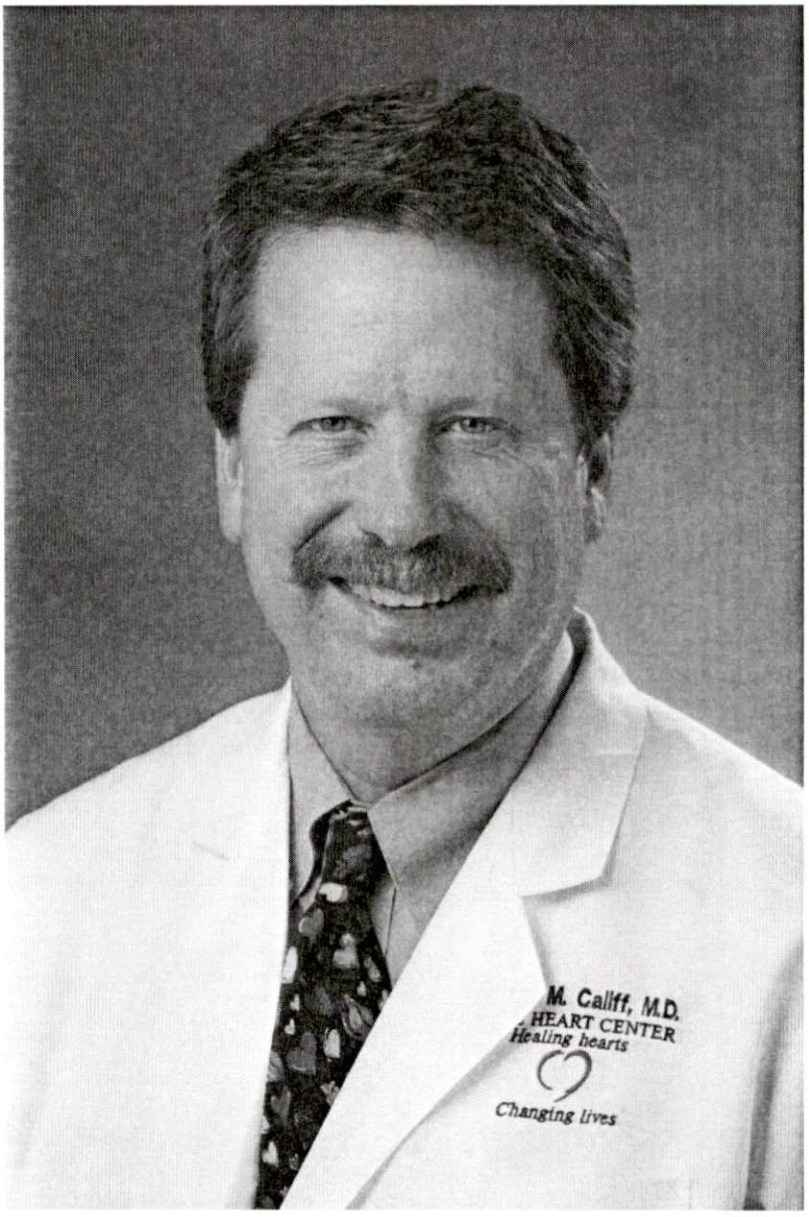
TIME

Candidate to Lead FDA Has Close Ties to Big Pharma



Dr. Robert Califf Jared Lazarus—Duke Photography

BY MASSIMO CALABRESI FEBRUARY 19, 2015

Last May, Duke University's Vice Chancellor for clinical research, Dr. Robert Califf, told an audience of executives that the American system for developing drugs and medical devices was in crisis. Using slides [pdf] developed by Duke's business school, he said the system was too slow and too expensive, and required disruption and transformation. Towards the end of his talk, he put up a slide that identified a key barrier to change: regulation.

Such views are not uncommon in industry, academic research and on Capitol Hill, but they are noteworthy coming from Califf because he could soon be America's top regulator overseeing the safety and efficacy of the country's drugs and medical devices. Califf is already set to become deputy commissioner at the Food and Drug Administration (FDA) next month. Now sources familiar with the process tell TIME he is on President Barack Obama's short list to run the agency following this month's announcement that its long-serving commissioner, Margaret Hamburg, will step down in March.

The White House declined to comment on pending personnel decisions, but word that Califf is in contention for the top spot at the FDA comes at a key moment. The agency faces potentially dramatic changes this year as Congress prepares to rewrite many of the rules for how drugs and medical devices are reviewed and tested for safety and efficacy. Califf is widely respected in the public and private sectors, but his candidacy is seen by some as a threat to the independence and authority of the FDA, thanks to his views on the need to accelerate change and his deep financial and intellectual ties to the pharmaceutical and medical device industries.

Califf says his salary is contractually underwritten in part by several large pharmaceutical companies, including Merck, Bristol-Myers Squibb, Eli Lilly and Novartis. He also receives as much as $100,000 a year in consulting fees from some of those companies, and from others, according to his 2014 conflict of

interest disclosure [pdf]. In an interview with TIME, Califf estimates that less than half of his annual income comes from research money provided by the pharmaceutical industry, though he says he is not certain because he doesn't tend to distinguish between industry and government research funding. He says he is divesting his holdings in two privately-held pharmaceutical companies he helped get off the ground.

Califf says such collaboration, not just between industry and academia, but with government, too, is the way of the future. "The greatest progress almost certainly will be made by breaking out of insular knowledge bases and collaborating across the different sectors," Califf says. He says there is "a tension which cannot be avoided between regulating an industry and creating the conditions where the industry can thrive, and the FDA's got to do both." He says it would be "useful to have someone [leading the FDA] who understands how companies operate because you're interacting with them all the time."

Diana Zuckerman, President of the National Center for Health Research, which advocates for FDA regulatory authority, says such ties "should be of great concern." Dr. Califf is "a very accomplished, smart physician who's been an important name in the field," Zuckerman says, but his "interdependent relationships" raise questions about his "objectivity and distance." She cites several studies suggesting the medical products industry uses such ties to influence the behavior and decision making of doctors and researchers, even when the scientists don't realize it.

The tension over Califf's collaboration with industry gets to the heart of the future of the FDA at a pivotal moment. While FDA defenders see the collaboration as a threat to its independence, others see close relationships between government, industry and academia as the model for the future. Califf heads a successful and powerful clinical research program, the Duke

Translational Medicine Institute, which brings together industry drug researchers, academic scientists and federal regulators to speed drug development and approval. Califf estimates 50-60% of its $320 million in annual research funding comes from industry.

Capitol Hill is considering codifying parts of that collaborative model for the FDA. The powerful Energy and Commerce Committee in the U.S. House of Representatives recently introduced a draft bill called 21st Century Cures, which would loosen the drug approval and post-market oversight process. Califf says because the bill is still in draft it is too early to pass an overall judgment on it but he says, "I support a lot of the concepts in the bill."

In the Senate, the Health, Education, Labor and Pensions (HELP) committee has begun work on its own bill, with committee chairman Lamar Alexander declaring, "It takes too long and costs too much to develop medical products." In a report paving the way for his legislation, Alexander concluded the FDA has grown too large, has fallen behind scientific innovation and threatens American leadership in biomedical innovation. Reform efforts in the Senate may be aided by the support of liberals like Elizabeth Warren who back looser regulations on the medical device industry.

The FDA uses a model for drug testing and oversight largely developed in the early 1960s, with phased trials before drugs and devices are approved for sale to ensure they are safe and effective, and "post-market" studies afterwards to monitor them. Over time, the agency has come to rely on the medical product industry for more than 60% of its budget for post-market monitoring. Accused of regulatory capture by those who see undue industry influence, the FDA has faced attacks from both sides.

That means the FDA has few defenders and will rely heavily on its next

commissioner to stand up for it in public and on Capitol Hill. "This is a very dangerous time for the agency," says Zuckerman of the National Center for Health Research, "It's under fire in a way that is unprecedented in the last 20 years."

Califf's supporters point out that he is among the ten most cited medical authors in America, and that he has spent his career as a clinician helping patients. Regarding the danger of regulators being "captured" by their interactions with industry, Califf says, "The difference between capture and collaboration towards improving human health is a pretty big difference."

The White House has set no time frame for its decision on Hamburg's replacement. It has announced the acting commissioner will be Dr. Stephen Ostroff, a scientist and long-time official at the Health and Human Services department, when she steps down in March.

Contact us at editors@time.com.

Shots

PUBLIC HEALTH

CDC Director Resigns Because Of 'Complex' Financial Entanglements

January 31, 2018 · 10:18 AM ET

JOE NEEL

Brenda Fitzgerald, Georgia Department of Public Health commissioner, and Gov. Nathan Deal respond to questions

about Ebola victims at Emory University Hospital and efforts to screen for Ebola in 2014. A report in *Politico* revealed documents showing several new investments, including in a tobacco company, by Centers for Disease Control and Prevention Director Brenda Fitzgerald.

David Tulis/AP

Dr. Brenda Fitzgerald, director of the Centers for Disease Control and Prevention, resigned Wednesday following reports that she bought shares in a tobacco company, among other financial dealings that presented a conflict of interest.

"Dr. Fitzgerald owns certain complex financial interests that have imposed a broad recusal limiting her ability to complete all of her duties as the CDC Director," according to a statement issued by Matt Lloyd, a spokesman for the Department of Health and Human Services. "Due to the nature of these financial interests, Dr. Fitzgerald could not divest from them in a definitive time period."

SHOTS - HEALTH NEWS

How To Drive Down Smoking In Groups That Still Light Up

A report in *Politico* published Tuesday revealed documents showing several new investments, including in a tobacco company, that Fitzgerald made after she took over the agency's top job. The CDC is a lead federal agency in preventing smoking and tobacco-related diseases.

Fitzgerald had come under fire on Capitol Hill for not divesting financial interests in other companies that present potential conflicts of interest, including drugmaker Merck, health insurer Humana and US Food Holding Co.

HEALTH

Trump Administration Appoints Dr. Brenda Fitzgerald As New CDC Director

LISTEN · 2:36 QUEUE Download Transcript

The *Politico* report, relying on documents obtained under the Freedom of Information Act, shows that one day after Fitzgerald purchased stock in Japan Tobacco, she toured the CDC's Tobacco Laboratory, which studies tobacco's toxic effects. She sold the tobacco shares on Oct. 26 and all of her stock holdings above $1,000 by Nov. 21, well into her term as CDC director.

Fitzgerald previous served as the commissioner of the Georgia Division of Public Health.

conflict of interest cigarettes tobacco cdc

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Thank you for taking the time to read my testimony.

I'm opposed to this bill for many reasons. If this bill gets passed the way it's written, I will be compelled to leave the state with my children. I'm literally a medical refugee from California. Throughout the bill, the word immunization is used synonymously with vaccination. They are overlapping terms. Immunization does not always follow vaccination. The have been numerous accounts of primary vaccine failure - failure to mount a protective immune response, as well as secondary vaccine failure - the gradual waning of the effect over time.
Besides that, there have been multiple disease outbreaks such as mumps, in which majority, if not all, of affected, had been vaccinated. Also, the pertussis vaccine has been shown to have the potential to spread from recently vaccinated individuals.

Section 1A, line 3, the amount of money this bill claims that vaccines save every year is very misleading. It doesn't take into account money paid out to vaccine injured children, as well as money spent on medical care for illnesses that may also be vaccine induced but have been not recognized by the vaccine court.
It also doesn't take into account that most of these communicable disease were redefined in stricter, more specific terms right after begin of vaccination for that particular disease, and thus the efficacy rates are skewed in favor of vaccination.

Section 3 (II) A, page 6 line 25/26. It requires the parent/guardian to submit a standardized form - I am absolutely opposed to this. If it is in any way similar to the form available today, it is very incriminating, and filled with incorrect/incomplete information. I have included a copy of the current form, highlighted the points I disagree with. Here are my corresponding footnotes:

1. The form claims that vaccines are one of the greatest public health achievements of the past century. The childhood diseases were no longer considered deadly before introduction of vaccines due to plumbing, sanitation, hygiene and better nutrition. Going through the natural course of measles, mumps, rubella, chickenpox diminishes the chance of having cancer later in life.
2. Vaccines are not tested against true placebos. I have provided a list of link to vaccine inserts (I did not have the resources to print the inserts, sorry). You can verify, for every vaccine on the list, the "control" group either received another vaccine or some of the adjuvants and ingredients in the vaccine. Also, the ingredients in the vaccines have not been tested for safety injection. Section 13.1 for each of these inserts states that the vaccine has not been tested for its carcinogenic properties.
   So, estimating that 3 million lives are saved every year from vaccines is based on the belief that vaccines are good. There is no factual science to support this.
3. Again, as the previous point. Yes, vaccines have been shown to prevent the diseases in most, for some time. But this statement is not acknowledging all the serious vaccine injuries, and death that can also be caused by vaccination.
4. "the benefits of preventing disease with a vaccine far outweighs the risks." We do not have double blind randomized controlled trials for vaccines. We have no comprehensive fully vaccinated vs nonvaccinated study for our current schedule, or, any schedule. I have included a pilot study of US 6 - 12 year old children, comparing their general health outcomes. The non vaccinated group did contract more communicable diseases, but were healthier overall in every other way. I have highlighted some interesting differences for you to glance at.

5. Declining the vaccine schedule "may endanger an unvaccinated child's health and others who come into contact with him/her." No. Based on my previous points, keeping my child unvaccinated is by far the less dangerous route for health to take. If any child is sick, they should be kept at home until recovered. This stands for all, vaccinated or not.
6. The information provided on these pages is very limited. The form does not inform of the risks of vaccination.

Forcing me to sign it in order to have kids attend in school is coercion, and I would be signing it under duress.
It seems to honor personal belief as well as religious exemption, but only if you let your child's info go into a tracking system.

Section 3 (II) , Page 5 line 24. Concerning medical exemptions, it takes away the doctor's authority to give one, because ACIP's acknowledgment of contraindication is so limited, even more than the CDC guidelines.
This bill is guaranteed to drive up personal belief as well as religious exemptions, because there will be vaccines added. Also, many the medical exemptions currently in place will no longer be valid as autoimmune issues, family history of vaccine injury and many more will not be recognized per ACIP guidelines.

How much money will have to be spent on this schooling, or re-education? This bill is attempting to "educate" many parents of children, many of whom have vaccine injured/killed children. A decision to not vaccinate is not taken lightly. This program will be a waste of money, time and effort. People who choose not to vaccinate have already made up their mind. No "schooling" will undo what I have learned through reading numerous books and studies, as well as my own observation of vaccinated and nonvaccinated childrens' health.

Until we are provided with an actual fully vaccinated vs non vaccinated comparison with long term health outcomes, the mantra vaccines are "safe and effective" is dubious at best.
Until the NCVIA of 1986, which shields manufacturers from liability, gets repealed, we won't know the true rate of adverse reactions to vaccines. I find it unethical to pass legislation that steps in direction of vaccine mandates (see California. This bill is similar to AB2109. Then SB77. and now SB276), providing only part of the information, knowing that under 1% of adverse reactions are ever reported to VAERS, knowing that the pharmaceutical companies that make these products, have no liability, do not test the vaccines for safety of injection versus actual inert placebo.

Thank you for reading my testimony.
Again, I urge you to please vote no on HB19-1312. We all want to act in the best interest for our children, and we all try our best to provide them with a healthy and safe environment.

Asia Mohammadi

Immunization

Non-Medical Exemption Form (Religious and Personal Belief)

Vaccines are one of the greatest public health achievements of the past century[1] and save an estimated 3 million children's lives[2] every year. The Colorado Department of Public Health and Environment strongly supports vaccination as one of the easiest and most effective tools in preventing diseases that can cause serious illness and even death.[3] For nearly all children, the benefits of preventing disease with a vaccine far outweigh the risks.[4] Declining to follow the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) immunization schedule for number, space and timing of doses, may endanger an unvaccinated child's health and others who come into contact with him/her.[5] Some vaccine-preventable diseases are common in other countries and unvaccinated children could easily get one of these diseases while traveling or from a traveler.

Colorado law C.R.S. § 25-4-902 requires all students attending any school in the state of Colorado to be vaccinated against certain vaccine-preventable diseases as established by Colorado Board of Health rule 6 CCR 1009-2, unless an exemption is filed. This law applies to students attending public, private and parochial kindergarten, elementary and secondary schools through 12th grade, colleges or universities, and child care facilities licensed by the Colorado Department of Human Services including child care centers, school-age child care centers, preschools, day camps, resident camps, day treatment centers, family child care homes, foster care homes, and Head Start programs. Prior to kindergarten, a non-medical exemption must be filed each time a student is due for vaccines according to the schedule developed by the ACIP.[1,2] From kindergarten through 12th grade, a non-medical exemption must be filed every year during the student's school enrollment/registration process.[1] Students with a recorded immunization exemption may be kept out of a child care facility or school during a disease outbreak; the length of time will vary depending on the type of the disease and the circumstances of the outbreak.

Please complete all required fields below; incomplete forms will not be accepted. *All fields are required unless noted optional.*

Type of Non-Medical Exemption Claimed: □ Personal Belief □ Religious

Student Information:

Last Name:	First Name:	(optional) Middle Name:
Gender: □ Female □ Male	Date of Birth:	
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

Parent/Guardian Completing This Form: □ Check if an emancipated student or student over 18 years old

Last Name:	First Name:	(optional) Middle Name:
Relationship to student: □ Mother □ Father □ Guardian		
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

School/Licensed Child Care Facility Information:

School Name/Licensed Child Care Facility:		
School District:		□ Check if Not Applicable
Address:		
City:	State:	Zip Code:
Phone Number:		Grade of Student:

[1] Colorado Board of Health rule 6 CCR 1009-2: https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=7698&fileName=6%20CCR%201009-2.

[2] 2018 Recommended Immunizations from Birth through 6 Years Old: www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf. Based on this schedule, a non-medical exemption would be submitted at 2 months, 4 months, 6 months, 12 months and 18 months of age.

Vaccine Preventable Disease Information

The information provided below is to ensure parents/guardians/students are informed about the risks of not vaccinating.

Diphtheria, tetanus, pertussis (DTaP, Tdap) - Unvaccinated children may be at increased risk of developing diphtheria, tetanus and/or pertussis if exposed to these diseases. Serious symptoms and effects of diphtheria include heart failure, paralysis, breathing problems, coma, and death. Serious symptoms and effects of tetanus include "locking" of the jaw, difficulty swallowing and breathing, seizures, painful tightening of muscles in the head and neck, and death. Serious symptoms and effects of pertussis (whooping cough) include severe coughing fits that can cause vomiting and exhaustion, pneumonia, seizures, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.pdf and http://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.pdf
Haemophilus influenzae type b (Hib) - Unvaccinated children may be at increased risk of developing invasive Hib disease if exposed to this disease. Serious symptoms and effects include bacterial meningitis, pneumonia, severe swelling in the throat, brain damage, deafness, infections of the blood, joints, bones, and covering of the heart, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hib.pdf
Hepatitis B - Unvaccinated children may be at increased risk of developing hepatitis B if exposed to this disease. Serious symptoms and effects include jaundice, life-long liver problems such as liver damage, scarring, liver cancer, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.pdf
Inactivated poliovirus (IPV) - Unvaccinated children may be at increased risk of developing polio if exposed to this disease. Serious symptoms and effects include paralysis of muscles that control breathing, meningitis, permanent disability, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/ipv.pdf
Measles, mumps, rubella (MMR) - Unvaccinated children may be at increased risk of developing measles, mumps, and/or rubella if exposed to these diseases. Serious symptoms and effects of measles include pneumonia, seizures, brain damage, and death. Serious symptoms and effects of mumps include meningitis, painful swelling of the testicles or ovaries, sterility, deafness, and death. Serious symptoms and effects of rubella include rash, arthritis, and muscle or joint pain. If a pregnant woman gets rubella, she could have a miscarriage or her baby could be born with serious birth defects such as deafness, heart problems, and mental retardation. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf
Pneumococcal conjugate (PCV13) - Unvaccinated children may be at increased risk of developing pneumococcal disease if exposed to this disease. Serious symptoms and effects include pneumonia, lung infections, blood infections, meningitis and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.pdf.
Varicella (chickenpox) - Unvaccinated children may be at increased risk of developing varicella if exposed to this disease. Serious symptoms and effects include severe skin infections, pneumonia, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.pdf

Required Vaccines for School Entry - Place an "X" next to each vaccine you are declining.

	Diphtheria, tetanus, pertussis (DTaP)		Inactivated poliovirus (IPV)
	Tetanus, diptheria, pertussis (Tdap)		Measles, mumps, rubella (MMR)
	Haemophilus influenzae type b (Hib)		Pneumococcal conjugate (PCV13)
	Hepatitis B		Varicella (chickenpox)

Statement of Exemption

I am the parent/guardian of the above-named student or am the student himself/herself (emancipated or over 18 years of age) and am declining the vaccine(s) indicated above due to a religious or personal belief that is opposed to vaccines. The information I have provided on this form is complete and accurate.

- I may change my mind at any time and accept vaccination(s) for my child/myself in the future.
- I can review evidence-based vaccine information at www.colorado.gov/cdphe/immunization-education, or www.ImmunizeforGood.com for additional information on the benefits and risks of vaccines and the diseases they prevent.
- I can contact the Colorado Immunization Information System (CIIS) at www.ColoradoIIS.com or my health care provider to locate my child's/my immunization record.[3]

I acknowledge that I have read this document in its entirety.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

(Optional) I authorize my/my student's school to share my/my student's immunization records with state/local public health agencies and the Colorado Immunization Information System, the state's secure, confidential immunization registry.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

[3] Under Colorado law, you have the option to exclude your child's/your information from CIIS at any time. To opt out of CIIS, go to www.colorado.gov/cdphe/ciis-opt-out-procedures. Please be advised you will be responsible for maintaining your child's/your immunization records to ensure school compliance.

Vaccination Quotes from Experts

"The decline in infectious diseases in developed countries had nothing to do with vaccinations, but with the decline in poverty and hunger."
–Dr. Gerhard Buchwald, MD

"Crib death" was so infrequent in the pre-vaccination era that it was not even mentioned in the statistics, but it started to climb in the 1950s with the spread of mass vaccination against diseases of childhood.
–Harris L. Coulter, PhD

"It is pathetic and ludicrous to say we ever vanquished smallpox with vaccines, when only 10% of the population was ever vaccinated."
–Dr. Glen Dettman

"Up to 90% of the total decline in the death rate of children between 1860-1965 because of whooping cough, scarlet fever, diphtheria, and measles occurred before the introduction of immunizations and antibiotics." –Dr. Archie Kalokerinos, MD

"We've got to stop calling chickenpox and measles diseases, because they're not. They're infections, and infections come and go in a week to ten days, and leave behind a lifetime of immunity. A disease is something that comes and stays, and frequently can't be cured. So when you vaccinate to avoid an infection, what you potentially are doing is causing a disease."
–Dr. Sherri J. Tenpenny D.O., Board Certified in Emergency Medicine and Osteopathic Manipulative Medicine

"I think that no person would permit anybody to get close to them with an inoculation if they would really know how they are made, what they carry, what has been lied to them about them and what the real percent of danger is of contracting such a disease which is minimal."
–Dr. Eva Snead

"In the Spring of 1948 measles was running in epidemic proportions in this section of the country. Our first act, then, was to have our own little daughters play with children known to be in the "contagious phase." When the syndrome of fever, redness of the eyes and throat, catarrh [inflammation of a mucous membrane], spasmodic bronchial cough, and Koplik spots [measles skin spots] had developed and the children were obviously sick, vitamin C was started. In this experiment it was found that 1000 mg every four hours, by mouth, would modify the attack . . . When 1000 mg was given every two hours all evidence of the infection cleared in 48 hours . . . the drug (vitamin C) was given 1000 mg every 2 hours around the clock for four days . . . These little girls did not develop the measles rash during the above experiment and although exposed many times since still maintain this "immunity."
–Fred R. Klenner, MD, "The Use of Vitamin C as an Antibiotic," Journal of Applied Nutrition – 1953.

"In a predictable reaction to the recent measles outbreaks, both Republicans and Democrats in Congress filed a "Vaccines Saves Lives" resolution last Friday. Claiming that there is "no credible evidence" that vaccines cause "life-threatening or disabling disease," the resolution interprets the vaccination issue as some kind of national security threat—thereby supposedly trumping your right to make informed decisions about your own and your children's health. If passed, this resolution will bolster the current backlash against vaccine exemptions and pave the way for states' efforts to mandate universal vaccinations."
–Alliance for Natural Health – February, 2015.

"The greatest threat of childhood diseases lies in the dangerous and ineffectual efforts made to prevent them through mass immunization.... There is no convincing scientific evidence that mass inoculations can be credited with eliminating any childhood disease."
–Dr. Robert Mendelsohn, MD

"Official data shows that large-scale vaccination has failed to obtain any significant improvement of the diseases against which they were supposed to provide protection"
–Dr. Sabin, developer of Polio vaccine.

"There is a great deal of evidence to prove that immunization of children does more harm than good."
–Dr. J. Anthony Morris (formerly Chief Vaccine Control Officer at the US Federal Drug Admin.)

"My suspicion, which is shared by others in my profession, is that the nearly 10,000 SIDS deaths that occur in the United States each year are related to one or more of the vaccines that are routinely given children. The pertussis vaccine is the most likely villain, but it could also be one or more of the others."
–Dr. Mendelsohn, MD

"The medical authorities keep lying. Vaccination has been a disaster on the immune system. It actually causes a lot of illnesses. We are changing our genetic code through vaccination."
–Guylaine Lanctot M.D., author of the best-seller 'Medical Mafia'

" You can't vaccinate believing that your children are protected and then feel that your children are not protected because somehow, some non-vaccinated child is carrying some secret organism that no one else is carrying. It just doesn't make any sense."
–Dr. Larry Palevsky, board-certified pediatrician

"My data proves that the studies used to support immunization are so flawed that it is impossible to say if immunization provides a net benefit to anyone or to society in general. This question can only be determined by proper studies which have never been performed. The flaw of previous studies is that there was no long term follow up and chronic toxicity was not looked at. The American Society of Microbiology has promoted my research…and thus acknowledges the need for proper studies."
–John B.Classen, M.D., M.B.A.

"If vaccines were good for us, there would be no reason for dishonesty and deceit."
–Joseph Mercola, DO

"The really sad thing is the amount of doctors who say to me, 'I know that vaccines are causing autism, but I won't say it on camera because the pharmaceutical industry will destroy my career just like they did to Andy Wakefield.'"
–Del Bigtree, Producer, Vaxxed

"No batch of vaccine can be proved safe before it is given to children."
— Surgeon General of the United States, Leonard Scheele, addressing an AMA convention in 1955.

"Congress needs to face the facts about vaccines. They are not 100% safe—nor are they guaranteed to stop diseases. From 2005 to 2014, no child in America died from measles, yet 108 babies died from the MMR (mumps, measles, rubella) vaccine. There is also an abundance of evidence that shows the dangers of exposure to even small amounts of mercury, which can still be found in flu vaccines. Mercury has been linked to severe neurological effects and even autism. Despite the widely touted belief that the link between vaccines and autism has been "debunked," researchers found eighty-three cases of autism among those compensated by the Vaccine Injury Compensation Program for vaccine-induced brain damage."
–Alliance for Natural Health – 2015.

"We predict that after a long disease-free period, the introduction of infection will lead to far larger epidemics than that predicted by standard models. "Large-scale epidemics can arise with the first substantial epidemic not arising until 52 years after the vaccination program has begun." [Guess what year 52 years from first created and licensed measles vaccine? 2015.]
–J.M. Herrernan Ph.D – 2009.

"Everyday millions of children are lined up and injected with toxic putrid substances grown on animal organs, cancer cells, aborted fetuses and other toxic substances. Few people are questioning how those viruses were obtained and how they were grown in a laboratory. If one would ask these sensible questions, one would become very enlightened about vaccine production. I warn you now, discussing vaccine-production will turn your stomach. Vaccines are made from the most vilest and filthiest substances on the earth. Since the definition of abomination is "anything that is filthy", the term describes vaccinations adequately and truthfully. The vaccine "cauldron" is full of putrid junk from bodies

exposed to disease and excreting morbid purulence. Science gathers this junk up in hopes of making vaccines for "preventing" disease; and we are being fooled while vaccinations cause increases in diseases."
–Dr. Joseph Mercola

"The fact is that many countries that call themselves free succumbed to medical dictatorship…people are sicker and less healthy…A country which mandates vaccination is not a free country…It is a country of zombies who do what they are told by vested interests who intimidate them and use them to make money."
–Dr. Viera Scheibner

"Parents are frightened into having their babies and children "immunized" against a whole series of diseases, having them inoculated with vaccines, serums, anti-toxins and toxoids of all kinds. The constant stream of propaganda carried on by the pharmaceutical houses and commercial medicine to keep this profitable business alive is filled with manufactured and "doctored" statistics, lies, distortions and statements designed to frighten parents. The whole purpose of this propaganda is not to secure the health and welfare of children, but to guarantee the steady inflow of profits to the physicians and manufacturing drug houses."
–Dr. Herbert Shelton

"There is no evidence whatsoever of the ability of vaccines to prevent any diseases. To the contrary, there is a great wealth of evidence that they cause serious side effects."
–Dr. Viera Scheibner

"[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."
–Suzanne Humphries, MD

"The explanation of an epidemic is simple, we are now seeing: 1 in 6 children with specific learning disabilities; 12-15% children with attention deficit disorder; 1 in 87 with autism spectrum – a 1700% increase over ten years; 1% sudden infant death; 40 deaths and 15,000 substantive adverse Gardasil reactions; 1 in 15 over 65 with dementia; 1 in 8 over 85; Chronic fatigue syndrome; Fibromyalgia; Seizure disorders; "West" syndrome Global developmental delay; 1 in 450 with type 1 diabetes; 1 in 2 men and 1 in 3 women will develop cancer over a lifetime; Gulf war syndrome affecting and disabling 250,000 troops and 42,000 deaths. These vaccinated soldiers show the exact same neurological damages after vaccination as the infants and children are exhibiting after each childhood vaccination. These are strokes – oxygen demand exceeding oxygen supply – conclusively! There is no such thing as an acquired genetic epidemic. The epidemic is an acquired phenomenon, from environmental factors, for which I can now conclusively show, vaccinations are the mass culprit for most of this."
–Dr. Andrew Moulden, PhD

"The 'victory over epidemics' was not won by medical science or by doctors–and certainly not by vaccines…..the decline…has been the result of technical, social and hygienic improvements and especially of improved nutrition. Here the role of the potato…deserves special mention…..Consider carefully whether you want to let yourself or your children undergo the dangerous, controversial, ineffective and no longer necessary procedure called vaccination, because the claim that vaccinations are the cause for the decline of infectious diseases is utter nonsense."–The Vaccination Nonsense (2004 Lectures)
–Dr. Med. G. Buchwald ISBN 3-8334-2508-3 page 108.

"There is no evidence that any influenza vaccine thus far developed is effective in preventing or mitigating any attack of influenza. The producers of these vaccines know that they are worthless, but they go on selling them, anyway."
–Dr. J. Anthony Morris (formerly Chief Vaccine Control Officer at the US Federal Drug Administration).

"But already before Salk developed his vaccine, polio had been constantly regressing; the 39 cases out of every 100,000 inhabitants registered in 1942 had gradually diminished from year to year until they were reduced to only 15 cases in 1952."
–M. Beddow Baylay, English surgeon and medical historian. Slaughter of the Innocent, Hans Reusch, Civitas Publishers, Switzerland, and Swain, New York, 1983.

"Operating on the false notion that universal vaccination will somehow arrest the advance of common disease (a reality readily proven false based on several examples, including the current flu vaccine which authorities admit will shield less than 18% of the vaccinated population from the flu), the new authoritarians demand that laws be passed to effectuate that objective, to compel against their will every man, woman, and child to be injected with vaccine…We must defend the rights of others to dissent against deprivations of right so that we may enjoy a like defense when we find ourselves out of step with the will of the majority."
–Jonathan Emord, Constitutional Attorney – 2015.

"If you want the truth on vaccination you must go to those who are not making anything out of it. If doctors shot at the moon every time it was full as a preventive of measles and got a shilling for it, they would bring statistics to prove it was a most efficient practice, and that the population would be decimated if it were stopped."
–Dr Allinson

"People ask why the 'real professionals' are not coming forth with the facts about vaccinations. The truth is that we are being given facts by the 'real professionals' – professionals that have absolutely nothing to profit from by telling the truth. Many doctors and practitioners, risking their professional status, are coming forth with research which is never told to the public. The safety concerns and protective ability of vaccinations have always been many. But, first and foremost, we should be very concerned about the current push to take away the personal freedom of choice which has many serious implications both for the present and future health of children and adults."
–Loretta Lanphier, NP, CN, CH – 2015.

"It's a socialist idea – herd mentality. You are at risk if you have evidence that is sufficient to show you are at risk. They say if you are not vaccinated you post a risk. But they are not proving it. They know scientifically that even if everyone is vaccinated, some will still contract the disease. It is impossible to ensure 100% vaccination. That would evoke the most gruesome police-state imaginable."
–Jonathan Emord, Constitutional Attorney – 2015.

"Industry has become FDA's client. People at FDA know that they have to be careful about upsetting industry" and that "even if a product doesn't work, . . . there is pressure on managers that gets transmitted down to reviewers to find some way of approving it."
–Dr. David B. Ross, Former FDA medical reviewer.

"Majorities are never the proof of truth."
–Dr. Walter R. Hadwen – 1896.

"Public health does not trump individual liberty."
–Lee Hieb, MD – 2015.

"I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless."
–David J. Graham, MD – Associate Director of the Food and Drug Administration's (FDA) Office of Drug Safety – 2004.

"FDA is inherently biased in favor of the pharmaceutical industry. It views industry as its client, whose interests it must represent and advance. It views its primary mission as approving as many drugs it can, regardless of whether the drugs are safe or needed."
–David J. Graham, MD – Associate Director of the Food and Drug Administrations's (FDA) Office of Drug Safety – 2005.

"When it comes to vaccinations, I just say NO. There are too many other options.

–Patrick Price, DC – 2015.

"There are 2 analogies I want to leave you with to illustrate the unreasonableness of CDER's (Center for Drug Evaluation and Research) standard of evidence as applied to safety, both pre- and post-approval. The second analogy is more graphic, but I think it brings home the point more clearly. Imagine for a moment that you have a pistol with a barrel having 100 chambers. Now, randomly place 95 bullets into those chambers. The gun represents a drug and the bullets represent a serious safety problem. Using CDER's standard, only when you have 95 bullets or more in the gun will you agree that the gun is loaded and a safety problem exists. Let's remove 5 bullets at random. We now have 90 bullets distributed across 100 chambers. Because there is only a 90% chance that a bullet will fire when I pull the trigger, CDER would conclude that the gun is not loaded and that the drug is safe."
–David J. Graham, MD – Associate Director of the Food and Drug Administrations' (FDA) Office of Drug Safety. Testimony before the U.S. Senate Committee on Finance – 2004.

"Jurist Oliver Wendelle Holmes Jr. decided that compulsory vaccination was constitutional under the 14th Amendment. His decision was a deviation from constitutional jurisprudence. Certainly some vaccines may be helpful and beneficial; however, individuals should not be compelled to vaccinate by the power of the state, particularly when well-known serious adverse reactions can occur. Rather than pushing mandatory vaccination, the government and medical establishment should devote resources to eliminating safety risks associated with vaccines."
–Jonathan Emord, Constitutional Attorney – 2015.

"Our children have the right to get infections. We have immune systems for that purpose… These are typically benign childhood conditions. We cannot sterilize the body [with vaccines]. We cannot sterilize our society. We need to be affected by these viruses… and we can treat it all naturally."
–Jack Wolfson, DO, cardiologist at Wolfson Integrative Cardiology, in a Jan. 29, 2015 CNN interview, "Watch Doctors Have Heated Debate over Vaccination."

"Medical and scientific research, as well as overwhelming clinical reports, have clearly demonstrated the potential for risk posed by many commonly administered vaccines. These same reports have indicated that the effectiveness of many of these vaccines has not been adequately proven. Based on such evidence, doctors of chiropractic have been joined by progressive medical doctors and public health administrators in questioning public policy regarding mandatory vaccines…It is the position of The World Chiropractic Alliance that… No person should be forced by government regulation or societal pressure to receive any medication or treatment, including vaccines, against his or her will. This includes mandated vaccines as a requirement for public school admission or for employment eligibility."
–The World Chiropractic Alliance – "Vaccinations and Freedom of Choice in Health Care" (accessed Aug. 21, 2014).

"AAPS does not oppose vaccines. AAPS has never taken an anti-vaccine position, although opponents have tried to paint that picture. AAPS has only attempted to halt government or school districts from blanket vaccine mandates that violate parental informed consent… The Centers for Disease Control admits that the reported number of adverse effects of vaccines is probably only 10% of actual adverse effects…Rampant conflicts of interest in the approval process has been the subject of several Congressional hearings, and a recent Congressional report concluded that the pharmaceutical industry has indeed exerted undue influence on mandatory vaccine legislation toward its own financial interests. The vaccine approval process has also been contaminated by flawed or incomplete clinical trials, and government officials have chosen to ignore negative results. For example, the CDC was forced to withdraw its recommendation of the rotavirus vaccine within one year of approval. Yet public documents obtained by AAPS show that the CDC was aware of alarmingly high intussuception rates months before the vaccine was approved and recommended. Mandatory vaccines violate the medical ethic of informed consent. A case could also be made that mandates for vaccines by school districts and legislatures is the de facto practice of medicine without a license."
–The Association of American Physicians and Surgeons (AAPS) – "Fact Sheet on Mandatory Vaccinations" Apr. 9, 2009.

"[W]e are standing publicly for the legal right to follow our conscience when making educated vaccine decisions for our families. Among us are parents with healthy children and those with children who have been hurt by one-size-fits-all vaccine mandates that ignore the genetic and biological differences which make some people more vulnerable than others for having severe reactions to prescription drugs and vaccines. No American should be legally forced to play vaccine roulette with a child's life…If we cannot be free to make informed, voluntary decisions about which pharmaceutical products we are willing to risk our lives for, then we are not free in any sense of the word. Because if

the State can tag, track down and force individuals against their will to be injected with biological products of unknown toxicity today, then there will be no limit on which individual freedoms the State can take away in the name of the greater good tomorrow."
–Barbara Loe Fisher, Co-founder and President of the National Vaccine Information Center – "Rally for Conscientious Exemption to Vaccination" Oct. 16, 2008.

"Prior to the universal varicella vaccination program, 95% of adults experienced natural chickenpox (usually as school aged children)—these cases were usually benign and resulted in long term immunity. This high percentage of individuals having long term immunity has been compromised by mass vaccination of children which provides at best 70 to 90% immunity that is temporary and of unknown duration—shifting chickenpox to a more vulnerable adult population where chickenpox carries 20 times more risk of death and 15 times more risk of hospitalization compared to children. Add to this the adverse effects of both the chickenpox and shingles vaccines as well as the potential for increased risk of shingles for an estimated 30 to 50 years among adults. The Universal Varicella (Chickenpox) Vaccination Program now requires booster vaccines; however, these are less effective than the natural immunity that existed in communities prior to licensure of the varicella vaccine."
–Gary S. Goldman, Ph.D.

"The original idea that vaccination could strengthen the herd's immunity, assumed that there was only one clinical event, and that one natural exposure equated life-long immunity. But this was not the case back when the diseases circulated freely. Vaccinators miss the point that the body defends most efficiently as a result of ongoing re-exposure. They try to mimic this with boosters. But the vaccination plan leaves the elderly(due to vaccine-induced immunity being short-lived and antigens taken out of circulation) and the very young(due to lack of transferable maternal immunity) more vulnerable to several diseases that were not a threat to them before vaccination. In the case of chicken pox, vaccination renders the elderly more apt to shingles infections, because the herd has now lost the continued and benign re-exposures to children with chicken pox."
–Suzanne Humphries, MD

"The formal demonstration that both maternal antibodies and early exposure to infection are required for long-term protection illustrated that constant re-infection cycles have an essential role in building a stable herd immunity. In a population that is not constantly exposed to the infection during early infancy under the immunologic umbrella of maternal antibodies or vaccinated thoroughly a serious risk of re-emerging infections may arise."
–Navarini AA et al. 2010. Long-lasting immunity by early infection of maternal-antibody-protected infants. Eur J Immunol. Jan;40(1):113-6. PMID: 19877011.

"I believe that when diseases disappear from sight, the disappearance is never solely by virtue of the vaccine. Yet the vaccine always gets the credit, because the blind faith in vaccines is prioritized over the scientific evidence. Evidence to the contrary of the value of vaccination is consistently snuffed out and kept away from the mainstream media, so that the herd never hears a peep of the truth. Instead, they get the "herd immunity" sound bite, which gives undeserved credit to the risk-benefit ratio of vaccination. Inside the web of half-truths and misinformation, the vaccine religion somehow justifies the public display of resentment and fear of the unvaccinated. "
–Suzanne Humphries, MD

"Vaccines are the most poisonous and dangerous health threat ever developed for children. They are designed to corrupt a pure mind, body and soul. We should have the natural right to choose what we put into our bodies. Nature is God's medicine!"
–Edward F. Group, III, DC, NP, DACBN, DCBCN, DABFM – 2015.

"Smallpox vaccination ended in the 1980s because smallpox had declined and because there was so much trouble with the old unsafe vaccine. That same trouble with the newer supposedly more safe smallpox vaccines is why smallpox vaccination ended after the 2003 first responder effort. Which makes you wonder just how much more trouble there was with the old smallpox vaccine which had a very long list of known bacterial and other "contaminants" because of its method of production. After the 2003 vaccines, reports of generalized vaccinia, autoinoculation, erythema multiforme, myopericarditis, ocular vaccinia, and postvaccinial encephalitis were reported. Smallpox was declared eradicated before clear distinctions between different poxviruses were made using DNA analysis. Symptoms alone are what were counted for smallpox during smallpox epidemics. Vaccination was a major source of smallpox

outbreaks, and only a small portion of the earth's entire herd was ever even vaccinated. Considering all of this, how can anyone believe that smallpox was eradicated with a vaccine?"
–Suzanne Humphries, MD

"I assert that it is beyond the functions of law to dictate a medical procedure, or enforce any scientific theory."
–Emeritus Professor F. W. Newman of University College, London – 1874.

"MLI (Measles-Like Illness) is common, particularly in younger age groups, and can be caused by a variety of pathogens that are difficult to differentiate clinically without laboratory guidance. In order of frequency, other common viral causes of rash-like illness – parvovirus B19, rubella, cytomegalovirus, and Epstein–Barr virus – were identified in our study."
–Wang, et al., "Evaluating measles surveillance using laboratory-discarded notifications of measles-like illness during elimination," Epidemiol. Infect. 2007, p. 1366.

"There is a terrible dichotomy between the information we as parents should expect from all the above-named sources, and what they give us – especially when you consider that there's not a doctor, nurse, pharmaceutical researcher or CVS pharmacist who can tell you, on a per-vaccination basis, whether your child will be susceptible to dire injury from the next administered vaccine, regardless of a history of ostensible non-reaction, because they don't know. Given the severity of the illnesses that can result from vaccines?"
–Shawn Siegel – Host of weekly radio/internet show, The Vaccine Myth: An Issue of Trust, on the Logos Radio Network.

"Most people in the U.S. do not even realize that U.S. law prevents anyone damaged by vaccines from suing the manufacturer. In 1986, Congress passed a law preventing legal liability to vaccine damages, because the drug companies manufacturing vaccines blackmailed them, by threatening to stop manufacturing vaccines without legal protection. There were so many lawsuits resulting from vaccine injuries and deaths prior to this time, that it was no longer profitable for them to continue marketing vaccines without legal protection. So instead of Congress requiring that drug companies manufacture safer vaccines, they complied with the drug companies' requests and passed legislation protecting the drug companies. In 2011 this law was upheld by the U.S. Supreme Court."
–Health Impact News – 2015.

"Any system of public health policy (vaccination policy in particular) requires the cooperation and trust of the public in the policy makers. If you have a situation to where you have to mandate vaccines, with very few exemptions, where in order to get social security benefits or to get your children into school, they have to be vaccinated according to the recommend schedule, this is not a measure of the success of the program, but a measure of its failure. The system in this country is failing very, very badly. The regulators have had a choice 1) to be honest and transparent with the public or 2) to lie and deceive the public and to increase the stringency of the mandates that they have enforced. That is the erroneous cost they have chosen to take and they have done so largely, I believe, in the interest of the pharmaceutical industry who are desperate to protect their profits. And also to cover up the extent to which the diseases they are vaccinating against are nowhere near as severe as they say…If we do not win this battle right now, we and our children's children will be owned by the pharmaceutical industry."
–Dr. Andrew Wakefield, leading expert in gut health – 2015.

"One of the 5 studies used to dismiss the vaccine-autism link was co-authored by Dr. Poul Thorsen, who has collaborated with the CDC from 1998 to the present time. Dr. Thorsen is featured on the Department of Health and Human Services Office of Inspector General's Most Wanted Fugitive List as he was indicted on April 14, 2011 by a Federal grand jury on 22 counts of fraud and embezzlement. Dr. Thorsen was installed as the lead investigator for a cohort of scientists from Denmark to investigate the vaccine autism link using Danish databases. Thorsen's work was funded by a CDC grant of over $10 million dollars. Most of the funds were disbursed after he coauthored the aforementioned thimerosal-autism paper, which was reviewed prior to publication by Dr. Diana Schendel. While compiling the results for this publication, Denmark researchers deliberately withheld critical data that would have revealed a decline in autism rates in Denmark after mercury-containing vaccines were removed from the Danish childhood vaccine schedule in 1992. The manuscript was initially rejected by the Journal of the American Medical Association and the Lancet, leading medical journals. Dr. Coleen Boyle of the CDC then took the unusual action of advocating for the paper by submitting a letter pushing for expedited review by the journal Pediatrics. The letter was signed by Dr. Jose Cordero, then Director of the CDC National Center for Birth Defects and Developmental

Disabilities. Dr. Thorsen has coauthored 36 peer-reviewed publications in collaboration with the CDC. Since his indictment by a Federal Grand Jury for fraud, he has coauthored four papers in collaboration with Dr. Schendel. Why is the branch of the CDC charged with responsibility for autism research collaborating with a fugitive charged with defrauding the very agency, the CDC, engaging in this critically important research? Why haven't any of his studies been retracted or been subjected to review?"
–Brian Hooker, Ph.D. Written testimony submitted to Congress – Autism Hearing – November, 2012.

"Let's be honest. The falling vaccination rate is hurting Big Pharma a heck of a lot more than it's hurting us. And that's what this is REALLY about — drug companies manipulating our government because they're worried they won't recoup the BILLIONS they spent developing vaccines we don't want. Well, the next time CDC gets an urge to write a report, maybe it should read the Declaration of Independence first. Because there's a little clause in there promising each of us life, liberty and the pursuit of happiness. As in it's your life, and you have the liberty to choose what you put into your body. And I don't give a damn whether our government is happy about it or not."
–Dr. William Campbell Douglass II – The Douglass Report – 2014.

"As a concerned, compassionate and considerate paediatrician, I can only arrive at one conclusion. Unvaccinated children have by far the best chance of enjoying marvelous health. Any vaccination at all works to cripple the chances of this end."
–Françoise Berthoud, MD [paediatrician] – 2010.

The U.S. vaccine market will grow at a CAGR of 5.3% between 2012 and 2018. The market, which valued US$12.8 billion in 2012, will reach US$17.4 billion by 2018. Pediatric vaccines were the leading sub-segment of the human vaccine segment in 2012. The segment of pediatric vaccines currently has an impressive share of the market and holds good future prospects owing to government compulsion for immunizing children in the U.S."
–Transparency Market Research, Mar. 19 2015.

The Theory of 'Herd Immunity. "As we see with the continual [measles] outbreaks, even at 95%, we still do not have full immunity. In China, the vaccination rates are even higher – 99%. But there are also still measles outbreaks there. So is the answer 100%? And what if at 100% you still get outbreaks? We've gone from herd immunity supposedly achieved at 55% to herd immunity that is clearly not achieved even at 95%. At what point will public health officials have to confront the possibility that herd immunity may not be the best theory on which to base vaccination policy?
–Marco Cacere, Author

"During the National Vaccine Advisory Committee's (NVAC) February 2015 meeting, American adults were put on notice by Big Brother that non-compliance with federal vaccine recommendations will not be tolerated. Make no mistake about this plan's [Healthy People 2020 Goals – adult immunization plan] intent, if "awareness" efforts and "incentivization" of vaccine policy do not increase adult vaccine uptake, the partnering with your employer and other community groups is meant to lower the hammer and force you to comply. The electronic tracking systems that are enthusiastically being embraced by not only the federal government but also state governments and employers, without regard for your privacy, will be used to identify noncompliers."
–Theresa Wrangham – NVIC Executive Director – 2015.

"Vaccination Is Not Immunization. When vaccines are effective, they do not confer complete or "natural" immunity. This is well-known, but hardly ever explained to parents and others. In fact, vaccines only confer an artificial, partial or temporary immunity. The only way to obtain full immunity from an infectious illness is if one actually goes through the illness and recovers fully. Vaccine-based "immunity", by way of contrast, diminishes in its protective effect after one or more years, assuming it was effective at all. As stated in an earlier section of this article, one does not know if one's vaccination was or is ever effective or not. There is no easy way to tell."
–Lawrence Wilson, MD – 2015.

"Researchers are now realizing that B. pertussis bacteria have evolved and become vaccine resistant. It is reminiscent of the way that bacteria have become resistant to antibiotics, thanks to the massive overuse of antibiotics in food production…A lowered risk [from a vaccine] might sound like a good thing, but if bacteria and viruses are evolving and becoming vaccine resistant, mirroring what we're seeing with growing resistance against antibiotics, the entire vaccine program would need a serious review. What if we're misusing vaccines like we've misused antibiotics, creating far worse diseases and reduced immune function in the process?"

–Joseph Mercola, DO – 2015.

"40 years ago when I started my practice, only 1 in 10,000 children had autism. Today it's 1 in 100. What is the only difference we have seen? The inordinate number of vaccines that are being given to children today. My partners and I have over 35,000 patients who have never been vaccinated. You know how many cases of autism we have seen? ZERO, ZERO. I have made this statement for over 40 years: 'NO VACCINES, NO AUTISM'."
–Dr. Mayer Eisenstein, MD

"I predict that Gardasil will become the greatest medical scandal of all time because at some point in time, the evidence will add up to prove that this vaccine, technical and scientific feat that it may be, has absolutely no effect on cervical cancer and that all the very many adverse effects which destroy lives and even kill, serve no other purpose than to generate profit for the manufacturers. Gardasil is useless and costs a fortune! In addition, decision-makers at all levels are aware of it! Cases of Guillain-Barré syndrome, paralysis of the lower limbs, vaccine-induced MS, and vaccine-induced encephalitis can be found, whatever the vaccine."
–Dr. Bernard Dalbergue, former Merck physician

from https://oawhealth.com/2015/04/01/vaccination-quotes-from-experts/

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Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

Anthony R Mawson[1]*, Brian D Ray[2], Azad R Bhuiyan[3] and Binu Jacob[4]

[1]Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[2]President, National Home Education Research Institute, PO Box 13939, Salem, OR 97309, USA

[3]Associate Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[4]Former graduate student, Department of Epidemiology and Biostatistics School of Public Health, Jackson State University, Jackson, MS 39213, USA

Abstract

Vaccinations have prevented millions of infectious illnesses, hospitalizations and deaths among U.S. children, yet the long-term health outcomes of the vaccination schedule remain uncertain. Studies have been recommended by the U.S. Institute of Medicine to address this question. This study aimed 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, and 2) to determine whether an association found between vaccination and neurodevelopmental disorders (NDD), if any, remained significant after adjustment for other measured factors. A cross-sectional study of mothers of children educated at home was carried out in collaboration with homeschool organizations in four U.S. states: Florida, Louisiana, Mississippi and Oregon. Mothers were asked to complete an anonymous online questionnaire on their 6- to 12-year-old biological children with respect to pregnancy-related factors, birth history, vaccinations, physician-diagnosed illnesses, medications used, and health services. NDD, a derived diagnostic measure, was defined as having one or more of the following three closely-related diagnoses: a learning disability, Attention Deficient Hyperactivity Disorder, and Autism Spectrum Disorder. A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated. The vaccinated were less likely than the unvaccinated to have been diagnosed with chickenpox and pertussis, but more likely to have been diagnosed with pneumonia, otitis media, allergies and NDD. After adjustment, vaccination, male gender, and preterm birth remained significantly associated with NDD. However, in a final adjusted model with interaction, vaccination but not preterm birth remained associated with NDD, while the interaction of preterm birth and vaccination was associated with a 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5). In conclusion, vaccinated homeschool children were found to have a higher rate of allergies and NDD than unvaccinated homeschool children. While vaccination remained significantly associated with NDD after controlling for other factors, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD. Further research involving larger, independent samples and stronger research designs is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health.

Abbreviations: ADHD: Attention Deficit Hyperactivity Disorder; ASD: Autism Spectrum Disorder; AOM: Acute Otitis Media; CDC: Centers for Disease Control and Prevention; CI: Confidence Interval; NDD: Neurodevelopmental Disorders; NHERI: National Home Education Research Institute; OR: Odds Ratio; PCV-7: Pneumococcal Conjugate Vaccine-7; VAERS: Vaccine Adverse Events Reporting System.

Introduction

Vaccines are among the greatest achievements of biomedical science and one of the most effective public health interventions of the 20th century [1]. Among U.S. children born between 1995 and 2013, vaccination is estimated to have prevented 322 million illnesses, 21 million hospitalizations and 732,000 premature deaths, with overall cost savings of $1.38 trillion [2]. About 95% of U.S. children of kindergarten age receive all of the recommended vaccines as a requirement for school and daycare attendance [3,4], aimed at preventing the occurrence and spread of targeted infectious diseases [5]. Advances in biotechnology are contributing to the development of new vaccines for widespread use [6].

Under the currently recommended pediatric vaccination schedule [7], U.S. children receive up to 48 doses of vaccines for 14 diseases from birth to age six years, a figure that has steadily increased since the 1950s, most notably since the Vaccines for Children program was created in 1994. The Vaccines for Children program began with vaccines targeting nine diseases: diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b disease, hepatitis B, measles, mumps, and rubella. Between 1995 and 2013, new vaccines against five other diseases were added for children age 6 and under: varicella, hepatitis A, pneumococcal disease, influenza, and rotavirus vaccine.

Although short-term immunologic and safety testing is performed on vaccines prior to their approval by the U.S. Food and Drug Administration, the long-term effects of individual vaccines and of the vaccination program itself remain unknown [8]. Vaccines are acknowledged to carry risks of severe acute and chronic adverse effects, such as neurological complications and even death [9], but such risks are considered so rare that the vaccination program is believed to be safe and effective for virtually all children [10].

There are very few randomized trials on any existing vaccine recommended for children in terms of morbidity and mortality, in

Correspondence to: Anthony R Mawson, Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA, E-mail: Anthony.r.mawson@jsums.edu

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part because of ethical concerns involving withholding vaccines from children assigned to a control group. One exception, the high-titer measles vaccine, was withdrawn after several randomized trials in west Africa showed that it interacted with the diphtheria-tetanus-pertussis vaccine, resulting in a significant 33% increase in child mortality [11]. Evidence of safety from observational studies includes a limited number of vaccines, e.g., the measles, mumps and rubella vaccine, and hepatitis B vaccine, but none on the childhood vaccination program itself. Knowledge is limited even for vaccines with a long record of safety and protection against contagious diseases [12]. The safe levels and long-term effects of vaccine ingredients such as adjuvants and preservatives are also unknown [13]. Other concerns include the safety and cost-effectiveness of newer vaccines against diseases that are potentially lethal for individuals but have a lesser impact on population health, such as the group B meningococcus vaccine [14].

Knowledge of adverse events following vaccinations is largely based on voluntary reports to the Vaccine Adverse Events Reporting System (VAERS) by physicians and parents. However, the rate of reporting of serious vaccine injuries is estimated to be <1% [15]. These considerations led the former Institute of Medicine (now the National Academy of Medicine) in 2005 to recommend the development of a five-year plan for vaccine safety research by the Centers for Disease Control and Prevention (CDC) [16,17]. In its 2011 and 2013 reviews of the adverse effects of vaccines, the Institute of Medicine concluded that few health problems are caused by or associated with vaccines, and found no evidence that the vaccination schedule was unsafe [18,19]. Another systematic review, commissioned by the US Agency for Healthcare Research and Quality to identify gaps in evidence on the safety of the childhood vaccination program, concluded that severe adverse events following vaccinations are extremely rare [20]. The Institute of Medicine, however, noted that studies were needed: to compare the health outcomes of vaccinated and unvaccinated children; to examine the long-term cumulative effects of vaccines; the timing of vaccination in relation to the age and condition of the child; the total load or number of vaccines given at one time; the effect of other vaccine ingredients in relation to health outcomes; and the mechanisms of vaccine-associated injury [19].

A complicating factor in evaluating the vaccination program is that vaccines against infectious diseases have complex nonspecific effects on morbidity and mortality that extend beyond prevention of the targeted disease. The existence of such effects poses a challenge to the assumption that individual vaccines affect the immune system independently of each other and have no physiological effect other than protection against the targeted pathogen [21]. The nonspecific effects of some vaccines appear to be beneficial, while in others they appear to increase morbidity and mortality [22,23]. For instance, both the measles and Bacillus Calmette–Guérin vaccine reportedly reduce overall morbidity and mortality [24], whereas the diphtheria-tetanus-pertussis [25] and hepatitis B vaccines [26] have the opposite effect. The mechanisms responsible for these nonspecific effects are unknown but may involve *inter alia*: interactions between vaccines and their ingredients, e.g., whether the vaccines are live or inactivated; the most recently administered vaccine; micronutrient supplements such as vitamin A; the sequence in which vaccines are given; and their possible combined and cumulative effects [21].

A major current controversy is the question of whether vaccination plays a role in neurodevelopmental disorders (NDDs), which broadly include learning disabilities, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD). The controversy has been fueled by the fact that the U.S. is experiencing what has been described as a "silent pandemic" of mostly subclinical developmental neurotoxicity, in which about 15% of children suffer from a learning disability, sensory deficits, and developmental delays [27,28]. In 1996 the estimated prevalence of ASD was 0.42%. By 2010 it had risen to 1.47% (1 in 68), with 1 in 42 boys and 1 in 189 girls affected [29]. More recently, based on a CDC survey of parents in 2011–2014, 2.24% of children (1 in 45) were estimated to have ASD. Rates of other developmental disabilities, however, such as intellectual disability, cerebral palsy, hearing loss, and vision impairments, have declined or remained unchanged [30]. Prevalence rates of Attention Deficit Hyperactivity Disorder (ADHD) have also risen markedly in recent decades [31]. Earlier increases in the prevalence of learning disability have been followed by declining rates in most states, possibly due to changes in diagnostic criteria [32].

It is believed that much of the increase in NDD diagnoses in recent decades has been due to growing awareness of autism and more sensitive screening tools, and hence to greater numbers of children with milder symptoms of autism. But these factors do not account for all of the increase [33]. The geographically widespread increase in ASD and ADHD suggests a role for an environmental factor to which virtually all children are exposed. Agricultural chemicals are a current focus of research [34-37].

A possible contributory role for vaccines in the rise in NDD diagnoses remains unknown because data on the health outcomes of vaccinated and unvaccinated children are lacking. The need for such studies is suggested by the fact that the Vaccine Injury Compensation Program has paid $3.2 billion in compensation for vaccine injury since its creation in 1986 [38]. A study of claims compensated by the Vaccine Injury Compensation Program for vaccine-induced encephalopathy and seizure disorder found 83 claims that were acknowledged as being due to brain damage. In all cases it was noted by the Court of Federal Claims, or indicated in settlement agreements, that the children had autism or ASD [39]. On the other hand, numerous epidemiological studies have found no association between receipt of selected vaccines (in particular the combined measles, mumps, and rubella vaccine) and autism [10,40-45], and there is no accepted mechanism by which vaccines could induce autism [46].

A major challenge in comparing vaccinated and unvaccinated children has been to identify an accessible pool of unvaccinated children, since the vast majority of children in the U.S. are vaccinated. Children educated at home ("homeschool children") are suitable for such studies as a higher proportion are unvaccinated compared to public school children [47]. Homeschool families have an approximately equal median income to that of married-couple families nationwide, somewhat more years of formal education, and a higher average family size (just over three children) compared to the national average of just over two children [48-50]. Homeschooling families are slightly overrepresented in the south, about 23% are nonwhite, and the age distribution of homeschool children in grades K-12 is similar to that of children nationwide [51]. About 3% of the school-age population was homeschooled in the 2011-2012 school year [52].

The aims of this study were 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, including acute and chronic conditions, medication and health service utilization, and 2) to determine whether an association found between vaccination and NDDs, if any, remained significant after adjustment for other measured factors.

Methods

Study planning

To implement the study, a partnership was formed with the National Home Education Research Institute (NHERI), an organization that has been involved in educational research on homeschooling for many years and has strong and extensive contacts with the homeschool community throughout the country (www.nheri.org). The study protocol was approved by the Institutional Review Board of Jackson State University.

Study design

The study was designed as a cross-sectional survey of homeschooling mothers on their vaccinated and unvaccinated biological children ages 6 to 12. As contact information on homeschool families was unavailable, there was no defined population or sampling frame from which a randomized study could be carried out, and from which response rates could be determined. However, the object of our pilot study was not to obtain a representative sample of homeschool children but a convenience sample of unvaccinated children of sufficient size to test for significant differences in outcomes between the groups.

We proceeded by selecting 4 states (Florida, Louisiana, Mississippi, and Oregon) for the survey (Stage 1). NHERI compiled a list of statewide and local homeschool organizations, totaling 84 in Florida, 18 in Louisiana, 12 in Mississippi and 17 in Oregon. Initial contacts were made in June 2012. NHERI contacted the leaders of each statewide organization by email to request their support. A second email was then sent, explaining the study purpose and background, which the leaders were asked to forward to their members (Stage 2). A link was provided to an online questionnaire in which no personally identifying information was requested. With funding limited to 12 months, we sought to obtain as many responses as possible, contacting families only indirectly through homeschool organizations. Biological mothers of children ages 6-12 years were asked to serve as respondents in order to standardize data collection and to include data on pregnancy-related factors and birth history that might relate to the children's current health. The age-range of 6 to 12 years was selected because most recommended vaccinations would have been received by then.

Recruitment and informed consent

Homeschool leaders were asked to sign Memoranda of Agreement on behalf of their organizations and to provide the number of member families. Non-responders were sent a second notice but few provided the requested information. However, follow-up calls to the leaders suggested that all had contacted their members about the study. Both the letter to families and the survey questions were stated in a neutral way with respect to vaccines. Our letter to parents began:

"Dear Parent, This study concerns a major current health question: namely, whether vaccination is linked in any way to children's long-term health. Vaccination is one of the greatest discoveries in medicine, yet little is known about its long-term impact. The objective of this study is to evaluate the effects of vaccination by comparing vaccinated and unvaccinated children in terms of a number of major health outcomes ..."

Respondents were asked to indicate their consent to participate, to provide their home state and zip code of residence, and to confirm that they had biological children 6 to 12 years of age. The communications company Qualtrics (http://qualtrics.com) hosted the survey website. The questionnaire included only closed-ended questions requiring yes or no responses, with the aim of improving both response and completion rates.

A number of homeschool mothers volunteered to assist NHERI promote the study to their wide circles of homeschool contacts. A number of nationwide organizations also agreed to promote the study in the designated states. The online survey remained open for three months in the summer of 2012. Financial incentives to complete the survey were neither available nor offered.

Definitions and measures

Vaccination status was classified as unvaccinated (i.e., no previous vaccinations), partially vaccinated (received some but not all recommended vaccinations) and fully vaccinated (received all recommended age-appropriate vaccines), as reported by mothers. These categories were developed on the premise that any long-term effects of vaccines would be more evident in fully-vaccinated than in partially-vaccinated children, and rare or absent in the unvaccinated. Mothers were asked to use their child's vaccination records to indicate the recommended vaccines and doses their child had received. Dates of vaccinations were not requested in order not to overburden respondents and to reduce the likelihood of inaccurate reporting; nor was information requested on adverse events related to vaccines, as this was not our purpose. We also did not ask about dates of diagnoses because chronic illnesses are often gradual in onset and made long after the appearance of symptoms. Since most vaccinations are given before age 6, vaccination would be expected to precede the recognition and diagnosis of most chronic conditions.

Mothers were asked to indicate on a list of more than 40 acute and chronic illnesses all those for which her child or children had received a diagnosis by a physician. Other questions included the use of health services and procedures, dental check-ups, "sick visits" to physicians, medications used, insertion of ventilation ear tubes, number of days in the hospital, the extent of physical activity (number of hours the child engaged in "vigorous" activities on a typical weekday), number of siblings, family structure (mother and father living in the home, divorced or separated), family income and/or highest level of education of mother or father, and social interaction with children outside the home (i.e., amount of time spent in play or other contact with children outside the household). Questions specifically for the mother included pregnancy-related conditions and birth history, use of medications during pregnancy, and exposure to an adverse environment (defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory). NDD, a derived diagnostic category, was defined as having one or more of the following three closely related and overlapping diagnoses: a learning disability, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD) [53].

Statistical methods

Unadjusted bivariate analyses using chi-square tests were performed initially to test the null hypothesis of no association between vaccination status and health outcomes, i.e., physician-diagnosed acute and chronic illnesses, medications, and the use of health services. In most analyses, partially and fully vaccinated children were grouped together as the "vaccinated" group, with unvaccinated children as the control group. The second aim of the study was to determine whether any association found between vaccination and neurodevelopmental disorders remained significant after controlling for other measured factors. Descriptive statistics on all variables were computed to determine frequencies and percentages for categorical variables and means (± SD) for continuous variables. The strength of associations

between vaccination status and health outcomes were tested using odds ratios (OR) and 95% Confidence Intervals (CI). Odds ratios describe the strength of the association between two categorical variables measured simultaneously and are appropriate measures of that relationship in a cross-sectional study [54]. Unadjusted and adjusted logistic regression analyses were carried out using SAS (Version 9.3) to determine the factors associated with NDDs.

Results

Socio-Demographic characteristics of respondents

The information contained in 415 questionnaires provided data on 666 homeschool children. Table 1 shows the characteristics of the survey respondents. Mothers averaged about 40 years of age, were typically white, college graduates, with household incomes between $50,000 to $100,000, Christian, and married. The reasons for homeschooling for the majority of respondents (80-86%) were for a moral environment, better family relationships, or for more contact with their child or children.

The children as a group were similarly mostly white (88%), with a slight preponderance of females (52%), and averaged 9 years of age. With regard to vaccination status, 261 (39%) were unvaccinated, 208 (31%) were partially vaccinated, and 197 (30%) had received all of the recommended vaccinations. All statistical analyses are based on these numbers.

Acute illness

Vaccinated children (N=405), combining the partially and fully vaccinated, were significantly less likely than the unvaccinated to have had chickenpox (7.9% vs. 25.3%, p <0.001; Odds Ratio = 0.26, 95% Confidence Interval: 0.2, 0.4) and whooping cough (pertussis) (2.5% vs. 8.4%, p <0.001; OR 0.3, 95% CI: 0.1, 0.6), and less likely, but not significantly so, to have had rubella (0.3% vs. 1.9%, p = 0.04; OR 0.1, 95% CI: 0.01, 1.1). However, the vaccinated were significantly more likely than the unvaccinated to have been diagnosed with otitis media (19.8% vs. 5.8%, p <0.001; OR 3.8, 95% CI: 2.1, 6.6) and pneumonia (6.4% vs. 1.2%, p = 0.001; OR 5.9, 95% CI: 1.8, 19.7). No significant differences were seen with regard to hepatitis A or B, high fever in the past 6 months, measles, mumps, meningitis (viral or bacterial), influenza, or rotavirus (Table 2).

Chronic illness

Vaccinated children were significantly more likely than the unvaccinated to have been diagnosed with the following: allergic rhinitis (10.4% vs. 0.4%, p <0.001; OR 30.1, 95% CI: 4.1, 219.3), other allergies (22.2% vs. 6.9%, p <0.001; OR 3.9, 95% CI: 2.3, 6.6), eczema/atopic dermatitis (9.5% vs. 3.6%, p = 0.035; OR 2.9, 95% CI: 1.4, 6.1), a learning disability (5.7% vs. 1.2%, p = 0.003; OR 5.2, 95% CI: 1.6, 17.4), ADHD (4.7% vs. 1.0%, p = 0.013; OR 4.2, 95% CI: 1.2, 14.5), ASD (4.7% vs. 1.0%, p = 0.013; OR 4.2, 95% CI: 1.2, 14.5), any neurodevelopmental disorder (i.e., learning disability, ADHD or ASD) (10.5% vs. 3.1%, p <0.001; OR 3.7, 95% CI: 1.7, 7.9) and any chronic illness (44.0% vs. 25.0%, p <0.001; OR 2.4, 95% CI: 1.7, 3.3). No significant differences were observed with regard to cancer, chronic fatigue, conduct disorder, Crohn's disease, depression, Types 1 or 2 diabetes, encephalopathy, epilepsy, hearing loss, high blood pressure, inflammatory bowel disease, juvenile rheumatoid arthritis, obesity, seizures, Tourette's syndrome, or services received under the Individuals with Disabilities Education Act (Table 3).

Partial *versus* full vaccination

Partially vaccinated children had an intermediate position between the fully vaccinated and unvaccinated in regard to several but not all health outcomes. For instance, as shown in Table 4, the partially vaccinated had an intermediate (apparently detrimental) position in terms of allergic rhinitis, ADHD, eczema, and learning disability.

Gender differences in chronic illness

Among the vaccinated (combining partially and fully vaccinated children), boys were more likely than girls to be diagnosed with a chronic condition – significantly so in the case of allergic rhinitis (13.9% vs. 7.2%, p = 0.03; OR 2.1, 95% CI: 1.1, 4.1), ASD (7.7% vs. 1.9%, p = 0.006; OR 4.3, 95% CI: 1.4, 13.2), and any neurodevelopmental disorder (14.4% vs. 6.7%, p = 0.01; OR 2.3, 95% CI: 1.2, 4.6) (Table 5).

Use of medications and health services

The vaccinated (combining the partially and fully vaccinated) were significantly more likely than the unvaccinated to use medication for allergies (20.0% vs. 1.2%, p <0.001; OR 21.5, 95% CI: 6.7, 68.9), to have used antibiotics in the past 12 months (30.8% vs. 15.4%, p <0.001; OR 2.4, 95% CI: 1.6, 3.6), and to have used fever medications at least once (90.7% vs. 67.8%, p <0.001; OR 4.6, 95% CI: 3.0, 7.1). The vaccinated were also more likely to have seen a doctor for a routine checkup in the past 12 months (57.6% vs. 37.2%, p <0.001; OR 2.3, 95% CI: 1.7, 3.2), visited a dentist during the past year (89.4% vs. 80.5%, p <0.001; OR 2.0, 95% CI: 1.3, 3.2), visited a doctor or clinic due to illness in the past year (36.0% vs. 16.0%, p <0.001; OR 3.0, 95% CI: 2.0, 4.4), been fitted with ventilation ear tubes (3.0% vs. 0.4%, p = 0.018; OR 8.0, 95% CI: 1.0, 66.1), and spent one or more nights in a hospital (19.8% vs. 12.3%, p = 0.012; OR 1.8, 95% CI: 1.1, 2.7) (Table 6).

Table 1. Characteristics of the respondents[a]

	Mean (SD)[a]
Age (n=407)	40.59 (6.7)
	Number (%)[a]
Race	
White	382 (92.5%)
Non-White	21 (7.6%)
Total	413
Education	
High School Graduate or Less	35 (8.5%)
Some College	114 (27.5%)
College Graduate	187 (45.2%)
Post-Graduates	78 (18.5%)
Total	414
Total Gross Household Income	
< $49,999	123 (30.8%)
$50,000-100,000	182 (45.5%)
> $100,000	95 (23.8%)
Total	400
Religious Affiliation	
Christianity	375 (91.2%)
Non-Christianity	36 (8.8%)
Total	411
Marital Status	
Married	386 (93.7%)
Not Married	26 (6.3%)
Total	412

[a]Missing observations are excluded.

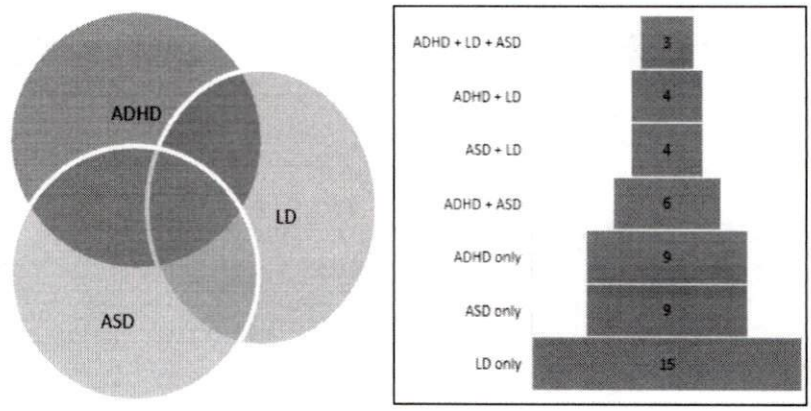

Figure 1. The overlap and distribution of physician-diagnosed neurodevelopmental disorders, based on mothers' reports

Table 2. Vaccination status and health outcomes – Acute Conditions

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Chickenpox						
Yes	32 (7.9%)	66 (25.3%)	98 (14.7%)	38.229	< 0.001	0.26 (0.2 - 0.4)
No	373 (92.1%)	195 (74.7%)	568 (85.3%)			
Otitis media						
Yes	80 (19.8%)	16(5.8%)	96 (14.4%)	26.643	< 0.001	3.8 (2.1 - 6.6)
No	325 (80.2%)	245 (94.2%)	507 (85.6%)			
Pneumonia						
Yes	26 (6.4%)	3 (1.2%)	29 (4.4%)	10.585	< 0.001	5.9 (1.8 - 19.7)
No	379 (93.6%)	258 (98.8%)	637 (95.6%)			
Whooping cough						
Yes	10 (2.5%)	22 (8.4%)	32 (4.8%)	12.326	< 0.001	0.3 (0.1 - 0.6)
No	395 (97.5%)	239 (91.6%)	634 (95.2%)			
Rubella						
Yes	1 (0.3%)	5 (1.9%)	6 (0.9%)	4.951	0.037	0.1 (0.01 - 1.1)
No	404 (99.6%)	256 (98.1%)	660 (99.1%)			

Table 3. Vaccination status and health outcomes – Chronic Conditions

Chronic Disease	Vaccinated (n=405)	Unvaccinated (n=261)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis					
Yes	42 (10.4%)	1 (0.4%)	26.21	< 0.001	30.1 (4.1 - 219.3)
	363 (89.6%)	260 (99.6%)			
Allergies					
Yes	90 (22.2%)	18 (6.9%)	29.44	< 0.001	3.9 (2.3 - 6.6)
No	315 (77.9%)	243 (93.1%)			
ADHD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
ASD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
Eczema (atopic dermatitis)					
Yes	38 (9.5%)	9 (3.6%)	8.522	0.035	2.9 (1.4 - 6.1)
No	367 (90.5%)	252 (96.4%)			
Learning Disability					
Yes	23 (5.7%)	3 (1.2%)	8.6803	0.003	5.2 (1.6 - 17.4)
No	382 (94.3%)	258 (98.9%)			
Neurodevelopment Disorder					
Yes	42 (10.5%)	8 (3.1%)	12.198	< 0.001	3.7 (1.7 - 7.9)
No	313 (89.5%)	253 (96.9%)			
Any Chronic Condition					
Yes	178 (44.0%)	65 (24.9%)	24.8456	< 0.001	2.4 (1.7 - 3.3)
No	227 (56.0%)	196 (75.1%)			

Table 4. Partial versus full vaccination and chronic health conditions

	Unvaccinated (n=261)	Partially Vaccinated (n=208)	Fully Vaccinated (n=197)	Total (n=666)	Chi-Square	P-value
Chronic Conditions						
Allergic rhinitis						
Yes	1 (0.4%)	17 (8.2%)	25 (12.7%)	43 (6.5%)	29.6306	< 0.001
No	260 (99.6%)	191 (91.8%)	172 (87.3%)	623 (93.5%)		
Allergies						
Yes	18 (6.9%)	47 (22.6%)	43 (21.8%)	108 (16.2%)	27.4819	< 0.001
No	243 (93.1%)	161 (77.4%)	154 (78.2%)	558 (83.8%)		
ADHD						
Yes	3 (1.2%)	8 (3.9%)	11 (5.6%)	22 (3.3%)	7.1900	0.075
No	258 (98.8%)	200 (96.1%)	186 (94.4%)	644 (96.7%)		
ASD						
Yes	3 (1.2%)	11 (5.3%)	8 (4.6%)	22 (3.3%)	6.7109	0.034
No	258 (98.8%)	197 (94.7%)	189 (95.4%)	644 (96.7%)		
Eczema (atopic dermatitis)						
Yes	9 (3.5%)	18 (8.7%)	20 (10.2%)	47 (7.1%)	8.8683	0.012
No	252 (96.5%)	190 (91.3%)	177 (89.8%)	619 (92.9%)		
Learning Disability						
Yes	3 (1.2%)	11 (5.3%)	12 (6.1%)	26 (3.9%)	8.8541	0.012
No	258 (98.8%)	197 (94.7%)	185 (93.9%)	640 (96.1%)		
NDD						
Yes	8 (3.1%)	21 (10.1%)	21 (10.7%)	50 (7.5%)	12.2443	0.002
No	253 (96.9%)	187 (89.9%)	176 (89.3%)	616 (92.5%)		
Any Chronic Condition						
Yes	65 (24.9%)	94 (45.2%)	84 (42.6%)	243 (36.5%)	25.1301	< 0.001
No	196 (75.1%)	114 (54.8%)	113 (57.4%)	423 (63.5%)		

Table 5. Chronic conditions and gender among vaccinated children

	Male (n=194)	Female (n=209)	Total (n=403)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis						
Yes	27 (13.9%)	15 (7.2%)	42 (10.4%)	4.8964	0.0269	2.1 (1.1 - 4.1)
No	167 (86.1%)	194 (92.8%)	361 (90.0%)			
Allergies						
Yes	50 (25.8%)	40 (19.1%)	90 (22.3%)	2.5531	0.1101	1.5 (0.91 - 2.4)
No	144 (74.2%)	168 (80. 9%)	313 (77.7%)			
ADHD						
Yes	13 (6.7%)	6 (2.9%)	19 (4.7%)	3.2856	0.0699	2.4 (0.90 - 6.5)
No	181 (93.3%)	203 (97.1%)	384 (95.3%)			
ASD						
Yes	15 (7.7%)	4 (1.9%)	19 (4.7%)	7.5810	0.0059	4.3 (1.4 - 13.2)
No	178 (92.3%)	205 (98.1%)	384 (95.3%)			
Eczema						
Yes	19 (9.89%)	19 (9.1%)	38 (9.4%)	0.0582	0.8094	1.1 (0.6 - 2.1)
No	175 (90.2%)	190 (90.9%)	365 (90.6%)			
Learning Disability						
Yes	14 (7.2%)	9 (4.3%)	23 (5.7%)	1.5835	0.2083	1.7 (0.7 - 4.1)
No	180 (92.8%)	200 (95.7%)	380 (94.3%)			
NDD						
Yes	28 (14.4%)	14 (6.7%)	42 (10.4%)	6.4469	0.0111	2.3 (1.2 - 4.6)
No	166 (85.6%)	195 (93.3%)	361 (89.6%)			
Any Chronic Condition						
Yes	94 (48.5%)	83 (39.7%)	177 (43.9%)	3.1208	0.0773	1.4 (1.0 - 2.1)
No	100 (51.5%)	126 (60.3%)	226 (56.1%)			

Factors associated with neurodevelopmental disorders

The second aim of the study focused on a specific health outcome and was designed to determine whether vaccination was associated with neurodevelopmental disorders (NDD) and, if so, whether the association remained significant after adjustment for other measured factors. As noted, because of the relatively small numbers of children with specific diagnoses, NDD was a derived variable combining children with a diagnosis of one or more of ASD, ADHD and a learning disability. The close association and overlap of these diagnoses in the

Table 6. Vaccination status, medication use and health services utilization

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Medication Use						
Medication for Allergy						
Yes	81 (20.0%)	3 (1.2%)	84 (12.6%)	51.170	< 0.001	21.5 (6.7 - 68.9)
No	324 (80.0%)	258 (98.8%)	582 (87.4%)			
Used antibiotics in the past 12 months						
Yes	124 (30.8%)	40 (15.4%)	164 (24.7%)	20.092	< 0.001	2.4 (1.6 - 3.6)
No	279 (69.2%)	220 (84.6%)	499 (75.3%)			
Used fever medication 1+ times						
Yes	350 (90.7%)	173 (67.8%)	523 (81.6%)	53.288	< 0.001	4.6 (3.0 - 7.1)
No	36 (9.3%)	82 (32.2%)	118 (18.4%)			
Using fitted ear drainage tubes						
Yes	12 (3.0%)	1 (0.4%)	13 (2.0%)	5.592	0.018	8.0 (1.0 - 66.1)
No	389 (97.0%)	260 (99.6%)	649 (98.0%)			
Used medication for ADHD						
Yes	7 (1.7%)	3 (1.2%)	10 (1.5%)	0.346	0.556	-
No	398 (98.3%)	256 (98.8%)	654 (98.5%)			
Used medication for Seizures						
Yes	4 (1.0%)	1 (0.4%)	5 (0.8%)	0.769	0.653	-
No	400 (99.0%)	258 (99.6%)	658 (99.2)			
Health Services Utilization						
Emergency Department visit in the past 12 months						
Yes	38 (9.5%)	23 (9.0%)	61 (9.3%)	0.047	0.828	-
No	364 (90.5%)	234 (91.0%)	598 (90.7%)			
Sick visit to doctor in the past year						
Yes	145 (36.0%)	41 (16.0%)	186 (28.2%)	31.096	< 0.001	3.0 (2.0 - 4.4)
No	258 (64.0%)	216 (84.0%)	474 (71.8%)			
Ever spent one or more nights in the hospital						
Yes	80 (19.8%)	32 (12.3%)	112 (16.8%)	6.267	0.012	1.8 (1.1 - 2.7)
No	325 (80.2%)	228 (87.7%)	553 (83.2%)			
Seen doctor for checkup in past 12 months						
Yes	233 (57.6%)	97 (37.2%)	330 (49.6%)	26.336	< 0.001	2.3 (1.7 - 3.2)
No	172 (42.4%)	164 (62.8%)	336 (50.4%)			
Seen dentist in the past 12 months						
Yes	362 (89.4%)	210 (80.5%)	572 (85.9%)	10.424	< 0.001	2.0 (1.3 - 3.2)
No	43 (10.6%)	51 (19.5%)	94 (14.1%)			

study is shown in the figure above (Figure 1). The figure shows that the single largest group of diagnoses was learning disability (n=15) followed by ASD (n=9), and ADHD (n=9), with smaller numbers comprising combinations of the three diagnoses.

Unadjusted analysis

Table 7 shows that the factors associated with NDD in unadjusted logistic regression analyses were: vaccination (OR 3.7, 95% CI: 1.7, 7.9); male gender (OR 2.1, 95% CI: 1.1, 3.8); adverse environment, defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory (OR 2.9, 95% CI: 1.1, 7.4); maternal use of antibiotics during pregnancy (OR 2.3, 95% CI: 1.1, 4.8); and preterm birth (OR 4.9, 95% CI: 2.4, 10.3). Two factors that almost reached statistical significance were vaccination during pregnancy (OR 2.5, 95% CI: 1.0, 6.3) and three or more fetal ultrasounds (OR 3.2, 95% CI: 0.92, 11.5). Factors that were not associated with NDD in this study included mother's education, household income, and religious affiliation; use of acetaminophen, alcohol, and antacids during pregnancy; gestational diabetes; preeclampsia; Rhogham shot during pregnancy; and breastfeeding (data not shown).

Adjusted analysis

After adjustment for all other significant factors, those that remained significantly associated with NDD were: vaccination (OR 3.1, 95% CI: 1.4, 6.8); male gender (OR 2.3, 95% CI: 1.2, 4.3); and preterm birth (OR 5.0, 95% CI: 2.3, 11.1). The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors.

In a final adjusted model designed to test for this possibility, controlling for the interaction of preterm birth and vaccination, the following factors remained significantly associated with NDD: vaccination (OR 2.5, 95% CI: 1.1, 5.6), nonwhite race (OR 2.4, 95% CI: 1.1, 5.4), and male gender (OR 2.3, 95% CI: 1.2, 4.4). Preterm birth itself, however, was not significantly associated with NDD, whereas the combination (interaction) of preterm birth and vaccination was associated with 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5) (Table 8).

Discussion

Following a recommendation of the Institute of Medicine [19] for studies comparing the health outcomes of vaccinated and unvaccinated

Table 7. Unadjusted analysis of potential risk factors for neurodevelopmental disorders

	NDD					
Vaccination Status	**Yes (N=50)**	**No (N=616)**	**Total* (N=666)**	**Chi-Square**	**P-value**	**OR (95% CI)****
Vaccinated	42	363	405	12.198	<0.001	3.7 (1.7 - 7.9)
Not Vaccinated	8	253	261			Ref
Race						
Non-White	9	71	80	1.8208	0.177	1.7 (0.7 - 3.6)
White	41	544	585			Ref
Child's Gender						
Male	32	283	315	5.9471	0.015	2.1 (1.1 - 3.8)
Female	18	331	349			Ref
Adverse Environment						
Yes	6	27	33	5.8706	0.053	2.9 (1.1 - 7.4)
No	40	523	563			Ref
Do not know	4	66	70			0.8 (0.3 - 2.3)
Medication during Pregnancy - Antibiotics						
Yes	10	61	71	4.950	0.026	2.3 (1.1 - 4.8)
No	40	555	595			Ref
Medication during Pregnancy –Vaccinated						
Yes	6	32	38	3.965	0.057	2.5 (1.0 - 6.3)
No	44	583	627			Ref
Preterm birth						
Yes	12	37	49	22.910	< 0.001	4.9 (2.4 - 10.3)
No	38	578	616			Ref
Ultrasound						
None	3	71	74	5.898	0.052	Ref
1-3 times	30	419	449			1.7 (0.5 - 5.7)
> 3 times	17	124	141			3.2 (0.92 - 11.5)

*Numbers may not add to column totals due to missing or incomplete data.

**Note that Odds Ratios are the cross-product ratios of the entries in the 2-by-2 tables, and are an estimate of the relative incidence (or risk) of the outcome associated with the exposure factor.

Table 8. Adjusted logistic regression analyses of risk factors and NDD*

	Adjusted Model (Model 1)	**Adjusted Model with Interaction (Model 2)**
Vaccination Status		
Vaccinated	3.1 (1.4 - 6.8)	2.5 (1.1 - 5.6)
Not Vaccinated	Ref	Ref
Race		
Non-White	2.3 (1.0 - 5.2)	2.4 (1.1 - 5.4)
White	Ref	Ref
Child's Gender		
Male	2.3 (1.2 - 4.3)	2.3 (1.2 - 4.4)
Female	Ref	Ref
Preterm birth		NS
Yes	5.0 (2.3 - 11.1)	
No	Ref	
Preterm birth and Vaccination interaction		
No interaction	Not in the model	Ref
Preterm and Vaccinated		6.6 (2.8 - 15.5)

*Number of observation read 666, number of observations used 629. NDD=47, Not NDD = 582

children, this study focused on homeschool children ages 6 to 12 years based on mothers' anonymous reports of pregnancy-related conditions, birth histories, physician-diagnosed illnesses, medications and healthcare use. Respondents were mostly white, married, and college-educated, upper income women who had been contacted and invited to participate in the study by the leaders of their homeschool organizations. Data from the survey were also used to determine whether vaccination was associated specifically with NDDs, a derived diagnostic category combining children with the diagnoses of learning disability, ASD and/or ADHD.

With regard to acute and chronic conditions, vaccinated children were significantly less likely than the unvaccinated to have had chickenpox and pertussis but, contrary to expectation, were significantly more likely to have been diagnosed with otitis media, pneumonia, allergic rhinitis, eczema, and NDD. The vaccinated were also more likely to have used antibiotics, allergy and fever medications; to have been fitted with ventilation ear tubes; visited a doctor for a health issue in the previous year, and been hospitalized. The reason for hospitalization and the age of the child at the time were not determined, but the latter finding appears consistent with a study of 38,801 reports to the VAERS of infants who were hospitalized or had died after receiving vaccinations. The study reported a linear relationship between the number of vaccine doses administered at one time and the rate of hospitalization and death; moreover, the younger the infant at the time of vaccination, the higher was the rate of hospitalization and death [55]. The hospitalization rate increased from 11% for 2 vaccine doses to 23.5% for 8 doses ($r^2 = 0.91$), while the case fatality rate increased significantly from 3.6% for those receiving from 1-4 doses to 5.4 % for those receiving from 5-8 doses.

In support of the possibility that the number of vaccinations received could be implicated in risks of associated chronic illness, a

comparison of unvaccinated, partially and fully vaccinated children in the present study showed that the partially vaccinated had increased but intermediate odds of chronic disease, between those of unvaccinated and fully vaccinated children, specifically for allergic rhinitis, ADHD, eczema, a learning disability, and NDD as a whole.

The national rates of ADHD and LD are comparable to those of the study. The U.S. rate of ADHD for ages 4-17 (twice the age range of children than the present study), is 11% [31]. The study rate of ADHD for ages 6 to 12 is 3.3%, and 4.7% when only vaccinated children are included. The national LD rate is 5% [32], and the study data show a rate of LD of 3.9% for all groups, and 5.6% when only vaccinated children are included. However, the ASD prevalence of 2.24% from a CDC parent survey is lower than the study rate of 3.3%. Vaccinated males were significantly more likely than vaccinated females to have been diagnosed with allergic rhinitis, and NDD. The percentage of vaccinated males with an NDD in this study (14.4%) is consistent with national findings based on parental responses to survey questions, indicating that 15% of U.S. children ages 3 to 17 years in the years 2006-2008 had an NDD [28]. Boys are also more likely than girls to be diagnosed with an NDD, and ASD in particular [29].

Vaccination was strongly associated with both otitis media and pneumonia, which are among the most common complications of measles infection [56,57]. The odds of otitis media were almost four-fold higher among the vaccinated (OR 3.8, 95% CI: 2.1, 6.6) and the odds of myringotomy with tube placement were eight-fold higher than those of unvaccinated children (OR 8.0, 95% CI: 1.0, 66.1). Acute otitis media (AOM) is a very frequent childhood infection, accounting for up to 30 million physician visits each year in the U.S., and the most common reason for prescribing antibiotics for children [58,59]. The incidence of AOM peaks at ages 3 to 18 months and 80% of children have experienced at least one episode by 3 years of age. Rates of AOM have increased in recent decades [60]. Worldwide, the incidence of AOM is 10.9%, with 709 million cases each year, 51% occurring in children under 5 years of age [61]. Pediatric AOM is a significant concern in terms of healthcare utilization in the U.S., accounting for $2.88 billion in annual health care costs [62].

Numerous reports of AOM have been filed with VAERS. A search of VAERS for "Cases where age is under 1 and onset interval is 0 or 1 or 2 or 3 or 4 or 5 or 6 or 7 days and Symptom is otitis media" [63] revealed that 438,573 cases were reported between 1990 and 2011, often with fever and other signs and symptoms of inflammation and central nervous system involvement. One study [64] assessed the nasopharyngeal carriage of *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis* during AOM in fully immunized, partly immunized children with 0 or 1 dose of Pneumococcal Conjugate Vaccine-7 (PCV7), and "historical control" children from the pre-PCV-7 era, and found an increased frequency of *M. catarrhalis* colonization in the vaccinated group compared to the partly immunized and control groups (76% vs. 62% and 56%, respectively). A high rate of *Moraxella catarrhalis* colonization is associated with an increased risk of AOM [65].

Successful vaccination against pneumococcal infections can lead to replacement of the latter in the nasopharyngeal niche by nonvaccine pneumococcal serotypes and disease [66]. Vaccination with PCV-7 has a marked effect on the complete microbiota composition of the upper respiratory tract in children, going beyond shifts in the distribution of pneumococcal serotypes and known potential pathogens and resulting in increased anaerobes, gram-positive bacteria and gram-negative bacterial species. PCV-7 administration also correlates highly with the emergence and expansion of oropharyngeal types of species. These observations have suggested that eradication of vaccine serotype pneumococci can be followed by colonization of other bacterial species in the vacant nasopharyngeal niche, leading to disequilibria of bacterial composition (dysbiosis) and increased risks of otitis media. Long-term monitoring has been recommended as essential for understanding the full implications of vaccination-induced changes in microbiota structure [67].

The second aim of the paper focused on a specific health outcome and sought to determine whether vaccination remained associated with neurodevelopmental disorders (NDD) after controlling for other measured factors. After adjustment, the factors that remained significantly associated with NDD were vaccination, nonwhite race, male gender, and preterm birth. The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors. This was shown in a final adjusted model with interaction (controlling for the interaction of preterm birth with vaccination). In this model, vaccination, nonwhite race and male gender remained associated with NDD, whereas preterm birth itself was no longer associated with NDD. However, preterm birth combined with vaccination was associated with a 6.6-fold increased odds of NDD.

In summary, vaccination, nonwhite race, and male gender were significantly associated with NDD after controlling for other factors. Preterm birth, although significantly associated with NDD in unadjusted and adjusted analyses, was no longer associated with NDD in the final model with interaction. However, preterm birth and vaccination combined was strongly associated with NDD in the final adjusted model with interaction, more than doubling the odds of NDD compared to vaccination alone. Preterm birth has long been known as a major factor for NDD [68,69], but since preterm infants are routinely vaccinated, the separate effects of preterm birth and vaccination have not been examined. The present study suggests that vaccination could be a contributing factor in the pathogenesis of NDD but also that preterm birth by itself may have a lesser or much reduced role in NDD (defined here as ASD, ADHD and/or a learning disability) than currently believed. The findings also suggest that vaccination coupled with preterm birth could increase the odds of NDD beyond that of vaccination alone.

Potential limitations

We did not set out to test a specific hypothesis about the association between vaccination and health. The aim of the study was to determine whether the health outcomes of vaccinated children differed from those of unvaccinated homeschool children, given that vaccines have nonspecific effects on morbidity and mortality in addition to protecting against targeted pathogens [11]. Comparisons were based on mothers' reports of pregnancy-related factors, birth histories, vaccinations, physician-diagnosed illnesses, medications, and the use of health services. We tested the null hypothesis of no difference in outcomes using chi-square tests, and then used Odds Ratios and 96% Confidence Intervals to determine the strength and significance of the association.

If the effects of vaccination on health were limited to protection against the targeted pathogens, as is assumed to be the case [21], no difference in outcomes would be expected between the vaccinated and unvaccinated groups except for reduced rates of the targeted infectious diseases. However, in this homogeneous sample of 666 children there were striking differences in diverse health outcomes between the groups. The vaccinated were less likely to have had chickenpox or whooping cough, as expected, but more likely to have been diagnosed with pneumonia and ear infections as well as allergies and NDDs.

What credence can be given to the findings? This study was not intended to be based on a representative sample of homeschool children but on a convenience sample of sufficient size to test for significant differences in outcomes. Homeschoolers were targeted for the study because their vaccination completion rates are lower than those of children in the general population. In this respect our pilot survey was successful, since data were available on 261 unvaccinated children.

To eliminate opportunities for subjectivity or opinion in the data, only factual information was requested and the questions involved memorable events such as physician-diagnosed diseases in a child. With regard to minimizing potential bias in the information provided by mothers, all communications with the latter emphasized neutrality regarding vaccination and vaccine safety. To minimize recall bias, respondents were asked to use their child's vaccination records. To enhance reliability, closed-ended questions were used and each set of questions had to be completed before proceeding to the next. To enhance validity, parents were asked to report only physician-diagnosed illnesses.

Mothers' reports could not be validated by clinical records because the survey was designed to be anonymous. However, self-reports about significant events provide a valid proxy for official records when medical records and administrative data are unavailable [70]. Had mothers been asked to provide copies of their children's medical records it would no longer have been an anonymous study and would have resulted in few completed questionnaires. We were advised by homeschool leaders that recruitment efforts would have been unsuccessful had we insisted on obtaining the children's medical records as a requirement for participating in the study.

A further potential limitation is under-ascertainment of disease in unvaccinated children. Could the unvaccinated have artificially reduced rates of illness because they are seen less often by physicians and would therefore have been less likely to be diagnosed with a disease? The vaccinated were indeed more likely to have seen a doctor for a routine checkup in the past 12 months (57.5% vs. 37.1%, $p < 0.001$; OR 2.3, 95% CI: 1.7, 3.1). Such visits usually involve vaccinations, which non-vaccinating families would be expected to refuse. However, fewer visits to physicians would not necessarily mean that unvaccinated children are less likely to be seen by a physician if their condition warranted it. In fact, since unvaccinated children were more likely to be diagnosed with chickenpox and whooping cough, which would have involved a visit to the pediatrician, differences in health outcomes are unlikely to be due to under-ascertainment.

Strengths of the study include the unique design of the study, involving homeschool mothers as respondents, and the relatively large sample of unvaccinated children, which made it possible to compare health outcomes across the spectrum of vaccination coverage. Recruitment of biological mothers as respondents also allowed us to test hypotheses about the role of pregnancy-related factors and birth history as well as vaccination in NDD and other specific conditions. In addition, this was a within-group study of a demographically homogeneous population of mainly white, higher-income and college-educated homeschooling families in which the children were all 6-12 years of age. Information was provided anonymously by biological mothers, obviously well-informed about their own children's vaccination status and health, which likely increased the validity of the reports.

Conclusions

Assessment of the long-term effects of the vaccination schedule on morbidity and mortality has been limited [71]. In this pilot study of vaccinated and unvaccinated homeschool children, reduced odds of chickenpox and whooping cough were found among the vaccinated, as expected, but unexpectedly increased odds were found for many other physician-diagnosed conditions. Although the cross-sectional design of the study limits causal interpretation, the strength and consistency of the findings, the apparent "dose-response" relationship between vaccination status and several forms of chronic illness, and the significant association between vaccination and NDDs all support the possibility that some aspect of the current vaccination program could be contributing to risks of childhood morbidity. Vaccination also remained significantly associated with NDD after controlling for other factors, whereas preterm birth, long considered a major risk factor for NDD, was not associated with NDD after controlling for the interaction between preterm birth and vaccination. In addition, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD above that of vaccination alone. Nevertheless, the study findings should be interpreted with caution. First, additional research is needed to replicate the findings in studies with larger samples and stronger research designs. Second, subject to replication, potentially detrimental factors associated with the vaccination schedule should be identified and addressed and underlying mechanisms better understood. Such studies are essential in order to optimize the impact of vaccination of children's health.

Competing Interests

The authors declare that they have no financial interests that had any bearing on any aspect of the conduct or conclusions of the study and the submitted manuscript.

Author contributions

AM designed the study, contributed to data analysis and interpretation, and drafted the paper. BR designed the study, contributed to data collection, and edited the paper. AB contributed to data analyses and edited the paper. BJ contributed to data analyses and editing. All authors read and approved the final version of the paper.

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Disclaimer

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http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Adenovirus Type 4 and 7; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM247515.pdf

Anthrax; http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM074923.pdf

BCG Tuberculosis; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM202934.pdf

Cholera Oral; LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM506235.pdf

Diphtheria & Tetanus Toxoids Absorbed; http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142732.pdf

DTaP;

Infanrix; http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm101568.htm

DAPTACEL; http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm101572.htm

Pediarix; Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus Vaccine Combined http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm136517.htm

KINRIX; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf

Quadracel; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf

Pentacel; Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf

PedvaxHIB; Haemophilus B Conjugate Vaccine (Meningococcal Protein Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf

ActHIB; Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf

HIBERIX; Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf

Comvax; Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109869.pdf

Havrix; Hepatitis A Vaccine, Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf

VAQTA; Hepatitis A Vaccine, Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf

Twinrix; Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110079.pdf

Recombivax HB; Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf

Engerix-B; Hepatitis B Vaccine (Recombinant) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

Gardasil; Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111266.pdf

Cervarix; Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM186981.pdf

Gardasil 9; Human Papillomavirus 9-valent Vaccine, Recombinant
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426460.pdf

Influenza Vaccines; NO name Influenza A (H1N1) 2009 Monovalent Vaccine (CSL Limited)
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182401.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf

Influenza Virus Vaccine, H5N1 FOR NATIONAL STOCKPILE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112836.pdf

Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted; http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM376464.pdf

FLUAD; FOR 65+ Influenza Vaccine, Adjuvanted http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM474387.pdf

AFLURIA QUADRIVALENT; 18+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM518295.pdf

Flucelvax Quadrivalent; 4+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM502899.pdf

FluLaval; 3+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112904.pdf

FluMist; 2-49 Influenza Vaccine Live, Intranasal http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm

Fluarix; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM335392.pdf

Fluvirin; 4+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123694.pdf

Agriflu; 18+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM371815.pdf

FLUCELVAX; 4+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM329134.pdf

Flublok; 18+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM336020.pdf

FluMist® Quadrivalent; 2-49 http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM294307.pdf

Fluarix Quadrivalent; 3+ Influenza Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf

FluLaval®; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM404086.pdf

Fluzone Quadrivalent; 2 Types- http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426679.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM513242.pdf

FluLaval®; 3+ Influenza Virus Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM404086.pdf

IXIARO; Japanese Encephalitis Vaccine, Inactivated, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142569.pdf

JE-Vax; 1+; Japanese Encephalitis Virus Vaccine Inactivated http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123761.pdf

M-M-R II; 1+ Measles, Mumps, and Rubella Virus Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM375080.pdf

PROQUAD; 1-12 Measles, Mumps, Rubella and Varicella Virus Vaccine LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123793.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123796.pdf

Menveo; 2-55 Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf

MenHibrix; 6 weeks-18 months Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM308577.pdf

Menactra; 9 months-55 years Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf

BEXSERO; 10-55 Neisseria meningitidis serogroup B http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf

TRUMENBA; 10-25 *Neisseria meningitidis* serogroup B. http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM421139.pdf

Menomune-A/C/Y/W-135; 2+ Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM308370.pdf

Pneumovax 23; 2+ Pneumococcal Vaccine, Polyvalent http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM257088.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM277628.pdf

Prevnar; 2, 4, 6 & 12-15 months Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM137038.pdf

Prevnar 13; 6 weeks-5 years Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197}Protein) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf

IPOL; 6 weeks+ Poliovirus Vaccine Inactivated (Monkey Kidney Cell) http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

IMOVAX; all ages Rabies Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133484.pdf

RabAvert; Rabies Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM312931.pdf

Rotarix; 6-24 weeks Rotavirus Vaccine LIVE Oral http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133539.pdf

RotaTeq; 6-32 weeks Rotavirus Vaccine LIVE Oral, Pentavalent http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142290.pdf

ACAM2000; Smallpox (Vaccinia) Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142572.pdf

No Trade Name; 7+ Tetanus and Diphtheria Toxoids, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM164127.pdf

TENIVAC; 7+ Tetanus and Diphtheria Toxoids Adsorbed For Adult Use http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152826.pdf

No Trade Name; 6 weeks until 7 ys Diphtheria and Tetanus Toxoid Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142732.pdf

Adacel; 10-64 Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM243729.pdf

Boostrix; 10+ Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf

Vivotif; 6+ Typhoid Vaccine Live Oral Ty21a http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142807.pdf

Typhin Vi; 2+ Typhoid Vi Polysaccharide Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142811.pdf

Varivax; Varicella Virus Vaccine LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM165651.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM165647.pdf

YF-Vax; 9 months+ Yellow Fever Vaccine http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142831.pdf

Zostavax; 50+ Shingles Zoster Vaccine, LIVE http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM132831.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM285015.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM176340.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM285016.pdf http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM249230.pdf

April 15, 2019

Good Afternoon!! I am Jennie McCabe. I ask you to vote NO on HB19-1312 based on the following concerns....

1. Section 1, Legislative declaration, has no sources listed for any of the statistics given. Section 6, Safety Clause, also has no sources listed for this claim. Statements need to be backed up with verifiable data, of which there is none given. **Without evidence how can we be assured these assertions are factual? It would be reprehensible to pass a law based on unverified statements.**

2. As specified on pages 1, 2, 4, 8, 9, the legislature will abdicate their authority to two regulatory bodies, CDPHE and the ACIP. In Colorado, The legislature is the correct avenue for making laws. **Legislators have the honor of having been elected to perform this job and it is not proper for legislators to abdicate their authority to anyone.**

3. Page 5 specifies that educational materials regarding the *benefits* of immunizations must be developed. A true education covers not just the benefits but also the drawbacks and other facets of an issue. The manufacturer themselves, in the vaccine package insert lists many drawbacks. I have the DTaP package insert for each of you, risks and adverse effects are discussed on pages 1, 3-13, and 15. In fact, the manufacturer states on page 17 and 18 that "The parent or guardian should be informed of the potential benefits, risks and potential for adverse reactions of immunization with INFANRIX..." **Why should the state of Colorado provide less information than the manufacturer does? Why provide information on only one side of the issue? This is not a true education and it is not acceptable to call it such or require Coloradoans be subject to such bias.**

4. This bill on pages 6 and 7 requires a standardized form be developed by the CDHPE and used by anyone claiming an exemption. This form has not been developed, it is still imaginary. **It would be unthinkable to pass a law requiring a form when said form is not even in existence, nor is it detailed in the law. Please vote no, on imaginary forms.**

HB-1312 is **NOT** good for Colorado. ***VOTE NO!***

Sincerely,

Jennie McCabe.

Jennie McCabe,

sheldonjennie@yahoo.com

Package insert Infanrix

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use INFANRIX safely and effectively. See full prescribing information for INFANRIX.

INFANRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)
Suspension for Intramuscular Injection
Initial U.S. Approval: 1997

----------INDICATIONS AND USAGE----------

INFANRIX is a vaccine indicated for active immunization against diphtheria, tetanus, and pertussis as a 5-dose series in infants and children 6 weeks to 7 years of age. (1)

---------- DOSAGE AND ADMINISTRATION ----------

A 0.5-mL intramuscular injection given as a 5-dose series: (2.2)

- One dose each at 2, 4, and 6 months of age.
- One booster dose at 15 to 20 months of age and another booster dose at 4 to 6 years of age.

---------- DOSAGE FORMS AND STRENGTHS ----------

Single-dose vials and prefilled syringes containing a 0.5-mL suspension for injection. (3)

----------CONTRAINDICATIONS----------

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis-containing vaccine, or to any component of INFANRIX. (4.1)
- Encephalopathy within 7 days of administration of a previous pertussis-containing vaccine. (4.2)
- Progressive neurologic disorders. (4.3) — ACIP does not list this as a contra-indication

---------- WARNINGS AND PRECAUTIONS ----------

- If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give INFANRIX should be based on potential benefits and risks. (5.1)
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions. (5.2)
- Syncope (fainting) can occur in association with administration of injectable vaccines, including INFANRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope. (5.3)
- If temperature ≥105°F, collapse or shock-like state, or persistent, inconsolable crying lasting ≥3 hours have occurred within 48 hours after receipt of a pertussis-containing vaccine, or if seizures have occurred within 3 days after receipt of a pertussis-containing vaccine, the decision to give INFANRIX should be based on potential benefits and risks. (5.4)
- For children at higher risk for seizures, an antipyretic may be administered at the time of vaccination with INFANRIX. (5.5)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including INFANRIX, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination. (5.6)

Doctors need to assess this

---------- ADVERSE REACTIONS ----------

Rates of injection site reactions (pain, redness, swelling) ranged from 10% to 53%, depending on reaction and dose number, and were highest following Doses 4 and 5. Fever was common (20% to 30%) following Doses 1-3. Other common solicited adverse events were drowsiness, irritability/fussiness, and loss of appetite, reported in approximately 15% to 60% of subjects, depending on event and dose number. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------

Do not mix INFANRIX with any other vaccine in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: /xxxx

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

INFANRIX® is indicated for active immunization against diphtheria, tetanus, and pertussis as a 5-dose series in infants and children 6 weeks to 7 years of age (prior to seventh birthday).

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Shake vigorously to obtain a homogeneous, turbid, white suspension. Do not use if resuspension does not occur with vigorous shaking. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

For the prefilled syringes, attach a sterile needle and administer intramuscularly.

For the vials, use a sterile needle and sterile syringe to withdraw the 0.5-mL dose and administer intramuscularly. Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. Use a separate sterile needle and syringe for each individual.

Do not administer this product intravenously, intradermally, or subcutaneously.

2.2 Dose and Schedule

the same dose for ages 6 weeks to 7 years? Isn't medicine normally based on weight? Sounds risky to me.

A 0.5-mL dose of INFANRIX is approved for intramuscular administration in infants and children 6 weeks to 7 years of age (prior to the seventh birthday) as a 5-dose series. The series consists of a primary immunization course of 3 doses administered at 2, 4, and 6 months of age (at intervals of 4 to 8 weeks), followed by 2 booster doses, administered at 15 to 20 months of age and at 4 to 6 years of age. The first dose may be given as early as 6 weeks of age.

The preferred administration site is the anterolateral aspect of the thigh for most infants younger than 12 months of age and the deltoid muscle of the upper arm for most children 12 months of age to 7 years of age.

2.3 Use of INFANRIX with Other DTaP Vaccines

Sufficient data are not available on the safety and effectiveness of interchanging INFANRIX and Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) vaccines from different manufacturers for successive doses of the DTaP vaccination series. Because the pertussis antigen components of INFANRIX and PEDIARIX® [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine] are the same, INFANRIX may be used to complete a DTaP vaccination series initiated with PEDIARIX.

2.4 Additional Dosing Information

If any recommended dose of pertussis vaccine cannot be given *[see Contraindications (4.2, 4.3), Warnings and Precautions (5.5)]*, Diphtheria and Tetanus Toxoids Adsorbed (DT) For Pediatric Use should be given according to its prescribing information.

3 DOSAGE FORMS AND STRENGTHS

INFANRIX is a suspension for injection available in 0.5-mL single-dose vials and prefilled TIP-LOK® syringes.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis-containing vaccine, or to any component of INFANRIX is a contraindication *[see Description (11)]*. Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with any of these components should be given. Alternatively, such individuals may be referred to an allergist for evaluation if immunization with any of these components is being considered.

4.2 Encephalopathy

Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including INFANRIX.

4.3 Progressive Neurologic Disorder

★ not listed as a contraindication per ACIP

Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication to administration of any pertussis-containing vaccine, including INFANRIX. Pertussis vaccine should not be administered to individuals with these conditions until a treatment regimen has been established and the condition has stabilized.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

doctor must evaluate

If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including INFANRIX, should be based on careful consideration of the potential benefits and possible risks. When a decision is made to withhold tetanus toxoid, other available vaccines should be given, as indicated.

5.2 Latex

★ Not accounted for by ACIP

The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic

reactions.

5.3 Syncope

Syncope (fainting) can occur in association with administration of injectable vaccines, including INFANRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

5.4 Adverse Events following Prior Pertussis Vaccination

If any of the following events occur in temporal relation to receipt of a pertussis-containing vaccine, the decision to give any pertussis-containing vaccine, including INFANRIX, should be based on careful consideration of the potential benefits and possible risks:

- Temperature of ≥40.5°C (105°F) within 48 hours not due to another identifiable cause;
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours;
- Persistent, inconsolable crying lasting ≥3 hours, occurring within 48 hours;
- Seizures with or without fever occurring within 3 days.

5.5 Children at Risk for Seizures

For children at higher risk for seizures than the general population, an appropriate antipyretic may be administered at the time of vaccination with a pertussis-containing vaccine, including INFANRIX, and for the ensuing 24 hours to reduce the possibility of post-vaccination fever.

5.6 Apnea in Premature Infants

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including INFANRIX, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

5.7 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the patient's immunization history for possible vaccine hypersensitivity. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

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 with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of INFANRIX could reveal adverse reactions not observed in clinical

trials.

Approximately 95,000 doses of INFANRIX have been administered in clinical studies. In these studies, 29,243 infants have received INFANRIX in primary series studies, 6,081 children have received a fourth consecutive dose of INFANRIX, 1,764 children have received a fifth consecutive dose of INFANRIX, and 559 children have received a dose of INFANRIX following 3 doses of PEDIARIX.

Solicited Adverse Events

In a US study, 335 infants received INFANRIX, ENGERIX-B® [Hepatitis B Vaccine (Recombinant)], inactivated poliovirus vaccine (IPV, Sanofi Pasteur SA), Haemophilus b (Hib) conjugate vaccine (Wyeth Pharmaceuticals Inc.), and pneumococcal 7-valent conjugate (PCV7) vaccine (Wyeth Pharmaceuticals Inc.) concomitantly at separate sites. All vaccines were administered at 2, 4, and 6 months of age. Data on solicited local reactions and general adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days) (Table 1). Among subjects, 69% were white, 16% were Hispanic, 8% were black, 4% were Asian, and 2% were of other racial/ethnic groups.

Table 1. Solicited Local Reactions and General Adverse Events (%) Occurring within 4 Days of Vaccination[a] with Separate Concomitant Administration of INFANRIX, ENGERIX-B, IPV, Haemophilus b (Hib) Conjugate Vaccine, and Pneumococcal Conjugate Vaccine (PCV7) (Modified Intent-to-Treat Cohort)

	INFANRIX, ENGERIX-B, IPV, Hib Vaccine, & PCV7		
	Dose 1	**Dose 2**	**Dose 3**
Local[b]			
N	335	323	315
Pain, any	31.9	30.0	29.8
Pain, Grade 2 or 3	9.0	8.7	8.9
Pain, Grade 3	2.7	1.5	1.3
Redness, any	18.2	32.8	39.0
Redness, >20 mm	0.3	0.0	1.9
Swelling, any	9.6	20.4	24.8
Swelling, >20 mm	0.6	0.0	1.3
General			
N	333	321	311
Fever[c] (≥100.4°F)	19.8	30.2	23.8
Fever[c] (>101.3°F)	4.5	9.7	5.8
Fever[c] (>102.2°F)	0.3	3.1	2.3
Fever[c] (>103.1°F)	0.0	0.3	0.3
N	335	323	315
Drowsiness, any	54.0	48.3	38.4
Drowsiness, Grade 2 or 3	17.6	12.4	11.1
Drowsiness, Grade 3	3.6	0.6	1.9
Irritability/Fussiness, any	61.5	61.6	56.5
Irritability/Fussiness, Grade 2 or 3	19.4	21.1	19.4
Irritability/Fussiness, Grade 3	3.9	3.4	3.2
Loss of appetite, any	27.8	26.6	23.8
Loss of appetite, Grade 2 or 3	5.1	3.4	5.4
Loss of appetite, Grade 3	0.6	0.3	0.0

Hib conjugate vaccine and PCV7 manufactured by Wyeth Pharmaceuticals Inc. IPV manufactured by Sanofi Pasteur SA.

Modified intent-to-treat cohort = All vaccinated subjects for whom safety data were available.

N = Number of infants for whom at least one symptom sheet was completed; for fever, numbers exclude missing temperature recordings or tympanic measurements.

Grade 2: Pain defined as cried/protested on touch; drowsiness defined as interfered with normal daily activities; irritability/fussiness defined as crying more than usual/interfered with normal daily activities; loss of appetite defined as eating less than usual/interfered with normal daily activities.

Grade 3: Pain defined as cried when limb was moved/spontaneously painful; drowsiness defined as prevented normal daily activities; irritability/fussiness defined as crying that could not be comforted/prevented normal daily activities; loss of appetite defined as no eating at all.

[a] Within 4 days of vaccination defined as day of vaccination and the next 3 days.

[b] Local reactions at the injection site for INFANRIX.

[c] Axillary temperatures increased by 1°C and oral temperatures increased by 0.5°C to derive equivalent rectal temperature.

In a US study, the safety of a booster dose of INFANRIX was evaluated in children 15 to 18 months of age whose previous 3 DTaP doses were with INFANRIX (N = 251) or PEDIARIX (N = 559). Vaccines administered concurrently with the fourth dose of INFANRIX included measles, mumps, and rubella (MMR) vaccine (Merck & Co., Inc.), varicella vaccine (Merck & Co., Inc.), pneumococcal 7-valent conjugate (PCV7) vaccine (Wyeth Pharmaceuticals Inc.), and any US-licensed Hib conjugate vaccine; these were given concomitantly in 13.2%, 6.3%, 37.4%, and 41.2% of subjects, respectively. Data on solicited adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days) (Table 2). Among subjects, 85% were white, 6% were Hispanic, 6% were black, 1% were Asian, and 2% were of other racial/ethnic groups.

Table 2. Solicited Local Reactions and General Adverse Events (%) Occurring within 4 Days of Vaccination[a] with INFANRIX Administered as the Fourth Dose following 3 Previous Doses of INFANRIX or PEDIARIX (Total Vaccinated Cohort)

	Group Primed with INFANRIX[b] N = 247	Group Primed with PEDIARIX[c] N = 553
Local[d]		
Pain, any	44.5	48.3
Pain, Grade 2 or 3	19.0	18.6
Pain, Grade 3	3.6	3.4
Redness, any	48.2	49.9
Redness, >20 mm	6.1	6.0
Swelling, any	32.8	32.7
Swelling, >20 mm	3.6	5.2
Increase in mid-thigh circumference, any	33.2	26.2
Increase in mid-thigh circumference, >40 mm	0.0	1.3
General		
Fever[e] (>99.5°F)	8.9	15.4
Fever[e] (>100.4°F)	4.5	6.7
Fever[e] (>101.3°F)	2.0	2.0
Drowsiness, any	35.6	31.3
Drowsiness, Grade 2 or 3	9.3	6.7
Drowsiness, Grade 3	2.4	1.3
Irritability, any	52.2	53.9
Irritability, Grade 2 or 3	18.2	19.7
Irritability, Grade 3	3.2	1.4
Loss of appetite, any	24.7	23.3
Loss of appetite, Grade 2 or 3	5.3	4.9
Loss of appetite, Grade 3	2.4	0.5

Total Vaccinated Cohort = All subjects who received a dose of study vaccine.

N = Number of subjects for whom at least one symptom sheet was completed.

Grade 2: Pain defined as cried/protested on touch; drowsiness defined as interfered with normal daily activities; irritability defined as crying more than usual/interfered with normal daily activities; loss of appetite defined as eating less than usual/no effect on normal daily activities.

Grade 3: Pain defined as cried when limb was moved/spontaneously painful; drowsiness defined as prevented normal daily activities; irritability defined as crying that could not be comforted/prevented normal daily activities; loss of appetite defined as eating less than usual/interfered with normal daily activities.

[a] Within 4 days of vaccination defined as day of vaccination and the next 3 days.

[b] Received INFANRIX, ENGERIX-B, IPV (Sanofi Pasteur SA), PCV7 vaccine (Wyeth

Pharmaceuticals Inc.), and Hib conjugate vaccine (Wyeth Pharmaceuticals Inc.) at 2, 4, and 6 months of age.

[c] Received PEDIARIX, PCV7 vaccine (Wyeth Pharmaceuticals Inc.), and Hib conjugate vaccine (Wyeth Pharmaceuticals Inc.) at 2, 4, and 6 months of age or PCV7 vaccine 2 weeks later.

[d] Local reactions at the injection site for INFANRIX.

[e] Axillary temperatures.

In a US study, the safety of a fifth consecutive dose of INFANRIX coadministered at separate sites with a fourth dose of IPV (Sanofi Pasteur SA) and a second dose of MMR vaccine (Merck & Co., Inc.) was evaluated in 1,053 children 4 to 6 years of age. Data on solicited adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days) (Table 3). Among subjects, 43% were white, 18% Hispanic, 15% Asian, 7% black, and 17% were of other racial/ethnic groups.

Table 3. Solicited Local Reactions and General Adverse Events (%) Occurring within 4 Days of Vaccination[a] with a Fifth Consecutive Dose of INFANRIX When Coadministered with IPV and MMR Vaccine (Total Vaccinated Cohort)

Local[b]	**N = 1,039-1,043**
Pain, any	53.3
Pain, Grade 2 or 3[c]	12.0
Pain, Grade 3[c]	0.6
Redness, any	36.6
Redness, ≥50 mm	20.0
Redness, ≥110 mm	4.1
Arm circumference increase, any	37.8
Arm circumference increase, >20 mm	7.4
Arm circumference increase, >30 mm	3.2
Swelling, any	27.0
Swelling, ≥50 mm	11.5
Swelling, ≥110 mm	1.8
General	**N = 993-1,036**
Drowsiness, any	17.5
Drowsiness, Grade 3[d]	0.8
Fever, ≥99.5°F	14.8
Fever, >100.4°F	4.4
Fever, >102.2°F	1.1
Fever, >104°F	0.0
Loss of appetite, any	16.0
Loss of appetite, Grade 3[e]	0.6

IPV manufactured by Sanofi Pasteur SA. MMR vaccine manufactured by Merck & Co., Inc.
Total Vaccinated Cohort = All vaccinated subjects for whom safety data were available.
N = Number of children with evaluable data for the events listed.
[a] Within 4 days of vaccination defined as day of vaccination and the next 3 days.
[b] Local reactions at the injection site for INFANRIX.
[c] Grade 2 defined as painful when the limb was moved; Grade 3 defined as preventing normal daily activities.
[d] Grade 3 defined as preventing normal daily activities.
[e] Grade 3 defined as not eating at all.

In the US booster immunization studies in which INFANRIX was administered as the fourth or fifth dose in the DTaP series following previous doses with INFANRIX or PEDIARIX, large swelling reactions of the limb injected with INFANRIX were assessed.

In the fourth-dose study, a large swelling reaction was defined as injection site swelling with a diameter of >50 mm, a >50 mm increase in the mid-thigh circumference compared with the pre-

vaccination measurement, and/or any diffuse swelling that interfered with or prevented daily activities. The overall incidence of large swelling reactions occurring within 4 days (Day 0-Day 3) following INFANRIX was 2.3%.

In the fifth-dose study, a large swelling reaction was defined as swelling that involved >50% of the injected upper arm length and that was associated with a >30 mm increase in mid-upper arm circumference within 4 days following vaccination. The incidence of large swelling reactions following the fifth consecutive dose of INFANRIX was 1.0%.

Less Common and Serious General Adverse Events

Selected adverse events reported from a double-blind, randomized Italian clinical efficacy trial involving 4,696 children administered INFANRIX or 4,678 children administered whole-cell DTP vaccine (DTwP) (manufactured by Connaught Laboratories, Inc.) as a 3-dose primary series are shown in Table 4. The incidence of rectal temperature ≥104°F, hypotonic-hyporesponsive episodes, and persistent crying ≥3 hours following administration of INFANRIX was significantly less than that following administration of whole-cell DTP vaccine.

Table 4. Selected Adverse Events Occurring within 48 Hours following Vaccination with INFANRIX or Whole-Cell DTP in Italian Infants at 2, 4, or 6 Months of Age

	INFANRIX (N = 13,761 Doses)		Whole-Cell DTP Vaccine (N = 13,520 Doses)	
Event	**Number**	**Rate/1,000 Doses**	**Number**	**Rate/1,000 Doses**
Fever (≥104°F)[ab]	5	0.36	32	2.4
Hypotonic-hyporesponsive episode[c]	0	0	9	0.67
Persistent crying ≥3 hours[a]	6	0.44	54	4.0
Seizures[d]	1[e]	0.07	3[f]	0.22

[a] $P < 0.001$.

[b] Rectal temperatures.

[c] $P = 0.002$.

[d] Not statistically significant at $P < 0.05$.

[e] Maximum rectal temperature within 72 hours of vaccination = 103.1°F.

[f] Maximum rectal temperature within 72 hours of vaccination = 99.5°F, 101.3°F, and 102.2°F.

In a German safety study that enrolled 22,505 infants (66,867 doses of INFANRIX administered as a 3-dose primary series at 3, 4, and 5 months of age), all subjects were monitored for unsolicited adverse events that occurred within 28 days following vaccination using report cards. In a subset of subjects (N = 2,457), these cards were standardized diaries which solicited specific adverse events that occurred within 8 days of each vaccination in addition to unsolicited adverse events which occurred from enrollment until approximately 30 days following the third vaccination. Cards from the whole cohort were returned at subsequent visits and were

supplemented by spontaneous reporting by parents and a medical history after the first and second doses of vaccine. In the subset of 2,457, adverse events following the third dose of vaccine were reported via standardized diaries and spontaneous reporting at a follow-up visit. Adverse events in the remainder of the cohort were reported via report cards which were returned by mail approximately 28 days after the third dose of vaccine. Adverse events (rates per 1,000 doses) occurring within 7 days following any of the first 3 doses included: unusual crying (0.09), febrile seizure (0.0), afebrile seizure (0.13), and hypotonic-hyporesponsive episodes (0.01).

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. These adverse events were reported voluntarily from a population of uncertain size; therefore, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination.

Infections and Infestations

Bronchitis, cellulitis, respiratory tract infection.

Blood and Lymphatic System Disorders

Lymphadenopathy, thrombocytopenia.

Immune System Disorders

Anaphylactic reaction, hypersensitivity.

Nervous System Disorders

Encephalopathy, headache, hypotonia, syncope.

Ear and Labyrinth Disorders

Ear pain.

Cardiac Disorders

Cyanosis.

Respiratory, Thoracic, and Mediastinal Disorders

Apnea, cough.

Skin and Subcutaneous Tissue Disorders

Angioedema, erythema, pruritus, rash, urticaria.

General Disorders and Administration Site Conditions

Fatigue, injection site induration, injection site reaction, Sudden Infant Death Syndrome.

* Parent education needs to include these as it plausible they were caused by the vaccine

OH NO!

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

In clinical trials, INFANRIX was given concomitantly with Hib conjugate vaccine, pneumococcal 7-valent conjugate vaccine, hepatitis B vaccine, IPV, and the second dose of MMR vaccine *[see Adverse Reactions (6.1), Clinical Studies (14.3)]*.

When INFANRIX is administered concomitantly with other injectable vaccines, they should be given with separate syringes. INFANRIX should not be mixed with any other vaccine in the same syringe or vial.

7.2 Immunosuppressive Therapies

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to INFANRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C – Education must include this warning.

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

8.4 Pediatric Use

Safety and effectiveness of INFANRIX in infants younger than 6 weeks of age and children 7 to 16 years of age have not been established. INFANRIX is not approved for use in these age groups.

11 DESCRIPTION

INFANRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) is a noninfectious, sterile vaccine for intramuscular administration. Each 0.5-mL dose is formulated to contain 25 Lf of diphtheria toxoid, 10 Lf of tetanus toxoid, 25 mcg of inactivated pertussis toxin (PT), 25 mcg of filamentous hemagglutinin (FHA), and 8 mcg of pertactin (69 kiloDalton outer membrane protein).

The diphtheria toxin is produced by growing *Corynebacterium diphtheriae* in Fenton medium containing a bovine extract. Tetanus toxin is produced by growing *Clostridium tetani* in a modified Latham medium derived from bovine casein. The bovine materials used in these extracts are sourced from countries which the United States Department of Agriculture (USDA) has determined neither have nor present an undue risk for bovine spongiform encephalopathy (BSE). Both toxins are detoxified with formaldehyde, concentrated by ultrafiltration, and

purified by precipitation, dialysis, and sterile filtration.

The acellular pertussis antigens (PT, FHA, and pertactin) are isolated from *Bordetella pertussis* culture grown in modified Stainer-Scholte liquid medium. PT and FHA are isolated from the fermentation broth; pertactin is extracted from the cells by heat treatment and flocculation. The antigens are purified in successive chromatographic and precipitation steps. PT is detoxified using glutaraldehyde and formaldehyde. FHA and pertactin are treated with formaldehyde.

Diphtheria and tetanus toxoids and pertussis antigens (PT, FHA, and pertactin) are individually adsorbed onto aluminum hydroxide.

Diphtheria and tetanus toxoid potency is determined by measuring the amount of neutralizing antitoxin in previously immunized guinea pigs. The potency of the acellular pertussis components (PT, FHA, and pertactin) is determined by enzyme-linked immunosorbent assay (ELISA) on sera from previously immunized mice.

Each 0.5-mL dose contains aluminum hydroxide as adjuvant (not more than 0.625 mg aluminum by assay) and 4.5 mg of sodium chloride. Each dose also contains ≤100 mcg of residual formaldehyde and ≤100 mcg of polysorbate 80 (Tween 80).

INFANRIX is available in vials and prefilled syringes. The tip caps of the prefilled syringes contain natural rubber latex; the plungers are not made with natural rubber latex. The vial stoppers are not made with natural rubber latex.

INFANRIX is formulated without preservatives.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Diphtheria

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

Tetanus

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

Pertussis

Pertussis (whooping cough) is a disease of the respiratory tract caused by *B. pertussis*. The role

of the different components produced by *B. pertussis* in either the pathogenesis of, or the immunity to, pertussis is not well understood. There is no well established serological correlate of protection for pertussis.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

14 CLINICAL STUDIES

14.1 Diphtheria and Tetanus

Efficacy of diphtheria toxoid used in INFANRIX was determined on the basis of immunogenicity studies. A VERO cell toxin neutralizing test confirmed the ability of infant sera (N = 45), obtained one month after a 3-dose primary series, to neutralize diphtheria toxin. Levels of diphtheria antitoxin ≥0.01 IU/mL were achieved in 100% of the sera tested.

Efficacy of tetanus toxoid used in INFANRIX was determined on the basis of immunogenicity studies. An in vivo mouse neutralization assay confirmed the ability of infant sera (N = 45), obtained one month after a 3-dose primary series, to neutralize tetanus toxin. Levels of tetanus antitoxin ≥0.01 IU/mL were achieved in 100% of the sera tested.

14.2 Pertussis

Efficacy of a 3-dose primary series of INFANRIX has been assessed in 2 clinical studies.

A double-blind, randomized, active Diphtheria and Tetanus Toxoids (DT)-controlled trial conducted in Italy assessed the absolute protective efficacy of INFANRIX when administered at 2, 4, and 6 months of age. The population used in the primary analysis of the efficacy of INFANRIX included 4,481 infants vaccinated with INFANRIX and 1,470 DT vaccinees. The mean length of follow-up was 17 months, beginning 30 days after the third dose of vaccine. After 3 doses, the absolute protective efficacy of INFANRIX against WHO-defined typical pertussis (21 days or more of paroxysmal cough with infection confirmed by culture and/or serologic testing) was 84% (95% CI: 76, 89). When the definition of pertussis was expanded to include clinically milder disease with respect to type and duration of cough, with infection confirmed by culture and/or serologic testing, the efficacy of INFANRIX was calculated to be 71% (95% CI: 60, 78) against >7 days of any cough and 73% (95% CI: 63, 80) against ≥14 days of any cough. Vaccine efficacy after 3 doses and with no booster dose in the second year of life was assessed in 2 subsequent follow-up periods. A follow-up period from 24 months to a mean age of 33 months was conducted in a partially unblinded cohort (children who received DT were offered pertussis vaccine and those who declined were retained in the study cohort). During this period, the efficacy of INFANRIX against WHO-defined pertussis was 78% (95% CI: 62, 87). During the third follow-up period which was conducted in an unblinded manner among children

from 3 to 6 years of age, the efficacy of INFANRIX against WHO-defined pertussis was 86% (95% CI: 79, 91). Thus, protection against pertussis in children administered 3 doses of INFANRIX in infancy was sustained to 6 years of age.

A prospective efficacy trial was also conducted in Germany employing a household contact study design. In preparation for this study, 3 doses of INFANRIX were administered at 3, 4, and 5 months of age to more than 22,000 children living in 6 areas of Germany in a safety and immunogenicity study. Infants who did not participate in the safety and immunogenicity study could have received a DTwP vaccine or DT vaccine. Index cases were identified by spontaneous presentation to a physician. Households with at least one other member (i.e., besides index case) aged 6 through 47 months were enrolled. Household contacts of index cases were monitored for incidence of pertussis by a physician who was blinded to the vaccination status of the household. Calculation of vaccine efficacy was based on attack rates of pertussis in household contacts classified by vaccination status. Of the 173 household contacts who had not received a pertussis vaccine, 96 developed WHO-defined pertussis, as compared with 7 of 112 contacts vaccinated with INFANRIX. The protective efficacy of INFANRIX was calculated to be 89% (95% CI: 77, 95), with no indication of waning of protection up until the time of the booster vaccination. The average age of infants vaccinated with INFANRIX at the end of follow-up in this trial was 13 months (range: 6 to 25 months). When the definition of pertussis was expanded to include clinically milder disease, with infection confirmed by culture and/or serologic testing, the efficacy of INFANRIX against ≥7 days of any cough was 67% (95% CI: 52, 78) and against ≥7 days of paroxysmal cough was 81% (95% CI: 68, 89). The corresponding efficacy of INFANRIX against ≥14 days of any cough or paroxysmal cough were 73% (95% CI: 59, 82) and 84% (95% CI: 71, 91), respectively.

Pertussis Immune Response to INFANRIX Administered as a 3-Dose Primary Series

The immune responses to each of the 3 pertussis antigens contained in INFANRIX were evaluated in sera obtained 1 month after the third dose of vaccine in each of 3 studies (schedule of administration: 2, 4, and 6 months of age in the Italian efficacy study and one US study; 3, 4, and 5 months of age in the German efficacy study). One month after the third dose of INFANRIX, the response rates to each pertussis antigen were similar in all 3 studies. Thus, although a serologic correlate of protection for pertussis has not been established, the antibody responses to these 3 pertussis antigens (PT, FHA, and pertactin) in a US population were similar to those achieved in 2 populations in which efficacy of INFANRIX was demonstrated.

14.3 Immune Response to Concomitantly Administered Vaccines

In a US study, INFANRIX was given concomitantly, at separate sites, with Hib conjugate vaccine (Sanofi Pasteur SA) at 2, 4, and 6 months of age. Subjects also received ENGERIX-B and oral poliovirus vaccine (OPV). One month after the third dose of Hib conjugate vaccine, 90% of 72 infants had anti-PRP (polyribosyl-ribitol-phosphate) ≥1.0 mcg/mL.

In a US study, INFANRIX was given concomitantly, at separate sites, with ENGERIX-B, IPV

(Sanofi Pasteur SA), pneumococcal 7-valent conjugate (PCV7), and Hib conjugate vaccines (Wyeth Pharmaceuticals Inc.) at 2, 4, and 6 months of age. Immune responses were measured in sera obtained approximately one month after the third dose of vaccines. Among 121 subjects who had not received a birth dose of hepatitis B vaccine, 99.2% had anti-HBsAg (hepatitis B surface antigen) ≥10 mIU/mL following the third dose of ENGERIX-B. Among 153 subjects, 100% had anti-poliovirus 1, 2, and 3, ≥1:8 following the third dose of IPV. Although serological correlates for protection have not been established for the pneumococcal serotypes, a threshold level of ≥0.3 mcg/mL was evaluated. Following the third dose of PCV7 vaccine, 91.8% to 99.4% of subjects (N = 146-156) had anti-pneumococcal polysaccharide ≥0.3 mcg/mL for serotypes 4, 9V, 14, 18C, 19F, and 23F, and 73.0% had a level ≥0.3 mcg/mL for serotype 6B.

15 REFERENCES

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3. Department of Health and Human Services, Food and Drug Administration. Biological products; Bacterial vaccines and toxoids; Implementation of efficacy review; Proposed rule. *Federal Register* December 13, 1985;50(240):51002-51117.
4. Centers for Disease Control and Prevention. General Recommendations on Immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2006;55(RR-15):1-48.

16 HOW SUPPLIED/STORAGE AND HANDLING

INFANRIX is available in 0.5-mL single-dose vials and disposable prefilled TIP-LOK syringes (packaged without needles):

NDC 58160-810-01 Vial in Package of 10: NDC 58160-810-11

NDC 58160-810-43 Syringe in Package of 10: NDC 58160-810-52

Store refrigerated between 2° and 8°C (36° and 46°F). Do not freeze. Discard if the vaccine has been frozen.

17 PATIENT COUNSELING INFORMATION

The parent or guardian should be:

- informed of the potential benefits and risks of immunization with INFANRIX, and of the importance of completing the immunization series.
- informed about the potential for adverse reactions that have been temporally associated with administration of INFANRIX or other vaccines containing similar components.

still education on pros and cons recommended by manufacturer.

- instructed to report any adverse events to their healthcare provider.
- given the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Manufactured by **GlaxoSmithKline Biologicals**

Rixensart, Belgium, US License 1617

Novartis Vaccines and Diagnostics GmbH

Marburg, Germany, US License 1754

Distributed by **GlaxoSmithKline**

Research Triangle Park, NC 27709

INF:XXPI

I trust that the depth and breadth of the carefully researched testimonies presented today will help you make a truly informed decision about this important legislation.

We have grave problems with corruption within **HHS** and the captured agencies under it's umbrella: The **CDC** and **FDA** and their committees like **ACIP**.

This is not the appropriate time to be promoting the type of legislation proposed in HB-1312 which serves to benefit the liability free pharmaceutical companies

https://www.usatoday.com/in-depth/news/investigations/2019/04/03/abortion-gun-laws-stand-your-ground-model-bills-conservatives-liberal-corporate-influence-lobbyists/3162173002/

and provides the personal data of a minority of children to the State.

This data can be used by pharmaceutical companies to promote their liability free products as happened recently in Indiana and Michigan. https://hslda.org/content/hs/state/mi/20151110.asp

This bill aims to adopt by rule the medical exemption recommendations as described by the **ACIP** p.8 lines 9-15.

It also aims to adopt the **ACIP** schedule which would double the required shots for school. p. 9 lines 7-27.

The ACIP is rife with conflicts of interest.

It is an unelected committee proven to be in a revolving door with Pharma.

The ACIP did not adopt evidence based guidelines to approve vaccines until 2010.

A Congressional investigation into ACIP found that among other things:

1- ACIP members have been found to have significant conflicts of interest, yet are given blanket waivers by the CDC that allow them to deliberate on any subject, regardless of their conflicts, for the entire year.

2- ACIP members are allowed to vote on vaccine recommendations, even when they have financial ties to drug companies developing related or similar vaccines

3- Members who are not allowed to vote on a recommendation due to financial conflicts are allowed to fully participate in the discussion leading up to a vote

The **CDC** owns over 50 vaccine patents, yet oversees the ACIP.

The right thing to do would be to create legislation to fix this corruption, not legislation which ignores it and harasses parents using exemptions. Vote NO on HB19-1312.

https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a4.htm

https://childrenshealthdefense.org/VSP/

https://www.bmj.com/content/350/bmj.h2362.full

https://childrenshealthdefense.org/wp-content/uploads/rfk-hhs-stipulated-order-july-2018.pdf

https://www.nvic.org/nvic-archives/conflicts-of-interest.aspx

https://childrenshealthdefense.org/news/the-u-s-needs-an-independent-vaccine-safety-organization/

ACIP

The Advisory Committee of Immunization Practices (ACIP) is the CDC committee that adds vaccines to the schedule. A year 2000 Congressional US Government Reform Committee investigation into Vaccine Policy Making found several troubling conflicts of interest with the ACIP.

HB 19-1312 seeks to require CDPHE to adopt the immunization recommendations from ACIP. **Page 9 lines 10-25.** This would force the health department to adopt the full ACIP Schedule and mandate those vaccinations in Colorado. As it is now, Colorado requires 8 different immunizations, which translates to 24 shots by the time a child leaves high school. The ACIP recommended schedule consists of 53 shots by the time a child leaves high school. Adopting all of the ACIP recommendations and making them required would more than double the required shots for school entry.

HB 19-1312 also seeks to force doctors to use only the ACIP guidelines for contraindications to vaccine administration when writing a medical exemption, instead of allowing doctors to use their professional judgment. **p. 8 lines 9-15.**

The conflicts of interest found in the Congressional investigation show that the ACIP is in a revolving door with Pharma:

- "The CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year."

- ACIP routinely used working groups where Pharma insiders would effectively craft vaccine policy.

- ACIP reflects "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."

<u>The majority of the eight ACIP members were conflicted in their most recent vote:</u>

The chairman served on Merck's Immunization Advisory Board.

Another member shared the patent on a vaccine under development for the very same disease, had a $350,000 grant from Merck to develop this vaccine, and was a consultant for Merck.

Another member was under contract with the Merck Vaccine Division, received funds from various vaccine manufacturers including Pasteur, and was under contract as a principal investigator for SmithKline.

Another member received a salary from Merck as well as other payments from Merck.

Another member was participating in vaccine studies with Merck, Wyeth, and SmithKline.

Another member received grants from Merck and SmithKline.

Not only were there these glaring conflicts of interest within the ACIP, but the **ACIP admitted that until 2011 they weren't even using evidence based guidelines to add vaccines to the schedule.**

<u>Colorado should not be relying on a corrupt agency to inform our vaccination policy.</u>

HHS

Since we don't have adequate safety testing of vaccines the only way to see if they are causing harm is through post licensing surveillance. This is done through a voluntary system called the Vaccine Adverse Events Reporting System (**VAERS)** run by the **HHS**. In 2010 HHS commissioned a study of VAERS to determine if they were capturing accurate data by monitoring medical records and comparing them to the VAERS data base. They found that **only one percent of injuries were reported.** Last year alone VAERS reported 59,117 injuries in America. If this is only 1% of injuries then we can extrapolate that number to over 5 million actual injuries. Has HHS fixed the problem? **NO.**

The I**nstitute of Medicine (IOM)**, are top scientists in the country that review vaccine safety science at **HHS.** The IOM reports that they do not have the ability to assess the safety of vaccines because the science does not exist.

The 1986 NCVIA stipulated that every two years the **HHS would submit a report to Congress on the state of vaccine safety.** Through a 2017 lawsuit by Robert F. Kennedy Jr. and Del Bigtree of the Informed Consent Action Network (ICAN) it was revealed that the **HHS has not once submitted the required reports. They have neglected their duty for over 30 years.**

CDC

The CDC has an $11.5 billion dollar budget and almost $5 **billion is allocated to purchase and promotions of vaccines** and a mere **$20 million is allocated to vaccine safety.**

Owns 56 vaccine patents.

CDC or NIH employees whose names appear on vaccine patents can receive up to $150,000 in licensing fees per year (in perpetuity).

The CDC website claims it does not accept commercial support, but a 2015 article in the British Medical Journal reports that the "despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."

Former CDC Director, Julie Gerberding, 2002-2009, oversaw numerous vaccine studies while at the CDC, many have been recently deemed unreliable by the IOM.

In 2010 Gerberding became President of Merck Vaccines with an estimated $2.5 million annual salary and lucrative stock options.

FDA - VRBPAC

The **FDA is in charge with licensing vaccines**. The year 2000 Congressional US Governmental Reform Committee investigation into Vaccine Policy making found conflicts of interest in two Committees. One was the FDA committee in charge of the **initial licensing** phase, the Vaccine and Related Biological Products Advisory Committee **(VRBPAC).** This committee has 15 voting members. **Findings Included:**

"The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industries."

"Conflict of interest rules employed by the FDA ..... have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have given waivers to participate in committee proceedings.....In many cases, significant conflicts of interest are not deemed to be conflicts at all."

Three of the five FDA committee members who voted to approve the rotavirus vaccine in 1997 had financial ties to the pharmaceutical companies that were developing different versions of the vaccine.

One of the members was the principle investigator for a Merck grant to develop a rotavirus vaccine.

One of the five members had a $9 million contract for a rotavirus vaccine.

One of the five members received approximately $1million towards vaccine development.

https://www.nvic.org/nvic-archives/conflicts-of-interest.aspx

https://childrenshealthdefense.org/VSP/

https://www.bmj.com/content/350/bmj.h2362.full

https://childrenshealthdefense.org/wp-content/uploads/rfk-hhs-stipulated-order-july-2018.pdf

https://childrenshealthdefense.org/news/the-u-s-needs-an-independent-vaccine-safety-organization/

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Transcription of a Press Conference by Robert F. Kennedy Jr., in response to HB 1312 Wednesday April 10. In the House Health an Insurance committee.

He is chairman of the board and prosecuting attorney for Children's Health Defence.

https://childrenshealthdefense.org

https://www.globalresearch.ca/cdc-medical-deep-state/5672873

Robert F. Kennedy, Jr Discusses Vaccines at The Autism Education Summit

https://www.youtube.com/watch?v=CUjrKBxdI9o transcribed on part 2

Aluminum adjuvants ~~a~~ mercury adjuvants are neuro toxic.

People have auto immune reactions. Parents should have informed consent. If there are auto immune reactions, doctors should have protocols for what the after effects could be and how to address them. Just telling the parents to give them an aspirin is not good enough for conditions that can last a lifetime.

Press: There is a lot of confusion about what is the scientific consensus. How does the average person sort it out.

Robert F. Kennedy, Jr. responded:

There is a huge difference between the scientific establishment and established science. Established science is not what the CDC says or what Merck says, it's what is published on Pub Med in peer reviewed publication, and what the institute of Medicine says, which is the congressionally appointed arbiter of what is science and what isn't science is.

CDC is a vaccine company. 50% of CDC's budged goes to selling and promoting vaccines. CDC owns 57 vaccine patents. It collects money on them. FDA gets 75% of its budget from the industry. FDA owns part of the Gardisil patent. Every time someone buys a $420 shot of Gardisil, FDA makes money. Individuals who worked on the patent get $150 thousand dollars a year in royalties. These are the division chairs, powerful people in these agencies. I learned from my dad, "Don't trust people in authority." People in authority lie.

transcribed so you can read instead of watching video

You have an industry that is minting and creating phony studies, like the tobacco industry. But the pharmaceutical companies have much more power with the press than the oil or tobacco companies, because they are the biggest advertisers. Of 22 ads on an evening news show, 17 are paid for by Pharma. If I put this issue on one of the news shows, they would get a call from the sponsor immediately. The news only gives Pharma talking points.

Robert F. Kennedy and Robert DeNero said, they would pay $100 K to any member of the press that could cite a study that indicated it is safe to inject mercury into a baby. I can show you 100's of studies that show its not. You can't trust the CDC. You have to go to what IOM actually says.

There are 141 active vaccine bills in the US right now in 35 states. Can you comment on the censorship across all the media?

I grew up with axiom you can't have democracy if you don't have free debate, no matter how controversial the issue. People say the CDC wouldn't lie to us about the health of children. Look at the Catholic church and the pedophile scandal. Look how the press collaborated with them. There was a movie that won an academy award about the Boston Globe who believed the institution was more important than the children that were getting hurt. People in the press have to guard themselves about the belief that the CDD and the vaccine program are so important that we can't entertain criticism about it. That's the mistake people made about the pedophile scandal. We can't talk about it or people will lose faith in this important institution.

What are the Democrats owing to these powerful, powerful multi-national titans? Mark Zukerbuerg and Jeff Besos are saying you have to stop criticism of a pharmaceutical product. Mainstream press is letting them get away with that—demanding censorship about corruption of public agencies.

Raise your hand if you have a child or family member that was injured by a vaccine? (off camera a lot must raise their hands) This isn't people's imagination; it's happening. You would have to ignore, or say these women are all hysterics. It's a time in history that both the press and the Democratic party start listing to women. And its time to remind the Democratic party of its central plank over the last 2 decades, "My Body, My Choice"! What ever happened to that?

Press: About Gardisil, several countries have barred Gardisil. Its my understanding that you have some information on why it is being pushed so heavily in this country, when there are risks.

Why Gardisil are on the market--we got it from Merck and public agencies. My concern about Gardisil is huge injury rate. I represent one girl who was top HS athletic star who got the Gardisil shot at age 15, and now she is in a wheel chair with seizures every 90 seconds. This is typical. I have letters, videos every week of children with "Gardisil syndrome". I believe every girl that gets a Gardisil shot is injured. You cannot inject those levels of aluminum into human

beings and not damage them. It goes into your brain and you may get dementia or Alzheimer's 20 years from now, but it will come out. Yale Medical School published a story in 2017 showed that women who were suffering OCD, anxiety, anorexia, or depression were much more likely to be vaccinated than those that weren't. I believe we are seeing much more recorded injury reported to the HMO's. There is a huge spike of teenagers that are having depression. It was on CBS. Teenage suicide rates going up. CDC can't explain why all these teens are suicidal, depressed, and loosing executive function, and can't deal with social situations. That's exactly what happens in dozens of animal models with animals injected with aluminum. You see these strange behaviors, and inability to function. What studies? Why can't they look t Gardisil. It's a huge human experiment society wide without any safely testing. They suddenly inject a whole generation with one of the most potent neurotoxins in the universe with huge levels of poison, much larger than EPA considers safe.

I'm not a doctor, but all I'm asking is that vaccines undergo the same safety testing that we require of other drugs. Is this radical? And not allowed to print? That vaccines aught to be safety tested like other drugs, against placebos. Its not radical, its something I think most American's would support. I know too much, I read this stuff, and I can't un-think it.

Press: Can you tell where you got the numbers?

All my numbers come from the manufacturer's insert. All manufacturers are required by Congress to include an insert to include a typical example of the studies. Anyone can look them up, but nobody does it, and if you did, nobody would take it. Those odds--2.3 %, showed auto immune disease, and 1 in 40 showed major injury within 6 months, nobody would make that bet. The death rate was double the background rate. The miscarriage rate was 5 times the background rate. The reproductive injury rate was about 5 times the background rate in this country. If you look at the manufactures insert, you can look it up, but doctors don't look it up. They believe what CDC and AAP tells them.

AAP is getting 80% of its income from these companies, its an industry that makes a lot of money from vaccines. Merck lied about this vaccine. It deceived the regulators and the public. There is no proof that the vaccine has any effect on cervical cancer. And there is proof that it actually gives you cancer. I know what I am talking about, its not on "belief". Let Merck sue me if I am saying anything wrong, but they won't.

Press: Bayer paid 4 million dollars in damages, but it doesn't matter that they paid, it doesn't prove anything about injury in this country.

HHS says fewer than 1% of vaccine adverse events are reported. Multiply that 4 billion by 100. (Harvard Health Sciences).

Press: I am African American. We have a lot of auto immune diseases that we can't explain.

There are many studies. You can go to Childrens Health Defence, and there is an article there called "The New Tuskeegee Experimant". (Actually titled CDC's Latest Tuskegee Experiment:

African American Autism and Vaccines (https://www.wnd.com/2011/06/313393/) Africans with pure African blood are more likely to suffer vaccine injury than African Americans. The CDC's most important study, called The Stephano 2004 Study, published in Pediactrics. The 5 researchers studied the MMR vaccine in Georgia. They thought it would be safe to study the MMR, because they thought the autism was caused by mercury. When they got the data back what they showed is black boys had a 205% chance of getting autism if they took the MMR vaccine on time at 36 months of age, compared to waiting. The superiors at CDC were ordered to bring all their data into a conference room and ordered to destroy their data, and then they published their data to Stephano, and said there is no added influence on blacks. We know that is a lie. Particularly mercury vaccines affect boys 4 to one over girls. The reason for that is because testosterone amplifies the neuro toxicity of the mercury molecule. Estrogen tends to affect the mercury molecule to protect the female brain. That is why you see such sexual dimorphism in neuro-developmental disorders. They tend to affect boys at a 4 to 1. There is a study where they gave Thymerisol (the mercury adjuvant) to rats. All 11 male rats died, no female rat even showed any illness. African Americans have as a rule higher testosterone rates than other Americans, so those vaccines, like flu vaccines, with much more mercury in them would affect African Americans much more by logic.

Those vaccines are given more in African American neighborhoods. They are the multidose, cheapest, and there are adverse effects.

In 2016, VAERS (Vaccine Adverse Effects Reporting) has these statistics. If only 1% are reported here are the numbers:

432 deaths → 43,200 deaths

1,091 permanent disabilities -> 109,100

4,132 hospitalization -> 413,200

10,254 emergency room visits -> 1,028,400

This is not science, its suggestive.

They only get post licensing stats of only 1%, because pre-licensing there are no studies, there are no stats. They came under a lot of criticism for that, so they decide to machine capture the numbers. The HMOs have all your vaccine records down to batch. And they have all your medical records.

They could do a cluster analysis to associate certain batches with certain injuries and could capture 100% of the injuries. They hired an agency, Health Care Research Quality. They gave 1 million dollars to a 3 year study on one HMO, Harvard Pilgrim HMO.

They found 10% having possible reactions, and CDC got freaked out and stopped responding to questions for testing and evaluation. One in 10 is a lot different than 1 in 100. As soon as the CDC found out the system worked it fired the people and refused to answer the phone.

In the statute of Congress, in 1986, IOM (Institute of Medicine) was ultimately responsible for the quality of vaccine science coming out of CDC. 1991. They determined 22 illnesses coming out of DTP vaccine. In the literature, 6 are shown to the related to the vaccine, in 4 showed not being related to the vaccine. But in 12 diseases, there is 0 literature. CDC was supposed to produce that literature for all these chronic childhood diseases: anemia, juvenile diabetes, chronic neurological damage, learning disabilities, attention deficit, all part of the chronic epidemic.

IOM thinks these are caused by vaccines, so it rebukes CDC and says if the research capacity is not improved, future reviews of vaccine safety will be similarly handicapped. They come back 3 years later, but now there are 54 conditions—12 shown to be correlated, 5 not correlated, and 38 we have no idea.

And in the 38 is SIDS. SIDS started appearing then, and it is the biggest killer of kids. We never heard of it before '89. CDC says, "We regret the uncertainty, and urge that more definitive research should be done."

15 years later, 2011. IOM's data: 155 diseases possibly related to vaccination, but they never studied autism—CDC has never studied whether autism is caused by vaccines—long after they decided no further studies should be done. IOM says, We think its an epidemic, and you say no studies should be done.

IOM has a book 750 pages long each section is a vaccine, with all the studies and analysis of all the studies. For example, Autism and the DTap Vaccine. There is only 1 study in '04 that said autism was caused by the vaccine. However CDC is not going to count this study, because it was a passive surveillance study and lacked a comparative unvaccinated population—that's their own system—it's so bad that any study based on it we won't count.

CDC's web site says that vaccines don't cause autism. You can't just say that you have to cite something. It cites the 2011 IOM report. That is not what it says. It says we have no clue. CDC has faith that every reporter is just going to look at that and never look at the IOM report.

We cannot have a democracy if we don't have a free and inquisitive press that is skeptical about broad pronouncements by government agencies that are interested in the outcome.

IOM says here are all the vaccines required, and there are the only 2 that have ever been studied for autism. This is a short list of the ingredients, and this is the only ingredient ever studied—Thimerisol. That isn't to say they are good studies, since Bill Thompson from CDC is saying, "We lied about it." At least they are studies—they are crap, but they are studies. None of the others have ever been studied.

IOM is saying we have an epidemic of autism, allergy, asthma, neuro-developmental diseases, epilepsy. No studies have ever looked at this. Here is the graph line for the increase in chronic diseases (goes way up as the increase in vaccinations)

Studies show flu vaccinated kids have 30% more rhinitis, due to the aluminum to give an allergic response to the antigen. It turns out the aluminum also gives an allergic response to anything else in the ambient environment at the time. If you get that shot as a little kid when there is a Timothy weed outbreak, you now have a lifetime allergy to Timothy weed. If there is a peanut oil excipient in that vaccine, you now have a lifetime allergy to peanuts.

There was a randomized study on flu shots, both placebo and flu vaccinated kids got the flu the same, but the vaccinated kids had 4.4 times more non-flu infections because it wrecks your immune system.

The CDC did a study that no independent scientist can ever get into, it is a locked box, looking at the vaccine records of 440,000 kids. CDC looked at it 2001 and looked at kids who got Thimerisol containing HepB vaccine in their 1st 60 days, and compared to kids who did not. And they never published the study. We got it thru the FOIA. You will see why. 1100% greater chance of getting an autism diagnosis. They knew right then what was causing the autism epidemic. The relative risk of smoking a pack of cigarettes a day for 20 years and getting lung cancer is 10—causation/proof. This is 11.35, beyond proof.

The senior CDC vaccine scientist, Dr William Thompson, wants to testify in front of Congress, but Congress won't subpoena him, because they don't want him to talk. And the press won't cover him. He says he has been cheating on every autism study for the last 20 years. He is the co-author of all these studies. He was in the room when they destroyed the first studies. In a voice recording, he said, "The whole system is paralyzed. We need Congress to come in and analyze the data, with an independent contractor to do it. I have great shame now when I meet families with autism-- I have been part of the problem. CDC put the research 10 years behind. Because the CDC has not been transparent; we have missed 10 years of research, because CDC is so paralyzed right now, by anything related to autism. They are not doing what they should be doing--looking for things associated with autism. I'm completely ashamed, that's what I did. " (what I could hear of the recording.)

It's shocking to me out of all the newspapers in the US, none have investigated this. In the 2000 investigation from the House Government reform Committee, all these are quotations from it, talking about the corruption: The cmmittee at the FDA that licenses all vaccines, they are not part of the FDA, they are brought in from the industry—they license the vaccines, based on this non-existent science. Then it goes to another committee called ASIP(?), and they add it to the schedule. And all of them have financial ties to the industry. This is typical. Look at this: For example, 3 of the 5 FDA advisory committees have voted to approve the Roto virus vaccine in December of '97, had financial ties to pharmaceutical companies that were developing different versions of the vaccine. One of the 5 voting members 's employer had a 9 million dollar contract for the Roto virus vaccine. One of the 5 voting members was a principle investigator for Merck grant to develop the Roto vaccine. One of the 5 voting members received a million dollars from vaccine manufacturers toward vaccine development. Those are the guys that licensed the Roto virus vaccine that your kids have to take. This is ASIP—go to

CDC—it admits it did not adopt evidence based guidelines for 2011. That raises the question, what were they basing it on? Just relationships, that's it. I'll show you the relationships. BTW, all the vaccines like MMR and Gardisil were already done. These 2 Committees brought this industry from 1 billion in '86, to 50 billion today, in 2019, and that's why we are getting all these new vaccines.

Here is a Congressional investigation of the CDC side, that mandates the vaccines. The majority of the ACIP members were conflicted: the chairman, served on Merck's advisory board. Another member shares a patent on a vaccine development for the very same disease that had a $350 thousand dollar grant to develop this vaccine. Its Paul Offen. He owned the patent, he voted it on, and he sold his patent back to Merck for $186 million dollars. And he is the darling of the media in this country. He can publish editorials every 6 months in the NY Times, and people die to get him on their shows. Another member was under contract with the Merck vaccine division to receive funds from various vaccine manufacturers including Pasteur—under contract. Another member received a salary from Merck. Another member was participating in vaccine studies with Merck. Another member received grants from Merck to approve a vaccine that Merck owned the patent for.

In case you think that was an anomaly, this was 11 years later, the HHS inspector general says 97% of committee members failed to make conflict disclosures. At least 58% had an unidentified potential conflict, and 32% had conflicts.

This is CDC's budget. $11.5 billion—5 billion goes to vaccine sales and promotion. CDC's website claims over 130 times, "CDC does not accept commercial support." But only 20 million is spent on safety.

From 2002-2009 Julie Gerberding was CDC director who brought us the MMR monopoly, and she brought us the Gardisil vaccine with all that crappy science. She oversaw numerous vaccine studies, which were recently deemed unreliable by the IOM. 2010, she became president of Merck Vaccines with an estimated $2.5 million annual salary, and lucrative stock options. That was her bribe for giving Gardisil to all our little girls and poisoning them. $38 million dollars to Julie Gerberding.

CDC or NIH employees whose names appear on vaccine patents can receive up to $150K in licensing fees per year in perpetuity.

$4,061,322,557.08 the amount paid out by the vaccine court.

The industry claim that "We erased Measles"—here is the chart of what actually happened. And you can do this for virtually almost all infectious diseases. They were erased by hygiene, chlorine, sewage treatment, and good food. And then the vaccine was introduced, 1963.

MMR was never safety tested. Nothing. They legaly have to say if they were, and they weren't. We know the MMR causes a lot of injuries, its one that causes more injuries than others. It causes 6 times the amount of seizures than actual measles does. But they say "Measles vaccine

saves lives." It was introduced in 1963. In 1962 408 people died of measles. So we can assume 408 people were saved from this vaccine every year. The question we don't know is, are more people dying? That's what we have to answer to have a cost benefit analysis. That's what science should do. Could we do better with a single measles vaccine? Could we improve those odds. Nothing like that is ever done. That is the problem, they don't study it.

This is recent study: if you get measles when you are young, you are much less likely to get certain forms of cancer. This is Non-Hodgekins Lymphoma, Hodgekins lymphohoma—by not having measles, you have a 40% chance of getting Non-Hodgekins Lymphoma. For Hodgekins lymphoma, it's a 230% greater chance. Heart disease was dramatically lessened if you had measles. Cardio vascular disease in a Japanese study. After 22 years, the people that didn't get vaccinated were by far the more long lived. The death rate 22 years later is a 3rd less without being vaccinated. Shouldn't this be studied? Shouldn't we be forcing the industry to study this?

Kat Shea oppose HB1312 Part 2
303 447-0474

RFK Jr. an environmental attorney going after the biggest polluters on the planet, especially the mercury emissions for coal burning plants. Almost all involve "scientific controversy". There is a huge gap between the industry "science", the phony industry "science" and the studies they produce that we call "grey literature". The science of mercury in vaccines and what it is actually saying and what the public media, the pharmaceutical industry, and the regulatory agencies were telling the public on what the science says.

I knew this generation of kids was very sick. My aunt Eunice Schriver created the special Olympics, we took care of all of them, but never saw kids with the disability of autism. Something new was happening to our kids. The explosion of all these new diseases. Gylphosate and many other toxins had become ubiquitous. We are swimming around in a toxic soup. I don't know if its mercury or aluminum or vaccines. But I know the vaccine schedule was exploding co-terminus/coincidental with this enormous explosion with neurodevelopmental disorders and chronic diseases in our children. Why? DBT and other mercury vaccines. In the early 80's the vaccine schedule started to grow, and people were getting sick, and they began litigating. The industry panicked thinking we are going to get sued more than we are making profits on these products, and if you want us to continue making these products you have to give us immunity from liability. In in 1986-7 this industry which gives more money to lobbying than any other was granted the holy grail, which is blanket immunity from injuries its product was causing.

When I was a child, I got 3 vaccines, and I was fully compliant. My children got 54, 69 doses of vaccines. That changed around 1989. When I was a kid the vaccines weren't even patented. They had never made money on vaccines. Now we have this product that the federal government is going to order 74 million children to purchase, and the margins are very, very high. The HPV vaccine costs s$450 per shot. And there is no advertising, no marketing, and no liability. It was a gold mine. So there was a gold rush for the FDA, and CDC to try to add new vaccines to this schedule. To add a new vaccine to the schedule is worth about a million dollars a year in profits.

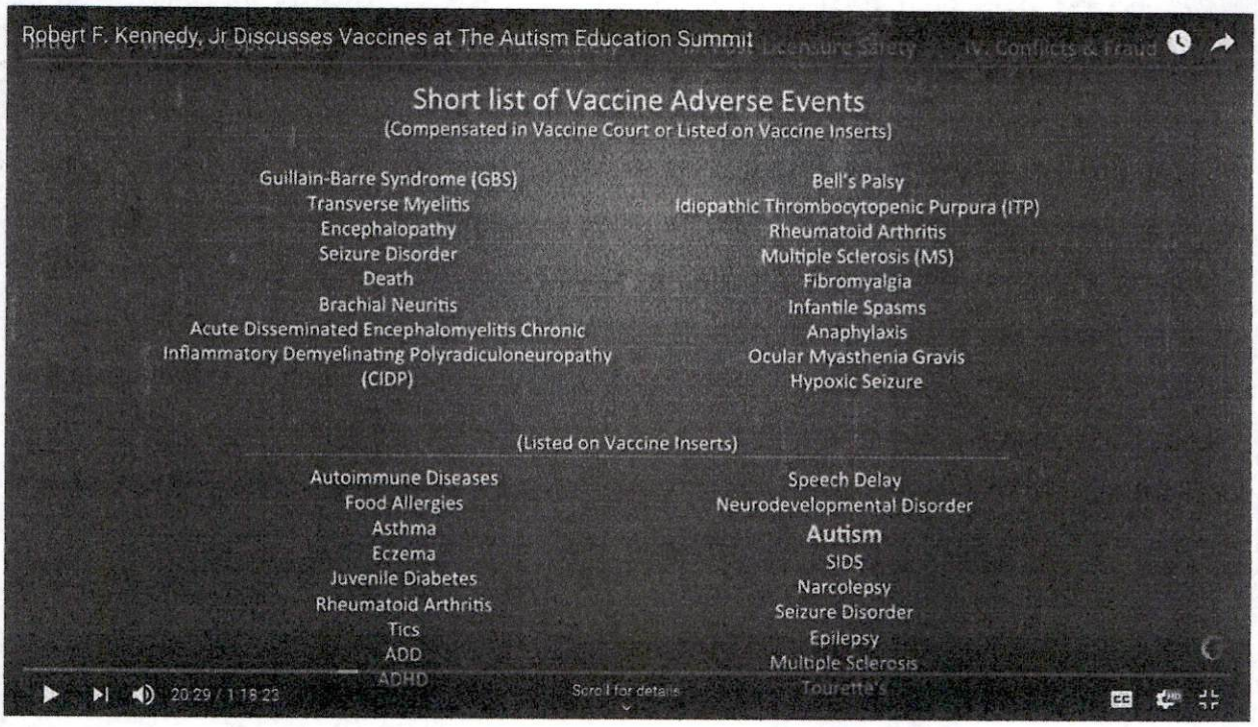
Maybe that is not bad, as long as the regulatory system is functional. And these vaccines receive the same kind of scrutiny as they are added to the market as a regular drug. Because of systemic corruption, that wasn't happening. Politicians were passing these new mandate bills, and they don't know, the Drs don't know this, and the public health regulators don't know this:

Feb 2018, Danish study with the most prominent was actually able to do a study comparing vaccinated children with unvaccinated children. CDC, WHO have discouraged any study on vaccinated vs. unvaccinated study. In Guinnea Bissow, Africa (sp) they actually found a population where ½ the population were vaccinated, and ½ were unvaccinated. The DPT vaccinated children had 10 times the mortality rate of unvaccinated. Some of the kids were given oral polio vaccine at the same time, and they only died at 5 times. They weren't dying of diphtheria, pertussis, and tetanus; it was wrecking their immune system. The things they were dying of nobody was associating with vaccines, like fevers, dysentery, cholera, and other diseases. Nobody noticed that these vaccinated kids were dying so fast. This study finally concluded that the DPT vaccine may kill more children from other causes than it does from diphtheria, pertussis and tetanus. This is the most popular vaccine in the world. Every child in Africa that is vaccinated is given this vaccine—and it was killing 10 times the children for 30 years and nobody noticed it until Peter Aabe did this study in Feb 2018.

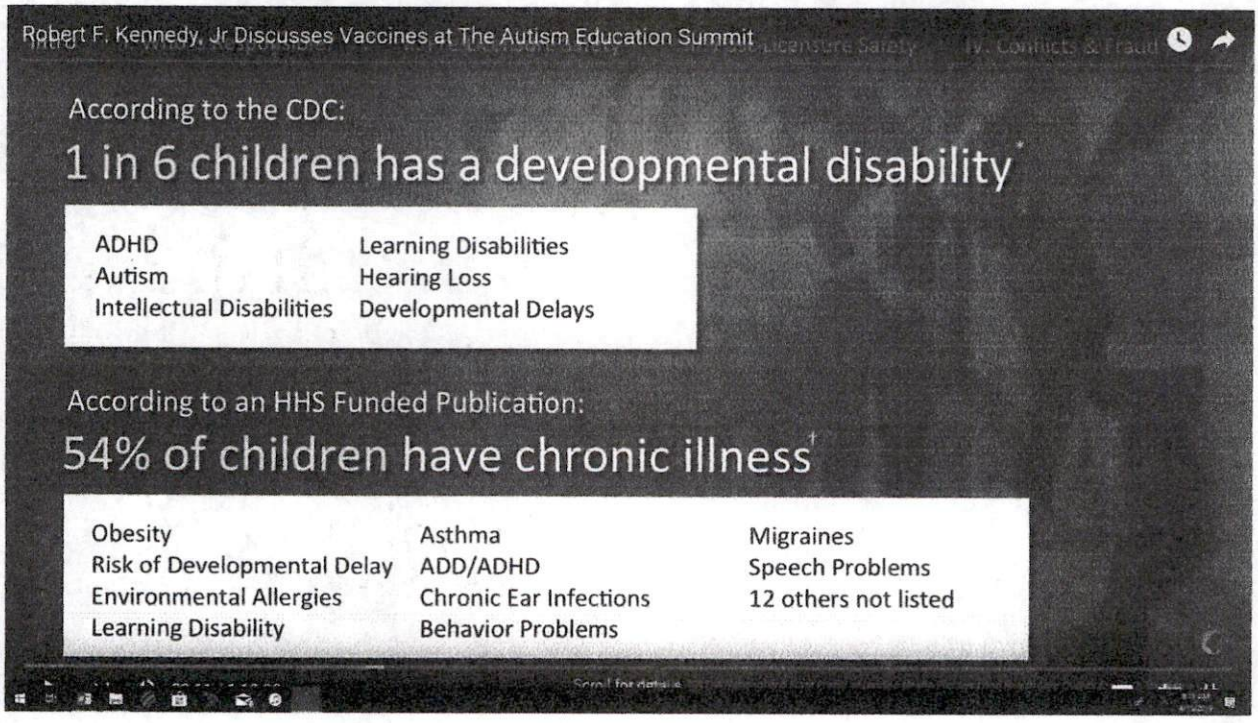
Could the same thing be happening in this country? Children are getting sick and no one is connecting the dots to the vaccination schedule, to mercury, to aluminum, or what ever. The answer is yes, it could

transcribed so you can get thru it faster than watching his video speech

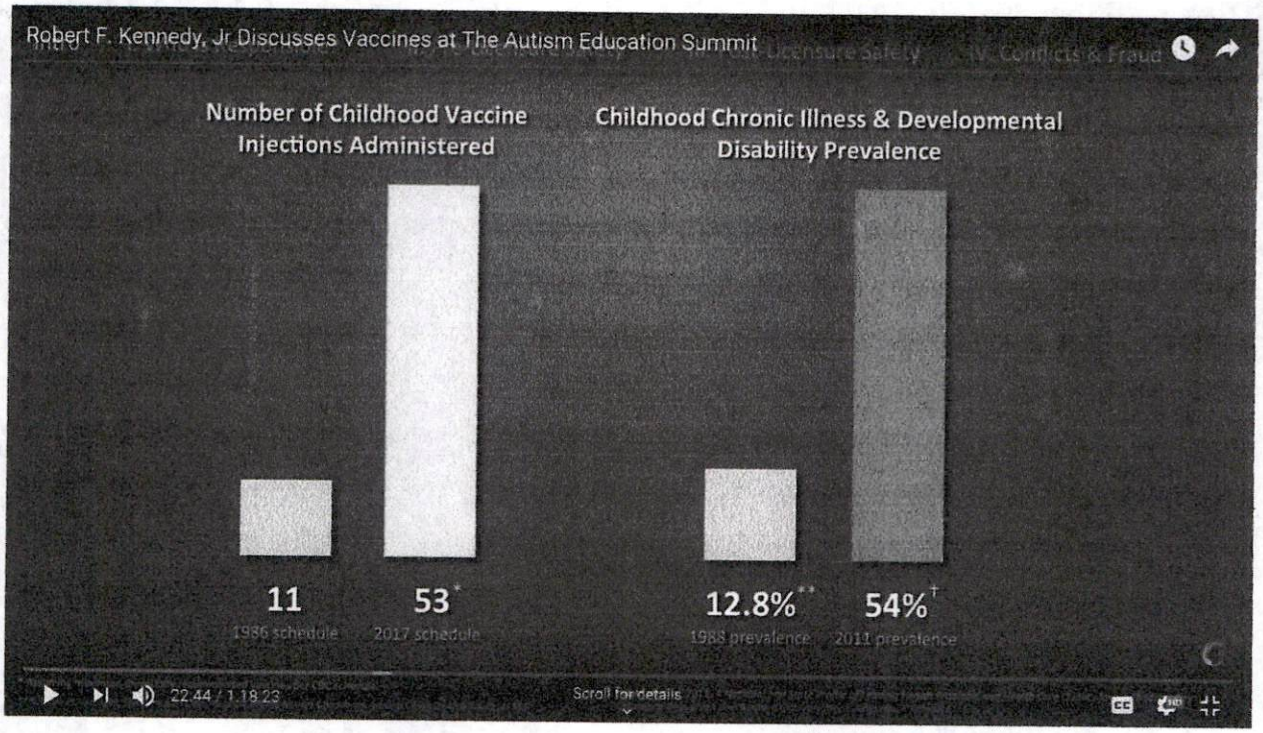
be happening. There is a list of injuries connected to vaccines. The top of the list is injuries that have been awarded compensated by the vaccine courts



These are injuries the manufacturer found when they were making the drug, and they are required to put those on the inserts. These are injuries the manufacturer feels they have to warn

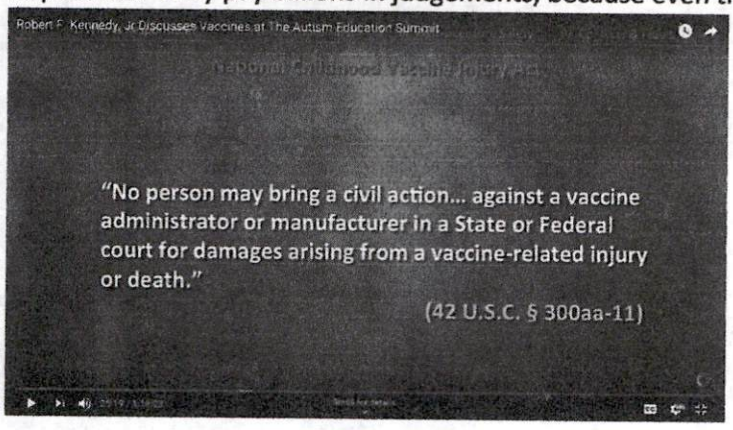


People about because there is some evidence that the vaccines are causing. Many of them are the same, as what are caused by vaccines—ADD, ADHD, the same ones we know are caused by vaccines.



In 1986 there were 11 vaccines, today there are 53. These are jabs, not doses, we went from 11 to 53. Today there are between 69 and 74 doses that kids have to take. The prevalence in 88 was 12 %, today its 54%. It tracks almost perfectly with the vaccine schedule.

Who is responsible for vaccine safety? In the rest of the world, (I know as a litigator), the guy who makes the product is responsible for making sure that it is safe. If the car engine blows, Toyota pays for it. If Vioxx causes a heart attack, Merck has to pay for it. They have an incentive to make sure it is safe as possible. They pay billions in judgements, because even though there are liable, they still don't it.

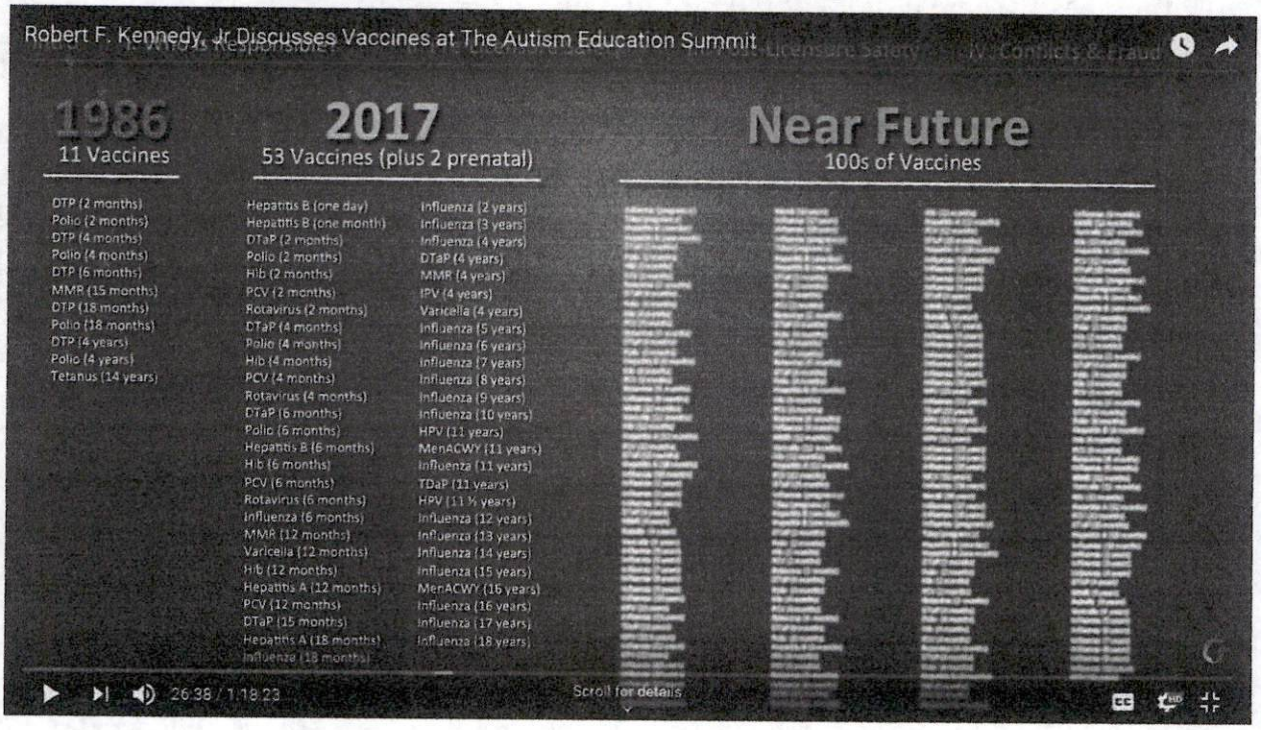


The consequences?

1. No incentive to conduct safety studies
2. Liability free market of 74 Million American children
3. Strong incentive to develop more vaccines.

The way the act is structured is the only way you can recover from a vaccine company is if it knew there was a harm and they failed to disclose it on its insert. There is a strong economic incentive not to look for harms. Then they have to disclose them, and if they fail, they are liable. Don't tell me about it—a very strong incentive to not look at vaccine safety.

Here is the incentive to develop more vaccines now we have 53 plus 2 prenatal, and there are 286 vaccines now under development:

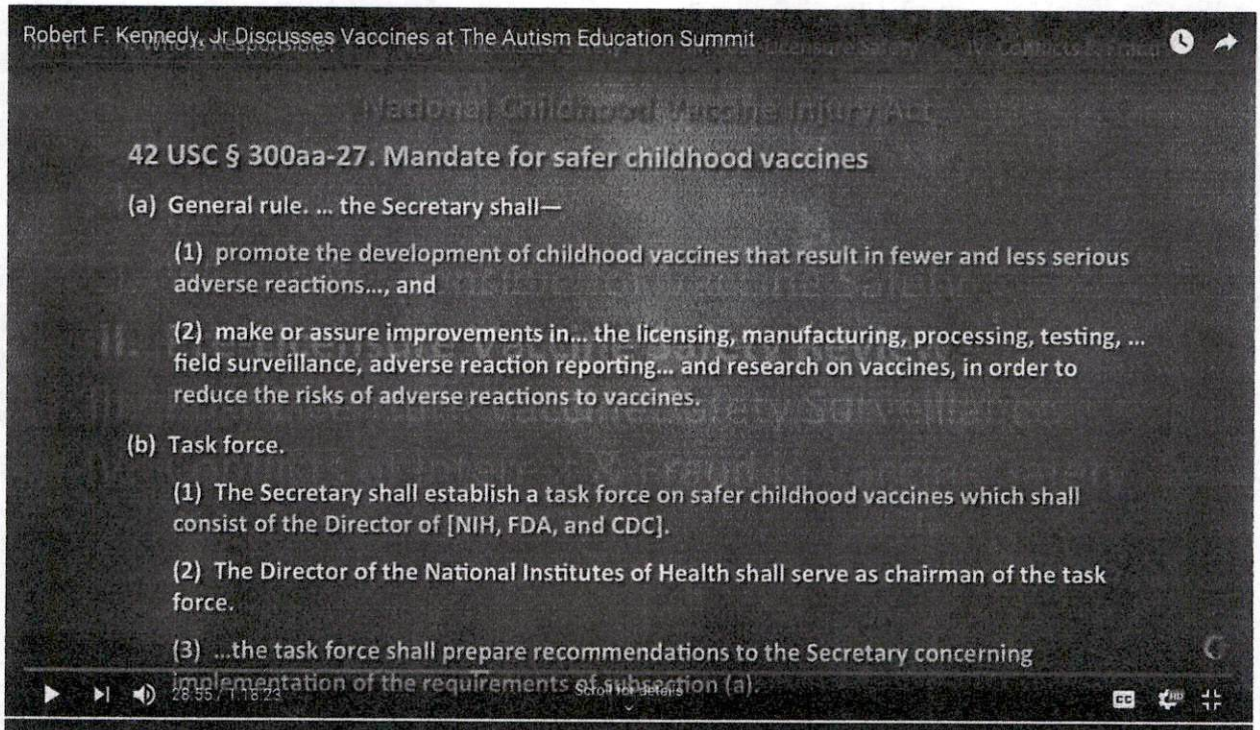


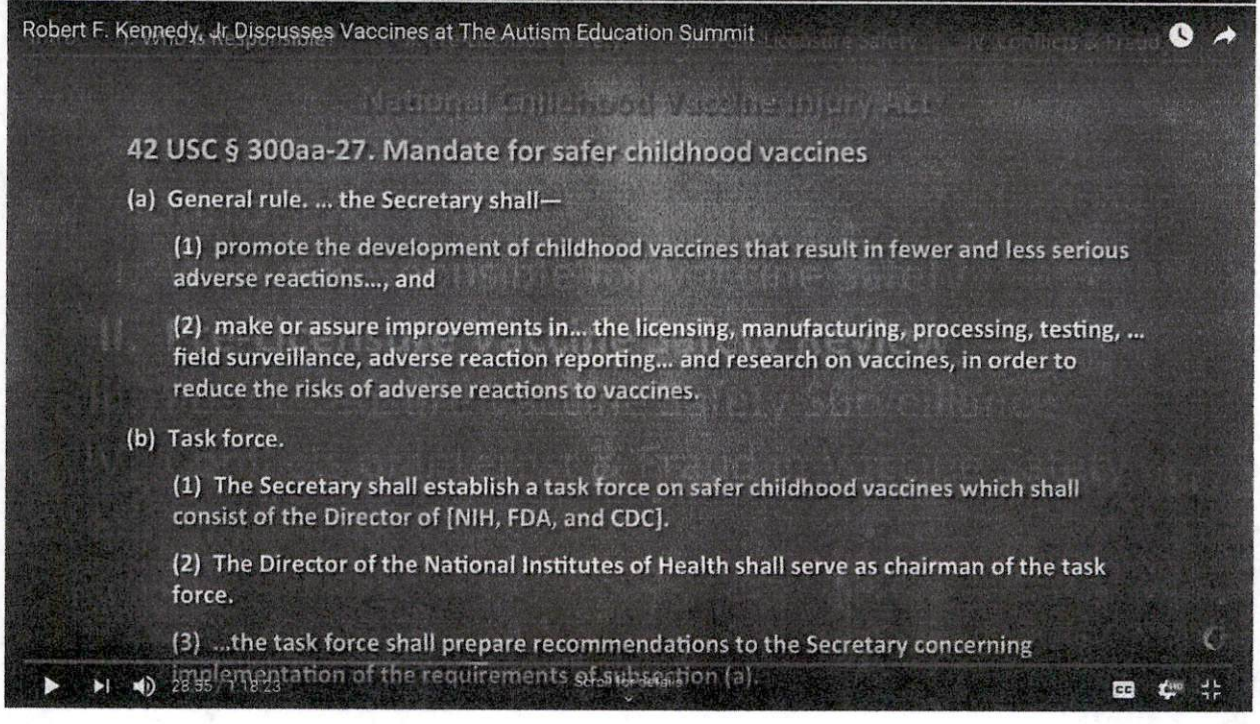
2300 clinical tests in the pipeline. Companies have no liability and no responsibility to make vaccines safe. We will compensate for this to have HHS, and FDA, CDC, HRSA, NIH will oversee safety.

Your doctor assumes that the same rigorous testing that happens on regular drug testing applies to vaccines. Double blind placebo tests is the gold standard. There is a study group, control group nor the researchers know who got what. Then the study goes 4.8 years and they look at health outcomes, do the math and see if the people taking the drug, like Lipitor are getting sick from diseases they didn't expect. Lot of the injuries don't show up for long term. You need an inert placebo.

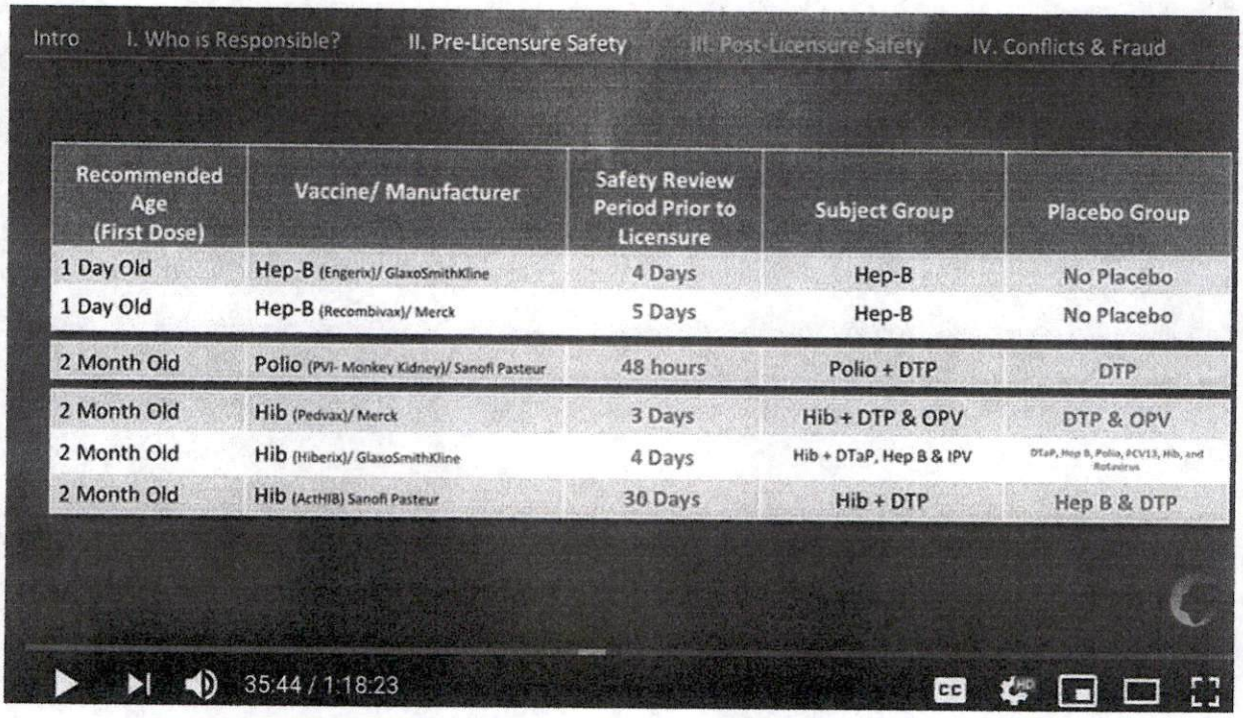
Here is vaccine safety testing. There are 2 Hep B vaccines approved for 1 day old babies. The safety review period was 4 days, and monitored for 4 and 5 days after each dose. If that child died or seizure on the 5th day or autism at 3 years old, it is as if it never happened. They only look at the kids for 4 days. ADD, food allergies, like it ever happened. NO placebo. That is not science—there is nothing to compare it to. Someone says it looks ok, without any research or math. There is no placebo—this isn't science!

Oral polio they looked at 48 hours before they approved it. The placebo was the DTP vaccine that they had to remove from the market because it was injuring so many children. The same one that in Africa is killing all these children. They need an inert placebo. They need an unvaccinated control group!



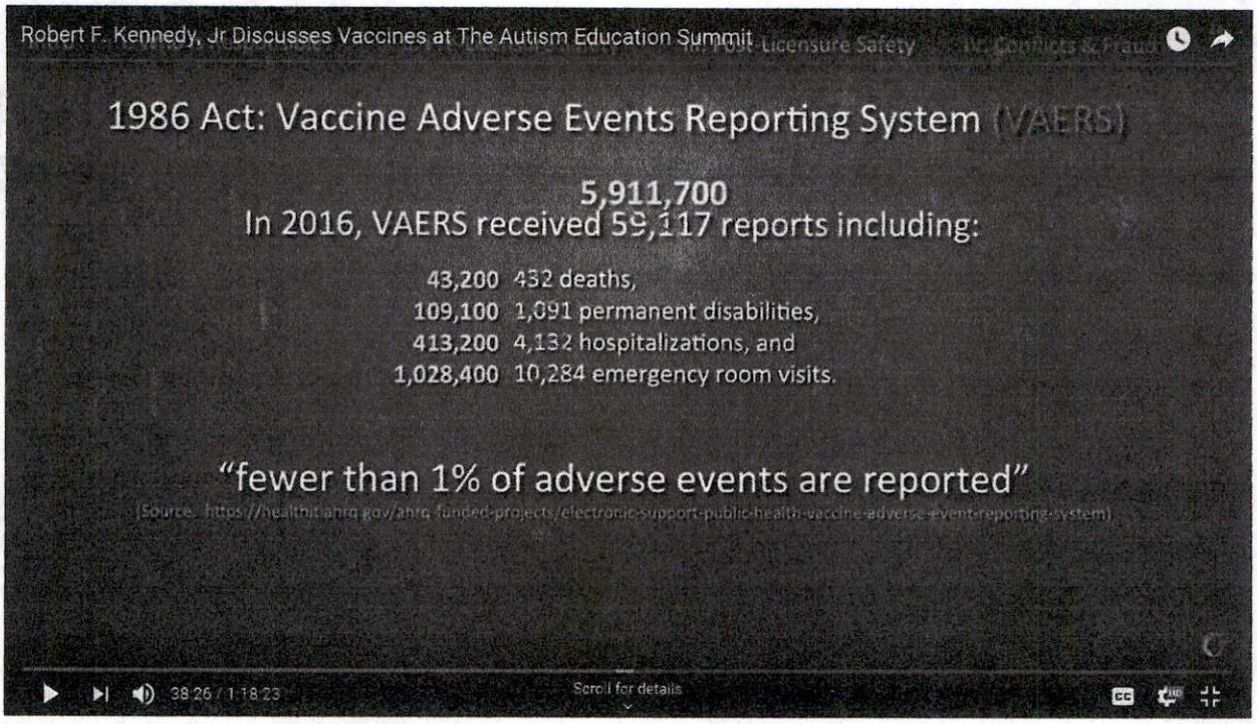


The Hib vaccine (and these are all on the manditory schedule) was compared to kids who got 6 other vaccines on the same day. How do you know if a kid got siezures, if you compare to a kid who got 6 other vaccines, including the Hib vaccine ? Then they say, its not that bad cause the other kids got sicker? This is the only sicience the FDA does prior to approving these drugs. This is no science or safety study. The only thing they know is if it treats the targeted disease. They have no idea if it causes all these other illnesses and ruined immune systems.



Recommended Age (First Dose)	Vaccine/ Manufacturer	Safety Review Period Prior to Licensure	Subject Group	Placebo Group
1 Day Old	Hep-B (Engerix)/ GlaxoSmithKline	4 Days	Hep-B	No Placebo
1 Day Old	Hep-B (Recombivax)/ Merck	5 Days	Hep-B	No Placebo
2 Month Old	Polio (PVI- Monkey Kidney)/ Sanofi Pasteur	48 hours	Polio + DTP	DTP
2 Month Old	Hib (Pedvax)/ Merck	3 Days	Hib + DTP & OPV	DTP & OPV
2 Month Old	Hib (Hiberix)/ GlaxoSmithKline	4 Days	Hib + DTaP, Hep B & IPV	DTaP, Hep B, Polio, PCV13, Hib, and Rotavirus
2 Month Old	Hib (ActHIB) Sanofi Pasteur	30 Days	Hib + DTP	Hep B & DTP

Once they start giving it to all the kids, there is post liscensur surveillance systems. VAERS Vaccine Adverse Eents Reporting System. But it is voluntary, with Drs, who gave the vaccine. Do you thing that Dr. will report that to VAERS? Some but not all. But HHS says fewer than 1% are actually reported. So multiply by 100. It could be automated, as HMOs have every record, down to batch numbers of vaccines. And they have the health records of every kid to do cluster analysis



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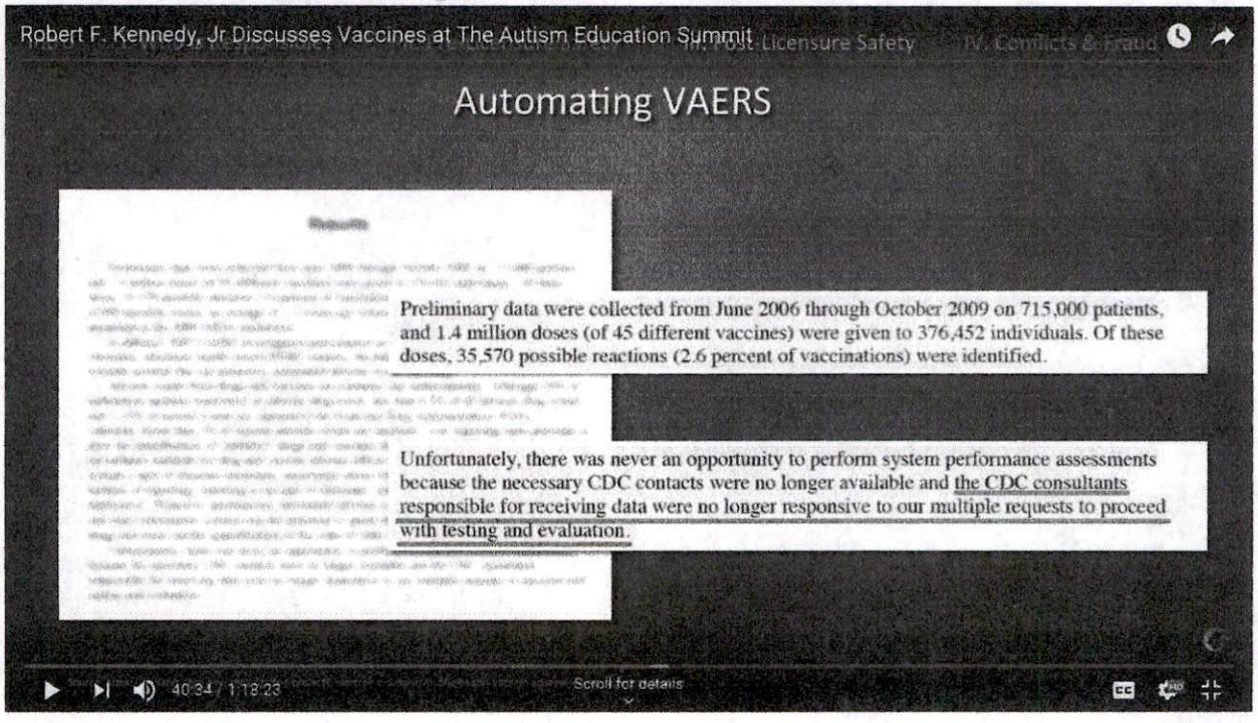
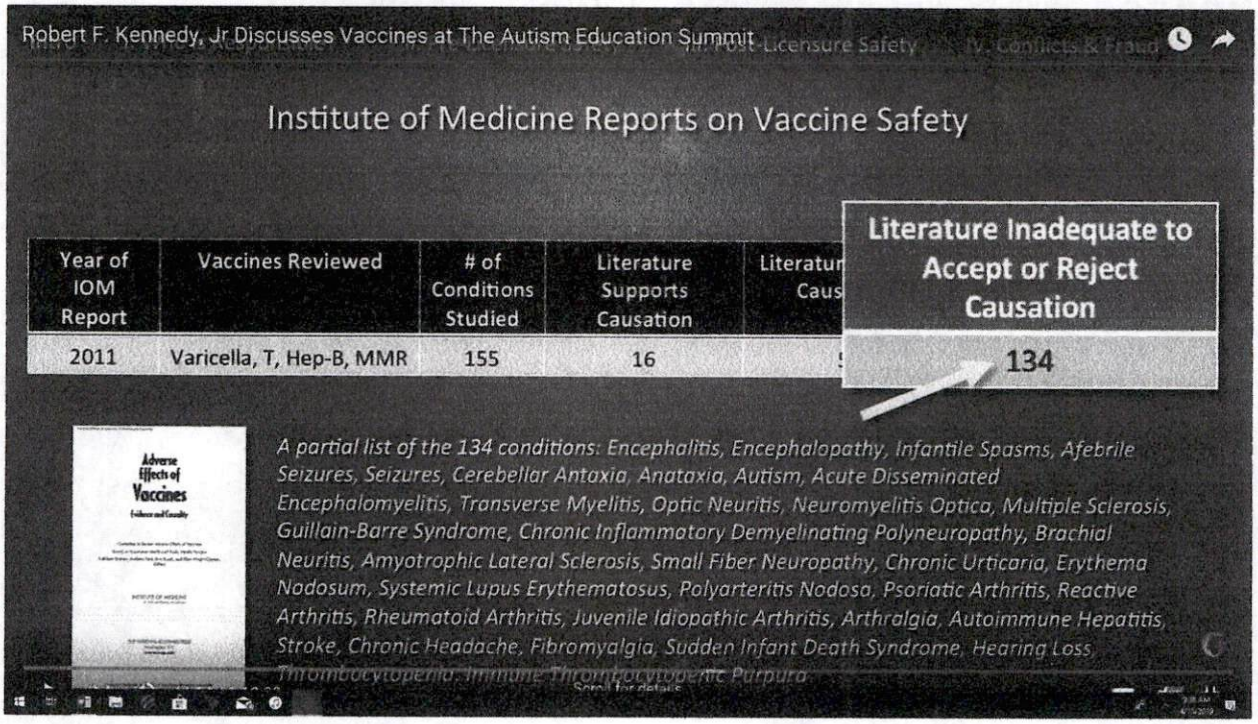
CDC hired a company to do this study. They found 10% of kids getting vaccinated are possibly getting sick. That is unacceptable to anybody. CDC shut it down, and silenced the consultntants.No pre-liscencing, and no post liscencing surveilance.

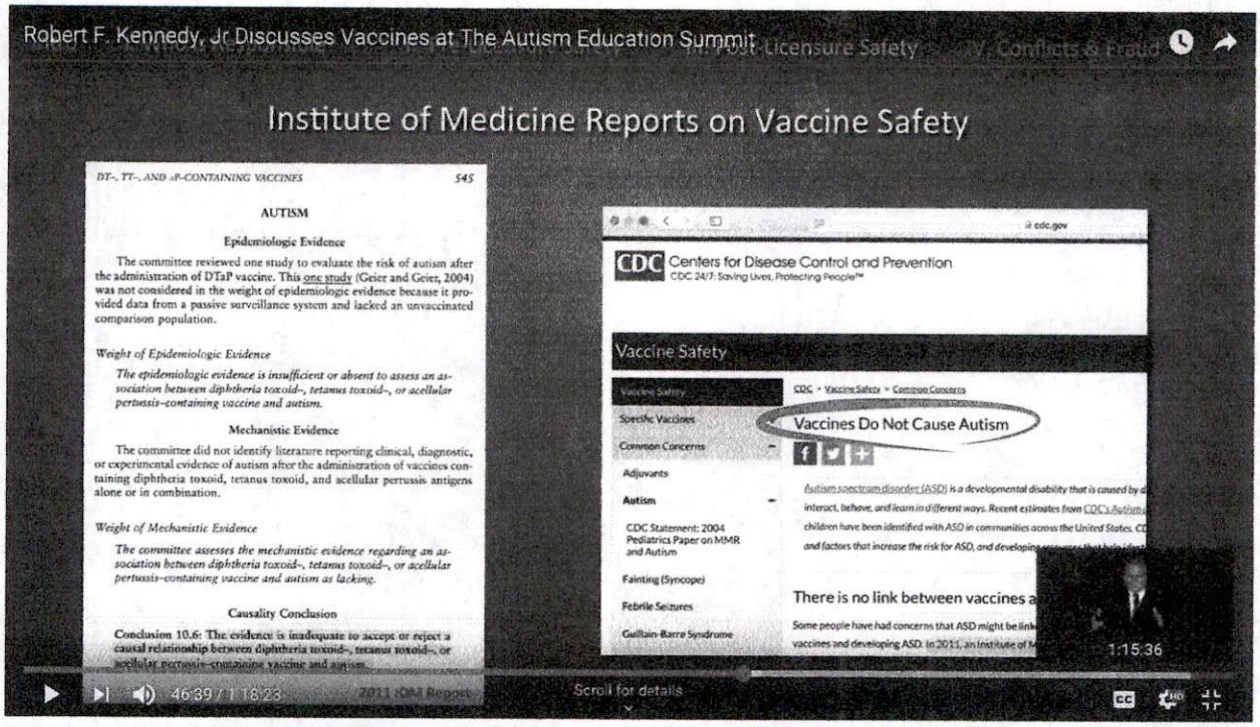


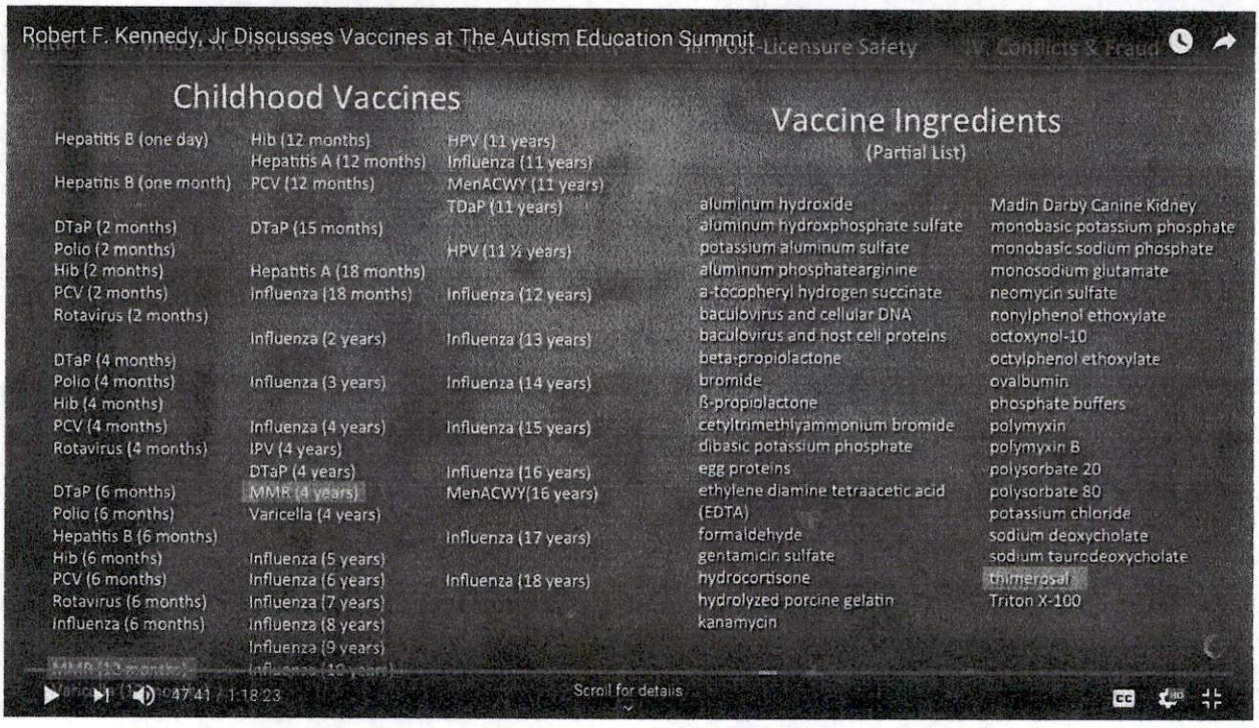
IOM looked at every vaccine to see what conditions are associated with it, and checked to see what studies were done. IOM is supposed to make sure CDC does a good job, staffed by the best scientists in the country. In 750 PAGE report, heres what they found. 22 kinds of injury, and the literature said vaccines cause 6, no causation for 4, and 12 they have no literature, no study at all—over ½ of conditions people believe are caused by vaccines. That was '91. In '94 there are 54 conditions, now 38 concitins with no study, no literature.



In 2011 there are now 155 conditions of which literature supports 16 causation, but still there are 134 with no sudies at all to verify or deny causation.

When IOM cited the one study that confirmed the relationship of autism and DPT vaccine, they then discounted it becausse the data was gathered from the governments own surveillence system VEARS , which they "considered unreliable" The one study that confirmed autism, they were going to throw out because of the government's own data base. Then CDC says DPT doesn't cause autism, citing this same report.

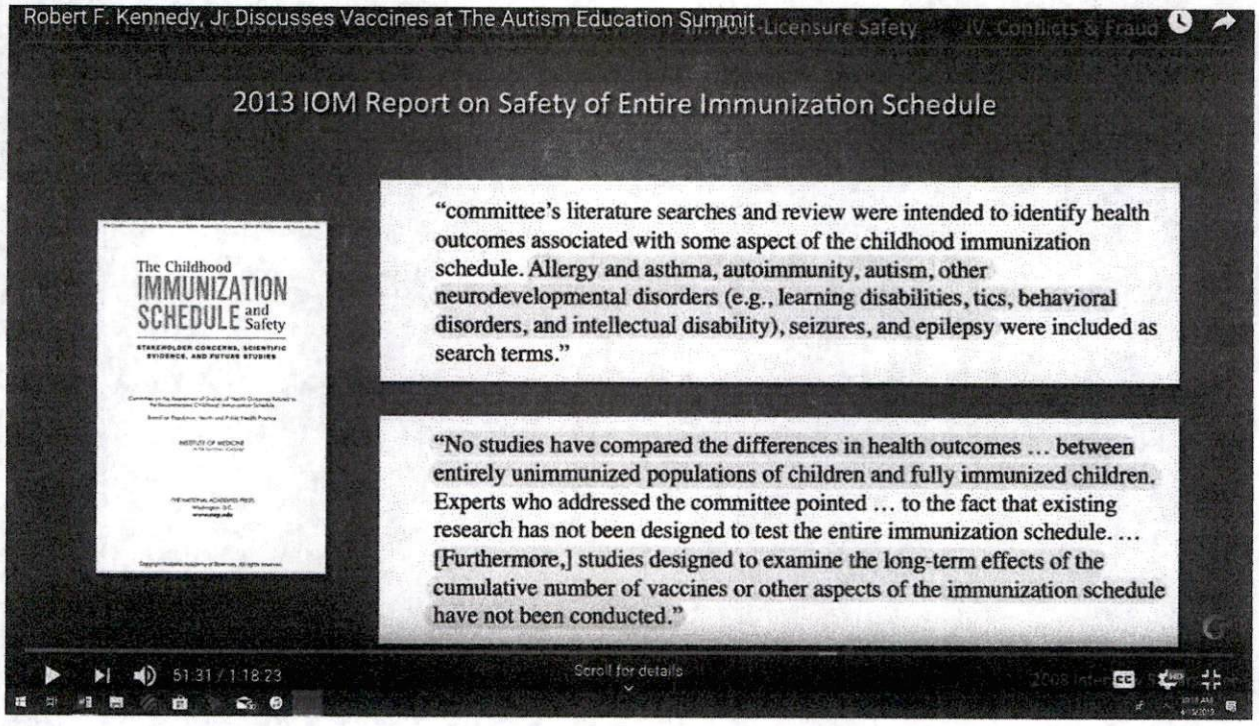




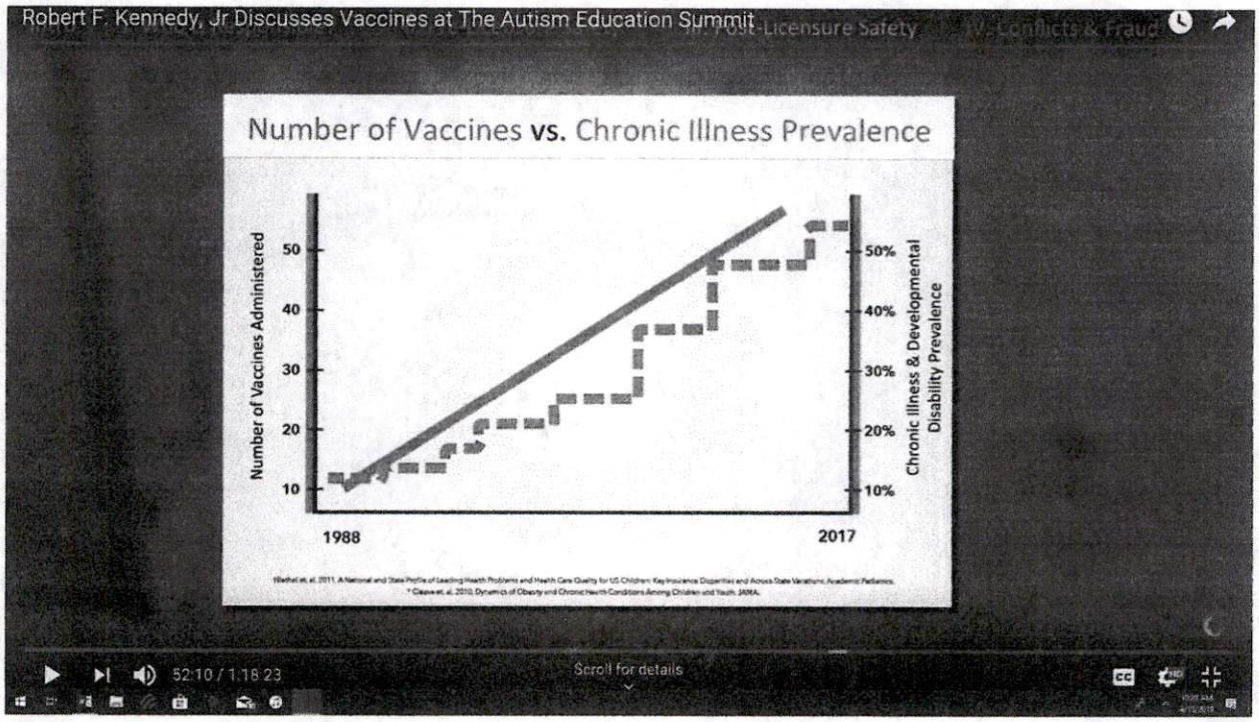
MMR and DPT have been the only vaccines to be studied. And of all the ingredients, only Thimerisol which is mercury have been studied. That is according to IOM! There is no vaccine safety science. Anyone who says they are safe, is basing it on a website that is lying.

Dr. Bernadine Healy, former Head of NIH spoke on the the evidence for "susseptible populations" and that the government has been too quick to discount the actual patients. Minute 50 of this whole talk. https://www.youtube.com/watch?v=CUjrKBxdI9o

These studies have to be done on individual vaccines and the cumulative effect of multiple vaccines. This is IOM.



From 1988 to present this is the exact correlation of increase in chronic illness and the almost identical increase in vaccination schedule:



The taxpayers are paying $27 million a year to maintain the CDC's Vaccine Safety Datalink, but no independent scientist is allowed to see these records. They have records to compare vaccinated and unvaccinated children. But they will not allow them to be seen.

• Is the State of Co. going to be liable for damages/deaths?

1) In United States law, the **Establishment Clause** of the First Amendment to the United States Constitution, together with that Amendment's Free Exercise Clause, form the constitutional right of freedom of religion. The relevant constitutional text is: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof...". You are forcing Your religious views on Me & Family Practices

The Establishment Clause was based on a number of precedents, including the Constitutions of Clarendon, the Bill of Rights 1689, and the Pennsylvania and New Jersey colonial constitutions. An initial draft by John Dickinson was prepared in conjunction with his drafting the Articles of Confederation. In 1789, then-congressman James Madison prepared another draft which, following discussion and debate in the First Congress, would become part of the text of the First Amendment of the Bill of Rights. The second half of the Establishment Clause includes the Free Exercise Clause, which allows individual citizens freedom from governmental interference in both private and public religious affairs. "Let's Take This To Court"!

2) The Establishment Clause is a limitation placed upon the United States Congress preventing it from passing legislation forcing an establishment of religion. The second half of the Establishment Clause inherently prohibits the government from preventing the free exercise of religion. While the Establishment Clause does prohibit Congress from preferring or elevating one religion over another, it does not prohibit the government's entry into the religious domain to make accommodations for religious observances and practices in order to achieve the purposes of the Free Exercise Clause. Furthermore, it does not prevent the placement of religious symbols on government premises.

Historical background

"Take Away our 2nd Amendment Right First"

Constitutions of Clarendon

The Constitutions of Clarendon, a 12th-century English law, had prohibited criminal defendants' using religious laws (at that time, in medieval England, canon law of the Roman Catholic Church) to seek exemption from criminal prosecution.

HB 1312

Donna Dunsmore
970-290-1401
(Against)

1689 Bill of Rights

From: Donna Davis-dunsmore donnadavisdunsmore@icloud.com
Subject: Witch Craft
Date: Apr 12, 2019 at 11:44:08 PM
To: donnadavisdunsmore@icloud.com

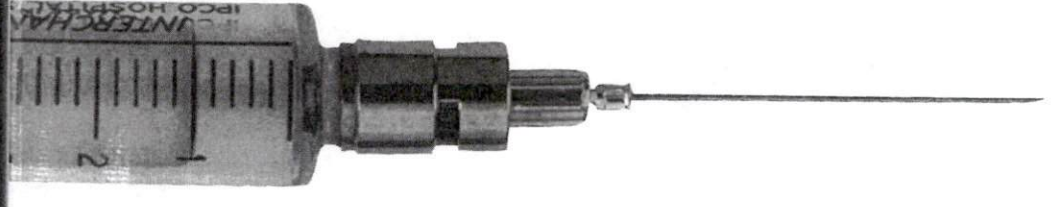
Sent from my iPad Vaccinations Are Modern Day Witch craft! Broth is fermented in an oven, the same as in a Witches Cauldron. But today heat treated with formaldehyde, which the FDA classifies as a carcinogen. Broth consists of proteins...instead of eye of Newt or part of an eel or salamander or owl meat as in ancient times. Now in Modern times it consists of .Egg, bovine, mice, guinea pig, cocker spaniel, monkey kidneys , in the 50's & 60's Jonas Salk's lab would remove the monkeys from their cages and anesthetize them. Their kidneys were quickly removed (while still alive) then the animals were killed by an overdose of ether. I saw videos of this being done in Africa, where the Rhesus monkeys come from for the production of vaccines only they did not give them ether. They just through them...Live into a pit after they removed their kidneys. It was very disturbing to watch! This was an Evil and Barbaric practice and SOME of the beginnings of Vaccinations as we know it today. Clearly inhuman! Pigs also are used in the production of vaccines. Most of these animals are, shall we say Not Kosher! That means they are Unclean. According to Leviticus Eleven these animals are unfit not only for human consumption but would also include Injection into the body not just ingestion and also for sacrificial purposes. If the animal was not fit as an offering at the temple it was not fit for the human body for consumption! The New Testament states ; Do you not know that ...Your body is the temple of the Holy Spirit. In Mark:5 the New Testament records Jesus casting out a Legion of devils into a herd of 2,000 head of swine... which by the way is The first recorded Case of ..."Deviled Ham" Ha! So,.. Jesus demonstrated and confirmed what he thought of pigs and what the Torah also states. The other Protein used in the production of vaccines is Aborted Fetal tissue!!! I was not informed that chopped up BABIES 👶 where used in the production of vaccines!! .... Chopped Up BABIES... then given to the Community in the form of an elixir or potion? Not drank as in Ancient times but Modern... Injected....and. .."THIS WILL WARD OFF SICKNESS

AND DISEASE!!" I was NOT informed!!! So, it is Clear to me that this is an Occult practice and Not a part of My faith ..IN....The One True & Living GOD , THE GOD of Abraham, THE GOD of Isaac & THE GOD Jacob!! The ONLY Sacrifice I recognize...Is the Sacrifice of Yeshuah Ha Mashiach , Jesus the Christ!! My LORD and My Savior!! I have heard statements " We Do the Lords Work". I would ask; Who is Your Lord?? What work are you doing?? Who Is Your god?? Matt. 7:21-23.

In Congress

THE VIRUS AND THE VACCINE

CONTAMINATED VACCINE, DEADLY CANCERS, and GOVERNMENT NEGLECT



"This well-researched, well-documented book unfurls a compelling scientific saga.... Not only that, it's written with the zing of a medical thriller, featuring fully realized characters, dramatic conflicts, high-level politics, and scientific egos big enough to levitate Stone Mountain."—*ATLANTA JOURNAL-CONSTITUTION*

DEBBIE BOOKCHIN & JIM SCHUMACHER

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— PUBLISHERS WEEKLY

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—STEPHEN S. HALL, *NEW YORK TIMES MAGAZINE* SCIENCE WRITER AND AUTHOR OF *MERCHANTS OF IMMORTALITY*

JONAS SALK'S POLIO VACCINE is regarded as a veritable medical miracle, for it largely eradicated one of the most feared diseases of the twentieth century. But the story of the vaccine has a dark side, one that has never been fully told before. Between 1954 and 1963, 98 million Americans received polio vaccinations contaminated with a carcinogenic monkey virus, now known as SV40. The government downplayed the incident, and it was generally accepted that although oncogenic to lab animals, SV40 was harmless to humans. But SV40 is showing up in human cancers today, and prominent researchers are demanding a serious public health response to this forgotten polio vaccine contaminant. In a page-turner in the tradition of *The Hot Zone*, this meticulously researched and powerfully written book takes readers on a side-by-side journey with some of today's most prominent cancer researchers and raises major questions about vaccine policy.

DEBBIE BOOKCHIN has been a journalist since 1979 and has won awards for her news, feature, and investigative reporting. She has written for the *Boston Globe*, the *New York Times*, and numerous other publications.

JIM SCHUMACHER is a lawyer and writer whose work has appeared in *Boston Magazine*, *Newsday*, and the *Atlantic Monthly*, among others. Bookchin and Schumacher are married to each other and live in Vermont with their daughter.

The article on which this book is based was originally published in the *Atlantic Monthly* in 2000 and earned a selection in the HarperCollins book *Best Science Writing 2001*.

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