Introduction

Following this introduction page is this reviewer’s analysis of an “ANSWER” by “Gregory Poland, M.D., Vaccine Research Group, Mayo Clinic, Rochester, Minn” in a *Chicago Tribune* article titled, “Foregoing immunizations puts child and others at risk”.

This reviewer originally downloaded this article on September 30, 2012 as part of an “htm” file from: [http://www.chicagotribune.com/health/sns-201209271830--tms--mayoclnctnmca20120927-20120927.0.4773252.story](http://www.chicagotribune.com/health/sns-201209271830--tms--mayoclnctnmca20120927-20120927.0.4773252.story)

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**Introductory Remarks**

First, to simplify this analysis, each portion of the article reviewed is first quoted in its original fonts.

Further, when the review addresses some specific sentence, clause, phrase, or word within the review, it is quoted in an *italicized* "Times New Roman" font.

Second, this reviewer's assessments, written in a “Verdana” font, follow each quoted portion of the article, and the reviewer indents his review remarks to separate them from the preceding part of the document that is being assessed.

Third, 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 analysis.

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.
Draft Review of
“MAYO CLINIC ANSWER:” by Gregory Poland, MD in
“Foregoing immunizations puts child and others at risk”

Main Review Topics

<table>
<thead>
<tr>
<th>Topic Addressed</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewer’s Initial Comments about the Article’s Title</td>
<td>1</td>
</tr>
<tr>
<td><strong>Start of Review</strong></td>
<td>1</td>
</tr>
<tr>
<td>Vaccination Does Not Provide Immunity</td>
<td>1</td>
</tr>
<tr>
<td>Childhood Vaccines: Not Proven Safe and Effective</td>
<td>2</td>
</tr>
<tr>
<td><strong>Vaccines and Vaccinations Do Not Meet Article’s Claims</strong></td>
<td>4</td>
</tr>
<tr>
<td>Vaccines for the Bacterial Meningitis Diseases</td>
<td>5</td>
</tr>
<tr>
<td>Meningococcal Meningitis Vaccines</td>
<td>5</td>
</tr>
<tr>
<td>Vaccines for <em>Haemophilus influenzae</em> type b (Hib)</td>
<td>8</td>
</tr>
<tr>
<td>Vaccines for <em>Streptococcus pneumoniae</em></td>
<td>9</td>
</tr>
<tr>
<td>Some Vaccines for Other Childhood Diseases</td>
<td>13</td>
</tr>
<tr>
<td><strong>Vaccination Choice?</strong></td>
<td>14</td>
</tr>
<tr>
<td><strong>Natural Immunity vs. Vaccination Protection</strong></td>
<td>15</td>
</tr>
<tr>
<td><strong>Vaccination and Disease Prevention?</strong></td>
<td>20</td>
</tr>
<tr>
<td>Vaccination and the Relative Risk of Illness and Death?</td>
<td>23</td>
</tr>
<tr>
<td>Vaccination and the Issue of Vaccination Harm</td>
<td>26</td>
</tr>
<tr>
<td><strong>Vaccine Safety and Effectiveness</strong></td>
<td>29</td>
</tr>
<tr>
<td>Proof of Safety?</td>
<td>29</td>
</tr>
<tr>
<td>Proof of Effectiveness?</td>
<td>31</td>
</tr>
<tr>
<td>IOM’s Review, “Adverse Effects of Vaccines: Evidence and Causality”</td>
<td>32</td>
</tr>
<tr>
<td>Vaccines and Autism?</td>
<td>32</td>
</tr>
<tr>
<td>Whooping Cough, Measles and Influenza</td>
<td>33</td>
</tr>
<tr>
<td>Vaccines Are Doing Their Job?</td>
<td>35</td>
</tr>
<tr>
<td><strong>The At-Risk Population Segments</strong></td>
<td>39</td>
</tr>
<tr>
<td><strong>Become Informed Before Considering Any Vaccination</strong></td>
<td>43</td>
</tr>
<tr>
<td><strong>The Long-Term Health Effects of Vaccination</strong></td>
<td>44</td>
</tr>
<tr>
<td><strong>Acknowledgments</strong></td>
<td>45</td>
</tr>
<tr>
<td>About the Writer, Gregory A. Poland, MD</td>
<td>46</td>
</tr>
<tr>
<td>About this Reviewer, Paul G. King, PhD</td>
<td>47</td>
</tr>
</tbody>
</table>
Draft Review Of
“MAYO CLINIC ANSWER:” by Gregory Poland, MD in
“Foregoing immunizations puts child and others at risk”

Reviewer’s Initial Comments about the Article’s Title

This article’s title begins by making a misleading generalization, “Foregoing immunizations puts child and others at risk”.

The reason that this generalization is misleading is that the article uses the word “immunizations” as though it were scientifically synonymous with the word “vaccinations”, when the use of “immunizations” implies immunity — lifetime or near-lifetime protection from the non-vector-borne viral and bacterial diseases for which we have vaccines recommended for universal use in some population.

At best, these vaccination programs only provide limited-duration disease protection to some percentage of those inoculated with the vaccines licensed and approved by the U.S. Food and Drug Administration (FDA) and recommended for population use by the U.S. Centers for Disease Control and Prevention (CDC).

As the rest of this article indicates, Dr. Poland is speaking for the use of vaccinations in place of allowing natural disease progression for these vaccine-covered non-vector-borne diseases when he uses the word “immunizations”.

Therefore, he is actually an advocate for limited-duration protection in some percentage of those who are vaccinated, a practice that he should know leaves many without any protection from the diseases for which they have been vaccinated.

Furthermore, injected vaccines provide, at best, incomplete and abnormal protection against the diseases for which protection is claimed.

Thus, the protection provided is both incomplete (it does not protect almost everyone) and abnormal (it does not properly engage the innate-immune-systems' components and, overall, dysregulates the immune system).

This is the case because these injected vaccinations bypass some or all of the layers of the humans' innate immune systems, which are crucial to acquiring and maintaining true immunity to the diseases for which these prophylactic (disease-preventive) vaccines are administered.

Moreover, for those vaccinated individuals who develop the limited-duration protection that such vaccines provide, these vaccinations, at best, only postpone the time period during which those who have been inoculated will, if exposed, be susceptible to contracting those diseases covered by the vaccines used.

With these fundamentals in mind, let us examine Dr. Poland’s answer to the question, “Isn’t it putting other kids at risk when some choose not to vaccinate?” from the viewpoint of sound science rather than ‘vaccinism’, the belief that vaccines and their use are the saviors of the health of modern humankind.

Start of Review

Vaccination Does Not Provide Immunity

“ANSWER: Yes, you are exactly right. Not immunizing a child puts that child -- as well as siblings, parents, friends and other people he or she may come in contact with -- at risk. The childhood
vaccines recommended in the United States have been proven safe and effective.”

First, since the context speaks about “childhood vaccines”, it is clear that Poland is speaking about the vaccination of children.

However, such vaccinations:

- Do not immunize a child in the scientific context of providing lifetime or near-lifetime protection from getting the disease at all or from being at risk of contracting the disease more than once,
- May not provide any protection at all to a given child,
- May only provide limited protection to those children who appear to be protected and that limited protection may become ineffective after a short period of time (e.g., 3 years or less), and/or
- May severely injure, permanently damage, and/or kill some of those who are given these vaccinations.

Childhood Vaccines: Not Proven Safe and Effective

With respect to Poland’s second statement, “The childhood vaccines recommended in the United States have been proven safe and effective”, this reviewer must disagree.

What is scientifically true about the “childhood vaccines recommended in the United States” is that they have been declared to be “safe”. However, as the vaccines’ package inserts attest, in general, they lack certain critical proofs of safety.

Using GlaxoSmithKline’s Kinrix® DTaP-IPV vaccine, which is usually given to children, as an instructive example, the recently revised [March 2012] current-format package insert states, in sections “8. USE IN SPECIFIC POPULATIONS”,

- “8.1 Pregnancy
  Pregnancy Category C
  Animal reproduction studies have not been conducted with KINRIX. It is also not known whether KINRIX can cause fetal harm when administered to a pregnant woman” [and, indirectly, to the developing child] “or can affect reproduction capacity.”

and “13 NONCLINICAL TOXICOLOGY”,

- “13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
  KINRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility”).

As this example establishes, GlaxoSmithKline (GSK) has not conducted the preclinical studies required to prove that this vaccine is not carcinogenic, not mutagenic, not teratogenic, not immune-system toxic, and/or not reproductively toxic to the developing child and the developing fetus.

Yet, to make a valid claim that a disease-preventive vaccine is a “safe” drug product, the vaccine manufacture must conduct appropriate, scientifically sound,

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1 Though this section’s title is a generalization, the subsection that addresses “pregnancy” not only addresses reproductive capability but also birth defects in the developing fetus that are caused by indirect vaccine ingredient exposures that are teratogens, substances which cause birth defects, and/or can otherwise harm the developing fetus.
2 Since the fetus is simply the child developing in utero, fetal effects are most certainly “developing child” effects that, at some point, are childhood effects for those children who survive them and are delivered alive.
From the pen of Paul G. King, PhD, Founder, FAME Systems

preclinical studies for carcinogenicity, mutagenicity and adverse reproductive
effects, including teratogenicity, and demonstrate that their vaccine does not
cause these adverse effects in suitable human-outcome-mimicking biological
model systems, including primates.

Having examined the package inserts for the 70-plus most-recent files for the
vaccines approved by the U.S. Food and Drug Administration (FDA) and listed in
its web site, almost all either lack a section “13” (or an equivalent statement of
compliance), or the manufacturers, which provide the language for the package
insert that the FDA has approved, state that the requisite studies to prove that
each vaccine is not carcinogenic, mutagenic, reproductively toxic or teratogenic
in humans have not been conducted.

Worse, these vaccines have not been proven to be effective in preventing
those inoculated with them from contracting the disease(s) for which they are
claimed to be protective.

Instead, as the preceding example demonstrates, the vaccine makers only
provide studies that show their vaccines develop some “adequate” levels of
antibody titers to certain antigens or behaved in a manner “consistent with
providing protection” (are “deemed to be efficacious”).

In the case of the “pertussis”-related components, these are simply “determined”
to be efficacious (because there “is no well established serological correlate of protection for
pertussis”) in protecting some percent of those who have had multiple vaccine
inoculations when the outcomes observed were compared to some previous
“pertussis”-containing vaccine (see, for example, section “12 CLINICAL PHARMA-
COLOGY” in the package insert for GlaxoSmithKline’s [GSK’s] Kinrix DTaP-IPV
vaccine [emphasis added],

“12.1 Mechanism of Action

Diphtheria: Diphtheria is an acute toxin-mediated infectious disease caused by toxigenic
strains of C. diphtheriae. Protection against disease is due to the development of neutralizing
antibodies to the diphtheria toxin. A serum diphtheria antitoxin level of 0.01 IU/mL is the lowest level
giving some degree of protection; a level of 0.1 IU/mL is regarded as protective.¹

Tetanus: Tetanus is an acute toxin-mediated disease caused by a potent exotoxin released by
C. tetani. Protection against disease is due to the development of neutralizing antibodies to the
tetanus toxin. A serum tetanus antitoxin level of at least 0.01 IU/mL, measured by neutralization
assays, is considered the minimum protective level.²,³ A level of ≥0.1 IU/mL is considered
protective.⁴

Pertussis: Pertussis (whooping cough) is a disease of the respiratory tract caused by B.
pertussis. The role of the different components produced by B. pertussis in either the pathogenesis
of, or the immunity to, pertussis is not well understood. There is no well established serological
correlate of protection for pertussis. The efficacy of the pertussis component of KINRIX was
determined in clinical trials of INFANRIX administered as a 3-dose series in infants (see INFANRIX
prescribing information).

Poliomyelitis: Poliovirus is an enterovirus that belongs to the picornavirus family. Three
serotypes of poliovirus have been identified (Types 1, 2, and 3). Neutralizing antibodies against
the 3 poliovirus serotypes are recognized as conferring protection against poliomyelitis.
disease⁵).

Thus, though the package insert may be legally correct, taken together the
cited sections testify that the preclinical safety of the vaccine was not established
and that the manufacturer did not prove that the example vaccine is effective.

Further, even GSK, the vaccine manufacturer, does not claim that: 1) this
vaccine is “safe” or 2) any of these components have been proven to be effective
in preventing any of the diseases for which the vaccine purportedly provides “protection” or “is considered” or “is regarded as” protective.

Thus, it is clear that Poland’s claim that the “childhood vaccines recommended in the United States have been proven safe and effective” is not supported by GSK’s claims in this instance nor, as far as this reviewer can ascertain, in any other instance.

However, this reviewer will leave it to the reader to confirm the general lack of proof of safety and effectiveness for the other FDA-approved vaccines that are recommended for universal administration to children or are allowed to be given to pregnant women during pregnancy thereby indirectly exposing the fetus (the nascent [developing] child) to the vaccines’ components.

**Vaccines and Vaccinations Do Not Meet Article’s Claims**

“They protect children from a variety of serious and sometimes fatal diseases, including diphtheria, measles, meningitis, polio, tetanus and whooping cough.”

Here, the writer makes a very broad generalization that, in one instance, “meningitis”, does not even identify the specific type of meningitis to which his comment applies.

Since there are no vaccines for the viruses and, in rare instances, fungal organisms that can cause meningitis (inflammation of membranes [meninges] that surround the brain and the spinal cord), the writer must be talking about bacterial meningitis which is commonly caused by three (3) kinds of bacteria, *Haemophilus influenzae* [type b] (for which there are only *Haemophilus influenzae* type b [Hib] vaccines, but no general *Haemophilus influenzae* vaccines, and Hib-component vaccines), *Neisseria meningitidis* (for which there are two (2) types of meningococcal meningitis vaccines and one recently approved combination vaccine [a Hib and meningitis serogroups C and Y vaccine]), and *Streptococcus pneumoniae* (for which there are the original Pfizer (Wyeth) 7-component Prevnar® vaccine, the current Pfizer 13-component Prevnar 13® vaccine, and Merck and Company’s (Merck’s) 23-component Pneumovax 23® vaccine for use in children in the United States of America [USA]).

Turning to the other diseases for which there is a childhood vaccine, this reviewer notes that, for some reason, Dr. Poland does not mention the hepatitis B, hepatitis A, human papilloma virus, influenza A and influenza B, mumps, rubella, rotavirus and *alphaherpes varicella zoster* (chickenpox [medically referred to as “varicella”] and shingles [medically referred to as “herpes zoster”]) vaccines.

For the diseases Poland lists, based on their overall annual disease incidence rates, the vaccine antigen components for diphtheria, polio, tetanus and measles seem to be efficacious and, absent significant disease-agent exposures in the population, these vaccines are seemingly protective though, based on the CDC recommendation for adults to periodically get a tetanus booster (or, more recently, a Tdap booster), the length of protection provided is limited for “tetanus” component (and, more recently, the “pertussis” components).

In contrast, for a variety of reasons³, the *Bordetella-pertussis*-components-containing vaccines for “whooping cough” are not effective in preventing those children who have the recommended multiple age-appropriate inoculations from

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³ Draft Review of “Anti-Vaccine Movement Causes the Worst Whooping Cough Epidemic in 70 Years”
being at risk of contracting whooping cough.

**Vaccines for the Bacterial Meningitis Diseases**

For bacterial meningitis disease, the vaccines all suffer from their failure to protect against all strains of the disease-causing organisms and from the fact that their claimed efficacy levels for the covered bacterial strains and/or bacterial types are usually less than 90% for the vaccinated healthy clinical trial subjects.

In addition, the disease protections provided neither apply to all of those who are vaccinated with these vaccines nor last for an extended period (i.e., greater than 30 years).

**Meningococcal Meningitis Vaccines**

For meningococcal meningitis, none of the current FDA-approved vaccines for meningitis caused by *Neisseria meningitidis* provide protection for the most common childhood-disease type (serogroup B) in the USA.

In addition, these vaccines only provide initial antibody-level-based efficacies in the 70%-85% range (for the healthy children used in the clinical trials) for two (serogroups C and Y) or four (serogroups A, C, W-135 and Y) of the 13 currently recognized serogroups, “A, B, C, H, I, K, L, M, X, Y, Z, 29E and W135”, although most human infections are caused by those *N. meningitidis* organisms belonging to serogroups A, B, C, W-135 and Y.

Further, the protection provided does not appear to last more than 5 years. However, even though about 10% of the population carry *N. meningitidis* bacteria in their nasal mucosa at any given time, notified clinical infections are rare (less than 1 case per 100,000 population).

For example, in 2010, the number of notified cases of meningococcal meningitis in the USA (as reported by the CDC in "TABLE 3") was 833 with only 280 cases in the A, C, W-135 and Y serogroups, 135 cases in the B serogroup, and 418 cases in another or an unidentified serogroup in a resident population of about 307,009,000 residents in the USA (or about 0.27 case per 100,000).

**MenVeo® Information**

With respect to safety issues, the package insert for Novartis’ MenVeo® [A, C, Y, and W-135] is free of serious side effects and other serious adverse events associated with meningococcal meningitis vaccinations for children and young adults.

The manufacturer states that this vaccine, MenVeo®, is safe and effective and can be used to prevent meningococcal meningitis in children and young adults aged 10–24 years. MenVeo® is indicated for the active immunization of children and young adults aged 10–24 years against meningococcal meningitis caused by *Neisseria meningitidis* serogroups A, C, W-135, and Y.

In conclusion, the efficacy and safety of this vaccine were confirmed in a clinical trial involving healthy children and young adults aged 10–24 years and performed in the USA.

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**TABLE 3. Reported cases and incidence* of notifiable diseases,† by age group — United States, 2010 (from the MMWR)**

<table>
<thead>
<tr>
<th>Disease</th>
<th>&lt;1 yr</th>
<th>1-4 yrs</th>
<th>5-14 yrs</th>
<th>15-24 yrs</th>
<th>25-39 yrs</th>
<th>40-64 yrs</th>
<th>&gt;65 yrs</th>
<th>Age not stated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal disease, invasive, all serogroups</td>
<td>112</td>
<td>(2.63)</td>
<td>91</td>
<td>(0.53)</td>
<td>46</td>
<td>(0.11)</td>
<td>158</td>
<td>(0.37)</td>
</tr>
<tr>
<td>Serogroup A,C,Y and W-135</td>
<td>25</td>
<td>(1.00)</td>
<td>18</td>
<td>(0.56)</td>
<td>15</td>
<td>(0.11)</td>
<td>257</td>
<td>(0.42)</td>
</tr>
<tr>
<td>Other serogroup</td>
<td>43</td>
<td>(0.61)</td>
<td>23</td>
<td>(4.61)</td>
<td>7</td>
<td>(3.43)</td>
<td>24</td>
<td>(0.06)</td>
</tr>
<tr>
<td>Serogroup B</td>
<td>3</td>
<td>(0.08)</td>
<td>1</td>
<td>(0.06)</td>
<td>1</td>
<td>(0.00)</td>
<td>4</td>
<td>(0.06)</td>
</tr>
<tr>
<td>Serogroup unknown</td>
<td>41</td>
<td>(0.06)</td>
<td>49</td>
<td>(0.29)</td>
<td>23</td>
<td>(0.06)</td>
<td>76</td>
<td>(0.18)</td>
</tr>
</tbody>
</table>

*per 100,000 population
†Totals reported to the Division of Viral Diseases, National Center for Immunization and Respiratory Diseases (NCIRD), as of June 30, 2011.

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W-135, Y] does not disclose the nature and amounts of the components, other than the actives and formaldehyde, which are in each vaccine dose.

Absent the nature and the amounts of the other components in the MenVeo vaccine, how can any prudent person accept any “trust me” representation that this vaccine is safe?

In addition, regarding safety for use in humans, the MenVeo package insert reports (emphasis added):

“8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category B
Reproduction studies have been performed in female rabbits at a dose of approximately 20 times the human dose (on a mg/kg basis) and have revealed no evidence of impaired fertility or harm to the fetus due to MENVEO. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, MENVEO should be given to a pregnant woman only if clearly needed.”

and

“13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
MENVEO has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility.”

Based on these statements, the safety for the use of MenVeo as a prophylactic vaccine has not been established and, based on the efficacy information in the package insert, its in-use efficacy is “not inferior” to that of Sanofi’s Menactra®, the comparable polysaccharide-conjugated meningococcal meningitis vaccine to which it was compared in a small clinical study.

However, no effectiveness data was provided in the MenVeo package insert that proved that the vaccinated subjects with adequate antibody titers were protected from contracting a covered strain when disease-susceptible model animals or human volunteers are exposed to said strains.

Similarly, the package inserts for Sanofi’s Menomune® [A, C, Y and W-135] and Menactra® [A, C, Y and W-135] vaccines provide the following information that bears on the issues of safety (emphasis added),

Menomune® Information (emphasis added)

“8. USE IN SPECIFIC POPULATIONS
8.1. Pregnancy
Pregnancy Category C. Animal reproduction studies have not been conducted with Menomune – A/C/Y/W-135 vaccine. It is also not known whether Menomune – A/C/Y/W-135 vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Menomune – A/C/Y/W-135 vaccine should be given to a pregnant woman only if clearly needed.”

and

“13. NON-CLINICAL TOXICOLOGY
13.1. Carcinogenesis, mutagenesis, impairment of fertility
Menomune – A/C/Y/W-135 vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.”

In addition, the multi-dose formulation of Menomune is preserved with Thimerosal (delivering nominally 25 μg of organic mercury per each 0.5-mL dose).

When it comes to effectiveness, the multi-dose formulation of the vaccine was shown to apparently aid in interrupting a Neisseria meningitidis serogroup A
outbreak in a U.S. Army training center but individual protection from disease after vaccination was not established.

However, no in-use clinical studies using volunteers have been conducted using the quadrivalent (4-strain-containing) vaccine for all of the covered strains of this polysaccharide vaccine, which can only be administered once because giving another dose significantly decreases the residual level of the circulating antibodies produced after the initial dose was administered.

“8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with Menactra vaccine. It is also not known whether Menactra vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well controlled studies in pregnant women. Menactra vaccine should only be given to a pregnant woman if clearly needed.

Assessment of the effects on animal reproduction has not been fully conducted with Menactra vaccine as effects on male fertility in animals has not been evaluated. The effect of Menactra vaccine on embryo-fetal and pre-weaning development was evaluated in one developmental toxicity study in mice. Animals were administered Menactra vaccine on Day 14 prior to gestation and during the period of organogenesis (gestation Day 6). The total dose given per time point was 0.1 mL/mouse via intramuscular injection (900 times the human dose, adjusted by body weight). There were no adverse effects on pregnancy, parturition, lactation or pre-weaning development noted in this study. Skeletal examinations revealed one fetus (1 of 234 examined) in the vaccine 2 group with a cleft palate. None were observed in the concurrent control group (0 of 174 examined). There are no data that suggest that this isolated finding is vaccine related, and there were no vaccine related fetal malformations or other evidence of teratogenesis observed in this study.

Healthcare providers are encouraged to register women who receive Menactra vaccine during pregnancy in Sanofi Pasteur Inc.’s vaccination pregnancy registry by calling 1-800-822-2463.

8.3 Nursing Mothers

It is not known whether Menactra vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Menactra vaccine is administered to a nursing woman.

8.4 Pediatric Use

Menactra vaccine is not approved for use in infants under 9 months of age. Available data show that infants administered three doses of Menactra vaccine (at 2, 4, and 6 months of age) had diminished responses to each meningococcal vaccine serogroup compared to older children given two doses at 9 and 12 months of age.”

and

“13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Menactra vaccine has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.”

Based on the information provided, neither of the two types of Sanofi’s meningococcal meningitis vaccines has been proven to be in-use safe for use as a prophylactic vaccine and the multi-dose vaccine formulation of the Menomune vaccine is preserved with Thimerosal (nominally, 25 μg of organic mercury per 0.5-mL dose).

The efficacy of the Menactra vaccine has been shown to be non-inferior to the efficacy of the Menomune vaccine but no in-use challenge studies have established that this vaccine is effective in preventing those who are vaccinated and
develop adequate antibody titer levels from contracting a covered vaccine strain when disease-susceptible model animals or human volunteers are then exposed to the covered strains in controlled experiments.

**GlaxoSmithKline’s MenHibrix® [Meningococcal Groups C & Y and Haemophilous b Tetanus-Toxoid Conjugate Vaccine] Information**

(emphasis added)

“8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with MENHIBRIX. It is also not known whether MENHIBRIX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

8.4 Pediatric Use

Safety and effectiveness of MENHIBRIX in children younger than 6 weeks of age and in children 19 months to 16 years of age have not been established.”

and

“13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

MENHIBRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.”

Although approved by the FDA for use in the USA, MemHibrix was developed for use in the United Kingdom (UK) and other countries where serogroups C and Y are the predominant groups of *N. meningitidis* in young children.

**Vaccines for Haemophilus influenzae type b (Hib)**

For *Haemophilus influenzae* type b [Hib], the 2010 data show that, in those under 5 years of age for whom the Hib vaccines are intended, there were 446 cases of *Haemophilus influenza* reported (CDC-reported “**TABLE 3**” on this page).

While Hib has reduced the number of cases of Hib in children under 5 years of age, the number of cases of nonserotype b has been trending higher.

| TABLE 3. Reported cases and incidence* of notifiable diseases,† by age group — United States, 2010 (from the MMWR) |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Disease                          | <1 yr                           | 1–4 yrs                          | 5–14 yrs                         | 15–24 yrs                        | 25 – >65 yrs                     | Age not stated | Total            |
|                                  | No.    | Rate     | No.    | Rate     | No.    | Rate     | No.    | Rate     | No.    | Rate     | No.    | Rate     | No.    | Rate     | No.    |
|----------------------------------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|--------|----------|
| Haemophilus influenzae, invasive disease, all ages, serotypes | 262    | (6.15)   | 184    | (1.08)   | 122    | (0.30)   | 99     | (0.23)   | 2424   | 60       | 3,151             |
| Age < 5 years                     |        |          |        |          |        |          |        |          |        |          |        |          |        |          |        |          |
| serotype b                        | 11     | (0.26)   | 12     | (0.07)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | 23     |
| nonserotype b                     | 123    | (2.89)   | 77     | (0.45)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | 200    |
| unknown serotype                  | 128    | (3.00)   | 95     | (0.56)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | —      | (0.00)   | 223    |

* **per 100,000 population**

† Totals reported to the Division of Viral Diseases, National Center for Immunization and Respiratory Diseases (NCIRD), as of June 30, 2011.

Because there are a number of Hib and Hib-containing vaccines approved for use in children, this reviewer will simply use Sanofi’s ActHIB® as an example of the general information pattern and note that, with respect to safety, this vaccine’s package insert reports (emphasis added),

“**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

Animal reproduction studies have not been conducted with ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) or saline diluent (0.4% Sodium Chloride). It is also not known whether ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) or saline diluent (0.4% Sodium Chloride) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ActHIB vaccine reconstituted with Sanofi Pasteur Inc. DTP or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) or saline diluent (0.4% Sodium Chloride) is NOT recommended for use in a pregnant woman and is not approved for use in children 5 years of age or older.”

Thus, the Hib and Hib-containing vaccine formulations lack true proof of safety for the person inoculated with any of them or for the child developing in utero, in the instances where, though not recommended by the manufacturer, a pregnant woman is vaccinated with them.

Further, the Hib and Hib-containing vaccines follow the general pattern of establishing efficacy through antibody titers but not proving, through a post-vaccination disease-exposure challenge study, that the vaccines are indeed effective in preventing disease.

Finally, the Hib and Hib-containing vaccines provide little or no protection against infections caused by other types of H. influenzae.

Therefore, the safety and effectiveness of the Hib vaccines have not been proven but rather simply “declared” even though the scientific studies required to establish safety and effectiveness have not been conducted by the vaccines’ manufacturers, who have an absolute, non-dischargeable duty to prove safety.

Vaccines for Streptococcus pneumoniae

For Streptococcus pneumoniae, more than 120 strains have been identified. Moreover, mutation and strain drift have already caused the vaccine maker of

<table>
<thead>
<tr>
<th>Serotype</th>
<th>Prevnar 13 (N=249-252 (95% CI))</th>
<th>Prevnar (N=250-252 (95% CI))</th>
<th>Difference in % Responders (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevnar Serotypes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>94.4 (90.9, 96.9)</td>
<td>98.0 (95.4, 99.4)</td>
<td>-3.6 (-7.3, -0.1)</td>
</tr>
<tr>
<td>6B</td>
<td>87.3 (82.5, 91.1)</td>
<td>92.6 (89.9, 95.7)</td>
<td>-5.5 (-10.9, -0.1)</td>
</tr>
<tr>
<td>9V</td>
<td>90.5 (86.2, 93.8)</td>
<td>98.4 (96.0, 99.6)</td>
<td>-7.9 (-12.4, -4.0)</td>
</tr>
<tr>
<td>14</td>
<td>97.6 (94.9, 99.1)</td>
<td>97.2 (94.4, 98.9)</td>
<td>0.4 (-2.7, 3.5)</td>
</tr>
<tr>
<td>18C</td>
<td>96.8 (93.8, 98.6)</td>
<td>98.4 (96.0, 99.6)</td>
<td>-1.6 (-4.7, 1.2)</td>
</tr>
<tr>
<td>19F</td>
<td>98.0 (95.4, 99.4)</td>
<td>97.6 (99.4, 99.1)</td>
<td>0.4 (-2.4, 3.4)</td>
</tr>
<tr>
<td>23F</td>
<td>90.5 (86.2, 93.8)</td>
<td>94.0 (90.4, 96.6)</td>
<td>-3.6 (-8.5, 1.2)</td>
</tr>
<tr>
<td>Additional Serotypes**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>95.6 (92.3, 97.8)</td>
<td>††</td>
<td>2.8 (-1.3, 7.2)</td>
</tr>
<tr>
<td>3</td>
<td>63.5 (57.1, 69.4)</td>
<td>††</td>
<td>-29.3 (-36.2, -22.4)</td>
</tr>
<tr>
<td>5</td>
<td>89.7 (85.2, 93.1)</td>
<td>††</td>
<td>-3.1 (-8.3, 1.9)</td>
</tr>
<tr>
<td>6A</td>
<td>96.0 (82.8, 98.1)</td>
<td>††</td>
<td>3.2 (-0.8, 7.6)</td>
</tr>
<tr>
<td>7F</td>
<td>98.4 (96.0, 99.6)</td>
<td>††</td>
<td>5.6 (1.9, 9.7)</td>
</tr>
<tr>
<td>1</td>
<td>95.6 (82.3, 97.8)</td>
<td>††</td>
<td>2.8 (-1.3, 7.2)</td>
</tr>
<tr>
<td>3</td>
<td>63.5 (57.1, 69.4)</td>
<td>††</td>
<td>-29.3 (-36.2, -22.4)</td>
</tr>
<tr>
<td>5</td>
<td>89.7 (85.2, 93.1)</td>
<td>††</td>
<td>-3.1 (-8.3, 1.9)</td>
</tr>
</tbody>
</table>

Noninferiority was met when the lower limit of the 95% CI for the difference between groups (Prevnar 13 minus Prevnar) was greater than -10%.

1 Antibody measured by a standardized ELISA involving pre-absorption of the test sera with pneumococcal C-polysaccharide and serotype 22F polysaccharide to reduce non-specific background reactivity.

2 Comparison for the 6 additional serotypes was to the lowest responder of the 7 common serotypes in Prevnar recipients, which for this analysis was serotype 6B (92.8%; 95% CI: 88.9, 95.7).

A Note – Clinical trial.gov NCT number is as follows: NCT00373958.
the original 7-strain vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F), the now Pfizer Prevnar® introduced in 2000 for use in very young children, to have to add six more strains and introduce Prevnar 13® in the USA and developed countries in 2010 while apparently still selling the 7-strain vaccine in some markets.

While the 13-strain vaccine does provide broader organism coverage (for *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F), its rate for certain serious adverse events was found to be about twice that of the original Prevnar vaccine although the population size (about 250 in each arm of the study) of the comparative clinical trial that was reported in the package insert (see the preceding “Table 13”) was not sufficiently large to assess the significance of these findings on a population-wide basis.

Looking at the appropriate CDC-reported “TABLE 3” entries in the 2002, 2004, 2006, 2008 and 2010 Notifiable-Disease reports for invasive *S. pneumoniae* (see “TABLE 3 Reported ...” on the following page), the effect of inoculating our children with Prevnar and our older children and adults with Merck’s Pneumovax 23 in conjunction with the ongoing use of antibiotics to treat those cases that the vaccines did not prevent has been to increase the cases of antibiotic-resistant *S. pneumonia* in the population in the period from 2002 through 2010.

Apparently, the introduction of Prevnar 13 in 2010 and the widening of its approved uses to include those over 50 years of age in 2011 may temporarily be being tracked, but the pertinent information is not being reported in the annual “Notifiable Disease” reports, issued by the U.S. CDC in their journal, the *Morbidity and Mortality Weekly Report (MMWR)*, about 1.5 years after the end of a given year.

These reports, which are summarized in a table that is displayed on the next page, indicate that these vaccines apparently may have slightly reduced the reported incidence of clinical disease cases.

Turning to the current package inserts, the pertinent information on the “Prevnar” vaccines’ “safety” is as follows.

*For Prevnar and Prevnar 13*

First, the FDA-approved package insert for the Pfizer Wyeth Prevnar 13 vaccine formulation inexplicably omitted “Section 13 NON-CLINICAL TOXICOLOGY”.

However, since the original Prevnar package insert reported the pertinent facts as shown below (emphasis added).

“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. It is not known whether Prevnar® can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity. This vaccine is not recommended for use in pregnant women”

and the Prevnar 13 package insert does not mention any studies to address this failure to ascertain the vaccine’s carcinogenicity, mutagenicity and reproductive toxicity, clearly there are proof-of-safety deficiencies for this vaccine.

Further, the Prevnar 13 package insert as updated in 2011 reports (emphasis added):

“8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

Pregnancy Category B

A developmental and reproductive toxicity study has been performed in female rabbits at a dose approximately 20 times the human dose (on mg/kg basis) and revealed no evidence of impaired female fertility or harm to the fetus due to Prevnar 13. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed."

Based on the preceding information, this vaccine has not been proven to be safe for use in prophylactic vaccination programs nor has it been proven to be

| TABLE 3. Reported cases and incidence* of notifiable diseases,† by age group — United States, 2010 (from the MMWR) |
|---|---|---|---|---|---|---|---|---|---|
| Disease | <1 yr | 1-4 yrs | 5-14 yrs | 15-24 yrs | 25-39 yrs | 40-64 yrs | >65 yrs | Age not stated | Total |
| No. | Rate | No. | Rate | No. | Rate | No. | Rate | No. | Rate |
| Streptococcus pneumoniae, invasive disease | | | | | | | | |
| [Drug Resistant?] all ages | 596 | (23.05) | 1,298 | (12.54) | 494 | (1.99) | 385 | (1.51) | 1,349 | (3.58) | 6,457 | (10.48) | 5,865 | (23.94) | 115 | 16,569 |
| age <5 years | 682 | (22.07) | 1,504 | (12.17) | — | (0.00) | — | (0.00) | — | (0.00) | — | (0.00) | — | 2,186 |
| Reported cases and incidence* of notifiable diseases,†† by age group — United States, 2008 (from the MMWR) | | | | | | | | |
| [Drug Resistant?] all ages | 177 | (4.16) | 355 | (8.49) | 96 | (1.17) | 74 | (0.31) | 260 | (0.41) | 1,234 | (1.16) | 1,251 | (1.37) | 1 | 3,448 |
| age <5 years | 873 | (28.32) | 1,302 | (42.67) | — | (0.00) | — | (0.00) | — | (0.00) | — | (0.00) | 355 | 2,530 |
| Reported cases and incidence* of notifiable diseases,††† by age group — United States, 2006 (from the MMWR) | | | | | | | | |
| [Drug Resistant?] all ages | 162 | (8.03) | 305 | (3.05) | 112 | (0.56) | 65 | (0.30) | 264 | (0.87) | 1,134 | (2.29) | 1,155 | (5.79) | 111 | 3,308 |
| age <5 years | 610 | (19.31) | 1,251 | (10.05) | — | (0.00) | — | (0.00) | — | (0.00) | — | (0.00) | 1,861 |
| Reported cases and incidence* of notifiable diseases,†††† by age group — United States, 2004 (from the MMWR) | | | | | | | | |
| [Drug Resistant?] all ages | 124 | (6.8) | 307 | (4.2) | 120 | (0.4) | 50 | (0.3) | 207 | (0.7) | 832 | (1.9) | 932 | (5.0) | 18 | 2,590 |
| age <5 years | 406 | (16.3) | 767 | (7.3) | — | (0.00) | — | (0.00) | — | (0.00) | — | (0.00) | — | 1,162 |
| Reported cases and incidence* of notifiable diseases,††††† by age group — United States, 2002 (from the MMWR) | | | | | | | | |
| [Drug Resistant?] all ages | 159 | (5.27) | 326 | (2.67) | 109 | (0.33) | 57 | (0.18) | 205 | (0.41) | 730 | (1.10) | 826 | (2.96) | 134 | 2,546 |
| age <5 years | 186 | (6.62) | 327 | (2.88) | — | (0.00) | — | (0.00) | — | (0.00) | — | (0.00) | 513 |

* per 100,000 population
† Totals reported for 2010 to the Division of Viral Diseases, National Center for Immunization and Respiratory Diseases (NCIRD), as of June 30, 2011.
†† Totals reported for 2008
††† Totals reported for 2006
†††† Totals reported for 2004
††††† Totals reported for 2002

use effective to the level claimed in the small-scale clinical trial, which was claimed to be as low as < 60% efficacy for Serotype 3, whose efficacy was compared to efficacy observed for Serotype 6B in the original Prevnar formulation.

However, since the original Prevnar package insert reported the pertinent facts as shown below (emphasis added),

"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. It is not known whether Prevnar® can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity. This vaccine is not recommended for use in pregnant women”, and the Prevnar 13 package insert does not mention any studies to address this failure to ascertain the vaccine’s carcinogenicity, mutagenicity and reproductive toxicity, clearly there are proof-of-safety deficiencies for this vaccine.

In addition, the Prevnar 13 package insert as updated in 2011 reports (emphasis added),

“8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category B
A developmental and reproductive toxicity study has been performed in female rabbits at a dose approximately 20 times the human dose (on mg/kg basis) and revealed no evidence of 20 impaired female fertility or harm to the fetus due to Prevnar 13. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed.”

Based on the preceding information, both vaccines have not been proven to be safe for use in prophylactic vaccination programs nor has the Prevnar 13 vaccine been proven to be in-use effective to the level claimed in the small-scale clinical trial, which was claimed to be as little as < 60% efficacy for Serotype 3, where the claimed efficacy results for the newer serotypes were compared to the efficacy that was observed for Serotype 6B in the original Prevnar formulation.

Merck’s Pneumovax 23® (emphasis added)

First, this vaccine covers 23 (“1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F”) of the more than 120 serotypes of S. pneumoniae.

Turning to the pertinent information bearing on the issues of Pneumovax 23’s safety, the package insert states (emphasis added),

“8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C: Animal reproduction studies have not been conducted with PNEUMOVAX 23. It is also not known whether PNEUMOVAX 23 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PNEUMOVAX 23 should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PNEUMOVAX 23 is administered to a nursing woman.

8.4 Pediatric Use
PNEUMOVAX 23 is not approved for use in children less than 2 years of age. Children in this age group do not develop an effective immune response to the capsular types contained in this polysaccharide vaccine.

The ACIP has recommendations for use of PNEUMOVAX 23 in children 2 years of age or older, who have previously received pneumococcal vaccines, and who are at increased risk for pneumococcal disease.5

8.5 Geriatric Use
...
8.6 Immunocompromised Individuals

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23” and, like Prevnar 13, the Pneumovax 23 package insert omits the “13 NON-CLINICAL TOXICOLOGY” statement regarding studies to show that the vaccine either is, or is not, carcinogenic, mutagenic or reproductively toxic, indicating that, though such studies are required to prove that the vaccine is safe, the required studies have not been conducted.

Clearly, based on the vaccine’s package insert, this vaccine has not been proven to be safe for use in any prophylactic vaccination program.

Turning to the issue of effectiveness, this reviewer notices that all that the studies alluded to in the package insert have done is prove the “efficacy” of the vaccine in generating a certain level of antibody titers but not the vaccine’s in-use effectiveness.

Finally, the fact that there are thousands of cases annually in children in a highly vaccinated population would seem to indicate that the S. pneumoniae vaccines are not even efficacious and/or protective for many of those who have been age-appropriately vaccinated.

Thus, the Prevnar, Prevnar 13, and Pneumovax 23 vaccines have not been proven to be safe for use in any prophylactic vaccination program nor have they been proven to be effective in preventing those children inoculated with all of the recommended doses of these vaccines from subsequently contracting pneumonia or meningitis caused by some strain of Streptococcus pneumoniae.

Some Vaccines for Other Childhood Diseases

Even though this reviewer could provide more examples of the failure of the manufacturers of vaccines to truly prove that a given vaccine is safe for prophylactic use and in-use effective in preventing those who are appropriately vaccinated from contracting “meningitis” – not that a given vaccine “appears to do no serious harm in some short-term clinical study” and that it “develops circulating antibody titers or antibody responses in the appropriate clinical trials” that are deemed to be efficacious in providing protection from disease.

Unfortunately, the general vaccination model for all injected vaccines (that the circulating antibodies [a part of the adaptive immune system’s response to the injected vaccine dose] developed protect those who are inoculated with them from getting the disease as if the performance of the child’s innate immune system components is not critical to the child’s properly resolving the disease infection and fully recovering from the disease) is fatally flawed because, in most instances, it is the innate immune system that must be involved if a person is to develop long-term protection for a given childhood disease.

Further, a 2012 study has shown that, for at least one viral disease, and for those who are inoculated in an abnormal manner (e.g., sprayed up the recipient’s nose [Medimune’s FluMist®]) or in an abnormal matrix (e.g., the liquid formulas of Merck’s Rotateq® and GlaxoSmithKline’s Rotarix® rotavirus vaccines), the

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6 Moseman EA, Innacone M, Bosurgi L, Tonti E, Chevrier N, Tumanov A, Fu Y-X, et al. B Cell Maintenance of Subcapsular Sinus Macrophages Protects Against Fatal Viral Infection Independent of Adaptive Immunity. Immunity 2012 Mar 23; 36(3): 415-426. [Note: Here, the researchers conclusively showed that the survival of the animals exposed to a particular infectious agent did not depend on their having been vaccinated and developing a significant antibody titer for the specific disease agent but rather only depended upon their mucosal immune systems’ ability to effectively thwart that disease agent’s penetration of the mucosa.]
vaccine protection may not be complete and may not protect those children who are inoculated with even such live-virus vaccines from getting the disease when they are subsequently exposed to it.

**Vaccination Choice?**

“Unless there is a valid medical contraindication, opting out of vaccines is a mistake.”

Poland would probably read the initial clause, "Unless there is a valid medical contraindication", to mean that there must be definitive medical proof that the vaccines will cause a severe adverse reaction in the specific child who is to be inoculated.

This reviewer, concerned about the future fiscal and physical health ramifications for the child who is to be inoculated and living in a developed country, is compelled to address this issue from the standpoints of:

1. “first, do no harm” and
2. “each vaccination should be proven to be safe and effective in producing disease protection in the inoculated child that lasts as long as the 'natural protection' ('immunity') acquired from a healthy person’s having the disease and recovering from it”.

Unless and until both of the preceding conditions are met, the use of all prophylactic (disease-preventive) vaccines should be medically contraindicated from the time the child is conceived onward.

First, from the maternal and paternal medical and dietary histories of families of each individual coupled with some appropriately tailored genetic, epigenetic and differential diagnostic work-ups, which should include specific testing for mitochondrial dysfunction, on the parents and, when possible, the individual who may be a candidate for a given vaccine, medicine can currently identify,

- The potential weakness and strengths of the individual with respect to his or her disease susceptibility,
- The probable risk of a serious adverse outcome from a given insult to the person’s current immune system, and
- The probability that giving the person a specific vaccine will provide limited-duration protection from a given disease and/or have a serious adverse effect on that individual.

Thus, every individual should have a medical exemption from vaccination until the requisite background information has been gathered and properly evaluated.

In a system driven by science rather than Establishment myth, all decisions concerning the vaccination of the individual should be “opting in” decisions and not the writer’s “opting out of vaccines” decisions.

This “opt in” approach should be adopted because, unlike other prophylactic medicines, a single vaccine dose may initiate and, in some, has initiated an immune-system “storm” that non-reversibly maims, progressively cripples, or kills the recipient of that vaccine dose even when others given doses of that vaccine from the same lot or, for multi-dose vials, the same vial have no apparent serious adverse effects.

Applying a “precautionary principle” that holds that evidence of harm, rather than definitive proof of harm, should prompt policy action: The documented vaccination-caused harms, including serious injury, permanent disability and
death, which vaccinated individuals have experienced, demand that, *absent proof of safety for a given child*, vaccination should be withheld until, minimally, the probability of harm can be determined to be near zero for that child.

Thus, *absent an actual epidemic level of some disease or, in some instances, a maternal disease infection (e.g., Hepatitis B), until the appropriate genetic (e.g., adverse single-nucleotide polymorphisms [SNPs] and known problematic deletions), immunogenicity testing (e.g., red-blood-cell typing and white-cell HLA [Human Leukocyte Antigen] typing) and immune-system maturity evaluations can be performed and verify that:*  
- The developing fetus or the developing child has no known possible contraindicating factors that may significantly increase that child’s risk of any serious adverse reaction to any vaccine recommended to be given, indirectly or directly, to that individual,
- The vaccine will provide long-term disease protection to that child, and
- The child has no active infection no matter how apparently minor,

in the USA, the fetus developing *in utero* and the child should have a medical exemption from any indirect or direct vaccine exposure.

Further, given:
- The general immunological reality that vaccines administered before: a) the child reaches the developmental maturity of the average 12-month-old child or b) breastfeeding ceases do not generally provide long-term disease protection to the child vaccinated with them;
- Delaying the start of the DTP series a couple of months greatly reduces the child’s risk of subsequently developing asthma, and
- Delaying the first MMR vaccination from 12 months of age to 15 months of age apparently increases the duration of the protection provided from measles,

the early childhood vaccination programs (the administration of any vaccine before the child is 12 months of age developmentally) should be either: a) completely abandoned or b) replaced by inoculation programs which start at: 1) *no sooner than* 15 months of age developmentally or 2) *not less than* two (2) weeks after the child stops breastfeeding, whichever occurs later.7

### Natural Immunity vs. Vaccination Protection

“The idea that vaccines are not needed because a child’s natural immunity provides enough protection is common among people who choose not to vaccinate their children.”

Here, the writer starts with a simplistic picture of “*a child’s natural immunity*” as if it only depends on the child.

Since humans are mammals, a significant part of the child’s “natural immunity” is connected to not only the mother but also to the mother’s milk.

In a “natural” society that understands and works with nature, for the child

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7 Given: a) the reality that, for safety reasons, the current rotavirus vaccines (Merck’s RotaTeq® and GlaxoSmithKline’s Rotarix®) cannot be administered after the child is 6 months of age and b) the fact that rotavirus was a declining low-level disease in the USA in 1998 except in the inner cities and Indian reservations, where sanitation is a problem, the general use of these vaccines should be abandoned in the USA because these live-virus intestinal diseases spread infection like the live polio vaccines do, which may cause unprotected children older than 6 months to be infected and have a serious adverse reaction (intussusception) that may be fatal.
From the pen of Paul G. King, PhD, Founder, FAME Systems

hood non-vector-borne communicable diseases for which there are CDC-recommended vaccines, because humans are mammals with a relatively long gestation period in utero and a relatively long post-natal developmental period (that may last for 30% of the child’s life expectancy), the scientific reality is:

◆ Disease protections provided by the child’s mother while he or she is developing in the womb,
◆ Coupled with the disease protections transferred and boosted by the mother’s diseases-protective breast milk that the healthy child born to a healthy mother (whose nutrition is not limited by war, famine or the consumption of highly processed food) consumes for a natural period of not less than two years as the child’s own immune systems develop, and
◆ The disease protections provided by the child’s immune systems’ being appropriately exposed to, and dealing with, certain non-vector-borne diseases as the child develops
combine to produce a healthy child with a healthy immune system that:

➢ Has extended protection from being re-infected by these childhood disease agents and related disease agents as well as
➢ A well-defined understanding of what is “self” and what is “not self” that is needed to protect the individual from being “attacked” by his or her own immune systems’ components.

Provided the child receives all of the necessary immune-system-developmen-tal inputs that he or she was naturally intended to receive and maintains a healthy diet and life style in a society where there is adequate sanitation, clean water, uncontaminated food, personal hygiene, and adequate shelter and clothing, then that child’s natural immune system will subsequently provide him or her with more than adequate disease protection (immunity) from most non-vector-borne communicable diseases if that child is exposed to the natural childhood diseases when and as nature intended.

“Although a natural infection may provide more complete immunity than a series of vaccinations, there’s a big price to pay.”

Here, for the childhood diseases for which we have a CDC-recommended vaccine, Dr. Poland begins by misrepresenting scientific reality.

For childhood diseases (diphtheria, tetanus, whooping cough, Haemophilus influenzae, Streptococcus pneumoniae, measles, mumps, rubella, polio, rotavirus, varicella [chickenpox], influenza and even hepatitis A and Neisseria meningitidis) for which we have a CDC-recommended childhood vaccine, natural infection not only provides “more complete” disease protection (the writer’s “immunity”) but also longer-duration disease protection, protection from related disease organisms, and even protection from developing certain cancers and metabolic diseases.

Factually, in addition to providing no “immunity” and less complete disease protection, the writer’s “a series of vaccinations”:

▪ Provides shorter-duration protection to those whom it protects at all,
▪ Provides little or no protection against related disease organisms in most instances,
▪ May simply delay the time when the vaccinated child is at risk of contracting the disease from the natural time period to a later time
when having the disease increases the severity of the disease (e.g., mumps and chickenpox),

- Fails to provide adequate reserves of immune factors to females that would allow them to provide adequate levels of disease-related immune factors for their children during gestation and, after birth, during breast feeding, and
- Does not provide protection against the development of certain cancers and metabolic disorders that having some childhood diseases in their natural time frames and recovering from these diseases may provide.

For injected vaccines, by directly introducing adventitious (unintentionally included) viruses and other organisms, foreign DNA fragments, and chemicals into the body in a manner that bypasses much of the human immune systems that are designed to keep these out or appropriately break them down (digest or alter) into those components that the body’s various systems can appropriately handle, these components:

- Create immune-system imbalances;
- Definitely increase the risk of autoimmune disease, persistent inflammation, and the risk of chronic diseases, including obesity; and
- Possibly infect the recipient with organisms (e.g., SV-40 contamination from the polio vaccines) and/or organism fragments that may have deleterious adverse effects on the person injected with the vaccine as well as, if communicable, his or her partners, offspring and/or others.

With respect to the writer's “there's a big price to pay”, this reviewer simply notes that: 1) based on the previous facts, there may be a bigger price to pay when one gets “a series of vaccinations” and 2) because of the inability of the body's innate and/or adaptive immune systems' components to properly block an invasive organism or detoxify a biological component or chemical added to a vaccine, there is an increasingly evident “chronic disease risk” price to pay when an individual has received the writer's “a series of vaccinations”.

Moreover, these components can have long-term toxic effects, to varying degrees and of variable durations, on all the body's systems and/or these effects may unbalance and weaken the immune system's overall ability to mount a proper response whenever faced with an invading entity when these vaccine components are converted into bioaccumulative toxicants, like Thimerosal's metabolites; and/or have long half-lives in the human body and adverse immune-system effects, like the almost insoluble polymeric hydrated hydroxy-aluminum salts, squalene, Lipid A, or other similar substances, that are used as circulating-immune-system-response-triggering agents (adjuvants).

“To become immune naturally, you have to get the infection first. With the infection comes the very real risk of severe and sometimes permanent complications, including hospitalization and death.”

With respect to Dr. Poland’s accurate but imprecise, “To become immune naturally, you have to get the infection first”, this reviewer first notes that, for the childhood diseases, unlike vaccination, provided the person who is “exposed” and becomes “immune” or “contracts a clinical case of the disease” and “recovers”, and continues to dwell among a population in which some individuals are continually having those communicable
childhood disease exposures and naturally shedding and recovering from them, that person generally only has to deal with contracting each natural childhood “infection” once during most of his or her lifetime.

In some instances, that one encounter may also reduce the child’s future risk for developing cancer (e.g., children who are naturally exposed to the alpha-herpes varicella zoster virus [commonly called the varicella zoster virus (VZV)] are less likely to subsequently develop a cancerous glioma).

However, the current CDC-recommended vaccination schedules require you to get the vaccinations for each disease two or more times before you may have even the limited protection from disease that childhood vaccination programs are claimed to provide to some or most who are inoculated with these vaccines.

Moreover, the current vaccination programs do not even initially offer the disease protections that public health officials, governmental agencies, and the media claim they provide.

In addition, as we are now observing, as time goes by and an increasing percent of the population only has the incomplete protections offered by the current vaccination programs, the population “needs” periodic “booster inoculations” of these vaccines in order for the vaccinated population to continue to be incompletely protected from said diseases.

Furthermore, as the population becomes “mostly” vaccinated, more and more “boosters” are needed because the incomplete protections provided by the previous vaccinations disappear more quickly.

This is the case because, as has been proven for VZV, the periodic childhood disease epidemics for the communicable childhood diseases for which we have vaccines serve to provide sub-clinical boosts to the cell-mediated immunity of those who have previously had these diseases and, thereby, prolong their period of protection from their again contracting a clinical case of such diseases.

Moreover, if the “disease” organism mutates significantly or the vaccine protections fail to mimic the disease agent’s immune-system-provoking pattern, the protection provided by vaccination fails to be protective in an increasing percentage of disease cases as other organisms or organism species for which the vaccine provides little or no protection to anyone are found more often (e.g., for the disease “whooping cough”, increasingly Bordetella [B.] species other than B. pertussis [covered by the “pertussis”-components-containing vaccines] are the cause of the disease).

In “natural infection”, the individual has to have contact with (by contact transference, inhalation, ingestion, or wound) some “living” organism that then must not only proliferate but also become invasive to the body, or some system thereof, in a manner that triggers a reactive immune-system cascade of events that produce the symptoms by which humans recognize a disease (e.g., the characteristic cough associated with whooping cough) or, for diseases that may not have obvious clinical symptoms in almost everyone (e.g., poliomyelitis), discover that a fellow human “has had an infection”.

Though the mode of exposure differs from the natural mode of exposure to varying degrees for the childhood diseases known as, measles, mumps, rubella, rotavirus, and varicella, do not all these CDC-recommended childhood live-virus vaccines infect those exposed to (inoculated with) them?

Similarly, are there not both live-virus and inactivated-(but not killed)-virus vaccines for influenza and polio?
Further, *for all of today’s other vaccines for childhood diseases* (the DTP, DT, Td, Tdap, and Hib vaccines) *and vaccines that are given to children during their childhood* (e.g., the hepatitis B and human papilloma virus vaccines), do they *not* rely upon adding abnormal ingredients (adjuvants) to trigger an immune response to the components of the “disease-causing organism” that are injected? Thus, all of these vaccines appear to abnormally “infect” the recipient in a non-natural manner with some component or components and to produce less complete or totally incomplete immune system responses to components in the vaccine that do not or may not clear the body *without*:

- Permanently altering the immune system,
- Altering the function of some other systems or the recipient’s gene expression pattern, and/or
- Becoming incorporated into the body in some manner that may:
  - Permanently alter the immune identity of the individual who is inoculated with them and/or
  - Adversely affect the ability of the individual to procreate and/or alter the expressed genetic make up of his or her children.

**Given the preceding actualities and the following realities:**

- Those producing these vaccines do not even know (or do not disclose) what are the maximum levels of all components in each vaccine dose or what the outcome will be from inoculating each person with a given dose of vaccine from each vaccine lot or, for vaccines in multi-dose vials, from each dose in such vials;
- *Neither* those governmental agencies who license, approve, and recommend each vaccine nor those who develop, manufacture and distribute each recommended vaccine nor those who administer these recommended vaccines to each person know how every facet of the human immune system ‘works’ or exactly how each component introduced abnormally into the body affects: a) the immune system, b) the nature of the ‘genetic’ expression profile, and/or c) the genetic make up of each living being; and
- All of the preceding entities and the educated public do now know that the immune system, the expression of the genes, and/or the genetic make-up of the inoculated individual is being affected by the components in each vaccine dose,

*each inoculation of a vaccine is an uncontrolled experiment whose outcomes are clearly not predictable for each individual inoculated with these vaccines.*

In contrast, for the natural childhood diseases for which we have a vaccine (e.g., measles), we know the general factors that affect the virulence of the disease and the risk of the rare serious complications that may occur (e.g., for measles, a diet deficient in vitamin A and vitamin C and inadequate vitamin D levels as well as general deficiencies in nutrition and the failure to provide supplementary higher doses of vitamin A and high doses of vitamin C [and L-lysine] when the disease first manifests).

Based on the preceding, the writer’s “*a series of vaccinations*” abnormally infects the person inoculated with a wide variety of materials and, *for some inoculated*
"For example, a natural polio infection could cause permanent paralysis. A natural mumps infection could lead to deafness. A natural chickenpox infection could cause pneumonia or death. A natural Haemophilus influenzae type B (Hib) infection could result in permanent brain damage."

Here, this reviewer must agree that the outcomes stated by the writer do rarely occur but notes that all of these and more may also occur after a child is inoculated with a vaccine for each of these diseases either directly when the vaccine is a live-virus vaccine (the writer's "polio", "mumps" and "chickenpox" examples), or indirectly caused by some out-of-control, immune-system, inflammatory reaction (the writer's "Haemophilus influenzae type B (Hib)" example).

Thus, serious adverse acute reactions can occur in those infected with the natural childhood disease as well as in those who have been inoculated with a vaccine – facts that the writer, like other vaccination proponents, did not disclose in his fear-mongering warnings.

**Vaccination and Disease Prevention?**

"Vaccinations help prevent these diseases and their complications."

This reviewer must disagree with the writer here because the evidence is that, for some of those repeatedly inoculated with a vaccine, the vaccine inoculations do not protect many of the vaccinated individuals from contracting the disease when they are exposed to it as the vaccines' package inserts clearly indicate.

For those who do obtain some initial protection from a disease, the vaccine inoculations generally only postpone the time at which the inoculated person will again be susceptible to contracting the disease or, for some, to developing a vaccination-induced chronic disease.

For the live-virus vaccines where the recipients are inoculated in a manner similar to the natural disease’s route of infection, these inoculations actually infect the inoculated persons in a manner that most of those who are inoculated will:

- have clinical cases of the disease,
- shed the disease-causing agent at a lower, the same, or a higher level than having the disease naturally, and
- have adverse reactions that are rare or unknown for the natural disease (e.g., the live rotavirus vaccines, which given most everyone inoculated with them, a case of rotavirus diarrhea and carry the atypical severe adverse risk of intussusception [bowel twisting and/or bowel-segment telescoping into adjacent segments] at an apparently higher frequency than natural rotavirus infection, which is often nonclinical in the USA).

For live-virus vaccines where the mode of exposure is abnormal (e.g., injection when the normal mode of exposure is inhalation or contact-transfer), those inoculated by injection may fail to clear the virus and/or have abnormal clinical cases of the disease or diseases and generally shed the disease-causing
agent or agents at a lower rate than the natural disease (e.g., the vaccines containing the live-virus measles and live-virus varicella ["chickenpox" and "shingles"] components).

Ironically, for some diseases, vaccination simply postpones the disease to a later time in life where having the disease has a much higher risk of serious permanent injury (e.g., the higher risk of reproductive system inflammation and reduced fertility associated with having mumps after one is sexually capable of procreation or the higher risk of lifelong joint inflammation when one contacts rubella after reaching adulthood).

In other bacterial instances, vaccination simply increases the vaccinated person’s risk of subsequently contracting a different strain or serotype of a particular disease (e.g., Hib and the pneumococcal pneumonia vaccines against *Streptococcus pneumoniae*) or some other disease organism that is now able to occupy the niche that the suppressed disease previously filled (e.g., pneumonia caused by a *Serratia marcesens*, another *Serratia* species, or by a *Legionella* species).

For the influenza viruses, there is increasing evidence of\(^8,9\), and an identified mechanism for\(^10\), the increased risk that inoculation with an influenza vaccine in a given year may increase the risk of an influenza infection from the same or a different influenza virus strain in a subsequent year.

Thus, the scientific evidence indicates that, at most, the vaccines that are given in childhood postpone the risk of contracting a childhood disease in some to most all of those who are vaccinated against that disease but may increase the risk of more serious adverse effects if that childhood disease is contracted later in life.

Moreover, the scientific evidence clearly indicates that, for several bacterial diseases, vaccination:

- Alters the nature of the specific disease organisms that causes the natural disease;
- May periodically require the alteration of the vaccine to cover a wider spectrum of the strains, types, serogroups, or serotypes of the disease organism\(^11\); and
- Over time, may fail to provide the claimed level of protection against a recognized childhood disease\(^12\).

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11. For example, the need for Pfizer Wyeth’s Prevnar 13 vaccine in 2010 to replace the original 7-valent Wyeth Prevnar vaccine when the disease rate for the originally non-covered serotypes started to significantly increase in children under 5 years of age about 4 years after the Prevnar vaccine was introduced in 2000 to the point that, in 2008, there were 5 times as many notified clinical cases of *S. pneumoniae* as in 2002.

12. For example, the "pertussis"-components-containing vaccines against *B. pertussis* are currently failing to stop "whooping cough" outbreaks and the incidence of "whooping cough" cases caused by other *B. species*, other bacterial organisms and viruses is continuing to increase to the point that more than 75% of those who have a clinical case of "whooping cough" are fully up to date with their CDC-recommended "pertussis"-components-containing vaccine inoculations in today’s "whooping cough" outbreaks.
Furthermore, for human influenza, there is growing evidence that, besides being ineffective in preventing those who are inoculated with influenza vaccines from subsequently contracting influenza or an influenza-like disease, vaccination with the current influenza vaccines may increase the vaccinated person’s risk of contracting influenza or an influenza-like disease (see footnotes “8” and “9”) by hampering the development of virus-specific CD8+ T-cell immunity (see footnote “10”).

Finally, for chickenpox, where the dormant herpes varicella zoster virus hiding in the infected person’s nervous system’s root ganglia can reactivate to cause “shingles”, and possibly for other childhood viral diseases and some bacterial diseases for which there are childhood vaccines that are only partially effective13, the maintenance of lifetime or near-lifetime protection from disease recurrence may require those who have had the “natural” disease to have periodic re-exposures to these disease organisms (via external innate-immune-system contact with the disease causing agents [called “exogenous boosting”])14).

For varicella (chickenpox), this exogenous boosting is required to stop the dormant “herpes” virus remaining in the body of those who have had native chickenpox and/or have been vaccinated with the vaccine strain of varicella from flaring up [or reactivating] in some portion of their body as “shingles”. For some of, or most of, the other viral childhood diseases15 (and, maybe, for

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13 Those instances where vaccination against the disease only reduces the incidence of clinical cases but does not come close to eliminating all clinical cases such that the pre-vaccine disease-incidence periodicity is not eliminated even in population groups where virtually “100%” of the children are completely vaccinated as the CDC recommends.

14 In the varicella vaccination instance, exogenous boosting and the negative impacts of its loss when vaccination is substituted for disease were recently discussed in some detail in 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 2012 May 31 online.

15 When universal vaccination is introduced into a population, where most of the older children and adults have natural disease immunity, the initial apparent efficacy of the vaccine in reducing disease incidence may be higher than the efficacy observed when more than 50% of the eligible population has been vaccinated. In immunology, this vaccine-performance boosting by those with natural immunity is called the “honeymoon effect” and the period of time for which the vaccine’s effectiveness is being boosted by this effect is called the “honeymoon period”. Based on a review of the measles vaccination programs’ uptake data and measles case data in France and the USA, this reviewer has found that there appears to be a honeymoon effect for the measles vaccine and that the “honeymoon period” for measles vaccination appears to be roughly 22-25 years. [See, pages 26 through 33 of http://dr-king.com/docs/120127_RevisitedRevUfAutsmControversyNeedForResponsibleScienceJournalsM_p.pdf for a detailed discussion of those findings.]

Based on this reviewer’s findings and the current 2-dose MMR vaccination program, with dosing by injection at 12-15 months and 4-6 years, does provide longer-term protection to most of those who receive 2 doses than many of the other vaccines given in early childhood.

However, the disease protection provided by this 2-dose program is apparently neither universal nor lifelong leading to the following competing realities:

- There are documented instances where adults who received both doses have developed clinical measles cases,
- The level of measles-disease protection passed to their offspring by vaccinated mothers is significantly less in terms of its breadth and persistence than the measles protection previously provided by the mother’s having had measles as a child – thus increasing the risk that a child may contract measles before he or she is old enough to be vaccinated,
- To counteract this, some countries set the age for the first dose to 9 months based on seroconversion studies but when infant mortality assessments were subsequently conducted, the age for the first dose was recommended to be increased to 12 months (see, Aaby P, Martins CL, Garly M-L, Rodrigues A, Benn CS, Whittle H. The optimal age of measles immunization in low-income countries: a secondary analysis of the assumptions underlying the current policy. BMJ Open 2012 Jul; 2(4): e000761 doi:10.1136/bmjopen-2011-000761),
- Moreover, there is some evidence that delaying the first vaccine dose until the child is close to at least 15 months of age instead of the recommended 12 months to 15 months of age may increase the duration of the disease protection provided (see, De Serres G, Boulianne N, Defay F, Brousseau N, et al. (, Skowronski DM) Higher Risk of Measles When the First Dose of a 2-Dose Schedule of Measles Vaccine Is Given at 12–14 Months Versus 15 Months of Age. Clin Infect Dis. 2012; 55(3): 394-402. doi: 10.1093/cid/cis439),
some of the highly contagious aerobic bacterial diseases also\textsuperscript{16}, having the disease naturally (in order to get “complete” immune-system protection) and then having periodic low-level re-exposures (to maintain the immune-systems disease agent awareness) may be required to minimize the risk for contracting the disease when again exposed to it.

In layman’s terms, for some of the childhood diseases and perhaps all of them, without periodic low-level disease-agent re-exposure, the human innate immune system may forget how to handle the disease in a manner that prevents a clinical occurrence/recurrence of that disease either in an altered form (in the case of “chickenpox” recurring as “shingles”) or as, for example, full-blown clinical measles cases from viral exposures that occur at some time after the person’s last vaccination.

Based on the preceding proven scientific realities and the identified and probable realities surrounding the need for periodic exogenous boosting to enable the overall human immune system to maintain extended disease-agent protection (immunity) from causing some form of the clinical disease, it is clear that the writer’s unqualified assertion,

\textit{“Vaccinations help prevent these diseases and their complications”}

is not supported by the available scientific evidence.

\textbf{Vaccination and the Relative Risk of Illness and Death?}

“By relying on natural immunity alone, the risk of illness and death is far higher than with a vaccine.”

Here, Dr. Poland begins by making a statement that he should know is not supported by the available factual evidence for childhood diseases.

This is the case because:

\begin{itemize}
  \item While there are “notifiable” disease records for most of the childhood diseases for which we have a vaccine and penalties for the failure of a healthcare provider to report a clinical case of each state’s “notifiable diseases” to that state’s health officials for all of the notifiable diseases tracked by the federal government,
  \item There are no similarly accurate records of the instances of “illness and death” attributable to any vaccine or vaccination event, or to some particular component or components in the vaccine or vaccines that were administered at a given time.
\end{itemize}

This records' disparity occurs because, unlike the “notifiable diseases”, which require the reporting of disease cases to public health officials, the tracking of post-vaccination adverse events, including “illness and death”, is limited to their being “voluntarily reported” to the jointly maintained CDC-FDA Vaccine Adverse

\textsuperscript{16} Periodic re-exposures may be partially responsible the significant difference in protection duration for contracting "whooping cough", where the vaccine immunity is on the order of 3 to 10 years after the last vaccine dose while the natural immunity apparently lasted for 10 to 50 years after having a clinical "whooping cough" infection (see, Wearing HJ, Rohini P. \textit{Estimating the Duration of Pertussis Immunity Using Epidemiological Sciences}. \textit{PLoS Pathol}. 2009 Oct: 5(10): e1000647 (11 pgs).
Events Reporting System (VAERS)\textsuperscript{17}.

However, unlike the notifiable diseases for which a single discovered failure to report carries significant penalties, there are no statutory or, at this time, direct regulatory penalties for any healthcare provider's or vaccine manufacturer's failure to comply with the statute requiring the recording and reporting of short-term adverse events\textsuperscript{18}.

Further, there are no requirements to ensure that each vaccinated person's health is tracked for an extended period of time and that all of his or her subsequent adverse health conditions are reported to discover those adverse events that may have a long "incubation" period before the adverse health consequences become identifiable and can be rationally related to one or more of the vaccines or a vaccine component or components that that vaccinated person received years earlier.

Since the reporting requirements for notifiable diseases have evolved into an active disease-surveillance system with significant penalties for the failure to report all of the cases observed, in general, most disease cases are reported leading to a notifiable disease reporting rate of more than 95% of all of the clinical cases of these diseases in most of the states in the USA.

In contrast, VAERS is a passive reporting system for adverse events, which is focused on short-term, symptom-noticeable adverse events.

For serious adverse events, no more than about 1% of the actual serious adverse events that occur may be reported (based in a study\textsuperscript{19} that was lead by Dr. Kessler, a former FDA Commissioner).

Moreover, typically less than 10% of all of the adverse events 'immediately' following vaccination are reported to VAERS.

Furthermore, most healthcare providers do not actively provide long-term follow up with their patients to verify that the persons in their practice who have been vaccinated have not developed any adverse reaction to the vaccines that these persons have received.

\textsuperscript{17} The CDC-FDA only maintains a searchable database of those reports that it receives and can, at some level, verify whose use for any study purpose is increasingly being actively discouraged. Moreover, the inclusion of adverse events reported during post-approval ("Phase IV") clinical trials in the general database introduces periodic biases during the period that these Phase IV studies are required to be conducted.

\textsuperscript{18} Title 42 of the United States Code (U.S.C.), Section (§) 300aa at paragraph 25 (42 U.S.C. § 300aa-25), as enacted on December 22, 1987 and amended, which currently reads in part,

"Sec. 300aa-25. Recording and reporting of information
(a) General rule
Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record ... with respect to each such vaccine -
(1) the date of administration of the vaccine,
(2) the vaccine manufacturer and lot number of the vaccine,
(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.
(b) Reporting
(1) Each health care provider and vaccine manufacturer shall report to the Secretary -
(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. ....
(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.
(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987."

Finally, there are almost no long-term (for 10 years or greater) vaccination-outcome tracking studies to identify the possibly vaccination-related outcomes that take years to manifest clinically.

Yet, even using the reported VAERS instances of death and comparing them to the serious disease-related deaths from the “Notifiable Disease” reports produced by the CDC, often the VAERS reports exceed the notifiable disease reports of death when the verified VAERS reports are multiplied by 10 to crudely correct for the severe under reporting of these post-vaccination-related events in children.

Moreover, the VAERS report category of death almost always exceeds, and often greatly exceeds, the corresponding deaths data values for notifiable diseases when, as the Kessler, et al. study (see footnote “19”) suggests, the VAERS reports are multiplied by a factor of 100 to correct for the serious under reporting observed for deaths.

Collectively, besides injection-site redness, the under-reporting-corrected, disease-connected, adverse-event reports to VAERS are crude estimates of the vaccination equivalent of notifiable clinical disease reporting for a given vaccine.

However, since increasingly more vaccine components are being given to our children at the same time (by using “combination vaccines” and multiple vaccine administration),

- Based on the reports in the VAERS database during the period from 1990 through 2010, the children’s risks for having a serious adverse event which causes hospitalization and death are increasing20, but
- The ability to unequivocally assign the adverse event to a particular disease-related component (e.g., the “pertussis”-toxoid component or the “endotoxicity level [expressed as “endotoxicity units” “EU”] in a DTP vaccine) or particular vaccine constituent (e.g., Thimerosal, bovine albumin, fetal DNA fragments) or vaccine constituent category (e.g., “aluminum adjuvant” or “oil-in-water adjuvant” present in one or more of the vaccines concomitantly administered) is becoming increasingly difficult and complicated.

However, in the USA today, there is increasing evidence that the net effect of our vaccination programs has been that they contribute to, and may possibly be a primary cause for, the overall decrease in the health of our children and ourselves.

For example, the rise in the incidence of chronic disease21 in the 2001-2006

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21 The other possible contributors are: a) genetically modified organisms (GMOs), increasingly found in the foods that we are consuming; b) those pervasively used bioactive chemicals that have serious adverse health effects (e.g., fluoride in water; aluminum salts in our water and sprayed on our food; mercury in fish, water, air, dental amalgams and non-vaccine pharmaceutical drugs; pesticides and their residues; bis-phenol A [BPA] and the related bis-phenol compounds; perfluoro-octanoic acid, DuPont’s Teflon® precursors and breakdown products, and related fluorinated compounds; dioxins; PCBs; flame retardants; and certain widely used pharmaceuticals including the hormone components in the birth control pill to name a few possibilities); and c) the increasing level of electromagnetic pollution to which we are being exposed by technologies that use microwaves (e.g., cell phone, smart power meters, microwave ovens and compact fluorescent lights).

However, given the rapid expansion needed to cause the observed shifts in health, the rapidly expanding (in terms of recommended vaccines and vaccine doses) vaccination programs; the introduction and increased population uptake of GMO foods; and, increasingly, the microwave pollution in our society seem to be the primary suspects for the major causal factors given the time patterns observed for the emergence of “new” epidemic chronic childhood diseases since the mid-1980s (childhood type 2 diabetes; childhood obesity, childhood neurodevelopmental diseases, disorders and syndromes; childhood behavioral disorders; childhood developmental
The suggestion that vaccines do more harm than good is not based in fact.

Actually, based on the available independent scientific studies published in recognized peer-reviewed journals, including, most recently, the clear failure of the chickenpox vaccination program in the USA, as published in the journal *Vaccine*, at least some of the current vaccination programs factually do more harm than good when all costs are included, including the programs costs and the costs contributed by those who are harmed by the vaccine.

Thus, the writer’s generalization,

“The suggestion that vaccines do more harm than good is not based in fact”

has been proven to be, and is, a false generalization.

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Moreover, for less-than-effective vaccine components, like the “pertussis” components in the DTP/DTaP/Tdap vaccines, the harm is disproportionately increasing as more doses are administered in an attempt to compensate for the obvious failure of the “pertussis” vaccine components to protect against all of the disease organisms that can cause the symptoms of the disease (whooping cough).

Thus, more dollars are wasted in these futile endeavors that do not contribute to the physical or fiscal health of the American public, but do further line the pockets of the manufacturers of the vaccines and the healthcare providers.

In addition, at a minimum, the start date for administering the initial DTP vaccines should be moved to four (4) months of age if the child is not nursing or to six (6) months or longer when the child is being breastfed given the marked decrease in the risk for childhood asthma when the start of the initial 3-dose DTP series is delayed by 2 months24.

With regard to the actions of the “vaccine experts”, as widely attributed to Albert E. Einstein but written down by the author Rita Mae Brown in her 1983 book Sudden Death on page 6825,

“[t]he definition of insanity is doing the same thing over and over again and expecting different results” seems to apply to the writer’s “committees of vaccine experts” who continue to recommend more “booster” vaccine doses of, for example, the DTaP and the Tdap vaccines, for the problematic ‘disease preventing’ components (the “ap”, acellular pertussis components in the example DTaP-IPV vaccine, GSK’s Kinrix).

These “committees of vaccine experts” even recommended a second dose for the varicella (chickenpox) vaccine although the vaccine was approved based on its universal use only being marginally cost effective on a societal basis26 in a one-dose vaccination program that was wrongly projected to: a) protect almost all [greater than 96%] who were vaccinated with one dose [actually, one dose protected less than 70% when more than 50% were vaccinated]; b) provide long-term protection ["In clinical trials, the vaccine has proven to be effective for greater than 10 years in preventing varicella. However, breakthrough infections (i.e., cases of varicella that occur in some vaccinated persons following exposure to wild-type virus) can occur, usually resulting in mild illness” (emphasis added, http://wonder.cdc.gov/wonder/prevguid/m0042990/m0042990.asp)] but it provides less than 10 years of protection at best] and c) have almost no risk of any serious adverse vaccination-related effect [e.g., since the late 1990s, Merck’s Varivax® generally was the vaccine with the most adverse reactions per year until the human papilloma virus (HPV) vaccines were introduced].

Further, to make the vaccine cost effective on even a societal cost basis, the vaccination costs [vaccine at $ 35.00 per dose and administration at $ 5.00 per dose (when the records keeping cost alone would have been several times that amount)] were underestimated and, even with these costs, the single-dose vaccination program was not cost effective even when the indirect medical costs were ignored [”When only direct medical costs were considered, the benefit-cost ratio was 0.90:1” (emphasis added, http://wonder.cdc.gov/wonder/prevguid/m0042990/m0042990.asp)].

24 McDonald KL, Huq SI, Lix LM, Becker AB, Kozarsky AL. Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma. J Allergy Clinical Immunol 2008; 121: 626-631.
25 See http://wiki.answers.com/Q/Who_first_said_the_definition_of_insanity_is_to_do_the_same_thing_over_and_over_and_expect_different_results.
26 Societal cost effectiveness is based on the savings from the days that a working parent loses when their child naturally contracts a disease and recovers naturally, usually without proper regard for, or consideration of, the full costs of the days lost caring for children who have serious adverse reactions to the vaccine.
Even after the varicella vaccine failed to meet the crucial criteria that were used to justify its approval on a societal cost-effectiveness basis (significantly less than 90% of those inoculated were protected from contracting the disease, the protection provided was the incomplete, limited-duration protection that most of today’s vaccines actually provide in highly vaccinated populations and serious, vaccination-associated, adverse events were reported), these “committees of vaccine experts” inexplicably recommended a second dose of vaccine rather than stopping a vaccination program that was already clearly not even societally cost-effective by the suspect criteria these “committees of vaccine experts” had used to justify the original chickenpox vaccination program.

Even after it was clear that the program would not only significantly increase our healthcare costs by hundreds of millions of dollars each year and increase the suffering in adults by about 50% from the extra shingles cases that vaccinating children against chickenpox would create for at least the next 30 to 50 years, these “committees of vaccine experts” continued to approve a second dose of the chickenpox vaccine rather than stopping this clearly ineffective and egregiously (grossly) non-cost-effective vaccination program, and apologizing to the American people for ever approving the program to begin with.

In a claimed attempt to slightly lessen the impact of the increased shingles cases upon adults, these “committees of vaccine experts” subsequently approved a “shingles” vaccine, Merck’s Zostavax® for those Americans over 60 years of age to complement Merck’s Varivax® varicella (chickenpox) vaccine.

The net for the American public is that they get to keep an ineffective, non-cost-effective chickenpox program that, without correcting for inflation and Merck’s price increases [as of March 2013, Varivax wholesale commercial cost is now $90.55 per dose], now costs more than twice its original cost and to have a shingles vaccine [with a wholesale cost of $159.318 per dose] that further raises our healthcare costs as well as continues annually adding more than $700 million to the costs associated with the increased shingles cases (mainly caused by the loss of the protective periodic exposures to the wild/native VZV previously shed annually by the children who had natural chickenpox) that the shingles vaccine will not stop.

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27 Except for a few vaccines, like measles, the percentage of those vaccinated who, by the vaccine maker’s antibody titer efficacy criteria, are presumed to be protected from contracting the disease is usually less than 90 % in many instances and less than 65% for some vaccines or, in multiple strain/serotype/serogroup/type vaccine components for a single childhood disease, some particular components.

28 In today’s world, in the USA where vaccination provides the bulk of the protection from disease in about two-thirds of the population, the lack of durable protection is actually used to justify the giving of additional doses and, based on our current understanding, the protection duration varies from not more than 1 year (for all of the current influenza vaccines) to about 3 years (for the “pertussis” components in the DTP/Tdap vaccines) to about 4 years (for the meningococcal meningitis vaccines) to about 25 years (for the measles component in the measles, mumps and rubella [MMR] vaccines used in the USA and France).

What actually protects most people from contracting a clinical case of most contagious diseases is the lack of exposure to those who are shedding the disease organisms that may cause the disease or, for polio, the high background level of very low levels of the vaccine-related strains of polio in the environment or being shed by those entering the USA from countries where the live-virus vaccines are being used.

Given the reports in the literature where adults in the USA are again being infected by rotavirus shed by those who have been directly or indirectly inoculated with the bioengineered human-bovine pentavalent hybridized rotavirus vaccine (Merck’s RotaTeq), it would seem that all adults in the USA are not protected from contracting a RotaTeq-vaccine-related infection, even though the CDC claims all are “immune” (protected from infection for a lifetime) to a human rotavirus infection by the time they are 5 years of age.

29 A hierarchical MedAlerts search for children under three years of age for the period from 1995 through 2011 who received a Varivax inoculation found that there were 75 vaccine-related death reports (4.4 reports per year on average) and 192 vaccine-related permanent-disability reports (11.3 reports per year on average).
Rather than being forced to stop the mass marketing of its varicella vaccines as it should have been, Merck now gets: a) a market that is potentially more than three (3) times the doses that it was initially approved to market in the USA and b) continued access to the vaccine markets in other nations where the vaccination program is or, if not now implemented, may become a money-losing and health-damaging proposition for the public in those nations.

Based on the preceding facts, it seems to this reviewer that these “committees of vaccine experts” are more interested in the health of Merck and the other vaccine makers than they are in the fiscal and physical health of the American public and those in the other countries where Merck and the other vaccine producers market FDA-approved vaccines which are not cost-effective and/or not effective in preventing disease.

**Vaccine Safety and Effectiveness**

“Vaccines are recommended in the U.S. only after they are closely evaluated by committees of vaccine experts. The data regarding vaccine effectiveness and safety are widely published for each vaccine. Anyone can review this information. It is available online from a variety of organizations, including the U.S. Centers for Disease Control and Prevention (CDC), National Network for Immunization Information and the American Academy of Pediatrics.”

Unfortunately, as their actions in the chickenpox program indicate, the writer’s “committees of experts” are packed with “experts” who are more concerned about the health of the vaccine makers than they are about the fiscal and physical health of the American public.

Moreover, as has been shown, the “information” that the writer and other vaccine apologists tout “regarding vaccine effectiveness and safety” does not provide proof of either attribute.

Factually, since neither today’s vaccine makers nor the vaccine providers can be sued for damages related to the harm caused to the persons inoculated with their vaccines in the USA, neither group has any incentive to ensure that the vaccines in the recommended national universal vaccination program are either safe or effective as well as a strong self-interest disincentive to support only vaccination programs that are truly cost-effective.

Further, since the vaccines are not required to be proven to be effective in protecting those given these vaccines, the vaccine makers can knowingly market vaccine components that are not even efficacious30 much less effective.

**Proof of Safety?**

In addition, even though there are explicit safety requirements, the FDA, the

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30 Currently a “qui tam” lawsuit, United States of America ex reators, Stephen A Krahling and John A Wlochowski, Plaintiffs v. Merck & Co., Inc., Defendant; 2:10-cv-04374 (CDJ) Document 12, AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, filed on 04/27/2012 in the UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA by insider whistle blowers alleging that Merck knowingly marketed an MMR vaccine to the federal government containing a mumps component that failed to meet its serological efficacy requirements by developing a false efficacy test to make it appear that the mumps component met its approved efficacy (titer-inducing) levels when, based on the law suits’ representations, the mumps component actually did not come close to meeting its licensed and approved titer levels in the scientifically sound analytical test protocol originally developed as surrogates for the protective level in humans given the Merck M-M-R II® vaccine – the test protocol upon which vaccine approval was granted and which Merck apparently knew that its mumps component production viral strains did not meet.
agency that approves vaccines, has knowingly failed to require the makers of vaccines to meet the pre-clinical toxicological requirements, which, for prophylactic (protective) vaccines designed to be given to healthy children and pregnant women, clearly requires the vaccine maker to prove, among other things, that their vaccine formulations are neither teratogenic, mutagenic, carcinogenic, nor reproductively toxic before any clinical trials are conducted.

Moreover, for vaccines containing a chemical compound or mixture of chemical compounds used as a preservative that is injected, the pre-clinical testing has, since 1968, been required to prove that the preservative level in a single injected dose is,

"... sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient...."\(^{31}\).

To meet the preceding requirement, the maker of a vaccine that is to be administered to developing children is supposed to conduct scientifically sound and appropriate pre-clinical toxicity studies in model animals using injections of the appropriate preservative-containing solutions that can be used to establish the human-comparable level of toxicity for the proposed preservative below which there is a valid no observed adverse effect level (NOAEL)\(^{32}\) on the most-toxicant-sensitive system, typically the central nervous system, in developing humans.

Moreover, the vaccine maker must use a level of the preservative that is below said NOAEL by some appropriate safety factor to meet the “sufficiently nontoxic ...” requirement, where the safety factor for highly toxic compounds must be at least 10 and should, if possible, be 100 or higher for preserved vaccines that are repeatedly injected.

Yet, the FDA has, since 1973, approved vaccine formulations preserved with Thimerosal, a mercury-based compound that is highly toxic and breaks down in the human body into bioaccumulative tissue-retained mercury compounds, without the vaccine’s maker’s proving: a) what is the appropriate NOAEL for injected Thimerosal in developing humans, or b) ensuring that the level of the Thimerosal used in a vaccine preserved with it is at least a factor of ten (10) lower than the NOAEL determined by the vaccine maker.

Further, there are similar “lack of proof of safety” concerns for the aluminum adjuvants used in many childhood vaccines.

Moreover, since these vaccines are intended to be given to healthy children as a preventative measure, all vaccines that lack pre-clinical proof that they are not teratogenic, mutagenic, carcinogenic, and/or reproductively toxic are not safe vaccines.

In addition, their administration to humans appears to violate one or more of the human experimentation restrictions set forth in the Nuremberg Code\(^{33}\), which

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\(^{31}\) See Title 21 (21) of the Code of Federal Regulations (C.F.R.) in section (§) 610 at point 15(a) [21 C.F.R. § 620.15(a)].

\(^{32}\) This “no effect” level is: a) usually labeled a no-observed-adverse-effect-level (NOAEL) for the preservative and b) the level below which the preservative can be considered to be “nontoxic”).

\(^{33}\) See http://en.wikipedia.org/wiki/Nuremberg_Code

*The ten points of the Nuremberg Code*

The 10 points are, (all from United States National Institutes of Health) [2]

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or
regulates human experimentation, that, after the human experimentation atrocities committed by Germany and Japan during World War II, the USA helped to fashion but refused to officially adopt.

Yet, knowing the preceding facts, the writer’s “committees of experts” routinely continue to recommend the universal use of vaccines for which one or more of the applicable safety standards have not been met.

Absent proof that all of the requisite safety studies for vaccines have been conducted and proven that the prophylactic vaccine is safe to administer to developing children, there can be no scientifically valid claim that a given childhood vaccine is safe.

Since many of the requisite pre-clinical safety studies for most vaccines have not been conducted (as the wording in many of the package inserts for vaccines that can be given to pregnant women and children explicitly admit or, by omitting the section for “13 NON-CLINICAL TOXICOLOGY”, tacitly acknowledge), these vaccines cannot be safe for prophylactic use in children, pregnant women, or, for that matter, adults and the elderly.

**Proof of Effectiveness?**

Because there are virtually no human-applicable, disease-challenge studies using informed volunteers or, where they exist, animals that can contract the human disease or diseases covered by the vaccine, where, in a double-blind study, disease-naïve subjects are randomly inoculated with the vaccine or inoculated with a sterile pH-balanced isotonic saline solution that is formulated to look like the vaccine, and, after a suitable period to allow vaccine protection to "develop", the originally naïve subjects have their blood sampled and are then exposed to "wild"/"native"/"non-vaccine" strains of the disease for which vaccination is claimed to provide the least protection.

All of the subjects should then be monitored for their response to the disease or diseases to which they are exposed and periodic blood samples drawn during the incubation period for the disease until this period has expired or, when the disease provides protection for multiple diseases, the longest incubation period has expired, the observed blood samples are analyzed and the codes are decoded and the study’s results are evaluated and its findings are reported.

In addition, these “committees of experts” also know that the vaccine that they are recommending for universal use has not been proven to be effective in preventing even that percentage of those who have been inoculated with them and develop a supposedly “protective” antibody titer from their subsequently contracting the disease or diseases supposedly “covered” by the vaccine.
All that this reviewer uncovers, when looking at the information to which this writer alludes, are disinformative studies that are designed, conducted, reviewed and submitted instead of (as surrogates for) the studies which are required by sound science and/or federal law (statute or regulation).

Moreover, lacking the mandate and the will to compel the vaccine makers to comply with the law, our federal regulatory agencies, to whom the legislators and the judiciary routinely grant unwarranted deference, accept these pseudo-scientific replacement (surrogate) studies because these agencies routinely place the interests of these vaccine manufacturers above the health of our children and the fiscal and physical health of the public.


“Among other evidence of vaccine safety, a 2011 comprehensive review of vaccines by the Institute of Medicine” [IOM] “failed to find any new or unsuspected autoimmune side effects from vaccines, and determined which side effects are likely caused by vaccines and which are not.”

Here, the writer is intentionally distorting the findings of “a 2011 comprehensive review of vaccines by the Institute of Medicine”, titled, “Adverse Effects of Vaccines: Evidence and Causality (ISBN 978-0-309-21435-3)”, when, without any qualification, he stated that this report “failed to find any new or unsuspected autoimmune side effects from vaccines” and “determined which side effects are likely caused by vaccines and which are not”.

First, as stated in the report’s “Preface” (emphasis added),

“Following in this tradition, the task of this Committee was to assess dispassionately the scientific evidence about whether eight different vaccines cause adverse events (AE), a total of 158 vaccine-AE pairs, the largest study undertaken to date, and the first comprehensive review since 1994”,

this committee only addressed the issue of “whether eight different vaccines cause adverse events (AE)” and “a total of 158 vaccine-AE pairs” – not all vaccines nor all possible adverse events for all vaccines, and most certainly not all possible “vaccine-AE pairs”.

Second, the side effects were not limited to “autoimmune side effects”.

Third, rather than the ‘black and white’ sorting of side effects implied by the writer’s assertion, the report’s “Preface” clearly indicated (emphasis added),

“the limitations of the currently available peer-reviewed data meant that, more often not, we did not have sufficient scientific information to conclude whether a particular vaccine caused a specific rare adverse event. Where the data was inadequate to reach a scientifically defensible conclusion about causation, the committee specifically chose not to say which way the evidence ‘leaned,’ reasoning that such indications would violate our analytic framework.”

Thus, the writer’s “determined which side effects are likely caused by vaccines and which are not” fails to include the reality that, in most instances, the committee could not even determine whether one of the eight (8) vaccines studied and a selected AE were, or were not, causally linked.

**Vaccines and Autism?**

“In addition, despite much controversy on the topic, researchers have found no connection between childhood vaccines and autism. In fact, the original study that ignited that debate years ago has been retracted.”
Here, the writer, Dr. Poland, simply parrots the misleading and disinformative statements made by other vaccine apologists without providing a substantiating reference or even citing or referencing the study to which he is alluding.

In fact, his “the original study that ignited that debate years ago” was a case-series article about bowel disease and a possible connection of that bowel disease to the MMR vaccines being administered in the United Kingdom (Wakefield AJ, Murch SH, Linnell AAJ, Casson DM, Malik M, Berelowitz M, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children. *Lancet*. 1998; 351: 637–641.) that did not link the MMR vaccine to “autism” (also known as Kanner syndrome).

Apparently, the first peer-reviewed published article34 to broach the possibility of a connection between a vaccine and “autism” (Kanner syndrome) raised the possibility of a link between a smallpox vaccination and the subsequent regression of the child into “a complete Kanner syndrome” (“autistic disorder”) in 1976 (22 years before the now-withdrawn paper was published) has neither been retracted nor even, to this reviewer’s knowledge, attacked.

Nor has that paper’s abstract’s concluding statement,

“But vaccination is recognized as having a starter function for the onset of autism”,

which apparently was simply reporting a recognized reality, been rebutted in any independent, scientifically sound and appropriate study of which this reviewer is aware.

Based on the preceding reality, by the mid-1970s, vaccination was recognized by the European medical community as a possible causal factor for “autism”.

Further, though many independent research groups around the world have reported a connection between Thimerosal at preservative levels in “childhood vaccines and autism”35 and, more recently, a connection between the aluminum adjuvants used in certain “childhood vaccines and autism”36,37 and there has been a few reports, a published study38 and a commentary39, which have found a causal link between the MMR “childhood vaccines and autism”, the Establishment and vaccine apologists have either attempted to discredit the possibility of this linkage, or, as is the case for MMR, pretend that these reports, the commentary, and the cited peer-reviewed published study do not exist.

**Whooping Cough and Measles**

“Lack of vaccinations has put many children at risk for diseases that are avoidable, including whooping cough and measles.”

Here the writer again distorts reality because it is exposure of the children to


Abstract

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

35 For some of the more recent relevant studies, see the articles listed in a tabulation submitted to the United Nations Environmental Program in June of 2012 titled, "TRACES THE DANGERS OF MERCURY IN VACCINES UNEP/INC4 SPECIAL EDITION Global Legally Binding Instrument on Mercury Treaty Punta del Este, Uruguay, June 2012”.


From the pen of Paul G. King, PhD, Founder, FAME Systems

the disease-causing biological entities that puts “children at risk for diseases”.

Moreover, absent exposures to these disease-causing biological entities, how can children be infected by these diseases?

Furthermore, since the vaccine for measles is a live-virus vaccine, inoculating children with a vaccine that contains a live measles virus infects all those who are vaccinated with such vaccines with the vaccine strain of the live measles virus in an abnormal manner and, when shed, can infect others.

Moreover, though those who are given a live-virus measles vaccine have an abnormal measles infection, that abnormal infection does not even protect all who have been vaccinated twice according to the current US schedule from subsequently contracting measles when exposed to a “wild” measles viral strain.

Factually, several who have been multiply vaccinated (up to 5 times) with the CDC-recommended MMR vaccine have been found to contract a clinical case of measles when they are subsequently exposed to a 'circulating' measles virus.

When it comes to the disease whooping cough, vaccination with the available “pertussis”-components-containing vaccines does not stop those who are vaccinated from contracting whooping cough because the vaccine is only partially protective against one of the several organisms, bacterial and viral, that can cause a child or adult to have the symptoms used to putatively diagnose a clinical case of whooping cough.

Further, because today’s “pertussis”-components containing vaccines do not provide all of the same antigens that are generated or generate the antigens in the order they are released when the natural infection occurs (e.g., adenylate cyclase toxin [ACT], which is initially generated when any Bordetella species infects the body; PT [pertussis toxin], which is generated when Bordetella pertussis infects the body; and FHA [filamentous hemagglutinin], PRN [pertactin] and fimbriae) in the order that they interact with the human immune system but rather only contain PT, FHA, PRN and/or fimbriae.

Consequently, when given to young children who have never had whooping cough, these “pertussis”-components-containing vaccines produce an ‘unnatural’ immune-system response pattern, which imprints the children’s underdeveloped immune system to initially respond to the vaccine’s antigens (epitopes) in a manner that initially ignores ACT – thereby allowing future exposures to any Bordetella species (B. species) not to be immediately recognized, when they begin to be infectious by releasing ACT, and dealt with before the B. species can further infect those who are re-exposed to it.

Thus, today’s “pertussis” vaccines that are recommended to be given to children generally only provide limited-duration and incomplete protection to some percentage of those who are multiply inoculated with these “pertussis”-containing vaccines, provide no protection against infection by other B. species, and, because the ACT assault is not recognized, may actually increase the risk of infection when those who are vaccinated are exposed to any B. species.

Further, most of the other vaccines given to children only postpone the time that the child is at risk in that percentage of children who are vaccinated and develop and maintain adequate “disease-protective” antibody levels after being inoculated with them according to the CDC’s recommended vaccination schedule.


41 See the discussion in the 18 August 2012 Internet article “Whooping cough and chameleons” by Hilary Butler.
Finally, in the case of influenza vaccines, inoculating with these may actually increase the vaccinated child’s subsequent risk of contracting a clinical case of influenza by altering the child’s immune system’s ability to appropriately respond to the actual influenza strain in a subsequent exposure to a circulating influenza virus\(^{42}\), do not provide protection from contracting influenza to all of those children vaccinated with them; and, for some children, may increase the vaccinated child’s risk of hospitalization by more than a factor of three\(^{43}\), when they do contract influenza.

**Vaccines Are Doing Their Job?**

“If these diseases seem uncommon, it simply means that vaccines are doing their job.”

The writer’s assertion here is not supported by the historical record when viewed in terms of notified instances of disease mortality, the only population health statistic in the USA that reliably approximates the actual experience of the population.

This “disease mortality” statistics show that, for all of the non-vector-borne childhood diseases which have been found in the USA since the 1800s and for which we have a CDC-recommended vaccination program as well as for some, like scarlet fever for which no effective vaccine was available and tuberculosis for which the ‘available’ vaccine was not recommended for mass use in the USA, disease mortality showed a consistently declining trend in which disease deaths for these childhood diseases had dropped by more than 80% from their early-1900s highs before each of the vaccines, which were FDA-approved for use and CDC-recommended for mass use, were introduced\(^{44}\).

In every case, improved sanitation, clean drinking water, hygiene, nutrition, living conditions, and, to a lesser extent, the introduction of antimicrobial drugs in the 1940s and 1950s were the chief factors causing this reduction in notifiable disease reports before the post-smallpox ‘modern’ prophylactic vaccines were introduced and recommended for mass ‘disease preventive’ use in humans.

The reasons that disease-case levels are not a reliable measure of disease change include the reality that only serious clinical disease cases and outbreak-related cases are, if properly identified, usually reported, while the disease cases caused by the inoculation of children with live-virus vaccines currently in use (e.g., influenza, measles, mumps, polio [mainly, in today’s developing countries], rotavirus, rubella, and varicella) are either ignored or misclassified as a “vaccine adverse event” and/or an other-cause event (e.g., SIDS [sudden infant death syndrome], SUID [sudden unexpected infant death] and SBS [shaken baby syndrome]) rather than, as they should be, counted as timing-related, post-vaccination-caused disease mortality or, when the transmission is secondary, vaccination-related disease mortality.

Furthermore, when assessing “disease mortality”, all of the post-vaccination-associated cases that may be causally linked to a child’s death should be counted.

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44 “Immunization Graphs: Natural Infectious Disease Declines, Immunization Effectiveness; and Immunization Dangers Prepared by: Raymond Obomsawin Ph.D. December, 2009”.
as a vaccination-related death unless another cause can be proven and the proper death toll reflected as notified disease deaths plus the possibly-causally-linked, post-vaccination-associated deaths.

Until the reporting of such vaccine-related death is made notifiable [under the current regime, where adverse-events reporting is voluntary and fewer than 1% of the vaccination-related deaths may be reported45], the mortality from each vaccine-covered disease should be expressed as notified disease cases plus 10 to 100 times the possibly-causally-linked-vaccination-associated deaths, as determined by a truly independent medical review.

Were the preceding actions to be taken, this reviewer is confident that, for certain vaccines administered in childhood, today’s national disease/disease-related death prevalence rate would, for most vaccines, probably be no less than, and possibly greater than, the death prevalence rate in the year prior to the CDC’s recommendation for the disease’s initial vaccination program.

Essentially, the current disease-assessment protocols are designed to conceal most of the vaccination-related deaths in the grossly under-reported, voluntary, adverse-event notifications.

Finally,

- IF the real reason for the use of vaccination is to weaken the overall health of those who are vaccinated,
- THEN, and only then, does the writer’s assertion, “vaccines are doing their job”, appear to be an accurate statement.

“Evidence clearly shows that children have died because of under-vaccination, and that diseases have spread needlessly due to the trend of parents opting out of vaccines for their children.”

Here, the writer asserts,

“Evidence clearly shows that children have died because of under-vaccination”

and that,

“diseases have spread needlessly due to the trend of parents opting out of vaccines for their children”.

However, these are assertions: a) for which the writer provides no supporting citations and b) that are logically unsupported one-sided generalizations.

Factually, both before and after the current universal vaccination programs were introduced, after being exposed to the vaccine-covered disease-causing agents, children have died from that disease because: 1) they were infected with a disease-causing agent, and 2) their body’s immune systems and the available curative treatments were unable to prevent their death46.

After the introduction of a mass vaccination program for a disease, in addition to the pre-vaccine realities that caused some children to die, children have also died from: 1) their body’s adverse reaction to that vaccine or some component in it and/or 2) from a subsequent lethal infection that was caused


46 Some of this information for some notifiable diseases is located in the tables reporting “deaths from ... notifiable diseases, United States, ...” located toward the end of most of the “annual” “Summary of Notifiable Disease ...” reports currently available from the “MMWR: Summary of Notifiable Diseases” Internet web page from 1993 onwards with disease-related deaths going back to 1982.
by: a) the drain on the children’s immune systems from the vaccination that prevented the children’s immune systems from mounting an effective disease defense and/or b), infrequently, microbially infected vaccine doses (note: some of these vaccination-related mortality (death) reports can be found in the VAERS database\textsuperscript{47}).

Overall, today’s reality is both vaccinated and non-vaccinated children die.

However, the vaccination-related deaths are poorly reported because, though most developed countries have a mandated reporting system for many diseases and penalize any healthcare provider found to be not reporting disease cases and outcomes for the clinical disease cases identified, they have no similar system for the reporting, verification and long-term tracking of all those who have been vaccinated to ensure the reporting of most all serious inoculation-related adverse reactions and vaccination-related deaths.

A second reality is that women who are vaccinated in childhood to prevent them from contracting childhood diseases pass less complete protection and less overall protection to their offspring in utero and/or, after birth, through their breast milk when they breastfeed than women who have had these childhood diseases, recovered from them and then nurse their babies (for a minimum of 6 months and, preferably, for 24 or more months\textsuperscript{48}).

Thus, one 'unintended' consequence of childhood vaccination programs is to increase the risk that children who are too young to be vaccinated will contract a childhood disease before the children’s immune systems have developed to the point that they can handle a given childhood disease with little risk of severe injury or death.

This consequence has been exacerbated by the failure of American mothers, seduced by the false claims of the "formula" purveyors, to breastfeed their newborns (or have a suitable surrogate nurse them) for not less than six (6) months and, preferably, 24 months.

Furthermore, with respect to the children’s overall health, the evidence, from surveys of parents\textsuperscript{49,50}, groups (e.g., the Pennsylvania Amish)\textsuperscript{51}, and physicians’ practices that:
- Do vaccinate their children (e.g., most practices that fully comply with the vaccination recommendations of the American Academy of Pediatrics

\textsuperscript{47} Reports of vaccination-related deaths can be found by performing the appropriate searches of VAERS for “death” adverse events using the MedAlerts “Search the VAERS Database” web page for the period from 1990 onwards, and saving or printing out and then reviewing the details of each of the reports identified.

\textsuperscript{48} In natural peaceful societies with adequate food supplies where breast feeding typically continues for two (2) or more years, there is almost no risk of the nursing child’s contracting a childhood disease that their mother has had as long as the child is nursing.

In societies that, for whatever reason, nurse their children for shorter periods or not at all, and rely upon vaccination to protect themselves and their children from childhood diseases, children routinely contract childhood diseases before their own developing immune systems are able to resolve the disease agent and fully recover from the disease. Moreover, though the evidence is that vaccination before a child is 12 months of age does not produce long-term immunity to most childhood diseases, public health officials routinely recommend vaccination at as early as six (6) to eight (8) weeks for many vaccine actives for the “childhood” and other diseases in an attempt to provide some short-term disease protection to most of those inoculated with them because, even if they are breastfed, their vaccinated mother’s breast milk does not provide effective disease protection.

Typically, the health of these vaccinated children is less than the health of the comparable breastfed children whose mothers had all of these childhood diseases and, through their breast milk, continually provide breast milk until the child is more than 2 years of age.

\textsuperscript{49} New Survey Shows Unvaccinated Children Vastly Healthier – Far Lower Rates of Chronic Conditions and Autism, posted on the Internet on 26 August 2011.

\textsuperscript{50} UNVACCINATED CHILDREN ARE HEALTHIER, last visited on 13 October 2012.

\textsuperscript{51} No Autism in Unvaccinated Amish Community, last visited on 13 October 2012.
From the pen of Paul G. King, PhD, Founder, FAME Systems

[AAP] and/or the American Academy of Family Practice [AAFP] and have health outcomes similar to those reflected in the NHANES [National Health and Nutrition Examination Survey] data reported in 2010[52], and

◆ Do not vaccinate their children (e.g., 33,000-plus children who were cared for by Chicago’s Homefirst Health Services practice[53]) and have much better overall health outcomes than the NHANES study reported, is that, on the whole, the initially healthy, non-vaccinated children are healthier than the initially healthy children who are vaccinated according to the CDC-recommended vaccination schedule when health is measured by the percentages of children who have one or more of the serious chronic medical conditions that afflict today’s children.

In addition, in a January 2013 study, published online in JAMA Pediatrics[54], the abstract cogently reported that the under vaccinated children of parents who intentionally chose fewer vaccine doses had “lower rates of outpatient visits” and “emergency department encounters” than a matched cohort of “age-appropriately vaccinated children”.

Tellingly, all of the children in the study were participants in Managed Care Organizations systems (MCOs) and generally conformed to these MCOs’ recommended “well care” visitation programs – none of the children were those whose parents refused all or almost all vaccinations or demanded a radically different vaccination schedule.

Along with the surveys that demonstrate chronic childhood illnesses occur at significantly lower rates in the never-vaccinated children as compared to the chronic illness rates in age-appropriately vaccinated children, these “unexpected” findings by a group that is favorably biased toward the current vaccination status quo clearly indicate that there should be a comparison of the health of the initially healthy never-vaccinated children to the health of a highly matched cohort of age-appropriately vaccinated children.

Since: a) both vaccinated and non-vaccinated children die; b) the Establishment, the writer and the mainstream media mainly focus on the deaths of those who are non-vaccinated or are too young to be vaccinated, and c) the children who die as a direct or indirect result of their being vaccinated are grossly under counted, there is no direct deaths-comparison method to answer the critical morbidity question for those instances where there is an FDA-approved, CDC-recommended vaccine for a given disease:

“Do more children annually die, directly or indirectly, from the disease, where there is an active disease morbidity monitoring network to capture disease-related deaths, or from the vaccination program for the disease, where we currently have a grossly deficient voluntary reporting system for vaccine-related deaths?”

Until:

53 NO AUTISM In Never-Vaccinated Children, last visited on 13 October 2102.
54 Glanz JM, Newcomer SR, Narwaney KJ, Hambidge SJ, Daley MF, Wagner NM, McClure DL, Xu S, Rowhani-Rahbar A, Lee GM, Nelson JC, Donahue JG, Naleway AL, Nordin JD, Lugg MM, Eric S. Weintraub ES. Population-Based Cohort Study of Undervaccination in 8 Managed Care Organizations Across the United States. JAMA Pediatr. 2013 Jan 21; ():1-8. doi:10.1001/jamapediatrics.2013.502. ONLINE FIRST. From the “ABSTRACT” (emphasis added): “In a matched cohort analysis, undervaccinated children had lower outpatient visit rates compared with children who were age-appropriately vaccinated (incidence rate ratio [IRR], 0.89; 95% CI, 0.89-0.90). ... In a second matched cohort analysis, children who were undervaccinated because of parental choice had lower rates of outpatient visits (IRR, 0.94; 95% CI, 0.93-0.95) and emergency department encounters (IRR, 0.91; 95% CI, 0.88-0.94) than age-appropriately vaccinated children.”

38
a. All of vaccinated children’s short-term and long-term vaccination-related adverse-events and health outcomes are tracked at least as accurately as disease morbidity and mortality, and

b. Independent scientifically sound and appropriate studies are conducted, the critical issue,

"Whether vaccination programs are truly fiscally and physically beneficial to our children’s overall long-term health",
cannot even be accurately addressed much less answered.

Turning to the second part of the writer’s assertion (emphasis added),

"diseases have spread needlessly due to the trend of parents opting out of vaccines for their children",

this reviewer knows of no published studies showing that “diseases have spread” in the USA because of any documented “trend of parents opting out of vaccines for their children”.

In general, the microorganisms that can cause a given childhood disease can be isolated from samples of the air, water and/or soil in most of the areas where Americans dwell or visit, and/or in some nasal, buccal, mucosal and phlegm samples from the population segments checked for such organisms.

In addition, even for “highly contagious” diseases, like measles, there are still isolated cases each year where no other-person source can be identified.

Finally, even though the number of cases are not routinely reported by the mainstream media, or the CDC, or reported as a notifiable disease, there are, for example, probably more than a hundred vaccination-related cases of measles annually in the USA

The At-Risk Population Segments

“As you point out, children who do not receive vaccines are not the only ones at risk. If a child contracts one of these serious diseases, it can spread to others. This is particularly dangerous for children who cannot get vaccinations because of medical problems or those whose bodies did not build up immunity after a vaccine. By choosing to not vaccinate her children, your sister-in-law puts the health and safety of other children in jeopardy, too.”

With respect to the writer’s first assertion,

“..., children who do not receive vaccines are not the only ones at risk”

the writer seems to be implying that the non-vaccinated children put those around them at risk of contracting those childhood diseases for which there is a recommended prophylactic vaccine.

This reviewer disagrees with the writer’s children-centric view because: a) absent his or her exposure to the disease-causing organisms, no child is at risk of contracting any communicable childhood disease, and b) increasingly, our age-appropriately vaccinated children are being disproportionally infected to the point that they developed most of the clinical cases of the disease in the recent outbreaks of, for example, whooping cough and mumps.

However, from the viewpoint of the vaccinated children, the writer’s assertion rings true because all of those who do “receive vaccines” are: a) in the near term, at some statistically small but real risk of serious adverse reactions, including

permanent disability, maiming and death whenever they are given a vaccine, and **b)** at risk of the long-term adverse effects from the harm that infection by the vaccine or adventitious viruses, DNA segments and recombinant DNA, and/or contact with the other components, like yeast proteins, adjuvants, surfactants, preservatives, antibiotics and the like in a given vaccine may induce in some of them.

Furthermore, while this reviewer accepts the validity of the writer’s “If a child contracts one of these … diseases, it can spread to others”, for the highly contagious childhood communicable diseases for which there is a CDC-recommended vaccine, this reviewer notes that this reality also applies to:

- Vaccinated children who, **despite being vaccinated**, still contract the disease, as well as to
- Vaccinated children who, **though they do not develop a clinical case of the disease**, shed live viral plaques after being vaccinated with a live virus vaccine, thereby infecting others, as much, *if not more so*, than it applies to a non-vaccinated child who contracts a contagious disease.

In addition, the vaccines for bacterial diseases promote bacterial mutation and population shifts in the circulating bacteria to which our children may be exposed, which can lead to, and has led to, the need to increase the number of strains in the vaccine as well as to increases in the prevalence of disease-causing organisms that are **not** covered by the vaccine.

For viruses, interactions between the “vaccine” strain(s) and the circulating “wild” strain(s) of the viral diseases for which we have vaccines have led to the rise of altered strains that are more virulent and/or more persistent in the environment than the original “wild” strains of the disease-causing virus(es).

Moreover, for the Hepatitis B vaccines given to young children for a disease that is **not** highly contagious and for which most children have **no** risk, Poland’s “it can spread to others” argument is patentley specious (false).

The recommendation for early childhood hepatitis B vaccination is especially concerning because: **a)** the protection provided by vaccination does not last into adulthood and **b)** causes the premature deaths of a significant number of liver cells in those subjects who have been vaccinated with such annealed-polymeric-hydrated-aluminum-salt-adjuvanted hepatitis B vaccines.

In addition to the harm to the immune systems and the liver’s cells associated with the vaccine’s hepatitis B antigens, harmful effects, similar to those seen in some of the children vaccinated ‘at birth’ in the joint CDC/FDA Vaccine Adverse Events Reporting System (VAERS) database, were found and, even for those who appeared to be protected initially, the protection wore off by the time they were preteens.

Moreover, recent studies have clearly shown that a hepatitis B vaccination program using an aluminum-adjuvanted vaccine containing hepatitis B surface antigen (HBsAg) produced by recombinant DNA techniques actually kills liver cells (where the aluminum adjuvant used initiated cell death in both the *in vitro* and *in vivo* studies).

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Further, given the preceding realities concerning the shedding of live virus by those inoculated with live-virus vaccines, if the writer were genuinely concerned about those who “who cannot get vaccinations because of medical problems”, then he would have stated the need to appropriately quarantine either:

a. Those persons with such “medical problems” from attending any public or private school or other childcare facility where children who have been recently vaccinated with a live-virus vaccine are allowed to attend, or

b. Those who have been recently vaccinated with a live-virus vaccine until the last one of those who have been vaccinated with a live-virus vaccine has received medical clearance to return to his or her school or daycare facility.

However, this reviewer has not found any evidence that vaccine apologists, public health officials, or this writer are lobbying for such quarantine regulations.

Additionally, because: a) vaccination only provides limited protection and not immunity to disease, and b), as again proven in a recent animal study and reported in 1992 for tetanus in three clinical cases, no level of vaccine-derived “disease-specific” antibodies necessarily translates into disease protection for the children who have that antibody “protective” level (titer), this reviewer must suggest that the misleading assertion “or those whose bodies did not build up immunity after a vaccine” should be ignored here.

The preceding suggestions reflect the reality that, “IF disease immunity exists for the non-vector-borne childhood diseases for which we have a CDC-recommended inoculation program, THEN it only exists for those, who have been infected by the naturally occurring disease organisms in a manner that fully engages all of the layers of their suitably mature human immune systems, who have resolved that disease in the manner that ‘nature’ intended that childhood disease to be resolved, and who continue to reside in an environment where they continue to receive periodic low-level re-exposures to that disease organism.”

Thus, if you seek disease “immunity” from such childhood diseases, then you need be ‘exposed to’ each such childhood disease after you are in the proper age range, effectively resolve that disease ‘exposure’, and you may need to continue to reside in an environment in which you will have periodic low-level exposures to the virus or bacteria that causes that disease – because vaccination does not and cannot provide disease immunity.

If vaccination could provide true disease immunity or ‘life-long’ protection, five.

induced cell death. The mouse liver hepatoma cell line Hepa1-6 was treated with two doses of adjuvanted (aluminium hydroxide) hepatitis B vaccine (0.5 and 1 μg protein per ml) and cell integrity was measured after 24, 48 and 72 h. Hepatitis B vaccine exposure increased cell apoptosis as detected by flow cytometry and TUNEL assay. Vaccine exposure was accompanied by significant increases in the levels of activated caspase 3, a key effector caspase in the apoptosis caspase. Early transcriptional events were detected by qRT-PCR. We report that hepatitis B vaccine exposure resulted in significant upregulation of the key genes encoding caspase 7, caspase 9, Inhibitor caspase-activated DNase (ICAD), Rho-associated coiled-coil containing protein kinase 1 (ROCK-1), and Apoptotic protease activating factor 1 (Apaf-1). Upregulation of cleaved caspase 3,7 were detected by western blot in addition to Apaf-1 and caspase 9 expressions argues that cell death takes place via the intrinsic apoptotic pathway in which release of cytochrome c from the mitochondria triggers the assembly of a caspase activation complex. We conclude that exposure of Hepa1-6 cells to a low dose of adjuvanted hepatitis B vaccine leads to loss of mitochondrial integrity, apoptosis induction, and cell death, apoptosis effect was observed also in C2C12 mouse myoblast cell line after treated with low dose of vaccine (0.3, 0.1, 0.05 μg/ml). In addition In vivo apoptotic effect of hepatitis B vaccine was observed in mouse liver.


there would be no need for more than one initial vaccine dose or for “booster doses” of the vaccine and no need to justify these boosters by using terms such as “recurrence” or “resurgence” of the disease.

Finally, the writer’s last statement here,

“By choosing to not vaccinate her children, your sister-in-law puts the health and safety of other children in jeopardy, too”

with the closing “too”, falsely implies that the sister-in-law’s choice “puts the health and safety of” her “children in jeopardy” even though, unless he were omniscient, this writer cannot know, and this reviewer does not claim to know, what the outcome of vaccinating this woman’s children would be.

The possible outcomes of vaccination are: a) no benefit and weakening of the children’s immune system when the vaccine does not induce the children’s bodies to produce sufficient levels of disease-protective responses, b) some limited-duration disease protection that weakens the children’s immune system overall and may, in some instances, increase their subsequent risk of contracting the disease (e.g., influenza vaccination to prevent a few strains of rapidly mutating influenza viruses), c) some limited-duration protection that increase the risk of harm from contracting the disease as the child gets older, d) some transient vaccination-related harm (e.g., injection-site redness swelling or a mild fever), e) some serious vaccination-related harm, f) permanent vaccination-related injury, g) possible vaccination-related death, or h) some combination of the preceding outcomes.

Similarly, because the organisms that can cause disease are circulating in the environment, there is no way that the writer can know, unless he is omniscient, that this woman’s decision will be the probable “cause” of any harm to any other person, including herself or her or others’ children.

Factually, given:

◆ Most children (>85% typically) in the USA have been given the age-appropriate number of doses of most of the recommended vaccines, and

◆ The careless manner in which recently vaccinated children are allowed to interact with others in childcare and school settings without proof that they are not infected by and/or are not shedding the diseases for which they have been vaccinated with a live-virus vaccine,

clearly the vaccinated children are much more likely, in general, to be infecting others than the small percentage of non-vaccinated children in most instances.

The sop that the writer and other vaccine apologists offer is an ambiguous claim that these serious risks are rare and/or not proven to be caused by the vaccination itself — without any ability to accurately forecast:

a. The probability that the child will, at some future date, be exposed to the disease in question in a manner that will cause them to have a clinical case of the disease,

b. The actual benefits, if any, that a particular child will receive from being vaccinated with a given dose of vaccine,

c. The lifetime impacts of that vaccine dose on each individual child’s immune system, or

d. Which, if any, of the identified possible risks for a given vaccine that a given child will experience.

Moreover, the more this reviewer has studied the published vaccine literature,
the clearer the reality has become that no person can make an informed-consent decision when it comes to any prophylactic vaccine.

This is the case because those who recommend, license, approve, promote, market and sell vaccines in the USA do all they can to tout and inflate the putative benefits of vaccines and vaccination programs while hiding and obscuring the risks and avoiding the statutory and/or regulatory mandates that require that vaccines be proven:

- To meet all of the applicable safety and in-use effectiveness requirements before they are allowed to be marketed and
- **For mass prophylactic ("disease preventive") use,** to be medically cost-effective when all of the costs, including the costs of any adverse events, disease-pattern exacerbations or induced chronic disease that the vaccination program might cause, are properly included.

As a **scientist,** this reviewer is **neither** pro- or anti-vaccine nor pro- or anti-vaccination *per se.*

However, until:

- Those vaccine components that are clearly less than effective (e.g., the "pertussis"-component-antigens in the current DTaP and Tdap vaccines as well as the apparently less-than-effective mumps component in the Merck M-M-R II vaccine) are: **a)** removed or **b)** replaced with effective components for the approved vaccines where the other components seem to provide at least intermediate-term protection;
- Those vaccination programs that are **neither** medically nor societally cost-effective programs (e.g., the early childhood hepatitis B vaccination program, the varicella vaccination programs, the influenza vaccination program, and the human papilloma virus vaccination program) are stopped;
- The starting age for all prophylactic vaccination program is moved to 12 months of age or later and, for any of the injected live-virus vaccines, preferably to 18 to 24 months of age; and,
- All vaccination programs are made strictly voluntary because, **given that the scientifically sound and appropriate information required for the average person to make such decisions is missing,** there is currently **no** way that any person can make an informed-consent decision about vaccinating,

this reviewer **cannot** support the current vaccines and vaccination programs for humans who are: **a)** pregnant, **b)** under 18 years of age (children) and/or **c)** 18 years of age or older (adults), because these lack scientifically sound proof of safety, effectiveness, and/or cost effectiveness.

**Become Informed Before Considering Any Vaccination**

“Parents who are hesitant about vaccinating their children should seek information from reliable sources. Don’t look to blogs or celebrity opinions for facts about vaccines.”

Here, this reviewer more than agrees with the writer that parents and other individuals "**should seek information from reliable sources**" about current vaccines and vaccination program recommendations and, if any, the sound science behind them.
Nevertheless, this reviewer does not automatically rule out reading “blogs or celebrity opinions for facts about vaccines” provided the information furnished is confirmed or verified by scientifically sound, independent, published articles that such sources cite and/or reference.

“Have a conversation with your child’s doctor. Ask questions. Review the CDC data. It is important that parents understand the value of vaccines.”

Here, this reviewer has no problem with the writer’s suggestions per se but would counsel everyone, to the extent they are able, to:

- Seek out reliable independent sources of information on vaccines and all of the recommended vaccination programs,
- Understand the short-term and long-term differences between “naturally acquired, disease-provided immunity” and “vaccination-acquired disease protection” for each childhood disease for which there is an FDA-approved vaccine,
- Understand the differences in the formulation of vaccines from different manufacturers,
- Read the vaccines’ package inserts,
- Avoid vaccines that do not fully disclose the nature and nominal level of each component in the vaccine dose (as disclosed in the package insert, the Pink Book’s Appendix B, and/or, for “new” vaccines, the pre-approval information that has been submitted by the vaccine maker to the FDA) and, when a similar vaccine is made by another producer, look at how the information provided differs from other similar vaccines.
- Read the independent vaccine/vaccination review information such as this article, and
- Study:
  - the risk of contracting the disease;
  - the nutrition factors that, when deficient, can increase the risk of serious complications or, when optimal, reduce the risk of serious infection;
  - the optimum age range for natural infection;
  - the age threshold, if any, for serious complications from each childhood disease; and
  - the holistic, natural remedies that are disease protective or can aid recovery from a given disease.

The Long-Term Health Effects of Vaccination

“Vaccines protect children’s health and the health of our communities overall.”

Unfortunately, when pro-vaccination propaganda and distortions are removed from the historical record, the general reality is that vaccines do not protect the overall health of our children or our communities.

As this reviewer has shown, when the theoretical “benefits” of vaccination

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60 Though the proponents of vaccination tend to minimize or ignore these realities, the ‘benefits’ include, but are not limited to, the lack of long-term immunity to all who are vaccinated as the CDC recommends, the failure to provide any disease protection for 5% to 20% or more of those vaccinated, the negatives of vaccines that simply postpone
are independently assessed, the reality is that many of today’s vaccination pro-
grams in the USA are not even cost effective.

Moreover, collectively, today’s vaccination programs are clearly associated
with the greatly increased incidence of negative chronic medical conditions that
afflict today’s initially healthy, fully vaccinated persons when compared to the
chronic medical conditions observed in initially healthy persons who have not
been vaccinated at all (see footnotes “22” and “49” through “53”).

“Childhood vaccinations save lives.”

Since:
◆ There is no accurate accounting of the children who die as a result of
being vaccinated in the USA and,
◆ In malnourished populations in other countries, some early childhood
vaccination programs have resulted in the deaths of up to half of the
vaccinated children 61,62,
this unqualified claim by the writer is simply one of the unsupported ‘slogans’
that vaccine acolytes and apologists, believers in the power of repetition, use to
ward off their lack of scientifically sound and appropriate evidence that supports
the claim that “[c]hildhood vaccinations save lives”.

Factually, in mostly vaccinated populations in the developed countries, the
current vaccination programs for the childhood communicable diseases have
clearly disrupted natural systems that provide disease immunity and are a major
causal factor in the current epidemics of chronic childhood medical conditions
that were rare or unknown before these vaccination programs were introduced.

Worse, in the developing nations and in the displaced indigenous peoples in
the developed nations, vaccination programs have been shown to often be more
genocidal than beneficial to these peoples' children63.

“-- Gregory Poland, M.D., Vaccine Research Group, Mayo Clinic, Rochester, Minn.”

As reviewed by Paul G. King, PhD, FAME Systems, Lake Hiawatha, NJ.

Acknowledgments

For contributing valuable insights and providing their personal experience-

62 The 3rd edition of Dr. Raymond Obomsawin's treatise, UNIVERSAL IMMUNIZATION Medical Miracle or Masterful Mirage.
63 "The Terror of Pediatric Medicine", first edition e-book by Mark Sircus as downloaded on 21 October 2012 from the
International Medical Veritas Association link: http://publications.imva.info/index.php/the-terror-of-pediatric-medicine-free, "Chapter 2 Unveiling the Nightmare", page 1, right-hand column (in the font color [red] used by the author),
“My final conclusion after forty years or more in this business is that the unofficial policy of the World Health Organisation and the unofficial policy of 'Save the Children's Fund’[1] and almost all those organisations is one of murder and genocide. They want to make it appear as if they are saving these kids, but in actual fact they don't. I am talking of those at the very top. Beneath that level is another level of doctors and health workers, like myself, who don't really understand what they are doing. But I cannot see any other possible explanation: It is murder and it is genocide. …' Dr. Archie Kalokerinos"
based knowledge in various areas, this reviewer thanks Mark R. Geier, MD, PhD, Gary S. Goldman, PhD, and F. Edward Yazbak, MD.

In addition, this reviewer thanks Gary S. Goldman, Melissa R. Troutman, Catherine J. Frompovich, and Susan Kreider for their support, questions, suggestions, corrections and alternative wordings, which have helped this reviewer to finalize this science-based assessment.

About the Writer, Gregory A. Poland, MD

Since, in the article being reviewed, the writer did not provide his background or plainly disclose his inherent conflicts of interest on the subject of vaccination, this reviewer offers the following information taken from the Mayo Clinic’s web site at: http://mayoresearch.mayo.edu/mayo/research/staff/poland_ga.cfm and links thereto concerning Gregory A. Poland, MD (poland.gregory@mayo.edu).

“Summary
Gregory A. Poland, M.D., studies the immunogenetics of vaccine response in adults and children. Dr. Poland and his team within the Vaccine Research Group aim to improve the health of individuals across the world by pursuing challenges posed by infectious diseases and bioterrorism through clinical, laboratory and epidemiologic vaccine research.

The Vaccine Research Group uses immunological testing, including serology, cell-mediated immunity, cell culture and cytokine assays; polymerase chain reaction (PCR) techniques and HLA typing for immunogenetic studies; and high-throughput assays, such as next-generation sequencing, transcriptomics, mass spectrometry and proteomic analysis.

Dr. Poland’s research has been continuously funded by the National Institutes of Health since 1991.

Focus areas
What is “vaccinomics?”

Coined by Dr. Poland and his team in 2007, the term "vaccinomics" refers to the development of personalized vaccines based on the increased understanding of immune response phenotype-genotype information. Through research, Dr. Poland and his team aim to explain how vaccine-induced immune responses and vaccine-related adverse events may be genetically determined — and therefore predictable.

Active projects:

✓ Influenza A and H1N1. This project will provide novel information describing how immune responses to inactivated influenza A and H1N1 vaccine are generated, particularly in older adults. This information is useful in designing new vaccines to control this deadly viral disease.

✓ Rubella. This project will develop comprehensive information on the contribution and influence of genetic variants on rubella vaccine-induced immune responses. These data will support a novel paradigm enabling the design of new rubella vaccines to protect public health and could also be used to inform vaccine development against other viral infections.

✓ Measles. This project focuses on genes that influence and determine the human immune response to the measles vaccine. This knowledge will allow a better understanding of how measles immunity develops after vaccination and why a range of immune responses occur.

✓ Smallpox. This project will focus on identifying individual genetic risk factors, enlarging our understanding of immune mechanisms, and defining biomarkers of risk and immunity that can assist in optimizing the development of new vaccines, diagnostic tests and therapeutics to protect humans
Significance to patient care

Data gleaned from Dr. Poland's research enable the design of new measles, rubella, mumps, smallpox and influenza vaccines to protect public health and could also be used to inform vaccine development against other viral infections.

Professional highlights

- Recipient, Research Career Achievement Award, Department of Medicine, Mayo Clinic, 2011
- Recipient, MERIT Award, National Institutes of Health, 2011
- Editor-in-Chief, Vaccine, 2010-present
- Founder and President, Edward Jenner Society, 2010-present
- Recipient, Secretary of Defense Award for Excellence, 2008
- First Recipient, Hsu-Li Distinguished Lectureship in International Epidemiology, Department of Epidemiology, University of Iowa, 2007
- Recipient, Charles Merieux Lifetime Achievement Award in Vaccinology, 2006
- Mary Lowell Leary Professor in Medicine, Mayo Clinic, 2004
- Recipient, Secretary of Defense Medal for Outstanding Public Service, 2003

Recent publications


Education

Post-Grad – Course work in Clinical Trials, Statistics, Research Design, Epidemiology and Molecular Biology
   Mayo Graduate School, College of Medicine, Mayo Clinic

Chief Resident – Department of Internal Medicine; Internal Medicine Chief Resident
   Abbott-Northwestern Hospital

Fellowship – Internal Medicine
   Abbott-Northwestern Hospital

Post-Grad – Department of Internal Medicine; Includes 12 months advanced training in Infectious Diseases
   University of Minnesota/Abbott-Northwestern Hospital

Post-Grad – Department of Physical Medicine and Rehabilitation
   University of Minnesota

M.D.
   School of Medicine, Southern Illinois University, Springfield

B.A. – Biology; Magna Cum Laude
   Illinois Wesleyan University

About this Reviewer, 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, 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/).

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

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.

In addition, 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 64.

Though, as a scientist, Dr. King is neither anti-vaccine nor anti-vaccination per se, his research into the “safety” and “effectiveness” of most of the vaccines given to our children and his religious beliefs compel him to reject the current prophylactic vaccines and vaccination programs because they are false gods that do not provide the disease “immunity” that they are purported to supply.