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Introductory Remarks

This author's essay follows these introductory remarks and a table-of-contents page.

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This essay is titled "**Influenza Vaccines and Vaccination Programs: Unsafe, Not Effective and Illness Causing**".

Re: Essay Formatting and Assertion Challenges

First, this essay is written in a "Georgia" font.

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

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

Respectfully,

<s>

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

Table of Contents for the Essay: "Influenza Vaccines and Vaccination Programs: Unsafe, Not Effective and Illness Causing"

Influenza Vaccines and Vaccination Programs: Unsafe, Not Effective and Illness Causing

BACKGROUND

For millennia, humans have survived and, *absent war, famine, or other living conditions or practices that favor disease*, thrived before the first 'vaccine' was introduced.

The use of vaccination to provide disease protection is based on incomplete, inaccurate, and poorly understood models and theories of the mechanisms that lead to the manifestation of diseases.

In addition, the proponents of disease protection via vaccination have only very recently acknowledged the reality that human life depends upon our symbiotic co-existence with a variety of microbial organisms, some of which can also appear to be 'pathogenic'.

Moreover, these microbial organisms serve vital roles in maintaining human health and, in the 1990s, scientists, recognizing the importance of these organisms, labeled this collection of microbial organisms as the "human microbiome"[1].

Unfortunately, to this day, the developers, and proponents for the use, of vaccines:

- Do not understand exactly how the human immune system functions[2];
- Are focused primarily on the adaptive[3] immune system's response to antigens; and
- *In general*, ignore the critical role of the innate immune system in maintaining the health of the body.

Worse, they wrongly claim that evidence of adaptive immunity, based on "antibody titer" and/or other similar evidence, can be used as a valid surrogate for proof that a given vaccination program provides disease protection to most of those inoculated with a given vaccine according to some fairly rigid, nationally recommended, vaccination schedule.

In addition, rather than being science-based, most of the current claims concerning the safety and effectiveness of vaccines are more the unfounded theories and beliefs of the developers, purveyors, advertisers, and defenders of our current vaccines and vaccination programs than anything else.

Returning to what disease-preventive (prophylactic) vaccines are, or are supposed to be, they are simply biologically-based pharmaceutical products (drugs) that are 'designed' to be given to currently 'healthy' individuals in order to prevent those appropriately

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1 See, https://en.wikipedia.org/wiki/Microbiome for a general definition of this term and its scope in humans.

2 The current lack of an essentially complete understanding of immune system function is confirmed by recent articles like Irvine DJ, Swartz MA, Szeto GL. Engineering synthetic vaccines using cues from natural immunity. *Nature Materials* 2013; 12, 978–990. doi: 10.1038/nmat3775.

3 In layman's terms, when used to describe the immune system, the term "adaptive" refers to that part of the immune system that adaptively produces specific antibodies to 'invading' microbial organisms and other antigens that have somehow evaded the innate immune system's barriers into the body's tissues, blood and lymph systems.

inoculated individuals from contracting certain diseases should those inoculated individuals be subsequently exposed to any of the causative agents for those diseases.

In the United States of America (USA), vaccines, which are regulated as drugs[4], are declared to be "safe" as is required by statute[5] in Title 42 of the United States Code (**42 U.S.C.**).

This statutory requirement is supposedly enforced by the United States (U.S.) Food and Drug Administration (FDA) when it approves each vaccine and the new or revised package insert for a given vaccine formulation for: **a)** one disease (e.g., the tetanus toxoid [TT] vaccine) or **b)** multiple diseases (e.g., the diphtheria, tetanus and pertussis [DTwcP, DTaP, and Tdap] vaccines).

For the definition of "safety" for a biological product[6], the FDA claims to rely on the definition set forth in Title 21 of the United States Code of Federal Regulations (see, 21 C.F.R. § 600.3(p), "... the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time").

However, vaccines are recommended for universal or population-segment use by the U.S. Centers for Disease Control and Prevention (CDC) even when the vaccine manufacturers do not actually establish that the vaccine meets all of the applicable safety standards for a drug product nor claim that the vaccine is effective in preventing those who have been appropriately vaccinated from subsequently contracting the disease or diseases for which the vaccine purports to provide disease prevention[7].

Using the vaccine for chickenpox as a definitive example, the FDA-approved vaccine, Merck's live-virus Varivax®, which was recommended for universal use in young children

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[4] 42 U.S.C. § 262(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act [21 U.S.C. 355].

[5] 42 U.S.C. § 262(a)(1)(C)(i)(I**)** (emphasis added), "... (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; and ..."

[6] 42 U.S.C. § 262(i) "Biological product" defined in this section, the term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[7] In general, the package inserts only refer to the persistence times for the antibodies to the disease antigens in the vaccines or, instances where no specific antibody titers can be measured (e.g., the pertussis vaccines), apparent durations for evidence of protection. Further, though antibody levels are thought to be sufficient for disease protection, in many instances in highly vaccinated populations, there have nonetheless been disease outbreaks. In addition, for certain diseases, like "whooping cough" and "influenza", science has shown that these vaccines are not effective in preventing those who have been fully vaccinated from getting "whooping cough" (see, http://dr-king.com/docs/120806_PGKDrftRevu_Anti_vaccineMovementCausesTheWorstWhoopingCoughEpidemicIn70Yrs_fnlr2b.pdf) or from viral "influenza" (see, "Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations" by Geier DA, King PG, Geier MR). Yet, instead of stopping these obviously ineffective vaccination programs, the CDC has simply added more and more doses of the vaccines containing the failed "pertussis" components for whooping cough and increased the ineffective influenza vaccine coverage to annually, or more often, for everyone 6 months of age and older, including pregnant women at any stage in their pregnancy. Obviously, such decisions are not based on any science but rather on increasing the revenues and profits for those who derive such from these vaccines, including, at a minimum, the vaccine makers, healthcare providers, healthcare facilities and the federal government who receives US$ 2.25 from each TDaP and Tdap vaccine dose administered and US$ 0.75 from each influenza vaccine dose administered. For example, under the current CDC recommendations and population uptake levels, the federal government receives about US$ 100 million annually from the influenza vaccines alone.

based on meeting a defined set of performance criteria established by the CDC's Advisory Committee on Immunization Practice (ACIP), failed to meet any of its initial performance criteria[8].

However, instead of revoking its obviously flawed recommendation for the universal use of Varivax, as it should have, the CDC's ACIP simply recommended adding a second dose of that vaccine to the CDC's ACIP-recommended vaccination schedule[9].

In addition, the FDA approved, and the CDC's ACIP recommended a shingles vaccine, Merck's Zostavax®, for adults 60 years and older because vaccination greatly reduced the shedding of the live virus that previously naturally supplied exogenous immune-system boosts to those the virus had infected, which suppressed the virus' recurrence as shingles.

ARE FDA-APPROVED INFLUENZA VACCINES SAFE?

General Safety Requirements – Not Carcinogenic, Mutagenic or Reproductively Toxic

Since:

1. The FDA's operative definition for the safety of a biological drug product, including any vaccine, as set forth in **21 C.F.R. § 600.3(p)** hinges on "relative freedom from harmful effect to persons affected ... by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time" (emphasis added),
2. The product is purportedly a prophylactic (disease-preventive) vaccine, and
3. The recipients are supposedly healthy at the time the vaccine is to be administered,

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[8] For the chickenpox disease, the initial criteria used to justify recommending the Merck Varivax® live-virus vaccine for Alpha herpes varicella zoster virus, medically termed as "varicella zoster virus" or "VZV", were: **a)** one dose would provide lifetime 'immunity' to those who were vaccinated; **b)** there would be no serious adverse effects from the vaccine; and **c)** the added medical costs of the vaccination program would be offset by the reduced societal costs (i.e., lost work time) incurred when working parents cared for their sick children. When the actual experience showed that one-dose protected less than 60% of those inoculated from getting chickenpox within a couple of years after being vaccinated, the protection provided was not nearly lifetime, and the costs from the excess shingles (medically called "herpes zoster") cases caused by the reactivation of the latent Alpha herpes varicella zoster virus sequestered in the body's root ganglia greatly exceeded the societal child-care costs "saved", sound medical science would require that this vaccination program be halted because it failed to meet all of the key criteria used to justify its approval. Scientifically, the Varivax vaccine is a clear failure; it is a vaccine that does not provide long-term, much less lifetime, disease protection from chickenpox; it is a vaccination program that has clearly increased the harm to children and adults caused by the increases in shingles cases it has caused; and, when the serious adverse reactions and deaths attributable to the vaccine and the increased shingles treatment costs are considered, the annual increased medical costs exceed US$ 1 billion (1,000 million) annually [see, Goldman GS, King PG. Review of the United States universal varicella vaccination program: Herpes zoster incidence rates, cost-effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data. *Vaccine* 2013 Mar 25; 31(13): 1680-1694, online May 31, 2012]. Yet, the CDC is still recommending this failed vaccination program.

[9] The CDC simply ignored the sound science and added a second dose of Varivax to its recommendations as well as, for the elderly most at risk of shingles, a shingles vaccine for those 60 years of age and older. Even after widespread administration of the second dose of the Varivax vaccine, no more than 80% of those doubly inoculated develop "adequate" anti-body titers, the vaccine provides protection that does not last more than 5 years in most who are vaccinated, the excess costs from the added shingles cases in the elderly now exceed US$ 700 million annually and, though once rare, shingles cases in children have become increasingly common.

a definition-compliant "safe" vaccine must be properly developed, tested in scientifically sound and appropriate preclinical studies, and verified to be free of all generally harmful effects before it is given to even 'volunteer' human beings in any clinical trial.

Under the current FDA expectations for preclinical studies, the "**Nonclinical Toxicology**" of the vaccine components, because, *by definition*, a component of a drug is a drug, and the candidate vaccine formulation are supposed to be assessed, in appropriate *in vitro* and *in vivo* studies that establish that:

a. The maximum levels of each component is "safe" and/or

b. The fully constituted vaccine formulation that contains the maximum permitted levels of all components other than the diluent is "safe".

Thus, each "safe" influenza vaccine formulation should have an appropriate section, "**13 Nonclinical Toxicology**", in its package insert to comply with the FDA's labeling regulations as set forth in **21 C.F.R. §§ 201.56(d)** and **201.57**, when the package insert complies thereto, as the package inserts for most all of the influenza vaccines seem to do.

Because:

a. Most influenza vaccines (the inactivated-influenza vaccines) are recommended to be given indirectly to the unborn child by vaccinating pregnant women,

b. All influenza vaccines, starting at various ages, are recommended for postnatal children who are rapidly developing humans who are more sensitive to adverse effects than adult humans, and

c. Most of the children who receive them are apparently 'healthy' before the vaccine is to be administered,

it is imperative that any such influenza vaccine be rigorously evaluated in scientifically sound and appropriate "**Nonclinical Toxicology**" studies.

Moreover, *according to the FDA's guidance documents for drug products*, these "**Nonclinical Toxicology**" studies must appropriately address carcinogenesis, mutagenesis (including teratogenicity), and the impairment of fertility before any vaccine formulation may ethically be given to any child either developing in the womb or at any time after he or she is born into this world.

However, for FDA-approved influenza vaccines, the reality is that, in almost all instances, the package inserts state that the required carcinogenicity, mutagenicity, and/or reproductive-effects testing has not been conducted (in section "**13. Nonclinical Toxicology**" of the package insert), or, *for the Sanofi Fluzone® Quadrivalent inactivated-influenza vaccine*, the influenza vaccine's package insert fails to provide any information at all about the required preclinical testing for carcinogenicity, mutagenicity and/or adverse reproductive effects [see, **Appendix A**].

Thus, all influenza vaccines for which:

1. The requisite preclinical tests for carcinogenicity, mutagenicity (including teratogenicity), and/or adverse reproductive effects are stated as not having been conducted, or

2. By omission, the package insert fails to declare that these required tests have been conducted

are not safe.

Therefore, all influenza vaccines are generally not safe.

Specific Component Safety Requirements for Preservatives (and Adjuvants[10])

In addition, for biological drug products, including vaccines, which are "preserved", the ***current good manufacturing practice***[11] (CGMP) minimums[12] for biological drug products[13], including vaccines, as set forth in **Title 21 of the United States Code of Federal Regulations (21 C.F.R.)** in section **610**[14], the preservative used must be proven to be "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient". Similarly, for vaccines that contain an adjuvant, the vaccine maker must demonstrate that the adjuvant "does not affect adversely the safety ... of the product".

Because the cited ingredient categories (adjuvant and preservative) are used in vaccines that are injected, the requisite proofs of safety for such vaccines must be established by appropriately injecting the substances used.

To establish that a vaccine preservative is "nontoxic", scientifically sound and appropriate, toxicological studies must be conducted to prove that the dose of preservative in a vaccine is not toxic to the most susceptible individual to which that vaccine may be given. To do this, the toxicity studies must establish the "no observed adverse-effect level" (NOAEL) for the most susceptible system in humans using chronic toxicity studies in an

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10 Currently, no FDA-approved influenza vaccine has a declared adjuvant, which is any immune-system stimulant. However, in addition to being toxic to bacteria, Thimerosal, at the levels in Thimerosal-preserved vaccines is a proven immune-system stimulant. Thus, though not declared, Thimerosal-preserved influenza vaccines are also implicitly adjuvanted vaccines.

11 21 U.S.C. § 351(a)(2)(B)
Sec. 351. Adulterated drugs and devices.
A drug or device shall be deemed to be adulterated -
(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture
(1) ...; or (2) ... (B) 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; ... [emphasis added].

12 21 C.F.R. § 211.1(a)
§ 211.1 Scope.
(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals [emphasis added].

13 21 C.F.R. § 211.1(b)
§ 211.1 Scope.
(b) The current good manufacturing practice regulations in this chapter as they pertain to drug products; in parts 600 through 680 of this chapter, as they pertain to drugs that are also biological products for human use; ... [emphasis added].

14 21 C.F.R. § 610.15(a)
Title 21: Food and Drugs, PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS, Subpart B—General Provisions
§ 610.15 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, ... 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. [Emphasis added.]

appropriate animal model from which the proper most-susceptible human toxicity threshold ($NOAEL_{injected\ Thimerosal,\ most\ susceptible\ human}$) can be reliably computed[15].

However, though required to do so since 1968, when the National Institutes of Health (NIH) regulated vaccines, and since 1973 (see footnote "**14**"), when the United States Congress transferred the regulation of vaccines to the FDA, and subsequently required the vaccine makers to submit all required proofs of safety to the FDA since 1999[16], the vaccine makers have apparently failed to establish the NOAEL values for Thimerosal-preserved vaccines in those developing humans (fetuses, neonates, and children), pregnant women, adults and/or elderly persons to whom these vaccines may be repeatedly administered.

Thus, contrary to law[17], the FDA has licensed Thimerosal-preserved influenza vaccines delivering nominally 50 micrograms (µg) of Thimerosal per 0.5-milliliter (mL) dose.

Using an FDA-recognized long-term chronic toxicity study that injected different levels of Thimerosal into separate groups of rats[18], the only published estimates for the upper limits on the NOAEL values for injected Thimerosal are "< 0.0086 µg Thimerosal/kg/day" [or < 0.0042 micrograms (µg) of organic mercury [o-Hg]/kg/day] in developing children and "< 0.086 µg Thimerosal/kg/day" [or < 0.042 µg of o-Hg/kg/day]) in adults[19].

Thus, using Thimerosal at a level that the FDA recognizes as suitable for an influenza vaccine preservative (nominally 100 µg of Thimerosal per mL of vaccine, for influenza vaccines administered to developing children and adults) greatly exceeds these NOAEL estimates for even the heaviest individuals.

Furthermore, to meet the regulatory requirement of "sufficiently nontoxic", the preceding values need to be divided by at least a factor of 10 or, in terms of organic mercury (o-Hg), < 0.00042 µg of o-Hg/kg/day in children and < 0.0042 µg of o-Hg/kg/day in adults.

Because the dose of organic-chemical-derived mercury (o-Hg),

- Is the ultimate toxicant,

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15 In general, for the preservatives used in vaccines, the organ toxicity thresholds in rats has been shown to be reasonably convertible into the corresponding organ toxicity thresholds in humans. Thus, multiple-level, chronic toxicity injection studies using appropriate solutions of the preservative and rats of both genders as the test subjects and the controls may be reliably used for establishing the related "nontoxic" level for the preservative injected into humans. However, for an adjuvant, because such substances directly affect the immune system, the spider monkey, or a similar primate, should be used because their immune systems are sufficiently close to that of humans while the immune systems of rats are not the same as those of humans.

16 21 C.F.R. § 601.2(a)

(a) General. To obtain a biologics license under section 351 of the Public Health Service Act for any biological product, the manufacturer shall submit an application to 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), on forms prescribed for such purposes, and shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance..[Emphasis added.]

17 21 C.F.R. § 601.4(a)

(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.]

18 Mason MM, Cate CC, Baker J. TOXICOLOGY AND CARCINOGENESIS OF VARIOUS CHEMICALS USED IN THE PREPARATION OF VACCINES. *Clin Toxicol*. 1971; 4(2): 185-204.

19 http://dr-king.com/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf, page 4.

- Is immediately delivered[20] and
- Does not leave the body for some time[21], and
- Is nominally on the order of 12.5 to 25 µg of o-Hg for developing children and 25 µg of o-Hg for adults,

the nominal dose of this toxicant in a single vaccination with a preserved vaccine probably exceeds its estimated "sufficiently nontoxic" level unless the developing child weighs more than 29,761 kg (65,614 pounds) or the adult weighs more than 5,952 kg (13,123 pounds).

Therefore, Thimerosal-preserved influenza vaccines [see, **Appendix A**] are clearly not "safe" to the CGMP requirement minimum, "sufficiently nontoxic", which has been in effect since 1968 under the NIH and since 1973 under the FDA.

Unfortunately, when it comes to adjuvants, there appear to be no suitable scientifically sound and appropriate toxicological injection studies of the adjuvanted vaccines or the adjuvants themselves that have established estimates of the NOAEL values needed to demonstrate that each different adjuvant "does not affect adversely the safety ... of the product".

Furthermore, because the manufacturers of the influenza vaccines have an absolute, nondischargeable duty to meet all of the safety requirements for such vaccines, the manufacturers' failures to meet any of the preceding safety requirements clearly render their vaccines adulterated drugs under 21 U.S.C. § 351(a)(2)(B) (see footnote "**11**") regardless of the actions or non-actions taken by the FDA.

Finally, those individuals or groups having "standing" to bring a legal action for the FDA' failure to enforce all of the safety requirements would also seem to have a statutory cause of legal action against the Secretary of Health and Human Services under 42 U.S.C. § 300aa-31, Citizen's actions [22] because of the Secretary's on-going failure:

- To make certain that vaccines are as "safe" as required by statute (since the FDA reports to the Secretary) and/or
- To "reduce the risks of adverse reactions to vaccines", as explicitly mandated by 42 U.S.C. §300aa-27(a)[23].

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[20] Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-dependent Distribution of [203]Hg-Mercury Compounds in Rat and Monkey as Studied by Whole Body Autoradiography. *J Hygenic Chem* (Japan) 1971; 17(2): 93-107.

[21] Sugita M. The biological half-time of heavy metals. The existence of a third, "slowest" component. *Int Arch Occup Environ Health* 1978; 41(1): 25-40.

[22] 42 U.S.C. § 300aa-31 Citizen's actions (emphasis added),

"(a) General rule

Except as provided in subsection (b) of this section, any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) of this section before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action."

[23] Sec. 300aa-27. Mandate for safer childhood vaccines (emphasis added),

"(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall -

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

General Component Safety

Finally, for all vaccines, especially those that are injected, the vaccine manufacturer should choose each component of a vaccine in a manner that its highest level in the finished vaccine is safe (nontoxic) to be given to the most sensitive individuals for whom that vaccine will be licensed (typically, the developing child [for childhood vaccines or vaccines given to pregnant women] or the elderly [for vaccines given to adults]).

This safety requirement arises and must be met because, by statutory definition, every article used as a component of a drug is a drug[24].

To meet this drug safety requirement, scientifically sound and appropriate toxicology studies must be conducted for each inherently toxic component used unless there are applicable published NOAEL values for those components in similar vaccines and a composite study of a solution of all these other components at their maximum levels (including the actives, the preservative components and, when used, the adjuvants) demonstrates that said solution is "sufficiently nontoxic" to the most susceptible segment of the population to whom the vaccine may be given.

CONCLUSION: TODAY'S INFLUENZA VACCINES ARE NOT "SAFE"[25]

Based on the preceding realities, it would appear that today's FDA-approved influenza vaccines do not meet all of their prerequisite safety requirements.

In all instances, the most recent package inserts for the FDA-approved vaccines either state that required safety studies (for carcinogenicity, mutagenicity [including teratogenicity], and/or adverse reproductive effects) have not been conducted or fail to fully address one or more of these safety requirements.

In addition, preserved influenza vaccines using Thimerosal as a preservative and adjuvanted vaccines apparently fail to have studies that show that they are, respectively, "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient" or do "not affect adversely the safety ... of the product".

Finally, some of the components used in certain vaccines lack proof that the level present is "safe" for susceptible individuals as explicitly required for drugs because all influenza vaccine components are drugs according to 21 U.S.C. § 321(g)(1)(D).

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(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."

[24] 21 U.S.C. § 321(g)(1)(D)

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component ... of any article specified in clause (A), (B), or (C). ... [emphasis added].

[25] Here, "safe" is defined as the vaccine manufacturer's having proved that their prophylactic ("disease preventive") influenza vaccines meet all of the applicable legal requirements for vaccine safety as per Titles 21 and 42 of the U.S.Code.

Since, under 21 U.S.C. § 351(a)(2)(B), any failure to meet any safety requirement deems a drug to be adulterated, it seems that all of today's FDA-approved influenza vaccines are adulterated drugs that are illegally placed into commerce.

Furthermore, under the National Vaccine Injury Compensation Act [NVICA] (42 U.S.C. § 300aa-1 through § 300aa-34 at §300aa-22(b)[26], the manufacturers' failure to comply with all of the applicable laws governing the proof of vaccine safety seems to establish that the influenza vaccine manufacturers have not "complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title" and are, therefore, liable for any and all substantiated claims of vaccine damage brought by any injured party because their influenza vaccine was not "properly prepared" and/or was not "accompanied by proper directions and warnings".

Furthermore, these failures to establish the safety of all components as required by law apply to the preclinical and clinical (design) stages in the development of a vaccine.

Thus, vaccine makers that have failed to prove the safety of their vaccines to all of the aforesaid safety requirement minimums appear to have, by design, created influenza vaccines that are *intentionally* defective, regardless of the approvals given by the FDA.

INFLUENZA VACCINES: NOT EFFECTIVE AND ILLNESS CAUSING

Influenza Vaccination Is Not Effective & Increases Vaccinees' Risk of Illness

Given recent peer-reviewed published studies on influenza vaccination[27,28], the cur

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[26] 42 U.S.C. 300aa-22(b)
TITLE 42 - THE PUBLIC HEALTH AND WELFARE, CHAPTER 6A - PUBLIC HEALTH SERVICE, SUBCHAPTER XIX – VACCINES, Part 2 - National Vaccine Injury Compensation Program, subpart b - additional remedies
Sec. 300aa-22. Standards of responsibility
(b) Unavoidable adverse side effects; warnings
(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought. [Emphasis added.]

[27] Cowling BJ, Fang VJ, Nishiura H, et al. Increased Risk of Noninfluenza Respiratory Virus Infections Associated with Receipt of Inactivated Influenza Vaccine. *Clin Infect Dis.* 2012 June 15; 54(12): 1778-1783. In the "DISCUSSION" section, this study reported (emphasis added), "In the prepandemic period of our study, we did not observe a statistically significant reduction in confirmed seasonal influenza virus infections in the TIV recipients (Table 3), although serological evidence (Supplementary Appendix) and point estimates of vaccine efficacy based on confirmed infections were consistent with protection of TIV recipients against the seasonal influenza viruses that circulated from January through March 2009 [16]. We identified a statistically significant increased risk of noninfluenza respiratory virus infection among TIV recipients (Table 3), including significant increases in the risk of rhinovirus and coxsackie/echovirus infection, which were most frequently detected in March 2009, immediately after the peak in seasonal influenza activity in February 2009 (Figure 1)".

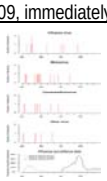

Figure 1.
Timing of influenza and other respiratory virus detections in 115 participants aged 6–15 years (*A*–*D*), compared with local influenza surveillance data (*E*). Solid red bars indicate detections in 69 participants who received 2008–2009 trivalent inactivated influenza vaccine, and black dashed bars indicate detections in 46 participants who received placebo. The bottom panel shows local laboratory surveillance data on the proportion of influenza virus detections among specimens submitted to the Public Health Laboratory Service (PHLS). Less than 2% of PHLS specimens were positive for influenza B throughout the year. "Other viruses" included coronavirus, human metapneumovirus, parainfluenza, and respiratory syncytial virus.

[28] Kelly H, Jacoby P, Dixon GA, Carcione D, et al. Vaccine Effectiveness against laboratory-confirmed influenza in healthy young children: a

rent influenza vaccines provide little, or no, effective protection from subsequently contracting either influenza A or influenza B to those who are inoculated with an influenza vaccine.

Moreover, if one is inoculated with a live-influenza-virus vaccine, then beginning in 2013 in the USA, that person is now probably infected with up to four strains of influenza, which, for up to three (3) weeks, some virus may be shed and infect other persons.

In addition, in the cited recent randomized, double-blind, true-placebo-controlled influenza vaccination study (see, footnote "**27**") of healthy children, ages 6 to 15 years, using inoculation with an inactivated-influenza vaccine for the test subjects and inoculation with sterile pH-balanced saline for the placebo controls and following the study group for about nine (9) months, after the study ended and the codes were broken, those who received the influenza vaccine had a 3.4-plus- to 4-fold increased risk of contracting a noninfluenza viral respiratory infection compared to those who received a placebo injection.

Further, the influenza vaccinees were not significantly more protected from subsequently contracting an influenza infection than the true-placebo-injected control subjects.

When the findings of the two cited studies are taken together, the reality is that getting an influenza vaccination clearly and significantly increases the inoculated person's risk for contracting the "flu"[29] and does not significantly protect the vaccinated person from

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case-control study. *Pediatr Infect Dis J* 2011; 30: 107–111. This study also found that those who were vaccinated and did not get a laboratory-confirmed case of influenza had a higher than expected levels of noninfluenza respiratory infections and, in this 2011 publication, reported (emphasis added), "We concluded that the use of ILI controls without influenza virus being identified is the appropriate choice of comparison group for the influenza cases in this study design. However, within the control group, we found that there was significantly higher vaccination coverage among those who tested positive for other respiratory viruses than among those who tested negative for all viruses. This could be interpreted to mean that influenza vaccination increases the risk of being infected by viruses other than influenza, but we believe that this explanation is biologically implausible."

29 "Flu" is any influenza-like illness (ILI), including but not limited to, influenza, a bad cold, an RSV infection, pneumonia, and other infections that produce influenza-like symptoms. In a recent paper, Doshi P, Influenza: marketing vaccine by marketing disease. BMJ 2013; 346 doi: http://dx.doi.org/10.1136/bmj.f3037 (Published 16 May 2013), the author found that, on average, less than 20% of all ILI cases were confirmed influenza cases as shown in "Fig.2",

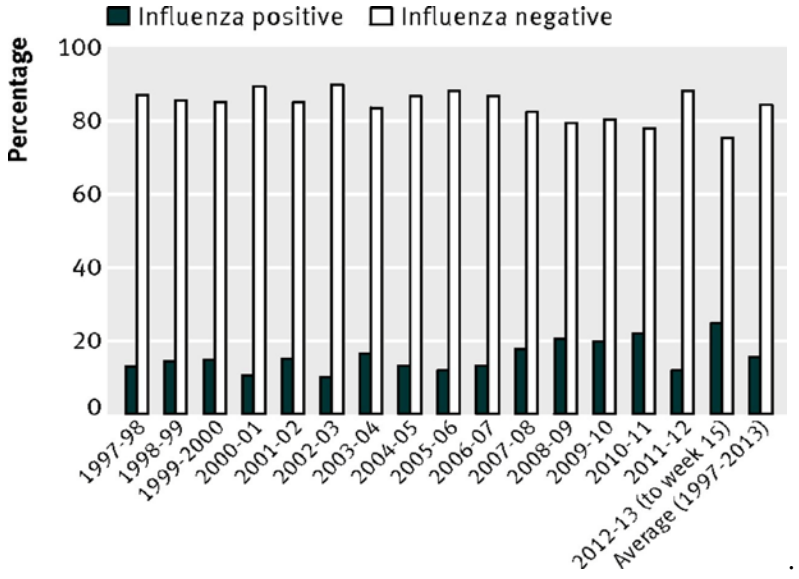

Fig 2 Proportion of specimens testing positive for influenza at World Health Organization (WHO) Collaborating Laboratories and National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories through the United States. Data are compiled and published by CDC.[28-43]

contracting influenza when they are subsequently exposed to someone shedding a live influenza A or influenza B virus.

Furthermore, there is the risk to immune-system integrity[30] that has been proven to be associated with the repeated injection of the same antigens, which seems to be a factor in the increasing level of childhood chronic diseases in children in the United States as well as the relatively poor infant mortality level for the USA among the "developed" nations[31].

Thus, influenza vaccination does not effectively protect those inoculated from subsequently contracting influenza and, in fact, actually increases the risk of noninfluenza viral respiratory illness in those who have been vaccinated (see, footnote "**27**").

The Proven Risk of Fetal Harm from Influenza Vaccination

Since the inactivated-influenza vaccines are the only ones recommended to be given to pregnant women and more than half of the available doses of the inactivated-influenza vaccines are preserved with Thimerosal, there is an added risk in those inactivated-influenza vaccine doses of induced fetal harm.

This fetal-harm risk has been established in retrospective studies of the effects from prenatal bolus doses of Thimerosal-preserved biological drugs (Rho(D)-immune globulins) that were given to pregnant women[32,33] and by the greatly increased fetal losses when, *in the 2009-2010 "flu" season*, two (2) doses of mostly Thimerosal-preserved inactivated-influenza vaccines were given to pregnant women[34].

Moreover, given the statements made by the vaccines' manufacturers in the package inserts for the influenza vaccines as approved by the U.S. Food and Drug Administration (FDA) and the cited scientific studies, giving influenza vaccines to pregnant women:

- Is not safe;
- Provides no significant protection to those who are vaccinated from contracting some strain of influenza A or influenza B when subsequently exposed to such strains especially when the strain is not the "same" as the strains in the vaccine;
- Provides no real protection to those who are vaccinated from subsequently contracting an ILI during the "flu" season;
- Increases the risk, probably by a factor of 3-plus-fold, that vaccinated pregnant women will subsequently contract a non-influenza respiratory infection; and

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30 Tsumiyama K, Miyazaki Y, Shiozawa S. Self-Organized Criticality Theory of Autoimmunity. PLoS ONE 2012 December 31; 4(12): e8382 (9 pages). doi:10.1371/journal.pone.0008382

31 Miller NZ, Goldman GS. Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity? *Human Experim Toxicol*. 2011 Sep; 30(9) 1420–1428. doi: 10.1177/0960327111407644.

32 Geier DA, Geier MR. A prospective study of thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. *J Maternal-Fetal and Neonat Med* 2007 May; 20(5): 385–390.

33 Geier DA, Mumper E, Gladfelter B, Coleman L, Geier MR. Neurodevelopmental Disorders, Maternal Rh-Negativity, and Rho(D) Immune Globulins: A Multi-Center Assessment. *Neuroendocrinol Lett* 2008; 29(2): 272-280.

34 Goldman GS. Comparison of VAERS fetal-loss reports during three consecutive influenza seasons. Was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season? *Hum Exp Toxicol* 2013 May; 32(5): 464-475. doi:10.1177/0960327112455067.

- Carries with it the risk of significant harm to those who are vaccinated with these influenza-virus-based vaccines as well as, for those women who are pregnant, some real risk of fetal damage and, at a lesser risk level, some risk of fetal loss that is significantly increased when the influenza vaccine given to pregnant women is preserved with Thimerosal, nominally at the 0.01% (100 parts-per-million [ppm]) level.

Influenza Vaccination in Children: No-To-Limited Effectiveness and Harmful

Rather than discuss all of the studies bearing on this issue, one need only read the "Main results"[35] and "Authors' conclusions"[36] subsections of the "ABSTRACT" and the "PLAIN LANGUAGE SUMMARY"[37] section of "Vaccines for preventing influenza in healthy children (Review)" by Jefferson T, Rivetti A, Di Pietrantonj C, Demicheli V, and Ferroni E, published by The Cochrane Library ( ) in *The Cochrane Library* 2012, Issue 8. [**Note:** a reprint of this Cochrane review can be downloaded from http://www.update-software.com/pdf/CD004879.pdf.]

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35 See "Main results" (emphasis added),

"We included 75 studies with about 300,000 observations. We included 17 RCTs [randomized clinical trials], 19 cohort studies and 11 case-control studies in the analysis of vaccine efficacy and effectiveness. Evidence from RCTs shows that six children under the age of six need to be vaccinated with live attenuated vaccine to prevent one case of influenza (infection and symptoms). We could find no usable data for those aged two years or younger.

Inactivated vaccines in children aged two years or younger are not significantly more efficacious than placebo. Twenty-eight children over the age of six need to be vaccinated to prevent one case of influenza (infection and symptoms). Eight need to be vaccinated to prevent one case of influenza-like-illness (ILI). We could find no evidence of effect on secondary cases, lower respiratory tract disease, drug prescriptions, otitis media and its consequences and socioeconomic impact. We found weak single-study evidence of effect on school absenteeism by children and caring parents from work. Variability in study design and presentation of data was such that a meta-analysis of safety outcome data was not feasible. Extensive evidence of reporting bias of safety outcomes from trials of live attenuated influenza vaccines (LAIVs) impeded meaningful analysis. One specific brand of monovalent pandemic vaccine is associated with cataplexy and narcolepsy in children and there is sparse evidence of serious harms (such as febrile convulsions) in specific situations."

36 See "Authors' conclusions" (emphasis added),

"Influenza vaccines are efficacious in preventing cases of influenza in children older than two years of age, but little evidence is available for children younger than two years of age. There was a difference between vaccine efficacy and effectiveness, partly due to differing datasets, settings and viral circulation patterns. No safety comparisons could be carried out, emphasising the need for standardization of methods and presentation of vaccine safety data in future studies. In specific cases, influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions. It was surprising to find only one study of inactivated vaccine in children under two years, given current recommendations to vaccinate healthy children from six months of age in the USA, Canada, parts of Europe and Australia. If immunisation in children is to be recommended as a public health policy, large-scale studies assessing important outcomes, and directly comparing vaccine types are urgently required. The degree of scrutiny needed to identify all global cases of potential harms is beyond the resources of this review.

This review includes trials funded by industry. An earlier systematic review of 274 influenza vaccine studies published up to 2007 found industry-funded studies were published in more prestigious journals and cited more than other studies independently from methodological quality and size. Studies funded from public sources were significantly less likely to report conclusions favourable to the vaccines. The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies. The content and conclusions of this review should be interpreted in the light of this finding."

37 See, "PLAIN LANGUAGE SUMMARY" (emphasis added),

"Vaccines for preventing influenza in healthy children

Children (< 16 years old) and the elderly (above 65 years old) are the two age groups that appear to have the most complications following an influenza infection. Influenza has a viral origin and often results in an acute respiratory illness affecting the lower or upper parts of the respiratory tract, or both. Viruses are mainly of two subtypes (A or B) and spread periodically during the autumn-winter months. However, many other viruses can also cause respiratory tract illnesses.

Diffusion and severity of the disease could be very different during different epidemics. Efforts to contain epidemic diffusion rely mainly on widespread vaccination. Recent policy from several internationally-recognised institutions, recommend immunisation of healthy children between 6 and 23 months of age (together with their contacts) as a public health measure.

The review authors found that in children aged from two years, nasal spray vaccines made from weakened influenza viruses were better at preventing illness caused by the influenza virus than injected vaccines made from the killed virus. Neither type was particularly good at preventing 'flu-like illness' caused by other types of viruses. In children under the age of two, the efficacy of inactivated vaccine was similar to placebo. It was not possible to analyse the safety of vaccines from the studies due to the lack of standardisation in the information given, but very little information was found on the safety of inactivated vaccines, the most commonly used vaccine in young children."

For children two (2) years of age or under, *where only inactivated-influenza vaccines are recommended by the CDC*, "Inactivated vaccines in children aged two years or younger are not significantly more efficacious than placebo".

Thus, more than not being effective in preventing influenza infection, giving inactivated-influenza vaccines to children two years of age or younger does not even produce any significant level of antibodies to the inactivated-influenza antigens.

Here, vaccine antibody levels are regarded as measures of, and define, vaccine "efficacy".

Therefore, since no significant antibody levels are produced in these children, there is no justification for the "disease preventive" (prophylactic) influenza vaccination in children two years of age or younger.

For children two to six years of age, "six children under the age of six need to be vaccinated with live attenuated vaccine to prevent one case of influenza (infection and symptoms)" and "[t]wenty-eight children over the age of six need to be vaccinated to prevent one case of influenza (infection and symptoms)".

Thus, *if these findings are valid*, then the live-virus influenza vaccine, which infects 80 % of those vaccinated with it with one to now four (4) live influenza viruses, the live-virus influenza vaccine is less than 17% effective in preventing those who are vaccinated with it from subsequently contracting another case of influenza.

Similarly, *if valid*, the inactivated-influenza vaccines are about 3.6% effective in preventing influenza in those inoculated with them.

However, remembering the abstract's admonition, "The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies", these findings are upper-limit estimates on the effectiveness for influenza vaccination in children.

Moreover, as the review reports, "Children (< 16 years old) ... appear to have the most complications following an influenza infection".

Thus, though "efficacious" (meaning produces a sufficient antibody-titer) in a significant percentage of those inoculated with them, influenza vaccination is not highly effective in preventing influenza infection in children and, *based on the recent studies cited initially*, increases the vaccinated children's risk of noninfluenza viral respiratory infection.

In addition, as the cited review reports, children have a significant level of "complications" (adverse reactions), including hospitalization, temporary and permanent disability, and death.

Influenza Vaccination: Low Effectiveness In Adults

For influenza vaccination in healthy adults, the most recent independent review of this influenza vaccination program for effectiveness in preventing illness and hospitalizations in those vaccinated as well as disease transmission, which was published by the Cochrane Collaboration in 2010[38], reported finding,

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[38] See: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001269.pub4/abstract The Cochrane Collaboration (Wiley publication) "Vaccines for preventing Influenza in Healthy Adults" by Tom Jefferson, Carlo Di Pietrantonj ,Alessandro Rivetti ,Ghada A Bawazeer ,Lubna A Al-Ansary ,Eliana Ferroni. Published Online: 7 JUL 2010" [Emphasis added.]

"In the relatively uncommon circumstance of vaccine matching the viral circulating strain and high circulation, 4% of unvaccinated people versus 1% of vaccinated people developed influenza symptoms (risk difference (RD) 3%, 95% confidence interval (CI) 2% to 5%). The corresponding figures for poor vaccine matching were 2% and 1% (RD 1, 95% CI 0% to 3%). These differences were not likely to be due to chance. Vaccination had a modest effect on time off work and had no effect on hospital admissions or complication rates. Inactivated vaccines caused local harms and an estimated 1.6 additional cases of Guillain-Barré Syndrome per million vaccinations".

Putting its findings into perspective, the review's "Plain language summary" reported (emphasis added),

"... under ideal conditions (vaccine completely matching circulating viral configuration) 33 healthy adults need to be vaccinated to avoid one set of influenza symptoms. In average conditions (partially matching vaccine) 100 people need to be vaccinated to avoid one set of influenza symptoms. Vaccine use did not affect the number of people hospitalised or working days lost but caused one case of Guillian-Barré syndrome (a major neurological condition leading to paralysis) for every one million vaccinations. Fifteen of the 36 trials were funded by vaccine companies and four had no funding declaration. Our results may be an optimistic estimate because company-sponsored influenza vaccines trials tend to produce results favorable to their products and some of the evidence comes from trials carried out in ideal viral circulation and matching conditions and because the harms evidence

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"Abstract

Background

Different types of influenza vaccines are currently produced worldwide. Healthy adults are presently targeted mainly in North America.

Objectives

Identify, retrieve and assess all studies evaluating the effects of vaccines against influenza in healthy adults.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, 2010, issue 2), MEDLINE (January 1966 to June 2010) and EMBASE (1990 to June 2010).

Selection criteria

Randomised controlled trials (RCTs) or quasi-RCTs comparing influenza vaccines with placebo or no intervention in naturally-occurring influenza in healthy individuals aged 16 to 65 years. We also included comparative studies assessing serious and rare harms.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data.

Main results

We included 50 reports. Forty (59 sub-studies) were clinical trials of over 70,000 people. Eight were comparative non-RCTs and assessed serious harms. Two were reports of harms which could not be introduced in the data analysis. In the relatively uncommon circumstance of vaccine matching the viral circulating strain and high circulation, 4% of unvaccinated people versus 1% of vaccinated people developed influenza symptoms (risk difference (RD) 3%, 95% confidence interval (CI) 2% to 5%). The corresponding figures for poor vaccine matching were 2% and 1% (RD 1, 95% CI 0% to 3%). These differences were not likely to be due to chance. Vaccination had a modest effect on time off work and had no effect on hospital admissions or complication rates. Inactivated vaccines caused local harms and an estimated 1.6 additional cases of Guillain-Barré Syndrome per million vaccinations. The harms evidence base is limited.

Authors' conclusions

Influenza vaccines have a modest effect in reducing influenza symptoms and working days lost. There is no evidence that they affect complications, such as pneumonia, or transmission.

WARNING:

This review includes 15 out of 36 trials funded by industry (four had no funding declaration). An earlier systematic review of 274 influenza vaccine studies published up to 2007 found industry funded studies were published in more prestigious journals and cited more than other studies independently from methodological quality and size. Studies funded from public sources were significantly less likely to report conclusions favorable to the vaccines. The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies. The content and conclusions of this review should be interpreted in light of this finding.

Plain language summary

Vaccines to prevent influenza in healthy adults

Over 200 viruses cause influenza and influenza-like illness which produce the same symptoms (fever, headache, aches and pains, cough and runny noses). Without laboratory tests, doctors cannot tell the two illnesses apart. Both last for days and rarely lead to death or serious illness. At best, vaccines might be effective against only influenza A and B, which represent about 10% of all circulating viruses. Each year, the World Health Organization recommends which viral strains should be included in vaccinations for the forthcoming season.

Authors of this review assessed all trials that compared vaccinated people with unvaccinated people. The combined results of these trials showed that under ideal conditions (vaccine completely matching circulating viral configuration) 33 healthy adults need to be vaccinated to avoid one set of influenza symptoms. In average conditions (partially matching vaccine) 100 people need to be vaccinated to avoid one set of influenza symptoms. Vaccine use did not affect the number of people hospitalised or working days lost but caused one case of Guillian-Barré syndrome (a major neurological condition leading to paralysis) for every one million vaccinations. Fifteen of the 36 trials were funded by vaccine companies and four had no funding declaration. Our results may be an optimistic estimate because company-sponsored influenza vaccines trials tend to produce results favorable to their products and some of the evidence comes from trials carried out in ideal viral circulation and matching conditions and because the harms evidence base is limited.. [sic]"

base is limited".

Thus, between 33 healthy adults ["under ideal conditions"] to 100 healthy adults ["in average conditions (partially matching vaccines)"] need to be vaccinated to prevent one (1) "set of influenza symptoms".

Essentially, under ideal conditions, 97% [32/33] are not protected; and under average conditions, 99% [99/100] are not protected from subsequently getting a "set of influenza symptoms" by receiving an annual influenza-vaccine inoculation.

Moreover, in the USA, using the number of doses of influenza vaccine distributed, ecological studies of outcomes observed for "yearly influenza death rate (1979, 1981, 1983, 1985, 1991, 1993, and 1995 through 2000)", "yearly influenza case rate (1982 through 1996)", and "yearly rate of hospitalization with influenza as the first-listed discharge diagnosis (1990 through 2000)" failed to find any correlation between these outcomes and the "number of influenza doses distributed/administered" (Geier DA, King PG, and Geier MR[39]).

Specifically, that study reported, for the "influenza vaccine percent population coverage (IVPPC)" (emphasis added),

1. "Figure 1 displays the rate per 10,000 persons of influenza as first-listed hospital discharge diagnosis. A linear regression of this rate as the dependent variable with the IVPPC as the independent variable gives the following regression line equation:

   Influenza as first-listed hospital discharge diagnosis (per 10,000 persons) = 0.021 IVPPC + 0.72.

   The regression-line correlation coefficient was 0.22 (95% correlation-coefficient CI = -0.44 to 0.72, R^2 = 0.048, *P* = 0.52)."

   [Note: For there to be a correlation between hospital discharge and influenza vaccination level, the "*P*" value would have to have been less than 0.05 versus the "0.52" value found and the computed mean correlation coefficient would have had to be greater than 0.7 versus the "0.22" value reported.]
2. "In Figure 2, the rate per 100 persons of influenza cases is displayed over time. The regression line equation for this rate versus IVPCC is:

   Case Rate (per 100 people) = 0.010 IVPPC + 40.

   The regression correlation coefficient for the regression line was 0.08 (95% correlation-coefficient CI = -0.55 to 0.65, R^2 = 0.006, *P* = 0.82)."

   [Note: For there to be a correlation between influenza case rate and influenza vaccination level, the "*P*" value would have to have been less than 0.05 versus the "0.82" value found and the computed mean correlation coefficient would have had to be greater than 0.7 versus the "0.08" value reported.]
3. "Figure 3 plots the rate of influenza deaths per 100,000 persons, along with the IVPCC. The regression line equation is:

   Death rate (per 100,000 persons) = -0.015 IVPPC + 0.75.

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39 http://www.jpands.org/vol11no3/geier.pdf. Geier, David A., King, Paul G., Geier, Mark R. Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations. J Am Phys Surg 2006 Sept; 11(3): 69-74. [Emphasis added.]
"ABSTRACT

A number of studies have reported that influenza vaccine (IV) administration has been less than optimally effective in certain subpopulations. This study examines yearly influenza death rate, yearly influenza case rate, and yearly rate of hospitalizations with influenza as the first-listed discharge diagnosis. By these measures, the yearly U.S. mass influenza vaccination campaign has been ineffective in preventing influenza in vaccine recipients. ..."

The regression line correlation was -0.25 (95% correlation-coefficient CI = -0.72 to 0.38, R^2 = 0.062, *P* = 0.43)".

[Note: For there to be a correlation between influenza death rate and influenza vaccination level, the "*P*" value would have to have been less than 0.05 versus the "0.43" value found and the computed mean correlation coefficient would have had to be greater than 0.7 versus the "- 0.25" value reported.]

Clearly, this multi-year study involving millions of Americans who were vaccinated each year established that influenza vaccines are ineffective.

In addition, a 2013 Cochrane review[40] found no population protective effect from vaccination of the healthcare workers caring for those over 60 years of age in long-term care facilities.

INFLUENZA VACCINATION: NONEFFECTIVE, ILLNESS CAUSING, AND HARMFUL

Factually, there are no scientifically sound true-placebo-controlled studies with extended follow up to track outcomes for at least 9 months that have shown that the influenza vaccination programs protect almost all of those who are vaccinated from subsequently contracting influenza.

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[40] http://www.ncbi.nlm.nih.gov/pubmed/23881655. Thomas RE, Jefferson T, Lasserson TJ. Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions. *Cochrane Database Syst Rev*. 2013 Jul 22; 7: CD005187. doi: 10.1002/14651858.CD005187.pub4.

"Abstract

BACKGROUND:

Healthcare workers' influenza rates are unknown but may be similar to those of the general public. Healthcare workers may transmit influenza to patients.

OBJECTIVES:

To identify all randomised controlled trials (RCTs) and non-RCTs assessing the effects of vaccinating healthcare workers on the incidence of laboratory-proven influenza, pneumonia, death from pneumonia and admission to hospital for respiratory illness in those aged 60 years or older resident in long-term care institutions (LTCIs).

SEARCH METHODS:

We searched CENTRAL 2013, Issue 2, MEDLINE (1966 to March week 3, 2013), EMBASE (1974 to March 2013), Biological Abstracts (1969 to March 2013), Science Citation Index-Expanded (1974 to March 2013) and Web of Science (2006 to March 2013).

SELECTION CRITERIA:

Randomised controlled trials (RCTs) and non-RCTs of influenza vaccination of healthcare workers caring for individuals aged 60 years or older in LTCIs and the incidence of laboratory-proven influenza and its complications (lower respiratory tract infection, or hospitalisation or death due to lower respiratory tract infection) in individuals aged 60 years or older in LTCIs.

DATA COLLECTION AND ANALYSIS:

Two authors independently extracted data and assessed risk of bias.

MAIN RESULTS:

We identified four cluster-RCTs (C-RCTs) (n = 7558) and one cohort study (n = 12,742) of influenza vaccination for HCWs caring for individuals ≥ 60 years in LTCFs. Three RCTs (5896 participants) provided outcome data that met our criteria. These three studies were comparable in study populations, intervention and outcome measures. The studies did not report adverse events. The principal sources of bias in the studies related to attrition and blinding. The pooled risk difference (RD) from the three cluster-RCTs for laboratory-proven influenza was 0 (95% confidence interval (CI) -0.03 to 0.03) and for hospitalisation was RD 0 (95% CI -0.02 to 0.02). The estimated risk of death due to lower respiratory tract infection was also imprecise (RD -0.02, 95% CI -0.06 to 0.02) in individuals aged 60 years or older in LTCIs. Adjusted analyses which took into account the cluster design did not differ substantively from the pooled analysis with unadjusted data.

AUTHORS' CONCLUSIONS:

The results for specific outcomes: laboratory-proven influenza or its complications (lower respiratory tract infection, or hospitalisation or death due to lower respiratory tract illness) did not identify a benefit of healthcare worker vaccination on these key outcomes. This review did not find information on co-interventions with healthcare worker vaccination: hand-washing, face masks, early detection of laboratory-proven influenza, quarantine, avoiding admissions, antivirals and asking healthcare workers with influenza or influenza-like-illness (ILI) not to work. This review does not provide reasonable evidence to support the vaccination of healthcare workers to prevent influenza in those aged 60 years or older resident in LTCIs. High-quality RCTs are required to avoid the risks of bias in methodology and conduct identified by this review and to test further these interventions in combination."

Most studies use antibody-titer-based "efficacy" surrogates for "effectiveness" with no true placebo controls and no extended monitoring, and speak of this measure of vaccination "efficacy" as if it actually were a valid measure of vaccination effectiveness.

Although influenza vaccination implicitly claims to protect those who are vaccinated from contracting "flu" (all ILIs), in reality, the current influenza vaccines provide only limited protection to some of the inoculees from their subsequently contracting the influenza A and influenza B strains that the vaccines contain; little or no protection from contracting other strains of these influenza viruses; and no protection from contracting other illnesses.

In addition, influenza vaccination provides no protection from, and actually seem to increase the risk of contracting, noninfluenza ILIs (see footnotes "**27**" and "**28**").

Obviously, influenza vaccination with the inactivated-influenza vaccines does not protect the unvaccinated from getting the "flu".

Moreover, the live-virus influenza vaccines infect about 80%[41] of those inoculated with at least one (1) of the now four (4) live strains of the influenza virus (two (2) live influenza A viruses and two (2) live influenza B viral strains), which those who are inoculated can shed for up to 21 days and, while shedding live viruses, they can infect others with whom they have close contact with the vaccine's viruses.

Furthermore, the independent review studies of influenza vaccination program effectiveness conducted by the Cochrane Collaboration (see footnotes "**38**" and "**40**") and, in the USA, a decades-spanning ecological study conducted by independent scientists (Geier DA, King PG, and Geier MR [see footnote "**39**"] show no significant direct influenza-protection benefits for those who are vaccinated with influenza vaccines.

Clearly, the current CDC influenza vaccination recommendations are an effort by the Establishment to maintain and grow a failed vaccination program that, *as the public is increasingly aware*, causes much more illness and harm than it prevents, while it increasingly enriches those who directly benefit from the influenza vaccination program and/or indirectly benefit from the illness and harms that this program causes.

Finally, given that the current CDC recommendation is that the general population be

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41 From 2009 Package Insert for MedImmune's FluMist (emphasis added),

"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 att 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.

The duration of FluMist vaccine virus replication and shedding have not been established."

given at least one influenza vaccination annually, there is an increasing risk to immune-system integrity (including but not limited to, allergic, anaphylactic, hyperimmune, and dysimmune reactions[42]).

More recently, autoimmunity has been proven to be associated with the repeated injection of the same antigen (see footnote "**30**").

Thus, repeated influenza vaccination will be, if it is not already, a causal factor in the increasing level of childhood chronic diseases in U.S. children[43] as well as a contributor to the relatively poor infant mortality level for the USA among the "developed" nations[44].

SUMMARY

This essay has clearly established that the current influenza vaccines are not as safe as biological drugs are required to be by law.

Additionally, it has established that:

- All of the current influenza vaccines are not really effective in preventing those inoculated with them from subsequently contracting influenza and
- The inactivated-influenza vaccines definitely increase the vaccinated persons' risk (by a factor of 3.4-plus to 4 over the nonvaccinated persons' risk) of subsequently contracting a noninfluenza viral respiratory infection, rendering these vaccines disease causing to some, *if not all*, who are inoculated with them.

In addition to not being effective, the live-virus influenza vaccines have been shown to infect at least 80% of those inoculated with one (1) or more of the now four (4) strains of live influenza viruses that these vaccine contain.

Furthermore, infection with these live-viruses is a prerequisite for the live-virus to provide any subsequent influenza-disease protection to the vaccinated persons and this infection guarantees that those infected will shed live virus for up to at least 21 days and infect some of the other people with whom they may have close contact.

Additionally, all of the Thimerosal-preserved inactivated-influenza vaccines have been proven to be harmful to the developing fetus and the developing child, as well as to contribute to the brain's cumulative inorganic-mercury level, which is a proven factor in all types of brain dysfunction and dementias as well as a factor in the peripheral neuropathies that have been associated with periodic low-level bolus-dose exposures to simple organic alkyl mercury compounds.

Moreover, these influenza vaccines can cause serious adverse reactions, including death, in those who are inoculated with them at risk levels that, on a population basis, may be acceptable to the Establishment but are clearly not acceptable to those who are directly or indirectly significantly affected.

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42 Schattner A. Consequence or coincidence? The occurrence, pathogenesis and significance of autoimmune manifestations after viral vaccines. *Vaccine* 2005; 23: 3876-3886.

43 http://www.medscape.com/viewarticle/717030?sssdmh=dm1.591574&src=nldne&uac=140083MY. Lowry F. Prevalence of Chronic Illness in US Kids Has Increased. Medscape Medical News 2010 Feb 16. [Last visited on 4 January 2014.

44 Miller NZ, Goldman GS. Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity? *Human Experim Toxicol*. 2011 Sep; 30(9) 1420–1428. DOI: 10.1177/0960327111407644.

These adverse reactions can include but not limited to, anaphylaxis, vasculitis, Guillian-Barré Syndrome, possibly Bell's Palsy and related disorders, and death.

Therefore, the current influenza vaccination program should be immediately abandoned and that program should be replaced by those alternative nutritional supplementation and dietary approaches, which have been shown to be somewhat effective in reducing the risk of contracting influenza and significantly reduced the risk of asthma attacks in children[45] as well as generally effective in reducing the risk of respiratory tract infections [46].

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45 http://ajcn.nutrition.org/content/early/2010/03/10/ajcn.2009.29094.abstract. Urashima M, Segawa T, Okazaki M, Kurihara M, Wada Y, Ida H. Randomized trial of vitamin D supplementation to prevent seasonal influenza A in schoolchildren. *Am J Clin Nutr* 2010 May; 91(5): 1255-. ajcn.29094 (emphasis added),

"Abstract

Background: To our knowledge, no rigorously designed clinical trials have evaluated the relation between vitamin D and physician-diagnosed seasonal influenza.

Objective: We investigated the effect of vitamin D supplements on the incidence of seasonal influenza A in schoolchildren.

Design: From December 2008 through March 2009, we conducted a randomized, double-blind, placebo-controlled trial comparing vitamin D3 supplements (1200 IU/d) with placebo in schoolchildren. The primary outcome was the incidence of influenza A, diagnosed with influenza antigen testing with a nasopharyngeal swab specimen.

Results: Influenza A occurred in 18 of 167 (10.8%) children in the vitamin D3 group compared with 31 of 167 (18.6%) children in the placebo group [relative risk (RR), 0.58; 95% CI: 0.34, 0.99; P = 0.04]. The reduction in influenza A was more prominent in children who had not been taking other vitamin D supplements (RR: 0.36; 95% CI: 0.17, 0.79; P = 0.006) and who started nursery school after age 3 y (RR: 0.36; 95% CI: 0.17, 0.78; P = 0.005). In children with a previous diagnosis of asthma, asthma attacks as a secondary outcome occurred in 2 children receiving vitamin D3 compared with 12 children receiving placebo (RR: 0.17; 95% CI: 0.04, 0.73; P = 0.006).

Conclusion: This study suggests that vitamin D3 supplementation during the winter may reduce the incidence of influenza A, especially in specific subgroups of schoolchildren. This trial was registered at https://center.umin.ac.jp as UMIN000001373".

[**Note:** Study problematic in that influenza B cases actually higher in the children given vitamin D supplementation than in the controls. However, the dose, 1200 IU per day, was probably insufficient. Given the age of the children, a dose of 2-4,000 IU per day would have been needed with a suitable probiotic, and all should have been given supplementary vitamin C to see the full effect. Ideally, the dose would have been adjusted to body weight with about 75 IU per kg of weight per day being the "dose" and the dose should have been given with a probiotic to ensure absorption. In addition, had the trial included a 2400 IU/d level, then the effect of level, if any, would have been observable. Ideally, each child's initial and final 25-hydroxy-vitamin-D levels would have been measured and the results also interpreted in terms of the levels of 25-hydroxy-vitamin D observed. Typically, the more recent studies failed to ensure absorption and did not, as they should have, use daily dosing with an absorption aid (a probiotic and/or vitamin K) at about 75 IU of vitamin D-3 per kg of body weight to ensure a therapeutic level of 25-hydroxy-vitamin D (about 55 ng/mL or higher [138 nm/L]) was attained. To that end, to be in the study, the children's pre-trial 25-hydroxy-vitamin-D levels should have exceeded 40 ng/mL (100 nm/L). These principles should be applied to any future study in which the goal is to understand the protective effect of vitamin D-3 on influenza as well as other influenza-like illnesses (ILIs) including the "common cold". Studies giving large bolus doses at weekly or monthly intervals should not be conducted unless there is some means to ensure that the dose is absorbed. Dosing at the equivalent of less than 60 IU of vitamin D-3 per kg of body weight should not be conducted unless there is also another supplementation level where the daily dose equals or exceeds 80 IU of vitamin D-3 per kg of body weight and an absorption aid (e.g., a good probiotic) or a labeled vitamin D-3 is used to ensure absorption occurs. Any evaluation should include adequate levels of other key vitamins and minerals (including, but not limited to daily intake of 1.2-5 g of the sodium form of vitamin C, 0.5-1 g of an absorbable form of magnesium and 0.5-1.5 g of an absorbable for of zinc, for example) in a healthy diet. {See also, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2678245/pdf/nihms-108004.pdf, Adams JS, Hewison M. Unexpected actions of vitamin D: new perspectives on the regulation of innate and adaptive immunity. *Nat Clin Pract Endocrinol Metab* 2008 Feb; 4(2): 80-90, for insight into the roles of 25-hydroxy-vitamin D in the immune system when its levels are maintained at levels sufficient (≥ 50 ng/mL [125 nm/L] for effective immune-system function.}].

46 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3543548/. CharanJ, Goyal JP, Saxena D, Yadav P. Vitamin D for prevention of respiratory tract infections: A systematic review and meta-analysis. *J Pharmacol Pharmacother*. 2012 Oct-Dec; 3(4): 300–303. [emphasis added]

"Abstract

Objectives: To explore the effect of vitamin D supplementation in prevention of respiratory tract infections on the basis of published clinical trials.

Materials and Methods: Clinical trials were searched from various electronic databases. Five clinical trials were suitable for inclusion. Outcome was events of respiratory tract infections in vitamin D group and placebo group. Data was reported as odds ratio with 95% confidence interval. Both random and fixed model was used for analysis. Analysis was done with the help of Comprehensive meta-analysis software 2.

Results: Events of respiratory tract infections were significantly lower in vitamin D group as compared to control group [Odds ratio = 0.582 (0.417 – 0.812) P = 0.001] according to random model. Results were similar in fixed model. On separate analysis of clinical trials dealing with groups of children and adults, beneficial effect of vitamin D was observed in both, according to fixed model [Odds ratio = 0.579 (0.416 – 0.805), *P* = 0.001 and Odd ratio = 0.653 (0.472 – 0.9040, *P* = 0.010 respectively]. On using random model beneficial effect persisted in children's group but became nonsignificant in adults group [Odds ratio = 0.579 (0.416 – 0.805), *P* = 0.001 and Odd ratio = 0.544 (0.278 – 1.063) *P* = 0.075 respectively]. [Note: The direction of the "Odd ratio" in all instances and a "*P*" value of "*0.075*" for the adults indicates that there was a positive effect for vitamin D-3 supplementation in the adults but that because of the variability in the magnitude of the effects observed in the adults, this effect was close to being significant. However, both models found a statistically significant, "*P* = 0.001" for the children.

Conclusion: Vitamin D supplementation decreases the events related to respiratory tract infections. There is need of more well conducted clinical trials to reach to a certain conclusion."

ACKNOWLEDGMENTS

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

In addition, Dr. King specifically thanks Catherine J. Frompovich, Melissa Troutman, and Gary S. Goldman for their support, suggestions, corrections and alternate wordings that helped him to finalize this essay.

ABOUT THE AUTHOR

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

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

Furthermore, Dr. King has, on several occasions, drafted legislation for submission to the Congress of the USA as well as to the legislatures of various States, submitted cogent comments in opposition to proposed changes to federal and state regulations that are not in the public interest or appear to be at odds with the law, reviewed numerous documents, and written articles on a multiplicity of vaccine-related and other issues.

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

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

More recently, Dr. King was the co-author of a paper in the journal ***Vaccine*** with Gary S. Goldman, PhD that reviewed the United States universal varicella vaccination program[47].

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

In addition, Dr. King was a co-author of a follow-up paper[48] published by the journal ***Human & Experimental Toxicology*** with Gary S. Goldman, PhD, that provided more evidence that the U.S. "universal varicella vaccination program is neither effective nor cost-effective".

Furthermore, Dr. King was also one of the authors of a paper in the journal *Int. J. Environ. Res. Public Health*, where the lead author was Janet K. Kern, PhD. This paper reviewed Thimerosal exposure and the roles of sulfation chemistry and thiol availability in autism[49].

In addition, Dr. King was one of the authors in a chapter, "Mercury Induced Autism"[50] (pages 1411-1432), in Comprehensive Guide to Autism Editors: Vinood B. Patel, Victor R. Preedy, Colin R. Martin. Springer New York (2014), where the lead author was Mark R. Geier, MD, PhD. This chapter presented the updated evidence that mercury, including the bolus doses delivered when certain preserved vaccines and preserved serum products given to pregnant women and young children, is a significant causal factor in "autism" and other developmental disorders, dysfunctions, and syndromes.

Finally, Dr. King was one of the authors of a paper, "A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States", in the journal, *Translational Neurodegeneration*, where the lead author was David A. Geier. This open-access paper added more evidence to the reality that there is a causal relationship between Thimerosal-preserved vaccine administration and the risk of a child's subsequently being diagnosed with an autism spectrum disorder in the USA[51].

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

48 Goldman GS, King PG. Vaccination to prevent varicella: Goldman and King's response to Myers' interpretation of Varicella Active Surveillance Project data . *Hum Exp Toxicol*. 2013 Dec. 10. [http://het.sagepub.com/content/early/2013/12/10/0960327113512340.full.pdf+html.] .

49 Kern JK, Haley BE, Geier DA, Sykes LK, King PG, Geier MR. Thimerosal Exposure and the Role of Sulfation Chemistry and Thiol Availability in Autism [Review]. *Int. J. Environ. Res. Public Health* 2013 Aug, 10, 3771-3800. OPEN ACCESS

50 See, http://www.researchgate.net/publication/258009647_Mercury_Induced_Autism/file/60b7d526955a643330.pdf for the entire chapter.

51 Geier DA, Hooker BS, Kern JK, King PG, Sykes LK, Geier MR. A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States. *Translational Neurodegeneration* 2013 Dec. 16; 2:25 (12 pages). In the first month after publication, it was accessed more than 10,500 times.

APPENDIX A

General Information, Including the Vaccine's Name, Maker, Composition, and Package Insert's Statement Concerning the Nonclinical Toxicological Studies that are Required for Carcinogenicity, Mutagenicity and/or Reproductive Toxicity

Under the current FDA expectations for preclinical studies, the "**Nonclinical Toxicology**" of the vaccine components, because, *by definition*, a component of a drug is a drug, and the candidate vaccine formulation are supposed to be assessed in appropriate *in vitro* and *in vivo* studies that establish: **a)** the maximum levels of each component is "safe" and **b)** the vaccine formulation containing the maximum permitted levels of all components other than the diluent is "safe".

Thus, each "safe" vaccine should have an appropriate section "**13 Nonclinical Toxicology**" in its package insert to comply with the FDA's labeling regulations as set forth in **21 C.F.R. §§ 201.56(d)** and **201.57**, when the package insert complies thereto or, for "older format" package inserts, appropriately addressed, as required in 1979 by the regulations then set forth in **21 C.F.R. §§ 201.56(e)** and **201.80** under "**Precautions**", in language addressing "Carcinogenesis, Mutagenesis, Impairment of Fertility". Because: **a)** certain vaccines are recommended to be given indirectly to the unborn child and/or directly to post-natal children who are rapidly developing humans who are more sensitive to adverse effects than adult humans and **b)** most of the children who receive them are supposedly healthy before the vaccine is to be administered, it is imperative that any such vaccine be rigorously evaluated in scientifically sound and appropriate "**Nonclinical Toxicology**" studies that, *according to the FDA's guidance documents for drug products*, must appropriately address carcinogenesis, mutagenesis (including teratogenicity), and the impairment of fertility before any vaccine formula may ethically be given to any child either developing in the womb or at any time after he or she is born into this world.

However, for FDA-approved vaccines that may be given to the developing child and those that may be given to pregnant women and adults, the reality is that either the package inserts state that the required carcinogenicity, mutagenicity, and reproductive-effects testing has not been conducted (in section "**13. Nonclinical Toxicology**" of the package insert) or do not provide any information about the required preclinical testing for carcinogenicity, mutagenicity and reproductive effects.

Along with the vaccine's trade name, maker and compositional information, the pertinent nonclinical toxicology statement for each of the FDA-approved influenza vaccines for each such influenza vaccine is presented, in the tabular form, on the pages that follow this introduction.

Table A1. Package Insert Safety Information for Influenza Vaccines, Where Some Contain Thimerosal, Part A

Vaccine's Registered Trade Name (if any)	**Vaccine's Manufacturer**	**Nominal Added Thimerosal Level**	**Mercury Level** **[Aluminum Level]** **{Formaldehyde Level}** **<Other>**	**Package Insert's "**Nonclinical Toxicology**" Statements**
Afluria * (egg based)	CSL Limited	**0 (single dose)**	**0** µg /0.5 mL dose [0] { 0 } See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility AFLURIA has not been evaluated for carcinogenic or mutagenic potential."
Afluria * (egg based)	CSL Limited	**0.01% (multi-dose)**	**24.5 µg / 0.5 mL dose)** [0] { 0 } See package insert for other components.	
Agriflu (egg based)	Novartis Vaccines and Diagnostics Ltd.	**0 (single dose)**	0 [0] {≤ 10 µg /0.5 mL dose} See package insert for other components.	"13. NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility AGRIFLU has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility."
Fluzone[5] (egg based)	Sanofi Pasteur, Inc. Only supplier for 6 months up to 2nd birthday	**0.01% (multi-dose; 5 ml vial)**	**25 µg/0.5 mL dose** [0] { < 100 µg/0.5 mL dose } <Octylphenol Ethoxylate¶ 150 µg/0.5 mL dose> See package insert for other components.	"13 NON-CLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Fluzone has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility"
Fluzone* (egg based)	Sanofi Pasteur, Inc. Only supplier for 6 months up to 2nd birthday	**0 (single-dose;** 0.25-mL & 0.5 mL syringes & **0.5-mL vial)**	**0** [0] { < 100 µg/0.5 mL dose } <Octylphenol Ethoxylate¶ 150 µg/0.5 mL dose> See package insert for other components.	
Fluzone Quadrivalent (egg based)	Sanofi Pasteur, Inc. Only supplier for 6 months up to 2nd birthday	**0 (single-dose;** 0.25-mL yellow-plunger syringe, 0.5 mL purple-plunger syringe & 0.5-mL vial)	**0** [0] { < 100 µg/0.5 mL dose } <Octylphenol Ethoxylate¶ 250 µg/0.5 mL dose> See package insert for other components.	Section "13. NONCLINICAL TOXICOLOGY" was not provided.
Fluzone High Dose – only for those 65 & older	Sanofi Pasteur, Inc.	**0 (single-dose;** gray plunger)	**0** [0] { < 100 µg/0.5 mL dose } <Octylphenol Ethoxylate¶ 250 µg/0.5 mL dose> See package insert for other components.	"13 NON-CLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Fluzone High-Dose has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility"
Fluzone Intradermal – only for adults through 64 years of age	Sanofi Pasteur, Inc.	**0 (single-dose**; 0.1-mL 'syringe')	**0** [0] { ≤ 20 µg /0.1mL} <Octylphenol Ethoxylate¶ 50 µg/0.1 mL dose> See package insert for other components.	"13 NON-CLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Fluzone Intradermal has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility."

* For influenza vaccines produced in both single-dose ('preservative free') & multi-dose formulas [Afluria, Fluzone (but not Fluzone Quadrivalent), & Fluvirin], these vaccines should be avoided unless there is definite proof that the dose being offered is a single-dose vial or syringe that was prefilled by the vaccine's manufacturer!

¶ Octylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TRITON X-' family.

§ Nonylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TERGITOL™ NP-' family.

Table A1. Package Insert Safety Information for Influenza Vaccines, Where Some Contain Thimerosal, Part B

Vaccine's Registered Trade Name (if any)	**Vaccine's Manufacturer**	**Nominal Added Thimerosal Level**	**Mercury Level** [Aluminum Level] {Formaldehyde Level} <Others>	**Package Insert's "Nonclinical Toxicology" Statements**
Fluvirin* (egg based)	Novartis Vaccines and Diagnostics Ltd.	**0.01% (multi-dose vial)**	**25 µg/0.5 ml dose** [0] { ≤ 0 µg/0.5 mL dose} <Egg proteins (≤ 1 µg ovalbumin), polymyxin (≤ 3.75 µg), neomycin (≤ 2.5 µg), betapropiolactone (≤ 0.5 µg) & nonylphenol ethoxylate§ (≤ 0.015% w/v.> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLUVIRIN® has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility."
Fluvirin* (egg based) – only for those 4 years of age & older	Novartis Vaccines and Diagnostics Ltd.	**< 0.0002 %** (single-dose 0.5-mL prefilled syringe)	**< 1 µg /0.5mL dose** [0] {≤ 0µg /0.5 mL dose } <Egg proteins (≤ 1 µg ovalbumin), polymyxin (≤ 3.75 µg), neomycin (≤ 2.5 µg), betapropiolactone (≤ 0.5 µg) & nonylphenol ethoxylate§ (≤ 0.015% w/v.> See package insert for other components	
Fluarix and Fluarix Quadrivalent (egg based)	GlaxoSmithKline Biologicals	**0 (single dose)**	**0** [0] {< 5µg /0.5 mL dose} <Trivalent: octoxynol-10 (TRITON® X-100) ≤ 85 µg, α-tocopheryl hydrogen succinate ≤ 100 µg, and polysorbate 80 (Tween 80) ≤ 415 µg & sodium deoxycholate ≤ 50 mcg. Tetravalent: octoxynol-10 (TRITON® X-100) ≤ 115 µg, α-tocopheryl hydrogen succinate ≤ 135 µg, polysorbate 80 (Tween 80) ≤ 550 µg & sodium deoxycholate ≤ 65 mcg.> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLUARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility." "13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLUARIX QUADRIVALENT have not been evaluated for carcinogenic or mutagenic potential. Vaccination of female rats with FLUARIX QUADRIVALENT, at doses shown to be immunogenic in the rat, had no effect on fertility."
FluMist Quadrivalent (egg based; bioengineered live viruses)	MedImmune Vaccines, Inc.	**0 (single dose)**	0 µg/0.2 mL dose [0] { 0 } <Quadrivalent: Dose contains 188 µg monosodium glutamate [MSG], 2000 µg hydrolyzed porcine gelatin, 2420 µg arginine, 13,680 µg sucrose, as well as residual amounts of ovalbumin (< 0.24 µg), gen-tamicin sulfate (< 0.015 µg) & ethylenediaminetetra-acetic acid (EDTA) (< 0.37 µg).> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FluMist Quadrivalent has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility."

* For influenza vaccines produced in both single-dose ('preservative free') & multi-dose formulas [Afluria, Fluzone (but not Fluzone Quadrivalent), & Fluvirin], these vaccines should be avoided unless there is definite proof that the dose being offered is a single-dose vial or syringe that was prefilled by the vaccine's manufacturer!

¶ Octylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TRITON X-' family.

§ Nonylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TERGITOL™ NP-' family.

Table A1. Package Insert Safety Information for Influenza Vaccines, Where Some Contain Thimerosal, Part C

Vaccine's Registered Trade Name (if any)	Vaccine's Manufacturer	Nominal Added Thimerosal Level	Mercury Level [Aluminum Level] {Formaldehyde Level} <Other>	Package Insert's "Nonclinical Toxicology" Statements
FluLaval (egg based)	ID Biomedical Corporation of Quebec	**0.01% (multi-dose only)**	**25 µg /0.5 ml dose** [0] { ≤25 µg /0.5 mL dose} <Residual amounts of ovalbumin (≤0.3 µg & sodium deoxycholate (≤50 µg).> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLULAVAL has not been evaluated for carcinogenic or mutagenic potential. Vaccination of female rats with FLULAVAL, at doses shown to be immunogenic in the rat, had no effect on fertility."
FluLaval Quad-rivalent (egg based) [**Note**: Only limited quantities will be available for 2013-2014 influenza season.]	ID Biomedical Corporation of Quebec	**0.01% (multi-dose only)**	**25 µg /0.5 ml dose** [0] { ≤25 µg /0.5 mL dose} < α-tocopheryl hydrogen succinate [a vitamin E] (≤320 µg), polysorbate 80 [a surfactant] (≤887 µg), and residual amounts of ovalbumin (≤0.3 µg) and sodium deoxycholate (≤50 µg.> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLULAVAL QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential. Vaccination of female rats with FLULAVAL QUADRIVALENT, at doses shown to be immunogenic in the rat, had no effect on fertility"
Flublok (engineered to be produced by an insect cell line)	Protein Sciences Corporation	**0 (single dose)**	**0** [0] { 0 } <Residual amounts of baculovirus & host cell proteins (≤ 28.5 mcg), baculovirus & cellular DNA (≤ 10 ng), & Triton X-100 (≤ 100 mcg).> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY Flublok has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Reproduction studies performed in female rats revealed no evidence of impaired fertility due to Flublok (see Pregnancy 8.1)."
Flucelvax (grown in Madin Darby Canine Kidney (MDCK) cell line)	Novartis Vaccines and Diagnostics, Inc.	**0 (single dose)**	**0** [0] { 0 } <Residual MDCK cell protein (≤ 8.4 µg), protein other than HA (≤ 120 µg), MDCK cell DNA (≤ 10 ng), polysorbate 80 (≤ 1125 µg), cetyltrimethly-ammonium bromide (≤ 13.5 µg), and β-propiolactone (≤ 0.5 µg).> See package insert for other components.	"13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLUCELVAX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. FLUCELVAX did not affect female fertility in a rabbit reproductive and developmental toxicity study."

* For influenza vaccines produced in both single-dose ('preservative free') & multi-dose formulas [Afluria, Fluzone (but not Fluzone Quadrivalent), & Fluvirin], these vaccines should be avoided unless there is definite proof that the dose being offered is a single-dose vial or syringe that was prefilled by the vaccine's manufacturer!

¶ Octylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TRITON X-' family.

§ Nonylphenol Ethoxylate is a non-specific name for a family of surfactants – e.g., DOW's 'TERGITOL™ NP-' family.