VACCINES

NOT SAFE, NOT EFFECTIVE

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The information contained in this report is only a small fraction of what is available on HealthAlertPhilly.org/VACCINES.htm

Suggestion: This report is best utilized by incorporating it into a 3-ring binder, using tabs below:

- **General** – RFK Jr.’s “10 Facts”, Our Goals, Vaccine Basics, and 1-pagers
- **Dr. Lawrence Palevsky, MD** – one of U.S.’s foremost holistic pediatricians
- **Immunity** – Compromised as a result of vaccines
- **CDC’s Vaccine Ingredients List (Excipient Summary)** – Many ingredients are toxic, such as aluminum, mercury, formaldehyde, etc.
- **U.S. Vaccine Injury Table** – Only lists injuries observed short-term
- **MMRV Vaccine Package Insert** – Note Sec 5.8 on Virus Transmission and Sec. 13 on vaccine risks, including: cancer, DNA damage, birth defects, miscarriage, or infertility. All vaccines have a Section 13
- **History of Vaccines** – Improved sanitation, diet, and living conditions saved lives, not vaccines, summary of Dr. Suzanne Humphries’ book, Dissolving Illusions
- **Polio Vaccine** – A good example of how easily vaccines can be contaminated
- **Fraud** – CDC whistleblowers, Merck whistleblowers, Merck shingles lawsuit, etc.
- **Alzheimer’s & Autism** – Connecting toxins, particularly aluminum, to encephalitis and other brain damage, including Alzheimer’s and autism
- **Military** – Used as pincushions and paying the price
- **Legality of Vaccine Court** – Unequal justice for victims of vaccines
- **Informed Consent laws** – Non-enforcement and therefore in violation
- **Patient Refusal Form** – An example of many pediatricians’ policy of dismissing patients who do not partially or fully vaccinate their children
- **Reference Information** – News, Books, Studies, Articles, Groups, Movies & Videos
10 Facts Every Parent Needs to Know About Vaccinations

“The greatest crisis that America faces today is the chronic disease epidemic in America’s children”

—Robert F. Kennedy, Jr., Chairman, Children’s Health Defense

The epidemic of poor health in American children started after 1986, coterminous with the passage of the National Childhood Vaccine Injury Act which resulted in an explosion of the vaccine schedule. For American kids born in 1986, only 12.8% had chronic diseases. That number has grown to 54% among the vaccine generation (those born after 1986) in lockstep with the expanding vaccine schedule.

1. Children have never been sicker than today. 54% of American children have serious chronic health conditions according to a 2011 survey funded by the U.S. Department of Health and Human Services (HHS). Conditions include neurodevelopmental disorders, asthma, allergies, mental health/behavioral disorders and obesity.

2. A growing body of peer-reviewed animal and human studies link childhood chronic illness epidemics to vaccines—including Vaccine Adverse Event Reports and manufacturers’ product inserts. The world’s most aggressive vaccine schedule has not given our country the world’s healthiest children. We now rank 35th in overall health outcomes—just behind Costa Rica, making the U.S., by most measures, including infant mortality, the sickest in the developed world.

3. Vaccine manufacturers and healthcare providers cannot be held liable for vaccine injuries. In 1986, Congress passed the National Childhood Vaccine Injury Act freeing companies from liability for injuries resulting from childhood vaccines—“no matter how toxic the ingredients, how negligent the manufacturer or how grievous the harm.” The act created the National Vaccine Injury Compensation Program (NVICP) that is governed by HHS. Over $4.2 billion has been paid by consumers for vaccine injuries. The U.S. vaccine schedule has more than tripled since the 1986 Act.

4. Vaccines CAN and DO cause injuries. The message that vaccine injuries are rare is not supported by facts and anecdotal evidence. An HHS-sponsored study by the Agency for Healthcare Research and Quality found that vaccine injuries, when tracked using electronic medical records, occurs in 1 in 39 vaccines given.

5. Post-licensure vaccine safety surveillance is failing the American people and children around the world. The Vaccine Adverse Event Reporting System (VAERS), where doctors and patients voluntarily report adverse vaccine events, received 58,381 reports in 2018, including 412 deaths, 1,237 permanent disabilities, and 4,217 hospitalizations. An HHS-funded review of VAERS concluded that “fewer than 1% of vaccine adverse events are reported” to VAERS. The CDC has refused to mandate or automate VAERS reporting.
6. None of the vaccines on the U.S. CDC recommended childhood vaccine schedule were tested against an inert saline placebo in clinical trials. Vaccines are regulated by the FDA as “biologics” and are not always put through the same level of safety testing as new pharmaceuticals. Pre-licensing clinical trials are sometimes as short as a few days or weeks, making it impossible to evaluate longer-term outcomes such as autoimmune illness or cancer. Clinical trials for Merck’s Recombivax hepatitis B vaccine administered on the first day of life monitored fewer than 150 infants and children for just five days after each dose.

7. HHS has ignored its statutory obligations to study vaccine injuries and improve vaccine safety. In 1986, Congress—recognizing that drug companies no longer had any incentive to make vaccines safe—ordered HHS to study vaccine injuries, work to improve vaccine safety, and report to Congress on its progress every two years. It has not sent one safety report to Congress in over 30 years.

8. Vaccines are neither completely safe nor effective and the concept of “herd immunity” is a myth. About 2%–10% of healthy individuals fail to mount antibody levels to routine vaccines, and vaccine-induced immunity wanes over time. Highly vaccinated populations frequently have outbreaks of pertussis, mumps, measles, and chickenpox. Many diseases were on the decline prior to the development of vaccines. Civil engineers, not vaccines, produced the large gains in life expectancy over the 20th century.

9. CDC Vaccine-Researcher-Turned-Whistleblower Dr. William Thompson, Ph.D. was denied the ability to testify regarding scientific fraud and destruction of evidence by senior CDC officials in critical CDC vaccine safety studies regarding an association between childhood vaccines and autism. Thompson invoked federal whistleblower status and alleges that the CDC destroyed evidence that black boys are 3.36 times more likely to develop autism if they receive the MMR vaccine before age three.

10. Conflicts of interest undermine children’s health. CDC, frankly, is a vaccine company; it owns 56 vaccine patents and buys and distributes $4.6 billion in vaccines annually through the Vaccines for Children program. Further, Pharma directly funds, populates and controls dozens of CDC programs through the CDC Foundation. The CDC and FDA have become dominated by the interests of vaccine manufacturers rather than acting in the public interest. The vaccine industry is forecasted to exceed $48 billion by 2025.

Facts About Children’s Poor Health:

- Over half of America’s children (54%) have one or more chronic health conditions.
- One in every two (49.5%) 13-18 year olds have been diagnosed with at least one mental health disorder.
- One in every six American children (17%) has a developmental disability according to the CDC.
- One in every eight American children (14%) requires special education services.
- One in twelve American children has asthma (8.4%).
- One in every 13 American children has at least one food allergy and two fifths of those with food allergies have a history of severe reactions including deadly peanut allergies.
- One in 285 U.S. children will be diagnosed with cancer before their 20th birthday. Each year, an estimated 15,780 U.S. children and adolescents ages 0 to 19 will be diagnosed with cancer.
 OUR GOALS

• End the use of vaccines

• End mandatory vaccines

• Mandate long term health studies of vaccines

• Mandate vaccine studies using true placebos

• Mandate vaccine studies comparing vaccinated vs unvaccinated population

• Full disclosure regarding Pennsylvania’s exemption law - Currently, parents are being bullied into vaccinating their children

• Full disclosure to parents and patients about vaccine safety and testing, including, but not limited to: The U.S. Vaccine Injury Table, The CDC Excipient (Ingredients) List, and FDA-required Vaccine Package Inserts

• Full access to doctors – In Pennsylvania, those who are not vaccinating their children partially or fully are being denied access to health care by many pediatricians and some doctors.

• Full access to the U.S. court system, not limited to U.S. Vaccine Court
VACCINE BASICS

Infectious diseases and their role in developing a healthy immune system:

- provide permanent immunity
- constitute a vital rite-of-passage for a healthy immune system
- provide mothers with antibodies that they pass on to their unborn babies
- best managed through healthy diet and living conditions, not toxic vaccines

Vaccines and their fundamental flaws:

- provide temporary immunity, if any, as in the case of flu vaccines
- re-engineer and permanently damage our natural immune system
- can cause "vaccine-strain" versions of the very diseases their manufacturers claim to prevent (Sec.5.8 of vaccine package inserts)
- can cause immune dysfunction, neurological damage, developmental disorders, chronic disease, DNA mutation, suicidal thoughts, and death
- contain a long list of toxic ingredients that can cause permanent damage and death, such as: mercury (thimerosal) in flu vaccines, aluminum, formaldehyde, barium, phosphates, MSG, polysorbate 80, DNA virus, human fetal tissue, monkey kidney cells, calf serum, detergents, etc.

Substandard research by vaccine industry, and weak oversight by U.S. government:

- held to a lower standard than other pharmaceuticals
- no studies for vaccines’ potential to 1) cause cancer, 2) damage DNA, or 3) impair fertility (Sec.13 of vaccine package inserts)
- no long-term studies (over 6 months) have been conducted
- no studies comparing vaccinated populations to unvaccinated populations
- no double blind ‘placebo’ studies, instead test groups receive different sets of vaccine ingredients
- both industry and government health agencies have engaged in fraud and data manipulation, according to whistleblowers and researchers

Government documents prove that vaccines are neither safe nor effective:

U.S. Vaccine Injury Table: http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf
FDA Vaccine Package Inserts: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
**VACCINE FACTS**

- Vaccines contain seriously toxic ingredients that have been linked to cancer, brain damage, immune dysfunction, chronic illness, infectious disease, and death.

- Section #13 of every vaccine package insert admits that the vaccine has NOT been evaluated for its potential to: 1) cause cancer, 2) damage DNA, or 3) impair fertility, in other words, no long term studies are conducted or taken into consideration.

- From 1955-1963, over 98 million Americans received polio vaccines contaminated with a cancer-causing monkey virus (SV40), which is still found in cancer tumors today.

- In 1986, Congress granted the vaccine industry blanket immunity from lawsuits and created a special Vaccine Court, which is staff by U.S. Attorneys who represent the government and industry, not victims.

- To date, over $4.2 billion dollars has been awarded to the victims of vaccines, a fraction of what victims would get in the normal court system.

- As few as 1% of all vaccine injuries are reported to the federal program, the Vaccine Adverse Event Reporting System (VAERS), due to poor doctor training.

- Doctors can and do receive financial incentives for vaccinating their patients.

- The CDC owns several patents on vaccines, is the largest buyer of vaccines, and has a revolving door with the vaccine industry.

- In 2004, CDC scientist and whistleblower, Dr. William Thompson, admitted through his attorney, that the MMR vaccine can cause autism.

- In 2010, Merck whistleblowers Krahling and Wlochowski sued the vaccine maker, alleging fraud in testing the MMR vaccine.

- Hundreds of independent studies and countless articles, books, documentaries, scientists, researchers, and doctors report fundamental problems with vaccines.

- Since the 1700's, it has been observed that healthy living conditions save lives, not vaccines. *(Dissolving Illusions by Dr. Suzanne Humphreys)*

Reference website: [HealthAlertPhilly.org/VACCINES.htm](http://HealthAlertPhilly.org/VACCINES.htm)
PARENTS & PATIENTS ARE **NOT INFORMED**...

- ... that in Pennsylvania, students can qualify for an exemption from vaccines.
- ... that vaccines do not confer permanent immunity, as natural exposure to infectious diseases does.
- ... that vaccines can spread the very disease they are meant to cure.
- ... that the (short-term only) harmful health effects of vaccines are published in the U.S. HRSA *Injury Table*, the CDC *Excipient Table* (vaccine ingredients), and the FDA *Vaccine Package Inserts*.
- ... that Section #13 of every vaccine package insert, admits that no vaccines, *not one*, have been evaluated for its potential to 1) cause cancer, 2) damage DNA, or 3) impair fertility in humans, meaning no long term studies were considered.
- ... that the “side effects” of some vaccines can result in SIDS (Sudden Infant Death Syndrome), as well as debilitating health consequences, including brain damage from encephalitis, that can result in Alzheimer’s and autism.
- ... that in 2004, CDC senior scientist and whistleblower Dr. William Thompson admitted through his attorneys that the MMR vaccine can cause autism.
- ... that if their children suffer an injury, they will not have full access to the U.S. legal system; that they will be required to file their lawsuit in a special federal Vaccine Court, where U.S. DOJ Attorneys will defend the vaccine industry and government health agencies *against* vaccine victims. And the awards, if any, will be a fraction of what they would receive in the usual U.S. court system.
VACCINES HAVE NOT SAVED MILLIONS OF LIVES

The history of vaccines is one of fraud and filth. Starting in the 1700s the medical profession, drug makers, and government officials first conspired to make profits at the expense of the public's health. They claimed credit for the decrease in deaths from infectious diseases when the real cause was improved sanitation and living standards. Many researchers now believe that the polio epidemic in the 1950s was caused by DDT and the polio vaccine itself. In fact, in 1955 Cutter Laboratories made a vaccine that gave over 120,000 people a virulent form of the disease. Worse yet, from 1955–1963 over 98 million Americans (plus people in other countries) received a polio vaccine that was contaminated with a cancer-causing monkey virus called SV40, which is still being found in cancer victims. Today, we have an epidemic of immune dysfunction, developmental disorders, disease, and chronic illness, all with links to vaccines. Yet, our federal health agencies keep promoting them. And that has to do with the money being made by business and industry, the medical profession, and the federal government itself, including the CDC, who owns several vaccine patents and is one of the largest purchaser of vaccines. Sources include, “Dissolving Illusions” by Dr. Suzzane Humphreys.

United States: Disease Mortality Rates

Despite common belief, infectious disease deaths DECREASED 85-90% BEFORE VACCINES were introduced in the US. Diseases WITHOUT VACCINES -- including Scarlet Fever, Tuberculosis, Cholera and Typhoid -- followed the SAME trend.

* “Trends in the Health of Americans During the 20th Century. Pediatrics

www.LearnTheRisk.org/diseases
# VACCINE DOSES for U.S. CHILDREN

<table>
<thead>
<tr>
<th>Year</th>
<th>Doses</th>
<th>Vaccines</th>
</tr>
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<tbody>
<tr>
<td>1960</td>
<td>5</td>
<td>Polio, Smallpox, DTP</td>
</tr>
<tr>
<td>1983</td>
<td>24</td>
<td>DTP (2 months), OPV (2 months), DTP (4 months), OPV (4 months), DTP (6 months), MMR (15 months), DTP (18 months), OPV (18 months), DTP (4 years), OPV (4 years), Td (15 years)</td>
</tr>
<tr>
<td>2018</td>
<td>72</td>
<td>Influenza (pregnancy), DTaP (pregnancy), Hep B (birth), Hep B (2 months), Rotavirus (2 months), DTaP (2 months), HIB (2 months), PCV (2 months), IPV (2 months), Rotavirus (4 months), DTaP (4 months), HIB (4 months), PCV (4 months), IPV (4 months), Hep B (6 months), Rotavirus (6 months), DTaP (6 months), HIB (6 months), PCV (6 months), IPV (6 months), Influenza (6 months), Influenza (7 months), HIB (12 months), PCV (12 months), MMR (12 months), Varicella (12 months), Hep A (12 months), DTaP (18 months)</td>
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*In 1986, pharmaceutical companies producing vaccines were given full federal protection from lawsuits resulting from vaccine injury or death via the Childhood Vaccine Act passed by Congress. If vaccines are so safe, why did they need a law to protect from liability? After this law, vaccines became **HIGHLY** profitable. There are almost 300 vaccines in development, and mandatory vaccine laws for children – and **ADULTS** – being pushed in most states.*

The US gives 2-3x more vaccines to children than most developed countries, yet we have skyrocketing rates of childhood issues that are **NOT** seen in other countries. Things like asthma, childhood diabetes, food allergies, childhood leukemia, developmental delays, tics, ADHD, autism, lupus, arthritis, eczema, epilepsy, Alzheimers, brain damage, etc... **It’s NOT a coincidence**

Vaccines contain toxic chemicals that do **NOT** belong in our bodies, such as aluminum, (known to cause brain and developmental damage even in small doses), polysorbate 80, MSG and formaldehyde (known to cause cancer in humans).

**RESEARCH, don't REGRET**

[www.LearnTheRisk.org](http://www.LearnTheRisk.org)
DO YOU KNOW WHAT’S IN A VACCINE?

NONE OF THESE SHOULD BE INJECTED INTO YOUR BODY

Aluminum
Known to cause brain damage at all doses, linked to ALZHEIMER’S DISEASE, dementia, seizures, autoimmune issues, SIDs and cancer. This toxin accumulates in the brain and causes more damage with each dose.

Beta-Propiolactone
Known to cause CANCER. Suspected gastrointestinal, liver, nerve and respiratory, skin and sense organ POISON.

Gentamicin Sulphate & Polymyxin B [antibiotics]
ALLERGIC reactions can range from mild to life-threatening.

Genetically Modified Yeast, Animal, Bacterial and Viral DNA
Can be incorporated into the recipient’s DNA and cause unknown GENETIC MUTATIONS.

Glutaraldehyde
Poisonous if ingested. Causes BIRTH DEFECTS in animals.

Formaldehyde [formalin]
Known to cause CANCER in humans. Probable gastrointestinal, liver, respiratory, immune, nerve and reproductive system POISON. Banned from injectables in most European countries.

Latex Rubber
Can cause life-threatening allergic reactions.

Human and Animal Cells
Human DNA from aborted BABIES. Pig blood, horse blood, rabbit brains, dog kidneys, cow hearts, monkey kidneys, chick embryos, calf serum, sheep blood & more. Linked to childhood leukemia and diabetes.

Mercury [thimerosal]
One of the most toxic substances known. Even if a thermometer breaks, the building is cleared and HAZMAT is called. Tiny doses cause damage to the brain, gut, liver, bone marrow, nervous system and/or kidneys. Linked to autoimmune disorders, and neurological disorders like AUTISM.

Monosodium Glutamate [MSG]
A toxic chemical that is linked to birth defects, developmental delays and infertility. Banned in Europe.

Neomycin Sulphate [antibiotic]
Interferes with vitamin B6 absorption which can lead to epilepsy and brain damage. Allergic reactions can range from mild to life-threatening.

Phenol/Phenoxyethanol [2-PE]
Used as anti-freeze. TOXIC to all cells and capable of destroying the immune system.

Polysorbate 80 & 20
Known to cause CANCER in animals and linked to numerous autoimmune issues and infertility.

Tri(n) Butylphosphate
Potentially toxic to the kidney and nervous system.

www.LearnTheRisk.org
The DTaP vaccine* insert lists SUDDEN INFANT DEATH as a side effect

*The DTaP vaccine is given to babies at 2, 4, 6 and 15 months.

HIGHLIGHTS OF PRESCRIBING INFORMATION
INFANRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)

6.2 Postmarketing Experience
In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for INFANRIX since market introduction are listed below. This list includes serious events and events that have a plausible causal connection to INFANRIX.

227 Cardiac Disorders
228 Cyanosis.
229 Respiratory, Thoracic, and Mediastinal Disorders
230 Apnea, cough.
231 Skin and Subcutaneous Tissue Disorders
232 Angioedema, erythema, pruritus, rash, urticaria.
233 General Disorders and Administration Site Conditions
234 Fatigue, injection site induration, injection site reaction. Sudden Infant Death Syndrome.

Source: fda.gov

LearnTheRisk.org
Know The Difference Between:
A Vaccine Information Statement & The Manufacturer's Package Insert

Vaccine Information Statement

DTaP Vaccine

What You Need To Know

1. Why get vaccinated?

1. Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

Diphtheria causes a thick coating in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus needs to feed in the third of 1 to 2 and 3 doses.

Tetanus (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus needs to feed in the third of 1 to 2 and 3 doses.

Pertussis (Whooping Cough) causes coughing spells so that there is little for air to enter, sleep, or breathe. These spells can last for weeks.

- It can lead to pneumonia, vomiting (vomiting and vomiting spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases.

Children ages 7 years and older should get a DTaP vaccine, and parents should give the 4th dose of DTaP if they stop the vaccine.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2. Who should get DTaP vaccine when?

Children should get 4 doses of DTaP vaccine, one dose at each of the following ages:

- 2 months
- 4 months
- 6 months
- 15-18 months
- 4 to 6 years

DTaP may be given at the same time as other vaccines.

Package Insert

VIIs are printed handouts from the CDC and lack information on the vaccine. Usually your doctor will give you one for each vaccine, and it's even printed on bright pretty paper.

VPI (vaccine package insert) is what you need to request from your doctor. This covers almost everything about the vaccine, including important topics such as adverse reactions, lack of studies, viral shedding, carcinogenesis, etc. It is usually 10+ pages long. If your doctor says they can't provide it, then see all package inserts at https://cfcapital.com/vaccine-inserts-human/
Dr. Lawrence Palevsky, MD, testifying at the Legislative Informational Forum, an informational forum on the science behind vaccines at the Connecticut state Capitol.

My name is Dr. Lawrence Palevsky, I’m a pediatrician, originally trained at NYU school of medicine. Graduated in 1987. Finished my residency at Mt. Sinai hospital in New York in 1990. Did a fellowship at the Bellevue Hospital in the outpatient department. The first nine years of my career were spent in ER’s running an intensive care unit, working in a neonatal intensive care unit, working in-patient in the hospital, working in a clinic and eventually having a private practice.

In 1983, when I started medical school, I was taught vaccines were safe and they effective and give them, but I was not taught about any of the science around their safety or any of the studies around how safety were done. And it wasn’t until 1998, that a mother came up to me and said, "Dr. Larry, did you know there's mercury in vaccines?" And I said, "No, I did not."

And as a medical student I was trained to critically think. If you see an observation you go after it and try to figure out if there’s a question to ask. So instead of just ignoring it, I looked further into the vaccine ingredients.

And I found that there were a number of vaccine ingredients that in animal studies were proven to be very dangerous to animals and I didn’t understand why these same ingredients were actually in vaccines.

I was starting to hear stories from parents, not dozens, not hundreds, but thousands of stories from parents who took a very healthy child into their doctor’s office and then found that their child lost much of their health whether it was their speech, whether it was seizures, whether it was death, whether it was asthma, allergies, eczema, whether it was autism, whether it was learning disabilities, whether it was inflammatory bowel disease, autoimmune diseases.

And every one of those parents were told it had nothing to do with the vaccine, every single one. And this continues today. But yet, when I look at the ingredients that are in the vaccines, I have the science to actually explain how these medical problems could be happening in these children.
Today 1 child in 5 is learning disabled. In 1976, it was 1 in 17. 1 in 6 under age 8, 1 in 2 adolescents, and 1 in 4 young adults is diagnosed with a mental, behavioral, or emotional disorder. 1 in 20 children under the age of 5 have seizures. 1 child in 40 develops autism.

The number of cases of children and adults with autoimmune diseases is rising exponentially. It's one of the highest rising diseases in this country. And the vaccine ingredients, if you are willing to look at them and understand how they work when they are injected into the body, can be seen to be responsible for every single one of these cases.

So, what are these ingredients? Well, when I was in medical school, we were taught that the body has something called the blood-brain barrier. The blood-brain barrier is like Fort Knox to the brain. Elements of the blood stream cannot get into the brain. And those elements include drugs, viruses, and bacteria, among other things that are in the blood.

Drug companies were very concerned about being able to develop drugs to get the drugs into the brain. And so, they used something called a nanoparticle - nanoparticle, very small particle bound to the drug. And they found that if they could put a nanoparticle onto a drug, they could get that drug to go into the brain.

And it shows in animal studies that they were able to do this. They then were able to take an emulsifier which is something that's good with water and fat, it can dissolve in both, and if they added the emulsifier to the nanoparticle bound to the drug they could increase drug entry into the brain twenty-fold. This is right out of animal studies that I have found. So you have a drug, you have a nanoparticle, and you have this emulsifier. The vaccines are constructed the same way.

You have the vaccine viruses and bacteria that are bound to a nanoparticle called aluminum. And that aluminum is a nanoparticle. And by definition, a nanoparticle has the potential to enter the brain. Most vaccines also contain polysorbate 80 or sorbitol. Both of those compounds are emulsifiers. Emulsifiers bind very tightly to the nanoparticle aluminum which is bound very tightly to the vaccine antigens.

This raises a question: if the vaccine model is the same model as the model that the drug companies are using to enhance the delivery of drugs into the brain, is it possible that vaccine ingredients are making their way into the brain of our children that could explain why so many parents are watching their kids deteriorate after vaccinations even though the doctors, the media, and the government say “absolutely no connection,” even though the science suggests that there is?

You cannot find a single study in the literature that addresses whether the injection of aluminum into the body penetrates the brain, whether any vaccine ingredients enter the brain, and whether polysorbate 80 enhances the delivery of any of those ingredients into the brain.

And when I could not find those studies I was concerned. Because I am told, you are told, vaccines are safe. They are evaluated and very, very distinctly tested for safety. But yet, you cannot find a study that says does aluminum get into the brain of children, does aluminum take other vaccine ingredients into the brain that don't belong in the brain.

Because when ingredients get across the blood brain barrier that don’t belong in the brain, they cause inflammation.

And inflammation is what we see in 1 in 5 children with learning disabilities and 1 in 40 children with autism.

All you have to do is ask the guidance counselors and if you get honest pediatricians who are telling you what they are seeing in their practice, they are seeing kids one after another with more and more brain disorders.
Now, as a medical doctor, who was taught to think and then went into the literature, and said, are proper science studies done, safety studies, where you take a vaccine and you inject it into 100 kids, and then you give 100 kids a saline placebo, meaning it’s inert - no study exists to actually evaluate the safety of a vaccine compared to a placebo group. None.

When vaccines are studied, the maximum amount of days that vaccines are studied are up to 10 days to two weeks. And unfortunately, the vaccine manufacturers preselect what side effects that they will allow to be associated with the vaccines.

So if a child has a vaccine reaction that is associated with the vaccine, the vaccine manufacturers will decide whether or not it should or should not be associated with the vaccine. And the public knows this and they are learning it more and more. So if your child develops seizures 5 months after a vaccine, your child is told by the doctor it had nothing to do with the vaccine. But that’s not true, because there are no studies to prove it. There is opinion. But there’s never been a study really addressing whether a vaccination at two months or even 9 hours of age could be related to an event that happened months or even years later. And yet, we have some of the sickest children in our country.

In New York we lost the religious exemption on June 13th because the unvaccinated children with a religious exemption were blamed for a measles outbreak. When I met with representatives in New York, I told them that there is no study to prove that unvaccinated children have ever been proven to start an epidemic. And he (one of the representatives) was surprised and he said I will vote against removing the religious exemption if I can’t find a study like you say. He could not find a study, but he voted to repeal the exemption anyway.

Because there are no studies, there are no studies proving that unvaccinated children are responsible. There’s consensus and here’s why there’s consensus. We are taught that vaccines stop the children from carrying the germs that we are vaccinating against. And study after study shows that children who are vaccinated can still carry the germ despite having received the vaccine. So the vaccinated are still capable of spreading disease, but the unvaccinated are being unfairly blamed because of a consensus opinion but not true science.

To repeat, no study, no science has ever proven that vaccines eliminate the existence of the organism in your body. If anything, science is showing that the vaccines cause the organisms to mutate. And there are plenty of articles showing that strains are replaced by new strains after vaccinations similarly to the way antibiotics are bringing about new strains of bacteria because of the overuse of antibiotics.

So why are we blaming the unvaccinated children? No study has ever been done in this country appropriately to address the health outcomes of children who were vaccinated versus the children who were unvaccinated.

I have been seeing families in my practice for over 20 years that have opted out of vaccination. They are the healthiest children I have ever seen. I have families who have older children who have been vaccinated, middle children who have been partially vaccinated, and then younger children who have not been vaccinated at all. And those families are rising in number and they see the difference between the health outcomes of their younger children who are rarely sick versus their older children who are getting I.E.P.’s in schools [Individualized Educational Program], needing medications, ER's, and constant health issues. And all I get when I state something like that is well that’s anecdotal.

Well, it’s anecdotal if you see it a couple of times but it’s not anecdotal when you see it for over 20 years and when you speak to parents and when you speak to teachers and when you speak to guidance counselors. And when I speak to pediatricians who are too afraid to come out in public.
There is pressure to ostracize the families who know the science and know the lack of science that’s available. There’s a lot of consensus. And when I think about the subject of vaccination, I want to ensure that if we are going to prevent infectious diseases in children, that we don’t create something worse in its place.

Unfortunately, we’re dealing with a lot of beliefs instead of actual science and beliefs go a long way.

I took the oath of first do no harm, but when I look into the science and I don’t see long term studies and I see only short term studies up to 4 to 10 days where the side effects are manipulated by the manufacturers who are the only ones doing the studies on the vaccines, and when I see no placebo groups and I see no studies of the single ingredients or the combined ingredients and I see the science, the biochemistry of the ingredients in animal studies where animals who are given the aluminum are found to have motor delays and behavior problems which is a great deal of what we are seeing in children today, I say are we first doing no harm?

And so, first do no harm means the precautionary principle. And more and more parents are understanding the dangers of vaccines, and that’s why we are seeing such pressure to mandate vaccines because more of the science is coming out.

In order to create herd immunity, you have to be able to prove that children who are vaccinated are immune. And the sad part about that is that whenever you vaccinate a population of children, you are always gonna have a population that doesn’t develop any antibodies at all. The estimates of that are about 10%. That vaccines will fail in 10% of the population. Vaccination, no antibody production. But the next group is even more suspicious. Because when you vaccinate and you do produce an antibody, there is science to show that the presence of an antibody doesn’t guarantee immunity either. And we don’t know the percentage of children who get a vaccine, develop an antibody but aren’t immune at all.

We assume that if we vaccinate, we are getting protection. We assume that if we vaccinate, we are stopping spread of disease. Those are assumptions that have never been solidified in science. And I’m happy to offer more explanations during the Q and A. I wouldn’t say that if I didn’t have the science to prove it.

The parents that I work with in New York, that I see around the country, are very concerned that their rights are being taken away, that their knowledge about the science is being pushed away by an agenda that only says unvaccinated children are a problem. Just to wrap up, in New York when we had the measles outbreak, I’m sorry in California when they had a measles outbreak, there were 194 cases. Of the 194 cases, 73 cases were due to the actual virus in the vaccine itself. 73, 38 percent. 73 cases were due to the measles virus causing measles.

All the literature states that measles virus infection is not true measles and should not be counted as a health threat. That means only 121 kids developed measles, 121 people. New York State did not do the proper testing that’s given down by the CDC to test every child to see if the children had measles strain, wild type measles, or a mutated measles.

There are cases around the country and around the world where in a 95 to 98% vaccinated population they had measles outbreaks because they found mutated viruses. As I said before, there are cases where the virus mutates, where there are strain replacements.

New York State did not do the proper testing of the 1,000 plus young children and adults who came down with measles. They wrote a little blurb on the CDC website of the two wild viruses that were responsible for the measles outbreak, but we in New York know that the testing was not done. 4,200 kids on Long Island had the religious exemption and were not vaccinated and there was not one case of measles on Long Island. Thank you.
Dr. Palevsky is a NYS licensed pediatrician, who utilizes a holistic approach to children’s wellness and illness. Dr.Palevsky received his medical degree from the NYU School of Medicine in 1987, completed a three-year pediatric residency at The Mount Sinai Hospital in NYC in 1990, and served as a pediatric fellow in the ambulatory care outpatient department at Bellevue Hospital, NYC, from 1990-1991. Since 1991, his clinical experience includes working in pediatric emergency and intensive care medicine, in-patient, and out-patient pediatric medicine, neonatal intensive care medicine, newborn and delivery room medicine, and conventional, holistic and integrative pediatric private practice. Dr. Palevsky is a diplomate of the American Board of Integrative Holistic Medicine, and Past-President of the American Holistic Medical Association. He received his pediatric board certification in 1990, and passed his pediatric board recertification exams in 1997, 2004, and 2011.
“Before vaccines were available, nearly everyone was infected with measles, mumps, and rubella viruses during childhood. The majority of people born before 1957 are likely to have been infected naturally and therefore are presumed to be protected against measles, mumps, and rubella.”

CDC recommends against vaccines for people who “are not feeling well” or have a parent or sibling with immune system problems, such as diabetes, which includes 1/3 of the U.S. population. “Diabetes is a chronic (long-lasting) disease that affects how your body turns food into energy. There are three main types of diabetes: type 1, type 2, and gestational diabetes (diabetes while pregnant). More than 100 million Americans are living with diabetes (30.3 million) or prediabetes (84.1 million).”
Atacking Ourselves: Top Doctors Reveal Vaccines Turn Our Immune System Against Us


The research is hard to ignore, vaccines can trigger autoimmunity with a laundry list of diseases to follow. With harmful and toxic metals as some vaccine ingredients, who is susceptible and which individuals are more at risk?

No one would accuse Yehuda Shoenfeld of being a quack. The Israeli clinician has spent more than three decades studying the human immune system and is at the pinnacle of his profession. You might say he is more foundation than fringe in his specialty; he wrote the textbooks. The Mosaic of Autoimmunity, Autoantibodies, Diagnostic Criteria in Autoimmune Diseases, Infection and Autoimmunity, Cancer and Autoimmunity – the list is 25 titles long and some of them are cornerstones of clinical practice. Hardly surprising that Shoenfeld has been called the "Godfather of Autoimmunology" – the study of the immune system turned on itself in a wide array of diseases from type 1 diabetes to ulcerative colitis and multiple sclerosis.

But something strange is happening in the world of immunology lately and a small evidence of it is that the Godfather of Autoimmunology is pointing to vaccines – specifically, some of their ingredients including the toxic metal aluminum – as a significant contributor to the growing global epidemic of autoimmune diseases. The bigger evidence is a huge body of research that's poured in in the past 15 years, and particularly in the past five years. Take for example, a recent article published in the journal Pharmacological Research in which Shoenfeld and colleagues issue unprecedented guidelines naming four categories of people who are most at risk for vaccine-induced autoimmunity.

"On one hand," vaccines prevent infections which can trigger autoimmunity, say the paper's authors, Alessandra Soriano, of the Department of Clinical Medicine and Rheumatology at the Campus Bio-Medico University in Rome, Gideon Nesher, of the Hebrew University Medical School in Jerusalem and Shoenfeld, founder and head of the Zabludowicz Center of Autoimmune Diseases in the Sheba Medical Center at Tel Hashomer. He is also editor of three medical journals and author of more than 1,500 research papers across the spectrum of medical journalism and founder of the International Congress on Autoimmunology. "On the other hand, many reports that describe post-vaccination autoimmunity strongly suggest that vaccines can indeed trigger autoimmunity. Defined autoimmune diseases that may occur following vaccinations include arthritis, lupus (systemic lupus erythematosus, SLE) diabetes mellitus, thrombocytopenia, vasculitis, dermatomyositis, Guillain-Barre syndrome and demyelinating disorders. Almost all types of vaccines have been reported to be associated with the onset of ASIA."

ASIA – or Autoimmune/inflammatory Syndrome Induced by Adjuvants (also known as Shoenfeld's syndrome) -- first appeared in the Journal of Autoimmunology four years ago. It is an umbrella term for a collection of similar symptoms, including Chronic Fatigue Syndrome, that result after exposure to an adjuvant – an environmental agent including common vaccine ingredients that stimulate the immune system. Since then an enormous body of research, using ASIA as a paradigm, has begun to unravel the mystery of how environmental toxins, particularly the metal aluminum used in vaccines, can trigger an immune system chain reaction in susceptible individuals and may lead to overt autoimmune disease.

Autoimmune disease results when the body’s system meant to attack foreign invaders turns instead to attack part of the body it belongs to (auto is Greek for self). If the immune system is like a national defence system, antibodies are like drones programmed to recognize a certain type of invader (a bacteria say) and to destroy them or mark them for destruction by other special forces. Autoantibodies are like drones that are misidentifying a component of the human body and have launched a sustained attack on it. If they mistakenly target a component of the conductive sheath around neurons, for example, nerve impulses stop conducting properly, muscles go into spasm and coordination fails; multiple sclerosis results. If autoantibodies erroneously focus on joint tissue; rheumatoid arthritis results. If they target the islets of Langerhans in the pancreas, Type 1 diabetes, and so on

"Throughout our lifetime the normal immune system walks a fine line between preserving normal immune reactions and developing autoimmune diseases," says the paper. "The healthy immune system is tolerant to self-antigens. When self-tolerance is disturbed,
dysregulation of the immune system follows, resulting in emergence of an autoimmune disease. Vaccination is one of the conditions that may disturb this homeostasis in susceptible individuals, resulting in autoimmune phenomena and ASIA."

Who is "susceptible" is the subject of the paper entitled, "Predicting post-vaccination autoimmunity: Who might be at risk?" It lists four categories of people: 1) those who have had a previous autoimmune reaction to a vaccine, 2) anyone with a medical history of autoimmunity, 3) patients with a history of allergic reactions, 4) anyone at high risk of developing autoimmune disease including anyone with a family history of autoimmunity, presence of autoantibodies which are detectable by blood tests and other factors including low vitamin D and smoking.

PREVIOUS REACTION

Regarding those who have had a previous adverse reaction to vaccines, the paper cites five relevant studies including the case of a death of a teenage girl six months following her third Gardasil injection against HPV virus. She had experienced a range of symptoms shortly after her first dose, including dizziness, numbness and tingling in her hands, and memory lapses. After her second injection, she developed "intermittent arm weakness, frequent tiredness requiring daytime naps," worse tingling, night sweats, chest pain and palpitations. A full autopsy was unrevealing but blood and spleen tissue analysis revealed HPV-16 L1 gene DNA fragments – matching the DNA found in vials of the Gardasil vaccine against cervical cancer – "thus implicating the vaccine as a causal factor." The DNA fragments had also been found to be "complexed with the aluminum adjuvant" which, according to the report, have been shown to persist for up to 8 to 10 years causing chronic immune system stimulation.

"Although data is limited," Shoenfeld and his colleagues concluded, "it seems preferable that individuals with prior autoimmune or autoimmune-like reactions to vaccinations, should not be immunized, at least not with the same type of vaccine."

ESTABLISHED AUTOIMMUNE CONDITION

The second group cited for vaccine exemption is patients with "established autoimmune conditions." Vaccines don't work so well in them, say Shoenfeld and his colleagues, and they are at "risk for flares following vaccination." Inoculations that contain live viruses including chickenpox, yellow fever and the measles, mumps and rubella triple vaccine (MMR) are "generally contraindicated" for people with autoimmune conditions because of the risk of "uncontrolled viral replication." But inactivated vaccines are not such a good idea either because they usually contain added ingredient aluminum, linked to autoimmunity.

The immunologists describe recent studies in which patients with autoimmune rheumatic disease given the influenza vaccine (without aluminum) suffered more joint pain and fever than controls and whose levels of autoantibodies (the drones that attack self) increased after receiving the flu vaccine. What's more, they developed new types of autoantibodies that weren't present before the vaccines, and those persisted. As the presence of autoantibodies can be predictive of developing autoimmune disease in patients without symptoms, even years ahead of disease onset, this is troubling to those who understand immunology.

A number of studies claim vaccines are safe for the "overwhelming majority of patients with established autoimmune diseases," the study allows, but they only looked at rheumatoid arthritis and lupus and not at severe and active cases so "the potential benefit of vaccination should be weighed against its potential risk," they cautioned.

PATIENTS WITH A HISTORY OF ALLERGY

Vaccine trials have usually excluded "vulnerable" individuals -- only extremely healthy individuals with no allergies are recruited. It's a "selection bias," say Soriano and Shoenfeld, and has likely resulted in serious adverse events being "considerably underestimated" in "real life where vaccines are mandated to all individuals regardless of their susceptibility." The true incidence of allergic reactions to vaccines, normally estimated at between one in 50,000 to one in a million doses, is probably much higher and particularly where gelatin or egg proteins are on the ingredients list, they say.

There's a long list of vaccine ingredients that are potential allergens: besides the infectious agents themselves, there are those from hen's egg, horse serum, baker's yeast, numerous antibiotics, formaldehyde and lactose, as well "inadvertent" ingredients such as latex. People's allergic histories have to be taken before vaccination say the researchers. But some signs of reaction don't show up until after the shot.

The public health nurse or GP might tell patients that a long-lasting swelling around the injection site after a vaccine is a normal reaction, for example. But that is not what the immunologists say. "[A]luminum sensitization manifests as nodules [hard lumps] at the injection site that often regress after weeks or months, but may persist for years." In such cases, they say, a patch test can be done to confirm sensitivity and to avoid vaccination.

According to a growing body of research, though, allergy may be only the beginning of many dangerous aluminum-induced phenomena.

THE TROUBLE WITH ALUMINUM

Aluminum has been added to vaccines since about 1926 when Alexander Glenny and colleagues noticed it would produce better antibody responses in vaccines than the antigen alone. Glenny figured the alum was inducing what he called a "depot effect" – slowing the release of the antigen and heightening the immune response. For 60 years his theory was accepted dogma. And over the same time, the vaccine schedule grew decade on decade, but few ever questioned the effects of injecting aluminum into the body, which is strange considering its known toxicity.
A PubMed search on aluminum and “toxicity” turns up 4,258 entries. Its neurotoxicity is well documented. It affects memory, cognition, psychomotor control; it damages the blood brain barrier, activates brain inflammation, depresses mitochondrial function and plenty of research suggests it is a key player in the formation of the amyloid “plaques” and tangles in the brains of Alzheimer’s patients. It’s been implicated in Amyotrophic Lateral Sclerosis and autism and demonstrated to induce allergy.

When kidney dialysis patients were accidentally infused with aluminum, the “dialysis-induced encephalopathy” (DAE) they developed neurological symptoms: speech abnormalities, tremors, memory loss, impaired concentration and behavioural changes. Many of the patients eventually went into comas and died. The lucky ones survived: when the source of toxicity, aluminum, was removed from their dialysis they recovered rapidly.

With these new observations, researchers began investigating the adjuvant effects of aluminum and in the past decade there has been a flurry of research. Far from being a sandbag that holds the antigen for a while and then gets excreted, it turns out that aluminum salts trigger a storm of defence action. Within hours of injection of the same aluminum oxyhydroxide in vaccines into mice, for example, armies of specialized immune cells are on the move, calling in grid coordinates for more specialist assault forces. Within a day, a whole host of immune system commandos are in play -- neutrophils, eosinophils, inflammatory monocytes, myeloid and dendritic cells, activating lymphocytes and secreting proteins called cytokines. The cytokines themselves cause collateral damage but they send out signals, directing cell-to-cell communication and recruiting other cells into action. If the next phase of the attack is launched: fibroblast growth factor, interferons, interleukins, platelet derived growth factor, transforming growth factor and tumour necrosis factor might all be engaged. There’s evidence that poorly understood and pesky inflammasomes, (currently a topic of cutting-edge cancer causation research) such as the Nod-like receptor 3 (NLRP) are activated too, but it’s all still too early to say exactly what they’re doing.

New research emerging from University of British Columbia has found that aluminum adjuvant injected into mice can alter the expression of genes associated with autoimmunity. And in their recent study published in the Proceedings of the National Academy of Sciences, immunologists at the University of Colorado found that even host DNA is recruited into the aluminum assault, that it rapidly coats injected alum, triggering effects that scientists have barely scratched the surface of understanding.

THE SIGNIFICANCE OF MACROPHAGIC MYOFASCIITIS

This mobility or “translocation” of aluminum in the body is perhaps the most disturbing of the mounting evidence in current aluminum research. In 1998, French researcher Romain Gherardi and his colleagues observed an emerging condition of unknown origin which presented in patients post-vaccination with Chronic Fatigue like symptoms including swollen lymph nodes, joint and muscle pain and a host of immune system commandos are in play -- neutrophils, eosinophils, inflammatory monocytes, myeloid and dendritic cells, armies of specialized immune cells are on the move, calling in grid coordinates for more specialist assault forces. Within a day, a whole host of immune system commandos are in play -- neutrophils, eosinophils, inflammatory monocytes, myeloid and dendritic cells, activating lymphocytes and secreting proteins called cytokines. The cytokines themselves cause collateral damage but they send out signals, directing cell-to-cell communication and recruiting other cells into action. If the next phase of the attack is launched: fibroblast growth factor, interferons, interleukins, platelet derived growth factor, transforming growth factor and tumour necrosis factor might all be engaged. There’s evidence that poorly understood and pesky inflammasomes, (currently a topic of cutting-edge cancer causation research) such as the Nod-like receptor 3 (NLRP) are activated too, but it’s all still too early to say exactly what they’re doing.

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Gherardi and his colleagues began injecting mice with aluminum to see what happened. Their research published in 2013 revealed that the metal particles were engulfed by macrophages and formed MMF-like granulomas that dispersed -- to distant lymph nodes, spleen, liver and eventually brain.

"This strongly suggests that long-term adjuvant biopersistence within phagocytic cells is a prerequisite of slow brain translocation and delayed neurotoxicity," writes Gherardi in his February 2015 review of the relevant research in Frontiers in Neurology.

A more frightening animal study of aluminum is that of Spanish veterinary researcher Lluis Lujan's study of ovine ASIA. After huge numbers of sheep in Spain died in 2008 in the wake of a compulsory multiple vaccine campaign against bluetongue in Spain in 2008, Lujan set out to find out what killed them – and he began by inoculating them with aluminum.

His 2013 study found that only 0.5% of sheep inoculated with aluminum vaccines showed immediate reactions of lethargy, transient blindness, stupor, prostration and seizures -- "characterized by a severe meningoencephalitis, similar to postvaccine reactions seen in humans.” Most of them recovered, temporarily, but postmortem exams of the ones who didn’t revealed acute brain inflammation.

The delayed onset "chronic" phase of the disease affected far more of the sheep -- 50-70% of flocks and sometimes virtually 100% of animals within a given flock, usually including all of those who had previously recovered. The reaction was frequently triggered by exposure to cold and began with restlessness and compulsive wool-biting, then progressed to acute redness of the skin, generalized weakness, extreme weight loss and muscle tremors, and finally, entered the terminal phase where the animals went down on their front quarters, became comatose and died. Post-mortem examinations revealed "severe neuron necrosis" and aluminum in the nerve tissue.

The immune system's reaction to aluminum "represents a major health challenge," Gerhardt declares in his recent review, and he adds that "attempts to seriously examine safety concerns raised by the bio-persistent character and brain accumulation of alum particles have not been made... A lot must be done to understand how, in certain individuals, alum-containing vaccines may become insidiously unsafe."

Back to the problem of which "certain individuals" should avoid vaccination to avoid autoimmune disease.

PEOPLE PRONE TO DEVELOP AUTOIMMUNITY

Soriano and Shoenfeld's identify a final category: anyone at risk of developing autoimmune disease. Since a number of them have been shown to have genetic factors that would include anyone with a family history of autoimmune disease. It also includes anyone who has...
tested positive for autoantibodies which can indicate disease years before symptoms show up. Vaccinations, the doctors say, "may trigger or worsen the disease."

Smokers too, have an exceptionally high risk of developing an autoimmune disease, says the report. The American Cancer Society estimates that about 18% of Americans smoke. That means about 42 million Americans have an elevated risk of developing an autoimmune disease and they're stacking the odds with every vaccine.

And finally, factors that Shoenfeld and Soriano associate with high risk of developing autoimmunity are high estrogen and low vitamin D - which means anyone taking birth control or hormone replacement therapy and, according to one 2009 study of vitamin D status, about three quarters of American teens and adults should be wary of vaccines.

Shoenfeld doesn't seem to mean to exclude all of these people from immunization, however. The paper concludes that "for the overwhelming majority of individuals, vaccines carry no risk of systemic autoimmune disease and should be administered according to current recommendations. Which is in stark contrast to the body of the paper. The final word is cautionary about weighing the "potential benefit of vaccination...against its potential risk."

It's exemplary of a strange sort of schizophrenia in a wide range of recent immunology papers. The doctors seem to be trying to reconcile a century of "safe and effective" vaccine dogma with the last decade's worth of terrifying research findings. There's a lot of "on the one hand" and "on the other hand" in them.

The new research seems about to gain the upper hand, however. A 2013 overview of ASIA by six immunologists including Shoenfeld, for example, is a catalogue of vaccine side effects from Gardasil deaths, narcolepsy epidemics, infertility, chronic fatigue, dead sheep and aluminum-addled brains. It is rife with statements that would have been virtually unheard of inside mainstream medicine a decade ago. Like this shocker:

"Perhaps, in twenty years, physicians will be dueling with better characterized particles of autoimmunity, and the vaccines may become fully safe as well as effective. Nonetheless the recognition of ASIA has initiated the change to put more efforts in identifying the good, the bad and the ugly of vaccines and in particular of adjuvants as triggers of autoimmunity." Bad and ugly of vaccines? What's wrong with the adjuvants? That's not in the CDC hand-out.

Or how about this one:

"Despite the huge amount of money invested in studying vaccines, there are few observational studies and virtually no randomized clinical trials documenting the effect on mortality of any of the existing vaccines. One recent paper found an increased hospitalization rate with the increase of the number of vaccine doses and a mortality rate ratio for 5-8 vaccine doses to 1-4 doses of 1.5, indicating a statistically significant increase of deaths associated with higher vaccine doses. Since vaccines are given to millions of infants annually, it is imperative that health authorities have scientific data from synergistic toxicity studies on all combinations of vaccines..." That could be any anti-vaxxer jabbering on...but it's not.

But here is the topper:

"The US Supreme Court ruled that vaccines makers are immune from lawsuits charging that the design of the vaccine is defective. Thus there is need for innovative critical trial design and the vaccines themselves should be redesigned." Immunologists including the world's leading authority on autoimmunity are saying it is time to take vaccines back to the drawing board.

Autoimmune disease is the third leading cause of morbidity and mortality worldwide and now among the top 10 killers of young American women. The American Autoimmune Related Diseases Association estimates that 50 million Americans suffer from one of 88 autoimmune diseases -- from type 1 diabetes to systemic lupus erythematosus -- and some research puts the figure at one in five globally. At least 40 more diseases are suspected to be immune-mediated. Most of them are devastating -- frequently crippling, expensive to treat and incurable. And they are increasing at an astonishing pace.

At this stage, it looks like the more the research pours in, the harder it is going to get for pro-vaccine immunologists to keep multiple personality disorder -- or complete nervous breakdown -- at bay. Ten years of cutting edge research into aluminum's effects on the immune system has revealed primarily how wrong they were. And how little they know. If, after 90 years, doctors finally have begun to seriously examine the mechanism and question the merits of injecting metal toxins into newborn babies, what have they yet to discover? ASIA sounds awful. (Too bad for all the people whose kids suffered through chronic fatigue when it was just a Freudian yearning to sleep with their mother.) But what if, like Lujan's sheep, the "negligible" minority that has been paying the price for the good of humanity is actually only the tip of the iceberg? What if some people with no apparent adverse immune reactions still have nanocrystals of aluminum silently depositing in their brains? What if ASIA really includes Alzheimer's? ALS, autism? ADD? And that's just the A's.

Even if immunologists keep wearing their rose coloured glasses, and vaccine ingredients are only responsible for a tiny fraction of the exploding autoimmunity, the "ugly" in vaccines will still get harder and harder to ignore. When everyone on the planet is getting injected, 20 years is a long time for disabled people to stack up while scientists "duel with the characterized particles of autoimmunity." In the fury over the Disneyland measles outbreak that is gripping the world's vaccine promoters, time is running out for doctors and researchers who see the "bad and ugly" side of vaccines and their adjuvants to do something about it. There's slim chance of a vaccine redesign in the absence of a profit incentive and a strong chance of universal vaccine mandates for one and all -- previous anaphylactic shock reaction or not.
Vaccination Destroys Natural Immunity

http://vaccineriskawareness.com/vaccination-and-natural-immunity

Vaccination is the Cause of Disease in Newborns.

Recently there has been an upswing of pertussis and 10 babies, mostly under the age of 3 months, died in California. News reports, doctors and parents were quick to blame the ‘unwashed unvaccinated’ for bringing about the epidemic but reality couldn’t be further from the truth.

There hasn’t been a ‘scare’ regarding DPT vaccines since the 1970’s and 80’s and the only ‘controversy’ in the news has been about the MMR, so the majority of parents still do get their children vaccinated with DPT containing vaccines, yet we have waves of epidemics occurring in all countries. Why?

The truth is, vaccination is destroying natural immunity and here’s how:

1. In the pre-vaccine era, it was unusual for a baby to get whooping cough as a newborn. Average age at presentation varied somewhere between 1 and 5 but due to vaccination programmes the age of onset has shifted to an earlier age group when it is more dangerous.

The Pediatric Infectious Disease Journal wrote: ‘Pertussis notification data from the prevaccine era provide indirect evidence that maternal antibodies provide short lived protection against fatal pertussis by demonstrating that the rate of pertussis deaths in the first month of life was approximately one-third of that in the second and third months of life.\(^24\) In contrast, pertussis surveillance data in the vaccine era no longer demonstrate a substantial difference in pertussis-related mortality between the first and second months of life (Table 1).\(^25\) This could be the consequence of reduced levels of circulation of \textit{Bordetella pertussis} in young women of childbearing age after the introduction of mass immunization.’

This means that prior to mass DPT vaccines being used, non-vaccinated mothers would pass transplacental antibodies to their babies which would protect them from pertussis in the first month of life, when it can be deadly, due to the fact that they had had, or been exposed to the illness themselves. After mass vaccination, the pertussis death rate in babies one month or less actually INCREASED due to the fact that vaccinated mothers could no longer confer immunity to their babies.

In fact, they knew this way back in 1978, when they wrote in the American Journal of Diseases in Children: ‘We reviewed 400 bacteriologically confirmed cases of pertussis in infants and children during the past 18 years. Several changes in the epidemiology have occurred in the most recent six-year period. The incidence of whooping cough in children has decreased by at least 50%, but the proportion of cases occurring in infants younger than 12 weeks of age has doubled to 30% of all cases. Formerly most young infants acquired their illness from siblings or other children, but in the recent period adults in the household were the most common source of infection to neonates and young infants. This observation plus the increasingly high level of immunization in preschool and school-aged children suggest that young adults with waning immunity and mild illness are a major reservoir for transmission of pertussis to infants too young to be immunized.’ (Am J Dis Child. 1978 Apr;132(4):371-3 – http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=645653&dopt=Abstract).

Of course, the point of pertussis vaccination is not to protect older children, for whom the disease is rarely fatal and for whom it represents a mere nuisance. The point of vaccination is to protect very young babies from getting it. However, vaccination has destroyed natural immunity so it has pushed the disease into the very age group it was designed to protect. The same has occurred with other diseases. Measles is now occurring in very young babies when it never used to and this is because vaccinated mothers cannot pass transplacental or breast milk immunity to their children.
The American Society of Tropical Medicine and Hygiene wrote: ‘There is growing evidence that measles vaccine–induced antibody levels wane over time, raising a concern that such a decrease in antibody levels could affect maternal passive immunity when vaccinated women reach childbearing years.9,10 Thus, the window of vulnerability of an infant may be even greater in vaccinated women than in with women with natural measles infection.’ (Am. J. Trop. Med. Hyg., 79(5), 2008, pp. 787–792, http://www.ajtmh.org/content/79/5/787.full.pdf).

Measles is of course much more serious in very young babies and in adults. The Israel Vaccine Research Institute wrote: ‘We rely on herd immunity and passive immunity to protect young infants before they can be protected directly by vaccination [26]. Diminishing maternal immunity increases the risk of infection among the youngest age groups.’ (The Return of Pertussis: Who is Responsible? What Can Be Done?, http://www.ima.org.il/imaj/ar06may-2.pdf).

So who is giving pertussis and other diseases to newly born babies? The press and medical profession blame parents of unvaccinated children, but the truth is, the unvaccinated are not disease vectors and they cannot transmit a disease unless they actually have it. If you study percentages in epidemics of pertussis, mumps, polio and influenza, you will find that the majority, if not ALL of those affected are already vaccinated. For instance, the Turkish Journal of Pediatrics found that in an epidemic of pertussis, 97.1% of cases were in fully vaccinated people, and not only that, they didn’t even know what level of vaccine induced antibodies correlates with immunity.

They wrote: ‘Thirty-four of the cases (97.1%) were fully vaccinated according to their ages. One case aged 2 months was not vaccinated. Because antibody levels were tested qualitatively and semi-quantitatively in our study and 34 of the cases (97.1%) were fully vaccinated according to their ages, a cut-off value to determine whether the positivity in their antibody level was due to vaccination or infection could not be specified. Although it has been reported that the detection of high levels of IgG antibodies against PT in a single serum sample is diagnostic of recent or acute infection with B. pertussis, when antibody levels according to age groups are known in the society19, the cut-off value indicating prevention has not yet been determined.’ (http://www.turkishjournalpediatrics.org/?fullTextId=673&lang=eng).

When medical professionals have actually bothered to try to find out where newborn babies are getting pertussis from, they have found out that they have generally got it from their own (vaccinated) mother and from previously vaccinated siblings. In the document, ‘Pertussis: Not only a Disease of Childhood’, the authors wrote: ‘In cases in which the source of infection can be traced, half of the children have been infected by their parents – usually by the mother. Older siblings are another frequent source of infection even if they have been vaccinated, because often their immunity has waned in the absence of a booster vaccination.’ (Dtsch Arztebl Int. 2008 September; 105(37): 623–628, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2680566/).

So in essence we have swapped lifelong natural immunity which was re-boosted by frequent exposures to the illness and protected our babies at their most vulnerable points, for vaccination which only delays disease and does not immunize, and severely hinders our ability to pass on trans placental immunity, thus putting our newborns at risk of infection from birth.

2. As the above research says, many cases of neonatal pertussis are actually contracted from the mother. If she had had pertussis as a child she would have gained lifelong immunity which would have made it impossible for her to infect her newborn baby. The vaccination industry, in destroying the natural immunity of mothers, have put this generation of children at heightened risk of death from infectious disease.

3. Most of today’s mothers do not breast feed beyond six weeks of age. In the pre-vaccine era, many more babies were breast fed and this meant that in addition to transplacental antibodies, mothers could pass breast milk antibodies to their children for any diseases they had encountered. Because many vaccinated mothers have not experienced the wild infection, they are unable or severely limited in passing breast milk antibodies to their babies and many do not breast feed at all, which also greatly increases the risk of acquiring an infectious disease in the neonatal period.

The American Journal of Tropical Medicine and Hygiene wrote: ‘When breast milk PRN titers were stratified by the woman’s age (< 24 and ≥ 24 years), higher titers of neutralizing antibodies were observed in women ≥ 24 years of age than in women < 24 years of age (P = 0.053). This finding could potentially be caused by a difference in vaccinated women versus women who had natural measles infection. Women greater than 24 years of age were born before the introduction of measles vaccine in Mozambique in 1981. In contrast, most women less than 24 years of age were born
after the measles vaccine was well established in the EPI program. Women whose immunity derives from natural measles exposure are likely to have generated mucosal IgA antibodies, including breast milk IgA, in addition to serum antibodies, consequent to the wild virus entering by the respiratory tract. In contrast, attenuated vaccine is administered subcutaneously and the mucosal IgA titer may be lower. As is the case for waning of serum antibodies, vaccinated women reaching childbearing age may have lower titers of breast milk antibodies.’ (Am J Trop Med Hyg November 2008 vol. 79 no. 5 787-792, http://www.ajtmh.org/content/79/5/787.full).

Numerous Studies have showed the same thing. When researchers in Belgium studied vaccinated and naturally immune women, they found the vaccinated women lost antibodies faster and could not confer as many to their babies. The BMJ wrote: ‘Vaccinated women had significantly fewer IgG antibodies (geometric mean titre 779 (95% confidence interval 581 to 1045) mIU/ml) than did naturally immune women (2687 (2126 to 3373) mIU/ml) (P<0.001). Maternal values were highly correlated with neonatal values \((r=0.93 \text{ at birth})\). Infants of vaccinated women had significantly lower antibody concentrations than did infants of naturally immune women.’ (BMJ 2010;340:c1626, http://www.bmj.com/content/340/bmj.c1626.full).

So the only reasons that parents are now being advised to get vaccinated to protect their newborns is because they are vaccinated and have diminished natural immunity and because most babies are formula fed from a very early age because parents aren’t told how vital breast milk is for the development of their baby’s immune system.

In fact, breast milk has been shown to NEUTRALIZE rotavirus vaccine – it is so potent it can kill rotavirus (and of course, today’s mothers are not vaccinated for rotavirus so their immune response isn’t impaired). Instead of celebrating how wonderful breast milk is at protecting our babies (after all, who needs a rotavirus vaccine if that’s what breast milk does?), medics say mothers should DELAY breastfeeding to ensure that the vaccine will work. They have moved so far away from what is natural and normal, this suggestion is not even shocking to them.

Pediatric Infectious Disease Journal wrote: ‘Breast milk from Indian women had the highest IgA and neutralizing titers against all 3 vaccine strains, while lower but comparable median IgA and neutralizing titers were detected in breast milk from Korean and Vietnamese women, and the lowest titers were seen in American women. Neutralizing activity was greatest against the 2 vaccine strains of human origin, RV1 and 116E. This neutralizing activity in one half of the breast milk specimens from Indian women could reduce the effective titer of RV1 by \(\sim 2\) logs, of 116E by 1.5 logs, and RV5 G1 strain by \(\sim 1\) log more than that of breast milk from American women. The lower immunogenicity and efficacy of rotavirus vaccines in poor developing countries could be explained, in part, by higher titers of IgA and neutralizing activity in breast milk consumed by their infants at the time of immunization that could effectively reduce the potency of the vaccine. Strategies to overcome this negative effect, such as delaying breast-feeding at the time of immunization, should be evaluated.’ (Pediatr Infect Dis J. 2010 Oct;29(10):919-23, http://www.ncbi.nlm.nih.gov/pubmed/20442687).

4. Finally, vaccines are changing the clinical presentation of the diseases. It has now been discovered that pertussis can occur without symptoms in vaccinated children. What this means is, that the child wouldn’t even be aware that he is sick, would still be going to school and mixing with lots of people including newborns and could pass on the infection to them without even knowing it. At least an unvaccinated child has a classic presentation so his parents would know to keep him at home during the 3 week infectious phase and away from newborns.

Medscape wrote: ‘The effects of whole-cell pertussis vaccine wane after 5 to 10 years, and infection in a vaccinated person causes nonspecific symptoms\(^6\text{-}^7\). Vaccinated adolescents and adults may serve as reservoirs for silent infection and become potential transmitters to unprotected infants\(^8\text{-}^{11}\). The whole-cell vaccine for pertussis is protective only against clinical disease, not against infection\(^15\text{-}^{17}\). Therefore, even young, recently vaccinated children may serve as reservoirs and potential transmitters of infection.’ (http://www.medscape.com/viewarticle/414768_3).

They blame this on the old whole cell DPT vaccine but in fact, according to Kaiser Permanente Division of Research, the acellular vaccine wanes 40% each year and is less effective. They wrote: ‘Waning and less effective acellular whooping cough vaccines likely contributed to the 2010 California whooping cough outbreak, according to researchers from the Kaiser Permanente Vaccine Study Center.

The Research is being presented this week at the 49th Annual Meeting of the Infectious Diseases Society of America, held in Boston MA. Researchers found that DTaP vaccine (given to children younger than 7 to develop immunity for
diphtheria, tetanus, and whooping cough) wanes about 40 percent each year. This means that if the vaccine is 90 percent effective after given, after the 5th dose (given before children enter kindergarten) it is less than 50 percent effective, according to the researchers.

This means that even if you and your kids get re-vaccinated for whooping cough on arrival of a new baby, you can still be infectious, you can still get whooping cough and you can still pass it to your newborn baby, all courtesy of our modern vaccination programmes and the fact we have abandoned our own God given natural immune systems!

Measles immunity fades sooner in babies of vaccinated mothers.

Babies born to mothers naturally immune to measles following infection are protected from the disease for longer than those whose mothers acquired measles immunity through measles-mumps-rubella immunisation, research has shown. Authors of the study, published online today in The Journal of Infectious Diseases, suggest that when the risk of measles is high, babies should receive their first MMR dose earlier than usual, even though the vaccine efficacy would be lower because their immune systems are not yet mature.

Researchers in the Netherlands compared the concentration of antibodies against viruses in blood samples taken from babies and women of childbearing age in the general population with the concentration in samples from babies and women in the orthodox protestant community, in whom vaccination uptake is low and in whom there have been recent outbreaks of measles, mumps, and rubella.

They estimated that protection by maternal antibodies among infants in the general population, most of whose mothers had been vaccinated, lasted just 3.3 months for measles, 2.7 months for mumps, 3.9 months for rubella, and 3.4 months for varicella. Babies living in the orthodox community, most of whose mothers had not been vaccinated, retained their immunity to measles for two months longer than babies in the general population. And mothers in the orthodox communities had higher concentrations of antibodies to rubella than those in the general population.

The study’s authors warn that as the first European cohort of vaccinated women is now reaching childbearing age, there could be a large pool of children unexpectedly vulnerable to infection because of the shortened duration of protection that they discovered. They suggest that when children’s risk of exposure to measles is high – for example, if they live in an area experiencing an outbreak, or if they are travelling to endemic areas – the age at which the first MMR dose is given should temporarily be reduced.

They conclude: “The average age at which a child loses the protection of its maternal antibodies and becomes susceptible to measles, mumps, and rubella lies well before the age of first MMR vaccination. It is extremely important to protect this large number of susceptible children, who have a high probability of a severe outcome when infected.

“An obvious solution is to lower the age at which the first dose of MMR is administered, but this could lower the vaccine efficacy because immunisation at a younger age is hampered by different factors, such as the immaturity of the immune response. An alternative solution is to temporarily lower the age at which the first dose of MMR vaccine is administered to one when the risk of exposure to measles is high.”

The authors of an accompanying editorial agree that early immunization would be the most effective strategy to protect babies under a year old when the risk of measles is high. Source: Onmedica, 9th May 2013. http://www.onmedica.com/newsarticle.aspx?id=7c4b2c09-5598-4935-8280-9b3ea650f54b

(continued)
Waning of Maternal Antibodies Against Measles, Mumps, Rubella, and Varicella in Communities With Contrasting Vaccination Coverage

**Background.** The combined measles, mumps, and rubella (MMR) vaccine has been successfully administered for >20 years. Because of this, protection by maternal antibodies in infants born to vaccinated mothers might be negatively affected.

**Methods.** A large cross-sectional serologic survey was conducted in the Netherlands during 2006–2007. We compared the kinetics of antibody concentrations in children and women of childbearing age in the highly vaccinated general population with those in orthodox Protestant communities that were exposed to outbreaks.

**Results.** The estimated duration of protection by maternal antibodies among infants in the general population, most of whom were born to vaccinated mothers, was short: 3.3 months for measles, 2.7 months for mumps, 3.9 months for rubella, and 3.4 months for varicella. The duration of protection against measles was 2 months longer for infants born in the orthodox communities, most of whom had unvaccinated mothers. For rubella, mothers in the orthodox communities had higher concentrations of antibodies as compared to the general population.

**Conclusions.** Children of mothers vaccinated against measles and, possibly, rubella have lower concentrations of maternal antibodies and lose protection by maternal antibodies at an earlier age than children of mothers in communities that oppose vaccination. This increases the risk of disease transmission in highly vaccinated populations.

In many industrialized countries, the introduction of measles, mumps, and rubella (MMR) vaccine into national immunization programs proved successful in reducing the incidence of these infectious diseases [1, 2]. Infants typically receive the first dose of vaccine around the first year of age [3]. Maternally derived antibodies provide the primary protection for infants prior to this first vaccine dose. The initial concentration of maternal antibodies in a newborn is highly correlated with the antibody concentration in their mother [4–8].

Subsequently, there is waning of the maternal antibody levels in the infant, leaving the child susceptible to infections.

Optimal timing of the first dose of vaccine can contribute to keeping this period as short as possible. This is important because, among European infants aged <1 year, measles risk and severity are greater than the risk and severity among those aged ≥1 year [9]. The optimal timing of the first MMR vaccine dose depends on 2 main factors. First, the infant’s immune system should be sufficiently mature to respond to the vaccine antigens. Second, levels of maternal antibodies must be low enough to ensure that they do not neutralize the live, attenuated strains in the vaccine. Insight in the kinetics and determinants of maternal antibody concentrations is therefore very important [10].

A known determinant of the maternal measles virus antibody concentration is the vaccination status of the mother. Mothers who received MMR vaccine tend to have a lower concentration of measles virus–specific antibodies than mothers who naturally acquired measles [11–13]. Infants born to measles-vaccinated mothers are hence likely to have lower levels maternal antibodies at birth and a shorter period of protection than infants of mothers who acquired measles naturally [14–16]. Source: J Infect Dis. (2013) doi: 10.1093/infdis/jit143 June 1, 2013 207 (11)
In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients.

Some excipients are added to a vaccine for a specific purpose. These include:

- **Preservatives**, to prevent contamination. For example, thimerosal.
- **Adjuvants**, to help stimulate a stronger immune response. For example, aluminum salts.
- **Stabilizers**, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These can include:

- **Cell culture materials**, used to grow the vaccine antigens. For example, egg protein, various culture media.
- **Inactivating ingredients**, used to kill viruses or inactivate toxins. For example, formaldehyde.
- **Antibiotics**, used to prevent contamination by bacteria. For example, neomycin.

The following table lists substances, other than active ingredients (i.e., antigens), shown in the manufacturers’ package insert (PI) as being contained in the final formulation of each vaccine. **Note:** Substances used in the manufacture of a vaccine but not listed as contained in the final product (e.g., culture media) can be found in each PI, but are not shown on this table. Each PI, which can be found on the FDA’s website (see below) contains a description of that vaccine’s manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: “Description.”

All information was extracted from manufacturers’ package inserts.

The date shown in the Date column of the table is the edition date of the PI in use in February 2020. If a date contains an asterisk (*), the PI was not dated and this is the date the PI was reviewed for this table.

If in doubt about whether a PI has been updated since this table was prepared, check the FDA’s website at: [http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm)

All influenza vaccine in this table are 2019-20 northern hemisphere formulation.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>10/2019</td>
<td>monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&amp;C Yellow #6 aluminum lake dye</td>
</tr>
<tr>
<td>Anthrax (Biothrax)</td>
<td>11/2015</td>
<td>aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde</td>
</tr>
<tr>
<td>BCG (Tice)</td>
<td>2/2009</td>
<td>glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose</td>
</tr>
<tr>
<td>Cholera (Vaxchora)</td>
<td>6/2016</td>
<td>ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate</td>
</tr>
<tr>
<td>Dengue (Dengvaxia)</td>
<td>6/2019</td>
<td>sodium chloride, essential amino acids (including L-phenylalanine), non-essential amino acids, L-arginine hydrochloride, sucrose, D-trehalose dihydrate, D-sorbitol, trometamol, urea</td>
</tr>
<tr>
<td>DT (Sanofi)</td>
<td>6/2018</td>
<td>aluminum phosphate, isotonic sodium chloride, formaldehyde</td>
</tr>
<tr>
<td>DTaP (Daptacel)</td>
<td>12/2018</td>
<td>aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol</td>
</tr>
<tr>
<td>DTaP (Infanrix)</td>
<td>12/2018</td>
<td>formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)</td>
</tr>
<tr>
<td>DTaP-IPV (Kinrix)</td>
<td>12/2018</td>
<td>Formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B</td>
</tr>
<tr>
<td>DTaP-IPV (Quadracel)</td>
<td>1/2019</td>
<td>formaldehyde, aluminum phosphate, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate, bovine serum albumin</td>
</tr>
<tr>
<td>DTaP-HepB-IPV (Pediarix)</td>
<td>2/2020*</td>
<td>formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (Pentacel)</td>
<td>1/2019</td>
<td>aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate</td>
</tr>
<tr>
<td>DTaP-IPV-Hib-HepB (Vaxelis)</td>
<td>12/2018</td>
<td>polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum</td>
</tr>
<tr>
<td>Ebola Zaire (ERVEBO)</td>
<td>2/2020*</td>
<td>Tromethamine rice-derived recombinant human serum albumin, host cell DNA benzonase, rice protein</td>
</tr>
<tr>
<td>Hib (ActHIB)</td>
<td>5/2019</td>
<td>sodium chloride, formaldehyde, sucrose</td>
</tr>
<tr>
<td>Hib (Hiberix)</td>
<td>4/2018</td>
<td>formaldehyde, sodium chloride, lactose</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Date</td>
<td>Contains</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hib (PedvaxHIB)</td>
<td>10/2018</td>
<td>amorphous aluminum hydroxyphosphate sulfate, sodium chloride</td>
</tr>
<tr>
<td>Hep A (Havrix)</td>
<td>2/2020*</td>
<td>MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic</td>
</tr>
<tr>
<td>Hep A (Vaqta)</td>
<td>12/2018</td>
<td>amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals</td>
</tr>
<tr>
<td>Hep B (Engerix-B)</td>
<td>2/2020*</td>
<td>aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate</td>
</tr>
<tr>
<td>Hep B (Recombivax)</td>
<td>12/2018</td>
<td>formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein</td>
</tr>
<tr>
<td>Hep B (Heplisav-B)</td>
<td>2017</td>
<td>yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxy nucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride, monobasic phosphate, polysorbate 80</td>
</tr>
<tr>
<td>Hep A/Hep B (Twinrix)</td>
<td>2/2020*</td>
<td>MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein, water</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV)</td>
<td>10/2018</td>
<td>amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein</td>
</tr>
<tr>
<td>Influenza (Afluria) Quadrivalent</td>
<td>12/2019</td>
<td>sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, succrose, neomycin sulfate, polymyxin B, beta-propiolactone, hydrocortisone thimerosal (multi-dose vials)</td>
</tr>
<tr>
<td>Influenza (Fluad)</td>
<td>4/2019</td>
<td>squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde</td>
</tr>
<tr>
<td>Influenza (Fluarix) Quadrivalent</td>
<td>©2019</td>
<td>octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride</td>
</tr>
<tr>
<td>Influenza (Flublok) Quadrivalent</td>
<td>4/2019</td>
<td>sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100</td>
</tr>
<tr>
<td>Influenza (Flucelvax) Quadrivalent</td>
<td>8/2019</td>
<td>Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials)</td>
</tr>
<tr>
<td>Influenza (Flulaval) Quadrivalent</td>
<td>2/2020*</td>
<td>ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution</td>
</tr>
<tr>
<td>Influenza (Fluzeon) Quadrivalent</td>
<td>2019</td>
<td>formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)</td>
</tr>
<tr>
<td>Influenza (Fluzone) High Dose</td>
<td>1/2019</td>
<td>egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde</td>
</tr>
<tr>
<td>Influenza (Flumist) Quadrivalent</td>
<td>8/2019</td>
<td>monosodium glutamate, hydrolyzed porcine gelatin, arginine, succrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)</td>
</tr>
<tr>
<td>Japanese Encephalitis (Ixiaro)</td>
<td>9/2018</td>
<td>aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, Vero cell DNA, sodium metabisulphite, Vero cell protein</td>
</tr>
<tr>
<td>Meningococcal (MenACWY-Menactra)</td>
<td>4/26/18</td>
<td>sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, diphtheria toxoid</td>
</tr>
<tr>
<td>Meningococcal (MenACWY-Menevo)</td>
<td>2/2020*</td>
<td>formaldehyde, CRM197 protein</td>
</tr>
<tr>
<td>Meningococcal (MenB – Bexsero)</td>
<td>2/2020*</td>
<td>aluminum hydroxide, sodium chloride, histidine, succrose, kanamycin</td>
</tr>
<tr>
<td>Meningococcal (MenB – Trumenba)</td>
<td>2018</td>
<td>polysorbate 80, aluminum phosphate, histidine buffered saline</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Date</td>
<td>Contains</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MMR (MMR-II)</td>
<td>2/2020*</td>
<td>vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride, WI-38 human diploid lung fibroblasts</td>
</tr>
<tr>
<td>MMRV (ProQuad) (Frozen: Recombinant Albumin)</td>
<td>2/2020*</td>
<td>MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum</td>
</tr>
<tr>
<td>MMRV (ProQuad) (Frozen: Human Serum Albumin)</td>
<td>2/2020*</td>
<td>MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum</td>
</tr>
<tr>
<td>MMRV (ProQuad) (Refrigerator Stable)</td>
<td>10/2018</td>
<td>MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, neomycin, bovine serum albumin</td>
</tr>
<tr>
<td>Pneumococcal (PCV13 – Prevnar 13)</td>
<td>8/2017</td>
<td>CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate</td>
</tr>
<tr>
<td>Pneumococcal (PPSV-23 – Pneumovax)</td>
<td>2/2020*</td>
<td>isotonic saline solution, phenol</td>
</tr>
<tr>
<td>Polio (IPV – Ipol)</td>
<td>2/2020*</td>
<td>calf bovine serum albumin, 2-phenoxethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium</td>
</tr>
<tr>
<td>Rabies (Inovax)</td>
<td>10/2019</td>
<td>human albumin, neomycin sulfate, phenol red, beta-propiolactone</td>
</tr>
<tr>
<td>Rabies (RabAvert)</td>
<td>©2018</td>
<td>chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphoterin B</td>
</tr>
<tr>
<td>Rotavirus (RotaTeq)</td>
<td>2/2017</td>
<td>dextran, Dulbecco’s Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan  [Porcine circovirus type 1 (PCV-1) is present in RotaTeq. PCV-1 is not known to cause disease in humans.]</td>
</tr>
<tr>
<td>Rotavirus (Rotarix)</td>
<td>2/2020*</td>
<td>dextran, Dulbecco’s Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan  [Porcine circovirus type 1 (PCV-1) is present in RotaTeq. PCV-1 is not known to cause disease in humans.]</td>
</tr>
<tr>
<td>Smallpox (Vaccinia) (ACAM2000)</td>
<td>3/2018</td>
<td>HEPES, 2% human serum albumin, 0.5 - 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP</td>
</tr>
<tr>
<td>Td (Tenivac)</td>
<td>11/2019</td>
<td>aluminum phosphate, formaldehyde, sodium chloride, water</td>
</tr>
<tr>
<td>Td (TDVAX)</td>
<td>9/2018</td>
<td>aluminum phosphate, formaldehyde, thimerosal</td>
</tr>
<tr>
<td>Tdap (Adacel)</td>
<td>1/2019</td>
<td>aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde, water</td>
</tr>
<tr>
<td>Tdap (Boostrix)</td>
<td>2/2020*</td>
<td>formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80</td>
</tr>
<tr>
<td>Typhoid (Typhim Vi)</td>
<td>3/2014</td>
<td>formaldehyde, phenol, polymethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride, sterile water</td>
</tr>
<tr>
<td>Typhoid (Vivotif Ty21a)</td>
<td>9/2013</td>
<td>sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin</td>
</tr>
<tr>
<td>Varicella (Varivax) Frozen</td>
<td>2/2020*</td>
<td>MRC-5 human diploid cells, including DNA &amp; protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum</td>
</tr>
<tr>
<td>Varicella (Varivax) Refrigerator Stable</td>
<td>10/2018</td>
<td>MRC-5 human diploid cells, including DNA &amp; protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum</td>
</tr>
<tr>
<td>Yellow Fever (YF-Vax)</td>
<td>2/2019</td>
<td>sorbitol, gelatin, sodium chloride</td>
</tr>
<tr>
<td>Zoster (Shingles) (Zostavax)</td>
<td>1/2019</td>
<td>MRC-5 human diploid cells, including DNA &amp; protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Date</td>
<td>Contains</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Zoster (Shingles) (Zostavax)</td>
<td>8/2018</td>
<td>MRC-5 human diploid cells, including DNA &amp; protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum</td>
</tr>
<tr>
<td>(Shingrix) Refrigerator Stable</td>
<td>2/2020*</td>
<td>sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-0-desacetylated monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract Quillaja saponaria Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA</td>
</tr>
</tbody>
</table>

A table listing vaccine excipients and media by excipient is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at [http://www.vaccinesafety.edu/components-Excipients.htm](http://www.vaccinesafety.edu/components-Excipients.htm).

February 2020
Vaccine Injury Table

Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after March 21, 2017

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Illness, disability, injury or condition covered</th>
<th>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Brachial Neuritis</td>
<td>2-28 days (not less than 2 days and not more than 28 days).</td>
</tr>
<tr>
<td></td>
<td>C. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>D. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Encephalopathy or encephalitis</td>
<td>≤72 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>D. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV)</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Encephalopathy or encephalitis</td>
<td>5-15 days (not less than 5 days and not more than 15 days).</td>
</tr>
<tr>
<td></td>
<td>C. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>D. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Illness, disability, injury or condition covered</td>
<td>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IV. Vaccines containing rubella virus (e.g., MMR, MMRV)</td>
<td>A. Chronic arthritis</td>
<td>7-42 days (not less than 7 days and not more than 42 days).</td>
</tr>
<tr>
<td></td>
<td>B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Vaccine-strain virus identified</td>
<td>Not applicable.</td>
</tr>
<tr>
<td></td>
<td>—If strain determination is not done or if laboratory testing is inconclusive</td>
<td>≤12 months.</td>
</tr>
<tr>
<td>V. Vaccines containing measles virus (e.g., MMR, MM, MMRV)</td>
<td>A. Thrombocytopenic purpura</td>
<td>7-30 days (not less than 7 days and not more than 30 days).</td>
</tr>
<tr>
<td></td>
<td>B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Vaccine-strain virus identified</td>
<td>Not applicable.</td>
</tr>
<tr>
<td></td>
<td>—If strain determination is not done or if laboratory testing is inconclusive</td>
<td>≤12 months.</td>
</tr>
<tr>
<td>VI. Vaccines containing polio live virus (OPV)</td>
<td>A. Paralytic Polio</td>
<td></td>
</tr>
<tr>
<td></td>
<td>—in a non-immunodeficient recipient</td>
<td>≤30 days.</td>
</tr>
<tr>
<td></td>
<td>—in an immunodeficient recipient</td>
<td>≤6 months.</td>
</tr>
<tr>
<td></td>
<td>—in a vaccine associated community case</td>
<td>Not applicable.</td>
</tr>
<tr>
<td></td>
<td>B. Vaccine-Strain Polio Viral Infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>—in a non-immunodeficient recipient</td>
<td>≤30 days.</td>
</tr>
<tr>
<td></td>
<td>—in an immunodeficient recipient</td>
<td>≤6 months.</td>
</tr>
<tr>
<td></td>
<td>—in a vaccine associated community case</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>VII. Vaccines containing polio inactivated virus (e.g., IPV)</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>VIII. Hepatitis B vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Illness, disability, injury or condition covered</td>
<td>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IX. Haemophilus influenzae type b (Hib) vaccines</td>
<td>A. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>X. Varicella vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Disseminated varicella vaccine-strain viral disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Vaccine-strain virus identified</td>
<td>Not applicable.</td>
</tr>
<tr>
<td></td>
<td>—If strain determination is not done or if laboratory testing is inconclusive</td>
<td>7-42 days (not less than 7 days and not more than 42 days).</td>
</tr>
<tr>
<td></td>
<td>C. Varicella vaccine-strain viral reactivation</td>
<td>Not applicable.</td>
</tr>
<tr>
<td></td>
<td>D. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>E. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>XI. Rotavirus vaccines</td>
<td>A. Intussusception</td>
<td>1-21 days (not less than 1 day and not more than 21 days).</td>
</tr>
<tr>
<td>XII. Pneumococcal conjugate vaccines</td>
<td>A. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>XIII. Hepatitis A vaccines</td>
<td>A. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>XIV. Seasonal influenza vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td></td>
<td>D. Guillain-Barré Syndrome</td>
<td>3-42 days (not less than 3 days and not more than 42 days).</td>
</tr>
<tr>
<td>XV. Meningococcal vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>XVI. Human papillomavirus (HPV) vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤4 hours.</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Illness, disability, injury or condition covered</td>
<td>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>B. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>C. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
<tr>
<td>XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage</td>
<td>A. Shoulder Injury Related to Vaccine Administration</td>
<td>≤48 hours.</td>
</tr>
<tr>
<td></td>
<td>B. Vasovagal syncope</td>
<td>≤1 hour.</td>
</tr>
</tbody>
</table>

(b) Provisions that apply to all conditions listed. (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) Qualifications and aids to interpretation. The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) Anaphylaxis. Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) Encephalopathy. A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) Acute encephalopathy. (A) For children less than 18 months of age who present:

(1) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(2) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.
(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

1. A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);
2. A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and
3. A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) Exclusionary criteria for encephalopathy. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

A. An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or perinatal central nervous system (CNS) injury); or

B. An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) Encephalitis. A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) Acute encephalitis. Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

A. Evidence of neurologic dysfunction consists of either:

1. One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

2. An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

B. Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm\(^3\) in children >2 months of age and adults; >15 WBC/mm\(^3\) in children <2 months of age); or at least two of the following:
(1) Fever (temperature ≥ 100.4 degrees Fahrenheit);

(2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) Exclusionary criteria for encephalitis. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) Intussusception. (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguish crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal
hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(5) Chronic arthritis. Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/detramatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) Brachial neuritis. This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.
(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura*. This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm³ with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) *Vaccine-strain measles viral disease*. This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *Vaccine-strain polio viral infection*. This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) *Shoulder injury related to vaccine administration (SIRVA)*. SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;
(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

(11) **Disseminated varicella vaccine-strain viral disease.** Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7-42 days after vaccination.

(12) **Varicella vaccine-strain viral reactivation disease.** Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(13) **Vasovagal syncope.** Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequel to an episode of syncope meeting the Table requirements.

(14) **Immunodeficient recipient.** Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(15) **Guillain-Barré Syndrome (GBS).** (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.
(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;

(B) A monophasic illness pattern;

(C) An interval between onset and nadir of weakness between 12 hours and 28 days;

(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,

(E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

(A) Bilateral ophthalmoparesis;

(B) Bilateral reduced or absent tendon reflexes;

(C) Ataxia;

(D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);

(E) A monophasic illness pattern;

(F) An interval between onset and nadir of weakness between 12 hours and 28 days;

(G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);

(H) No alteration in consciousness;

(I) No corticospinal track signs; and

(J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with
a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) Glossary for purposes of paragraph (c) of this section—(1) Chronic encephalopathy. (i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) Injected refers to the intramuscular, intradermal, or subcutaneous needle administration of a vaccine.

(3) Sequela means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) Significantly decreased level of consciousness is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) Seizure includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.
(e) **Coverage provisions.** (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.
MMRV Vaccine Package Insert

Note Section 5.8 – Risk of Vaccine Virus Transmission

and

Sec. 13 – “ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.”

In other words, the MMRV vaccine (measles, mumps, rubella, varicella) has not been evaluated for its potential to: cause cancer, damage DNA, cause miscarriages and birth defects, or impair fertility.

All vaccine package inserts have a Section 13, admitting NO evaluations for cancer, DNA damage, & impaired fertility, meaning -

NO LONG TERM STUDIES WERE CONDUCTED OR CONSIDERED
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ProQuad safely and effectively. See full prescribing information for ProQuad.

ProQuad®
Measles, Mumps, Rubella and Varicella Virus Vaccine Live Suspension for subcutaneous injection
Initial U.S. Approval: 2005

INDICATIONS AND USAGE
ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age. (1)

DOSAGE AND ADMINISTRATION
A 0.5-mL dose for subcutaneous injection only. (2.1)
- The first dose is usually administered at 12 to 15 months of age. (2.1)
- A second dose, if needed, is usually administered at 4 to 6 years of age. (2.1)

DOSAGE FORMS AND STRENGTHS
Suspension for injection (0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using only accompanying sterile diluent. (2.2, 3)

CONTRAINDICATIONS
- History of anaphylactic reaction to neomycin or hypersensitivity to gelatin or any other component of the vaccine. (4.1)
- Primary or acquired immunodeficiency states. (4.2)
- Family history of congenital or hereditary immunodeficiency. (4.2)
- Immunosuppressive therapy. (4.2, 7.3)
- Active untreated tuberculosis or febrile illness (>101.3°F or >38.5°C). (4.3)
- Pregnancy. (4.4, 8.1, 17)

WARNINGS AND PRECAUTIONS
- Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R® II and VARIVAX® administered separately. (5.1, 6.1, 6.3)
- Use caution when administering ProQuad to children with a history of cerebral injury or seizures or any other condition in which stress due to fever should be avoided. (5.2)
- Use caution when administering ProQuad to children with anaphylaxis or immediate hypersensitivity to eggs (5.3) or contact hypersensitivity to neomycin. (5.4)
- Use caution when administering ProQuad to children with thrombocytopenia. (5.5)
- Avoid close contact with high-risk individuals susceptible to varicella since transmission of varicella vaccine virus may occur between vaccinees and susceptible contacts. (5.8)
- Defer vaccination for at least 3 months following blood or plasma transfusions, or administration of immune globulins (IG). (5.9, 7.1)
- Avoid using salicylates for 6 weeks after vaccination with ProQuad. (5.10, 7.2, 17)
- Avoid pregnancy for 3 months following vaccination with measles, mumps, rubella, and/or varicella vaccines. (8.1, 17)

ADVERSE REACTIONS
The most frequent vaccine-related adverse events reported in ≥5% of subjects vaccinated with ProQuad were:
- injection-site reactions (pain/tenderness/soreness, erythema, and swelling)
- fever
- irritability. (6.1)
- Systemic vaccine-related adverse events that were reported at a significantly greater rate in recipients of ProQuad than in recipients of the component vaccines administered concomitantly were:
- fever
- measles-like rash. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

DRUG INTERACTIONS
- Tuberculin testing should be administered anytime before, simultaneously with, or at least 4 to 6 weeks after ProQuad. (7.4)
- ProQuad may be administered concomitantly with Haemophilus influenzae type b conjugate vaccine and/or hepatitis B vaccine at separate injection sites. (7.5)
- ProQuad may be administered concomitantly with pneumococcal 7-valent conjugate vaccine and/or hepatitis A vaccine (inactivated) at separate injection sites. (7.5)

USE IN SPECIFIC POPULATIONS
Pregnancy: Do not administer ProQuad to females who are pregnant. Pregnancy should be avoided for 3 months following vaccination with ProQuad. (4.4, 8.1, 17)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: XX/XXXX

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ProQuad® is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose and Schedule

FOR SUBCUTANEOUS ADMINISTRATION ONLY

Each 0.5-mL dose of ProQuad is administered subcutaneously.

The first dose is usually administered at 12 to 15 months of age but may be given anytime through 12 years of age.

If a second dose of measles, mumps, rubella, and varicella vaccine is needed, ProQuad may be used. This dose is usually administered at 4 to 6 years of age. At least 1 month should elapse between a dose of a measles-containing vaccine such as M-M-R® II (measles, mumps, and rubella virus vaccine live) and a dose of ProQuad. At least 3 months should elapse between a dose of varicella-containing vaccine and ProQuad.

2.2 Preparation for Administration

CAUTION: Preservatives, antiseptics, detergents, and other anti-viral substances may inactivate the vaccine. Use only sterile syringes that are free of preservatives, antiseptics, detergents, and other anti-viral substances for reconstitution and injection of ProQuad.

Withdraw the entire volume of the supplied diluent into a syringe. Use only the diluent supplied with the vaccine since it is free of preservatives or other anti-viral substances.

Inject the entire content of the syringe into the vial containing the powder. Gently agitate to dissolve completely.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Visually inspect the vaccine before and after reconstitution prior to administration. Before reconstitution, the lyophilized vaccine is a white to pale yellow compact crystalline plug. ProQuad, when reconstituted, is a clear pale yellow to light pink liquid.

Withdraw the entire amount of the reconstituted vaccine from the vial into the same syringe and inject the entire volume.

TO MINIMIZE LOSS OF POTENCY, THE VACCINE SHOULD BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION. IF NOT USED IMMEDIATELY, THE RECONSTITUTED VACCINE MAY BE STORED AT ROOM TEMPERATURE, PROTECTED FROM LIGHT, FOR UP TO 30 MINUTES. DISCARD RECONSTITUTED VACCINE IF IT IS NOT USED WITHIN 30 MINUTES.

2.3 Method of Administration

Inject the vaccine subcutaneously into the outer aspect of the deltoid region of the upper arm or into the higher anterolateral area of the thigh.

Use With Other Vaccines

Use different injection sites to administer each vaccine if other vaccines are administered concomitantly. [See Drug Interactions (7.5).]

3 DOSAGE FORMS AND STRENGTHS

ProQuad is a suspension for injection supplied as a 0.5-mL single dose vial of lyophilized vaccine to be reconstituted using the sterile diluent supplied [see How Supplied/Storage and Handling (16)].

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Do not administer ProQuad to individuals with a history of anaphylactic reactions to neomycin. If vaccination with ProQuad is medically necessary for such individuals, they are advised to consult an allergist or immunologist and should receive ProQuad only in settings where anaphylactic reactions can be appropriately managed.
Do not administer ProQuad to individuals with a history of hypersensitivity to gelatin or any other component of the vaccine or following previous vaccination with ProQuad, VARIOVAX® (varicella virus vaccine live), or any measles-, mumps-, or rubella-containing vaccine [see Description (11) and Warnings and Precautions (5) for exceptions].

4.2 Immunosuppression

Do not administer ProQuad to individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; or to individuals on immunosuppressive therapy (including high-dose systemic corticosteroids) [see Drug Interactions (7.3)]. Vaccination with a live, attenuated vaccine, such as varicella, can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressive drugs. ProQuad may be used by individuals who are receiving topical corticosteroids or low-dose corticosteroids, as are commonly used for asthma prophylaxis or in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Do not administer ProQuad to individuals with primary and acquired immunodeficiency states, including AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Measles inclusion body encephalitis, pneumonia, and death as a direct consequence of disseminated measles vaccine virus infection have been reported in severely immunocompromised individuals inadvertently vaccinated with measles-containing vaccine. In addition, disseminated varicella vaccine virus infection has been reported in children with underlying immunodeficiency disorders who were inadvertently vaccinated with a varicella-containing vaccine.

Do not administer ProQuad to individuals with a family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated.

4.3 Concurrent Illness

Do not administer ProQuad to individuals with active untreated tuberculosis or to individuals with an active febrile illness with fever >101.3°F (>38.5°C).

4.4 Pregnancy

Do not administer ProQuad to individuals who are pregnant because the effects of the vaccine on fetal development are unknown. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following administration of ProQuad [see Use in Specific Populations (8.1) and Patient Counseling Information (17)].

5 WARNINGS AND PRECAUTIONS

5.1 Fever and Febrile Seizures

Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with dose 1 of both M-M-R II and VARIOVAX administered separately [see Adverse Reactions (6.3)].

5.2 History of Cerebral Injury or Seizures

Exercise caution when administering ProQuad to persons with a history of cerebral injury, individual or family history of convulsions, or any other condition in which stress due to fever should be avoided. Healthcare providers should be alert to the temperature elevations that may occur following vaccination.

5.3 Hypersensitivity to Eggs

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic or other immediate hypersensitivity reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. Carefully evaluate the potential risk-to-benefit ratio before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution; adequate treatment should be readily available should a reaction occur [see Contraindications (4.1)](2).

Children with egg allergy are at low risk for anaphylactic reactions to measles-containing vaccines (including M-M-R II), and skin testing of children allergic to eggs is not predictive of reactions to M-M-R II
vaccine. Persons with allergies to chickens or feathers are not at increased risk of reaction to the vaccine.

5.4 Contact Hypersensitivity to Neomycin
Most often, neomycin allergy manifests as a contact dermatitis, which is not a contraindication to receiving measles-, mumps-, rubella-, or varicella-containing vaccine.

5.5 Thrombocytopenia
Carefully evaluate the potential risk-to-benefit ratio before considering vaccination with ProQuad in children with thrombocytopenia or in those who experienced thrombocytopenia after vaccination with a previous dose of measles, mumps, rubella, and/or varicella vaccine. No clinical data are available regarding the development or worsening of thrombocytopenia in individuals vaccinated with ProQuad. Cases of thrombocytopenia have been reported after primary vaccination with measles vaccine; measles, mumps, and rubella vaccine; after varicella vaccination; and following re-vaccination with measles vaccine or M-M-R II [see Adverse Reactions (6.2)].

5.6 Use for Post-Exposure Prophylaxis
The safety and efficacy of ProQuad for use after exposure to measles, mumps, rubella, or varicella have not been established.

5.7 Use in HIV-Infected Children
The safety and efficacy of ProQuad for use in children known to be infected with human immunodeficiency viruses have not been established.

5.8 Risk of Vaccine Virus Transmission
Post-licensing experience with VARIVAX suggests that transmission of varicella vaccine virus may occur between healthy vaccine recipients (who develop or do not develop a varicella-like rash) and contacts susceptible to varicella, as well as high-risk individuals susceptible to varicella.

High-risk individuals susceptible to varicella include:
- Immunocompromised individuals;
- Pregnant women without documented positive history of varicella (chickenpox) or laboratory evidence of prior infection;
- Newborn infants of mothers without documented positive history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.

Vaccine recipients should attempt to avoid, to the extent possible, close association with high-risk individuals susceptible to varicella for up to 6 weeks following vaccination. In circumstances where contact with high-risk individuals susceptible to varicella is unavoidable, the potential risk of transmission of the varicella vaccine virus should be weighed against the risk of acquiring and transmitting wild-type varicella virus.

Excretion of small amounts of the live, attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk. However, transmission of the rubella vaccine virus to infants via breast milk has been documented [see Use in Specific Populations (8.2)].

There are no reports of transmission of the more attenuated Enders' Edmonston strain of measles virus or the Jeryl Lynn™ strain of mumps virus from vaccine recipients to susceptible contacts.

5.9 Immune Globulins and Transfusions
Immune globulins (IG) administered concomitantly with ProQuad contain antibodies that may interfere with vaccine virus replication and decrease the expected immune response. Vaccination should be deferred for at least 3 months following blood or plasma transfusions, or administration of IG.

The appropriate suggested interval between transfusion or IG administration and vaccination will vary with the type of transfusion or indication for, and dose of, IG (e.g., 5 months for Varicella Zoster Immune Globulin [VZIG]) {2}. Following administration of ProQuad, any IG including VZIG should not be given for 1 month thereafter unless its use outweighs the benefits of vaccination {2}. [See Drug Interactions (7.1).]

5.10 Salicylate Therapy
Avoid the use of salicylates (aspirin) or salicylate-containing products in children and adolescents 12 months through 12 years of age, for six weeks following vaccination with ProQuad due to the association...
of Reye syndrome with aspirin therapy and wild-type varicella infection. [See Drug Interactions (7.2) and Patient Counseling Information (17).]

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. Vaccine-related adverse reactions reported during clinical trials were assessed by the study investigators to be possibly, probably, or definitely vaccine-related and are summarized below.

Children 12 Through 23 Months of Age Who Received a Single Dose of ProQuad

ProQuad was administered to 4497 children 12 through 23 months of age involved in 4 randomized clinical trials without concomitant administration with other vaccines. The safety of ProQuad was compared with the safety of M-M-R II and VARIVAX given concomitantly (N=2038) at separate injection sites. The safety profile for ProQuad was similar to the component vaccines. Children in these studies were monitored for up to 42 days postvaccination using vaccination report card-aided surveillance. Safety follow-up was obtained for 98% of children in each group. Few subjects (<0.1%) who received ProQuad discontinued the study due to an adverse reaction. The race distribution of the study subjects across these studies following a first dose of ProQuad was as follows: 65.2% White; 13.1% African-American; 11.1% Hispanic; 5.8% Asian/Pacific; 4.5% other; and 0.2% American Indian. The racial distribution of the control group was similar to that of the group who received ProQuad. The gender distribution across the studies following a first dose of ProQuad was 52.5% male and 47.5% female. The gender distribution of the control group was similar to that of the group who received ProQuad. Vaccine-related injection-site and systemic adverse reactions observed among recipients of ProQuad or M-M-R II and VARIVAX at a rate of at least 1% are shown in Table 1. Systemic vaccine-related adverse reactions that were reported at a significantly greater rate in individuals who received a first dose of ProQuad than in individuals who received first doses of M-M-R II and VARIVAX concomitantly at separate injection sites were fever (≥102°F [≥38.9°C] oral equivalent or abnormal) (21.5% versus 14.9%, respectively, risk difference 6.6%, 95% CI: 4.6, 8.5), and measles-like rash (3.0% versus 2.1%, respectively, risk difference 1.0%, 95% CI: 0.1, 1.8). Both fever and measles-like rash usually occurred within 5 to 12 days following the vaccination, were of short duration, and resolved with no long-term sequelae. Pain/tenderness/soreness at the injection site was reported at a statistically lower rate in individuals who received a first dose of ProQuad than in individuals who received first doses of M-M-R II and VARIVAX concomitantly at separate injection sites (22.0% versus 26.8%, respectively, risk difference -4.8%, 95% CI: -7.1, -2.5). The only vaccine-related injection-site adverse reaction that was more frequent among recipients of ProQuad than recipients of M-M-R II and VARIVAX was rash at the injection site (2.4% versus 1.6%, respectively, risk difference 0.9%, 95% CI: 0.1, 1.5).

Table 1: Vaccine-Related Injection-Site and Systemic Adverse Reactions Reported in ≥1% of Children Who Received ProQuad Dose 1 or M-M-R II and VARIVAX at 12 to 23 Months of Age (0 to 42 Days Postvaccination)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ProQuad (N=4497)</th>
<th>M-M-R II and VARIVAX (N=2038)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=4424)</td>
<td>(n=1997)</td>
</tr>
<tr>
<td>Injection Site*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness/soreness†</td>
<td>22.0</td>
<td>26.7</td>
</tr>
<tr>
<td>Erythema†</td>
<td>14.4</td>
<td>15.8</td>
</tr>
<tr>
<td>Swelling†</td>
<td>8.4</td>
<td>9.8</td>
</tr>
<tr>
<td>Ecchymosis</td>
<td>1.5</td>
<td>2.3</td>
</tr>
<tr>
<td>Rash</td>
<td>2.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Systemic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever†</td>
<td>21.5</td>
<td>14.9</td>
</tr>
<tr>
<td>Irritability</td>
<td>6.7</td>
<td>6.7</td>
</tr>
<tr>
<td>Measles-like rash†</td>
<td>3.0</td>
<td>2.1</td>
</tr>
<tr>
<td>Varicella-like rash†</td>
<td>2.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Rash (not otherwise specified)</td>
<td>1.6</td>
<td>1.4</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>1.3</td>
<td>1.1</td>
</tr>
</tbody>
</table>
Rubella-like rashes were observed in <1% of subjects following a first dose of ProQuad. In these clinical trials, two cases of herpes zoster were reported among 2108 healthy subjects 12 through 23 months of age who were vaccinated with their first dose of ProQuad and followed for 1 year. Both cases were unremarkable and no sequelae were reported.

**Children 15 to 31 Months of Age Who Received a Second Dose of ProQuad**

In 5 clinical trials, 2780 healthy children were vaccinated with ProQuad (dose 1) at 12 to 23 months of age and then administered a second dose approximately 3 to 9 months later. The race distribution of the study subjects across these studies following a second dose of ProQuad was as follows: 64.4% White; 14.1% African-American; 12.0% Hispanic; 5.9% other; 3.5% Asian/Pacific; and 0.1% American Indian. The gender distribution across the studies following a second dose of ProQuad was 51.5% male and 48.5% female. Children in these open-label studies were monitored for at least 28 days postvaccination using vaccination report card-aided surveillance. Safety follow-up was obtained for approximately 97% of children overall. Vaccine-related injection-site and systemic adverse reactions observed after Dose 1 and 2 of ProQuad at a rate of at least 1% are shown in Table 2. In these trials, the overall rates of systemic adverse reactions after ProQuad (dose 2) were comparable to, or lower than, those seen with the first dose. In the subset of children who received both ProQuad dose 1 and dose 2 in these trials (N=2408) with follow-up for fever, fever ≥102.2°F (≥38.9°C) was observed significantly less frequently days 1 to 28 after the second dose (10.8%) than after the first dose (19.1%) (risk difference 8.3%, 95% CI: 6.4, 10.3). Fever ≥102.2°F (≥38.9°C) days 5 to 12 after vaccinations were also reported significantly less frequently after dose 2 (3.9%) than after dose 1 (13.6%) (risk difference 9.7%, 95% CI: 8.1, 11.3). In the subset of children who received both doses and for whom injection-site reactions were reported (N=2679), injection-site erythema was noted significantly more frequently after ProQuad (dose 2) as compared to ProQuad (dose 1) (12.6% and 10.8%, respectively, risk difference -1.8, 95% CI: -3.3, -0.3); however, pain and tenderness at the injection site was significantly lower after dose 2 (16.1%) as compared with after dose 1 (21.9%) (risk difference 5.8%, 95% CI: 4.1, 7.6). Two children had febrile seizures after ProQuad (dose 2); both febrile seizures were thought to be related to a concurrent viral illness [see Adverse Reactions (6.3) and Clinical Studies (14)]. These studies were not designed or statistically powered to detect a difference in rates of febrile seizure between recipients of ProQuad as compared to M-M-R II and VARIVAX. The risk of febrile seizure has not been evaluated in a clinical study comparing the incidence rate after ProQuad (dose 2) with the incidence rate after concomitant M-M-R II (dose 2) and VARIVAX (dose 2). [See Adverse Reactions (6.1), Children 4 to 6 Years of Age Who Received ProQuad After Primary Vaccination with M-M-R II and VARIVAX.]

**Table 2: Vaccine-Related Injection-Site and Systemic Adverse Reactions**

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ProQuad Dose 1 (N=3112)</th>
<th>ProQuad Dose 2 (N=2780)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=3019)</td>
<td>(n=2695)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td><strong>Injection-Site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness/soreness*</td>
<td>21.4</td>
<td>15.9</td>
</tr>
<tr>
<td>Erythema*</td>
<td>10.7</td>
<td>12.4</td>
</tr>
<tr>
<td>Swelling*</td>
<td>8.0</td>
<td>8.5</td>
</tr>
<tr>
<td>Injection-site bruising</td>
<td>1.1</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Systemic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever*†</td>
<td>20.4</td>
<td>8.3</td>
</tr>
<tr>
<td>Irritability</td>
<td>6.0</td>
<td>2.4</td>
</tr>
<tr>
<td>Measles-like/Rubella-like rash</td>
<td>4.3</td>
<td>0.9</td>
</tr>
</tbody>
</table>

* Injection-site adverse reactions for M-M-R II and VARIVAX are based on occurrence with either of the vaccines administered.
† Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 0 to 4 postvaccination.
‡ Temperature reported as elevated (≥102°F, oral equivalent) or abnormal.
N = number of subjects vaccinated.
n = number of subjects with safety follow-up.
Varicella-like/Vesicular rash 1.5 0.1
Diarrhea 1.3 0.6
Upper respiratory infection 1.3 1.4
Rash (not otherwise specified) 1.2 0.6
Rhinorrhea 1.1 1.0

* Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 1 to 5 postvaccination.
† Temperature reported as elevated (≥102°F, oral equivalent) or abnormal.
N = number of subjects vaccinated.
n = number of subjects with safety follow-up.

Children 4 to 6 Years of Age Who Received ProQuad After Primary Vaccination with M-M-R II and VARIVAX

In a double-blind clinical trial, 799 healthy 4- to 6-year-old children who received M-M-R II and VARIVAX at least 1 month prior to study entry were randomized to receive ProQuad and placebo (N=399), M-M-R II and placebo concomitantly (N=205) at separate injection sites, or M-M-R II and VARIVAX (N=195) concomitantly at separate injection sites [see Clinical Studies (14)]. Children in these studies were monitored for up to 42 days postvaccination using vaccination report card-aided surveillance. Safety follow-up was obtained for >98% of children in each group. The race distribution of the study subjects following a dose of ProQuad was as follows: 78.4% White; 12.3% African-American; 3.8% Hispanic; 3.5% other; and 2.0% Asian/Pacific. The gender distribution following a dose of ProQuad was 52.1% male and 47.9% female. Injection-site and systemic adverse reactions observed after Dose 1 and 2 of ProQuad at a rate of at least 1% are shown in Table 3. [See Clinical Studies (14).]

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ProQuad + Placebo (N=399)</th>
<th>M-M-R II + Placebo (N=205)</th>
<th>M-M-R II + VARIVAX (N=195)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td><strong>Systemic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever *,†</td>
<td>2.5</td>
<td>2.0</td>
<td>4.1</td>
</tr>
<tr>
<td>Cough</td>
<td>1.3</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Irritability</td>
<td>1.0</td>
<td>0.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Headache</td>
<td>0.8</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>0.5</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>0.3</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.3</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>0.0</td>
<td>0.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Injection-Site</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain *,†</td>
<td>41.1</td>
<td>34.5</td>
<td>36.6</td>
</tr>
<tr>
<td>Erythema</td>
<td>24.4</td>
<td>13.4</td>
<td>15.6</td>
</tr>
<tr>
<td>Swelling *,†</td>
<td>15.6</td>
<td>8.1</td>
<td>10.2</td>
</tr>
<tr>
<td>Swelling</td>
<td>3.5</td>
<td>3.8</td>
<td>2.4</td>
</tr>
<tr>
<td>Swelling</td>
<td>1.5</td>
<td>1.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1.0</td>
<td>0.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Nodule</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

* Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 1 to 5 postvaccination.
† Temperature reported as elevated (≥102°F, oral equivalent) or abnormal.

Safety in Trials That Evaluated Concomitant Use with Other Vaccines

ProQuad Administered with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and Haemophilus influenzae type b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine
In an open-label clinical trial, 1434 children were randomized to receive ProQuad given with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP) and *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine concomitantly (N=949) or non-concomitantly with ProQuad given first and the other vaccines 6 weeks later (N=485). No clinically significant differences in adverse events were reported between treatment groups [see Clinical Studies (14)]. The race distribution of the study subjects who received ProQuad was as follows: 70.7% White; 10.9% Asian/Pacific; 10.7% African-American; 4.5% Hispanic; 3.0% other; and 0.2% American Indian. The gender distribution of the study subjects who received ProQuad was 53.6% male and 46.4% female.

**ProQuad Administered with Pneumococcal 7-valent Conjugate Vaccine and/or Hepatitis A Vaccine, Inactivated**

In an open-label clinical trial, 1027 healthy children 12 to 23 months of age were randomized to receive ProQuad (dose 1) and pneumococcal 7-valent conjugate vaccine (dose 4) concomitantly (N=510) or non-concomitantly at different clinic visits (N=517). The race distribution of the study subjects was as follows: 65.2% White; 15.1% African-American; 10.0% Hispanic; 6.6% other; and 3.0% Asian/Pacific. The gender distribution of the study subjects was 54.5% male and 45.5% female. Injection-site and systemic adverse reactions observed among recipients of ProQuad administered concomitantly or non-concomitantly with pneumococcal 7-valent conjugate vaccine at a rate of at least 1% are shown in Table 4. No clinically significant differences in adverse reactions were reported between the concomitant and non-concomitant treatment groups [see Clinical Studies (14)].

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ProQuad + PCV7 (N=510)</th>
<th>PCV7 (N=258)</th>
<th>ProQuad (N=259)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=498)</td>
<td>(n=250)</td>
<td>(n=255)</td>
</tr>
<tr>
<td><strong>Injection-Site - ProQuad</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain†</td>
<td>24.9</td>
<td>N/A</td>
<td>24.7</td>
</tr>
<tr>
<td>Erythema†</td>
<td>12.4</td>
<td>N/A</td>
<td>11.0</td>
</tr>
<tr>
<td>Swelling†</td>
<td>10.8</td>
<td>N/A</td>
<td>7.5</td>
</tr>
<tr>
<td>Bruising</td>
<td>2.0</td>
<td>N/A</td>
<td>1.6</td>
</tr>
<tr>
<td><strong>Injection-Site - PCV7</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain†</td>
<td>30.5</td>
<td>29.6</td>
<td>N/A</td>
</tr>
<tr>
<td>Erythema†</td>
<td>21.1</td>
<td>24.4</td>
<td>N/A</td>
</tr>
<tr>
<td>Swelling†</td>
<td>17.9</td>
<td>20.0</td>
<td>N/A</td>
</tr>
<tr>
<td>Bruising</td>
<td>1.6</td>
<td>1.2</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Systemic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever†,‡</td>
<td>15.5</td>
<td>10.0</td>
<td>15.3</td>
</tr>
<tr>
<td>Measles-like rash</td>
<td>4.4</td>
<td>0.8</td>
<td>5.1</td>
</tr>
<tr>
<td>Irritability</td>
<td>3.8</td>
<td>3.6</td>
<td>3.5</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>1.6</td>
<td>0.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Varicella-like/vesicular rash</td>
<td>1.6</td>
<td>0.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0.8</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.6</td>
<td>0.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Rash</td>
<td>0.4</td>
<td>0.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Somnolence</td>
<td>0.0</td>
<td>0.0</td>
<td>1.2</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine, dose 4.
† Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 1 to 5 postvaccination.
‡ Temperature reported as elevated (≥102°F, oral equivalent) or abnormal.
N/A = Not applicable.
N = number of subjects vaccinated.
n = number of subjects with safety follow-up.

In an open-label clinical trial, 699 healthy children 12 to 23 months of age were randomized to receive 2 doses of VAQTA® (hepatitis A vaccine, inactivated) (N=352) or 2 doses of VAQTA concomitantly with 2 doses of ProQuad (N=347) at least 6 months apart. An additional 1101 subjects received 2 doses of VAQTA alone at least 6 months apart (non-randomized), resulting in 1453 subjects receiving 2 doses of VAQTA alone (1101 non-randomized and 352 randomized) and 347 subjects receiving 2 doses of VAQTA concomitantly with ProQuad (all randomized). The race distribution of the study subjects following
a dose of ProQuad was as follows: 47.3% White; 42.7% Hispanic; 5.5% other; 2.9% African-American; and 1.7% Asian/Pacific. The gender distribution of the study subjects following a dose of ProQuad was 49.3% male and 50.7% female. Vaccine-related injection-site adverse reactions (days 1 to 5 postvaccination) and systemic adverse events (days 1 to 14 post VAQTA and days 1 to 28 post ProQuad vaccination) observed among recipients of VAQTA and ProQuad administered concomitantly with VAQTA at a rate of at least 1% are shown in Tables 5 and 6, respectively. In addition, among the randomized cohort, in the 14 days after each vaccination, the rates of fever (including all vaccine- and non-vaccine-related reports) were significantly higher in subjects who received ProQuad with VAQTA concomitantly after dose 1 (22.0%) as compared to subjects given dose 1 of VAQTA without ProQuad (10.8%). However, rates of fever were not significantly higher in subjects who received ProQuad with VAQTA concomitantly after dose 2 (12.5%) as compared to subjects given dose 2 of VAQTA without ProQuad (9.4%). In post-hoc analyses, these rates were significantly different for dose 1 (relative risk (RR) 2.03 [95% CI: 1.42, 2.94]), but not dose 2 (RR 1.32 [95% CI: 0.82, 2.13]). Rates of injection-site adverse reactions and other systemic adverse events were lower following a second dose than following the first dose of both vaccines given concomitantly.

### Table 5: Vaccine-Related Injection-Site Adverse Reactions Reported in ≥1% of Children Who Received VAQTA or ProQuad Concomitantly with VAQTA 1 to 5 Days After Vaccination with VAQTA or VAQTA and ProQuad

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VAQTA</td>
<td>ProQuad + VAQTA</td>
<td>VAQTA</td>
<td>ProQuad + VAQTA</td>
</tr>
<tr>
<td></td>
<td>(N=1453)</td>
<td>(N=347)</td>
<td>(N=1301)</td>
<td>(N=292)</td>
</tr>
<tr>
<td></td>
<td>(n=1412)</td>
<td>(n=328)</td>
<td>(n=1254)</td>
<td>(n=264)</td>
</tr>
<tr>
<td>Injection-Site - VAQTA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness*</td>
<td>29.2%</td>
<td>27.1%</td>
<td>30.1%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Erythema*</td>
<td>13.5%</td>
<td>12.5%</td>
<td>14.3%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Swelling*</td>
<td>7.1%</td>
<td>9.1%</td>
<td>9.0%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Injection-site bruising</td>
<td>1.9%</td>
<td>2.4%</td>
<td>1.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Injection-Site - ProQuad</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness*</td>
<td>N/A</td>
<td>30.5%</td>
<td>N/A</td>
<td>26.2%</td>
</tr>
<tr>
<td>Erythema*</td>
<td>N/A</td>
<td>13.4%</td>
<td>N/A</td>
<td>12.9%</td>
</tr>
<tr>
<td>Swelling*</td>
<td>N/A</td>
<td>6.7%</td>
<td>N/A</td>
<td>6.5%</td>
</tr>
<tr>
<td>Injection-site bruising</td>
<td>N/A</td>
<td>1.5%</td>
<td>N/A</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

* Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 1 to 5 postvaccination.

### Table 6: Vaccine-Related Systemic Adverse Reactions Reported in ≥1% of Children Who Received VAQTA* or ProQuad Concomitantly with VAQTA 1 to 14 Days After VAQTA or Vaccination with ProQuad and VAQTA and 1 to 28 Days After Vaccination with ProQuad and VAQTA

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VAQTA†</td>
<td>ProQuad + VAQTA†</td>
<td>VAQTA†</td>
<td>ProQuad + VAQTA†</td>
</tr>
<tr>
<td></td>
<td>(N=1453)</td>
<td>(N=347)</td>
<td>(N=1301)</td>
<td>(N=292)</td>
</tr>
<tr>
<td></td>
<td>(n=1412)</td>
<td>(n=328)</td>
<td>(n=1254)</td>
<td>(n=264)</td>
</tr>
<tr>
<td>Fever‡§</td>
<td>5.7%</td>
<td>14.9%</td>
<td>15.2%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Irritability</td>
<td>5.8%</td>
<td>7.0%</td>
<td>7.3%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Measles-like rash</td>
<td>0.0%</td>
<td>3.4%</td>
<td>3.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>0.6%</td>
<td>2.7%</td>
<td>3.0%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1.5%</td>
<td>1.8%</td>
<td>2.4%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Cough</td>
<td>0.6%</td>
<td>2.1%</td>
<td>2.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1.1%</td>
<td>0.3%</td>
<td>0.9%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

* Systemic adverse events for subjects given VAQTA alone were collected for 14 days postvaccination.
† Safety follow-up for systemic adverse reactions was 14 days for VAQTA and 28 days for ProQuad + VAQTA.
In an open-label clinical trial, 653 children 12 to 23 months of age were randomized to receive a first dose of ProQuad with VAQTA and pneumococcal 7-valent conjugate vaccine concomitantly (N=330) or a first dose of ProQuad and pneumococcal 7-valent conjugate vaccine concomitantly and then vaccinated with VAQTA 6 weeks later (N=323). Approximately 6 months later, subjects received either the second doses of ProQuad and VAQTA concomitantly or the second doses of ProQuad and VAQTA separately. The race distribution of the study subjects was as follows: 60.3% White; 21.6% African-American; 9.5% Hispanic; 7.2% other; 1.1% Asian/Pacific; and 0.3% American Indian. The gender distribution of the study subjects was 50.7% male and 49.3% female. Vaccine-related injection-site and systemic adverse reactions observed among recipients of concomitant ProQuad, VAQTA, and pneumococcal 7-valent conjugate vaccine and ProQuad and pneumococcal 7-valent conjugate vaccine at a rate of at least 1% are shown in Tables 7 and 8. In the 28 days after vaccination with the first dose of ProQuad, the rates of fever (including all vaccine- and non-vaccine-related reports) were comparable in subjects who received the 3 vaccines together (38.6%) as compared with subjects given ProQuad and pneumococcal 7-valent conjugate vaccine (42.7%). The rates of fever in the 28 days following the second dose of ProQuad were also comparable in subjects who received ProQuad and VAQTA together (17.4%) as compared with subjects given ProQuad separately from VAQTA (17.0%). In a post-hoc analysis, these differences were not statistically significant after ProQuad (dose 1) (RR 0.90 [95% CI: 0.75, 1.09]) nor after dose 2 (RR 1.02 [95% CI: 0.70, 1.51]). No clinically significant differences in adverse reactions were reported among treatment groups [see Clinical Studies (14)].

Table 7: Vaccine-Related Injection-Site Adverse Reactions
Reported in ≥1% of Children Who Received ProQuad + VAQTA + PCV7* Concomitantly or VAQTA Alone Followed by ProQuad + PCV7 Concomitantly (1 to 5 Days After a Dose of ProQuad)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VAQTA + ProQuad + PCV7 (N=330) (n=311)</td>
<td>VAQTA Alone Followed by ProQuad + PCV7 (N=323) (n=302)</td>
</tr>
<tr>
<td>Injection-Site - ProQuad</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness†</td>
<td>21.2%</td>
<td>24.2%</td>
</tr>
<tr>
<td>Erythema†</td>
<td>13.5%</td>
<td>11.9%</td>
</tr>
<tr>
<td>Swelling†</td>
<td>7.4%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Bruising</td>
<td>1.9%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Injection-Site - VAQTA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness†</td>
<td>20.6%</td>
<td>15.3%</td>
</tr>
<tr>
<td>Erythema†</td>
<td>9.6%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Swelling†</td>
<td>6.8%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Bruising</td>
<td>1.3%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Rash</td>
<td>1.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Injection-Site - PCV7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/tenderness†</td>
<td>25.4%</td>
<td>27.6%</td>
</tr>
<tr>
<td>Erythema†</td>
<td>16.4%</td>
<td>16.6%</td>
</tr>
<tr>
<td>Swelling†</td>
<td>13.2%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Bruising</td>
<td>0.6%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine.
† Designates a solicited adverse reaction. Injection-site adverse reactions were solicited only from Days 1 to 5 postvaccination at each vaccine injection site.
N/A = Not applicable.
N = number of subjects vaccinated.
n = number of subjects with safety follow-up.

Table 8: Vaccine-Related Systemic Adverse Reactions
Reported in ≥1% of Children Who Received ProQuad + VAQTA + PCV7* Concomitantly, or VAQTA Alone Followed by ProQuad + PCV7 Concomitantly (1 to 28 Days After a Dose of ProQuad)
### Adverse Reactions

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Dose 1 (%)</th>
<th></th>
<th>Dose 2 (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>VAQTA + ProQuad + PCV7 (N=330) (n=311)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAQTA Alone Followed by ProQuad + PCV7 (N=323) (n=302)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAQTA + ProQuad (N=273) (n=265)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAQTA Alone Followed by ProQuad (N=240) (n=230)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever†‡</td>
<td>26.4</td>
<td>27.2</td>
<td>9.1</td>
<td>9.6</td>
</tr>
<tr>
<td>Irritability</td>
<td>4.8</td>
<td>6.3</td>
<td>1.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Measles-like rash†</td>
<td>2.3</td>
<td>4.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Varicella-like rash†</td>
<td>1.0</td>
<td>1.7</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Rash (not otherwise specified)</td>
<td>1.3</td>
<td>1.3</td>
<td>0.4</td>
<td>1.3</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>1.0</td>
<td>1.3</td>
<td>1.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Viral infection</td>
<td>1.0</td>
<td>0.7</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>0.0</td>
<td>0.7</td>
<td>1.1</td>
<td>0.0</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine.
† Designates a solicited adverse reaction.
‡ Temperature reported as elevated or abnormal.
N = number of subjects vaccinated.
n = number of subjects with safety follow-up.

### 6.2 Post-Marketing Experience

The following adverse events have been identified during post-approval use of either the components of ProQuad or ProQuad. Because the events are in some cases described in the literature or reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

#### Infections and infestations
- Subacute sclerosing panencephalitis (see below), encephalitis (see below), aseptic meningitis (see below), meningitis, measles, atypical measles, pneumonia, respiratory infection, infection, varicella (vaccine strain), influenza, herpes zoster, orchitis, epididymitis, cellulitis, skin infection, retinitis, bronchitis, parotitis, sinusitis, impetigo, herpes simplex, candidiasis, rhinitis.
- Although not reported following vaccination with ProQuad, cases of encephalitis or meningitis caused by vaccine strain varicella virus have been reported in immunocompetent individuals previously vaccinated with VARIVAX (same varicella vaccine strain as in ProQuad) months to years after vaccination. Reported cases were commonly associated with preceding or concurrent herpes zoster rash (see below).

#### Blood and the lymphatic system disorders
- Aplastic anemia, thrombocytoopenia, regional lymphadenopathy, lymphadenitis.

#### Immune system disorders
- Anaphylaxis and related phenomena such as angioneurotic edema, facial edema, and peripheral edema, anaphylactoid reaction.

#### Psychiatric disorders
- Agitation, apathy, nervousness.

#### Nervous system disorders
- Measles inclusion body encephalitis [see Contraindications (4.2)], acute disseminated encephalomyelitis, transverse myelitis, cerebrovascular accident, encephalopathy (see below), Guillain-Barré syndrome, optic neuritis, Bell’s palsy, polyneuropathy, ataxia, hypersonnia, afebrile convulsions or seizures, febrile seizure, headache, syncope, dizziness, tremor, paraesthesia.

#### Eye disorders
- Necrotizing retinitis (in immunocompromised individuals), retrobulbar neuritis, ocular palsies, edema of the eyelid, irritation eye.

#### Ear and labyrinth disorders
- Nerve deafness, ear pain.

#### Vascular disorders
- Extravasation blood.
Respiratory, thoracic and mediastinal disorders

Pneumonitis [see Contraindications (4.3)], pulmonary congestion, wheezing, bronchial spasm, epistaxis, sore throat.

Gastrointestinal disorders

Hematochezia, abdominal pain, mouth ulcer.

Skin and subcutaneous tissue disorders

Stevens-Johnson syndrome, Henoch-Schönlein purpura, erythema multiforme, acute hemorrhagic edema of infancy, purpura, skin induration, panniculitis, pruritus.

Musculoskeletal, connective tissue and bone disorders

Arthritis and/or arthralgia (usually transient and rarely chronic, see below); pain of the hip, leg, or neck; myalgia; musculoskeletal pain.

General disorders and administration site conditions

Injection-site complaints (burning and/or stinging of short duration, edema/swelling, hive-like rash, discoloration, hematoma, induration, lump, vesicles, wheal and flare), varicella-like rash, warm to touch, stiffness, warm sensation, inflammation, injection-site hemorrhage, injection-site injury.

Deaths have been reported following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals. Death as a direct consequence of disseminated measles vaccine virus infection has been reported in severely immunocompromised individuals in whom a measles-containing vaccine is contraindicated and who were inadvertently vaccinated. However, there were no deaths or permanent sequelae reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982 to 1993 (3).

Encephalitis and encephalopathy have been reported approximately once for every 3 million doses of M-M-R II or measles-, mumps-, and rubella-containing vaccine administered since licensure of these vaccines. The risk of serious neurological disorders following live measles virus vaccine administration remains less than the risk of encephalitis and encephalopathy following infection with wild-type measles (1 per 1000 reported cases) (4,5).

In severely immunocompromised individuals who have been inadvertently vaccinated with measles-containing vaccine; measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported [see Contraindications (4.2)]. In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

Recipients of rubella vaccine may develop chronic joint symptoms. Arthralgia and/or arthritis, and polyneuritis after wild-type rubella virus infection vary in frequency and severity with age and gender, being greatest in adult females and least in pre-pubertal children. Following vaccination in children, reactions in joints are uncommon (0 to 3%) and of brief duration. In women, incidence rates for arthritis and arthralgia are higher than those seen in children (12 to 26%), and the reactions tend to be more marked and of longer duration (e.g., months or years). In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and adult women.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Chronic joint symptoms have been reported following administration of rubella-containing vaccine.

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of infection with wild-type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated measles vaccine distribution in the United States (US), the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. The association with wild-type measles virus infection is 6 to 22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.

Cases of aseptic meningitis have been reported to Vaccine Adverse Event Reporting System (VAERS) following measles, mumps, and rubella vaccination. Although a causal relationship between other strains of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.
Cases of thrombocytopenia have been reported after use of measles vaccine; measles, mumps, and rubella vaccine; and after varicella vaccination. Post-marketing experience with live measles, mumps, and rubella vaccine indicates that individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia following the first dose of a live measles, mumps, and rubella vaccine may develop thrombocytopenia with repeat doses. Serologic testing for antibody to measles, mumps, or rubella should be considered in order to determine if additional doses of vaccine are needed [see Warnings and Precautions (5.5)].

The reported rate of zoster in recipients of VARIVAX appears not to exceed that previously determined in a population-based study of healthy children who had experienced wild-type varicella (6). In clinical trials, 8 cases of herpes zoster were reported in 9454 vaccinated individuals 12 months to 12 years of age during 42,556 person-years of follow-up. This resulted in a calculated incidence of at least 18.8 cases per 100,000 person-years. All 8 cases reported after VARIVAX were mild and no sequelae were reported. The long-term effect of VARIVAX on the incidence of herpes zoster is unknown at present.

The vaccine virus (Oka/Merck strain) contained in ProQuad may establish latency of varicella zoster virus in immunocompetent individuals, with the potential for later development of herpes zoster [see Adverse Reactions (6.2), Infections and Infestations].

6.3 Post-Marketing Observational Safety Surveillance Study

Safety was evaluated in an observational study that included 69,237 children vaccinated with ProQuad 12 months to 12 years old. A historical comparison group included 69,237 age-, gender-, and date-of-vaccination (day and month) matched subjects who were given M-M-R II and VARIVAX concomitantly. The primary objective was to assess the incidence of febrile seizures occurring within various time intervals after vaccination in 12- to 60-month-old children who had neither been vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections (N=31,298 vaccinated with ProQuad, including 31,043 who were 12 to 23 months old). The incidence of febrile seizures was also assessed in a historical control group of children who had received their first vaccination with M-M-R II and VARIVAX concomitantly (N=31,298, including 31,019 who were 12 to 23 months old). The secondary objective was to assess the general safety of ProQuad in the 30-day period after vaccination in children 12 months to 12 years old.

In pre-licensure clinical studies, an increase in fever was observed 5 to 12 days after vaccination with ProQuad (dose 1) compared to M-M-R II and VARIVAX (dose 1) given concomitantly. In the post-marketing observational surveillance study, results from the primary safety analysis revealed an approximate two-fold increase in the risk of febrile seizures in the same 5 to 12 day timeframe after vaccination with ProQuad (dose 1). The incidence of febrile seizures 5 to 12 days after ProQuad (dose 1) (0.70 per 1000 children) was higher than that in children receiving M-M-R II and VARIVAX concomitantly (0.32 per 1000 children) [RR 2.20, 95% confidence interval (CI): 1.04, 4.65]. The incidence of febrile seizures 0 to 30 days after ProQuad (dose 1) (1.41 per 1000 children) was similar to that observed in children receiving M-M-R II and VARIVAX concomitantly [RR 1.10 (95% CI: 0.72, 1.69)]. See Table 9. General safety analyses revealed that the risks of fever (RR=1.89; 95% CI: 1.67, 2.15) and skin eruption (RR=1.68; 95% CI: 1.07, 2.64) were significantly higher after ProQuad (dose 1) compared with those who received concomitant first doses of M-M-R II and VARIVAX, respectively. All medical events that resulted in hospitalization or emergency room visits were compared between the group given ProQuad and the historical comparison group, and no other safety concerns were identified in this study.

In this observational post-marketing study, no case of febrile seizure was observed during the 5 to 12 day postvaccination time period among 26,455 children who received ProQuad as a second dose of M-M-R II and VARIVAX. In addition, detailed general safety data were available from more than 25,000 children who received ProQuad as a second dose of M-M-R II and VARIVAX, most of them (95%)

<table>
<thead>
<tr>
<th>Time Period</th>
<th>ProQuad cohort (N=31,298)</th>
<th>MMR+V cohort (N=31,298)</th>
<th>Relative risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Incidence per 1000</td>
<td>n</td>
</tr>
<tr>
<td>5 to 12 Days</td>
<td>22</td>
<td>0.70</td>
<td>10</td>
</tr>
<tr>
<td>0 to 30 Days</td>
<td>44</td>
<td>1.41</td>
<td>40</td>
</tr>
</tbody>
</table>
between 4 and 6 years of age, and an analysis of these data by an independent, external safety monitoring committee did not identify any specific safety concern.

7 DRUG INTERACTIONS

7.1 Immune Globulins and Transfusions
Immune globulins (IG) administered concomitantly with ProQuad contain antibodies that may interfere with vaccine virus replication and decrease the expected immune response. Vaccination should be deferred for at least 3 months following blood or plasma transfusions, or administration of IG.

The appropriate suggested interval between transfusion or IG administration and vaccination will vary with the type of transfusion or indication for, and dose of, IG (e.g., 5 months for Varicella Zoster Immune Globulin [VZIG]) (2). Following administration of ProQuad, any IG including VZIG should not be given for 1 month thereafter unless its use outweighs the benefits of vaccination (2). [See Warnings and Precautions (5.9).]

7.2 Salicylates
Reye syndrome has been reported following the use of salicylates during wild-type varicella infection. Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with ProQuad. [See Warnings and Precautions (5.10) and Patient Counseling Information (17).]

7.3 Corticosteroids and Immunosuppressive Drugs
ProQuad may be used in individuals who are receiving topical corticosteroids or low-dose corticosteroids for asthma prophylaxis or replacement therapy, e.g., for Addison's disease. ProQuad should not be given to individuals receiving immunosuppressive doses of corticosteroids or other immunosuppressive drugs. Vaccination with a live, attenuated vaccine, such as varicella or measles, can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressive drugs [see Contraindications (4.2)].

7.4 Drug/Laboratory Test Interactions
Live, attenuated measles, mumps, and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after ProQuad.

7.5 Use with Other Vaccines
At least 1 month should elapse between a dose of a measles-containing vaccine such as M-M-R II and a dose of ProQuad, and at least 3 months should elapse between administration of 2 doses of ProQuad or varicella-containing vaccines.

ProQuad may be administered concomitantly with Haemophilus influenzae type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant). Additionally, ProQuad may be administered concomitantly with pneumococcal 7-valent conjugate vaccine, and/or hepatitis A (inactivated) vaccines. [See Clinical Studies (14).]

There are no data regarding the administration of ProQuad with inactivated poliovirus vaccine or with other live virus vaccines.

There are insufficient data to support concomitant vaccination with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed. [See Clinical Studies (14).]

Children under treatment for tuberculosis have not experienced exacerbation of the disease when vaccinated with live measles virus vaccine; no studies have been reported to date of the effect of measles virus vaccines on children with untreated tuberculosis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
ProQuad vaccine contains live attenuated measles, mumps, rubella and varicella viruses. The vaccine is contraindicated for use in pregnant women because infection during pregnancy with the wild-type viruses is associated with maternal and fetal adverse outcomes.

For women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of administration of ProQuad, the healthcare provider should be aware of the following: (1) Reports have indicated that contracting wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects, and prematurity have been observed subsequent to
infection with wild-type measles during pregnancy. There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy; (2) Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and fetus, there is no evidence that it causes congenital malformations in humans; (3) In a 10-year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome; and (4) Wild-type varicella, if acquired during pregnancy, can sometimes cause congenital varicella syndrome.

Available data on inadvertent administration of ProQuad to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

There are no relevant animal data.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively.

Data

Human Data

In a 10-year CDC survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome.

8.2 Lactation

Risk Summary

It is not known whether varicella, measles, or mumps vaccine virus is excreted in human milk. Studies have shown that lactating postpartum women vaccinated with live rubella vaccine may secrete the virus in breast milk and transmit it to breastfed infants. [See Warnings and Precautions (5.8).]

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for ProQuad, and any potential adverse effects on the breastfed child from ProQuad or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Do not administer ProQuad to infants younger than 12 months of age or to children 13 years and older. Safety and effectiveness of ProQuad in infants younger than 12 months of age and in children 13 years and older have not been studied. ProQuad is not approved for use in persons in these age groups. [See Adverse Reactions (6) and Clinical Studies (14).]

8.5 Geriatric Use

ProQuad is not indicated for use in the geriatric population (≥ age 65).

11 DESCRIPTION

ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live) is a combined, attenuated, live virus vaccine containing measles, mumps, rubella, and varicella viruses. ProQuad is a sterile lyophilized preparation of (1) the components of M-M-R II (Measles, Mumps, and Rubella Virus Vaccine Live): Measles Virus Vaccine Live, a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; Mumps Virus Vaccine Live, the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; Rubella Virus Vaccine Live, the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts; and (2) Varicella Virus Vaccine Live (Oka/Merck), the Oka/Merck strain of varicella-zoster virus propagated in MRC-5 cells. The cells, virus pools, bovine serum, and recombinant human albumin used in manufacturing are all tested to provide assurance that the final product is free of potential adventitious agents.

ProQuad, when reconstituted as directed, is a sterile suspension for subcutaneous administration. Each 0.5-mL dose contains not less than 3.00 log10 TCID50 of measles virus; 4.30 log10 TCID50 of mumps virus; 3.00 log10 TCID50 of rubella virus; and a minimum of 3.99 log10 PFU of Oka/Merck varicella virus.

Each 0.5-mL dose of the vaccine contains no more than 21 mg of sucrose, 11 mg of hydrolyzed gelatin, 2.4 mg of sodium chloride, 1.8 mg of sorbitol, 0.40 mg of monosodium L-glutamate, 0.34 mg of sodium phosphate dibasic, 0.31 mg of recombinant human albumin, 0.17 mg of sodium bicarbonate,
72 mcg of potassium phosphate monobasic, 60 mcg of potassium chloride; 36 mcg of potassium phosphate dibasic; residual components of MRC-5 cells including DNA and protein; <16 mcg of neomycin, bovine calf serum (0.5 mcg), and other buffer and media ingredients. The product contains no preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ProQuad has been shown to induce measles-, mumps-, rubella-, and varicella-specific immunity, which is thought to be the mechanism by which it protects against these four childhood diseases.

The efficacy of ProQuad was established through the use of immunological correlates for protection against measles, mumps, rubella, and varicella. Results from efficacy studies or field effectiveness studies that were previously conducted for the component vaccines were used to define levels of serum antibodies that correlated with protection against measles, mumps, and rubella. Also, in previous studies with varicella vaccine, antibody responses against varicella virus ≥5 gpELISA units/mL in a glycoprotein enzyme-linked immunosorbent assay (gpELISA) (not commercially available) similarly correlated with long-term protection. In these efficacy studies, the clinical endpoint for measles and mumps was a clinical diagnosis of either disease confirmed by a 4-fold or greater rise in serum antibody titers between either postvaccination or acute and convalescent titers; for rubella, a 4-fold or greater rise in antibody titers with or without clinical symptoms of rubella; and for varicella, varicella-like rash that occurred >42 days postvaccination and for which varicella was not excluded by either viral cultures of the lesion or serological tests. Specific laboratory evidence of varicella either by serology or culture was not required to confirm the diagnosis of varicella. Clinical studies with a single dose of ProQuad have shown that vaccination elicited rates of antibody responses against measles, mumps, and rubella that were similar to those observed after vaccination with a single dose of M-M-R II [see Clinical Studies (14)] and seroresponse rates for varicella virus were similar to those observed after vaccination with a single dose of VARIVAX [see Clinical Studies (14)]. The duration of protection from measles, mumps, rubella, and varicella infections after vaccination with ProQuad is unknown.

12.6 Persistence of Antibody Responses after Vaccination

The persistence of antibody at 1 year after vaccination was evaluated in a subset of 2107 children enrolled in the clinical trials. Antibody was detected in 98.9% (1722/1741) for measles, 96.7% (1676/1733) for mumps, 99.6% (1796/1804) for rubella, and 97.5% (1512/1550) for varicella (≥5 gpELISA units/mL) of vaccinees following a single dose of ProQuad.

Experience with M-M-R II demonstrates that antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination [13]. Varicella antibodies were present for up to ten years postvaccination in most of the individuals tested who received 1 dose of VARIVAX.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

14 CLINICAL STUDIES

Formal studies to evaluate the clinical efficacy of ProQuad have not been performed.

Efficacy of the measles, mumps, rubella, and varicella components of ProQuad was previously established in a series of clinical studies with the monovalent vaccines. A high degree of protection from infection was demonstrated in these studies {14-21}.

*Immunogenicity in Children 12 Months to 6 Years of Age*
Prior to licensure, immunogenicity was studied in 5845 healthy children 12 months to 6 years of age with a negative clinical history of measles, mumps, rubella, and varicella who participated in 5 randomized clinical trials. The immunogenicity of ProQuad was similar to that of its individual component vaccines (M-M-R II and VARIVAX), which are currently used in routine vaccination.

The presence of detectable antibody was assessed by an appropriately sensitive enzyme-linked immunosorbent assay (ELISA) for measles, mumps (wild-type and vaccine-type strains), and rubella, and by gpELISA for varicella. For evaluation of vaccine response rates, a positive result in the measles ELISA corresponded to measles antibody concentrations of ≥255 mIU/mL when compared to the WHO II (66/202) Reference Immunoglobulin for Measles.

Children were positive for mumps antibody if the antibody level was ≥10 ELISA units/mL. A positive result in the rubella ELISA corresponded to concentrations of ≥10 IU rubella antibody/mL when compared to the WHO International Reference Serum for Rubella; children with varicella antibody levels ≥5 gpELISA units/mL were considered to be seropositive since a response rate based on ≥5 gpELISA units/mL has been shown to be highly correlated with long-term protection.

**Immunogenicity in Children 12 to 23 Months of Age After a Single Dose**

In 4 randomized clinical trials, 5446 healthy children 12 to 23 months of age were administered ProQuad, and 2038 children were vaccinated with M-M-R II and VARIVAX given concomitantly at separate injection sites. Subjects enrolled in each of these trials had a negative clinical history, no known recent exposure, and no vaccination history for varicella, measles, mumps, and rubella. Children were excluded from study participation if they had an immune impairment or had a history of allergy to components of the vaccine(s). Except for in 1 trial [see ProQuad Administered with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and Haemophilus influenzae type b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine below], no concomitant vaccines were permitted during study participation. The race distribution of the study subjects across these studies following a first dose of ProQuad was as follows: 66.3% White; 12.7% African-American; 9.9% Hispanic; 6.7% Asian/Pacific; 4.2% other; and 0.2% American Indian. The gender distribution of the study subjects across these studies following a first dose of ProQuad was 52.6% male and 47.4% female. A summary of combined immunogenicity results 6 weeks following administration of a single dose of ProQuad or M-M-R II and VARIVAX is shown in Table 10. These results were similar to the immune response rates induced by concomitant administration of single doses of M-M-R II and VARIVAX at separate injection sites (lower bound of the 95% CI for the risk difference in measles, mumps, and rubella seroconversion rates were >-5.0 percentage points and the lower bound of the 95% CI for the risk difference in varicella seroprotection rates was either >-15 percentage points [one study] or >-10.0 percentage points [three studies]).

Table 10: Summary of Combined Immunogenicity Results 6 Weeks Following the Administration of a Single Dose of ProQuad (Varicella Virus Potency ≥3.97 log<sub>10</sub> PFU) or M-M-R II and VARIVAX (Per-Protocol Population)

<table>
<thead>
<tr>
<th>Group</th>
<th>Antigen</th>
<th>n</th>
<th>Observed Response Rate (95% CI)</th>
<th>Observed GMT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProQuad (N=5446*)</td>
<td>Varicella</td>
<td>4381</td>
<td>91.2% (90.3%, 92.0%)</td>
<td>15.5 (15.0, 15.9)</td>
</tr>
<tr>
<td></td>
<td>Measles</td>
<td>4733</td>
<td>97.4% (96.9%, 97.9%)</td>
<td>3124.9 (3038.9, 3213.3)</td>
</tr>
<tr>
<td></td>
<td>Mumps (OD cutoff)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>973</td>
<td>98.8% (97.9%, 99.4%)</td>
<td>105.3 (98.0, 113.1)</td>
</tr>
<tr>
<td></td>
<td>Mumps (wild-type ELISA)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>3735</td>
<td>95.8% (95.1%, 96.4%)</td>
<td>93.1 (90.2, 96.0)</td>
</tr>
<tr>
<td></td>
<td>Rubella</td>
<td>4773</td>
<td>98.5% (98.1%, 98.8%)</td>
<td>91.8 (89.6, 94.1)</td>
</tr>
<tr>
<td>M-M-R II + VARIVAX (N=2038*)</td>
<td>Varicella</td>
<td>1417</td>
<td>94.1% (92.8%, 95.3%)</td>
<td>16.6 (15.9, 17.4)</td>
</tr>
<tr>
<td></td>
<td>Measles</td>
<td>1516</td>
<td>98.2% (97.4%, 98.8%)</td>
<td>2239.6 (2138.3, 2345.6)</td>
</tr>
<tr>
<td></td>
<td>Mumps (OD cutoff)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>501</td>
<td>99.4% (98.3%, 99.9%)</td>
<td>87.5 (79.7, 96.0)</td>
</tr>
<tr>
<td></td>
<td>Mumps (wild-type ELISA)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>1017</td>
<td>98.0% (97.0%, 98.8%)</td>
<td>90.8 (86.2, 95.7)</td>
</tr>
<tr>
<td></td>
<td>Rubella</td>
<td>1528</td>
<td>98.5% (97.7%, 99.0%)</td>
<td>102.2 (97.8, 106.7)</td>
</tr>
</tbody>
</table>
Immunogenicity in Children 15 to 31 Months of Age After a Second Dose of ProQuad

In 2 of the 4 randomized clinical trials described above, a subgroup (N=1035) of the 5446 children administered a single dose of ProQuad were administered a second dose of ProQuad approximately 3 to 9 months after the first dose. Children were excluded from receiving a second dose of ProQuad if they were recently exposed to or developed varicella, measles, mumps, and/or rubella prior to receipt of the second dose. No concomitant vaccines were administered to these children. The race distribution across these studies following a second dose of ProQuad was as follows: 67.3% White; 14.3% African-American; 8.3% Hispanic; 5.4% Asian/Pacific; 4.4% other; 0.2% American Indian; and 0.10% mixed. The gender distribution of the study subjects across these studies following a second dose of ProQuad was 50.4% male and 49.6% female. A summary of immune responses following a second dose of ProQuad is presented in Table 11. Results from this study showed that 2 doses of ProQuad administered at least 3 months apart elicited a positive antibody response to all four antigens in greater than 98% of subjects. The geometric mean titers (GMTs) following the second dose of ProQuad increased approximately 2-fold each for measles, mumps, and rubella, and approximately 41-fold for varicella.

Table 11: Summary of Immune Response to a First and Second Dose of ProQuad in Subjects <3 Years of Age Who Received ProQuad with a Varicella Virus Dose ≥3.97 Log_{10} PFU

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Serostatus Cutoff/Response Criteria</th>
<th>Dose 1 N=1097</th>
<th>Observed Response Rate (95% CI)</th>
<th>Observed GMT (95% CI)</th>
<th>Dose 2 N=1097</th>
<th>Observed Response Rate (95% CI)</th>
<th>Observed GMT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>≥120 mIU/mL†</td>
<td>915</td>
<td>98.1% (97.0%, 98.9%)</td>
<td>2956.8 (2786.3, 3137.7)</td>
<td>915</td>
<td>99.5% (98.7%, 99.8%)</td>
<td>5958.0 (5518.9, 6432.1)</td>
</tr>
<tr>
<td></td>
<td>≥255 mIU/mL</td>
<td>943</td>
<td>97.8% (96.6%, 98.6%)</td>
<td>2966.0 (2793.4, 3149.2)</td>
<td>943</td>
<td>99.4% (98.6%, 99.8%)</td>
<td>5919.3 (5486.2, 6386.6)</td>
</tr>
<tr>
<td>Mumps</td>
<td>≥OD Cutoff (ELISA antibody units)</td>
<td>920</td>
<td>98.7% (97.7%, 99.3%)</td>
<td>106.7 (99.1, 114.8)</td>
<td>920</td>
<td>99.9% (99.4%, 100%)</td>
<td>253.1 (237.9, 269.2)</td>
</tr>
<tr>
<td>Rubella</td>
<td>≥10 IU/mL</td>
<td>937</td>
<td>97.7% (96.5%, 98.5%)</td>
<td>91.1 (85.9, 96.6)</td>
<td>937</td>
<td>98.3% (97.2%, 99.0%)</td>
<td>158.8 (149.1, 169.2)</td>
</tr>
<tr>
<td>Varicella</td>
<td>&lt;1.25 to ≥5 gpELISA units</td>
<td>864</td>
<td>86.6% (84.1%, 88.8%)</td>
<td>11.6 (10.9, 12.3)</td>
<td>864</td>
<td>99.4% (98.7%, 99.8%)</td>
<td>477.5 (437.8, 520.7)</td>
</tr>
<tr>
<td></td>
<td>≥OD Cutoff (gpELISA units)</td>
<td>695</td>
<td>87.2% (84.5%, 89.6%)</td>
<td>11.6 (10.9, 12.4)</td>
<td>695</td>
<td>99.4% (98.5%, 99.8%)</td>
<td>478.7 (434.8, 527.1)</td>
</tr>
</tbody>
</table>

* Includes the following treatment groups: ProQuad + Placebo followed by ProQuad (Visit 1) (Protocol 009) and ProQuad (Middle and High Dose) (Protocol 011).
† Samples from Protocols 009 and 011 were assayed in the legacy format Measles ELISA, which reported antibody titers in Measles ELISA units. To convert titers from ELISA units to mIU/mL, titers for these 2 protocols were divided by 0.1025.
The lowest measurable titer postvaccination is 207.5 mIU/mL. The response rate for measles in the legacy format is the percent of subjects with a negative baseline measles antibody titer, as defined by the optical density (OD) cutoff, with a postvaccination measles antibody titer ≥207.5 mIU/mL.

Samples from Protocols 009 and 011 were assayed in the legacy format Rubella ELISA, which reported antibody titers in Rubella ELISA units. To convert titers from ELISA units to IU/mL, titers for these 2 protocols were divided by 1.28.

ProQuad (Middle Dose) = ProQuad containing a varicella virus dose of 3.97 log10 PFU.
ProQuad (High Dose) = ProQuad containing a varicella virus dose of 4.25 log10 PFU.
ELISA = Enzyme-linked immunosorbent assay.
gpELISA = Glycoprotein enzyme-linked immunosorbent assay.
N = Number vaccinated at baseline.
n = Number of subjects who were per-protocol Postdose 1 and Postdose 2 and satisfied the given prevaccination serostatus cutoff.
CI = Confidence interval.
GMT = Geometric mean titer.
PFU = Plaque-forming units.

Immunogenicity in Children 4 to 6 Years of Age Who Received a First Dose of ProQuad After Primary Vaccination With M-M-R II and VARIVAX

In a clinical trial, 799 healthy 4- to 6-year-old children who had received M-M-R II and VARIVAX at least 1 month prior to study entry were randomized to receive ProQuad and placebo (N=399), M-M-R II and placebo concomitantly at separate injection sites (N=205), or M-M-R II and VARIVAX concomitantly at separate injection sites (N=195). Children were eligible if they were previously administered primary doses of M-M-R II and VARIVAX, either concomitantly or non-concomitantly, at 12 months of age or older. Children were excluded if they were recently exposed to measles, mumps, rubella, and/or varicella, had an immune impairment, or had a history of allergy to components of the vaccine(s). No concomitant vaccines were permitted during study participation. [See Adverse Reactions (6.1) for ethnicity and gender information.]

A summary of antibody responses to measles, mumps, rubella, and varicella at 6 weeks postvaccination in subjects who had previously received M-M-R II and VARIVAX is shown in Table 12. Results from this study showed that a first dose of ProQuad after primary vaccination with M-M-R II and VARIVAX elicited a positive antibody response to all four antigens in greater than 98% of subjects. Postvaccination GMTs for recipients of ProQuad were similar to those following a second dose of M-M-R II and VARIVAX administered concomitantly at separate injection sites (the lower bound of the 95% CI around the fold difference in measles, mumps, rubella, and varicella GMTs excluded 0.5). Additionally, GMTs for measles, mumps, and rubella were similar to those following a second dose of M-M-R II given concomitantly with placebo (the lower bound of the 95% CI around the fold difference for the comparison of measles, mumps, and rubella GMTs excluded 0.5).

Table 12: Summary of Antibody Responses to Measles, Mumps, Rubella, and Varicella at 6 Weeks Postvaccination in Subjects 4 to 6 Years of Age Who Had Previously Received M-M-R II and VARIVAX (Per-Protocol Population)

<table>
<thead>
<tr>
<th>Group Number (Description)</th>
<th>n</th>
<th>GMT (95% CI)</th>
<th>Seropositivity Rate (95% CI)</th>
<th>% 4-Fold Rise in Titer (95% CI)</th>
<th>Geometric Mean Fold Rise (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measles</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 (N=399)</td>
<td>367</td>
<td>1985.9</td>
<td>100%</td>
<td>4.9%</td>
<td>1.21</td>
</tr>
<tr>
<td>(ProQuad + placebo)</td>
<td></td>
<td>(1817.6, 2169.9)</td>
<td>(99.0%, 100%)</td>
<td>(2.9%, 7.6%)</td>
<td>(1.13, 1.30)</td>
</tr>
<tr>
<td>Group 2 (N=205)</td>
<td>185</td>
<td>2046.9</td>
<td>100%</td>
<td>4.3%</td>
<td>1.28</td>
</tr>
<tr>
<td>(M-M-R II + placebo)</td>
<td></td>
<td>(1815.2, 2308.2)</td>
<td>(98.0%, 100%)</td>
<td>(1.9%, 8.3%)</td>
<td>(1.17, 1.40)</td>
</tr>
<tr>
<td>Group 3 (N=195)</td>
<td>171</td>
<td>2084.3</td>
<td>99.4%</td>
<td>4.7%</td>
<td>1.31</td>
</tr>
<tr>
<td>(M-M-R II + VARIVAX)</td>
<td></td>
<td>(1852.3, 2345.5)</td>
<td>(96.8%, 100%)</td>
<td>(2.0%, 9.0%)</td>
<td>(1.17, 1.46)</td>
</tr>
<tr>
<td><strong>Mumps</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 (N=399)</td>
<td>367</td>
<td>206.0</td>
<td>99.5%</td>
<td>27.2%</td>
<td>2.43</td>
</tr>
<tr>
<td>(ProQuad + placebo)</td>
<td></td>
<td>(188.2, 225.4)</td>
<td>(96.0%, 99.9%)</td>
<td>(22.8%, 32.1%)</td>
<td>(2.19, 2.69)</td>
</tr>
<tr>
<td>Group 2 (N=205)</td>
<td>185</td>
<td>308.5</td>
<td>100%</td>
<td>41.1%</td>
<td>3.69</td>
</tr>
<tr>
<td>(M-M-R II + placebo)</td>
<td></td>
<td>(269.6, 352.9)</td>
<td>(98.0%, 100%)</td>
<td>(33.9%, 48.5%)</td>
<td>(3.14, 4.32)</td>
</tr>
<tr>
<td>Group 3 (N=195)</td>
<td>171</td>
<td>295.9</td>
<td>100%</td>
<td>41.5%</td>
<td>3.36</td>
</tr>
<tr>
<td>(M-M-R II + VARIVAX)</td>
<td></td>
<td>(262.5, 333.5)</td>
<td>(97.9%, 100%)</td>
<td>(34.0%, 49.3%)</td>
<td>(2.84, 3.97)</td>
</tr>
<tr>
<td><strong>Rubella</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Immunogenicity Following Concomitant Use with Other Vaccines**

**ProQuad with Pneumococcal 7-valent Conjugate Vaccine and/or VAQTA**

In a clinical trial, 1027 healthy children 12 to 15 months of age were randomized to receive ProQuad and pneumococcal 7-valent conjugate vaccine concomitantly (N=510) at separate injection sites or ProQuad and pneumococcal 7-valent conjugate vaccine non-concomitantly (N=517) at separate clinic visits. [See Adverse Reactions (6.1) for ethnicity and gender information.] The statistical analysis of non-inferiority in antibody response rates to measles, mumps, rubella, and varicella at 6 weeks postvaccination for subjects are shown in Table 13. In the per-protocol population, seroconversion rates were not inferior in children given ProQuad and pneumococcal 7-valent conjugate vaccine concomitantly when compared to seroconversion rates seen in children given these vaccines non-concomitantly for measles, mumps, and rubella. In children with baseline varicella antibody titers <1.25 gpELISA units/mL, the varicella seroprotection rates were not inferior when rates after concomitant and non-concomitant vaccination were compared 6 weeks postvaccination. Statistical analysis of non-inferiority in GMTs to *S. pneumoniae* serotypes at 6 weeks postvaccination are shown in Table 14. Geometric mean antibody titers (GMTs) for *S. pneumoniae* types 4, 6B, 9V, 14, 18C, 19F, and 23F were not inferior when antibody titers in the concomitant and non-concomitant groups were compared 6 weeks postvaccination.

### Table 13: Statistical Analysis of Non-Inferiority in Antibody Response Rates to Measles, Mumps, Rubella, and Varicella at 6 Weeks Postvaccination for Subjects Initially Seronegative to Measles, Mumps, or Rubella, or With Varicella Antibody Titer <1.25 gpELISA units at Baseline in the ProQuad + PCV7 Treatment Group and the ProQuad Followed by PCV7 Control Group (Per-Protocol Analysis)

<table>
<thead>
<tr>
<th>Assay Parameter</th>
<th>ProQuad + PCV7 (N=510)</th>
<th>ProQuad followed by PCV7 (N=259)</th>
<th>Difference (percentage points)$^*$† (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles % ≥255 mIU/mL</td>
<td>406 97.3%</td>
<td>204 99.5%</td>
<td>-2.2 (-4.6, 0.2)</td>
</tr>
<tr>
<td>Mumps % ≥10 Ab units/mL</td>
<td>403 96.6%</td>
<td>208 98.6%</td>
<td>-1.9 (-4.5, 1.0)</td>
</tr>
<tr>
<td>Rubella % ≥10 IU/mL</td>
<td>377 98.7%</td>
<td>195 97.9%</td>
<td>0.9 (-1.3, 4.1)</td>
</tr>
<tr>
<td>Varicella % ≥5 gpELISA units/mL</td>
<td>379 92.5%</td>
<td>192 87.9%</td>
<td>4.5 (-0.4, 10.4)</td>
</tr>
</tbody>
</table>
conjugate vaccine. Statistical analysis of non-inferiority in GMT to observed when VAQTA was administered separately from ProQuad and pneumococcal 7-valent received VAQTA concomitantly or non-concomitantly with ProQuad and pneumococcal 7-valent conjugate vaccine alone. Statistical analysis of non-inferiority of conjugate vaccine as compared to the proportion with a titer ≥ 5 gpELISA units/mL when ProQuad was non-inferior when ProQuad was administered with VAQTA and pneumococcal 7-valent conjugate vaccine is shown in Table 14. The conclusion of non-inferiority is based on the lower bound of the 2-sided 95% CI on the fold-difference being greater than 0.5, i.e., excluding a decrease equal to or more than the prespecified criterion of 2-fold difference at the 1-sided alpha = 0.025 level.

N = Number of subjects vaccinated in each treatment group, n = Number of subjects with measles antibody titer <255 mIU/mL, mumps antibody titer <10 ELISA Ab units/mL, rubella antibody titer <10 IU/mL, or varicella antibody titer <1.25 gpELISA units/mL at baseline and with postvaccination serology contributing to the per-protocol analysis. Ab = antibody; ELISA = Enzyme-linked immunosorbent assay; gpELISA = Glycoprotein enzyme-linked immunosorbent assay; CI = Confidence interval.

Table 14: Statistical Analysis of Non-Inferiority in GMTs to S. pneumoniae Serotypes at 6 Weeks Postvaccination in the ProQuad + PCV7* Treatment Group and the PCV7 Followed by ProQuad Control Group (Per-Protocol Analysis)

<table>
<thead>
<tr>
<th>Serotype</th>
<th>Parameter</th>
<th>Group 1 (ProQuad + PCV7 (N=510))</th>
<th>Group 2 (PCV7 followed by ProQuad (N=258))</th>
<th>Fold-Difference†‡ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>GMT</td>
<td>410</td>
<td>193</td>
<td>1.2 (1.0, 1.4)</td>
</tr>
<tr>
<td>6B</td>
<td>GMT</td>
<td>410</td>
<td>192</td>
<td>1.1 (0.9, 1.2)</td>
</tr>
<tr>
<td>9V</td>
<td>GMT</td>
<td>409</td>
<td>193</td>
<td>1.2 (1.0, 1.3)</td>
</tr>
<tr>
<td>14</td>
<td>GMT</td>
<td>408</td>
<td>193</td>
<td>1.1 (1.0, 1.3)</td>
</tr>
<tr>
<td>18C</td>
<td>GMT</td>
<td>408</td>
<td>193</td>
<td>1.2 (1.0, 1.3)</td>
</tr>
<tr>
<td>19F</td>
<td>GMT</td>
<td>408</td>
<td>192</td>
<td>1.1 (1.0, 1.3)</td>
</tr>
<tr>
<td>23F</td>
<td>GMT</td>
<td>413</td>
<td>197</td>
<td>1.1 (1.0, 1.3)</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine.
† Estimated responses and their fold-difference were based on statistical analysis models adjusting for study center and prevaccination titer.
‡ ProQuad + PCV7 / PCV7 followed by ProQuad.

In a clinical trial, 653 healthy children 12 to 15 months of age were randomized to receive VAQTA, ProQuad, and pneumococcal 7-valent conjugate vaccine concomitantly (N=330) or ProQuad and pneumococcal 7-valent conjugate vaccine concomitantly followed by VAQTA 6 weeks later (N=323). [See Adverse Reactions (6.1) for ethnicity and gender information.] Statistical analysis of non-inferiority of the response rate for varicella antibody at 6 weeks postvaccination among subjects who received VAQTA concomitantly or non-concomitantly with ProQuad and pneumococcal 7-valent conjugate vaccine is shown in Table 15. For the varicella component of ProQuad, in subjects with baseline antibody titers <1.25 gpELISA units/mL, the proportion with a titer ≥ 5 gpELISA units/mL 6 weeks after their first dose of ProQuad was non-inferior when ProQuad was administered with VAQTA and pneumococcal 7-valent conjugate vaccine as compared to the proportion with a titer ≥ 5 gpELISA units/mL when ProQuad was administered with pneumococcal 7-valent conjugate vaccine alone. Statistical analysis of non-inferiority of the seropositivity rate for hepatitis A antibody at 4 weeks postdose 2 of VAQTA among subjects who received VAQTA concomitantly or non-concomitantly with ProQuad and pneumococcal 7-valent conjugate vaccine is shown in Table 16. The seropositivity rate to hepatitis A 4 weeks after a second dose of VAQTA given concomitantly with ProQuad and pneumococcal 7-valent conjugate vaccine (defined as the percent of subjects with a titer ≥10 mIU/mL) was non-inferior to the seropositivity rate observed when VAQTA was administered separately from ProQuad and pneumococcal 7-valent conjugate vaccine. Statistical analysis of non-inferiority in GMT to S. pneumoniae serotypes at 6 weeks postvaccination among subjects who received VAQTA concomitantly or non-concomitantly with ProQuad and pneumococcal 7-valent conjugate vaccine is shown in Table 17. Additionally, the GMTs for S.
pneumoniae types 4, 6B, 9V, 14, 18C, 19F, and 23F 6 weeks after vaccination with pneumococcal 7-valent conjugate vaccine administered concomitantly with ProQuad and VAQTA were non-inferior as compared to GMTs observed in the group given pneumococcal 7-valent conjugate vaccine with ProQuad alone. An earlier clinical study involving 617 healthy children provided data that indicated that the seroresponse rates 6 weeks post vaccination for measles, mumps, and rubella in those given M-M-R II and VAQTA concomitantly (N=309) were non-inferior as compared to historical controls.

Table 15: Statistical Analysis of Non-Inferiority of the Response Rate for Varicella Antibody at 6 Weeks Postvaccination Among Subjects Who Received VAQTA Concomitantly or Non-Concomitantly With ProQuad and PCV7* (Per-Protocol Analysis Set)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group 1: Concomitant VAQTA with ProQuad + PCV7 (N=330)</th>
<th>Group 2: Non-concomitant VAQTA separate from ProQuad + PCV7 (N=323)</th>
<th>Difference† (percentage points): Group 1 – Group 2 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% ≥5 gpELISA units/mL‡</td>
<td>n</td>
<td>Estimated Response†</td>
<td>n</td>
</tr>
<tr>
<td>225§</td>
<td>93.2%</td>
<td>232§</td>
<td>98.3%</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine.
N = Number of subjects enrolled/randomized; n = Number of subjects contributing to the per-protocol analysis for varicella; CI = Confidence interval.
† Estimated responses and their differences were based on a statistical analysis model adjusting for combined study center.
‡ 6 weeks following Dose 1.
§ Initial Serostatus <1.25 gpELISA units/mL.
The conclusion of similarity (non-inferiority) was based on the lower bound of the 2-sided 95% CI on the risk difference excluding a decrease of 10 percentage points or more (lower bound >-10.0). This indicated that the risk difference was statistically significantly greater than the pre-specified clinically relevant difference of -10 percentage points at the 1-sided alpha = 0.025 level.

Table 16: Statistical Analysis of Non-Inferiority of the Seropositivity Rate (SPR) for Hepatitis A Antibody at 4 Weeks Postdose 2 of VAQTA Among Subjects Who Received VAQTA Concomitantly or Non-Concomitantly With ProQuad and PCV7* (Per-Protocol Analysis Set)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group 1: Concomitant VAQTA with ProQuad + PCV7 (N=330)</th>
<th>Group 2: Non-concomitant VAQTA separate from ProQuad + PCV7 (N=323)</th>
<th>Difference† (percentage points): Group 1 - Group 2 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% ≥10 mIU/mL‡</td>
<td>n</td>
<td>Estimated Response†</td>
<td>n</td>
</tr>
<tr>
<td>182§</td>
<td>100.0%</td>
<td>159§</td>
<td>99.3%</td>
</tr>
</tbody>
</table>

* PCV7 = Pneumococcal 7-valent conjugate vaccine.
CI = Confidence interval; N = Number of subjects enrolled/randomized; n = Number of subjects contributing to the per-protocol analysis for hepatitis A.
† Estimated responses and their differences were based on a statistical analysis model adjusting for combined study center.
‡ 4 weeks following receipt of 2 doses of VAQTA.
§ Regardless of initial serostatus.
The conclusion of non-inferiority was based on the lower bound of the 2-sided 95% CI on the risk difference being greater than -10 percentage points (i.e., excluding a decrease of 10 percentage points or more) (lower bound >-10.0). This indicated that the risk difference was statistically significantly greater than the pre-specified clinically relevant difference of -10 percentage points at the 1-sided alpha = 0.025 level.

Table 17: Statistical Analysis of Non-Inferiority in Geometric Mean Titers (GMT) to S. pneumoniae Serotypes at 6 Weeks Postvaccination Among Subjects Who Received VAQTA Concomitantly or Non-Concomitantly With ProQuad and PCV7* (Per-Protocol Analysis Set)

<table>
<thead>
<tr>
<th>Serotype</th>
<th>Group 1: Concomitant VAQTA with ProQuad + PCV7 (N=330)</th>
<th>Group 2: Non-concomitant VAQTA separate from ProQuad + PCV7 (N=323)</th>
<th>Fold-Difference† (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Estimated Response†</td>
<td>n</td>
<td>Estimated Response†</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ProQuad Administered with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and Haemophilus influenzae type b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine

In a clinical trial, 1913 healthy children 12 to 15 months of age were randomized to receive ProQuad plus diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP) and *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine concomitantly at separate injection sites (N=949), ProQuad at the initial visit followed by DTaP and *Haemophilus influenzae* type b conjugate and hepatitis B (recombinant) vaccine given concomitantly 6 weeks later (N=485), or M-M-R II and VARIVAX given concomitantly at separate injection sites (N=479) at the first visit. [See Adverse Reactions (6.1) for ethnicity and gender information.] Seroconversion rates and antibody titers for measles, mumps, rubella, varicella, anti-PRP, and hepatitis B were comparable between the 2 groups given ProQuad at approximately 6 weeks postvaccination indicating that ProQuad and *Haemophilus influenzae* b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine may be administered concomitantly at separate injection sites (see Table 18 below). Response rates for measles, mumps, rubella, varicella, *Haemophilus influenzae* type b, and hepatitis B were not inferior in children given ProQuad plus *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccines concomitantly when compared to ProQuad at the initial visit and *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccines given concomitantly 6 weeks later. There are insufficient data to support concomitant vaccination with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (data not shown).

Table 18: Summary of the Comparison of the Immunogenicity Endpoints for Measles, Mumps, Rubella, Varicella, *Haemophilus influenzae* type b, and Hepatitis B Responses Following Vaccination with ProQuad, *Haemophilus influenzae* type b Conjugate (Meningococcal Protein Conjugate), and Hepatitis B (Recombinant) Vaccine and DTaP Administered Concomitantly Versus Non-Concomitant Vaccination with ProQuad Followed by These Vaccines

<table>
<thead>
<tr>
<th>Vaccine Antigen</th>
<th>Parameter</th>
<th>Concomitant Group</th>
<th>Non-Concomitant Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=949</td>
<td>N=485</td>
<td>Risk Difference (95% CI)</td>
</tr>
<tr>
<td>Measles</td>
<td>% ≥120 mIU/mL</td>
<td>97.8%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Mumps</td>
<td>% ≥10 ELISA Ab units/mL</td>
<td>95.4%</td>
<td>95.1%</td>
</tr>
<tr>
<td>Rubella</td>
<td>% ≥10 IU/mL</td>
<td>98.6%</td>
<td>99.3%</td>
</tr>
<tr>
<td>Varicella</td>
<td>% ≥5 gpELISA units/mL</td>
<td>89.6%</td>
<td>90.8%</td>
</tr>
<tr>
<td>HiB-PRP</td>
<td>% ≥10 mcg/mL</td>
<td>94.6%</td>
<td>96.5%</td>
</tr>
<tr>
<td>HepB</td>
<td>% ≥10 mIU/mL</td>
<td>95.9%</td>
<td>98.8%</td>
</tr>
</tbody>
</table>
**HiB-PRP = *Haemophilus influenzae* type b, polyribosyl phosphate; HepB = hepatitis B; LB = lower bound, limit for non-inferiority comparison.**

15 REFERENCES


16 HOW SUPPLIED/STORAGE AND HANDLING

No. 4171 — ProQuad is supplied as follows:

1. a package of 10 single-dose vials of lyophilized vaccine, NDC 0006-4171-00 (package A)
2. a separate package of 10 vials of sterile water diluent (package B).

**Storage**

To maintain potency, ProQuad must be stored frozen between -58°F and +5°F (-50°C to -15°C). Use of dry ice may subject ProQuad to temperatures colder than -58°F (-50°C).
Before reconstitution, store the lyophilized vaccine in a freezer at a temperature between −58°F and +5°F (−50°C and −15°C) for up to 18 months. Any freezer (e.g., chest, frost-free) that reliably maintains an average temperature between −58°F and +5°F (−50°C and −15°C) and has a separate sealed freezer door is acceptable for storing ProQuad. Routine defrost cycling of a frost-free freezer is acceptable.

ProQuad may be stored at refrigerator temperature (36° to 46°F, 2° to 8°C) for up to 72 hours prior to reconstitution. Discard any ProQuad vaccine stored at 36° to 46°F which is not used within 72 hours of removal from 5°F (−15°C) storage.

Protect the vaccine from light at all times since such exposure may inactivate the vaccine viruses.

**IF NOT USED IMMEDIATELY, THE RECONSTITUTED VACCINE MAY BE STORED AT ROOM TEMPERATURE, PROTECTED FROM LIGHT, FOR UP TO 30 MINUTES.**

**DISCARD RECONSTITUTED VACCINE IF IT IS NOT USED WITHIN 30 MINUTES.**

**DO NOT FREEZE RECONSTITUTED VACCINE.**

Diluent should be stored separately at room temperature (68° to 77°F, 20° to 25°C), or in a refrigerator (36° to 46°F, 2° to 8°C).

For information regarding the product or questions regarding storage conditions, call 1-800-MERCK-90.

### 17 PATIENT COUNSELING INFORMATION

**Instructions**

Provide the required vaccine information to the patient, parent, or guardian.

Inform the patient, parent, or guardian of the benefits and risks associated with vaccination.

Inform the patient, parent, or guardian that the vaccine recipient should avoid use of salicylates for 6 weeks after vaccination with ProQuad [see Warnings and Precautions (5.10) and Drug Interactions (7.2)].

Instruct postpubertal females to avoid pregnancy for 3 months following vaccination [see Indications and Usage (1), Contraindications (4.4) and Use in Specific Populations (8.1)].

Inform patients, parents, or guardians that vaccination with ProQuad may not offer 100% protection from measles, mumps, rubella, and varicella infection.

Instruct patients, parents, or guardians to report any adverse reactions to their health care provider. The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, including but not limited to the reporting of events required by the National Childhood Vaccine Injury Act of 1986. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967, or report online at http://www.vaers.hhs.gov.

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For patent information: www.merck.com/product/patent/home.html

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VACCINES HAVE NOT SAVED MILLIONS OF LIVES

The history of vaccines is one of fraud and filth. Starting in the 1700s the medical profession, drug makers, and government officials first conspired to make profits at the expense of the public's health. They claimed credit for the decrease in deaths from infectious diseases when the real cause was improved sanitation and living standards. Many researchers now believe that the polio epidemic in the 1950s was caused by DDT and the polio vaccine itself. In fact, in 1955 Cutter Laboratories made a vaccine that gave over 120,000 people a virulent form of the disease. Worse yet, from 1955–1963 over 98 million Americans (plus people in other countries) received a polio vaccine that was contaminated with a cancer-causing monkey virus called SV40, which is still being found in cancer victims. Today, we have an epidemic of immune dysfunction, developmental disorders, disease, and chronic illness, all with links to vaccines. Yet, our federal health agencies keep promoting them. And that has to do with the money being made by business and industry, the medical profession, and the federal government itself, including the CDC, who owns several vaccine patents and is one of the largest purchaser of vaccines. Sources include, “Dissolving Illusions” by Dr. Suzzane Humphreys.

United States: Disease Mortality Rates

Historical Statistics of the United States: Colonial Times to 1970 Part 1

Despite common belief, infectious disease deaths DECREASED 85-90% BEFORE VACCINES were introduced in the US. Diseases WITHOUT VACCINES -- including Scarlet Fever, Tuberculosis, Cholera and Typhoid -- followed the SAME trend.
*Trends in the Health of Americans During the 20th Century. Pediatrics

www.LearnTheRisk.org/diseases
### STORY AT-A-GLANCE

- Arguments are provided against typical vaccine justifications that diseases like smallpox and polio were eradicated by vaccination
- Historical data reveals that smallpox was eradicated through efforts like isolation, improved nutrition, hygiene, and sanitation
- Incidence of polio was dramatically “reduced” because the disease was redefined, and serological testing was introduced—not because of success of the vaccine

By Dr. Mercola [https://articles.mercola.com/sites/articles/archive/2015/01/18/history-vaccination.aspx](https://articles.mercola.com/sites/articles/archive/2015/01/18/history-vaccination.aspx)

Vaccines are one of the most controversial medical therapies, and it's impossible to make an informed decision unless you know both sides of the story. In the process of knowing both sides, the historical context is critical.

Dr. Suzanne Humphries, author of *Dissolving Illusions: Disease, Vaccines, and the Forgotten History*,¹ is a nephrologist who has committed the latter part of her medical career to exposing the "lost history" of vaccinations.

Barbara Loe Fisher of NVIC commented that this is one of the rare books that conducted in-depth research documenting the medical history related to mass vaccination programs and infectious diseases.

I have read the book from cover to cover and would strongly recommend that you pick up a copy if you have even the remotest interest in this topic, especially if you believe in the safety and necessity of vaccines, as the comprehensive documentation will likely cause you to reevaluate your position.

It is an absolutely fascinating read, and in some ways demonstrates that enforcement of vaccine programs could be far worse today, when compared to historical standards when people were imprisoned and even killed when they refused to comply.

I will likely reread the book again so I can be well armed to articulately express my concerns on why one needs to have serious reservations on the validity of vaccines, based on historical precedents.

**Why This Book Was Written**

Dr. Humphries' interest in this area began in 2009, when several of her patients told her that they'd been perfectly healthy until they got one vaccine or another. Prior to this, she'd been, as she says, "agnostic" about vaccination.

"*I had vaccinated my dialysis patients; I, myself, was vaccinated; and I pretty much believed what I was taught in medical school,"* she says.

Then she started noticing that her patients were being ordered to get vaccinated on their first day of admission into the hospital—often when they had serious diseases: inflammatory diseases, heart attacks, congestive heart failure, and one patient with cancer on chemotherapy.

"*My patients were getting vaccinated on their first hospital day before I even saw them, and the order had my name on it,"* she says. "This alerted me that there was something going on that I had not approved of."

*I complained to the hospital administration about it. It was from resistance that I was met with that, ironically, led me into this path."
Countering Vaccine Arguments Led to Startling Conclusions

The conventional paradigm states that vaccines are safe and effective, and can be given to virtually anybody regardless of how sick they are.

In order to address and counter the arguments she was given for this routine policy, she had to research vaccination, which led her to discover that there is absolutely nothing in the medical literature to support vaccinating an acutely ill person.

"At some point, they called in an expert to set me straight," she says. "The arguments that I got from the experts still were not lining up with science.

My patients were acutely ill, they had inflammatory diseases, and I didn't want them vaccinated. I was told that I was confusing the nursing staff by discontinuing vaccines in my patients. That was how it all started."

Arguments often used by vaccine advocates include the oft-parroted sound byte that 'diseases like smallpox and polio were eradicated by vaccination.' Hence vaccines rank among the greatest medical interventions known.

As a result, she ended up researching smallpox and polio—even though it really had nothing to do with what was happening to her patients. Alas, this was when Dr. Humphries started coming to some really startling conclusions.

"In my research, I was startled [to realize] that what I found was completely counter to what I have been told and taught my entire life. I now don't believe that smallpox vaccines eradicated smallpox. I now don't believe that polio vaccines eradicated polio.

The stories are very twisted, long, and complicated, and the vaccines have changed over time. It's really easy to kind of throw up smokescreens here and there and make whatever argument one might want to, because people are so ignorant and because the story is so complicated."

The Story Behind the Smallpox Vaccine

Every vaccine has a story behind it, Dr. Humphries says. The smallpox vaccine, for example, was actually developed long before the medical establishment knew anything about the human immune system. The revelations on smallpox alone are fascinating enough to purchase this book, and is far more detailed than the summary in this article.

The vaccine was actually developed based on a rumor circulating among dairy maids. The rumor was that when a dairy maid had been infected with cowpox—which is a common infection on the udder of the cow—she would no longer be susceptible to smallpox.

The rumor was a persistent one, as rumors can be, despite the fact that there were plenty of dairy maids who developed smallpox after having cowpox. But this rumor is what led Edward Jenner to develop the first smallpox vaccine.

"Basically, it was made by scraping pus off the belly of a cow," Dr. Humphries says. "Sometimes there was some goat genetic disease in there. There was horsepox mixed in there.

There was sometimes human pox mixed in and some glycerin. They would shake it up; they would take kind of a prong, and puncture the skin several times...

What I didn't realize was that there were many people who developed serious smallpox disease and died after they were vaccinated. The severity of disease was often worse in the vaccinated than the unvaccinated.

There are statistics that show that the death rate was higher in the vaccinated than the unvaccinated."

When the smallpox vaccine was developed, there was also no way to accurately diagnose the type of pox disease a person had. It may have been chickenpox, monkeypox, or smallpox, but back then, any kind of pox disease was considered smallpox—even though the vaccine didn't actually have the human smallpox virus in it. Animal pox virus was always used. According to Dr. Humphries, it was the most contaminated vaccine that's ever been on the market.
"If you look at a town like Leicester in England, that town was noticing that they had one of the highest vaccination rates in the vaccinated world and their smallpox breakout was higher than ever," Dr. Humphries says. "The people in the town had a rally. The mayor and some of the health officials were there. They all agreed that they were going to stop vaccinating... The result was quite different from the predictions.

The predictions were that there was going to be a bonfire of disease set upon the planet and that these people in Leicester were risking the health of the world by not making vaccination mandatory. But once they stopped smallpox vaccines they had the lowest rate of smallpox infection and deaths.

What we show in our book – and we show the graphs of the disease rates and the death rates – was that both of them went down precipitously after the vaccinations were stopped. That story right there tells you that vaccines were not what made the disease go away; what made the disease go away was isolation and sanitation."
Antibody Is the Wrong Way to Ascertain Immunity

One of the major arguments against vaccine-induced immunity is that it primarily stimulates the humoral immune system and not the cellular immune system. Antibodies are produced by the humoral immune system and then routinely measured to determine “immunity.” The problem with this approach is that you can have high antibody levels and still get the disease. It’s very difficult and expensive to measure the cellular immune response, and immunologists admit that they are still in the dark about a lot of the finer points of the overall immune response.

When you use antibody titers or blood levels to check for immunity, all you're doing is getting a picture of what happened (you had an immune response); it doesn't tell you whether you're going to be immune in the future, because antibodies are only one aspect of the immune response, and in some cases are not even necessary to easily combat the sickness and become immune.

For example, those with agammaglobulinemia—a disease where you cannot make antibodies — can get infected with measles, recover uneventfully, and still respond to subsequent challenges of the virus in a normal healthy fashion and not get sick. These individuals will have lifelong immunity to measles, the same as someone without agammaglobulinemia.

Traditionally, the way immunity is determined is to do a test that measures antibodies, which is the humoral immune system. But there's no good way to assess the cellular immune system. It's a really imprecise science at best. As Dr. Humphries notes:

"It's not only imprecise; sometimes it's downright inaccurate. You can have very high antibody levels, like numerous case reports of people who have hugely high antibody levels for tetanus, or normal antibodies, and have gotten some of the worst cases of tetanus. I have papers that show that people without antibody for polio have actually been able to respond to the virus as if they were already immune. The antibody really is a real wrong roadmap to look at to tell what's really going on. Sometimes there's correlation, but it's certainly not a given."

The Story Behind the Polio Vaccine

The other prime argument for the justification and support of today's highly aggressive vaccination program is the alleged success of the polio vaccine. But here again, the historical perspective fails to support the vaccination paradigm.
"The story behind polio is absolutely fascinating when you look at the politics that went on researching the vaccine, and how scientists were fired if they disagreed with the program going on through the National Foundation of Infantile Paralysis (NFIP) in the late 1940s and early 1950s. That was the vaccine that Jonas Salk developed," Dr. Humphries says.

Before the Salk vaccine became available, if you were admitted to the hospital any doctor could diagnose you with polio based on two physical examinations within 24 hours, to check for paralysis in one or more muscle groups. We now know that a number of viruses can cause paralysis, but back then, all instances were thought to be due to polio virus. When the polio vaccine was developed, a problem emerged. Swedish scientists were trying to tell the US scientists that formaldehyde inactivation was not going to work as planned.

Their warning, however, fell on deaf ears. This was unfortunate, as they turned out to be correct. Live poliovirus, which was put in an injectable vaccine, would appear to be inactivated right after it was made, but sometimes it would "resurrect" in the vial... In essence, the formaldehyde did not kill off all the polioviruses in these vaccines, which led to live polio viruses being injected. As a result, more people developed paralysis from the vaccine in 1955 than would have developed it from a wild, normal natural poliovirus.

Something had to be done to make it appear as though the vaccine was working. So what they did was change the diagnostic criteria for polio. Sadly this is a very common practice in medicine. When the observations don't fit your expectations, change or rig the system so that they do. With polio, the original criteria was two examinations within 24 hours. This was changed to two examinations within 60 days. This was helpful in cooking the books, because within 60 days, most people recover from their bout with poliomyelitis.

"All those people who were formerly called polio were no longer categorized as polio because they recovered from their paralysis within that time," Dr. Humphries explains.

Then there was the issue of testing. Prior to the vaccine, there was no testing done on blood or stool samples. After the vaccine came along, there was an epidemic in Michigan around 1958. About 2,000 people were diagnosed with polio. In disbelief over the outbreak, serological testing was done, and they discovered that the polio virus was found in only a small minority—about one-quarter of those who displayed symptoms of infection. Interestingly, in the remainder they discovered a different virus or no virus at all! And, subsequently, those patients were no longer "counted" as having polio.

"So simply by doing the diagnostic testing and changing the diagnostic criteria, the rates of polio plummeted, whether or not there was ever a vaccine. These were the kind of things that were going on back then," Dr. Humphries says.

Oral Polio Vaccine Propagates Transmission of Vaccine Virus

It's important to realize that the injected polio vaccine does nothing to prevent transmission of the virus, and after an oral polio vaccine you become a reservoir of virus that can mutate or combine with other bowel viruses, creating new strains that are often more virulent to those around you. According to Dr. Humphries, the only thing the injectable vaccine theoretically does is give you some blood immunity, similar to tetanus. This means it is only going to be effective if your blood meets the virus before the virus meets your nervous system.

Once vaccine makers realized just how difficult it was to inactivate the polio virus, and many people ended up contracting polio from the vaccine, they decided to abandon the injectable polio vaccine and create an oral vaccine instead, which is more similar to the natural route of infection. Again, controversy ensued. The oral vaccine did interrupt transmission of the wild type virus, but it propagated transmission of the vaccine virus instead.

"The fact of the matter is that you can attenuate a virus all you want, which means that you pass it through different animals to make it mutate enough that it's not quite as lethal or virulent at some point. But once you put that vaccine or that virus back into its natural host, it mutates back to the way it was," Dr. Humphries explains.

"You can give a baby an oral polio vaccine and it can be attenuated. But even in the vial, before you give it to that baby, those viruses are starting to revert back to their former problematic state. And then once the baby swallows that, the baby will generate some immunity in the intestine. But what's going to come out of that baby is going to be mutated vaccine virus. Oftentimes this is problematic, especially in people who are immunosuppressed."
In the 1990s the US quit using the oral vaccine, and switched back to the injectable vaccine. To address the hazards of injecting improperly or inadequately inactivated polio virus, certain adjustments to the formulation were made. Modern polio vaccines are propagated and inactivated differently from earlier versions, and different countries also use different strains of the polio virus. Older polio viruses used to contain three strains of the virus. Today, some countries will only use one or two.

**Polio Was 'Eradicated' NOT by the Vaccine But Through Redefinition**

As noted by Dr. Humphries, it's very easy to defeat the polio vaccine argument, as most incidences of polio disappeared because the disease was redefined—not because there was an actual change in disease prevalence. In fact, it could be argued that the vaccine did more harm than good, since some versions caused polio, and others propagated new mutated strains of the virus. According to Dr. Humphries, at one point, the only polio cases in the US were vaccine-induced. Yet even though there are no cases of wild polio being discovered, the polio vaccine remains part of the US vaccine program...

"Even today, you can just go on to the CDC website and the Morbidity and Mortality Weekly Report (MMWR). You can see that cases of polio in this country by and large occur when people get the oral vaccine in another country and then come here. When they say that polio is only a plane ride away, the truth is that disease from polio vaccine is also a plane ride away... Like I said, the injected vaccines do not interrupt propagation of the virus. If somebody comes to this country who has recently had an oral polio vaccine and he's shedding a highly virulent strain, people in this country can start passing it around."

**Polio Epidemic Historically Related to Increase in Sugar Consumption**

Here's another interesting tidbit that no one ever talks about: In the past, it has sometimes been suggested that a large part of the polio epidemic was related to increases in sugar consumption. Dr. Benjamin Sandler wrote an entire book about this, and Dr. Humphries refers to his work in her book as well. She explains the connection as follows:

"Polio's an enterovirus [i.e. a virus that enters the body through the gastrointestinal tract and thrives there]. The integrity and the flora population in your bowel is extremely important when it comes to dealing with any kind of bowel infection. A diet that's high in sugar is going to 1) impair your cell-mediated immune system and 2) trash your gut flora... [It was] shown that in populations who cut back on their sugar intake, the rates of polio plummeted... But it was so unbelievable that nobody really listened to him.

It was the same as when Dr. Frederick Klenner tried to say that he cured 100 percent of patients with intravenous vitamin C and [it] just didn't register. The... low-sugar diet was very effective because of the effect it has on the immune system and on the bowel flora. The same with dichlorodiphenyltrichloroethane (DDT); DDT really trashes the bowel, the intestinal walls, and the flora.... Not only can DDT give you all the symptoms of polio all by itself, it can also make the poliovirus much more virulent and active in the body for the same reason: it disturbs the normal function of the bowel."

DDT exposure has also been linked to Alzheimer's disease, and it's worth noting that the contemporary equivalent of DDT, glyphosate, according to Dr. Don Huber, professor emeritus at Purdue University, is far more toxic than DDT. It definitely has been shown to decimate your microbiome, and glyphosate preferentially kills bacteria known to be beneficial for human health.

**'You Cannot Dabble in the Topic of Vaccination’**

Dr. Humphries left a successful practice making $300,000 a year to be a poorly paid researcher. For her it was worth it, because her integrity wouldn't allow her to turn a blind eye to what she knew to be wrong.

"If you want to make these [vaccine] arguments, we have to have information and we have to have knowledge. We have to understand the history, the medical literature, the biology, the chemistry, the physiology, and the immunology. That is
not easy. You cannot dabble in the topic of vaccination. If you do, you're likely going to be toppled by the pro-vaccine lobby because they're doing their homework.

I felt it was more important to do my homework and make these arguments that I wanted to make... I do lectures if people invite me. I have toured through Scandinavia. Our book has been translated into two different languages [Spanish and German]... Right now I'm really immersed in the topic of infant immunity because there is so much information that has just come out in the past few years that, in my opinion, turns the vaccine paradigm for infants completely on its head.

Instead of arguing about any particular vaccine, if you understand the way the infant immune system is designed, you can automatically see that if you were going to toss any kind of a vaccine in there, you might give them some short-term immunity, but you're also going to change their immune systems so that it can't function the way it was designed to function... The arguments against vaccines when you really understand the infant immune system I think are irrefutable."

Science of Epigenetics Changes Everything Yet Again...

Epigenetics is another field where biology is being turned on its head and all the old paradigms are being tossed out. Epigenetic science now tells us that our genes are NOT our destiny, and the problem is that once you start to epigenetically tinker with the infant immune system, you are basically depositing what Dr. Humphries refers to as "little cluster bombs" that will eventually "explode into a big problem." As an example, she cites a study by Nikolaj Orntoft, in which African girls were injected with a tetanus vaccine to see which genes might be upregulated or downregulated. What they found is that there's really no way to predict which genes will be affected.

So not only will each individual have a unique response to any given vaccine, based on their current health status, we're also epigenetically predisposed to respond differently in terms of the side effects we might develop. This means that having a vaccine compensation table for reimbursement for vaccine damage is nonsensical as we're bound to have different genes upregulated after vaccines are given.

"We can have cancer genes upregulated, or autoimmune diseases upregulated. This has been shown in modern literature that used these highly sophisticated gene techniques to actually watch what happens after the vaccine is injected. I think this is really powerful information to show that, when vaccines started, they knew nothing about the immune system. Then scientists knew something about the immune system, but now we know about the genetics of the immune system and the epigenetics of the immune system, and that's got to be taken into account..."

Most Doctors Are Completely Uninformed, Which Means You Cannot Make an Informed Choice

Dr. Humphries stresses the importance of "thinking long and hard" about how much information you've been given before your child is given a vaccine.

"[Vaccines] can have tumorigenic kidney cells of a cocker spaniel in it. It can have human fetal cells with retroviruses. [It can have] aluminum, which is one of the most horrible things to inject into any sort of life form, especially into a muscle... Parents really need to know that their doctors are not informed and therefore they cannot give informed consent, and that they really need to think about it because you cannot unvaccinate.

The fear of, "Oh, what if my child gets a disease"—that's where knowing the history is really important because what we're talking about is under which conditions people become susceptible. That's really more important than transmission. Because, yes, measles transmits very rapidly through the population, but it actually has a lot of benefits to the immune system—so much so that they're using it to treat cancer today."

We really need to understand each disease—what the risk of it is, how it's transmitted, what the vaccine effectiveness is, and what the risks are. Dr. Humphries also notes that the human body is designed in such a perfect way that there is a system in place to handle just about anything that happens to it, provided we've treated our body properly.
"Babies who come into this world in a normal and natural way, who are breastfed for an appropriate amount of time, that’s the best protection you could ever give to your baby’s immune system or brain. Consider that when the fear starts to creep in. If you’re breastfeeding your baby, you’re already giving the most powerful thing on the planet that can be given to that baby," she says.

More Information

People have been scared into believing vaccines are the answer to prevent disease, but when you look at the historical evidence, the arguments used simply fall apart. There’s just no question that improving your innate immune system—through reducing sugar and processed foods in your diet, improving your gut flora, leading a healthy lifestyle, and having adequate vitamin D levels, ideally through sensible sun exposure,—will provide a far more effective immune response and virtually eliminate any risk of developing a life threatening infection.

The key is to have the courage to trust in this truth—that your body is designed to maintain health. Its natural course and direction is to be healthy not sick. If you have a healthy lifestyle, exposure to nearly all of these infectious agents will ultimately make you healthy and stronger. This is similar to exercise, which actually tears your body down to make it stronger. Nature actually knows what it’s doing, whereas putting chemicals into your body based on human theories (or rumors!) that are oftentimes completely wrong, is unlikely to produce better results. As noted by Dr. Humphries:

"We have a highly profitable, lucrative religion that involves the government, industry, and academia. That religion is vaccination. People believe in vaccines. They’ll tell you, they believe in vaccines. But you ask them what they know about vaccines and it will be almost nothing. In fact the people who argue the loudest usually know the least when it comes to trying to convince you to take the vaccine. That’s been my experience.

Medical schools are bereft of information on the history of vaccination, on the contents of them, and the potential problems. We have the go-to doctors, like Dr. Paul Offit, teaching doctors how to talk to vaccine-refusing parents. We have doctors like Dr. Robert Jacobson putting out PowerPoint presentations to give to doctors, literally telling them to persuade the parents rather than to inform them...

Doctors are really being systematically brainwashed. Not only that, but if doctors do start to see problems... wake up to it; do their own research, and buck the system, they risk being treated the way I was. I was well respected through the entire state of Maine. People were referring their patients to me. My colleagues would come to me with their medical problems... But once I started to argue against the practice of vaccination, I was automatically tossed into the category of a quack..."

To learn more, I couldn't more highly recommend Dr. Humphries excellent book, Dissolving Illusions: Disease, Vaccines, and the Forgotten History, available in paper back and Kindle on Amazon. You can also find more information on the book's website, dissolvingillusions.com. I have read it cover to cover and plan on doing so again as there are loads of powerful information that helps combat the blindly foolish acceptance of nearly all media and professionals on the value of vaccinations.
The SV40 Virus: Has Tainted Polio Vaccine Caused An Increase in Cancer?

https://www.nvic.org/vaccines-and-diseases/Polio-SV40/BLFTestimonySV40.aspx

Oral Presentation
Barbara Loe Fisher
Co-founder & President
National Vaccine Information Center
September 10, 2003

Subcommittee on Human Rights and Wellness
U.S. House Government Reform Committee
U.S. House of Representatives, Washington, D.C.
“The SV40 Virus: Has Tainted Polio Vaccine Caused an Increase in Cancer?”


The shocking story you are about to hear involves a pharmaceutical company which used monkeys to make polio vaccine, government health agencies responsible for making sure the vaccine was not contaminated with monkey viruses, and individuals who are now are dying from cancerous tumors that contain a monkey virus which appears to have contaminated that polio vaccine. At the heart of this tragic story is a violation of the public trust and the informed consent ethic. It is a story about what happens when the legal and moral duty for industry and government to insure that a vaccine will not harm individuals is sacrificed to insure acceptance and mass use of a vaccine by the entire population. It shows what can happen when Congress, which has oversight authority over federal health agencies, blindly trusts and fails to verify.

I began speaking and writing about monkey virus contamination of polio vaccines ten years ago when questions were raised in the medical literature about whether the use of monkeys infected with monkey viruses to produce oral polio vaccines was responsible for HIV and the AIDS epidemic. (Attachment 2: Kyle, W.S. 1992. Simian retroviruses, polio vaccine, and origin of AIDS. The Lancet 339: 600-601.) Between 1994 and 1997 I submitted several Freedom of Information Act (FOIA) requests to the government regarding testing of certain lots of oral polio vaccine for monkey virus contamination (Attachment 3 – Correspondence between BL Fisher and FDA) During the course of my research I discovered that it was well known that the first polio vaccine produced in the 1950’s – the inactivated polio vaccine created by Jonas Salk – was made using rhesus monkeys that were infected with a monkey virus called simian virus 40 or SV40.

It was in 1960 that an NIH scientist named Bernice Eddy discovered that rhesus monkey kidney cells used to make the Salk polio vaccine and experimental oral polio vaccines could cause cancer when injected into lab animals. Later that year the cancer-causing virus in the rhesus monkey kidney cells was identified as SV40 or simian virus 40, the 40th monkey virus to be discovered. (Shorter, e. 1987. The Health Century) Sadly, the American people were not told the truth about this in 1960. The SV40 contaminated stocks of Salk polio vaccine were never withdrawn from the market but continued to be given to American children until early 1963 with full knowledge of federal health agencies. Between 1955 and early 1963, nearly 100 million American children had been given polio vaccine contaminated with the monkey virus, SV40. (Institute of Medicine, National Academy of Sciences . 2002. Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer. Washington, D.C.: National Academy Press)

Today, U.S. federal health agencies admit the following two facts: 1. Salk polio vaccine released for public use between 1955 and 1963 was contaminated with SV40; and 2. SV40 has been proven to cause cancer in animals. In fact, at a conference on SV-40 and human cancers held by the National Institutes of Health in 1997, which I attended, there was no disagreement among both government and non-government scientists about these two facts. The only disagreement was whether SV40 was actually being identified...
in the cancerous tumors of children and adults alive today and, if it was, whether the monkey virus was in fact responsible for their cancer. Non-government scientists working in independent labs around the world said, “Yes.” But the scientists connected with the U.S. government said “No.” (Transcript of FDA, CDC, NIH, NIP, NVPO January 27-28, 1997 Workshop on Simian Virus 40: A Possible Human Polyomavirus).

Today, there are scientists associated with the US government who continue to deny that SV40 causes human cancer or that SV40 associated cancers have had any effect on cancer rates since the early 1960’s. However, highly credentialed non-government scientists in multiple labs around the world continue to identify SV40 in human brain and lung cancers of children and adults and are finding that SV40 is also associated with bone cancers and Non-Hodgkin’s Lymphomas. The majority of these independent scientists have concluded that, yes, SV40 does cause human cancers. (Attachment 4 – Gazdar AE, Butel JS, Carbone M. 2002. SV40 and human tumours: myth, association or causality? Nature 2: 957-964) And in a report published in 2001, the Institute of Medicine Immunization Safety Review Committee stated that “in light of the biological evidence supporting the theory that SV40 contamination of polio vaccines could contribute to human cancers, the Committee recommends continued public health attention in the form of policy analysis, communication and targeted biological research.”

Up until this hearing today, the world scientific community has assumed that the only polio vaccine that was contaminated with SV40 and released for use by millions of Americans was Jonas Salk’s killed polio vaccine, which stopped being used in 1963 because it was replaced by Albert Sabin’s live oral polio vaccine. Why? Because the oral polio vaccine manufacturer and federal health agencies have told everyone that while the Salk vaccine was made using the SV40 infected rhesus monkey kidney tissues, after 1963 the oral polio vaccine was made using African Green monkeys, which are rarely infected with SV40. The vaccine manufacturer and government officials have insisted that the switch from rhesus monkey to African Green as well as testing protocols to detect SV40 prevented SV40 from contaminating oral polio vaccine after 1963. (Attachment 5: Statement of Bonnie Brock, Lederle, at Jan. 27-28, 1997 Workshop on SV40, transcript pages 300-307).

However, you will be presented with evidence today that suggests (Attachment 6: Kops SP. 2000. Oral polio vaccine and human cancer: a reassessment of SV40 as a contaminant based upon legal documents. Anticancer Research 20: 4745-4749. and Oral Testimony, Stanley Kops, Esq. Subcommittee on Human Rights and Wellness, US Government Reform Committee, September 10, 2003): 1. the original seed stocks of oral polio vaccine were made using the rhesus monkey and were contaminated with SV40; 2. the major oral polio vaccine manufacturer did not adequately test their master seed stocks which reportedly contained SV40 but used them to produce vaccine released for use by American children from the 1960’s through the 1990’s; 3. Federal regulatory agencies either did not know or knew and did not do anything about evidence that SV40 contaminated oral polio vaccine was released for use by the public from the 1960’s through the 1990’s; If SV40 contaminated rhesus monkeys were used to produce original oral polio vaccine seed stocks, and if these seed stocks were used to produce oral polio vaccine that was swallowed by American children through the 1990’s, and if SV40 does cause human brain, lung and bone cancers, then this could explain why children today, who were not born before 1963 and never got the SV40 contaminated Salk vaccines, are now sick and dying from cancerous tumors containing DNA from a monkey virus that was in those vaccines.

Pediatric brain cancer, once rare, rose during the past few decades according to the National Cancer Institute. But we don’t know how many of these children had or have SV40 in their brain tumors because nobody checks. How many of these children are sick and dying because the manufacturer of oral polio vaccine did not follow the rules and government health agencies didn’t enforce the rules? Since 1999, the US has discontinued use of the live oral polio vaccine and American children are now getting a killed polio vaccine that is reportedly SV40 free.

So why is it important today to find out whether or not the oral vaccine used to eradicate polio was in fact contaminated with a cancer causing monkey virus, and that the vaccine manufacturer knew it, and that government health agencies looked the other way? It is important because if it is true, then a precedent has been set. And that precedent may well be affecting decisions being made by government health agencies today about what kinds of animal tissue cultures vaccine manufacturers will be allowed to use to make new vaccines and what kinds of tests will be required to insure that the vaccines do not contain animal viruses or other contaminants.
Drugs and vaccines are very different. Drugs are used to cure sick people while vaccines are required by law in this country to be given to healthy people, primarily children. The standards for proof of safety and efficacy of vaccines should be higher than for any other pharmaceutical product we use.

I have just ended a four year term as the consumer voting member of the FDA Vaccines and Related Biological Products Advisory Committee. My service on that committee gave me a new appreciation for the dedicated work of a number of fine scientists employed by the FDA, who take their regulatory duties very seriously and are working hard to regulate the vaccine industry with very limited resources and limited support within and outside of government. However, there are legitimate concerns which I and others have voiced in the past and continue to have about whether government standards for requiring vaccine manufacturers to prove the safety and efficacy of vaccines are high enough and whether the tests used by the manufacturers and the government to insure the safety of vaccines are good enough.


I urge this Committee and other congressional committees to carefully review the transcripts of meetings of the FDA Vaccines and Related Biological Products Advisory Committee, specifically those which were held in 1998; 2000; 2001 and dealt with adventitious agent contamination of vaccines. Vaccine manufacturers are asking the FDA for permission to use cells from human and animal cancer tumors – that is cancer cells – to make HIV and other viral vaccines in the future that would be used on a mass basis by the American population. There has been a federal ban on use of cancer cells to produce vaccines since 1954 but active consideration is being given now to lift that ban despite the acknowledged risks of contamination with adventitious agents, including residual DNA and RNA. (Attachment 8: Excerpt from November 19, 1998 FDA Vaccines and Related Biological Products Advisory Committee meeting, transcript pages 29-52).

There is frank admission that the limitations of technology and lack of scientific knowledge means there can be no guarantee the vaccines will not be contaminated with substances that could prove harmful to humans one day. Nevertheless, there are plans to set allowable thresholds for adventitious agent contamination of vaccines being made out of cancer cells that would contain residual DNA and RNA. (Attachment 9: Excerpts from May 12, 2000 FDA Vaccines and Related Biological Products Advisory Committee meeting transcript and Attachment 10: Excerpts from May 16, 2001 FDA Vaccines and Related Biological Products Advisory Committee meeting transcript) I do not think Congress or the public understands any of this. There should be a much wider discussion in the larger scientific community outside of federal health agencies and the pharmaceutical industry, as well as in Congress and by the public at large before decisions are made to proceed with producing vaccines that use cancer cells and have legally allowable thresholds of adventitious agent contamination.

Past is often prologue. So much can be learned from understanding the mistakes of the past so that the same mistakes are not made in the future. Outstanding questions about the links between vaccines, government vaccine policies and the epidemic of chronic disease in our children, including autism, learning disabilities, ADHD, asthma, diabetes and, as we have discussed today, cancer are not going away. Questions about the links between vaccines that US military soldiers are required to take, including anthrax and smallpox vaccines, and the subsequent death or permanent health problems being suffered by those previously healthy, young recruits are not going away. They will never go away when the main defense of industry and government health officials is that when anything bad happens after vaccination it is just a coincidence. I can tell you, the American public, especially parents, are not buying it. And they shouldn’t buy it, especially when the kind of evidence that you will hear today suggests official government and industry denials are simply a way of avoiding taking responsibility for failing to do everything they can to minimize the risks of vaccines.

We owe it to our children and grandchildren to do everything we can to find out the truth about vaccine risks and make the mass vaccination system as safe as it can be. I believe that can only be done if Congress exercises more oversight authority over federal health agencies responsible for vaccine research, development, regulation, policymaking, promotion and monitoring of vaccine side effects. Conflict of interest legislation is urgently needed to separate government health agencies from financial and other ties with the vaccine industry so that government health officials can be free to do the job they are supposed to do: protect the health and well being of every American and not simply protect the
Before I conclude, I would like to thank you, Chairman Burton, for all you have done during the past three years to investigate and bring to the attention of Congress and the American people the fact that our nation’s mass vaccination system must be reformed to make it safer. You have had the courage to stand up for those who suffer greatly when a vaccine’s risks turn out to be 100 percent for them or their child and you have done it against great opposition from powerful special interest groups with vested interests in protecting the status quo. Your tireless efforts on behalf of so many will not be in vain because the truth will shine bright and clear in the end no matter how long it takes.
CDC Senior Scientist and whistleblower, Dr. William Thompson, admits that African American males who receive the MMR vaccine before age 36 months are at ‘increased’ risk for autism, meaning that all children are at risk for autism from the MMR vaccine.

FOR IMMEDIATE RELEASE-AUGUST 27, 2014: STATEMENT OF WILLIAM W. THOMPSON, Ph.D., REGARDING THE 2004 ARTICLE EXAMINING THE POSSIBILITY OF A RELATIONSHIP BETWEEN MMR VACCINE AND AUTISM

My name is William Thompson. I am a Senior Scientist with the Centers for Disease Control and Prevention, where I have worked since 1998.

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal Pediatrics. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at ‘increased’ risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed. (The emphasis are Lynn Landes’s of HealthAlertPhilly.org)

I want to be absolutely clear that I believe vaccines have saved and continue to save countless lives. I would never suggest that any parent avoid vaccinating children of any race. Vaccines prevent serious diseases, and the risks associated with their administration are vastly outweighed by their individual and societal benefits.

My concern has been the decision to omit relevant findings in a particular study for a particular sub group for a particular vaccine. There have always been recognized risks for vaccination and I believe it is the responsibility of the CDC to properly convey the risks associated with receipt of those vaccines.

I have had many discussions with Dr. Brian Hooker over the last 10 months regarding studies the CDC has carried out regarding vaccines and neurodevelopmental outcomes including autism spectrum disorders. I share his belief that CDC decision-making and analyses should be transparent. I was not, however, aware that he was recording any of our conversations, nor was I given any choice regarding whether my name would be made public or my voice would be put on the Internet.

I am grateful for the many supportive e-mails that I have received over the last several days. I will not be answering further questions at this time. I am providing information to Congressman William Posey, and of course will continue to cooperate with Congress. I have also offered to assist with reanalysis of the study data or development of further studies. For the time being, however, I am focused on my job and my family.

Reasonable scientists can and do differ in their interpretation of information. I will do everything I can to assist any unbiased and objective scientists inside or outside the CDC to analyze data collected by the CDC or other public organizations for the purpose of understanding whether vaccines are associated with an increased risk of autism. There are still more questions than answers, and I appreciate that so many families are looking for answers from the scientific community.

My colleagues and supervisors at the CDC have been entirely professional since this matter became public. In fact, I received a performance-based award after this story came out. I have experienced no pressure or retaliation and certainly was not escorted from the building, as some have stated.

Dr. Thompson is represented by Frederick M. Morgan, Jr., Morgan Verkamp, LLC, Cincinnati, Ohio, morganverkamp.com

**Former Merck Scientists Sue Merck Alleging MMR Vaccine Efficacy Fraud**


Stephen A. Krahling and Joan A. Wlochowski, former Merck virologists blew the whistle by filing a *qui tam* action lawsuit — U.S. v Merck & Co. — in August 2010. The scientists allege that the efficacy tests for the measles, mumps, rubella vaccine (MMR) were faked. The document was unsealed in June, 2012. [https://www.kellergrover.com/cases/whistleblower-actions/active-cases-whistleblower-actions/united-states-ex-rel-krahling-and-wlochowski-v-merck-co](https://www.kellergrover.com/cases/whistleblower-actions/active-cases-whistleblower-actions/united-states-ex-rel-krahling-and-wlochowski-v-merck-co)

This is a major federal case alleging fraud in vaccine testing; it encapsulates how medical research can be manipulated to achieve desired results, and why it may be wise to question the integrity and the validity of “science-based medicine.”

The suit charges that Merck knew its measles, mumps, rubella (MMR) vaccine was less effective than the purported 95% level, and it alleges that senior management was aware and also oversaw testing that concealed the actual effectiveness. According to the lawsuit, Merck began a sham testing program in the late 1990’s to hide the declining efficacy of the vaccine. The objective of the fraudulent trials was to “report efficacy of 95% or higher regardless of the vaccine’s true efficacy.”

According to Krahling and Wlochowski’s complaint, they were threatened with jail were they to alert the FDA to the fraud being committed.

In January 31, 2016, the court ordered that discovery, the process of gathering evidence, must be completed by 1 March 2017, over a year from now. The court also ordered that expert discovery needs to be completed by 31 October 2017. Other motions must be filed by 20 December 2017. A motion for class action certification must be filed by 1 March 2018; and Merck must file its opposition to class certification by 5 April 2018.

The plaintiffs charge that Merck defrauded the U.S. for more than a decade by faking a vaccine efficacy rate of 95% even though the real rate was significantly lower.

“As the single largest purchaser of childhood vaccines (accounting for more than 50 percent of all vaccine purchasers), the United States is by far the largest financial victim of Merck’s fraud. *But the ultimate victims here are the millions of children who every year are being injected with a mumps vaccine that is not providing them with an adequate level of protection against mumps. And while this is a disease the CDC targeted to the single largest purchaser of childhood vaccines (accounting for more than 50 percent of all vaccine purchasers), the United States is byo eradicate by now, the failure in Merck’s vaccine has allowed this disease to linger with significant outbreaks continuing to occur,*” the suit alleges. ([Forbes](https://www.forbes.com), June 6, 2012)

According to the suit, the objective of the fraudulent trials was to “report efficacy of 95% or higher regardless of the vaccine’s true efficacy.”

“For the new testing method, the children’s blood was tested for its ability to neutralize the virus using the vaccine strain virus, instead of the wild type strain that is much more infective, and the one that your children would most likely catch... But still it was not 95% effective. In order to make the blood pass the test, antibodies from rabbits was added. The addition of rabbit antibody increased the efficacy to 100%. But that was not the end, because the test has to be done on pre-vaccine blood and post-vaccine blood.

*Just the addition of rabbit antibody made the pre-vaccine blood go from 10% positive to 80% positive and that was such an obvious sign of foul play that yet another manipulation had to be made.*

The desired end result is to have very low pre-vaccine antibody and 95% or more post-vaccine efficacy as measured by antibody neutralization. So, yet one more change in procedure was made: The pre-vaccine tests were all redone...by fabricating the “plaque” counts on the pre-vaccine blood samples, counting plaques that were not there. What this allowed was a mathematical dilution of the pre-vaccine positive blood counts.” ([Court House News Service](https://www.courthousenews.com), June 27, 2012)
In an attempt to prevent shingles, some patients may have unintentionally contracted the virus from their shingles vaccination.

The shingles vaccine Zostavax may cause serious injuries, including shingles, blindness, and even death. Injured patients are now filing lawsuits against Zostavax’s manufacturer Merck (and its owner, Bayer) for failing to warn about the potential side effects.

If you or a loved one were injured by Zostavax, please contact us. Our attorneys are investigating these claims to help patients seek justice.

WHAT ARE THE SIDE EFFECTS OF THE ZOSTAVAX VACCINE?

The vaccine only works in about half of patients, and even then it will only last for about six years.

Zostavax is a shingles vaccine for patients 50 years and older, an age when the virus is more common. It’s caused by dormant chickenpox viruses which can lay in the body’s nervous system for years, eventually creating shingles. The virus is typically characterized by a painful band of blisters on one side of the torso.

Zostavax uses a weakened form of the herpes zoster virus—commonly referred to as shingles—in order to activate the immune system. After fighting the weakened version of the virus, the body builds immunity. At best, the vaccine only works in 50 percent of patients, and even then it will only last for about six years.

For patients who are immunocompromised, their bodies may not be able to fight off the small dose of the virus. This can cause a host of injuries, including chickenpox and shingles itself.

Lawsuits claim that even though Merck knew Zostavax could cause shingles, it didn’t list this as a side effect until December 2014—years after the vaccine was approved by the FDA in 2006.

The FDA reports that Zostavax side effects can include the following:

- Shingles
- Chickenpox
- Rash
- Hives
- Headache
- Fever
- Nausea
- Joint pain
- Muscle pain
- Eye disorders, including necrotizing retinitis
- But some plaintiffs allege that Zostavax caused even more serious complications, like blindness, hearing loss, paralysis, brain damage, and fatal liver failure.
DOES MERCK FACE OTHER VACCINE LAWSUITS?

Merck is currently battling another lawsuit for its mumps, measles, and rubella (MMR) vaccine. In 2010, two former Merck scientists accused the company of manipulating clinical test results to maintain its U.S. monopoly on the MMR vaccine.

Merck scientists accused the company of manipulating clinical test results.

The court documents allege that Merck noticed in the late 1990s that the vaccine was falling below the 95 percent efficiency requirement necessary to sell the vaccine. Instead of improving the vaccine, Merck allegedly tinkered with the clinical trial results—which the two whistleblowers say they were asked to help carry out.

The former Merck scientists allege that this fraudulent testing may have contributed to the major outbreaks of mumps in 2006 and 2009, because children were receiving weaker vaccinations.

WHAT ARE SOME NOTABLE VACCINE SETTLEMENTS?

Many pharmaceutical companies are protected under the 1986 National Childhood Vaccine Injury Act, which requires that patients file injury claims with the federal government. However, Zostavax is not listed in the act’s injury table, allowing injured patients to file lawsuits in court.

Since the creation of the National Vaccine Injury Compensation Program, injured patients have received $3.6 billion. In some cases, injured patients have been able to recover millions for the harm they suffered.

In 2014, Sarah Behie received $4.5 million, with an eventual payout of $11.6 million, after a flu shot left her partially paralyzed. In 2010, she developed Guillain-Barre syndrome (GBS), a rare side effect of flu shots in which the immune system attacks the nervous system.

In 2013, U.S. courts paid nearly $6 million for Gardasil, Merck’s HPV vaccination for females aged 9 to 26 years old. The settlement compensated 49 injured patients who suffered from severe side effects, including GBS, seizures, blindness, and even death.

WHAT DO ZOSTAVAX LAWSUITS ALLEGE?

More than 50 lawsuits against Merck and Bayer were recently combined in a multi-district litigation in the Eastern District of Pennsylvania, a venue for which ClassAction.com advocated. On Sept. 25, 2018, our attorney Michael Goetz was appointed a co-lead counsel position in the Zostavax litigation.

Zostavax lawsuits allege some combination of the following:

- Zostavax can cause serious side effects, including death.
- Merck failed to warn patients of the vaccine’s potential side effects.
- Merck employees “intentionally, willfully, and knowingly misrepresented” the safety of Zostavax.
How the CDC Uses Fear to Increase Demand for Flu Vaccines

By Jeremy R. Hammond, CHD Contributing Writer

NOVEMBER 08, 2018

The US Centers for Disease Control and Prevention (CDC) claims that tens of thousands of people die annually from the flu, but what the public isn’t told is that these numbers come from controversial models that may greatly overestimate, which happens to align with the CDC’s stated aim of using fear marketing to increase demand for flu vaccines.

The mainstream media reinforce this characterization by misinforming the public about what the science says.

A New York Times article from earlier this year, for example, in order to persuade readers to follow the CDC’s recommendation, cited scientific literature reviews of the prestigious Cochrane Collaboration to support its characterization of the influenza vaccine as both effective and safe. The Times claimed that the science showed that the vaccine represented “a big payoff in public health” and that harms from the vaccine were “almost nonexistent”.

What the Cochrane researchers actually concluded, however, was that their findings “seem to discourage the utilization of vaccination against influenza in healthy adults as a routine public health measure” (emphasis added). Furthermore, given the known serious harms associated with specific flu vaccines and the CDC’s recommendation that infants as young as six months get a flu shot despite an alarming lack of safety studies for children under two, “large-scale studies assessing important outcomes, and directly comparing vaccine types are urgently required.”

The CDC also recommends the vaccine for pregnant women despite the total absence of randomized controlled trials assessing the safety of this practice for both expectant mother and unborn child. (This is all the more concerning given that multi-dose vials of the inactivated influenza vaccine contain mercury, a known neurotoxin that can cross both the placental and blood-brain barriers and accumulate in the brain.)

The Cochrane researchers also found “no evidence” to support the CDC’s assumptions that the vaccine reduces transmission of the virus or the risk of potentially deadly complications—the two primary justifications claimed by the CDC to support its recommendation.
The CDC nevertheless pushes the influenza vaccine by claiming that it prevents large numbers of hospitalizations and deaths from flu. To reinforce its message that everyone should get an annual flu shot, the CDC claims that hundreds of thousands of people are hospitalized and tens of thousands die each year from influenza. These numbers are generally relayed by the mainstream media as though representative of known cases of flu. The aforementioned *New York Times* article, for example, stated matter-of-factly that, of the 9 million to 36 million people whom the CDC estimates get the flu each year, “Somewhere between 140,000 and 710,000 of them require hospitalization, and 12,000 to 56,000 die each year.”

...the average number of deaths each year for which the cause is actually attributed on death certificates to the influenza virus is little more than 1000.

On September 27, the CDC issued the claim at a press conference that 80,000 people died from the flu during the 2017 – 2018 flu season, and the media parroted this number as though fact.

What is not being communicated to the public is that the CDC’s numbers do not represent known cases of influenza. They do not come directly from surveillance data, but are rather controversial estimates based on controversial mathematical models that may greatly overestimate the numbers.

To put the matter into perspective, the average number of deaths each year for which the cause is actually attributed on death certificates to the influenza virus is little more than 1,000.

The consequence of the media parroting the CDC's numbers as though uncontroversial is that the public is routinely misinformed about the impact of influenza on society and the ostensible benefits of the vaccine. Evidently, that's just the way the CDC wants it, since the agency has also outlined a public relations strategy of using fear marketing to increase demand for flu shots.

In other words, the CDC considers it to be a problem that people are increasingly doing their own research and becoming more adept at educating themselves about health-related issues.

The CDC’s “Problem” of “Growing Health Literacy”

Before looking at some of the problems with the CDC’s estimates, it’s useful to examine the mindset at the agency with respect to how CDC officials view their role in society. An instructive snapshot of this mindset was provided in a presentation by the CDC’s director of media relations on June 17, 2004, at a workshop for the Institute of Medicine (IOM).

In its presentation, the CDC outlined a “Recipe for Fostering Public Interest and High Vaccine Demand”. It called for encouraging medical experts and public health authorities to “state concern and alarm” about “and predict dire outcomes” from the flu season. To inspire the necessary fear, the CDC encouraged describing each season as “very severe”, “more severe than last or past years”, and “deadly”.

One problem for the CDC is the accurate view among healthy adults that they are not at high risk of serious complications from the flu. As the presentation noted, “achieving consensus by ‘fiat’ is difficult”—meaning that just because the CDC makes the recommendation doesn’t mean that people will actually follow it. Therefore it was necessary to cause “concern, anxiety, and worry” among young, healthy adults who regard the flu as an inconvenience rather than something to be terribly afraid of.

The larger conundrum for the CDC is the proliferation of information available to the public on the internet. As the CDC bluntly stated it, “Health literacy is a growing problem”.

...
In other words, the CDC considers it to be a problem that people are increasingly doing their own research and becoming more adept at educating themselves about health-related issues. And, as we have already seen, the CDC has very good reason to be concerned about people doing their own research into what the science actually tells us about vaccines.

One prominent way the CDC inspires the necessary fear, of course, is with its estimates of the numbers of people who are hospitalized or die each year from the flu.

...many if not most people diagnosed with ‘the flu’ may not have actually been infected with the influenza virus at all, given the large number of other viruses that cause the same symptoms and the general lack of lab confirmation.

The Problems with the CDC’s Estimates of Annual Flu Deaths

Among the relevant facts that are routinely not relayed to the public by the media when the CDC’s numbers are cited is that only about 7% to 15% of what are called “influenza-like illnesses” are actually caused by influenza viruses. In fact, there are over 200 known viruses that cause influenza-like illnesses, and to determine whether an illness was actually caused by the influenza virus requires laboratory testing—which isn’t usually done.

Furthermore, as the authors of a 2010 Cochrane review stated, “At best, vaccines may only be effective against influenza A and B, which represent about 10% of all circulating viruses” that are known to cause influenza-like symptoms. (That’s the same review, by the way, that the Times mischaracterized as having found the vaccine to be “a big payoff in public health”.)

While the CDC now uses a range of numbers to describe annual deaths attributed to influenza, it used to claim that on average “about 36,000 people per year in the United States die from influenza”. The CDC switched to using a range in response to criticism that the average was misleading because there is great variability from year to year and decade to decade. And while switching to the range did address that criticism, other serious problems remain.

One major problem with “the much publicized figure of 36,000”, as Peter Doshi observed in a 2005 BMJ article, was that it “is not an estimate of yearly flu deaths, as widely reported in both the lay and scientific press, but an estimate—generated by a model—of flu-associated death.”

Of course, as the media routinely remind us when it comes to the subject of vaccines and autism (but seem to forget when it comes to the CDC’s flu numbers), temporal association does not necessarily mean causation. Just because someone dies after an influenza infection does not mean that it was the flu that killed him. And, furthermore, many if not most people diagnosed with “the flu” may not have actually been infected with the influenza virus at all, given the large number of other viruses that cause the same symptoms and the general lack of lab confirmation.

The “36,000” number came from a 2003 CDC study published in JAMA that acknowledged the difficulty of estimating deaths attributable to influenza, given that most cases are not lab-confirmed. Yet, rather than acknowledging the likelihood that a substantial percentage of reported cases actually had nothing to do with the influenza virus, the CDC researchers treated it as though it only meant that flu-related deaths must be significantly higher than the reported numbers.

The study authors pointed out that seasonal influenza is “associated with increased hospitalizations and mortality for many diagnoses”, including pneumonia, and they assumed that many cases attributed to other
illnesses were actually caused by influenza. They therefore developed a mathematical model to estimate the number by instead using as their starting point all “respiratory and circulatory” deaths, which include all “pneumonia and influenza” deaths.

In his aforementioned BMJ article, Peter Doshi reasonably asked, “Are US flu death figures more PR than science?”

Of course, not all respiratory and circulatory deaths are caused by the influenza virus. Yet the CDC treats this number as “an upper bound”—as though it was possible that 100% of all respiratory and circulatory deaths occurring in a given flu season were caused by influenza. The CDC also treats the total number of pneumonia and influenza deaths as “a lower bound for deaths associated with influenza”. The CDC states on its website that reported pneumonia and influenza deaths “represent only a fraction of the total number of deaths from influenza”—as though all pneumonia deaths were caused by influenza!

The CDC certainly knows better. In fact, at the same time, the CDC contradictorily acknowledges that not all pneumonia and influenza deaths are flu-related; it has estimated that in an average year 2.1% of all respiratory and circulatory deaths and 8.5% of all pneumonia and influenza deaths are influenza-associated.

So how can the CDC maintain both (a) that 8.5% of pneumonia and influenza deaths are flu-related, and (b) that the combined total of all pneumonia and influenza deaths represents only a fraction of flu-caused deaths? How can both be true?

The answer is that the CDC simply assumes that influenza-associated deaths are so greatly underreported within the broader category of deaths coded under “respiratory and circulatory” that they dwarf all those coded under “pneumonia and influenza”.

In his aforementioned BMJ article, Peter Doshi reasonably asked, “Are US flu death figures more PR than science?” As he put it, “US data on influenza deaths are a mess.” The CDC “acknowledges a difference between flu death and flu associated death yet uses the terms interchangeably. Additionally, there are significant statistical incompatibilities between official estimates and national vital statistics data. Compounding these problems is a marketing of fear—a CDC communications strategy in which medical experts ‘predict dire outcomes’ during flu seasons.”

Setting aside pneumonia and looking just at influenza-associated deaths from 1979 to 2002, the annual average according to the NCHS data was only 1,348.

Illustrating the problem, Doshi observed that for the year 2001, the total number of reported pneumonia and influenza deaths was 62,034. Yet, of those, less than one half of one percent were attributed to influenza. Furthermore, of the mere 257 cases blamed on the flu, only 7% were laboratory confirmed. That’s only 18 cases of lab confirmed influenza out of 62,034 pneumonia and influenza deaths—or just 0.03%, according to the CDC’s own National Center for Health Statistics (NCHS).

Setting aside pneumonia and looking just at influenza-associated deaths from 1979 to 2002, the annual average according to the NCHS data was only 1,348.

The CDC’s mortality estimates would be compatible with the NCHS data, Doshi argued, “if about half of the deaths classed by the NCHS as pneumonia were actually flu initiated secondary pneumonias.” But the NCHS criteria itself strongly indicated otherwise, stating that “Cause-of-death statistics are based solely on the underlying cause of death ... defined by WHO as ‘the disease or injury which initiated the train of events leading directly to death.’”
The CDC researchers who authored the 2003 study acknowledged that underlying cause-of-death coding “represents the disease or injury that initiated the chain of morbid events that led directly to the death”—yet they fallaciously coupled pneumonia deaths with influenza deaths in their model anyway.

At the time Doshi was writing, the CDC was publicly claiming that each year “about 36,000 [Americans] die from flu”, and as seen with the example from the New York Times, the range of numbers is likewise presented as though representative of known cases of flu-caused deaths. Yet the lead author of that very CDC study, William Thompson of the CDC’s National Immunization Program, acknowledged that the number rather represented “a statistical association” that does not necessarily mean causation. In Thompson’s own words, “Based on modelling, we think it’s associated. I don’t know that we would say that it’s the underlying cause of death.” (Emphasis added.)

Of course, the CDC does say it’s the underlying cause of death in its disingenuous public relations messaging. As Doshi noted, Thompson’s acknowledgment is “incompatible” with the CDC’s “misrepresentation” of its flu deaths estimates. The CDC, Doshi further observed, was “working in manufacturers’ interest by conducting campaigns to increase flu vaccination” based on estimates that are “statistically biased”, including by “arbitrarily linking flu with pneumonia”.

...there are otherwise significant limitations of the CDC’s models that potentially result in spurious attribution of deaths to influenza.

More “Limitations” of the CDC’s Models

While the media present the CDC’s numbers as though uncontroversial, there is in fact “substantial controversy” surrounding flu death estimates, as a 2005 study published in the American Journal of Epidemiology noted. One problem is that the CDC’s models use virus surveillance data that “have not been made available in the public domain”, which means that its results or not reproducible. (As the journal Cell reminds, “the reproducibility of science” is “a lynch pin of credibility”). And there are otherwise “significant limitations” of the CDC’s models that potentially result in “spurious attribution of deaths to influenza.”

To illustrate, when Peter Doshi requested access to virus circulation data, the CDC refused to allow it unless he granted the CDC co-authorship of the study he was undertaking—which Doshi appropriately refused.

While the number of confirmed H1N1-related child deaths was 371, the CDC’s claimed number was 1,271 or more.

In the New York Review of Books, Helen Epstein has pointed out how the CDC’s dire warnings about the 2009 H1N1 “swine flu” never came to pass, as well as how “some experts maintain that the CDC’s estimates studies overestimate influenza mortality, particularly among children.” While the number of confirmed H1N1-related child deaths was 371, the CDC’s claimed number was 1,271 or more. To arrive at its number, the CDC used a multiplier based on certain assumptions. One assumption is that some cases are missed either because lab confirmation wasn’t sought or because the children weren’t in a hospital when they died and so weren’t tested. Another is that a certain percentage of test results will be false negatives.

However, Epstein pointed out, “according to CDC guidelines at the time”, any child hospitalized with severe influenza symptoms should have been tested for H1N1. Furthermore, “deaths in children from infectious diseases are rare in the US, and even those who didn’t die in hospitals would almost certainly have been autopsied (and tested for H1N1)…. Also, the test is accurate and would have missed few cases. Because it’s
unlikely that large numbers of actual cases of US child deaths from H1N1 were missed, the lab-confirmed count (371) is probably much closer to the modeled numbers ... which are in any case impossible to verify.”

As already indicated, another assumption the CDC makes is that excess mortality in winter is mostly attributable to influenza. A 2009 Slate article described this as among a number of “potential glitches” that make the CDC’s reported flu deaths the “least bad” estimate”. Referring to earlier methods that associated flu deaths with wintertime deaths from all causes, the article observed that this risked blaming influenza for deaths from car accidents caused by icy roads. And while the updated method presented in the 2003 CDC study excluded such causes of death implausibly linked to flu, related problems remain.

As the aforementioned American Journal of Epidemiology study noted, the updated method “reduces, but does not eliminate, the potential for spurious correlation and spurious attribution of deaths to influenza.” Furthermore, “Methods based on seasonal pattern begin from the assumption that influenza is the major source of excess winter death.” The CDC’s models therefore still “are in danger of being confounded by other seasonal factors.” The authors also stated that they could not conclude from their own study “that influenza is a more important cause of winter mortality on an annual timescale than is cold weather.”

*Once the CDC has its estimated hospitalization rate, it then multiplies that number by the ratio of deaths to hospitalizations to arrive at its estimated mortality rate. Thus, any overestimation of the hospitalization rate is also compounded into its estimated death rate.*

As a 2002 BMJ study stated, “Cold weather alone causes striking short term increases in mortality, mainly from thrombotic and respiratory disease. Non-thermal seasonal factors such as diet may also affect mortality.” (Emphasis added.) The study estimated that of annual excess winter deaths, only “2.4% were due to influenza either directly or indirectly.” It concluded that, “With influenza causing such a small proportion of excess winter deaths, measures to reduce cold stress offer the greatest opportunities to reduce current levels of winter mortality.”

CDC researchers themselves acknowledge that their models are “subject to some limitations.” In a 2009 study published in the American Journal of Public Health, CDC researchers admitted that “simply counting deaths for which influenza has been coded as the underlying cause on death certificates can lead to both over- and underestimates of the magnitude of influenza-associated mortality.” (Emphasis added.) Yet they offered no comment on how, then, their models account for the likelihood that many reported cases of “flu” had nothing whatsoever to do with the influenza virus. Evidently, this is because they don’t, as indicated by the CDC’s treatment of all influenza deaths plus pneumonia deaths as a “lower bound”.

For another illustration, since it takes two or three years before the data is available to be able to estimate flu hospitalizations and deaths by the usual means, the CDC has also developed a method to make preliminary estimates for a given year by “adjusting” the numbers of reported lab-confirmed cases from selected surveillance areas around the country. The “80,000” figure claimed for last season’s flu deaths is just such an estimate. The way the CDC “adjusts” the numbers is by multiplying the number of lab-confirmed cases by a certain amount, ostensibly “to correct for underreporting”. To determine the multiplier, the CDC makes a number of assumptions to estimate (a) the likelihood that a person hospitalized for any respiratory illness would be tested for influenza and (b) the likelihood that a person with influenza would test positive.

*Caveats such as that, however, are not communicated to the general public by the CDC in its press releases or by the mainstream media so that people can make a truly informed choice about whether it’s worth the risk to get a flu shot.*
Once the CDC has its estimated hospitalization rate, it then multiplies that number by the ratio of deaths to hospitalizations to arrive at its estimated mortality rate. Thus, any overestimation of the hospitalization rate is also compounded into its estimated death rate.

One obvious problem with this is the underlying assumption that the percentage of people who (a) are hospitalized for respiratory illness and have the flu is the same as (b) the percentage of those who are hospitalized for respiratory illness, are actually tested, and test positive. This implies that doctors are not more likely to seek lab confirmation for people who actually have influenza than they are for people whose respiratory symptoms are due to some other cause.

Assuming that doctors can do better than a pair of rolled dice at picking out patients with influenza, it further implies that doctors are no more likely to order a lab test for patients whom they suspect of having the flu than they are to order a lab test for patients whose respiratory symptoms they think are caused by something else.

The CDC’s assumption thus introduces a selection bias into its model that further calls into question the plausibility of its conclusions, as it is bound to result in overestimation. In a 2015 study published in *PLoS One* that detailed this method, CDC researchers acknowledged that, “If physicians were more likely to recognize influenza patients clinically and select those patients for testing, we may have over-estimated the magnitude of under-detection.” And that, of course, would result in an overestimation of both hospitalizations and deaths associated with influenza.

Caveats such as that, however, are not communicated to the general public by the CDC in its press releases or by the mainstream media so that people can make a truly informed choice about whether it's worth the risk to get a flu shot.

**Conclusion**

In summary, to avoid underestimating influenza-associated hospitalizations and deaths, the CDC relies on models that instead appear to greatly overestimate the numbers due to the fallacious assumptions built into them. These numbers are then mispresented to the public by both public health officials and the mainstream media as though uncontroversial and representative of known cases of influenza-caused illnesses and deaths from surveillance data. Consequently, the public is grossly misinformed about the societal disease burden from influenza and the ostensible benefit of the vaccine.

It is clear that the CDC does not see its mission as being to educate the public in order to be able to make an informed choice about vaccination. After all, that would be incompatible with its view that growing health literacy is a threat to its mission and an obstacle to be overcome. On the other hand, a misinformed populace aligns perfectly with the CDC’s stated goal of using fear marketing to generate more demand for the pharmaceutical industry’s influenza vaccine products.

*This article is an adapted and expanded excerpt from part two of the author’s multi-part exposé on the influenza vaccine. Sign up for Jeremy’s newsletter to stay updated with his work on vaccines and receive his free downloadable report, “5 Horrifying Facts about the FDA Vaccine Approval Process”.*

*Sign up for free news and updates from Robert F. Kennedy, Jr. and the Children’s Health Defense. CHD is planning many strategies, including legal, in an effort to defend the health of our children and obtain justice for those already injured. Your support is essential to CHD’s successful mission.*
The CDC’s Influenza Math Doesn’t Add Up: Exaggerating the Death Toll to Sell Flu Shots


Every year at about this time, public health officials and their media megaphones start up the drumbeat to encourage everyone (including half-year-old infants, pregnant women and the invalid elderly) to get a flu shot. Never mind that more often than not the vaccines don’t work, and sometimes even increase the risk of getting sick.

To buttress their alarmist message for 2018-2019, representatives from the Centers for Disease Control and Prevention (CDC) and other health agencies held a press conference and issued a press release on September 27, citing a particularly “record-breaking” (though unsubstantiated) 80,000 flu deaths last year. Having “medical experts and public health authorities publicly...state concern and alarm (and predict dire outcomes)” is part and parcel of the CDC’s documented playbook for “fostering public interest and high...demand” for flu shots. CDC’s media relations experts frankly admit that “framing” the current flu season as “more severe than last or past years” or more “deadly” is a highly effective strategy for garnering strong interest and attention from both the media and the public.

If accurate, 80,000 deaths would represent an enormous (and mystifying) one-year jump—tens of thousands more flu deaths compared to the already inflated numbers presented for 2016 (and every prior year).

Peter Doshi (associate editor at The BMJ and a MIT graduate) has criticized the CDC’s “aggressive” promotion of flu shots, noting that although the annual public health campaigns deliver a “who-in-their-right-mind-could-possibly-disagree message,” the “rhetoric of science” trotted out each year by public health officials has a “shaky scientific basis.” Viewed within the context of Doshi’s remarks, the CDC’s high-flying flu numbers for 2017-2018 raise a number of questions. If accurate, 80,000 deaths would represent an enormous (and mystifying) one-year jump—tens of thousands more flu deaths compared to the already inflated numbers presented for 2016 (and every prior year). Moreover, assuming a roughly six-month season for peak flu activity, the 80,000 figure would translate to an average of over 13,300 deaths per month—something that no newspaper last year came close to reporting.
The CDC’s statistics are impervious to independent verification because they remain, thus far, unpublished—despite the agency’s pledge on its website to base its public health pronouncements on high-quality data derived openly and objectively. Could the CDC’s disappointment with influenza vaccination coverage—which lags far behind the agency’s target of 80%—have anything to do with the opacity of the flu data being used to peddle the unpopular and ineffective vaccines?

**Fudging facts**

There are a variety of reasons to question the precision with which the CDC likes to imbue its flu statistics. First, although the CDC states that it conducts influenza mortality surveillance with its partner agencies, there is no actual requirement for U.S. states to report adult flu deaths to the CDC. (In public health parlance, adult influenza deaths are not “reportable” or “nationally notifiable.”) In fact, the only “flu-associated deaths” that the CDC requires states and other jurisdictions to report are deaths in children—180 last year.

...when actual death certificates are tallied, influenza deaths on average are little more than 1,000 yearly.

How did the CDC reach its as-yet-unpublished conclusion—widely shared with the media—that 79,820 American adults in addition to 180 children died from the flu in 2017-2018? The agency states that it relies on death certificate data. However, members of the Cochrane research community have observed that “when actual death certificates are tallied, influenza deaths on average are little more than 1,000 yearly.”

Other knowledgeable individuals have also noted that the death records system in the U.S. is subjective, incomplete and politicized, and have suggested that citizens should adopt a “healthy skepticism about even the most accepted, mainstream, nationally reported CDC or other ‘scientific’ statistics.” This skepticism may be especially warranted for the influenza stats, which are so inextricably intertwined with the CDC’s vaccination agenda that the statistical techniques and assumptions that the agency uses focus specifically on “project[ing] the burden of influenza that would have occurred in the absence of vaccination.”

skepticism may be especially warranted for the influenza stats, which are so inextricably intertwined with the CDC’s vaccination agenda

Notwithstanding its incessant use of influenza statistics to justify its flu vaccine policies, the CDC tries to have it both ways, cautioning that because “influenza activity reporting...is voluntary,” influenza surveillance in the U.S. “cannot be used to ascertain how many people have become ill with influenza during the influenza season.” A larger problem is that the vital statistics that form the basis of the CDC’s surveillance data conflate deaths from pneumonia and influenza (P&I). The CDC concedes that this conflation complicates the challenge of specifically estimating flu deaths:

The system “tracks the proportion of death certificates processed that list pneumonia or influenza as the underlying or contributing cause of death. This system...does not provide an exact number of how many people died from flu” [emphasis added].

Curiously, the CDC presented its cause-of-death data slightly differently prior to 2015. Through 2014, the agency’s annual National Vital Statistics Reports included tables showing influenza deaths and pneumonia deaths as separate line items. Those reports made it abundantly clear that pneumonia deaths (at least as transmitted by death certificates) consistently and dramatically outstripped influenza deaths. The table below illustrates this pattern for 2012-2014.
Starting in 2015, the annual vital statistics reports began displaying P&I together and eliminated the distinct line items. At present, only one tool remains to examine mortality associated with influenza as distinct from pneumonia—the CDC’s interactive FluView dashboard—which provides weekly national breakdowns. The dashboard shows the same general pattern as in the annual reports—that is, lower numbers of influenza deaths and much higher numbers of pneumonia deaths. Bearing in mind all the shortcomings and potential biases of death certificate data, dashboard reports for the first week of March (week 9) for the past three years show 257 influenza deaths versus 4,250 pneumonia deaths in 2016, and 534 and 736 flu deaths (versus over 4,000 annual pneumonia deaths) in 2017 and 2018, respectively.

**When clinicians in outpatient settings do order testing, relatively few of the “flu” specimens—sometimes as low as 1%—actually test positive for influenza.**

Semantic shenanigans

Semantics also play a key role in the CDC’s slippery communications about “flu.” For example, CDC’s outpatient surveillance focuses on the broad category of “influenza-like illness” (ILI)—an almost meaningless term describing general symptoms (fever, cough and/or sore throat) that any number of non-influenza viruses are equally capable of triggering. Cochrane lists several problems with the reliance on ILI to make inferences about influenza:

- There is “no reliable system to monitor and quantify the epidemiology and impact of ILI” and no way of knowing what proportion of ILI is caused by influenza.
- There are almost no reliable data on the number of ILI-related physician contacts or hospitalizations—and no one knows what proportion of ILI doctor visits and hospitalizations are due to influenza.

“Pneumonia,” too, is a catch-all diagnosis covering lung infections caused by a variety of different agents: viruses (non-influenza as well as influenza), bacteria, fungi, air pollutants and many others. Interestingly, hospitalization is a common route of exposure to pneumonia-causing pathogens, and mortality from hospital-acquired pneumonia exceeds 60%. In a plausible scenario, an adult hospitalized for suspected (but unconfirmed) “flu” could acquire a lethal pneumonia bug in the hospital, and their death might be chalked up to “flu” regardless of the actual facts, particularly because clinicians do not necessarily order influenza testing. When clinicians in outpatient settings do order testing, relatively few of the “flu” specimens—sometimes as low as 1%—actually test positive for influenza. Over the past couple of decades, the proportion of specimens testing positive has averaged around 15%—meaning that about 85% of suspected “flu” specimens are not, in fact, influenza.

**Roughly four-fifths of the vaccine injury and death cases settled through the National Vaccine Injury Compensation Program are flu-vaccine-related.**

Propaganda with a purpose

It takes little subtlety to recognize that the principal reason for flu hyperbole is to sell more vaccines. However, more and more people—even infectious disease specialists—are realizing that flu shots are fraught with problems. Roughly

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four-fifths of the vaccine injury and death cases settled through the National Vaccine Injury Compensation Program are flu-vaccine-related. A University of Toronto-based expert recently stated, “We have kind of hyped this vaccine so much for so long we are starting to believe our own hype.”

Pro-flu-vaccination studies—through their skillful placement in prestigious journals—tend to drown out other influenza studies that should be ringing warning bells. Published peer-reviewed studies show that:

- Previous influenza vaccination, particularly in those who get a flu shot every year, diminishes or “blunts” the already low effectiveness of flu shots.
- Getting vaccinated against influenza increases susceptibility to other severe respiratory viruses and also to other strains of influenza.
- Mothers who receive influenza vaccines during pregnancy face an increased risk of miscarriages and their offspring face elevated risks of birth defects and autism.

A systematic review of influenza vaccine trials by Cochrane in 2010 urges the utmost caution. Noting that “studies funded from public sources [have been] significantly less likely [than industry-funded studies] to report conclusions favorable to the vaccines,” and citing evidence of “widespread manipulation of conclusions,” the Cochrane reviewers’ bottom line is that “reliable evidence on influenza vaccines is thin.” We should all keep those words in mind the next time the CDC and the media try to mischaracterize flu facts and science.
Doctors Incentivized by CDC to Increase Vaccination Coverage

https://thevaccinereaction.org/2016/08/doctors-incentivized-by-cdc-to-increase-vaccination-coverage/

by Rishma Parpia

Published August 11, 2016

STORY HIGHLIGHTS

- The CDC administers a program known as AFIX to push health care providers to raise coverage rates among children and adults with all federally recommended vaccines.

- A centralized surveillance database known as Immunization Information Systems (IIS) is the cornerstone of this program.

- IIS encourages competition among staff by providing incentives and rewards for those who increase the vaccination rate the most.

Many people have encountered going to their physician’s office or their child’s pediatrician’s office and being coerced into “getting up-to-date with their shots.” This is not a rare or random occurrence. There is a method and approach that federal health officials expect health care providers to enforce in order to ensure that vaccination coverage goals are met at the local level.

CDC’s AFIX Approach to Increasing Vaccination Coverage

In 1993, the U.S. Centers for Disease Control and Prevention (CDC) began a program for health care providers known as Assessment, Feedback, Incentive and eXchange (AFIX).¹ The purpose of the program is to enlist health care providers to improve service delivery of federally recommended vaccines and increase vaccination coverage levels by identifying areas of low vaccine uptake and improving delivery practices.² The following is a brief description of the four components of the AFIX program:

Assessment
The assessment component is the first step to evaluating the health care provider’s immunization records for children up to the age of 18. The CDC executes the assessment phase.

The goal of this stage is to identify opportunities for improving vaccine coverage levels and reducing missed vaccination opportunities.² The CDC defines a “missed opportunity” as a “healthcare encounter in which a person is eligible to receive a federally recommended vaccine but does not receive the vaccine.”²
The CDC expects health care providers to enter all vaccine records into the Immunization Information Systems (IIS), which is the CDC’s main source of data for assessment of vaccine coverage levels in the U.S. IIS is a national electronic vaccine surveillance tool and its functionality continues to expand.

The CDC states:

Population-based IIS will be the cornerstone of the nation’s immunization system. Responsibility for IIS development rests with state and local communities, with assistance from federal and state agencies, and private partners. With the increased IIS functionality comes the ability to execute population-based Assessments, utilize a Geographic Information System (GIS), and provide real-time interface with other data systems. This functionality and interface can streamline the process for Assessment of immunization coverage.

In addition, the CDC website notes:

An IIS provides a single data source for all community immunization providers, enabling access to records of children receiving vaccinations at multiple providers. It provides a reliable immunization history for every enrolled child and can also produce accurate immunization records if needed for school or summer camp entry.

The CDC also utilizes computer software known as Comprehensive Clinic Assessment Software Application (CoCASA) that...

provides detailed reports on the specific diagnosis of the problem, for example, whether children start their series on time, whether and when patients drop out of the system, and whether vaccines are given simultaneously. CoCASA can also help to raise awareness on issues such as record keeping and documentation and the need for reminder and recall systems.

This indicates that a centralized national electronic medical/vaccine record keeping system is being operated by the CDC and that a patient’s medical records, including vaccination history, is now or will be readily available to all health care providers, hospitals, federal and state government agencies, schools, etc. This has serious implications for medical privacy, exercise of medical informed consent rights and the potential for abuse of personal information by social service and law enforcement agencies, as well as doctors discriminating against children and adults who have not received every federally recommended vaccine.

Feedback
After the assessment is completed, the feedback process begins. It involves informing vaccine providers and their staff, including frontline staff such as clerical staff and office managers, about observations and results from the assessment. The observations include quality improvement strategies, patient dropout rates, missed opportunities and what CDC officials consider to be the inappropriate use of contraindications.

Incentives
Once the feedback is provided to health care providers, the incentives component comes into play. It involves techniques and strategies aimed to encourage staff and clinics to improve their vaccine provider services with the ultimate purpose of increasing compliance with use of all federally recommended vaccines. The CDC states:

While most health care professionals are motivated by an intrinsic desire to improve health care, extrinsic rewards, or incentives, are often helpful. An incentive is something that incites or has a tendency to incite determination or action. Often times, incentive programs cannot only help providers move forward in achieving their immunization goals; they can also enhance performance over time.
The incentives are categorized into informal and formal. Informal incentives are less costly and include letters of recommendation, free vaccination information materials, etc.

Formal incentives are more lucrative, complex and costly. These include grants, scholarships and promotions of clinics as “Immunization Champions”, etc. The organizations that sponsor these incentives include coalitions promoting mandatory vaccination, medical trade associations, managed care/HMOs and vaccine manufacturers, many of whom have potential conflicts of interest.

**eXchange**

The last stage involves the exchange of information necessary to raise vaccine coverage levels. This stage goes hand in hand with other incentives. The CDC follows up with health care providers to share information on how their practice’s vaccine coverage status compares to state norms and other vaccine providers in their local area. Information is also exchanged on vaccine compliance strategies that have been successfully used by other providers.

**CDC’s Recommended Strategies for Reducing Missed Opportunities**

According to the CDC, several studies have shown that eliminating missed opportunities has the potential to increase vaccination rates by 20 percent. There are a number of strategies that CDC encourages vaccine providers to use to avoid “missed opportunities” for vaccination, which include:

- Reminder and recall messages to patients.
- Improving provider education on the principles of vaccination and vaccination scheduling.
- Abiding by standing orders. The CDC defines standing orders as “protocols whereby non-physician immunization personnel may vaccinate clients without direct physician involvement at the time of the immunization. Standing orders are implemented in settings such as clinics, hospitals, and nursing homes.”

It is important to understand the aggressive strategies that health care providers are being taught to use to increase use of all federally recommended vaccines. Regardless of what vaccination or other health care choices you make for yourself or your family, it is so important to take the time to become fully informed about all the risks involved and defend your right to make a voluntary decision. It is your basic human right.
How Much Money Do Pediatricians Really Make From Vaccines?

If you want to be sure your pediatrician has your child’s best interest, this is mandatory reading. Pediatricians around the country have begun refusing to accept families who opt out of some or all vaccines. Thanks to a tip sent to Wellness & Equality by a reader, now we know why.

When my friend’s child suffered a life-threatening reaction to a vaccine a week after her first birthday, my friend assumed her pediatrician would write her a medical exemption from future vaccines. Shortly after receiving a routine set of vaccines, the happy, vibrant one-year-old spiked a 106 degree fever, began having seizures, and was hospitalized. When the unexplained “illness” passed after a week in the hospital, the little girl had lost her ability to walk.

My friend describes how her daughter, who had learned to walk several months earlier at 9 months, suddenly “stumbled around like a drunk person” for weeks following the vaccines. My friend met with a team of pediatricians, neurologists, and naturopathic doctors, and they agreed:

Her daughter had suffered a brain injury caused by a reaction to one of the vaccines. Hoping the injury would be temporary and that she might recover and ease her brain inflammation if they could help her small body quickly eliminate the vaccine additives that caused the reaction, my friend’s daughter underwent an intensive detoxification program overseen by a nutritionist. Slowly, her daughter relearned to walk.

My friend is a practicing attorney who graduated from a Top 10 college. The evidence was overwhelming that her daughter’s reaction had been caused by vaccines, she told me. But a few months later, when she took her daughter back into the pediatrician for a visit, he wanted to vaccinate her daughter again. She was baffled. Why?

After a reader sent us a link to a PDF file of Blue Cross Blue Shield’s Physician Incentive Program available online, Wellness & Equality learned that insurance companies pay pediatricians massive bonuses based on the percentage of children who are fully vaccinated by age 2.
So how much money do doctors really make from vaccines? The average American pediatrician has 1546 patients, though some pediatricians see many more. The vast majority of those patients are very young, perhaps because children transition to a family physician or stop visiting the doctor at all as they grow up.

As they table above explains, Blue Cross Blue Shield pays pediatricians $400 per fully vaccinated child. If your pediatrician has just 100 fully-vaccinated patients turning 2 this year, that’s $40,000. Yes, Blue Cross Blue Shield pays your doctor a $40,000 bonus for fully vaccinating 100 patients under the age of 2. If your doctor manages to fully vaccinate 200 patients, that bonus jumps to $80,000.

But here’s the catch: Under Blue Cross Blue Shield’s rules, pediatricians lose the whole bonus unless at least 63% of patients are fully vaccinated, and that includes the flu vaccine. So it’s not just $400 on your child’s head—it could be the whole bonus. To your doctor, your decision to vaccinate your child might be worth $40,000, or much more, depending on the size of his or her practice.

If your pediatrician recommends that your child under the age of 2 receive the flu vaccine—even though the flu vaccine has never been studied in very young children and evidence suggests that the flu vaccine actually weakens a person’s immune system over the long term—ask yourself:

Is my doctor more concerned with selling me vaccines to keep my child healthy or to send his child to private school?

Sources:

The Physician Alliance Blue Cross Blue Shield Incentive Program

Update 4/30/2017: After Wellness & Equality published this article, Blue Cross Blue Shield locked online access to their incentive program and then removed the page altogether. Clearly this incentive program was never intended to be public knowledge and created a bit of PR issue for them. Fortunately, another website managed to save the entire BCBS incentive program booklet and has published it in entirety online… You can read it here: Blue Cross Blue Shield Physician Incentive Program – http://www.whale.to/c/2016-BCN-BCBSM-Incentive-Program-Booklet.pdf
Look WHO’s Talking! Vaccine Scientists Confirm Major Safety Problems

What Vaccine Scientists Say Behind Closed Doors . . .

By the Children’s Health Defense Team

Rarely does the general public get to hear what vaccine scientists and public health officials really think about vaccines. Instead, the simplistic (and propagandistic) mantra aired ad infinitum for public consumption is that vaccines are “safe and effective”—full stop. As the transcripts from the secret Simpsonwood meeting revealed two decades ago, however, when the experts are among themselves, they tell a different story—and, as a new behind-closed-doors video powerfully reveals, they are still far from convinced of their own safety message.

The bombshell video footage, published by Del Bigtree’s The Highwire, captures a series of statements—profoundly unsettling in their matter-of-factness—made by professionals who, in early December, attended the World Health Organization’s (WHO’s) two-day Global Vaccine Safety Summit. The summit’s aims were to “take stock of [the] accomplishments” of WHO’s Global Advisory Committee on Vaccine Safety (GACVS) and work toward finalizing the agency’s Global Vaccine Safety Blueprint 2.0 strategy 2021-2030. Attendees included GACVS members (past and present), vaccine program managers, regulatory authorities, drug safety staff, “and representatives of UN agencies, academic institutions, umbrella organizations of pharmaceutical companies, technical partners, industry representatives and funding agencies.”

What did this crème de la crème of the vaccine establishment say during their two-day powwow? Among other discussion points, attendees admitted that:

- Vaccines can be fatal.
- The design of safety studies makes it difficult to spot problems.
- Safety monitoring is inadequate.
- Vaccine adjuvants increase risk.

Every single one of these revelations—startling mostly because of who was caught on camera saying it—referred to problems that Children’s Health Defense and other vaccine-risk-aware organizations and individuals have been reporting on for years.

[W]e’re not able to give clear-cut answers when people ask questions about the deaths that have occurred due to a particular vaccine . . .
Fatal vaccines

Not quite a year ago, Indian pediatrician Dr. Soumya Swaminathan stepped into the newly created and prominent position of WHO Chief Scientist, moving up from a stint as WHO Deputy Director-General of Programs. At the December vaccine summit, she admitted:

[W]e’re not able to give clear-cut answers when people ask questions about the deaths that have occurred due to a particular vaccine, and this always gets blown up in the media.

Dr. Swaminathan acknowledged that the vaccine community ought to be prepared to provide “a very factual account of what exactly has happened and what the cause of the deaths are”; astoundingly, however, she conceded that “in most cases there is some obfuscation”—with the result that “there’s less and less trust . . . in the system.” Indian physicians have furnished examples of just such “obfuscation,” showing, for example, how a national committee attributed 96% of deaths in Indian infants who had just received pentavalent vaccines as either coincidental or unclassifiable.

What earned Dr. Swaminathan a place at the WHO vaccine table, when she is primarily known for her research and programmatic work on tuberculosis? It turns out that she has been an enthusiastic cheerleader for expanding human papillomavirus (HPV) vaccination in India. In early 2018, the Indian government decided against including the HPV vaccine in India’s Universal Immunization Program, swayed by feedback from India’s medical community (which is “split over the vaccine’s use”) and by the concerns of the influential Hindu organization RSS, which argued that adding the HPV vaccine would “divert scarce resources from more worthwhile health initiatives diverting it to this vaccine of doubtful utility and that its adverse effects will erode confidence in the national immunisation programme.” Ignoring these concerns as well as HPV vaccines’ disastrous global track record, Swaminathan—speaking on behalf of WHO—promptly urged India to reconsider. In late 2019, she joined other authors in a Lancet Oncology article that made light of “a few deaths” in HPV vaccine demonstration projects in two Indian states while praising the “successful introduction” and safety of HPV vaccination in two other states.

... agreed that vaccine pre-licensure clinical trials may not be powered enough (meaning they are too small to detect statistically significant effects) and that the generally inadequate follow-up of trial participants complicates safety evaluation.

Flawed safety studies

Several WHO summit speakers described the lack of “good science” and the inability of vaccine clinical trials to provide meaningful information about safety and risk. Describing the “tyranny of small numbers” and the “relatively small sample sizes” typical of vaccine clinical trials, for example, Dr. David Kaslow characterized these features as “a real conundrum” but offered no suggestions for solving it. This, despite being Director of the Center for Vaccine Innovation and Access at PATH (a Seattle-based global health organization), holding over a dozen vaccine-related patents and having a quarter-century of experience in vaccine research and development at PATH, the Bill & Melinda Gates Foundation, Merck and the National Institutes of Health.

Dr. Marion Gruber, Director of the U.S. Food and Drug Administration’s (FDA’s) Office of Vaccines Research and Review, with “over 20 years of experience in the regulatory review and approval of . . . vaccines and related biologics,” unblushingly agreed that vaccine pre-licensure clinical trials “may not be powered enough” (meaning they are too small to detect statistically significant effects) and that the generally inadequate follow-up of trial participants “complicates safety evaluation.” Presumably, Gruber could spearhead the design of more useful pre-licensure studies in her capacity as the senior official responsible for research pertaining to the development, manufacturing and testing of vaccines”—but, like Kaslow, she apparently had no solutions to propose. The FDA’s squalid history of approving vaccines tested without placebos and often with only a few days of follow-up—and its encouragement of off-license use of vaccines in pregnant women—cast doubts on Gruber’s sincerity in raising these issues.

Inadequate safety monitoring
Dr. Robert Chen is a 30-year veteran of the U.S. Centers for Disease Control and Prevention (CDC) and currently directs the Task Force for Global Health’s Brighton Collaboration. Chen’s webpage credits him with decades-long efforts to “create the vaccine safety infrastructure needed to meet the ‘post-modern’ challenges of mature immunization programs where adverse events are more prominent than the nearly eliminated” vaccine-preventable diseases—yet at the WHO summit, he declared that safety monitoring databases remain incapable of “teasing out” vital information such as details about manufacturers and lot numbers. Dr. Swaminathan chimed in that “we really don’t have very good safety monitoring systems in many countries.”

...the first lesson is, while you’re making your vaccine, if you can avoid using an adjuvant, please do so.

Risky adjuvants

WHO summit attendees had numerous comments about vaccine adjuvants—none of them reassuring. For example, the Coordinator of the WHO’s Initiative for Vaccine Research (Dr. Martin Howell Friede) remarked, “We do not add adjuvants to vaccines because we want to do so” but because vaccines will not “work” without them. Friede, who held “several senior management positions in the vaccine industry” prior to moving to WHO, added:

I give courses every year on “How do you develop vaccines?” “How do you make vaccines?” And the first lesson is, while you’re making your vaccine, if you can avoid using an adjuvant, please do so. Lesson two is, if you’re going to use an adjuvant, use one that has a history of safety. And lesson three is, if you’re not going to do that, think very carefully.

Friede also noted that the “primary concern” with vaccine adjuvants is systemic adverse events: “The major health concern which we are seeing are accusations of long term . . . effects.” Friede then passed the baton back to regulators such as the FDA’s Gruber, who characterized “safety and effectiveness evaluation of adjuvants combined with vaccine antigens” as “complicated.”

Nor have the domestic or international vaccine communities ever been forthright about the lack of research on key elements of the entire [childhood vaccine] schedule—the number, frequency, timing, order, and age at administration of vaccines.

Vote of no confidence—for good reason

One of the few attendees to articulate vaccine safety issues from the child’s standpoint was Dr. Bassey Okposen, a Program Manager for Nigeria’s vaccine program. Okposen had celebrated Nigeria’s “high immunisation coverage” in 2018, but at the 2019 WHO meeting, he ventured to ask whether vaccines containing “different antigens from different companies” and “different adjuvants and different preservatives and so on” could be “cross-reacting amongst themselves”—wondering aloud whether “the possibility of cross-reactions” had ever been studied. In fact, toxicologists are keenly aware that individual toxins have synergistic effects when combined, but vaccine researchers seem uninterested. Nor have the domestic or international vaccine communities ever been forthright about the lack of research on key elements of the entire [childhood vaccine] schedule—the number, frequency, timing, order, and age at administration of vaccines.

The WHO may wish to draw attention to and scapegoat those who exhibit “vaccine hesitancy,” but the global cadre of vaccine experts has only itself to blame. As Professor Heidi Larson stated to her peers at the WHO summit, the crisis of confidence is now extending to “a very wobbly health professional front line that is [also] starting to question vaccines and the safety of vaccines.” Larson directs a slick program designed to restore vaccine confidence, but she was the first to acknowledge that “You can’t repurpose the same old science to make it sound better if you don’t have the science that’s relevant to the new problem.” We might add that the “same old science” never was terribly good to begin with.
The Anatomy of a False Flag Disease – Ebola, Swine Flu, Zika, SARS...

By Paul A. Philips, Wake Up World

There’s no better example of the deceptive world we live in than the manufacture of a disease. Epidemic or pandemic, whether it’s the zika virus or others such as ebola, swine flu, bird flu, SARS... all these diseases share a number of common repetitive patterns throughout their deceptive histories.

So, here are 10 common repetitive patterns making up the anatomy of a manufactured, ‘false flag’ disease.

1. A disease outbreak suddenly finds its way into the spotlight of mass media attention. Through unquestioning blind acceptance, going into agreement with the general consensus through mass media spin the sheep-like public immediately assume that the official authoritative view regarding the disease outbreak is correct...

2. Questioning at the early stages reveals suspicious circumstances. Those not readily accepting the official view, able to think for themselves, through questioning suspect that a deception may be at work: For starters, something to immediately arouse suspicion at least at the early stages of the scare is the fact that these diseases have existed before and had only produced temporary mild feverish, flu-like symptoms. So why the sudden epidemic outbreak of a so-called deadly virus?

3. Unfounded assertions, errors and contradictions. As with other false flag diseases, the Zika deadly virus claim was found by independent investigative journalists such as Jon Rappoport to have a number of unfounded assertions, irreconcilable errors and contradictions: The first stage when proving that a particular virus is responsible for an epidemic is to show its presence in every case or prove overwhelmingly by percentage. But in the realm of a false flag disease this doesn’t happen.

4. Either the disease doesn’t exist or its affect on the population is grossly exaggerated. Furthering with the above, listed symptoms used to diagnose the disease have been known to be very broad, as for example, in the case of SARS. A person may be diagnosed with SARS but because the lists of symptoms to confirm the disease are so broad then they could have other unrelated illnesses such as a heavy cold. The same situation has occurred with the Swine flu and other so-called deadly outbreaks...

5. The ‘one condition = one causation’ scam. Unfounded assertions, irreconcilable errors and contradictions continue to exist in the form of the official claim that the false flag disease has only one condition and is linked to only one cause, in spite of evidence to the contrary.

For example, the one condition, AIDS, has been linked (and indeed still is) to the one cause HIV virus. How can this be the case when:

- A) Any virus, such as the common cold, would affect 50% males and 50% females, as with AIDS in Africa. So how can the one cause HIV virus be used to explain AIDS when the affected ratio in the USA is 85% males and 15% females??
• B) Taking the case of Africa. The umbrella term AIDS includes many illnesses. However, instead of taking into account that these illnesses are largely the result of poverty (poor sanitation, unclean water, malnutrition, dysentery, parasitic infection... etc), people have been programmed to accept that AIDS in Africa is simply all down to one virus, HIV.

Notably, the USA’s 85% males and 15% females AIDS ratio is the same gender ratio for drug addiction. In other words, whether it’s in the USA or Africa, through a number of different circumstances AIDS is the result of a failed immune system, but these multiple causative factors are ignored. (Notably, scientific developments in the treatment of AIDS [1] [2] are also ignored by the medical establishment, while pharmaceutical giant Merck’s HIV vaccine was shown to increase the risk of infection [3]. ~ Editor)

6. The mass media fanfare, hyping and fear-mongering continues.

It continues on a lack of evidence or false scientific data, assumption and guesswork. People challenging the official view could be met with invalidation or even ridicule from those ignorant of the truth. The faked deadly disease is one of a number of false ‘Bogeymen’, like fake terrorism, designed by the powers-that-be to keep us in a constant state of fear. Then, to add to the theatre of illusion something common in false flags, there are crisis actors as in the case of Ebola.

7. WHO (World Health Organization) declares a global health emergency. Once again, false justification and ignorance continues. Anyone from the outside looking in would write this off as complete madness had they not worked out the ulterior motive behind the false flag disease which is:

8. A small number of individuals in high places greatly profit. Yes, those hoary old chestnuts power, profit and political gains reveal the truth behind the reason for a false flag disease. It’s the classic problem, reaction, solution scenario.

   • Problem: The powers that be secretly manufacture and orchestrate a fake disease.
   • Reaction: Predictably, believing the official line that a disease is at work, people affected demand help and want treatment.
   • Solution: The authorities, health authorities such as the WHO, corporations like Big Pharma with approval from corrupt politicians and the mainstream media see that those affected are given questionable help. Questionable medicines such as vaccinations (which in some cases had just happened to be in the development stages just before the outbreak!) and expensive invasive drugs that make huge profits from sales while a ton of revenue money goes to Big Government...

With a solution like this it doesn’t take a genius to see why the powers that be had secretly created the problem to begin with. Further, the fake disease helps advance hidden agendas such as a population reduction using a ‘deadly virus’ cover as an excuse to implement birth control... Why is the Ebola virus patented?

9. Cover up. The fake disease scenario has been used as a convenient cover up for hiding a number of inconvenient truths, as in the case of the zika virus:

   • The Mayo Clinic has stated that a number of genetic and environmental factors could cause microcephaly. Instead of looking at the high numbers of poisonous vaccines, pesticides like glyphosate, metolachlor and atrazine deliberately sprayed in Brazil which can cause microcephaly, where there’s a lack of sanitation, mal-nutrition, the authorities have blamed it on the zika virus (remember, one condition = one cause).

Conveniently, this ignores the evil biotech and agricultural corporations with their poisons and allows them to continue to profiteer and exploit those suffering in misery and distress, as for instance in the case of receiving ongoing funding for the development of GM mosquitoes to deal with the problem. It’s quite simple, if you poison the populace with the above, as in the case of pregnant mothers, then terrible things can happen: Neurotoxins from the poisons can get into the mother and affect the developing foetal brain and cause microcephaly.

10. The disease soon becomes forgotten. In spite of all the claims, how the Bogeyman disease is going to take countless lives by the hour, sweeping epidemically across the globe, nothing ever comes of it. The mass media cover soon stops without a whisper, and then people quickly forget about the disease.

Finally...The same old movie script will keep repeating itself over and over until people finally wake up, deconstruct these false flags by recognising their repetitive deceptions, then, through public outrage, demand that certain actions be taken and certain changes be made to get justice.

Faked diseases or other false flags, will their constant repetitiveness be the perpetrators’ downfall? Will the perpetrators’ false flags finally get worked out, having served as catalysts for a massive public wake up call?
Aluminum and Alzheimer's disease: after a century of controversy, is there a plausible link? (summary)

The brain is a highly compartmentalized organ exceptionally susceptible to accumulation of metabolic errors. Alzheimer's disease (AD) is the most prevalent neurodegenerative disease of the elderly and is characterized by regional specificity of neural aberrations associated with higher cognitive functions.

Aluminum (Al) is the most abundant neurotoxic metal on earth, widely bioavailable to humans and repeatedly shown to accumulate in AD-susceptible neuronal foci.

In spite of this, the role of Al in AD has been heavily disputed based on the following claims: 1) bioavailable Al cannot enter the brain in sufficient amounts to cause damage, 2) excess Al is efficiently excreted from the body, and 3) Al accumulation in neurons is a consequence rather than a cause of neuronal loss.

Research, however, reveals that:

1) very small amounts of Al are needed to produce neurotoxicity and this criterion is satisfied through dietary Al intake,

2) Al sequesters different transport mechanisms to actively traverse brain barriers,

3) incremental acquisition of small amounts of Al over a lifetime favors its selective accumulation in brain tissues, and

4) since 1911, experimental evidence has repeatedly demonstrated that chronic Al intoxication reproduces neuropathological hallmarks of AD.

Misconceptions about Al bioavailability may have misled scientists regarding the significance of Al in the pathogenesis of AD. The hypothesis that Al significantly contributes to AD is built upon very solid experimental evidence and should not be dismissed. Immediate steps should be taken to lessen human exposure to Al, which may be the single most aggravating and avoidable factor related to AD.
Blue Cross Plans Say Alzheimer’s Has Tripled Among Adults Ages 30 To 64


Early-onset dementia and Alzheimer’s disease jumped 200% among commercially insured Americans between the ages of 30 and 64 over a recent five-year period, a new analysis of Blue Cross and Blue Shield health insurer claims shows.

The report, the latest from the Blue Cross Blue Shield Association, shows 131,000 people between the ages of “30 and 64 were diagnosed with either form of dementia” in 2017. The average age of someone “with either condition is 49 and women are disproportionately impacted than men,” the report, which is the latest in the trade group’s “The Health of America” series, shows.

In 2017, there were 12.6 diagnoses per 10,000 adults of either early-onset dementia and Alzheimer’s disease for commercially insured adults aged 30 to 64, the report said. That compares to 4.2 diagnoses per 10,000 adults of early-onset dementia and Alzheimer’s disease combined for the same 30 to 64 age group in 2013.

“The increase in early-onset dementia and Alzheimer’s diagnoses among a generation who typically wouldn’t expect to encounter these conditions for several decades is concerning, especially since there is no cure for Alzheimer’s disease,” said Dr. Vincent Nelson, vice president of medical affairs for the Blue Cross Blue Shield Association, which gathered data for the report from a database of medical claims of more than 48 million commercially insured Blue Cross customers.

The Blue Cross Blue Shield Association is a large health insurance industry trade group and lobby and its members include: Anthem, which operates Blue Cross and Blue Shield plans in 14 states; Health Care Service Corp. which operates Blues plans in five states; and Florida Blue.

The report calls attention to data that shows where healthcare providers, insurers and others need to focus to improve quality and reduce costs. The cost of providing care for Americans with Alzheimer’s disease has eclipsed a quarter trillion dollars, according to the Alzheimer’s Association, as baby boomers age and the U.S. healthcare system struggles to find people to care for this fast-growing population.

“Further education and research is needed to learn more about early-onset dementia and Alzheimer’s, how to treat these conditions and what can be done to better prevent diagnoses,” Nelson said.

Here are some other highlights from the Blue Cross Blue Shield Association report:

· “Diagnosis rates of early-onset dementia and Alzheimer’s disease are higher in the East, the South and parts of the Midwest, while western states show lower rates of diagnosis.”
· “86% of people with early-onset Alzheimer’s disease received brain imaging in the year prior to diagnosis.”
· “57% of people with early-onset Alzheimer’s disease filled an antidepressant medication in the year prior to diagnosis.”
· More than 37,000 “commercially insured Americans between the ages of 30 and 64 were diagnosed with early-onset Alzheimer’s disease in 2017.”
Brain Tissue Of Autistic People Saturated With Aluminum

"... it's estimated that children who receive the recommended vaccine schedule in the United States receive close to 5,000 mcg within the first couple years of life. This is almost 500 times the safe level of aluminum for an infant."


Aluminum in vaccines has long been suspected as one of the probable causes of autism. Now new research out of Keele University and Kings College Hospital in the UK is substantiating this suspicion. The researchers found significant amounts of aluminum in the brains of deceased persons who had been diagnosed with autism during their lifetime.

Autism spectrum disorder refers to neurodevelopmental conditions that can range from mild to severe. Keep in mind, a staggering 1 in 68 children are diagnosed with autism – according to the U.S. Centers for Disease Control and Prevention (CDC) – an agency known to be covering up the greatest medical scandal of our time.

The records show that boys are 4.5 times more likely to have autism than girls.

The evidence is clear: Autistic individuals have high levels of aluminum in their brain

In past studies of the link between autism and the aluminum in vaccines, the researchers mainly tested hair, urine and blood samples for aluminum levels. For the current study, the researchers sought to test the brain tissue of deceased persons who had been diagnosed within the autism spectrum.

For this study, the brain tissue of 5 persons ranging in age from 15 to 50 was tested. The amounts of aluminum were found to be extraordinarily high as compared with people not diagnosed with autism. Abnormal amounts of aluminum were found in the cells of the vasculature, meninges and white and gray matter of all subjects tested. And, this research was published in the Journal of Trace Elements in Medicine and Biology.

Babies injected with up to 500 times the amount of aluminum considered “safe” by the CDC

Health professionals and parents alike have railed against the addition of aluminum as an adjuvant (delivery mechanism) in vaccines for many years. The so-called “safe amount” of aluminum exposure for adult humans is 25 mcg, and just 10 mcg for infants.

Yet, it's estimated that children who receive the recommended vaccine schedule in the United States receive close to 5,000 mcg within the first couple years of life. This is almost 500 times the safe level of
aluminum for an infant. No doubt, toxic substances are being injected into the youngest among us and it’s all ‘legal.’ (and, wrong!)

In 2013, University of British Columbia researchers published findings that showed a direct correlation between autism and pediatric vaccines that contained an aluminum adjuvant. The toxicity of these vaccines causes severe autoimmune and inflammatory reactions in many who receive them.

It’s wake up time: We must demand the removal of aluminum in vaccines

The hepatitis vaccine alone, administered on the first day of life, exposes infants to around 250 mcg of aluminum. And that’s just the beginning of a seemingly endless schedule of vaccines that children are expected to receive in the first few years of life.

The CDC knows full well that aluminum is toxic to the human system, and yet it is used in an array of vaccines for babies, children and adults. It’s time to recognize the most obvious of facts: this practice is brutal and inhumane and the medical/scientific community should work together to find a safer solution.

Sources for this article include:

ScienceDirect.com
CDC.gov
HippocraticPost.com
US CDC: Autism Rate At Least 1 in 29 (DSM-5), 1 in 59 (DSM-IV)

CDC’s latest report of the rate of ASD diagnosis is stunning: 1 in 59 kids by age 8, four years ago, had a diagnosis of ASD. In boys, the rate was 1 in 34. News outlets report that ASD rates are still increasing, and no one knows why. But a close read of the report reveals that actual rates could be much higher:

(1) They used DSM-IV criteria for prevalence data. DSM-5 was published May, 2013 – so the prevalence data using DSM-5 only should have been applied. Their use of DSM-IV criteria results in a lower rate. Using DSM-5 criteria, the rate is 1 in 29.

(2) They had a committee of experts review the cases of people at the 11 monitoring sites – any ONE of the members of the committee could rule OUT a case of ASD if they thought the DSM-IV criteria did not apply, or if other diagnoses better explained the child’s condition. I review the importance of understanding the difference between co-occurrence and co-morbidity in “The Environmental and Genetic Causes of Autism”. A child with Down’s syndrome, for example, could also have an autism diagnosis. ASD can occur to any human brain with other recognizable conditions. In some cases, where biological pathways overlap (e.g., seizures), the co-occurrence is true co-morbidity, but seizure disorder would not replace a diagnosis of ASD. They did not review all non-ASD diagnoses to allow anyone ONE member of the committee to RULE IN non-ASD diagnoses and false negative diagnoses of ASD.

So the rates to report for 2014 prevalence (reported in 2018) are “at least” 1 in 59 (DSM-IV), and “at least” 1 in 29 (DSM-5). I have adjusted SafeMind’s plot to reflect the binary nature of CDC’s report. They are a fantastic organization who should have your support. They have not been consulted on this adjustment, and the views expressed in this analysis are my own. Source: https://jameslyonsweiler.com/2018/04/27/us-cdc-autism-rate-at-least-1-in-29-dsm-v-1-in-59-dsm-iv/
Next Decade Will Add More Trillions to Looming Public Financial Burden

The lifetime cost of autism for U.S. cases identified in the 30 years between 1990 and 2019 is estimated to be $7 trillion. If costs for the next decade 2020-2029 are included, the lifetime cost will reach up to $15 trillion. The findings were reported in a new study in the journal Research in Autism Spectrum Disorders. In “The Lifetime Social Cost of Autism: 1990–2029”, authors Janet Cakir, Richard Frye, and Stephen Walker compiled findings from peer-reviewed published studies on the number of cases of autism for the decades 1990-2019 and the lifetime cost of autism per person in the U.S.

For prevalence, they used the two best known Federal monitoring systems: the CDC’s Autism and Developmental Disabilities Monitoring Network (ADDM) and the National Health Interview Survey (NHIS) by the National Center for Health Statistics. They estimated that 2 million new cases of autism were identified between 1990 and 2019. They factored in the severity of autism, specifically the comorbidity of intellectual disability which increases lifetime costs, and the estimated number of years living with autism. The number of years with autism is determined by the age of diagnosis and the person’s lifespan, which for those on the spectrum is shortened relative to the typically developing population.

For costs, they included the “social costs” across the lifespan. The costs are those incurred beyond what typically developing people would incur. They consist of medical and healthcare-related spending, therapies, special education services, lost wages for the person with ASD as well as parents/caregivers, accommodations, and respite care. The costs only reflect what society pays, not the expenses families incur out of their own pockets. Nor do the calculations reflect what the actual needs are of the person with autism, which are often greater than the resources available.

The average lifetime cost of autism per person was calculated to be $3.6 million. Projecting this amount to the autism prevalence data, they estimated the national social costs for all cases identified 1990-2019 to be $7 trillion. The greatest cost over the lifespan is from lost employment, followed by adult care. Medical care and education expenses were the lowest components.

Future costs for the 10 year period 2020-2029 were also estimated. During this period, if the autism rate is assumed to plateau at the prevalence of the most recent decade (2010-2019), the number of new cases will be 1 million and the lifetime cost for these 1 million will be over $4 trillion, bringing the 40 year total to $11 trillion. If prevalence continues to rise at the same rate as the past 30 years (1990-2019), over 2 million new cases will be identified and the cost will be another $7 1/2 trillion, for a total of almost $15 trillion.

The study reported costs by each of the 50 states as well as the national total. States with more generous social benefits and higher populations have seen and will see the highest economic burdens.

The authors characterize the financial burden of autism as significant. They suggest investing in screening to lower the age of diagnosis and increasing access to early intensive behavior intervention to help reduce disability, resulting in lower costs as the person ages. Another way to reduce financial burden, they conclude, is to identify the modifiable risk factors for autism to find ways to lower prevalence.

The Health Resources & Services Administration just released new dollar figures reflecting payouts from the National Vaccine Injury Compensation Program. The payouts for vaccine injuries just went past the whopping $4 billion mark. Using the government’s own conclusion that only 1% of all vaccine injuries are reported, the $4 billion is just the tip of the iceberg. Despite assurances from CDC and our Federal agencies that all vaccines are safe, the payouts say otherwise. Vaccine injuries can and do happen—to previously healthy children and adults. Consumers deserve to know the facts about the full range of vaccine risks.

By the Children’s Health Defense Team

In most public health communications about vaccination, officials gloss over vaccine risks, dismissing any possible “side effects” as mild. However, vaccination programs have always resulted in more serious vaccine injuries for some. In the 1970s and early 1980s, for example, the diphtheria-pertussis-tetanus (DPT) vaccine and its whole-cell pertussis component had chalked up so much vaccine damage that a television documentary likened receiving a DPT shot to playing “vaccine roulette.”

After the DPT debacle began attracting widespread attention, vaccine manufacturers started pressuring Congress for protection from vaccine injury lawsuits. Congress obliged. In 1986, President Reagan signed into existence a radical piece of legislation—the National Childhood Vaccine Injury Act (NCVIA)—which launched what the Act described as an “alternative remedy to judicial action for specified vaccine-related injuries.” A key component of the legislation involved creating the National Vaccine Injury Compensation Program (NVICP), which was given responsibility for deciding (through the workings of a special “vaccine court”) whether specific injuries and individuals would be eligible for financial compensation.

While government-funded Department of Justice (DOJ) lawyers vigorously represent and defend the interests of HHS and vaccine manufacturers, the consumer-unfriendly system forces the vaccine-injured to meet an exceptionally high burden of proof.

Over the vaccine court’s 30-year history, individuals and families have filed over 20,000 petitions for vaccine injury compensation. This month, even as 12% of filed petitions remained unadjudicated, the payouts crossed over the $4 billion threshold. This amount was awarded in response to barely a third (31% or 6,276) of the filed petitions. There is no telling how much more money the taxpayer-funded program might have shelled out if the court had not chosen to dismiss the remaining petitions (56%)—possibly doing so fraudulently in at least some cases.

Running the Gauntlet

Over the three decades, despite the stated intent to furnish an “accessible and efficient forum for individuals found to be injured by certain vaccines,” the NVICP has devolved into a protracted and litigious David-versus-Goliath battleground. The vaccine court, in actuality, is “not a court at all but...a consumer-funded government claims program that uses...employees of Health and Human Services (HHS), rather than judges to make decisions on compensation.” While government-funded
Department of Justice (DOJ) lawyers vigorously represent and defend the interests of HHS and vaccine manufacturers, the consumer-unfriendly system forces the vaccine-injured to meet an exceptionally high burden of proof. For dismissed claims, there is no assurance that the program will even cover attorneys’ fees and costs.

Children’s Health Defense recently called attention to a glaring example of the NVICP’s pro-industry and anti-vaccine-injured bias. In 2007 and 2008, DOJ attorneys exhibited “highly unethical and appallingly consequential official misconduct” during an Omnibus Autism Proceeding (OAP) orchestrated to determine the fate of 5,400 families who had filed claims for vaccine-induced autism. The potential value of the claims exceeded $100 billion—an amount that “would have bankrupted the [compensation] program many times over.” HHS’s Department of Justice lawyers, “under pressure” to deprive petitioners of their rightful relief, successfully achieved that aim through allegedly fraudulent means. In September 2018, Children’s Health Defense Chairman Robert F. Kennedy, Jr. and Rolf Hazlehurst (parent of one of the vaccine-injured children involved in the OAP) requested that the DOJ Inspector General and Congress investigate this fraud and obstruction of justice by HHS and DOJ officials.

Individuals who file claims with VICP must meet specific “medical criteria” and are out of luck unless their illness, disability, injury or condition is covered in the NVICP’s Vaccine Injury Table and manifests within a specified time frame. As an illustration of the difficulties that NVICP petitioners may encounter, consider someone who experiences myocarditis (heart inflammation) following vaccination. A 2018 article in BMJ Case Reports recently observed that myocarditis is one of “the more serious vaccine-related sequela” and “has been reported following many different vaccines.”

Another recent article in a European medical journal describes post-vaccination reports of myopericarditis (inflammation of both the pericardium and the heart muscle) and other autoimmune disorders and offers two extremely plausible mechanisms “by which vaccines can cause autoimmune reactions.” In the Vaccine Injury Table, however, the only place where cardiac symptoms are mentioned is in connection with anaphylaxis—with the table’s notes indicating that “there are no specific pathological findings to confirm a diagnosis of anaphylaxis”—and most autoimmune illnesses are also conspicuously absent.

**Tip of the Iceberg**

By anyone’s accounting, the $4 billion paid out to date by the NVICP is an attention-getting amount of money. However, that amount pales in comparison to the billions of dollars’ worth of autism claims that the vaccine court unfairly dismissed. According to HHS, moreover, “fewer than 1% of vaccine adverse events are reported,” and studies confirm that many health providers are unfamiliar with the system for reporting vaccine injuries. The shocking underreporting of vaccine injuries also fails to account for the fact that one in six individuals who experience an “adverse event following immunization” (AEFI) have a recurrence with subsequent vaccination, often rated as “more severe than the initial AEFI.” If even a small percentage of these unreported and recurrent vaccine injuries were brought forward for compensation, the entire NVICP house of cards—and the CDC’s deceptive claims of unassailable vaccine safety—would crumble.

**A Gold Rush: Liability Protection Encourages More Vaccines**

Instead, whether intended or not, the end result of the 1986 Act and the NVICP has been to create a “gold rush” environment that encourages manufacturers to develop even more vaccines, while conveniently exempting them from liability for the injuries and deaths that result from their powerful immune-system-altering products. With no incentive to make vaccines safe and a large and lucrative market guaranteed by the Centers for Disease Control and Prevention’s childhood vaccine schedule—as well as a growing effort to foist unnecessary and dangerous vaccines on adults—vaccine manufacturers appear to have it made. The public and vaccine safety advocates must continue to remind the government that the approximately 6,300 claims that have been compensated over the NVICP’s 30-year history represent the very tip of the iceberg.
Relevance of Neuroinflammation and Encephalitis in Autism (ASD)

Janet K. Kern,1,* David A. Geier,1 Lisa K. Sykes,2 and Mark R. Geier1

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Discussion

The dramatic rise in ASD began in the 1990s, and in the past two decades, the rates of ASD have increased by 289% (Boyle et al., 2011). The sudden and dramatic rise in ASD prevalence has, in some ways, caught the medical community “off guard.” In the midst of the meteoric rise in rates of autism and ASD, significant new research into the physical symptoms has been done. The challenge now is to incorporate this new research about the physical symptoms of autism into the practice of medicine that historically has stereotyped autism as a purely psychiatric disorder. For the benefit of patients, the physical symptoms of autism must be recognized and treated. For children with ASD, particularly those who have begun to regress into ASD and show other signs of neurological regression, testing for encephalitis may be warranted. Particularly, given the documented cases of children with regressive ASD and NMDA Encephalitis who tested positive for anti-NMDA receptor antibodies, routine testing for anti-NMDA receptor antibodies in ASD should be seriously considered. The study by Scott et al. (2014), mentioned earlier, of the child who regressed into autism and recovered from treatment for NMDA, indicates that there is benefit to recognizing the possibility of encephalitis in children with ASD. The delay in incorporating new research findings into medical practice standards is unfortunate because if a diagnosis of autism or ASD were recognized in the medical community as having a possible component of encephalitis that could be tested and treated appropriately, such treatment for encephalitis would likely reduce, and possibly eliminate, ASD symptoms in some children. Future studies should include treatments for neuroinflammation in ASD.

Abstract

Go to:

Introduction

Autism or autism spectrum disorder (ASD) is a childhood neurodevelopmental disorder that is behaviorally defined and psychiatrically diagnosed based on a spectrum of qualitative impairments in social interaction and communication, and in restricted and stereotyped patterns of behavior, interests, and activities (American Psychiatric Association, 2013). In addition, children diagnosed with an ASD diagnosis have a high prevalence of various co-morbid medical conditions (Banaschewski et al., 2011; Geier et al., 2012; Ozsvadjian et al., 2014). Despite this fact, an ASD diagnosis still remains under the diagnostic criteria of a purely psychiatric disorder.

In recent years, many studies indicate that children with an ASD diagnosis have brain pathology suggestive of ongoing neuroinflammation or encephalitis (encephalitis is defined as brain inflammation) in different regions of the brain (Enstrom et al., 2005; Pardo et al., 2005; Vargas et al., 2005; Zimmerman et al., 2005; Chez et al., 2007; Morgan et al., 2010, 2012; Tetreault et al., 2012). Encephalitis is medical diagnosis code G04.90 in the International Classification of Disease, 10th revision, clinical modification (ICD-10-CM). However, even though the research indicates that the brain inflammation is relatively common in these children, children with an ASD diagnosis are not generally given the medical diagnosis of encephalitis. Instead, they continue to be diagnosed using purely psychiatric diagnostic codes. This may be due, in part, to original misconceptions about the disorder when it was first identified in 1943 by Leo Kanner, who
attributed it to the emotional unavailability of the affected child’s mother. While erroneous, this misconception
originally and lastingly branded autism as a psychiatric disorder. Now, despite decades of published scientific and
medical literature documenting its physical symptoms, autism is most often still treated as a psychiatric condition with
psychiatric medications.

As a result, critical new research into the physical symptoms of autism is often neglected. Additionally, the time lag
between new research findings being published and their being incorporated into medical practice standards further
contributes to a delay in the recognition and treatment of the physical symptoms of autism or ASD. It is crucial that new
landmark findings from neuroscience, about the brain pathology found in ASD, be translated into the practice of
medicine because this will drive new medically directed and targeted treatments, which may be more effective and safer
than previous interventions guided by psychiatric labels. The current use and safety of psychiatric medications in autism
and ASD will be discussed later in this paper.

The purpose of this review of the literature, is to examine the evidence of neuroinflammation/encephalitis in those with
an ASD diagnosis and to address how a medical diagnosis of encephalitis could benefit these children by driving more
immediate and targeted treatments. The review begins with evidence of neuroinflammation in ASD. Although there are
numerous studies that show markers of systemic inflammation in ASD (Rossignol and Frye, 2014), this review focuses on
the brain and cerebral spinal fluid (CSF).

Go to:

Autism, Neuroinflammation, and Encephalitis

As mentioned previously, there are many studies showing children with an ASD diagnosis have ongoing
neuroinflammation/encephalitis in different regions of the brain (see Table 1; Enstrom et al., 2005; Pardo et al.,
2005; Vargas et al., 2005; Zimmerman et al., 2005; Chez et al., 2007; Morgan et al., 2010, 2012). Active
neuroinflammatory processes are found throughout the brain in both the cerebral cortex and in the cerebellum of
patients with autism (Vargas et al., 2005). Of critical importance to this issue is that post-mortem brain tissue studies
examining the brains of children with an ASD diagnosis reveal significant evidence of neuroinflammation/encephalitis
regardless of the child’s age, indicating that they were suffering from sustained neuroinflammation/encephalitis
processes. As Herbert (2005) described, brain abnormalities in those diagnosed with an ASD reveal significant ongoing
neuroinflammation to be a central element of the observed brain pathology.

Table 1

Evidence of neuroinflammation/encephalitis in the brains and cerebral spinal fluid (CSF) of subjects with autism
spectrum disorder (ASD).

<table>
<thead>
<tr>
<th>Studies</th>
<th>N</th>
<th>Findings</th>
<th>Researchers’ Conclusion</th>
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</thead>
<tbody>
<tr>
<td>Vargas et al.,</td>
<td>15</td>
<td>(1) Marked activation of microglia and astroglia, and cytokine profiling indicated that macrophage chemoattractant protein (MCP)-1 and tumor growth factor-beta1, derived from neuroglia, were the most prevalent cytokines in brain tissues</td>
<td>Active neuroinflammatory process in those with an ASD diagnosis</td>
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<td>2005</td>
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<td></td>
<td>6</td>
<td>(2) CSF showed a unique proinflammatory profile of cytokines, including a marked increase in MCP-1</td>
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<td>Li et al.,</td>
<td>8</td>
<td>Proinflammatory cytokines (TNF-alpha, IL-6, and GM-CSF), Th1 cytokine (IFN-gamma) and chemokine (IL-8) were significantly increased in the brains of ASD patients compared</td>
<td>Brain inflammation in those with an ASD diagnosis and</td>
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<td>2009</td>
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<td>Studies</td>
<td>N</td>
<td>Case/Control</td>
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<td><strong>Young et al., 2011</strong></td>
<td>9/9</td>
<td></td>
<td>Neurons, astrocytes, and microglia all demonstrated increased extranuclear and nuclear translocated NF-κB p65 expression in brain tissue from ASD donors relative to samples from matched controls</td>
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<td><strong>Morgan et al., 2010</strong></td>
<td>13/9</td>
<td></td>
<td>Microglial activation and increased microglial density in the dorsolateral prefrontal cortex in those with autism</td>
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<td><strong>Morgan et al., 2012</strong></td>
<td>13/9</td>
<td></td>
<td>Microglia are more frequently present near neurons in the autism cases at a distance interval of 25 μm, as well as 75 and 100 μm</td>
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<tr>
<td><strong>Wei et al., 2011</strong></td>
<td>6/6</td>
<td></td>
<td>Interleukin (IL)-6 increased in the cerebellum of autistic subjects</td>
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<tr>
<td><strong>Tetreault et al., 2012</strong></td>
<td>11/12</td>
<td></td>
<td>Individuals with autism had significantly more microglia compared to controls in the fronto-insular and visual cortex</td>
</tr>
<tr>
<td><strong>Suzuki et al., 2013</strong></td>
<td>20/20</td>
<td></td>
<td>Excessive microglial activation in multiple brain regions in young adult subjects with an ASD diagnosis was found using regional brain [11C][R]-PK11195 binding potential as a representative measure of microglial activation</td>
</tr>
<tr>
<td><strong>Fatemi et al., 2008</strong></td>
<td>24/22</td>
<td></td>
<td>The levels of recognized indicators of inflammatory processes in brain tissue, including Aquaporin 4 and Connexin 43 were examined in the brains of those with an autism diagnosis. The study found that, in contract to controls, in evaluations using the brain’s β-actin level as a reference, Aquaporin 4 expression was decreased significantly in cerebellum, while, in Brodmann’s area 9 (superior frontal cortex), Connexin 43 was elevated in the brains of those diagnosed with autism.</td>
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<tr>
<td>Studies</td>
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<td>Findings</td>
<td>Researchers’ Conclusion</td>
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<tr>
<td>Chez et al., 2007</td>
<td>10</td>
<td>Elevation of cerebrospinal fluid levels of TNF-α was significantly higher (mean = 104.10 pg/mL) than concurrent serum levels (mean = 2.78 pg/mL)</td>
<td>Indicative of CNS inflammatory mechanisms</td>
</tr>
<tr>
<td>Laurence and Fatemi, 2005</td>
<td>3</td>
<td>Elevated levels of GFAP in the frontal, parietal, and cerebellar cortices using age-matched autism and control post-mortem brain specimens</td>
<td>Indicative of microglial and astroglial activation</td>
</tr>
<tr>
<td>Rosengren et al., 1992</td>
<td>47/13</td>
<td>GFAP levels in CSF in children with autism were higher than those in normal control children</td>
<td>Indicate reactive astrogliosis in the CNS</td>
</tr>
<tr>
<td>Ahlsen et al., 1993</td>
<td>47/25</td>
<td>Average levels of GFAP in the CSF of children with autism three times higher than control group</td>
<td>Reactive gliosis</td>
</tr>
<tr>
<td>Bailey et al., 1998</td>
<td>6/8</td>
<td>Cerebellum in autism showed an increase in GFAP</td>
<td>Reactive gliosis</td>
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<tr>
<td>López-Hurtado and Prieto, 2008</td>
<td>8/7</td>
<td>The mean density of glial cells was greater in the autistic cohort than controls in area 22 (p &lt; 0.001), area 39 (p &lt; 0.01), and area 44 (p &lt; 0.05)</td>
<td>Results are consistent with accelerated neuronal death in association with gliosis and lipofuscin accumulation</td>
</tr>
<tr>
<td>Rose et al., 2012</td>
<td>12/12</td>
<td>3-chlorotyrosine (3-CT; an established biomarker of a chronic inflammatory response) significantly increased in autism cerebellum and BA22</td>
<td>Chronic inflammatory response</td>
</tr>
<tr>
<td>Crawford et al., 2015</td>
<td>14/14</td>
<td>Levels of GFAP immunoreactivity were significantly elevated (P = 0.008) in anterior cingulate cortex (Brodmann area 24;</td>
<td>Activation of white matter astrocytes in the anterior cingulate cortex as a result of a</td>
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</tbody>
</table>
These findings, showing evidence of inflammation in brain tissue in ASD, are evidenced by biomarkers of inflammation/encephalitis in the CSF and blood of individuals diagnosed with an ASD (Zimmerman et al., 2005; Chez et al., 2007). Neuroinflammation, in general, is characterized by the reactivity of microglial cells and astrocytes, activation of inducible NO-synthase (i-NOS), and increased expression and/or release of cytokines and chemokines (Monnet-Tschudi et al., 2011). All of these neuroinflammatory processes have been observed in those with an ASD diagnosis. Table 1 summarizes evidence supporting the presence of neuroinflammation/encephalitis in the brains and CSF of select individuals who have an ASD diagnosis. To date, there are at least 16 studies which reveal neuroinflammation to be an element of the ASD pathology. The following section discusses the specific biomarkers of neuroinflammation found in ASD, and their relevance and interplay.

### Biomarkers of Neuroinflammation in ASD

In those with an ASD diagnosis, some important biomarkers indicative of brain inflammation, include (but are not limited to): (1) microglial and astrocytic activation (Vargas et al., 2005); (2) a proinflammatory profile of cytokines (Vargas et al., 2005); and (3) nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) activation (Young et al., 2011). The presence of one or more of these biomarkers can influence and potentiate the others. Moreover, activated microglial and astocytes, proinflammatory cytokines, and aberrant NF-κB activity can ultimately create an environment of excessive brain inflammation, which can lead to destruction of critical brain tissue (Rodriguez and Kern, 2011). In other words, those conditions can intensify brain inflammation making matters worse. A brief explanation is as follows.

**Microglia**

Microglia are a type of glial cell. They are the resident macrophages in the central nervous system (CNS) and act as the first and main form of active immune defense in the brain and spinal cord. Microglia as an innate immune response cell react in a proinflammatory fashion to attack infectious agents or altered proteins/cells, but then shift to a more anti-inflammatory phenotype to remove debris and repair the damage. Microglia can play both a beneficial and a detrimental role, and thus it is not easy to separate their contributions in disease onset and progression (Carson et al., 2007).

Vargas et al. (2005) and several others (e.g., Pardo et al., 2005; see Table 1) reported that individuals who had an ASD diagnosis had neuroinflammation processes present in both brain tissue and/or CSF and that microglial activation appeared to be part of a sustained neuroinflammatory process. Unfortunately however, when the neuroinflammatory process is sustained, microglial activation can contribute to disease progression which can result in loss of healthy brain tissue (Rogers et al., 2007; Smith et al., 2012). In a sustained neuroinflammatory state, microglia can adopt an amoebic phenotype and start engulfing synapses and other healthy brain tissue (Rodriguez and Kern, 2011). The consequence of synapses and other neuronal tissue being engulfed is cell loss and reduced connectivity, both of which are found in the brains of those with an ASD diagnosis (Rodriguez and Kern, 2011).

**Astrocytes**

Although the inflammatory responses in the CNS are primarily mediated by microglia, evidence suggests that astrocytes (also a type of glial cell in found in the brain) are key regulators of neuroinflammation in the CNS (Guerra et al., 2011; Cekanaviciute et al., 2014). Astrocytes are found to be activated in those with an ASD diagnosis. Moreover, when astrocytes are hypertrophic and proliferative, they up-regulate the expression of glial fibrillary acidic protein (GFAP; Stichel and Muller, 1998), and GFAP is also found to be elevated in the brains and CSF in those with an ASD diagnosis (Ahlsen et al., 1993; Laurence and Fatemi, 2005; see Table 1). Ahlsen et al. (1993), for example, observed that GFAP levels were threefold higher in the CSF of children diagnosed with an ASD in comparison to controls.

**Cytokines**

The presence of one or more of these biomarkers can influence and potentiate the others. Moreover, activated microglial and astocytes, proinflammatory cytokines, and aberrant NF-κB activity can ultimately create an environment of excessive brain inflammation, which can lead to destruction of critical brain tissue (Rodriguez and Kern, 2011). In other words, those conditions can intensify brain inflammation making matters worse. A brief explanation is as follows.
Cytokines are small proteins that are used in cell signaling, and they include: chemokines, interferons, interleukins, lymphokines, and tumor necrosis factor (TNF). Proinflammatory cytokines promote inflammation. In those diagnosed with an ASD, the brain and CSF have a unique and elevated proinflammatory profile of cytokines in comparison to controls (Vargas et al., 2005; Chez et al., 2007; Li et al., 2009; see Table 1). As reported by Li et al. (2009), proinflammatory cytokines [TNF-alpha, interleukin (IL)-6 and granulocyte-macrophage colony-stimulating factor], Th1 cytokine (interferon-gamma) and chemokine (IL-8) are increased in the brains of individuals with ASD. Proinflammatory cytokines are also found to be increased in the peripheral blood of those with an ASD diagnosis in comparison to controls (Zimmerman et al., 2005; Molloy et al., 2006).

Nuclear Factor Kappa-Light-Chain-Enhancer of Activated B Cells (NF-κB)

NF-κB is a protein found in almost all cell types. This protein is a transcription factor that will promote gene expression of several inflammatory mediators. It mediates the regulation of cellular immune responses by promoting the expression of inflammatory cytokines and chemokines and by establishing a feedback mechanism that can produce chronic or excessive inflammation (Young et al., 2011). Thus, when NF-κB becomes aberrantly active, it has the potential to produce chronic or excessive inflammation (Young et al., 2012). NF-κB activation induces numerous proinflammatory gene products including cytokines, cyclooxygenase-2 (COX-2), and inducible nitric oxide synthase (iNOS; Park and Youn, 2013). In individuals with an ASD diagnosis, Young et al. (2011) found NF-κB is aberrantly expressed in the orbitofrontal cortex, in comparison to controls, as part of a molecular cascade leading to inflammation, especially of resident immune cells in brain regions that are associated with the behavioral and clinical symptoms of those with an ASD diagnosis. Although, one study did not find aberrant NF-κB in the brains of children with ASD (Malik et al., 2011), peripheral blood markers confirm abnormal NF-κB activity. Naik et al. (2011) for example, evaluated for NF-κB in peripheral blood samples of 67 children with autism and 29 control children and found a significant increase in NF-κB DNA binding activity in the peripheral blood samples of children with autism. They further stated that autism may arise, at least in part, from an NF-κB pathway gone awry. Other studies corroborate their findings (Ziats and Rennert, 2011).

The research findings in this section suggest that excessive neuroinflammation is an element of the neuropathology in those with an ASD diagnosis. The following section estimates the percentage of children with an ASD diagnosis who may be affected.

Estimation of the Percentage of Children with an ASD Diagnosis Who are Affected

The percentage of children with an ASD diagnosis who have neuroinflammation/encephalitis remains unclear. Due to the state of various subtypes in ASD, some children diagnosed with an ASD may not have neuroinflammation. However, evidence from clinical research suggests that neuroinflammation is common among those with an ASD diagnosis. An examination of the evidence supporting a link between neuroinflammation and autism that might be used to estimate the percentage of children affected follows.

Of the studies that examined neuroinflammatory biomarkers in the brain and CSF of those with an ASD diagnosis, most suggested that all of the children examined showed signs of brain inflammation (Vargas et al., 2005). In some studies, the authors overtly concluded that the neuroinflammation was found in all of the individuals they examined (Chez et al., 2007; López-Hurtado and Prieto, 2008; Rose et al., 2012). For example, Rose et al. (2012), who studied brain samples from 12 children with autism and 12 controls, mentioned that all of the markers examined were significantly altered in autism, including 3-chlorotyrosine (3-CT), an established biomarker of a chronic inflammatory response, which was significantly increased. López-Hurtado and Prieto (2008) also mentioned, in their study of eight individuals with autism and seven controls, that the autistic subjects of all ages demonstrated greater density of glial cells in comparison to controls (up to double).

However, there are a few studies where the authors mentioned that the biomarkers of neuroinflammation studied were found in some but not all of the individuals examined. For example, Morgan et al. (2010) examined the dorsolateral prefrontal cortex of male cases diagnosed with autism (n = 13). The authors stated that the microglia were activated in 9 of 13 cases with autism (69%). Tetreault et al. (2012) observed all but one individual diagnosed with an ASD (out of the 11 studied) had higher levels of microglial activation than controls. Thus, 91% showed microglial activation or neuroinflammation. However, Tetreault et al. (2012) also stated that the one individual without the microglia activation or neuroinflammation was an outlier, behaviorally, with respect to other individuals diagnosed with autism and examined.

Thus, based on the available research, a conservative estimate suggests that at least 69% of individuals with an ASD diagnosis have microglial activation or neuroinflammation. However, given the lower number of subjects analyzed in each of the presented studies, this estimate should be considered with care. The actual percentage could conceivably be
more or less. For a more accurate estimate, a larger study is needed – one that quantitatively examines multiple regions of the brain for glial activation in concert with an assessment of other markers of activation (e.g., cytokines); this would permit researchers to determine more precisely the frequency/percentage of individuals with an ASD diagnosis who also show microglial activation.

How Neuroinflammation May Contribute to the Development Of ASD: Regression, Encephalitis, and Clinical Symptoms

Knowledge of the effects of sustained and exaggerated neuroinflammation and microglia activation on brain connectivity is critical to understand how neuroinflammation could contribute to the development of an ASD. Sustained and exaggerated microglial activation can lead to cell loss and loss of connectivity. As mentioned earlier, in a sustained neuroinflammatory state, microglia can adopt an amoebic phenotype and start engulfing synapses and other healthy brain tissue with deleterious consequences for neurons and synaptic architecture (Lu et al., 2011; Rodriguez and Kern, 2011). Furthermore, when microglia are triggered to switch to an inflammatory phenotype, not only can this lead to microgliosis and neuroinflammation resulting in a disruption of normal neuroimmune homeostasis, but also this detrimental process can continue long after the initial insult or cause for the activation has been resolved (Lu et al., 2011).

As mentioned, the consequence of sustained microglial activation is cell loss and reduced connectivity, both of which are found in the brains of those with an ASD diagnosis (Rodriguez and Kern, 2011). An examination of the scientific literature in ASD clearly shows that connectivity is disrupted (Wass, 2011). Numerous studies show loss of connectivity in ASD (Kern et al., 2015). In addition, the issues of connectivity in ASD have been shown to correlate with ASD symptom severity – the greater the cell loss and connectivity issues, the worse the ASD symptom severity (Kikuchi et al., 2014; Kern et al., 2015). Neuronal cell loss and reduced connectivity could understandably lead to neurological loss of skills and abilities or regression. Once a threshold of sufficient neuronal cell loss and neuronal disconnection has been reached, a child would then become clinically symptomatic, i.e., show signs of regression or loss of skills and abilities.

In addition, astrogliosis, usually associated with chronic neuroinflammation and found in ASD, has beneficial as well as detrimental effects (Kern et al., 2012; Skripuletz et al., 2013). Astrogliosis is sometimes accompanied by microgliosis and demyelination (Skripuletz et al., 2013). Neuronal demyelination could also lead to neurological loss of skills and abilities and possibly characterize the regression scenario in ASD.

The concept of regression (loss of previously acquired skills and abilities) in some children with ASD has been validated by many studies (Tuchman, 1996; Davidovitch et al., 2000; Goldberg et al., 2003; Ozonoff et al., 2005, 2010; Werner and Dawson, 2005; Hansen et al., 2008; Stefanatos, 2008; Malhi and Singhi, 2012; Kern et al., 2014a,b). For example, Werner and Dawson (2005) evaluated home videotapes of children with autism between their first and second birthday parties with and without a reported history of regression, as well as videotapes of typically developing children. Analyses revealed that infants diagnosed with an ASD with regression show similar use of joint attention and more frequent use of words and babble compared with typical infants at 12 months of age. In contrast, infants diagnosed with an ASD characterized by early onset of symptoms and no regression displayed fewer joint attention and communicative behaviors at 12 months of age. By 24 months of age, both groups of toddlers diagnosed with an ASD displayed fewer instances of word use, vocalizations, declarative pointing, social gaze, and orienting to name as compared with typically developing 24-month-olds.

According to Ozonoff et al. (2005), children with ASD can be divided into three groups: an early onset group, a definite regression group, and a heterogeneous mixed group (delays-plus-regression). They, for example, found that approximately 52% had regressed. Similarly, in a study of 135 children with ASD, Kern et al. (2014a) also found that children with ASD could be divided into these three groups of children and reported that 61% were reported to have regressed. The skills most frequently reported to be lost were speech, eye contact, pointing, and socialization. Other skills mentioned were non-verbal communication, responsiveness, interest in others, expression, ability to imitate and, to a much lesser extent, motor skills. Problems noted were tantrums, behavioral issues, apparent deafness, and sensory issues (oversensitivity and undersensitivity).

Considering the Possible Forms and Causes of Encephalitis in ASD

According to the Encephalitis Society, encephalitis is inflammation of the brain, and this inflammation is caused by either an infection invading the brain (Infectious Encephalitis) or the immune system attacking the brain in error (post-infectious or Autoimmune Encephalitis; Encephalitis Society, 2015). Autoimmune Encephalitis usually follows a viral
infection (such as those that cause rashes in childhood) or immunizations. However, it has been recognized recently that there are other types of Autoimmune Encephalitis resulting from the brain being attacked by the body's immune system. Some of these types of Autoimmune Encephalitis include Potassium channel complex antibody associated Encephalitis, N-methyl D-aspartate (NMDA) receptor Encephalitis, and Hashimoto's Encephalitis.

Importantly, in cases of brain inflammation from infection, the pathogen does not necessarily have to enter the brain. Brain inflammation (and microglia) can be activated by systemic infection and inflammation (Teeling and Perry, 2009). For example, inflammatory stimuli in the periphery [e.g., lipopolysaccharide (LPS) and inflammatory cytokines] can induce transcripts for interleukin (IL)-1β, IL-6, and tumor necrosis factor-a (TNF-a) in discrete brain areas (Ban et al., 1992; Laye et al., 1994). Thus, pathogens and even peripheral cytokines need not enter the brain to elicit changes. As described by Jang and Johnson (2010), cells associated with the peripheral innate immune system (e.g., macrophages and monocytes) can produce inflammatory cytokines such as IL-1β, IL-6, and TNF-a that facilitate communication between the periphery and the brain during infection. Additionally, several studies find that peripheral cytokines can enter the brain (Banks and Kastin, 1991; Gutierrez et al., 1993; Banks et al., 1994a, b, 1995).

Systemically produced pro-inflammatory mediators can signal the brain, leading to activation of microglial cells; and even though this process can be a normal part of our defense (and in most individuals causes no damage to neurons), in some susceptible individuals the systemic inflammation leads to inflammatory responses in the brain and increased neuronal death (Teeling and Perry, 2009). Evidence indicates that this may be the case in some cases of ASD. As mentioned in a previous section, sustained brain inflammation is found in ASD, as well as neuronal cell loss (Kern et al., 2013). In addition, studies show that children with ASD have elevated blood inflammatory markers. For example, Masi et al. (2015) completed a meta-analysis on studies comparing plasma and serum concentrations of cytokines in unmedicated individuals with ASD and controls, and they found significantly altered concentrations of cytokines in ASD. They stated that the findings strengthen the evidence of an abnormal cytokine profile in ASD where inflammatory signals dominate.

Based on this information, it is possible that an element of encephalitis or neuroinflammation exists in ASD and can be characterized as Post Infectious Encephalitis secondary to a systemic infection. Notably, regression in ASD is sometimes reported to follow fever, rashes, infection, and immunizations (Kern et al., 2014b). However, there is also evidence for Autoimmune Encephalitis such as NMDA Encephalitis, and there are documented cases of NMDA Encephalitis in ASD (which will be discussed in more detail later).

Having an autoimmune type encephalitis in ASD is certainly biologically plausible. Children with ASD have an elevated prevalence of specific immune-related comorbidities, such as allergies and autoimmune diseases (Zerbo et al., 2015). Symptoms of immune dysfunction in ASD include (but are not limited to): neuroinflammation, presence of autoantibodies, increased T cell responses, and enhanced innate NK cell and monocyte immune responses, etc. (Mead and Ashwood, 2015). Moreover, these responses are frequently associated with more impairment in core ASD features such as impaired socialization and communication, and repetitive and abnormal behaviors (Mead and Ashwood, 2015).

Interestingly, neurotoxic effects and neuroinflammation were observed in young Wistar rats that were injected (intracerebroventricularly) with autism sera within hours after birth. According to Kazim et al. (2015), the rats injected with the autism sera demonstrated developmental delay and deficits in social communication, interaction, and novelty. The neurobiological changes and the behavioral autistic features were ameliorated by treatment with a ciliary neurotrophic factor (CNTF) small peptide mimetic, Peptide 6 (P6), which is known to have neuroprotective effects (Kazim et al., 2015).

From the evidence presented in this section, it may be plausible that encephalitis in ASD has various underlying factors. Importantly, studies which report a regression of patients into an ASD diagnosis following encephalitis include infectious encephalitis, post-infectious or Autoimmune Encephalitis, or purely Autoimmune Encephalitis (such as NMDA Encephalitis; Ghaziuddin et al., 2002; Cretten et al., 2012; González-Toro et al., 2013; Marques et al., 2014; Scott et al., 2014). What the possible external triggers of this inflammatory process in children with autism may be is the subject of the following section.

Go to: Possible External Triggers of the Inflammation Process in Autism

As mentioned earlier, systemic inflammation and/or infection can gain access to the CNS via blood flow and elicit an inflammatory response the brain (Sankowski et al., 2015). The resulting inflammatory mediators could interfere with neuronal and glial well-being, leading to a disruption in brain homeostasis and persistent inflammation and immune activation in the brain, ultimately resulting in cognitive and behavioral manifestations (Sankowski et al., 2015). Thus, it is...
plausible that systemic inflammation and/or infection could trigger the inflammation or encephalitis seen in the brains of children with an ASD.

In addition, the production of brain autoantibodies, notably found in children with ASD and in specific cases of autistic regression and encephalitis, could also be secondary to various types of external triggers. Researchers have suggested various exposures that can contribute to the production of brain autoantibodies in autism (Mostafa and Refai, 2007; Mostafa and Al-Ayadhi, 2015).

To this point, a study by Vojdani et al. (2003) provides evidence to support the hypothesis that there are external triggers, such as the ones mentioned previously, that can instigate the production of brain autoantibodies in children with autism. Vojdani et al. (2003) measured IgG, IgM, and IgA antibodies against CD26, CD69, streptokinase (SK), gliadin, and casein peptides and against ethyl mercury bound to human serum albumin in patients with autism. From the results, they proposed that bacterial antigens (SK), dietary peptides (gliadin, casein) and Thimerosal (ethyl mercury) in individuals with pre-disposing HLA molecules, bind to CD26 or CD69 and induce antibodies against these molecules. Their study demonstrated that dietary peptides, bacterial toxins, and xenobiotics bind to lymphocyte receptors and/or tissue enzymes, resulting in and autoimmune reaction in children with autism.

It is conceivable that this process could begin with a single exposure or trigger; however, a combination of exposures or factors could also trigger a cascade of events resulting in brain inflammation and production of brain autoantibodies. Numerous studies have shown that toxins and pathogens can work synergistically – where the effect of the combination of their presence is greater than the sum of their individual effects (Kern et al., 2012).

Issues with Current Mainstream Treatments and Therapies

As previously mentioned, another benefit of recognizing encephalitis in those with an ASD diagnosis is that this recognition might lead to more targeted and potentially more effective medical treatments. The current mainstream treatments and therapies for those with an ASD diagnosis emphasize educational interventions such as applied behavioral analysis (ABA) and/or psychoactive drugs such as Risperdal. These types of treatments do not address the patient’s underlying medical illness or disease pathology. This may be the reason for the dismal findings reported in a 2011 article in Pediatrics by Al-Qabandi et al. (2011). These researchers reported that although there are many available therapeutic approaches to childhood autism, none are curative or have well-established efficacy. This finding continues even with the promotion of early intervention.

In addition, the psychiatric or antipsychotic medications frequently prescribed in ASD (e.g., risperidone or Risperdal), have serious side effects. For example, antipsychotics such as Risperdal can cause: neuroleptic malignant syndrome (a potentially fatal reaction); tardive dyskinesia (abnormal facial, shoulder and limb movements, which can be permanent); breast swelling or tenderness; low white blood cells; low platelets; high blood sugar; and many other serious side effects (PDR.net, 2014).

Treatment Response and Timeliness

Recent research suggests that even though parental concerns that their child might have ASD are generally expressed early on and reliably (Kern et al., 2014a,b; Sacrey et al., 2015), common responses to these concerns from healthcare providers are often reassuring or passive which subsequently delays diagnosis and treatment (Zuckerman et al., 2015). Another possible benefit of recognizing encephalitis or brain inflammation as a potential component of ASD is that this may drive a more timely response. If providers understand that the affected child may have an identifiable medical condition which would respond to appropriate and prompt medical treatment, they may be more likely to initiate medical intervention.

Evidence to Suggest Effectiveness in Treating Encephalitis in ASD

Several studies that link encephalitis with the onset of autism or an ASD, also report the improvement or amelioration of autism/ASD symptoms when the encephalitis was treated (González-Toro et al., 2013; Scott et al., 2014). For example, Scott et al. (2014) reported on a 33-month-old boy who presented with irritability, insomnia, decreased appetite, and symptoms of autistic regression following an upper respiratory tract infection. He displayed loss of
previously acquired skills, including: language (eventually becoming mute and non-communicative), the ability to interact socially, and eye contact. The child was found to have anti-NMDA receptor encephalitis. Treatment with intravenous (IV) immunoglobulins and steroids resulted in the child’s reacquisition of language and social skills and in the resolution of his abnormal movements. According to the authors, reacquisition of language and social skills were observed after the third day of treatment. He also began to show interest in his parents again and his eye contact improved. After the initial IV treatment was completed, he was started on high-dose steroids (2 mg/kg/d) for 2 weeks, with a slow tapering off over the next 6 weeks. During that time, he continued to make significant improvements and his behavior and personality were restored to their pre-illness state. In addition, he regained the ability to use multiple short phrases.

A similar case (González-Toro et al., 2013) involved a 5 years old female who lost previously acquired skills and evolved into autism. After showing positive anti-NMDA receptor antibodies in her cerebrospinal fluid, she was diagnosed with anti-NMDA receptor encephalitis. An intravenous perfusion of corticoids, immunoglobulins, and rituximab was used. According the researchers, the child essentially recovered except for a slight language disorder that was still noted 6 months after treatment.

Thus, as these reports suggest, another benefit to recognizing encephalitis as a physical condition in those with an ASD diagnosis is that it might lead to more targeted and possibly more effective medical treatments. As suggested by McDougle and Carlezon (2013), addressing the neuroimmunological pathophysiology in ASD offers exciting new possibilities for therapy.

In the aforementioned cases, the drugs used were intravenous steroids and immunoglobulins (and rituximab). However, there are several studies which report on other pharmaceutical and nutraceutical treatments that can reduce microglial activation and/or the levels of their associated inflammatory cytokines. If encephalitis were routinely assessed as a component in autism and ASD, then in those cases where it is identified, more benign treatments might be available than the current psychiatric medication choices, and their use might be more efficacious in producing a positive outcome. The authors of this review are not recommending any treatment in particular, and acknowledge that, in any treatment regimen, the risk/benefit ratio would have to be considered. That said, further research into the diagnosis and treatment of encephalitis as a potential component of ASD is merited.

Discussion

The dramatic rise in ASD began in the 1990s, and in the past two decades, the rates of ASD have increased by 289% (Boyle et al., 2011). The sudden and dramatic rise in ASD prevalence has, in some ways, caught the medical community “off guard.” In the midst of the meteoric rise in rates of autism and ASD, significant new research into the physical symptoms has been done. The challenge now is to incorporate this new research about the physical symptoms of autism into the practice of medicine that historically has stereotyped autism as a purely psychiatric disorder. For the benefit of patients, the physical symptoms of autism must be recognized and treated. For children with ASD, particularly those who have begun to regress into ASD and show other signs of neurological regression, testing for encephalitis may be warranted. Particularly, given the documented cases of children with regressive ASD and NMDA Encephalitis who tested positive for anti-NMDA receptor antibodies, routine testing for anti-NMDA receptor antibodies in ASD should be seriously considered. The study by Scott et al. (2014), mentioned earlier, of the child who regressed into autism and recovered from treatment for NMDA, indicates that there is benefit to recognizing the possibility of encephalitis in children with ASD. The delay in incorporating new research findings into medical practice standards is unfortunate because if a diagnosis of autism or ASD were recognized in the medical community as having a possible component of encephalitis that could be tested and treated appropriately, such treatment for encephalitis would likely reduce, and possibly eliminate, ASD symptoms in some children. Future studies should include treatments for neuroinflammation in ASD.

Author Contributions

JK was the main writer and analyzed data, DG reviewed the manuscript structure, ideas and science, LS co-wrote and edited structure, ideas, and science, and MG evaluated and reviewed manuscript ideas and science. All authors read and approved the final manuscript.
Conflict of Interest Statement

The authors have been involved in vaccine/biologic litigation. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Some people are capable of holding passionate emotions in check, while others express those feelings to anyone who will listen. Whether or not the emotions are expressed, the feelings are generally the same. I am one who used to wear my heart on my sleeve. I felt that talking about my issues or concerns could help me grow past them. I later discovered that at times this “sharing” would come back to bite me in my backside.

Right now, though, I have to speak up because I am angry! I am angry that society cannot pull their heads out of their backside long enough to hear what is being said. Sometimes I have to really bite my tongue when really all I want to do is grab the person I am talking to by the face and say, “Hello, is there anyone in there? Do you comprehend what I am saying? Are you capable of making a decision on your own, one that has not been conditioned into your mind?”

As children, we are taught that we are supposed to respect our elders, our teachers, our pastors or preachers, doctors, dentists, etc. When we are given direction as to how to handle a particular situation, we are advised to follow through with that direction. When we begin to grow, often there are times that we struggle with what society says is “right” or “wrong.” Society may say that it is morally wrong for two men or two women to have a relationship together. But in our heads, we may have this little voice that says, Why? Why is it so wrong for two individuals who love each other to be with each other? How does it affect me personally? As we grow up we find out that many of the people we were taught to trust are not what we thought. More questions go through our minds. Who can we trust? Anger may not even be the correct term for what I feel. Betrayal may be a better term for it.

I have not always made the smartest decisions in life. I have allowed others to persuade me by using the same kind of conditioning I see happening with most new mothers. I was taught to believe that a doctor would have my best interest at heart, that he or she took an oath to treat a patient respectfully, while ensuring that the patient receives optimum care. It is crap! Not all doctors have an individual’s best interest at heart. Some of them are trying to increase their bank accounts, while more and more patients are becoming sicker. A vaccine or pill will not cure what damage has already been done. Often these same vaccines and prescription drugs are the root of the problem. And that’s the case with my husband.

My husband was very healthy when we met. If he got a cold, he was over it within 48 hours. He was exposed to whooping cough and he was fine. He was exposed to the flu, and his body reacted normally. The only time he ever got severely sick was when he spent 21 days in the field, and the temperatures were below zero.

My husband was in the military. He spent five years in the National Guard before spending another 20 years on active duty. During this time, he was exposed to many things. The worst, I believe, being the vaccines he was given starting in 2001. As he prepared to deploy to Bosnia for a peace-keeping mission, he stood in a single-file line that wound through an obstacle course of cubicles. I remember him receiving a combination of yellow and typhoid fever vaccines along with an anthrax vaccine. That night as he lay in bed, he shook from fever. He was down for the weekend due to these vaccines. Was this a
“normal” reaction? We thought it was possible, especially given that he had never received these types of vaccines before. We dismissed it and spent the little time we had together before he left.

When he came home, the process went like this: be at XYZ location at _______ time in order to get your boosters. Boosters? Why would he need boosters? He was not being exposed to these infectious diseases at home. These vaccines were not recommended for the general population. The other men who deployed with him did not do so unvaccinated. So tell me, who and what was he being protected from?

All of these vaccines were given on top of the mandatory vaccinations, you know: MMR, hepatitis B, and influenza to name a few.

In 2006, he would deploy again. Somehow the individual administering the previous vaccines failed to write them down in my husband’s records. In order to have a “deployable” status, he was required to be revaccinated. He had the anthrax vaccine twice in less than a week. He was also given the smallpox vaccine. The funny thing is the doctor told him that he was not allowed to be around infants or pregnant women after having this “safe” vaccine.

He was on a 15-month rotation and, as a military family, we were advised to give him time to reintegrate when he returned. The days, months, and years went by, and the person who stepped foot on that plane was not the same one who returned. Although he tried to control his outbursts, there were times that he was incapable of doing so. There are times now, although they occur a lot less frequently than they did then, that he reminds me of the Incredible Hulk. I wait to see if he is going to turn green and rip his shirt off. He is not the same. He will never be the same.

As the years and the deployments came and went, his body began to shut down. While on the last deployment, he was prescribed medication to help “prevent” malaria. After extensive research, it was revealed that the medication was doing more harm than good. He went to his physician and expressed his concerns. They were dismissed. Not only did he suffer from night terrors, irritability, and psychosis, but it also led to him thinking that perhaps life would be better without him. This from a person who felt that taking one’s own life was a coward’s way out of things. Something triggered him to rethink his decision. When he came home, he was very quiet. Getting him to express how he felt was like pulling teeth with rusty pliers. Today, the medication has had the time to run its course, but his body is left compromised from a need to over-vaccinate.

After the last deployment, he knew he was done with the military. It was just a matter of finishing his enlistment and waiting for his retirement. He thought, What will I do after I am done? And the first thing that came to mind was continuing his education. He spoke with an academic advisor who told him he would need a series of vaccines or proof of immunity. He thought with all the vaccines that he had received that there would be no issue, right? WRONG! The results come back that he was no longer immune to rubella. How is that even possible? How do we go about vaccinating and getting boosters only to learn that our bodies are compromised and we don’t even have immunity?

He was sick of the vaccinations and tired of feeling miserable every time he received a vaccine. The influenza shot no longer was effective. He suffered more from the vaccine than if he had the flu. You see, my husband is growing sicker and sicker. The colds that once began as a two-day stint started lasting between four and five days. Then he would be miserable for a week. Now a common cold can keep him out of commission anywhere from ten to sixteen days before he recovers. The recovery phase is kind of a joke, as it does not last long – if he’s lucky, two weeks. In the last six months, he has been sick approximately eight times. EIGHT TIMES! Yet, his records at the VA state that he is a healthy white male. It also indicates that he should be capable of performing any given task. What they do not want to hear is that he has significant “unexplained” memory loss. He is not capable of remembering what is supposed to happen later in the afternoon, much less what he is supposed to do next week. It is as if he is experiencing the onset of Alzheimer’s. Recently we went to the
hospital because he had the flu. The nurse there said, “I hope that you have had a better experience at the VA than I did, because they treated me like crap.”

Individuals should not be forced to have whatever vaccines that the government sees fit. I realize that there are many people who do not believe in vaccine damage, and that is their right as individuals. However, they should not have the right to force vaccines onto those of us who believe our children and spouses are sick because they have become the guinea pigs for our government. Unfortunately, many Americans, especially soldiers, sign over their rights when they take the oath to serve their country. These individuals are no longer considered human in the eyes of the government; instead they belong to the United States military. If they refuse to receive these vaccines, they are faced with punishments like being extra duty, being demoted, fined, or jailed, or even dishonorable discharge.

Like many others in the military, my husband spent his entire career wanting to fight for justice. Now that he is out of the military, there is no justice for what has happened to him. I am not anti-vaccine; I am pro-rights. If individual can make a decision to serve their country and be competent enough to do so, then they damn sure should be capable of making the decision on whether or not they want to receive vaccines that they are not required to receive in the civilian world.

I am losing faith in a society who is making our children and soldiers sicker in an effort to fill the pockets of multi-million dollar corporations.

~ Elisha G.

Elisha G. and her husband of almost 16 years have four children. She loves writing, cooking, baking, photography, and take care of others by lending a hand to those in need.
A series of recent Mumps outbreaks appears to provide empirical evidence that the MMR vaccine is ineffective in protecting children and adults against Mumps, which in adults poses serious risks.

Since December, 2018, the U.S. Navy warship Fort McHenry which was deployed to the Persian Gulf, has been quarantined, stranded at sea because of a Viral Mumps Outbreak that has stricken 27 sailors and Marines. All service members on the ship had been vaccinated with the MMR — measles/mumps/rubella—vaccine, but the vaccine is defective. The mumps takes 25 days to incubate.

*Business Insider* reports that *The Navy’s Fighting To Get A Rare Viral Mumps Outbreak Under Control After It Stranded A US Warship At Sea* (March 29, 2019)

US Warship Fort McHenry

“The first troubling case appeared on December 22, shortly after the ship departed Mayport Naval Station in Florida for its current deployment.

*The Navy’s Bureau of Medicine and Surgery (BUMED) later explained to BI that “based on clinical presentation and laboratory testing, these cases are currently classified as probable cases of mumps,” one of a number of illnesses that all US military personnel are vaccinated against.”*

While outbreaks of influenza and other common illnesses occur every year aboard Navy vessels, the situation on the Fort McHenry is unusual, the Navy explained. “It is not common for us to see outbreaks of vaccine-preventable viral infections.” The ship hasn’t made a port call since early January and now isn’t likely to for at least another month — a very long stretch at sea that’s a morale killer for the crew. Typically deployed US warships have port calls at least once a month to repair systems and rest the crew.

“The Navy’s position is that vaccines are effective at reducing the incidence and severity of vaccine-preventable diseases,” BUMED told BI. Unfortunately, “the mumps portion of the measles, mumps, and rubella (MMR) vaccine is the least effective of the three components, providing 88% effectiveness after completion of the two dose series”

Even as the Navy Bureau of Medicine acknowledged the vaccine’s ineffectiveness, all of the 700 servicemembers on the Fort McHenry received booster MMR vaccine shots. [Earlier *Business Insider* report:*A Rare Virus Outbreak At Sea Has Left A US Navy Warship Quarantined For Over 2 Months* (March 13, 2019)

A lawsuit filed by two former Merck scientists in 2010, alleges that the company committed fraud by faking efficacy tests for the mumps component of the MMR vaccine in order to maintain its monopoly on the MMR market. [details here]

“The suit refers to a 2006 mumps outbreak in the Midwest, in which 6,500 cases were reported among a highly vaccinated population, and another outbreak in 2009, in which 5,000 cases were confirmed. By comparison, the annual average of mumps cases in the U.S. in the two decades preceding the 2006 outbreak was 265; before the introduction of the single-shot Mumpsvax vaccine in 1967, there were approximately 200,000 cases of the disease, according to the 55-page document. [Forbes, 2012]
While that lawsuit languishes, Merck’s MMR vaccine is causing mumps outbreaks in adults, who are at higher risk of serious complications including: pain and tenderness of the testicles, inflammation of breast tissues, meningitis or encephalitis, and deafness.

We reported that a recent mumps outbreak in 186 children and adults at Texas migrant detention facilities, following vaccination with the MMR – shows that the MMR is not only ineffective against mumps, the MMR has CAUSED both vaccinated and unvaccinated children and adults to be infected with measles and mumps.

U.S. immigration authorities now acknowledge more than 2,200 people have been exposed to a mumps outbreak at Immigration Detention facilities at Pine Prairie, Louisiana and Aurora, Colorado as well as Texas. A spokesman said 236 detainees have had confirmed or probable cases of mumps in 51 facilities in the past year. There were no reported cases between 2016 and 2018 at any ICE facilities. In 2016, there was a measles outbreak at an immigrant detention center in Eloy, Arizona, which contributed to a statewide outbreak after some employees refused to get vaccinated.

Vaccines are far from perfect; in fact, they are classified as “unavoidably unsafe”; worse still, is that some mandated vaccines for infants and young children are known to be unsafe, while the efficacy of others is poor. Ineffective vaccines put both vaccinated and unvaccinated children at risk of infectious disease.

The 2015 measles outbreak at Disneyland was widely misrepresented by concealing the fact that CDC officials knew that unvaccinated children were not to blame. They knew, but concealed the fact that: “Of the 194 measles virus sequences obtained in the United States in 2015, 73 were identified as vaccine sequences.” Not until 2017, was the truth acknowledged by a CDC official in a specialized microbiology journal.

When confronted with recent mumps outbreaks, CDC officials acknowledged that “even people who previously had one or two doses of the MMR vaccine can still become infected.” However, they disingenuously claim that “scientists don’t know why this is...”

The documents in the Merck whistleblower scientists’ lawsuit were unsealed in 2012. These 55 pages provide evidence to explain why the MMR vaccine provides poor protection against mumps.

Why is the public being deceived about the known facts? One major reason for the deception is a gross financial conflict of interest. CDC’s mission is ostensibly to protect the public health. However, CDC officials are reluctant to tell the truth about vaccine safety and efficacy because of the agency’s extensive intertwined financial partnerships with vaccine manufacturers through the CDC Foundation.
In a landmark 7-2 ruling, the United States Supreme Court has decided that the administrative law “judges” (ALJs) who serve within the U.S. Securities and Exchange Commission (SEC) and other federal agencies aren’t actually constitutional because they’re appointed by staff members rather than the president or department heads.

As clearly laid out in the Appointments Clause of the U.S. Constitution, there are certain protocols that must take place in the appointment of “Officers of the United States,” a class of government officials that Justice Elena Kagan stated are “distinct from mere employees.”

In the case of ALJs at the SEC, such persons must be nominated by the president and confirmed by the Senate in order for them to actually qualify as such “Officers.” Only lower-ranking officers can be appointed by the president without the Senate, by department heads, or by the courts – which isn’t the case with ALJs.

“The SEC has statutory authority to enforce the nation’s securities laws. One way it can do so is by instituting an administrative proceeding against an alleged wrongdoer,” Kagan stated, adding that, “By law, the Commission may itself preside over such a proceeding. But the Commission also may, and typically does, delegate that task to an ALJ.”

“An ALJ assigned to hear an SEC enforcement action has extensive powers” that include gathering evidence, issuing subpoenas, examining witnesses, and imposing sanctions, she added. “As that list suggests, an SEC ALJ exercises authority comparable to that of a federal district judge conducting a bench trial.”

Since decisions made by ALJs are binding even when the Commission chooses not to review them, this unilateral action qualifies ALJs as officers of the United States, as defined by the Constitution. And as such, they must be appointed and confirmed through proper legal means, which is currently not the case.”

Vaccine “courts” are even more unconstitutional than ALJs at the SEC

But wait –how, then, do the kangaroo vaccine “courts” operate within constitutional bounds? Vaccine court “judges” are similarly appointed to make critical rulings about vaccine injuries, though none of them are appointed in accordance with these guidelines. Does this mean that it’s time for their legitimacy to face a review by the Supreme Court?

This would seem to be the logical next-step, seeing as how vaccine “courts” have long functioned as a bail-out system for vaccine corporations – which represent the only industry in the world that’s never held liable for injury and death caused by its products, by the way.

Vaccine “courts” were established as part of the infamous National Vaccine Injury Compensation Program, which came to be back in 1986 following a stream of lawsuits from parents of vaccine-injured children against vaccine companies. Passed by then-President Ronald Reagan, the new rules would shield the vaccine industry from such lawsuits, instead sending them to newly-established vaccine “courts.”
“It was supposed to be a friendly, fast alternative program that didn’t require the protections plaintiffs would have in civil litigation,” wrote Jenna Greene in an article originally published for The National Law Journal (which has since been archived).

“It’s the complete opposite,” she added.

Since tens of thousands of children are now being harmed by vaccines without consequence, this issue is far more pressing. The Supreme Court needs to take a very close look at the concept behind vaccine “courts” and why they were established in the first place. It surely has nothing to do with promoting childhood safety, and everything to do with vaccine companies protecting their profit cow.

For more news about corruption in the vaccine industry, including its routine abuse of vaccine “court” to cover up its crimes, explore RuleBySecrecy.com.
Vaccines: Why are informed consent laws being ignored?


Consent Laws

By Norma Erickson

Vaccines – Informed Consent Consent Laws: Throughout the 20th century, countless medical consumers have battled to obtain the right to informed consent. Although the U.S. Constitution does not specifically address the issue, multiple court cases have upheld the premise that the constitutionally guaranteed right to privacy insures that people are protected from governmental interference when deciding private matters, such as when they make decisions about accepting or refusing medical care. Every medical consumer now has the legal right to participate in their health care decisions via the doctrine of informed consent. It is our responsibility to preserve this right for future generations.

What is informed consent?

According to the National Institutes of Health your doctor must disclose and discuss the following in order to comply with informed consent laws:

- Your health problem and the reason for the treatment
- What happens during the treatment
- The risks of the treatment and how likely they are to occur
- How likely the treatment is to work
- Other options for treating your health problem
- Unknown risks or possible side effects that may happen later
- If treatment is needed now or can wait

Ask yourself, when was the last time a vaccine-provider discussed the potential side-effects of a vaccine or alternative options with you prior to the administration of the vaccine? If you have allergies, did they discuss the possibility of an allergic reaction to any components of the vaccine being administered? Did they discuss efficacy of the vaccine?

According to the National Institutes of Health web site, not only is your doctor required to discuss the seven topics above; they are required to obtain written consent for the following:

- Most surgeries, even when they are not done in the hospital
- Other advanced or complex medical tests and procedures.
- Radiation or chemotherapy to treat cancer
- Most vaccines
- Some blood tests, such as HIV testing (need for written consent varies by state)
Only after all pertinent facts have been discussed to the point where you understand them, are you able to exercise your right to informed consent. In order to do so, you must be mentally competent to make an informed decision and have attained the legal age of consent. Only then are the laws of informed consent satisfied.

How did citizens obtain the right to informed consent?

Many people assume informed consent was achieved after the Nuremberg trials as a direct response to the atrocities committed in the name of research. Actually, the battle was being waged much earlier.

In a 1905 opinion on the Parmelia Davis\textsuperscript{2} (uterus and ovaries were removed without her permission) case, the Supreme Court declared that Americans' rights as free citizens prohibited:

“a physician or surgeon, however skillful or eminent... to violate without permission the bodily integrity of his patient... and [to operate] on him without his consent or knowledge.”

In a 1914 Supreme Court decision involving a patient who had consented to only a portion of the surgery which was actually performed, (Mary Schloendorff) Justice Benjamin Cardozo\textsuperscript{3} added,

“Every human being of adult years and sound mind has the right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained”

In spite of these rulings, it was not until 1957 that patients acquired the right to be told not only what the doctor was going to do, but also that action’s possible positive and negative effects. In 1957, the California Court of Appeals\textsuperscript{5} ruled for plaintiff Martin Salgo (left paralyzed following a hospital diagnostic procedure) writing:

“A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”

How does this apply to vaccines?

Vaccines are a medical intervention. As with any medical procedure, there are risks involved to certain individuals. Under the informed consent doctrine, you have a right to know these risks and alternative treatments prior to granting your consent. Remember, informed consent is the law – not simply an option.

According to the NIH, you have the right to refuse any medical procedure if you are able to understand your health condition, your treatment options, and the risks and benefits of each option. Your doctor or other health care provider may tell you they do not think this is the best choice for you. But, your health care providers should not try to force you to have a treatment you do not want to have.

However, all \textit{50 states mandate} (require) vaccinations for daycare, pre-school, school attendance and/or as a condition of employment. All 50 states also allow exemptions from vaccination for one or more of the following: medical, religious, or philosophical reasons. The rules for obtaining these exemptions vary widely from state to state. Whether you realize it or not – this is an intrusion on your right to informed consent.

Many states, like Oregon, are trying to further erode the concept of informed consent by making it more difficult for parents to exercise their rights under the guise of vaccine education. Will this ‘education’ include all of the information you need to make an informed choice?

According to the basic principles of informed consent, the only time government entities should be allowed to interfere with your right to exercise informed consent is during a bona fide public health emergency, a life threatening medical emergency, the patient’s incompetence, or if you waive your rights.

How can medical consumers retain their right to informed consent?
It has taken decades of painful litigation to force the medical community to allow people a voice in their own healthcare decisions. Almost as soon as that right was assured, lobbying began to try return to the ‘more comfortable’ status quo. Should your right to informed consent be legislated away regarding vaccines and vaccination policies, you can rest assured your rights to informed consent regarding other medical procedures and practices will follow.

What can you do to protect your rights? Political activist, author and healthcare rights advocate, Catherine J. Frompovich puts forth the following suggestions:

1. Introduce language to amend any current laws/regulations restricting informed choice that exist in any state.
2. Make sure any pending legislation includes language preserving the right to informed consent.
3. In the interest of public health and safety, introduce a Vaccine/Vaccination Education/Information Bill in all 50 states, requiring the following:

   (1) Any medical consumer over the age of consent must receive Vaccine/Vaccination Information containing the following data:

   (a) A complete list of ingredients in each vaccine, including excipients, adjuvants and antigens; and

   (b) A complete list of potential adverse reactions as listed on vaccine package inserts for each vaccine proposed for administration; and

   (c) Complete instructions on how to file adverse reaction reports to VAERS (Vaccine Adverse Event Reporting System);

(2) Require all cases adjudicated within the Vaccine Injury Compensation Program be made available for public review under John/Jane Doe status

The right to fully informed consent did not simply materialize out of thin air. The battle to guarantee this right was long and painful. The right to informed consent was gained at the expense of many people’s health and/or lives.

Rights come with responsibilities. It is our responsibility to make sure the sacrifices of others were not made in vain. It is our responsibility to preserve the right to fully informed consent for future generations. The alternative is unthinkable.

References:

1. History and Development of the Doctrine of Informed Consent; Hana Osman, MSWW
2. Informed Consent; Medline Plus, National Institutes of Health
4. Spock, Feminists, and the Fight for Participatory Medicine; Michael L. Millenson
Vaccination Education Packet

Enclosed are several documents including:

1) Parental Refusal of Immunizations – Policy Statement of Coastal Children’s Clinic
2) Refusal To Vaccinate signature form
3) CDC’s Recommended Immunization Schedule for ages 0-6 years
4) CDC’s Catch-Up Immunization Schedule
5) CDC’s Vaccine Information Sheets for Hib Vaccine, Pneumococcal Conjugate Vaccine, and Diphtheria Tetanus & Pertussis Vaccine
6) Children’s Hospital of Philadelphia Questions & Answers Session
7) Vaccines Are Safe article by Richard G. J udelsohn, MD
8) Inoculated Against Facts article by Paul A. Offit, MD
9) American Academy of Pediatrics’ Fact Sheet on Autism and Vaccine Safety
10) Resources for parents and physicians as available on the Web and library

You have been given this Education Packet because of concerns you have over the safety of childhood vaccinations and/or because you have chosen to delay one or more very important vaccines – vaccines that we require of our patients to remain our patient.

Please review the information presented. We feel this is the best available and should help you to realize that vaccination is in the best interest of all children. There are no medical interventions – vaccines, medicines, surgeries, and procedures – that are one hundred percent safe. Just by driving here you have put yourself at a small risk. We feel that there is no question but that any possible risk of vaccination is much less than the risk of catching a disease without the vaccination.

Please review this information and our policy concerning refusal of vaccination. We ask that you call our office in the next two weeks to either schedule a conference to answer additional questions you may have, or to schedule an immunization visit, or to arrange for transfer of your children’s records to another physician’s office.
Parental Refusal Of Immunizations
Policy Statement - Coastal Children’s Clinic

We at Coastal Children’s Clinic are dedicated to providing the best care that we can for our patients. We feel to do this effectively we must enter into a partnership based on mutual trust with the parents of our patients so that together we can achieve this goal. Recently, there has been a trend of unjustified fear of side effects from vaccines by well-meaning parents. We believe that immunizations are one of the most important health interventions a parent can do on behalf of their children, and we want all of our patients to benefit from this modern lifesaving tool.

While we recognize and respect the parents’ role as the ultimate decision maker for their child’s healthcare, we believe strongly that we are obligated to deliver the best and safest healthcare possible for our patients and our community. We feel professionally uncomfortable caring for children who will not receive a minimal set of vaccinations. These preventable diseases can and do cause severe illness, brain damage and death. Although we strongly support all recommended vaccines, there are three series that we must insist that our patients receive in a timely manner to remain a patient in our practice.

The minimal three vaccines are: Diphtheria, Tetanus and Acellular Pertussis (DTPa); Hemophilus Influenza Type B (Hib); and Pneumococcal Conjugate Vaccine (Prevnar). Attached is the schedule for these vaccines as well as all recommended vaccines. While we believe that vaccines are very safe, and clearly safer than not having vaccines, we recognize that there are risks associated with all interventions and therapies. Please see the attached CDC Vaccine Information Sheets for the three vaccines we require.

We hope that you take the time to read quality papers and internet sites about the benefits of vaccines. The best internet site for vaccine education can be found at www.vaccine.chop.edu which is hosted by one of the finest children’s hospitals in the country, The Children’s Hospital of Philadelphia. The federal government also maintains an informative site at the CDC web site: www.cdc.gov/vaccines. Our providers and staff are pleased to answer any questions in person or loan you a videotape / DVD that was developed by The Children’s Hospital of Philadelphia.
We hope that you will review the accurate information about immunizations here as well as on respected internet sites and consider allowing your child(ren) to receive this important protection. These and all other childhood vaccines are available through our office at modest cost, or through the local county health department at no charge.

As a group practice, we feel we must implement a consistent policy in regard to Parental Refusal Of Immunizations. Refusal of these three vaccinations indicates a significant difference of philosophy of care and it would be best that we terminate our doctor-patient relationship. It is our hope that no patient is discharged from our practice due to vaccine refusal.

If you cannot meet us halfway and obtain at least the three required vaccine series, we will with great reluctance send a letter to you discharging your child(ren) from our care. If your child requires medical care within the following 30 days we will provide that care. After that period our obligation ends. When you have chosen another pediatrician, please complete and return by mail or fax the attached Authorization to Transfer Medical Records form. We will then forward your medical records to this new provider.

Some of us are old enough to have practiced pediatrics without Hib, Pevnlar and the newer DTaP. In those days many of our journals were filed with articles describing which antibiotics work best for meningitis and whether or not we could use steroids to preserve hearing in the patients who survived. We became good at managing patients with acute meningitis as well as the complications that followed meningitis – seizures and CSF shunts. These articles and patients are quite rare now because meningitis is rare. We for one do not want to practice pediatrics like that again.

Unfortunately, there seems to be an increasing frequency of parents refusing all vaccinations nationally. This places children in unnecessary and potentially severe risk, and we feel obligated to do everything we can to reduce the number of children needlessly exposed. It is to this group that this letter speaks. It is our hope that the majority of families with ill-founded fears of vaccines will reconsider and obtain for their children all recommended vaccines. If not, and you are unwilling to obtain at least the three minimal vaccinations we require to remain a patient with us, we ask that you find another doctor’s office to care for your children. If you would like to stay with us, please schedule a visit in the next week to begin the vaccination series.

March, 2008
Coastal Children’s Clinic - Refusal to Vaccinate Documentation

Child’s Name: ____________________________ Child’s ID # ____________________________
Parent's/Guardian’s Name(s): ____________________________
The Physicians and Staff of Coastal Children’s Clinic have advised me that my child (named above) should receive:

<table>
<thead>
<tr>
<th>Recommended</th>
<th>Declined</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Haemophilus influenzae type b (Hib)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Pneumococcal conjugate vaccine (Prevenar)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Diphtheria, Tetanus, acellular Pertussis (DTaP / Tdap)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Measles, mumps, rubella (MMR) vaccine</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Varicella (chickenpox – Varivax)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Polio vaccine (IPV)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Hepatitis B (HBV)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Meningococcal (Menactra – MCV-4)</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Hepatitis A</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Rotavirus</td>
<td>☐</td>
</tr>
<tr>
<td>☐ Other</td>
<td>☐</td>
</tr>
</tbody>
</table>

I have read or been given the Vaccine Information Sheet(s) from the CDC explaining the vaccine(s) and the disease(s) they prevent. I have had the opportunity to discuss these with my child’s doctor or nurse, who has answered all of my questions regarding the recommended vaccine(s). I understand the following:

- The **purpose** of and the need for the recommended vaccine(s)
- The **risks and benefits** of the recommended vaccine(s)
- If my child does not receive the vaccine(s), the **consequences** may include:
  - contracting the illness the vaccine should prevent. (The outcomes of these illnesses may include one or more of the following: pneumonia, illness requiring hospitalization, death, brain damage, meningitis, seizures, and deafness. Other severe and permanent effects from vaccine preventable diseases are possible as well.)
  - transmitting the disease to others
  - the need for my child to stay out of childcare or school during disease outbreaks and for prolonged periods.

- My health care provider, the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention have all strongly recommended that the vaccine(s) be given to my child. Nevertheless I have decided to decline the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled “declined.”

I also understand that I am to specifically tell any and all nurses and physicians employed by Coastal Children’s Clinic that my child has not been fully immunized whenever I call with questions about fever, cough or other symptoms of illness so that they may modify their advice as appropriate for a non-immunized child.

I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others that my child might come in contact with.

I know that I may re-address this issue with my health care provider at any time, and that I may change my mind and accept vaccination for my child anytime in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Parent/Guardian Signature ____________________________ Date ______________
Witness ____________________________ Date ______________

I have had the opportunity to re-discuss my decision not to vaccinate my child and still decline the recommended immunizations as indicated by the dates and my initials below:
REFERENCE INFORMATION

- hundreds of independent studies, books, articles, and documentaries -

(more can be found online and at HealthAlertPhilly.org/VACCINES.htm)

NEWS SOURCES:

- Health Impact News - https://healthimpactnews.com/?totalItems=0&limit=10&start=1&sort=date&find=VACCINES
- Dr. Mercola - https://vaccines.mercola.com
- VAXXTER - https://vaxxter.com/category/uncategorized/vaccine-tales

BOOK LIST:

List from ChildrensHealthDefense.org - https://childrenshealthdefense.org/store
List from Dr. Tenpenny - http://www.drtenppelinystore.com/vaccine-products.html

- 2018: How to End the Autism Epidemic by J.B. Handley
- 2016: Miller’s Review of Critical Vaccine Studies: 400 Important Scientific Papers by Neil Z. Miller
- 2016: Murder by Injection by Eustace Clarence Mullins
- 2015: Vaccine Whistleblower: Exposing Autism Research Fraud at the CDC by Kevin Barry
- 2015: Vaccination Is Not Immunization by Dr. Tim O'Shea
- 2014: The Big Autism Cover-Up: How and Why the Media Is Lying to the American Public by Anne Dachel
- 2013: Dissolving Illusions, Disease Vaccines and the Forgotten History by Dr. Suzanne Humphries
- 2013: Vaccination Voodoo: What YOU Don't Know About Vaccines by Catherine J Frompovich
- 2011: The Vaccine Epidemic by Louise Kuo Habakus
- 2011: Vaccine-nation: Poisoning the Population, One Shot at a Time by Andreas Moritz
- 2010: What Your Doctor May Not Tell You About Children’s Vaccinations by Dr. Stephanie Cave MD and Deborah Mitchell
- 2008: Saying No to Vaccines: A Resource Guide for All Ages by Dr. Sherri J. Tenpenny
- 2005: The Virus and the Vaccine: Contaminated Vaccine, Deadly Cancers, and Government Neglect by Debbie Bookchin
- 1993: 100 Years of Orthodox Research, Vaccination: The Medical Assault on the Immune System by Dr. Viera Scheibner
- 1920: The Horrors of Vaccination by Charles Michael Higgins
MOVIES & VIDEOS:

- TRAGIC STORIES AND VIDEOS FROM PARENTS: https://vaccine-injury.info/about.cfm
- VACCINES REVEALED: https://www.vaccinesrevealed.com
- HEALING FROM VACCINES: https://healingfromvaccines.com/masterclass
- VAXXED: From Cover-up to Catastrophe http://vaxxedthemovie.com/
  - also see https://brightfuture83.wordpress.com/2016/05/17/infant-mortality-autismvaxxed-sterility/
- Interview: The History of Vaccines interview of Dr. Suzanne Humphries - http://articles.mercola.com/sites/articles/archive/2015/01/18/history-vaccination.aspx
- Shots in the Dark - Silence on Vaccines http://topdocumentaryfilms.com/shots-in-the-dark/
- Vaccine Nation https://www.youtube.com/watch?v=i8nrdybZZzA
- DPT: SHOTS IN THE DARK https://www.youtube.com/watch?v=VtOh6vFnWg4&app=desktop

ONLINE GROUPS & MORE INFORMATION:

- Pennsylvania
  - Health Alert Philly - http://www.healthalertphilly.org/VACCINES.htm
  - Coalition for Informed Consent - http://informedconsentpa.org
- National:
  - National Vaccine Information Center - http://www.nvic.org
  - Children’s Health Defense - https://childrenshealthdefense.org, Robert F. Kennedy, Jr., Founder
  - Vaccine Risk Awareness - http://vaccineriskawareness.com
  - Age of Autism - https://www.ageofautism.com/
  - VAXXTER: https://vaxxter.com Dr. Sherri Tenpenny’s website
  - Stop Mandatory Vaccination - http://www.stopmandatoryvaccination.com
  - Vaccination Liberation Army - http://www.vaclib.org (This website has lots of info, but not well organized)
  - Safe Minds - http://www.safeminds.org
  - Vaccine Truth - http://www.vaccinetruth.com

(more can be found online and at HealthAlertPhilly.org/VACCINES.htm)