

# Facility Automation Management Engineering (FAME) Systems

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Wednesday, 25 August 2010

To All:

Following this page is this reviewer's response to a Food and Drug Administration (FDA) web page: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm220649.htm>, "last updated on August 5, 2010", that this reviewer downloaded on 11 August 2010.

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This response, titled:  
**"FORMAL REVIEW OF: The FDA's '2010-2011 Influenza Season Vaccine Questions and Answers'"**,  
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 article will be quoted in an *italicized "Times New Roman"* font and extensive quotes will be indented.

Second, the remarks by this reviewer are presented, as they are in this introduction, in a "Tahoma" font and indented to clearly separate them from the source.

Further, this reviewer's remarks are in a "Tahoma" font except when he quotes: **a)** from or refers to any US statute, regulation or the Constitution of the USA, where the text will be in a "Franklin Gothic Medium Cond" font or **b)** from other sources, where the quotations will be in an "Arial Narrow" font.

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 this formal review.

Respectfully,

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## FORMAL REVIEW OF: The FDA's "2010-2011 Influenza Season Vaccine Questions and Answers"

### "Key Facts"

**Actually, the following bullets are simply FDA's misleading and inaccurate "spin" on a given fact as well as FDA or other federal agency propaganda designed to support clearly in-use ineffective national influenza-inoculation programs for children and adults.**

- "• Vaccines for the 2010-2011 influenza season are approved by FDA for the prevention of influenza in children, adolescents, and adults, including the elderly."

While the "approved by FDA for the prevention of influenza ..." may be an accurate representation of the views of the US Food and Drug Administration, a more factually accurate statement would be:

"Though approved by the FDA for the prevention of influenza, the existing FDA-approved influenza vaccines have never been shown in any US-wide retrospective statistical evaluation to be in-use effective in protecting most (> 75 %) of those inoculated with such vaccines from contracting influenza or some other flu-like illness during the annual 'flu season'".

Moreover, it appears that those inactivated-influenza vaccine formulas that are also "Thimerosal preserved" have been illegally approved by the FDA since 1973 because, as far as this reviewer can ascertain and as Congress found when it investigated in the early 2000s<sup>1</sup>, the manufacturers of those "Thimerosal preserved" vaccine formulations have never conducted (as required by 21 CFR 610.15(a) since 1973) and, after 1999, never submitted (as required by 21 CFR Sec. 601.2(a), a regulation required by 42 U.S.C. Sec. 262(a)(2)(A)) and falling within the overarching reach of 21 U.S.C. Sec. 351(a)(2)(B)) the toxicity studies required to prove that the level of Thimerosal in said preserved formulations is "sufficiently non-toxic ..." as required by 21 CFR Sec. 610.15(a) before (as required by 21 CFR 601.4(a) and 42 U.S.C. 262(c)(2)(A)(i)(I)) the FDA can legally approve or license any Thimerosal-preserved biological drug product, which the

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<sup>1</sup> An 81-page Congressional report issued in April 2003: "Mercury in Medicine – Taking Unnecessary Risks – A Report Prepared by the Staff of the Subcommittee on Human Rights and Wellness Committee on Government Reform United States House of Representatives Chairman Dan Burton April 2003" that, among the outcomes reflected in its "**Findings**" subsection, reported: "3. **Manufacturers of vaccines and thimerosal**, (an ethylmercury compound used in vaccines), **have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds**" (report, page 6; emphasis added).

Thimerosal-preserved inactivated-influenza-virus vaccines most certainly are.

- “• There are several vaccines approved by FDA available in both nasal spray and injectable (a “shot”) forms.”

As written, this statement is both inaccurate and misleading.

Based on this reviewer’s understanding of reality, a factual, non-misleading statement would be:

“There several influenza vaccines approved by the FDA for the 2010-2011 flu season, one nasal-spray formulation and 6 injectable (‘shot’ / ‘jab’) formulations”.

- “• Because the influenza viruses that cause people to get sick can change, each year’s vaccine may be different from the previous year. Therefore, it is important to get the influenza vaccine every year.”

Because viruses “*can change*” is not a valid reason, much less, an important reason to get any vaccine every year.

For example, the poliovirus and the rotavirus can and do change fairly rapidly, but the CDC is not recommending that everyone should be vaccinated every year for these much more highly contagious and easily transmitted diseases.

Similarly, measles is a highly contagious disease with many strains and sub-strains but the CDC is also not recommending annual measles-vaccine shots.

- “• The vaccines approved by FDA to protect against influenza have a long and successful track record of safety and effectiveness in the United States.”

This statement is another example of, at best, misleading and Orwellian doublespeak.

Factually, influenza vaccines do have a long “*track record*” since they have been given to humans since the 1950s.

However, to be in-use “*successful*”, they would have to have protected more than 90 % of all those inoculated with them from getting influenza – and this has not happened.

In fact, the only published, peer-reviewed US-wide retrospective population study, covering the period from 1979 – 2000/2001, found that

flu vaccines were in-use ineffective<sup>2</sup> – an actuality that no subsequent published peer-reviewed study has rebutted.

Further, if possibly causing thousands of pregnant women to miscarry shortly after being inoculated with a flu vaccine in the 2009-2010 flu season is any measure of the safety of influenza vaccines, then, at best, they are not generally safe.

Moreover, no independent (i.e., a study not funded, influenced or overseen by the federal government or the vaccine industry) study has established that:

- ◆ Thimerosal-preserved influenza vaccines meet the safety-standard *minimums* established for “Thimerosal preserved” vaccines,
- ◆ Any influenza vaccine is in-use effective, or
- ◆ The initial, interim, 2009, and current 2010 CDC-recommended vaccination programs are truly cost effective.

Worse, *based on repeated attempts to establish measures of the infectivity of influenza viruses in humans (like the studies done for measles)*, influenza viruses are not highly infective in healthy people<sup>3</sup>.

Thus, the bottom line appears to be that influenza vaccines are a medical ‘con’ designed to enrich the overall “healthcare” Establishment at the expense of the physical and fiscal health of the American public – to make the USA into a nation in which all of the citizens will have one or more lifelong chronic diseases, syndromes, and/or disorders requiring continual medication and frequent visits to the healthcare providers but no cure to those who are afflicted.

Finally, the continual abnormal-route challenge/rechallenge exposure of those who are annually, or more frequently, inoculated increases the risk for a severe adverse reaction to person who is repeatedly inoculated with highly related antigens in this manner.

“● Influenza or “the flu” is a contagious respiratory illness caused by influenza viruses.”

This reviewer can only agree that influenza viruses are somewhat

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<sup>2</sup> Geier DA, King PG, Geier Mr. Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program and Policy Considerations. *J. Am. Physicians and Surgeons* 2006 Fall; **11**(3): 69-74.

<sup>3</sup> Cannell JJ, Zasloff M, Garland CF, Scragg R, Giovannucci E. On the epidemiology of influenza. *Virology* 2008 Feb 25; **5**: 29. [Among the issues this paper addresses, this recent electronically published review article reports the lack of high sick-to-well infectivity for human influenza.]

contagious (see Footnote 3) viruses that can cause respiratory illnesses.

"It is a serious threat to public health and can cause mild to severe illness, and at times can lead to death."

Except for the purported 1918 influenza-caused epidemic, influenza viruses are no more a threat to public health than the more aggressive "cold" or other viruses" and, increasingly, *Serratia marcescens* and other bacterial lung infections, which are often misdiagnosed and treated and tracked as if they were clinical influenza cases, when they most certainly are not even influenza cases.

- "• The Centers for Disease Control and Prevention's (CDC) [recommends] that everyone 6 months of age and older receive the influenza vaccine every year."

The FDA's statement here is both inaccurate and misleading.

The CDC's recommendations are much more complex.

For example, in the last flu inoculation season (September 2009 through June of 2010), the CDC recommended that pregnant women get 2 flu shots (one seasonal and one pandemic) and children get from 2 to 4 flu shots depending on their age and previous vaccination status.

In this flu inoculation season (starting in August and running through June of 2010) the CDC is recommending that many children get 2 flu shots (i.e., those who have not been inoculated for influenza, those children under 9 years of who only got a seasonal flu shot in 2009-2010 flu season, and those children under 9 who were only given one 2009-A-H1N1 flu shot in the 2009-2010 flu inoculation season).

In addition, the CDC's recommendations exclude certain groups such as those who are allergic to eggs or any other component of the flu vaccine; and, *for the Thimerosal-containing vaccine formulas*, those who are allergic to Thimerosal.

- "• The 2010-2011 seasonal influenza vaccine includes three strains; an A (H1N1) that is the same strain that is the cause of the pandemic that began in 2009, an A (H3N2) that is different than last year's seasonal vaccine[,], and a B strain that is the same as last year's formulation."

This statement is misleading because, among other realities, there was no real pandemic that began in 2009 and the strains of "2009-A-H1N1" influenza vaccines in the 2010-2011 influenza vaccines are only related to the A-H1N1 influenza virus strains that truly caused influenza infections in the 2009-2010 flu season because the 2009-A-H1N1 influenza viruses were mutating in 2009.

Further, these viral substrains of 2009-A-H1N1 have certainly mutated enough by mid-2010 that these vaccine-antigens will only generate antibodies in those who are inoculated that will, at best, furnish limited protection against this year's circulating A1N1 flu strains.

As has been the case in previous years, a readily apparent driver for the retention of all or, in this year, two of the four virus strains produced for a previous year's influenza vaccines is that the vaccine manufacturer will have near-zero process development costs for the retained strains and can use up their leftover stock virus components in making this year's vaccines –

- ◆ Increasing the profit per dose and the number of doses that can be produced in the available time window, and
- ◆ Decreasing the time to market for the finished vaccine (as it did for the 2010-2011 flu inoculation season which is starting a full month earlier [mid-August 2010] than any flu vaccine in 2009 and 2 full months earlier than for last season's inactivated-influenza vaccines).

Thus, producibility, manufacturers' agreement to produce, and producer profits are the major drivers, and not the best "population protective" guess as to what will be the "circulating influenza viruses", which, in large part, determine the strains the World Health Organization (WHO) and, in the USA, the CDC/FDA recommend for each year's flu vaccines.

Therefore, as has been the case in previous years, this "season's" flu vaccine will only contain one "new" strain, a mutated A-H3N2 strain, a A/Perth/16/2009-like influenza virus.

- "● This year, two different vaccines are not needed, only one. During last year's influenza season, two different vaccines were needed; one to prevent seasonal influenza and another to prevent influenza that is the cause of the 2009 (H1N1) pandemic."

Again, this statement is misleading because there is no scientifically sound and appropriate evidence that the two vaccines were "needed" – only proof that two types of influenza vaccines were both approved by the FDA and recommended by the CDC.

In addition, there is no in-use proof that those inoculated with either or both of last year's vaccines were effectively protected from contracting a "flu" or "flu-like" illness in the 2009-2010 flu inoculation season.

- “• Each year there are two flu seasons due to the occurrence of influenza at different times in the Northern and Southern Hemispheres.

This statement is patently false because cases of influenza occur year round – only the peak times for the incidence of cases differ between the hemispheres because they occur during the “winter” season, whenever that occurs.

The 2009 outbreaks of “2009-A-H1N1” influenza cases during the late spring and early summer in Mexico and the USA clearly establish the validity of this reviewer’s “year-round cases” assertion.

“Some influenza vaccine manufacturers produce vaccines for use in both the Northern Hemisphere and the Southern Hemisphere.”

While currently true, this situation has only recently become a reality because the influenza vaccine makers have been consolidating and/or, *like CSL Limited's agreement with the US Merck and Company*, forming bilateral marketing agreements with other pharmaceutical manufacturers around the world.

- “• In Australia and New Zealand, use of the 2010 Southern Hemisphere formulation of one influenza vaccine, manufactured by CSL Limited, has been associated with an increased incidence of fever and febrile seizure among young children, mainly among those less than 5 years of age. Therefore, the Warnings and Precautions section of the Prescribing Information for Afluria, the U.S. licensed Northern Hemisphere formulation made by CSL Limited, has been changed to include a statement to inform healthcare providers about the occurrence of these events.”

Here, the statements being made are deceptive because they omit the reality that the 0.25-mL dose (the dosage for children under 3 years of age) of the 2010-2011 CSL Afluria vaccine was not approved for use by the US FDA.

Therefore, this dosage form will not be available in the USA for the 2010-2011 fu season so that the “*Warnings and Precautions section of the Prescribing Information for Afluria, the U.S. licensed Northern Hemisphere formulation made by CSL Limited*” only applies to the Thimerosal-preserved multi-dose formulation administered to children and adults over 3 years of age and the 0.5-ml single-dose no-Thimerosal formulation for children 3 to 18 years of age and adults.

- “• The available data suggest that the increased rates of fever and febrile seizure in those children mainly less than 5 years of age, are only associated with the Southern Hemisphere formulation of CSL’s vaccine. The available data

regarding the safety of other influenza vaccines for children used in the Southern Hemisphere do not suggest an increased rate of fever or febrile seizure."

Collectively, these two statements are misleading because the body of data for the other vaccines used in Australia is limited because CSL produced most all of the doses of vaccine used.

In addition, there was no pre-established intensive monitoring program for adverse events in the influenza vaccines used in Australia to ascertain the true background incidence for the adverse reactions seen (based on the results from prior years) and the incidence for such adverse events in the Australian 2010 flu season from mid-March through mid-September 2010, which is still a month away.

- "• FDA, in collaboration with CDC, will closely monitor the continued safety of all influenza vaccines."

There is no evidence to support the FDA's promise here to "*closely monitor*" the safety of vaccines because, *based on its historical performance*, all the FDA will be monitoring are the flu-vaccine-related adverse events that happen to be reported to the Vaccine Adverse Events Reporting System (VAERS), the passive reporting system maintained jointly by the FDA and the CDC.

Ironically, the Secretary of the DHHS promised a similar program to "*closely monitor*" the safety of the pandemic flu program but then failed to implement one.

The CDC's current *disclosed* programs are designed to monitor the "reported" incidence of influenza and, with the FDA, simply record whatever adverse events happen to be reported to VAERS.

Both the CDC and the FDA have not yet noticed and/or reported on the more than 200 adverse-event reports of miscarriage in pregnant women shortly after they received a flu shot – even though this reviewer, working with CoMeD, the Coalition for Mercury-free Drugs, and NCOW, the National Coalition of Organized Women, has noticed, tracked, and reported on these flu-vaccine-associated adverse events of miscarriage and stillbirth since October of 2009.

Further, *as far as this reviewer can ascertain*, the FDA has not restructured its ability to monitor and report so that it can conduct an active surveillance program for adverse events after a flu inoculation.

Thus, the FDA's assertion here is, at best, meaningless and, at worst, intentionally deceptive.



**"Detailed Information:**

**What strains are included in the 2010-2011 seasonal influenza vaccine?**

Each year, influenza infections are caused by Influenza A and Influenza B viruses. Three strains of influenza virus that cause people to get sick are included in the vaccine each year, a representative strain of Influenza A (H1N1), Influenza A (H3N2) and Influenza B. Because the influenza viruses that cause people to get sick can change, each year's vaccine may be different from the previous year."

The statements here are misleading because:

- a. They fail to disclose that there are 10s to 100s of strains of influenza virus and other viruses and bacteria that can infect humans and cause the "flu-like" symptoms that are most often used to count and estimate the number of "flu" infections,
- b. The strains in the vaccines provide little to no protection against other influenza strains of the same types to those inoculated with a flu vaccine,
- c. Based on post-year assessments using the CDC's generous definition of in-use effectiveness, the in-use effectiveness of the influenza vaccines is often much less than 50%, and
- d. The only independent multi-year US study (see Footnote 2) of the in-use effectiveness of influenza vaccination using the data reported by governmental sources and the markers: **1)** influenza cases, **2)** influenza-related deaths and **3)** influenza-related hospitalizations, found no statistically significant correlation between the doses of vaccines administered per 10,000 population and: **i)** the flu-related deaths per 10,000 population, or **ii)** the flu-related hospital admissions per 10,000 population, or **iii)** the estimated cases of influenza per 10,000 population for the period from 1979 through the 2000-2001 flu seasons.

Even the statement that "... *each year's vaccine may be different from the previous year*" is misleading because: **1)** there have been years where the circulating strains of influenza did change but, *when the manufacturers of the US-approved vaccines objected*, the strain was not changed to match even what was projected to be the circulating strain and **2)** the "Influenza B" strain is merely a guess as to which of the two circulating strains will be dominant in a given year – a guess that appears to be wrong as often as not.

Moreover, the FDA's statement conceals the reality that, *even if and when the strains in the vaccine do not change*, the FDA still approves and the CDC still recommends "new" flu vaccine for administration in a mass program each year in a manner designed to grow the revenue of the vaccine makers and the federal government (who, on paper, receives \$ 0.75 for each dose of vaccine administered to, *in theory*, support the National Vaccine Injury Compensation Program (NVICP) that currently has a multi-billion dollar surplus and who, *last flu season*,

raked in about US\$ 150 million from the “seasonal” and “2009-A-H1N1” influenza vaccination programs [while the vaccine makers probably pocketed in excess of US\$ 1 billion in profit in the US alone] and, based on a projected 170,000,000 doses of vaccines this year, stands to rake in more than US\$ 125 million this flu season – with the manufacturers probably making in excess of US\$ 820 million in profit from the flu season alone) – what a cash cow, one that is established, defined, recommended, promoted, and, in some aspects, overseen by the federal government who is paid US\$ 0.75 per dose. And for this US\$ 0.75, the federal government then protects the public health officials, vaccine makers, and healthcare providers from being sued for the harm caused by the vaccines and does not even requires that these vaccines be in-use effective in protecting those who are vaccinated from contracting influenza – a nice “racket” (of the RICO kind) if ever there was one.

“This year, the B strain remains the same as last year’s seasonal vaccine, but the H1N1 and H3N2 strains are different. However, the H1N1 strain in this year’s vaccine is the same strain as the pandemic (H1N1) 2009 influenza virus.”

Here, the bottom line is that only the A-H3N2-like strain of the influenza virus used to make the 2010-2011 seasonal flu vaccines will be different from the strains in both types (live-virus and inactivated-virus) of the flu vaccines approved and recommended for the 2009-2010 flu season.

Moreover, there is no assurance, *only some early evidence*, that even the changed A-H3N2-like viruses used to make this season’s flu vaccines will match the circulating A-type influenza viruses or the major A-type virus that will be circulating in the USA between August 2010 and the end of June 2011.

If, as claimed, the influenza virus rapidly mutates, there is a high probability that B-like strain and the A-H1N1-like (the 2009 pandemic strain) strain will not match the circulating influenza viruses.

Obviously, by keeping the B-strain and the A-H1N1 strains the “same” as the prior year’s strains, the vaccine makers’ developmental costs are be minimized (essentially, zero) and their profits may be even higher than this reviewer projects.

The retention of two of the three strains that were in last years vaccines also permits the leftover stocks of the monovalent vaccine ‘concentrates’ that the vaccine makers may have had to be used up – further increasing the vaccine makers overall profit.

But, *in their defense*, these are the strains that the pharmaceutical-industry-influenced “independent” World Health Organization (WHO) recommended – just as this same “independent” WHO changed the definition of “pandemic” so that

the highly profitable, *to the pharmaceutical industry and the healthcare providers*, 2009-A-H1N1 “pandemic” hoax could be perpetrated on us.

### **“Why should I get the influenza vaccine?”**

Influenza or “the flu” is a contagious respiratory illness caused by influenza viruses and occurs most often in the winter and spring. It is a serious threat to public health and can cause mild to severe illness, and at times can lead to death. Although no vaccine is 100% effective against preventing disease, vaccination is the best protection against influenza and can prevent many illnesses and deaths.”

Based on the recent publications on the protective effects of taking additional amounts (in the 1000 IU to 5000 IU range) of vitamin D-3 daily against all of the strains of the A-type influenzas<sup>4</sup> and the general immune-system strengthening and self-production of antibiotics that having a vitamin D-3 level, as measured in the blood by having a circulating 25-hydroxy-vitamin-D-3 level in excess of 65 nanogram per milliliter (65 ng/mL) or 26 nanomole per liter (26 nM/L)<sup>5</sup>, this statement is an obvious misrepresentation of factual reality.

This is the case because, at best, the vaccines only provided limited protection to some percentage of those inoculated against the strains in the influenza vaccine administered and inoculation with these vaccines actually weakens the inoculee’s immune system’s ability to “fight off” other infectious diseases for weeks, months or years after the person is vaccinated.

“The best time to get the vaccine is in the fall before influenza viruses start to circulate, but getting it anytime throughout the winter months when flu season often peaks is also recommended.”

If the preceding statement were true, then why would the FDA be allowing the 2010-2011 flu vaccines to be given to anyone in mid-August of 2010, when “*the fall*” does not begin in the continental USA until the end of September 2010?

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<sup>4</sup> “Despite Anti-Vitamin D Bias, CDC Stumbles on Deficiency Link to H1N1 Deaths” Posted By Dr. Mercola. <http://articles.mercola.com/sites/articles/archive/2009/09/22/Low-Vitamin-D-Increases-Flu-Death-Risk-in-Kids.aspx>. “Vitamin D better than vaccines at preventing flu, report claims” – from the March 15, 2010 Times (UK), <http://www.timesonline.co.uk/tol/news/uk/scotland/article7061778.ece>.

<sup>5</sup> “Is Vitamin D An Antibiotic? Antimicrobial Peptides” Dr. Liu and colleagues at UCLA, publishing in this March’s edition of the prestigious journal Science, showed that vitamin D might be, in effect, a potent antibiotic. Vitamin D increases the body’s production of naturally occurring antibiotics: antimicrobial peptides. Antimicrobial peptides are produced in numerous cells in the human body where they directly and rapidly destroy the cell walls of viruses and bacteria, including tuberculosis. Furthermore, Liu showed that adding vitamin D to African American serum (African Americans have higher rates of TB) dramatically increased production of these naturally occurring antibiotics. Liu PT, Stenger S, Li H, Wenzel L, Tan BH, Krutzik SR, Ochoa MT, Schaubert J, Wu K, Meinken C, Kamen DL, Wagner M, Bals R, Steinmeyer A, Zugel U, Gallo RL, Eisenberg D, Hewison M, Hollis BW, Adams JS, Bloom BR, Modlin RL Toll-like receptor triggering of a vitamin D-mediated human antimicrobial response. *Science* 2006 Mar 24; 311(5768): 1770–1773.” <http://www.vitamincouncil.org/newsletter/2006-june-july.shtml>

Further, since the ever-mutating influenza viruses are continually in circulation and all that changes is the population's susceptibility to infection (which increases as the days grow shorter, the mean temperature drops and the effectiveness of the sun's ability to generate vitamin D in the skin wanes), the first part of this statement ("*[t]he best time to get the vaccine is in the fall before influenza viruses start to circulate*") is knowingly false.

The rest of the statement is just the added FDA advertising/propaganda to help ensure that as many as possible will get vaccinated so that all of the vaccine that the makers made will be used up and everyone who profits will make their maximum profit with little or no real benefit to most of those who are inoculated and real risk of serious harm and possibly death to a few of those who are inoculated with a given flu vaccine.

### **"What are the available forms of influenza vaccine?"**

FDA has licensed two forms of influenza vaccine for use in the United States: the inactivated vaccine (sometimes called the "flu shot") and the live attenuated vaccine, which is a nasal spray.

The inactivated vaccine contains inactivated, or killed, virus and is given with a needle in the arm."

First, the inactivated-influenza vaccines are not killed and to equate inactivation with killing, as the "*[t]he inactivated vaccine contains inactivated, or killed, virus*" statement does is a knowing misrepresentation.

Factually, inactivated viruses are viruses that have been treated, usually with an aldehyde (e.g., formaldehyde), under mild conditions to only greatly reduce their ability to replicate without destroying their structural integrity (which would kill them).

"The nasal spray vaccine contains live viruses that are weakened, or attenuated, and is administered into the nose with a nasal sprayer."

Again, this initial portion of the FDA's statement here is a knowing and calculated misrepresentation.

Factually, the three live viruses in MedImmune's seasonal nasal-spray vaccine are genetically engineered or genetically modified organisms (GMOs) that are claimed not to infect the entire body of persons inoculated with them but supposedly only superficially infect the nasal sinuses and adjacent areas provided: **1**) the body temperature of the persons inoculated with this live-virus vaccine is sufficiently high (not below 36 °C [96.8 °F]) and **2**) the inoculees have no defect in those areas where the sheathed olfactory nerves penetrate into the inoculees' brain.

"Neither vaccine will cause influenza."

Based on the adverse effects reported for adults on pages 7 and 8 of the 2010-2011 package insert for MedImmune's FluMist:

**"Adverse Reactions in Adults**

In adults 18-49 years of age in Study AV009, summary of solicited adverse events occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo include runny nose (44% 125020-1324 FluMist vs. 27% placebo), headache (40% FluMist vs. 38% placebo), sore throat (28% FluMist vs. 17% placebo), tiredness/weakness (26% FluMist vs. 22% placebo), muscle aches (17% FluMist vs. 15% placebo), cough (14% FluMist vs. 11% placebo), and chills (9% FluMist vs. 6% placebo).

In addition to the solicited events, other adverse reactions from Study AV009 occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo were: nasal congestion (9% FluMist vs. 2% placebo) and sinusitis (4% FluMist vs. 2% placebo)" [emphasis added],

and the transmission study data published on pages 17-18 of said package insert:

**"14.5 Transmission Study**

FluMist contains live attenuated influenza viruses that must infect and replicate in cells lining the nasopharynx of the recipient to induce immunity. Vaccine viruses capable of infection and replication can be cultured from nasal secretions obtained from vaccine recipients.

The relationship of viral replication in a vaccine recipient and transmission of vaccine viruses to other individuals has not been established.

Using the frozen formulation, a prospective, randomized, double-blind, placebo-controlled trial was performed in a daycare setting in children <3 years of age to assess the transmission of vaccine viruses from a vaccinated individual to a non-vaccinated individual. A total of 197 children 8-36 months of age were randomized to receive one dose of FluMist (n = 98) or placebo (n = 99). Virus shedding was evaluated for 21 days by culture of nasal swab specimens. Wild-type A (H3N2) influenza virus was documented to have circulated in the community and in the study population during the trial, whereas Type A (H1N1) and Type B strains did not.

At least one vaccine strain was isolated from 80% of FluMist recipients; strains were recovered from 1-21 days post vaccination (mean duration of 7.6 days ± 3.4 days). The cold-adapted (ca) and temperature-sensitive (ts) phenotypes were preserved in 135 tested of 250 strains isolated at the local laboratory. Ten influenza isolates (9 influenza A, 1 influenza B) were cultured from a total of seven placebo subjects. One placebo subject had mild symptomatic Type B virus infection confirmed as a transmitted vaccine virus by a FluMist recipient in the same playgroup. This Type B isolate retained the ca, ts, and all phenotypes of the vaccine strain, and had the same genetic sequence when compared to a Type B virus cultured from a vaccine recipient within the same playgroup. Four of the influenza Type A isolates were confirmed as wild-type A/Panama (H3N2). The remaining isolates could not be further characterized.

Assuming a single transmission event (isolation of the Type B vaccine strain), the probability of a young child acquiring vaccine virus following close contact with a single FluMist vaccinee in this daycare setting was 0.58% (95% CI: 0, 1.7) based on the Reed-Frost model. With documented transmission of one Type B in one placebo subject and possible transmission of Type A viruses in four placebo subjects, the probability of

acquiring a transmitted vaccine virus was estimated to be 2.4% (95% CI: 0.13, 4.6), using the Reed-Frost model” (emphasis added),

it is clear to this reviewer that the FDA’s statement here is false for the live-virus vaccine’s viral components – the excess symptoms of influenza in the live-virus inoculees and transmission to others clearly point to some of the inoculee’s contracting influenza after being vaccinated with MedImmune’s FluMist vaccine.

“The Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) provides annual recommendations for the prevention and control of influenza, including use of vaccines. As of this year, they recommend that everyone in the United States 6 months of age and older receive the seasonal influenza vaccine.”

While the FDA’s statements here are generally reporting what the CDC, by publishing the ACIP’s recommendations in the CDC’s official journal, the weekly *Morbidity and Mortality Weekly Report (MMWR)*, is recommending, the FDA fails to report that these recommendations were made: **1)** without proof of safety, in-use effectiveness and/or in-use cost effectiveness for all of the influenza vaccines; **2)** in spite of the Pregnancy Category B and C ratings for all of these vaccines for pregnant women – ratings that are given because proof of safety for the fetus and the mothers’ reproductive capacity have not been generated; **3)** without proof that these vaccines do not increase the risk of mutation and cancer in those who are inoculated with them; **4)** without proof that repeated injection of these vaccines is not irreversibly damaging the inoculees’ immune systems; and **5)** without proof that that each dose is “sufficiently nontoxic ...” to the degree required by 21 CFR 610.15(a) for those influenza vaccine formulations that are Thimerosal-preserved.

#### **“What vaccines are available for the 2010-2011 influenza season?”**

The following vaccines will be available for adults:” [Reviewer’s notes in a 10-point “Tahoma” font with quotes from the package insert in an “Arial Narrow” font.]

- Afluria  
manufactured by CSL Limited Both the 10-dose, 5-mL vial (Thimerosal-preserved) and the 0.5-mL “no Thimerosal” syringe were removed from CDC price list on 13 Aug 2010. Vaccine had a febrile seizures problem when used in Australia. Thimerosal, a mercury derivative, is not used in the manufacturing process for the single dose presentations. Thus, the single-dose products contain no preservative. The multi-dose presentation contains Thimerosal, added as a preservative; each 0.5 mL dose contains 24.5 mcg of mercury. Both formulations are labeled “Pregnancy Category C” because the requisite teratogenicity “studies have not been conducted”. Mutagenicity and carcinogenicity studies are also lacking. In general, a “single 0.5 mL dose of AFLURIA contains sodium chloride (4.1 mg [4,100 mcg]), monobasic sodium phosphate (80 mcg), dibasic sodium phosphate (300 mcg), monobasic potassium phosphate (20 mcg), potassium chloride (20 mcg), and calcium chloride (1.5 mcg). From the manufacturing process,

each 0.5 mL dose may also contain residual amounts of sodium taurodeoxycholate ( $\leq 10$  ppm [ $< 5$  mcg/0.5-mL dose]), ovalbumin ( $\leq 1$  mcg), neomycin sulfate  $\leq 0.2$  picograms [pg], polymyxin B ( $\leq 0.03$  pg), and beta-propiolactone ( $< 25$  nanograms). .... The rubber tip cap and plunger used for the preservative-free, single-dose syringes and the rubber stoppers used for the multi-dose vial contain no latex". [Note: Unused doses and the used vials and syringes of the "Thimerosal preserved" formulation should be disposed of as items containing hazardous mercury waste.]

- Agriflu manufactured by Novartis Vaccines and Diagnostics A "no Thimerosal" formulation for adults 18 years of age and over in single-dose syringes w/o needle – 10 per carton. As of 13 August 2010, this vaccine was not listed on the CDC's "Pricing List". It carries a "Pregnancy Category B" teratogenicity warning based on 2 reproductive toxicity studies in rabbits vaccinated 3 times with 0.5-mL doses of vaccine (prior to mating, gestation day 7 and gestation day 20) with a cumulative relative exposure of about 15 times human dose; but post-natal developmental effects on offspring were incompletely assessed. Mutagenicity and carcinogenicity studies are also lacking. "Each 0.5 mL dose may contain residual amounts of egg proteins ( $< 0.4$  mcg), formaldehyde ( $\leq 10$  mcg), polysorbate 80 [a surfactant] ( $\leq 50$  mcg), and CTAB [cetyltrimethylammonium bromide, a surfactant and biocide] ( $\leq 12$  mcg). Each dose may also contain residual amounts of neomycin ( $\leq 0.02$  mcg by calculation) and kanamycin ( $\leq 0.03$  mcg by calculation), which are used during the initial stages of manufacture. The syringe plunger does not contain latex".

- Fluarix manufactured by GlaxoSmithKline Biologicals A "no Thimerosal" vaccine for individuals 3 years of age and older. Those who are allergic to latex MAY need to avoid this vaccine or handling the syringes in which it is filled. Has a "Pregnancy Category B" teratogenicity rating based on a rat study that does not appear to have been published and that appears to have used a "no Thimerosal" Fluarix vaccine at  $> 50$  times the relative human dose. Mutagenicity and carcinogenicity studies are also lacking. "Each 0.5-mL dose also contains octoxynol-10 (TRITON® X-100, a surfactant)  $\leq 0.085$  mg [ $\leq 85$  mcg],  $\alpha$ -tocopheryl hydrogen succinate [a "vitamin E"; antioxidant]  $\leq 0.1$  mg, and polysorbate 80 (Tween 80; a surfactant)  $\leq 0.415$  mg [ $\leq 415$  mcg]. Each dose may also contain residual amounts of hydrocortisone [a steroid]  $\leq 0.0016$  mcg, gentamicin sulfate  $\leq 0.15$  mcg, ovalbumin [egg protein]  $\leq 0.05$  mcg, formaldehyde  $\leq 5$  mcg, and sodium deoxycholate [a steroidal/choleretic]  $\leq 50$  mcg from the manufacturing process. The tip caps of the prefilled syringes may contain natural rubber latex. The rubber plungers do not contain latex".

- FluLaval manufactured by ID Biomedical Corporation **A Thimerosal-preserved formulation ONLY for adults packaged in multi-dose vials that should be avoided – especially by pregnant women!** Has a "Pregnancy Category B" teratogenicity rating apparently obtained using the same rat study for Fluarix, a "no Thimerosal formulation" – that is clearly at odds with the serious adverse generational and multi-generational effects reported in peer-reviewed published studies of pregnant rats and their offspring, where the female rats were once injected with low levels (sub-acute levels) of an ethylmercury compound and studied vs. control female rats that received sterile saline injections. Mutagenicity and carcinogenicity studies are also lacking. "Thimerosal, a mercury derivative, is added as a preservative. Each dose contains 25 mcg mercury. Each dose may also contain residual amounts of egg proteins ( $\leq 1$  mcg ovalbumin),

formaldehyde ( $\leq 25$  mcg), and sodium deoxycholate ( $\leq 50$  mcg). Antibiotics are not used in the manufacture of this vaccine. The vial stopper does not contain latex". **[Note:** Unused doses and the used vials and syringes containing residual amounts of this "Thimerosal preserved" vaccine should be disposed of as items containing hazardous mercury waste.]

for adults up to age 49 years [not for the 50 & older crowd for which it produces significantly lower titer levels for the three viral components] of age [and children as young as 2 years of age], manufactured by MedImmune A bioengineered live-virus vaccine that infects all those who are inoculated with it to varying degrees and can be spread to others. **Not recommended by CDC for administration to pregnant women or women who may be pregnant or are trying to get pregnant.** Mutagenicity and carcinogenicity studies are also lacking. "FluMist (Influenza Vaccine Live, Intranasal) is a live trivalent vaccine for administration by intranasal spray. The influenza virus strains in FluMist are (a) cold-adapted (ca) (i.e., they replicate efficiently at 25°C, a temperature that is restrictive for replication of many wild-type influenza viruses); (b) temperature-sensitive (ts) (i.e., they are restricted in replication at 37°C (Type B strains [which may be able to replicate efficiently in those humans with a 36.5 °C "normal" body temperature and impaired ability to sustain a fever]) or 39°C (Type A strains [which can easily replicate in the human body with a nominal temperature of 37 +/- 0.5 °C]), temperatures at which many wild-type influenza viruses grow efficiently); and (c) attenuated (att) (they do not produce classic influenza-like illness in the ferret model of human influenza infection [but do infect some humans as the clinical trial data showed]). The cumulative effect of the antigenic properties and the ca, ts, and att phenotypes is that the attenuated vaccine viruses replicate [more easily] in the nasopharynx to induce protective immunity.

- FluMist

No evidence of reversion has been observed in the recovered vaccine strains that have been tested (135 of possible 250 recovered isolates) [see Clinical Studies (14.5)]. For each of the three reassortant strains in FluMist, the six internal gene segments responsible for ca, ts, and att phenotypes are derived from a master donor virus (MDV), and the two segments that encode the two surface glycoproteins, hemagglutinin (HA) and neuraminidase (NA), are derived from the corresponding antigenically relevant wild-type influenza viruses that have been recommended by the USPHS for inclusion in the annual vaccine formulation. Thus, the three viruses contained in FluMist maintain the replication characteristics and phenotypic properties of the MDV and express the HA and NA of wild-type viruses that are related to strains expected to circulate during the 2010-2011 influenza season. For the Type A MDV, at least five genetic loci in three different internal gene segments contribute to the ts and att phenotypes. For the Type B MDV, at least three genetic loci in two different internal gene segments contribute to both the ts and att properties; five genetic loci in three gene segments control the ca property.

Specific pathogen-free (SPF) eggs are inoculated with each of the reassortant strains and incubated to allow vaccine virus replication. The allantoic fluid of these eggs is harvested, pooled and then clarified by filtration. The virus is concentrated by ultracentrifugation and diluted with stabilizing buffer to obtain the final sucrose and potassium phosphate concentrations. Ethylene diamine tetracetic acid (EDTA) is added to the dilution buffer for H3N2 strains. The viral harvests are then sterile filtered to produce the monovalent bulks. Each lot is tested for ca, ts, and att phenotypes and is also tested extensively by in vitro and in vivo methods to detect adventitious agents. Monovalent bulks from the three strains are subsequently blended and diluted as required to attain the desired potency with stabilizing buffers to produce the trivalent bulk vaccine. The bulk vaccine is then filled directly into individual sprayers for nasal administration.

Each pre-filled refrigerated FluMist sprayer contains a single 0.2 mL dose. Each 0.2 mL dose contains 106.5-7.5 FFU of live attenuated influenza virus reassortants of each



of the three strains: A/California/7/2009 (H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008. Each 0.2 mL dose also contains 0.188 mg [188 mcg] /dose monosodium glutamate [an excitotoxin & flavor enhancer], 2.00 mg [2,000 mcg]/dose hydrolyzed porcine gelatin [pig gelatin that devout Moslems and Israelites (Jews) and others for whom pig products are forbidden], 2.42 mg [2,420 mcg]/dose arginine [an essential amino acid], 13.68 mg [13,680 mcg]/dose sucrose [table sugar], 2.26 mg [2,260 mcg] /dose dibasic potassium phosphate [a pH buffering agent], 0.96 mg [960 mcg] /dose monobasic potassium phosphate, [a pH buffering agent] and <0.015 mcg/mL gentamicin sulfate. FluMist contains no preservatives. The tip attached to the sprayer is equipped with a nozzle that produces a fine mist that is primarily deposited in the nose and nasopharynx. FluMist is a colorless to pale yellow liquid and is clear to slightly cloudy”.

manufactured by Novartis Vaccines and Diagnostics This is a trivalent inactivated-influenza vaccine for persons 4 years of age and older. “Pregnancy Category C” – teratogenicity studies not done. Mutagenicity and carcinogenicity studies are also lacking. “FLUVIRIN® is a sterile suspension for intramuscular injection. Each 0.5-mL dose contains 15 mcg hemagglutinin from each of the following 3 influenza virus types: A/California/7/2009, NYMC X-181 (H1N1); A/Victoria/210/2009, NYMC X-187 (H3N2) (an A/Perth/16/2009-like virus); and B/Brisbane/60/2008. [see DESCRIPTION (11)]

FLUVIRIN® is available in two presentations: 1) Prefilled syringe, 0.5-mL. Thimerosal, a mercury derivative used during manufacture, is removed by subsequent purification steps to a trace amount  $\leq 1$  mcg mercury per 0.5 -mL dose). 2) Multidose vial, 5-mL. Contains thimerosal, a mercury derivative, added as a preservative. Each 0.5-mL dose from the multidose vial contains 25 mcg mercury”.

- Fluvirin

“The 0.5-mL prefilled syringe presentation is formulated without preservative. However, thimerosal, a mercury derivative used during manufacturing, is removed by subsequent purification steps to a trace amount ( $\leq 1$  mcg mercury per 0.5-mL dose).

The 5-mL multidose vial formulation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5-mL dose from the multidose vial contains 25 mcg of mercury.

Each dose from the multidose vial or from the prefilled syringe may also contain residual amounts of egg proteins  $\leq 1$  mcg ovalbumin), polymyxin ( $\leq 3.75$  mcg), neomycin ( $\leq 2.5$  mcg), betapropiolactone [residual virus inactivating agent] (not more than 0.5 mcg) and nonylphenol ethoxylate (not more than 0.015% w/v [0.075 mg (75 mcg)/dose; a surfactant]).

The tip caps of the FLUVIRIN® prefilled syringes may contain natural rubber latex. The multidose vial stopper and the syringe stopper/plunger do not contain latex” (emphasis added). [Note: Unused doses and the used vials and syringes containing any amount of the “Thimerosal preserved” formulation should be disposed of as items containing hazardous mercury waste.]

manufactured by sanofi pasteur Inc. Available in two (2) formulations (“no Thimerosal” and “Thimerosal preserved”) that are both approved for use in humans who are 6 months of age or older. “Pregnancy Category C” – teratogenicity studies have not been done. Mutagenicity and carcinogenicity studies are also lacking.

- Fluzone

For both formulations, “the carrier is a sodium phosphate-buffered isotonic sodium chloride solution of unspecified composition; for a 0.5-mL dose, the level of residual formaldehyde is  $\leq 100$  mcg, octylphenol ethoxylate is  $\leq 100$  mcg; gelatin 0.05 % [0.25 mg (250 mcg); type unspecified]. Each 0.5-mL dose of the “Thimerosal preserved”, multi-dose-vial formula nominally contains 50 mcg of Thimerosal (25 mcg of mercury)”.

“The tips caps of the Fluzone and Fluzone High-Dose prefilled syringes may contain natural rubber latex. Vial presentations of Fluzone do not contain latex”.

[**Note:** Unused doses and the used vials and syringes containing any amount of the “Thimerosal preserved” formulation should be disposed of as items containing hazardous mercury waste.]

- **Fluzone High-Dose** specifically for the elderly population 65 years of age and older, manufactured by sanofi pasteur Inc. **Contains a 4-times higher level of antigens but is a “no Thimerosal” formulation;** carries a higher risk of adverse immune-system events than regular vaccine; no proof of in-use effectiveness in preventing those who are vaccinated from contracting a flu-like illness that will generally be diagnosed as flu during the “flu season”. Mutagenicity and carcinogenicity studies are also lacking. For this formula, the carrier is also a “sodium phosphate-buffered isotonic sodium chloride solution of unspecified composition; for the 0.5-mL dose, the level of residual formaldehyde is  $\leq 100$  mcg, octylphenol ethoxylate is  $\leq 250$  mcg; and there is no gelatin”.

The following vaccines will be available for children:

- **Afluria** manufactured by CSL Limited **But only the 0.5-mL dose of the “no Thimerosal” formulation is on the CDC’s pricing list and it is only generally recommended by CDC for children 9 years of age and older. This vaccine is a “Pregnancy Category C” vaccine because the required toxicity studies have NOT been conducted.** Mutagenicity and carcinogenicity studies are also lacking. **FDA did not approve 0.25-mL dose for children 6 months to 3 years of age PROBABLY because of “9 times higher than EXPECTED risk if febrile seizures. CDC, after reviewing the seizures risk, removed the 10-dose vial from the CDC’s pricing list on 13 August 2010.** [**Note:** The rest of the information is the same as for the corresponding adult vaccine.]
- **Fluarix** manufactured by GlaxoSmithKline Biologicals **A “no Thimerosal vaccine for individuals 3 years of age and older. Those who are allergic to latex MAY need to avoid this vaccine or handling the syringes in which it is filled.** Has a “Pregnancy Category B” teratogenicity rating based on a rat study that does not appear to have been published and that appears to have used a “no Thimerosal” Fluarix vaccine at > 50 times the relative human dose. Mutagenicity and carcinogenicity studies are also lacking. [**Note:** The rest of the information is the same as for the adult vaccine.]
- **FluMist** manufactured by MedImmune **A bioengineered live-virus vaccine that infects all those who are inoculated with it to varying degrees and can be spread to others. In spite of increased risk of respiratory complications for children under 5 years of age, this vaccine is approved for use in children 2 years of age and older. Not recommended by CDC for administration to pregnant women or women who may be pregnant or are trying to get pregnant.** Mutagenicity and carcinogenicity studies are also lacking. “FluMist (Influenza Vaccine Live, Intranasal) is a live trivalent vaccine for administration by intranasal spray”. [**Note:** The rest of the information is the same as for the adult vaccine.]

- Fluzone  
manufactured by sanofi pasteur Inc. The information for Fluzone for children is the same as the information for the adult vaccine except that 0.25-mL pre-filled syringes are offered for children between 6 months and 3 years of age. These doses contain half the amount of ingredients as the amounts found for the 0.5-mL "adult", single-dose "no Thimerosal" pre-filled syringes containing Fluzone flu vaccine. "Pregnancy Category C" – **teratogenicity studies have not been done**. Mutagenicity and carcinogenicity studies are also lacking. [Note: The rest of the information is the same as for the adult vaccines.]
- Fluvirin  
manufactured by Novartis Vaccines and Diagnostics Since this drug product is not approved for use in children under 4 years of age, the information for its formulations is the same as that described for the vaccine formulas available for adults. "Pregnancy Category C" – **teratogenicity studies have not been done**. Mutagenicity and carcinogenicity studies are also lacking. [Note: The rest of the information is the same as for the adult vaccines.]

### **"Why is the H1N1 strain that caused the 2009 pandemic included in the 2010-2011 seasonal vaccine?"**

The strains that are included in the 2010-2011 seasonal influenza vaccine are based on a review of information gathered from the strains of flu viruses that infected people around the world during the previous year, how they have changed, as well as disease trends. All of this information is used to forecast which viruses are likely to circulate in the United States in the upcoming influenza season. This season's vaccine contains three influenza strains. One of the three is the H1N1 strain that is the cause of the 2009 pandemic because it still continues to infect people."

Based on the information contained in the package inserts provided for all of the vaccines, the H1N1 component is the manufacturer's variants of the influenza virus type: A/California/7/2009, NYMC X-181 (Fluvirin, Novartis), A/California/07/2009 X-179A (Fluzone, sanofi pasteur), A/California/7/2009, NYMC X-181 (Afluria, CSL), A/California/7/2009 NYMC X-179A (FluLaval, IDC Biomedica subsidiary of GlaxoSmithKline), A/California/7/2009 NYMC X-181 (Fluarix, GlaxoSmithKline), A/California/7/2009, NYMC X-181 (Agriflu, Novartis), and an unidentified bioengineered subtype of A/California/7/2009.

From these representations, it is clear that at least three subtypes, A/California/7/2009 NYMC X-179A, A/California/7/2009, NYMC X-181, and an unidentified bioengineered subtype of A/California/7/2009, will be available for the 2010-2011 flu season with a bigger concern for the sub-subtypes of the vaccines derived from the A/California/7/2009, NYMC X-181 subtype based on the "9-fold higher risk of febrile seizures in the CSL "Afluria"-type product than for the other products approved for use in Australia in the now-ending Southern Hemisphere's flu inoculation season.

However, given the package insert's description of the 2009-A-H1N1 viruses in the inactivated-influenza pandemic vaccines:

- ◆ "A/California/7/2009 (H1N1)v-like virus" (CSL),
- ◆ "A/California/07/2009 (H1N1) v-like virus" (sanofi-pasteur), and
- ◆ "A/California/7/2009 (H1N1)v-like virus" (Novartis)

and the more detailed descriptions in the 2010-2011 package inserts, it is probable that the influenza viruses in the 2010-2011 influenza vaccines:

- ◆ Are only "highly similar" but not the "same" and
- ◆ MAY provide different levels on in-use protection and risk to those inoculated with each of them.

**"Is only one vaccine needed this year?"**

Yes. Last year the pandemic influenza virus emerged after the seasonal influenza vaccine was made, so an additional vaccine was needed for the new influenza virus that caused the pandemic."

Based on in-use effectiveness studies for prevention of contracting flu-like and flu-related illnesses, the influenza vaccines are not effective.

**"Do I need to get influenza vaccine again this year?"**

**Not unless you want to get an ineffective vaccine.**

"Yes, influenza viruses can change from year-to year, so it is important to get the vaccine every year for the new influenza season."

No, if you are an adult, you would be better off, depending on your weight, age, and health taking 30-50,000 IU of vitamin D-3 for 3 days followed by at least 3-10,000 IU of vitamin D-3 daily throughout the flu season and, unless you live in the South and get a lot of sun exposure in the Summer or the equivalent, probably year round.

For non-breastfed children, depending upon their weight and health, an extra 1,000 IU of vitamin D-3 per day for the youngest to an extra 5,000 IU per day for the oldest would be effective in preventing those who follow this regimen from contracting all strains of Type A influenza viruses as well as many other infectious viruses (e.g., common cold viruses, and corona viruses) and should reduce the risk of a severe infection if infected by a Type B strain – a much more in-use effective preventive therapy for influenza than the current vaccines are.

"Some years the vaccine may not exactly match the influenza viruses that cause disease in people, but it does not mean that the vaccine is not benefiting people. It can still be helpful by causing milder illness, preventing flu-related complications, and by providing some protection over following years."

These statements are biased influenza-vaccine apologists' propaganda.

If the recent Canadian findings are any indicator of reality, getting a flu vaccine in one year may increase your risk of getting influenza in a subsequent year<sup>6</sup>.

Moreover, your risk of a serious adverse reaction increases every time you get another dose of a flu vaccine.

This is the case because the initial dose abnormally challenges your immune system and each subsequent dose abnormally rechallenges your immune system thereby increasing the risk of a serious adverse reaction – including Guillian Barré syndrome and death.

Finally, if the flu shots you get are preserved with Thimerosal (49.55% mercury by weight), each shot deposits a significant portion of the mercury dose into your tissues where it bioaccumulates with a half-life of between 15 and 20 years depending upon the tissue in which it is bound.

Estimates from the 1980s when all flu vaccines were Thimerosal-preserved and the targeted population was the elderly, getting 2 to 5 flu shots in a 5-year period increases the risk of being diagnosed with Alzheimer's disease 10 years later by more than a factor of 10 over those who declined to be vaccinated or only received one flu shot – indicating that the mercury in the se flu shots damages the function of the human brain. In the last decade, being inoculated with Thimerosal-preserved vaccines has been proven to be a dose-dependent risk factor in neurodevelopmental disorders and other serious developmental and behavioral medical conditions in children.

**“Since the 2009 H1N1 pandemic influenza strain is included in this year’s seasonal vaccine, if I already received the vaccine during the pandemic, is it okay to get it again?”**

**The unbiased answer is no!**

**This is the case because the 2009-A-H1N1 viruses (A/California/7/2009-like influenza viruses) used in the 2009-2010 influenza vaccines have already mutated into one or more other strains A-H1N1 against which vaccines based on the 2009 strains will probably provide little or no real protection.**

“In addition to the H1N1 strain, the vaccine also contains an influenza B strain and a new influenza H3N2 strain, so the vaccine is needed to protect against these additional influenza viruses which are predicted to cause illness this year.”

Factually, based on the early cases data and the Southern Hemisphere's

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<sup>6</sup> Viboud C, Simonsen L. Does Seasonal Influenza Vaccination Increase the Risk of Illness with the 2009 A/H1N1 Pandemic Virus? J. *PLoS Medicine* 2010 April; **7**(4): e1000259.

circulating influenza strains, the influenza B strain and the 2009-A-H1N1 strain are likely to provide little or no in-use protection for those inoculated from getting the “flu”.

Only the “A-H3N2” strain seems to provide some protection from the circulating A-H3N2 strains of the influenza virus.

Overall, the vaccine will most probably be significantly less than 50% in-use effective in protecting those who are inoculated with any of the 2010-2011 flu vaccines.

“Receiving the H1N1 strain again, in the context of this year’s new seasonal vaccine, is important to continue protection against this particular strain.”

This statement seems to be nothing more than pure vaccine apologist propaganda aimed at helping: **a)** the vaccines’ makers sell their product (at an overall cost to the public of about 1.2-plus billion dollars US), **b)** the healthcare providers’ getting paid for dispensing the vaccine; **c)** the healthcare providers (at an overall cost that easily exceeds 1.5 billion dollars US) and flu-illness-treatment facilities increase their profits (by another 300-plus million dollars US), and **d)** the federal government line its pockets with the \$ 0.75 tax per dose included in the cost of each vaccine dose of vaccine administered (or about 125-plus million dollars US).

**“Why was the Warnings and Precautions section of the prescribing information changed for Afluria?”**

Southern Hemisphere countries are currently experiencing their 2010 influenza season. An increased number of fevers and febrile seizures have been reported in children, predominantly among those less than 5 years of age, following administration of the influenza vaccine manufactured by CSL Limited, which is approved as Afluria in the United States.

The Warnings and Precautions section of Afluria’s prescribing information has been revised to include a statement to inform healthcare providers about this increased incidence of fever and febrile seizures in young children, mainly less than 5 years of age, following administration of the Southern Hemisphere formulation of CSL’s influenza vaccine. This change is based on information gathered after the vaccine was given in Australia and New Zealand.

Various investigations into the cause(s) of these febrile seizures are still ongoing. FDA is collaborating with Australia’s regulatory authority (Therapeutic Goods Administration), other international regulatory counterparts, and CSL to obtain additional information, stay apprised and take part in the investigations.”

Given the actions by the US FDA (in declining to license the 0.25-mL prefilled syringe presentation for the 2010-2011 flu season) and the US CDC’s delisting of:

- The Thimerosal-preserved Afluria vaccine formulation from the CDC's vaccine pricing list for adults and children as of 13 August 2010 and
- The 0.5-mL pre-filled syringe presentation from the adult pricing list as of 13 August 2010,

it seems clear that rather than trying to find the cause of the "*febrile seizures*" associated with the "Afluria" formulations, the federal government has chosen to reduce the risk that it will receive adverse "febrile seizure" reports to VAERS in adults.

Obviously, the CDC has reduced this risk by removing the following vaccines from the CDC's pricing list: **a)** both the approved 2010-2011 Afluria formulations (Thimerosal-preserved and no-Thimerosal) for adults; and **b)** the FDA-approved multi-dose formulation for children.

In addition, the CDC further reduced the risk for adverse-event reports to VAERS by recommending the FDA-approved 0.5-mL "no Thimerosal" prefilled-syringe formulation only for general use in children 9 years of age or older<sup>7</sup>.

The removal of these vaccines from the CDC's pricing list will reduce their use because the States' departments of health and many healthcare providers use the CDC's pricing lists for ordering the vaccines, including flu vaccines, which they purchase<sup>8</sup>.

Clearly, these actions indicate that the 2010-2011 FDA-approved Afluria formulations carry a significant risk for febrile seizures in adults, where it is much more difficult to get away with claiming a febrile seizure after vaccination is just a coincidence – the excuse used to dismiss many, if not most, of the serious post-vaccination adverse events observed in surviving children who have a serious adverse reaction shortly after being vaccinated.

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<sup>7</sup> Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Use of CSL Seasonal Influenza Vaccine (Afluria) in the United States During 2010—11 – MMWR August 13, 2010; 59(31); 989-992): "Recommendations

Based on the available information, ACIP recommendations for the 2010--11 influenza season in the United States include the following:

- Afluria should not be used in children aged 6 months through 8 years.
- Other age-appropriate, licensed seasonal influenza vaccine formulations, including other TIVs and LAIV, have not been associated with an increased risk of fever or febrile seizures, are safe, and should be used for prevention of influenza in children aged 6 months through 8 years.
- If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5--8 years who has a medical condition that increases the child's risk for influenza complications (3), Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine.
- Afluria may be used in persons aged  $\geq 9$  years."

<sup>8</sup> In this regard, Novartis' Agriflu has not, as of 13 August 2010, been listed on the CDC's pricing list.

**“What are “Warnings and Precautions” in vaccine labeling?”**

A Warning or Precaution is added to the labeling of a vaccine to make the healthcare provider aware of important information, such as a potential adverse event and to advise the health care provider how to use the vaccine most safely and effectively.”

Since most healthcare providers do not read the *“labeling of a vaccine”* (the “package insert”), this answer is, at best, misleading.

The more probable answer is that the “Warnings and Precautions” in a influenza vaccine’s package insert are put there to protect the vaccine’s maker from being liable for any “failure to warn” lawsuits should anyone choose to pursue such after going through the “vaccine court’s” administrative processes even though the persons injured are neither provided this package insert nor explicitly given the information contained therein in a manner that they might give informed consent to accept the risks outlined in aforesaid *“labeling”* (package inserts) for the influenza vaccines.

**“Will Afluria still be available in the United States?”**

Yes, although the manufacturer will not be supplying the 0.25[-]mL presentation to the United States that is used in children 6 months – 35 months of age, the 0.5[-]mL single dose, prefilled syringe and 5[-]mL multi-dose vial presentation will be distributed. The Indications and Usage section of the prescribing information has not changed.”

First, the FDA’s *“the manufacturer will not be supplying the 0.25-mL presentation to the United States that is used in children 6 months – 35 months of age”* glosses over the reality that US FDA did not approve the 2010-2011 *“0.25-mL presentation”* of Afluria.

Moreover, given the CDC’s actions to remove Afluria pricing for all but the 0.5-mL “no Thimerosal” formulation approved to be given to children 3 years of age and older from its pricing lists, the response provided is clearly misleading.

“Specific recommendations for the use of Afluria will be made by the ACIP.”

Since this page was last updated on 5 August 2010 and the CDC published the CDC ACIP’s recommendations for Afluria on 13 August by the ACIP, this statement was accurate at the time it was published (see: Update: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Use of CSL Seasonal Influenza Vaccine (Afluria) in the United States During 2010—11 – *MMWR* August 13, 2010; 59(31); 989-992).

**“Does this change to Afluria’s Prescribing Information also affect other seasonal influenza vaccines?”**

No. The available data regarding the safety of other childhood influenza vaccines used in the Southern Hemisphere do not suggest an increased rate of fever or febrile seizures in



children less than five years of age."

Since some of the influenza vaccine formulations that are FDA-approved for the 2010-2011 flu season were not distributed in the Southern Hemisphere (as the following FDA statements confirm), this FDA statement is, at best, knowingly misleading.

**"What other seasonal influenza vaccines are approved by FDA specifically for use in children?"**

**Unless the word "specifically" is removed from this statement, this statement is misleading.**

**This is a reality because these six trivalent (three different flu virus subtypes) influenza vaccine formulations (5 inactivated-viruses and 1 live-virus), including the Thimerosal-preserved formulations marketed by sanofi pasteur, Novartis Vaccines and Diagnostics and CSL Ltd, and the reduced-Thimerosal formula marketed by Novartis, have been specifically approved by the US FDA for use in children and adults.**

**Thus, they are not specifically approved for use in children.**

**Moreover, unless approved for use children, it is not proper for such vaccines to be given to children.**

**If they were only approved for use in children, as the use of the word "specifically" implies, these vaccines would properly be characterized as "childhood" vaccines – which they are not.**

- Fluarix, manufactured by GlaxoSmithKline Biologicals, is [a "no Thimerosal" inactivated-influenza vaccine (inactivated by formaldehyde), carrying a "Pregnancy Category B" teratogenicity warning, that is FDA-] approved for use in individuals 3 years of age and older [Note: This vaccine formulation was not supplied to any country in the Southern Hemisphere. Thus, there is no in-use safety data for this vaccine formulation.]
- FluMist, manufactured by MedImmune, is [a bioengineered live-virus influenza vaccine, carrying a "Pregnancy Category C" teratogenicity warning, that is FDA-] approved for use in individuals 2-49 years of age [Note: This vaccine formulation was not supplied to any country in the Southern Hemisphere. Thus, there is no in-use safety data for this vaccine formulation.]
- Fluvirin, manufactured by Novartis Vaccines and Diagnostics, is [available in 2 formulations, a "reduced Thimerosal" single-dose formulation and a "Thimerosal preserved multi-dose formulation and is an inactivated-influenza vaccine (inactivated by betapropiolactone) that both carry a "Pregnancy Category C" teratogenicity warning and are FDA-] approved for use in individuals 4 years of age and older [Note: Neither of the Fluvirin vaccines were supplied by Novartis to

Southern Hemisphere. Thus, there is no in-use safety data for these vaccine formulations.]

- Fluzone, manufactured by sanofi pasteur, is [available in 2 formulations, a “no Thimerosal” single-dose formulation and a “Thimerosal preserved multi-dose formulation and is an inactivated-influenza vaccine (inactivated by formaldehyde) that both carry a “Pregnancy Category C” teratogenicity warning and are FDA-approved for use in individuals 6 months of age and older [Note: Though apparently the “no Thimerosal” and “Thimerosal preserved” vaccine formulas (but not the “High dose” formula) were, based on what is being reported, supplied to some countries in the Southern Hemisphere. However, there appears to be little in the way of in-use adverse-event-related safety data and no in-use effectiveness data for the vaccine formulations supplied.]

### **“Where there similar reports of adverse events for the other influenza vaccines?”**

FDA has contacted all of the manufacturers who are licensed by FDA to produce inactivated influenza vaccines for the United States for information about adverse events in pediatric populations for any seasonal 2010 trivalent influenza vaccine distributed in the Southern Hemisphere. Included in the request was information about: febrile reactions, febrile seizures, and all seizure events from clinical studies and/or commercial distribution.

GlaxoSmithKline and Novartis did not supply influenza vaccine to the Southern Hemisphere for the 2010 influenza season. Sanofi pasteur supplied the Southern Hemisphere 2010 formulation of its U.S.–licensed vaccine, Fluzone, to Brazil. They also distribute a vaccine that is not licensed in the United States (Vaxigrip) in Australia, New Zealand and other Southern Hemisphere countries. We are not aware of reports of febrile seizures in young children from countries using either of these vaccines.”

Here, the FDA’s response to its own question fails to disclose whether, or not, CSL Ltd, GlaxoSmithKline, Novartis and sanofi pasteur complied with the FDA’s “request” with respect to all of the clinical studies they conducted or if sanofi pasteur complied with this “request” for the Fluzone vaccine it distributed in Brazil and/or the Vaxigrip vaccine distributed in Australia.

### **“What are febrile seizures?”**

Febrile means “relating to a fever” or an unusually high body temperature. In some children, having a fever can cause a seizure. During a febrile seizure, a child often has spasms or jerking movements and may lose consciousness.

Although febrile seizures can be frightening for the child’s caregivers, most are harmless. The majority of children who have febrile seizures recover quickly and have no lasting effects. Nearly one-half of children who have one febrile seizure will have at least one more.

Approximately 1 in 25 (4%) [vaccinated<sup>9</sup>] young children will have at least one febrile seizure, usually between 6 months and 5 years of age. The peak age for febrile seizures [in vaccinated children] is 18 and 24 months of age.

Febrile seizures usually last only a minute or two. They are most common with fevers that go up fast and reach 102° F (38.9° C) or higher, but can also occur when a fever is going back down. Febrile seizures may happen with any condition that causes a fever, including common childhood illnesses like ear infections and viral infections, such as influenza or roseola and sometimes vaccinations.

If a [vaccinated] member of a child's immediate family has febrile seizures, that [vaccinated] child is more likely to have a febrile seizure [following vaccination – as would be expected when there are genetic susceptibility factors<sup>10</sup>].

Even with the corrections provided by this reviewer to improve the accuracy of the preceding statements, these statements are simply vaccine apologist propaganda.

This is the case because, as far as this reviewer can ascertain, there are no double-blind, true-placebo-controlled studies for each influenza vaccine formulation in a population of not less than 2000 subjects (1,000 test and 1,000 matched controls) that involve a test group who are vaccinated with the influenza vaccine and a matched control group of never previously vaccinated children who would be given sham injections of a pH-balanced sterile saline solution with both groups being monitored for not less than 6 years to determine the true differential occurrence of febrile seizures between the vaccinated and the unvaccinated in the short run (within a few days of vaccination) and the long-term cognitive differences using brain scans between the vaccinated and the sham vaccinated groups.

### **“What are FDA’s plans to monitor the safety of Afluria and other seasonal influenza vaccines?”**

FDA has requested additional data from Australia’s Therapeutic Goods Administration and New Zealand, and is working with the Pan American Health Organization (PAHO) and CDC to gather additional information on febrile seizures following use of 2010 seasonal formulations of influenza vaccines in other countries in the Southern Hemisphere.

Additionally, FDA is requiring CSL Limited to conduct a study of Afluria in children to obtain additional information regarding the febrile events that were seen in the Southern

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<sup>9</sup> As far as this reviewer can ascertain, there is no population-established rate or percentage for “febrile seizures” in children who have never been vaccinated.

<sup>10</sup> Since the FDA admits that family history is critical risk factor, perhaps the regulations for vaccination should be changed to require the family history of a child or adult, as contained in the individual's permanent medical records or equivalent, to be examined and no obvious vaccination-associated risks identified before that individual could legally be given a vaccine.

Hemisphere<sup>[11]</sup>.

Furthermore, as with all vaccines, FDA in collaboration with CDC, will continue to monitor adverse events associated with the administration of vaccines and reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). VAERS is a program created as an outgrowth of the National Childhood Vaccine Injury Act of 1986 (NCVIA) and is administered by FDA and CDC. VAERS accepts reports of adverse events that may be associated with U.S. licensed vaccines from health care providers, manufacturers, and the public. FDA and CDC continually monitor VAERS reports for any unexpected patterns or changes in reporting rates of adverse events."

If, as the FDA claims here, the "*FDA and the CDC continually monitor VAERS reports for any unexpected patterns or changes in reporting rates of adverse events*", why is it that neither the CDC nor the FDA noticed the significant increase (> 20 times the previous years' maximums [ $< 9$  in any year;  $< 3$  in the years before the CDC began to recommend flu vaccines for pregnant women] for such events) in miscarriages and still births following the 2009-A-H1N1 vaccinations in October of 2009 as this reviewer and the persons with whom this reviewer works did?

Why have both agencies failed to notice or report on this increased risk in miscarriages and stillbirths after the CDC was notified<sup>12</sup> of such by both a colleague of this reviewer and reports on various Internet web sites?

Why, after there have been more than 170 of these reports to VAERS and NCOW has collected 70 reports, has neither the CDC nor the FDA issued any notice about the problem to: **a)** the public, **b)** the healthcare providers who administered these influenza vaccines to pregnant women, and **c)** the pregnant

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<sup>11</sup> As stated, the FDA's statement is simply Orwellian doublespeak as stated. At a minimum, a double-blind, placebo-controlled study would be needed of children who received each formulation of Afluria, "no Thimerosal" and "Thimerosal-preserved", and matched control groups that received a sterile buffered saline so that the magnitude of the effects could be seen and the magnifying effect, if any, of Thimerosal on the incidence of febrile seizures could be assessed. No retrospective study that simply looked at the reported febrile seizures observed would be able to accurately assess the risk of and the risk factors for such seizures in a given unvaccinated population of Australian children much less in the US population.

<sup>12</sup> In 2009, the Director of NCOW informed the CDC of the significant increase in the number of miscarriages in pregnant women just after they received a flu shot, mostly an 2009-A-H1N1 flu shot since that was the second one given and posted those reports on the NCOW website, <http://www.progressiveconvergence.com/>, in a periodically updated section at the top left-hand side of the main page which contained the following three (3) entries:

- [Data on H1N1-Vaccine-Related Miscarriages](#) (Updated Apr. 22, 2010)
- [ACIP vs FDA/Manufacturers](#) package insert-Pregnant Women
- [Public Service Announcement](#)

and submitted an as-yet-unanswered FOIA request to the CDC in February 2010 for all of the non-personal information on the 52 deaths of pregnant women that the CDC claimed were flu-related deaths.

women who suffered a miscarriage (so that they might file an appropriate claim for compensation with the appropriate administrative “court”)?

In this reviewer’s view, these adverse events have been suppressed in order not to inform pregnant women of the miscarriage risk associated with injecting them with influenza vaccines, in general, or the much higher fetal-death risk associated with Thimerosal-preserved vaccines, in specific.

**“Links on this page:**

1. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr59e0729a1.htm>
2. <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm>

Page Last Updated: 08/05/2010”

### **Reviewer’s Concluding Remarks**

The independent scientific studies have clearly proven influenza vaccines either are not in-use effective or have not been proven to be in-use effect.

Further, many toxicological studies have shown that Thimerosal at vaccine levels causes damage to developing children and, over time, adults such that, at a minimum, since the vaccine makers have failed to prove their safety to the “sufficiently nontoxic ...” standard minimum set forth in **21 CFR 610.15(a)** require since 1973 and required to be submitted to the FDA (see **21 CFR 601.2(a)**) since 1999, there would be no FDA-approved Thimerosal-preserved flu shots if the FDA had, as the law requires it to do, complied with **21 CFR Sec. 601.4(a)**.

Had there been no Thimerosal-preserved flu shots, many, if not most all, of the miscarriages and stillbirths reported to VAERS would not have occurred.

Based on all of the preceding, the Thimerosal-preserved flu shots are clearly illegally approved (by the FDA’s knowing non-compliance with **21 CFR Sec. 601.4(a)**) and, under **21 U.S.C. Sec. 351(a)(2)(B)**, adulterated drugs that should not be administered to any person.

Moreover, because these are illegally approved and adulterated drugs, any apparent vaccine injuries caused by them fall outside of the scope of the National Vaccine Injury Compensation Program (**42 U.S.C. Sec. 300aa-10 through 300aa-34**).

This reality would allow injured parties or their parents or guardians to bring damage-claim lawsuits naming the healthcare providers who administered them

and the drug companies who provided them to be sued in a civil court in the manner provided by Amendment 7 of the Constitution of the United States of America in federal court and under the applicable states' statutes for injuries inflicted by the knowing injection of adulterated drugs (vaccines) knowingly distributed by the vaccine manufacturers.

Obviously, the FDA, a federal agency, has an earned reputation of: **a)** protecting the manufacturers of drugs from legal actions and **b)** not protecting the public by ensuring that the drugs that said manufacturers are truly proven to be safe to the applicable current good manufacturing practice (CGMP) minimums established by statute and/or regulation, and, *in the case of vaccines*, not ensuring that vaccines meet the CGMP regulations promulgated as required by 42 U.S.C. Sec 262(a)(2)(A)<sup>13</sup>, including 21 CFR Sec. 610.15(a)<sup>14</sup> for preserved biological drug products, as required by 42 U.S.C. Sec. 262(a)(2)(C)(i)(I)<sup>15</sup> and regulated by 21 CFR 601.4(a)<sup>16</sup>.

Hopefully, Congress will recognize these unfortunate realities and, *at a minimum*, change the FDA's Mission Statement for all drugs and drug products to state:

"With respect to drugs and drug products, the FDA's only missions shall be to:

- Ensure that all drug and drug products are: **a)** safe to the applicable CGMP standard minimums established by statute or regulation or, in the absence of either statute or regulation, by appropriate, scientifically sound toxicological studies which use a placebo as a control that is a truly inert dosage form that has no active or reactive components (e.g., a "sugar pill" for solid dosage forms and sterile, pH-balanced isotonic saline for injectables), **b)** in-use effective for the uses for which they are approved, and **c)** as

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<sup>13</sup> § 262(a)(2)(A) ... The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses. (emphasis added)

<sup>14</sup> § 610.15(a)

Constituent materials.

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, ... (emphasis added)

<sup>15</sup> § 262(a)(2)(C)(i)(I)

(C) The Secretary shall approve a biologics license application -

(i) on the basis of a demonstration that -

(I) the biological product that is the subject of the application is safe, pure, and potent; ...

(emphasis added)

<sup>16</sup> § 601.4 Issuance and denial of license.

(a) A biologics license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research that the establishment(s) and the product meet the applicable requirements established in this chapter. A biologics license shall be valid until suspended or revoked. (emphasis added)

determined by independent studies, cost-effective for use in the population segments for which they are approved<sup>17</sup> and

- Strictly enforce all of the statutes and regulations that govern the lawful manufacture, sale, and distributions of drugs and drug products in a manner that ensures the manufacturers meet or exceed the applicable CGMP minimums for said drugs, including all components used in the manufacture of drugs and all drug products”.

All drug approval and drug supplement activities shall be ancillary activities that shall only be conducted when the firm that is submitting applications for such has, *for its existing drugs and drug products*, paid all applicable fees, met every requirement, including all post-marketing Phase IV studies and annual reporting requirements in a manner that meets or exceeds all the applicable requirement minimums, and said firm is in full compliance with all the applicable CGMP requirements for said firm and its subsidiaries and/or partners.”

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<sup>17</sup> As corollaries, Congress should mandate that: 1) those drug products failing to meet their safety and/or effectiveness minimums shall be immediately withdrawn from the market whenever such failings are established; and 2) the use of drugs that meet their safety and effectiveness minimums but do not meet independently determined, population cost-effectiveness standards shall be restricted and these drug products, including vaccines, shall not allowed to be recommended, promoted, or purchased, for mass prophylactic use, or any other use, by any federal agency.

## About This Reviewer

In addition to the information available on his web page, <http://www.dr-king.com/>, this reviewer, Paul G. King is the Science Advisor and current Secretary for the Coalition for Mercury-Free Drugs (CoMeD, Inc., a 501(3)(c) corporation), <http://www.mercury-freedrugs.org>, the current District 33 Democratic Committeeman for Township of Parsippany-Troy Hills, Morris County, NJ, a some-time poet, Taoist philosopher and servant of Elohim through Jesus Christ.

As a scientist and student of the federal regulations and statutes that govern drugs, including vaccines, Dr. King has led CoMeD, on two (2) separate occasions, in the drafting and submission of a "Citizen Petition" seeking to have the federal government comply with the law, and, *based on the improper denial of the Citizen Petition submitted*, a federal lawsuit seeking to have the Federal District Court for the District of Columbia compel the Secretary of the Department of Health and Human Services and the Commissioner of the FDA to comply with the statutes and regulations regulating their lawful conduct. The second civil suit, 1:2009-cv-00015, is still being litigated at the present time.

Additionally, Dr. King has, on several occasions, drafted legislation for submission to the Congress of the USA as well as to the legislatures of various States, submitted cogent comments in opposition to proposed changes to federal regulations that are not in the public interest or appear to be at odds with the law, reviewed numerous documents, and written several articles on a variety of vaccine-related and other issues – including a formal request for correction of false and misleading statements by the FDA in a previous posted document under the applicable Data /Information Quality regulations.

Finally, Dr. King has: **a)** provided various groups with his analysis of various other Congressional bills, resolutions and treaty documents, and **b)** been an author of several papers bearing on issues related to the toxicity of Thimerosal and other compounds and, if any, their connection to various chronic neurodevelopmental, other developmental and behavioral abnormalities that appear to be well-above (> 1 in 10 children; asthma), above (> 1 in 100 children; the autism spectrum disorders), at (~ 1 in 400 children; type 1 diabetes), or near epidemic levels (childhood type 2 diabetes).