |                                |
| nonneuroinvasive   | 4              |                                |
| eastern equine encephalitis virus disease                            | 8              | NR ( 2 of 6 cases)             |
| Powassan virus disease   | 1              | NR                             |
| St. Louis encephalitis virus disease,                                | 10             | NR ( 2 of 12 cases)            |
| neuroinvasive  | 7              |                                |
| nonneuroinvasive   | 3              |                                |
| <u>West Nile virus disease</u> ,                                     | 4,269          | NR                             |
| neuroinvasive  | 1,495          |                                |
| nonneuroinvasive   | 2,774          |                                |
| western equine encephalitis virus disease                            | NR             | NR ( 0 of "0" cases)           |
| Ehrlichiosis   | 1,455          | NR ( 0 of 875 cases)           |
| human granulocytic   | 646            |                                |
| human monocytic  | 578            |                                |
| human, other or unspecified agent                                    | 231            |                                |
| Giardiasis   | 18,953         | NR ( 1 of 20,636 cases)        |
| <u>Gonorrhea</u>   | 358,356        | NR ( 2 of 330,132 cases)       |
| <b>Haemophilus influenzae</b> , invasive disease                     |                |                                |
| all ages, all serotypes  | 2,436          | NR ( 11 of 2,085 cases)        |
| <5 years of age  |                |                                |
| serotype B (3 doses)   | 25             |                                |
| nonserotype B  | 175            |                                |
| unknown serotype   | 179            |                                |

<sup>1</sup> McNabb SJN, Jajosky RA, Hall-Baker PA, Adams DA, Sharp P, Worsham C, Anderson WJ, Aponte JJ, Jones GF, Nitschke DA, Rey A, Wodajo MS. Summary of Notifiable Diseases --- United States, 2006. *MMWR*, 2008 March 21; **55**(53): 1-94.

|  |                |                            |
|--|----------------|----------------------------|
| Hansen disease (leprosy)   | 66             | NR ( 5 of 105 cases)       |
| Hantavirus pulmonary syndrome  | 40             | NR ( 0 of 24 cases)        |
| Hemolytic uremic syndrome, postdiarrheal                                     | 288            | NR ( 27 of 200 cases)      |
| <b>Hepatitis A, acute (3 doses)</b>  | <b>3,579</b>   | NR ( 58 of 5,683 cases)    |
| <b>Hepatitis B, acute (4+ doses)</b>   | <b>4,713</b>   | NR ( 556 of 6,212 cases)   |
| Hepatitis B, chronic   | NR             | NR ( 87 of NR cases)       |
| Hepatitis B virus, perinatal infection                                       | NR             | NR                         |
| Hepatitis C, acute   | 766            | NR ( 4.099? of 720? cases) |
| (Hepatitis C, chronic)   | ----           | NR ( 487 of NR cases)      |
| <u>Human immunodeficiency virus (HIV) infection</u>                          | NR             | (See AIDS deaths)          |
| <u>Influenza cases</u>   | NR             | NR                         |
| Influenza-associated pediatric mortality (2 doses initially, then 1 dose/yr) | ----           | 43 ( 51 of NR cases)       |
| Legionellosis§   | 2,834          | NR ( 72 of 2,093 cases)    |
| Listeriosis  | 844            | NR ( 57 of 753 cases)      |
| <u>Lyme disease</u>  | <u>19,931</u>  | NR ( 6 of 19,804 cases)    |
| Malaria  | 1,474          | NR ( 8 of 1,458 cases)     |
| <b>Measles (2+ doses)</b>  | <b>55</b>      | NR ( 0 of 37 cases)        |
| <b>Meningococcal disease, invasive§</b>                                      | <b>1,194</b>   | NR ( 138 of 1,361 cases)   |
| serogroup A, C, Y & W-135 (2+ doses)   | 318 [ 58.56%]  |                            |
| serogroup B [no vaccine for type "B"]  | 193 [ 35.54%]  |                            |
| other serogroup  | 32 [ 5.90%]    |                            |
| total seotyped   | 543 ["100.0%"] |                            |
| serogroup unknown  | 661            |                            |
| <b>Mumps (2+ doses)</b>  | <b>6,584</b>   | NR ( 0 of 258 cases)       |
| <b>Pertussis (5+ doses)</b>  | <b>15,632</b>  | NR ( 16 of 25,827 cases)   |
| Plague   | 17             | NR ( 1 of 3 cases)         |
| Poliomyelitis, paralytic   | "0"            | NR ( 0 of "0" cases)       |
| Psittacosis  | 21             | NR ( 0 of 12 cases)        |
| Q fever  | 169            | NR ( 1 of 70 cases)        |
| <b>Rabies</b>  |                |                            |
| animal   | 5,543          | NR                         |
| <b>human</b> (vaccination after exposure)                                    | <b>3</b>       | NR ( 3 of 7 cases)         |
| <u>Rocky Mountain spotted fever</u>  | <u>2,288</u>   | NR ( 5 of 1,713 cases)     |
| <b>Rubella (2+ doses)</b>  | <b>11</b>      | NR ( 1 of 10 total cases)  |
| <b>Rubella, congenital syndrome</b>  | <b>1</b>       | NR ( 5 of 10 total cases)  |
| <u>Salmonellosis</u>   | <u>45,808</u>  | NR ( 30 of 42,197 cases)   |
| Severe acute respiratory syndrome--  |                |                            |
| associated coronavirus (SARS-CoV) disease                                    | "0"            | NR                         |
| Shiga toxin-producing Escherichia coli (STEC)¶                               | 4,432          | NR ( 4 of NR cases)        |
| <u>Shigellosis</u>   | <u>15,503</u>  | NR ( 0 of 14,627 cases)    |
| Smallpox (currently 0 doses)   | "0"            | "0" ( 0 of "0" cases)      |
| Streptococcal disease, invasive, group A                                     | 5,407          | NR ( 121 of 4,395 cases)   |
| Streptococcal toxic-shock syndrome   | 125            | NR                         |
| <b>Streptococcus pneumoniae, invasive disease</b>                            |                |                            |
| age <5 years (3 doses)   | <b>1,861</b>   | NR ( 13 of 1,162 cases)    |
| <b>Streptococcus pneumoniae, invasive disease,</b>                           |                |                            |
| drug-resistant all ages  | 3,308          | NR                         |
| <u>Syphilis</u>  |                |                            |
| all stages   | <u>36,935</u>  | NR ( 43 of 33,401 cases)   |
| primary & secondary  | 9,756          | NR                         |
| congenital (<1 yr)   | 349            | NR                         |
| <b>Tetanus (5+ doses)</b>  | <b>41</b>      | NR ( 4 of 34 cases)        |
| Toxic-shock syndrome (other than streptococcal)                              | 101            | NR ( 71 of 95 cases)       |
| Trichinellosis   | 15             | NR ( 0 of 5 cases)         |
| <u>Tuberculosis</u>  | <u>13,779</u>  | NR ( 657 of 14,517 cases)  |
| Tularemia  | 95             | NR ( 1 of 134 cases)       |
| Typhoid fever  | 353            | NR ( 0 of 322 cases)       |
| Vancomycin-intermediate Staphylococcus aureus infection (VISA)               | 6              | NR                         |
| Vancomycin-resistant Staphylococcus aureus infection (VRSA)                  | 1              | NR                         |
| <b>Varicella infection (morbidity) (1+ doses)</b>                            | <b>48,445</b>  |                            |
| <b>Varicella (mortality)</b>   |                | "0" ( 19 of 32,951)        |
| Yellow fever   | "0"            | "0" ( 0 of NR cases)       |

where there is a U.S.-licensed vaccine for some diseases (in **bold**) but none for other diseases — some of which are endemic to the USA, and have thousands of annual cases and a mortality that is greater than 1% (e.g., Coccidioidomycosis: 6 – 9-thousand cases annually and a mortality greater than 1.5 %).

Moreover, the author also fails to note that, *for whatever reasons*, in spite of levels of compliance exceeding 90% in childhood, the vaccine components for mumps in the MMR vaccine and for pertussis in the DTaP/Tdap vaccines do not provide effective control for these diseases since thousands of cases of each disease occur annually in the USA.

To support his generalization, the author next states:

*“This year’s measles outbreak — the biggest in nearly a decade — may be the first warning shot, says Dr. Offit. Nearly all of the 131 people affected so far, many of them children, were purposely not vaccinated against the disease, according to a new report from the Centers for Disease Control and Prevention (CDC), in Atlanta, Georgia.”*

an observation that miscasts: **a)** multiple isolated measles outbreaks as a single “measles outbreak” and **b)** the 131 cases as if that were a significant number in a nation of more than 306 million people (or about 0.043 case of measles per 100,000 residents in the USA in 2008) when it is obvious that 131 cases are not a significant number.

Moreover, considering that the recommended vaccine is the Merck MMR® II live measles, mumps and rubella vaccine, the concern about these few measles cases is obviously misplaced because, *though the CDC typically reported roughly 230 – 390 cases of mumps each year in the period from 1999 to 2005<sup>2</sup>*, no similar concern was raised in for mumps in 2006 when the number of reported mumps cases suddenly jumped to 6,536 mumps cases, or more than 15 times higher than the 387 cases of mumps reported in 1999.

Based on the CDC’s MMWR reports for cases by age range (in the “Summary of Notifiable Diseases, “Table 3” data for 2006 and 1999) tabulated below:

| Age Rng →                     | <1 yr               | 1-4 yr              | 4-14 yr             | 15-24 yr            | 25-39 yr            | 40-64 yr            | >=65 yr             | Unkn           | Total          |
|-------------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|----------------|----------------|
| Year                          | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>(per 100K) | Cases<br>..... | Cases<br>..... |
| 2006                          | 18<br>(0.44)        | 351<br>(2.72)       | 1,097<br>(2.72)     | 2,270<br>(5.39)     | 1,283<br>(2.10)     | 1,329<br>(1.39)     | 198<br>(0.54)       | 98<br>.....    | 6,584          |
| 1999                          | 4<br>(0.11)         | 61<br>(0.41)        | 156<br>(0.40)       | 42<br>(0.11)        | 62<br>(0.10)        | 44<br>(0.06)        | 7<br>(0.02)         | 11<br>.....    | 387            |
| Ratio of Incidences 2006/1999 | 4.00                | 6.63                | 6.80                | 49.0                | 21.0                | 23.2                | 27.0                | -----          | -----          |

the largest increase in cases occurred in the 15-24-year olds, the very group that: **a)**, *for males*, having mumps is most likely to render them sterile and **b)**, *if the vaccine were effective and provided truly long-term protection*, should still have been protected.

Perhaps, the 15-fold increase in mumps cases in 2006 was not worth mentioning or similarly reporting because a significant percentage of those getting mumps had received 2 doses of the MMR II vaccine and should have been protected but were not.

Perhaps, this is also the reason that students entering or in some colleges are being asked to get another MMR vaccination even though another shot is not yet being recommended by the CDC and, *if one were to be recommended*, the MMR vaccination program would also probably cease to be societally cost effective.

<sup>2</sup> From 1999 to 2005, there were 387, 338, 266, 270, 231, 258 and 314 reported mumps cases, respectively, in each of the years from 1999 through 2005.

Perhaps, it might be better for male children to have mumps in their early school years when there is no risk of sterility rather than to be vaccinated and be at risk of sterility should they contract mumps after puberty as about 2,000 males between the ages of 14 and 40 did in 2006.

Having put the measles outbreaks in perspective, this reviewer will now examine the facts, and not the hyperbole introduced by the author of this article, by examining the CDC report<sup>3</sup> to which the author alludes.

First, the actual report begins (with underlining added for emphasis):

“Sporadic importations of measles into the United States have occurred since the disease was declared eliminated from the United States in 2000 (1). During January–July 2008, 131 measles cases were reported to CDC, compared with an average of 63 cases per year during 2000–2007.\* This report updates an earlier report on measles in the United States during 2008 (2) and summarizes two recent U.S outbreaks among unvaccinated school-aged children. Among those measles cases reported during the first 7 months of 2008, 76% were in persons aged <20 years, and 91% were in persons who were unvaccinated or of unknown vaccination status. Of the 131 cases, 89% were imported from or associated with importations from other countries, particularly countries in Europe, where several outbreaks are ongoing (3,4). The findings demonstrate that measles outbreaks can occur in communities with a high number of unvaccinated persons and that maintaining high overall measles, mumps, and rubella (MMR) vaccination coverage rates in the United States is needed to continue to limit the spread of measles.

Measles cases in the United States are reported by state health departments to CDC using standard case definitions† and case classifications. Cases acquired outside the United States are categorized as importations. Those acquired inside the United States are considered importation associated if they are linked epidemiologically via a chain of transmission to an importation or have virologic evidence of importation.§ Other cases are classified as having an unknown source. In the United States, recommendations for MMR vaccination include a single dose at age 12–15 months and a second dose at the time of school entry (5). Vaccination as early as age 6 months is recommended for U.S. children traveling abroad and is sometimes recommended within U.S. communities during outbreaks of measles.

During January 1–July 31, 2008, 131 measles cases were reported to CDC from 15 states and the District of Columbia (DC): Illinois (32 cases), New York (27), Washington (19), Arizona (14), California (14), Wisconsin (seven), Hawaii (five), Michigan (four), Arkansas (two), and DC, Georgia, Louisiana, Missouri, New Mexico, Pennsylvania, and Virginia (one each). Seven measles outbreaks (i.e., three or more cases linked in time or place) accounted for 106 (81%) of the cases. Fifteen of the patients (11%) were hospitalized, including four children aged <15 months. No deaths were reported.

Among the 131 cases, 17 (13%) were importations: three each from Italy and Switzerland; two each from Belgium, India, and Israel; and one each from China, Germany, Pakistan, the Philippines, and Russia. This is the lowest percentage of imported measles cases since 1996 (Figure 1). Nine of the importations were in U.S. residents who had traveled abroad, and eight were in foreign visitors. An additional 99 (76%) of the 131 cases were linked epidemiologically to importations or had virologic evidence of importation. The source of measles acquisition of 15 cases (11%) could not be determined.

Among the 131 measles patients, 123 were U.S. residents, of whom 99 (80%) were aged <20 years (Table). Five (4%) of the 123 patients had received 1 dose of MMR vaccine, six (5%) had received 2 doses of MMR vaccine, and 112 (91%) were unvaccinated or had unknown vaccination status. Among these 112 patients, 95 (85%) were eligible for vaccination, and 63 (66%) of those were unvaccinated because of philosophical or religious beliefs (Figure 2).”

As the proverbial potter who puts the handles on the pot where he wants them, the author focuses on the cases in the “*not vaccinated*” group while ignoring the reality that,

<sup>3</sup> Grigg MA, Brzezny AL, Dawson J, Rietberg K, DeBolt C, Linchangco P, Smith S, Jones S, Vernon M, Counard C, Chugh R, Nelson S, Green K, Petit C, Vercillo J, Cesario S, Hunt K, Conover C, Daniels J, McMahon K, Redd SB, Gallagher KM, Armstrong GL, Anderson LJ, Seward JF, Rota PA, Rota JS, Lowe L, Bellini WJ. Update: Measles --- United States, January--July 2008. *MMWR*, 2008 August 22; **57**(33): 893-896.

though vaccinated, there were 11 people (or about 9.6%) of the 114 who contracted a case of measles in the USA (the other 17 contracted it in a foreign country).

In addition, the report's tabulated data:

TABLE. Number and percentage of U.S. residents with measles, by age group and vaccination status — United States, January–July 2008

| Vaccination status                                     | Age group  |           |             |           |           |          | Total<br>No. (%) |
|--|------------|-----------|-------------|-----------|-----------|----------|------------------|
|  | <12 mos    | 12–15 mos | 16 mos–4yrs | 5–19 yrs  | 20–49 yrs | ≥50 yrs  |                  |
|  | No. (%)    | No. (%)   | No. (%)     | No. (%)   | No. (%)   | No. (%)  |                  |
| Unvaccinated   |            |           |             |           |           |          |                  |
| Too young (aged <12 mos)                               | 16 (100.0) |           |             |           |           |          | 16 (13.0)        |
| Born before 1957                                       |            |           |             |           |           | 1 (50.0) | 1 (0.8)          |
| Philosophical or religious beliefs against vaccination |            |           | 9 (50.0)    | 52 (94.5) | 2 (9.1)   |          | 63 (51.2)        |
| Missed opportunity or reason unknown                   |            | 8 (80.0)  | 7 (38.9)    |           | 1 (4.5)   | 1 (50.0) | 17 (13.8)        |
| Vaccinated (≥1 dose)                                   |            | 1 (10.0)  | 2 (11.1)    | 3 (5.5)   | 5 (22.7)  |          | 11 (8.9)         |
| Unknown vaccination status                             |            | 1 (10.0)  |             |           | 14 (63.6) |          | 15 (12.2)        |
| <b>Total</b>   | <b>16</b>  | <b>10</b> | <b>18</b>   | <b>55</b> | <b>22</b> | <b>2</b> | <b>123</b>       |

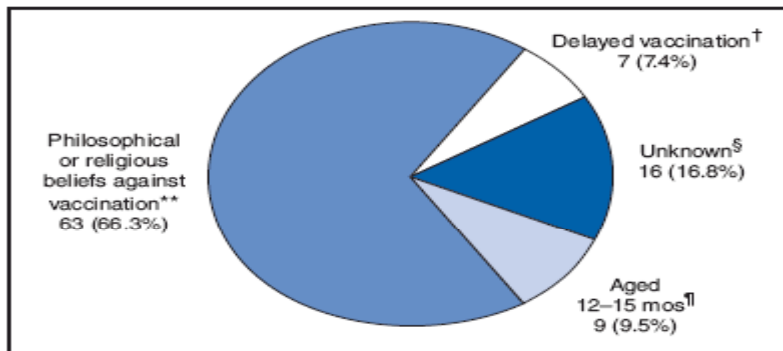
while interesting, fails to provide the data on:

- The number of vaccinated individuals who had contact with the primary case in each outbreak but did not get measles,
- The number of unvaccinated individuals who were exposed to the primary case but did not get measles,
- The number of vaccinated and unvaccinated contacts to the initial case source who had protective and/or significant levels of antibodies to the contact's strain of measles and/or the MMR vaccine's strain of measles, and
- The information on the source of the measles for the isolated single cases in "DC, Georgia, Louisiana, Missouri, New Mexico, Pennsylvania, and Virginia" and/or the reasons the CDC could not determine a source of the measles disease in fifteen cases.

Moreover, the report failed to provide the logic used to classify each "Unknown vaccination status" measles case.

Furthermore, based on an examination of the report's cryptically titled "FIGURE 2",

FIGURE 2. U.S. residents with measles who were eligible\* for vaccination against measles, by reason for not receiving measles vaccine — United States, January–July 2008



\* N = 95. Does not include infants aged <12 months, persons born before 1957, foreign visitors, and persons who were vaccinated.

† Includes children aged 16 months to 4 years who had not been vaccinated.

§ Includes persons who were age eligible for vaccination but whose vaccination status was unknown or who were unvaccinated for unknown reasons.

¶ Includes eight children eligible for vaccination, but not yet vaccinated, and one child whose vaccination status was unknown.

\*\* Includes persons who were unvaccinated because of their own or their parents' beliefs. This category includes 61 persons aged ≤18 years and two persons aged 20–50 years. None of the persons in this category cited medical reasons for not having been vaccinated.

this reviewer notes: **a)** the number of foreign visitors must have been the “8” not included in the report’s “**Table**”, which reflected 123 of the 131 CDC-reported cases and **b)**, *because 17 were “imported” cases (“17 [13%] were importations: three each from Italy and Switzerland; two each from Belgium, India, and Israel; and one each from China, Germany, Pakistan, the Philippines, and Russia”)*, 9 of the “importations” were U.S. residents returning to the USA from a trip to a foreign country.

“‘We have to take this seriously,’ says Anne Schuchat, M.D., director of the CDC National Center for Immunization and Respiratory Diseases. ‘I do not want to see the day where thousands of kids get this disease and die when we have the tools to prevent it.’”

Based on the outcomes observed, for the “131” measles cases in these outbreaks, only 15 (11.45%) were hospitalized and there were no deaths, this reviewer finds that Ann Schuchat’s “fear mongering” assertion of a “*day where thousands of kids get this disease and die*” is: **a)** not supported by the facts and **b)** baseless in today’s USA.

Given the current treatment tools (i.e., dietary supplementation with vitamins A, C, and D-3 to boost immune system performance and reduce the risk of measles’ severe side effects and antibiotics to fight the secondary pneumonia infections that can follow measles’ infection), which we now have, no otherwise healthy child should die in the USA even if the number of children contracting measles were to increase to thousands of children annually.

Given the preceding realities, this reviewer finds that the author also seems to be guilty of indirect fear mongering when he repeats this obvious vaccine apologist’s unsupported statements.

“But, here are four of the most common concerns parents have:”

Here, this responder agrees that the stated concerns in the remainder of this article are some of “*the most common concerns parents have*”.

However, this responder also notes that this author fails to address all of the concerns contained in the author’s headings and, *for the concerns he does address*, the author neither provides nor cites evidence that fully supports the author’s assertions.

### “**The worry: Vaccines cause autism**”

What’s behind it: This claim first came to the forefront in 1998, after a British study linked the MMR vaccine to 12 children with autism. Prior to this, there had been some concern that thimerosal, a mercury-based preservative common in many vaccines at the time, also may have been partly or totally to blame for some cases of autism.”

Here, the author’s statements are, at best, confusing.

Worse, they distort the actual historical record.

First of all, the theory: “*Vaccines cause autism*” actually appears to have been introduced in a 1976 article, [Autistic syndrome (Kanner) and vaccination against smallpox (author’s transl)] [Article in German] *Klin Padiatr.* 1976 Mar; **188**(2): 172-80 (with the PubMed [<http://www.ncbi.nlm.nih.gov/sites/entrez>] abstract located using the search terms “autism vaccine”), which contains the following text (with underlining added for emphasis):

“Klin Padiatr. 1976 Mar;188(2):172-80. ...

[Autistic syndrome (Kanner) and vaccination against smallpox (author's transl)][Article in German]  
Eggers C.

... 3-4 weeks following an otherwise uncomplicated first vaccination against smallpox a boy, then aged 15 months and last seen at the age of 5 1/2 years, gradually developed a complete Kanner syndrome. The question whether vaccination and early infantile autism might be connected is being discussed. A causal relationship is considered extremely unlikely. But vaccination is recognized as having a starter function for the onset of autism.”

Moreover, this theory was mentioned in three other articles published well before the 1998 article referred to here:

1. Coulter HL. Author responds to review of vaccination, social violence, and criminality. *J Autism Dev Disord*. 1993 Jun; **23**(2): 422-424,
2. Moeschler JB, Charman CE, Berg SZ, Graham JM Jr. Rett syndrome: natural history and management. *Pediatrics*. 1988 Jul; **82**(1): 1-10, and
3. Stubbs EG. Autistic children exhibit undetectable hemagglutination-inhibition antibody titers despite previous rubella vaccination. *J Autism Child Schizophr*. 1976 Sep; **6**(3): 269-274.

Furthermore, the author's: “... in 1998, after a British study linked the MMR vaccine to 12 children with autism” clearly misstates both the “FINDINGS” and the “INTERPRETATION” in that *Lancet* article<sup>4</sup>, titled “Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children”, which the researchers clearly reported in the article's abstract (with underlining added for emphasis):

“FINDINGS: Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in the colon in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls (p=0.003), low haemoglobin in four children, and a low serum IgA in four children. INTERPRETATION: We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.”

and only identified “associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers”.

In simple terms, this study:

- Linked the novel gastrointestinal disease being studied with developmental regression in some previously normal children,
- Noted this apparent association was time-linked with possible environmental triggers plural – not a singular trigger like an initial MMR vaccination –, and
- Did not link “the MMR vaccine to 12 children with autism” as the article's author states that it did.

Apparently, one of the reasons this paper came to the forefront was: The healthcare establishment in the United Kingdom (U.K.) needed something to distract the public from the fiasco created by their recommending an MMR vaccine that contained the highly toxic Urabe strain of mumps, where the public backlash to the harm caused by this vaccine was already causing the MMR vaccination levels in the U.K. to drop.

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<sup>4</sup> Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 1998 Feb 28; **351**(9103): 637-641.

This paper gave them the pretext needed to transfer the blame for the drop off in MMR uptake from: the government's craven decision to recommend using the toxic Urabe-mumps-strain-containing MMR vaccine in the U.K. to: Some irresponsible researchers who "linked" the MMR vaccine to autism even though these researchers themselves clearly did not claim they had found any such link.

Moreover the author's next statement:

*"Prior to this, there had been some concern that thimerosal, a mercury-based preservative common in many vaccines at the time, also may have been partly or totally to blame for some cases of autism."*

is a masterpiece in both misrepresentation and understatement.

Factually, the author, *as many other vaccine apologists do*, intentionally confuses the use of Thimerosal (used, *since the 1930s*, as a preservative in some vaccines and other biological drug formulations containing it without toxicological proof of safety) with what Thimerosal, a trade name for sodium ethylmercury thiosalicylate, is:

- A highly toxic, highly water soluble organic mercury compound that is:
  - 49.55-weight-percent (-wt%) mercury,
  - A human carcinogen, mutagen, teratogen and immune-system disruptor at biological concentrations below 1 part per million, and
  - Converted in the body into bioaccumulative mercury species that, *in humans*, accumulate in the brain, hair, heart, kidneys, skin, teeth, vascular system, and other tissues, and
- A marginal compound, *at best*, for use in a vaccine formulation as a preservative because, at preservative levels, Thimerosal:
  - Readily and non-reversibly breaks down into ethylmercury chloride, ethylmercury hydroxide and sodium thiosalicylate when it is dissolved in saline, the basic constituent for the liquid vaccine formulations in which it is used,
  - Readily binds to the sulfur-containing antigenic materials in most vaccines and
  - Rapidly denatures the viruses in the current live-virus vaccines.

Next, the author's "*common in many vaccines at the time*" conceals the reality that Thimerosal is currently being used at preservative levels (without the required proofs of toxicological safety) in nine (9) vaccines that are currently FDA-approved for use in children, including the 2008 – 2009 principal formulation for Sanofi's Fluzone® and the only available formulation for Novartis' Fluvirin®, the only two (2) inactivated-influenza vaccines approved for administration to those under 18 years of age.

Further, the author's "*... there had been some concern that thimerosal ... also may have been partly or totally to blame for some cases of autism*" conceals the reality that there is an overwhelming and growing body of toxicological and other evidence that Thimerosal mercury poisons developing children exposed to Thimerosal-containing vaccines to the point that some of them (perhaps up to 2 % in the USA who were directly [by being injected with Thimerosal-preserved and Thimerosal-containing vaccines from birth onwards] and/or indirectly [when their mother is injected with a Thimerosal-preserved vaccine or dosed with another Thimerosal-preserved drug product (e.g., some FDA-approved nasal spray formulations)]) develop the clinical neurological and behavioral symptoms of subacute mercury poisoning that are used to diagnose an autism spectrum disorder (ASD).

“The facts: So far, ten studies involving thousands of children have failed to find any connection between the MMR and autism. Plus, the original paper suggesting a connection between the two was formally retracted by 10 of its 13 authors in 2004. ...”

First, since the 1998 article was published in the *Lancet*, not “*ten studies*” but more than 200 articles, notes, letters, and reviews, including eight published so far in 2008, have been indexed in PubMed on both sides of the MMR-autism link/no link controversy – clearly indicating that the jury is still out on the issue of a link between the measles component in the MMR vaccine and autism as well as the nature of that purported link.

Moreover, the failure of any number of epidemiological studies, *including those alluded to by the author, “to find any connection between the MMR and autism” cannot* be used to rule out a possible link.

Finally, the author’s assertion:

*“Plus, the original paper suggesting a connection between the two was formally retracted by 10 of its 13 authors in 2004”*

is simply false.

Factually, the 10 authors’ letter<sup>5</sup> only retracted the “INTERPRETATION”, *as the title of this letter clearly indicates*, of the “FINDINGS” in the 1998 paper and, *tellingly*, this partial retraction occurred in 2004 – 6 years after the original publication – coincidentally at the time the U.K. medical establishment began its on-going “investigation” into the fitness to practice medicine of the authors who refused to retract this “INTERPRETATION”.

“As for the thimerosal issue, there’s a bit more backstory worth explaining: First, it’s absolutely true that mercury can be harmful. The kind in contaminated fish and water builds up in the body when ingested and can cause severe nerve damage. However, the type of mercury that’s in thimerosal doesn’t accumulate in the body. ‘It’s never been linked to any adverse effect,’ says William Schaffner, M.D., professor of preventive medicine at Vanderbilt University Medical Center, in Nashville, Tennessee.”

As vaccine apologists, *as this author and William Schaffner appear to be*, find the truth to be inconvenient, they simply make inaccurate “expert” statements.

The author’s initial statement about mercury:

*“First, it’s absolutely true that mercury can be harmful”*

is a half-truth because no safe level has been proven for any level of injected mercury-containing solution in developing children.

The author’s third statement:

*“However, the type of mercury that’s in thimerosal doesn’t accumulate in the body.”*

is simply false.

Factually, although Thimerosal and its mercury-containing breakdown products do rapidly leave the blood after a Thimerosal containing solution is injected into animals and children, some studies have shown that the mercury in Thimerosal does accumulate in the body – including in the brain.

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<sup>5</sup> Murch SH, Anthony A, Casson DH, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Valentine A, Davies SE, Walker-Smith JA. Retraction of an interpretation. *Lancet*. 2004 Mar 6; **363**(9411): 750.

Moreover, William Schaffner's quoted remark:

*"It's never been linked to any adverse effect"*

is again simply false.

Many studies in developing fertilized eggs<sup>6</sup>, hamsters<sup>7</sup>, mice<sup>8</sup>, monkeys<sup>9</sup>, pheasants<sup>10</sup>, pigs<sup>11</sup>, and rats<sup>12</sup> as well as mostly fatal direct infant exposures<sup>13,14</sup> and indirect exposures<sup>15</sup> in Iraqi children nursed by mothers who, *while nursing after giving birth*, unknowingly consumed wheat contaminated with an ethylmercury-containing fungicide have all shown serious adverse effects, *including severe birth defects and death*, in those studied that were clearly linked to *"the type of mercury"*, organic "ethylmercury", in Thimerosal.

In addition, comparative studies<sup>9,11,16,17,18,19,20</sup> using various mercury compounds have found some effect and toxicity differences but they have not found that ethylmercury compounds are significantly less toxic than methylmercury compounds.

Apparently, William Schaffner was either: **a)** unaware of the facts and failed to do an appropriate literature search, or **b)** was apparently making a knowingly false statement, if the author quoted him accurately here.

“Plus, autism rates have continued to rise even after drug companies voluntarily phased out the preservative from all vaccines given to kids (with the exception of some flu shots) in 2001. Clearly, we are far from understanding everything we need to about the range of autistic disorders. And that's

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- <sup>6</sup> Digar A, Sensharma GC, Samal S. Lethality and teratogenicity of organic mercury (Thimerosal) in the chick embryo. *J Anat Soc India* 1987; **36**:153-159.
  - <sup>7</sup> Laurente J, Remuzgo F, Ávalos B, Chiquinta J, Ponce B, Avendaño R, Maya L. Neurotoxic effects of thimerosal at vaccines doses on the encephalon and development in 7 days-old hamsters. *An Fac Med Lima* 2007; **68**(3): 222-237.
  - <sup>8</sup> Hornig M, Chian D, Lipkin WI. IMMEDIATE COMMUNICATION. Neurotoxic effects of postnatal thimerosal are mouse strain dependent. *Mol Psychiatry*. 2004 Sep; **9**(9): 833-845.
  - <sup>9</sup> Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal. *Environ Health Perspec*. 2005; **113**: 1015-1021.
  - <sup>10</sup> Spann JW, Heath RG, J. F. Kreitzer JF, Locke HN. Ethyl mercury p-toluene sulfonanilide: lethal and reproductive effects on pheasants. *Science*. 1972; **175**: 328-330
  - <sup>11</sup> Tryphonas L, Nielsen NO. Pathology of chronic alkylmercurial poisoning in swine. *Am J Veterinary Research*. 1973; **34**(3): 379-392.
  - <sup>12</sup> Goncharuk GA. Experimental investigations of the effect of organomercury pesticides on generative functions and on progeny. *Hyg. Sanit*. 1971; **36**: 40-43.
  - <sup>13</sup> Axton JMH. Six cases of poisoning after a parenteral organic mercurial compound (merthiolate). *Postgrad Med J*. 1972; **48**: 417-421.
  - <sup>14</sup> Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR. Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic. *Archives of Disease in Childhood*. 1977; **52**: 962-964.
  - <sup>15</sup> Damluji SF, Tikriti S. Mercury poisoning from wheat. *Br Med J*. 1972 Mar 25; **1**(803): 804.
  - <sup>16</sup> Orct T, Blanusa M, Lazarus M, Varnai VM, Kostial K. Comparison of organic and inorganic mercury distribution in suckling rat. *J Appl Toxicol*. 2006 Nov 1; **26**(6): 536-539.
  - <sup>17</sup> Magos L, Brown AW, Sparrow S, Bailey E, Snowden RT, Skipp WR. The comparative toxicology of ethyl- and methylmercury. *Arch Toxicol*. 1985; **57**(4): 260-267.
  - <sup>18</sup> Chao ES-E, Gierthy JF, Frenkel GD. A Comparative Study Of The Effects Of Mercury Compounds On Cell Viability And Nucleic Acid Synthesis In HeLa Cells. *Biochemical Pharmacology*. 1984; **33**: 1941-1945.
  - <sup>19</sup> Engley FB, Jr. Mercurials as disinfectants. Evaluation of mercurial antimicrobial action and comparative toxicity. *Soap and Chemical Specialties*. 1956 Dec.: 200, 201, 203, 205, 223, 224 and 225.
  - <sup>20</sup> Morton HE, North LL, Engley FB, Jr. The bacteriostatic and bacteriocidal actions of some mercury compounds on hemolytic Streptococci In vivo and in vitro studies. *JAMA* 1948; **136**(1): 37-41.

why ‘the possible link between vaccines and autism has been taken very seriously,’ says Dr. Schuchat. ‘But at this point, after so many studies, it’s safe to say these two hypotheses have been eliminated as possible causes.’”

Here the author’s:

*“Plus, autism rates have continued to rise even after drug companies voluntarily phased out the preservative from all vaccines given to kids (with the exception of some flu shots) in 2001”*

begins with several knowing misrepresentations of the facts concerning “autism rates” and the presence of Thimerosal in vaccines.

### Have USA Autism Rates Continued To Rise?

First of all, the CDC has not even attempted to rigorously track autistic disorder (the disorder defined by Dr. Leo Kanner and commonly referred to as “autism”) cases across the USA and has chosen to only do essentially limited records-review surveys for an autism spectrum disorder (ASD), which, *in the USA*, commingles children with a diagnosis of: **a)** autistic disorder, **b)** pervasive developmental disorder – not otherwise specified (PDD-NOS) or **c)** Asperger’s syndrome.

Further, the CDC apparently did not even attempt to correct the survey data for underascertainment or for sampling bias.

Given the preceding actualities, this reviewer understands:

- *Though increasing*, the disjoint point estimates that have appeared are essentially ASD point estimates and
- The apparent increases are linked to better ascertainment of cases in most instances with an uncorrected 2002 “national” 14-site survey rate of about 1 in 150 in 2002 eight-year olds – culminating in the most recent (2008) and highest estimates coming from a Minneapolis school district (1 in 56 children in school) or for the Somali refugees’ children in that school district (1 in 28) where vitamin D deficiency may have increased the apparent vaccination-related incidence rate for an ASD diagnosis in these highly vaccinated school-age Somali children.

However, the anecdotal evidence is that, *while ASD case rates may still be increasing*, the severity of the cases has been decreasing since 2002, and the distribution of cases is shifting from: Mainly autistic disorder followed by PDD-NOS toward: Mainly PDD-NOS followed by autistic disorder.

Furthermore, a careful examination of the now-hidden data on “autistic disorder” cases in the California state department of health’s monitoring indicates that, *if anything*, the increases seen after the 1999 – 2001 dip appear to be related to:

- a. Better ascertainment of the existing cases,
- b. An influx in out-of-state cases, and/or
- c. Other diagnosis-related factors

because, *incongruously*, increases were seen in the numbers of cases in the age categories beyond age 8.

Thus, lacking any valid national underascertainment-corrected prevalence rates for autism (autistic disorder) by birth cohort for each year from, for example, 1980 onwards in the USA, this reviewer finds that it is not possible to determine if autism (autistic disorder) is currently increasing or decreasing in the USA.

Furthermore, even if the USA rate ASD cases in 2002 could be approximated by the CDC's survey<sup>21</sup> of 8-year olds in 14 states, which reported an ASD rate of about 67 per 10,000, and the most recent data from Denmark indicates an ASD rate of < 8 per 10,000, where most USA children would have received Thimerosal-preserved vaccines from birth and, if their mothers were Rh negative, probably one or more Thimerosal-preserved Rho(D) serum injections, it would appear that the 2002 ASD rate in USA 8-year-olds is apparently more than 8 times higher than the comparable ASD rate in Denmark, where: **a)** no Thimerosal-containing vaccines have been in their recommended vaccination programs since the early 1990s, **b)** there is no recommendation for influenza vaccination for pregnant women and young children, **c)** most children would have received no Thimerosal-preserved vaccines or serums and **d)** their general ASD rate is about 8 per 10,000.

### Phase Out of Thimerosal In USA Vaccines?

Factually, regarding Thimerosal in vaccines: though the number of vaccine formulations containing any level of Thimerosal has been reduced, several of today's FDA-approved non-influenza vaccines<sup>22</sup> still contain some level of Thimerosal (see reviewer's **Table "1"** on the next page).

Of the seventeen FDA-approved vaccine formulations apparently still available or currently being stockpiled for use, all but four (4) inactivated influenza vaccines can be given to some children and all ten (10) of the Thimerosal-preserved vaccines can be administered to pregnant women and/or nursing mothers.

Furthermore, the potential harm from Thimerosal was increased in 2002 when the CDC's Advisory Committee on Immunization Practice (ACIP) began recommending that inactivated-influenza vaccines be given to pregnant women<sup>23</sup> without toxicological proof of safety to the developing human in the womb and in spite:

- All doses of the U.S.-licensed flu vaccine's containing Thimerosal with almost all doses of the 2002–2003 influenza vaccine for pregnant women and children being Thimerosal-preserved, and
- Published findings that Thimerosal-preserved flu shots given to pregnant women significantly increased their children's risk of being born with serious birth defects<sup>24</sup>. [**Note:** Among other adverse Thimerosal-preserved-influenza-vaccine-related teratogenic effects, the study found that Thimerosal exposure during the first 4 months of pregnancy was associated with a statistically significant standardized increased risk (SRR = 2.69) for birth defects.]

Also, given the facts that Thimerosal's ethylmercury components: **a)** cross the placental barrier<sup>12</sup> and **b)** preferentially accumulate in the developing fetus<sup>25</sup>, it should be

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<sup>21</sup> Rice C, Baio J, VanNarden-Braun K, Doernberg N, Kirby RS, Canino C, Swanson M, Pettygrove S, Cunniff C, Meaney FJ, Miller L, Robinson C, Newschaffer C, Landa R, Trevathan E, Constantino J, Daniels J, Zahorodny W, Desposito F, Pinto-Martin J, Giarelli E, Levy S, Charles J, Zimmerman J, McMahon W, Becker-Cottrill B, Durkin M et al. Prevalence of Autism Spectrum Disorders --- Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States, 2002. *MMWR*, 2007 February 9; **56**(SS01); 12-28.

<sup>22</sup> <http://www.fda.gov/cber/thimerosal/htm#t3>.

<sup>23</sup> Bridges CB, Fukuda K, Uyeki TM, Cox NJ, Singleton JA. Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2002 Apr 12; **51**(RR03): 1-31.

<sup>24</sup> Heinonen OP, Slone D, Shapiro S. **Birth Defects and Drugs in Pregnancy** (Littleton: Publishing Sciences Group, Inc., 1977).

<sup>25</sup> Gasset AR, Itoi M, Ishii Y, et al. Teratogenicities of ophthalmic drugs. II. Teratogenicities and accumulation of Thimerosal. *Arch Ophthalmol*. 1975; **93**: 52-55.

**Table “1.” March 2008 FDA-licensed Thimerosal-containing Vaccines**

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

| No. [8] | Vaccine                            | Trade Name                        | Manufacturer   | Thimerosal Concentration[1]                       | Mercury per dose   |
|---------|------------------------------------|-----------------------------------|--|---|--|
| 1       | DTaP                               | Tripedia[2]                       | Sanofi Pasteur, Inc  | ≤ 0.00012%  | ≤ 0.3 µg/0.5 mL<br>(young children)  |
| 2       | DTaPH (Tripedia + ActHIB [2])      | TriHIBit                          | Sanofi Pasteur, Inc/SA   | ≤ 0.00012%  | ≤ 0.3 µg/0.5 mL<br>(young children)  |
| 3       | DT                                 | None                              | Sanofi Pasteur, Inc  | < 0.00012% (single ds)                            | < 0.3 µg/0.5 mL<br>(older children & adults)   |
| 4/1     | DT (available but not marketed)[3] | None                              | Sanofi Pasteur, Ltd [3]  | 0.01%   | <b>25 µg/0.5 mL</b><br>(older children & adults)   |
| 5/2     | Td                                 | None                              | Mass Public Health   | 0.0033%   | <b>8.3 µg/0.5 mL</b><br>(older children & adults)  |
| 6       | Td                                 | Decavac                           | Sanofi Pasteur, Inc  | ≤ 0.00012%  | ≤ 0.3 µg /0.5 mL<br>(older children & adults)  |
| 7/3     | TT                                 | None                              | Sanofi Pasteur, Inc  | 0.01%   | <b>25 µg/0.5 mL</b><br>(older children & adults)   |
| 8       | HepA/HepB                          | Twinrix                           | GlaxoSmithKline Biologicals  | < 0.0002%   | < 1.0 µg / 1.0 mL  |
| 9/4     | Influenza                          | Afluria                           | CSL Limited  | 0.01% (multi-dose)                                | <b>24.5 µg /0.5 mL</b><br>(adults including pregnant women)  |
| 10/5    | Influenza                          | Fluzone [6]                       | Sanofi Pasteur, Inc  | 0.01%   | <b>25 µg/0.5 mL</b><br>(3 yrs & up, including pregnant women)<br><b>12.5 µg/0.25 mL</b><br>(6- 35- months olds)-           |
| 11/6    | Influenza                          | Fluvirin                          | Novartis Vaccines and Diagnostics Ltd  | 0.01%   | <b>25 µg/0.5 mL</b><br>(4 yrs & up, including pregnant women)  |
| 12      | Influenza                          | Fluvirin (Preservative Free)      | Novartis Vaccines and Diagnostics Ltd  | < 0.0004%   | < 1 µg/0.5 mL<br>(4 yrs & up, including pregnant women)  |
| 13      | Influenza                          | Fluarix                           | GlaxoSmithKline Biologicals  | < 0.0004%   | < 1 µg/0.5 mL<br>(adults including pregnant women)   |
| 14/7    | Influenza                          | FluLaval                          | ID Biomedical Corporation of Quebec  | 0.01%   | <b>25 µg/0.5 mL</b><br>(adults including pregnant women)   |
| 15/8    | Japanese Encephalitis [7]          | JE-VAX                            | Research Foundation for Microbial Diseases of Osaka University (distributed by Sanofi-Pasteur, Inc in USA) | 0.007%  | <b>35 µg/1.0mL</b><br>(>3 years of age)<br><b>17.5 µg/0.5 mL</b><br>(1 to 3 yrs of age)                                    |
| 16/9    | Meningococcal                      | Menomune A, C, AC and A/C/Y/W-135 | Sanofi Pasteur, Inc  | 0.01% (multidose)                                 | <b>25 µg/0.5 mL</b><br>(*2 yrs and up; though the other meningococcal vaccine, Sanofi’s Menactra is now being recommended) |
| 17/10   | Avian Influenza [9]                | Influenza Virus Vaccine, H5N1     | Sanofi Pasteur Inc.  | 0.0098%<br>(multidose with doses at 0 & 2 months) | <b>49 µg/1.0 mL</b><br>(98 µg in 2-dose regimen; 18 to 64 yrs of age)  |

**Table Footnotes**

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of Thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose. Vaccines with a nominal “preservative” level of mercury have **bolded** mercury values.
2. Sanofi Pasteur’s Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. This vaccine is not marketed in the US but it is available.
4. ....
5. ...
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. Aventis Pasteur distributes JE-VAX. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).
8. The numbers in **red** are the count for the current Thimerosal-preserved vaccine formulations that have FDA approval.
9. Approved April, 17 but not in “Table 3” as it is currently only licensed for use in a pandemic outbreak; approvals for children are pending or deferred.

apparent to the unbiased reader that injecting a mother with a Thimerosal-preserved flu shot increases the risk of: **a)** mercury poisoning and **b)** serious teratogenic effects (serious birth defects) in her child.

Therefore, it appears that the CDC officials have been knowingly engaged in a shell game whereby the decrease in the mercury-poisoning risk by removal of Thimerosal from some vaccines and the reduction in others was, and is, knowingly being offset by adding an ineffective vaccine<sup>26,27,28,29,30</sup>, the Thimerosal-preserved influenza vaccine that contains Thimerosal at levels proven to be poisonous, teratogenic, mutagenic, carcinogenic, and immune-system-disruptive in developing and adult humans<sup>31</sup>, to the recommended vaccination schedules for pregnant women and children from 6 months to 23 months of age in 2002, and increasing the age range to 39 months in 2004, to 59 months in 2006, to 59/107 months in 2007 and, *most recently*, to 203 months in 2008.

Therefore, it is clear that drug companies have not voluntarily phased out Thimerosal from all vaccines given to children but rather phased it out of some, reduced its level in others, and intentionally left Thimerosal in some vaccine at preservative levels, mostly at the 0.01% level.

To cover up the decrease in the level of harm as the maximum Thimerosal exposure decreased, it is evident that, *in 2002*, CDC officials knowingly added the Thimerosal-preserved inactivated-influenza vaccine to the recommended vaccination schedule for pregnant women and children starting at 6 months of age:

- Without proof of safety to the requisite minimum standard, “*sufficiently nontoxic ...*”<sup>32</sup> and
- With the certain knowledge that injecting Thimerosal-preserved flu shots into pregnant women will increase the risk of severe birth defects (specifically, cleft palate, hydrocephaly, and pyloric stenosis) in their children<sup>24</sup> as well as the risk of mercury poisoning because the specific dose to which the fetus will be exposed will be significantly higher than the former specific dose of Thimerosal in the “day of birth” dose of a Thimerosal-preserved hepatitis B vaccine (e.g., Merck’s Energix® B) that was recommended for all babies prior to 2000.

Obviously, the author’s “*phased out ... from all vaccines given to kids (with the exception of some flu shots) in 2001*” is false because, as *this reviewer’s Table “1”* shows, preservative levels of Thimerosal remain in several vaccines which are approved for administration

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<sup>26</sup> Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *J Am Phys Surg* 2006; **11**(3): 69-74.

<sup>27</sup> Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet* 2005; 365:773-780.

<sup>28</sup> Simonsen L, Reichert TA, Viboud C, Blackwelder WC, Taylor RJ, Miller MA. Impact of influenza vaccination on seasonal mortality in the US elderly population. *Arch Intern Med.* 2005; **165**: 265-272.

<sup>29</sup> Maeda T, Shintani Y, Nakano K, Terashima K, Yamada Y. Failure of inactivated influenza A vaccine to protect healthy children aged 6-24 months. *Pediatr Int.* 2004; **46**: 122-125.

<sup>30</sup> Centers for Disease Control and Prevention. Assessment of the effectiveness of the 2003-04 influenza vaccine among children and adults-Colorado, 2003. *MMWR.* 2004; **53**: 707-710.

<sup>31</sup> a. 1-Sept-1993 – Lilly & Company Material Safety Datasheet on Thimerosal.

b. 22-Dec-1999 – Lilly & Company Material Safety Datasheet on Thimerosal.

c. 30-Sept-2001 – Gihon Laboratories Material Safety Datasheet on Thimerosal.

d. 28-July-2003 – Merck Material Safety Datasheet on Thimerosal.

<sup>32</sup> Title 21 of the Code of Federal Regulations, Section 610.15(a) [21 C.F.R. § 610.15(a)].

to children.

While the author's next statements:

*"Clearly, we are far from understanding everything we need to about the range of autistic disorders. And that's why 'the possible link between vaccines and autism has been taken very seriously,' says Dr. Schuchat",*

are plainly true, they conceal the reality that, *given the actions by the CDC, vaccine makers and public health officials outlined in the preceding narrative, "we" all understand:*

- The link between Thimerosal and *"autism has been taken very seriously,"* and
- Knowing the seriousness of that link, the healthcare officials, who are responsible for allowing this to occur and continue, are doing their best to proverbially "muddy the waters" to obscure both the link and the harm Thimerosal in vaccines and other drugs has caused and is still causing.

Finally, given all of the preceding actualities, the last statement:

*"But at this point, after so many studies, it's safe to say these two hypotheses have been eliminated as possible causes",*

is simply the regurgitation of another vaccine apologist's dismissive newspeak, which uses the expression *"it's safe to say"* to hide the reality that the viability of these two hypothesis has been repeatedly established by the tens of studies that this author and the people he quotes apparently cannot find or refuse to read, much less, study even though this reviewer, a vaccine safety and effectiveness advocate, has had no similar difficulties.

### **"The worry: Too many shots too soon is risky"**

Here, the author begins by inappropriately combining two separate vaccine concerns, *"Too many" vaccines at once and vaccination "too soon"* into a single concern, *"Too many shots too soon ..."*.

#### The "Too Many At Once" Concern

*"What's behind it: Late last year, the parents of 9-year-old Hannah Poling won a lawsuit in which they claimed that their daughter's autism had been triggered by the five 'catch-up' shots for nine diseases she received in one day. She got the injections in 2000, when she was 19 months old. The highly publicized case underscored fears — also raised by actress Jenny McCarthy, who has a son she believes has recovered from autism — that the practice of giving multiple vaccines at once is too much for a small child's body to handle."*

Superficially, the author's remarks support the "too many vaccines at once" concern.

However, instead of presenting this issue as a valid concern, the author's rhetoric, *"... highly publicized case underscored fears ..."* and *"also raised by actress Jenny McCarthy, who has a son she believes has recovered from autism"*, clearly attempts to undermine the validity of this concern through the use of the words *"fears"* and *"believes"* instead of more supportive words such as *"concerns"* and *"thinks"*.

Moreover, an examination of the author's statement concerning *Hannah Poling v. Sec. HHS* finds it is filled with inaccuracies.

The most glaring of these inaccuracies are tabulated in the reviewer's **Table "2"** on the next two pages.

Moreover, *leaving out the weakening expressions*, this reviewer agrees that this “*highly publicized case*” also underscores the reality that “*the practice of giving multiple vaccines at once*” was certainly “*too much*” for 19-month-old Hannah Poling’s “*body to handle*”.

Since there are many other cases where giving multiple vaccines in a single day has had similar outcomes, it would appear that, *under the medical “precautionary principle”*, multiple-vaccine “catch up” programs should immediately be suspended.

Finally, these other “catch up” vaccination cases clearly underscore the disconnect between primacy of preserving our children’s health and the hubris of those who, *knowing that multiple inoculation has seriously injured some children*, would still risk a child’s current health by making such national inoculation recommendations.

**Table “2”. A Comparison Of The Author’s Claim And Factual Reality**

| Author’s Claim  | Factual Reality  |
|---|--|
| <p><i>“Late last year, the parents of 9-year-old Hannah Poling won a lawsuit ...”</i></p> | <ol style="list-style-type: none"> <li>1. There was <u>no</u> lawsuit – and <u>no</u> administrative hearing.</li> <li>2. In 2002, the parents of then 4-year-old Hannah Poling, born Dec. 27, 1998, filed a “Vaccine Injury” petition with the U.S. Court of Federal Claims (USCFC) as set forth in the National Vaccine Injury Compensation Program (NVICP) [USCFC Case: 02-1466V] that alleged that their daughter’s subsequent autistic disorder and recurring seizures had been caused by the Thimerosal in the vaccines she received at 19-months of age.</li> <li>3. In mid-2007, Hannah Poling’s case had been selected as one of the three test cases in the “Omnibus Autism Proceeding” for the theory that “Thimerosal in vaccines is a causal factor for autism” – these test cases were scheduled to be heard in 2008.</li> <li>4. In late 2007, <i>before the medical experts for the Polings were scheduled to file their reports</i>, medical personnel in the Division of Vaccine Injury Compensation (DVIC) of the U.S. Department of Health and Human Services (DHHS) [the respondent to the parents’ petition], after reviewing her parents’ petition, her medical records and the affidavits in her file conceded that Hannah Poling’s 19-month vaccinations were a causal factor in Hannah’s diagnosed autistic disorder.</li> <li>5. On November 9, 2007, the USCFC issued a “<b>RESPONDENT’S RULE 4(c) REPORT</b>” that formalized the DVIC’s findings in language that was carefully worded to skirt the Thimerosal and autism issues: “In sum, DVIC has concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations Hannah received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder. Therefore, respondent recommends that compensation be awarded to petitioners in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii).”</li> <li>6. Though, <i>at this time</i>, the DVIC concluded that her seizure disorder was <u>not</u> vaccine-related, in early 2008, <i>after reviewing the experts’ filed reports</i>, the DVIC conceded that Hannah’s seizure disorder was vaccine related and that Hannah’s “underlying mitochondrial disorder” was actually an underlying mitochondrial dysfunction – not an inherent disorder.</li> <li>7. As of November 2008, the compensation for Hannah Poling has <u>not</u> been awarded and, <i>though the parents, parents’ attorney and the experts have waived all privacy rights and petitioned to have all records released to the public and the U.S. Department of Justice has concurred that all these records are releasable to the public</i>, the special masters overseeing the vaccine cases have refused to release the records.</li> </ol> |

**Table “2”. A Comparison Of The Author’s Claim And Factual Reality (Continued)**

| Author's Claim   | Factual Reality  |
|--|--|
| <p>"... in which they claimed that their daughter's autism had been triggered by the five 'catch-up' shots for nine diseases she received in one day."</p> | <ol style="list-style-type: none"> <li>1. The Poling's petition claimed that Hannah Poling's clearly regressive autistic disorder and her complex partial seizure disorder had been caused by the preservative level of Thimerosal in the DTaP and Hib vaccines that mercury poisoned Hannah and caused the underlying mitochondrial dysfunction that was observed and documented.</li> <li>2. In addition, the Polings cited the major vaccine components themselves (diphtheria toxoid, tetanus toxoid, the three pertussis toxins, the Haemophyllis influenzae serogroup B antigen, three inactivated polioviruses, the live measles, mumps and rubella virus strains, and the Herpes varicella zoster virus) as contributory factors.</li> <li>3. The experts' reports, a published study and her medical records established that, among her medical conditions, Hannah Poling had a diagnosed: <b>a)</b> mitochondrial disorder, <b>b)</b> autistic disorder, and <b>c)</b> complex partial seizure disorder, all of which were, <i>in the main</i>, the result of Hannah Poling's having been mercury poisoned by the two Thimerosal-preserved vaccines she received at 19 months of age.</li> <li>4. Hannah's mercury-poisoning-related diagnoses were aggravated by the 14 vaccine antigen components in the five inoculations Hannah received for 9 diseases in one day.</li> <li>5. There is no evidence Hannah had any in-born mitochondrial disorder or that she had mitochondrial dysfunction <u>before</u> she was inoculated at 19-months of age with 5 vaccines in a single "well baby" visit.</li> </ol> |

"The facts: Hannah Poling was born with a disorder that affects her mitochondria (the structures within cells that produce energy). And though the family won the settlement on the theory that this underlying vulnerability could have made her more susceptible to vaccine injury, there's actually no proof that she — or any other child with mitochondrial disease — was in fact at any increased risk, says neurologist John Shoffner, M.D., associate professor of biology at Georgia State University, in Atlanta, Georgia, one of the doctors who diagnosed Hannah's disorder. ..."

Since the actual scientific evidence, agreed to by the medical personnel in the DVIC, after they reviewed the filed experts' reports, in their early 2008 concession that vaccines contributed to Hannah's "complex partial seizure disorder", has clearly established that Hannah Poling only developed her mitochondrial dysfunction, not a mitochondrial disorder, after her 19-month shots, the author's "*Hannah Poling was born with a disorder that affects her mitochondria*" is a patently false statement.

In addition, the author's next statement, purportedly based on remarks by John Shoffner who is claimed to be "*one of the doctors who diagnosed Hannah's*" non-existent mitochondrial disorder, again replaces the factual record with his own fabrications:

- "*And though the family won the settlement*" – when the truth is medical professionals in the DVIC conceded the case and the "*settlement*" is still pending
- "*... won the settlement on the theory that this underlying vulnerability could have made her more susceptible to vaccine injury*" – when the truth is the key theory: **a)** advanced by Hannah Poling's parents, **b)** supported by the scientific evidence, and **c)** used as the basis for selecting the Poling case in 2007 as one test case for the Omnibus Autism Proceeding's "theory 2", that "Thimerosal in vaccines is a causal factor for autism" and, thus, the two Thimerosal-preserved vaccines given to Hannah at 19-months of age were the major causal factor for the vaccine injuries that Hannah Poling has been diagnosed to have (in the probable order these injuries occurred): **a)** mitochondrial dysfunction, **b)** regressive autistic disorder, and **c)**

complex partial seizure disorder – with multiple antigens in the shots she received at one time being significant secondary exacerbating factors.

- “...more susceptible to vaccine injury, there’s actually no proof that she — or any other child with mitochondrial disease — was in fact at any increased risk” – when the facts are:
  - a. Injecting Thimerosal-preserved vaccines into young children has been proven to cause mitochondrial dysfunction,
  - b. The FDA has failed to compel and the vaccine makers have refused to provide the required proof that their Thimerosal-preserved vaccines are “sufficiently nontoxic ...” [as required by 21 C.F.R. § 610.15(a)] and did not put Hannah Poling or any other child “at any increased risk”, and
  - c. Since failure to comply with 21 C.F.R. § 610.15(a), a current good manufacturing practice (CGMP) minimum for vaccine safety since 1968, renders any non-complying biological drug product an adulterated drug under Title 21 of the United States Code Section 351, paragraph “(a)”, subparagraph “(2)”, clause “(B)” [21 U.S.C. § 351(a)(2)(B)<sup>33</sup>], it is, and has been since 1968, illegal to put any such drug product into commerce<sup>34</sup> much less administer any such adulterated biological drug product to anyone.

“‘There is no evidence that the contents of vaccines are the cause of autism or mitochondrial disorders,’ he says. What’s more, because even common illnesses like colds, the flu, and rotavirus can cause significant harm to these children, doctors strongly advise they receive all the recommended shots.”

Apparently quoting John Shoffner, the author writes:

*“There is no evidence that the contents of vaccines are the cause of autism or mitochondrial disorders”*

even though, *based on the preceding discussions*, there certainly is evidence that some of “*the contents of vaccines are*” a causal factor for autism spectrum disorders.

In addition, though there are no articles linking Thimerosal, *which is still a component in many FDA-approved vaccines in the USA*, to “*mitochondrial disorders*” per se, there are numerous publications showing that Thimerosal adversely affects mitochondrial function and/or causes mitochondrial dysfunction, *the medical condition that Hannah Poling actually developed after her 5 inoculations at 19 months of age*, including:

1. Yel L, Brown LE, Su K, Gollapudi S, Gupta S. Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria. *Int J Mol Med.* 2005 Dec; **16**(6): 971-977.
2. Humphrey ML, Cole MP, Pendergrass JC, Kiningham KK. Mitochondrial mediated thimerosal-induced apoptosis in a human neuroblastoma cell line (SK-N-SH). *Neurotoxicol.* 2005 Jun; **26**(3): 407-416.

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<sup>33</sup> With underlining added for emphasis: 21 U.S.C. § 351, “(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture ... (2)(B). A drug or device shall be deemed to be adulterated— if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; ...”

<sup>34</sup> 21 U.S.C. § 331(a):

“The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”

3. Redondo PC, Salido GM, Rosado JA, Pariente JA. Effect of hydrogen peroxide on Ca<sup>2+</sup> mobilisation in human platelets through sulphhydryl oxidation dependent and independent mechanisms. *Biochem Pharmacol*. 2004 Feb 1; **67**(3): 491-502.
4. Makani S, Gollapudi S, Yel L, Chiplunkar S, Gupta S. Biochemical and molecular basis of thimerosal-induced apoptosis in T cells: a major role of mitochondrial pathway. *Genes Immun*. 2002 Aug; **3**(5): 270-278.
5. Butler DM, Allen KM, Garrett FE, Lauzon LL, Lotfizadeh A, Koch RA. Release of Ca<sup>2+</sup> from intracellular stores and entry of extracellular Ca<sup>2+</sup> are involved in sea squirt sperm activation. *Dev Biol*. 1999 Nov 15; **215**(2): 453-464.
6. Parys JB, Missiaen L, De Smedt H, Droogmans G, Casteels R. Bell-shaped activation of inositol-1,4,5-trisphosphate-induced Ca<sup>2+</sup> release by thimerosal in permeabilized A7r5 smooth-muscle cells. *Pflugers Arch*. 1993 Sep; **424**(5-6): 516-522.
7. Missiaen L, Taylor CW, Berridge MJ. Luminal Ca<sup>2+</sup> promoting spontaneous Ca<sup>2+</sup> release from inositol trisphosphate-sensitive stores in rat hepatocytes. *J Physiol*. 1992 Sep; **455**: 623-640.
8. Missiaen L, Taylor CW, Berridge MJ. Spontaneous calcium release from inositol trisphosphate-sensitive calcium stores. *Nature*. 1991 Jul 18; **352**(6332): 241-244.
9. Liu TP. Ultrastructure of mitochondria in the corpora allata of honeybees infected by *Nosema apis* before and after treatment with anti-*Nosema* drugs. *Tissue Cell*. 1990; **22**(4): 511-515.
10. Collin HB, Carroll N. In vivo effects of thimerosal on the rabbit corneal endothelium: an ultrastructural study. *Am J Optom Physiol Opt*. 1987 Feb; **64**(2): 123-130.
11. Collin HB. Ultrastructural changes to corneal stromal cells due to ophthalmic preservatives. *Acta Ophthalmol (Copenh)*. 1986 Feb; **64**(1): 72-78.
12. Freitag H, Kadenbach B. Inhibition of malate transport and activation of phosphate transport in mitochondria by ethylmercurithiosalicylate. *FEBS Lett*. 1980 Aug 11; **117**(1): 149-151.
13. Freitag H, Kadenbach B. Ethylmercurithiosalicylate--a new reagent for the study of phosphate transport in mitochondria. *FEBS Lett*. 1980 Jun 2; **114**(2): 295-298.
14. Van Horn DL, Edelhauser HF, Prodanovich G, Eiferman R, Pederson HF. Effect of the ophthalmic preservative thimerosal on rabbit and human corneal endothelium. *Invest Ophthalmol Vis Sci*. 1977 Apr; **16**(4): 273-280.

A more-general PubMed search using the search terms, “mercury, mitochondria”, returned more than 300 articles, which found that the exposure of living systems to both inorganic and organic mercury compounds adversely impacted the mitochondrial systems examined at levels 50 times or more *lower than* the level of mercury (0.005%; 50 ppm) in a typical Thimerosal-preserved vaccine.

Thus, the quoted assertion is not supported by the facts that have clearly established causal links between some of the contents in some vaccines (the measles virus and Thimerosal) and autistic spectrum disorders, and, *at best*, misleading when it speaks of the causal links between “*contents of vaccines*” and “*mitochondrial disorders*”.

What’s more, the author’s final statement:

*“What’s more, because even common illnesses like colds, the flu, and rotavirus can cause significant harm to these children, doctors strongly advise they receive all the recommended shots”*,

is a masterpiece in newspeak because it:

- Speaks of “*colds*” (for which there are no vaccines) and “*the flu*” (for which there are no in-use effective vaccines),

- Misrepresents “*rotavirus*” as a common illness when, *except in areas with poor sanitation, housing and diet*, rotavirus was not a common disease in the USA until the societally non-cost-effective rotavirus vaccines, *which are not shots and which infect all those inoculated with them with rotavirus*, were introduced, and
- Uses these diseases as justification for the author’s “*doctors strongly advise they receive all the recommended shots*”.

In effect, this statement advocates increasing the risk of serious vaccine injury to children with a mitochondrial disorder and implies a promise that the “*recommended shots*” will protect these mitochondrially damaged children from harm when though Hannah Poling, *who had no mitochondrial disorder*, was severely damaged when she received 5 shots on the same day.

Hopefully, all who read this statement will see that it is: **a)** illogical and misleading, **b)** not relevant to the “too many shots at once” issue, **c)** financially self-serving for the doctors, and **d)** financially problematic for the parents.

“So what does all of this mean for parents of healthy kids? Not much — getting more than one shot at a time isn’t the huge physical stress it seems to be. Their immune systems handle far greater challenges from everyday exposure to germs on shared toys, doorknobs, and the playroom floor.”

This paragraph is simply a regurgitation of the unsupported assertions of many other vaccine apologists.

In general, if, *in response to getting more than one shot at a time*, the child has a significant adverse reaction, then even that apparent physical stress should not be ignored or, *as the author does here*, downplayed.

Moreover, it is simply wrong to compare the injection of pathogens or other antigens into the body, *bypassing the immune system’s outer layers*, to “*everyday exposure to germs on shared toys, doorknobs, and the playroom floor*”, *which do engage these external layers of the human immune system*.

If the author were simply a journalist, perhaps this inappropriate comparison could be overlooked, however, *because the author is a medical doctor*, such “apples and oranges” comparisons would appear to be reprehensible.

“As Dr. Offit explains it: Think about the bugs that caused your child’s last ear infection. Each single bacterium has 2,000 to 3,000 components that stimulate an immune response from the body. As those bacteria multiply, the challenge to the immune system increases exponentially. Your baby feels awful and likely has a high fever and lots of pain. The body pulls out the stops to fight it off. Now compare that to this: ‘The entire fourteen-shot course of childhood vaccinations contains only about 150 immunological components altogether,’ says Dr. Offit. This is about a tenth of the challenge posed by exposure to just one microscopic germ.”

Not content with his own improper “apples and oranges” comparison, the author next writes about an inappropriate comparison that Paul Offit, M.D., *a well-known vaccine apologist and benefited patent holder for Merck’s Rotateq® vaccine*, uses to mislead people about the relative risk from all shots to that of a lone unidentified bacterium.

First, this example glosses over the fact that children are not simultaneously exposed to multiple diseases, while the current national recommended inoculation schedule permits the inoculation of children under 2 years of age with vaccines containing

immune-system-reactive antigens for 8 to 13 diseases as well as other antigenic materials (e.g., adjuvants, Thimerosal, gelatin, and egg albumin).

Moreover, this example also ignores the fact that injections bypass the external layers of the human immune system so that the antigenic responses their “*immunological components*” provoke do not occur in the normal sequential order or the bodily environment during an actual exposure to a disease.

In addition, for those vaccines that contain virtually insoluble inorganic aluminum hydroxyl polymers, used as adjuvants to “stimulate” the immune system, *when engaged by the circulating macrophage branch of the immune system*, these adjuvants produce extended cytokine release by the macrophages that are attempting to engulf and “digest” the injected virtually insoluble aluminum hydroxyl polymeric materials they encounter – and increase the risk of auto-immunogenic reactions and disease in those injected with such adjuvants<sup>35,36,37,38</sup>.

In addition, unlike a natural bacterial infections that start with a few bacteria that, *when the body’s immune system does not recognize and attack them first*, can multiply exponentially, the injected “*immunological components*” in vaccines are typically in the millions to ensure that sufficient antibody levels will be produced by each injection – even though the antibody titer levels do not, *per se*, guarantee disease immunity.

Furthermore, unlike most childhood diseases, *except chicken pox*, where contracting the childhood disease produces near lifetime immunity from future infection in almost everyone who has the disease, multiple doses (currently, 2 to 5+ childhood inoculations for each vaccine) are required to produce protection with, *in some cases*, the “need” for “booster” doses every “10” years to ensure extended protection – an obvious cash windfall for the vaccine maker and the healthcare establishment but, *in many cases*, a less-than-societally-cost-effective medical intervention for the public.

Finally, it is absurd to compare:

- a. The human immune-system’s reaction to a single bacterium, regardless of how many thousand components that may, *when their level is high enough*, “stimulate an immune response from the body” with:
- b. Its reaction to millions of copies of “*immunological components*” in each vaccine dose.

“What’s more, the bacteria and viruses used in vaccines are either killed or altered, says Martin Myers, M.D., author of ‘**Do Vaccines Cause That?!**’ There are just enough to induce immunity, but not enough to make someone sick — and certainly not enough to overload the immune system of a healthy child. As with any medical intervention, side effects, including soreness, rashes, and fever,

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<sup>35</sup> Lach B, Cupler EJ. Macrophagic myofasciitis in children is a localized reaction to vaccination. *J Child Neurol*. 2008 Jun; **23**(6): 614-619.

<sup>36</sup> Ryan AM, Bermingham N, Harrington HJ, Keohane C. Atypical presentation of macrophagic myofasciitis 10 years post vaccination. *Neuromuscul Disord*. 2006 Dec; **16**(12): 867-869. Epub 2006 Sep 26.

<sup>37</sup> Gherardi RK, Coquet M, Cherin P, Belec L, Moretto P, Dreyfus PA, Pellissier JF, Chariot P, Authier FJ. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminum hydroxide in muscle. *Brain*. 2001 Sep; **124**(Pt 9): 1821-1831.

<sup>38</sup> Authier FJ, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, Ranoux D, Pelletier J, Figarella-Branger D, Granel B, Maisonobe T, Coquet M, Degos JD, Gherardi RK. Central nervous system disease in patients with macrophagic myofasciitis. *Brain*. 2001 May; **124**(Pt 5): 974-983.

are possible, but most are mild and short-lived. In rare instances, some children experience fever-induced seizures following shots, but though these are frightening, they cause no permanent harm.”

The initial statement attributed to “*Martin Myers, M.D.*” is obviously overly simplistic and misleading.

Factually, today’s vaccines contain: **a)** modified bacterial toxins (e.g., diphtheria and tetanus toxoids in today’s DTaP, DT, Td, and Tdap vaccines), **b)** isolated toxic components (e.g., “purified” bacterial fragments isolated from killed lysed pertussis cells in the DTaP and Tdap vaccines), **c)** synthetic antigenic materials (e.g., the antigens in the hepatitis B and HPV vaccines), **d)** polysaccharides isolated from the cell walls of the disease organism (e.g., Sanofi’s Menomune® vaccine formulas), **e)** polysaccharides conjugated to a toxoid (e.g., Sanofi’s Menactra vaccine formulas), **f)** “attenuated” live virus strains (e.g., the measles, mumps and rubella strains in Merck’s MMR® II vaccine formulations), **g)** inactivated viruses (e.g., the inactivated polio and influenza vaccines), **h)** bioengineered viruses (e.g., the cold-adapted live influenza viruses in MedImmune’s FluMist® vaccine formulations and the five human-bovine hybridized viruses in Merck’s RotaTaq rotavirus vaccine formulation), and **i)** cross-protective viruses (e.g., the live vaccinia virus vaccines used to protect those vaccinated from contracting smallpox).

With respect to the author’s:

*“There are just enough to induce immunity, but not enough to make someone sick — and certainly not enough to overload the immune system of a healthy child”*,

since the dose of vaccine typically given to a baby is at best half of the dose given to an adult, and the doses for children over three, weighing as little as 6 kg (13.3 lb), are the same as the doses for adults who typically weigh 40 kg (88 lb) or more, the doses given are obviously more than “*just enough to induce immunity*”.

Additionally, since some develop acute and chronic medical conditions and a few die shortly after receiving a single vaccination, vaccinations are certainly “*enough to make someone sick*” and, *in the cases where immune-system-collapse is a causal factor in the sudden death of a previously healthy child*, most certainly was “*enough to overload the immune system of a healthy child*” in such cases.

Based on: **a)** the preceding realities, **b)** the adverse vaccination outcomes, including death, reported to the Vaccine Adverse Events Reporting System (VAERS) database, **c)** the thousands of cases filed with the National Vaccination Injury Compensation Program (NVICP) and **d)** the billions of dollars paid out to compensate the families for the vaccine-related harm done and the vaccine-related deaths, it should be obvious that author’s statements here are, *at best*, knowing misrepresentations.

“One common response to these concerns is to break up combination vaccines (which may contain up to five inoculations in one) or to spread them out. But that carries significant risks of its own. ‘Too often, an immunization delayed is an immunization missed,’ says Dr. Schaffner. ‘It’s hard enough for parents to keep track.’ ...”

Here, after stating two rational approaches to reducing vaccination risk (“*to break up combination vaccines ... or to spread them out*”), the author:

- Makes an unsubstantiated claim, that either of the stated approaches “*carries significant risks of its own*”, and
- Quotes vaccine-apologist Schaffner’s concern that a vaccination may be missed,

*“Too often, an immunization delayed is an immunization missed,” says Dr. Schaffner. “It’s hard enough for parents to keep track”*

as if these unstated risks or the worry that a vaccination will be missed were more important than reducing the risk of serious vaccine injury or vaccine-related death – risks that the author does not even mention here.

“More troubling, during the gaps, kids are susceptible to catching serious diseases they could have been protected from. Vaccines are scheduled when they are for precise reasons: It’s a balance between finding the time when the baby’s immune system can respond and knowing when he’s most in danger of catching the infection, says Dr. Schuchat. Give a shot late and a child is left unprotected at his most vulnerable time.”

In response to what is obviously vaccination propaganda, this reviewer simply asks how can anyone think that it is medically appropriate to give the hepatitis B vaccine at birth, 1 to 2 months, and at 6 to 18 months (with an additional 4-month dose if combination vaccines are used) to young children who are in virtually no danger of catching hepatitis B, knowing that: **a)** the protection provided will “wear off” just at the time when they become sexually active and at risk of IV drug use in their teens and **b)** the risk of a serious adverse reaction, including death and permanent injury, greatly exceeds the risks associated with a healthy child’s having hepatitis B?

How is this attuned to the time when the child is *“most in danger of catching the infection”*?

Moreover, as the scheduling of the current national vaccination programs are presented here, it is clear to this reviewer that the current vaccination programs are blind to and do not consider, *as they surely should*, the long-term risks of chronic disease that accompany giving any vaccine to a child at birth or before the child’s immune systems have reached the “2-years post-partum” stage of development.

Finally, *underneath the rhetoric*, it seems clear that today’s national vaccination programs are currently scheduled:

- At the behest of the vaccine makers (who demand that there be a national program so that the vaccine can be added to the NVICP – protecting them from most lawsuits for the harm their vaccines may cause),
- For the scheduling convenience and financial interests of those who administer the vaccines (whose representative populate the CDC’s Advisory Committee On Immunization Practice [ACIP]), and
- For the long-term financial interests of all facets of a healthcare establishment interested in growing its customer base and increasing its profitability

with little or no regard for the overall fiscal and/or physical health of our children and ourselves.

How else would national vaccination programs for new vaccines with demonstrated clinical trial issues (e.g., human-animal hybridized rotavirus vaccines [with intussusception and Kawasaki’s disease problems] and the HPV vaccine [with fainting, seizure, and Guillian-Barre issues]) be rolled out without any actual in-use experience in the most-susceptible general population segments?

How else would the program be continuing to recommend DTaP at 2, 4 and 6 months when there is clear evidence that delaying the start of the program for at least 2 months could significantly reduce the rate for chronic asthma in children?

[**Note:** There is also clear evidence that there may be no need for an early Diphtheria or

Tetanus vaccination program because:

- a. There are no longer any reported cases of diphtheria in any age group in the population of the USA – not even imported cases,
- b. Almost all cases of tetanus occur in the elderly,
- c. Tetanus only develops in deep puncture wounds that are not properly disinfected,
- d. There are effective antibiotics to treat both diseases, and
- e. Very few tetanus cases occur in farming communities of the Amish, who do not vaccinate.

Moreover, *even with the current high levels of compliance and a 5+ dose DTaP/Tdap vaccination program that may not even be societally cost-effective*, from:

- a. The thousands of cases annually<sup>39</sup>,
- b. The cyclic nature in the number of cases reported, and
- c. The reported healthcare providers' tendency to diagnose chronic bronchitis instead of whooping cough in both fully vaccinated older children and adults,

it is apparent that the current pertussis vaccination program is not societally cost effective and the move to replace tetanus-diphtheria (Td) boosters with the Tdap vaccines, *more expensive vaccines with one more component than the existing tetanus-diphtheria booster vaccines presently used*, only serves to further line the pockets of the vaccines' makers, fill the tax coffers of the NVICP, and increase the patient pool for the healthcare establishment because the Tdap vaccines have a higher risks for serious side-effects than the Td vaccines they are to replace.]

“Robert Sears, M.D., author of **The Vaccine Book: Making the Right Decision for Your Child**, offers parents an alternative to the American Academy of Pediatrics schedule — but he does so with Dr. Schuchat’s concerns in mind. There are certain vaccines, including those that protect against meningitis, rotavirus, and pertussis, that he does not recommend delaying for the same reason she gives. However, he willingly offers families the option of postponing hepatitis A and B as well as polio, mainly because these illnesses do not pose the same threat to infants as the others.”

Here, the author is simply offering the views of another vaccination advocate, Robert Sears, MD, who apparently also sees no problem postponing the vaccines for polio and hepatitis A and B.

However, this passage offers little evidence that the “too many vaccinations at once” issue is not a valid concern that should be taken seriously.

### The “Vaccination Too Soon” Concern

Ironically, though the author presented the issue as “*The worry: Too many shots too soon is risky*”, outside of his vague and unsupported:

*“Vaccines are scheduled when they are for precise reasons: It’s a balance between finding the time when the baby’s immune system can respond and knowing when he’s most in danger of catching the infection, says Dr. Schuchat. Give a shot late and a child is left unprotected at his most vulnerable time.”*

contained in his discussion of the reasons not to break up or delay vaccination beyond the applicable recommendations, he does not explicitly address the “vaccination too soon” concern.

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<sup>39</sup> For the period 1999 – 2006, the number of annual pertussis cases reported was: 7,288, 7,867, 7,580, 9,771, 11,647, 25,827, 25,616, and 15,652, respectively.

Although the evidence for the effect of delaying a given vaccination series is sparse<sup>40</sup>, and the evidence for delaying the overall program until the child is older (e.g., to 2 years) is indirect (e.g., in 1975, shifting from a U.S.-type program starting at 2 months to a program starting at 2 years lifted Japan's "first-year infant mortality" standing from 17<sup>th</sup> in major nations in the world to 1<sup>st</sup> a few years later – where it has stayed) ***these findings clearly indicate that vaccination of infants during their first year of life is a net negative for their survival*** – the opposite of what would be the case if: **a)** vaccination were effective in preventing disease and **b)** the vaccination programs' only side effects were minor in nature.

Based on the preceding realities, perhaps the author did not want to address the "too soon" issue because, *at some level*, he too recognized that the U.S. vaccination programs start too soon.

### **“The worry: Vaccines contain toxins**

What's behind it: Vaccines do contain a variety of substances besides the viral or bacterial components. There are preservatives as well as adjuvants, which are substances that help vaccines grab the attention of the immune system and prompt it to create antibodies. One adjuvant that some are focusing on is aluminum, which at chronic high levels can contribute to nerve, brain, and kidney damage.”

Here, the author begins well by admitting that vaccines “*do contain a variety of substances besides the viral or bacterial components*” but then fails to mention those substances that are toxins or to identify which of these toxins are, *at the levels found in vaccines*, potentially toxic to some of those vaccinated who, *for whatever reasons*, are more susceptible to these toxins even at the “low” levels present in today's vaccines.

Moreover, he chooses to only mention two categories of substances: **1)** “*preservatives*”, which he does not define or address, and **2)** “*adjuvants*”, which he understandably defines as “*substances that help vaccines grab the attention of the immune system and prompt it to create antibodies*”, since the dictionary definition<sup>41</sup> for adjuvant is “a substance mixed with an immunogen in order to elicit a more marked immune response”, which properly portrays the role of the adjuvant as a passive rather than an active one.

Unfortunately, this superficial discussion ignores other both added and adventitious ingredients, like added proteins (e.g., albumin and gelatin) that, *when present in an injected vaccine containing an adjuvant and/or other immunogens*, may induce food allergies or food intolerances in the person injected with a vaccine containing it and adventitious animal viruses, phages, and prions that may be present in some vaccines (e.g., simian virus 40 [SV-40] in viruses grown in monkey kidneys).

Moreover, though the author mentions and attempts to discuss aluminum adjuvants, he does not mention, much less address, any preservative, including the most toxic bioaccumulating one, Thimerosal.

Given the author's approach, it is obvious that he:

- Neither intends to critically address the issue of the toxins in vaccines

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<sup>40</sup> McDonald KL, Huq SI, Lix LM, Becker AB, Kozyrskyj AL. Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma. *J Allergy Clin Immunol*. 2008 Mar; **121**(3): 626-631. Epub 2008 Jan 18.

<sup>41</sup> **Webster's New Universal Unabridged Dictionary**, 2001, page 25, column 3, “ad•ju•vant (əj' ə vənt)” or an equivalent dictionary.

- Nor intends to admit:
  - a. There is no real justification for the use of a preservative in U.S. vaccines currently, and/or
  - b. Given the increased-autoimmune-risk downside of adjuvants and the ability to minimize their level by increasing the concentration of the specific immunogens, the use aluminum adjuvants should be reduced as much as possible in the current vaccine formulations and not used in any future vaccines.

Moreover, the author's final statement here:

*“One adjuvant that some are focusing on is aluminum, which at chronic high levels can contribute to nerve, brain, and kidney damage”,*

exposes his lack of understanding that aluminum adjuvants are not soluble aluminum hydroxyl compounds but rather insoluble polymeric aluminum hydroxyl materials.

“Because several new vaccines containing aluminum have been added to the schedule, some parents and doctors worry that the extra exposure might push levels out of the safety zone — particularly given that there's already aluminum pretty much everywhere: in water, breast milk, formula, and the air we breathe. ‘I'm concerned that health officials haven't done any human-infant research to make sure the amount of aluminum in the vaccines is safe,’ says Dr. Sears.”

Since aluminum adjuvants are practically insoluble in aqueous systems at the near pH 7.4 levels found in the human body, the soluble aluminum concerns expressed in this paragraph are misplaced concerns.

As this reviewer has previously outlined, and provided supporting documentation for, the presence of these non-living insoluble polymeric hydroxyl aluminum materials are, *in conjunction with the vaccine immunogens*, the causal factor for the various observed harms, *which persists for extended periods of time*, to the human immune system and, *by this means*, the use of these aluminum adjuvants appears to fundamentally weaken the overall human immune system and increase autoimmune disease risk.

Hopefully, as the understanding of the danger that aluminum adjuvants represent becomes more widespread, the public will rise up and demand that these harmful aluminum adjuvants be removed from vaccines and, *if any adjuvant must be used*, replaced with ones that, after or as they cause immune-system activation for the needed period of time, degrade into harmless substances that are either excreted or otherwise utilized by the body.

“The facts: Everyday exposure to aluminum is generally not considered hazardous — most adults ingest 7 to 9 milligrams (mg) every day through food alone (up to 200 mg if they pop antacids), and formula contains anywhere from .05 mg/L to .93 mg/L. Very little of the aluminum taken in orally is absorbed, and what does make it into the bloodstream is excreted within days. Although the aluminum in vaccines is, of course, injected, there doesn't seem to be evidence it poses any danger for healthy kids. The amount of aluminum injected is no more than .85 mg per dose, and the CDC, the Institute of Medicine, and the World Health Organization have all deemed the levels babies receive from shots to be safe.”

First, the facts presented here are either not relevant to injected aluminum adjuvants or, *as this reviewer has already established previously*, the author's remarks are incorrect.

Obviously, the author is wrong about injected aluminum adjuvants, as the pertinent references cited earlier have established, because there is a growing body of evidence that the aluminum adjuvant used in a given vaccine does pose a danger to some otherwise healthy children and adults of all ages.

Furthermore, the author's statement:

*"The amount of aluminum injected is no more than .85 mg per dose, and the CDC, the Institute of Medicine, and the World Health Organization have all deemed the levels babies receive from shots to be safe"*

is at odds with the applicable FDA CGMP regulation set forth at 21 C.F.R. § 610.15(a), which, *among other things*, states:

*"An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:*

- (1) 0.85 milligrams if determined by assay;*
- (2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or*
- (3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in §600.2 of this chapter)."*

Clearly, U.S. vaccine manufacturers are allowed to have up to 1.25 mg of aluminum in a polymeric aluminum hydroxyl adjuvant in a vaccine dose and not the 0.85 mg of aluminum per dose stated by the author.

However, rather than allowing *"the CDC, the Institute of Medicine, and the World Health Organization"* to deem *"the levels babies receive from shots to be safe"*, the law requires scientifically sound evidence that the added adjuvant *"does not affect adversely the safety or potency of the"* biological drug product.

Given the existing body of evidence and the fact that the amounts babies receive are *"deemed ... to be safe"*, it clearly seems that, *like the use of Thimerosal as a preservative without the requisite proof of safety*, the vaccine makers have been and are using a polymeric aluminum hydroxyl material as an adjuvant without *"satisfactory evidence that it does not affect adversely the safety ... of the product"*.

Thus, until and unless safety can be established by satisfactory long-term immunological studies for each currently FDA-approved vaccine, this reviewer calls on the Secretary of Health and Human Services, *under the Secretary's statutory authorities as set forth in 42 U.S.C. § 300aa-27*, to:

- ❑ Review all of the vaccine formulations that use an aluminum adjuvant,
- ❑ *Where there are several such vaccines for a given vaccination program*, suspend the licenses for all but the vaccines with the lowest level of aluminum adjuvant under the statutory authority explicitly granted to the Secretary in 42 U.S.C. § 300aa-27(a)(2), and
- ❑ Under that same statutory authority:
  - Order the makers of the vaccine formulations with higher adjuvant levels to:
    - Prove that the long-term immunological safety of their vaccine is the same as the vaccine with the least level of aluminum adjuvant to have the suspension lifted on the vaccines that have a higher level or

- Replace their current formulation with a formulation that is safe and either has no adjuvant, a biodegradable adjuvant that has been proven safe, or a level of aluminum adjuvant that is no higher than the level in the vaccines whose licenses have not been suspended, and
- When all the remaining approved non-suspended vaccine formulations for given vaccine type have, *in order of preference*:
  - No adjuvant,
  - A biodegradable adjuvant that has been proven safe, or
  - The least practical level of a polymeric aluminum hydroxy adjuvant,permanently revoke the approvals and licenses for all of the other less safe vaccine formulations that use polymeric aluminum species as an adjuvant.

“However, if you still have concerns, you can ask your doctor to choose low- or no-aluminum vaccines when possible. In the instances when it’s not, Dr. Sears will work with aluminum-wary parents by having them bring their babies in once a month between 2 and 7 months of age (rather than bimonthly) so that they get just one aluminum-containing shot at a time. ‘If doctors don’t meet worried parents halfway, the problem of kids not getting vaccinated will continue,’ says Dr. Sears.”

First, given the unnecessary risk of long-term immune-system damage that a vaccine containing an adjuvant based on a polymeric aluminum hydroxy material may cause in susceptible children and the current lack of a rapid test to identify those children, who are most susceptible, this reviewer must suggest that such aluminum adjuvated vaccines be avoided.

Moreover, while this reviewer agrees that spreading out the doses of aluminum adjuvants a child receives is: **a)** better than not doing so and **b)** a viable near-term option, this reviewer thinks that “no aluminum” vaccines are the better option.

Finally, in addition to proceeding as suggested for vaccine formulations containing an aluminum-based adjuvant, this reviewer again recommends that the Secretary of HHS take action to restore the public’s confidence in the safety of vaccines by proceeding to: **a)** permanently and irreversibly ban the use of any level of Thimerosal in the manufacture of any U.S.-licensed vaccine and **b)** irreversibly revoke the licenses and approvals for Thimerosal-preserved vaccines under the Secretary’s statutory authorities as set forth in 42 U.S.C. § 300aa-27(a)(2).

### “The worry: It’s healthier to contract some diseases naturally

What’s behind it: The immunity one develops against chicken pox and measles after having the illness is more complete than the protection from the shot. Because that fact is so appealing, chicken pox and measles parties — where parents intentionally expose a child to the viruses — have been around for years, and are now on the upswing.”

Here the author is a master of understatement because, for the communicable childhood diseases and the other communicable diseases for which there is an FDA-licensed vaccine delivered by a shot/jab, the immunity one develops against all these diseases is “*more complete than the protection from the shot*”/jab.

In addition, a woman’s disease-acquired immunity provides more complete immunity to the children she bears.

Further, *except for chickenpox*, the immunity provided by having these diseases and recovering from them typically lasts much longer, *typically for a lifetime*, than the protection provided by vaccination, *which lasts 10 years or less in most cases*.

Moreover, while almost all who have these diseases and recover have extended immunity, typically, less than 95 % (and, *in some instances*, less than 80%) develop intermediate-term immunity even when they are “fully” vaccinated.

Thus, *given the reduction in circulating “wild” disease viruses*, this reviewer understands the upswing in “*chicken pox and measles parties*”, where educated parents know that there is a current need to help nature along.

“Rebecca Foster threw one after her husband, Kevin Burget, came down with shingles, an illness that’s caused by the same virus behind chicken pox. The Brooklyn, New York, couple had elected not to vaccinate their then 2-year-old son, Hart, against chicken pox (he’d had all his other shots), and they seized the opportunity for the toddler to get it from his dad. The two shared lots of hugs and lots of cups — and sure enough, Hart picked up the pox. ‘He hardly itched. It was very mild — not like the horror stories we’d heard,’ says Foster. ...

Knowing other parents might want their kids exposed, the couple posted a notice on a local e-mail listserve inviting interested families to come over; two ultimately showed up for a playdate with Hart, during which sharing everything, including lollipops, was encouraged. The visiting kids didn’t get sick, but their parents were highly grateful for the chance. ‘They brought presents,’ says Foster.”

While this is one anecdotal story, it underscores: **a)** the reality that chickenpox is a mild disease in truly healthy children, and **b)** the need to have “chickenpox” parties at the first sign of chickenpox because those infected are most contagious shortly before they break out in pox and for a brief period thereafter.

In contrast, in Japan, where chickenpox is endemic and only about 25% of the children are inoculated, there is much less need for such parties because almost 75% of the each year’s cohort of children contract chickenpox.

“The facts: The potential complications of both chicken pox and measles are far more dangerous than any posed by the shots. ‘Many young parents think these infections are trivial,’ Dr. Schaffner says, ‘which only means they’ve never seen a child seriously ill with either of them.’ Consider this: Complications include seizures, pneumonia, or encephalitis (brain inflammation); one or two of every thousand children who come down with measles die or are mentally impaired. In pregnant women, measles can cause miscarriage and premature birth. Chicken pox can lead to staph or strep infections.”

Here, the author is simply distorting the facts in an attempt to raise the parents’ fear of their children’s contracting measles or chickenpox.

He does this by pointing to the severe adverse disease outcomes, including death, experienced by a few children, who, typically, are not truly healthy and/or not appropriately treated when these children show the first symptoms of either disease.

Yet, he fails to note that the maker of the U.S.-licensed vaccines for measles and chickenpox has knowingly failed to evaluate the potential of the measles and chickenpox vaccines to be carcinogenic and/or mutagenic, nor their potential to impair fertility, while there is no evidence that this reviewer has yet found that having measles or chickenpox in childhood increases the children’s carcinogenic or mutagenic

risk or impairs their fertility.

Moreover, the author is also being disingenuous because he fails to point out that the serious adverse reactions, including other chronic diseases, associated with:

- The current live-virus vaccine for measles, the Merck's MMR II vaccine in the USA, which, based on the vaccine's package insert (leaflet), include:
  - Body as a Whole: Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; and irritability;
  - Cardiovascular System: Vasculitis;
  - Digestive System: Pancreatitis; diarrhea; vomiting; parotitis; and nausea.
  - Endocrine System: Diabetes mellitus;
  - Hemic and Lymphatic System: Thrombocytopenia; purpura; regional lymphadenopathy; and leukocytosis;
  - Immune System: Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history;
  - Musculoskeletal System: Arthritis; arthralgia; and myalgia;
  - Nervous System: Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE); subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; and paresthesia;
  - Respiratory System: Pneumonitis; sore throat; cough; and rhinitis;
  - Skin: Stevens-Johnson syndrome; erythema multiforme; urticaria; rash; measles-like rash; pruritis;
  - Special Senses — Ear: Nerve deafness; and otitis media;
  - Special Senses — Eye: Retinitis; optic neuritis; papillitis; retrobulbar neuritis; and conjunctivitis;
  - Urogenital System: Orchitis; and
  - Other: Death from various, and in some cases unknown, causes has been reported rarely following vaccination with the measles, mumps, and rubella vaccine;

or

- The current live-virus vaccine for chickenpox, Merck's Varivax®, which, based on the vaccine's package insert (leaflet), include:
  - Phase III Clinical Trials, First Dose, followed for 42 days after dose:
    - Varicella-like rash (injection site), 3.4% at 8–19 days;
    - Varicella-like rash (generalized), 3.8% at 5–26 days;
    - (In  $\geq 1\%$  in the clinical trial, in order of decreasing incidence): upper respiratory illness, cough, irritability/ nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, heat rash/prickly heat, arthralgia, eczema/dry skin/ dermatitis, constipation, and itching;
    - (<1 %): Pneumonitis; and

- (<0.1%): Febrile seizures;
- Two Doses, 3 months apart, followed for 42 days after each dose:
  - First dose: Varicella-like rash (injection site), 3% at 6–20 days;
  - First dose: Varicella-like rash (generalized), 5.5% at 7–21 days;
  - Second dose: Varicella-like rash (injection site), 1.0% at 0–6 days;
  - Second dose: Varicella-like rash (generalized), 0.9% at 0–23 days;
  - Other: (≥1%, in order of decreasing incidence): upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, diarrhea, stiff neck, irritability/nervousness, lymphadenopathy, chills, eye complaints, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, constipation, lower respiratory illness, allergic reactions (including allergic rash, hives), contact rash, and cold/canker sore.
- Additional adverse reactions:
  - Body as a Whole: Anaphylaxis in individuals with or without an allergic history.
  - Hemic and Lymphatic System: Thrombocytopenia (including ITP).
  - Nervous/Psychiatric: Encephalitis; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; non-febrile seizures; aseptic meningitis; dizziness; and paresthesia.
  - Respiratory: Pharyngitis, and Pneumonia/Pneumonitis.
  - Skin: Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; and herpes zoster.

And, *since less than 10% of all vaccine adverse events are reported to VAERS*, the actual in-use risk levels for these serious adverse vaccination reactions are either underestimated or unknown.

“Dr. Myers has seen the effects of those infections firsthand. He recalls a 19-month-old whose parents decided he was getting too many shots at once and left off the chicken pox vaccine. ‘The boy came to our hospital with staph and strep skin infections. It required powerful antibiotics to save him.’”

Here, the author reports an anecdotal story of a case seen by a “*Dr. Myers*” that is offered as an example of serious skin infection complications implicitly from the child’s having chickenpox even though, *based on the manufacturer’s package insert*, the same skin-disease outcomes, or worse (e.g., Stevens-Johnson syndrome), could have been found had the child been vaccinated against chickenpox.

Lacking a complete medical history on this child, neither this reviewer nor other readers can ascertain: **a)** the health of the child prior to infection, **b)** the reasons, *if any*, for the outcomes observed and **c)** the reasons for the infections and/or their progression to the point that the use of “*powerful antibiotics*” was required.

“To be fair, most kids who get chicken pox will not end up in the hospital. But, like Dr. Myers’s patient, a few will — and there’s a good chance their parents never would have believed it could happen to them. ‘We’d all love to have absolute truths and guarantees, but that’s not always attainable,’ says Dr. Shoffner. Vaccines are no exception. ‘We have to make the best decisions we can with the best information available to us.’”

Had the author truly wished “(t)o be fair”, he would have pointed out that some children will also be hospitalized from a serious reaction to the chickenpox vaccine.

Finally, Dr. Shoffner quoted remarks:

*“We’d all love to have absolute truths and guarantees, but that’s not always attainable”*

and

*“We have to make the best decisions we can with the best information available to us”*,

conceal the reality that, *like the author here*, those in the Establishment who write articles like this one and/or act as experts are careful to point out the worst possible risks for the disease but loathe to speak to the worst possible risks or ensure that all the risk information is honestly presented so that a parent could easily find valid estimates for each disease and vaccination risk as well as those interventions that can be used to mitigate both sets of risks.

### **Reviewer’s Concluding Remarks**

Given the substantiated information presented in this review, it should be clear that the author, “*Dr. Walt*”, has either:

- Failed to separate fact from fiction because of the author’s lack of knowledge and understanding of the facts themselves, or
- Knowingly chosen to write this article so that it employs all of the attributes of doublespeak<sup>42</sup>, “*the deliberate, calculated misuse of language*”, to defend even the most problematic of today’s vaccination programs.

Hopefully, after reading this response to Dr. Walt’s article and verifying the accuracy of the information provided or cited, the reader will, at least, know Dr. Walt’s article does little to separate fact from fiction when it comes to:

- Vaccines,
- The CDC-recommended vaccination programs, and/or
- Proof of vaccination safety and effectiveness.

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<sup>42</sup> In **Doublespeak: From “Revenue Enhancement” to “Terminal Living” – How Government, Business, Advertisers, and Others Use Language to Deceive You**, a 1989 book by William Lutz (Harper; ISBN 0-060-161-34-5), the defining attributes of an article that can be characterized as “doublespeak” include the intentional use of language to: misinform; distort reality; pretend to communicate; make the bad seem good; avoid or shift responsibility; make the negative appear positive; create a false verbal map of the world; limit, corrupt and prevent thought; make the unpleasant appear attractive or tolerable, and/or create incongruity between reality and what is said or not said.

### **Information About The Author and This Responder/Reviewer**

If the reader wants to more information about Dr. Larimore, they can visit his Internet web site: <http://www.drwalt.com/> and click on the “About Dr. Walt” tab.

Should the reader wish to know more about this responder/reviewer, they can visit his Internet web site: <http://www.dr-king.com/> and click on the “Credentials” link. **[Note:** The current text of many of Dr. King’s pertinent articles on vaccines and Thimerosal are posted on, and can be downloaded from, the “Documents” section of <http://www.mercury-freedrugs.org/>, the web site of CoMeD.]