

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 2**”, resumes the review on page 26 of the report. [Note: Because of its length, this review has been divided into 2 parts – “Part 1” reviewed the first 25 pages of the body of the report; “Part 2” covers the rest of the report and provides other info (references, an “About This Reviewer” brief & 2 appendices).]

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**.

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

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]

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

Part 2 of 2 Parts

“requests 4 and 5

A list of all vaccines and the years they were introduced into the schedule of Florida Pre and post 1980 vaccine schedules (comparison, list of all vaccinations received since 1980 and when added to the vaccine schedule)

Florida adopts the same Routine Childhood and Adolescent ~~Immunization~~ Vaccinations Schedules as published by the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP).

- The schedules contain recommended ~~immunizations~~ vaccinations, ages and spacing to assist healthcare providers plan preventive healthcare with parents for their children.
- ~~Immunizations~~ Vaccinations are provided as a standard of care by the healthcare provider irrespective of school entry requirements.
- Vaccination is one of a small group of medical interventions with direct and simultaneous benefits to individuals and communities. The more vaccinated individuals there are in a community, the greater the protection against disease. This is called herd immunity.
- School ~~immunization~~ vaccination laws were first established to control outbreaks of smallpox and are now used to avoid epidemics of vaccine-preventable contagious diseases, such as measles and pertussis (whooping cough) that can be spread in the close contact of the classroom.
- It is important to note that not all of the ~~immunizations~~ vaccinations on the routine schedule are required for child care and schools in Florida. There is often confusion between what is recommended as part of medical care and what is required for school.

The table below illustrates the increased number of vaccines since 1980 that are available to prevent a greater number of communicable diseases and the complications that may develop.”

Vaccines in the Routine Childhood and Adolescent Schedule Pre and Post 1980		
Vaccines	Pre 1980	Post 1980 to Present
*Diphtheria-Tetanus-Pertussis (DTaP)	X	X
*Haemophilus influenzae type b (Hib)		X
Hepatitis A		X
*Hepatitis B		X
Human Papillomavirus (HPV)		X
Influenza (Flu)		X
*Measles-Mumps-Rubella (MMR)	X	X
Meningococcal (MCV4)		X
*Pneumococcal (PCV)		X
*Polio	X	X
Rotavirus		X
Smallpox **	X	
*Varicella		X
* Immunizations -Vaccinations required by Florida for school and/or child care		
** Vaccine was/is actually a cowpox, Vaccina, vaccine against smallpox - not a smallpox vaccine per se		

Except for correcting the use of the words “immunization” and “immunizations” when “vaccination” and “vaccinations” are more accurate and adding a footnote to the table, this reviewer accepts that these paragraphs accurately reflect the policies and views of the Florida Department of Health (DoH) though this reviewer finds some of these are problematic.

26 REQUEST 4 AND 5

“request 6

Investigate other states’ opt-outs for non-fatal vaccinations that have been added in the last 20 years.

While there are no states to date that have laws in place for an ‘Opt-Out’ for a specific vaccine, 18 states have laws allowing philosophical exemption for ~~immunizations~~-vaccinations.”

More importantly, *unlike nations where parents and guardians are free to choose vaccines and when to vaccinate and the national government freely provides those vaccines that have been proven to be safe and in-use health-cost effective*, the States, Commonwealths, Districts, Territories and Protectorates that comprise the USA have elected to mandate vaccination and provide limited exemptions that may allow some to decline vaccination on medical, religious, and philosophical.

The real reason that any path to exemption is provided is that having such exemptions protects the states from being directly held financially responsible for any harm that may occur as a result of vaccination – which would be the case, *under U.S. law*, if the “states” were to provide no “choice”.

In the fairer states, the exemptions provided include a philosophical exemption but, *as with the other exemptions provided*, some states erect onerous requirements that discourage people from freely exercising this exemption option.

Should the apparent vaccination-fueled chronic-disease epidemics continue to increase and the vaccine apologists, public health officials, vaccine makers, healthcare providers and elected government officials continue to ignore these and/or claim that they have no known causes or that the causes are complex, then, this reviewer predicts that the public outrage will grow to the point that all demand that: **a)** the laws in all states be changed to “opt in” laws and **b)** there be no vaccination requirements for attending any school, engaging in any lawful activity and/or activity or holding any position or office.

When this occurs, then the governmental agencies will become the providers of only those vaccines that have truly been proven safe and truly cost-effective for the individual.

Given this possibility, this reviewer would strongly counsel the Florida DoH and all other similar agencies to determine, based on their own active surveillance programs, which vaccine components are: **a)** truly in-use effective for their state’s population, **b)** provide long-term protection to almost everyone vaccinated, and **c)** meet, or exceed, the U.S. safety standards.

Then, they should eliminate all vaccine components that do not meet the preceding requirements from the Florida required vaccination programs.

Moreover, this reviewer strongly suggests that all those involved in any facet of the vaccine establishment had better prove, *in appropriate human case studies and animal-model toxicity studies*:

- What the underlying vaccine-related causal factors are in the epidemic increase in various chronic diseases and
 - Unequivocally reveal the truth about the causal links found,
- or face the loss of all credibility and the wrath of the inflamed public, who will demand that they be appropriately tried for their malfeasances and, if found guilty, appropriately sentenced.

“In contrast, 47 states provide exemptions for religious beliefs and one state provides for religious exemption from ~~immunizations~~ ~~vaccinations~~ in child care and pre-K only.

- Florida provides exemptions from ~~immunization~~ ~~vaccination~~ for religious beliefs and medical reasons as identified by the child’s healthcare provider.
- Public health balances its responsibility to provide appropriate ~~immunization~~ ~~vaccination~~ exemptions while also protecting the susceptible, ~~un-immunized~~ ~~un-vaccinated~~ students from exposure in the classroom. If this balance is lost, the possible outcome would be pockets of diseases that should be prevented by vaccine. While most people do not suffer severe complications, all vaccine-preventable-diseases may result in a fatal outcome.

The ~~immunization~~ ~~vaccination~~ coverage rate for the MMR vaccine is high in Florida and nationally as well. However, public health remains vigilant to any significant drop in these coverage rates in order to protect children and adults from measles, mumps and rubella. Florida has experienced small outbreaks in communities that have low or no ~~immunization~~ ~~vaccination~~ coverage rates.

Great Britain has experienced a rise in measles and mumps case reduction because fewer parents are immunizing their children.

- ~~Immunization~~ ~~Vaccination~~ rates in England dropped and the number of measles and mumps cases rose significantly following a publication in *The Lancet* of a 1998 paper and the subsequent media coverage that suggested an association with the combination measles, mumps and rubella vaccine—MMR—and the development of autism.”

Though the initial statements only misuse the word “immunization” and related forms thereof, the preceding statements on measles and England are a craven distortion of the facts.

Factually, the uptake rates for the MMR vaccine used in England were falling before the 1998 paper was published in *The Lancet*.

The uptake rates were falling in the United Kingdom because MMR vaccine that had been being offered to the English public contained a virulent strain of mumps, the Urabe strain, that Canada had already stopped using on safety grounds since a safer vaccine MMR vaccine, Merck’s MMR II, was available.

Apparently, the UK public health officials elected to provide the less safe Urabe-mumps-containing MMR vaccine because it was less expensive than the safer MMR vaccine.

- “2007 saw the highest number of measles cases recorded in England and Wales since the current method of monitoring the disease was introduced in 1995.”

While this reviewer accepts that the report’s statement is correct, he notes that the report failed to provide the case numbers or the corresponding number of deaths for 1995 and 2007 so that an assessment of this statement’s significance could be made.

- “*The Lancet* article was withdrawn following further scientific review.”

The report knowingly misrepresents the facts about the article in question:

Factually,

1. The UK medical establishment attempted to blame the paper for the decline in vaccination when the adverse outcomes from the less-safe MMR vaccine containing the more virulent Urabe strain of mumps was the culprit;
 2. There was no scientific review but rather a medical witch hunt against the article's principle author, Dr. Andrew Wakefield (and those who refused to speak against the paper) that is still going on in 2008;
 3. In 2004, *eight years after the Wakefield et al. study was published in **The Lancet***, 10 of the 13 original authors signed a statement that only repudiated the study's "Interpretation" of the findings but nothing else; and
 4. The paper was not withdrawn.
- "Low vaccine uptake over the past decade means there is now a large group of children who either haven't been vaccinated or who have received just one dose. These children are susceptible to not only measles but to mumps and rubella as well."

Again, the statement made here distorts the facts because:

1. Many of the unvaccinated have had mumps, rubella and/or measles and are no longer vulnerable to the diseases with which they contracted and then recovered;
 2. All those who are vaccinated are abnormally infected with measles mumps and rubella so that the immunity developed, *if any*, is incomplete and does not last as long as the natural immunity acquired from having the disease; and
 3. Some children who did not receive the MMR vaccine have been given the MR vaccine, or the individual measles, mumps, and/or rubella vaccines.
- "While ~~immunization~~ vaccination levels were reduced from 92% to 85%, measles cases increased from 112 to 958 for the years 1995 to 2007."

First, there seems to be a disconnect between the information reported in cases data and the years for the measles data because the maximum number of measles cases on the report's "measles" graph on the next page appears to be about 1100 cases in the 2004 – 2005 and, *based on the apparent "50" cases from the graph for the 2006 – 2007 period*, the probable number of measles cases in "2007" should have been closer to 100 than to 1,000 cases.

Moreover, based on the "measles" graph, there was no significant rise in measles cases until the single-dose uptake rate in 2-year olds dropped below 82 %

Though there are other concerns, this reviewer finds these apparent discrepancies are very troubling and they need to be addressed and corrected.

Additionally, this reviewer finds that this report fails to mention the actual number of children reportedly killed or seriously injured when they were given the MMR vaccine – in the U.S., this is a considerable number.

Since most of the vaccine-related deaths are not reported, one can presume that the "true" measles death rate (from contracting measles "naturally" or by being injected with the live measles virus in the MMR vaccine) may not have changed significantly.

As the population of England was increasing because of a large influx of immigrants from other nations during this period, without population-segment rate breakouts for native and immigrant populations and for the different socioeconomic groups, it is not possible to assess how much of the increase in measles cases is from: **a)** decreased vaccine uptake, **b)** the influx of immigrants bringing new strains of measles against which the MMR vaccine used was/is not fully protective, or **c)** other factors (like a favorable climate for transmission).

Finally, no report was made of the serious adverse events, *including death*, that are known to be associated with the MMR vaccine.

Given all of the preceding realities, this reviewer must: **a)** discount this statement and **b)** request that the Florida DoH provide the missing information.

- “Fearing the vaccine more than the disease: the graphs on the following page reflect the decrease in the percent of 2-year-olds in England who received at least one dose of MMR, and the rise in the cases of measles and mumps reported. Source: Health Protection Agency, United Kingdom.”

First, this reviewer finds it curious that the report failed to include a graph for rubella cases – perhaps there was no significant effect even when the uptake fell below 82 %.

Second, this reviewer finds it curious that the number of mumps cases in the “mumps” graph provided does not track the time and uptake-level trends in the “measles” graph.

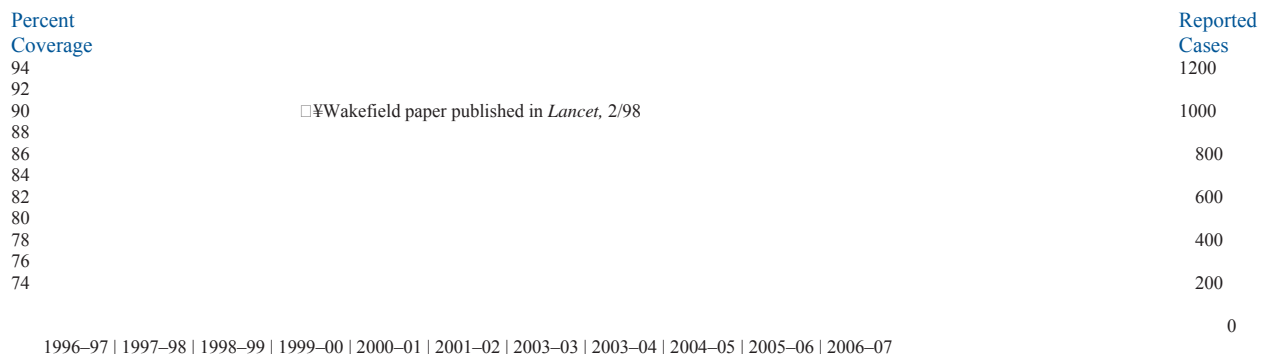
At a minimum, the “mumps” graph indicates that factors other than uptake among 2-year olds were affecting the number of cases reported.

Finally, these graphs provide no evidence the public feared “*the vaccine more than the disease*” – only that the English parents and guardians of different cohorts of “*two-year-olds*”, for whatever reasons, had different levels of vaccine acceptance.

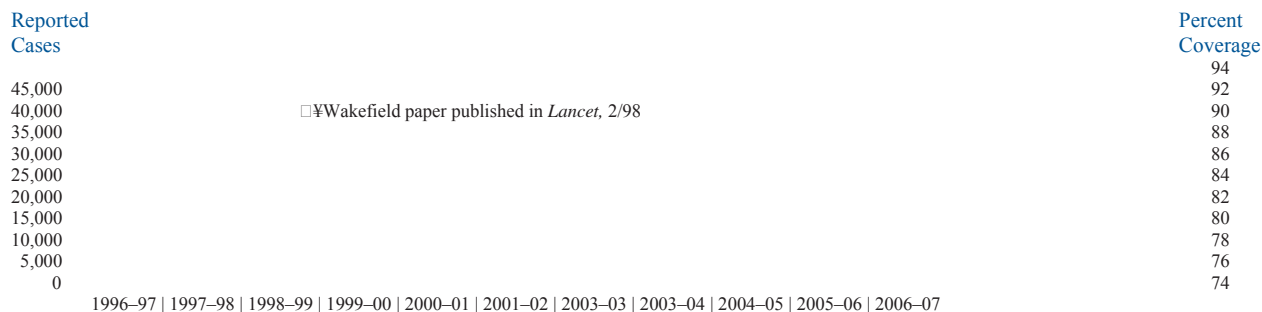
Hopefully, the Florida DoH will address and resolve the apparent anomalies in the “measles” and the “mumps” graphs provided as well as address the “rubella” cases during the same time period.

27 REQUEST 6

Percent of 2-year-olds in England who Received at Least One Dose of MMR and the Number of Measles Cases Reported



Percent of 2-year-olds in England who Received at Least One Dose of MMR and the Number of Mumps Cases Reported



Factually, MMR uptake in the UK was dropping before the paper by Wakefield et al. was published in 1998.

This drop was precipitated by the public concern caused by the UK government's decision to license an MMR vaccine that contained the highly virulent Urabe strain of the mumps virus because it was less expensive than the MMR vaccine containing a safer mumps strain.

This choice resulted in a sudden surge in adverse outcomes, including death, shortly after that vaccine was given to the child.

Thus,

- The UK government's actions,
- The subsequent sharp increase from the MMR vaccine with the Urabe strain of mumps and
- The public's concern about the increased vaccine harm caused by that MMR vaccine were largely responsible for the fall in MMR uptake, *and not the Wakefield et al. paper.*

Finally, this decrease in MMR uptake was slow to turn around even after the UK's government finally "recognized" the vaccine problem, but, *without informing the public about this Urabe-strain problem*, chose to cover it up and to simply offer MMR vaccines that had a safer strain of mumps.

"Public confidence in England for the MMR vaccine is now high with more than 8 out of 10 children receiving one dose of MMR by their second birthday. While the percentage of children being vaccinated is rising again, England has had to declare measles and mumps endemic again as it will take years to reverse the disease trend."

Again, this reviewer finds the report's statements here to be somewhat problematic because, *from the graphs*, measles cases are close to the low levels seen before the start of 2004 and, *since rubella cases are not mentioned*, the low vaccination rates for MMR apparently did not adversely affect the number of rubella cases.

This leaves the problematic and perplexing "mumps" cases data which: **a)** does not appear to track the data for the "MMR" uptake and **b)**, *even when the vaccine uptake levels were close to 90%*, indicates that there were 2,000-plus to 6,000 cases annually in England while, *for the period 1999 through 2005 in the USA where the population is roughly 6 times larger*, there were less than 400 cases annually – levels 5 to 15 times lower than in the UK, *but in 2006*, with uptake levels higher than 92%, there were more than 6,000 cases in the USA, while, *in England with apparently 80+ % uptake levels*, there were more than 35,000 cases – more than 5 times the cases in the USA.

Taken together, these facts indicate that some factor other than uptake, *perhaps viral strain related*, has a significant impact on the number of cases in both the USA and the UK.

Hopefully, *after reviewing this reviewer's concerns*, the report's authors will address and resolve the incongruities in the information provided.

28 REQUEST 6

“request 7

Which vaccines given to children under the age of two still have thimerosal? Flu shot has thimerosal? Did DOH mandate that all vaccines have none? How long has this been in place?

Which vaccines given to children under the age of two still have thimerosal? Flu shot has thimerosal? Routinely recommended childhood vaccines have not contained thimerosal as a preservative since 2001.”

Since: **a)** the CDC's ACIP added the Thimerosal-preserved influenza vaccines to U.S. schedule for the routinely recommended childhood vaccines as well as pregnant women in 2002 and **b)** the expiration dates for some lots of some of the other routinely-recommended Thimerosal-preserved vaccines extended into 2004, *if not later*, the last statement here is factually inaccurate, *to say the least*.

Fortunately, *unlike New Jersey*, Florida has not yet mandated the less-than-effective influenza vaccines or a vaccination exemption for this vaccination, as a prerequisite for attending childcare facilities and schools for children 6 months to 59 months of age.

“All vaccines for children under the age of two are available without thimerosal. Table 1, produced by the U.S Food and Drug Administration, lists all vaccines routinely recommended for children 6 years of age and younger. This table illustrates the absence of thimerosal as a preservative in childhood vaccines.”

Factually, the most recent FDA/CBER **Table 1**, *shown below and on the next page*, contains two Thimerosal-preserved vaccines, highlighted in ***bolded italics***, that are clearly listed in the FDA's "**Table 1**", rendering the report's "*This table illustrates the absence of thimerosal as a preservative in childhood vaccines*" statement factually inaccurate.

Table 1. Thimerosal Content of Vaccines Routinely Recommended for Children 6 Years of Age and Younger - (updated 7/18/2005*)

*Since this update, a biologics license application was approved for Rotavirus Vaccine, Tradename-RotaTeq (Merck), that is thimerosal free and never contained thimerosal.

Vaccine	Tradename (Manufacturer)	Thimerosal Status Concentration**(Mercury)	Approval Date for Thimerosal Free or Thimerosal / Preservative Free (Trace Thimerosal)*** Formulation
DTaP	Infanrix (GlaxoSmithKline Biologicals)	Free	Never contained more than a trace of thimerosal, approval date for thimerosal-free formulation 9/29/2000
	Daptacel (Sanofi Pasteur, Ltd)	Free	Never contained Thimerosal
	Tripedia (Sanofi Pasteur, Inc)	Trace ($\leq 0.3 \mu\text{g Hg}/0.5\text{mL dose}$)	03/07/01
DTaP-HepB-IPV	Pediarix (GlaxoSmithKline Biologicals)	Free	Never contained more than a Trace of Thimerosal, approval date for thimerosal-free formulation 1/29/2007
Pneumococcal conjugate	Prevnar (Wyeth Pharmaceuticals Inc)	Free	Never contained Thimerosal
Inactivated Poliovirus	IPOL (Sanofi Pasteur, SA)	Free	Never contained Thimerosal
Varicella (chicken pox)	Varivax (Merck & Co, Inc)	Free	Never contained Thimerosal
Mumps, measles, and rubella	M-M-R-II (Merck & Co, Inc)	Free	Never contained Thimerosal
Hepatitis B	Recombivax HB (Merck & Co, Inc)	Free	08/27/99
	Engerix B (GlaxoSmithKline Biologicals)	Free	03/28/00, approval date for thimerosal-free formulation 1/30/2007

Haemophilus influenzae type b conjugate (Hib)	ActHIB (Sanofi Pasteur, SA) OmniHIB (GlaxoSmithKline)	Free	Never contained Thimerosal
	PedvaxHIB (Merck & Co, Inc)	Free	08/99
	HibTITER, single dose (Wyeth Pharmaceuticals, Inc.) ¹	Free	Never contained Thimerosal
Hib/Hepatitis B combination	Comvax (Merck & Co, Inc)	Free	Never contained Thimerosal
Influenza	Fluzone (Sanofi Pasteur, Inc)	<i>0.01% (12.5 µg/0.25 mL dose, 25 µg/0.5 mL dose)²</i>	
	Fluzone (Sanofi Pasteur, Inc) ³ (no thimerosal)	Free	12/23/2004
	Fluvirin (Novartis Vaccines and Diagnostics Ltd)	<i>0.01% (25 µg/0.5 mL dose)</i>	
	Fluvirin (Novartis Vaccines and Diagnostics Ltd) (Preservative Free)	Trace (<1ug Hg/0.5mL dose)	09/28/01
Influenza, live	FluMist (MedImmune Vaccines, Inc)	Free	Never contained Thimerosal

** 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.

*** The term "trace" has been taken in this context to mean 1 microgram of mercury per dose or less.

¹ HibTiITER was also manufactured in thimerosal-preservative containing multi-dose vials but these were no longer available after 2002.

² Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.

³ A trace thimerosal containing formulation of Fluzone was approved on 9/14/02 and has been replaced with the formulation without thimerosal.

- “According to data, there is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site.”

First, the maximum allowed “nominal” dose of Thimerosal in a 0.5-mL dose of a Thimerosal-preserved vaccine is about 50 micrograms [50 µg] of Thimerosal (100 ppm Thimerosal), which translates into a mercury concentration of about 50 µg of mercury per mL:

- A concentration that is about 250 times the EPA maximum concentration for hazardous liquid “mercury” waste (0.2 µg of mercury per mL [0.2 ppm]), and
- A dose that, *on the mercury toxicity scale*, is anything but a “low” dose.

Moreover, Eli Lilly documents (furnished in now-sealed court cases involving Eli Lilly and Thimerosal-containing drugs) reported Thimerosal toxicity from vaccine doses of 1-ppm Thimerosal (0.5 ppm mercury) – a level that still 2.5 times the EPA’s toxic-waste threshold (0.2-ppm mercury).

Based on the EPA’s threshold of 0.2 ppm for the total concentration of mercury species in a liquid that classifies that liquid as a hazardous waste, no dose of mercury in a Thimerosal-preserved vaccine is a “low” dose and, *in vaccines containing a lesser level of Thimerosal*, a low dose of mercury might be a 0.5-mL dose that contains less than 0.001 micrograms of mercury (< 2 nanograms of Thimerosal).

“However, in July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.”

Factually, the bulk of the scientific toxicity evidence shows that the 100-ppm level of Thimerosal in most-Thimerosal-preserved vaccine is more than 100 times higher than the level of Thimerosal that, *in developing animal studies (using fertilized chicken eggs, hamsters, mice, pheasants, pigs, rats, and monkeys), multigenerational studies (using rodents), developing studies, human cell studies, and human tissue studies*, has been shown to cause adverse health effects in the animals, developing cell systems, and skin tissues treated with a simple covalently bonded ethyl mercury compound or with Thimerosal, the sodium salt of ethylmercury thiosalicylate.

- “There are licensed flu vaccines available for infants 6 months and older that are thimerosal free.”

Factually, there is only a limited number of doses (roughly 8 – 10 million doses) of one “no Thimerosal” FDA-licensed human influenza vaccine that is available for infants 6 months of age and older, Sanofi’s “no Thimerosal” Fluzone.

The other FDA-licensed “*thimerosal free*” flu vaccines that are approved for use in children are:

1. The “no Thimerosal” live-virus MedImmune FluMist vaccine, which:
 - a. is also only available in a limited number of doses (roughly 5 million doses),
 - b. is currently licensed for those 2 to 49 years of age, and
 - c. because it is a live-virus vaccine, can infect those who are inoculated with the vaccine as well as those who have contact with the inoculees for up to 3 weeks (21 days) after the inoculees receive the vaccine, and
2. The currently unavailable Novartis “trace Thimerosal” inactivated-virus flu vaccine for those who are 4 years of age and older.

Given the reality that the CDC’s current recommendation is for “every” child 6 months to 18 years of age to get one flu vaccination dose and for some children to get 2 doses, *a month (for the inactivated vaccine) to 6 weeks (for the live-virus vaccine) apart*, it is clear that there is not enough FDA-approved childhood “Thimerosal free” influenza doses to meet the about 75 million doses needed for this age group.

“How long has this been in place?”

- As a precautionary measure, the U.S. Public Health Service (including the FDA, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA)), and the American Academy of Pediatrics issued two Joint Statements, urging vaccine manufacturers to reduce or eliminate thimerosal in vaccines as soon as possible (CDC 1999 and CDC 2000). The U.S. Public Health Service agencies have collaborated with various investigators to initiate further studies to better understand any possible health effects from exposure to thimerosal in vaccines.”

First, for better accuracy, the report’s narrative here should be revised to read:

“As a precautionary measure, the U.S. Public Health Service, U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) along with the American Academy of Pediatrics (AAP) issued two Joint Statements, the first (CDC 1999) urging manufacturers to remove all the Thimerosal from vaccines as soon as possible, and the second (CDC 2000) changing the ‘remove’ request to simply reducing the level of Thimerosal in vaccines as soon as possible. The CDC has overseen retrospective epidemiological studies, which have been

‘iteratively revised’³⁰ to minimize the chance of finding any link between the administration of Thimerosal-preserved vaccines (and/or the MMR vaccine) and any neurodevelopmental disorder, including ‘autism’ (autistic spectrum disorder). To date, the comprehensive Thimerosal toxicity studies actually required to *better understand any possible health effects from exposure to Thimerosal in vaccines*, that were originally assigned to the National Institute of Mental Health (NIMH) in 1999 were put on hold in 2000 and, *as of mid-September 2008*, not complete – most of the required studies have not even been initiated.”

Factually, the U.S. Public Health Service (USPHS), FDA, NIH, CDC, and HRSA are equal-rank agencies in the Department of Health and Human Services (DHHS); and all report to the Secretary of Health and Human Services (HHS).

Additionally, numerous independent studies, conducted outside of the CDC’s oversight, have found and reported causal links between: **a)** the level of exposure to Thimerosal-preserved vaccines, or their equivalent, in developing human and developing animal studies and **b)** the risk of neurodevelopmental disorders, *including autistic disorder*, as well as other developmental conditions in developing children.

Further, case studies have established that most of the children who have a diagnosis in the “autism spectrum” are mercury poisoned and many of these children are either poor excretors, *or non-excretors*, of the mercury in serums and vaccines to which they were exposed from conception through the first 12 months of life.

In fact, the causal link between Thimerosal and autism had become so well accepted that Dr. Larry Needham, Chief, Organic Analytical Toxicology Branch, Nat’l Center for Environmental Health, CDC presented a slide that showed Thalidomide, Lead, Ethanol, ‘Retinoids’, Valproic Acid, and Thimerosal as causal agents for autism spectrum disorders in his April 2007 presentation to Institute of Medicine³¹.

Finally, in the Fall of 2007, medical professionals in the Department of Health and Human Services conceded³² that the vaccinations given to Hannah Poling when she was 19-months of age were causal factors in the regressive autism she subsequent developed before her case, *scheduled to be heard as a test case in the ongoing Omnibus Autism Proceeding in the U.S. Court of Federal Claims for the hypothesis: Thimerosal in vaccines is a causal factor in autism*, could be heard and even before the petitioners’ experts, Drs. Andrew Zimmerman and Mark R. Geier, *testifying on behalf of Hannah Poling and her parents*, were scheduled to file their formal reports confirming that:

- ❖ Hannah had developed regressive autism and, later, seizures, as a result of adverse reactions to the vaccinations she received at 19 months of age, and
- ❖ She was mercury poisoned by the Thimerosal-preserved vaccines she received at that time.

³⁰ One of the fundamental tenets of sound epidemiological study is that, once the study is designed, the study’s design should not be revised when the findings are not what those designing the study hoped they would be. In the U.S. studies of the Vaccine Safety Datalink (VSD) by CDC researchers, the Verstraeten et al. studies, repeatedly violated this fundamental tenet and, after seeing results strongly associating the level of early-developmental Thimerosal exposure with the risk for autistic disorder and other neurodevelopmental disorders, these researchers repeatedly revised the study design until the computed link became non-statistically significant. Furthermore, the CDC-overseen studies in Canada, United Kingdom (UK), Denmark and Sweden have been similarly compromised.

³¹ April 2007 (PowerPoint Presentation) by Dr. Larry Needham, Chief, Organic Analytical Toxicology Branch, Nat’l Center for Environmental Health, CDC, “Exposure (To Stressors) and Autism Spectrum Disorders” to the IOM.

³² *Hannah Poling v. Sec. HHS*, VICP case 02-1466V, vaccinations as a causal factor in child’s autism was conceded by DHHS medical professionals in a report filed with the “Vaccine Court” on November 9, 2007.

Given all of the preceding realities and the supporting studies published in 2008, this reviewer finds it hard to believe that anyone would continue to misrepresent the state of knowledge concerning the proven causal links between:

- ❖ Some children's receiving bolus doses of organic mercury from Thimerosal-preserved vaccines and
 - ❖ The subsequent onset of regressive autism in children, who, *like Hannah Poling*, are poor excretors of mercury, *for whatever reasons*, during their early developmental period (from conception through three to five years post partum).
- "At present, all routinely recommended vaccines for U.S. infants are available only as thimerosal-free formulations or contain only trace amounts of thimerosal (≤ 1 micrograms mercury per dose), with the exception of inactivated influenza vaccine. Inactivated influenza vaccine for pediatric use is available in a thimerosal-preserved formulation and in formulations that contain either no thimerosal or only a trace of thimerosal, but the latter is in more limited supply (see Table 1). All [other] pediatric vaccines in the routine infant ~~immunization~~ vaccination schedule are manufactured without thimerosal as a preservative. As of January 14, 2003, the final lots of vaccines containing thimerosal as a preservative expired. These changes have been accomplished by reformulating products as more expensive single dose vials that do not contain a preservative."

While the report's first statement here is true, the realities are:

- *For the inactivated influenza vaccines*, Thimerosal-preserved inactivated influenza vaccines: **a)** are still approved for infants from 6-months of age onwards and **b)**, *in all but a few states*, can "legally" be given to pregnant women at any time during their pregnancy (even though all inactivated influenza vaccines are Pregnancy C drugs indicating that safety for the developing fetus has not been established),
- *Thimerosal is a proven human teratogen, mutagen, carcinogen, and immune-system disruptor at levels below 1 ppm, and*
- Retrospective population studies have shown that the children born to mothers who received a Thimerosal-preserved inactivated flu shot during pregnancy had significantly increased risks for certain birth defects (cleft palate when the flu shot was given to the mother in her first trimester of pregnancy; and hydrocephaly and pyloric stenosis across the pregnancy)³³.

With respect to the report's statement:

"As of January 14, 2003, the final lots of vaccines containing thimerosal as a preservative expired", it is obvious, given the Thimerosal-preserved influenza vaccines in the childhood vaccination schedule, that this statement is not true.

Furthermore, some lots of other formerly Thimerosal-preserved vaccines expired well after January 14, 2003.

"Did DOH mandate that all vaccines have none?" There is no DOH mandate regarding thimerosal in vaccines. Bills were introduced by the legislators during the last few sessions and were not passed. The Florida Department of Health provides and recommends thimerosal-free vaccine for children."

Since there are about 12 million U.S. children under three years of age needing up to 14 million doses of influenza vaccine, not to mention about 20 million more children between 3 and 8 years of age and about 40 million children between 8 and 18 who all need a flu shot under the current CDC recommendations and, for the 8 million children under 2, needing 10 million doses of Sanofi's "no Thimerosal" vaccine (where only 8- to 10-million doses are

³³ Heinonen OP, Slone D, Shapiro S. **Birth Defects and Drugs in Pregnancy**. Littleton, Massachusetts: Publishing Sciences Group, Inc., 1977.

produced – leaving a probable deficit of available doses of that vaccine for these children and “none” for children from 3 years to 18 years of age).

Moreover, there are only about 5 million doses of FluMist for those 2 years of age and up, needing 3-plus million doses a year for each age cohort from age “2” up to “18”, it seems that there is a net-deficit for “no Thimerosal” vaccines for children of on the order of 35-plus million doses of “no Thimerosal” vaccine, because, this year, no “trace Thimerosal” Fluvirin influenza vaccine appears to be available.

Thus, unless the percent coverage is less than 25% and the states, like California (where 15% of American children reside), that have outlawed giving anything but “no Thimerosal” and “trace Thimerosal” flu vaccines to children under 3 years of age and needing about 10 million doses of flu vaccine for all of their children, or, *in some states*, the need for “no/trace Thimerosal” vaccines is up to age 8, haven’t pre-ordered all of the available “no Thimerosal” vaccine doses (Fluzone and FluMist) for their children, it would seem that Florida will have a hard time getting sufficient doses of “no Thimerosal” vaccine that is approved for use in children (because only Fluzone, Fluvirin and Flu Mist are approved for administration to children).

Therefore, this reviewer finds the report’s statement (with underlining added for emphasis):

“*The Florida Department of Health provides and recommends thimerosal-free vaccine for children*” is less than credible given the scarcity of “no Thimerosal” doses approved for children (Sanofi’s “no Thimerosal” Fluzone) and the apparent ongoing unavailability of “trace Thimerosal” doses approved for children (Novartis’ “trace Thimerosal” Fluvirin).

“**Thimerosal.** Thimerosal is a mercury-containing organic compound. Since the 1930s (Powell, 1931), it has been widely used as a preservative in a number of biological and drug products, including many vaccines, to help prevent potentially life threatening contamination with harmful microbes. It has been used to kill bacteria and prevent contamination in antiseptic ointments, ...”

Here the report is a master of both understatement and distortion.

Factually, Thimerosal is a highly toxic organic mercury compound whose metabolites bioaccumulate in the human body and, in normal excretors of mercury, accumulate in the brain with a half-life of about 20 years and in other organs with half-lives of 10 to 20 years.

Thimerosal and its ethylmercury metabolites are also known human teratogens (inducers of birth defects when administered to pregnant women), mutagens, carcinogens and immune system disruptors at levels below 1 ppm.

Without toxicological proof that the Thimerosal level used is:

- ❖ Safe to use,
- ❖ Truly effective as a preservative in the product formulations to which it has been added, or
- ❖ Since 1968, “sufficiently nontoxic ...” to the extent specified in 21 C.F.R. Sec. 610.15(a), drug manufacturers, *including vaccine makers*, have:
 - a. Used Thimerosal in the manufacture of their drug products without the required proof of safety, and
 - b. Claimed that, *at levels between 10 and 100 ppm, depending on the formulation*, Thimerosal is a “preservative”.

Given the preceding, since January 1968, when the current good manufacturing practice (CGMP) safety minimum requiring proof that the “preservative used” is “sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient” and the vaccine makers failed to provide the toxicological proof that their vaccines

were safe to this standard, all Thimerosal-preserved vaccines have been adulterated drugs under 21 U.S.C. Sec 351(a)(2)(B) because, *as both the FDA and the vaccine manufacturers have repeatedly admitted*, the manufacturers have knowingly failed to comply with the current good manufacturing practice (CGMP) safety minimum for proof that it is “sufficiently nontoxic ...”, as currently set forth in 21 C.F.R. Sec. 610.15(a), and thereby rendered their Thimerosal-preserved vaccines adulterated under 21 U.S.C. Sec. 351(a)(2)(B).

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“... creams, jellies, and sprays used by consumers and in hospitals, including nasal sprays, eye drops, contact lens solutions, immunoglobulins, vaccines, antivenins, and tattoo inks. Thimerosal does not reduce the potency of the vaccines that it protects (Baker 2008).”

With respect to the report’s statements:

“It has been used to kill bacteria and prevent contamination in antiseptic ointments, creams, jellies, and sprays used by consumers and in hospitals, including nasal sprays, eye drops, contact lens solutions, immunoglobulins, vaccines, antivenins, and tattoo inks. Thimerosal does not reduce the potency of the vaccines that it protects (Baker 2008)”,

this reviewer notes that the requisite “proof of safety” to the standard “sufficiently nontoxic ...” has not been provided for any of these products, and studies attempting to verify safety in “*antiseptic ointments, creams, jellies, and sprays used by consumers and in hospitals*” led to a 1982 FDA report recommending banning its use as an antiseptic and, *in 1998*, to the FDA’s banning the use of Thimerosal in all over-the-counter “*antiseptic ointments, creams, jellies, and sprays*” and in vaginal contraceptives because Thimerosal was found to be: **a)** ineffective and **b)** unsafe for use in such products.

Additionally, Thimerosal has not been used as a preservative in plasma products and infused “immunoglobulin” products for more than 3 decades because serious patient mercury intoxication (poisoning) was observed in the 1940s in the first instance, and in the 1970s in persons receiving multiple-milliliter doses of these drug products in the second instance.

While the existing stocks of FDA-approved antivenins contain Thimerosal or, *if they are lyophilized*, phenylmercuric acetate in the diluent, current manufacture has been suspended because the antivenin makers have committed to producing mercury-free antivenin products.

Moreover, though not yet banned from “*nasal sprays, eye drops, contact lens solutions*”, most of the manufacturers of such products voluntarily removed Thimerosal from their formulations in the late 1990s/early 2000s.

Finally, *except for 10 vaccine formulations*, 5 of which are for inactivated influenzas (four human and one avian), all of the current FDA-approved vaccine formulations nominally provide *not more than* 1 µg of mercury per dose and most their doses are “no Thimerosal” and “no preservative” formulations although the FDA has, *as yet*, failed to revoke the licenses of the replaced Thimerosal-preserved vaccine formulations or, *as required by law*, declare all of the existing Thimerosal-preserved vaccine formulations adulterated drugs under 21 U.S.C. Sec 351(a)(2)(B) and force them off of the market.

Thus, because of repeated studies showing lack of proof of safety and product-lifetime effectiveness and public pressure, most all vaccines and other drug products with a declared level of Thimerosal have been either banned or “voluntarily” removed from the U.S. market.

“Thimerosal is metabolized or degraded to ethylmercury and thiosalicylate. Ethylmercury is an organomercurial that should be distinguished from methylmercury, a substance that has been the focus of considerable study.”

The information provided here is, *at best*, inaccurate.

Factually, *when dissolved in water*, Thimerosal, sodium ethylmercury thiosalicylate, slowly disproportionates into ethylmercury hydroxide and sodium thiosalicylate.

In the presence of trace levels of metal ions, particularly, copper, and dissolved oxygen, *common components found in living systems and vaccine formulations*, this disproportion reaction is driven by the removal of the thiosalicylate formed by its being oxidized to the disulfide.

When Thimerosal is dissolved in sterile saline, the basis solution for many vaccine formulations, the disproportionation reaction produces both ethylmercury chloride and ethylmercury hydroxide.

Moreover, in the presence of direct sunlight, the “mercuric” mercury, Hg^{2+} , in Thimerosal can be photolytically converted to metallic mercury, Hg^0 , and, *though this reaction has not been fully studied*, possibly S-ethyl thiosalicylate.

While the report’s glib statement:

“Ethylmercury is an organomercurial that should be distinguished from methylmercury, a substance that has been the focus of considerable study”

is essentially true, Thimerosal and other ethylmercury compounds, *including those also used as agricultural fungicides from the 1930s through the 1970s*, have been the subject of more study than the vaccine apologists are willing to admit or cite.

Ethylmercury is not methylmercury—Significant Differences		
	Methyl Mercury	Ethyl Mercury
Health risk	Toxic chemical; scientific evidence of health risk	No Scientific evidence of health risk has been accumulating since the 1930s and the current body of toxicological, case study and legal case concessions by the medical professionals in the Poling case have clearly proven that Thimerosal is a health risk at levels below 1 ppm and probably below 0.01 ppm in those who are” non-excretors”.
Sources	Toxic chemical found in the environment and food: <ul style="list-style-type: none"> • Biotransformed products from the emissions of coal-fired power plants, mercury-diaphragm chlor-alkali plants, crematoria, and cement kilns and dental waste found Coal power plant emissions in air and water • Seafood 	Thimerosal (used as a preservative previously used in vaccines) <ul style="list-style-type: none"> • All early childhood vaccines have thimerosal-free versions
Amount	60 µg in one 6 oz can of albacore tuna BUT: <ol style="list-style-type: none"> U.S. children < 12 months of age do <u>not</u> eat tuna. Light tuna typically has < 25 µg of mercury per can. Typically, < 25% of the mercury in ingested fish is absorbed into the body; ~ 70 % – 80 % is bound up in the gut and is excreted <u>without</u> being absorbed. 	0 or less not more than 1 µg per dose in a “trace Thimerosal vaccine or 24.5-25 µg per dose in Thimerosal-preserved vaccines
Metabolism	Accumulates in body Based on Burbacher et al., methylmercury hydroxide is less bioaccumulative in the brain than Thimerosal’s ethylmercury hydroxide/chloride metabolites since 9 of the 17 test subjects failed to have a detectable level of “inorganic”	Excreted from body Accumulates in body Data from animal studies in monkeys and hamsters and post-mortem autopsies of the brains of children diagnosed with an autism spectrum disorder have proven that mercury from any Thimerosal accumulates in the body’s organs to

	mercury whereas all 17 of those injected with Thimerosal had detectable levels of both organic mercury and “inorganic” mercury.	varying degrees (see below). From the findings in developing monkeys and hamsters, the level of accumulation in the brain varies by more than factor of 10 in a given strain of monkey or hamster. Based on studies by Sugita (Sugita M. The biological half-time of heavy metals. The existence of a third, “slowest” component. <i>Int Arch Occup Environ Health</i> 1978; 41(1): 25-40), the half-lives of accumulating mercury in tissue is on the order of 10 to 20 years.
Exposure (half-life)	1.5 months in blood The value reported appears to be the half-life in the monkey brain or blood? Factually, in Burbacher et al., the portion of the methylmercury hydroxide, which was fed to young monkeys, found in the brain and metabolized there into “inorganic mercury had an indeterminate half-life (see Burbacher TM, et al. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal. <i>Environ Health Persp</i> 2005; 113(8): 1015-1021).	Less than 1 week in blood Again half-life reported here appears to be for mercury in blood from the INJECTED Thimerosal metabolized into ethylmercury hydroxide and ethylmercury chloride. Here, the data from Burbacher et al. indicates that, <i>on average</i> , up to 3 times as much “inorganic” mercury accumulated in the brains of the monkeys injected with Thimerosal as compared to methylmercury hydroxide force fed to another group of these monkeys. Again, the “inorganic mercury’s half-life was indeterminate and clearly much > 180 days.

In animal feeding studies, the comparative toxicity data indicate that though the acute toxicity of these alkyl mercury compounds are similar.

However, studies designed to feed developing animals less than lethal doses of these compounds have, *in some instances*, found the ethyl mercury compound used was significantly more toxic than the methyl mercury compound to which it was compared³⁴.

Hopefully, *after reviewing this reviewer’s remarks and the paper in question*, the authors of this report will, *at least*, correct their misuse of the half-life data for mercury in blood as if it were the half-life of mercury in the body as a whole or in any organ, including the brain.

Factually, *for bioaccumulative poisons like the alkyl organic mercury compounds in the preceding study by Tryphonas et al.*, studies injecting an appropriate dose of Thimerosal that contains a small percentage of Thimerosal that has radiolabeled mercury atoms; and then collecting and monitoring all of the body’s elimination products until the data from the radiolabel indicates half of the mercury dose injected was recovered outside of he body would be needed to establish the half-life of the mercury in Thimerosal or methylmercury hydroxide injected into the test subjects.

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Turning to the table of vaccines presented in this report for children under 6 years of age, this reviewer simply notes that two (2) of the vaccines (highlighted in ***bolded italics***) listed in that “Table 1” are Thimerosal preserved vaccines.

Table 1. Thimerosal Content of Vaccines Routinely Recommended for Children 6 Years of Age and Younger (FDA website http://www.fda.gov/cber/vaccine/thimerosal.htm —accessed 8/1/2008)			
Vaccine	Tradename (Manufacturer)	Thimerosal Status Concentration**(Mercury)	Approval Date for Thimerosal Free or Thimerosal/ Preservative Free

³⁴ Tryphonas L, Nielsen NO. Pathology of chronic alkylmercurial poisoning in swine, “ *American Journal of Veterinary Research*. 1973; 34(3): 379-392.

			(Trace Thimerosal)*** Formulation
DTaP	Infanrix (GlaxoSmithKline Biologicals)	Free,	Never contained more than a trace of thimerosal, approval date for thimerosal free formulation 9/29/2000
	Daptacel (Sanofi Pasteur, Ltd)	Free	Never contained Thimerosal
	Tripedia (Sanofi Pasteur, Inc)	Trace ($\leq 0.3 \mu\text{g Hg}/0.5\text{mL dose}$)	03/07/01 Thimerosal-Preserved formula was in distribution until after Apr. 2003/4.
DTaP-HepB-IPV,	Pediarix (GlaxoSmithKline Biologicals)	Free	Never contained more than a Trace of Thimerosal, approval date for thimerosal-free formulation: 1/29/2007
Pneumococcal conjugate	Prevnar (Wyeth Pharmaceuticals Inc)	Free	Never contained Thimerosal
Inactivated Poliovirus	IPOL (Sanofi Pasteur, SA)	Free	Never contained Thimerosal
Varicella (chickenpox)	Varivax (Merck & Co, Inc)	Free	Never contained Thimerosal
Mumps, measles & rubella	M-M-R-II (Merck & Co, Inc)	Free	Never contained Thimerosal
Hepatitis B	Recombivax HB (Merck & Co, Inc)	Free	08/27/99 Thimerosal-Preserved formula was in the distribution chain until after Sept. 2001/2.
	Engerix B (GlaxoSmithKline Biologicals)	Free	03/28/00 Thimerosal-Preserved formula was in the distribution chain until after Apr. 2002/3. approval date for thimerosal-free formulation: 1/30/2007 Trace-Thimerosal formula will be in the distribution chain until after Feb. 2009/10.
Haemophilus influenzae type b conjugate (Hib)	ActHIB (Sanofi Pasteur, SA) OmniHIB (GlaxoSmithKline)	Free	Never contained Thimerosal
	PedvaxHIB (Merck & Co, Inc)	Free	08/99 Thimerosal-Preserved formula was in the distribution chain until after Sept. 2001/2.
	HibTITER, single dose (Wyeth Pharmaceuticals, Inc.) ¹	Free	Never contained Thimerosal
Hib/Hepatitis B combination	Comvax (Merck & Co, Inc)	Free	Never contained Thimerosal
Influenza NOTE: Fluvirin (Novartis) is only licensed for use in children over four years old.	Fluzone (Sanofi Pasteur, Inc)	0.01% (12.5 $\mu\text{g}/0.25 \text{ mL dose}$, 25 $\mu\text{g}/0.5 \text{ mL dose}$)²	
	Fluzone (Sanofi Pasteur, Inc) ³ (no thimerosal)	Free	12/23/2004 Trace-Thimerosal formula was marketed in the 2002/3 and 2003/4 "flu" seasons.
	Fluvirin (Novartis Vaccines & Diagnostics Ltd)	0.01% (25 $\mu\text{g}/0.5 \text{ mL dose}$)	
	Fluvirin (Novartis Vaccines and Diagnostics Ltd) Preservative Free	Trace ($< 1 \mu\text{g Hg}/0.5\text{mL dose}$)	09/28/2001 Not available in U.S. after 2005 because of microbial contamination
Influenza, live	FluMist (MedImmune Vaccines, Inc)	Free	Never contained Thimerosal

* Since this update, Rotavirus Vaccine was licensed, that is thimerosal free.
** 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.
*** The term "trace" has been taken in this context to mean 1 microgram of mercury, or less, per dose or less.
¹ HibTITER was also manufactured in thimerosal-preserved containing multidose vials but these were no longer available after 2002.
² Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.
³ A trace thimerosal containing formulation of Fluzone was approved on 9/14/02 and has been replaced with the formulation without thimerosal.

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Internet resources

- <http://www.fda.gov/cber/vaccine/thimerosal.htm>
- <http://www.cdc.gov/flu/about/qa/thimerosal.htm>
- <http://www.vaccines.mil/default.aspx?cnt=adverseEvents/Thimerosal>
- http://www.immunizationinfo.org/thimerosal_mercury_detail.cfv?id=136
- http://www.immunizationinfo.org/thimerosal_mercury_detail.cfv?id=3
- <http://iaomt.org/testfoundation/thimcontent.htm>

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In addition to the pertinent references in this reviewer’s list of references at the end of this review, this reviewer recommends the following website:

<http://www.mercury-freedrugs.org>

as a resource for information on Thimerosal in vaccines and other drugs, and related issues as well as some information on vaccines and vaccination.

“request 8

The Task Force wanted data on numbers of vaccine preventable diseases for the 18 states with philosophical exemptions.

Vaccine-preventable disease levels have been successfully reduced in the U.S. with the advent of immunizations-vaccines. However, these diseases still exist and can once again become common—and deadly—if vaccination coverage does not continue at high levels. Even though most infants and toddlers have

received all recommended vaccines by age 2, many ~~underimmunized~~ ~~undervaccinated~~ children remain, leaving the potential for outbreaks of disease.

The following table reflects the numbers of vaccine-preventable diseases for the 18 states [36% of states] with philosophical exemptions for ~~immunizations~~ ~~vaccination~~. This data was provided by the Centers for Disease Control and Prevention (CDC). Florida data has been added to correspond with the data from the 18 states with philosophical exemptions.

- It is not possible to draw any conclusions about the effect of philosophical exemptions on disease rates from these data alone. Incidence rates (cases per 100,000 children per year) would have to be compared between states with and without philosophical exemptions.
- Such a comparison must take account of other factors in addition to the size of the population of children, such as introductions of disease from outside the U.S., and socio-economic factors.”

In general, this reviewer agrees that comparisons between states with and without any category of exemption, not just philosophical, is complicated; but, *though not without some uncertainty*, the comparison between a) California or b) all of the states with a philosophical exemption as well as large population, diverse ethnic and socioeconomic groups and significant immigration and c) the U.S, *as a whole*, might be of some use.

- “Experience has shown that, while reported case numbers may be low one year, introduction of a disease into a susceptible community can escalate into an outbreak very quickly.”

This reviewer accepts the general premise here.

However, he notes that, in fully vaccinated populations, any outbreak would be localized and not spread provided the vaccine and the vaccination program are truly effective.

Thus, the recent focus on measles outbreaks in a population with high levels (>92%) of MMR vaccination is problematic because the level of measles and congenital rubella cases has remained very low on this population while, *in the U.S.*, the levels of mumps cases has remained at a significantly higher level and, *in 2006*, jumped to 6,000+ cases without any CDC explanation of the reason for the sudden increase in mumps cases.

Moreover, *with only a slightly lower uptake level*, the tolerated level of annual mumps incidence is more than an order of magnitude higher in England, *based on the data provided in this report*, than it is in the USA, *based on CDC’s annual notifiable disease reports*.

Finally, this reviewer notes that, *for MMR vaccination in both the USA and England*, there seems to be much less concern about mumps “resurgence” than measles, even when the uptake percentage in England dipped to near 80%.

These and other anomalies makes this reviewer concerned about whether the intent of the information being broadcast about measles by the CDC: a) is based on a genuine concern or b) is rather intentional fear mongering designed to herd the public into the acceptance of even more vaccines and/or distract them from the epidemic rise in children of a number of chronic diseases that the CDC and public health officials seem not to even see and about which they are almost silent.

- “The CDC’s *Morbidity and Mortality Weekly Report (MMWR)* reported in its August 23, 2008, issue about the US measles experience for the first half of 2008. They state: ‘*The number of measles cases reported during January 1–July 31, 2008, is the highest year-to-date since 1996. This increase was not the result of a greater number of imported cases, but was the result of greater viral transmission after importation into the United States, leading to a greater number of importation-associated cases. These importation-associated cases have occurred largely among school-aged children who were eligible for vaccination but whose parents chose not to have them vaccinated.*’
- 2006 paper published in the Journal of the American Medical Association (Omer SB, Pan WKY, Halsey NA et al: ‘Non-medical Exemptions to School Immunization Requirements: Secular Trends and Association of

State Policies with Pertussis Incidence,' *JAMA* 2006, **296**:1757–1763) showed that pertussis (whooping cough) incidence was 50% higher in states with easier availability of non-medical exemptions to school immunization requirements, and with available personal belief exemptions.

- A 2000 paper in the same journal (Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE: 'Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization,' *JAMA* 2000, **284**:3145–3150) showed that in Colorado, which has had a philosophical exemption since 1977, the risk of measles and pertussis is elevated 22-fold and 6-fold, respectively, in exemptors compared to vaccinated children. They also showed that the rate of measles in vaccinated children was higher in counties with high proportions of exemptors."

First, this reviewer notes that the preceding three bullet points are clearly examples of biased reporting.

This is the case because they apparently do not reflect the impact of the findings on the overall health of the children affected.

Second, if the measles vaccines were "herd protective", why would we see "*the rate of measles in vaccinated children was higher in counties with high proportions of exemptors*" even though the overall rates exceed 90%?

Third, *absent any reporting of the absolute rates*, how can anyone interpret the importance of the relative numbers reported (e.g., if the rate is "<1 in a million", then even a 100 % increase translates into a risk of "< 2 in a million" – a change of little population concern).

Based on his understanding of reality, this reviewer finds that these bullet points are, at best, pro-vaccine-biased warnings that are of little, or no, importance when it comes to the fundamental issue, *which this report again avoids discussing*: the overall health of our children and ourselves.

Is the overall health of the public improving, holding steady, or declining?

This reviewer clearly sees that, *when both acute and chronic medical conditions are considered*:

- a. The health of American children is declining,
- b. Infant mortality in the USA is unacceptably high in comparison to Japan's,
- c. Life expectancies in the USA are below those of the other advanced industrial nations and apparently starting to decline, and
- d. Any past gains from the suppression of disease by vaccination in the USA have been more than offset by the increases in chronic disease that are clearly mostly attributable to the current inclusion of childhood vaccines that:
 - i. Are not for acute life-threatening and once highly contagious diseases (e.g., measles and diphtheria), but
 - ii. Are rather for lifestyle and/or rarely immediately fatal diseases that mostly affect adults (e.g., hepatitis B, *herpes zoster varicella* as shingles, and HPV).

Given the reality of the declining overall public health in the USA and its apparent connection to the overall increases in vaccine doses and vaccines, the CDC's recommended vaccination programs and Florida's vaccination requirements are obviously in need of an urgent review and reassessment.

Hopefully, *after reading this review*, the Florida DoH and the public will recognize the same realities, do the necessary review and appropriately alter the Florida vaccination requirements across the board.

Based on the review of the data for California in which a significant fraction of the population of the USA resides and the overall disease numbers reported for these 18 states and the USA, it seems that, for MMR, having a philosophical exemption appears to “lower” the disease risk both in California and in the 18 states with a general philosophical exemption as a whole compared to the overall number of 2006 cases in the USA for measles, mumps and rubella.

However, for the diphtheria and pertussis (and hepatitis B) cases data, the disease risk appears to be slightly higher.

2006 Comparison of Vaccine-Preventable Disease Cases, Among States with Philosophical Exemptions for Immunizations, Florida and U.S.								
2006	Measles*	Mumps**	Rubella*	Tetanus*	Pertussis**	Hep B acute*	Polio (paralytic)*	Diphtheria**
Arizona	0	40	0	1	508	u	0	0
Arkansas	0	8	0	1	112	87	0	0
California [-15% of US pop.]	6	31	1	11	1,749	427	0	0
% of US Total [% of "15%"]	10.9 [72.7] ^{1,3}	0.471 [3.14] ³	9.09 [60.1] ³	26.8 [179] ²	11.2 [74.6] ³	9.06 [60.4] ³	---	---
Colorado	1	51	0	0	710	34	0	0
Idaho	0	7	0	0	88	15	0	0
Louisiana	0	3	0	3	24	63	0	0
Maine	0	0	0	0	174	26	0	0
Michigan	1	84	1	3	632	141	0	0
Minnesota	1	180	0	0	320	32	0	0
New Mexico	0	3	0	0	147	24	0	0
North Dakota	0	14	0	1	43	1	0	0
Ohio	0	45	0	3	644	123	0	0
Oklahoma	0	10	0	1	64	96	0	0
Texas	0	58	0	1	954	833	0	0
Utah	0	5	0	1	779	26	0	0
Vermont	0	0	0	0	110	4	0	0
Washington State	2	42	0	0	377	74	0	0
Wisconsin	0	842	0	0	221	33	0	0
Total of states above	11	1,423	2	26	7,656	2,039	0	0
% of US Total [% of 36%] ¹	20.0 [55.6]	21.6 [60.0]	18.2 [50.5]	63.1 [176]	49.0 [136]	43.3 [120]	---	---
Florida	4	15	1	2	228	420	0	0
% of US Total	7.3	0.23	9.1	4.9	1.5	8.9	---	---
U.S. Total	55	6,584	11	41	15,632	4,713	0	0

* Confirmed Cases **Confirmed and Probable Cases

¹ Since the vaccine given is the MMR vaccine, the average of the percentages should show the “deleterious” effect of philosophical exemption if and only if the MMR average is > 100% of the expected level based on the population. For MMR, the average percentage is 45.3% of the expected % based on California’s population.

² For the DTaP vaccine, ignoring diphtheria because there are no cases and tetanus because the annual data indicate wide fluctuations in the states reporting cases, the relative pertussis % of 74.6 again indicates that the CA “exemption” effect led to a reduced incidence over that expected.

³ Moreover, excluding Tetanus cases, the average level for the other 5 diseases, where cases were observed, is less than 55% of the expected percents.

⁴ Presuming that, on average, the 18 states have a total population that is about the same % of the U.S total population as the 18 states are of the 50 states, then the data indicate that the philosophical exemption’s only significant effect on cases observed is seen with the DTaP and the Hep B vaccines. Since no cases are seen for diphtheria, the effect for the DTaP vaccine again indicates that this vaccination program may not provide adequate long-term protection for the tetanus and pertussis components, although, based on the population breakdowns provided by the CDC, it provides more than adequate childhood and early adult protections for severe tetanus cases. For Hep B, one could argue that philosophical exemption may have contributed to an apparent “20%” excess in disease cases; however, this is probably an artifact because most all of the cases of acute hepatitis B cases, except for those born to mostly untreated Hep-B-infected mothers, are found in adults and not in children (see Table “14”).

Since the table provided in the report fails to furnish the separate numbers for the cases occurring in children:

- Too young to be vaccinated,
- Who are partially vaccinated,
- Who were exempt, and

➤ The corresponding categories for adults, this reviewer finds that the information provided cannot be used to address the real impacts on disease incidence in a population, *if any*, of a philosophical exemption, where such exemptions are available.

Table “14” 2006 Hepatitis B Cases, Percentages, and Incidence Rates (per 100K Cases) by Age Group in Years,

Age Group	<1 yr	1-4 yrs	5-14 yrs	15-24 yrs	25-39 yrs	40-64 yrs	≥ 65 yrs	Age not stated	Total
Cases	5	1	8	381	1,922	2,037	247	10	4,713
Incidence (per 100,000)	0.12	0.01	0.02	0.92	3.21	2.17	0.69	---	---
Percentage	0.106	0.021	0.170	8.084	40.781	43.221	5.241	0.212	100

34 REQUEST 8

“request 9

Provide a state breakdown of school entry immunization exemptions, broken down by type and uptake rate.

All fifty states have medical exemptions to vaccines, such as a serious allergy to a vaccine component. Forty-eight states, including Florida, provide for religious exemptions. Additionally, there are 18 states that have philosophical exemptions for school entry. Two additional states have a philosophical exemption for child care entry only.

- Vaccines are recommended by the Centers for Disease Control and Prevention (CDC) and professional societies, such as the American Academy of Pediatrics. These organizations make science-based recommendations; states set requirements, usually when children enter child-care centers and elementary schools as entry requirements. These requirements help prevent the spread of communicable diseases in these group settings.”

While, the narrative here clearly presents the views of the Florida Department of Health, this reviewer notes that the *current* recommendations made by the CDC and/or by the American Academy of Pediatrics (AAP) are clearly not science-based decisions.

Factually:

1. To be added to the list of vaccines covered by the National Vaccine Injury Program (NVICP), the vaccine only needs to be recommended by the CDC for inclusion into the national program.
2. In the past, the CDC has, *in at least one instance*, recommended a vaccine for inclusion in the national vaccination program even before the FDA approved the vaccine (e.g., Wyeth’s RotaShield rotavirus vaccine) without having any U.S. data on post-approval in-use experience and, *less than 2 years later*, this vaccine was removed from use because of the in-use harm that it actually caused.
3. In 2006, the CDC recommended a new rotavirus vaccine (Merck’s recently approved RotaTeq) be added to the national childhood vaccination program – again without any U.S. post-approval in-use experience that it was safe to do so – and, in spite of serious in-use adverse events (intussusception and Kawasaki’s disease) has continued to recommend this vaccine as well as a 2008-approved rotavirus vaccine, SmithKlineBeecham’s Rotarix.

4. Worse, the CDC has added Merck's Gardasil HPV vaccine to the national childhood vaccination schedule at the time it was approved, without any in-use U.S. data and, *in spite of thousands of reports to VAERS of serious adverse reactions, including death*, continues to recommend it.

Obviously, *since there was no in-use experience for the aforementioned vaccines*, there can be no valid science-based decision to recommend a vaccine for the national program because the small groups of children used in the clinical trials to obtain the FDA approvals for these vaccines do not match the population of American children for whom these vaccines are being recommended.

Worse, for RotaShield, the CDC's decision was made before the FDA approved the vaccine.

Moreover, when the CDC made its recommendations for all of the rotavirus vaccines, it was clear that these national vaccination programs were not, and, *even without any serious adverse reactions*, would not be cost-effective for the American public.

Based on the preceding realities, the CDC obviously added these vaccines to the national childhood vaccination schedule in order to place them under the NVICP and thereby shield the vaccine's makers and the healthcare providers from the civil lawsuits for the harm the CDC knew that these vaccines would, *based on the results from the biased clinical trials conducted*, cause.

With respect to the AAP, it simply appears to act as a virtual rubberstamp for the CDC's and the vaccine makers' wishes, often publishes CDC-recommended papers without critical scientific review, and has repeatedly refused to publish critiques of those studies by independent scientists.

With respect to the report's "*states set requirements, usually when children enter child-care centers and elementary schools as entry requirements*", this reviewer finds that, increasingly the CDC and the vaccine makers lobby the health departments and politicians who, ignoring:

- The fact that the vaccination program is not cost-effective on any basis,
- The absence of sufficient in-use experience with the vaccine,
- The potential adverse impacts on the overall health of the population, and
- The concerns of the people of their state,

add the vaccine to their entry requirements for "*child-care centers and ... schools*".

In this regard, this reviewer finds that the Florida DoH is to be commended because it:

- Seems to have been more resistant to this lobbying than some states and
- Has not yet mandated some of the recent CDC-recommended vaccines as entry requirements to "*enter child-care centers and ... schools*".

- "School ~~immunization~~ vaccination requirements have largely contributed to a significant drop in diseases and the complications that can be prevented by ~~immunizations~~ vaccinations. *Before the measles vaccine, measles caused 100,000 American children to be hospitalized and 3,000 to die every year. In the early 1970s, public health officials found that states with vaccine mandates had rates of measles that were 50 percent lower than states without mandates.*"

First of all, *though this reviewer accepts that the data presented is valid*, he again notes that: **a)** there is no report of a comparative assessment of the overall health of the children in these two groups of states, and **b)** absent the average incident rates in the group of states with vaccine mandates and the population sizes of the two groups of states as well as the baseline average measles rates in each group of states before the measles vaccine was introduced, there is no way anyone can assess the import of this relative "50 percent lower" claim.

Second, since the count for “measles cases” ignores those “measles cases” caused in those inoculated with a live-virus measles vaccine, the actual percentage of this decrease in measles cases is probably significantly less than the percentage claimed.

Further, this example fails to address today’s vaccination program realities for, *for example*, hepatitis A.

Therefore, this reviewer finds that the general assertions:

“School immunization requirements have largely contributed to a significant drop in diseases and the complications that can be prevented by ~~immunizations~~ vaccinations”, made here, *while they may be substantive*, **a)** again misrepresent vaccinations as “immunizations”; **b)** are overly broad; and **c)** are not supported by the evidence presented.

In addition, with respect to the report’s assertion:

“Before the measles vaccine, measles caused 100,000 American children to be hospitalized and 3,000 to die every year”, this reviewer notes that, *since the early 1960s death rates from measles were less than 1,000 per year (see reviewer’s Figure “1”) before an effective measles vaccine was introduced in 1963*, the report’s “3,000 to die every year” statement, to say the least, misrepresents the annual measles deaths in the period just prior to the introduction of an effective measles vaccine³⁵.

- “Florida balances the need to protect the health of students in the classroom while respecting those with a religious opposition to ~~immunizations~~ vaccinations. During an outbreak, any child who does not have protection against that specific disease is excluded from school. This includes children who have either medical or religious exemptions.”

First, this reviewer finds the statements here to be misleading because, *if one were truly balancing competing imperatives*, the balance would be a two-way street and not, as presented here, a one-way one.

Furthermore, the statements here would have also addressed these same issues for the staff and visitors.

Moreover, the statement:

“During an outbreak, any child who does not have protection against that specific disease is excluded from school”, intentionally misrepresents what Florida schools do.

In general, Florida schools exclude those who lack proof of vaccination against the specific disease unless they can prove they are protected from contracting that specific disease (generally by having proof that they have had that specific disease), while allowing those children who are vaccinated according to Florida requirements to attend school without requiring any proof that the vaccinations the children have received are protecting each child from contracting that specific disease.

Moreover, *unless the day-care centers and schools also exclude all, including staff, who have been recently vaccinated with any live-virus vaccine from attending for a period of not less than 21 days after vaccination*, Florida day-care centers and schools are ignoring the need to protect the health of its “unprotected” (the unvaccinated who have not had the disease and those vaccinated but not protected) attendees or students, and staff and visitors from those attendees or students, staff and visitors who may be shedding live virus and may thereby infect these unprotected individuals with whom they interact.

³⁵ From the graph in reviewer’s Figure “1”, it appears that one has to go back into the late 1930s to find years where “3,000” died of measles; by 1950, annual measles deaths had dropped below “1,000”.

Thus, the report's language here should be revised to simply state what Florida is actually doing.

Finally, this reviewer can only hope that the Florida DoH will upgrade the information it provides to address the live-virus vaccine, live-virus disease, staff and visitor quarantine and risk issues he has raised.

- “The finding that lower ~~immunization~~ vaccination rates caused higher rates of disease shouldn't be surprising. In 1991 a massive epidemic of measles in Philadelphia centered on a group that chose not to ~~immunize~~ vaccinate their children; as a consequence nine children died from measles.”

While this reviewer is saddened by the death of any child, this reviewer finds that the account presented is at odds with the facts on several points.

A quick Google search found:

<http://stason.org/TULARC/child-parent/vaccinations/1-3-What-is-herd-immunity.html>

which contained the following text:

"The nation [U.S.] has experienced a marked increase in measles cases during 1989 and 1990. Almost one half of all cases have occurred in *unvaccinated* preschool children." (JAMA. 1991 Sep 18. 266(11). P 1547-52.)

'Beginning in October, 1990, a large measles outbreak involving predominantly *unvaccinated* preschool age children occurred in Philadelphia. By June, 1991, 938 measles cases had been reported to the Philadelphia Health Department. In addition to these cases, 486 cases and 6 measles-associated *deaths* occurred between November 4, 1990, and March 24, 1991, among members of 2 Philadelphia church groups that do not accept vaccination.' (Pediatr-Infect-Dis-J. 1993 Apr. 12(4). P 288-92.)"

Factually, the “1991 a massive epidemic of measles in Philadelphia” was only a large measles outbreak, that outbreak spanned the period from October 1990 to June 1991, and involved 1,424 cases of measles.

In the 2 churches that did not accept vaccination there “486 cases of measles and 6 measles-associated *deaths*” – meaning that 98.77 % of those in these churches recovered and only 1.23 % died.

Absent the ages of those who died and the exact cause of death listed on their death certificates, one cannot make any further presumptive statements other than to say that the 480 who recovered had/have near lifetime immunity from being infected from that point forward.

Presuming the overall measles-associated death toll was 9 and the overall cases were 1,424, this translates into a 99.74 % survival rate and, since the account that this reviewer found did not mention the other three measles-associated deaths indicates that these may have been individuals who had been vaccinated and still contracted a case of measles to which they ultimately succumbed.

Returning to the literature, this reviewer found: ***Morbidity and Mortality Weekly Report*** 1993 May 21; 42(19): 378-381, which states (with text underlining added for emphasis):

“Measles -- United States, 1992

As of January 2, 1993 (week 53), local and state health departments reported a provisional total of 2200 * measles cases for 1992 (1) -- a 77% decrease from the 9643 cases reported for 1991 (2), and a 92% decrease from the 27,786 cases reported for 1990 (3). Cases were reported from 36 states and the District of Columbia. This provisional total is one of the lowest annual totals reported in the United States; fewer cases were reported only in 1982 (1714 cases) and 1983 (1497 cases) (4). This report summarizes epidemiologic characteristics of measles cases reported for 1992 and compares them with cases reported during 1989-1991.

From 1989 through 1992, the median age of persons reported with measles declined steadily (12.0 years in 1989, 5.7 years in 1990, 5.2 years in 1991, and 4.9 years in 1992), while the proportion of cases among infants increased. Of measles cases in 1992, 22.2% occurred among children less than 12 months of age, an increase from 19.2% in 1991

and 17.0% in 1990; 27.9% of reported cases were among children aged 1-4 years, compared with 30.1% for 1991. Persons aged greater than or equal to 5 years accounted for 49.7% of reported cases, compared with 50.6% in 1991. A provisional total of three measles-associated deaths was reported in 1992 for Texas (two) and Alaska (one).

Texas and Kentucky reported the largest outbreaks (990 and 443 cases, respectively) during 1992. The outbreak in Texas continued the pattern of outbreaks reported during 1989-1991 affecting predominantly unvaccinated preschool-aged children (2,3). Seventy-one percent of cases in this outbreak were reported from Nueces and Hidalgo counties; the other cases were reported from 22 (9%) of 254 counties in the state. Most (75%) cases were among children aged less than 5 years; 35% of cases were among children less than 12 months of age. In comparison, in Kentucky, measles transmission occurred predominantly among children aged 5-19 years (218 cases {49%}). Fifty-one percent of cases from the Kentucky outbreak were reported from Jefferson County (Louisville); the remaining cases were reported from 34 (28%) of 120 counties in the state.

Reported by: State and local health depts. Div of Immunization, National Center for Prevention Svcs, CDC.

Editorial Note

Editorial Note: During 1989-1991, a period of increased measles transmission, approximately 55,000 cases and 132 suspected measles-associated deaths were reported. However, from mid-October 1992 through January 1993, no outbreaks of measles (i.e., five or more epidemiologically related cases) were reported, suggesting that the measles resurgence in the United States has ended. During the first 18 weeks of 1993, 80 measles cases were reported, representing only 13% of the number reported for the same period during 1992. Possible explanations for the end of the measles resurgence include a decrease in susceptible populations following widespread transmission of the virus; improved vaccination coverage in the susceptible population; an overall decrease in the occurrence of measles in the Western Hemisphere (5); and the periodic cyclicality in measles transmission that has been noted since the prevaccine era.

The magnitude of the recent resurgence is not likely to have substantially reduced susceptibility (2), even in cities with the highest incidence of measles. For example, retrospective surveys of school enterers in 15 cities indicated that coverage against measles ranged from 51% to 79% at the time of the second birthday (6,7); based on these findings, approximately 800,000-2 million U.S. children aged 12-23 months would be susceptible. However, during 1989-1992, approximately 9300 cases of measles were reported among children aged 12-23 months -- a number insufficient to have substantially reduced overall susceptibility in this age group.

A reduction in measles susceptibility may have occurred through increased measles vaccination levels among preschool-aged children. From 1971 through 1985, the United States Immunization Survey (USIS) demonstrated that measles vaccine coverage among children aged 1-4 years ranged from 61% to 66% (CDC, unpublished data, 1986). By comparison, the National Health Interview Survey (NHIS) in 1991 targeted the same population as the USIS and documented measles vaccine coverage to be 78% among children aged 1-4 years -- the highest level ever reported (CDC, unpublished data, 1993).

The estimates of increased vaccine coverage, based on the NHIS, are consistent with data indicating increased measles vaccine administration in the public sector. During 1991 and 1992, 1,358,117 and 1,344,901 doses, respectively, of measles vaccine were administered in public clinics to children aged 12-23 months -- a 42% and 41% increase, respectively, when compared with 1988 (953,535 doses), the year before the measles resurgence (CDC, unpublished data, 1993). In addition, in 1992, provisional totals of reported mumps (2433) and rubella (147) (1) were the lowest since reporting began in 1968 and 1966, respectively, reflecting the contribution of increased vaccination with combined measles-mumps-rubella (MMR) vaccine.

In contrast to vaccination coverage for measles, mumps, and rubella, coverage against other diseases has not increased substantially. In particular, NHIS findings for 1991 indicated that only 66% of children aged 1-4 years had received three or more doses of diphtheria and tetanus toxoids and pertussis vaccine (DTP), and 51% had received three or more doses of oral poliovirus vaccine (OPV) (Table 1) -- coverage comparable to or lower than that reported in previous years. Overall, only 42% of preschool-aged children had received all age-appropriate vaccinations **, although this level may underestimate coverage because parents may have failed to recall some doses of multiple-dose vaccines (8). However, this level is substantially lower than the national health objective for the year 2000 of 90% complete series coverage by the second birthday (objective 20.11) (9).

Strategies to improve vaccination levels include 1) reducing barriers to vaccination (e.g., increasing the number of clinic hours when vaccinations are given and the availability of walk-in vaccination services); 2) taking advantage of all opportunities to vaccinate (e.g., simultaneous use of multiple vaccines whenever possible, excluding from vaccination only persons with valid contraindications); 3) using innovative vaccine delivery techniques (e.g., vaccination in hospital

emergency departments); 4) increasing the number of children who return for vaccination at the appropriate age by improving follow-up and recall systems; and 5) providing education about vaccination to parents (10).

A major comprehensive childhood vaccination initiative is under way to improve levels among preschool-aged children. The principal components of this initiative are 1) improving the vaccine delivery infrastructure through increased federal funding for this purpose (e.g., increasing vaccination clinic personnel and hours of operation, particularly in the inner cities); 2) assuring universal access to vaccination services; and 3) assuring that computerized systems are established in each state for tracking the vaccination status of all children.

To sustain the decrease in transmission of measles in the United States, and to achieve similar results with other vaccine-preventable diseases, age-appropriate vaccination coverage efforts must be improved -- particularly among preschool-aged children living in inner-city areas. Transmission of measles among preschool-aged children is likely to recur unless measles vaccine coverage is improved and age-appropriate vaccination is ensured.

References

1. CDC. Table II. Cases of selected notifiable diseases, United States, weeks ending January 2, 1993, and December 28, 1991 (53rd week). *MMWR* 1993; **41**: 981.
2. CDC. Measles surveillance -- United States, 1991. In: CDC surveillance summaries (November 20). *MMWR* 1992; **41**(no. SS-6): 1-12.
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4. CDC. Summary of notifiable diseases, United States 1991. *MMWR* 1992; **40**(no. 53): 57-62.
5. Pan American Health Organization. Reported cases of EPI diseases. *EPI Newsletter* 1992; **14**: 7.
6. CDC. Measles vaccination levels among selected groups of preschool-aged children -- United States. *MMWR* 1991; **40**: 36-39.
7. CDC. Retrospective assessment of vaccination coverage among school-aged children -- selected U.S. cities, 1991. *MMWR* 1992; **41**:103-107.
8. Valadez JJ, Weld LH. Maternal recall error of child vaccination status in a developing nation. *Am J Public Health* 1992; **82**: 120-122.
9. Public Health Service. Healthy people 2000: national health promotion and disease prevention objectives. Washington, DC: US Department of Health and Human Services, Public Health Service, 1991; DHHS publication no. (PHS) 91-50213: 76.
10. CDC. Standards for pediatric immunization practices. Atlanta: US Department of Health and Human Services, Public Health Service, 1993."

Based on the preceding document, it is clear that, at the end of the 1980s and extending into the early 1990s, there was a general resurgence in measles in the USA that peaked at 27,786 cases in 1990, and that the coverage level (in the high 60s to 70s in percentage in those age 1 to 4 years of age) was insufficient to prevent measles cases surging from a background of about 2000 before (1987) and after (1992) the resurgence peaking in 1990.

Given the much higher vaccination level to day, the surge in measles cases in late 2007 through mid-2008 may be but another cyclic up-tick in an environment where the background rate for annual measles cases is, *with 2 doses of MMR and >90% coverage*, currently about 50 cases/year instead of the <2400 cases/year seen in 1980's and early-1990's America.

Moreover, *except for the 1989 – 1990 outbreak in the Philadelphia area*, very few measles-associated deaths have since occurred and, *apparently because of vaccination-related factors*, the percentage of measles cases in those who are too young to be vaccinated (under 1 year of age increased) from 17.0% in 1990 to 22.2 % in 1992.

However, the preceding realities indicate that this example has little to do with today's world where the uptake level is >90 % for 2 doses of MMR instead of <70% for 1 dose of measles vaccine.

“And in 2005, a 17-year-old unvaccinated girl who unknowingly brought measles back with her from Romania attended a church gathering of 500 people in Indiana and caused the largest outbreak of measles in the United States in ten years; this outbreak was limited to children whose parents had chosen not to vaccinate them.”

As this reviewer has previously reported in other reviews addressing the outbreak in Indiana referred to in this report, this outbreak was not “limited to children whose parents had chosen not to vaccinate them”.

In fact, the person most seriously affected was the hospital lab worker in his 30s who, *though vaccinated*, contacted measles and then developed measles-related pneumonia.

Blatant factual distortion, *such as reported here*:

- Does little to increase public confidence in our vaccination programs and
- Undermines the credibility of public health officials and other vaccine apologists who continually make such statements.

“These events showed that, for contagious diseases like measles and pertussis, it’s hard for unvaccinated children to successfully hide among herds of vaccinated children.”

First, since the only events reported here are for measles, it is somewhat disingenuous to associate the contagiousness of pertussis with that of measles.

Second, these events only show that it is difficult for unprotected, *including the never vaccinated and the vaccinated who fail to be protected by the vaccinations they have received*, individuals to avoid contracting measles when they are exposed to live measles virus, including, *in some cases*, the live measles virus shed by those who have been vaccinated with any live-virus measles vaccine.

Furthermore, it is not appropriate to speak of “herds of vaccinated ...” here because both of the examples provided here speak to exposure in population segments where the most affected groups mentioned were comprised of mostly unvaccinated children and adults.

“The following table reflects school entry exemptions and school population data for the states with a philosophical exemption.”

35 REQUEST 9

Accepting that the information provided in this table is correct, this reviewer notices that, in those states with complete surveys at both grade levels, the % of philosophical exemptions declines in the “Grade School” survey from the “Kindergarten” survey’s percentages.

In Florida, where most children were surveyed and there is no philosophical exemption, the religious exemption also declines from 0.6 % to 0.4%.

Since, *for the philosophical exemption*, these declines are the confounded confluence of several factors, this reviewer only notes that those factors include:

- ❖ Use of an exemption by parents to delay the timing of vaccinations that they eventually have administered to their children, and
- ❖ Increased use of an exemption to avoid all or certain vaccines as vaccination concerns grow for these vaccines.

School Immunization Assessment Survey Results, 2006/2007 School Year																
	Kindergarten							Middle School								
	Children Enrolled	Children Surveyed	Medical		Religious		Philosophical		Children Enrolled	Children Surveyed	Medical		Religious		Philosophical	
Arizona	90,719	89,915	166	0.2%	•		1,822	2.0%	87,089	86,633	147	0.2%	•		1,246	1.4%
Arkansas	36,790	36,790	16	0.0%	36	0.1%	123	0.3%	34,109	34,109	2	0.0%	27	0.1%	520	0.2%
California	503,160	503,160	827	0.2%	*		*7,108	1.4%	NA	NA	NA	NA	NA	NA	NA	NA
Colorado	64,468	956	•		1	0.1%	55	5.8%	62,420	1,428	1	0.1%	7	0.5%	42	2.9%
Idaho	21,663	21,663	65	0.3%	77	0.4%	538	2.5%	20,565	20,565	35	0.2%	82	0.4%	382	1.9%

Louisiana, ,	148,538	*148,538	20	0.0%	•		•		NA		NA		NA		NA
Maine	14,751	13,826	62	0.4%	15	0.1%	373	2.7%	33,918		•		•		•
Michigan	134,898	134,898	969	0.7%	499	0.4%	3,549	2.6%	131,209	131,209	560	0.4%	427	0.3%	2,311
Minnesota	67,337	67,337	382	0.6%	*			5.8%	66,804	66,804	303	0.5%	*		*3043
New Mexico	28,067	27,845	49	0.2%	*243	0.9%	*		27,220	26,623	17	0.1%	*128	0.5%	*
North Dakota	7,641	7,092	11	0.2%	11	0.2%	46	0.6%	18,731	14,662	11	0.1%	15	0.1%	31
Ohio	150,212	148,112	392	0.3%	*		*1,232	0.8%	NA		NA		NA		NA
Oklahoma	49,348	48,220	81	0.2%	104	0.2%	194	0.4%	NA		NA		NA		NA
Texas	352,969	344,176	2,260	0.7%	*		*6,478	1.9%	331,513	321,408	1,579	0.5%	*		*2,689
Utah	47,486	46,062	93	0.2%	16	0.0%	1,176	2.6%	39,627	38,835	49	0.1%	18	0.0%	979
Vermont	6,838	6,838	20	0.3%	5	0.1%	164	2.4%	7,760	7,760	33	0.4%	14	0.2%	123
Washington	77,218	75,288	213	0.3%	106	0.1%	3,077	4.1%	79,744	73,991	212	0.3%	141	0.2%	2,964
Wisconsin	71,298	1,560	5	0.3%	2	0.1%	25	1.6%	NA		NA		NA		NA
Florida	226,536	226,536	479	0.2%	1,249	0.6%	---		216,892	216,892	494	0.2%	836	0.4%	---

* Religious and Philosophical exemptions included together.

Information was obtained from the Centers for Disease Control and Prevention’s 2006-2007 School Entry Immunization Assessment Report—this report may be viewed at the following web address: <http://www2.cdc.gov/nip/schoolsurv/rptgmenu.asp>

Florida does not have an exemption for philosophical reasons

36 REQUEST 9

“request 10

DOH/DOE: The number of unvaccinated people in Florida and incidence. Funding an epidemiological study.

Data is not available to provide the number of unvaccinated people in Florida. Reporting of all ~~immunizations~~ vaccinations administered in Florida into the centralized ~~immunization~~ vaccination registry is voluntary and not mandated by law. The following provides a description and considerations for designing a study of vaccine exposure and autism spectrum disorders.”

For conditions that are subpopulation related, *as neurodevelopmental disorders seem to be*, straight raw epidemiological studies of the unvaccinated versus those who have received even one dose of vaccine using the outcomes “autism” and/or “autism spectrum disorders (ASDs)” should be recognized as exercises designed not to find significant evidence of a linkage.

“Summary

This document reviews options available for an epidemiologic study to address the question, ‘Is the rate of autism or autism spectrum disorders (ASDs) significantly lower in Florida children who have received no doses of any vaccine, than in children who have received one or more doses of vaccine?’”

If the goals was to answer the question about the rates for autism and/or ASDs in Florida children where reasons for no vaccination were not related to a pre-existing health issues as compared the rates in Florida children where the children have been fully vaccinated until age 6 or they are diagnosed with an ASD, then this reviewer might support such studies provided they were not designed by a person or persons who, *because of their position or patronage*, were predisposed to minimize any link that such studies might find.

“The smaller the difference one wants to detect in a study, the larger the needed number of study subjects is. Also, sample size has to be very large for a study where both the exposure (no vaccines) and the disease (autism) are uncommon. Such a study requires an adequate number of subjects who have both the exposure and the

disease. Autism spectrum disorders taken together have a cumulative incidence of 5 to 10 children per 1000 by age 8, and receiving no vaccines is quite rare, at 1% or less of all children at age 2 to 3 years old. A study would likely have to include most, or all, autistic children in the state. There is no central registry of all these children, or of the vaccine status of all children.

The best option is an alternative cohort study design, in which immunization histories are obtained for all autistic children in a certain age range in a defined geographic area, and the size of the population of children with no or some doses of vaccine received by that age living in that area is estimated from immunization surveys. If a wide enough age range of children is included, and if significant data access issues can be resolved, it might be possible to do such a study in the geographic area covered by the CDC-sponsored University of Miami ASD prevalence project.

Because of the large sample sizes needed for any of these studies, they are likely to be expensive to carry out. While an exact dollar amount cannot be estimated without knowing precisely which question is to be answered, and thus what the details of the study design would be, it would be wise to assume such a study would take at least two years to complete.”

The Case-Control Alternative

Rather than even attempt to conduct the types of retrospective studies outlined above, the Florida DoH would do well to identify as many children with an ASD that they can find, assign them to the appropriate cohort year, and then, *as part of a full differential diagnostic workup, including genetic screening*, screen all of these children for the following markers:

1. *For those who have not received prolonged effective mercury-specific chelation treatments with DMPS or DMSA that are designed to lower level of tissue-bound mercury and/or lead in the body*, mercury and/or lead poisoning based on the LabCorp random-sample urine porphyrin profile analysis “UPPA”,
2. Full panel hormones assessment in blood, with special focus on the androgen levels, DHEA, DHEA-S, and the hormones that control their levels in unaffected children,
3. Transsulfuration metabolites in blood and bile levels,
4. Levels of glutathione, reduced glutathione, cysteine, homocysteine,
5. The strength assessment and mitochondrial function markers in blood, and
6. Methylation markers.

As controls, the researchers should choose matched children with no evidence of neurodevelopmental deficit or behavioral problems and perform the same work ups.

Next, the researchers should compare the findings from the group with an ASD diagnosis to the diagnostic outcomes for the control group.

Then, those markers for each ASD diagnosis that are the most significantly elevated or depressed in the test group over the levels in the matched controls not only identify those markers as the key markers for each ASD but can also be used to appropriately screen all Florida children for assessing their ASD risk.

Since the ASDs are conditions where the diagnosed child has significant deficits, the goal should be to use the key markers developed to identify future children who may be at risk of developing an ASD and appropriately intervene to stop that development or lessen its impacts on the child’s development.

One advantage of these studies is that children newly diagnosed with a given ASD could be dynamically added to the test cohort as they are identified and the appropriate differential diagnostic workups used to confirm the causal factors for the ASD diagnosis assigned.

One interested party has described the study question as whether autism ever occurs in children who have received no vaccines. Since autism was first described as a syndrome in the early 20th century, before vaccines came into use, receipt of vaccines is not a necessary precursor to or cause of autism or autism spectrum disorders.”

First, serums for diphtheria and tetanus were in use in the USA in the 1930s, and the vaccinia (cowpox) vaccine for smallpox had been in widespread use and the rabies vaccine had been in use in humans since the late 18th/early 19th centuries.

Thus, *contrary to the narrative in the report*, vaccines obviously predate autistic disorder (autism) or the other autism spectrum disorders in all but the surreal history created here by those who fabricated it.

However, this reviewer concedes the reality that “*receipt of vaccines is not a necessary precursor to or cause of autism or autism spectrum disorders*” although the evidence is, *and medical professionals have conceded*, that the receipt of vaccines can be a sufficient causal factor for a child to be diagnosed with autistic disorder or another autism spectrum disorder.

Moreover, *looking into American history*, autism was diagnosed after the start of the use of organic mercury compounds as biocides (mainly alkylmercury fungicides) in agriculture in the 1930s through the 1970s – a use that abruptly ended when researchers recognized the bioaccumulative toxicity of these compounds.

In addition, starting in the 1930s, organomercurials were used as antiseptics (mainly, Thimerosal and Mercurochrome) until being banned from over-the-counter [O-T-C] antiseptic drugs in 1998.

The FDA also banned the use of Thimerosal in vaginal O-T-C contraceptives in 1998.

The use of organomercury compounds (mainly Thimerosal and, to a much lesser extent, phenyl mercury acetate) as preservatives in biological preparations, injected and infused medicines (vaccines, plasma, immunoglobulin products, antisera [principally, snake and spider antivenins], and other biopharmaceutical products) also began in the 1930s.

However, the use of Thimerosal in all but vaccines, *and possibly some monoclonal antibody products*, was voluntarily discontinued by the manufacturers starting in the 1950s with plasma, then proceeding to most immunoglobulin, antisera, and other drug products so that most uses had been abandoned by the start of the 21st century.

Thus, *by 2002*, the principal remaining disclosed use of alkylmercury compounds in medicine in the USA was the use of Thimerosal in vaccines.

Given:

- ❖ The strong temporal and proximity connection between organic mercury compound use starting in the 1930s and the definition of “autistic disorder” by Dr. Kanner in the USA in the 1940s as well as
- ❖ The strong probable link between the use of Calomel (inorganic mercury; mercury (I) chloride [Hg_2Cl_2]) and “Pink” disease, which disappeared a few years after all Calomel-containing medicines were taken off the market in the 1940s in the USA but not until 1956 in Australia,

the link between the inadvertent or adwerent exposure to alkyl (organic) mercury compounds in the mid 1930s and the characterization of “autistic disorder” in the early 1940s seems to clearly establish that “autistic disorder”, a cause-unknown disorder, and the other ASDs are simply various manifestations of subacute mercury poisoning in a genetically diverse population of developing children exposed to low but toxic and bioaccumulative doses of Thimerosal from before birth onwards.

If the reader wishes to pursue this line of reasoning, he or she should consider visiting the Internet website: <http://www.mercury-freedrugs.org> and read the evidence presented there in the many pertinent documents discussing this issue that are posted there by this reviewer in the “Documents” webpage

Based on all the research papers that this reviewer has studied, the evidence is overwhelming that vaccine-derived Thimerosal mercury poisoning has been and, *to a somewhat lesser extent*, still is a major causal factor in most of the children who have an ASD diagnosis.

Moreover, the recent reduction in the average level of Thimerosal exposure from the removal of Thimerosal, or the reduction in the level of Thimerosal in, some vaccines has been offset by adding the mostly Thimerosal-preserved influenza vaccine to the vaccination recommendations for pregnant women as well as for children 6-months of age to:

- 23 months of age in 2002,
- 36 months of age in 2003/4 with 2 doses the first time vaccinated,
- 59 months of age in 2005/6,
- 59months/107 months of age in 2007, and
- 18 years of age in 2008/9³⁶.

“So perhaps the question can be reformulated as, ‘Is the rate of autism or autism spectrum disorders (ASDs) significantly lower in children who have received no doses of any vaccine, than in children who have received one or more doses of vaccine?’”

As those who are posing these questions know all too well, the questions asked need to be much more specific and to be population-segment targeted if one seeks to find causal links.

However, *when possible causal links have been established*, attempting to answer questions such as this is a waste of resources better spent in assessing the magnitude of the risk for each possible causal factor identified using case-control studies to elucidate the probable impact for each of the established causal factors.

“A closely related question would be, ‘Is the rate of autism or ASDs greater in children in proportion to the number of doses of vaccines received?’ While this latter question would have to be refined in an actual study design, the question would be whether children who have received 4 different injections have a higher rate than those who have received 3 injections, which in turn is higher than in those who have received 2, 1, or 0 injections.

³⁶ Coincidentally, as the total maximum level of Thimerosal-derived mercury exposure from the non-influenza vaccines has declined, the CDC has broadened the recommendations for the use of influenza in children.

The CDC has done this even though several studies have clearly established that the influenza vaccines are not effective in protecting those vaccinated from contracting influenza and there is a proven dietary influenza preventative (“daily” intake of (or sun-exposure to produce) 1,000 to 5,000 IU [25 to 125 micrograms] of vitamin D-3, a vitamin that has recently been proven to have other significant health benefits).

Moreover, the CDC’s recommendations that pregnant women should be given a flu shot that can be Thimerosal-preserved (and, when it is, exposes their developing fetus to a 25-microgram bolus of Thimerosal-derived mercury) is even more troubling because: a) all inactivated influenza vaccines are Pregnancy Class C drugs having unknown fetal safety, b) studies published in a 1977 book, *Birth Defects and Drugs in Pregnancy*, by Heinonen et al., clearly established that pregnant women given Thimerosal-preserved flu shots were an associated factor in the increased levels of severe birth defects (cleft palate, hydrocephaly, pyloric stenosis) seen in their offspring, and c) Thimerosal is a proven human teratogen at levels below 1 ppm (levels more than 100 times lower than the level of Thimerosal in a Thimerosal-preserved vaccine).

Based on the preceding realities, it seems clear to this reviewer that the CDC is adding Thimerosal to offset the drop in mercury exposure so that the number of children diagnosed in the ASD spectrum will not decline precipitously.

Supporting this reality are the general observations by those who treat children with an ASD diagnosis that the severity in each category, autistic disorder, PDD-NOS, and Asperger’s, is dropping and, in some states, a percentage shift from autistic disorder to PDD-NOS and from PDD-NOS to Asperger’s is being observed.

Perhaps that explains the reason the CDC has refused to do any “autistic disorder only” or separate category surveys or to update their 2002 surveys of 8-year-olds nominally born in 1994 in New Jersey, the state with the highest ASD rate, as reported in 2007, to a 2007 survey of 6-year olds born in 2001 in New Jersey before, coincidentally, the New Jersey mandate to vaccinate all children up to age 3 became effective.

The measurement of vaccine exposure in such a study would also have to be refined to take account of the number of different antigens contained in each vaccine dose received.”

Since independent researchers have already conducted these studies using both VAERS and the VSD and found causal linkages between the cumulative dose of mercury and the risk for various neurodevelopmental disorders including autistic disorder (autism), this reviewer sees no need to more of such studies.

Perhaps more studies looking at the impact of measles doses on neurodevelopmental disorders would be helpful since, *for the current MMR vaccine*, the measles component has the most potential to cause neurodevelopmental damage to the central nervous system and, *for the current DTaP/Tdap vaccines*, perhaps a similar doses study for the effect of the dose of pertussis toxin might be informative.

“The material that follows is based on answering the original question, about ASD risk associated with no vaccine versus any vaccine. Different questions may be of interest, for example comparisons of ASD risk in relation to the age at first dose of vaccine, or number of doses of vaccine or number of antigens received by a certain age, or the maximum number of antigens administered on any one visit. Addressing these would involve similar study designs and sample size considerations as those described here, but the details would be different. In particular, the needed level of detail about exact immunization histories needed for these alternative questions may not be available in the statewide 2-year-old survey and thus the best option mentioned above may not be feasible.”

Since valid UPPA testing in children with an ASD diagnosis have established that >75% of those with an ASD diagnosis are mercury poisoned, it would seem better to set up a screening program to perform a valid UPPA test on all Florida children who are 8 years of age and younger and who have not been previously extensively chelated with DMSA or DMPS to reduce their body burden of mercury and other heavy metals, and then do a differential diagnostic work up designed to find all medical conditions on the children who the UPPA test results indicating they have indications of heavy-metal toxicity (body burden) from mercury, and/or lead, and/or arsenic.

“Study design options

In general, epidemiologic studies fall into three categories: cohort studies, case-control studies, and cross-sectional studies. All are designed to see if there is an association, not due to chance, between particular exposures and particular disease outcomes.

In cohort studies, people are enrolled based on whether they do or do not have a particular exposure or characteristic of interest, and then are followed over time to determine whether they develop the outcomes of interest. If there is an association between the exposure and the disease, there will be an increased rate of the disease in those with the exposure compared to the rate in those not exposed. Subjects must be enrolled as exposed or unexposed without any knowledge of their eventual outcome. Cohort studies can be prospective, where subjects are enrolled now and followed into the future, or historical, where subjects are enrolled retrospectively, often many years after the fact, and then followed until the present.”

Since the ASD epidemic seems to be at, or near, its peak, and there are many other childhood medical conditions that may be vaccine related and are already at epidemic levels, cohort studies would waste valuable time in which properly diagnosed children could be treated before the harm from their medical condition becomes non-reversible.

Thus, cohort studies should have the least priority.

Moreover, retrospective epidemiological population database surveys should be limited to those medical conditions where there is no established/conceded link between the medical

condition and one or more vaccines/vaccine components (e.g., childhood asthma or childhood idiopathic cardiomyopathy).

“In case-control studies, people are enrolled based on whether or not they have a particular disease, and are then studied to determine whether they had certain exposures of interest in the past. If there is an association between the exposure and the disease, the proportion of those with the disease who have the exposure will be higher than the proportion among those without the disease. Subjects must be enrolled as cases or controls without knowing whether they had the exposure of interest.”

While this reviewer supports the use of case-control studies and finds that, when the medical condition is at epidemic levels as it is for autistic disorder, the other ASDs, and many other childhood disorders that, *in the 1960s*, were unknown or virtually unknown, (e.g., childhood type 2 diabetes), this is the preferred approach that should be used in all such studies.

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“In cross-sectional studies, people are enrolled from a population without knowing whether they are exposed or not, and without knowing whether they have the disease of interest or not. This approach is commonly used in a random sample questionnaire survey of people from a population, for example the population of people who partook of a meal that was followed by a gastroenteritis outbreak, or the population of a town with a suspected waterborne disease outbreak.

Cohort studies are particularly useful with reasonably common diseases, and can be used to study multiple outcomes. They usually take a long time to complete, unless done as historical cohort studies. If the study is historical, the investigator usually has much less control over how exposure was measured or assessed. Cohort studies are very inefficient for rare diseases, because large numbers of subjects have to be enrolled to be reasonably sure an adequate number of cases will occur for study. Case-control studies are particularly useful with rare diseases, but again retrospective exposure assessment can be limiting. Case-control studies also require large sample sizes if the exposure is also rare.”

Since this reviewer has no problem with the statements being made here, he sees no need to review them in depth.

“Baseline data for Florida

Data from the Florida DOH annual random sample of two-year-old immunization levels show that quite consistently, from year to year, about 1% of Florida children aged 2 to 2.9 years old have received no doses of vaccine. A federal telephone survey carried out nationally each year suggests that the Florida percentage is much lower, with around 0.3% of children having no vaccine doses on board at age 2 to 2.9 years. That same federal study shows that children with no vaccines fall into three quite diverse groups: children with low-education, low-income parents who do not have access to health care services; children with high-education, high-income parents, who have access to health care services but do not ~~immunize~~ **vaccinate** their children for religious or philosophical reasons; and children with medical contraindications to vaccination.

While we do not have exactly comparable data available at school entry, the percentage with no vaccines on board cannot be lower for any birth cohort than it was at age 2 to 2.9 years old.

The expected prevalence of autism and ASD by age 8 years, using the methods of the CDC-sponsored autism surveillance sites, is about 5 to 10 children per 1000, or 0.5 to 1%. If the percentage with no immunizations is 1%, then for each one-year birth cohort of 220,000 live births, there would be about 2200 unimmunized children at age 2. The expected number of autistic children (that is, children with a diagnosis of an autism spectrum disorder) by age 8 in that cohort of 2200 children would be 11 to 22. If we were to combine 5 one-year birth cohorts, the expected number would be 55 to 110 autistic children by age 8. These children would amount to approximately 0.5 to 1.0% of all autistic children in Florida, if there was no protective effect of non-vaccination.

These calculations would have to be refined to account for children who move in or out of Florida between birth and age 8 years. Also, by age 8 some of the children with no doses of vaccine at age 2 to 2.9 years will have received one or more doses of vaccine, perhaps for attendance at daycare or school. For purposes of this proposed study, the investigators would need to be clear about what they would consider to be a child not exposed to vaccines: never exposed before autism diagnosis, or not exposed prior to a particular age.”

This reviewer finds the information reported here to be plausible and helpful even if the true rate for all ASD cases is closer 1.5 to 3 % of children than it is to 1% or less.

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“Cohort study options

A straightforward cohort study would involve identifying all the totally unimmunized unvaccinated children who had been born in Florida in a certain time period, verifying they have received no doses of vaccine by age 2 or 3, and then determining if they have developed autism by some specified age. A similar cohort of immunized vaccinated children would also be followed up. This is not practical, as there is no central registry of children at this age who have not received any vaccines.

An alternative approach to a cohort study might be to gain access to a complete list of Florida-born autistic children in Florida, such as might be the result of applying the methods of the current Miami-Dade county prevalence study to the entire state. The entire population of live-born infants for a five-year study period could be considered to be the cohort of interest. We would then ascertain the complete immunization vaccination history of all these autistic children, and thus identify all those who have never received doses of any vaccine, only a few doses, or a full complement of vaccines. The denominators for these two incidence rates would be the estimated number of children who had zero and any doses of vaccine by age 3, from the annual Florida immunization vaccination survey.

We can then estimate incidence rates in the birth cohort, for those who have received no doses of vaccine by age 3 and those who have received one or more doses of any vaccine by age 3.

One weakness of this approach is that we have two conflicting estimates for the percentage of Florida children aged 2 to 2.9 years old, one from a Florida Department of Health survey and one from a national survey with many Florida respondents. One would have to decide which of these to rely on. The fact that the immunization vaccination histories of the autistic children would have been derived from a different methodology than either of the surveys would also be a methodologic issue.

Another weakness is that there is currently no state-wide autism registry using the CDC/University of Miami methods. If this study were to be done with just Miami-Dade County subjects in the CDC-funded University of Miami prevalence study, it would have only about 15% as large a sample size as a statewide study. This reduction in sample size would result in about a tenfold reduction in statistical power to detect a two-fold difference in incidence between the two groups.

It is important to do a study of this type in a setting where the probability of inclusion in the study is the same for all persons with the same condition (ASD here). Including data from the health and special education information systems of many different school systems is not advisable, without the kind of quality control that is included in the CDC-sponsored prevalence study area projects.

Study size would likely be further reduced by exclusion from the numerator and denominator of the rates of some or all of the children who had medical contraindications to some or all vaccines. Such children might be at increased risk of developing ASDs or other neurodevelopmental conditions, and thus would not be a good population to include in the proposed study.

Any study of this type would need to account for numerous potential confounders of the relationship between vaccine receipt and ASDs, since healthy children who receive no vaccines are different in many ways from those who do receive vaccines. One way to recruit children who have received no doses of any vaccine would be from religious communities who object to immunization vaccination. In some states, such communities are highly visible and localized and it would be relatively easy to recruit families systematically from such communities. In Florida, however, families with such beliefs can be found in all parts of the state in relatively

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small numbers. The impression of county health department staff is that the parental decision to request a religious exemption at school entry is highly individual, even among families who belong to religious communities that have objections to immunizations vaccinations.

At school entry, approximately 0.6% of children entering kindergarten (in 2007, this was 1,362 children) are enrolled with religious exemptions, as well as 0.4% of children in seventh grade (925 children). DOH does not know the identities of these children. Children attending school on religious exemptions may have received some doses of vaccine. It would probably be worth determining how many children could be recruited for an epidemiologic study in Florida through religious congregations and religiously-oriented schools, and how many of those would be totally ~~unimmunized~~ **unvaccinated**. If the number is sufficient, such children could serve as the basis for a cohort study.”

Given the reality that cohort studies take time, it is or should be obvious that, *when diseases are at epidemic levels: a) the cohort-study approach should not be pursued and b) discussing it in detail, in this section, detracts from this report’s real-world relevance.*

“Case-control study options

In a case-control study, we would select a group of autistic children (cases), and a group of non-autistic children (controls) of the same age, and determine their immunization histories. A project of this type could be done by sampling the case subjects from the records of one or more large autism treatment centers or school systems, and selecting control subjects at random from the same communities from which the cases came.

Sample size issues are also important here, however. It would take approximately 7,000 subjects (2,000 cases and 5,000 controls) to have an 88% certainty of being able to detect an odds ratio of 2.0 (that is, the odds of disease are twice as high in the exposed as in the non-exposed), for the association between “any vaccine receipt” and ASD. In Florida, in each one-year birth cohort about 1,100 to 2,200 autism cases are expected. If five one-year birth cohorts are included in the study, about 5,500 to 11,000 children would be available for study, so from 10 to 40% of all autistic children in the state would have to be included as cases in the study.”

While this reviewer finds the narrative provided initially useful, when it begins to discuss sample size considerations, the discussion veers from reality into the surreal because the small (<100 cases) case-control studies on children with ASDs and their matched controls that have been published have, *for the factors assessed*, found that the magnitudes of the effects identified have been anything but small so far.

In addition, since the state public health officials have access to most of Florida’s children and each vaccine’s disorder-causing effects extend beyond ASDs in specific and neurodevelopmental disorders in general to encompass many other identified chronic childhood medical conditions where the apparent odds ratios exceed 5.0, it would seem that the Florida DoH should start these studies as soon as possible.

Moreover, *given its access and reach*, the Florida DoH should be able to complete the requisite studies in less than 18 months – since independent researchers, *with much less access and reach*, have been able to complete their definitive case-control studies in less than a year.

Hopefully, after reading the existing peer-reviewed case-control studies published in 2006, 2007 and 2008, the authors of this section of the report will appropriately revise this section.

“Cross-sectional study options

In a cross-sectional design, we would enroll children in the study in some region of the state, for example at school entry, without knowing either their ~~immunization~~ **vaccination or their autism diagnosis status.** The assumption here is that all children who reach school-entry age are registered for school, even if they are moderately or profoundly disabled. The biggest challenge of a study of this type would be assuring uniform diagnostic criteria for ASDs across multiple schools and school districts.

School personnel already ascertain ~~immunization~~ vaccination status at the moment of school entry, which in principle should allow identification of children with no doses of any vaccine. This may or not be recorded unambiguously for children seeking enrollment under medical or religious exemptions; this would have to be explored further. Also, if the desire is to identify children who had received no doses by a particular cut-off age like 2 or 3 years, then full ~~immunization~~ vaccination histories would have to be obtained for all children, to find those who had received at least some vaccines between age 3 and school entry but none before.

Sample size considerations would argue strongly against this study design. Unless a very large fraction of the state or the whole state was included in the project, the number of subjects enrolled for the study who turned out to be autistic would be too small to allow for adequate study power to detect a small increase in risk.”

This reviewer agrees with the report’s findings that the Florida DoH should not attempt to use a cross-sectional design to attempt to assess the causal links between each vaccine in the Florida vaccination program and ASDs because of:

- ❖ The large population size required,
- ❖ The complexity in establishing the true level of exposure for some vaccine components that, *for nominally the same vaccine*, have had multiple formulation changes, with overlapping distribution, in the period from 1999 through 2008, and
- ❖ The need to include CDC-recommended vaccines that some Florida children received and are receiving even though they are not “recommended”.

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“request 11

What is the risk of waiting until 24 to 30 months to introduce ~~immunizations~~ vaccinations?

In general, infants are our most vulnerable population to infectious diseases. Their ability to fight off potential deadly diseases has not fully developed in comparison to older children and adults. Any delay in providing this necessary prevention increases the risk of their contracting these life-threatening diseases and developing severe complications or death.”

Here, this reviewer finds that the narrative is much too simplistic.

Case 1: The Nursing Naturally Immune Mother³⁷

If the child is carried by and, after delivery, nursed by a mother who, *by having been exposed and developed “natural” immunity to the diseases to which her child may be exposed*, supplies full antibody protection to her child through her breast milk, that child may be “fully” protected from these diseases while the child’s immune system develops until his or her immune system can handle exposure to these diseases without being significantly harmed by these diseases.

Thus, *for these mothers*, delaying any consideration of vaccination while nursing and/or feeding her child her expressed milk may not increase “*the risk of their contracting these life-threatening diseases and developing severe complications or death*”.

Moreover, since the natural period of nursing extends to from two to four years, a mother who nurses and/or feeds the child her expressed milk until she starts to dry up may be easily able

³⁷ Though the custom has fallen into disfavor in the USA, those who, for medical reasons, cannot nurse their baby may want to consider reviving this practice and/or using human milk supplied by LaLeche League mothers to feed their baby and, thereby, provide most of the protections that she herself would otherwise have provided.

to wait until her child is 24 to 30 months of age to begin vaccination with those vaccines she thinks are appropriate.

Given the first live-virus vaccines are recommended for 12-15 months of age, it would probably be best that lactating mothers nurse for at least 12 months if at all possible.

If vaccination is planned for her children, a lactating mother who plans to nurse longer than 12 months may want to consider starting the planned vaccinations at least 6 months prior to the intended end of nursing.

Case 2: The Nursing Mother with Both Natural and Vaccine-acquired Immunities or Only Vaccine-acquired Immunities

For the diseases for which she has natural immunity and/or the ones for which vaccination confers long-term protection, the reality is that it may be safe for these mothers to delay vaccination for these diseases until she stops nursing.

For those disease for which the vaccines do not confer long-term immunity and having the communicable disease does, then, these parents should not be too worried about having her child contract these diseases while breastfeeding.

However, *even while nursing*, if she plans to vaccinate her children, she may want to consider starting some of the vaccinations for them before she stops nursing.

Case 3: Children Who Are Neither Nursed Nor Fed Human Milk

These are the children for whom there is a significant early disease risk that only increases if vaccination is significantly delayed.

However, as a recent study on the effect of delaying the start of the DTaP vaccine series by “2 months” showed, short delays can significantly reduce the risk of adverse vaccine effects associated with the development of chronic medical conditions.

Given the trade-offs inherent in these decisions, the parents or guardians of children who are not breastfed face difficult choices for which there are no guaranteed right answers.

However, these parents or guardians may be able to use the background case rates in the USA for children under 1 and children 1 to 4 as an aide in making these decisions.

In addition, *for these children*, the risks for disease increase if they are placed in a childcare environment and, *in these cases*, significantly delaying vaccination may significantly increase their risk of infection before their immune systems may be able to provide an effective defense against the disease they have contracted.

Hopefully, these broad generalizations will help the reader to frame their risks in terms of how at one with nature their feeding and care choices are as well as how much exposure risk that the parents, caregivers, and the children may have.

- “Many of the diseases vaccines protect against are very dangerous to infants. Newborns, babies, and toddlers can all be exposed to diseases from parents, other adults, brothers and sisters, at child care, on a plane, or even at the grocery store. International travel is easier than ever—an infant can be exposed to diseases from other countries without a parent knowing.
- Infants and children stand to benefit the most from vaccines, as they are the most vulnerable to disease and the least likely to have been previously exposed to infection and acquired natural immunity.
- Waiting until a child is 24 to 30 months of age to be immunized exposes the young infant to serious and possibly deadly diseases that can be prevented.”

Here, this reviewer finds that the three preceding bullets present the biased views of those who neither recognize nor appreciate all of the advantages/protections that extended

breastfeeding provides to the developing infant nor even see the problems presented by replacing breastfeeding with formula feeding.

- “Many people think that they don’t have to vaccinate their children because the risk of vaccine-preventable diseases is so low. However, lapsing immunization rates are the reason why epidemics begin—both in this country and abroad. It has happened in our time, and can happen again if children fail to be vaccinated. —Between 1989 and 1991, lapsing rates of MMR vaccinations among preschoolers in the US led to a sharp jump in the number of measles cases. 55,000 people became sick and 120 died.”

Here, this reviewer finds that the writers of this report are again attempting to rewrite history.

As the excerpt from the ***Morbidity and Mortality Weekly Report*** 1993 May 21; **42(19): 378-381** stated:

“Possible explanations for the end of the measles resurgence include a decrease in susceptible populations following widespread transmission of the virus; improved vaccination coverage in the susceptible population; an overall decrease in the occurrence of measles in the Western Hemisphere (5); and the periodic cyclicality in measles transmission that has been noted since the prevaccine era”,

there was no lapses in “*rates of MMR vaccinations among preschoolers in the US*” between 1989 and 1991, though improved coverage and the subsequent introduction of a second dose of the MMR vaccine did finally reduce the “baseline” measles rates to the current < 60 cases per year background measles rate.

“—From January 1 through April 25, 2008, CDC received a total of 64 reports of confirmed measles cases in nine states—the highest number for the same time period since 2001.

—Of the 64 people infected by the measles virus, only 1 had documentation of prior vaccination. Among the other 63 case patients were 14 infants who were too young to be vaccinated.

—Many of the cases among US children occurred in children whose parents claimed exemption from vaccination due to religious or personal beliefs, or in children too young to be vaccinated. Disease transmission occurred in a variety of community and healthcare settings, including homes, childcare centers, schools, hospitals, emergency rooms, and doctors’ offices.”

What this narrative fails to note is that others may have been vaccinated but lacked “*documentation of prior vaccination*” or that these cases and the others that have raised the total to 130+ cases:

- Occurred in multiple disjoint locales,
- Were caused by exposure to imported cases of measles from outside of the USA in almost all of the reported instances of measles “outbreaks”,
- Contrary to CDC definitions, which require at least 3 cases for the cases to be considered an outbreak, included instances where 2 cases occurred in a given locale were called an outbreak, and
- Occurred against a background average of 50+ cases annually, where, based on recent history from 1989 through 2007, an isolated cases level of 250+ cases in a given 12 months would be needed before any alarm should be considered and 1,000+ cases would be needed before there might be a genuine concern.

Based on the preceding realities, it is clear that the report’s narrative here is a not-so-subtle form of fear mongering.

- “For almost all of the diseases that are vaccine-preventable, incidence and mortality rates were very high in infants and toddlers before vaccines were introduced. The major exceptions would be hepatitis A and B, and even there, transmission from mother to unborn baby was an important route of transmission. Even polio, which we sometimes think of as a disease of school-age children because of the epidemics in that age group in the early 1950s, was originally named “infantile paralysis.”

Ignoring the fear mongering, this reviewer is pleased to find that hepatitis A and hepatitis B are recognized as exceptions to the “*very high*” incidence and mortality rates in “*infants and toddlers before vaccines were introduced*”, although this reviewer is disappointed that chickenpox was not also mentioned.

However, this reviewer is disappointed that the reasons for the low incidence and mortality rates for hepatitis A and hepatitis B in children were not stated.

Instead, the report focuses on the “*route of transmission*”, which, *per se*, has little to do with the incidence and mortality rates for these diseases, when the principle source of the transmission to the children is mothers who, as a *group*, have very low levels of transmissible disease.

Overall, this reviewer finds that the report would be improved if this passage were simply deleted.

- “During 1997–2000, out of 28,187 reported cases of pertussis (whooping cough), one quarter were in children under age 6 months. Almost 81% of the hospitalizations, 57% of the pneumonias, 58% of the encephalopathies, and over 93% of the deaths were in children under 6 months old. (CDC. Pertussis—United States, 1997–2000. *MMWR* 2002; **51**: 73–76).”

First, given the current vaccination program for the DTaP/Tdap vaccines, most all of the pertussis cases in children under 6 months would probably have occurred even if the vaccination rate were almost 100%.

Moreover, *to the extent that the current DTaP vaccines are designed to only protect all of those vaccinated from the adverse effects of the pertussis toxins but does not effectively protect those vaccinated from being carriers for the pertussis bacteria*, most all of those with severe adverse effects will disproportionately fall on those who contract pertussis but are too young to be protected from the pertussis toxins by vaccination.

- “Most children are protected from measles by antibodies passively transferred from their mother until they are about a year old. Incidence of the infection then rises rapidly after the first birthday. This is why measles vaccine is recommended to be given at the first birthday, and even earlier during outbreaks. Waiting until children are 2 years old to give measles vaccine would allow development of a very large pool of ~~##~~ immunized unvaccinated and unprotected children aged 12 to 24 months—about 200,000 at any one time in Florida alone—who could easily maintain an extensive measles epidemic. Among 67,032 measles cases occurring in the United States in 1987–2000, 43% were under 5 years old. Among these children, 41.4 % had one or more complications, 26% were hospitalized, and 0.3% died (97 children). Complication rates were much lower in people aged 5 to 9 years (18.1%), and 10 to 19 years (12.8%), and then were higher in adults aged 20 to 29 (29%) and aged 30 and over (34.1%).”

Accepting that the preceding are the realities for measles in a population that does not breastfeed its children for extended periods of time, simply encouraging Florida mothers to breast feed their children for at least 2 years (by providing the appropriate support and, *for those who cannot nurse for medical reasons*, wet nurses) rather than the current “6 months”:

- Would:
 - Reduce the risk that children younger than 2 years of age would contract measles or other common contagious disease and
 - Improve the overall health of Florida’s babies as well as the mental health of Florida’s nursing mothers, and
- Could reduce the risk for vaccine-related childhood chronic diseases in those whose parents decided to appropriately postpone the start of the “Florida required” vaccinations.

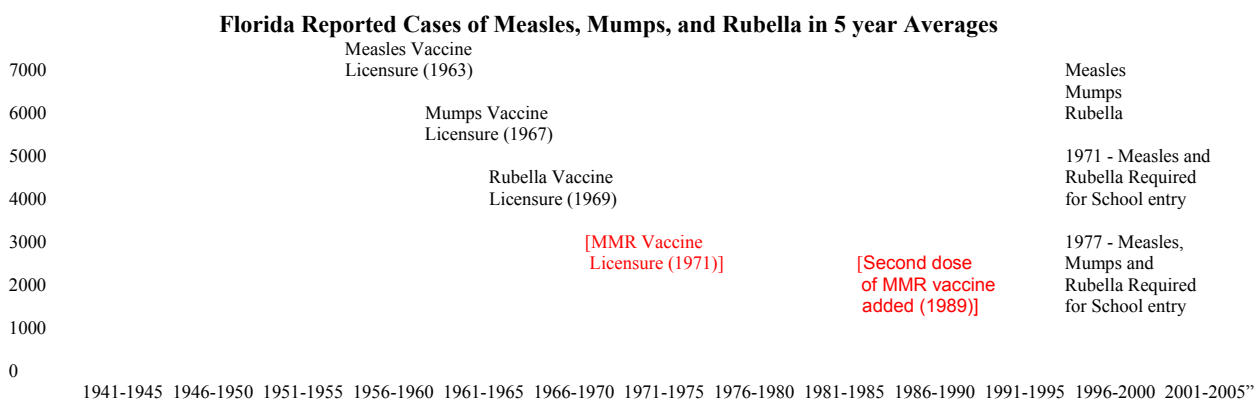
Perhaps the outcomes from having an extended-breastfeeding program might encourage the reintroduction of other natural childrearing practices that produce happier and more healthy babies, and happier mothers with stronger maternal protective bonds to their children.

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- “In the 1920s, more than 125,000 diphtheria cases, with 10,000 deaths, were reported annually in the US, with the highest fatality rates among the very young and the elderly.” (Nelson Textbook of Pediatrics, 18th Edition, Saunders, 2007, page 1153).”

Since, *in the early 21st century*, the current sanitation/hygiene/diet/antibiotic/vaccination-driven reality is “0” cases of diphtheria, this reviewer sees little reason to include this isolated bullet point – especially, because the data for this bacterial disease seems to indicate that, *unlike pertussis and tetanus*, the risk of being exposed to diphtheria and contracting diphtheria is nearly “0”, and, *with the advent of antibiotics*, there are now effective antibiotics that can be used to effectively treat an isolated case should one be identified unlike in the 1920s example tossed in here.

- “The following chart reflects the decline in the disease rate of measles, mumps and rubella in Florida with the date of vaccine licensure.



While this chart is informative, it is also misleading because it does not indicate the date for the MMR vaccine was licensed (1971) nor the date (1989) at which, *to control measles in a highly vaccinated population*, the CDC added a recommendation for administering a second dose of the now MMR II vaccine to children attending grades K-12 as well as to those in college (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5522a4.htm>).

This addition was made in recognition of the failure in a highly vaccinated (>95%) populations of the single-dose of MMR to provide adequate protection from contracting measles and mumps for those who were only given a single inoculation with the MMR II vaccine.

Furthermore, *in apparent recognition of the failure of the MMR vaccine to provide long-term immunity even with two (2) doses of MMR vaccine in some*, the CDC now (as of 2006) recommends:

- The titers for measles be checked when a women completes or terminates a pregnancy and
- When the titers are low or absent, the woman should be given an MMR shot before being discharged – even though a measles-only vaccine would be more appropriate if the only low titers were those for measles.

If measles antibody titers are important, then, it would be better if a women had her titers checked before trying to conceive and, if they are low, be offered a measles-only vaccine to boost titers before attempting to conceive.

- “While the risk of infants and children coming into contact with vaccine-preventable diseases is lower since the advent of ~~immunizations~~ vaccinations, the best way to keep that risk down is to keep those vaccinations up. Any decline in ~~immunization~~ vaccinations—either on a community, national or even an individual basis—can open up a window on vaccine-preventable diseases that ~~immunizations~~ vaccinations have done such a great job keeping closed.”

This reviewer can only support this position for those vaccine that are safe and truly cost-effective even when the costs of caring for those injured by that vaccine are fully reflected in that vaccine’s costs.

- “Before the Haemophilus influenzae type b (Hib) vaccine was introduced, mortality rates from meningitis due to that organism in the early 1980s were 5 times as high in children under one year of age as in children one to four years old. (Schoendorf KC, Kiely JL, Adams WG, Wenger JD, “National trends in Haemophilus influenza meningitis mortality and hospitalization among children,” 1980 through 1991).”

This reviewer again finds the narrative here does not address the reality that the Hib vaccines have been a failure in preventing Hi cases and Hi deaths in young children – even though these vaccines did reduce the annual cases of Hib.

Factually, the Hib vaccines: **a)** are clearly not cost-effective; **b)** may be a causal factor in the increases in Hi cases; and **c)** have caused adverse changes in the strains of bacteria and the nature of the bacteria occupying the Hib niche.

Thus, *as this reviewer has previously pointed out in detail*, Hib vaccines are poster children for vaccines that do not protect the physical and financial health of American children but are significant financial contributors to their manufacturers’ and healthcare providers’ bottom lines.

- “The problem is even a low risk of contact with vaccine-preventable diseases places unvaccinated infants and children at-risk. The only disease that has been completely wiped out in the world is smallpox (which is why smallpox is the only vaccine that is no longer needed). The rest of the diseases that children are ~~immunized~~ vaccinated against still make occasional appearances and may pose a risk to anyone who isn’t fully vaccinated.”

This reviewer agrees with the report’s view that low-risk of exposure is still a risk.

- “Experts frequently say that the diseases that are uncommon in the U.S. are only a plane ride away. That’s because outbreaks in this country often begin when an unvaccinated person travels to a country where vaccination isn’t routine, and where diseases like polio, diphtheria, or measles still occur. The traveler then picks up the disease, and brings it home—a dangerous souvenir that can then be passed around to anyone who isn’t vaccinated or hasn’t yet been fully vaccinated (including those who are at greater risk, such as infants and pregnant women). Foreign visitors can also bring diseases into the country.”

Given the stated realities stated here and the availability today of rapid screening tests for incipient infection, why is it that the CDC still refuses to implement a visual check of all passengers arriving at American ports, borders, and airports for disease onset symptoms, and, *for those showing any disease symptoms*, quarantining them until the screening tests find that they are not contagious?

- “Why ~~immunize~~ vaccinate infants? Today’s low risks could potentially grow into high risks. If enough parents stop ~~immunizing~~ vaccinating their children, diseases that have been under control for years can actually make comebacks, causing epidemics.”

This reviewer can only warn those who are promoting vaccination that their continued misrepresentation of the facts about diseases and the vaccines that purport to safely and effectively, *but are not*, continues to erode the public's trust in their written statements and the vaccination programs they are promoting.

Thus, this reviewer must again recommend that the writers of this section of the report cease and desist from such fear mongering, clean up your act, and only present factually accurate and complete information that is pertinent to today's world – not to the world of the 1920s.

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“supporting documents

The following Florida Statutes and Administrative Codes assure provision of immunizations for eligible children and details immunization requirements for childcare and school.

Medicaid and Insurance Benefits for Eligible Children

Section 409.815, F.S., lists Medicaid benefits and also lists benchmark benefits (KidCare) which include preventive health services including services recommended in the “Guidelines for Health Supervision of Children and Youth” as developed by the American Academy of Pediatrics and immunizations and injections.

Medicaid policy for the Child Health Check-up (EPSDT is a mandatory Medicaid service) lists the periodicity of visits and addresses the content of care, including routine immunizations. In addition under OBRA 89, states must provide all medically necessary services identified during and EPSDT screen (known as child health check up in Florida) without regard to whether those services are included in the state's Medicaid state plan.

Section 627.6579, F.S., addresses requirements for commercial insurance regarding child health supervision and also includes routine immunizations.

Mandated School Immunizations

The following is a summary of required school immunizations, which are detailed in the “Immunization Guidelines—Florida Schools, Child Care Facilities and Family Day Care Homes,” which are referenced in Rule 64D-3.046, Florida Administrative Code.

Requirements: Prior to entry, attendance or transfer to preschools, schools (K-12), licensed childcare facilities, and family daycare homes, each child shall have on file a Florida Certification of Immunization, DH 680, documenting the following:

PUBLIC/NON-PUBLIC SCHOOLS K-12 (CHILDREN ENTERING, ATTENDING, OR TRANSFERRING TO FLORIDA SCHOOLS): Four or five doses of diphtheria, tetanus, and pertussis vaccine; three or four doses of polio vaccine; two doses of measles, mumps, and rubella vaccine; two or three doses of hepatitis B vaccine; one dose of varicella vaccine (kindergarten effective school year 2001/2002, then each year an additional grade); two doses of varicella vaccine (kindergarten effective school year 2008/2009, then each year an additional grade

PUBLIC/NON-PUBLIC SCHOOLS SEVENTH GRADE: one dose tetanus diphtheria (TD) vaccine; Effective with the 2009/2010 school year, one dose of tetanus-diphtheria-pertussis vaccine (Tdap)

PUBLIC/NON-PUBLIC PRE-K (AGE-APPROPRIATE DOSES AS INDICATED): diphtheria, tetanus, and pertussis vaccine; polio vaccine; measles, mumps and rubella vaccine; hepatitis B vaccine; varicella vaccine (effective school year 2001/2002); Haemophilus influenzae type b (Hib) vaccine

LICENSED CHILDCARE FACILITIES AND FAMILY DAYCARE HOMES: Children entering or attending licensed childcare facilities and family daycare homes shall have received as many of the following age-appropriate immunizations as are medically indicated in accordance with the current Recommended Childhood Immunization Schedule: diphtheria, tetanus, and pertussis vaccine; polio vaccine; measles, mumps and rubella vaccine; varicella vaccine; Haemophilus influenzae type b (Hib) vaccine; Pneumococcal Conjugate vaccine

AUTHORITY: K-12: section 1003.22, Florida Statutes, and Rule 64D-3.046, Florida Administrative Code

LICENSED CHILDCARE FACILITIES, FAMILY DAYCARE HOMES AND SPECIALIZED CHILDCARE FACILITIES FOR THE CARE OF MILDLY-ILL CHILDREN: sections 402.305 & 402.313, Florida Statutes, and Rules 65C-22.006 and 65C-25.002 and 25.008, Florida Administrative Code”

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Dr. Julia Gill

Charles Alexander

Cameron Noblit

Phyllis Yambor

Janet Hamilton

Leah Eisenstein

Kate Goodin

John Keegan

Childrens Medical Services

Dr. Joseph Chiaro

Dr. Phyllis Sloyer

Family Health Services

Annette Phelps

Dr. Bill Sappenfield

Vivienne Treharne

County Health Department Directors

and Administrators

Dr. Kevin Sherin

Dr. John Lanza

Dr. Gladys Branich

Statewide Research Office

Dr. Robert L. Hood

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127. U.S. Office of Special Counsel, 1730 M Street, N.W., Suite 218, Washington, D.C. 20036-4505, "OSC Forwards Public Health Concerns on Vaccines to Congress, ...". For more info visit www.osc.gov or call 1-800-872-9855.
128. Special Counsel Scott Bloch's letter to Congress addressed to: "The Honorable Judd Gregg, United States Senate, Chairman, Committee on Health, Education, Labor and Pensions, 428 Dirksen Senate Office Building, Washington, D.C. 20510-6300 and The Honorable Joe Barton, U.S. House of Representatives, Chairman, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515" [OSC File Nos.: DI-04-1399, et al.]
129. 15 July 2005 (Confidential Letter) Liz Birt, J.D., L.L.M. (former legal counsel to the Government Reform Committee, US House of Representatives) & Jim Moody, J.D. to Lauren Fuller, Chief Investigative Counsel, United States Senate Health, Education, Labor, and Pensions (H.E.L.P.) Committee regarding "Thimerosal Timeline" and "Statement of Criminal Charges".
130. April 2007 (PowerPoint Presentation) by Dr. Larry Needham, Chief, Organic Analytical Toxicology Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, "Exposure (To Stressors) and Autism Spectrum Disorders" to the Institute of Medicine of the US National Academy of Sciences.
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About the Reviewer

The reviewer, Paul G. King, PhD, is a PhD Analytical Chemist with a MS in Inorganic Chemistry, a technical degree in Computer Programming and Systems Analysis and 30-plus-year career in the biocides and pharmaceuticals industries.

Dr. King is a recognized expert in the areas of quality control, quality systems, and CGMP compliance, who has been involved with various projects addressing general drug and vaccine issues, related nutrition issues, including, since 1999, vaccines and mercury poisoning in developing children from conception onwards where Thimerosal bolus dosing is a major causal factor.

For more information on his credentials, background, activities and interests, you can visit his web site: <http://www.dr-king.com>.

End of Part 2 of 2 of the Review

APPENDIX A

REVISED VACCINATION RECOMMENDATIONS

PREFACE

This document contains information designed to provide pregnant women, parents and guardians of children alternative vaccination approaches based the fundamental factors that should be considered in choosing the set of long-term safe and long-term effective vaccines that may be safely given from birth until they are 18 years of age to developing children who reside in the United States of America.

The recommendations being made are based on an in-depth review of the available safety and effectiveness information published by the CDC and independent researchers on the vaccines in the current CDC-recommended vaccination program for U.S. children.

Revised Recommendations for Vaccines

The following table presents the current Florida vaccination requirements and the suggested revised list of vaccination requirements with the rationale for not including each vaccine³⁸ that

Table 1. Current and Suggested Revised Florida Requirements for Vaccination

Vaccines ¹	Current Florida Childcare & School Vaccination Requirements	Revised Requirements – Restricted To Vaccines Which Are <u>Effective</u> In Preventing A Disease To Which A Child May Be Exposed
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- ³⁸
- a.** Besides reducing: **a)** the number and severity of adverse events and **b)** the risk of inducing chronic disease, these recommendations will increase the overall long-term health of Florida’s children and should also reduce the vaccine-related costs currently borne by the parents, employers and the State of Florida.
 - b.** In the revised recommendations proposed, the basis recommendations will be that: **a)** the vaccines used must not contain any level of Thimerosal; **b)** where both live-virus and inactivated virus vaccines exist, only the inactivated-virus vaccines should be used; and **c)** where only live-virus vaccines exist for the current recommended vaccines, to safen vaccination against these diseases (as required by 42 U.S.C. 300aa-279a)(2)), the government will demand that they be replaced with equally effective inactivated-virus vaccines within 5 years so that the current disease problems associated with live-virus vaccines will cease to cause the disease in some who are vaccinated as well as some who have contact with those who have been recently vaccinated.
 - c.** For those vaccines that are live-virus vaccines and not recommended, the U.S. government, acting under its broad vaccine safening authority in 42 U.S.C. Sec. 300aa-279a)(2), should immediately remove these vaccines from the recommended vaccination schedules and, *for those having inactivated counterparts*, immediately revoke the live-virus vaccines’ U.S. licenses for discretionary use.
 - d.** For vaccines that are Thimerosal-preserved and not in the proposed revised requirements, the government should immediately revoke their U.S. licenses and approvals because they are obviously adulterated drugs under 21 U.S.C. Sec. 351(a)(2)(B). [**Note:** Until the “no Thimerosal” version of JE-Vax, Japanese encephalitis, is available, the current imported vaccine should be temporarily allowed to be used for children traveling or relocating to areas where this disease is endemic.] In general, these approvals should be revoked because, *as the FDA and the vaccines makers have testified before Congress*, the vaccine makers have knowingly failed to comply with a CGMP safety minimum, namely, 21 C.F.R. Sec. 610.15(a), which, among its requirements, requires the Thimerosal in a Thimerosal-preserved vaccine must be proven to be “sufficiently nontoxic ...” at the single-dose level. Further, since an Eli Lilly study report from the early 1970s reported single-dose toxicity at a 1-ppm level of Thimerosal – a level 33 to 100 times lower than the nominal 33-ppm to 100-ppm levels in Thimerosal-preserved vaccines, it is obvious that all Thimerosal-preserved vaccines cannot meet the “sufficiently nontoxic ...” safety standard set forth in 21 C.F.R. Sec. 610.15(a). In addition, all doses of these vaccines in distribution should be recalled and destroyed as the hazardous waste that they most certainly are (the EPA limit for mercury in a liquid solution is 0.2 ppm)
 - e.** For all vaccines that contain a level of Thimerosal that exceeds 0.1 ppm and are not in the revised recommended requirements, the U.S. government should also suspend their approvals until the vaccine maker can prove they are safe to give to those persons who are “non-excretors” and/or low excretors of mercury. In the case of those on the revised recommended requirements list with levels of Thimerosal (<0.1 ppm) that are on the list, their use should: **a)** require explicit informed consent prior to administration and **b)** be restricted to situations where the corresponding no-Thimerosal vaccines are temporarily not available because of a temporary production problem.

No-Thimerosal Diphtheria-Tetanus-Pertussis (DTaP) [Or, <i>in some cases</i> , a no-Thimerosal Diphtheria-Tetanus (DT) vaccine may be an option for those with proof of having had an infection with pertussis before the next dose of DTaP vaccine is scheduled.]	X	X
Hepatitis A (HepA) [Not cost-effective for general use; may be useful in conjunction with gamma globulin in an outbreak situation.]		
Hepatitis B (HepB) [Not cost-effective; disease risk almost non-existent; if exposed most children fully recover with <u>no</u> chronic infection; use increases risk of childhood MS ~ 4 years after initial series ends; at birth dose provides <u>no</u> immunity and may significantly harm to long-term ability of the child's immune system to differentiate self from other than self]	X	
Haemophilus influenzae type b (Hib) [Not in-use effective and appears to actually increase long-term risk to an invasive haemophilus influenzae infection from other strains as well as infection by other organisms; <u>not</u> cost effective.]	X	
Human Papillomavirus (HPV) [No proof of long-term safety and evidence of significant risks for serious side effects; does <u>not</u> provide protect the child from HPV infection by all strains or, in some cases (up to 20%), the vaccine strains; <u>no</u> evidence that vaccination is better at providing long-term immunity than having the natural disease; <u>no</u> proof that vaccination translates into protection from cervical cancer 30+ years later; <u>no</u> proof of long-term (>30 years) protection needed to justify use as an "anti-cancer" vaccine; <u>not</u> cost-effective.]		
Influenza (Flu) [No proof of in-use effectiveness in children; has a proven risk of mercury poisoning from doses that contain Thimerosal; live-virus formulation risks spreading influenza and/or creating more virulent strain and infects child with 3 related live influenza viruses. Moreover, a much safer dietary supplementation program exists using vitamin D-3 that protects against all strains of the human influenza instead of only 3 strains.]		
Meningococcal (MCV4) [Does <u>not</u> protect against the "B" strain that causes 25% to 50% of all cases; protection against A, C, Y & W-135 strains is <u>not</u> long-term (actually, <6 years) and the "protection" given effectively does <u>not</u> exceed 80% for the strains from which it may provide protection. Since risk is in populations where hygiene is a problem (1st-year college students in dorms; and military inductees in basic training; improved hygiene for the college students and protection from dirt inhalation during basic training for the military would seem to be more cost-effective.)		
Measles-Mumps-Rubella (MMR) {, Measles-Rubella, Measles, Mumps} [In the revised recommendations, options of giving each of these live-virus vaccines in different orders and combination will be suggested where, <i>because it is generally immunosuppressive</i> , the last dose recommended will be a measles only vaccine dose.]	X	X
Pneumococcal (PCV7) [Not long-term in-use effective; after 5 years cases increasing; adverse strain shift evident; MSRA strains invading niche; other disease organisms invading niche. Better strategy to treat cases with alternative "antibiotics" (e.g., olive-leaf extract and/or oil of oregano and naturopathic ear oils).]	X	
Poliovirus (IPV)	X	X
Rotavirus [Not cost effective; seems to cause the disease in everyone inoculated; side-effect risk <u>not</u> at least 10X lower than disease as it should be; when there was/is no vaccination program, most children were "immune" by age 5 <u>without</u> having a clinical case requiring medical intervention.]		
No Thimerosal Tetanus-Diphtheria {-Pertussis} (Td / {Tdap}) [In revised requirements, an option could be provided for the Tdap instead of the Td vaccine.]	X	X
Varicella [Not long-term effective; <u>not</u> societally cost-effective; the herpes varicella zoster (HVZ) vaccines cause more harm than they prevent chickenpox cases or delay shingles cases, since, <i>in general</i> , the vaccines, at best, only delay the 1st instance of the disease as chickenpox but increase the risk of recurrence as shingles, a much more serious and lethal outbreak of HVZ, in children and adults.]	X	

1. The reason for excluding a current vaccine in the Florida program from recommended use for all children and other key information are included in brackets "[]"

GENERAL REVISED CHILDHOOD VACCINATION REQUIREMENTS SCHEDULE

The following table presents a set of recommended vaccination requirements that address the time windows for all children who can be vaccinated and whose parents or guardians choose to have them vaccinated rather than seeking an exemption from vaccination.

Table 2. Suggested General Dosing Plan For Revised Florida Requirements

Vaccine	Dose Number	Current Florida Requirements	Revised Florida Requirements	Notes
DTaP (OR DT)	1	2 months	6-36 months	For those children who contract pertussis at any point during the this schedule, parents may either continue with the DTaP vaccine, since the vaccine is designed to provide protection against pertussis toxins and not pertussis per se, or switch to the DT vaccine because, <i>for almost all children who have pertussis and recover</i> , there is little risk of their harboring or being re-infected by pertussis. If, <i>after any DTaP shot</i> , the child gets a high fever, any neurological signs such as seizures or staring spells strong consideration should be given to discontinuing: a) all further DTaP shots and b) the Tdap, and switching to DT and Td shots.
	2	4 months	9-39 months	
	3	6 months	12-42 months	
	4	12-18 months	18-45 months	
	5	4-6 years	5-7 years	
Td (OR Tdap)		11-12 years	12-13 years	
MMR	1	12-18 months	---	Reviewing the effectiveness of the component viruses, the data shows that the current 2-dose MMR program is not effective for mumps since in the 2006 mumps outbreaks, 69% of those who contracted mumps were vaccinated. Thus, it may be better to remove mumps from the equation and only vaccinate against measles and rubella initially (hence returning to the MR, measles-rubella vaccine should be an allowed option and measles only should be allowed for families who choose to let their child get mumps & rubella. Then, since having rubella during pregnancy is the critical concern, only females who do <u>not</u> contract rubella in the 3 yr to 8-year period should be given a 2 nd (or 1 st) doses if they have not had rubella by age 8. Similarly, mumps vaccination need only be given to males who have not had mumps by age 10. In all instances, a 2 nd dose of measles should be given, at least 3 months after measles because measles is immunosuppressive.
	2	4-6 years	---	
MMR or MR or MEASLES ONLY (for those who want their sons & daughters to get rubella)	1		24-48 months	
RUBELLA (females only)	2,1		8-9 years	
MUMPS (males only)	2,1		9-10 years	
MEASLES OR POSITIVE TITERS (Measles vaccine IIF the titers test shows a lack of antibodies to measles)	2		10-11 years	A booster for measles vaccine is required only if a blood titer test shows a lack of measles antibodies.
Polio	1	2 months	7-36 months	Since the only risk for paralytic polio seems to be from imported polio virus and clinical cases of paralytic polio are almost non-existent, there is almost no risk in delaying the start of the polio series and spreading it out. However, IVP vaccines should not be given with any other vaccine.
	2	4 months	10-39 months	
	3	12-18 months	13-45 months	
	4	4-6 years	6-10 years	

Additional Vaccines That Are Not Required But Should Remain Available for Use

Though not in the required schedule, the following vaccines should remain available for childhood vaccination for those who may, under certain circumstances, decide to use them or for use in a serious outbreak/pandemic situation or for use in certain groups that have a high risk of contracting a serious case of the disease:

- Anthrax, if approved for use in children,
- Cholera,
- Hepatitis A (HepA),
- Hepatitis B (HepB),
- Haemophilus influenzae type b (Hib),
- Japanese encephalitis,
- Meningococcal (MCV4),
- Pneumococcal (PCV7),
- Rabies,
- Rotavirus,
- Tetanus Toxoid (TT),

- Typhoid Fever,
- Vaccina for Smallpox,
- Yellow Fever, and
- FDA-licensed and approved for use in children combination vaccines made from the revised list of required and optional (additional) component vaccines.

Vaccines That Should Be Removed From The Market

Based on the available information, no child should be vaccinated with the following vaccines:

- Avian Influenza,
- Influenza (Flu),
- Measles-mumps-rubella-varicella (MMRV), and
- Varicella,

REVISED RECOMMENDED CHILDHOOD VACCINATION REQUIREMENTS SCHEDULE FOR CHILDREN WHO ARE NOT BREASTFED FOR AT LEAST SIX MONTHS

The following table presents the suggested vaccination plan for infants who are not breastfed for at least 6 months post partum.

Table 3. Suggested Dosing Plan For Non-breastfed Children For Florida Requirements

VACCINE	DOSE NUMBER	CURRENT FLORIDA REQUIREMENTS	REVISED FLORIDA REQUIREMENTS
DTaP (OR DT)	1	2 months	6 month
	2	4 months	9 months
	3	6 months	12 months
	4	12-18 months	18 months
	5	4-6 years	4-5 years
Td (or Tdap)		11-12 years	12-13 years
MMR	1	12-18 months	---
	2	4-6 years	---
MMR or MR or MEASLES ONLY (for those who want their sons & daughters to get rubella)	1		24 -27 months
RUBELLA (females only)	2,1		8-9 years
MUMPS (males only)	2,1		9-10 years
MEASLES OR MEASLES TITER	2		10-11 years
POLIO	1	2 months	7-8 months
	2	4 months	10-11 months
	3	12-18 months	13-14 months
	4	4-6 years	6-7 years

Some Additional Thoughts on Alternate Vaccine Schedules

The issue of an appropriate vaccine schedule is a very complex one that needs to involve individual choice and informed consent.

Each parent needs, with the help of their pediatrician or other health care provider, to decide what is right for their child.

Each parent needs to find a pediatrician or other health care provider that is willing to take the time to work with him or her to decide what is right for that child.

If a doctor refuses to work with parents then the parents should find a new doctor; and it would not hurt to tell other parents which doctors are willing to work with parents and which are not so that the later can be avoided.

Additionally, every State needs to have a waiver for any one who wishes to use it.

All waiver decisions need to be made with informed consent, based on:

- Accurate and complete information for each vaccine about each vaccination risk and its approximate rate;
- The theoretical benefits of each vaccination, their minimum and typical durations, the need for, availability of and risks with booster doses, and the percentage of those vaccinated who are protected for the minimum duration; and
- The probability of infection, the duration of infection, the nature and probability of each adverse infection outcome, and the preventive/supportive dietary inputs that are known to minimize disease duration and minimize the risk of serious disease complications if they choose not to vaccinate or to defer vaccination until some later date,

without any form of pressure on the decisions being made.

That being said, here are some key issues concerning the childhood vaccination schedule for U.S. Children:

- ❖ All vaccines that have Thimerosal (mercury) are to be avoided^{A1}.
- ❖ One must think long and hard about any influenza vaccination because many major studies have shown this vaccine has little or no efficacy^{A2}.

^{A1} The number one offender in this category in the US is the influenza vaccine. Most influenza vaccine in the US has full dose Thimerosal (25 µg/adult dose). Do not use any influenza vaccine that comes in multi-dose vials. Insist on single dose "no Thimerosal" influenza vaccines. Live nasal influenza vaccine does not contain Thimerosal, but by the company's clinical trial outcomes, those taking the live vaccine need to be quarantined for three weeks to prevent the spread of any of the three vaccine strains of influenza or mutated forms thereof to those who are unvaccinated especially those particularly vulnerable to being damaged by influenza such as anyone with a respiratory disorder, anyone with AIDS, anyone who has had recent surgery, anyone with a transplanted organ, and anyone with a suppressed immune system. Therefore it appears to me to be unethical to use this vaccine on anyone not agreeing to be quarantined for 21 days, which currently seems to be everyone taking this vaccine.

^{A2} This is particularly true when the vaccine in use does not match all of the strain of influenza that are circulating in the USA during the current "flu season". This was true for the 2007-2008 flu season and, in fact, is generally true more than half of the time for the flu vaccines given in the U.S. flu season.

Further, recent studies have shown that giving adequate doses of vitamin D-3 (1,000 to 5,000 IU daily) gives over 90% protection against all strains of human influenza.

In addition, Tamiflu is a prescription medication that: **a)** *when taken prophylactically*, prevents the flu at a very high rate of protection though it has significant psychotropic side effects in some who take it in this manner, and **b)** also is recommended as a treatment of flu provided the person infected starts taking it within 2 days of infection. If taken in the first two days of getting the flu, it greatly shortens the course and makes it much milder. This medication can be obtained before the flu season and it has a shelf life of 10 years especially if kept in the refrigerator.

- ❖ Pregnant women should consider not taking the influenza vaccine or any vaccine as good OB practice suggests exposure to as few foreign substances during pregnancy as is possible. Pregnant women should definitely refuse any vaccine with any mercury as developing fetuses have been repeatedly shown to be very sensitive to damage by mercury.
- ❖ When considering any influenza vaccine, one should be aware that no more than about 10 children per year out 4.5 million births die of influenza and thus the risk of influenza death in childhood is very, very rare.
- ❖ DTaP vaccination is probably warranted and it should be considered^{A3} in early childhood when whooping cough is far worse in children than it is later in life.
- ❖ No routine vaccines should be given to any child who is deemed to not be in good health at the time of the vaccination^{A4}.
- ❖ Polio vaccine is probably warranted for children unless they have a known immune deficiency. Only the IPV should be used.
- ❖ Strong consideration to ending the policy of giving routinely administering hepatitis B (Hep B) on the day of birth should be considered^{A5}.
- ❖ MMR vaccination considerations: (a) Strong consideration should be given to taking the measles vaccine due to the fact that although death from this disease is rare, measles can be a somewhat severe disorder in some individuals^{A6}; (b) Rubella vaccination should be considered for girls because pregnant women who lack this immunity can put their developing fetuses at risk for rubella syndrome which is a devastating problem for babies if they contract rubella during pregnancy^{A7}. (c) Mumps vaccination should be strongly considered for administration to boys who have not had mumps by age 9^{A8}.

These options should be considered when one is thinking about giving a flu vaccine.

In conclusion influenza vaccine should not be a part of the routine vaccine schedule. It perhaps could be an option but only if it is free of Thimerosal and then only for children over the age of five.

Finally, the live influenza vaccine should be banned immediately due to the fact that a person taking the live influenza can give the flu to others around them, It is advised that anyone taking the live flu vaccine be quarantined for 3 week and especially should avoid contact with any susceptible person of which the population is full of such persons. Therefore in all practicality the vaccine must be banned for the "social contract" that the public health hold so dear. Additionally, the general use of live influenza vaccine may increase the risk developing hybrid influenza strains including bird flu because it makes it far more likely that a person would have two strain of flu at once allowing for recombination between the strains.

^{A3} A less aggressive schedule of DTaP might be considered such as one shot at 6, 9 and 12 months of age. It is crucial to watch each child for several days following these shots. If the child gets a high fever, any neurological signs such as seizures or staring spells strong consideration should be given to discontinuing all further DTaP shots. Serious consideration to not giving any vaccine to children over the age of 7 should be given because whooping cough is rarely as serious in disease in older children and adults.

^{A4} If the child has even a cold it is prudent to delay the vaccinations until the child is fully recovered. Strong consideration should be given to not giving any vaccines to any child who has or is suspected of developing any neurodevelopmental or neurological disorder..

^{A5} A possible exception to this is if the mother giving birth is Hep B positive. Most if not all US hospitals test the hepatitis status of their pregnant women. On a few per 1,000 women of childbearing age in most of the US are positive for Hep B. In these cases, an infectious disease consult should be done to determine whether it is better to give the newborn: a) Hep B vaccine or b) Hep B hyper-immune gamma globulin in an attempt to prevent Hep B transmission to the newborn. Hep B vaccination should be delayed until the teenage years when an evaluation of each should be done by the parents and their doctors to determine the risk of hepatitis B exposure; only those engaging in high-risk exposure (such as having unprotected sex with multiple sex partners or using drugs are candidates for contracting hepatitis B in adolescence. Healthcare providers, food handlers, and first responders should be offered but not required to take Hep B vaccination.

^{A6} Since measles temporarily suppresses the immune system, it is probably best to ensure that no vaccines be given for at least one year following a measles vaccination. Thus, a good time to give the measles vaccine might be at about 3 years of age so as to put it well beyond the usual onset time for autism. If a booster for measles vaccine is considered at around 10 years of age, it should only be given after blood titers are done and the titers test shows an absence of a protective level of measles antibodies.

^{A7} This vaccination is probably best given in the early teenage yeas as pregnancy before that is unlikely and to give rubella vaccine before that risks that the protection may not last long enough to be of use. Women planning pregnancy should consider having their titers check prior to getting pregnant and they should consider a booster prior to becoming pregnant. It is very important that pregnant

- ❖ Chicken pox vaccine: Chicken pox vaccination should be totally optional because the chickenpox disease is usually relatively mild^{A9}.
 - ❖ Rotavirus vaccine: Though this vaccine is designed to protect against a common form of infant diarrhea, it should not be mandated for general use^{A10}.
 - ❖ Gardasil (HPV) vaccines: Since, by the companies' own studies, the HPV vaccine have a very low efficacy, there is no proof that they are effective in preventing cervical cancer in most of those vaccinated with the HPV vaccines, or that the initial 3-shot regimen provides any long-term protection against either the vaccine's HPVs or against cervical cancer, this vaccine should not be administered to children^{A11}.
 - ❖ A high priority should be given to replacing all live vaccines with inactivated ones ASAP.
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End of Appendix A

women not take the rubella vaccine while they are pregnant as it may pose a significant risk to the fetus. Women taking rubella vaccine booster prior to becoming pregnant should take necessary precautions to ensure that they do not become pregnant for at least 3 months after taking the rubella vaccine. Except under unusual circumstances, boys need not be administered the rubella vaccine.

^{A8} Giving a mumps vaccine should be considered because mumps can cause cryptorchism in young adult males. This vaccine should probably be given after ten years of age because mumps is not a major problem in young boys and the immunity is often not life long. The worse thing to do is to postpone mumps in boys until their late teens or early twenties. Perhaps adequate titers should be confirmed in the late teen-age years and re-boosting should only be considered when the titers are inadequate. Except under unusual circumstances, girls need not be administered the mumps vaccine. For those wanting to give all three vaccines to their child, one alternative would be: rubella vaccine at 27 months, mumps at 30 months and measles at 33 to 36 months.

^{A9} There is considerable evidence that allowing some members of a population to get chickenpox will actually lessen the chance of that population developing shingles. Pregnant women may want to check their titers against chicken pox since there is some evidence that chicken pox may pose some threat to their developing fetus, although this evidence is equivocal. Chickenpox and, in fact, any vaccine should not be given during pregnancy. Also, no live-virus vaccine should be given to mothers: **a)** after delivery, **b)** when they are nursing, or **c)** when their children are under 2 years of age.

^{A10} Though rotavirus is common in the U.S., very few, if any, infants die from having a rotavirus infection. The first rotavirus vaccine was introduced a few years ago (in 1998) and then withdrawn due to the fact that it caused an unacceptable rate of intussusceptions and other gastrointestinal side effects. Some of these side effects are very serious or life threatening. The newly introduced rotavirus once again has been associated with a high rate of these and other serious side effects. The rotavirus vaccines may well be appropriate for use in third world countries where the lack of clean water results in many deaths due to the disease but serious consideration should be given to declining this vaccine in the US for routine use since this disease is relatively benign here.

^{A11} Most HPV strains that can cause genital warts and cervical infection are not covered by these vaccines, which are being recommended for administration to young girls at around nine years of age. Moreover, the length of the protection it provides is not known. Moreover, vaccination does not alleviate the necessity for PAP smears since it only claims to protect against a very small percentage of cervical cancer cases. Death from cervical cancer in women who have regular PAP smears is quite rare. The vaccine has only been given to about 2 million girls and there have already been reported many deaths, and other serious reactions following its use. No long-term safety studies have been done. Serious consideration should be given to not using this vaccine especially in young girls, at least until long-term efficacy and safety studies have been done and long-term safety and effectiveness have been proven. At this time, boys should not be given an HPV vaccine.

APPENDIX B

DRAFT FLORIDA INFORMED-CONSENT FORM FOR VACCINATION

The text that follows contains a proposed Informed-Consent Form for Florida in draft form.

FLORIDA VACCINE INFORMED CONSENT FORM

Vaccines have and will continue to play an important role in helping to prevent infectious diseases. Therefore, the State of Florida has passed legislation requiring all children going to school to either be vaccinated with the following vaccines or to sign a waver stating that the parent or guardian has been fully informed as to the benefits and risks of vaccination and has in the basis of this information and their own personal beliefs elected to sign a waiver of these vaccines. The **only** vaccines that are required to be: a) taken or b) waived in the State of Florida are (1) diphtheria, (2) tetanus, (3) polio, (4) measles, (5) rubella, and (6) mumps. It is a violation of your rights and it is a crime in Florida for any health care provider, public health personnel, school or other official to try to tell that any other vaccine are required for your child or for them to fail to tell of your right to waiver any vaccine. There are a large number of other vaccines that are totally optional under Florida law. These should be fully discussed with your doctor or other health care provider to help you to make an informed consent decision as which one are right for you and your child. No vaccine can be given to your child without first getting your informed consent. It is a violation of your rights and it is a crime in Florida for anyone to fail to provide you with complete information on any vaccine or to try to force or coerce you in any way regarding your rights or in freely making an informed consent decision concerning the vaccination of your child.

If you feel that anyone has tried to violate your rights concerning your decisions on vaccines or if you have any unanswered questions please call: 1-8nn-eee-mmmm.

Any suspected adverse reaction to vaccination is to be reported to a national database called The Vaccine Adverse Events Reaction System. If you feel that your child has suffered an adverse reaction to any vaccination and your health care provider has failed to report this to the database, please call 1-8ii-jjj-kkkk.

The United State Government has a no fault program to compensate any person who can show that they have been damaged by covered vaccines. This fund is paid for by a small tax paid on each vaccine taken. If you think you or your child has been damaged by a vaccine you are invited to petition this program for compensation. The program will pay for all expenses including legal and medical expenses incurred by petitioning the program win or loose so long as the petition is brought in good faith however, all claims must be file within three years of the first symptom of the damage. For help in filing a claim in this program please call 1-8jj-kkk-llll.

After reading, having studied the information provided on each vaccine and having had your questions answered, please put your initials in the appropriate box, and then sign, date, and print you name below your signature for the option that you have selected:

PERMISSION TO VACCINATE

By signing below, I freely and with informed consent understand that, if any vaccine is a live-virus vaccine, my vaccinated child should be kept from contacting other people for from 14 to 28days after inoculation, and I am now consenting to have my child vaccinated today with the following vaccines:

Signature of parent or guardian

today's date

Printed name of parent or guardian

WAIVER OF VACCINATION

By signing below, I freely and with informed consent decline the following vaccines for my child. I understand that, when there is a declared epidemic of the disease for which I have declined to vaccinate my child, my child **may** be asked to stay home from school during the epidemic **unless** he/she has had the disease and I am declining the following vaccines:

Signature of parent or guardian

today's date

Printed name of parent or guardian

End of Appendix B
