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Wednesday, 1 May 2013

Introductory Remarks

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

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This essay is titled "**Vaccines: 'the Safest of Medicines' or 'the Biggest Lie'?**".

Introductory Remarks

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 review for which they have independent[a], scientifically sound, peer-reviewed published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and, where appropriate, revise his views and this essay.

Respectfully,

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[To whom all responses should be directed]

[a] To qualify as an independent document, the study should be published by researchers who have no direct or indirect conflicts of interest from their ties to either those commercial entities who profit from the sale of 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.

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Vaccines: 'the Safest of Medicines' or 'the Biggest Lie'?

INTRODUCTION

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. Moreover, the use of vaccination to provide disease protection is based on a theory, "the germ theory of disease", that does not explain, nor, *until very recently*, address 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' when, for whatever reasons, a given human body is 'sick'.

Unfortunately, to this day, the developers of vaccines do not understand exactly how the human immune system functions; are focused on the adaptive immune system; 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 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 drug products (drugs) that are 'designed' to be given to currently 'healthy' individuals in order to prevent those appropriately 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[1], are declared to be "safe" as is required by statute[2] in Title 42 of the United States Code (**42 U.S.C.**) purportedly 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) or **c)** a group of vaccine formulations for a given disease (e.g., the Thimerosal-preserved, no-Thimerosal, high-dose and intradermal influenza vaccine formulations

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1 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].

2 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 ..."

bearing the registered-trademarked name Fluzone® that are made by Sanofi Pasteur).

For the definition of "safety" for a biological product[3], the FDA purports 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[4]. Moreover, using the vaccine for chickenpox as a definitive example, when an FDA-approved vaccine that has been recommended for universal use based on meeting a defined set of performance criteria established by the CDC's Advisory Committee on Immunization Practice (ACIP) failed to meet its initial recommendation criteria, instead of revoking its obviously flawed recommendation for universal use as it should have, the ACIP simply recommended adding more doses of the vaccine to the ACIP-recommended vaccination schedule[5].

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[3] 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.

[4] 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 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 as well as for 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.

[5] For the chickenpox disease, the initial criteria used to justify recommending the Merck Varivax® live-virus vaccine for Alphaherpes 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 (if lost work time) incurred when 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 Alphaherpes 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. Instead, 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 (Merck's Zostavax®) for those over 60 years of age. Even after

A 'SAFE' VACCINE?

General Safety – 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,

a definition-compliant "safe" vaccine must be properly developed, tested in scientifically sound and appropriate preclinical studies, and determined to be free of all generally harmful effects before it is administered 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 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 set forth in then 21 C.F.R. §§ 201.56(e) and 201.80 in language addressing "Carcinogenesis, Mutagenesis, Impairment of Fertility" under "Precautions".

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" or "Precautions" 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, the reality is that, in almost all instances, either the

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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. 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 still recommends this failed vaccination program.

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 older format inserts, under the "**Precautions**" section), or fail to provide any information at all about the required preclinical testing for carcinogenicity, mutagenicity and/or adverse reproductive effects [see, **Appendix A**].

Thus, all 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

clearly are not safe.

Specific Component Safety – Preservatives and Adjuvants

In addition, for all biological drug products, including vaccines, which are "preserved", the ***current good manufacturing practice***[6] (CGMP) minimums[7] for biological drug products[8], including vaccines, as set forth in **Title 21 of the United States Code of Federal Regulations (21 C.F.R.)** in section **610**[9], 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 in an appropriate carrier.

To establish that a vaccine preservative is "nontoxic", scientifically sound and appropriate toxicological studies must be conducted that prove that that 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

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6 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].

7 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].

8 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].

9 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.]

system in humans using chronic toxicity studies in an animal model from which the proper most-susceptible human toxicity thresholds (NOAELs) can be reliably computed[10].

However, though required to do so since 1968, when the National Institutes of Health (NIH) regulated vaccines, and since 1973 (see footnote "**9**"), when the United States Congress transferred the regulation of vaccines to the FDA, and subsequently required to submit all required proofs of safety to the FDA since 1999[11], the vaccine makers have refused to establish the NOAEL values for Thimerosal-preserved vaccines in the developing human, pregnant woman, adult and/or elderly person to whom these vaccines may be repeatedly administered and, contrary to law since 1977[12], the FDA has licensed these Thimerosal-preserved vaccines delivering 15 to 50 micrograms of Thimerosal per vaccine dose.

Using an FDA-recognized long-term chronic toxicity study that injected multiple levels of Thimerosal into rats[13], the only published estimate for the upper limits on the NOAEL for injected Thimerosal ("< 0.0086 µg Thimerosal/kg/day" [< 0.0042 µg organic mercury/kg/day] in developing children and "< 0.086 µg Thimerosal/kg/day" [< 0.042 µg organic mercury/kg/day] in adults)[14] has shown that using Thimerosal at a level that the FDA recognizes as suitable for a vaccine preservative, nominally, 30 to 100 micrograms (µg) of Thimerosal per milliliter (mL) of vaccine for developing children and, nominally, 50 to 100 micrograms (µg) of Thimerosal per milliliter (mL) of vaccine for adults, greatly exceeds these NOAEL estimates for any individual's weight.

Further, 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 (Hg), < 0.00042 µg organic Hg/kg/ day in developing children and < 0.0042 µg organic Hg/kg/day in adults.

Because the dose of organic-chemical-derived mercury, which is the ultimate toxicant, that is immediately delivered[15] and which does not leave the body for some time[16], is nominally on the order of 7.5 to 25 micrograms of organic-chemical-derived mercury (organic mercury) for

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10 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 sexes as the test subjects and the controls may be reliably used for establishing the related "nontoxic" level for the preservative injected into humans. 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.

11 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.]

12 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.]

13 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.

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

15 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.

16 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.

developing children and 12.5 to 25 micrograms of organic-chemical-derived mercury (organic mercury) for adults, the nominal maximum dose of this toxicant in a single vaccination with a preserved vaccine probably exceeds its estimated "sufficiently nontoxic" level unless the child weighs more than 59,524 kg (131,228 pounds) or the adult weighs more than 5,952 kg (13,123 pounds). Even if only a "nontoxic" level were what is required, few, if any, adults and no children weigh more than 595 kg (1,312 pounds)!

Therefore, Thimerosal-preserved vaccines [see, **Appendix B**] 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 even estimates of the NOAEL values needed to demonstrate that each different adjuvant "does not affect adversely the safety ... of the product".

Worse, in most instances, the vaccine makers have failed to disclose the exact nature of the many polymeric hydrated aluminum salts used as adjuvants or their retention half-lives in the human body.

Finally, since the manufacturers of the 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, regulated as drugs, adulterated drugs under 21 U.S.C. § 351(a)(2)(B) (see footnote "**6**") regardless of the actions or non-actions taken by the FDA.

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, for adults, the elderly).

This safety requirement arises because, by statutory definition, every article used as a component of a drug is a drug[17].

To meet this drug safety requirement, scientifically sound and appropriate toxicology studies must be conducted for each 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 (besides the actives, the preservative components and, in many instances, the adjuvants) demonstrates that said solution is nontoxic to the most susceptible segment of the population to whom the vaccine may be given.

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[17] 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].

CONCLUSION: Today's Vaccines Are Not as Safe as Required by Law

Based on the preceding realities, it would appear that today's FDA-approved vaccines do not meet the safety requirements that they are required to meet. 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 address one or more of these safety requirements. In additions, preserved 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 of drugs because all vaccine components are drugs according to 21 U.S.C. § 321(g)(1)(D).

Since, under 21 U.S.C. § 351(a)(2)(B), any failure to meet any safety requirement deems a drug to be adulterated, it would seem that all of today's FDA-approved vaccines are adulterated drugs which are illegal to be placed in commerce and which, for the purposes of 42 U.S.C. § 300aa-1 through § 300aa-34 (The National Vaccine Injury Compensation Act NVICA]) at §300aa-22(b)[18], seems to establish that the 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 vaccine was not "properly prepared" and/or was not "accompanied by proper directions and warnings".

Finally, to the extent that these failures to establish safety as required by law apply to the preclinical and clinical (design) stages in the development of a vaccine, vaccine manufacturers that have failed to prove the safety of their vaccines to all of the aforesaid safety standards have, by design, created vaccines that are intentionally defective, regardless of the approvals given by the FDA.

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[18] 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.]

About the Author, Paul G. King, PhD

In addition to the information available on his Internet web site, http://www.dr-king.com/, Paul G. King, PhD Analytical Chemist, Founder of ***FAME Systems***, is the Science Advisor to, and the current Secretary for, the Coalition for Mercury-Free Drugs (**CoMeD, Inc.**), which is a 501(3)(c) not-for-profit corporation that maintains an Internet web site at http://www.mercury-freedrugs.org/) and Advisor to the National Coalition of Organized Women (NCOW) that currently maintains two (2) Internet web sites, http://www.progressiveconvergence.com/ and http://vaccineliberationarmy.com/.

As a scientist and student of the federal regulations and statutes that govern drugs, including vaccines, Dr. King has led CoMeD, on two separate occasions, in submitting 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 subsequent 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 Commissioner of the FDA to comply with the statutes, laws (regulations) and policies that regulate the lawful conduct of the Secretary of the DHHS, the FDA commissioner, and CDC and FDA officials. The second civil federal lawsuit, 1:2009-cv-00015, is still being litigated (on appeal to the full U.S. Court of Appeals for the District of Columbia Circuit [11-5035, Motion for Reconsideration, 04/27/2012]).

In addition, 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 variety of vaccine-related and other issues.

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

Moreover, he been an author of several 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), above (> 1 in 100 children; the autism spectrum disorders), at (> 1 in 1000 children; non-genetic childhood type 1 diabetes), or approaching (life-threatening peanut allergy) epidemic childhood levels in the USA.

Most recently, Dr. King was the co-author of a paper in the journal Vaccine with Gary S. Goldman, PhD, which reviewed the United States universal varicella vaccination program and found that the current CDC-recommended vaccination program was neither effective in preventing those who are vaccinated from getting chickenpox nor, since it greatly increases the public's risk of having clinical cases of shingles, cost effective for universal use (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).

Though, as a scientist, Dr. King is neither anti-vaccine nor anti-vaccination *per se*, his research into the "safety" and "effectiveness" of the prophylactic vaccines that are recommended to be given to our children and/or to ourselves has found that: **a)** these vaccines generally do not meet one or more of the safety standards they are represented to meet, **b)** some vaccines are not effective in providing long-term protection from contracting the diseases for which they are represented to provide, and **c)** a few seem to cause more harm than they prevent disease.

Based on the preceding deficiencies, King's religious beliefs also compel him to reject the current prophylactic vaccines and their associated vaccination programs, because they are false gods that are neither safe (i.e. meet all of their required proofs of safety), nor effective (i.e., provide the persistent disease "immunity" that they are purported to furnish to those repeatedly inoculated with them).

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APPENDIX A

Required Nonclinical Toxicological Studies for: Carcinogenicity, Mutagenicity and Reproductively 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 that: **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" or "Precautions" 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 or 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, for older format inserts, under the "Precautions" section) or do not provide any information about the required preclinical testing for carcinogenicity, mutagenicity and, *except when only given to women over 60 years of age or to men over 80 years of age*, reproductive effects.

- ***For vaccines whose package inserts conform to the "current" format,***

  A. Either section "13 Nonclinical Toxicology" is missing from the package insert

  [Examples include: **1)** Merck's Varivax®, (both frozen and refrigerated formulas) chickenpox vaccines; **2)** Barr Labs' live, unattenuated adenovirus types 4 & 5 virus vaccine for military use in ages 17-50; **3)** Emergent BioDefense Operations Lansing Inc.'s Biothrax® (anthrax vaccine) for ages 18-65[A-1] **w**ith trials in children pending, **4)** Merck's Pneumovax® 23 (polyvalent {from 23 S. pneumoniae strains} pneumococcal polysaccharide) vaccine, **5)** Pfizer's (Wyeth Pharmaceuticals') Prevnar® 13 (pneumococcal 13-valent S. pneuomoniae conjugate {Diphtheria CRM $_{197}$ Protein}) vaccine, and **6)** Sanofi Pasteur Biologicals Co.'s ACAM2000® (live, 'smallpox' {vaccinia virus}) vaccine],

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A

[-1] Despite no section "13 NONCLINICAL TOXICOLOGY" in the package insert for Biothrax states, the information in section "8 USE IN SPECIFIC POPULATIONS",

"8.1 Pregnancy

Pregnancy Category D. [See Warnings and Precautions (5)]

Male Fertility: A retrospective study was performed at an in-vitro fertilization clinic to evaluate whether Anthrax may impact reproductive function in men. This study compared semen parameters, embryo quality, and pregnancy outcomes in 254 male clients who stated that they had received BioThrax, with those of 791 male clients who did not.[2] Prior receipt of BioThrax did not influence semen parameters (including concentration, motility, and morphology), fertilization rate, embryo quality or clinical pregnancy rates."

indicates that some attempt was made to address the issue of the impairment of reproduction in both sexes.

B. Or contains wording that, in effect, states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility"

<*vaccine name*> "has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility."

[**1)** Merck's Zostavax® (high-level *Alphaherpes varicella zoster virus* vaccine), **2)** GlaxoSmithKline's [GSK's] (Meningococcal {sero-groups C & Y} & Hib vaccine), **3)** GSK's Infanrix® (DTaP {absorbed} vaccine), **4)** Sanofi Pasteur, Ltd.'s Daptacel® (DTaP {absorbed}) vaccine, **5)** GSK's Pediarix® (DTaP {absorbed}, Hep B (Recombinant) & Inactivated Poliovirus vaccine), **6)** GSK's Kinrix® (DTaP {absorbed} and Inactivated Poliovirus vaccine), **7)** Sanofi Pasteur Ltd.'s Pentacel® (DTaP {absorbed}, Inactivated Poliovirus and Hib {Tetanus-Toxoid Conjugate} vaccine), **8)** GSK's Hiberix® (Hib {Tetanus-Toxoid Conjugate}), **9)** GSK's Havrix® (Hepatitis A, inactivated) vaccine, **10)** Merck's VAQTA® (Hepatitis A, inactivated) vaccine, **11)** GSK's Twinrix® (Hepatitis A {Inactivated} & Hepatitis B {Recombinant}) vaccine, **12)** Merck's Recombivax HB® (Hepatitis B Vaccine {Recombinant}) vaccine, **13)** GSK's Engerix-B® (Hepatitis B {Recombinant}) vaccine, **14)** Sanofi Pasteur, Inc.'s H5N1 Influenza Virus Vaccine (Thimerosal-preserved, inactivated), **15)** ID Biomedical Corporation of Quebec's FluLaval® (Thimerosal-preserved, inactivated trivalent) influenza vaccine, **16)** MedImmune LLC's FluMist® (live, cold-adapted, trivalent influenza) vaccine, **17)** GSK's Fluarix®(trivalent, inactivated) influenza vaccine, **18)** Novartis' Fluviron® (inactivated, trivalent, Thimerosal-containing) influenza vaccines, **19)** Sanofi Pasteur Inc.'s Fluzone® (including Thimerosal-preserved), the Fluzone High-Dose for the elderly, and the Fluzone Intradermal (trivalent, inactivated influenza) vaccines, **20)** MedImmune LLC's FluMist® Quadravalent (two [2] "A" and two [2] "B" strains of live, cold-adapted viruses) influenza vaccine, **21)** Merck's ProQuad® (live measles, mumps, rubella and varicella vaccine {MMRV} in both frozen and refrigerated formulations, **22)** GSK's MenHibrix® (N.-meningitidis-polysaccharides {Type C and Y} and Hib polysac-charide all conjugated to Tetanus Toxoid) vaccine, **23)** Sanofi Pasteur's Menactra® (N.-meningitidis-polysaccharides {Types A, C, Y, and W-135} conjugated to Diphtheria CRM_{197} Protein) vaccine, **24)** Sanofi Pasteur's Menomune® (N.-meningitidis-poly-saccharides {Types A, C, Y, and W-135} vaccine {the multi-dose formula is Thimerosal-preserved; the single-dose contains no preservative}, **25)** GSK's Rotarix® (live, oral, human rotavirus) vaccine, **26)** Merck's RotaTeq® (live, oral, pentavalent rota virus [bovine-human hybridized {GE}]) vaccine, **27)** Sanofi Pasteur Ltd.'s TENIVAC® (aluminum-adjuvant-absorbed tetanus toxoid & reduced diphtheria toxoid) vaccine, **28)** Sanofi Pasteur, Ltd.'s Adacel® (aluminum-adjuvant-adsorbed, tetanus, reduced diphtheria and detoxified pertussis) vaccine, and **29)** GSK's Boostrix® (aluminum-adjuvant-adsorbed, tetanus, reduced diphtheria and reduced pertussis) vaccine],

C. Or contains wording that, in effect, states,

"13 NONCLINICAL TOXICOLOGY

<*vaccine name*> "has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. ..."

[**1)** Protein Sciences Corporation's FluBlok® (insect-derived, GE, trivalent,

inactivated influenza) vaccine and **2)** Novartis' Flucelvax (dog-kidney-derived, trivalent, inactivated influenza) vaccine],

D. Or contains wording that, in effect, states,

"13 NONCLINICAL TOXICOLOGY

<*vaccine name*> "has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility."

[**1)** Novartis' Agriflu® (trivalent, inactivated influenza virus) vaccine, and **2)** Novartis' MenVeo®, meningococcal (Groups A, C, Y, and W-135) polysaccharide-fragment conjugated to-Diphtheria CRM197) vaccine {component composition concealed}],

E. Or contains wording that states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

GARDASIL has not been evaluated for the potential to cause carcinogenicity or genotoxicity.

GARDASIL administered to female rats at a dose of 120 mcg total protein, which is equivalent to the recommended human dose, had no effects on mating performance, fertility, or embryonic/fetal survival.

The effect of GARDASIL on male fertility has been studied in male rats at an intramuscular dose of 0.5 mL/rat/occasion (120 mcg total protein which is equivalent to the recommended human dose). One group of male rats was administered GARDASIL once, 3 days prior to cohabitation, and a second group of male rats was administered GARDASIL three times, at 6 weeks, 3 weeks, and 3 days prior to cohabitation. There were no treatment-related effects on reproductive performance including fertility, sperm count, and sperm motility. There were no treatment-related gross or histomorphologic and weight changes on the testes."

[Merck's Gardasil® (Recombinant Human Papillomavirus [HPV] Quadravalent {Types 6, 11, 16 and 18}) vaccine],

F. Or contains wording that states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

CERVARIX has not been evaluated for its carcinogenic or mutagenic potential.

Vaccination of female rats with CERVARIX, at doses shown to be significantly immunogenic in the rat, had no effect on fertility"

[GSK's Cervarix® (Recombinant Human Pappillomavirus [HPV] Bivalent {Types 16 and 18) vaccine],

G. Or contains wording that, in effect, states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Neither Influenza A (H1N1) 2009 Monovalent Vaccine nor" <*vaccine name*> "has been evaluated for carcinogenic or mutagenic potential or for impairment of fertility." [or with the names reversed]

[**1)** CSL Ltd's Influenza A (H1N1) 2009 Monovalent Vaccine and both of its Afluria® Trivalent Influenza vaccines, **2)** MedImmune LLC's Influenza A (H1N1) 2009 Monovalent Intra-nasal Live Vaccine and its FluMist® (live, cold-adapted trivalent influenza) vaccine, **3)** ID Biomedical Corporation of Quebec's Influenza A (H1N1) 2009 Monovalent (Thimerosal-preserved, inactivated) vaccine and its FluLaval® (Thimerosal-preserved, inactivated trivalent influenza) vaccine, **4)** Novartis' Influenza A (H1N1) 2009 Monovalent (inactivated) vaccines and its Fluviron® (inactivated trivalent influenza) vaccines), and **5)** Sanofi Pasteur, Inc.'s Influenza A (H1N1) 2009 Monovalent (inactivated) vaccine formulas and its Fluzone® (inactivated trivalent influenza) vaccine formulas],

H. Or contains wording that, in effect, states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

<*vaccine name*> "has not been evaluated for carcinogenic or mutagenic potential."

[CSL Ltd's Afluria® (inactivated trivalent influenza) vaccine formulas],

I. Or contains wording that, in effect, states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

<*vaccine name*> "has not been evaluated for carcinogenic or mutagenic potential. Vaccination of female rats with" <*vaccine name*> ", at doses shown to be immunogenic in the rat, had no effect on fertility."

[GSK's Fluarix® Quadravalent (Two "A" and two "B" strains, inactivated) influenza vaccine],

J. Or contains wording that, in effect, states,

"13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

<*vaccine name*> "has not been evaluated for carcinogenic or mutagenic potential." <*vaccine name*> "was found to have no effect on fertility of female rats at intramuscular doses of up to 300-fold excess relative to the projected human dose (on a mg/kg basis) administered prior to and after mating .... The effect of IXIARO on male fertility has not been evaluated."

[Licensed by Intercell AG, Vienna, Austria, made by Intercell Biomedical, Livingston, UK, and distributed by Novartis, Ixiaro® (inactivated, human-cancer-cell propagated, Japanese Encephalitis virus) vaccine]

K. Or contains wording that, in effect, states,

" 13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed with DECAVAC vaccine to evaluate carcinogenicity, mutagenic potential, or impact on fertility. "

[Sanofi Pasteur, Inc.'s DECAVAC® (reduced-Thimerosal, aluminum-adjuvant-adsorbed tetanus toxoid and reduced diphtheria toxoid) vaccine],

or,

■ ***For vaccines whose package inserts that still conform to the "previous" format***, the vaccines

A. Either fail to mention "Carcinogenesis, Mutagenesis, Impairment of Fertility" (e.g., Sanofi Pasteur, SA's Imovax® [inactivated rabies virus grown in human cancer cells] vaccine)

B. Or, under "**Precautions**", state (emphasis added),

1. For Merck's M-M-R® II vaccine,

"*Carcinogenesis, Mutagenesis, Impairment of Fertility*

M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."

Pregnancy Category C

Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination ....

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: (1) ..., none of the newborns had abnormalities compatible with congenital rubella syndrome;[48] (2) Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous

abortion. ..., there is no evidence that it causes congenital malformations in humans;[37] and (3) Reports have indicated that contracting wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy.[57,58] There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. ...."

[Merck's M-M-R® II, December 2007 – statements clearly indicate mutagenic potential for this vaccine; but, the vaccine's mutagenic and carcinogenic potential are 'unknown' as is its potential to impair fertility],

2. For Organon Teknika Corp LLC's BCG live, attenuated TB vaccine, states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

BCG VACCINE has not been evaluated for carcinogenic, mutagenic potentials or impairment of fertility.

Pregnancy Category C

Animal reproduction studies have not been conducted with BCG VACCINE. ...."

[Organon Teknika Corp LLC's BCG vaccine, year not specified, in previous format, last update with FDA in January of 2011. "BCG VACCINE for percutaneous use, is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of Mycobacterium bovis[1]"],

3. For Organon Teknika Corp LLC's TICE® BCG live, attenuated TB vaccine, the 2009 package insert states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

TICE® BCG has not been evaluated for its carcinogenic, mutagenic potentials or impairment of fertility.

Pregnancy

Teratogenic Effects – Pregnancy Category C

Animal reproduction studies have not been conducted with TICE® BCG. ..."

[Organon Teknika Corp LLC's TICE BCG 2009 package insert, where the TICE® strain used in this BCG VACCINE preparation was developed at the University of Illinois from a strain originated at the Pasteur Institute so that the vaccine is sold as the TICE BCG vaccine],

4. For Sanofi Pasteur, Inc's Thimerosal-preserved tetanus toxoid vaccine without any aluminum adjuvant, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed to evaluate carcinogenicity, mutagenic potential, or impact on fertility.

PREGNANCY CATEGORY C

Adequate immunization by routine boosters in non-pregnant women of child-bearing age can obviate the need to vaccinate women during pregnancy (see DOSAGE AND ADMINISTRATION section).

Animal reproduction studies have not been conducted with Tetanus Toxoid. The risk to the fetus from tetanus toxoid is unknown. The ACIP recommends that an appropriate tetanus toxoid-containing preparation be given to inadequately immunized pregnant women because it affords protection against neonatal tetanus.[10] Waiting until the second trimester is a reasonable precaution to minimize any theoretical teratogenic concern.[5] ...."

[Sanofi Pasteur, Inc.'s 2005 packager insert],

5. For Sanofi Pasteur's Inc aluminum-adjuvanted, diphtheria and tetanus toxoids

adsorbed vaccine, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed to evaluate carcinogenicity, mutagenic potential, or impact on fertility.

PREGNANCY

THIS VACCINE IS NOT RECOMMENDED FOR PERSONS 7 YEARS OF AGE AND OLDER."

[Sanofi Pasteur Inc.'s 2005 package insert; no "Pregnancy Category" assigned],

6. For Sanofi Pasteur, Inc.'s Tripedia® diphtheria, tetanus, pertussis (adsorbed) vaccine for children, the package insert states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

Tripedia vaccine has not been evaluated for its carcinogenic or mutagenic potentials or impairment of fertility.

Pregnancy Category C

Animal reproduction studies have not been conducted with Tripedia vaccine. .... Tripedia vaccine is NOT indicated for women of child-bearing age."

[Sanofi Pasteur Inc.'s 2005 package insert],

7. For Merck's PedvaxHib® Haemophylis influenzae type B (Meningococcal-Protein Conjugate) vaccine for children, the package insert states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

Liquid PedvaxHIB has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with PedvaxHIB. Liquid PedvaxHIB is not recommended for use in individuals 6 years of age and older."

[Merck's 2011 package insert],

8. For Sanofi Pasteur SA's ActHib® Haemophylis Influenzae type B (Tetanus-Toxoid Conjugate) vaccine for children, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

PREGNANCY CATEGORY C

..."

[Sanofi Pasteur SA's 2009 package insert],

9. For Merck's Comvax® Haemophylis Influenzae type B (Meningococcal-Protein Conjugate) and Hepatitis B (Recombinant) vaccine for children, the package insert states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

COMVAX has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with COMVAX.

..."

[Merck's 2011 package insert.]

10. For 'Sanofi Pasteur Inc.'s distributed' JE Vax®, Inactivated Japanese Encephalitis virus from mouse brain, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed to evaluate carcinogenicity, mutagenic potential, or impact on fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Japanese Encephalitis Virus Vaccine. ..."

[Sanofi Pasteur Inc.'s 2005 Package Insert; this vaccine is no longer available in the USA.]

11. For Merck's Attenuvax®, live measles virus (Enders' attenuated Edmonston strain and propagated in chick embryo cell culture), the package insert states,

"*Carcinogenesis, Mutagenesis, Impairment of Fertility*

ATTENUVAX has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with ATTENUVAX. ..."

[Merck's 2006 Package Insert, this vaccine is no longer available in the USA.]

12. For Pfizer's (Wyeth Pharmaceuticals' Prevnar®, 7-valent (seven [7] strains of S. pneumoniae polysaccharides conjugated to Diphtheria CRM197 Protein) vaccine, the package insert states,

"*CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY*

Prevnar® has not been evaluated for any carcinogenic or mutagenic potential, or impairment of fertility.

PREGNANCY

Pregnancy Category C

Animal reproductive studies have not been conducted with this product. ...."

[Wyeth Pharmaceuticals' 2002 Package Insert; this vaccine is being supplanted by the Prevnar 13 vaccine in the USA]

13. For Sanofi Pasteur, SA's IPOL® (poliovirus inactivated, three types of poliovirus from monkey kidney cells: Type 1 [Mahoney], Type 2 [MEF-1] and Type 3 [Saukett]) vaccine, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not been conducted.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with IPOL vaccine. ...."

[Sanofi Pasteur SA's IPOL 2012 Package Insert],

14. For Novartis'RabAvert (inactivated rabies virus that is grown in chicken fibroblasts) vaccine, the package insert states,

"Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies with RabAvert have not been conducted to assess the potential for carcinogenesis, mutagenesis, or impairment of fertility.

Use in Pregnancy

Pregnancy Category C. Animal reproductive studies have not been conducted with RabAvert. ...."

[Novartis' 2012 Package Insert],

15. For Merck's Meruvax® II, live rubella virus (Wistar Institute [WI] 27/3 strain that is propagated in WI human lung fibroblasts) vaccine, the package insert states,

"*Carcinogenesis, Mutagenesis, Impairment of Fertility*

MERUVAX II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with MERUVAX II. ...."

[Merck's 2006 Package Insert; this vaccine is no longer available in the USA]

16. For MassBiologics' 'Td' (reduced-Thimerosal-containing, aluminum-adjuvant-adsorbed, tetanus toxoid & reduced diphtheria toxoid) vaccine, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed with MassBiologics' Td to evaluate carcinogenicity, mutagenic potential, or impairment of fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with MassBiologics' Td. ...."

[MassBiologics' 2009 Package Insert],

17. For Sanofi Pasteur, Inc.'s 'TTOX' or 'TT adsorbed' (aluminum-adjuvant-absorbed tetanus toxoid) vaccine, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed with Tetanus Toxoid Adsorbed manufactured by Aventis Pasteur Inc. to evaluate carcinogenicity, mutagenic potential, or impact on fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Tetanus Toxoid Adsorbed manufactured by Aventis Pasteur Inc. ...."

[Aventis Pasteur Inc.'s 2005 Package Insert],

18. For Berna Biotech Ltd.'s Vivotif® (oral, live, typhoid *Salmonella typhi, strain* Ty21a) vaccine, the package insert states,

"*Carcinogenesis, Mutagenesis, Impairment of Fertility*

Long-term studies in animals with Vivotif have not been performed to evaluate carcinogenic potential, mutagenic potential or impairment of fertility.

Pregnancy

Category C

Animal reproduction studies have not been conducted with Vivotif. ...."

[Berna Biotech, Ltd.'s 2006 Package Insert]

19. For Sanofi Pasteur, SA's Typhim Vi® (isolated cell-surface Vi polysaccharide from *Salmonella enterica* serovar Typhi, *S typhi* Ty2, strain) vaccine, the package insert states,

"CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Typhim Vi vaccine has not been evaluated for its carcinogenic potential, mutagenic potential or impairment of fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Typhim Vi vaccine. ….”

[Sanofi Pasteur, Inc.'s 2005 Package Insert]

20. For Sanofi Pasteur, Inc.'s YF-VAX® (live 17D-204 strain of yellow fever virus cultured in avian-leukosis-virus-free [ALV-free] chicken embryos) vaccine, the package insert states,

“Carcinogenesis, Mutagenesis, Impairment of Fertility

YF-VAX vaccine has not been evaluated for its carcinogenic or mutagenic potential or its effect on fertility.

Pregnancy Category C

Animal reproduction studies have not been conducted with YF-VAX vaccine. ….”

[Sanofi Pasteur, Inc.'s 2010 Package Insert]

After reviewing the preceding information for the FDA-approved vaccines for which a package insert was available on the FDA web site, the reader should see that the vaccine manufacturers have been allowed to provide no proofs, or even statements, of 'cancer' or 'mutation' safety and, in most instances, no assertions of 'safety' with respect to reproductive and reproduction capability by the FDA, who approves all such labeling, which is supposed to comply with the current regulations set forth in 21 C.F.R. § 201.

Turning to the dark side of “modern” vaccine history, during the development of the first polio vaccines (the original 'Salk' injected inactivated polio and the follow-on 'Sabin' live, oral), animal studies did indicate that, when injected into test animals, the original developmental 'Salk' vaccines did show evidence that the injected inactivated polio vaccine candidates caused mutations and cancers in the test animals. However, wanting nothing to get in the way of the launch of the 'Salk' polio vaccination programs, this information was suppressed and the 'Salk' vaccines were launched as the savior of mankind from the scourge of paralytic polio in the mid-1950s.

When the initial campaigns caused an increase in paralytic polio instead of preventing it, the failures were blamed on a “problem with the 'complete' inactivation of the polio virus” and, to ensure that the vaccine programs were perceived as 'successful', government health officials, the medical establishment and the vaccine manufacturers colluded to surreptitiously change the definition of “polio” disease from “medical viral-disease cases with paralysis lasting more than 24 hours” to “paralytic polio” (medical viral-disease cases with paralysis lasting for months), 'Coxachie virus' (medical viral-disease cases with paralysis that could be identified as being caused by a Coxachie virus) and 'aseptic meningitis' (the 90-plus percent of medical viral-disease cases that were previously “polio” with transient paralysis, where the causal virus was not identified but rather cases where bacterial (or rarely fungal or ameobic) infection was ruled out).

'Miraculously', there was more than a 10-fold drop in “polio” cases and the Establishment propaganda continued to bury the probable carcinogenicity and mutagenicity associated with the polio vaccines. In addition, though prophylactic vaccines should be proven to be non-carcinogenic and non-mutagenic before they are given to any human “volunteer”, the reality, as the 'current' package inserts for the vaccines clearly show, is that this critical “vaccine safety” requirement has been simply ignored.

However, the reality that a contaminant monkey (simian) virus, the 40th simian virus discovered [SV-40], which was present in the polio vaccines from adventitious contamination when the original polio vaccines and vaccine seed stocks were grown in monkey kidney cells, was and is

carcinogenic and/or mutagenic. Worse, most all viral vaccines and other vaccines may contain one or more adventitious substances, including viruses and DNA, recombinant DNA, RNA, and/or bioactive fragments thereof, and/or other substances (e.g., Thimerosal) that are, or may be, mutagenic or carcinogenic. Obviously, the requirement to ensure that vaccines are not carcinogenic or mutagenic is not only ignored but also hidden from the public because the vaccines do cause cancer and mutations in some percentage of those who are injected with them.

Worst of all, SV-40 not only infects humans injected with vaccines containing it but has also incorporated itself into the human genome so that those seriously infected with SV-40 are not only at a higher risk of having certain cancers but also pass that risk on to their children.

Clearly, absent proof that a given vaccine does not and cannot cause cancer or mutation, all such vaccines are inherently unsafe. Since all of the current vaccines approved by the FDA in the USA have no proof that they are not carcinogenic or mutagenic, all the current FDA-approved vaccines are not only unsafe but also adulterated drugs that cannot legally be administered to any person.

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APPENDIX B

Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines

Vaccine	Trade Name	Manufacturer	Thimerosal **Percent**[1]	**Nominal Added** Mercury **Mass per Dose**[6,7]
Anthrax	BioThrax	Emergent BioDefense Operations Lansing, LLC	0	0
DTaP	Tripedia[2]	Sanofi Pasteur, Inc.	≤ 0.00012%	≤ 0.3 µg/0.5 mL dose
	Infanrix	GlaxoSmithKline Biologicals	0	0
	Daptacel	Sanofi Pasteur, Ltd.	0	0
DTaP-HepB-IPV	Pediarix	GlaxoSmithKline Biologicals	0	0
DT	No Trade Name	Sanofi Pasteur, Inc.	< 0.00012% (single dose)	< 0.3 µg/0.5mL dose
		Sanofi Pasteur, Ltd.[3]	0.01%	25 µg/0.5 mL dose
Td	No Trade Name	MassBiologics	≤ 0.00012%	≤ 0.3 µg / 0.5 ml dose
	Decavac	Sanofi Pasteur, Inc.	≤ 0.00012%	≤ 0.3 µg / 0.5 ml dose
	No Trade Name	Sanofi Pasteur, Ltd.	0	0
Tdap	Adacel	Sanofi Pasteur, Ltd.	0	0
	Boostrix	GlaxoSmithKline Biologicals	0	0
TT	No Trade Name	Sanofi Pasteur, Inc.	0.01%	25 µg/0.5 mL dose
Hib	ActHIB	Sanofi Pasteur, SA	0	0
	Hiberix	GlaxoSmithKline Biologicals	0	0
	PedvaxHIB liquid	Merck & Co, Inc.	0	0
Hib/HepB	COMVAX4	Merck & Co, Inc.	0	0
Hepatitis B	Engerix-B Pediatric/adolescent Adult	GlaxoSmithKline Biologicals	0 0	0 0
	Recombivax HB Pediatric/adolescent / Adult (adolescent) Dialysis	Merck & Co, Inc.	0 0 0	0 0 0
Hepatitis A	Havrix	GlaxoSmithKline Biologicals	0	0
	Vaqta	Merck & Co, Inc.	0	0
HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	0	0
IPV	IPOL	Sanofi Pasteur, SA	0	0
	Poliovax	Sanofi Pasteur, Ltd.	0	0
Influenza	Afluria	CSL Limited	0 (single dose) 0.01% (multidose)	0 (single dose) 24.5 µg/0.5 mL (multidose)
	Agriflu	Novartis Vaccines and …	0	0

Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines [continued]

Vaccine	Trade Name	Manufacturer	Thimerosal	**Mass per Dose**[6,7]

			Percent[1]	
Influenza	Fluzone[5] (multi-dose)	Sanofi Pasteur, Inc.	0.01%	25 µg/0.5 mL dose
	Fluvirin (multi-dose)	Novartis Vaccines and Diagnostics Ltd.	0.01%	25 µg/0.5 ml dose
	Fluzone (single-dose)	Sanofi Pasteur, Inc.	0	0
	Fluvirin (single-dose prefilled syringe)	Novartis Vaccines and Diagnostics Ltd.	≤ 0.0002 %	≤ 1 µg/0.5 ml dose
	Fluarix	GlaxoSmithKline Biologicals	0	0
	FluBlok (insect-derived GE vax)	Protein Sciences Corporation	0	0
	FluMist and FluMist Quadrivalent, live	MedImmune Vaccines, Inc.	0	0
	FluLaval	ID Biomedical Corp. of Quebec	0.01%	25 µg/0.5 ml dose
Japanese Encephalitis	IXIARO	Intercell AG	0	0
MMR, Live	MMR-II	Merck & Co, Inc.	0	0
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc.	0.01% (multi-dose) 0 (single dose)	25 µg/0.5 dose 0
	Menactra A, C, Y and W-135	Sanofi Pasteur, Inc.	0	0
	Menveo	Novartis Vaccines and …	0	0
Meningococcal & Hib	MenHibrix	GlaxoSmithKline Biologicals	0	0
Pneumococcal	Prevnar 13 (Pneumo Conjugate)	Wyeth Pharmaceuticals Inc.	0	0
	Pneumovax 23	Merck & Co, Inc.	0	0
Rabies	IMOVAX	Sanofi Pasteur, SA	0	0
	Rabavert	Novartis Vaccines and ...	0	0
Smallpox (Vaccinia)	ACAM2000	Acambis, Inc.	0	0
Typhoid Fever	Typhim Vi	Sanofi Pasteur, SA	0	0
	Vivotif	Berna Biotech, Ltd.	0	0
Varicella, Live	Varivax	Merck & Co, Inc.	0	0
Yellow Fever	Y-F-Vax	Sanofi Pasteur, Inc.	0	0
Zoster Vaccine, Live	Zostravax	Merck & Co., Inc.	0	0

Table Footnotes

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 ml dose or nominally 25 µg of Hg per 0.5 ml dose; [maximum level is nominally 31.2 µg of Hg per 0.5 ml dose].
2. Sanofi Pasteur's Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. This vaccine is not marketed in the US, but it is available here.
4. COMVAX is not licensed for use under 6 weeks of age because of decreased response to the Hib component.
5. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose).
6. The level is the nominal level of mercury from Thimerosal and, legally, the specific amount in a dose can vary from 85% to 125% of the nominal level.
7. This column only reflects the mercury from added Thimerosal; in general, vaccines contain 0.0005 to 0.0025 micrograms of mercury per 0.5-mL dose from the other components added to the vaccine formulations ingredients.