

Facility Automation Management Engineering (FAME) Systems

33 Hoffman Avenue, Lake Hiawatha, NJ 07034 – Tel. 973 263-4843

Friday, 17 October 2008

To All:

The text following this page is a draft review of the text electronically extracted from a report, “Florida’ Governor’s Task Force on Autism Spectrum Disorders – Task Force Requests to the Florida Department of Health” received as a file, labeled: “autismrept_9-16-08.pdf”, on 17 September 2008.

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This formal review, which is titled: “A Draft Review of: ‘Florida Governor’s Task Force on Autism Spectrum Disorders –Task Force Requests to the Florida Department of Health’, Part 1”, begins on the first page in the body of the report. [Note: Because of its length, this review has been divided into 2 parts – “Part 1” reviews the first 25 pages of the body of the report; “Part 2” covers the rest of the report (pages 26-43) and includes additional information provided by this reviewer.]

Introductory Remarks

First, *to simplify this review*, when portions of the report are addressed in the review, the statements in this report will be quoted in a “Times New Roman” font.

Second, remarks by this reviewer, Paul G. King, PhD, will be presented in indented text following each part of the report that is being reviewed.

In addition, this reviewer’s remarks and suggested changes will be in a **dark blue** “News Gothic MT” font except, when he quotes: **a)** from or refers to any federal statute or regulation, the text will be in a “Lydian” font or **b)** from other sources, the quotations will be in an “Arial Narrow” font.

When this reviewer quotes from statements made in the author’s article, this reviewer will use an *italicized* “Times New Roman” font; suggested word corrections will be made in **red**.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and revise his views and the final review.

Respectfully,

<ds>

Paul G. King, PhD,
Founder,

FAME Systems

33A Hoffman Avenue
Lake Hiawatha, NJ 07034-1922

Email: drking@gti.net
Tel. 1-973-263-4843, after 19:00 Eastern Time
[To whom all inquiries should be directed]

“Florida”
Governor’s
Task Force on
**Autism Spectrum
Disorders**

Task Force Requests to the Florida Department of
Health

FLORIDA DEPARTMENT OF **'Fla'**
HEALTH

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(Image only)

3 LETTER

Task Force Requests to the Florida Department of Health Re: Immunizations and Related Data

1. Develop a side-by-side chart of CDC and Florida vaccinations schedule and recommendations and highlight differences.
2. List of vaccinations generally, then broken down by fatal and non-fatal illnesses
3. List of vaccine-preventable illnesses, incidence and outcome (number of cases and number of deaths)
4. A list of all vaccines and the years they were introduced into the schedule of Florida.
5. Pre and post 1980 vaccine schedules (comparison, list of all vaccinations received since 1980 and when added to the vaccine schedule)
6. Investigate other states' opt-outs for non fatal vaccinations that have been added in the last 20 years.
7. Question which vaccines given to children under age of two still have thimerosal? Flu shot still has thimerosal? Did DOH mandate that all vaccines have none? How long has this been in place? (2003)?
8. Data on numbers of vaccine preventable diseases for the 18 states with philosophical exemptions.
9. State breakdown of school entry immunization exemptions, broken down by type and uptake rate.
10. DOH/DOE the number of unvaccinated people in Florida, and incidence. Funding epidemiological study.
11. Risk of waiting until 24 or 30 months to introduce immunizations.

4 REQUESTS 1-11”

A Draft Review of the ‘Task Force Requests to the Florida Department of Health’ Report

Part 1 of 2 Parts

Introduction

Lest any take this reviewer’s remarks as those of someone who is anti-vaccine, this reviewer again reiterates that, *given the scientific information available*, he currently supports national vaccination programs for those vaccines that have truly been proven to be both generally safe and medically cost-effective, provided the individual parent’s constitutional right to “due process of law” is neither abridged nor ignored.

Having made clear his position as an advocate for:

- a. Banning the use of mercury compounds in medicine to safen vaccines,
- b. Vaccine safety, and
- c. Medically cost-effective vaccines,

this reviewer will now assess the statements made in this report.

“Department of Health Response on Immunization Related Issues to the Governor’s Task Force on Autism Spectrum Disorders”

The report begins by falsely equating vaccination with immunization¹.

While the goal of vaccination should be to protect those vaccinated in the same manner and for as long as having the disease (that individuals are being inoculated against) does without causing those vaccinated to get a clinical case of the disease, the realities are that vaccination:

- Does not provide any immunity in some,
- Provides, at best, incomplete immunity in most instances and
- Does not give the long-term immunity that having the disease provides, even with 2 to 5 doses of the vaccine or, *in the case of the current in-use-ineffective influenza vaccines*, one or more doses each year.

Thus, this difference needs to be recognized and the language used corrected to reflect reality.

Factually, people are inoculated with a vaccine or, *simply*, vaccinated to *hopefully* provide them with some level of some type of immunity that will:

- Last for a significant period of time, and
- Protect most of those inoculated from having a clinical case of disease if they are exposed to the disease some time after being vaccinated.

Unfortunately, whether inhaled, introduced into the skin or injected, vaccines expose our immune systems to a number of non-disease-related vaccine components (serum, adventitious organisms, antibiotics, toxins [Thimerosal, aluminum adjuvants, 2-phenoxyethanol] and food substances [e.g., gelatin, MSG, egg albumin]) that present their own immune-system risks to the people being vaccinated.

¹ If you truly want to be immunized, then, in most cases, you should contract the native communicable childhood diseases when you are in the appropriate age range after your parents make certain that your vitamin and mineral levels (particularly, for vitamins: oil-soluble A, the Bs, C, D-3, E, K-2 and, for minerals: magnesium, potassium, selenium, silica, and zinc) are at optimal levels and you have a healthy intake of omegas and DHA as well as a balance nutritious diet. For chickenpox, your parents should try to make sure that, after you have and recover from your initial case of chickenpox, you get periodic re-exposures to the causative virus, herpes varicella zoster, from other infected children or adults having a case of shingles to re-boost your immunity (exogenous boosting) at 2 – 4 year intervals until you reach puberty and 5 – 10 year intervals thereafter.

“Millions of people have benefited from vaccines for more than two centuries. The history of vaccines and immunization began in the 1790s with Edward Jenner’s creation of the world’s first vaccine for smallpox. Before the existence of vaccines, diseases such as smallpox, measles, rubella, diphtheria, polio, and pertussis (whooping cough) were common childhood killers and left many survivors disabled for life. Fortunately, in Florida and the United States, these devastating diseases have been almost eliminated due to the widespread use of safe, effective, and affordable vaccines. In fact, smallpox, a disease that has caused countless suffering and death for centuries, was eradicated worldwide through vigorous vaccination programs. There is little else in medicine that can compare to this achievement. With concerted effort, other diseases, such as polio and measles (a disease that infects approximately thirty million children per year, killing approximately 750,000 of them), can similarly be eradicated.

Public health professionals and the World Health Organization (WHO) rank immunizations in the top ten health achievements of the past century. Immunization is as important as the development of safe drinking water and public sanitation practices.”

Public health officials, no doubt, and, perhaps, *“the World Health Organization (WHO) rank immunizations in the top ten health achievements of the past century”.*

But, *for most of the communicable childhood diseases*, clean water, modern sanitation, healthy food, and decent housing had reduced deaths in the “developed” nations from these communicable diseases by roughly 91–95 % from their peak levels before an effective vaccine was even available.

Why is it that articles by those that are pro-vaccine invariably begin with statements that extol the impact of the “early” vaccines and equate those impacts to the greater public health success stories.

Based on the facts, 90% of the impact of these diseases was removed by the provision of clean potable water, sanitary sewers, wastewater treatment, and sanitary garbage collection and disposal as well as improvements in the provision of adequate shelter and nutrition to most of the American public?

Accurately, other than smallpox deaths, more than 90 % of the declines in the level of deaths from the serious contagious diseases endemic in the United States (e.g., cholera, measles, and rubella) occurred before there were vaccines for them.

For example, the estimated annual average pre-vaccine cases and deaths from measles that the vaccine apologists use for their comparisons are usually based on the years 1953-1962,² the decade prior to the 1963 introduction of an effective measles vaccine.

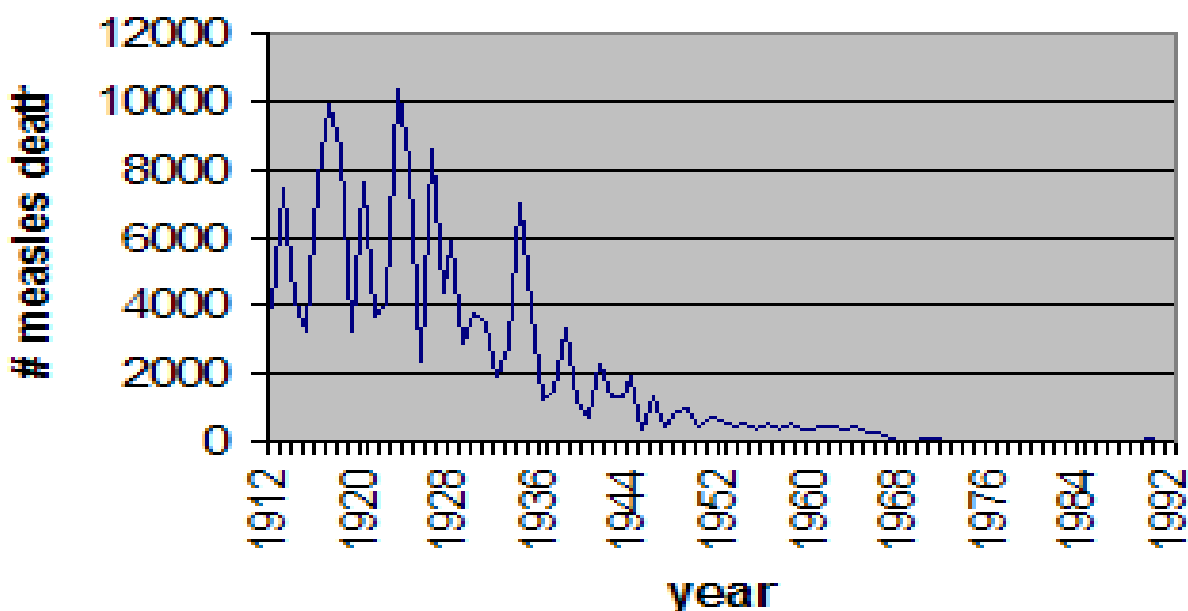
By then (**see Figure “1”** on the next page), the annual number of deaths in the 1953-1962 period (<800 per year) had already dropped by more than 93% from the peak annual deaths in the 1915-1924 period (> 10,000 in 1924).²

Ignoring the earlier years *inaccurately* presents the magnitude of the decline in measles that is attributable to vaccination as the most significant factor.

Clearly, the real major factors in the decline in measles deaths were pre-vaccine factors, such as significant increases in the availability of safe food and drinking water as well as major improvement in sanitation, housing and nutrition, and the general availability of antibiotic drugs starting in the late 1940s.

² Centers for Disease Control (CDC). Reported Measles Cases, Deaths, Deaths-to-Cases Ratio and Estimated Population in the United States, 1912-1984. Provisional Data; Doc #0051m

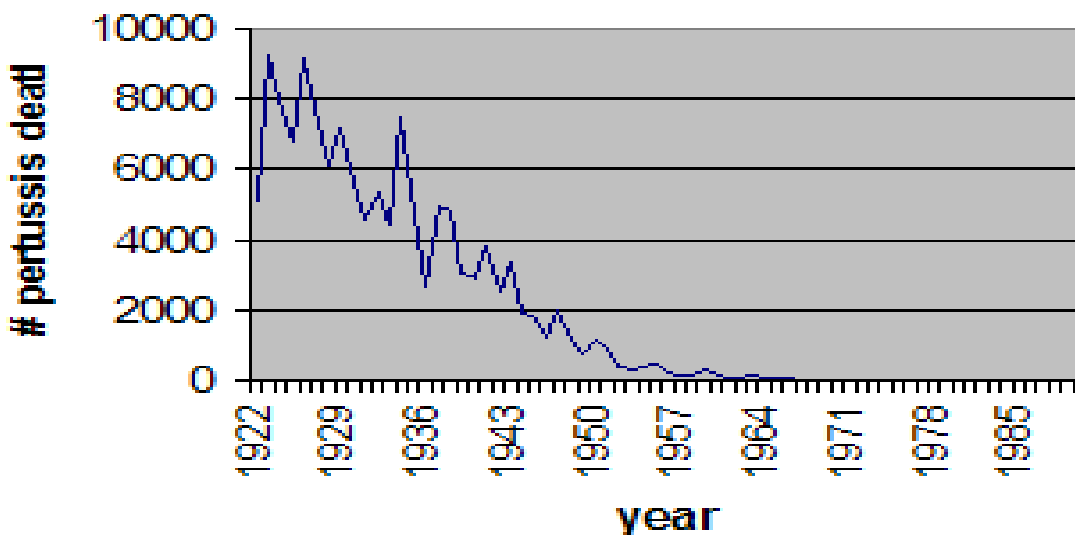
Figure "1" Measles deaths by year, 1912 to 1993



Lest the reader think that this is an isolated instance, the data for pertussis deaths from 1922-1999³ (see Figure "2") shows a similar pattern.

Again, more than 91 % of the drop in annual deaths occurred before the United States had an effective standardized vaccine (in the 1950s).

Figure "2" Pertussis deaths by year, 1922 to 1999



In addition, *since pertussis is a bacterial disease*, the penicillin antibiotics introduced into U.S. medicine after World War II also directly contributed to the decrease in deaths at the same time as the first standardized pertussis vaccines were becoming available.

Ignoring the earlier years, *as this report appears to do*, again *inaccurately* attributes most of the decline in deaths and cases to vaccination instead of the other factors.

³ "Pertussis (Whooping Cough) – Reported cases and deaths per 100,000 population, by year, United States, 1922-1981." [Graph]. In Centers for Disease Control, Annual Summary 1981: reported morbidity and mortality in the United States. *Morbidity and Mortality Weekly Report (MMWR)*. 1982 Oct; 30(54): 65.

Finally, this part of the introduction also ignores the impact of penicillins and other antibiotics on bacterial disease rates, pathogen prevalence, and exposure risk.

“Vaccines protect infants, children, and adults from the unnecessary harm and premature death caused by a number of severe communicable diseases.”

Factually, vaccines only truly protect most of those who are vaccinated “*from the unnecessary harm and premature death caused by*” a few of the severe communicable diseases for which we have a reasonably safe and in-use effective vaccine.

These reasonably safe and in-use effective vaccine are typically the vaccines for some of the once prevalent American childhood diseases for which we have vaccines (measles, polio, rubella, and diphtheria)⁴.

In addition, there are no effective vaccines for many of the worst U.S. communicable diseases (e.g., syphilis, gonorrhea, AIDS, Chlamydia), or for diseases, *like malaria*, that are endemic outside of America.

“Vaccination is the single most effective communicable disease prevention strategy.”

Were this report less biased in favor of vaccines, this overly broad generalization would not have been made.

Also, the validity of this statement depends upon factors such as:

1. Mode of transmission⁵,
2. Prevalence of the disease organism in the population and/or the environment,
3. Ease of transmission,
4. Barriers to transmission,
5. Ability to disrupt reservoir or vector population, and
6. *For all vaccines*, the absence of ingredients that provoke anaphylaxis in a significant part of the population, which is targeted for inoculation; and, *for live-virus vaccines*, the absence significant pre-existing B-cell and/or T-cell immune suppression.

Obviously, here is no need for routine cholera vaccination in the USA because most of the potable water is treated to remove this water-borne disease organism⁶.

⁴ The vaccines for other childhood diseases, the mumps, tetanus, and pertussis components of the current vaccines, have significant problems in that they provide less-than-effective in-use immunity in the long-term and, *as more vaccine doses are given*, the side effect risks increase rapidly (from the adverse effects of repeated immune system re-challenge). Furthermore, the vaccines for hepatitis B are given at times when there is almost no disease risk apparently to minimize the risk of the autoimmune diseases these vaccines are known to cause and/or exacerbate. Aside from the vaccine-associated risks, the Hib, influenza, meningococcal and pneumococcal vaccines suffer from the severe long-term problems associated with incomplete strain coverage. The live-virus rotavirus vaccines are extremely problematic because they not only give everyone inoculated with them a case of rotavirus but also, *through shedding*, those inoculated spread their previously non-indigenous bioengineered (previously, monkey-human [Wyeth’s RotaShield®] and, now, human-bovine [Merck’s RotaTeq®] hybrids) and/or “attenuated” [recent GlaxoSmithKline Biochemicals’ Rotarix®] rotaviruses throughout the population.

⁵ Modes of Transmission: **a)** intimate direct [person-to-person {e.g., syphilis, gonorrhea, herpes simplex 2, and HPV}], **b)** direct environment mediated [person’s excretions or emissions transferred by casual touch or sneeze {e.g., common cold and influenza}], **c)** indirect environment mediated [person-to-the environment-to-person [{e.g., cholera}], **d)** indirect vector mediated [vector-to person to vector cycle {e.g., Lyme disease, where “deer” tick bites humans to transmit *Borrelia burgdorferi* to humans}], and **e)** indirect vector-excrement mediated, where vector is the reservoir and sheds disease into environment where humans contact the shed excrement and contract the disease {e.g., the hanta viruses where humans contract the disease from rat/mouse droppings}}).

⁶ For water-borne diseases, obviously treating the drinking water to remove these is a more effective control strategy than trying to vaccinate the population with a vaccine that would not be 100% effective and does not provide lifetime protection. Thus, vaccination for cholera need only be carried out in the U.S. when, *because of interruption of the supply of potable water*, there is a disease outbreak. This approach also ensures that the entire population is not unnecessarily exposed to the potential adverse reactions to the cholera vaccine.]

Similarly, because Japanese encephalitis is not endemic to the USA, there is no need to vaccinate the general population against it.

“Vaccines are also among the most cost-effective medical interventions available, providing huge savings in direct medical care costs, as well as indirect costs such as lost time from work and school.”

Again, the preceding statement is a generalization that is only true for some of the vaccines recommended for general use today.

Moreover, *in some cases*, this statement is not true unless the costs of both the short-term and long-term harms caused by a given vaccine are ignored.

In some cases, like the early childhood hepatitis B program, *where the protection provided wears off before the disease risk becomes real*, and the influenza program, *where the vaccines provide at best limited protection to most of those vaccinated and retrospective studies have established that they lack in-use effectiveness in the USA*, the vaccination programs are clearly not cost effective.

In the case of the influenza vaccines, where the majority of the doses still contain Thimerosal and most of these are Thimerosal preserved, these flu shots add to the cumulative⁷ subacute mercury poisoning of the vaccinated population to the point that:

- Some exhibit some of the clinical symptoms of mercury poisoning,
- Some develop chronic diseases earlier because mercury poisoning is known to hasten and exacerbate the development of these diseases, and
- A small percentage exhibit impaired neurological function including, *in children*, the majority of those diagnosed with neurodevelopmental disorders and, *in an increasing number of older adults*, various adult dementias including Alzheimer's disease.

When the costs of the harms caused by vaccines, *including the direct medical care, added educational costs for the affected children, and long-term custodial care for the injured elderly*, as well as indirect costs (*such as losses to the capable work force, decreased work productivity, and shortened productivity lifetimes*) are included, many of the current vaccine programs are not medically cost effective and a few are not even societally cost-effective.

For example, the early childhood vaccination program for hepatitis B is not medically cost effective because:

- The costs of vaccinating the population translate into more than a million dollars for each case of childhood hepatitis B prevented, and
- More are harmed by, and die from, hepatitis B vaccination than from having childhood hepatitis B, which, *in the majority of the childhood cases in children with healthy immune systems*, resolves itself without becoming a chronic disease.

Moreover, the protection provided by the early childhood hepatitis B program quickly wears off.

Thus, *when children become at risk (by being sexually active in their “mid teens” or IV drug users in their late teens)*, most have less than adequate protection to from contracting hepatitis B, if exposed.

For the chickenpox vaccine, Merck's Varivax®, the reality is that the original program was justified as being *barely* societally cost-effective by ignoring:

- The adverse effects of vaccination,
- The increases in shingles cases that would result and their costs, and

⁷ Yes, contrary to the unsupported assertions in this report, Thimerosal is a bioaccumulative mercury poison in humans with a half-life of the end-point metabolic product, “inorganic mercury”, in body tissues and organs that is on the order of 10 to 20 years in people who actually excrete mercury efficiently and, *in those who are poor or non-excretors*, are significantly longer to lifetime, for those who are truly non-excretors.

- The biological reality that one dose cannot provide lifetime protection.

Today, *when the effectiveness of the national vaccination program with one dose dropped below 75%*, the CDC, *ignoring the fact that a subsequent vaccination program dose would not be even societally cost-effective*, simply recommends two (2) doses.

Thus, the current 2-dose chickenpox vaccination program is *clearly* a waste of the public's healthcare dollars; but adding the second dose did "double" Merck's revenue stream for their *herpes varicella zoster* vaccine for chickenpox.

Moreover, adding the second dose has failed to return vaccination effectiveness to the 90+ % level seen during the one-dose program's "honeymoon" period, *when exogenous boosting by exposure to the native chickenpox strain was still effective in suppressing disease recurrence*.⁸

Further, the CDC, has even now recommended that a third dose of vaccine may be required, particularly for those entering college.

Given the preceding realities for HVZ, we should abandon the CDC's current vaccination recommendations for *herpes varicella zoster* and, *as rapidly as possible*, return to letting our children naturally acquire chickenpox, usually a mild disease that very rarely causes death, and, *when the naturally infected mother breastfeeds her child*, the mother's milk seems to provide protective antibodies to postpone the risk of contracting the disease until the child's immune system has matured enough to cope with having chickenpox.

Then, *as the Japanese do*, we should provide the vaccine for the few who may need it as well as those who understand the tradeoffs and want to postpone their children's risk of having chickenpox until their children are older.

Thus, the reality is that only a few of the current national vaccination programs are truly medically cost-effective (e.g., measles, rubella, diphtheria, polio) and some may be societally cost-effective (e.g., mumps, tetanus, and pertussis).

Finally, *based on the information reported for the costing of the original 1998 RotaShield vaccine*, rotavirus was: **a)** a naturally declining disease in the USA and **b)** confined to the lower socioeconomic groups mainly in the inner cities, the current rotavirus vaccines would only be societally cost-effective if the total cost per dose were less than about \$6.00, and medically cost-effective if the dose cost were less than \$2.00, provided the costs to the families of the children harmed by this virulent live-virus in the vaccine were simply ignored.

"Unlike other areas of health care, widespread immunization has effectively leveled racial-ethnic disparities in this country."

Here, the report is being disingenuous, because, in America, *in general*, and Florida, widespread vaccination effectively levels most socio-economic barriers and not the racial-ethnic ones *per se*.

The rotavirus vaccines are a "poster child" example of the socio-economic leveling effect of vaccines.

Absent the live-virus vaccines, clinical rotavirus infections were confined to the lower socio-economic groups and a few of those who came in contact with them.

⁸ Factually, medical science has recognized that, to prevent reactivation of the dormant herpes varicella zoster (HVZ) viral disease organisms from the initial infections, everyone needs periodic exogenous (external re-exposure) to HVZ and, sadly, childhood shingles cases are becoming increasingly common, and, to address the realized increase in adult shingles cases, Merck has introduced Zostavax, essentially a third dose of their live "attenuated" HVZ virus, clearly rendering the overall HVZ vaccination programs only cost-effective to Merck, the healthcare establishment and public health officials, but not cost-effective for the physical and financial health of the public.

Yet, as the CDC has reported, though most children did not have a clinical case of rotavirus, all children seemed to have acquired long-term immunity by “5” years of age – obviously from low-level exposures that generated subclinical disease cases.

However, in states where the rotavirus vaccines have been introduced and/or mandated, children from all socio-economic groups are getting clinical infections and having the severe outcomes, including death — outcomes that used to be confined to the children in the lower socio-economic groups because the live-virus rotavirus vaccines infect all given them with a level of rotaviruses sufficient to induce clinical symptoms in most and severe symptoms in some.

In addition, in the case of the bioengineered human-animal hybrid rotavirus vaccines, shedding by the inoculated child has been found to infect some adults who were previously “naturally immune” to the native rotavirus organisms.

Apparently, those who treat vaccination as a “religion” have forgotten the lessons learned with the live poliovirus vaccines and the previous now-withdrawn Wyeth’s RotaShield vaccine, and, to profit Merck and, now, GlaxoSmithKline, have again allowed our children to be unnecessarily infected with a live intestinal virus that, in some, is highly virulent even though these vaccines: **a)** are clearly not even short-term societally cost effective in the USA, and **b)** will result, and have already resulted in, increased deaths and disease (intussusception and Kawasaki’s disease for RotaTeq; and intussusception and pneumonia for Rotarix) because almost all of our 4-million-plus newborns will be infected if the CDC/AAP recommendations for the rotavirus vaccines⁹ are followed.

“Florida’s child care and school entry immunization requirements ensure that students are protected against communicable diseases in settings where such diseases are easily transmitted.”

While this statement is laudable on its face, the inclusion of the Hib and PCV vaccines in the Florida requirements is problematic because the long-term evidence is that the Hib and the PCV vaccines create more long-term disease problems than they solve.

With a true effectiveness closer to 15% than to 85% or above, the national use of the Hib has caused strain drift and alternate organism invasion that, together, have created a childhood disease conditions that are significantly harder to treat and are increasing antibiotic resistant.

Consulting the CDC’s “Summary of Notifiable Diseases – United States, 2002” report,¹⁰ this reviewer finds the following for reported “Haemophilus influenzae” cases:

“Haemophilus influenzae, Invasive Disease

In 2002, 331 cases of invasive Haemophilus influenzae disease in children aged <5 years were reported; 34 (10%) were reported as H. influenzae type b (Hib), 144 (44%) were reported as other serotypes or non-typeable isolates, and 153 (46%) were reported with serotype information unknown or missing. The continued remarkably low number of invasive Hib infections in children (down from an estimated 20,000 cases annually in the prevaccine era) is a result of the successful delivery of highly effective conjugate Hib vaccines to children, beginning at age 2 months (1,2).

⁹ To get the rotavirus vaccines approved, liberties were taken with the clinical trial process by conducting the trials in populations where sanitation was poor and the natural risk of infection with the native human rotavirus strains was high to ensure the background disease rates would be somewhat comparable to the vaccination disease rates even though, because of sanitation and hygiene, the risk in the general American population is much lower than in the trial areas. Such practices would seem to be criminal when the target market for approval was the USA, but may have been appropriate for developing countries where the majority of the population lives in poverty and lacks proper sanitation.

¹⁰ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5153a1.htm> last visited 31 December 2007. *MMWR* 2004 April 30; 51(53): 1-84.

Because discrepancies in serotyping results have occurred between laboratories, CDC requests that state health departments obtain and send all invasive *H. influenzae* isolates from children aged <5 years to CDC for serotype confirmation (3,4).

1. CDC. Progress toward elimination of *Haemophilus influenzae* type b disease among infants and children--United States, 1998--2000. *MMWR* 2002; 51: 234-237.
2. Zhou, F, Bisgard KM, Yusuf H, et al. Impact of universal *Haemophilus influenzae* type b vaccination starting at 2 months of age in the United States: an economic analysis. *Pediatrics* 2002; 110: 653-661.
3. LaClaire LL, Tondella ML, Beall DS, et al. Identification of *Haemophilus influenzae* serotypes by standard slide agglutination serotyping and PCR-based capsule typing. *J Clin Microbiol* 2003; 41: 393-396.
4. CDC. Serotyping discrepancies in *Haemophilus influenzae* type b disease---United States, 1998--1999. *MMWR* 2002; 51: 706-707."

Moreover, that summary report's "**Table 1**" lists 1,743 cases of invasive *Haemophilus influenzae* and the total reported cases for children under 5 is 331.

And, the 2002 report's "down from an estimated 20,000 cases annually in the prevaccine era" statement shows that the government had no solid data for cases of *Haemophilus influenzae*, or disease prevalence data for the Hib strain in children under 5 before the current Hib vaccines were introduced in the 1980s.

Next, consulting the CDC's "*Summary of Notifiable Diseases - United States, 2005*" report,¹¹ this reviewer finds the following for reported "*Haemophilus influenzae*" cases:

- Oddly, there is no paragraph discussing *Haemophilus influenzae* in the report.
- However, this "2005" report's "**Table 1**" lists:
 1. 2,304 cases of invasive *Haemophilus influenzae*; a 32% increase from 2002.
 2. For children under five:
 - a. 9 serotype B cases (a 70+ % decrease from 2002),
 - b. 135 nonserotype B cases (a 6+ % decrease from 2002),
 - c. 217 unknown serotype cases (a 42 % increase from 2002), and
 - d. 361 total cases (a 9% increase from 2002).

Given the increase in unknown serotype cases,

- The CDC's 2002 request "that state health departments obtain and send all invasive *H. influenzae* isolates from children aged <5 years to CDC for serotype confirmation" was ignored, and/or
- The CDC did not confirm the serotyping or serotype the majority of the isolates submitted as "unknown serotype cases," and/or
- New strains of this disease were emerging that, *lacking suitable anti-sera*, the states and/or the CDC could not serotype.

Subsequently, consulting the CDC's "*Notice to Readers: Final 2006 Reports of Nationally Notifiable Infectious Diseases*,"¹¹ this reviewer finds in its "**Table 2**" the following data are reported for "*Haemophilus influenzae*" cases:

1. 2,436 cases of invasive *Haemophilus influenzae*; a 6% increase from 2005 cases.
2. For children under five:
 - a. 29 serotype B cases (a 320+ % increase from 2005)
 - b. 175 nonserotype B cases (a 30 % increase from 2005),
 - c. 179 unknown serotype cases (an 17+ % decrease from 2005), and

¹¹ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5633a4.htm> last visited 31 December 2007. *MMWR*, 2007 August 24; 56(33): 851,853-863.

d. 383 total cases (a 6 % increase from 2005).

Based on all the recent published CDC data available to this reviewer, it appears that the Hib vaccines are shifting the distribution of serogroups toward other serogroups.

Furthermore, recent reports indicate that other organisms that are more difficult to treat than Hib are beginning to fill the bacterial “niche” left by the Hib vaccine.

In addition, studies have reported that there is a “causal relationship between the haemophilus b vaccine and the development of insulin dependent diabetes ... 3 – 4 years after four doses of Hib”.¹²

Since the cost impacts of both the short-term adverse effects (serious harm) and the long-term adverse effects to health (e.g., insulin-dependent diabetes) were not considered in the initial licensing of the Hib vaccines and there has been a significant increase in infections by other microorganisms filling the niche created by the Hib vaccine, rather than continuing this line of reasoning, which looks to modify the strains in the vaccine, the public needs to reconsider whether or not a vaccine for Hib is *medically* cost-justifiable because the published data seem to indicate that this is not the case.

Turning to the pneumococcal vaccine (PCV-7) for children, factually, this pneumococcal vaccine, Wyeth’s Prevnar®, may have been very successful in decreasing infections but only when caused by those 7 strains (of the about 90 strains of *Streptococcus pneumoniae*) that are presently in the licensed vaccine (estimated as responsible for “74”% of the non-penicillin-resistant strains and “100”% of the penicillin-resistant strains based on a 1993-1994 CDC survey).

Using 1999 as the base year, we can see that by the end of 2001, *almost 2 years after the vaccine was introduced early in 2000*, vaccination of those <5 years of age has significantly reduced the total number of drug-resistant cases for all ages by about 63% and the actual cases in those <5 are only about 17% of the total number of the penicillin-resistant cases.

However, *in each successive year*, not only has the total number of such cases begun to increase (2004 and onwards) but also the percentage of those cases in the “< 5” group increases in every year for which there are data (see (in **Table “3”**)).

Table “3” CDC Data for Invasive Drug-Resistant Cases of *S. pneumonia* ¹³

Year	U.S. Total Cases	U.S. Cases In Those < 5	<5’s % of U.S. Total	Florida Cases	Florida Cases In < 5s	<5’s % of Florida Total
1999	4,618	-----	-----	711	-----	-----
2000	4,533	-----	-----	1,154	-----	-----
2001	2,896	498	17.20	265	-----	-----
2002	2,546	513	20.15	609	-----	-----
2003	2,356	845	35.86	606	-----	-----
2004	2,590	1,162	44.86	583	69	11.83
2005	2,996	1,495	49.90	614	79	12.87
2006	3,308	1,861	56.28	774	72	9.30

Since, from 2001, the percent increase for cases in the under 5s is about 374 % (or an average annual percentage increase of about 75%, it is clear that the vaccine’s effectiveness against antibiotic-resistant *S. pneumonia* is, *for whatever reasons*, significantly declining and more than 50% of the antibiotic-resistant cases are now occurring in the under 5s.

¹² <http://www.vaccines.net/newpage112.htm> last visited 31 December 2007.

¹³ Taken from the appropriate sections of the CDC’s annual “Summary of Notifiable Diseases” reports.

Clearly, the PCV-7 vaccines have upset the previous “natural balance” where penicillin-resistant cases in the those < 5 were probably less than 17 % of the total of such cases.

“When most children are immunized, even vulnerable children, who are not able to be immunized due to medical reasons, are protected. This concept, known as “herd immunity,” is the key to the low levels of vaccine-preventable diseases in Florida, nationally and in most developed countries. Herd immunity occurs when a large portion of the population (85–98% depending on the disease) receives vaccine against a disease. Such high immunization coverage rates protect susceptible individuals in a group because, due to immunity in most of the group, transmission of disease cannot be sustained.”

First, “*herd immunity*” is at best a theory that, *if valid*, is only valid when the vaccine provides adequate long-term protection for all the current *strains* of the disease organism and the disease organism is not capable of mutating into strains (stereotypes) that are not covered by the vaccine.

Given the preceding reality, the better term is “herd protection” since vaccination does *not* ensure immunity even in fully vaccinated populations.

Thus, *at best*, the theory of “herd protection” only applies to the more simple bacteria and viruses that lack the ability to rapidly mutate into strains that are not covered by the vaccine.

However, unless the vaccine provokes the human immune system in the same exact manner as the disease organisms covered, then, *of necessity*, the protection provided is not only incomplete but also less durable than that conveyed by being periodically exposed to and, *in some instances*, contracting a clinical case of the disease.

Thus, *with the possible exception of the current rotaviruses (which infect everyone with rotavirus strains claimed to provide complete protection) and the currently discontinued live-virus vaccina (cowpox) vaccine used to eliminate the natural smallpox virus, and the live-virus polio vaccines*, the best the other current vaccines that are recommended for “universal” use can do is to provide incomplete herd protection – an obviously inferior form of “immunity”, which does not ensure long-term protection to most of those inoculated with these vaccines.

In nations, like the USA, the western European nations, Japan and Australia, *where the risk of exposure to a given disease organism is low and restricted to excursions into the regions where the disease is endemic or to exposures to immigrants and visitors from those nations who were infected just before they traveled to the USA*, it is difficult to support the concept of “incomplete herd immunity” when some who have been vaccinated contract the disease after being exposed to these “foreign-origin” infections.

For diseases, like measles, the “incomplete herd immunity” provided by infection with 2 doses of live-virus measles and rubella vaccine components seems to be both long-term and general, since very few, *who have been inoculated with a live-virus measles vaccine and rubella or a combination measles, mumps and rubella vaccine and who have recovered*, subsequently contract measles after exposure to “foreign origin” measles.

However, for mumps, the live-virus vaccine component does not seem to provide robust long-term protection to those who have been vaccinated because, *with the same level of coverage (where more than 93% get two doses of the MMR vaccine)*, thousands contract mumps each year.

In 2006 in the USA according to the CDC¹⁴, for example, there were 24 “Indigenous” and 31 “Imported” measles cases (55 cases in total) and only 11 cases of rubella *versus* 6,584 mumps cases – or about 120 times as many mumps cases as measles cases.

¹⁴ Summary of Notifiable Diseases --- United States, 2006. *MMWR* 2008 March 21; 55(53): 1-94.

Similarly, the current “5-dose”-plus DTaP regimen is very effective against diphtheria and effective against tetanus, where no cases of diphtheria and only 11 cases of tetanus (mainly in the elderly) were reported in 2006.

But there were 15,632 reported cases of pertussis, indicating that the current pertussis vaccine component does not provide effective long-term “herd protection” under the current vaccination programs based on the observed level of clinical disease cases.

“The fact that early childhood immunization and child care/school entry immunization requirements lead to herd immunity, is an important reason for their effectiveness in reducing the spread of communicable diseases. The huge reductions now seen in most of the vaccine-preventable diseases did not occur until states implemented school and child care immunization entry requirements.”

Even accepting that this generalization is valid for all the vaccines mandated by Florida, *which the data clearly show is not the case*, the growth in the mandated vaccination programs also seem to be factor in the appearance of, *or large increases in*, chronic diseases during childhood that, *prior to the 1950s*, were either unknown or very rare in children (e.g., asthma, COPD, type 2 diabetes, IDCM, obesity and MS) as well as large increases in severe food intolerances and life-threatening food and environmental allergies to the point that many of these medical conditions are at epidemic levels today.

Thus, it would appear that the public health officials, healthcare establishment and the vaccine makers have foisted a Faustian bargain off on the American public in which, *to displace acute childhood diseases*, we have been, *and are being*, forced to accept the vaccine-induced or vaccine-exacerbated burden of chronic diseases that enriches them and impoverishes the American public today.

Hopefully, we will:

1. Wake up,
2. Demand independent proof of:
 - a. Long-term safety,
 - b. Long-term effectiveness,
 - c. Overall medical cost-effectiveness, and
 - d. Very low (< 1 in 100,000 doses) or no increased chronic-disease risk,for each existing vaccine component in the current national vaccination program, and
3. Only retain those components that are truly safe, long-term effective, medically cost-effective, and free from any significant increased risk of chronic disease.

5 DEPARTMENT OF HEALTH RESPONSE

“Without herd immunity, those who are too young to be immunized, and/or have medical or religious contraindications to immunization, and/or have diseases that cause immunodeficiency, would all be at much greater risk for infections and their sequelae. That is, when fewer children are immunized, then children who cannot be immunized are much more vulnerable to getting infected with a disease—a disease that can be prevented when most people are immunized.”

This ever so carefully crafted scenario sounds plausible until the reader remembers that vaccinating with live-virus vaccines as we do for many of the diseases (e.g., smallpox, influenza, measles, mumps, rubella, varicella, and, *until recently*, polio) actually increases the risk that those who are either unvaccinated or vaccinated but not now protected will contract the disease from the viruses shed by some of those who have been recently vaccinated.

Factually, the risks to the unvaccinated and unprotected vaccinated populations are not known for most live-virus vaccine components because we do no active surveillance for clinical and sub-clinical diseases caused by all vaccines.

Instead of such active population surveillance, in America, we rely on a voluntary reporting system (the Vaccine Adverse Events Reporting System [VAERS]) that, *according to the CDC*, receives, *on average*, notices for less than 10% of the adverse events, *including death*, that are typically only immediately (within a month of the vaccination date) associated with vaccine administration.

However, unlike *what the adverse events system should do*, this system does not track any segment of the population for the decades required to establish possible/probable links between: **a)** vaccination and **b)** the subsequent manifestation of some delayed-onset vaccination-related condition or disease.

Finally, *for, for example, mumps and pertussis*, it is clear that the vaccines are not as effective as advertised in the current vaccination programs.

Further, *for varicella*, the current 2-dose regimen is not even societally cost-effective and, *when the costs for the harm from vaccination and the third dose (e.g., Zostavax) are factored in*, it is clear that the national chickenpox program is a large financial and health loss for the American public.

Thus, only the healthcare establishment and the vaccine makers profit from both these programs and the costs of the consults and medications needed to treat the adverse outcomes from: **a)** the increased occurrence of shingles in adults and **b)** the previously unknown, or very rare, childhood shingles cases in babies and young children.

“Section 1003.22 of the Florida Statutes requires immunization for school entry and attendance, and allows for medical (temporary and permanent) or religious exemption from immunizations. The Florida child care and school entry immunization requirements cover public and private schools, childcare facilities, and family childcare homes. They are in accordance with the recommendations from the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics [AAP], the American Academy of Family Physicians [AAFP], and the American Medical Association [AMA]. These organizations set the standard of care and practice that health care providers, health plans, and insurance companies follow with respect to providing immunizations.”

This reviewer accepts that this section of the report accurately reflects Florida’s law and practices with respect to vaccination, which, as most do, the report’s writers yet again mischaracterize as “*immunization*”.

Since the vaccine makers and their lobbyists and hangers on exert significant influence on the decisions of the ACIP, AAP, AAFP and AMA, this reviewer finds that the report should have included the general recommendations of the vaccine makers, although, *to be fair*, the vaccine makers do provide information on vaccine risks that the aforementioned groups either: **a)** do not openly provide or **b)** gloss over.

“Florida Statutes require specific immunizations for infants and children who attend child care, family childcare homes, pre-kindergarten and school. Immunization entry requirements for school and child care settings relate to factors such as whether the disease is communicable in child care and school settings, whether the vaccine has been on the market long enough to assess for previously undetected side effects, and whether the vaccine is covered by insurance and health plans.”

This reviewer accepts that this section of the report accurately reflects Florida’s rationale for adding vaccines to the Florida vaccination schedule.

However, this reviewer is surprised that the Florida considerations for vaccines do not, *according to what is reported here*, extend to assessment of the cost-effectiveness of the vaccines recommended even though the state and its residents bear a significant part of the vaccination costs even when *“the vaccine is covered by insurance and health plans”*.

“Immunization safety is of utmost concern to parents, health care providers, the public health community, legislators and vaccine manufacturers.”

While this reviewer would agree that vaccination safety is of utmost concern to parents and the guardians of children, this reviewer finds that, as a group, *“health care providers, the public health community, ... and vaccine manufacturers”* have no real concerns about vaccine safety or vaccine effectiveness because the National Vaccine Injury Compensation Act of 1986, as amended, [NVICA] effectively protects them from being sued for the harm caused by any covered vaccine.

In addition, legislators, who receive significant contributions from these groups and their lobbyists, seem to be more focused on the concerns of these special interests than on those of the parents and guardians of children and, *for that matter*, the children’s concerns.

Finally, only when: **a)** the parents and guardians make vaccination an issue that decides who the majority of the electorate will support in a given election or **b)** the legislator’s child or grandchild is significantly harmed by, *or dies from*, vaccination do most legislators seem to be genuinely worried about the safety of vaccines.

“Vaccines undergo rigorous and lengthy testing for both safety and efficacy prior to approval by the Food and Drug Administration (FDA).”

Here the report is simply mistaken – the safety testing is anything but rigorous and lengthy.

Further, efficacy testing is allowed when some effectiveness testing should be required before a vaccine is approved for inclusion in the national program; and the efficacy testing conducted does not last long enough (for at least 10 years) nor, where possible, require effectiveness challenge in populations experiencing a significant disease outbreak.

Factually, the vaccine makers do almost all the testing of vaccines with little or no active oversight of the trials.

Moreover, *in recent years*, the vaccine makers have been allowed to reduce the depth and length of their safety studies to the point that most safety studies only follow the clinical trial patients inoculated for a few days to a couple of months for safety effects.

Furthermore, for efficacy, they are allowed to use surrogate and, *in some cases*, indirect surrogate endpoints for efficacy in efficacy trials that: **a)** last only for a few years and **b)** do not actively assess long-term vaccine safety.

In addition, to save the manufacturers both cost and time, the FDA has reduced: **a)** the number of clinical trials required and **b)** the minimum number of subjects allowed for a given trial.

Unfortunately, these decisions also reduce the clinical trials’ ability to detect uncommon adverse effects or “rare” adverse effects in certain subpopulations.

Moreover, instead of rigorously requiring that sterile saline be used as a placebo in all safety trials, the FDA has allowed the vaccine makers to use the vaccine formulation without the disease antigens and other experimental vaccines as the placebo.

Sadly, allowing these alternative placebo choices: **a)** minimizes the vaccine’s relative risks for the adverse outcomes observed and **b)** artificially inflates the short-term safety of the vaccine.

Furthermore, the vaccine makers seeking to obtain approvals from the U.S. FDA are increasingly being allowed to choose clinical trial subjects from locations where the background disease rate is significant even when these locations do not reflect the disease risks for the American population.

Because, in such situations, the firms are allowed to report the relative adverse safety outcomes for the vaccine-test arm of the trial to those observed for the placebo arm of the trial instead of the U.S. background adverse outcomes' rates, permitting this also: **a)** minimizes the vaccine's apparent adverse safety profile and **b)** artificially decreases the trial's "relative risk" with respect to the American public's "relative risk" for in-use adverse outcomes.

The net result has been that the FDA is approving increasingly less safe and/or less effective vaccines.

In addition, the approvals obtained are increasingly based on the manufacturer's knowingly biased safety and/or biased inferential efficacy assessments for the vaccine.

Moreover, active surveillance, *where required*, is increasingly less concerned about the actual in-use adverse experiences observed because the U.S. governmental regulatory agencies are:

- Ignoring the pre-vaccine background rates for the serious adverse effects linked to the vaccine's use and
- Increasingly framing their views in terms of the relative observed risk "in use" incidence rates compared to the corresponding "control arm" adverse outcomes rates observed in the biased condition phase-III clinical vaccine trials conducted in populations with a background disease rate that is much higher than the general U.S. rate.

"Today's vaccines are much more pure than those produced decades ago. This increased purity has the effect that the total number of antigens (from the vaccines themselves and from other substances in the vaccine preparation) introduced to the body is much less, even as the number of recommended vaccines has increased."

Since the vaccine makers and the Secretary of Health and Human Services and his subordinates are under legal mandates to do all in their power to safen vaccines, it is good to know that the vaccine makers and the governmental agencies have somewhat safened some vaccines.

However, unless:

- All of the other substances in all of the vaccines are the same,
- All of the other substances have been proven to be safe to the standards that have been established for them by law, and
- The vaccines are free of all adventitious viruses and prions,

increased purity does not assure improved safety as the number of: **a)** vaccines, **b)** vaccine doses, and/or **c)** vaccines given together all increase.

Specifically, the failure to prove that vaccines in which Thimerosal is a preservative have a preservative level that is "sufficiently nontoxic ..." for the dose of vaccine administered as required under 21 C.F.R. Sec. 610.15(a), *a current good manufacturing practice (CGMP) minimum, as the vaccine makers have admitted they have not done and the FDA has illegally overlooked*, renders these Thimerosal-preserved vaccines adulterated under **21 U.S.C. Sec. 351(a)(2)(B)** and makes these drugs illegal and all those involved subject to legal sanction.

Until the FDA: **a)** bans the use of Thimerosal-preserved vaccines and **b)** obtains proof that the level of Thimerosal is nontoxic to all recipients with at least a 100X safety margin (because Thimerosal is a highly toxic bioaccumulative poison that is also a proven human

carcinogen, mutagen, teratogen and immune-system disruptor at levels below 1 ppm), all Thimerosal-containing vaccines and other Thimerosal-containing drugs *apparently* do not meet the safety expectations set forth in the U.S. Federal Food, Drug, and Cosmetic Act, as amended.

“Concerns about vaccine safety have been addressed since the time when vaccines were first introduced. Public health authorities and governmental bodies must balance the right to immunize for the “common good” with individual rights and concerns.”

In light of the realities discussed in the preceding paragraphs, this reviewer finds this statement in the report to be disingenuous, at best.

“The U.S. Supreme Court, in 1905, ruled in *Jacobson v. Massachusetts* that the need to protect the public health through compulsory smallpox vaccination outweighed the individual’s right to privacy. This justification is consistently applied to child care and school entry immunization requirements, with allowances for religious beliefs and medical conditions.”

Factually, the Supreme Court ruling only applies to a condition when there was an actual pandemic smallpox outbreak (an epidemic) under conditions where: **a)** there was much less than adequate sanitation, **b)** there were no effective alternative curative treatments and **c)** a significant percentage (about 30%) of those infected would die from the disease – conditions that do not apply in America today.

Moreover, unlike most vaccines, though the *vaccina* vaccine does have some risk of death (about 1 in 10,000), inoculation with it and recovery from that one-time inoculation with *vaccina* is known to convey near lifetime (> 50 year) immunity to smallpox to almost everyone vaccinated

Thus, that Supreme Court decision does not apply to “compulsory” vaccination:

1. In the absence of an actual disease epidemic for which there is no alternative curative treatments,
2. For diseases that are not highly infectious and/or probably spread by a vector for the disease,
3. For diseases that are lifestyle related,
4. For diseases that have no real risk of death, and/or
5. For diseases where there is no proof that the vaccine provides near lifetime protection.

Therefore, the Supreme Court decision has been consistently misapplied to mandate vaccination under conditions where the guarantees of bodily integrity and due process of law in the U.S. Constitution should render such mandates unconstitutional on their face because, *contrary to law*, truly informed consent cannot be given.

This is *currently* the case because the vaccine information that is provided by today’s vaccine, healthcare and public health establishments: **a)** inflates the theoretical benefits and **b)** minimizes and/or hides the risks associated with each vaccine.

“Recently, some parents and vaccine safety advocacy groups have raised questions about a purported link between Autism Spectrum Disorders (ASD) and vaccines.”

From November 9, 2007 onwards, there has been no purported link between ASD and vaccines.

Shortly before that date, *after reviewing her medical records, the testimony of her parents, and her published case report*, medical professionals in the U.S. Department of Health and Human Services conceded that Hannah Poling’s vaccinations at 19 months were a causative factor in her diagnosed autism spectrum disorder.

Therefore, *from that date forward*, there is no longer a “*purported link between Autism Spectrum Disorders (ASD) and vaccines*” but rather a conceded link.

Moreover, *before this vaccine injury case was conceded prior to any hearing, Hannah Poling v. Sec. HHS (02-V-1466)* was designated as a “vaccine Thimerosal is a causal factor in autism” (Theory 2) case in the Omnibus Autism Proceeding in the United States Court of Federal Claims.

This case was selected as a “test” case because Hannah Poling had a diagnosis of autism (autistic disorder) and had been established to be have been mercury poisoned by the Thimerosal in the Thimerosal-preserved vaccines she received in her 19-month vaccinations.

Therefore, those who wrote this report need to get beyond “*purported link*” and deal with the reality of: **a)** a conceded ASD-vaccine link and **b)** a vaccine Thimerosal-ASD link.

“Factors such as the preservative thimerosal (previously used in diphtheria, tetanus, pertussis, Haemophilus influenzae type b, and hepatitis B vaccines); the MMR (measles, mumps, rubella) vaccine; and the number, timing and spacing of vaccines have all been suggested at one time or another as causing or triggering ASD.”

First, let us tell the truth about Thimerosal in vaccines.

Factually, Thimerosal is not a preservative; Thimerosal is a highly toxic mercury compound whose metabolites are bioaccumulative poisons that have half-lives of up to 20 years in the human body¹⁵.

Thimerosal has been, *and is still being*, used as a preservative in some U.S.-licensed vaccines, including in most doses of the inactivated influenza vaccines.

Moreover, *in many developing countries*, Thimerosal is still being used as a preservative in many of the vaccines and serum products, for which the U.S. had licensed a Thimerosal-preserved formulation for use prior to 1999.

Further, ignoring:

- Its 1999 promise to remove Thimerosal from vaccine formulations,
- Its 2000 promise to reduce the level of Thimerosal in vaccine formulations,
- The vaccine makers’ failure to comply with 21 CFR Sec. 610.15(a), and
- The mandate to safen vaccines set forth in 42 U.S.C. Sec. 300aa-27(a)(2),

the FDA has continued to license new Thimerosal-preserved vaccine formulations, which, *without the requisite proof of safety*, the CDC has continued to include in the U.S. national vaccination schedule.

At present, the list of Thimerosal-containing vaccines that are FDA-approved and in use in the USA can be found in the **Table “4”** on the next page.

Examining this table, one finds that, *including the “avian flu” vaccine*: **a)** there are still at least seventeen (17) FDA-approved vaccines that contain some level of Thimerosal, **b)** ten (10) are Thimerosal preserved, **c)** twelve (12) can be given to children of some age, including seven (7) that are Thimerosal preserved, and **d)**, *when you count the fetus as a developing child*, all can be given to developing children.

Having established the on-going presence of Thimerosal in vaccines given to children from before birth to age 18, this reviewer can agree that factors such as the Thimerosal-preserved vaccines, the MMR vaccine; and “*the number, timing and spacing of vaccines have been suggested as causing or triggering*” neurodevelopmental disorders, including any of the recognized autism spectrum disorders (ASDs).

¹⁵ Sugita M. The biological half-time of heavy metals. The existence of a third, “slowest” component. *Int Arch Occup Environ Health* 1978; **41**(1): 25-40.

Table “4” March 2008 FDA-licensed Thimerosal-containing Vaccines

[Taken From: FDA’s “Table 3: Thimerosal and Expanded List of Vaccines - (updated 3/14/2008) Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines” & Recent approvals]

No. [8]	Vaccine	Trade Name	Manufacturer	Thimerosal Concentration [1]	Mercury per dose
1	DTaP	Tripedia [2]	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg/0.5 mL (young children)
2	DTaPH (Tripedia + ActHIB [2])	TriHIBit	Sanofi Pasteur, Inc/SA	≤ 0.00012%	≤ 0.3 µg/0.5 mL (young children)
3	DT	No Trade Name	Sanofi Pasteur, Inc	< 0.00012% (single ds)	< 0.3 µg/0.5 mL (older children & adults)
4/1	DT (available but not marketed [3])	No Trade Name	Sanofi Pasteur, Ltd [3]	0.01%	25 µg/0.5 mL (older children & adults)
5/2	Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL (older children & adults)
6	Td	Decavac	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg/0.5 mL (older children & adults)
7/3	TT	No Trade Name	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL (older children & adults)
8	HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002%	< 1.0 µg/1.0 mL (adults)
9/4	Influenza	Afluria	CSL Limited	0.01% (multi-dose)	24.5 µg/0.5 mL (adults including pregnant women)
10/5	Influenza	Fluzone [6]	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL (children 3 yrs & up, including pregnant women) 12.5 µg/0.25 mL (6- 35- months olds)-
11/6	Influenza	Fluvirin	Novartis Vaccines and Diagnostics Ltd	0.01%	25 µg/0.5 mL (children 4 yrs & up, including pregnant women)
12	Influenza	Fluvirin (Preservative Free)	Novartis Vaccines and Diagnostics Ltd	< 0.0004%	< 1 µg/0.5 mL (children 4 yrs & up, including pregnant women)
13	Influenza	Fluarix	GlaxoSmithKline Biologicals	< 0.0004%	< 1 µg/0.5 mL (adults including pregnant women)
14/7	Influenza	FluLaval	ID Biomedical Corporation of Quebec	0.01%	25 µg/0.5 mL (adults including pregnant women)
15/8	Japanese Encephalitis [7]	JE-VAX	Research Foundation for Microbial Diseases of Osaka University (distributed by Sanofi-Pasteur, Inc in USA)	0.007%	35 µg/1.0mL (≥3 years of age) 17.5 µg/0.5 mL (1 to 3 yrs of age)
16/9	Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc	0.01% (multi-dose)	25 µg/0.5 mL (children “2”yrs and up; though, Sanofi’s Menactra is now being recommended)
17/10	Avian Influenza [9]	Influenza Virus Vaccine, H5N1	Sanofi Pasteur Inc.	0.0098% (multi-dose with doses at 0 & 2 months)	49 µg/1.0 mL (98 µg in 2-dose regimen; adults 18 to 64 yrs of age)

TABLE FOOTNOTES

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of Thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose. Vaccines with a nominal “preservative” level of mercury have **bolded** mercury values.
2. Sanofi Pasteur’s Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. This vaccine is not marketed in the US but it is available.
4.
5. ...
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. Aventis Pasteur distributes JE-VAX. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).
8. The second numbers, in **bolded italics**, are the count for the current Thimerosal-preserved vaccine formulations that have FDA approval.
9. Approved April 17 2008, but not in “Table 3” as it is currently only licensed for use in a pandemic outbreak; approvals for children are pending or deferred.

“Because of these concerns, the medical and public health communities have sought to rigorously examine the scientific evidence for or against an association between vaccines and ASD.”

Though this statement sounds good, the factual evidence supports the reality that the medical and public health establishments have joined ranks to avoid rigorous, scientifically sound assessments of any association between vaccines and ASD.

Though rigorous science would:

- ❖ Demand in-depth toxicological assessment for the toxicity (acute, short- and long- term chronic, reproductive, carcinogenic, mutagenic, teratogenic and immune dysfunction) of Thimerosal in each vaccine formulation to ascertain the minimum level at which reproducible toxic effects are seen in the appropriate Thimerosal-sensitive animal-model species and then,
- ❖ Set a level 100 times lower than the observed minimum-toxic-effect level to provide an adequate safety margin for all who may be inoculated with a Thimerosal-containing vaccine,

the vaccine makers, medical and public health establishments have avoided doing these toxicity assessment studies and setting science-based limits based on the results observed.

Instead, they have attempted to substitute retrospective population-record epidemiological studies that: **a)** are overseen by the CDC and/or CDC/industry-tied “academic” organizations and **b)** can, *at best*, only establish the statistical probability of the possibility of an association between vaccine Thimerosal and various neurodevelopmental disorders, *including ASDs*, as well as other developmental and behavioral disorders.

6 DEPARTMENT OF HEALTH RESPONSE

“Authoritative evidence-based recommendations for or against medical screenings and interventions increasingly set the standard of care.”

As independent assessments have repeatedly shown, those making standard of care recommendations are increasingly influenced by the deep-pocketed pharmaceutical, medical and healthcare establishments, who seem more interested in expanding their markets than in the health of the public.

“The evidence must come from convincing scientific studies—i.e., methodologically rigorous, of high statistical power and subjected to critical peer review prior to publication. Thus, medical interventions where harms outweigh benefits are quickly abandoned, while those demonstrating that the benefits outweigh harms are adopted and promoted.”

Factually, *for vaccine safety*, the evidence in the case of Thimerosal must come appropriate prospective toxicity studies in sensitive animal-model studies that include vaccination-timing studies designed to match the children’s developmental periods.

For studying the MMR vaccine link to harmful outcomes, the studies must track the outcomes for thousands of American children from the date of vaccination until several years afterward to capture the true incidence of those adverse events known to cause harm in some who are vaccinated with the MMR vaccine according to the package insert for the vaccine, *which reports these adverse events but does not establish their incidence rates or the factors affecting the adverse outcomes observed*, and, *so that we can see the effect*, studies of matched children who, *for religious or philosophical reasons*, do not receive the MMR vaccine.

In the course of these studies, the adverse effects of the second dose of the MMR vaccine in humans must be the subject of in-depth study of the immune system response to this immune-system rechallenge to infection by injection as well as the pathophysiological changes observed in those individuals who have a “bad” reaction to the second dose.

Then and only then, will the information needed to understand the links and the factors affecting these links be available to determine the causal links, *if any*, in each case.

Unfortunately, *except for Thimerosal in preserved vaccines*, the independent studies and the independent review of CDC/industry-influenced studies required to ascertain the facts have not been conducted.

In the case of Thimerosal,

- Toxicity studies in monkeys, mice, pigs, pheasants, rats, chicken eggs and hamsters as well as in *in vitro* systems and
- Studies from the post-mortem biopsies of the brains of children who died shortly after the external application of Thimerosal¹⁶ or
- In-depth differential medical diagnostic workups and critical biochemical toxicity marker evaluations of those who had a diagnosis of autistic disorder, an ASD, and/or other neurodevelopmental disorders

have clearly established that surface exposure to Thimerosal-based antiseptics or vaccination with Thimerosal-preserved vaccines can mercury poison the recipient to the point that those who are mercury-poisoned exhibit the set of neurological deficit symptoms used to diagnose an ASD.

Recent publications from researcher groups on four continents (Australia, Europe, North America and South America) have *clearly* established that children who: **a**) received the majority of their principal early mercury exposure from Thimerosal-derived mercury in the vaccines and other Thimerosal-containing drugs to which they were exposed during gestation and early childhood and **b**) were also diagnosed with an ASD are mercury poisoned^{17,18,19,20,21}.

Moreover, recent studies in developing hamsters given weight and developmental-age proportional doses of Thimerosal²² have again established that giving Thimerosal-preserved vaccines causes pathophysiological symptoms and behaviors similar to those exhibited by mercury-poisoned children who have an ASD diagnosis.

“The scientific studies addressing vaccine safety are too numerous to describe here but the Department of Health has compiled a bibliography (included in the Supporting Documents Section) of many of the pertinent studies.”

In contrast to the selective list provided in the report’s bibliography, this reviewer has included a more-comprehensive cross-section of the pertinent literature on studies involving Thimerosal and other alkylmercury compounds (as well as some references that bear on other issues this reviewer has raised) in a list at the end of this review.

¹⁶ Fagan DG, Pritchard JS, Clarkson TW. Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic. *Arch Dis Child*. 1977; 52: 962-964.

¹⁷ Austin DW, Shandley K. An investigation of porphyrinuria in Australian children with autism. *J Toxicol Environ Health A*. 2008; **71**(20):1349-51.

¹⁸ Geier DA, Mumper E, Gladfelter B, Coleman L, Geier MR. Neurodevelopmental disorders, maternal Rh-negativity, and Rho(D) immune globulins: a multi-center assessment. *Neuro Endocrinol Lett*. 2008 Apr; **29**(2): 272-280.

¹⁹ Geier DA, Geier MR. A prospective assessment of androgen levels in patients with autistic spectrum disorders: biochemical underpinnings and suggested therapies. *Neuro Endocrinol Lett*. 2007 Oct; **28**(5): 565-573.

²⁰ Nataf R, et al. Porphyrinuria in childhood autistic disorder: implications for environmental toxicity. *Toxicol Appl Pharmacol* 2006; 214: 99-108.

²¹ Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure. *Neurotox Res* 2006; **10**: 57-64.

²² Laurente J, Remuzgo F, Ávalos B, Chiquinta J, Ponce B, Avendaño R, Maya L. Neurotoxic effects of thimerosal at vaccine doses on the encephalon and development in 7 days-old hamsters. *An Fac Med Lima* 2007; **68**(3): 222-237.

“Similarly, a critique of the quality of the various studies is beyond the scope of this document. However, in summary, the reviews of the scientific literature by recognized medical and public health authorities, such as the prestigious Institute of Medicine (IOM), indicate that vaccines are not associated with ASD.”

Unfortunately the studies upon which the IOM committee, *paid and guided by the CDC*, relied have all been shown to be: **a) not** accessible to independent review and **b), *in general***, fatally flawed in their design, execution and/or analysis.

Since:

- Independent researchers have been denied access to the raw datasets used in the studies upon which the IOM relied;
- The datasets for the key U.S. studies (the studies headed by Verstraeten et al.) have been lost;
- A subsequent IOM committee found that the epidemiological studies were problematic and their findings unreliable, and
- Dr. Gerberding, head of the CDC, has testified to Congress that the types of epidemiological approaches used in the studies in which the aforementioned IOM committee²³ relied are unreliable approaches to addressing the issue of causality,

the 2004 IOM committee's reported findings must be disregarded as the published epidemiological studies upon which that committee chose to rely are not only unreliable but also both non-reviewable and, *for the U.S. studies*, non-reproducible.

Finally, *other than the justification that that is what that IOM committee elected to do*, there is, and was, no scientific justification for ignoring the then-existent body of published peer-reviewed toxicological studies that clearly showed toxicological effects in animals and developing children from the equivalent of vaccine-dose exposures and, *in many cases*, lower than vaccine exposures to Thimerosal and/or the other ethyl mercury compounds, like the alkylmercury compounds into which Thimerosal is metabolized in the human body (**see** the pertinent articles in the reviewer-supplied bibliography).

“The IOM is part of the United States National Academy of Sciences, a nongovernmental, not-for-profit organization chartered to provide national advice on issues relating to biomedical science, medicine, and health. It uses a volunteer workforce of scientists and has a formal peer review process. Thus, it works outside the framework of the U.S. federal government to provide independent guidance and analysis. In their report ‘Immunization Safety Review: Vaccines and Autism,’ the IOM Immunization Safety Review Committee stated ‘...the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism. The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism. The committee further finds that potential biological mechanisms for vaccine-induced autism that have been generated to date are theoretical only.’”

For the scientific reasons stated in the previous discussion and the fact that the “...*the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism. The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism*” clearly shows that this IOM committee only considered the now-discredited epidemiological studies and, *in the case of Thimerosal*, clearly ignored the substantial body of toxicological evidence that clearly established that the sub-acute mercury poisoning from vaccine-level exposures to Thimerosal can and does cause neurodevelopmental deficits in those children that it mercury poisoned, which, *for some mercury-poisoned children*, include the set of symptoms used to diagnose an ASD.

²³ Institute of Medicine (IOM) meeting held at the National Academy of Sciences in Washington, DC on February 9, 2004.

Thus, these statements should be ignored because they are based on discredited epidemiological studies.

“Similarly, the WHO’s Global Advisory Committee on Vaccine Safety reviewed the evidence and released a July 2006 statement concluding that ‘there is no evidence of toxicity in infants, children or adults exposed to thimerosal (containing ethyl mercury) in vaccines.’”

Given the published toxicity studies showing that infants and children who have been exposed to Thimerosal-preserved vaccines have been, *and are*, mercury poisoned by that Thimerosal exposure (using a scientifically proven indirect urine porphyrin profile analysis [UPPA] test that had been proven to indicate mercury poisoning in those with routine workplace exposure to metallic mercury, mercury amalgam materials, and other mercury compounds), it is obvious that “*the WHO’s Global Advisory Committee on Vaccine Safety*” conclusory statement: **a)** is incorrect and **b)** ignores the body of studies showing neurological harm from subacute exposures to alkyl mercury compounds, including Thimerosal and various other ethyl and methyl mercury compounds.

Moreover, lacking in-depth studies in adults, the data from exposures in infants and children clearly indicate that toxic effects would be observed in adults who have received annual inoculations with Thimerosal-preserved influenza vaccines for several consecutive years (>3) were the requisite studies to be conducted.

“Despite the many scientific studies that demonstrated no causal connection between thimerosal and ASD, in July 1999, U.S. Public Health Service agencies and the American Academy of Pediatrics recommended that thimerosal be removed from vaccines as a precautionary measure aimed at reducing any additional exposure to mercury. Today, all vaccines recommended for use in infants and young children are available in forms that have no or only trace amounts of thimerosal. The term ‘trace’ in this context means 1 microgram (1 millionth of a gram) of mercury per dose or less. To put this into context, according to an FDA survey of commercial seafood, a 6 oz can of albacore tuna contains, on average, 60 micrograms of mercury.”

First, this reviewer agrees that the July 1999 statement was made.

Second, *while true in the USA*, the second assertion ignores: **a)** the reality some of these vaccines are still available in Thimerosal-preserved formulations and **b)** the fact that neither the Thimerosal-preserved nor the “trace Thimerosal” childhood vaccines have been proven to be safe to give to developing children.

Third, how many typical American children under the age of 13 months eat any albacore tuna?

How many American children under 2 years of age eat a whole 6-oz can of any tuna?

Moreover, since the general evidence is that: **a)** less than 25% of the mercury in the tuna is absorbed into the body (with the rest being excreted in the feces) and **b)** the absorption is a slow process when tuna is eaten, the “effective dose” of mercury from eating this “theoretical” can of “*albacore tuna*” is less than 15 micrograms!

So, *other than to be disinformative*, what is the point of including this obviously irrelevant example?

“Methyl mercury, from sources such as seafood and coal plant emissions, is a well known toxicant. It is not readily eliminated by the human body and therefore accumulates and poses health risks. On the other hand, ethyl mercury (from thimerosal) is more rapidly metabolized and eliminated so poses much less risk.”

First of all coal plants do not emit methyl mercury [technically, dimethyl mercury: (H₃C)₂Hg].

Actually, they emit inorganic mercury salts and, in some cases, metallic mercury –mercury species, which enter the environment and are slowly converted into methyl mercury compounds by the bioorganisms living there.

Second, methylmercury compounds and their metabolism products are, *in general*, not readily eliminated by the human body and, *therefore*, do pose health risks.

However, based on the available material safety data sheet (MSDS), Thimerosal and the ethyl mercury compounds into which Thimerosal is initially metabolized as well as the secondary “inorganic” mercury metabolites formed from the ethyl mercury compounds are as toxic, *or more toxic*, to the human body than the corresponding methylmercury compounds.

Moreover, though the human body does metabolize Thimerosal more rapidly than the methylmercury compounds typically used in comparative studies using both, there is no mass-balance-based evidence that the mercury from Thimerosal is “eliminated” from the body – in fact, the evidence from studies using mercury-radiolabeled [²⁰³Hg₈₀] ethyl mercury chloride clearly shows that the mercury bioaccumulates and is not eliminated from the body²⁴.

Factually, the studies by Burbacher et al.²⁵, *upon which this report seems to rely*, only indicate that INJECTED Thimerosal and its ethyl mercury metabolites clear the blood faster than INGESTED methylmercury hydroxide.

In addition, *unlike the methylmercury hydroxide and the mercury species sequestered in fish*, Thimerosal is a strong immune-system disruptor at levels below 0.01 ppm.

“Referring again to the WHO’s 2006 statement, ‘...the pharmacokinetic profile of ethyl mercury is substantially different from that of methyl mercury. The half-life of ethyl mercury is short (less than one week) compared to methyl mercury (1.5 months), making exposure to ethyl mercury in blood comparatively brief. Further, ethyl mercury is actively excreted via the gut, unlike methyl mercury that accumulates in the body.’”

Here the WHO statement speaks in half-truths and is disinformative.

The half-lives of various compounds of mercury in blood do differ and the half-life for injected Thimerosal in blood appears to be significantly shorter than the half-life of ingested methylmercury hydroxide in blood.

However, unlike the studies using ethyl mercury chloride containing a radioactive mercury isotope, ²⁰³Hg₈₀, the different modes of administration and the lack of a mass balance or the determination of the fate and half-lives of the mercury species in the various tissues of the human body preclude any valid assessment of the degree of bioaccumulation in body tissues and the half-lives thereof for the two compounds used in the most vaccine-like studies to which this report seems to be referring.

Moreover, in the Burbacher et al. study in developing monkeys supposedly administered vaccine-equivalent doses of methylmercury hydroxide (by forced ingestion) and Thimerosal (by injection) in a protocol designed to mimic the developmental-age timing comparable to the 1999 vaccination schedule, the imputed²⁶ average level for “inorganic mercury” in the

²⁴ Shiraki H, Nagashima K. Essential neuropathy of alkylmercury intoxications in humans from the acute to the chronic stage with special reference to experimental whole body autoradiographic study using labeled mercury compounds. *Neurotoxicology* 1977; 1: 247-260.

²⁵ Burbacher TM, et al. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal. *Environ Health Persp* 2005; 113(8): 1015-1021.

²⁶ This average brain mercury levels were compared after correcting for the fact that about half of the monkeys fed MMH had undetectable levels of “inorganic mercury” in their brains while all of the monkeys injected with Thimerosal had detectable levels of “inorganic mercury” that, on average, were more than twice the level in the fraction of MMH-fed monkeys that had a detectable level thereof.

brains of the monkeys given Thimerosal was 3 times the level in the monkeys that were force fed methylmercury hydroxide (MMH).

In addition, the data showed no decline in the level of “inorganic mercury” in the monkeys’ brains 120 days after mercury exposure ceased.

Taken together, these data indicate that, *in the brain*, injected Thimerosal produces “3” times the level of the long-term brain toxicant (“inorganic mercury”) than fed MMH.

Thus, in this human-applicable study, the data clearly shows that Thimerosal is significantly more toxic to the brain than MMH and that Thimerosal’s end-metabolite in the brain, “inorganic mercury” accumulates to a level that is “3” times that for MMH.

Therefore, the excretion of some “ethyl mercury in the gut” is a red herring that, *given the preceding facts*, has no bearing on the relative bioaccumulation of “inorganic mercury” in the brain, where it causes the neurodevelopmental harm seen in studies designed to study the effects of this mercury poisoning on the developing brain.

Finally, a recent Peruvian study by Laurente et al.²² using baby hamsters, an animal more sensitive to the global effects of Thimerosal than either the monkeys or the strains of rats and mice typically used, found: **a)** significant neurodevelopmental deficits and **b)** significant adverse effects on overall growth and key organ development.

This study used a Thimerosal-dosing pattern that was weight- and developmental-age-adjusted to mimic the dosing for the Thimerosal doses and developmental age for American children being inoculated at 2, 4 and 6 months under the recommended 2001 U.S. early-childhood vaccination program.

The study was a three-armed study where: **a)** saline, or **b)** saline plus glucose or **c)** saline plus Thimerosal was given to the young hamsters in each of the three groups of hamsters at days: 7, 9 and 11 in the hamsters’ development and, *after identical access to the same food and water*, the hamsters were evaluated at “day 25” to allow time for Thimerosal to be “fully” metabolized.

When the hamsters were evaluated on “day 25”, the only group showing overt adverse developmental effects was group “**c**”, which had:

1. An average total weight (11.3 g) that was only about 55% of the average weights for the other two groups (20.55 g),
2. An average brain weight (0.76 g) that was only about 79% of the average brain weights for the other two groups (0.965 g), and
3. An average caudal skull length (7.5 cm) that was only about 86% of the average lengths for the other two groups (8.7 cm).

Furthermore, significant differences were only seen in the Thimerosal-injected group for the tissues that were also examined.

Specifically, neurotoxic effects were also only observed in the Thimerosal-treated group at the encephalic level as well as in the hippocampus (regions CA1, CA3 and DG), cerebral cortex, and cerebellum (Purkinje and granule cells); with decrease in neuronal density, neuronal necrosis, axonal demyelination, and gliosis.

Finally, the data indicated that statistical risk in developing any of the preceding tissue alterations was only significant in the animal group receiving saline plus Thimerosal.

“A robust immunization program has tremendous benefit to individual and public health. Calls for opposing immunizations and/or school entry vaccination requirements, or for providing easier and more numerous ways to obtain exemptions for required vaccinations, are resulting in growing numbers of individuals not properly

immunized. This, in turn, is leading to increases in outbreaks of vaccine preventable disease such as measles and pertussis.”

Since “complete” immunization is an unobtainable goal for most vaccines, *unless they activate the human immune system in the same manner as the natural disease does*, everyone should start calling most of these programs vaccination programs because, *with the current exception of the rotavirus vaccines and possibly the live-virus influenza vaccine*, that is what these programs are – vaccination programs that, at best, only provide incomplete protection from disease.

Moreover, everyone needs to admit that these vaccination programs require multiple exposures (inoculations) to produce protection that is typically much less complete and of shorter duration than the protection (immunity) produced by natural exposure for those diseases, where near lifetime immunity is the outcome for those who recover from having a given disease only once in most instances.

Then, everyone needs to:

- Admit that recommending universal chickenpox vaccination is a bad idea and
- Abandon this losing approach to minimizing the health risks and costs associated with managing this disease.

When:

- The ineffective HVZ and human influenza vaccines are removed from the U.S. recommended vaccination schedules for children, adults and pregnant women,
- Only those vaccine components that are truly safe and medically cost-effective or, *where valid estimates for the total direct and indirect costs of the adverse effects of vaccination are included*, at least societally cost-effective are retained in the recommended U.S. vaccination programs, and
- All vaccines are produced in full compliance with all the applicable CGMP laws,

then, *and only then*, everyone can begin to discuss the “appropriate” balancing of societal imperatives against the individual liberties guaranteed by the Constitution of the United States of America, provided the pernicious biasing efforts of the special interests who profit from ever more vaccines are removed from the discussion.

Next, *absent some immune system evaluation*, everyone should understand that, *at the individual level*, there is little or no *a priori* guarantee that multiple exposures to the current vaccines, *the current state of vaccination*, will produce adequate long-term protection from disease without causing major short-term and/or long-term adverse effects in that individual – be that person a developing fetus, neonate, baby, child, or adult.

This complexity of outcomes in individuals arises because vaccines contain not only disease organisms or disease-related antigens but also other substances that, *when injected (as most vaccines are), inhaled (as the live-virus flu vaccine is) or ingested (as the current rotavirus vaccines are)*, may, or do, also interact with the human immune system in ways that, *in some*, may produce local and global long-term harmful effects including, *in a few instances*, inducing life-threatening allergies and/or chronic disease conditions.

Thus, *at the individual level*, where prior informed consent is supposed to be obtained, everyone is faced with the reality that the benefits of vaccination are theoretical and, *for the individual being inoculated*, not at all assured.

Moreover, the true risks of both: **a)** vaccinating and **b)** not vaccinating are typically obscured by: **i)** the overwhelming pro-vaccine propaganda to which the American public is exposed today and **ii)** the lack of accurate statistics for the probability of each serious risk, starting from the worst risk, death; listing all the other risks in descending order of lifetime harm and

the cost of harm, and progressing to the most common inoculation-related risks that apply to most drugs to which patients are exposed in the same manner.

Thus, we need to overhaul our current vaccine information in a manner where it is truly informative but devoid of propaganda, and then proceed to openly address the group-protection issues for those vaccine components that are truly safe, long-term effective, and medically cost-effective.

For the safe, effective, and medically cost-effective vaccine components, we can then proceed to keep only these in the recommended national vaccination program, and, *except for those vaccines that are neither safe nor truly effective*, put the other vaccine components in an optional vaccines program where they remain available for those who may need, or *want to be*, vaccinated with them.

Next, everyone needs to admit that the scientifically sound data that we have today for vaccination outcomes, *at best*: **a)** only applies at the group level and **b)** is incomplete because:

1. There are no universal active surveillance programs for adverse vaccination effects and
2. The current passive surveillance programs (VAERS and MedWatch) are fundamentally designed to address only a tiny fraction of the mostly short-term adverse events, which mainly healthcare providers and the vaccine companies grossly underreport.

Tuning to the “imported disease” issues, it would seem that, given today’s rapid screening tests, all those: **a)** returning from a country where certain highly contagious diseases are endemic and **b)** exhibiting any signs of infection should be screened for active infection for those diseases that are highly contagious and those testing positive appropriately quarantined until they are no longer infectious.

It would seem that this approach would: **a)** reduce the risk for imported-disease outbreaks, **b)** lessen the impetus to rush to revaccinate when we do have an outbreak and **c)** also reduce the costs associated with the localized outbreaks we now have.

Moreover, *in addition to vaccination*, it seems that we should be investigating the human immune system to find the optimal ranges for all vitamins, minerals, and other essential substances and adjusting the mandated food supplementation levels to ensure that Americans consuming a balanced diet will have levels of these nutrients that are in the optimal-health range.

Further, *rather than only relying on vaccination to fight communicable disease outbreaks*, we need to study the effects of short-term high-dose supplementation with key vitamins, minerals and other essential substances on the reduction in the severity and duration of a given disease²⁷.

With respect to the report’s, “*Calls for opposing immunizations and/or school entry vaccination requirements, or for providing easier and more numerous ways to obtain exemptions for required vaccinations, are resulting in growing numbers of individuals not properly immunized. This, in turn, is leading to increases in outbreaks of vaccine preventable disease such as measles and pertussis*”:

1. First, this reviewer finds that the report’s “*not properly immunized*” is, *at best*, gratuitous and, *in a society that recognizes the right to choose an exemption*, totally uncalled for.
2. Factually, though the national percentage of children with vaccination exemptions has increased, the number of pertussis cases has actually dropped recently making the

²⁷ For example, studies with higher levels of daily supplementation with vitamin D-3 have recently shown not only that higher vitamin D-3 levels reduce the risks for some diseases, e.g., flu, but also that this supplementation improves overall health and ones positive outlook on life.

report's attempt to link pertussis case rates to today's increases in exemptions a specious claim.

3. The failure on the part of those pushing ever-increasing vaccination programs to recognize the concomitant increases in chronic diseases that these programs have apparently created – effectively attempting to force the public to accept epidemics of life-long chronic disease in return for freedom from short-term acute diseases from which almost all healthy children recover without any serious long-term adverse effects.
4. Finally, those who are on any side of these issues need to: **a)** treat each vaccine component separately and **b)** stop attempting to make the choices “all or none” decisions.

7 DEPARTMENT OF HEALTH RESPONSE

“This is occurring not just in the United States but in a number of developed countries such as the Netherlands, Great Britain, Switzerland, France and Israel. In fact, Great Britain has recently had to rescind its 1980's declaration that measles was no longer endemic (that is, children in Great Britain can now contract measles even if no new cases are brought in from the outside). Thus, children and adults in developed nations are increasingly suffering from significant illness, disability and death due to vaccine-preventable diseases. With the ease and volume of international travel today, Florida is highly vulnerable to the importation of such diseases, especially if the number of children immunized, and herd immunity levels, decline.”

While everyone should have some concern for what is happening in other nations, our principal concern should be for the realities in America today.

With this in mind, this reviewer is tired of hearing fear mongering about the potential harm from acute childhood diseases that might return if more Americans choose exemptions from those who refuse to acknowledge, much less address, the multiple epidemics of chronic diseases that, *based on our current understanding of how the human immune system functions*, are clearly tied to the increasing number of vaccines given to our children before their immune systems have matured to the point that, *in societies that breastfeed their children*, these diseases usually occur (with little harm to most all children in those instances where the infectious disease has existed for many generations) after the child is two years of age.

Until our vaccination programs are changed in a manner that stops the current chronic disease epidemics, then everyone should accept that more Americans will seek vaccine exemptions and, *no matter the level of fear mongering*, choose to risk their children's having yesterday's acute diseases to avoid the increasing risks of their child's having one of today's growing list of chronic diseases.

When the choice is, *for example*, vaccinate your young child against hepatitis B (a disease that he or she has almost no risk of contracting [< 1 on $\sim 250,000$] and, *in most instances after they become sexually active*, if exposed, his or her body's immune system will overcome the disease and develop complete immunity in most cases) and have a > 1 in $\sim 25,000$ risk of your child's developing childhood multiple sclerosis (MS), who could fault that parent for choosing not to let their child receive the hepatitis B series?

“The suggestion that immunizations might lead to developmental disorders is troubling to parents. Florida's parents have access to and clear explanations of the recent findings published in medical journals that confirm that there is no causal link between vaccines and autism or other neurological conditions.”

First, this reviewer agrees that the reality that vaccinations “*might lead to developmental disorders is troubling to parents*”.

Second, this reviewer notes that there are many recent findings published in medical and toxicology journals that have confirmed a causal link between vaccines, or some component in some vaccines, and other neurological conditions.

Moreover, even the U.S. epidemiological studies by Verstraeten et al., *on which the 2004 IOM relied*, found a causal link between Thimerosal exposure and the group of neurological conditions labeled “tics” – a group that includes Turrette’s syndrome.

Thus, if the Florida Department of Health were truly concerned about providing Florida parents with the facts about vaccines, then this report’s obviously biased:

“It is important that Florida’s parents have access to and clear explanations of the recent findings published in medical journals that confirm that there is no causal link between vaccines and autism or other neurological conditions”

would have been stated as:

“It is important that Florida’s parents have access to and clear explanations of the recent findings published in” scientific peer-reviewed journals that present the factual information on both sides of the argument linking vaccines to autism or other neurodevelopmental, developmental and behavioral conditions so that they can understand the issues and decide for themselves based on the evidenced presented.

Given the biased statement in the report here, it is clear that the Florida Department of Health is only interested in presenting its self-serving pro-vaccine view of this issue.

Moreover, the absence of the recent published studies establishing links between vaccines and autism or other neurodevelopmental, developmental and behavioral conditions clearly supports this reviewer’s perception of this “vaccine education” issue.

“The Florida Department of Health supports efforts by the CDC and others to identify the biological and environmental causes of autism and other developmental disabilities. The Florida Department of Health monitors all issues pertaining to immunizations and stays abreast of all vaccine research in order to stop vaccine-preventable diseases without compromising the health and safety of children and adults. The Florida Department of Health and the CDC place a high priority on vaccine safety and the integrity and credibility of vaccine safety research.”

While this reviewer finds the rhetoric here very “inspiring”, the information in this report indicates that there is not much substance supporting the rhetoric.

Given a bibliography that failed to include hundreds of pertinent studies on both sides of the issues raised in this report about Thimerosal in vaccines and the possibility of a causal link between the MMR vaccine administration and subsequent diagnosis of an ASD, as well as up-to-date information on the links between vaccination and various chronic childhood diseases (e.g., asthma, type 2 diabetes, MS, and obesity), lethal allergies, and clinical levels of intolerance to foods (e.g., gluten, casein, and soy) and other natural biological substances (e.g., pollens, and yeasts) that did not exist or were rare occurrences in the 1950s, 1960s and 1970s, this reviewer finds that the Florida Department of Health has done a less than stellar job of staying “*abreast of all vaccine research*”.

Finally, since the Florida Department of Health and the CDC continue to recommend that vaccines that are deemed to be adulterated under 21 U.S.C. Sec. 351(a)(2)(B) because their vaccine manufacturer has knowingly failed to comply with the CGMP requirement minimum set forth in 21 C.F.R. Sec. 610.15(a) with respect to ensuring that the Thimerosal used as a preservative in some FDA-approved vaccines is safe to the “sufficiently nontoxic...” standard established therein, this reviewer finds that neither agency places “*a high priority on vaccine safety*”.

8 DEPARTMENT OF HEALTH RESPONSE

“Questions and Answers on ~~Immunizations~~ Vaccinations”

Let us be clear, the questions and answers provided in this section are questions and answers on “**Vaccinations**” and not “**Immunizations**” because vaccination does not ensure that the person, *even when multiply inoculated with the vaccine*, has any protection from the disease/diseases for which that vaccine may provide protection, much less the near lifetime protection required to equate it with disease immunity.

Moreover, it is clear that some vaccines (e.g., the chickenpox vaccine) do not provide long-term protection; some are not in-use effective (e.g., the influenza vaccines); and, under 21 U.S.C. Sec. 351(a)(2)(B) in the statutes implementing the Federal Food, Drug, and Cosmetic Act, as amended, Thimerosal-preserved vaccines that have not been proven to be safe to the explicit safety CGMP (current good manufacturing practice) minimum set forth in 21 C.F.R. Sec. 610.15(a), “Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, ...”, are, therefore, adulterated drugs.

Given our current understanding of the human immune system, if “we” truly want to immunize our children, then, *when they were the “appropriate age”*, we would:

1. For the common highly contagious communicable childhood diseases, carefully expose our children to other children, who are shedding the disease or, *in the case of smallpox*, expose our children to the surrogate cowpox virus that does provide full protection against the disease,
2. Allow these exposures under carefully controlled conditions after: **a)** ensuring that their bodies had optimal levels of all vitamins, minerals and key nutrients and **b)** preloading them with those vitamins (e.g., vitamin A for measles) and minerals (e.g., zinc and selenium) that are known to help our immune systems “resolve” the infection and develop near-lifetime immunity,
3. Treat their post-exposure disease symptoms appropriately, and
4. Rigorously protect our children from exposure to all life-style-related diseases.

Then, *with the exception of chickenpox*, our children would be immune to the diseases that they have had.

With these issues in mind, from this point on, this reviewer will, as he did in the title for this section:

1. Replace each misuse of the word “*immunize*”, or any of its forms, from here onwards with the appropriate derivative of “vaccinate” or “protect” and then,
2. Address each of the points made by this report.

“The best way to protect each of our children is to protect all of our children.”

Who can argue with this statement – certainly not this reviewer.

“Why do we **immunize** **vaccinate** our children?”

- To protect them from disease, disability, and death.

In the pre-vaccine era, diseases that are now vaccine-preventable were major causes of life-long disability as well as death.”

Were there no risks of “*disease, disability and death*” from any vaccination and were the vaccines in the current recommended vaccination program restricted to only those “*pre-*

vaccine era” highly contagious diseases, then, *perhaps*, this reviewer would have no problem with this response.

However, this reviewer notes that this pro-vaccine-biased answer ignores several important vaccination-related realities.

To simplify our discussion, let us: **a)** consider two vaccine instances, **i)** the MMR vaccine and **ii)** all of the DPT vaccines, and **b)** examine: **i)** the annual measles and pertussis deaths reported in the CDC’s summary of notifiable disease reports as a measure of the residual “disease” cases from whatever source and **ii)** the appropriate VAERS reports as indirect indicators of the annual harm done by these composite vaccines.

Measles-related Realities

First, *as has been previously stated*, inoculation of about 8 million American children annually does seem to provide near-universal protection for measles and rubella.

Moreover, *based on the measles cases, as summarized in Table “5”*, there is no evidence

Table “5” Measles Data 2002—2006

Year	Measles Cases	N (%) of Cases with an unassigned source	Measles Deaths
2002	44	8 (18)	0
2003	56	11 (20)	2
2004	37	4 (15)	0
2005	66	9 (14)	0
2006	55	3 (5.4)	0
Average	51.6	7 (13.5)	“<1”

of a significant increasing time-trend in measles cases that would be needed to support a claim that measles has returned, even though, *in the first three quarters of*

Table “6” VAERS Search – Any Measles Vaccine & Adverse Reports By Category 2002—2006

Year Vaccinated	Event Category	Count	“Guestimated” Total Count
2002	Death	8	[80]
	Life Threatening	41	[410]
	Permanent Disability	41	[410]
	Hospitalized	143	[1,430]
	Hospitalized, Prolonged	1	[10]
	Emergency Room	1,502	[15,020]
2003	Death	5	[50]
	Life Threatening	30	[300]
	Permanent Disability	36	[360]
	Hospitalized	143	[1,430]
	Hospitalized, Prolonged	6	[60]
	Emergency Room	1,545	[15,450]
2004	Death	5	[50]
	Life Threatening	43	[430]
	Permanent Disability	30	[300]
	Hospitalized	132	[1320]
	Hospitalized, Prolonged	6	[60]

	Emergency Room	1,483	[14,830]
2005	Death	<u>6</u>	[60]
	Life Threatening	35	[350]
	Permanent Disability	17	[170]
	Hospitalized	122	[1,220]
	Hospitalized, Prolonged	6	[60]
	Emergency Room	1,347	[13,470]
2006	Death	<u>8</u>	[80]
	Life Threatening	42	[420]
	Permanent Disability	30	[300]
	Hospitalized	165	[1,650]
	Hospitalized, Prolonged	8	[80]
	Emergency Room	1,443	[14,430]

2008, the number of reported U.S. cases is about 3 times the average for the 5-year period where CDC summaries of notifiable cases have been reported.

Turning to the man-made MMR-inoculation-related infections, based on a simple category search of the Vaccine Adverse Event Reporting System (VAERS) database by a knowledgeable epidemiologist,

<http://wonder.cdc.gov/controller/datarequest/D8.jsessionid=3B462407EBBE8A5627809C...>,

this reviewer reports the results shown in **Table “6”** on the previous page.

In addition, since:

- a. The reporting to VAERS is strictly voluntary,
- b. Studies on the percentage of adverse events that are reported to the U.S. Center for Disease Control and Prevention (CDC) have found that there was significant underreporting, and
- c. “*Less than 10%*” is the general level of reporting used by many researchers when estimating the actual level of the adverse events reported in VAERS,

this reviewer has simply multiplied the results found by 10 to get his guesstimated numbers of total adverse events occurring in a given year and entered the result in braces, “[]”, in **Table “6”**, in a column that is labeled “***Guestimated’ Total Count***”.

Reviewing the reported data for “measles” in VAERS, this reviewer can only wonder why, *at a minimum*, the CDC is not required to report all VAERS measles-vaccine deaths as a notifiable death and all unique severe adverse events as a measles case unless the investigation of the VAERS report proves that the measles virus was not a causal factor – perhaps in separate columns labeled “Measles-vaccine-related Measles Deaths” and “Measles-vaccine-related Cases”, respectively.

For the 258 identified clinical measles cases, there were 2 deaths, indicating a rough death risk of 1 in 129 cases for this data but, when the reported measles cases for 2007 and the first part of 2008 are included, the apparent death risk is less than 1 in 400 cases of measles (0.25%).

Beyond that, this reviewer has only presented the reported information and his guesstimated total count data:

- To prove the validity of this reviewer’s claim that measles have never left America and
- As food for thought for those who read this review to ponder.

Pertussis-related Realities

Since there are no annual cases of diphtheria and only a few cases annually of tetanus, the pertussis component is key to the overall effectiveness of the DTap and DTP vaccines.

In this case, the VAERS reports for all DTaP and DTP vaccines can be used to estimate the level of harm inflicted on the population (in the same period, 2002 through 2006, which was used for the evaluation of “adverse events” to VAERS for measles).

Table “7” and the “**Pertussis Notes**” box that follows it on the next page summarize the information for clinical pertussis cases reported by the CDC.

The first thing to note is that there are no deaths reported for cases of pertussis, but the information reported to VAERS for the DTaP vaccine formulations, including the

Table “7” Pertussis Data 2002—2006

Year	Tetanus Cases	Pertussis Cases	Pertussis Cases Information
2002	25	9,771	Overall Incidence = 3.4/100 K; 21% for infants <6 months (108.8/100 K); 3% for those 6-11 months (15.4/100 K); 14% for those 1-4 yrs (8.9/100 K); 10% for those 5-9 yrs (4.8/100 K); 29% for those 10-19 yrs (7.0/100 K); 23% for those >20 yrs (1.2/100 K) with >94% U.S. coverage.
2003	20	11,647	Overall Incidence = 4.0/100 K; 17% for infants <6 months (103.1/100 K); 2% for those 6-11 months (12.2/100 K); 9.8% for those 1-4 yrs (7.5/100 K); 7.3% for those 5-9 yrs (4.4/100 K); 39% for those 10-19 yrs (11.1/100 K); 24.5% for those >20 yrs (1.4/100 K).
2004	34	25,827	Overall Incidence = 8.9/100 K. Incidence in: <6 months (136.5/100 K); 6-11 months (31.8/100 K); 1-4 yrs (16.9/100 K [2,582 cases]); 5-9 yrs (12.6/100 K); 10-19 yrs (23.9/100 K); >20 yrs (3.5/100 K). [Note: 3,233 cases for those < 1 yr; corresponding cases breakdowns <u>not</u> provided.]
2005	27	25,616	Overall Incidence = 8.9/100 K. Incidence in: <6 months (160.81/100 K). 60% of cases in adolescents aged 10-19 years and adults aged >20 years. [3,957 cases for those < 1 yr; corresponding cases breakdowns <u>not</u> provided.]
2006	41	15,234	Overall Incidence = 5.35/100 K. Incidence in: <6 months (84.21/100 K). [2,029 cases for those < 1 yr; corresponding cases breakdowns not provided.]

Pertussis Notes:

- 2002:** Adolescents and adults can become susceptible to disease when vaccine-induced immunity wanes, approximately 5--10 years after pertussis vaccination. The incidence of reported pertussis among children aged 7 months to 9 years has been relatively stable, suggesting protection against pertussis by routine vaccination according to the recommended schedule.
- 2003** Adolescents and adults can become susceptible to disease when vaccine-induced immunity wanes, approximately 5--10 years after pertussis vaccination.
- 2004** Although infants have the highest morbidity associated with pertussis, adolescents and adults now account for the majority (67%) of reported cases. They become susceptible to disease when vaccine-induced immunity wanes, approximately 5--10 years after pertussis vaccination (2). Two tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (Tdap) products were licensed by the Food and Drug Administration in 2005 as single-dose booster vaccines to provide protection against tetanus, diphtheria, and pertussis. CDC's Advisory Committee on Immunization Practices (ACIP) recommends the routine use of Tdap vaccines among adolescents aged 11--18 years in place of tetanus and diphtheria toxoids (Td) vaccines (3). ACIP also has made a provisional recommendation that adults aged 19--64 years receive a single dose of Tdap to replace the next dose (4). The primary objective of administering the adolescent pertussis booster is to protect adolescents and adults against pertussis. Strategies for use of Tdap in adults are under review.
- 2005** Adolescents and adults might be a source of transmission of pertussis to young infants who are at higher risk for severe disease and death (1). In addition to routine use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in adolescents aged 11--18 years as recommended by the Advisory Committee on Immunization Practices (ACIP) in 2005, ACIP recommends use of Tdap for a single dose to replace the next dose of Td for adults aged 19--64 years (2,3). Use of Tdap also is recommended for certain populations of adults, including health-care workers and persons in close contact with infants aged <12 months (3,4).
- 2006** Adolescents and adults might be a source of transmission of pertussis to young infants who are at higher risk for severe disease and death and are recommended to be vaccinated with tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) (1,2). In 2006, coverage with Tdap in adolescents aged 13--17 years was 10.8%, compared with 49.4% coverage with tetanus and diphtheria toxoids vaccine (Td) (3). **The decrease in reported pertussis incidence in 2006 is unlikely to be related to use of Tdap and is more likely related to the cyclical nature of disease.**

Tdap, vaccines, as **Table “8”** (on the next page) shows.

Reviewing this data and knowing the U.S. timeline for the phased-in displacement of:

- a. Thimerosal-preserved DTaP vaccines with “Trace-Thimerosal” vaccines (effectively starting in 2001 and complete by 2004) followed by:
- b. “Trace-Thimerosal” DTaP vaccines with the “no Thimerosal” formulations (effectively starting in 2003 and continuing into 2008),

this reviewer notices that there appears to be a significant concomitant/parallel decrease in VAERS for reports of DTaP-related deaths:

Year Inoculated	VAERS Reports of Deaths Associated with Both DTaP and Tdap vaccines	Change from 2001 VAERS Reports of Deaths (78)	% Change from 2001
2002	67	- 11	- 14
2003	61	- 17	- 22
2004	41	- 37	- 47
2005	26	- 52	- 67
2006	20	- 58	- 74

but, there is no similar trend for the other VAERS categories – indicating that the removal of Thimerosal from the acellular formulas of the multi-component diphtheria,

Table “8” VAERS Search – Any DTaP and DTP Vaccine, And Adverse Reports By Category 2002—2006

Year Vaccinated	Event Category	Count	“Guestimated” Total Count
2002	Death	67	[670]

	Life Threatening	60	[600]
	Permanent Disability	43	[430]
	Hospitalized	295	[2,950]
	Hospitalized, Prolonged	4	[40]
	Emergency Room	1,955	[19,550]
2003	Death	61	[610]
	Life Threatening	45	[450]
	Permanent Disability	36	[360]
	Hospitalized	262	[2,620]
	Hospitalized, Prolonged	8	[80]
	Emergency Room	1,952	[19,520]
2004	Death	41	[410]
	Life Threatening	51	[510]
	Permanent Disability	31	[310]
	Hospitalized	187	[1,870]
	Hospitalized, Prolonged	6	[60]
	Emergency Room	1,569	[15,690]
2005	Death	26	[260]
	Life Threatening	34	[340]
	Permanent Disability	16	[160]
	Hospitalized	171	[1,710]
	Hospitalized, Prolonged	9	[90]
	Emergency Room	1,374	[13,740]
2006	Death	20	[200]
	Life Threatening	38	[380]
	Permanent Disability	34	[340]
	Hospitalized	224	[2,240]
	Hospitalized, Prolonged	9	[90]
	Emergency Room	1,739	[17,390]

tetanus and pertussis vaccines has apparently reduced the vaccine-related deaths reported to VAERS.

Moreover, the number of reported vaccine-associated deaths was significantly higher for the DTaP/Tdap vaccines than for the MMR vaccine.

But, the adverse event reports for the MMR and the DTaP/Tdap vaccines were very similar in the “Life Threatening” and “Permanent Disability” categories for the period 2002 through 2006 – indicating that the reported less-than-death harm attributed to both categories of vaccines were similar.

Again, these findings lead credence to the acute toxicity effect of Thimerosal because:

1. The measles vaccines, which did not contain Thimerosal exhibited no time-related drop in any of the severe categories of harm, including death, but
2. The deaths reported for the DTap vaccines (including the recent Tdap reports) exhibited a time-related decrease that appears to track the removal of Thimerosal from these vaccines.

While not definitive, the preceding findings clearly seem to provide indirect evidence for the toxicity of Thimerosal in infants.

- “To save on health care costs, including out-of-pocket expenses by the family.”

Since: **a)** the lifetime healthcare costs for a child, “including out-of-pocket expenses by the family”, with permanent disabilities in today’s America is in the millions of dollars and **b)** with the addition of additional doses for the older vaccines, the costs of the annual vaccination programs have risen to the point that those who are pro-vaccine no longer claim that our vaccination programs are medically cost-effective and, *in many cases*, the overall program is clearly not societally cost-effective, the “healthcare savings” argument is clearly a specious argument!

Factually, *except for the 2-dose MMR vaccine and the 5-dose DTaP/DT vaccines*, which, *because of price controls on the vaccines*, may be societally cost-effective when all of the real costs are considered, today’s programs do not “save on health care costs”, when the costs of taking care of those transiently and permanently harmed are considered!

This lack of savings on overall healthcare costs is so apparent for the newer vaccines (vaccines approved in 1986 or later) that the pro-vaccine advocates either do not discuss them or, *ignoring the costs to those families whose children are harmed and the costs of administration, recordskeeping and adverse-events reporting*, generally only publish studies (*typically, underwritten by the vaccine’s manufacturers*) that find these newer vaccines are “societally cost-effective” at prices above the initial per-dose prices that the vaccine’s manufacturer wishes to establish for each new vaccine formulation.

- “To protect other children who are not “immune” from our children if our children develop one of the vaccine-preventable diseases. —This includes children for whom vaccines are not safe, who are too young to be ~~immunized~~ vaccinated, in whom the vaccine did not work, or who are not ~~immunized~~ vaccinated for other reasons.”

If protection of other children were the reason we vaccinate our children, then how could we justify using any live-virus vaccine because, *after a child inoculated with such vaccines*, there is some risk that the inoculated child will shed live virus and infect others (the report’s “children for whom vaccines are not safe, who are too young to be” “vaccinated”“, *in whom the vaccine did not work, or who are not* “vaccinated” “for other reasons” as well as unprotected adults) with whom the inoculated child has contact for some period of time after inoculation with a live-virus vaccine.

The reality of this problem was the reason we abandoned the use of the live-virus oral polio vaccine (OPV) in the USA in the late 1990s.

Yet, the U.S. governmental, vaccine, healthcare, and public health establishments have ignored this hard-earned lesson, and licensed, recommended, and, *in some states*, included the live-virus influenza and rotavirus vaccines in their “mandated” vaccination schedules – thereby guaranteeing that: **a)** some who should not be exposed to these live-virus vaccines will be exposed, and **b)** some of those so exposed will contract one of these live-virus vaccines’ diseases.

Moreover, the approval of the current rotaviruses is especially egregious because these live-virus organisms survive and reproduce in the gut, and are excreted into the environment where they survive for extended periods and virtually guarantee that, *like polio*, other will be infected and be at risk of developing not only the disease but also the worst complications of the disease-inducing viruses in the rotavirus vaccines (e.g., intussusception and Kawasaki’s disease, *when the vaccine is RotaTeq*²⁸, or, *when the vaccine is Rotarix*, intussusception and pneumonia) with possibly lethal outcomes.

²⁸ Geier DA, King PG, Sykes LK, Geier MR. RotaTeq vaccine adverse events and policy considerations. *Med Sci Monit.* 2008 Mar; 14(3): PH9-PH16.

Obviously, because the CDC's current list of recommended vaccines includes the following live virus components: measles, mumps, rubella, *herpes varicella zoster* (which initially causes chickenpox), human influenza (FluMist, used since 2003), and 5 strains of bioengineered human-bovine rotavirus (RotaTeq; approved in 2006) or a single attenuated strain of human rotavirus (Rotarix; approved in 2008), protecting other's children (who, *for whatever reasons*, have not been inoculated) is not the primary reason "we" are asked to infect "our" children with doses of these live viruses.

If protecting other's children were the goal of the vaccinate-at-all-costs advocates, then, *at a minimum*, they would be demanding that ALL live-virus vaccines be replaced with inactivated-virus vaccines – and this is not what is happening.

“Why do we keep **immunizing** **vaccinating** children when the diseases are gone?”

- The reason we have so few cases in the US is that our **immunization vaccination** levels are so high.”

While this reviewer agrees that high vaccination levels are a reason that the diseases for which there are approved vaccines that the states in USA routinely administer, this reviewer notes that the disease rates for many other communicable diseases for which:

- There is a vaccine but no recommended general vaccination programs (e.g., cholera, smallpox, and yellow fever) or
- There is no approved vaccine (e.g., malaria, dengue fever)

also generate no, or few, cases in the USA.

Moreover, there are diseases for which there are vaccines against which routine vaccination is recommended even though these vaccines are not in-use effective in preventing the disease in the USA (e.g., all of the influenza vaccines).

These realities need to be considered and the role of sanitation, hygiene, healthy diet and antibiotic, antifungal and antiviral drugs not only recognized but also raised and, *where possible*, used to replace vaccination.

- “All the vaccine-preventable diseases (except smallpox) still occur in the rest of the world, at rates higher than in the US, and most still occur in the US at low levels, especially in **underimmunized** undervaccinated populations.”

While the preceding statement is true, this reviewer notes that the USA vaccinates against chickenpox even though, because of: **a**) the nature of the viral disease organism, *herpes varicella zoster* [HVZ], and **b**) the means by which our immune systems suppress resurgence after initial infection (periodic exogenous exposure to the live virus), the current vaccination programs are not only less than effective but also increase the rates of the follow-on resurgences of the HVZ as shingles and have apparently disrupted the transfer of maternal immunity to her offspring since the USA is now experiencing an “epidemic” of childhood shingles cases even in those too young to be vaccinated, when, *before the vaccine*, childhood shingles cases were virtually non-existent.

Here, the pro-vaccine advocates have imposed a program that costs hundreds of millions of dollars annually, does not provide effective immunity, and has increased the costs and prevalence of previously almost unknown childhood shingles cases as well as shingles cases in the elderly to the point that Merck has introduced an FDA-approved HVZ vaccine formulation, Zostavax, for the elderly – outcomes much worse than promoting appropriate dietary supplementation before and during our children's having chickenpox naturally, and recognizing and facilitating the needed exogenous boosting post-chickenpox as well as encouraging prolonged (natural) breastfeeding of our children (typically, for a 2-year or longer period).

Those who are pro-vaccine need to stop being fixated on developing and deploying vaccines for every disease and to focus on the use of vaccines as a last resort and only for those disease organisms for which there is no effective recuperative dietary regimen and/or no other effective preventive or curative medical interventions.

The public needs to understand the preceding realities and demand that the existing vaccines that are neither safe nor effective be banned from the U.S. market and those that are safe but not medically cost effective or, at a minimum, independently determined to be societally cost-effective when all of the costs, including the adverse-event cost, are considered for not only the current number of doses but also at least one additional dose that seems, *based on the history of our current vaccines*, to be required.

Then and only then, should “we”, *in the absence of significant disease risk*, continue the national vaccination programs for those vaccine components that are both safe and cost-effective.

Approved vaccines that are not medically safe should be discontinued.

Those vaccines that are simply not societally cost-effective should be removed from the CDC’s national recommendations and the states’ mandates, and only offered as an option that, *after weighing the pros and cons*, individuals may elect to use.

- “Any of these diseases can be reintroduced into any community in the US at any time. Florida receives very large numbers of visitors, from all over the world.”

Given the large number of visitors, from all over the world, and the relative few incidents where they: **a)** bring in a disease and **b)** spread it to others, this reviewer finds that, *given the availability of rapid (< 4-hour) screening tests for the most contagious diseases*, perhaps it is time that, *on arrival in the USA*, we started holding, screening, and quarantining all visitors and immigrants who exhibit any symptoms of illness as a means to help protect the American public from imported-disease exposure and infection – if “we” are truly concerned about imported disease cases.

“How do vaccines protect children who have not been ~~immunized~~ vaccinated?”

- If almost all children in a population are ~~immune to~~ vaccinated against a disease, a child who is exposed and does develop a clinical case of the disease will be surrounded by ~~immune~~ protected children, and the spread of infection will ~~stop~~ probably not occur.
- With slightly lower ~~immune rates~~ vaccination levels, the outbreak may not stop by itself, but, when it does not, public health prevention activities such as isolating cases (*quarantine*) and giving antibiotics, antifungals, vitamins (e.g., vitamins C and D-3 for influenza), minerals (e.g., zinc and magnesium for viral infections) and key nutrients (e.g., lysine for *herpes* viruses), antivirals, and vaccines or immune globulins, as appropriate, to those who have had contact with those actively shedding the disease ~~contacts~~ can ~~stop~~ be used to end the outbreak.”

[Note: Here, this reviewer has simply corrected the text to better reflect what is actually true.]

“How effective are vaccines?”

- The vaccines in common use against vaccine-preventable diseases are all highly effective. Some are close to 100% effective, some as low as 85%.”

Here, this reviewer finds the response is not only inaccurate, but also improperly framed because the question and the answer should have been framed in terms of the disease-antigen components of each vaccine.

This is the case because several vaccines are multi-component vaccines (e.g., MMR, MMRV, DTaP, DTaP Hib, and Tdap).

Factually, *based on the observed in-use (real world) outcomes*, there are certain single-disease vaccines and components in multiple-disease vaccines that are problematic.

For example, the human influenza vaccines are problematic because their tested level of “efficacy” may be less than 70% and, because of “strain mismatch”, their in-use effectiveness may be close to zero.

For components in multiple-disease vaccines, *even though the “aP” component in the DTaP vaccines have a claimed “single-dose efficacy” that exceeds 80%*, the in-use effectiveness of vaccines with an aP component is closer to 70% than it is to 80-plus %, based on need to give 4-plus doses of “DTaP” vaccines containing this component to reduce the number of pertussis cases to 10,000 to 25,000 cases annually.

Moreover, if any vaccines were “*close to 100% effective*”, then only 1 dose would be needed for lifetime protection and the post-vaccination cases among the vaccinated would be nearly “zero”.

For the current recommended vaccine components, it appears that only the measles and the rubella components of the MMR vaccine, *where the vaccination program specifies 2 doses*, have anywhere near “zero” annual cases among those who receive only one dose of the MMR vaccine (a requirement if a vaccine component were to be “*close to 100% effective*”) and, perhaps, the diphtheria component in the DTaP vaccine – although the total lack of reported diphtheria cases in those under 6 months of age seems to indicate that diphtheria bacteria are either virtually non-existent or incapable of triggering a recognized clinical case of the disease even in American newborns.

Thus, *excluding human influenza and HVZ vaccine components, which are less than effective*, this reviewer finds that the long-term *effectiveness* of vaccine components in the current U.S.-licensed vaccines seems to range from about 70 % to 95-plus %.

- “Only vaccines that have been determined to be effective at preventing spread of the disease in the population are used in the United States.”

Given the use of:

- Inactivated human-influenza-virus vaccines and the vaccines containing live HVZ, both of which are ineffective and have been shown not to prevent the spread of disease in the long term and, *for HVZ, actually* infect the inoculees with HVZ,
- The live-virus human influenza vaccine, which spreads the disease to contacts and is not in-use effective in preventing disease spread,
- The other live-virus vaccine components, measles, mumps and rubella, which infect some percentage of those inoculated with them, and
- The rotavirus vaccines, which give clinical cases of rotavirus to many of those vaccinated as well as to some percentage of those with contact them or their feces or their feces-contaminated materials in the United States,

this reviewer finds that the report's assertion (“*Only vaccines that have been determined to be effective at preventing spread of the disease in the population are used in the United States*”) here is a knowing distortion of factual reality.

“Before a vaccine is recommended for widespread use, a careful assessment is made by a national expert panel, based on the best available science. The panel assesses the seriousness of the disease if it is not prevented, the vaccine’s effectiveness in preventing the disease, and the frequency and consequences of adverse reactions to the vaccine. A vaccine is recommended to be included in the national immunization schedule when, on balance, the

benefit to the whole community of routine ~~immunization~~ inoculation with that vaccine is much greater than the risks.”

Again, the facts are at odds with the statements being made here.

In the past, the CDC’s ACIP (a CDC panel packed with “experts” with known conflicts of interest and/or loyalties to vaccine development and/or the vaccine manufacturers) recommended the now-withdrawn RotaShield for widespread use even before the FDA approved it.

Currently, the CDC’s ACIP is recommending new vaccines for widespread use: **a)** before there is any significant post-FDA-approval in-use experience – just after the FDA approval (e.g., the RotaTeq rotavirus vaccine) – or **b)** before there is any proof that the vaccine, Merck’s Gardasil®, is effective as a preventive for the key disease (cervical cancer) that is the sole justification to recommend widespread use.

To facilitate the ACIP’s rubberstamping newly FDA-approved vaccines, the FDA has allowed the vaccine makers to: **a)** use other than saline as the placebo (e.g., the hepatitis B vaccine clinical trials and the recent Gardasil clinical trials); **b)** conduct fewer and/or smaller clinical trials in non-representative populations (unlike the U.S. population as a whole) where there is a significant background disease incidence and, *because of poor hygiene and sanitation*, the trial subjects in the control arm of the clinical trial have a significant risk of contracting the disease, which, *when the vaccine contains live viruses*, can be a case of the virus being shed by those in the test arm of the clinical trial who have been inoculated with the candidate vaccine (e.g., the rotavirus vaccines trials); and **c)** conduct clinical trials using vaccine formulations devoid of a preservative level and use that safety and adverse-event data for approval of a Thimerosal-preserved vaccine (e.g., Sanofi’s recently approved bird-flu vaccine).

Given the preceding, no a fair assessment can be made for vaccines such as these and, *given the chicanery permitted and notwithstanding FDA-approval*, none of these vaccines should have been recommended for widespread use until: **a)** the requisite unbiased safety and effectiveness (not efficacy) studies were conducted and **b)** impartial review by non-conflicted but knowledgeable experts determined that these vaccines were safe and effective in preventing the disease or diseases that were key to determining that *“the benefit to the whole community of routine ~~immunization~~ inoculation with that vaccine is much greater than the risks”*.

9 DEPARTMENT OF HEALTH RESPONSE

“Why do we require ~~immunization~~ vaccination for attendance in child care or public school?”

- Most vaccine-preventable diseases spread easily where children are gathered together. Getting the ~~immunization~~ vaccination coverage rate close to 100% can stop outbreaks from spreading if the disease is introduced.”

[**Note:** Corrections were made in the preceding text to better align the statements with reality.]

First, the disease-spread statement is overly broad, because only those diseases easily spread without intimate inter-personal contact are easily spread when young children, those under age 6 (the group that receives most of the vaccine doses), congregate.

Second, getting the vaccination coverage close to 100% can only reduce the risk that, *if introduced*, the disease will spread to the children, who are, *for whatever reason*, not protected from contracting that disease.

- “High ~~immunization~~ vaccination coverage protects the few children who are not ~~immune to~~ protected from contracting a clinical case of the disease.

—Non-~~immune~~ **protected** children at child care or school include those who have medical reasons why vaccines are not safe for them, those in whom the vaccine did not work, those with religious exemptions to ~~immunization~~ **vaccination**, and those too young to have received certain vaccines.”

[**Note:** Corrections were made in the preceding text to align the statements with reality.]

- “A few children are not protected against some of the diseases they were ~~immunized~~ **vaccinated** against. Going to child care or school with other ~~immunized~~ **vaccinated** children protects these children.”

[**Note:** Corrections were made in the preceding text to better align the report's statements with reality and the context of this portion of the report.]

Provided the vaccinations with live viruses occurred at least a month prior to the non-protected children's or staffer's going to child care or school with the vaccinated, this reviewer agrees with these assertions.

However, when vaccination with a live-virus is given to any member, including those who oversee the group or class or work with it, of a group in a childcare or school setting during the period during a period the group is in child care or at school, then the person or persons inoculated with the live-virus vaccine should be quarantined from that group for a period of not less than 7 days, *when the risk of infection and subsequent viral shedding is low*, to 21 days, *when the risk of infection is significant and/or the virus is shed for a significant period of time after the person or persons are vaccinated*.

“**Is it fair to require children to be ~~immunized~~ **vaccinated** to attend child care or school?**”

- High ~~immunization~~ **vaccination** levels protect both the ~~immunized~~ **vaccinated** children and the few who are not ~~immune~~ **protected**.”

[**Note:** Corrections were made in the preceding text to better align the report's statements with reality and the context of this portion of the report.]

First, even with the suggested changes, this statement is overly broad, to say the least.

Factually, high vaccination levels only partially protects those who, *when vaccinated*, develop a protective level of antibodies for the biological component antigens in the vaccine and not all who are vaccinated.

Moreover, immediately after vaccination with a live-virus-containing vaccine, those who are inoculated may, *in some instances*, shed the live virus and may infect some who are not protected, *including those too young to be vaccinated*, when the vaccinees interact with those who are not protected from the disease organisms being shed.

- “Child care and school ~~immunization~~ **vaccination** laws have been shown to be a very effective way to achieve and maintain very high ~~immunization~~ **vaccination** coverage levels.”

[**Note:** Corrections were made in the preceding text to better align the statements with reality.]

First, this statement is valid only for those vaccines that are truly safe and effective.

Second, IF: **a)** everyone recognizes the safety and effectiveness of the recommended vaccines and vaccination programs and **b)** the appropriate vaccines are readily available at nominal prices for all children, THEN there would be no need for any mandates (laws) requiring vaccination as a condition of attendance or employment.

Compulsive laws are only needed when the vaccines and/or vaccination programs are problematic and/or the vaccination costs are prohibitive.

Moreover, compulsory vaccination laws are an oddity in the truly democratic developed neighboring nations (Canada on the north, the United Kingdom on the east, and Japan on the west), which, in general, have no forced vaccination laws and do not have any significantly higher overall disease problems than the USA does and, for Japan, today's overall infant mortality is about half of that of the USA, today's life expectancy is more than 4 years longer, and the levels of chronic diseases are significantly lower.

- “In effect, society has made an agreement: I agree to ~~immunize~~ **vaccinate** my child if you agree to ~~immunize~~ **vaccinate** yours. All the children benefit from their own protection against serious diseases, and also from being surrounded by ~~immune~~ **vaccinated** children.”

[Note: Corrections were made in the preceding text to better align the statements with reality.]

Given that the compulsory vaccination laws are the mandated “children” of the vaccine makers and public health officials, who, *by whatever means*, have conspired to mandate vaccination even when the vaccine is neither truly adequately safe (e.g., the withdrawn vaccines, like RotaShield and LymeRix) nor truly effective in preventing those vaccinated from getting the disease (e.g., the influenza and chickenpox vaccines):

- Society has made no such agreement, and
- Since those actually making these decisions are usually administrative public health officials who are not even elected, though some elected official or officials must concur, there is clearly no such individual (“I”) agreement in the USA or the state of Florida.

Only when there is no legal compulsion, can individuals, *aided by the removal of barrier to vaccine access and assured of the in-use safety and effectiveness of the vaccines approved and recommended by their government*, make the societal agreement reflected in this report.

Since none of the prerequisite conditions (lack of compulsory laws, no barriers to vaccine access, and only vaccines that have been proven to be in-use safe and effective are recommended for use) exist, there can be no such truly consensual societal agreement about vaccination in the USA today.

- “Some children experience side effects to vaccine doses they receive. Most are mild, a few rare ones are not. No vaccine is totally free of side effects, though all have improved over the years as researchers have helped manufacturers to refine their manufacturing processes.”

The preceding is a disingenuous pro-vaccine view of reality that is intentionally misleading and knowingly false.

First of all, almost all children experience minor side effects, including pain, from the inoculations they receive.

Many have local site reactions, redness at the injection site, and localized swelling.

Beyond the injection-site side effects, vaccines cause a wide variety of increasingly dangerous acute side effects, *including death*, that today collectively have helped put the USA at the bottom of the list of developed nations in terms of 1st-year infant mortality, as well as some delayed side effects that take months or years to develop; typically, are chronic as well as, *in most cases*, debilitating, quality-of-life damaging, and life shortening (leading today's American to have a shorter “average” life span than Cubans and, *unlike many “developed” nations*, a declining life expectancy).

With respect to the report's assertion:

“No vaccine is totally free of side effects, though all have improved over the years as researchers have helped manufacturers to refine their manufacturing processes”,

both the short-term and longer-term outcomes being observed today paint a far different picture.

Factually, regardless of the help researchers have given to vaccine manufacturers, or perhaps because of it, today's vaccination programs have clearly traded:

- The suppression of: **a)** acute childhood (measles, mumps, rubella, diphtheria, tetanus) and **b)** lifestyle (hepatitis B and HPV) diseases using childhood vaccination programs
- For epidemic increases in chronic diseases (e.g., childhood type 2 diabetes, childhood asthma, childhood COPD, childhood MS, severe childhood obesity, precocious puberty, life-threatening food allergies, food intolerances, and air-borne pollens, animal danders, and dusts – to name some) that, *though unknown or very rare in the 1950s, 1960s and early 1970s*, are seen everywhere today.

Since the vaccine makers are effectively shielded from being sued for the harm their vaccines cause and are rewarded with the ever-increasing prices they can charge (with concomitantly increasing profits), the vaccine makers and their supporters have no incentive to ensure their vaccines are a net benefit to the American public.

Moreover, all facets of the “healthcare” establishment have an incentive to support more vaccines because they are benefiting from the ever-increasing chronic disease customer bases that our current recommended vaccination programs are creating.

Thus, *in today's greed-driven society*, those who effectively control the vaccines and the vaccination programs and provide us our healthcare are, *as those in the housing and banking establishment*, looking out for their personal financial interests at the expense of the physical, mental and financial health of the American public.

Moreover, though some vaccines have “improved” (e.g., the change from DTwP to DTap vaccines, the removal of Thimerosal from some vaccines, and the reduction of the level of Thimerosal in others), the increasing number of vaccines and vaccine doses for each type of vaccine have clearly produced negative effects that have more than offset the positive effects of improving some vaccines.

As Americans know all too well, when it comes to vaccines,

- **“improved”** has nothing to do with proven to be long-term safe and effective,
 - **“safe”** has no long-term meaning and, *since the risks are hidden or under reported and the clinical safety trials are biased to minimize the relative risks reported*, the reported data is of little comfort to the parent faced with deciding whether or not his or her child should receive a vaccine, and
 - **“efficacy”** is an advertisers claim that is not guaranteed to apply to any particular child or to apply for that child's lifetime, and does not usually equate to reduced costs or even fair costs (less than the theoretical costs if a child contracts the disease) to the American public.
- “All children benefit from the vaccines, including the doses they have received themselves and the ones other children have received, but only a few develop severe side effects.
—Compensation mechanisms are in place for injured children and their families—the National Vaccine Injury Compensation Program, and compensation lawsuits.”

This statement is obviously false – because the few, who develop severe side effects, include those children whom the vaccine's side effects kill.

- Please, what is the “benefit” to all those previously healthy children killed by being given a vaccine?

- ❑ What is the benefit to those children whose brains are severely and irreparably damaged from being vaccinated?
- ❑ Finally, why doesn't this report address the odds for each established severe-side-effect risk for each vaccine?

With respect to the so-called compensation mechanisms that “*for injured children and their families—the National Vaccine Injury Compensation Program, and compensation lawsuits*”:

- Why does the report fail to mention that the compensation mechanisms provided by the National Vaccine Injury Compensation Program (NVICP) have a very short (3-years from the first symptom that could be linked to the claimed vaccine injury) window for filing a claim?
- Why does the report fail to mention the NVICP process is anything but non-adversarial, quick, and fair?
- Why not mention that about half of the petitions for compensation that are filed are dismissed?
- Why not mention that the state and federal courts have increasingly refused to allow individual to sue outside of the NVICP even where the NVICP statutes explicitly provide for such lawsuits?
- Finally, why not mention that today the NVICP effectively shields the vaccine maker and the healthcare establishment from being sued for the harm caused by giving a vaccine to your child?

“**Why do we have religious exemptions to ~~immunization~~ vaccination requirements?**”

[**Note:** A correction was made in the preceding text to better align this statement with reality.]

- “Almost all states have such exemptions.”

First, this “because” answer begs the question.

Factually, after states began to mandate certain vaccines starting in the early 1900s, in the states that have religious exemptions, a religious group, the Christian Scientists, who fundamentally believes that injecting/infusing a person with any foreign substance is an abomination to God, sued for a religious exemption and won their lawsuits in the courts and/or persuaded their government representatives to enact such exemptions in the Commonwealth of Puerto Rico, all other commonwealths, territories, and protectorates governed by the federal government, in the armed forces of the USA, and in all United States of America, except for Mississippi and West Virginia.

- “Having religious exemptions strikes a balance among respect for the genuine convictions of some families, the desire for all children to have access to public schools, and the desire to protect all residents of our communities from infectious diseases.”

While this statement fundamentally speaks to balancing the individual's constitutionally guaranteed right of religious freedom against conflicting secular laws, the individual's constitutional right is misleadingly portrayed as “*the genuine convictions of some families*” (as if it were a group right); and the secular laws are misleadingly portrayed as “*the desire to protect all residents of our communities from infectious diseases*” (instead of the desire to force vaccination since, as *the report has already admitted and the CDC's annually reporting affirms*, vaccination does not protect “*all residents of our communities from infectious diseases*” nor even all who have been “fully” vaccinated.)

- “As long as the proportion of children in a school who receive religious exemptions is very low, it is still possible to attain high overall coverage and protect all the children in the school.”

Again, *since there are other control strategies for controlling the risk for and spread of infectious diseases*, the USA can keep disease rates low even if the “*the proportion of children in a school who receive religious exemptions*” were to increase to much higher levels.

For example, visual examinations coupled with rapid-disease-screening technologies for those entering the country as visitors or immigrants who exhibit any physical symptoms of disease, holding of all until the results from the screening come back, and quarantining the few who test positive for an incipient highly communicable disease and those with whom they had close contact until those who are coming down with the disease are no longer shedding the disease and the close contacts either contract the disease or test negative 24- to 48-hours later for incipient disease eruption.

Thus, the report’s statements here are simply self-serving pro-vaccine propaganda – devoid of any real substance.

- “If there are cases of one of the vaccine-preventable diseases in a childcare center or school, all **unimmunized** children **who are unvaccinated and have no proof of having had the disease** will be excluded for the duration of the outbreak. Children with either medical or religious exemptions will be excluded. Taking this step reduces, but does not eliminate, the hazard to the other children of allowing some children to attend schools without being **immunized vaccinated**.”

[**Note:** Corrections were made in the preceding text to better align the report’s statements with reality and the context of this portion of the report.]

In addition to the preceding, those who are enrolled in childcare center or school and receive any live-virus vaccine while enrolled should be quarantined from that childcare center or school until they are shown not to be shedding that virus or at least 21 days, whichever is shorter, so that these live-virus inoculees do not risk infecting their fellow students.

Yet, this pro-vaccine report fails to even recognize the preceding live-virus vaccination reality – much less address it.

10 DEPARTMENT OF HEALTH RESPONSE

“request 1

Develop a side-by-side chart of CDC and Florida vaccinations schedule and recommendations and highlight differences

The Florida Department of Health adopts, coordinates, and recommends the routine ‘Childhood and Adolescent Immunization Schedules’ in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC) and the CDC’s Advisory Committee on Immunization Practices (ACIP).”

This reviewer understands that, *by taking this stance*, the Florida Department of Health has abrogated its state’s duty to protect the health and safety of its citizens because these are duties reserved unto the states.

- “The ACIP’s ‘Recommended Immunization Schedules’ are recognized as a standard of practice by physicians, healthcare providers, state **immunization vaccination** programs and other entities involved in **immunizations vaccinations**.”

[**Note:** Corrections were made in the preceding text to better align the statements with reality.]

This reviewer understands that this report is simply the healthcare, healthcare providers, and public health establishment's view of what is the current state of affairs and, *if they continue to have their way*, what this "reality" will continue to be.

- “There are no differences between the CDC recommended ~~immunization~~ vaccination schedule and that of Florida.”

[Note: Corrections were made in the preceding text to better align the statement with reality.]

As the following tables report in the report shows, *though recommended by the CDC*, Florida does not currently require/mandate any hepatitis A, HPV, influenza, meningococcal, or rotavirus vaccines as a requirement for childcare or attending grades K–12.

Furthermore, the report's statement, *while semantically correct*, only reports the views of those who prepared this report and not the views of the people of Florida.

- “~~Immunization~~ Vaccination schedules are updated each year for healthcare providers to refer to and share with parents when planning the medical preventive care of their infants and children.”

[Note: Corrections were made in the preceding text to better align this statement with reality.]

As the following tables report in the report shows, *though recommended by the CDC*, Florida does not currently require the hepatitis, HPV, influenza, meningococcal, and rotavirus vaccines.

- “While many ~~immunizations~~ vaccines are licensed and recommended by CDC for routine medical care, it is important to note that NOT all of the routinely recommended ~~immunizations~~ vaccinations are required for entry/attendance in Florida schools. It is important to distinguish the difference between which ~~immunizations~~ vaccinations are recommended for routine medical care and which are required for school.”

[Note: Corrections were made in the text to better align these statements with reality.]

As the following tables in the report show, *though recommended by the CDC*, Florida apparently does not currently require vaccination with the vaccines for: **1)** hepatitis A, **2)** HPV, **3)** influenza, **4)** meningococcal, and **5)** rotavirus.

- “~~Immunization~~ Vaccination requirements for school are set by grade level in contrast to age groups listed on the recommended schedule. This uniform requirement facilitates all children having the most protection as medically possible for many diseases that can be transmitted in the classroom.

—One example is the diphtheria-tetanus-pertussis-containing vaccine (Dtap): While the 5th dose of Dtap is recommended for children 4 to 6 years of age, the 5th dose is required for entry into Kindergarten. Traditionally, children entering Kindergarten are 5 to 6 years of age. A copy of the routine recommended schedule is included in this section.

The following table details the recommended ~~immunization~~ vaccines in contrast to those required for school.

Vaccines	Routine CDC/ACIP Immunization Vaccination Recommendations	Florida Childcare and School Immunization Vaccination Requirements
Diphtheria-Tetanus-Pertussis (DTaP)	X	X
Hepatitis A (HepA)	X	
Hepatitis B (HepB)	X	X
Haemophilus influenzae type b (Hib)	X	X
Human Papillomavirus (HPV)	X	
Influenza (Flu)	X	
Meningococcal (MCV4)	X	
Measles-Mumps-Rubella (MMR)	X	X
Pneumococcal (PCV)	X	X

Poliovirus (IPV)	X	X
Rotavirus	X	
Tetanus-Diphtheria (Td)	X	X
Varicella	X	X

11 REQUEST 1

“The following table further illustrates the number of vaccines available for prevention of certain communicable diseases in contrast to the vaccines that are required for child care and school and the year the requirement was introduced.”

CDC/ACIP Recommended Vaccines and Immunization Vaccination Requirements for Florida Schools.										
CDC Recommended Immunization Schedule for Persons Aged 0–19 Years UNITED STATES, 2008								Year Immunization Requirements First Initiated for Florida Schools K to 12 and Child Care		
CDC Recommended Vaccination Schedule for Persons Aged 0–19 Years UNITED STATES, 2008*								Year Vaccination Requirements First Initiated for Florida Schools K to 12 and Child Care*		
	Birth	2 mos	4 mos	6 mos	12–18 mos	4–6 yrs	11–12 yrs.	K–12	7 th	Child Care
DTaP		X	X	X	X	X		1971	NR	1976
Flu	Annual							NR	NR	NR
Hep A					X			NR	NR	NR
Hep B	X	X	X	X				1998	1997	NR
Hib		X	X	X	X			NR	NR	1992
HPV							X	NR	NR	NR
Meningitis							X	NR	NR	NR
MMR					X	X		1977	1997	NR
MR								1971	NR	1976
Pneumo		X	X	X	X			NR	NR	2008
Polio		X	X		X	X		1971	NR	1976
Rotavirus		X	X	X				NR	NR	NR
Td							X	NR	1997	NR
Varicella					X	X		1997/1998	NR	2001

* Corrections to properly align headers and correctly use vaccination.
 Florida recommends immunizations in accordance with the CDC’s “Advisory Committee on Immunization Practices” (ACIP), the American Academy of Pediatrics and the American Academy of Family Physicians
 All ACIP routinely recommended ~~immunizations~~ vaccinations are not mandated for entry/attendance in Florida schools
 MR: Measles & Rubella (Phased out with licensure of the MMR); MMR: Measles, Mumps & Rubella; NR: Not Required

12 REQUEST 1

“requests 2 and 3

List of vaccinations generally, then broken down by fatal and non-fatal illnesses. List of vaccine-preventable illnesses, incidence and outcome (number of cases and number of deaths).

While some vaccine-preventable diseases are of short duration and without serious complications, the viruses and bacteria that cause these diseases can all result in serious complications, long-term disabilities, and even death.”

While the preceding statement is valid, the report fails to reflect the reality that the vaccinations themselves can also result in serious complications, long-term disabilities, and even death.

“Varicella (chickenpox) is one example: Most children and adults experience an uncomfortable inconvenience with a low-grade fever and rash and no serious complications from varicella. However, a small percent of children and adults experience complications such as secondary skin infections, pneumonia, meningitis, encephalitis, and possible death.”

While the preceding statements are true, the report fails to point out that some who are vaccinated with the *herpes varicella zoster* vaccines can also experience severe adverse reactions, including meningitis, encephalitis, and death.

“Varicella vaccine was licensed in 1995. When a new vaccine is introduced it is often slow to be fully utilized, this was the case with varicella vaccine. To note: during 1998, Florida reported six deaths from acute varicella. Two of the adult deaths were linked to children in the home and one child was exposed in the classroom. In contrast, one death was reported in Florida in 2006 from varicella.”

Obviously, *while this information is informative*, the 1998 deaths in adults are usually not deaths related to chickenpox but rather to shingles, the more virulent and deadly form of *herpes varicella zoster* (HVZ) infection from the localized eruptive resurgence in HVZ replication when the person is not periodically externally exposed to live HVZ (exogenously reboosted).

Moreover, the information reported fails to state whether the child's case was a case of: **a)** chickenpox or **b)** childhood shingles case, and does not provide the child's medical history and the official cause(s) of death.

Further, the nature and status of the other three cases was not reported.

The preceding case reporting oddities lead this reviewer to infer that these may have been cases in individuals who had been vaccinated with the vaccine strain of HVZ and then had an eruptive resurgence of the HVZ virus (shingles).

Moreover, since neither chickenpox, *the name of the initial infection with both the vaccine and native strains of HVZ*, nor shingles, *the name given to cases of the re-eruptive form of HVZ infection*, were “notifiable” (reporting required by law) diseases in Florida for the period in question (1995-2006) nor nationally for the period 1991-2003, this data cannot be relied upon to reflect the true state of affairs in Florida with respect to HVZ disease cases because: **a)** *without a “notifiable disease” mandate*, case reporting is entirely voluntary and **b)** voluntary reporting tends to increase after a new vaccine is recommended and then to decrease as time passes and complacency sets in.

In addition, this reviewer notes that, *in an obvious but unstated response to the decrease in single-dose vaccination effectiveness*, in 2006, the CDC's ACIP added a second-dose recommendation (as the CDC reported in its annual summary report on notifiable diseases for 2006²⁹).

²⁹ Summary of Notifiable Diseases --- United States, 2006. *MMWR* 2008; **55**(53): 1-94, with added underlining:

“**Varicella (Chickenpox)**

Since implementation of the varicella vaccine program in 1995, varicella morbidity and mortality have declined substantially. During 1995-2006, the number of cases declined 85%, the number of hospitalizations declined 85%, and the number of deaths declined 82% (1). In 2006, the Advisory Committee on Immunization Practices (ACIP) updated recommendations for varicella vaccination to include a second dose for children and catch-up vaccination for persons without evidence of immunity (2). With this new recommendation, case-based and outbreak surveillance for varicella will become increasingly important. In 2006, a total of 33 states and the District of Columbia reported varicella data through the National Notifiable Diseases Surveillance System (NNDSS): 23 (70%) sites reported case-based data and 10 (30%) reported aggregate data. An additional 12 states conducted either statewide or sentinel case-based varicella surveillance but did

Had the vaccine been as effective as the reported Florida data indicates, there would have been no need for the CDC's ACIP to add a second dose of HVZ vaccine to the recommended vaccination schedule as they did in 2006.

Thus, this reviewer finds that the CDC's actions are clearly at odds with the implied "vaccine reduces cases and deaths" scenario presented in this section of the report.

"The following tables provide a brief description of the diseases and case information pre and post ~~immunization~~ vaccination for the U.S. and Florida."

Historical Comparison of Vaccine-Preventable Disease Cases and Deaths with Vaccine Licensure from 1900 to 2006. (U.S.: Estimated Annual Averages.)					
Disease	Pre-Vaccines		Post-Vaccines (2006)		
	Cases/Year	Deaths/Year	Cases	Deaths	
<i>Congenital Rubella Syndrome</i>	20,000	2,160	1	0	
Diphtheria	21,053	1,822	0	0	
H. influenzae (Hib)	20,000	1,000	<50	<5	
Hepatitis A	117,333	137	15,298	18	
Hepatitis B (Acute)	66,232	237	13,169	47	
Invasive Pneumo	63,067	6,500	41,550	4,850	
<i>Measles</i>	530,217	440	55	0	
<i>Mumps</i>	162,344	39	6,584	0	
Pertussis	200,752	4,034	15,632	27	
<i>Polio (Acute)</i>	19,794	1,393	0	0	
<i>Polio (Paralytic)</i>	16,316	1,879	0	0	
<i>Rubella</i>	47,745	17	11	0	
<i>Smallpox</i>	29,005	337	0	0	
Tetanus	580	472	41	4	
<i>Varicella (chickenpox)</i>	4,085,120	105	612,768	19	
Total	5,399,558	20,572	705,109	4,965	

Since: **a)** the pre-vaccine year is not given, **b)** the numbers are "estimates", and **c)** the numbers of vaccine-related cases are not included in 2006 for the live-virus vaccines (*italicized* by this reviewer in the preceding table), which cause some of those receiving them to have the disease, this reviewer can only note that the data provided overstates the "decreases" shown, and also fails to address the vaccines' harm, as any honest comparison would.

13 REQUESTS 2 AND 3

Historical Comparison of Vaccine-Preventable Disease Cases and Deaths with Vaccine Licensure from 1934 through 2007. (Florida: Estimated Annual Averages.)					
Disease	Pre-Vaccines		Post-Vaccines (2006)		
	Cases/Year	Deaths/Year	Cases	Deaths	
<i>Congenital Rubella Syndrome</i>	N/A	N/A	N/A	N/A	
Diphtheria	319	36	0	0	
H. influenzae (Hib)	378	9	10	0	
Hepatitis A	816	6	171	2	
Hepatitis B (Acute)	1,364	44	368	38	
Invasive Pneumo					
<i>Measles</i>	5,723	11	5	0	
<i>Mumps</i>	3,732	1	21	0	
Pertussis	723	58	211	0	
<i>Polio (Acute & Paralytic)</i>	416	24 ^{††}	0	0	
<i>Rubella</i> [¶]	1,580	1	0	0	
<i>Smallpox</i>	442	N/A	0	0	

not report these data through NNDSS. Although varicella was not a notifiable disease in Indiana in 2006, a total of 910 cases were reported.

1. Roush SW, Murphy TV, Vaccine Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007;298:2155--63.
2. CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007;56 (No. RR-4)."

Tetanus	57	37	5	1
<i>Varicella (chickenpox)</i>	4,772	3	1,321	0
Total	20,322	161	2,112	41
¶ Excludes congenital rubella syndrome				
†† Deaths include only those attributable to acute Polio				
This table displays actual reported cases, not adjusted for changes in population between 1934 and 2007.				

The Florida table suffers from the same problems as the table provided for the U.S. data that precedes it.

“Another vaccine success story relates to the prevention of *Haemophilus influenzae* type B (Hib) disease. Prior to the introduction of an effective vaccine to prevent this disease, Hib was the leading cause of [bacterial] meningitis among children younger than 5 years of age with about two-thirds of all cases occurring in children less than 18 months of age.”

While the graph provided does show a decrease in type B (“Hib”) invasive disease cases of *Haemophilus influenzae* (“Hi”), the national data show (see Table “9” on the next page) that the incidence and cases of Hi was increasing in both those under 5-years old and those over 5-years old.

Thus, the national Hib vaccination programs, *introduced in “1985”*, showed initial positive results (decrease cases of disease) overall (1992 – 1996) and possibly a decrease in cases in children under 5 in the same time period.

These outcomes were probably the case because this period was part of the “nature’s honeymoon” period where the vaccine was having its intended effect and the effects of strain change and other factors had not yet overcome the vaccine’s positive effects.

However, starting in 1997 and continuing through 2006, there has been a clear annual increase in the number of invasive Hi cases overall (at an average rate of about 11 % per year) as well as an increase in the total invasive Hi cases in children under 5 years of age (at a rate of about 7% per year).

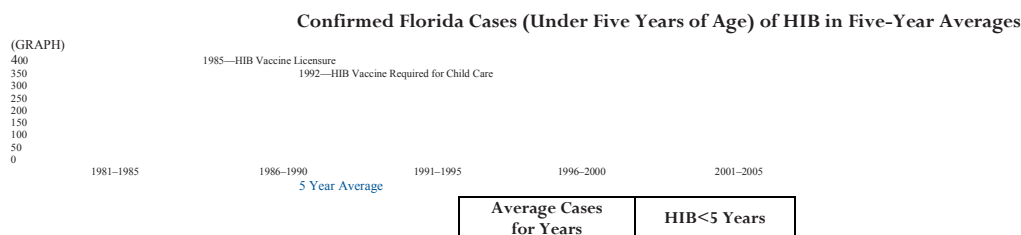
For Hib, the available data do indicate a decline in Hib cases, but, *prior to 2002*, the CDC found that the Hib “cases” data is not reliable – the Hib test used by the state labs gave false positives.

Moreover, *given the sharp 2006 increase in Hib cases over 2005*, 29 in 2006 versus 9 in 2005, it may be that the Hib strain of Hi has, itself, mutated and this circulating mutated Hib strain may have acquired the ability to not be intercepted by the antibodies produced by repeated inoculation with a FDA-licensed Hib vaccine component.

Should the upward trend in Hi and Hib cases continue, then the Hib program may need to be abandoned and alternative approaches used to minimize Hi infection.

“The following graph demonstrates the decrease in Hib disease for children less than 5 following the licensure of Hib vaccine.”

As a more complete review of invasive Hi cases has shown, this graph and its data insert are, at best, misleading.



1981–1985	375
1986–1990	344
1991–1995	43
1996–2000	8
2001–2005	1

Table “9” Invasive-Disease Cases of Haemophilus influenzae 1992 – 2006

Year	Total Notifiable Cases	% Change From Prior Year ¹	Notifiable Cases In Children Under 5			
			Total cases (% increase/year) ²	“b” type Cases (% increase/year) ⁴	“not b type” Cases	“unidentified” Cases
1992	1,412	-----	NN ³	NN	NN	NN
1993	1,419	0.50	NN	NN	NN	NN
1994	1,174	- 17.27	NN	NN	NN	NN
1995	1,180	0.51	NN	NN	NN	NN
1996	1,170	- 0.85	NN	NN	NN	NN
1997	1,162	-0.68	NN	NN	NN	NN
1998	1,194	2.75	NN	NN	NN	NN
1999	1,309	9.63	261 (---)	71	144	46
2000	1,398	6.80	293 (12.3)	55	172	66
2001	1,597	14.23	329 (12.3)	---	---	---
2002	1,743	9.14	331 (0.61)	34 (---)	144	153
2003	2,013	15.49	376 (13.6)	32 (- 5.9)	117	227
2004	2,085	3.58	331 (- 12.0)	19 (- 40.6)	135	177
2005	2,304	10.50	361 (9.1)	9 (- 52.6)	135	217
2006	2,436	5.73	383 (6.1)	29 (222.2)	175	19

1. Overall % increase from 1997 to 2006 is 109.6% or about 11%/year on average
2. “NN” = Not notifiable – no national data available.
3. In children < 5, % increase from 2000 to 2006 is 46.7% or about 6.8% per year on average.
4. In children <5, % change from 2002 to 2006 is – 14.7 % or about –1.8 % per year, on average. [Note: The CDC found state lab’s serotyping before 2002 to be problematic.]

14 REQUESTS 2 AND 3

“The state of Florida has experienced a large population boom since the early 1900s. In fact, the population in 2007 (18,762,014 residents) was more than 11 times the population of 1934 (1,585,596 residents). This drastic change in population makes it difficult to make fair comparisons of the burden of vaccine-preventable diseases over time, as a larger population would be expected to have a larger number of cases, all else being equal. To address this, we have used the 2007 population (18,762,014 residents) to estimate the number of cases that would have been reported for each year, had the population size been comparable to the 2007 population. This “standardized” estimate was calculated by dividing the 2007 population by the population for a given historical year to get a population ratio. The number of cases reported for that given year was multiplied by the population ratio. For example, the 2007 population (18,762,014 residents) was 10.1 times the population in 1939 (1,853,660 residents). The number of cases reported in 1939 was multiplied by 10.1 to estimate the number of cases that would have been reported in 1939 if the 1939 population was [sic; were] equal to the 2007 population.

The following table (Table 1) presents a summary of these standardized estimates of select vaccine-preventable disease cases occurring in census years for 1940 to 2000. These standardized estimations are

represented in the charts on the following pages as a dashed line. The actual number of cases reported for each year is represented in the charts as a solid line. Note that as the population size approaches the 2007 population, the dashed line and the solid line converge.”

Table 1. Summary of Standardized Estimates of Select Vaccine-preventable Disease Cases Occurring in Census Years 1940 through 2000. (Please see information above for an explanation as to how these estimates were calculated.)								
Rates from	Diphtheria	Measles	Mumps	Whooping cough	Polio	Rubella	Smallpox	Tetanus
1940	2,185	22,581	2,596	3,752	323	1,479	69	167
1950	645	16,620	9,657	3,133	3,133	299	0	286
1960	274	15,362	16,476	1,587	244	3,130	0	105
1970	38	4,160	8,309	260	0	9,828	0	44
1980	0	826	373	130	0	208	0	8
1990	1	855	281	84	0	24	0	9
2000	0	2	8	78	0	2	0	1

15 REQUESTS 2 AND 3

Reported and Standardized* Diphtheria Cases in Florida, 1934–2007

(GRAPH)

Reported and Standardized* H. influenzae Meningitis Cases in Florida, 1982–2007

(GRAPH)

16 REQUESTS 2 AND 3

Reported and Standardized* Hepatitis A Cases in Florida, 1970–2007

(GRAPH)

Reported and Standardized* Hepatitis B (Acute) Cases in Florida, 1970–2007

(GRAPH)

17 REQUESTS 2 AND 3

Reported and Standardized* Measles Cases in Florida, 1934–2007

(GRAPH)

Reported and Standardized* Mumps Cases in Florida, 1935–2007

(GRAPH)

18 REQUESTS 2 AND 3

Reported and Standardized* Pertussis Cases in Florida, 1934–2007

(GRAPH)

Reported and Standardized* Polio Cases in Florida, 1934–2007

(GRAPH)

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Reported and Standardized* Smallpox Cases in Florida, 1934–2007

(GRAPH)

Reported and Standardized* Rubella Cases in Florida, 1937–2007

(GRAPH)

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Reported and Standardized* Tetanus Cases in Florida, 1935–2007

(GRAPH)

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This reviewer finds that, while informative, the reports statements and the graphs provided are misleading because the report intentionally does not even mention, *much less address*, the other major factors (e.g., improving sanitation, hygiene, and potable water supply, and better housing and availability of safe food) that were principally responsible for the decreases from 1934 to the late 1940s as well as the major impact of better antibiotics, antifungals and, more recently, antivirals on stopping the spread of disease and reducing not only the number of cases but also the number of deaths in the USA during the period from the late 1940s until the present.

Ideally, the reader will remember these other key factors and consider them.

“Vaccine-Preventable Diseases

We have also taken this opportunity to provide descriptions of the vaccine-preventable diseases.”

Rather than simply provide descriptions of the common “*vaccine-preventable diseases*”, the report practices selective and self-serving fear mongering.

The report does this by going beyond the description of the disease to include selective information on the most adverse outcomes from contracting a given disease, usually death, without including the information that describes the current risk of not being vaccinated in terms of the probability of that risk or even mentioning the supportive therapies that, if used, can reduce that risk.

In addition, this report does not provide any information about the associated adverse outcomes of vaccination or their risk as any truly informative report would if it were not simply trying to instill fear in the reader – apparently to pressure the reader toward vaccination.

To the extent possible, this reviewer will attempt to balance the information presented with some idea of the risks for the most adverse disease outcomes.

“Measles

Measles is a highly contagious disease that is transmitted by respiratory droplets and airborne spread. Symptoms include rash, high fever, cough, runny nose, and red, watery eyes (lasts about a week). The disease can result in severe complications, including pneumonia, encephalitis, seizures, and death.”

While the information provided speaks to the adverse effects of having measles, it does not address, much even mention the adverse effects, including death, that some of those inoculated with the vaccine stain of a live measles virus may experience.

Moreover, the report fails to note that, in the period from 2002 through 2006, only 2 U.S. children who had a confirmed case of measles died in 2003 (see Table “5”) as a result of contracting measles, with a crude death risk probability of less than 1 in 100 million, but that roughly 50 to 80 children annually died from the adverse effects of MMR vaccination (see Table “6”), with a crude annual death risk of about 1 in 6 million.

From Merck’s 2006 package insert for their live-virus measles vaccine, ATTENUVAX®, under “Adverse Reactions”, Merck states:

"ATTENUVAX. (Measles Virus Vaccine Live) 9243206

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of polyvalent vaccine containing measles:

Body as a Whole

Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Diarrhea, vomiting, nausea.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history.

Musculoskeletal

Arthralgia, myalgia.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS); subacute sclerosing panencephalitis (SSPE); Guillain-Barré syndrome (GBS); febrile convulsions; afebrile convulsions or seizures; ataxia; ocular palsies.

Experience from more than 80 million doses of all live measles vaccines given in the U.S. through 1975 indicates that significant central nervous system reactions such as encephalitis and encephalopathy, occurring within 30 days after vaccination, have been temporally associated with measles vaccine very rarely.²⁸ In no case has it been shown that reactions were actually caused by vaccine. The Centers for Disease Control and Prevention has pointed out that "a certain number of cases of encephalitis may be expected to occur in a large childhood population in a defined period of time even when no vaccines are administered".²⁹ However, the data suggest the possibility that some of these cases may have been caused by measles vaccines. The risk of such serious neurological disorders following live measles virus vaccine administration remains far less than that for encephalitis and encephalopathy with natural measles (one per two thousand reported cases).³⁰

Post-marketing surveillance of the more than 200 million doses of M-M-R and M-M-R II that have been distributed worldwide over 25 years (1971-1996) indicates that serious adverse events such as encephalitis and encephalopathy continue to be rarely reported.¹⁰

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 6-22 cases of SSPE per million cases of

measles. The results of a retrospective case-controlled study conducted by the Centers for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.³¹

Respiratory System

Pneumonitis (see CONTRAINDICATIONS); cough; rhinitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; urticaria; rash.

Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); swelling; vesiculation at injection site.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

Other

Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established. No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982-1993.³²

Moreover, neither this report nor the Merck insert address what are the true incidence rates for each of the serious “side effects” of vaccination stated by Merck.

“Although measles is no longer a common disease in the United States, it remains widespread in most countries of the world, including some countries in Europe. Current outbreaks in the United States highlight the ongoing risk of measles importations from other countries by people who travel.”

In spite of the preceding measles disease realities and the commonness of measles in Europe where some countries have, for whatever reasons, opted not to try to vaccinate all their children and allow parents to choose to have their children contract measles and, thereby, get natural lifetime immunity to having a recurrence of measles, this reviewer finds that there is no evidence that these alternative approaches have led to either higher total healthcare costs or death rates provided the adverse effects of measles vaccination are included in the assessment of these factors.

“Measles causes ear infections in nearly one out of every 10 children who get it. As many as one out of 20 children with measles gets pneumonia, and about one child in every 1,000 who get measles will develop encephalitis. (This is an inflammation of the brain that can lead to convulsions, and can leave your child deaf or mentally retarded.) For every 1,000 children who get measles, one or two will die from it. Measles can also make a pregnant woman have a miscarriage, give birth prematurely, or have a low-birth-weight baby.”

While the reports statements are seem accurate, the risks for the adverse effects seen in measles cases also appear to be risks to those who are vaccinated with MMR.

Also, this reviewer notes that, because most natural measles cases occur in children before they are 7 years of age and measles is highly contagious, there was little risk that a pregnant woman would contract measles during pregnancy before there was a measles vaccine and also, *because all mothers had immunity to measles*, their babies were protected from getting measles while they were being breastfed, which protected their babies for the first years of life from contracting measles – an advantage that is obviously lessened in measles-vaccinated mothers’ breastfeeding.

Finally, this report fails to note that vitamin-A deficiency worsens disease severity in children who contract measles and that, for vitamin-A deficient children, giving an otherwise healthy baby a mega-dose (50,000 IU) fat-soluble vitamin-A for two days at the onset of a case of measles lessens disease severity and seems to be protective against the severe outcomes seen in a small percentage of cases.

“Before the measles vaccine became available, there were approximately 450,000 measles cases and an average of 450 measles-associated deaths were reported each year. Widespread use of measles vaccine has led to a greater than 99% reduction in measles cases in the U.S. compared with the pre-vaccine era.”

Accepting that the report’s “*an average of 450 measles-associated deaths were reported each year*” before the measles vaccine was introduced is accurate, this reviewer again notes that factors other than vaccination, like antibiotics for the pneumonia cases, antivirals for the cases of brain-invasive measles, and vitamin-A supplementation to aid the immune system in killing off the live measles virus and immunizing the body from future infection by measles, have also been major contributors to the decline observed and, when the “*MMR-associated deaths*” reported to VAERS are considered and a conservative underascertainment factor is applied, the average decrease in deaths from the early 1960s may be less than 90%.

Moreover, *because a live-virus is given to about 4 million children twice and the annual average number of measles infections is about 8,000,000 with some underreported percentage of these having some adverse clinical aspects of having measles, the actual annual average number of “measles cases” may not have declined significantly.*

“Mumps

Mumps is an acute viral illness that is spread through direct contact with respiratory secretions or saliva. Symptoms include fever, headache, muscle aches, tiredness, and swelling of salivary glands. Severe complications are rare. However, mumps can cause encephalitis, meningitis, inflammation of the testicles (orchitis), ovaries and/or breasts (oophoritis and mastitis), spontaneous abortion, and deafness (which is usually permanent).”

First, this reviewer is “surprised” that nothing was said about the success of vaccination against mumps mostly using Merck’s MMR® II vaccine.

Second, this reviewer notes that death is not a symptom of mumps and that inflammation of the testicles (orchitis), ovaries and/or breasts (oophoritis and mastitis), and spontaneous abortion are symptoms occurring after puberty, mainly in adults.

With these realities in mind, let us examine the recent, CDC’s reported history for mumps cases in the USA from 1999 through 2006 (as shown in **Table “10”**).

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Table “10” CDC’s “Summary of Notifiable Diseases” Report For Mumps (1999 – 2006)
[Cases and Incidence per 100,000 Population]

Year	Total Cases	Breakdown of Cases by Age Group – Cases (Incidence Rate)							
		Unk.	<1 year	1-4 yrs	5-14 yrs	15-24 yrs	25-39 yrs	40-64 yrs	>65 years
1999	387	11 ---	4 (0.11)	61 (0.41)	156 (0.40)	42 (0.14)	62 (0.11)	44 (0.06)	7 (0.02)
2000	338	14 ---	4 (0.10)	53 (0.35)	102 (0.26)	34 (0.09)	68 (0.11)	58 (0.07)	5 (0.02)
2001	266	7 ---	2 (0.05)	47 (0.31)	83 (0.20)	24 (0.06)	48 (0.08)	49 (0.06)	6 (0.02)
2002	270	2 ---	4 (0.11)	51 (0.33)	100 (0.24)	25 (0.06)	38 (0.06)	43 (0.05)	7 (0.02)
2003	231	4 ---	2 (0.05)	30 (0.19)	70 (0.17)	17 (0.04)	44 (0.07)	58 (0.07)	6 (0.02)
2004	258	1 ---	1 (“0.03”)	43 (“0.3”)	60 (“0.1”)	37 (“0.1”)	39 (“0.1”)	59 (“0.1”)	8 (“0.02”)
2005	314	2 ---	1 (“0.03”)	60 (“0.3”)	75 (“0.2”)	67 (“0.2”)	60 (“0.1”)	49 (“0.1”)	10 (“0.03”)
2006	6,584	38 ---	18 (0.44)	351 (2.17)	1097 (2.72)	2,270 (5.39)	1,283 (2.10)	1,329 (1.30)	198 (0.54)

Though, through 2005, the mumps vaccine cases showed good control with less than 400 cases per year, the 20-fold increase in 2006 cases from 2005 cases indicates that there are some non-obvious issues with the mumps control strategy that need to be addressed.

The following are the CDC's views as expressed in the 2006 "Summary of Notifiable Diseases":

"Mumps

Since vaccine licensure in 1967, the number of cases of mumps in the United States has declined steadily. Since 2001, an average of 265 mumps cases (range: 231--293 cases) has been reported each year (1). However, in 2006, the largest mumps outbreak in >20 years occurred, with >5,000 cases reported (1--3). The outbreak began in Iowa in December 2005, peaked in April 2006, and declined to lower levels of reporting during summer 2006 (3). The majority of cases occurred during March--May, 2006 (3). The outbreak was primarily focal in geographic distribution; 84% of cases were reported by six contiguous Midwestern states (Illinois, Iowa, Kansas, Nebraska, South Dakota, and Wisconsin) (3). In contrast to the childhood age range traditionally associated with mumps disease, young adults aged 18--24 years were the age group most highly affected (1--3). In 2006, a total of 63% of reported cases occurred in females; previously, no gender differences in case rates had been reported (3).

In response to the outbreak, the Advisory Committee on Immunization Practices (ACIP) updated criteria for mumps immunity and mumps vaccination recommendations (4). Acceptable presumptive evidence of immunity to mumps includes one of the following: 1) documentation of adequate vaccination, 2) laboratory evidence of immunity, 3) birth before 1957, or 4) documentation of physician-diagnosed mumps. Documentation of adequate vaccination now requires 2 doses of a live mumps virus vaccine for school-aged children (grades K--12) and adults at high risk (i.e., persons who work in health-care facilities, international travelers, and students at post--high school educational institutions). Health-care workers born before 1957 without other evidence of immunity should now consider 1 dose of live mumps vaccine. During an outbreak, a second dose of live mumps vaccine should be considered for children aged 1--4 years and adults at low risk if affected by the outbreak; health-care workers born before 1957 without other evidence of immunity should strongly consider 2 doses of live mumps vaccine.

1. CDC. Mumps epidemic--Iowa, 2006. MMWR 2006;55:366--8.
2. CDC. Update: multistate outbreak of mumps--United States, January 1--May 2, 2006. MMWR 2006;55:559--63.
3. CDC. Update: mumps activity--United States, January 1--October 7, 2006. MMWR 2006;55:1152--3.
4. CDC. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for the control and elimination of mumps. MMWR 2006;55:629--30."

Moreover, the CDC's failure here to report, much less discuss, the breakdown of the percentages of the mumps cases in those who were: **a)** unvaccinated and had not previously had mumps, **b)** unvaccinated and previously had had mumps, **c)** vaccinated with one dose, **d)** vaccinated with two (2) doses, and **e)** vaccinated with more than two (2) doses, clearly indicates that, *since most of the cases occurred in "young adults aged 18--24 years"* (nominally born in 1982 -- 1988), the vaccination program used failed to be effective in preventing some who were vaccinated from subsequently contracting mumps when exposed "2" decades later to the disease.

When it comes to the vaccination risk, there is no accurate way to apportion the adverse risk for the MMR vaccine among the component diseases, measles, mumps and rubella, so that the rough death risk for the MMR vaccination of about 1 in 5 million applies equally to all three diseases even though, *unlike measles*, the CDC reports no deaths in the period 2002 -- 2006 period caused by contracting mump and the death probability is "zero" for mumps.

Thus, this reviewer finds that the CDC's response amounts to recommending additional mumps vaccination (Merck's MUMPSVAX®) when it is clear that, *when imported cases of mumps were introduced into a mostly vaccinated population*, "herd protection" failed and, *as the Japanese have realized*, unlike the measles vaccine, the current mumps vaccines do not confer long-term protection to most of those vaccinated much less the near lifetime immunity conferred by having mumps, a disease that is, *for most*, only uncomfortable and, *for all*, is not lethal.

Certainly, adopting the Japanese control strategy, *which only recommends vaccinating children who are pre-teens or older who have not had mumps*, might be safer and would certainly be more cost-effective than vaccinating almost all children earlier only to find out

that, 2 decades later when the mumps vaccinees are exposed to the mumps virus, a significant percentage now have inadequate protection.

“Rubella

Rubella is an acute viral disease that causes fever and rash and is spread by contact with an infected person, through coughing and sneezing. Complications include birth defects if the pregnant woman has rubella. An infant with congenital rubella syndrome may have the following: deafness, cataracts, heart defects, mental retardation, and liver and spleen damage (at least a 20% chance of damage to the fetus if a woman is infected early in pregnancy).”

The program for rubella has been very successful (see Table “11”).

Table “11” CDC’s “Summary of Notifiable Diseases” Report For Rubella (1999 – 2006)
[Cases and Incidence per 100,000 Population]

Year	Total Cases	Breakdown of Cases by Age Group – Cases (Incidence Rate)							
		Unk.	<1 year	1-4 yrs	5-14 yrs	15-24 yrs	25-39 yrs	40-64 yrs	>65 years
1999	267	3	16 (0.12)	15 (0.10)	4 (0.01)	111 (0.29)	97 (0.16)	20 (0.02)	1 (0.00)
2000	176		2 (0.05)	8 (0.05)	7 (0.02)	89 (0.24)	64 (0.11)	6 (0.01)	0 (---)
2001	23		1 (0.03)	1 (0.01)	2 (0.00)	3 (0.01)	11 (0.02)	3 (0.00)	2 (0.01)
2002	18		0 (---)	0 (---)	2 (0.0)	0 (---)	13 (0.02)	3 (0.0)	0 (---)
2003	7		0 (---)	0 (---)	2 (0.0)	3 (0.01)	2 (0.00)	0 (---)	0 (---)
2004	10		0 (---)	2 (0.0)	4 (0.0)	1 (0.0)	3 (0.0)	0 (---)	0 (---)
2005	11	1	1 (0.0)	0 (---)	1 (0.0)	1 (0.0)	2 (0.0)	5 (0.0)	10 (“0.03”)
2006	11		0 (---)	0 (---)	0 (---)	0 (---)	4 (0.01)	7 (0.01)	0 (---)

Moreover, most all the rare congenital rubella cases seem to be occurring in recent mostly Hispanic immigrants who have either not been vaccinated or had incomplete vaccination/protection.

This data again confirms that only measles and perhaps rubella should be in the recommended vaccination program for “all” children in the USA – with both definitely being recommended for female children.

In addition, increased efforts should be made to check female immigrants of childbearing age for evidence of adequate protection from rubella infection; and those lacking such evidence should be offered the vaccine.

Hopefully, after reviewing this reviewer’s remarks and the case data, the Florida Department of Health will notify Merck and the CDC that the MMR vaccine should be replaced with the MR vaccine starting in 2010.

Based on the scant information available, the overall risk of population death risk for rubella disease and rubella vaccination are probably less than 1 in 200 million for the disease and, *because MMR is the vaccine*, also probably < 1 in 6 million for the vaccine.

However, because of the risk of severe harm to the fetus when the mother has rubella during pregnancy, it is best that females should either contract rubella before puberty or be vaccinated with a rubella vaccine (e.g., Merck’s MERUVAX® II) or a vaccine containing the

rubella component (e.g., Merck's MMR II) and/or have their rubella titers checked before they try to get pregnant and consider vaccination if their rubella antibody titers are low.

“Tetanus

Tetanus is a disease of the nervous system caused by bacteria that enters the body through a break in the skin (not just a rusty nail). Symptoms include lockjaw, stiffness in the neck and abdomen; difficulty swallowing followed by severe muscle spasms, seizure-like activity, and severe autonomic nervous system disorders. Death occurs in about 10–20% of cases.”

The CDC's reported data indicates that the vaccination program for tetanus is a success – where the majority of the residual U.S.- origin cases occur in intravenous drug users and those who have either no vaccination history or no recent (within 20 years) vaccination history.

Moreover, with this success has come the realization that tetanus boosters for adults are probably needed no more frequently than every decade.

Finally, though 50 cases and no more than 6 deaths are reported annually (see Table “12”) in an overall population roughly 300 million, cases in those under 12 have become very rare and seem to be found only in those who have never been vaccinated.

**Table “12”
CDC's “Summary of Notifiable
Diseases” Report's Cases For Tetanus
(1999 – 2006)**

Year	Clinical Cases	Reported Deaths
1999	40	2
2000	35	6
2001	37	6
2002	25	5
2003	20	4
2004	34	4
2005	27	--
2006	41	--
Average	32.4	~ 4.5

In the USA today, the average annual death risk from tetanus disease is roughly 2 in 100 million and vaccination seems to have been a significant factor in suppressing death in those who contract this disease.

Even though the death risk from the combination vaccines offered today for children (vaccines that include diphtheria, tetanus and acellular pertussis), *based on the guesstimated adverse events from the actual reports to VAERS*, is about 10 times that for the MMR vaccine, the data seem to indicate that the acellular pertussis component is the main contributor to deaths in this group of vaccines.

Provided the vaccine formulation contains no Thimerosal, it would probably be much safer to use a vaccine that only contains diphtheria and tetanus (e.g., the DT and Td vaccines) and address pertussis using an alternative control strategy.

In addition, a recent study has shown that postponing the start of the administration of the current DTaP vaccines significantly reduce the risk for other serious side effects to these vaccines.

Based on those studies, until the diphtheria, tetanus and acellular pertussis combination vaccines can be phased out and the supply of “no Thimerosal” DT and Td vaccines increased, it may be prudent to at least change the early DTaP schedule from inoculating at 2, 4 and 6 months of age to start the series at vaccination at 6 months of age or later to reduce the risk of vaccinations’ inducing a chronic disease (e.g., asthma) in American children.

“H Flu: Haemophilus influenzae type b (Hib) (Invasive)

H Flu is a disease which is most serious for children under age one. It is spread by coughing and sneezing. Symptoms are serious and include: meningitis, pneumonia, epiglottitis (a severe throat infection), skin infections, and arthritis. Children who survive Hib meningitis may develop permanent neurological disability, including brain damage, hearing loss, and mental retardation. 5% to 10% cases of Hib meningitis are at risk of dying.”

Since the problematic nature of Hib has been discussed at length, this reviewer sees no need to address those issues again.

With respect to serious symptoms listed, this reviewer notes that these are very rare and, though the apparent number of Hib cases is falling, the in-use testing used to identify Hib does not reliably reflect all Hib cases, and, more importantly, the overall annual cases of invasive Hi are increasing as shown in **Table “13”** while the total annual cases of invasive Hi in children under 5 do not seem to be declining though the reported cases of Hib *may* be declining (the Hib data is clouded by CDC-reported testing problems).

Table “13” Haemophilis influenzae (Hi), Invasive Disease Cases, Incidence per 100K Cases, and Deaths (1999 – 2006)

Year	Overall		Children under 5 yrs Old		Deaths
	Cases	Incidence	Cases	Incidence	
1999	1,309	0.48	~	~ 1.5	6
2000	1,398	0.51		~ 1.6	6
2001	1,597	0.57		~ 1.9	11
2002	1,743	0.62	331	~ 1.7	7
2003	2,013	0.70	376	~ 2.0	5
2004	2,085	0.72	331	~ 1.7	11
2005	2,304	0.78	361	~ 1.9	---
2006	2,496	0.82	382	~ 2.0	---

Since the percentage of cases of identified annual Hib cases in the under 5s (as identified in the CDC’s summary reports) are currently on the order of < 20 per ~ 2,500 total cases (about 0.8%) and only a tiny fraction of children with Hib get Hib meningitis (< 0.01%), the current risk of a child’s dying from Hib meningitis is probably < 1 in a million – not the misleading and potentially concerning “5% to 10% cases of Hib meningitis are at risk of dying”.

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“Chickenpox (Varicella)

A disease caused by infection with the varicella zoster virus, which is spread by coughing and sneezing (highly contagious) and by direct contact. Symptoms include rash with blister-like lesions and fever. Serious complications from chickenpox include bacterial infections which can involve many sites of the body including the skin, tissues under the skin, bone, lungs (pneumonia), joints, and blood. Other serious complications are due directly to infection with the varicella-zoster virus and include viral pneumonia, bleeding

problems, and infection of the brain (encephalitis). Many people are not aware that before a vaccine was available approximately 10,600 persons were hospitalized and 100 to 150 died as a result of chickenpox in the U.S. every year.”

Here, the report is intentionally misleading.

This is the case because most of the annual pre-vaccine hospitalizations and deaths were from cases of shingles (the recurring form of *herpes varicella zoster*), and not from chickenpox (the disease’s presentation when first infected by *herpes varicella zoster*).

Since, in spite of greater than 95% uptake for the single dose that, *to justify the vaccine’s approval by the FDA*, was claimed to provide long-term protection, the effectiveness of vaccination dropped to below 75% even as the percentage vaccinated with one dose of Merck’s VARIVAX® vaccine exceeded 95%.

Since exogenous boosting is required to maintain protection after initial infection and the vaccine not only provides incomplete protection but, because the vaccine strain (Oka/Merck) of *herpes varicella zoster* is shed at a much lower rate than the native strain, vaccination also does not provide the “herd protection” that our children’s having chickenpox confers to those of all ages who has already had chickenpox.

In addition, the antibodies passed from VARIVAX-vaccinated mother to her nursing child do not seem to provide protection from *herpes varicella zoster*’s resurgence as shingles because, *as mothers have become mostly vaccinated*, the incidence of the once almost unknown childhood shingles cases in the very young (<2 years old) has become noticeable.

The stopgap measures, adding another dose of VARIVAX for school-age children or worse a dose of Merck’s PROQUAD® (which apparently causes more than double the incidence of certain severe adverse “varicella” reactions than VARIVAX) and adding an explicit shingles vaccine (Merck’s ZOSTAVIX®) for the elderly, only make the *herpes varicella zoster* vaccination program less than societally cost effective by now a factor of 3 but these also do not stop the increase in cases of shingles in our babies, children, adolescents, and younger adults because none of these vaccines provide the exogenous boosting needed to protect the “herd” of those infected with *herpes varicella zoster* (HVZ) from having the disease recur as shingles, its more virulent and more lethal form.

Thus, only Merck has benefited, and is benefiting, because sales of its HVZ vaccines have more than doubled and the increases in shingles cases have fueled the market for antiviral drugs to control shingles.

Here is a case where, *except for the drug manufacturers*, the “cure” is much worse than the disease to the point that it is clear, to any independent knowledgeable scientist, that, *at a minimum*, any recommended/required HVZ vaccination program should be immediately abandoned.

Then, every parent should be encouraged to have their immune-system sound and physically healthy 3- to 6- year-old children have chickenpox and, *once they are actively shedding*, invite all similarly healthy older children, and all family members, friends and acquaintances to visit their child to get the “exogenous” boosting they need if, *for children*, they have not been so exposed in the last 2 – 3 years, or, *for adults*, if they have not been so exposed in the last 5 to 10 years.

Similarly, *when someone has an outbreak of shingles*, adults should be encouraged to consider immediately visiting with them to help maintain the protection from HVZ that the shingles outbreak can confer.

Since U.S. experience has shown that HVZ vaccines are not suitable for use in a mass vaccination program, the single-component HVZ vaccines should only be kept on the market

for those who, *for some reason*, wish to get periodically vaccinated with HVZ instead of having chickenpox or being periodically exogenously boosted by coming into contact HVZ-infected persons who are shedding HVZ (options that Japan has elected to pursue).

“Pneumococcal disease

Pneumococcal disease is a leading cause of serious illness in children and adults throughout the world leading to ear infections, pneumonia, bacteremia (an infection in the bloodstream), and meningitis. It is one of the most common causes of death in America from a vaccine-preventable disease. Children less than 5 years old in childcare programs are at 2 to 3 times more likely to experience invasive pneumococcal infections than children in home care.”

For the sound reasons that this reviewer has previously discussed, the vaccination programs for “*Streptococcus pneumoniae*” should be abandoned and other strategies used to control the spread of *S. pneumoniae* and treat those that are infected with it.

At the onset of symptoms of any respiratory infection, for example, one may increase supplementation with vitamin C, the B vitamins, vitamin D-3, omega-3 fatty acids containing vitamin E, magnesium, potassium and zinc as well as the giving of olive-leaf extract and/or oil of oregano, which both have strong antibacterial activity.

Again, these mass vaccination programs need to be stopped because they do not fully protect those getting these vaccines from getting a bacterial lung infection with other strains of *S. pneumoniae* or other adventitious organisms who, with the suppression of the vaccine-antigenic strains of *S. pneumoniae*, occupy the biological niche formerly occupied by the vaccine-antigenic strains of *S. pneumoniae* suppressed by vaccination, like other strains of *S. pneumoniae* and various *Serratia* species.

“Whooping Cough (Pertussis)

Pertussis can be a serious illness, particularly for babies and young children. More than 50% of babies with reported cases of pertussis must be hospitalized. Coughing can be so severe that it is hard for babies to eat, drink or breathe.

- Babies may bleed behind the eyes and in the brain from coughing.
- The most common complication is bacterial pneumonia. About 1 child in 10 with pertussis also gets pneumonia, and about 1 in every 50 will have convulsions.
- Brain damage occurs in 1 out of every 250 children who get pertussis.
- Pertussis causes about 10–20 deaths each year in the United States.”

Historically, *like diphtheria and tetanus*, the development of pertussis vaccines predates the development of the penicillin antibiotics even though the first effective standardized vaccines were not available until the early 1950s.

However, even with the use of 6 doses (5 DTaP and, recently, 1 Tdap replacing the Td previously recommended) today, the vaccination protection provided is: **a)** less than complete and **b)**, *given the occurrence of thousands of cases annually*, much less than long term.

Given the failure of additional doses to translate into effective long-term protection and the fact that the major contributor to the adverse effects, *including death*, in the vaccine is the acellular pertussis component’s toxins, it may be time to abandon the vaccination approach and implement an alternative, more effective strategy for controlling pertussis.

Again, the judicious use of vitamin, mineral and nutrient supplements as well as the better of the herbal products that are used in complementary and alternative medicine (CAM) to: **a)** protect against whooping cough (e.g., olive leaf extract and oil of oregano) and/or **b)**, *in some*

settings, to treat the initial symptoms of infection, may be a strategies that, with targeted antibiotics, given after a rapid bacterial screening test has identified the organism and the antibiotics to which it is most susceptible, may be more effective in treating pertussis and minimizing its possible harmful effects.

However, given the hundreds of annual deaths that appear to be principally associated with the pertussis component in the current vaccines, it is clear that the pertussis component in these vaccines is still highly problematic even though:

- a. Replacing the previous whole-cell pertussis component with the current “purified” acellular component did significantly reduce vaccine toxicity and
- b. Removing Thimerosal from all of the DTaP vaccines has apparently further reduced the toxicity of the DTaP vaccines.

Hopefully, after reviewing the scientific evidence, the Florida Department of Health will reach the same conclusions and press the CDC to develop a safer alternative approach to replace the pertussis vaccine, and direct the U.S. Secretary of Health and Human Services to compel (under the authority granted to him in 42 U.S.C. Sec. 300aa-27(a)(2)) the vaccine makers to switch to safer “no Thimerosal” DT (and, for the older children, Td) vaccine formulations to replace the current DTaP (and Tdap) vaccine formulations to maintain the relatively safe and highly effective long-term protections against the toxins diphtheria and tetanus organisms.

On balance, this reviewer finds that the need for 5 vaccines to provide sufficient long-term protection and the harm caused by the pertussis component renders the current DTaP/DTP/Tdap vaccines, which protect against toxins and not the disease organisms themselves, not societally cost-effective and in need of safening in the manner outlined in the discussion provided here.

24 REQUESTS 2 AND 3

“Hepatitis B

Hepatitis B is a serious disease caused by a virus that attacks the liver and can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. It is contracted when someone is exposed to blood from an infected person. Infants are at risk if their mother is infected prior to or during birth; other risks include occupational exposure through needlesticks, having sex with an infected person, and by sharing drugs, needles, or ‘works’ when injecting drugs.”

First, this reviewer would add is the reality that, in most children and adults with healthy immune systems, the exposed person’s immune system not only rids the body of hepatitis B virus to which it is exposed but also develops early immune-system protection that minimizes the risk of re-infection.

Second, this reviewer notes that hepatitis B immune serum (from those who have had hepatitis B and successfully overcome it) is required to prevent the children born to mothers that are infected with hepatitis B from being infected with hepatitis B.

Third, this reviewer notes that there is little, or no, “protect the child from disease” justification for the current U.S. at-birth and early-childhood hepatitis B vaccination program because the incomplete protection wears off at about the time the child reaches adolescence – the time when the risky-sex and drug-use risk factors become a real concern in children.

Regardless of the vaccine apologists’ cover story, *since studies have shown that the at-birth dose produces no real immunity to hepatitis B one year later*, the real reason an at-birth dose is recommended for the hepatitis B vaccines is that this practice is an attempt to imprint the child’s nascent immune system with the active components in the vaccine and, *thereby*, reduce the risk that the child will develop childhood multiple sclerosis (MS), and possibly other “autoimmune” diseases, which hepatitis B vaccines are known to “cause” beginning

about 3 to 5 years after the last dose of hepatitis B in the usual vaccination series is given to the child.

While the “day one” inoculation does reduce the subsequent risk of childhood MS, again the realities are that the current U.S. hepatitis B vaccination program:

- Is not population protective,
- Provides little, or no, long-term protection to those who are vaccinated,
- Is not even societally cost effective,
- May increase the long-term risk that those who are vaccinated will, if exposed, develop chronic hepatitis B, and
- Chiefly benefits the vaccine manufacturers and the healthcare establishment.

Given the preceding realities, this reviewer must also recommend that the current early childhood hepatitis B vaccination program be removed from the general vaccination schedule.

Moreover, because the at-birth dose has the potential to cause permanent immune-system damage, the manufacturers be told to safen and refine this vaccine to reduce the “zero day” risks and provide a vaccine that, *when given in no more than a 3-dose regimen to pre-teens:* **a)** is safer than the current vaccines, **b)** provides long-term immunity to more than 95% of those vaccinated, and **c)** does not carry a long-term risk that the person vaccinated may develop MS or another long-term chronic disease (e.g., type 2 diabetes).

“Polio

Polio is an infectious disease caused by a virus that lives in the throat and intestinal tract. It is most often spread through person-to-person contact with the stool of an infected person and may also be spread through oral/nasal secretions.

Polio was one of the most dreaded childhood diseases of the 20th Century in the United States. There were usually about 13,000 to 20,000 cases of paralytic polio reported each year in the US before the introduction of Salk inactivated polio vaccine (IPV) in 1955. Polio peaked in 1952 when there were more than 21,000 reported cases. The number of cases of polio decreased dramatically following introduction of the vaccine and the development of a national vaccination program. In 1965, only 61 cases of paralytic polio were reported compared to 2,525 cases reported cases just five years earlier in 1960.

The last cases of naturally occurring paralytic polio in the United States were in 1979, when an outbreak occurred among the Amish in several Midwestern states. From 1980 through 1999, there were 152 confirmed cases of paralytic polio cases reported. Of the 152 cases, eight cases were acquired outside the United States and imported. The last imported case caused by wild poliovirus into the United States was reported in 1993.”

Though this reviewer finds this part of the report replete with distortions, half-truths and misrepresentations in the manner in which it portrays the history of polio and the manner in which it omits the problems (like SV-40 infection and contamination with other live animal viruses in both the early inactivated polio vaccines and the live-virus oral polio vaccines that, though they were used from the 1960s to through the 1990s in the USA, this report does not even mention as well as other problems), this reviewer sees nothing to be gained by rehashing these issues yet again³⁰.

Moreover, since the current inactivated polio vaccines (IPVs) are grown in human cells and fetal calf serum, though not eliminated, the risk of vaccinee contamination with animal viruses has been significantly reduced.

³⁰ For those who wish to read more on the realities of polio and the polio vaccination programs “success”, this reviewer recommends that they read pages 3 and 4 in this reviewer’s previous article, “A Review of: ‘Vaccinations are still needed for kids By Meg Fisher, MD’ (27 January 2008; 27 pages)”, which is posted in the “Documents” section of the CoMeD web site: <http://www.mercury-freedrugs.org/>.

Thus, *though the long-term risks from viral contaminants are unknown*, the current vaccination IVP vaccination program seems to be adequately safe in the short-term and provides long-term protection against the current endemic polio viruses, which: **a)** are all derived from the viruses in the live-virus oral polio vaccine (OPV) that the U.S. used for more than 25 years and **b)** being added to by the imported vaccine strains being shed by travelers from lands where live poliovirus vaccines are still being used and their poliovirus-related strains are endemic.

25 REQUESTS 2 AND 3

End of Part 1 of 2 of the Review
