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Introduction

Following this page is this reviewer's assessment of "**Vaccines are effective, save many lives**" by Dr. Julie Lyons, which was downloaded on February 5, 2012 from the online publication at http://www.mtexpress.com/index2.php?ID=2005140580.

This assessment, titled "A Review of '**Vaccines are effective, save many lives**'", begins on the next page.

Introductory Remarks

First, to "simplify" this review, when portions of the article, *which are quoted in the original "Georgia" font*, that are being evaluated are specifically addressed in this review, those portions will be quoted in an *italicized* "*Georgia*" font.

Second, this reviewer's assessments are written in a "Franklin Book Gothic" font, follow each quoted portion of the article, and are indented to clearly separate the review remarks from the preceding portion of the document that is being addressed.

Third, when other sources are quoted, 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 review.

Respectfully,

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[To whom all responses should be directed]

[a] To qualify, the study should be published by researchers who have no 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 actively promote inoculation programs using vaccines.

A Review of Julie Lyons' "Vaccines are effective, save many lives"

Overall, the document that is being reviewed is an 'opinion' article in which the writer strives to convince the reader of what seem to be the writer's unsubstantiated *belief*s about vaccines and the unqualified outcome of their use, "*save many lives*".

In assessing each portion of the writer's narrative, this reviewer strives to weigh the accuracy of the assertions made by the writer and, where needed, provide the independent evidence that supports, or refutes, the validity of the writer's remarks.

This reviewer hopes that the writer and any other reader of this assessment will find the information provided both thought provocative and educational.

In addition, this reviewer hopes that, as an article he once read did for him, this review will encourage the reader to study and assess the truth behind what this reviewer presents for him- or her- self.

The reviewer has this hope because he understands that each vaccination is a life-altering, non-reversible reality for the recipient as well as for those who care for, or about, that recipient.

With the preceding remarks as this review's foundation, the reviewer now turns to assessing each portion of the writer's statements.

"Whether or not to vaccinate your child has become an emotional topic over the past several years. Media reports that vaccinations are dangerous are widespread, and it's difficult to sort through the vast amount of information out there and figure out what's truth and what's fiction. Furthermore, it can be daunting when you arrive at the doctor's office and find out that your baby needs five shots for her routine checkup."

In general, this reviewer agrees with the preceding statements made by the writer, "*Dr. Julie Lyons*".

"I approach the topic of vaccines as a scientist: How do they work, are they effective, are they safe and how do we know?"

Here, the writer begins by making an assertion, "*I approach the topic of vaccines as a scientist*", which, if true, would indicate that the writer has some graduate-level degree in a hard science or, at a minimum, a Bachelor's degree in biology or chemistry with course work in immunology, or, failing that, the writer spends many tens of hours each month in studying immunology, vaccines and vaccination issues.

However, the rest of the writer's statement, "*How do they work, are they effective, are they safe and how do we know?*", indicates that her approach is apparently more that of the questioning 'philosopher' than that of the scientist who, by definition uses the scientific method and would ask more fundamental questions, such as , "How exactly does the healthy immune system function?" and "How does a given vaccine work in harmony with the immune system to provide its protection?".

"Children are born with a full immune system."

At best, the writer begins by making a knowingly[1] misleading statement.

This is the case because the neonate is born with an undeveloped (or 'empty') immune system that is intended to develop "naturally" over a period of years.[2]

In nature, the human newborn is initially protected from disease by the immune factors and disease-inhibitors in his or her mother's initial 'yellow milk' (colostrum) followed by her breast milk, which 'nature' expects will provide the child's principal source of nourishment for 2 to 5 years provided the nursing mother is healthy, drinks adequate quantities of clean water, and has a dietary intake that is sufficiently rich in good fats, protein, complex carbohydrates, crucial vitamins and minerals, and other nutrients to support generating the requisite quantities of healthy breast milk.

"When an unknown bacteria or virus is discovered by the immune system, the body produces antibodies to help protect against future invasions by the same invader."

Here, the writer either is again being intentionally misleading or, *though the writer should have this knowledge*, does not understand how the human immune system seems to function.[3]

"The human body is capable of making thousands of antibodies. Vaccines are dead or greatly weakened parts of viruses or bacteria."

While this reviewer agrees that the "natural" human body is "*capable of making thousands of antibodies*", this reviewer is not aware of any studies that show that the human body actually makes multiple thousands of different antibodies because many attempts at 'infection' are handled by the immune system's innate immunity components that do not require the generation of disease-entity-specific antibodies.

In addition, the healthy, vitamin-D-3 sufficient[4] human body makes its own antibiotics (targeted antimicrobial peptides)[5] that, if effective, may limit the body's need to produce disease-agent-specific antibodies.

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1 Used in the context that a medical doctor with a board certification in 'Family Practice' knows, should know or is responsible for knowing that the human immune system of a neonate is not "*born with a full immune system*." Thus, any statement that is at odds with the facts is a knowingly false statement. [See, for example, http://legal-dictionary.thefreedictionary.com/Knowingly, "Consciously; willfully; subject to complete understanding of the facts or circumstances" and **21 U.S.C. Section 321(bb)**, "*(bb) The term 'knowingly' or 'knew' means that a person, with respect to information -*
(1) has actual knowledge of the information, or
(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information"]

2 http://www.ehow.com/about_5312356_development-immune-system-children.html, "**Development of the Immune System in Children**", which presents a layperson-level discussion of the development of the human immune system in children that clearly refutes the writer's false "*Children are born with a full immune system*" assertion.

3 See, for example, http://repro-med.net/repro-med-site2/index.php?option=com_content&view=article&id=27:an-introduction-to-the-immune-system&catid=11:about-the-program&Itemid=37, "**An Introduction to the Immune System**", which presents a reasonably accurate overview of the general human innate and adaptive immune-system functions from the viewpoint of a physician involved in aiding human reproduction.

4 Currently, a "healthy' level of vitamin "D-3" translates to a blood level of 25-hydroxy-vitamin D that exceeds 65 nanogram (ng) per milliliter (mL) or 133 nanomole (nM)/liter (L) with a probable upper limit for healthy humans that does not exceed 150 ng/mL or 375 nm/L, although current mainstream medical thinking sets 50 – 80 ng/mL (125 – 200 nm/L) as the healthy range [http://www.vitamindcouncil.org/about-vitamin-d/vitamin-d-deficiency/am-i-vitamin-d-deficient/]

5 Liu PT, Stenger S, Li H, Wenzel L, Tan BH, Krutzik SR, Ochoa MT, Schauber J, Wu K, Meinken C, Kamen DL, Wagner M, Bals R, Steinmeyer A, Zugel U, Gallo RL, Eisenberg D, Hewison M, Hollis BW, Adams JS, Bloom BR, Modlin RLToll-like

Lastly, the mucosal immune system, which has the highest level of the most antigen exposures, is fundamentally an immunosuppressive component of the human immune system that tends to suppress the production of antibodies.[6]

With respect to the writer's assertion that vaccines are "*dead or greatly weakened parts of viruses or bacteria*", the reviewer again observes that this statement is not factually accurate.

Vaccines that contain live weakened viruses (e.g., the MMR II, and Varivax vaccines) are not "*dead or greatly weakened parts of viruses*"; similarly, MedImmune's FluMist® seasonal live-influenza vaccine, which contains 3 bioengineered ['cold-adapted'] strains of influenza, and Merck's RotaTeq® live-rotavirus vaccine, which contains 5 bioengineered human-bovine hybridized strains of rotavirus are examples of vaccines that contain live, infective bioengineered strains of pathogenic (disease causing) viruses.

In the case of those vaccines that do not contain live viruses, the actives are much more complex and range from: **a)** "simple" inactivated toxins (toxoids) (e.g., the diphtheria and/or tetanus toxoids in the diphtheria-tetanus (DT) vaccines, the Td vaccines, and TT vaccines, where the diphtheria and/or tetanus toxoids are usually absorbed onto an aluminum adjuvant, and **b)** 'purified' cellular components (currently those vaccines that contain acellular pertussis components [the "…aP" and "…ap" vaccines – DTaP and Tdap] to: **c)** cell-surface polysaccharide components from one or more strains of the disease agent (e.g., Sanofi's Menomune® A, C, Y, W-135 meningococcal meningitis vaccine); **d)** cell-surface polysaccharides conjugated to a toxoid (e.g., Sanofi's Menactra® A, C, Y, W-135 meningococcal meningitis vaccine where the polysaccharides are conjugated to the diphtheria (D) toxoid; **e)** the bioengineered vaccines where a yeast is genetically engineered to produce a key part of the outer capsule of a virus (e.g., hepatitis B and certain human papilloma viruses), the viral-related particles are collected along with some yeast, purified and co-precipitated with an adjuvant to form the final active [e.g., Merck's Recombivax HB® Hepatitis B Vaccine (Recombinant), which is a non-infectious subunit viral vaccine derived from hepatitis B surface antigen (HBsAg) produced in yeast cells, and Merck's Gardasil® Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18)

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receptor triggering of a vitamin D-mediated human antimicrobial response. ***Science*** 2006 Mar 24; **311**(5768): 1770–1773.

6 See, http://pediatrics.aappublications.org/content/111/Supplement_3/1595.full, Mayer, Lloyd. Mucosal Immunity ***Pediatrics*** 2003 Jun; **111**(suppl 3): "The mucosal immune system is recognized by differences from its systemic counterpart. In many ways, it is the opposite of what might be viewed as systemic immunity, suppression rather than active immune responses. It is thought that this difference reflects the distinct challenges of each system: the mucosa directly exposed to the external environment and taxed with antigenic loads consisting of commensal bacteria, dietary antigens, and viruses at far greater quantities on a daily basis than the systemic immune system sees in a lifetime. It is recognized that the mucosal immune response is also distinct, largely focused on suppressing immunity rather than promoting it.[1–4] The mucosal immune system uses a number of mechanisms to protect the host against an aggressive immune response to luminal constituents.

These include a strong physical barrier; the presence of luminal enzymes that alter the nature of the antigen itself; the presence of specific regulatory T cells in both the organized and disorganized lymphoid tissue of the gut; and the production of an antibody, secretory immunoglobulin A (sIgA), which is highly suited for the hostile environment of the gut (Fig 1). All of these in concert eventuate in the immunosuppressed tone of the gastrointestinal (GI) tract.

1. Mayer L. Review article: local and systemic regulation of mucosal immunity. ***Aliment Pharmacol Ther***.1997; **11**(suppl 3): 81– 88.
2. Mayer L. Mucosal immunity and gastrointestinal antigen processing. ***J Pediatr Gastroenterol Nutr.***2000; **30**(suppl): S4– S12.
3. Elson CO. Induction and control of the gastrointestinal immune system. ***Scand J Gastroenterol Suppl*** 1985; **114** :1– 15.
4. Nagler-Anderson C, Shi HN. Peripheral nonresponsiveness to orally administered soluble protein antigens. **Crit Rev Immunol** 2001; **21**(1–3): 121– 131"

Vaccine, Recombinant, which is a non-infectious recombinant quadrivalent vaccine prepared from the purified virus-like particles (VLPs) of the major capsid (L1) protein of HPV Types 6, 11, 16, and 18, where the L1 proteins are produced by separate fermentations in recombinant *Saccharomyces cerevisiae* (a yeast) and self-assembled into VLPs; the VLPs are released from the yeast cells by cell disruption and purified by a series of chemical and physical methods; and the purified VLPs are adsorbed on a preformed aluminum-containing adjuvant (amorphous aluminum hydroxyphosphate Sulfate)].

Hopefully, after reading the preceding, even the writer will realize and accept the fact that the writer's statement here is not accurate.

"When your child gets a vaccine, the body makes antibodies, so that if your child is exposed to the virus or bacteria at a later date, the body can fight it before getting sick. Through vaccines, your child becomes protected from the disease without ever getting the illness."

Again, the writer's statements are misleading and, at best, an over simplification of the processes involved in the body's making antibodies as well as a knowing distortion of the outcomes of inoculation with a vaccine because some percentage of those inoculated either develop no antibodies or an antibody level that is not thought to be sufficient to provide any subsequent protection from the disease if the inoculees is exposed to that disease and a few develop abnormally high levels of antibodies, where these high levels are indicative of immune-system malfunction.

Moreover, for some diseases, even having a level of antibodies that should provide protection from contracting a clinical case of a given disease, when exposed, some children may still contract the disease.

However, for live-virus vaccines, the writer's claim of protection "*from the disease without ever getting the illness*" is also knowingly false.

Actually, for live-virus vaccines, the person inoculated, at best, appears to be protected for a limited time without contracting a severe clinical case of the disease.

For live-virus vaccines that are delivered by injection (a mode of exposure that differs from the disease-exposure route), the child usually has a subclinical infection but may develop the full disease (e.g., atypical measles after a measles-containing vaccine or a full-body rash after the Varivax vaccine) or rarely have one of the serious complications associated with the live-virus' disease (e.g., for Varivax, "*Body as a Whole*: Anaphylaxis in individuals with or without an allergic history; *Hemic and Lymphatic System*: Thrombocytopenia; *Nervous/Psychiatric*: Encephalitis; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; non-febrile seizures; dizziness; and paresthesia; *Respiratory*: Pharyngitis; and *Skin*: Stevens-Johnson syndrome; erythema multiforme; Henoch-Schänlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; herpes zoster")

In addition, some percentages of those inoculated with live-virus vaccines by injection do shed sufficient live-virus quantities to be contagious and infect others.

For those live-virus vaccines that are delivered nasally (e.g., the MedImmune FluMist®, trivalent live influenza-virus vaccine) or orally (e.g., the Merck RotaTeq® live recombinant 5-strain rotavirus vaccine) not only does everyone develop some level of

actively shedding viral infection, but there is also a period where the shedding can infect others and the infections may be as serious as, or more serious than, contracting the disease "naturally" could have been.

Worse, in the case of FluMist, the bioengineered influenza viruses may invade the brain with lethal results – when there is a 'rare' defect (for which there is no 'routine' check) in the tissue seal where the olfactory nerves enter the brain.

In the case of RotaTeq, in the Phase III clinical trials, there were 3 times as many cases of severe potentially life-threatening bowel twisting (intussusception) in the inoculated group as compared to the control group, but this was presented as not being "statistically significant" because the trial did not test sufficient subjects.

In addition, because RotaTeq is a genetically engineered mixture of 5 human-bovine hybridized viruses, not only can shedding infect other children who have not been previously exposed to any rotavirus but also shedding can infect and has infected adults who, supposedly by 5 years of age, had previously had a rotavirus infection and recovered, possibly because the bioengineered rotavirus strains are sufficiently different from the human rotavirus strains – including tertiary transmission in which the shed viruses from an inoculated child infect a 'playmate' who then, in turn, infect that playmate's care givers, who are not careful enough when changing the diaper of the child with the secondary infection.

Turning to the other types of vaccines, with respect to the inactivated influenza vaccines, this reviewer notices that the interim abnormal weakening of the vaccinee's overall immune systems after vaccination can result, and has resulted, in the person's contracting a "cold" or a non-covered strain of the "flu" shortly after vaccination.

Since, *for some of the vaccine-covered diseases*, the circulating levels of disease organisms are low and/or the exposure risk is low (e.g., *Corynebacterium diphtheriae* and. *Clostridium tetani,* which, *because they are facultative anaerobes*, usually only exists in the spore form in the general oxygenated environment in which we live) or the disease is generally very mild (e.g., the polio viruses), or the infectivity of the disease organism is so very low, if it exists, that the post-vaccination rate of infection escapes notice (e.g., *Neisseria meningitidis: where 10-15% of the population carries it, but today less than 1 in 100,000 have a clinical infection*).

Thus, the reality is that, after inoculation: **1)** only some percentage of those inoculated with a vaccine are protected (based on antibody titer, the Establishment's claimed antibody-level-based protection percentages (the vaccine 'efficacies') range from < 60% (e.g., influenza) to ≤ 96% (e.g., measles); and **2)** the Establishment claims the protection provided lasts from "1" season (e.g., the influenza vaccines) to "3 years" (e.g., the pertussis [whooping cough] components of the DTaP and Tdap vaccines) to "not more than 5 years (e.g., the meningococcal meningitis vaccine and the human papilloma vaccines) to, *at the high end*, "25 years" (e.g., measles).

Finally, based on how the human immune systems develop after birth and as confirmed by at least one pro-vaccine immunologist, all of the vaccines administered before the child is 12 months beyond his or her full-term delivery date apparently do not provide long-term protection from disease for the many does of vaccines given to

the child (e.g., the measles vaccination protection-failure risk in young children[7])

Yet, the CDC's current vaccination recommendations for young children under the age of 1 year of age include:

Vaccine	**Mass Inoculation At Months** (starting before 15 months)		
Hepatitis B	Dose1: "0"	Dose2: 1-2	Dose3: 6–18
Rotavirus	Dose1: 2	Dose2: 4	Dose3: 6
Diphtheria, tetanus, pertussis	Dose1: 2	Dose2: 4	Dose3 : 6
Haemophilus influenzae type b	Dose1: 2	Dose2: 4	Dose3 : 6
Pneumococcal	Dose1: 2	Dose2: 4	Dose3 : 6
Inactivated poliovirus	Dose1: 2	Dose2: 4	Dose3 : 6–18
Influenza	Dose1: 6	Dose2: 7	
Measles, mumps, rubella	Dose1 : 12–18		
Varicella	Dose1 : 12–18		
Hepatitis A	Dose1 : 12–23		

Were all vaccination to be postponed until the child was beyond 12 months of post-partum developmental age, the mass-vaccinated child would avoid the equivalent of about 18 vaccination events; the rotavirus inoculations would be eliminated and, because of interference factors, after the MMR II and Varicella vaccines were given at 15 months, instead of 12 months, no other vaccines would be given until after the child is 27 months of age, which would be no problem for the flu vaccine[8] or, in the USA, the rotavirus vaccine.[9]

Given zero ("0") notifiable cases of diphtheria in young children in the USA and a "near zero" cases of tetanus in young children and the availability of antisera and antibiotics for both in the USA, there seems to be no medical need for a diphtheria or tetanus mass vaccination program in children or, for diphtheria, even in adults.

Further, since the pertussis vaccination program is not truly in-use effective in preventing cases of "whooping cough" and related coughing diseases in the population of the USA and vaccination provides much–shorter-duration protection (ca. 3 years) than having the disease and recovering from it (greater than 10 years), encouraging mass breastfeeding for 2 years and postponing this program until the children are older should be pursued provided the resulting later-childhood program

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7 See, for example, http://www.nvic.org/vaccines-and-diseases/MMR.aspx, "In the national outbreak of measles during the late 1980's and early 1990's, it also became apparent that children who had been vaccinated before 15 months of age were also at risk for vaccine failure, especially if their mothers had recovered naturally from measles disease as children. An MMR vaccine manufacturer states "Infants who are less than 15 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin, the younger the infant, the lower the likelihood of seroconversion." The manufacturer goes on to advise that infants vaccinated at less than 12 months of age will have to be revaccinated after 15 months of age even though "there is some evidence to suggest that infants immunized at less than one year of age may not develop sustained antibody levels when later immunized."

The measles outbreaks in the late 1980's and early 1990's in the U.S. also demonstrated that babies, whose young vaccinated mothers had never naturally recovered from measles infection as children, were vulnerable to measles infection from birth. The young vaccinated mothers did not have natural maternal antibodies to transfer to their newborns to protect them from measles in the first year of life. In the 1989-91 measles outbreak in the U.S., the largest increase in measles cases was in infants under one year old."

8 There is growing evidence that giving influenza vaccines before a child is 2 years (24 months) of age provides no protection to the child. [See, for example, Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. ***Lancet*** 2005; **365**: 773-780.]

9 Tucker AW, Haddix AC, Bresee JS, Holman RC, Parashar UD, Glass RI. Cost-effectiveness Analysis of a Rotavirus Immunization Program for the United States. ***JAMA*** 1998; **279**(17): 1371-1376 – from the "COMMENT" section of page 1375, column 1, which clearly indicates that the incidence of rotavirus was on the decline in 1998 and, for medical-cost-effectiveness projections, the vaccine should be priced less than $ 9.00 per dose presuming that the trend toward reduced hospitalizations did not continue.

for "whooping cough" were to be found medically cost-effective.

"Vaccines are clearly effective. They have saved the lives of millions of children around the world. Because of vaccinations, we rarely see polio, tetanus, pertussis (whooping cough), measles, mumps and even chicken pox in children anymore. Rates of hospitalization in children have dropped dramatically in the past 20 years because of the use of vaccines. That being said, they are not always 100 percent effective in every child. Many vaccines require two to three rounds before they protect your child from disease. Usually, though, if your child does get sick, it's a less serious version of the disease. We see this with the chicken pox and zoster vaccines."

Though this writer states, "*Vaccines are clearly effective. They have saved the lives of millions of children around the world*", the writer provides no data to support this assertion.

That there is an apparent correlation between the decline in disease and the increase in vaccination is a fact but there is a greater correlation with better living conditions and this decline in the level of fatal disease incidence in the USA.

However, as the pro-vaccine apologists are fond of saying, "correlation is not proof of causation".

Further, although it is true that "*we rarely see polio, tetanus, pertussis (whooping cough), measles, mumps and even chicken pox in children anymore*", it is also true that, *in childhood*, we see asthma and COPD, ADHD, diabetes, cancers and leukemias, chronic gastrointestinal disorders, obesity, and other chronic developmental and behavioral conditions at epidemic[10] and near epidemic levels, when, before the 1930s, these conditions were rare (<1 in 10,000) and/or unknown.

With respect to the writer's claim, "*Rates of hospitalization in children have dropped dramatically in the past 20 years because of the use of vaccines*", this writer observes that this writer provides no references to substantiate her claim and does not limit her assertion to childhood diseases for which there is a vaccine.

In addition, the rates of hospitalization and emergency department utilization for children with serious chronic medical conditions[11] and behavioral (psychiatric[12]) disorders seem to have more than offset any decline from the decrease in diseases for which there is a mass vaccination program.

Further, without any substantiation or qualification, the writer states, "*That being said, they are not always 100 percent effective in every child. Many vaccines require two to three rounds before they protect your child from disease*" which first misrepresents the reality that, no matter how many "rounds" some receive, they do not all develop and maintain "protective" levels of the expected antibodies.

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10 Since the early 1950s, when "paralytic polio" cases, where the paralysis lasted for at least 24 hours, were occurring at the level of 1 in 3,000 people, public health officials declared that level of "paralytic polio" to be an epidemic level, this reviewer has elected to accept that level as the threshold for an epidemic level. Yet, today, we have childhood asthma at levels greater than 1 in 10 and public health officials are not only not expressing any real concern about this disease level but also not even calling it an epidemic.

11 See, for example, http://www.pulsus.com/cps2005/abs/91.htm (childhood type I diabetes 1995-2008) and http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4941a1.htm (childhood asthma 1987-1998).

12 See, for example, http://commcgi.cc.stonybrook.edu/am2/publish/Medical_Center_Health_Care_4/SBU_RESEARCHER_REPORTS_MAJOR_INCREASE_IN_HOSPITALIZATION_RATES_FOR_CHILDREN_ADOLESCENTS_WITH_PSYCHIATRIC_DISORDERS.shtml.

Moreover, the requirement of multiple rounds in vaccines given before a child is two years of age testifies to the reality that vaccinations given while the human immune system is rapidly developing: **a)** do not provide long-term protection (lasting levels of "disease protective" antibodies) in many, if not most all, children, and **b)** tend to increase the risk for allergic and other immune and autoimmune conditions in the children given vaccines during that period.

After all, if one wanted to protect a child from becoming infected by the child's mother's hepatitis B infection at birth, anti-hepatitis-B immune globulin would be given and not a dose of the hepatitis B vaccine, which is actually given in an apparent attempt to have the infant's immune system accept the vaccine ingredients as part of the "inner immune self" of the newborn in order to reduce the developing child's subsequent risk of childhood MS when the child is subsequently vaccinated against hepatitis B and/or to reduce the risk of other immune/autoimmune disorders associated with the aluminum adjuvants or the other components that are present in the hepatitis B or in many other vaccines.

Factually, the birth dose of a hepatitis-B vaccine does not appear to translate into any long-term protective level of anti-hepatitis-B antibodies.[13]

Furthermore, the influenza vaccines are not in-use effective[14,15,16] and, for Sanofi's Menactra®, meningococcal meningitis vaccine, *which has never been tested for effectiveness*, the clinical trial data in the package insert reported estimated initial ("28-day"), antibody-level-based mean *efficacies* in children of "88%" for the "Y" strain; "73%" for the "A" strain and "63%" for the "C" and "W-135" strains.[17].

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13 Petersen KM, Bulkow LR, McMahon BJ, Zanis C, Getty M, Peters H, Parkinson AJ. Duration of hepatitis B immunity in low risk children receiving hepatitis B vaccinations from birth. ***Pediatr Infect Dis J*** 2004 Jul; **23**(7): 650-655, where the abstract concludes with (emphasis added), "Anti-HBs disappeared by 5 years of age in most children who were vaccinated with hepatitis B vaccine from birth. Although most children showed immunologic memory, one-third failed to demonstrate an anamnestic response to a booster dose. Additional long term studies of low risk infants are needed to determine duration of protection and the necessity for or timing of booster doses" but apparently the public-health establishment, seeing these findings, elected to do no follow-up studies. This seems to indicate that at least one-third of the children vaccinated with the current "recombinant" hepatitis B vaccines at birth , 2 months and 6 months have no long-term protection from hepatitis B infection when subsequently exposed to the disease after the age of 7 years and the remaining two-thirds may not be protected if exposed to the hepatitis B virus.

14 Geier DA, King PG, Geier MR. Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations. ***J Am Physi Surg*** 2006 Fall; **11**(3): 69-74.

15 Jefferson T. Influenza vaccination: policy versus evidence. ***BMJ*** 2006 Oct; **333**: 912-915.

16 Emborg H-D, Krause TG, Hviid S, Simonsen J, Mølbak K. Effectiveness of vaccine against pandemic influenza A/H1N1 among people with underlying chronic diseases: cohort study, Denmark, 2009-10. ***BMJ*** 2011; **344**: d7901 doi: 10.1136/bmj.d7901 (Published 25 January 2012).

17 Package insert for Menactra (sanofi pasteur 15 May 2009 v3 284 Menactra® LE5748-9) [available from fda.gov in a FDA file descriptor ending with: _UCM131170.pdf], page 5, (emphasis added and formatting modified):

"Table 1: Comparison of Bactericidal Antibody Responses* to Menactra vaccine and Menomune–A/C/Y/W-135 vaccine 28 Days After Vaccination for a Subset of Participants Aged 2–3 Years

		Menactra vaccine N‡ = 48-52		Menomune–A/C/Y/W-135 vaccine N‡ = 50-53	
Serogroup			(95% CI)§		(95% CI)§
A	% ≥1:8†	73	59,84	64	50,77
C	% ≥1:8†	63	48,76	38	25,53
Y	% ≥1:8†	88	75,95	73	59,84
W-135	% ≥1:8†	63	47,76	33	20,47

* Serum Bactericidal Assay with an exogenous human complement (SBA-H) source.

† The proportion of participants achieving at least an SBA-H titer of 1:8 was assessed using a 10% non-inferiority margin and a one-sided Type I error rate of 0.025.

‡ N = Number of subset participants with at least one valid serology result at Day 0 and Day 28.

§ The 95% CI for the Geometric Mean Titer (GMT) was calculated based on an approximation to the normal distribution.

Thus, the writer's claim of *effectiveness*, not efficacy, "*Vaccines are clearly effective*", is clearly at odds with factual reality for some vaccines and purely speculative for other vaccines where their in-use effectiveness has not even been studied, much less proven.

Moreover, the writer's assertion, "*they are not always 100 percent effective in every child*", is more rhetoric than substance because it obscures two (2) realities: **1)** as a group vaccines are not effective in a large percentage of the children inoculated with them; and **2)** some vaccines are simply not in-use effective at all in children, adults or the elderly.

Finally, this writer states, "*Usually, though, if your child does get sick, it's a less serious version of the disease. We see this with the chicken pox and zoster vaccines*", but again provides no comparative study to substantiate the "*less serious version of the disease*" claim.

This reviewer understands that, *even if untrue*, this claim would be made because, *having failed to protect the "fully vaccinated" child from contracting the disease as the public-health establishment claims the vaccinations given will do*, the "healthcare" providers are compelled to claim some residual benefit from vaccination although none may exist *especially* because this benefit cannot be disproven.

After all, there is no way to uninfect and then unvaccinate the vaccinated child who has contracted a vaccine-covered disease; and then reinfect that child with the same disease organism so that the severity of the first infection following vaccination can be compared to the severity of the disease before vaccination.

"The most common question I get from parents is, 'Are vaccines safe?' In general, vaccines are extremely safe. Vaccines undergo testing for 10 years or more before they are made public. Once in use, vaccines are continually monitored for safety and effectiveness. However, like any medication, vaccines can cause side effects. The most common side effects are fever or soreness at the sight of the shot. Severe reactions are possible, but are very uncommon."

With respect to the writer's, "*In general, vaccines are extremely safe*", response to the parents question, "*'Are vaccines safe?'*", this reviewer finds the writer's response to be, at best, disingenuous.

This is the case because, when asking this, the parents' question really is, "Are the vaccines you are proposing to give to my child today safe for my child?"

"*In general*", parents are not concerned about the overall safety of "*vaccines*" but rather are focused on the safety of giving a vaccine or vaccines to the parents' child or children.

Thus, this reviewer must recommend that any parent reading this passage simply discard it as the propaganda that it is.

Returning to the narrative, the writer's "*Vaccines undergo testing for 10 years or more before they are made public*", ignores the reality that the safety "*testing*" performed is not scientifically sound[18] and, *because no in-use effectiveness tests are*

[18] The safety testing is not scientifically sound because fails to use a true placebo [pH-buffered, isotonic sterile saline] as a placebo in each vaccine safety trial. This omission renders that vaccine safety trial scientifically unsound and fatally flawed

performed on 'volunteer' subjects, the testing fails to prove vaccine effectiveness.

Further, the writer is simply mistaken when it comes to **a)** "fast-tracked vaccines (e.g., Merck's Gardasil) or **b)** "emergency" vaccines (e.g., the 2009 A-H1N1 influenza vaccines) because their safety testing periods are respectively: **i)** much less than "*10 years*" or **ii)** abbreviated, non existent, or being performed while the vaccine is being used in a mass vaccination campaign.

Moreover, the clinical trails conducted are <u>not</u> appropriate because the time periods for the observation of the vaccine-related adverse-event responses exhibited by the test subjects are much too short [typically, days or weeks, when they should span months or years or, *for vaccines that claim either long-term or delayed protection*, decades].

With respect to the writer's assertion, "*Once in use, vaccines are continually monitored for safety and effectiveness*", this reviewer finds that the factual historical record appears to diverge from the blanket "*continually monitored for safety and effectiveness*" claim in the following key respects:

1. Today, "*continual*" monitoring is performed by conflicted interests (those who are more concerned with promoting vaccination [the federal government, the vaccine makers, and their grantees and affiliates]). *Rather than take action to protect the public's health and fiscal interests*, they 'hide' the data from the public and usually publish news releases, talking points, and even 'peer-reviewed' articles [which generally, are more propaganda than sound science] that, *for the safety risks seen*, tend to downplay and obscure the vaccine-associated risk seen by claiming that it is: **a)** coincidental (e.g., fainting after an HPV shot), **b)** inconsequential (e.g., adventitious viruses [e.g., SV-40 in polio vaccines] and/or viral DNA fragments [e.g., pieces of the genetically engineered capsid-production-related DNA in the HPV vaccines]) and/or **c)** <u>not</u> greater than some, *usually biased, theoretical or projected* background disease-associated rate that is also associated with an infective vaccine (e.g., intussusception 3-7 days after a rotavirus dose or fetal death following an inactivated-influenza "flu" shot).
2. When "*effectiveness*" monitoring finds that a given mass vaccination program is less effective (typically, expressed as providing protection for a shorter period of time than originally claimed), instead of canceling or modifying the existing vaccination program, additional doses of the original vaccine or a related vaccine are recommended <u>even when</u> the added doses or dose transform(s) the initial mass vaccination program into a program that is <u>not</u> cost-effective.
3. When monitoring unequivocally finds that a given vaccine is: **a)** <u>not</u> safe (e.g., the FDA-approved vaccine for Lyme disease) or **b)** <u>not</u> as safe as a similar vaccine (e.g., the diphtheria, tetanus and whole-cell pertussis [DTwP] vaccines which are much less safe than the diphtheria, tetanus

because the use of either no placebo [the comparative vaccine trial], some other vaccine or experimental vaccine, or some solution that contains the most toxic of the components in the vaccine other than the active(s), obscures the magnitude of the adverse effects observed in the test subjects.

and acellular pertussis [DTaP] vaccines), the vaccines are simply allowed to be withdrawn from the United States (US) market without revocation of their licenses (so that the vaccine manufacturer may continue to make and market the unsafe or less safe vaccines in other countries while 'truthfully' claiming that that said US-withdrawn vaccines are FDA-licensed).

4. When independent studies clearly prove that a given vaccine or vaccine type is in-use ineffective (e.g., the influenza vaccines) [see footnotes "12"-"14"], public health officials and agencies, the vaccine makers and the vaccination providers, *all protected by the National Vaccine Injury Compensation Act of 1986 as amended (**NVICPA; 42 U.S.C. Sections 300aa-1** through **300aa-34**) from being held accountable*, ignore such findings and not only continue their efforts to push these vaccines but also increase the propaganda [including less-than-scientifically-sound publications in peer-reviewed journals] to ensure that the public continues to take these ineffective vaccines.

5. When independent studies clearly prove that, rather than providing protection from disease, the vaccine actually spreads the disease and/or, *when the overall fiscal costs, and physical harm, to the public from the vaccination program are factored in*, the vaccination program is, *at best*, 'ineffectual' (e.g., the childhood and adult vaccination programs for the *Herpes varicella zoster*,[19] the childhood rotavirus vaccination program,[20]

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19 When the chickenpox (Herpes varicella zoster [HVZ) vaccination program was recommended, it was justified on the basis that a single dose given at the time the MMR vaccine is administered would provide long-time protection, there would be no negative cost impacts from adverse reactions to the vaccine or increased recurrence of shingles, and the reduction in parental time off to care for infected children would more than pay for the costs of vaccination and the projected milder disease from the vaccination. As stated in Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP). ***MMWR*** 1996 July 12; **45**(RR11);1-25 (emphasis added):

"Cost Benefit of Vaccine

A recent cost-effectiveness study (96) was performed using current estimates of morbidity and mortality (CDC, unpublished data), mathematical modeling of the projected impact of vaccination (97), and current direct and indirect costs. Unlike a previous study published in 1985 (98), the recent analysis accounted for potential changes in the frequency and severity of varicella-related complications resulting from expected changes in the epidemiology and age distribution of varicella following widespread use of varicella virus vaccine. Additional efficacy data for 1985-1993 were available, and empiric data on medical utilization and costs of work-loss resulting from varicella were used. The results of this study, which were determined using an estimated cost of $35 per dose of vaccine and $5 for vaccine administration, indicated a savings of $5.40 for each dollar spent on routine vaccination of preschool-age children when direct and indirect costs were considered. When only direct medical costs were considered, the benefit-cost ratio was 0.90:1. Benefit-cost ratios were only slightly lower when lower estimates of the short-term and long-term effectiveness of the vaccine were used."

(96) Lieu TA, Cochi SL, Black SB, et al. Cost-effectiveness of a routine varicella vaccination program for U.S. Children. ***JAMA*** 1994; **271**: 375-381.

(97) Halloran ME, Cochi SL, Wharton M, Fehrs L. Theoretical epidemiologic and morbidity effects of routine varicella immunization of preschool children. ***Am J Epidemiol*** 1994; **140**: 81-104.

(98) Preblud SR, Orenstein WA, Koplan JP, Bart KJ, Hinman AR. A benefit-cost analysis of a childhood varicella vaccination programme. ***Postgrad Med J*** 1985; **61**(suppl): 17-22.

Therefore, the recommendations for mass vaccination against chickenpox was only cost effective in a "modeled" system where the costs of administration were significantly underestimated and, apparently, no provision was made to include the costs of adverse reactions to vaccination.

However, by 2006, it was obvious that another dose of HVZ vaccine was needed to provide apparently adequate protection and, even though this would make the chickenpox program cost ineffective, the ACIP recommended a second dose be added to the vaccination program to "reduce" the incidence of "breakthrough" chickenpox and return the percentage of children protected in a highly vaccinated population to the 95-plus percentage level seen initially when most of the population had already had a primary case of chickenpox (see: Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP) ***MMWR*** 2007 June 22; **56**(RR-4): 1-40).

In addition, even after a more concentrated vaccine formulation was licensed and recommended for the older members of the population, estimates indicate that the net annual excess costs from the increased level of re-emergence of HVZ as "shingles" were about $ 700 million in 2004 and increasing based on the realities of inflation (see: Patel MS,

and the childhood vaccination program for hepatitis B[21]), public health officials and agencies, the vaccine makers and the vaccination providers,

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Gebremariam A, Davis MM. Herpes zoster-related hospitalizations and expenditures before and after introduction of the varicella vaccine in the United States. ***Infect Control Hosp Epidemiol***. 2008 Dec; **29**(12): 1157-1163).

Thus, the vaccination program using an attenuated live HVZ virus costs significantly more than it is worth even if the costs engendered by the serious adverse events associated with the approved vaccines Merck's Varivax® and ProQuad® for children and Zostavax® for older Americans are ignored.

20 The rotavirus vaccines' saga is illustrative of the actions taken to "convert" a vaccine type (oral live-virus rotavirus vaccines that infect the gastrointestinal system), which has safety concerns by redefining what "safety" means.

Under **21 CFR Sec. 600.3(p)**, "The word safety means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." Thus, for a vaccine administered as a prophylactic (preventive) measure to healthy children, the vaccine needs to be free from any serious adverse effects because the children are supposed to be healthy (free of disease) when inoculated and, if the vaccine is safe, remain that way after they are inoculated with the vaccine.

When it comes to natural rotavirus infection, according to the United States (US Centers for Disease Control and Prevention (CDC), most children develop immunity to human rotaviruses by the time they are 5 years of age even though most do <u>not</u> develop a clinical infection.

Therefore, when the first rotavirus was introduced in the late 1990s, the definition of "safety" was, as the federal administrative code expects, the freedom from serious adverse-event side effects. On that basis, when reports of intussusception (a very serious, life-threatening and potentially life altering/fatal adverse event) following vaccination started to occur, the RotaShield® rotavirus vaccine produced by then American Home Products' Lederle division (now Pfizer Wyeth Lederle), was rapidly withdrawn from the market because these reports of obviously vaccine-associated intussusception occurring mainly 3-7 days after inoculation.

Thus, for a rotavirus vaccine to have the level of "safety" required to satisfy 21 CFR § 600.3(p), it would have to cause intussusception at a rate *significantly less* (i.e., at a 10 times, or more, lower rate than the rate of intussusception in clinical rotavirus cases) *than* the "natural" disease causes intussusception.

To minimize the chance that a future rotavirus vaccine would be withdrawn, the definition of "safety" was changed to <u>not</u> having a statistically significant increase in intussusception cases over the "background" rate and, to maximize the "background" rate, the clinical trials in the United States of America (USA) were conducted by Merck using children living in American-Indian reservations. When cases of intussusception occurred after inoculation with the candidate vaccine, the vaccine was still approved because, *though the number of cases in the inoculated children was higher than the number in the control group of children*, the excess number was <u>not</u> statistically significant given the size of the trial. Thus, instead of adhering to the definition of safety appropriate to prophylactic biological products, the vaccine makers and the federal officials responsible for approving vaccines again collusively changed the definition of "safety".

To maintain this false definition, most of the subsequent clinical and post-approval studies have used this perverted definition of "safety" to justify approving and/or maintaining the approval of the new rotavirus vaccines, Merck's RotaTeq® and GlaxoSmithKline's Rotarix®. To minimize the fatalities in the USA, increased attention is being given to infants presenting with diarrhea.

Moreover, though live-rotavirus vaccine infect all who are inoculated with them, the pretense was, and is being, made that the inoculated children are <u>not</u> infected <u>unless</u> they have a clinical case of diarrhea with the confirmed presence of vaccine-related antibodies.

Finally, to downplay the risk of infecting others, a "1 in 20" rate of shedding was estimated based on the carefully controlled clinical trials using only healthy children.

Taken together, the twisted definition of safety, the artificially inflated background rates, the artificial rate of infection, and the minimized rate of shedding are used to "advertise" the rotavirus vaccines as "safe" when they are <u>not</u> truly safe.

At least two Independent studies [Geier DA, King PG, Sykes LK, Geier MR. RotaTeq vaccine adverse events and policy considerations. ***Med Sci Monit*** 2008 Mar; **14**(3): PH9-PH16 and Geier DA, King PG, Sykes LK, Geier MR. The temporal relationship between RotaTeq immunization and intussusception adverse events in the Vaccine Adverse Event Reporting System (VAERS). ***Med Sci Monit*** 2012 Feb; **18**(2): PH12-PH17] in which this reviewer is a minor author have clearly shown that the current RotaTeq and, *by inference*, Rotarix rotavirus vaccines are <u>not</u> sufficiently safe (and coupled with an estimate that, to be medically cost effective to use in a mass vaccination program in the USA, these vaccines would have to have a "health care system" cost, *allowing for inflation*, of no more than twice $ 9.00 a dose (or up to twice $ 27.00 for 3 doses in the initial inoculation sequence) [Tucker AW, Haddix AC, Bresee JS, Holman RC, Parashar UD. Cost-effectiveness Analysis of a Rotavirus Immunization Program for the United States. ***JAMA*** 1996 May; **279**(17): 1371-1376]), these vaccines are <u>neither</u> safe <u>nor</u>, *with a current per-dose cost of $72.339 for RotaTeq [$217.017 per 3-dose regimen] and $106.57 [$213.14 per 2-dose regimen] for Rotarix*, medically cost-effective by about a factor of 4.

Finally, the current rotavirus vaccination programs only provide protection to about 75% of those healthy non-breastfeeding children who complete the inoculation sequence and survive and lesser levels of protection to breastfed infants and infants who are less than healthy.

21 <u>See</u>, for example, the abstracts of: **a)** Petersen KM, Bulkow LR, McMahon BJ, Zanis C, Getty M, Peters H, Parkinson AJ. Duration of hepatitis B immunity in low risk children receiving hepatitis B vaccinations from birth. ***Pediatr Infect Dis J.*** 2004 Jul; **23**(7): 650-655, with emphasis added: "CONCLUSIONS: <u>Anti-HBs disappeared by 5 years of age in most children who were</u>

> *all protected by the National Vaccine Injury Compensation Act of 1986 as amended (**NVICPA**; **42 U.S.C. Sections 300aa-1** through **300aa-34**) from being held accountable*, also ignore such findings and not only continue their efforts to push these vaccines but again also increase the propaganda to ensure that the public takes such problematic vaccines.

Furthermore, with respect to the writer's "*Severe reactions are possible, but are very uncommon*", this reviewer simply observes that the writer fails to define the occurrence rate that the writer considers "*very uncommon*" – 1 in 100? 1 in 1,000? 1 in 10,000? 1 in 100,000?

Additionally, the CDC's general rate claims for the 'risk' of a severe adverse event are often about 100 times lower than the real risks (for example, in 2003, the claimed risk for smallpox-inoculation-related death was '1 in a million' but the first responders, *who trustingly accepted the CDC's claim at face value*, refused further inoculation when those initially inoculated experienced a confirmed-vaccine-inoculation-related death rate of about 1 per ten thousand inoculated[22]).

Finally, the overall risk of a severe adverse reaction is of little import to the person who is to be inoculated or whose child is to be inoculated – what that person really wants to know is what is the risk for that person or his or her child.

"Some families worry that vaccines containing mercury and thimerosal can cause autism. Research to prove or disprove a possible relationship between thimerosal and autism is

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vaccinated with hepatitis B vaccine from birth. Although most children showed immunologic memory, one-third failed to demonstrate an anamnestic response to a booster dose. Additional long term studies of low risk infants are needed to determine duration of protection and the necessity for or timing of booster doses"; **b)** Gallagher CM, Goodman MS. Hepatitis B Vaccination of Male Neonates and Autism Diagnosis, NHIS 1997–2002. ***J Toxicol Environ Health, A*** 2010; **73**: 1665-1677, with emphasis added: "Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk"; **c)** Girard M. Autoimmune hazards of hepatitis B vaccine. Autoimmunity Rev 2005; 4: 96– 100, with emphasis added: "Then, a review is made of data suggesting that HBV is remarkable by the frequency, the severity and the variety of its complications, some of them probably related to a mechanism of molecular mimicry leading to demyelinating diseases, and the others reproducing the spectrum of non-hepatic manifestations of natural hepatitis B. To be explained, this unusual spectrum of toxicity requires additional investigations based upon complete release of available data"; **d)** Gallagher C, Goodman M. Hepatitis B triple series vaccine and developmental disability in US children aged 1–9 years. ***Toxicol Environ Chem*** 2008; **90**(5): 997-1008, with emphasis added: "This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys"; and **e)** Hamza H, Cao J, Li X, Zhao S. In vivo study of hepatitis B vaccine effects on inflammation and metabolism gene expression. ***Mol Biol Rep*** 2011 June 21; online: DOI 10.1007/s11033-011-1090-x (9 pages), with emphasis added: "Seven of these genes, which were related to inflammation and metabolism, were chosen and confirmed by quantitative real-time reverse transcription polymerase chain reaction (qRT-PCR) at 1, 4 and 7 days. The expression level of these genes can be considered as a biomarker for the effects of the vaccine".

22 http://www.the-injury-lawyer-directory.com/article_smallpox.html (emphasis added):

"Smallpox Vaccine Injuries and First Responders

The Smallpox Vaccination Program launched in January 2003, with the goal of vaccinating 450,000 first responders against smallpox by the end of February 2003, to protect them in case of bio-terrorism. By the end of March 2003, only about 29,000 first responders had been vaccinated, three people had died from the vaccine and dozens more had suffered adverse reactions.

Because the smallpox vaccinations are voluntary, most first responders are not eligible for worker's compensation claims to cover injuries caused by the vaccine.

On April 16, 2003 congress passed the Smallpox Emergency Compensation Act. Compensation was made available to those who received vaccinations during the period of January 24, 2003 through February 24, 2004 and included: …

The Smallpox Emergency Compensation Act provided compensation for injury, illness, disability, condition or death caused by the vaccine. Compensation included:

- All reasonable and necessary medical care to treat the injury
- Death benefits of either a lump sum payment of $262,100 or, if there are children under the age of 18, up to $50,000 per year
- Permanent and total disability benefits equal to 66 2/3 percent of wages (75 percent in the case of dependents) up to $50,000 per year for life
- Partial disability benefits of up to $262,100, payable at the same rate as permanent disability benefits and capped annually at $50,000 per year

According to the CDC, "in a recent study of adult primary vaccinees, 36% were sufficiently ill to miss work, school, or recreational activities or to have trouble sleeping. …"

ongoing. However, to date, no scientific linkage has been established."

First, while technically true, the writer's initial statement, "*Some families worry that vaccines containing mercury and thimerosal can cause autism*", makes it seem that mercury and Thimerosal are separate 'ingredients' when this is not the case.[23]

Second, the writer's "*no scientific linkage has been established*" remark about the linkage between injected Thimerosal in vaccines and the risk of subsequent neurodevelopmental harm, including autism, is clearly at odds with reality.[24]

"In fact, the original suggestion of autism-associated vaccination came from scientist Andrew Wakefield, whose study of 12 children has been invalidated and disproved by the scientific community. Unfortunately, it started a frenzy of media activity that has placed doubt in the public's mind about the safety of vaccination."

First, the writer is mistaken because the first paper that suggested a link between a vaccine and autism was: Eggers C. [Autistic syndrome (Kanner) and vaccination against smallpox (author's transl)]. ***Klin Padiatr***. 1976 Mar; **188**(2): 172-180, where the translation of the abstract states (emphasis added), "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

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23 Factually, Thimerosal is a trade name for sodium ethylmercurithiosalicylate, a highly toxic organic mercury compound that is a human carcinogen, mutagen, teratogen and immune-system disruptor at levels below 1 ppm (part-per-million; <0.0001%). To date, no toxicologically safe limit for injected Thimerosal has been established for the developing fetus, the developing child or adults. In addition, because most all of the inorganic and organic compounds added to a vaccine formulation contain low levels of inorganic mercury, even vaccines that use no Thimerosal in their manufacture typically end up with "mercury" test levels in the 0.001 to 0.005 ppm range – well below the typical "50" ppm level of mercury in the Thimerosal-preserved vaccines that have been causally linked to the adverse regressive developmental events. However, only the Thimerosal-derived mercury has been linked to adverse neurodevelopmental outcomes – not the very low levels of inorganic mercury from the vaccine's other ingredients.

24 In addition to the applicable studies that have been published by Dr. Mark R. Geier and David A. Geier, with whom this reviewer sometimes collaborates, the following are a few of the studies that clearly establish a causal link between injected Thimerosal and various aspects of the developmental harm that it causes and/or the persistence and effects of its metabolites in the body: **a)** Laurente J, Remuzgo F, Ávalos B, Chiquinta J, Ponce B, Avendaño R, Maya L. [Neurotoxic effects of thimerosal at vaccines doses on the encephalon and development in 7 days-old hamsters]. ***An Fac Med (Lima)*** 2007 Sep; **68**(3): 222-237 [Spanish]; **b)** Marques RC, Dórea JG, et a. Hair mercury in breast-fed infants exposed to thimerosal-preserved vaccines. ***European J Pediatrics*** 2007; **166**(9): 935-941; **c)** Minami T, Miyata E, Sakamoto Y, Yamazaki H, Seiji Ichida S. Induction of metallothionein in mouse cerebellum and cerebrum with low-dose thimerosal injection. ***Cell Biol Toxicol 2010***; **26**(2): 143-152; **d)** Rodrigues JL, Serpeloni JM, Batista BL, Souza SS, Barbosa F. Identification and distribution of mercury species in rat tissues following administration of thimerosal or methylmercury. ***Arch Toxicol*** 2010; **84**(11): 891-896; **e)** Olczaka M, Duszczyk M, Mierzejewski P, Meyza K, Majewska MD. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. ***Behavioural Brain Res*** 2011 Sep; **223**(1): 107-118; **f)** Ida-Eto M, Akiko Oyabu A, Ohkawara T, Tashiro Y, Narita N, Narita M. Embryonic exposure to thimerosal, an organomercury compound, causes abnormal early development of serotonergic neurons. ***Neurosci Lett*** 2011 Nov; **505**(2): 61-64; **g)** Shandley K, Austin DW. Ancestry of Pink Disease (Infantile Acrodynia) Identified as a Risk Factor for Autism Spectrum Disorders. ***J Toxicol Environ Health, A*** 2011; **74**(118): 1185-1194; **h)** Sulkowski ZL, Chen T, Midha S, Zavacki AM, Sajdel-Sulkowska EM. Maternal Thimerosal Exposure Results in Aberrant Cerebellar Oxidative Stress, Thyroid Hormone Metabolism, and Motor Behavior in Rat Pups; Sex- and Strain-Dependent Effects. ***Cerebellum*** 2011 Oct 21; online: DOI: 10.1007/s12311-011-0319-5; **i)** Hewitson L, Houser LA, Stott C, Sackett G, Tomko JL, Atwood D, Blue L, White ER. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving A Thimerosal-Containing Hepatitis B Vaccine: Influence of Gestational Age and Birth Weigh. ***J Toxicol Environ Health, A*** 2010; **73**(19): 1298-1313; and **j)** Olczak M, Duszczyk M, Mierzejewski P, Wierzba-Bobrowicz T, Majewska MD. Lasting neuropathological changes in rat brain after intermittent neonatal administration of thimerosal. ***Folia Neuropathol***. 2010; **48**(4): 258-269.

having a starter function for the onset of autism".

Further, the suggestion reported in the case series paper, for which Andrew Wakefield was the lead author in a group of 13 authors, was a connection made by the parents of the patients (not by Andrew Wakefield *per se*) and that connection was between the MMR vaccination their child received and the "pervasive developmental disorder" into which their child subsequently *regressed*, where the neurodevelopmental regression was accompanied their child's serious gastrointestinal distress.

Though the "Wakefield" study, Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. ***Lancet***. 1998 Feb 28; **351**(9103): 637-641, has been removed from the original publishing journal, ***The Lancet***, the scientific community has neither invalidated nor disproved the actual findings in that study.

Some Establishment articles were published claiming that those 'researchers' could not duplicate the original study's findings of vaccine-strain-measles' genetic material in the tissues lining the gut of many of the children studied, but these failed to explicitly duplicate the types of cases and/or the studies reported in the original 'Wakefield' paper.

Factually, the findings in the 1998 Wakefield paper have been substantiated.[25]

"Others might worry that giving too many vaccines might overwhelm the immune system. However, the infant immune system can respond to many antigens simultaneously. Several studies have validated this claim, and it's even safe to give vaccines with a concurrent mild illness."

First, this reviewer agrees that some parents "*worry that giving too many vaccines might overwhelm the immune system*".

However, the writer's second statement, "*the infant immune system can respond to many antigens simultaneously*", is, *in the context of injected vaccines*, either a disingenuous assertion or the undiscerning parroting of the vaccine propaganda endlessly pushed by the Establishment.

Factually, the infant immune[26] system grows from totally undeveloped at birth to fully active by two years of age and the child's immune system has, for thousands of years, been developed to block antigens from entering the body by the outer layers

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25 See, for example: **a)** Wang, LW, Tancredi DJ, Thomas DW. The Prevalence of Gastrointestinal Problems in Children Across the United States With Autism Spectrum Disorders From Families With Multiple Affected Members. ***J Devlop Behav Pediatrics*** 2011 Jun; **32**(5): 351-360; **b)** Pang KH, Hain GD. Croaker Constipation in children with autism and autistic spectrum disorder. ***Pediatric Surg Internat*** 2011; **27**(4): 353-358; **c)** Wasilewska J, Jarocka-Cyrta E, Kaczmarski M. [Gastrointestinal abnormalities in children with autism]. ***Pol Merkur Lekarski***. 2009 Jul; **27**(157): 40-43 [Polish]; **d)** MacDonald TT, Domizio P. Autistic enterocolitis; is it a histopathological entity? ***Histopath*** 2007 Feb; **50**(3):371-379; discussion 380-384; **e)** Ashwood P, Anthony A, Torrente F, Wakefield AJ. Spontaneous mucosal lymphocyte cytokine profiles in children with autism and gastrointestinal symptoms: mucosal immune activation and reduced counter regulatory interleukin-10. ***J Clin Immunol*** 2004 Nov; **24**(6): 664-673; and **f)** Critchfield JW, van Hemert S, Ash M, Mulder L, Ashwood P. The Potential Role of Probiotics in the Management of Childhood Autism Spectrum Disorders. ***Gastroenterol Res Pract*** 2011; 2011: 161358 (online 26 Oct 2011) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205659/.

26 http://www.wellness.com/reference/allergies/newborn-immune-system, a simplified view that begins with:
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of the immune system, the skin, tears, and mucosa that cover the tissues.

Against the preceding realities and recognizing that about "90%" of the human immune system resides on the inner surfaces of the gastrointestinal system and much of the remaining "10%" resides in the mucosa covering the rest of the body's organs, an infant's immune system is better off, if the developing infant is exposed to multiple antigens at any one time, when that exposure is first intercepted by the outer layers of the infant's immune system.

In addition, because: **a)** the natural exposures to antigens are taken in by superficial contamination, inhalation and ingestion, and **b)**, in nature, the infant's initial diet is colostrum followed by breast milk for the first two years that not only provides nourishment but also provides immune support factors and antibodies from the nursing mother,[22] the infant is *naturally* equipped to "handle" concomitant natural exposures to antigens.

However, the preceding ability to handle multiple natural exposures to antigens does not extend to antigens that are artificially injected into the infant because doing so bypasses more than "90%" of the infant's immune system.

Further, when the exposure is made in an abnormal manner, each artificially injected antigen can damage the inner immune systems in a number of ways.

For example, vaccine adjuvants (which 'activate' the macrophagic immune system) and preservatives (which inhibit key biochemical pathways and/or damage the cells' mitochondrial power producing systems) 'poison' various parts of the immune system; disrupt the balance between the various key components in the inner immune systems; and/or decrease the threshold between what the immune recognizes as 'self', which it should preserve, and 'not self', which it is supposed to destroy.

Moreover, based on just the number of vaccine actives given at one time for the interval between 2 and 8 vaccine-type actives at once, the data in the Vaccine Adverse Events Reporting System (VAERS), jointly maintained by the CDC and the FDA, seem to indicate that, *for a given "age"*, both hospitalizations and deaths increase as the number of vaccine actives administered at once increases.[27]

Additionally, there is a growing body of evidence that never vaccinated children are significantly healthier than comparable fully vaccinated children are.[28]

A baby's immune system is not fully developed until he/she is about six months-old. In the meantime, pregnant mothers pass immunoglobulin antibodies from their bloodstream, through the placenta, and to the fetus. These antibodies are an essential part of the fetus's immune system. They identify and bind to harmful substances, such as bacteria, viruses, and fungi that enter the body. This triggers other immune cells to destroy the foreign substance.

Immunoglobulin G (IgG) is the only antibody that crosses the placenta to the fetus during pregnancy. IgG antibodies are the smallest, but most abundant antibodies, making up 75-80% of all the antibodies in the body. They are present in all body fluids and they are considered to be the most important antibodies for fighting against bacterial and viral infections. These antibodies help protect the fetus from developing an infection inside the womb.

Immediately after birth, the newborn has high levels of the mother's antibodies in the bloodstream. Babies who are breastfed continue to receive antibodies via breast milk. Breast milk contains all five types of antibodies, including immunoglobulin A (IgA), immunoglobulin D (IgD), immunoglobulin E (IgE), IgG, and immunoglobulin M (IgM). This is called passive immunity because the mother is "passing" her antibodies to her child. This helps prevent the baby from developing diseases and infections.

During the next several months, the antibodies passed from the mother to the infant steadily decrease. When healthy babies are about two to three months old, the immune system will start producing its own antibodies. During this time, the baby will experience the body's natural low point of antibodies in the bloodstream. This is because the maternal antibodies have decreased, and young children, who are making antibodies for the first time, produce them at a much slower rate than adults.

Once healthy babies reach six months of age, their antibodies are produced at a normal rate."

27 These observations are supported by a private communication from a colleague who has studied this issue at length.

28 See, for example: **a)** Kemp T, Pearce N, Fitzharris P, Crane J, Fergusson D, St George I, Wickens K, Beasley R. Is infant

Thus, the writer's assertions, "*Several studies have validated this claim, and it's even safe to give vaccines with a concurrent mild illness*", are simply the writer's unsubstantiated assertions.

Finally, to risk making a sick child sicker, even one who appears to have a "*mild illness*", by injecting them with agents that, *at least initially*, will further provoke and weaken the child's immune system defies common sense — and serves to underscore the reality that the childhood vaccination program is more concerned about vaccinating on schedule than it is about protecting the health of the child.

"When families come to me with concerns about vaccinations, I try to identify what bothers them the most. Many times, education and answering questions about fears help to alleviate anxiety. Sometimes at a parent's request we will provide alternate schedules to break up the shots. However, this is not necessary, and can lead to increased number of shots and doctor visits."

Here, this reviewer simply notes that he hopes the writer's answers to the families' questions are more accurate than the writer's comments, and that, unlike the writer's remarks in the article being reviewed, those answers are substantiated by scientifically sound and appropriate studies.

Moreover, this reviewer is glad to read that the writer is somewhat open to "*alternative schedule*" to break up the inoculations and observes that the writer's, "*this is not necessary, and can lead to increased number of shots and doctor visits*" starts with an opinion, the writer's; and ends by stating the obvious realities that come with breaking up the "*shots*".

Sadly, the failure of the vaccine makers to provide single-active vaccines for diphtheria, tetanus, and pertussis or for measles, mumps and rubella *conveniently* limits the degree to which an alternate schedule can "*break up the shots*".

"In 2008, Idaho had the lowest vaccination rate in the country at 60 percent. Over the past few years, the state has been making efforts to improve this, and as of 2010, the rate had improved to 70 percent."

Since the writer fails to provide any information about the nature of the specific vaccines that form the basis for the "*60%*" and "*70%*" claims and confuses "*vaccination rate*" with the vaccination level (percentage), this reviewer is compelled to ask:

- "What were the vaccines included in the coverage assessment set in 2008 and 2009?
- "When were these vaccines added to the basis set?"
- "Has the average health of the vaccinated children increased? Decreased? Or remained the same?"

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immunization a risk factor for childhood asthma or allergy? ***Epidemiol***, 1997 Nov; **8**(6): 678-680; **b)** http://www.ias.org.nz/wp-content/uploads/IAS1992study.pdf for the results of a 1992 survey that were finally published in 2005 with the title, "Unvaccinated Children are healthier"; and **c)** http://childhealthsafety.wordpress.com/2011/08/26/new-survey-shows-unvaccinated-children-vastly-healthier-far-lower-rates-of-chronic-conditions-and-autism/ as of August of 2011, last visited 12 Jan 2012.

- "Has the level of disease cases for vaccine-covered diseases decreased? Increased? Or stayed the same?"

"This means that 30 percent of our children are not vaccinated, and therefore are at risk of contracting disease and being hospitalized."

Here, this reviewer finds that the writer's fear-mongering rhetoric is at odds with two (2) realities: **1)** the reported "70%" only means that that percentage of the children in the survey group did not meet the unspecified compliance standard at the time of the survey – the current "vaccination status" of that group of children, the children of the families and individuals who were surveyed, and the children whose parents were not surveyed are not known; and **2)** for the childhood diseases, for which there is a vaccine, most healthy children who get these childhood diseases resolve the 'infection' without being hospitalized.

"Due to increased immigration and intercontinental movement, the diseases we have not seen in years are on the rise, including polio, measles and pertussis."

Here, though the writer fails to specify the region of the country that she is addressing, this reviewer will presume that she is referring to Idaho and notes that the first notified case of paralytic polio in the USA since 2000 was not found in Idaho

Moreover, it was vaccine-strain-related case caused by a secondary infection from a live-virus polio inoculation given to the infected woman's son years before – and that secondary infection caused her paralysis and led to her death, which was reported by the CDC in "Summary of Notifiable Diseases --- United States, 2009" published in ***MMWR*** 2011 May 13; **58**(53): 1-100.

Finally, for a cogent understanding of the actual situation today for measles and pertussis, this reviewer recommends this writer and the interested readers read the pertinent sections of this reviewer's draft version of "A Review of Seth Mnookin's 'The Autism Vaccine Controversy and the Need for Responsible Science Journalism' (27 January 2012, 37 pages)".

"For more information visit http://www.cdc.gov/vaccines."

This reviewer recommends that this writer and any interested reader should read, and learn from, the second edition of "Vaccine Safety Manual For Concerned Families and Health Practitioners" by Neil Z. Miller, ISBN: 978-188121737-4, which is currently available from Amazon.com for $ 13.29 plus shipping and handling and in which this reviewer has no financial interest; or, for an online source, much of the pertinent information on vaccines is published online by the National Vaccine Information Center (NVIC) at http://www.nvic.org/.

"Dr. Julie Lyons is board certified in family medicine. She sees patients at St. Luke's Clinic—Family Medicine in Hailey."

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