# Exhibit 316

## Conflicts of Interest Undermine Children's Health

Children's Health Defense

May 2019

# CONFLICTS OF INTEREST

# Undermine Children's Health

Children's Health Defense

May 2019

# CONTENTS



# LIST OF ACRONYMS

**AAFP** . . . . American Academy of Family Physicians
**AAP** . . . . . American Academy of Pediatrics
**ACIP** . . . . . Advisory Committee on Immunization Practices
**ACOG** . . . . American College of Obstetricians and Gynecologists
**ACP**. . . . . American College of Physicians
**AHIP**. . . . . America's Health Insurance Plans
**CBER** . . . . Center for Biologics Evaluation and Research
**CDC** . . . . . Centers for Disease Control and Prevention
**CDER** . . . . Center for Drug Evaluation and Research
**CEPI** . . . . . Coalition for Epidemic Preparedness Innovations
**CHC** . . . . . Community Health Center
**DOD** . . . . . U.S. Department of Defense
**DOJ**. . . . . U.S. Department of Justice
**DPT**. . . . . Diphtheria-pertussis-tetanus
**DTaP** . . . . Diphtheria-tetanus-acellular pertussis
**ECBT**. . . . . Every Child by Two
**EIS** . . . . . CDC Epidemic Intelligence Service
**FACA** . . . . Federal Advisory Committee Act
**FDA** . . . . . U.S. Food and Drug Administration
**GSK** . . . . . GlaxoSmithKline
**HepA** . . . . Hepatitis A
**HepB** . . . . Hepatitis B
**HHS** . . . . . U.S. Department of Health and Human Services
**Hib** . . . . . *Haemophilus influenzae* type b
**HMO**. . . . . Health maintenance organization
**HPV** . . . . . Human papillomavirus
**IAC** . . . . . Immunization Action Coalition
**ICAN**. . . . . Informed Consent Action Network
**IOM** . . . . . Institute of Medicine
**IPV** . . . . . Inactivated poliovirus
**JAMA** . . . . Journal of the American Medical Association
**MMR** . . . . Measles-mumps-rubella
**MMRV** . . . Measles-mumps-rubella-varicella
**NCVIA** . . . National Childhood Vaccine Injury Act
**NEJM** . . . . New England Journal of Medicine
**NIH**. . . . . National Institutes of Health
**NVICP** . . . National Vaccine Injury Compensation Program
**OAP** . . . . . Omnibus Autism Proceeding
**OGR** . . . . . U.S. House Committee on Oversight and Government Reform
**OIG**. . . . . Office of the Inspector General
**PR**. . . . . Public relations
**Td** . . . . . Tetanus-diphtheria
**Tdap**. . . . . Tetanus-diphtheria-acellular pertussis
**VAERS** . . . Vaccine Adverse Event Reporting System
**VFC**. . . . . Vaccines for Children Program
**VSD** . . . . . Vaccine Safety Datalink

# EXECUTIVE SUMMARY

- Confidence in vaccine programs is declining worldwide. Nearly nine in ten U.S. pediatricians have encountered parents who question the Centers for Disease Control and Prevention (CDC) vaccine schedule.
- Factors contributing to the erosion of public trust include growing awareness of outsized vaccine industry profits, lack of scientific integrity and transparency, politicization of vaccine recommendations and misleading safety claims that exaggerate benefits and conceal risks.
- Conflicts of interest and unethical behavior encumber the key public and private players involved in U.S. and global vaccination programs to such an extent that public skepticism is not only understandable, but justified.
- In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA), giving pharmaceutical companies blanket immunity from liability for injuries resulting from childhood vaccines. The liability protections converted vaccines from a "neglected corner of the drugs business" into a major economic driver of the pharmaceutical industry.
- Four pharmaceutical giants—GlaxoSmithKline, Merck, Pfizer and Sanofi Pasteur—manufacture and profit from every vaccine on the U.S. childhood vaccine schedule.
- The NCVIA also created the National Vaccine Injury Compensation Program (NVICP), a burdensome administrative mechanism that allows vaccine-injured individuals to seek financial compensation. In three decades, the program has paid out $4 billion to a subset—barely a third—of petitioners, dismissing well over half of filed claims.

- NVICP claims represent the tip of a vast vaccine injury iceberg. As per the U.S. Department of Health and Human Services, fewer than 1% of vaccine adverse events ever get reported.
- Government officials have found many ways to limit the number of NVICP petitioners awarded compensation, for example, exhibiting "highly unethical and appallingly consequential official misconduct" in a 2007-2008 Omnibus Autism Proceeding for thousands of families filing claims for vaccine-induced autism.
- The Food and Drug Administration (FDA) and the CDC have played a pivotal role in the U.S. vaccine "renaissance." Because the two regulatory agencies work hand in glove with vaccine companies to protect and grow the liability-free childhood vaccine market, neither has the impartiality required to oversee vaccine safety. The CDC owns over 50 vaccine-related patents; the CDC also purchases half of all U.S. childhood vaccines—a 15-fold increase from three decades ago.
- Vaccine makers, the CDC and other government and private partners have fudged vaccine science for decades, attending secret meetings; hiding, destroying or fraudulently manipulating publicly funded data; and engaging in other unethical actions.
- In exchange for guaranteed advertising revenues from pharmaceutical companies, medical journals play a key role in suppressing studies that question vaccine safety, while publishing skewed write-ups that are more marketing than science.
- Most medical trade groups and physicians have been willing participants in the U.S. vaccine program due to the financial incentives that can result in thousands of dollars of kickbacks for enforcing the CDC-recommended schedule, despite acknowledgement by Congress and the Supreme Court that vaccines are "unavoidably unsafe."
- The status quo is untenable. Three urgently needed steps include repealing the NCVIA, eliminating vaccine mandates and establishing a fully transparent and independent vaccine safety commission. It is essential that conflicts of interest be addressed so that sound science—rather than deep pockets—can form the basis of vaccine policy-making.

# I. INTRODUCTION

## Vaccination as Orthodoxy

Vaccination has been a cornerstone of U.S. government public health policy for decades. Although the ***Centers for Disease Control and Prevention*** (CDC)—initially called the Communicable Disease Center—opened its doors in the early 1940s with a mandate primarily focused on malaria eradication, it rapidly pushed to "extend its responsibilities to other communicable diseases," including many of the illnesses subsequently targeted by vaccination.[1]

The CDC has operated as the standard-bearer for the nation's vaccination efforts ever since. However, a close look at the agency's behavior—and the statements of internal whistleblowers—reveals that, for all intents and purposes, the CDC functions as a subsidiary of a "rapacious" pharmaceutical industry[2] in partnership with the ***U.S. Food and Drug Administration*** (FDA) and numerous "outside parties and rogue interests"[3] that all benefit from their endorsement of a highly profitable vaccine orthodoxy. The powerful vaccine "gospel" has swept up regulators, medical trade associations, physicians, science journals, the popular press and others "in a kind of consensus dogma" that has become "more important than the children [these institutions were] supposed to protect."[4]

## The Medical Marketplace Comes First

Economic and political interests have steered U.S. vaccination programs since at least the 19th century, when the medical establishment and its government and industry allies recognized that vaccination provided a new income stream and a compelling opportunity "to augment their authority in a competitive medical marketplace."[5] Historical documents show that, from the earliest days, vaccine proponents have promoted a one-sided

The powerful vaccine "gospel" has swept up regulators, medical trade associations, physicians, science journals, the popular press and others "in a kind of consensus dogma" that has become "more important than the children [these institutions were] supposed to protect."

agenda, sidelining deeper inquiry into safety and efficacy and castigating individuals who dare to raise questions (see "Silencing Debate"). In a blatant example of the pot calling the kettle black, Dr. William Bailey belligerently declared in an 1899 issue of *Public Health Papers and Reports* (a precursor to the *American Journal of Public Health*) that vaccination's "enemies are organized and aggressive in their warfare against it."[6]

Over a century later, it is clear that vaccine policy-makers are the ones whose "organized and aggressive" public relations (PR) apparatus is relentlessly waging war on questioners, effectively branding them as heretics.[7] Independent scientists who cast doubt on vaccine orthodoxy find themselves facing personal attacks rather than impartial scrutiny of their research.[8] Meanwhile, the CDC demands that parents unhesitatingly allow their children to receive endless vaccine doses during pregnancy, infancy, childhood and adolescence. If someone (even an experienced doctor) dares to propose a less immunologically burdensome approach, the PR machine instantly jumps into overdrive to discredit him or her, despite the fact that respected, peer-reviewed science—including from the ***Institute of Medicine*** (IOM)—supports these concerns.[9]

## Waning Public Confidence

Although a barrage of assurances, both nationally and globally, tells consumers that vaccines are safe, confidence in vaccine programs is declining worldwide.[10] The medical journal *Pediatrics* reported in 2013 that nearly nine in ten U.S. pediatricians (87%) had encountered parents who questioned the CDC childhood vaccine schedule, up from 75% of children's doctors in 2006.[11] The surveyed pediatricians also reported receiving frequent requests to follow an alternative vaccine schedule (almost one in five parents) and, over the seven-year period, a doubling of the percentage of parents refusing at least one vaccine.

Even the most ardent vaccine proponents recognize that this erosion of public trust is at least partially their own fault—the result of factors such as "heightened [public] awareness of the profit motives of the vaccine industry," lack of transparency on the part of industry and conflicts of interest among policy-makers.[12] These observers even admit that "financial and bureaucratic reasons" prompt "vaccine manufacturers, health officials, and medical journals… not…to acknowledge the risks of vaccines."[13] When companies perpetuate misleading vaccine safety claims—exaggerating the benefits and concealing the risks—and regulators obligingly politicize their vaccine recommendations and decisions,[14] trust is damaged still further.[15]

In 1967, when childhood vaccines were much fewer and farther between, Dr. Graham Wilson (one-time Director of the Public Health and Laboratory Service for England and Wales) warned of the need to pay ongoing attention to vaccine safety,[16] stating, "It is for us, and for those who come after us, to see that the sword which vaccines and antisera have put into our hands is never allowed to tarnish through over-confidence, negligence, carelessness, or want of foresight on our part." Forty years later, Congressional Representative ***Dave Weldon***, himself a physician, harshly criticized the federal agencies charged with ensuring vaccine safety for failing to heed Wilson's cautions.

The U.S. government's *Healthy People 2020* initiative states that "childhood

### Silencing Debate

"Debate on vaccine safety is a Kafkaesque taboo on network news channels, which accept upwards of $5.4 billion annually from pharma, or on the editorial pages of America's newspaper conglomerates, many of which have financial ties to drug companies. . . . Instead of fact-based discourse, the debate… has devolved into 'argument by credential' and its corollary, 'argument by insult.' By reducing the issue to a binary choice—you're either pro-vaccine or anti-vaccine—journalists marginalize safety advocates…, vilify the parents of vaccine-injured children and silence debate on a complex issue. …The American public is entitled to an honest, probing and robust discussion about this critical public health issue—a debate based on facts, not rooted in fear, nor on blind faith in regulators and the pharmaceutical industry."

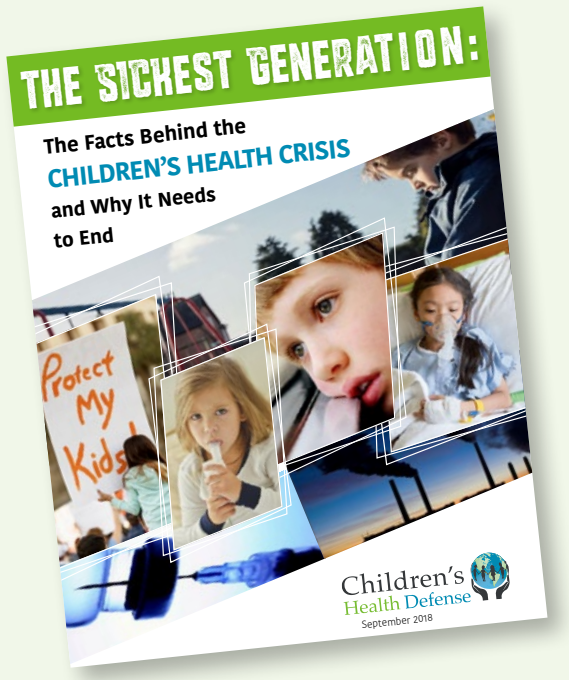
*—Robert F. Kennedy, Jr.*

SOURCE: https://childrenshealthdefense.org/news/why-im-not-anti-vaccine-and-why-we-should-all-want-to-study-vaccine-safety/

immunization programs provide a very high return on investment,"[17] but Americans should be asking just who is garnering the positive returns. Globally, the vaccine industry is on track to more than double its worldwide revenues by 2024—from $32.5 billion in 2015 to a projected $77 billion[18]—but highly vaccinated children in the U.S. and elsewhere are suffering. As described by ***Children's Health Defense*** in the eBook, *The Sickest Generation: The Facts Behind the Children's Health Crisis and Why It Needs to End*,[19] children's health has worsened dramatically since the late 1980s—"precisely the same time that the U.S. started expanding the types and total number of vaccines required for school attendance." Over half of American children have at least one chronic illness,[20] and neurodevelopmental disorders[21] and pediatric autoimmune conditions[22] have climbed to historically unprecedented levels. There is abundant evidence that vaccines are making children sicker, not healthier—representing an unquestionably negative return on investment for children, families and society.

This eBook takes the position that conflicts of interest and unethical behavior encumber the key public and private players involved in U.S. and global vaccination programs to such an extent that public skepticism is not only understandable, but justified. (For the reader's convenience, the names of key players are ***bolded and italicized*** upon first mention.) The loss of confidence in vaccine safety must be addressed with independent, unbiased science. The following sections illustrate how lack of integrity and ethical betrayals are impeding sound public health policy and vaccine safety science, while gravely undermining children's health.

There is abundant evidence that vaccines are making children sicker, not healthier—representing an unquestionably negative return on investment for children, families and society.




Children's Health Defense eBook, *The Sickest Generation: The Facts Behind the Children's Health Crisis and Why It Needs to End*

# II. CO-OPTED LEGISLATORS AND THE LEGAL LANDSCAPE

## The Legislation that Changed Everything

In 1986, President ***Ronald Reagan***, with reportedly "mixed feelings," signed into law a piece of legislation crafted by then-Representative ***Henry Waxman*** (now a health industry lobbyist); the legislation radically altered the vaccine policy landscape in the United States (see "Reagan's 'Mixed Feelings'").[23] Called the ***National Childhood Vaccine Injury Act*** (NCVIA), the legislation was ***Congress's*** response to intense pressure from vaccine industry lobbyists seeking protection from lawsuits related to the infamously brain-damaging diphtheria, whole-cell pertussis and tetanus (DPT) vaccine.[24]

The industry's lobbying efforts paid off in spades. Replacing judicial action with a more circumscribed "alternative remedy…for specified vaccine-related injuries,"[25] the Act created the ***National Vaccine Injury Compensation Program*** (NVICP), funded by taxpayers through an excise tax on childhood vaccines. With the stroke of a pen, Congress essentially abolished vaccine injury lawsuits against vaccine manufacturers (or health providers), while creating an administrative mechanism (subsequently nicknamed "vaccine court")[26] from which individuals could seek—but not necessarily obtain—redress for vaccine injuries through "Special Masters" designated to serve as arbiters.

The NCVIA gave pharmaceutical companies what amounted to blanket immunity[27] from liability for injuries resulting from childhood vaccines—"no matter how toxic the ingredients, how negligent the manufacturer or how grievous the harm"[28]—while also exempting companies from the transparency and document discovery normally associated with litigation.

### Reagan's "Mixed Feelings"

According to a *New York Times* report, at the time of the signing of the National Childhood Vaccine Injury Act, President Ronald Reagan "said he had approved the bill 'with mixed feelings' because he had 'serious reservations' about the vaccine compensation program." Reagan's Justice Department had urged him to veto the Act.

SOURCE: Reagan signs bill on drug exports and payment for vaccine injuries. *The New York Times*, Nov. 15, 1986.

Summarizing the legislation's far-reaching implications, ***Robert F. Kennedy, Jr.*** has stated:[29]

> *"That extraordinary law eliminated a principal cost associated with making…drugs and left the industry with little economic incentive to make vaccines safe. It also removed lawyers, judges and courts from their traditional roles as guardians of vaccine safety. Since the law's passage, industry revenues have skyrocketed from $1 billion to $44 billion."*

The NCVIA requires that the ***Department of Health and Human Services*** (HHS) review childhood vaccine safety on a biannual basis and report to Congress on measures taken to improve safety. However, that stipulation appears to have been intended largely as window dressing, because—as revealed in a recent lawsuit filed by the ***Informed Consent Action Network*** (ICAN) and Robert F. Kennedy, Jr.—HHS officials have never complied with the statutory safety review and reporting requirements *even once* in over thirty years.[30]

## Compensation…for a Few

In the three decades since the NVICP's creation, American households have filed roughly 20,000 petitions for vaccine injury compensation. The program has paid out $4 billion to a subset—barely a third (31%)—of petitioners, while dismissing well over half (56%) of filed claims as undeserving of any compensation.[31] Another 12% of petitions remains unadjudicated. Injured parties filed an average of 1,200 claims per year over the last three years, triple the average number of claims filed annually just a few years previously.[32] For the most part, however, parents, attorneys, health care professionals and members of the general public are unaware of the NVICP's existence[33] and, according to HHS, fewer than 1% of vaccine adverse events are ever reported.[34] Thus, NVICP claims represent only the tip of a vast vaccine injury iceberg.

Despite Congress's professed intent to create a non-adversarial, "accessible and efficient forum for individuals found to be injured by certain vaccines,"[35] in practice, the NVICP pits HHS and its subsidiary agencies (including the CDC) as adversaries against injured petitioners. HHS employees are free to decide on or reject compensation claims,[36] and ***Department of Justice*** (DOJ) lawyers represent and defend the interests of HHS.[37] Petitioners also face a three-year statute of limitations from the time of the vaccine injury and must meet a strenuous burden of proof if—as is almost always the case—their illness, disability, injury or condition does not fall within the narrow parameters of the NVICP's Vaccine Injury Table.[38]

As set out by the NCVIA, the Vaccine Injury Table was supposed to establish "statutory presumptions of causation" for selected injuries and adverse events occurring within prescribed time periods after vaccination, making the path to compensation less burdensome (at least for those injuries); however, because HHS can—almost at will—"add or delete injuries and conditions for which compensation would be available and…change the applicable time periods by which the onset of symptoms must occur," the agency has not hesitated to take advantage of this provision to "eliminate avenues to compensation."[39] Very few new injuries have been added to the Table, despite the large number of vaccines piled onto the childhood schedule since 1986.

### Letter to DOJ Inspector General and Congress

"During the Omnibus Autism Proceeding, Department of Justice attorneys…acted in concert with their client, the Department of Health and Human Services, to intentionally misrepresent the opinion of their own expert witness, and to willfully conceal from the vaccine court and petitioners critical material evidence showing how vaccines may cause autism. The same DOJ attorneys subsequently intentionally misled the United States Court of Appeals for the Federal Circuit. As a result, fraud was ultimately perpetrated upon the Supreme Court of the United States."

*—Robert F. Kennedy, Jr., and Rolf Hazlehurst*

SOURCE: "Request for Office of Inspector General to investigate fraud and obstruction of justice." https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/

HHS and the DOJ have found many ways to limit the number of petitioners awarded compensation. Robert F. Kennedy, Jr. has called attention to "highly unethical and appallingly consequential official misconduct"[40] exhibited by DOJ lawyers in a 2007-2008 Omnibus Autism Proceeding (OAP) orchestrated on behalf of 5,400 families who had filed claims for vaccine-induced autism.[41] The claims' potential value exceeded $100 billion—an amount that "would have bankrupted the [compensation] program many times over."[42] The DOJ lawyers, under pressure to deprive petitioners of their rightful relief, achieved that aim through allegedly fraudulent means. In September, 2018, Kennedy, Jr. and ***Rolf Hazlehurst*** (one of the OAP parents) requested that the DOJ Inspector General and Congress investigate this fraud and obstruction of justice (see "Letter to DOJ Inspector General and Congress").

## Regulatory Vacuum

The DOJ actions initiated during the OAP had a number of legal spillover effects, culminating in a disastrous (for the vaccine-injured) decision (*Bruesewitz v. Wyeth*) by the ***U.S. Supreme Court*** in 2011 that reiterated and even broadened the NCVIA's basic no-liability premise. In their 2011 majority ruling, Justices asserted that the Act "preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects."[43] At the time, none of the Justices "had reason to know that HHS was not acting in good faith" nor that DOJ attorneys, in earlier cases, had "conceal[ed] critical material evidence and mis[led] the special masters and the U.S. Court of Appeals."[44]

In a dissent to the 2011 decision, Justices Sotomayor and Ginsburg commented that vaccine manufacturers, "given the lack of robust competition in the vaccine market, will often have *little or no incentive to improve the designs of vaccines that are already generating significant profit margins*" [emphasis added].[45] The two Justices predicted—quite accurately—that the Court's unfortunate decision would leave a "regulatory vacuum" and would make it even harder to strike a balance between "compensating vaccine-injured children and stabilizing the childhood vaccine market."

In 2016, the ***Bill & Melinda Gates Foundation*** and the ***Wellcome Trust***—the world's two wealthiest charitable foundations and two of the biggest global funders of vaccine development[46] and vaccine programs[47]—teamed up with vaccine manufacturers and government partners from a variety of countries to launch the ***Coalition for Epidemic Preparedness Innovations*** (CEPI).[48] According to a recent analysis in the *Emory Law Journal*, the blanket immunity ushered in by the NCVIA has been so successful for vaccine manufacturers that CEPI is looking to export it, creating "liability protection and compensation mechanisms based on the U.S. model for vaccine liability" around the world.[49] The law journal author, Professor ***Mary Holland***, cautions that this would be unfortunate for the developing world because vaccines are likely to end up being "less safe than they could be," with an inevitable loss of public confidence "both in vaccines and in those recommending them."

## The Beneficiaries of Liability Protection

The liability protections offered by the NVICP have sparked a gold rush[50] of vaccine development since the NCVIA's passage in 1986, converting vaccines from a "neglected corner

Two Supreme Court justices, in the *Bruesewitz v. Wyeth* case, predicted quite accurately that the Court's decision would leave a "regulatory vacuum" and would make it even harder to strike a balance between "compensating vaccine-injured children and stabilizing the childhood vaccine market."

of the drugs business"[51] into a major economic driver of the medical and pharmaceutical industries.

In the U.S., four companies have been the principal beneficiaries. The four pharmaceutical giants—***GlaxoSmithKline*** (GSK), ***Merck***, ***Pfizer*** and ***Sanofi Pasteur***—manufacture every vaccine on the U.S. childhood vaccine schedule (see Table 1). For several of the childhood and adolescent vaccines, Merck enjoys a unique monopoly position in the U.S. Other companies such as ***Seqirus*** and ***MedImmune*** are crowding into the increasingly lucrative adult vaccine market.

In the context of the highly consolidated global pharmaceutical market valued at $1.1 trillion (U.S. dollars), Pfizer and Merck were the first and second top-ranking companies in 2016 in terms of total revenues, and Merck was number-one-ranked in terms of annual revenue *growth*.[52] The companies' strong vaccine sales have helped ensure record profits (see "A Lucrative Business").[53] Pfizer's $136-a-shot Prevnar-13 vaccine (with four doses advised before preschool age) earned the company nearly $4 billion in a single year, "about double what it made from high-profile drugs like Lipitor and Viagra."[54]

None of the leading vaccine manufacturers are strangers to lawsuits or large financial settlements for other drugs in their product line that, unlike vaccines, are subject to courtroom liability. Over the past decade, in fact, GSK, Pfizer, Merck and others have all paid out billions in punitive settlements for products deemed to be deceptive or harmful.[55] In the case of Merck, the company's payouts included $950 million[56] in

**Table 1. Manufacturers of Vaccines for Children and Adolescents in the United States**

| Childhood Vaccines | Manufacturers and Brand Names | | | |
|---|---|---|---|---|
| | GSK | Merck | Pfizer | Sanofi |
| DTaP | Infanrix | — | — | Daptacel |
| DTaP+IPV | Kinrix | — | — | Quadracel |
| DTaP+IPV+HepB | Pediarix | — | — | — |
| DTaP+IPV+Hib | — | — | — | Pentacel |
| HepA | Havrix | Vaqta | — | — |
| HepB | Engerix-B | Recombivax | — | — |
| Hib | Hiberix | PedvaxHIB | — | ActHIB |
| HPV | — | Gardasil-9 | — | — |
| IPV | — | — | — | Ipol |
| Influenza | Fluarix, FluLaval | — | — | Fluzone |
| MMR | — | MMR II | — | — |
| MMR+varicella | — | ProQuad | — | — |
| Meningococcal | Bexero, Menveo | — | Trumenba | Menactra |
| Pneumococcal | — | Pneumovax-23 | Prevnar-13 | — |
| Rotavirus | Rotarix | RotaTeq | — | — |
| Td | — | — | — | Tenivac |
| Tdap | Boostrix | — | — | Adacel |
| Varicella | — | Varivax | — | — |

Key: DTaP: Diphtheria-tetanus-acellular pertussis; HepA: Hepatitis A; HepB: Hepatitis B; Hib: *Haemophilus influenzae* type b; HPV: Human papillomavirus; IPV: Inactivated poliovirus; MMR: Measles-mumps-rubella; Tdap: Tetanus-diphtheria-acellular pertussis.
SOURCE: "U.S. vaccine names." https://www.cdc.gov/vaccines/terms/usvaccines.html.

The liability protections offered by the NVICP have sparked a gold rush of vaccine development since the NCVIA's passage in 1986, converting vaccines from a "neglected corner of the drugs business" into a major economic driver of the medical and pharmaceutical industries.

federal fines following evidence of a "deliberate corporate conspiracy"[57] related to its bestselling painkiller Vioxx. The FDA approved the drug in 1999 but Merck reluctantly withdrew it from the market in 2004 after studies showed that it doubled serious health risks and had resulted in at least 60,000 deaths.[58] Merck pleaded guilty to criminal charges over its illegal marketing of Vioxx and settled 27,000 lawsuits for $4.85 billion.[59]

Merck brought its human papillomavirus (HPV) vaccine, Gardasil, to market in the aftermath of the Vioxx scandal. Dubbed by some as the "**H**elp **P**ay for **V**ioxx" vaccine, Gardasil has been a major revenue booster. In a single quarter of 2016, for example, in which Merck posted a profit of $2.2 billion,[60] the company saw a 38% jump in sales of HPV vaccines (due to "increased pricing and demand"). Similar trends have been evident for Merck's other vaccines, with a 27% increase in measles-mumps-rubella-varicella (MMRV) vaccine sales in the same quarter of 2016 after the CDC added the vaccine to its pediatric stockpile. Growing global vaccine sales, including in China, helped Merck continue to "beat Wall Street expectations" in 2018.[61]

From a consumer standpoint, Merck's track record with Vioxx raises the question of whether the American public can believe Merck's claims about the safety of its vaccines. Can a company that confessed to illegal activity and paid out almost $5 billion to settle lawsuits for a drug it knew to be harmful be considered trustworthy when it markets expensive and profitable vaccines such as Gardasil? In 2008, an investigation by the *Philadelphia Inquirer* described an unpublished FDA review of one of Merck's largest U.S. vaccine plants, which identified contaminated children's vaccines and a failure to follow good manufacturing practices—noting 49 areas of concern in all.[62] The plant leadership's response to the FDA's troubling findings was that "Nobody's perfect." Previously, in 2007, Merck had to recall over a million doses of two childhood vaccines because it "could not guarantee the products' sterility."[63]

Can a company that confessed to illegal activity and paid out almost $5 billion to settle lawsuits for a drug it knew to be harmful be considered trustworthy when it markets expensive and profitable vaccines such as Gardasil?

### A Lucrative Business

According to a *New York Times* report on "soaring" vaccine prices, many factors work in favor of record-breaking vaccine profits:

- Reformulation of old vaccines with a higher price tag
- Market entry of new vaccines at "once-unthinkable" prices
- Requirements for multiple doses and boosters
- Monopoly market positions for some vaccines
- Patents on manufacturing processes (vaccine patent applications rose "tenfold in the 1990s to more than 10,000")
- Guaranteed purchases by the federal government (Vaccines for Children Program)
- Guaranteed coverage by private insurance and the Affordable Care Act, meaning that "patients often do not notice the prices"

SOURCE: Rosenthal E. The price of prevention: vaccine costs are soaring." *The New York Times*, July 2, 2014.

# III. ROLE OF OUR FEDERAL AGENCIES

Both the FDA and CDC have played a pivotal role in the U.S. vaccine "renaissance"[64] that has burgeoned since the late 1980s. Working hand in glove with the vaccine companies to protect and grow the liability-free childhood vaccine market, they have helped ensure billions of dollars in corporate revenues with little need for vaccine makers to advertise or market their products. Although credible accusations have surfaced for years—aired by legislators,[65] researchers,[66] watchdog groups[67] and many others—that both the FDA and CDC lack the impartiality required to make accurate judgments about vaccine safety, the two agencies have continued with business-as-usual. With vaccine promotion superseding vaccine safety monitoring as organizational goals, conflicts of interest are baked into the agencies' DNA.

## FDA Rubber Stamping

At the FDA, regulatory oversight of vaccines—classified as "biological products" rather than drugs—falls under the jurisdiction of the ***Center for Biologics Evaluation and Research*** (CBER). The Center for Drug Evaluation

With vaccine promotion superseding vaccine safety monitoring as organizational goals at FDA and CDC, conflicts of interest are baked into the agencies' DNA.

and Research (CDER) handles other drugs and certain over-the-counter products. For both CDER[68] and CBER,[69] "it is the responsibility of the company seeking to market a drug [or biologic] to test it and submit evidence that it is safe and effective."

Both drug and vaccine manufacturers have an obvious interest in painting a rosy picture of their products, but the classification of vaccines as "biologics" allows vaccine makers to speed their products to market with far less onerous safety testing than is required of other new drugs. In fact, the conduct and design of vaccine prelicensing studies often have fatal flaws that make it nearly impossible to identify possible safety risks.

For example, prelicensing clinical trials often have an absurdly brief period of observation (sometimes as short as a few days or weeks), which makes it impossible to evaluate longer-term outcomes such as autoimmune illness or cancer. The clinical trials for Merck's Recombivax hepatitis B vaccine (approved for administration on the first day of life) monitored fewer than 150 infants and children for five days after each dose.[70] Buried in the vaccine's package insert is the information that autoimmune diseases and "an apparent hypersensitivity syndrome… of delayed onset [have] been reported days to weeks after vaccination."

Placebo-controlled trials are widely recognized as the gold standard for evaluating vaccine safety and efficacy, but prelicensing studies typically test new vaccines against existing vaccines instead of using true placebos (defined as "an inert substance, such as a saline injection").[71] This type of vaccine-to-vaccine comparison makes it possible to mask adverse reactions by claiming that there are no differences between groups.[72]

## HPV Vaccines as a Case Study

CBER claims that its approval process reflects a commitment to maximizing benefits and minimizing risks.[73] However, the history of FDA/CBER approval of HPV vaccines illustrates the insincerity of that assertion. The HPV vaccines Gardasil and Gardasil-9 represent a case study of risk-laden vaccines that should have attracted far stronger up-front regulatory scrutiny.[74] Instead, the FDA not only gave Gardasil an initial free pass but has repeatedly reapproved it and Gardasil-9 for wider use. (Gardasil-9 is a newer nine-type formulation containing more than twice the amount of neurotoxic aluminum adjuvant as Gardasil.) Since 2006, the FDA's decisions have included:

- **2006:** Granting fast-tracked approval for the original quadrivalent Gardasil vaccine[75] (girls and women aged 9 to 26 years)
- **2009:** Approving Gardasil's use in boys and men (ages 9-26)
- **2014:** Approving Gardasil-9[76] (girls ages 9-26, boys ages 9-15)
- **2015:** Approving Gardasil-9 for boys ages 16-26
- **2018:** Approving Gardasil-9 for older women and men (ages 27-45)[77]

"During Gardasil's clinical trials, an extraordinary 49.5% of the subjects receiving Gardasil reported serious medical conditions within seven months of the start of the clinical trials. Because Merck did not use a true placebo in its clinical trials, its researchers were able to dismiss these injuries as sad coincidences."

*—Letter from Children's Health Defense Chairman Robert F. Kennedy, Jr. to the Chair of the CDC's Advisory Committee on Immunization Practices (ACIP), February 25, 2019*

SOURCE: https://childrenshealthdefense.org/wp-content/uploads/02-26-19-Final-3-Gardasil-9-ACIP-2-25-19.pdf.

In 2009, the FDA also okayed GSK's HPV vaccine, Cervarix, but Merck's FDA-facilitated stranglehold on the market prompted the company to withdraw Cervarix from the U.S. in 2016.[78] Merck is now aggressively expanding its Gardasil "franchise" into other countries,[79] generating unprecedented worldwide demand, while continuing to "rev up" U.S. sales.[80]

An eight-month investigation by *Slate* identified numerous troubling aspects of the clinical trials that formed the basis of U.S. and European regulators' decision to approve Gardasil.[81] The *Slate* reporter minced no words when criticizing regulators for allowing "unreliable methods to be used to test the vaccine's safety" (see "Baffling Procedures"). These included Merck's use of "a convoluted method" that made it difficult to objectively evaluate and report side effects; its failure to document "symptom severity, duration, outcome, or overall seriousness"; restriction of adverse event reporting to just 14 days following each injection; and reliance on the subjective opinion of clinical trial investigators regarding "whether or not to report any medical problem as an adverse event." Not infrequently, clinical trial participants who shared complaints of debilitating symptoms with trial investigators were dismissed with the response, "This is not the kind of side effects we see with this vaccine."

In fact, numerous post-licensure studies show that all three HPV vaccines have grave risks, including impaired fertility,[82] demyelinating disease,[83] chronic limb pain,[84] circulatory abnormalities[85] and autoimmune illness,[86] to name just some of the disabilities reported in the aftermath of the vaccines' introduction. Overall, the "rate of reported serious adverse reactions (including deaths) from HPV vaccination" is many times higher than cervical cancer mortality rates.[87] A current civil case brought on behalf of a 24-year-old who has suffered from systemic autoimmune dysregulation since receiving her third Gardasil vaccine at age 16 alleges that Merck "committed fraud during its clinical trials and then failed to warn [vaccine recipients] about the high risks and meager benefits of the vaccine."[88] The trial's legal team is benefiting from the support of an "A-team" of plaintiffs' law firms and attorneys, including Robert F. Kennedy, Jr.

Recent data suggest that HPV vaccines may actually be *increasing* cervical cancer risks. A 2017 study out of Australia—a country that has heavily promoted routine HPV vaccination since 2007—reported an increased risk of difficult-to-detect malignant cervical lesions among the HPV-vaccinated.[89] In all countries where HPV vaccination coverage is high, including Australia, "official cancer registries show "an increase in the incidence of invasive cervical cancer" in the vaccinated age groups.[90] In England, for example, "2016 national statistics showed a worrying and substantial increase in the rate of cervical cancer…at ages 20-24"—the first HPV-vaccinated cohort.[91]

Despite clear indications that the proper decision would be to take HPV vaccines off the market, the FDA and CDC have continued to look the other way (see "Patents and Profits"). Both agencies' unwavering support for Gardasil have clearly helped Merck's commercial bottom line, so much so that the CDC director at the time of Gardasil's approval (***Julie Gerberding***) went on to be appointed president of Merck's profitable vaccine division (worth $5 billion globally) in 2009.[92] The two agencies' willingness to aggressively promote HPV vaccination despite its readily apparent dangers illustrate a "public

### Baffling Procedures

**The author of an eight-month *Slate* investigation on Gardasil's shoddy prelicensing clinical trials reported:**

*"Experts I talked to were baffled by the way Merck handled safety data in its trials. According to. . . a professor. . . who studies side effects, letting investigators judge whether adverse events should be reported is 'not a very safe method of doing things, because it allows bias to creep in.' . . . Of the short follow-up, . . . 'It's not going to pick up serious long-term issues, which is a pity. Presumably, the regulators believe that the vaccine is so safe that they don't need to worry beyond 14 days.'"*

SOURCE: Joelving F. What the Gardasil testing may have missed. *Slate*, Dec. 17, 2017.

health flimflam" of the first order.[93] Before the U.S. introduction of HPV vaccination, a decades-long pattern of declining cervical cancer rates was already well underway,[94] thanks to routine cervical cancer screening. HPV vaccines have never even been proven to prevent cervical cancer.[95] In 2016, researchers admitted that they would be unable to ascertain HPV vaccines' long-term efficacy for "at least another 15-20 years."[96]

## CDC-Guaranteed Market

The CDC's ***Advisory Committee on Immunization Practices*** (ACIP) has issued annual vaccine recommendations for the U.S. civilian population since 1995,[97] working with leading medical trade organizations such as the ***American Academy of Pediatrics*** (AAP), the ***American Academy of Family Physicians*** (AAFP), the ***American College of Physicians*** (ACP) and the ***American College of Obstetricians and Gynecologists*** (ACOG).[98] ACIP's industry-beholden membership roster reads like a "who's who" of the individuals and organizations who spearhead the nation's vaccine business: fifteen voting members from leading medical schools, children's hospitals and universities; eight ex officio members from federal agencies such as the FDA and the ***Department of Defense*** (DOD); and thirty non-voting representatives serving as liaisons with entities ranging from Sanofi to ***Cigna*** and ***Planned Parenthood*** (with the latter being a leading provider of HPV vaccines).[99]

The conflicts of interest that hold ACIP members captive to pharmaceutical industry interests are well known and well documented. In the early 2000s, a four-month investigation by United Press International (UPI) identified "a web of close ties"[100] and financial entanglements between ACIP members and vaccine companies, including:

### Patents and Profits

U.S. government health agencies profit handsomely from their ownership or co-ownership (with private sector partners) of patents, and, in the case of the CDC and the National Institutes of Health (NIH), many of the patents are vaccine-related. For example, an early 2017 analysis of Google Patents results showed that the CDC held 56 patents pertaining to various aspects of vaccine development, manufacturing, delivery and adjuvants. By April 2019, the search terms "vaccine Centers for Disease Control" retrieved 155 results in the Google Patents search engine, and a separate legal website displayed 10 screens worth of CDC patents, both vaccine- and non-vaccine-related. The author of the 2017 analysis suggests that the large number of patents held by the CDC "deserves an in-depth review to determine exactly what current financial relationships with vaccine makers now exist and what . . . current impact those revenue streams are likely having on vaccine safety positions."

The influence of profit-generating patents on NIH policy also warrants scrutiny. According to an in-depth report by Mark Blaxill, because "NIH frequently funds research with commercially valuable outcomes," when NIH patents its inventions, the patents become "valuable commercial property" for HHS, the patents' owner. Some of the key technologies underlying the development of the HPV vaccines Gardasil and Cervarix emerged from research patented by the NIH's National Cancer Institute (NCI), which then licensed the technology to Merck, MedImmune and GSK. By 2009, HPV licensing had become NIH's top generator of royalty revenues. Blaxill describes Gardasil as "perhaps the leading example of a new form of unconstrained government self-dealing, in arrangements whereby [HHS] can transfer technology to pharmaceutical partners, [and] simultaneously both approve and protect their partners' technology licenses while also taking a cut of the profits."

SOURCES: Blaxill M. A license to kill? Part 1: how a public-private partnership made the government Merck's Gardasil partner. *Age of Autism*, May 12, 2010. https://www.ageofautism.com/2010/05/a-license-to-kill-part-1-how-a-publicprivate-partnership-made-the-government-mercks-gardasil-partner.html.

Padmanabhan S et al. Intellectual property, technology transfer and developing country manufacture of low-cost HPV vaccines—a case study of India. *Nat Biotechnol* 2010;28(7):671-678.

"Patents assigned to Centers for Disease Control and Prevention." https://patents.justia.com/assignee/centers-for-disease-control-and-prevention.

Taylor G. Examining RFK Jr.'s claim that the CDC "owns over 20 vaccine patents." *GreenMedInfo*, Jan. 17, 2017. http://www.greenmedinfo.com/blog/examining-rfk-jrs-claim-cdc-owns-over-20-vaccine-patents.

Vaccine patents assigned to Centers for Disease Control. https://patents.google.com/?q=vaccine&assignee=centers+for+disease+control&oq=vaccine+centers+for+disease+control.

The conflicts of interest that hold ACIP members captive to pharmaceutical industry interests are well known and well documented. In the early 2000s, a four-month investigation by United Press International (UPI) identified "a web of close ties" and financial entanglements between ACIP members and vaccine companies.

- Sharing vaccine patents
- Owning vaccine company stock
- Getting research funding or money to monitor vaccine testing
- Receiving funding for academic departments or appointments

In 2003, Congressman ***Dan Burton*** described the "paradox" of the CDC "routinely allow[ing] scientists with blatant conflicts of interest to serve on influential advisory committees that make recommendations on new vaccines, as well as policy matters," even though "these same scientists have financial ties, academic affiliations, and other vested interests in the products and companies for which they are supposed to be providing unbiased oversight."

As per the Federal Advisory Committee Act (FACA), individuals appointed to ACIP must file an Office of Government Ethics form and annually update a financial disclosure report. Voting members also are expected to publicly disclose "all vaccine-related interests and work" at the beginning of each ACIP meeting. However, the CDC has shown itself only too willing to issue conflict of interest waivers if it ascertains (as it routinely does) that "the need for the individual's services outweighs the potential for conflicts of interest created by the financial interests involved."[101] According to an investigation by the ***Committee on Government Reform*** in 2000, the CDC not only frequently grants waivers but also looks the other way when ACIP members provide incomplete financial disclosure.[102] Moreover, a loophole allows a considerable amount of ACIP's work to get done in ***Work Groups*** whose members are exempt from the FACA procedural conflict-of-interest requirements, even though the Work Groups "serve a key scientific role in support of vaccine policy development."[103]

After ACIP makes its vaccine recommendations, the CDC publishes them in the *Morbidity and Mortality Weekly Report*. The recommendations (in CDC officials' own words) "have [a] major impact on immunization policies and practice in the United States and in other countries."[104] Stated another way, ACIP's "imprimatur" is a "golden ticket"[105] for vaccine manufacturers. Vaccines on the CDC's schedule become virtually mandatory for American children attending a "public or private elementary, middle or secondary school, child care center, nursery school, family day care home or developmental center,"[106] with the only exceptions being the small proportion of children who have a vaccine exemption for medical, religious or philosophical reasons.

Vaccine exemptions are currently available to varying degrees in 47 states.[107] Reflecting the public's growing concerns about vaccine safety, the use of non-medical exemptions increased by 19% from 2009 to 2013.[108] However, all three types of exemptions are under aggressive attack. Supported by pharmaceutical industry lobbying, 12 of 13 exemption-related bills signed into law between 2011 and 2017 "limited the ability to exempt," erecting more legal barriers for concerned parents.[109]

Within the no-liability context of the 1986 Act, the CDC and ACIP opened the floodgates for a dramatic expansion of the childhood vaccine schedule. In the early 1980s, children received three vaccines for seven illnesses[110]—two combination vaccines (diphtheria-tetanus-pertussis and measles-mumps-rubella) and a polio vaccine—totaling two dozen doses by age 18.[111] In the decade following 1989 (beginning soon after the NCVIA's implementation), the

The CDC has shown itself only too willing to issue conflict of interest waivers if it ascertains (as it routinely does) that "the need for the individual's services outweighs the potential for conflicts of interest created by the financial interests involved."

# CDC Recommended Childhood Vaccine Schedule: 1986 vs 2019

| 1986 ⇒ | 12 shots 24 antigens 8 diseases | | 2019 ⇒ | 54 shots 70 antigens 16 diseases | |
|---|---|---|---|---|---|
| DTP (2 Months) | MMR (15 Months) | DTP (4 Years) | Hep B (1 day) | Influenza (7 Months) | Influenza (5 years) |
| Polio (2 Months) | DTP (18 Months) | Polio (4 Years) | Hep B (1 Month) | MMR (12 Months) | Influenza (6 Years) |
| DTP (4 Months) | Polio (18 Months) | Td (14 Years) | DTaP (2 Months) | Varicella (12 Months) | Influenza (7 Years) |
| Polio (4 Months) | Hib (2 Years) | | Polio (2 Months) | Hib (12 Months) | Influenza (8 Years) |
| DTP (6 Months) | | | Hib (2 Months) | Hep A (12 Months) | Influenza (9 Years) |
| | | | PCV 13 (2 Months) | PCV 13 (12 Months) | Influenza (10 Years) |
| | | | Rotavirus (2 Months) | DTaP (15 Months) | HPV (11 Years) |
| | | | DTaP (4 Months) | Hep A (18 Months) | Meningococcal ACWY (11 Years) |
| | | | Polio (4 Months) | Influenza (18 Months) | Tdap (11 Years) |
| | | | Hib (4 Months) | Influenza (2 Years) | Influenza (11 Years) |
| | | | PCV 13 (4 Months) | Influenza (3 Years) | HPV (11.5 Years) |
| | | | Rotavirus (4 Months) | Influenza (4 years) | Influenza (12 years) |
| | | | DTaP (6 Months) | DTaP (4 Years) | Influenza (13 Years) |
| | | | Polio (6 Months) | MMR (4 Years) | Influenza (14 Years) |
| | | | Hep B (6 months) | Polio (4 Years) | Influenza (15 Years) |
| | | | Hib (6 Months) | Varicella (4 Years) | Meningococcal ACWY (16 Years) |
| | | | PCV 13 (6 Months) | | Influenza (16 years) |
| | | | Rotavirus (6 Months) | | Influenza (17 Years) |
| | | | Influenza (6 Months) | | Influenza (18 years) |

Children's Health Defense

*Note:* DTP, DTaP, Tdap and MMR vaccines contain three antigens each.

SOURCE: CDC Recommended Childhood Vaccine Schedule, Birth to 18

CDC packed multiple doses of several more vaccines into the childhood schedule, including those for *Haemophilus influenzae* type b (Hib), hepatitis B (on the day of birth) and varicella (chickenpox), as well as a rotavirus vaccine (withdrawn a year after its introduction).[112] Next, in the first decade of the 2000s, the CDC recommended an even larger batch of new vaccines, going after not just children but also adolescents and adults: hepatitis A, HPV, meningococcal conjugate, pneumococcal conjugate, rotavirus (again) and zoster (shingles), along with an adult tetanus-diphtheria-pertussis booster (Tdap) and a massive expansion of influenza vaccine recommendations for all ages.[113] At present, the childhood vaccine schedule requires almost six dozen doses through age 18 for sixteen diseases.[114]

## Unheeded Warnings

- **1961:** A leading polio researcher states in *Science* that "even after licensing, a new vaccine product must be considered to be on trial" because of the many "new variables" that accompany large-scale vaccine production and rollout.
- **1999:** The head of CBER's Viral Products Division contends that advances in vaccine technology are "outpacing researchers' ability to predict potential vaccine-related adverse events."

SOURCES: Bodian D. Poliomyelitis immunization: mass use of oral vaccine in the United States might prevent definitive evaluation of either vaccine. *Science* 1961;134:819-822.

"Vaccine technology outpacing ability to predict adverse events, FDAer says." https://childrenshealthdefense.org/wp-content/uploads/FDA-Pink-Sheets-99.pdf.

The CDC is a major player in the vaccine marketplace, buying half of all childhood vaccines in the U.S.[115] and then selling them to contracted public health agencies through the ***Vaccines for Children (VFC) Program***,[116] which pushes free and low-cost vaccines on indigent children. Over the past three decades, the CDC's vaccine purchases have increased 15-fold as the average cost of fully vaccinating a child to age 18 rose from $100 to $2,192—while vaccine companies have raked in the profits.[117] In addition to the CDC's ownership of dozens of vaccine-related patents, the agency's involvement with vaccine manufacturers also extends to licensing agreements and collaboration on projects to develop new vaccines.[118]

## Subpar Postlicensure Safety Monitoring

In former times, researchers and regulators knew that approval of a vaccine did not preempt the need for ongoing safety monitoring (see "Unheeded Warnings"). Nowadays, however, the CDC, FDA and other government agencies play more of a cheerleader role, assuring residents that the U.S. has "the safest, most effective vaccine supply in history." The vaccine industry, too, brags about the "exhaustive and continuous" safety assessment of vaccines, including post-approval.[119] All of these statements blithely continue to skirt around the fact—attested to by the $4 billion in NVICP payouts[120]—that vaccines cause permanent disability[121] and death[122] with some regularity.

As part of the NCVIA, legislators gave a nod to the potential for vaccine damage by mandating that the CDC and FDA jointly establish a safety monitoring system to collect and analyze "spontaneous reports of adverse events that occur in persons following vaccination."[123] That system—the ***Vaccine Adverse Event Reporting System*** (VAERS)—has received nearly 700,000 reports of post-vaccination adverse events since 1990 (see "Vaccine Adverse Reactions").[124] Recalling HHS's estimate that only 1% of vaccine injuries get reported,[125] it is likely that millions of adverse reactions to vaccines are occurring in the U.S. every year—yet, precisely because these injuries nearly always go unreported, official discussions of vaccine safety remain hugely misleading.

When discussing VAERS, CDC and FDA researchers like to have it both ways.[126] On the one hand, they praise the system for guiding further safety evaluations, but on the other hand,

### Vaccine Adverse Reactions

**Package inserts** catalog a range of adverse reactions that sometimes affect over half of vaccine trial participants. These include:

- Injection-site reactions (e.g., pain, redness, "increase in arm circumference")
- Immune system responses such as fever and swollen lymph nodes
- Allergic reactions such as hives, rash, rhinitis and runny nose
- Diarrhea, vomiting, upper respiratory infection
- Fatigue, drowsiness, lethargy, malaise, loss of appetite
- Muscle aches and pain
- Headaches, febrile seizures
- Behavioral indictors of distress such as irritability, restlessness or inconsolable or prolonged crying

**VAERS reports** include adverse events of even greater severity. To date, VAERS has received thousands of reports for each of the following symptoms:

- Arthralgia (joint pain signaling an allergic reaction to medication)
- Breathing difficulties
- Chest discomfort and pain
- Convulsions
- Death
- Decreased mobility
- "Feeling abnormal"
- Gait disturbances
- Increased heart rate, palpitations
- Loss of consciousness
- Musculoskeletal pain, extremity pain
- Otitis media (ear infection)
- Pneumonia
- Screaming
- Skin disorders
- Sleep disorders
- Stupor
- Tremors
- Viral infections

NVICP has paid out over $4 billion proving that vaccines cause permanent disability and death with regularity.

the agencies warn that "VAERS data interpreted alone or out of context can lead to erroneous conclusions about cause and effect as well as the risk of adverse events occurring following vaccination."

They also take pains to point out that "an adverse health event or health problem that occurs following or during administration of a vaccine… might be caused by a vaccine or might be *coincidental* and not related to vaccination" [emphasis added]. In fact, CDC authors who churn out boilerplate articles about vaccine safety exhibit a fondness for the notion that post-vaccination mishaps are simply a fluke (see "Coincidence?"). Industry, too, likes to tell the public that it has "guidelines and algorithms" to differentiate between a post-vaccination adverse event that "may" be causally related to a vaccine and an event that is coincidental to vaccination.[127]

Physicians are critical intermediaries between patients and vaccine manufacturers, but many factors work to prevent them from recognizing and reporting adverse events, including the lack of medical school training on vaccine adverse reactions and low awareness of VAERS. A large and nationally representative study of health care providers (including physicians, mid-level providers and nurses) found that whereas slightly more than a third (37%) had ever identified a post-vaccination adverse event, only 17% of that subgroup had ever made a report to VAERS.[128] A qualitative study of health providers in Australia (where vaccine policies are, in key ways, similar to those in the U.S.) found that many providers experienced "confusion" about the types of events that would constitute "reportable" adverse events and also were unclear on how to define "serious" adverse events.[129]

## Captured Agencies

Captured agencies operate "essentially as…advocate[s] for the industries they regulate," abrogating their duty to act in the public's interest.[130] Vaccine and drug fast-tracking provide a clear example of regulatory capture. In 1992, Congress passed the Prescription Drug User Fee Act, allowing pharmaceutical companies to make payments to the FDA (called "user fees") in exchange for expedited approval of drugs and biologics, including vaccines.[131] Additional legislation in 2012 further facilitated "accelerated approval" by allowing the FDA to use "surrogate endpoints" to evaluate a drug or vaccine rather than waiting to assess longer-term clinical benefits.[132] According to a 2015 report in *Fortune* magazine, pharmaceutical companies are more than willing to pay "big bucks" to speed up the approval process[133] and, in the process, they gain extraordinary leverage over regulatory decision-making.[134] Whereas the FDA was publicly funded prior to 1992, by fiscal year 2017, three-fourths (75%) of the FDA's annual budget increase came from user fees,[135] with the pharmaceutical industry in essence paying FDA regulators' salaries.

Some of the vaccines most readily approved by the FDA and heavily promoted by the CDC in recent years are for conditions for which there was not only little rationale for vaccination to begin with but which have created new dangers. Gardasil, which Judicial Watch has called a "large-scale public health experiment," is a case in point.[136] The FDA gave Gardasil a speedy six-month review despite evident concerns about long-term safety.

Other difficult-to-justify but money-spinning vaccines continue to be touted as beneficial in the face of substantial evidence to the contrary. The rationale for the varicella (chickenpox)

### Coincidence?

CDC authors have admitted to "rare cases where a known or plausible theoretical risk of death following vaccination exists," citing:

- Anaphylaxis
- Vaccine-strain systemic infection after giving live vaccines to persons with compromised immune systems
- Intussusception after rotavirus vaccine
- Guillain-Barré syndrome after inactivated influenza vaccine
- Fall-related injuries associated with post-vaccination fainting
- Systemic or neurologic disease following yellow fever vaccination
- Serious complications from smallpox vaccination, including brain inflammation and heart problems
- Vaccine-associated paralytic polio from oral polio vaccine

Nonetheless, CDC researchers assert that "adverse events including deaths that are temporally associated with vaccination" are usually "coincidental"—even though "loved ones and others might naturally question whether it was related to vaccination"!

SOURCE: Miller ER, Moro PL, Cano M, Shimabukuro TT. Deaths following vaccination: what does the evidence show? *Vaccine* 2015;33(29):3288-3292.

and rotavirus vaccines is particularly dubious. Varicella[137] and rotavirus[138] were nearly universal and mostly benign childhood infections before the introduction of the vaccines; in the U.S. and other wealthy countries, their impact was largely measured in terms of "healthcare costs, missed daycare, and loss of time from work for parents/guardians" rather than in terms of serious illness or mortality.[139] Moreover, childhood chickenpox infections served an important purpose for all, conferring lifelong immunity to infected children while boosting adults' immunity to the related shingles (herpes zoster) virus.[140] With mass varicella vaccination, shingles started cropping up to an unprecedented extent in both children and adults,[141] presenting what some researchers have described (understatedly) as "perverse public health implications."[142]

The introduction of rotavirus vaccines resulted in a substantially increased risk in infants of an otherwise rare bowel complication called intussusception—a problem that the FDA knew about but chose to ignore during the prelicensing regulatory review process.[143] Although the FDA subsequently withdrew its approval for one of the problematic rotavirus vaccines, the two still on the market display the same intussusception risks[144] as well as both being contaminated with foreign DNA from porcine viruses capable of causing severe immunodeficiency in pigs.[145] Had the presence of these "adventitious agents" been discovered prior to vaccine licensure, the FDA probably would have been forced to shelve the vaccines, yet they remain on the vaccine schedule to this day.[146]

The FDA's cavalier vaccine safety stance is also apparent in its mixed messages about aluminum. Guided by "unfounded assumptions" and


"misrepresentations of past science," the agency allows problematically high amounts of aluminum adjuvant in vaccines to be injected into infants and children,[147] even though it views aluminum as a toxic contaminant in parenteral (intravenous) nutrition products given to neonates.[148] A 2018 study reveals how CBER wrongly calculates aluminum adjuvant toxicity, allowing amounts of aluminum "derived from data that demonstrated that this amount of aluminum per dose enhanced the antigenicity and effectiveness of the vaccine"—but which did "not include safety considerations."[149] When the researchers properly accounted for variables such as body weight and the simultaneous administration of multiple aluminum-containing vaccines during a single doctor's visit, they concluded that modern vaccine schedules "place infants at risk of acute, repeated, and possibly chronic exposures of toxic levels of aluminum."[150]

The FDA's cavalier vaccine safety stance is also apparent in its mixed messages about aluminum. The agency allows problematically high amounts of aluminum adjuvant in vaccines to be injected into infants and children, even though it views aluminum as a toxic contaminant in parenteral (intravenous) nutrition products given to neonates.

## Exaggerated Effectiveness

Alongside their many misplaced claims about vaccine safety, the FDA and CDC—as echo chambers for the vaccine

industry—also have misinformed the public about vaccine effectiveness. Back in 1899, doctor William Bailey (vaccination enthusiast and member of the State Board of Health in Louisville, Kentucky) was honest enough to caution that "nothing is gained by claiming too much" about vaccine-induced immunity and stated that "the degree of immunity may vary with time and circumstance"[151] (presaging the troublesome modern phenomena of vaccine failure[152] and waning immunity[153]).

In the present day, officials are only too willing to "claim too much," conveniently ignoring historical evidence that reductions in infectious disease had little to do with vaccines and far more to do with improvements in sanitation and nutrition.[154] Officials also seem to have little interest in modern evidence documenting many vaccines' inability to provide the promised protection, even when vaccine coverage is widespread.[155]

The acellular version of pertussis (whooping cough)—a component of U.S. vaccines such as DTaP and Tdap—is one of the vaccines noted for its abysmal effectiveness.[156] The vaccine is supposed to protect against the respiratory infection caused by *Bordetella pertussis*. Instead, according to recent studies, pertussis is making a "surprising" comeback; between 1990 and 2005, pertussis epidemics increased in the U.S. "in both size and frequency," and over half of all cases occurred in highly vaccinated adolescents aged 10 to 20 years old.[157]

In fact, not only is pertussis at its highest level since the mid-1950s, but, according to CDC researchers, it is showing signs of being vaccine-resistant.[158] The CDC researchers also note "substantial heterogeneity among vaccine recipients in terms of the durability of the protection they receive."

West Africa has used the DTP vaccine since the 1980s—formulated with a whole-cell pertussis component instead of acellular pertussis—and it has an even more horrifying safety and effectiveness track record than its acellular counterparts. Research published in 2017 by a prestigious team of international scientists and led by vaccinology expert Dr. Peter Aaby found that DTP vaccination had a negative effect on child survival, with fivefold higher mortality in young DTP-vaccinated infants (ages three to five months) compared to as-yet-unvaccinated infants.[159] When the researchers published results in 2018 for slightly older DTP-vaccinated children (ages six months to three years), they continued to observe more than double the risk of death as similarly situated unvaccinated children.[160] Explaining that vaccines can increase susceptibility to other infections, the researchers concluded in 2017 that "all currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis" and added in 2018 that "all studies of the introduction of DTP have found increased overall mortality."

## Learning from History?

**During a smallpox outbreak in the early 1870s, a doctor observed that smallpox mortality doubled (from roughly 7% to 15%) *after* adoption of smallpox vaccination. The doctor also noted that the vaccinated often contracted severe smallpox more readily than the unvaccinated:**

*"Never, however, did the faith in vaccination receive so rude a shock as in the Great Small-Pox Epidemic of 1871 and 1872. Every country in Europe was invaded with a severity greater than had ever been witnessed during the three preceding centuries. . . . What was even more significant, many vaccinated persons in almost every place were attacked by small-pox before any unvaccinated persons took the disease. These facts are sufficient to overthrow the entire theory of the protective efficacy of vaccination."*

SOURCE: Wilder A. *The Fallacy of Vaccination*. New York, NY: The Metaphysical Publishing Company; 1899. https://collections.nlm.nih.gov/ext/dw/101229606/PDF/101229606.pdf.

# IV. TAINTED SCIENCE

The CDC and its governmental and private partners have fudged vaccine science for decades, leaving—by now—a well-documented trail of cover-ups and skullduggery.[161] Some of the more notorious episodes involve secret meetings, attempts to keep publicly funded data out of the reach of independent scientists, destruction of data, fraudulent manipulation of data and other crimes, including embezzlement. Far from being exceptions, these incidents illustrate a longstanding culture of dishonesty and ethical violations at the heart of the U.S. vaccine enterprise.

## Manipulating Thimerosal Data

In June, 2000, the CDC convened a scientific review panel at the Simpsonwood Retreat Center near Atlanta.[162] At the gathering (intended to be secret), over 50 experts—representing the CDC and FDA, state and international public health agencies and vaccine companies—met to discuss what they described as "theoretical concerns" about the risks of thimerosal-containing vaccines.

The lead Simpsonwood speaker, ***Thomas ("Tom") Verstraeten, MD***, was a junior physician-biostatistician working in the CDC's Epidemic Intelligence Service (EIS). Verstraeten had been conducting analyses designed to assess the impact of thimerosal-containing vaccines on neurodevelopmental disorders in children. His earliest tables—never reported on or published but obtained through a Freedom of Information Act request by the autism advocacy organization ***SafeMinds***—demonstrated "striking" and statistically significant effects "supportive of a causal relationship between vaccine mercury exposure and childhood developmental disorders (especially autism)."[163] These initial analyses, dubbed "Generation Zero" by SafeMinds, found consistently elevated risks (2-11 times higher) in the high-exposure groups compared to the zero-exposure group, with the strongest effects "for the

Notorious episodes involve secret meetings, attempts to keep publicly funded data out of the reach of independent scientists, destruction of data, fraudulent manipulation of data and other crimes, including embezzlement. These incidents illustrate a longstanding culture of dishonesty and ethical violations at the heart of the U.S. vaccine enterprise.

highest levels of mercury exposure at the earliest time of exposure."

Between February 2000 and November 2003, Verstraeten and his CDC supervisors produced four further rounds of analyses that—with each round or "generation"—reduced or eliminated the elevated and statistically significant risks apparent in the Generation Zero data. This reflected, according to SafeMinds, "deliberate" methodological choices that took the findings in a direction "towards insignificance." When going over the "Generation One" analysis at Simpsonwood, Verstraeten made it clear that he was caught in the middle. On the one hand, he described a safety signal that would "never go away"—showing that thimerosal exposure in infancy displayed a statistically significant dose-related association with subsequent neurological damage—but he also hinted at the pressure that he was under to "turn everything around" and "make it go away" (see "Undeniable Safety Signal"). Meanwhile, other Simpsonwood attendees cautioned that "we have to be very, very careful that we got it right when we decide to make a policy call on this." By the close of the meeting, all but one Simpsonwood attendee had agreed to rate the association between thimerosal and neurodevelopmental disorders as "weak."

In a post-Simpsonwood email in July, 2000 to Harvard researcher ***Philippe Grandjean***—a leading mercury and neurotoxicology expert—Verstraeten apologized for dragging Grandjean into a "nitty-gritty discussion" about thimerosal and neurodevelopment. Verstraeten stated, "I do not wish to be the advocate of the anti-vaccine lobby and sound like being convinced that thimerosal is or was harmful, but at least I feel we should use sound scientific argumentation and not let our standards be dictated by our desire to disprove an unpleasant theory."

Despite Verstraeten's scruples, others at the CDC—with Julie Gerberding at the helm—proceeded to hastily publish a handful of poorly designed epidemiological studies intended to shore up the Simpsonwood consensus. Authored by industry-funded scientists, the studies examined a single neurodevelopmental outcome (autism) and seemingly absolved thimerosal of any responsibility for causing it. A study of the data presented at Simpsonwood was published in *Pediatrics* in 2003,[164] with Verstraeten (now working at GlaxoSmithKline) as lead author. Although the publication used the later generations of analyses—featuring reworked exclusion criteria, exposure measures and statistical models—Verstraeten contested the notion that he or the CDC had "watered down" the original results. In a letter to the editor of *Pediatrics* in 2004,[165] he described the study's results as "neutral," stating, "The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required."

Around the same time, a handful of other CDC-sponsored epidemiological studies were published that intentionally used data from non-U.S.

## Undeniable Safety Signal

*"The bottom line to me is you can look at this data and turn it around and look at this, and add this stratum, I can come up with risks very high. I can come up with very low risks, depending on how you turn everything around. You can make it go away for some and then it comes back for others. To me the bottom [line] is, well, there is some things that just will never go away. If you make it go away here, it will pop up again there. So the bottom line is, okay, our signal will simply not just go away."*

*—Thomas Verstraeten, Simpsonwood*

SOURCE: Simpsonwood transcript, p. 153 https://childrenshealthdefense.org/government/federal-agency-documents/simpsonwood-documents/

populations with far lower exposure to thimerosal (including Sweden,[166] the Danish general population,[167] Danish psychiatric departments[168] and the United Kingdom[169]). This made it easier to disguise potential associations between thimerosal and neurodevelopmental disorders. Despite many solid critiques of these and other gerrymandered studies,[170] the CDC continues to trot them out as evidence of thimerosal's putative safety to this day.[171]

## Outsourcing the Vaccine Safety Datalink

Verstraeten's dataset, which included over 100,000 children born over the five-year period from 1992 to 1997, came from the ***Vaccine Safety Datalink*** (VSD). The VSD is a taxpayer-funded collection of millions of medical and vaccine records from large health maintenance organizations (HMOs), established by the CDC in 1990 to facilitate safety studies of vaccines already on the market.[172] Researchers at the CDC and the participating HMOs regularly publish vaccine-favorable studies using VSD data, often drawing on the same prelicensing tactic of comparing one vaccine with another to ensure a result of "no significantly elevated risk" in the group of interest.[173]

In 2001, one year after Verstraeten shared his VSD-based thimerosal findings at Simpsonwood, the CDC outsourced VSD management and coordination to a private company—***America's Health Insurance Plans*** (AHIP)—giving AHIP responsibility for maintaining the "strategic direction" of VSD projects.[174] Although the CDC claims that it "tries to accommodate" requests from independent investigators to use VSD data,[175] in practice, AHIP's private control has made the data virtually impenetrable to anyone other than CDC- and HMO-approved researchers. In 2005, the IOM released a consensus report, titled *Vaccine Safety Research, Data Access, and Public Trust*,[176] which admitted to "the limited ability of independent external researchers to conduct high-quality corroboration studies or studies of new hypotheses…*after January 1, 2001*" [emphasis added], including studies that "members of the public consider to have high priority" (Chapter 5).[177]

In 2002, two external researchers sought to gain access to VSD data. They persisted until successful—but only at the price of dealing with numerous hurdles that are hard to construe as anything but intentional obstruction on the CDC's part.[178] These included:

- Having to submit a 200-page proposal and undergoing a months-long initial approval process at the CDC
- Having to submit separate proposals and undergo lengthy approvals at each of the HMOs, sometimes at considerable expense (and sometimes with approval granted and then retracted)
- Encountering CDC refusal to allow reanalysis of data from published CDC VSD-based studies (with the CDC responding in multiple instances that the raw data no longer existed or that the dataset had been "damaged")
- Getting charged thousands of dollars in user fees to access the data in a windowless room secured by armed guards

Researchers at the CDC and the participating HMOs regularly publish vaccine-favorable studies using Vaccine Safety Link Datalink data, often drawing on the same prelicensing tactic of comparing one vaccine with another to ensure a result of "no significantly elevated risk" in the group of interest.

*"The treatment that these well-published researchers have received from the CDC…has been abysmal and embarrassing. I would be curious to know whether Dr. Verstraeten [by then at GSK] …was required to go through the same process…to continue accessing the VSD."*

—Congressman Dave Weldon, writing to CDC Director Julie Gerberding

## Throwing Autism-MMR Data in the Trash

Around the same time period (the early 2000s), ***Dr. William Thompson***, long-time CDC vaccine safety scientist, was assigned to a CDC study intended to extricate the MMR vaccine from its controversial association with autism. Unexpectedly, the data refused to cooperate, showing a 250% increase in autism in African-American boys who received the MMR vaccine before their third birthday (compared to African-American boys who received the vaccine after age three).[179] When the MMR study was published in 2004,[180] the publication failed to report these critical findings, despite the fact that "a greater risk specifically for African-Americans deserves additional, immediate investigation."[181] The data analysis also showed an increased risk of autism in MMR-vaccinated children who had been developing normally and had no other medical problems, but the published article "mentioned the effect…only in passing."[182]

A decade later, in 2014, Thompson sought federal whistleblower protection and testified to Congressman ***William Posey*** about the fraudulent omission of key autism results in the 2004 MMR paper. Thompson alleged that he had acted at the direction of senior CDC officials, including Branch Chief ***Frank DeStefano*** (lead author on the published paper), who ordered Thompson and his co-authors to dump the datasets into a giant garbage can to get rid of the evidence establishing a causal vaccine-autism connection.[183] Thompson handed over thousands of pages of documents to Congressman Posey revealing widespread fraud in the CDC's vaccine division. He also expressed willingness to appear, under subpoena, before the ***House Committee on Oversight and Government Reform*** (OGR). However, the OGR Committee Chairman at the time, former Representative ***Jason Chaffetz***, stonewalled until he left office in 2017. (According to a report in *The Guardian*, drug companies had been the single largest donor[184] to his political campaigns.)

## Turning a Blind Eye

Reflecting the almost Keystone-Cops-like atmosphere at the CDC, another infamous mid-2000s episode remains unresolved to this day. The "most wanted fugitives" webpage on HHS's Office of Inspector General (OIG) website shows that a visiting Danish scientist at CDC named ***Dr. Poul Thorsen*** "executed a scheme to steal [CDC-awarded] grant money" over a six-year period from 2004 to 2010.[185] The indictment describes how Thorsen diverted over $1 million of CDC funds to his personal bank account through fraudulent invoicing (as well as misallocating additional monies), eventually taking refuge in Denmark to escape prosecution for 22 counts of wire fraud and money laundering.[186] Thorsen has been on the OIG's "most wanted" list since 2012. Although his whereabouts in Denmark are well-known, HHS and DOJ have made no effort to push for extradition, despite urging from Congressman Posey to pursue the matter as a high priority.[187]

Thompson…acted at the direction of senior CDC officials, including Branch Chief Frank DeStefano… who ordered Thompson and his co-authors to dump the datasets into a giant garbage can to get rid of the evidence establishing a causal vaccine-autism connection.

The CDC embraced Thorsen as one of its own before, during and after the embezzlement. Thorsen was an insider to such an extent that he (a foreign scientist) had a CDC government email address and CDC credit union account.[188] From the time of his arrival at the CDC, the agency seized on the allegedly unscrupulous Thorsen as an ideal partner to cook up and publish slanted epidemiological studies out of Denmark that masked the MMR-autism and thimerosal-autism associations, including studies that appeared in the *New England Journal of Medicine*[189] and *Pediatrics*[190] in 2002 and 2003, respectively. Senior CDC officials "continued to include him in discussions well after it was obvious he had forged documents and stolen money," also arranging in-person meetings and continuing to collaborate and publish with Thorsen after his indictment.[191] Nor was the CDC troubled by the fact (uncovered by Children's Health Defense in 2017 but known by the CDC since 2009) that Thorsen and his collaborators failed to request or obtain required ethical clearances for the 2002 MMR study as well as a later study.[192] Instead of retracting the unapproved studies, CDC supervisors simply covered up the illicit activity.[193]

## Generating Favorable IOM Findings

The IOM (now the ***Health and Medicine Division*** of the ***National Academies of Sciences, Engineering, and Medicine***) is a private, nonprofit entity that has had a mandate since 1970 to provide the U.S. government with "independent, objective analysis" on matters of health.[194] The IOM has authored dozens of reports on vaccines.[195] However, the organization's independence on this topic is open to question, given that its members[196] are drawn from the ranks of the very same government agencies, schools of medicine, schools of public health, hospitals and private foundations that have uncritically supported existing vaccine policies for decades.

The IOM produces reports specifically requested and paid for by federal agencies—including the CDC—as well as other organizations. The IOM develops its scope of work "in collaboration with the study's sponsor" and then carries out its deliberations behind closed doors.[197] In September, 2000, the CDC and the ***National Institutes of Health*** (NIH) commissioned an IOM committee to research and write a series of eight specific immunization safety reviews, with the scope closely dictated by the CDC (see "The IOM Reviews").

The first two IOM reports, published in 2001, focused on thimerosal-containing vaccines and neurodevelopmental disorders[198] and the MMR vaccine and autism,[199] respectively. In the former, the IOM authors endorsed the biological plausibility of the hypothesis that "exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders," concluding (like Verstraeten) that they could neither accept nor reject a causal relationship. They called for removal of thimerosal from *all* vaccines given to infants, children and pregnant women as a precautionary step and recommended more basic science, clinical and epidemiological research—recommendations that remain largely unheeded to this day. The second IOM report came out against a population-level causal relationship between the MMR vaccine and autism, yet it, too, stated that it could not disprove "the proposed biological models" in individual children and reiterated the need for further research.

The IOM produces reports specifically requested and paid for by federal agencies—including the CDC—as well as other organizations.

### The IOM Reviews

From 2001-2004, the Institute of Medicine (IOM) produced a series of eight immunization safety reviews:

- Thimerosal-containing vaccines and neurodevelopmental disorders (2001)
- Measles-mumps-rubella vaccine and autism (2001)
- SV40 contamination of polio vaccine and cancer (2002)
- Multiple immunizations and immune dysfunction (2002)
- Hepatitis B vaccine and demyelinating neurological disorders (2003)
- Vaccinations and sudden unexpected death in infancy (2003)
- Influenza vaccines and neurological complications (2004)
- Vaccines and autism (2004)

SOURCE: https://www.ncbi.nlm.nih.gov/books/NBK206941/

Although the IOM meetings took place behind closed doors, an insider leaked transcripts of the 2001 meetings. Well before any evidence had been reviewed, the Committee Chairman, ***Dr. Marie McCormick***, stated, "CDC…wants us to declare…these things are pretty safe on a population basis" (p. 33); she later added, "we are not ever going to come down that [autism] is a true side effect [of a vaccine]" (p. 97).[200] The Committee Study Director, ***Dr. Kathleen Stratton***, likewise clarified, "…The line we will not cross in public policy is pull the vaccine, change the schedule. …We wouldn't say compensate, we wouldn't say pull the vaccine, we wouldn't say stop the program" (p. 74). The transcripts suggest that, at its core, the committee was little better than a "kangaroo court"; in the words of a parent organization, "the fix was in" from the start.[201]

By the time the IOM committee wrote its 2004 report,[202] the group "managed to produce the outcome CDC was looking for."[203] Written in what Congressman Dave Weldon characterized as an "atmosphere of intimidation" driven by "a desire to sweep these issues under the rug,"[204] the 2004 report reexamined the hypothesis that vaccines—specifically the MMR vaccine and thimerosal-containing vaccines—might be associated with autism. This time, however—using tactics such as "changing their charter, avoiding case reports, and disregarding biological evidence"[205]—the IOM categorically rejected both hypothesized relationships. Leaving behind the 2001 position of "biological plausibility," the 2004 report dismissed "potential biological mechanisms for vaccine-induced autism" as "only theoretical."

The initiation of the ***Omnibus Autism Proceeding*** (OAP) in 2002 undoubtedly fed into the IOM committee's about-face. The OAP presented the NVICP's Special Masters with the politically thorny task of evaluating 5,400 petitions asserting that vaccines had caused autism, either as a result of thimerosal, the MMR vaccine or a combination of the two.[206] The Special Masters eventually dismissed all of the OAP petitions, ruling that "none of the theories of autism causation… were proven." To support this ruling, they not only drew on the flawed epidemiological studies published by Thompson, DeStefano, Thorsen and others but also had the IOM's damning 2004 report close at hand.

In one of its only concessions to biological plausibility, a brief section of the 2004 IOM report discussed the "hypothesis" of genetic susceptibility to vaccine injury, citing the field known as pharmacogenetics—"genetic variants in humans that… change the way individuals react to certain medications."[207] The IOM authors suggested that "something similar might be operating in infants and young children exposed to certain vaccines or vaccine components." In addition, they noted that "this hypothesis cannot be excluded by epidemiological data from large population groups that do not show an association between a vaccine and an adverse outcome" because "a rare event caused by genetic susceptibility *could be missed even in large study samples*" [emphasis added]. A few years later, the NVICP reluctantly conceded just such a possibility, awarding over $1.5 million in immediate compensation and an estimated $20 million over her lifetime to a vaccine-injured child, Hannah Poling, after admitting that administration (in a single day) of five vaccines for nine diseases had worsened her underlying mitochondrial disorder and resulted in autism.[208] *TIME* magazine reported, "…There's no denying that the court's

In one of its only concessions to biological plausibility, a brief section of the 2004 IOM report discussed the "hypothesis" of genetic susceptibility to vaccine injury, citing the field known as pharmacogenetics—"genetic variants in humans that… change the way individuals react to certain medications."

decision to award damages…puts a chink—a question mark—in what had been an unqualified defense of vaccine safety with regard to autism. If Hannah Poling had an underlying condition that made her vulnerable to being harmed by vaccines, it stands to reason that other children might also have such vulnerabilities."[209]

Unfortunately, the 2004 IOM report also declared that "from a public health perspective the committee does not consider a significant investment in studies of the theoretical vaccine-autism connection to be useful at this time." Thus, the report's net effect was not only to buttress the government's assertion that vaccines do not cause autism (facilitating its dismissal of OAP claims) but also to halt financial support for much-needed studies, including studies of genetic susceptibility.

## Ensuring Medical Journal Complicity

The vaccine industry and its government accomplices could not routinely block meaningful science and fabricate misleading studies without having enticed medical journals into a Faustian bargain. Pharmaceutical companies supply journals with needed income, and in return, the journals play a key role in suppressing studies that raise critical questions about vaccine risks—which would endanger profits.

Advertising is one of the most obviously beneficial ways that medical journals' "exclusive and dependent relationship" with the pharmaceutical industry plays out.[210] According to a 2006 analysis in *PLOS Medicine*, drugs and medical devices are the *only* products for which medical journals accept advertisements.[211] The pharmaceutical industry "puts a high value on

advertising its products in print journals" because journals reach doctors—the "gatekeeper between drug companies and patients."[212] In fact, studies show that journal advertising generates "the highest return on investment of all promotional strategies employed by pharmaceutical companies."[213] Almost nine in ten drug advertising dollars are directed at physicians. In the U.S. in 2012, drug companies spent $24 billion marketing to physicians, with only $3 billion spent on direct-to-consumer advertising.[214] (By 2015, however, consumer-targeted advertising had jumped to $5.2 billion,[215] a 60% increase that has reaped rewards—see "Vaccine Advertising Pays Off.")

Advertising is such an established part of journals' modus operandi that high-end journals such as *The New England Journal of Medicine* (NEJM) boldly invite medical marketers to "make NEJM the cornerstone of their advertising programs," promising "no greater assurance that your ad will be seen, read, and acted upon."[216] In addition, medical journals benefit from pharmaceutical companies' bulk purchases of thousands of journal reprints (see "Cash Cows") and industry's sponsorship of journal subscriptions and journal supplements.

### Vaccine Advertising Pays Off

Heavy-duty vaccine advertising directed at consumers pays off in doctor-patient encounters. In 2015, Pfizer's Prevnar-13 vaccine was the nation's eighth most heavily advertised drug; after the launch of the intensive advertising campaign, Prevnar "awareness" increased by over 1,500% in eight months, and "44% of targeted consumers were talking to their physicians about getting vaccinated specifically with Prevnar." Slick ad campaigns have also helped boost uptake of "unpopular" vaccines like Gardasil.

SOURCES: Helfand C. Pfizer's Prevnar conundrum: how to convince "invincible" baby boomers they need a shot? *FiercePharma*, Apr. 10, 2017.

Ramsey L. A shocking new ad is shaming parents for not giving their children this unpopular vaccine. *Business Insider,* Jul. 15, 2016.

Fifteen years ago, an editor at *The BMJ* wrote about other ways in which drug company funding can bias medical journals (and the practice of medicine).[217] For example:

- Advertising monies enable prestigious journals to get thousands of copies into doctors' hands for free, which "almost certainly" goes on to affect prescribing.
- Journals are willing to accept even the most highly misleading advertisements. From 1997 to 2002, the FDA flagged dozens of instances of advertising violations, including ads that overstated a drug's effectiveness or minimized its risks.
- Journals will guarantee favorable editorial mentions of a product in order to earn a company's advertising dollars.
- Journals can earn substantial fees for publishing supplements even when they are written by "paid industry hacks"—and the more favorable the supplement content is to the company that is funding it, the bigger the profit for the journal.

## Funding Research

According to the *Journal of the American Medical Association* (JAMA), as of 2003, nearly three-fourths of all funding for clinical trials in the U.S.—presumably including vaccine trials—came from corporate sponsors.[218] The pharmaceutical industry's funding of studies (and investigators) is a factor that helps determine which studies get published, and where.

In 2009, researchers published a systematic review of several hundred influenza vaccine trials.[219] Noting "growing doubts about the validity of the scientific evidence underpinning [influenza vaccine] policy recommendations," the authors showed that

although vaccine-favorable studies were "of significantly lower methodological quality," even these poor-quality studies—*when funded by the pharmaceutical industry*—got far more attention than equivalent studies not funded by industry. The authors commented:

> *"[Studies] sponsored by industry had greater visibility as they were more likely to be published by high impact factor journals and were likely to be given higher prominence by the international scientific and lay media, despite their apparent equivalent methodological quality and size compared with studies with other funders."*

In their discussion, the authors also described how the industry's vast resources enable lavish and strategic dissemination of favorable results. For example, companies often distribute "expensively bound" abstracts and reprints (translated into various languages) to "decision makers, their advisors, and local researchers," while also systematically plugging their studies at symposia and conferences.

At the same time, and in defiance of ***World Health Organization*** standards

### Cash Cows

"Major [clinical] trials are very good for journals in that doctors around the world want to see them and so are more likely to subscribe to journals that publish them. Such trials also create lots of publicity, and journals like publicity. Finally, companies purchase large numbers of reprints of these trials. . . and the profit margin to the publisher is huge. These reprints are then used to market the drugs to doctors, and the journal's name on the reprint is a vital part of that sell."

SOURCE: Smith R. Medical journals and pharmaceutical companies: uneasy bedfellows. *BMJ* 2003;326(7400):12-2-1205.

that describe reporting of clinical trial results as a "scientific, ethical, and moral responsibility," it appears that as many as half of all clinical trial results go unreported—particularly when their results are negative; experts warn that "unreported studies leave an incomplete and potentially misleading picture of the risks and benefits of treatments."[220]

## Debasing and Censoring Results

Researchers have reported "a significant association between funding sources and pro-industry conclusions,"[221] documenting the potential for drug company funding to encourage methodological bias[222] and debasement[223] of study designs and analytic strategies. Bias may be present in the form of inadequate sample sizes, short follow-up periods, inappropriate placebos or comparisons, use of improper surrogate endpoints, unsuitable statistical analyses or "misleading presentation of data."[224] Many vaccine studies flagrantly illustrate these and other types of biases and selective reporting,[225] resulting in skewed write-ups that are more marketing than science—as journal insiders have admitted (see "Untrustworthy Research"). In formulaic articles that medical journals are only too happy to publish, the conclusion is almost always the same, no matter the vaccine: "We did not identify any new or unexpected safety concerns."

As an example of the use of inappropriate statistical techniques to exaggerate vaccine benefits, an influenza vaccine study reported a "69% efficacy rate" even though the vaccine failed "nearly all who [took] it."[226] As explained by Dr. David Brownstein, the study's authors used a technique called relative risk analysis to derive their 69% statistic because it can make "a poorly performing drug or therapy look better than it actually is." However, the absolute risk difference between the vaccine and the placebo group was 2.27%, meaning that the vaccine "was nearly 98% ineffective in preventing the flu."

The ***Cochrane Collaboration*** (which bills its systematic reviews, ironically, as the international gold standard for high-quality, "trusted" evidence) recently furnished another example of industry-biased conclusions. In May, 2018, Cochrane published a systematic review highly favorable to HPV vaccination,[227] declaring no increased risk of serious adverse effects and—barely refraining from using the word "coincidence"—stating that deaths observed in HPV studies "have been judged not to be related to the vaccine." Cochrane claims to be free of conflicts of interest, but its roster of funders includes national governmental bodies and international organizations pushing for HPV vaccine mandates as well as the ***Bill & Melinda Gates Foundation*** and the ***Robert Wood Johnson Foundation***—both of which are staunch funders and supporters of HPV vaccination.[228] The Robert Wood Johnson Foundation's president is a former top CDC official who served as acting CDC director during the H1N1 "false pandemic" in 2009 that ensured millions in windfall profits for vaccine manufacturers.[229]

Two months after publication of Cochrane's HPV review, researchers affiliated with the ***Nordic Cochrane Centre*** (one of Cochrane's member centers) published an exhaustive critique, declaring that the reviewers had done an incomplete job and had "ignored important evidence of bias."[230] The critics itemized numerous methodological

### Untrustworthy Research

"It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as [editor-in-chief of the *New England Journal of Medicine*]."

SOURCE: Marcia Angell. Drug companies & doctors: a story of corruption. *The New York Review of Books,* Jan. 15, 2009.

***According to the Journal of the American Medical Association (JAMA), as of 2003, nearly three-fourths of all funding for clinical trials in the U.S.—presumably including vaccine trials—came from corporate sponsors.***[218]

and ethical missteps on the part of the Cochrane reviewers,[231] including failure to count nearly half of the eligible HPV vaccine trials, incomplete assessment of serious and systemic adverse events and failure to note the industry funding behind many of the reviewed studies. They also upbraided the Cochrane reviewers for not paying attention to key design flaws in the original clinical trials, including the failure to use true placebos and the use of surrogate outcomes for cervical cancer.

In response to the criticisms, the editor-in-chief of the Cochrane Library initially stated that a team of editors would investigate the claims "as a matter of urgency."[232] Instead, however, Cochrane's Governing Board quickly expelled one of the authors of the critique, Danish physician-researcher ***Peter Gøtzsche***, who helped found Cochrane and was the head of the Nordic Cochrane Centre. Gøtzsche has been a vocal critic of Cochrane's "increasingly commercial business model," which he suggests is resulting in "stronger and stronger resistance to say anything that could bother pharmaceutical industry interests."[233] Adding "insult to injury," Gøtzsche's direct employer, the Rigshospitalet hospital in Denmark, is now trying to fire Gøtzsche (see "Scientific Censorship in Action"). In response, Gøtzsche plans to launch an ***Institute for Scientific Freedom***.[234]

Another favored tactic used to keep vaccine-critical studies out of medical journals is to either censor them on the front end by refusing to publish them (even if peer reviewers recommend their publication) or concoct excuses to retract articles after publication. In recent years, journals have retracted articles written by top international scientists, accusing them of making "unjustified claims" because they dared to question the safety of the aluminum adjuvant in Gardasil[235] or wanted to discuss the need for transparency in autism research.[236]


## Using Front Groups

Physician organizations such as the ***American Academy of Pediatrics (AAP)*** benefit substantially from pharmaceutical industry advertisements in their affiliated medical journals, with advertising representing anywhere from a tenth to a third of the organization's total revenues.[237] Advertising income not infrequently outpaces revenues earned from subscriptions.

The AAP is particularly notorious as a vaccine industry front group,[238] receiving funding from Merck, Pfizer, Sanofi, GSK and others. The AAP also gets substantial funding from the CDC—over $20 million since 2009—over a third of which is explicitly vaccine-related.[239] The AAP's journal ***Pediatrics*** published several of the studies ginned up by the CDC to hide

### Scientific Censorship in Action

"Firing me sends the unfortunate signal that if your research results are inconvenient and cause public turmoil, or threaten the pharmaceutical industry's earnings, . . . you will be sacked."

SOURCE: Peter Gøtzsche. Why we're establishing an Institute for Scientific Freedom. *Mad in America,* Dec. 30, 2018.

any relationship between thimerosal-containing vaccines and autism, including the Verstraeten study (which was rejected by two other journals first). In more recent years, *Pediatrics* has led the way in browbeating vaccine questioners by drumming up faked concerns about "vaccine hesitancy"[240] and parental noncompliance.[241]

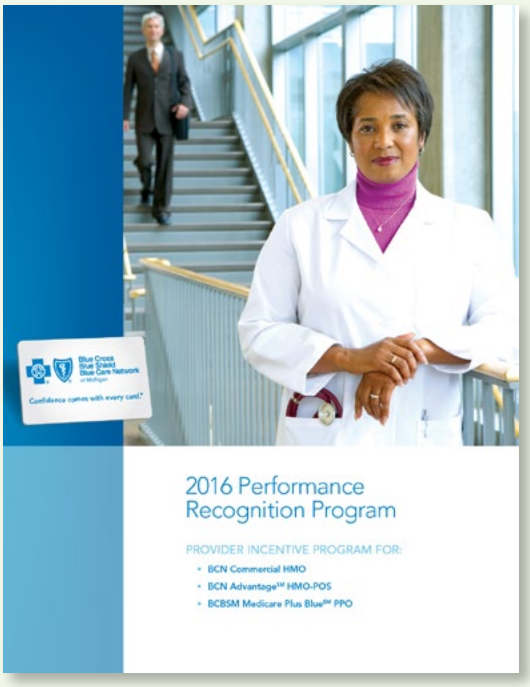
Other leading front groups that routinely propagate misleading information about vaccine safety include the ***Immunization Action Coalition*** (IAC) and ***Every Child by Two*** (ECBT). A 2017 analysis[242] in *The BMJ* showed that—far from being credible and independent sources of information—these outfits, like AAP, receive significant funding from vaccine manufacturers and the CDC, with a third of ECBT's annual funding coming from the latter. With industry and CDC funding in hand, these front groups guarantee vaccine makers' ability "to influence policy without having to stand on the front lines."[243]

## Coopting Physicians

Encouraged by trade groups such as the AAP, physicians have, by and large, been willing participants in the U.S. vaccine program. For multiple reasons, few doctors are willing to rock the boat, no matter how many vaccines are added to the schedule. Physicians' complacency about vaccines begins in medical school, where doctors are taught that vaccines are "wonderful" but learn nothing about vaccine ingredients, risks, effects on brain and immune system function or any other aspects critical to understanding vaccine safety and effectiveness.[244]

Pediatric well-child visits ensure a steady stream of repeat customers and revenue. The CDC advises practices to administer vaccines at about half of the visits through the adolescent years, with 11 visits recommended by the AAP over a child's first 30 months (and annually thereafter).[245] In addition, various financial incentive programs encourage pediatricians and family doctors to follow the CDC vaccine schedule, including insurers who give bonus payments to practice groups who achieve specified vaccination targets; practices publish and share these medical and clinical data to show "how the care…each [physician] give[s] to kids compares with the care given by their peers," thereby exerting pressure on doctors to toe the line rather than object to the targets.[246]

An example of a pay-for-performance model is the Michigan Blue Cross Blue Shield "Performance Recognition Program," which uses "meaningful" payments to reward Blue Care Network HMO providers "who encourage their patients to get preventive screenings and procedures."[247] For vaccination, providers receive $400 for each eligible two-year-old who has received all 24-25 vaccines by that age (including flu shots)—but only if the provider manages to administer each and every shot




2016 Blue Cross Blue Shield Blue Care Network Incentive Program Booklet

Providers receive $400 for each eligible two-year-old who has received all 24-25 vaccines by that age—but only if the provider administers each and every shot to at least 63% of his or her patients. Pediatricians who achieve the 63% threshold stand to make an additional $40,000 in bonus payments for every 100 fully vaccinated two-year-olds.

to at least 63% of his or her patients. Pediatricians who achieve the 63% threshold therefore stand to make an additional $40,000 in bonus payments for every 100 fully vaccinated two-year-olds,[248] creating a formidable incentive not to let any patients slip through the cracks, and a disincentive to continue serving families who decline one or more vaccines. In fact, a survey of pediatricians found that twice as many pediatricians (12%) reported "always" booting uncooperative families out of their practices in 2013 as in 2006,[249] and the AAP has pronounced it "ethical and legal" to do so.[250]

A 2010 study[251] of publicly funded community health centers (CHCs) serving low-income patients in Houston furnished another evocative example of how pay-for-performance models work. Even in the less-than-posh CHC setting, physicians could receive up to $12,000 annually in incentive payments for meeting vaccination and other targets. As the researchers explained:

- CHC physicians received financial incentives "if the clinic as a whole met or exceeded the thresholds for 2 of 3 indicators" (Pap smears, mammography and childhood vaccinations).
- If the clinics achieved two out of the three targets at the 80% to 90% level, all physicians received bonuses—"to encourage teamwork." Publications by medical trade groups confirm the trend toward payment systems that "reward teamwork."[252]
- Physician awareness of the incentive program was high "because results were reviewed regularly during monthly staff meetings."

Ironically, the study found no evidence whatsoever that the financial incentives improved clinical quality of care

for patients. In fact, the researchers concluded that there is little proof that any pay-for-performance initiative—whether sponsored by health plans, employers, or the government—is improving health care. Moreover, as reported by *Modern Healthcare* magazine:

> *"The tendency of pay-for-performance to 'dangle money' before doctors has side effects. It turns the intrinsic professional and moral obligation of doing the best thing for the patient into a market transaction governed by price"*[253]

Or, as Upton Sinclair famously stated decades ago, "It is difficult to get a man to understand something when his salary depends upon his not understanding it."

Author Upton Sinclair famously stated decades ago, "It is difficult to get a man to understand something when his salary depends upon his not understanding it."


# V. WHAT'S NEEDED

The passage of the NCVIA in 1986 emboldened vaccine manufacturers and their public- and private-sector accomplices—notably the CDC—to systematically hide the serious damage caused by their products. In addition to making a mockery of pre-licensing safety testing and post-marketing surveillance, these entities have regularly manipulated (or destroyed) data to fraudulently exaggerate the benefits and effectiveness of vaccination. Manufacturers have also used their money and power to subordinate the mainstream media, medical journals and medical front groups, making it possible to publish and broadcast deceptive studies that whitewash questions inconvenient to the financial bottom line.

Clearly, pharmaceutical companies have a strong interest in continuing to expand the lucrative vaccine market, both in the U.S. and globally. GlaxoSmithKline, for example, has a current portfolio of over 40 vaccines (targeting 22 diseases and "every stage of life") and sells almost 800 million vaccine doses worldwide each year, with 70% of sales in emerging market countries.[254] The company's website indicates that it is eager to expand still further, calling attention to the "more than 25 million children… born every year in India alone" and the "more than a billion" adults worldwide over age 60.[255] The other three companies that are dominant in the U.S. market (Merck, Pfizer and Sanofi) are equally keen to broaden their worldwide reach.[256]

From multiple standpoints—not least of which is children's dismal state of health—the status quo is untenable. Three of the most urgent steps to be taken include repealing the NCVIA, eliminating vaccine mandates (making both childhood and adult vaccination voluntary) and addressing conflicts of interest by establishing a fully transparent and independent vaccine safety commission.

From multiple standpoints—not least of which is children's dismal state of health—the status quo is untenable.

## Repeal the NCVIA

The NCVIA has been an unmitigated disaster. As New York University law professor Mary Holland has written, the Act's passage has allowed the government and vaccine manufacturers to ride roughshod over three important legal protections: free and informed consent to an invasive medical procedure; accurate and complete information about vaccine ingredients and possible side effects; and the right to sue manufacturers and medical practitioners directly in the event of injury.[257] According to Professor Holland, the absence of these legal protections for vaccination is "striking" compared to "almost all other medical interventions."

The legal protections listed by Holland are interrelated. For example, an individual cannot exercise truly informed consent unless he or she has access to full and unbiased information.[258] Recognizing this, one provision of the NCVIA was a mandate for the CDC to develop (and health care providers to distribute) patient education materials about vaccine risks and benefits. However, not only has the CDC repeatedly dumbed down the materials in a variety of ways, but research suggests that many doctors do not comply with the legal requirement to hand out (much less discuss) them.[259] Instead, the public continues to be blandly assured that vaccine injuries are a "one in a million" event and is never told that 99% of vaccine injuries go unreported. Under the circumstances, no meaningful assessment of vaccine risks is possible.

Research shows that by eliminating consumers' ability to sue, the NCVIA has had a tangibly negative effect on vaccine safety. After an extensive analysis of nationwide and state-level U.S. data, a researcher reported in 2017 that vaccines licensed after NCVIA's passage were associated with "a significantly higher incidence of adverse events" compared to vaccines licensed prior to the law's passage. The researcher concluded that "product safety deteriorates when consumers are no longer able to sue manufacturers."[260] Repealing the NCVIA and reinstating product liability would not solve all of the ethical problems that permeate the pharmaceutical industry's business culture, but it could curtail the vaccine "free-for-all" environment that has prevailed since 1986 and might incentivize manufacturers to treat vaccines in the same way as drugs and put safety on a more even footing with profits.

NCVIA repeal would also draw greater attention to the exorbitant financial stress experienced by vaccine-injured individuals and families.[261] The NVICP not only has "failed to compensate generously" but, far more often than not, does not compensate at all (see "Barriers to Vaccine Injury Compensation").[262] Moreover, despite the NCVIA legislation's focus on *childhood* vaccines, 71% of compensated claims have been for vaccine injuries in adults,[263] leaving many vaccine-injured children and their families out in the financial cold. In the only study ever conducted to explore petitioners' experiences with the NVICP, petitioners described the vaccine injury claims process as "confusing, time-consuming, too lengthy, and traumatic," and about half rated the award amount as "inadequate to cover past and future medical care."[264] In short, whereas Congress marketed the NVICP as a speedy, non-adversarial, no-fault compensation mechanism that would free the injured of the need to prove vaccine-related causation, it has turned out to be slow and litigious, requiring proof of causation for more than 90% of claims filed. As one individual

### Barriers to Vaccine Injury Compensation

Numerous factors contribute to the low levels of vaccine injury compensation:

- Public and medical ignorance about vaccine injury
- Ignorance about the NVICP
- The NVICP's three-year statute of limitations
- Adversarial litigation context
- Inconsistent judgments by the vaccine court
- Delayed and below-market compensation for attorneys and medical experts
- Medical expert fear of "anti-vaccine" stigma
- Unavailability of medical documentation
- Impossibly high burden of proof for "off-table" injuries

SOURCES: Holland M. Reconsidering compulsory childhood vaccination. Public Law & Legal Theory Research Paper Series, Working Paper No. 10-64, New York University School of Law.

Boehm J. Critics say vaccine injury fund has strayed from original purpose. *Cronkite News,* May 8, 2015.

familiar with the system has stated, "even when cases are fairly simple, 'the government will fight.'"[265]

## Eliminate Vaccine Mandates

Medical informed consent—"the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine"—is meaningless if an individual does not have the option of "determin[ing] what shall be done with his body" and declining a given medical intervention.[266] Vaccination in the U.S. makes a mockery of this ethical principle because vaccines are increasingly compulsory—for school attendance,[267] health care employment,[268] participation in the military,[269] immigration[270] and more. Vaccine proponents[271] and medical ethicists[272] also have proven themselves willing to blur the lines of informed consent in other ways, arguing, for example, that "adolescent autonomy" and improved vaccine uptake justify eliminating parental consent requirements for HPV vaccination in preteens and adolescents. (This argument prevailed in California in 2011 when then-Governor Jerry Brown signed a bill allowing minors as young as 12 to consent on their own to the HPV and hepatitis B vaccines.[273])

As summarized by law professor Mary Holland, compulsory vaccination policies in the U.S. have not had positive results. Instead, they have given rise to a wide variety of unintended and undesirable consequences, including:

- Unnecessary vaccinations that have wreaked havoc with children's normal immune system development[274]
- Unsafe vaccines
- Inadequate warnings about vaccine risks

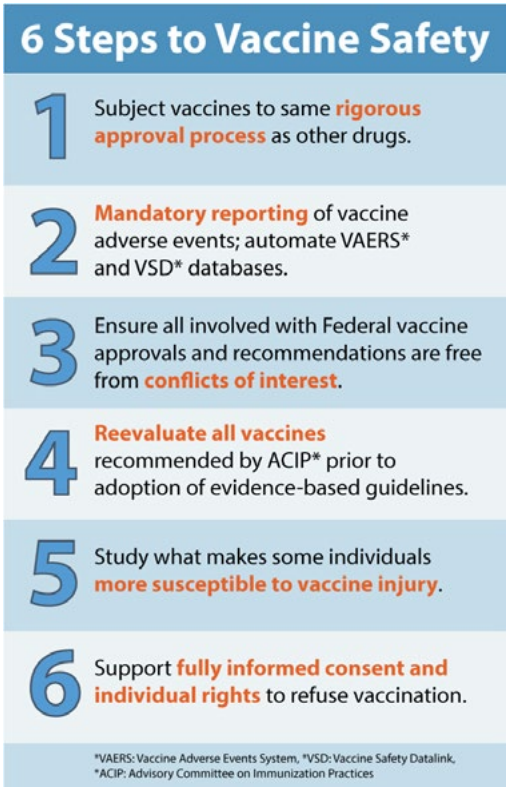
- Conflicts of interest in national vaccine policy
- Insufficient compensation for the vaccine-injured
- An alarming decline in children's health and well-being

Research also shows that there is no relationship "between mandatory vaccination and rates of childhood immunization."[275] Rather than trying to corral the small percentage of individuals who are currently eligible for medical, religious and philosophical vaccine exemptions into a "vaccinate-at-all-costs" police-state dragnet, the U.S. should recommit to international principles of informed consent and make all vaccines voluntary. Unfortunately, there is an accelerating trend toward greater use of mandates and "other legal instruments" not only in the U.S. but in Europe. There, some experts have cautioned that legal sanctions are being applied by "those who want to punish a country—or, in the case of vaccinations, a citizen—that deviates from the norm."[276] These experts warn that mandates often have a high cost in the court of public opinion.

Research also shows that there is "between mandatory vaccination and rates of childhood immunization."[275] Rather than trying to corral the small percentage of individuals who are currently eligible for medical, religious and philosophical vaccine exemptions into a "vaccinate-at-all-costs" police-state dragnet, the U.S. should recommit to international principles of informed consent and make all vaccines voluntary.

## Address Conflicts of Interest

As this eBook has sought to illustrate, conflicts of interest—far from being occasional aberrations—are part and parcel of the U.S. vaccination program, and they have had a decisive and negative impact on children's health. Over the years since the passage of the NCVIA, a handful of courageous legislators who have been troubled by the "cozy corporate alliances" that exist between industry and captured federal regulators[277] have put forth pleas for an objective and non-conflicted vaccine safety commission to investigate and resolve safety problems.[278] Some researchers, likewise, have called for an independent National Vaccine Safety Board—separate from the CDC or any branch of government—to "ensure optimal vaccine safety."[279] A 2006 editorial in *Nature* concurred that in light of waning public confidence in vaccine safety, a strong case could be made for establishing a "well-resourced independent national agency that commands the trust of both the government and the public in matters of health protection."[280]


In early 2017, Children's Health Defense Chairman Robert F. Kennedy, Jr. discussed the creation of a vaccine safety commission with president-elect Trump and also met with high-level NIH and FDA officials.[281] Thus far, the Administration has not pursued the idea, despite the glaring need to introduce transparency to the U.S. vaccination program. In March, 2018, Children's Health Defense took to the halls of Congress and shared its multipronged Vaccine Safety Project with every member, arguing (among other actions) for the need to subject vaccines to a scientifically rigorous approval process, require reporting of vaccine adverse events, ensure that all parties involved with federal vaccine approvals and recommendations are free from conflicts of interest and support fully informed consent and individual rights to refuse vaccination.[282] Hopefully, concerned parents, health care professionals, legislators and others will lend their voices to these reasonable requests so that conflicts of interest can be abolished once and for all, and sound science—rather than deep pockets—can form the basis of vaccine policy-making.

Hopefully, concerned parents, health care professionals, legislators and others will lend their voices to these reasonable requests so that conflicts of interest can be abolished once and for all, and sound science—rather than deep pockets—can form the basis of vaccine policy-making.

# ENDNOTES


1 "Our history—our story." https://www.cdc.gov/about/history/index.html.

2 Interview with Robert F. Kennedy, Jr. "Mercury, vaccines and the CDC's worst nightmare." https://childrenshealthdefense.org/about-us/mercury-vaccines-cdcs-worst-nightmare/.

3 Letter from CDC SPIDER to Carmen S. Villar, Office of the Director, Centers for Disease Control and Prevention. https://usrtk.org/wp-content/uploads/2016/10/CDC_SPIDER_Letter-1.pdf.

4 Interview with Kennedy, Jr. "Mercury, vaccines and the CDC's worst nightmare."

5 Lanzarotta T, Ramos MA. "Mistrust in medicine: the rise and fall of America's first vaccine institute." *Am J Public Health* 2018;108(6):741-747.

6 Bailey W. "History of vaccination." *Public Health Pap Rep* 1899;25:219-222.

7 Hammond J. "On the crime of heresy against the vaccine religion." Children's Health Defense, May 12, 2017. https://childrenshealthdefense.org/news/crime-heresy-vaccine-religion/.

8 Bragazzi NL, Watad A, Amital H, Schoenfeld Y. "Debate on vaccines and autoimmunity: do not attack the author, yet discuss it methodologically." *Vaccine* 2017;35(42):5522-5526.

9 "Countering Dr. Sears." http://www.immunize.org/talking-about-vaccines/countering-dr-sears.asp.

10 Schuster M, Eskola J, Duclos P, the SAGE Working Group on Vaccine Hesitancy. "Review of vaccine hesitancy: rationale, remit and methods." *Vaccine* 2015;33(34)4157-4160.

11 Hough-Telford C, Kimberlin DW, Aban I, et al. "Vaccine delays, refusals, and patient dismissals: a survey of pediatricians." *Pediatrics* 2016;138(3).

12 Gopichandran V. "Public trust in vaccination: an analytical framework." *Indian J Med Ethics* 2017;2(2):98-104.

13 DeLong G. "Conflicts of interest in vaccine safety research." *Account Res* 2012;19(2):65-88.

14 Schuster et al., "Review of vaccine hesitancy."

15 Larson HJ, de Figueiredo A, Xiahong Z, et al. "The state of vaccine confidence 2016: global insights through a 65-country survey." *EBioMedicine* 2016;12:295-301.

16 "Statement of Rep. Dave Weldon, MD (FL-15). Introduction of The Vaccine Safety and Public Confidence Assurance Act of 2007." Apr. 19, 2007. https://worldmercuryproject.org/wp-content/uploads/2016/11/Weldon_Statement_Vaccine_Safety_final.pdf.

17 "Immunization and infectious diseases." https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.

18 "Vaccine market size expected to surpass $77 billion at 10.3% CAGR by 2024 | Million Insights." https://www.prnewswire.com/news-releases/vaccine-market-size-expected-to-surpass-77-billion-at-103-cagr-by-2024—million-insights-681224391.html.

19 Children's Health Defense. *The Sickest Generation: The Facts Behind the Children's Health Crisis and Why It Needs to End*. September 2018. https://childrenshealthdefense.org/ebook-sign-up/.

20 Bethell CD, Kogan MD, Strickland BB, Schor EL, Robertson J, Newacheck PW. "A national and state profile of leading health problems and health care quality for US children: key insurance disparities and across-state variations." *Acad Pediatr* 2011;11(3 Suppl):S22-S33.

21 Zablotsky B, Black LI, Blumberg SJ. "Estimated prevalence of children with diagnosed developmental disabilities in the United States, 2014-2016." NCHS Data Brief No. 291, November 2017.

22 Lipman TH, Levitt Katz LE, Ratcliffe SJ, et al. "Increasing incidence of type 1 diabetes in youth: twenty years of the Philadelphia Pediatric Diabetes Registry." *Diabetes Care* 2013;36(6):1597-1603.

23 Pear R. "Reagan signs bill on drug exports and payment for vaccine injuries." *The New York Times*, Nov. 15, 1986.

24 Challoner A. "How can vaccines cause damage?" [Letter] *BMJ* 2004;328:483. https://www.bmj.com/rapid-response/2011/10/30/how-can-vaccines-cause-damage.

25 "H.R. 5546 - National Childhood Vaccine Injury Act of 1986." https://www.congress.gov/bill/99th-congress/house-bill/5546.

26 Attkisson S. "Vaccine court." *CBS News*, June 27, 2008.

27 Holland MS. "Liability for vaccine injury: The United States, the European Union, and the developing world." *Emory Law Journal* 2018;67(3):415.

28 Kennedy, Jr. RF. "Vaccines and the liberal mind." Children's Health Defense, June 14, 2018. https://childrenshealthdefense.org/news/vaccines-and-the-liberal-mind/.

29 Ibid.

30 Children's Health Defense. "RFK, Jr. proves HHS is in violation of the 'mandate for safer childhood vaccines' as stipulated in the Vaccine Injury Compensation Act." Sept. 13, 2018. https://childrenshealthdefense.org/child-health-topics/federal-failures/rfk-jr-proves-hhs-is-in-violation-of-the-mandate-for-safer-childhood-vaccines-as-stipulated-in-the-vaccine-injury-compensation-act/.

31 "Vaccine injury compensation data." https://www.hrsa.gov/vaccine-compensation/data/index.html.

32 "Data and statistics." https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-sept-2018.pdf.

33 U.S. Government Accountability Office. "Vaccine injury compensation: most claims took multiple years and many were settled through negotiation." GAO-15-142, Nov. 21, 2014.

34 Ross L, Klompas M. *Electronic Support for Public Health—Vaccine Adverse Event Reporting System (ESP:VAERS)*. Rockville, MD: The Agency for Healthcare Research and Quality (AHRQ), Grant Final Report, R18 HS 017045.

35 "About the National Vaccine Injury Compensation Program." https://www.hrsa.gov/vaccine-compensation/about/index.html.

36 Children's Health Defense. "Vaccine injury payouts: consumers on the hook for over $3.8 billion as vaccine makers rake in profits." March 22, 2018. https://childrenshealthdefense.org/news/vaccine-injury-payouts-taxpayers-on-the-hook-for-over-3-8-billion-as-vaccine-makers-rake-in-profits/.

37 Holland, "Liability for vaccine injury."

38 "Vaccine injury table." https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf.

39 Holland, "Liability for vaccine injury."

40 Children's Health Defense. "Request for Office of Inspector General to investigate fraud and obstruction of justice." Sept. 20, 2018. https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/.

41 Conte L. "Misconduct, mitochondria and the Omnibus Autism Proceedings." Children's Health Defense, Oct. 4, 2018. https://childrenshealthdefense.org/news/misconduct-mitochondria-and-the-omnibus-autism-proceedings/.

42 Children's Health Defense, "Request for Office of Inspector General to investigate fraud and obstruction of justice."

43 Richey W. "Parents can't sue drug firms when vaccines cause harm, Supreme Court says." *The Christian Science Monitor*, Feb. 22, 2011.

44 Children's Health Defense, "Request for Office of Inspector General to investigate fraud and obstruction of justice."

45 "Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)." https://supreme.justia.com/cases/federal/us/562/223/.

46 "Wellcome Trust-funded vaccines company acquired by GSK." https://wellcome.ac.uk/news/wellcome-trust-funded-vaccines-company-acquired-gsk.

47 https://www.gavi.org/about/partners/bmgf/.

48 http://cepi.net/partners.

49 Holland, "Liability for vaccine injury."

50 Children's Health Defense, "Request for Office of Inspector General to investigate fraud and obstruction of justice."

51 "A smarter jab." *The Economist*, Oct. 14, 2010.

52 "Top 10 pharmaceutical companies 2017." https://www.igeahub.com/2017/03/14/top-10-pharmaceutical-companies-2017/.

53 Grover N. "Merck's profit tops estimates." *Business Insider*, May 2, 2017.

54 Rosenthal E. "The price of prevention: vaccine costs are soaring." *The New York Times*, July 2, 2014.

55 Kohls G. "Merck & company and big pharma's nefarious search for profits." *America Out Loud*, Dec. 12, 2018.

56 Wilson D. "Merck to pay $950 million over Vioxx." *The New York Times*, Nov. 22, 2011.

57 Cockburn A. "When half a million Americans died and nobody noticed." *The Week*, Apr. 27, 2012.

58 Herper M. "David Graham on the Vioxx verdict." *Forbes*, Aug. 19, 2005.

59 Cockburn, "When half a million Americans died and nobody noticed."

60 Loftus P, Hufford A. "Merck revenue and profit rise on cancer drugs, vaccines." *The Wall Street Journal*, Oct. 25, 2016.

61 Sagonowsky E. "Boosted by China launch, Merck's Gardasil turns in a big first-quarter performance." *FiercePharma*, May 8, 2018.

62 Stark K. "FDA report shows problems at Merck vaccine plant." *The Inquirer*, Apr. 24, 2008.

63 Ibid.

64 "A smarter jab." *The Economist*, Oct. 14, 2010.

65 Burton D. "Federal Advisory Committee Act (FACA): Conflicts of interest and vaccine development—preserving the integrity of the process." *Medical Veritas* 2008;5:1670-1696.

66 "Conflicts of interest as a health policy problem: industry ties and bias in drug approval." https://ethics.harvard.edu/conflicts-interest-health-policy-problem-industry-ties-and-bias-drug-approval.

67 Herper M. "The FDA's conflict of interest problem." *Forbes*, Feb. 24, 2005.

68 "How drugs are developed and approved." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/.

69 "About CBER." https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123340.htm.

70 "Highlights of prescribing information: Recombivax HB hepatitis B vaccine." https://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf.

71 Rid A, Saxena A, Baqui AH, et al. "Placebo use in vaccine trials: recommendations of a WHO expert panel." *Vaccine* 2014;32(37):4708-4712.

72 Kennedy, Jr. RF. "New study: vaccine manufacturers and FDA regulators used statistical gimmicks to hide risks of HPV vaccines." Children's Health Defense, Aug. 11, 2017. https://childrenshealthdefense.org/news/new-study-vaccine-manufacturers-fda-regulators-used-statistical-gimmicks-hide-risks-hpv-vaccines/.

73 "About CBER."

74 Holland M, Rosenberg KM, Iorio E. *The HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed*. New York, NY: Skyhorse Publishing; 2018.

75 "Gardasil approval history." https://www.drugs.com/history/gardasil.html.

76 "Gardasil 9 approval history." https://www.drugs.com/history/gardasil-9.html.

77 McGinley L. "FDA approves HPV vaccine for people up to 45." *The Washington Post*, Oct. 5, 2018.

78 Sagonowsky E. "GSK exits U.S. market with its HPV vaccine Cervarix." *FiercePharma*, Oct. 21, 2016.

79 Liu A. "With nod in older adults, Merck drives HPV shot Gardasil 9 into big new market." *FiercePharma*, Oct. 8, 2018.

80 Sagonowsky E. "'Unprecedented' demand for Merck's Gardasil drives monster Q3." *FiercePharma*, Oct. 29, 2018.

81 Joelving F. "What the Gardasil testing may have missed." *Slate*, Dec. 17, 2017.

82 DeLong G. "A lowered probability of pregnancy in females in the USA aged 25-29 who received a human papillomavirus vaccine injection." *J Toxicol Environ Health A* 2018;81(14):661-674.

83 Alvarez-Soria MJ, Hernández-González A, Carrasco-García de León S, del Real-Francia MA, Gallardo-Alcañiz MJ, López-Gómez JL. ["Demyelinating disease and vaccination of the human papillomavirus"]. [Article in Spanish]. *Rev Neurol* 2011;52(8):472-476.

84 Ikeda S. ["Neurologic complications in HPV vaccination"]. [Article in Japanese]. *Brain Nerve* 2015;67(7):835-843.

85 Brinth LS, Pors K, Theibel AC, Mehlsen J. "Orthostatic intolerance and postural tachycardia syndrome as suspected adverse events of vaccination against human papilloma virus." *Vaccine* 2015;33(22):2502-2605.

86 Souayah N, Michas-Martin PA, Nasar A, et al. "Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009." *Vaccine* 2011;29(5):886-889.

87 Tomljenovic L, Shaw CA. "Human papillomavirus (HPV) vaccine policy and evidence-based medicine: are they at odds?" *Ann Med* 2013;45(2):182-193.

88 Redwood L. Court hears Gardasil science and moves forward. Children's Health Defense, Jan. 29, 2019. https://childrenshealthdefense.org/news/court-hears-gardasil-science-and-moves-forward/.

89 Talia KL, Stewart CJR, Howitt BE, Nucci MR, McCluggage WG. "HPV-negative gastric type adenocarcinoma in situ of the cervix: a spectrum of rare lesions exhibiting gastric and intestinal differentiation." *Am J Surg Pathol* 2017;41(8):1023-1033.

90 Delépine G. Paradoxical effect of anti-HPV vaccine Gardasil on cervical cancer rate. Jan. 31, 2019. http://docteur.nicoledelepine.fr/paradoxical-effect-of-anti-hpv-vaccine-gardasil-on-cervical-cancer-rate/.

91 Castanon A, Sasieni P. Is the recent increase in cervical cancer in women aged 20-24 years in England a cause for concern? *Prev Med* 2018;107:21-28.

92 "Dr. Julie Gerberding named president of Merck Vaccines." https://www.fiercebiotech.com/biotech/dr-julie-gerberding-named-president-of-merck-vaccines.

93 Redwood, 2019. Court hears Gardasil science.

94 "Cancer stat facts: cervical cancer." https://seer.cancer.gov/statfacts/html/cervix.html.

95 Tomljenovic L, Spinosa JP, Shaw CA. "Human papillomavirus (HPV) vaccines as an option for preventing cervical malignancies: (how) effective and safe?" *Curr Pharm Des* 2013;19(8):1466-1487.

96 Nicol AF, Andrade CV, Russomano FB, Rodrigues LLS, Oliveira NS, Provance Jr. DW. "HPV vaccines: a controversial issue?" *Braz J Med Biol Res* 2016;49(5):e5060.

97 "General Committee-related information." https://www.cdc.gov/vaccines/acip/committee/index.html.

98 "ACIP recommendations." https://www.cdc.gov/vaccines/acip/recommendations.html.

99 "ACIP committee members." https://www.cdc.gov/vaccines/acip/members/index.html.

100 Benjamin M. "UPI investigates: the vaccine conflict." UPI, July 21, 2003.

101 Advisory Committee on Immunization Practices Policies and Procedures. January 2018. https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf.

102 "Conflicts of interest in vaccine policy making." http://www.vaccineinfo.net/issues/conflictofinterest/conflicts_of_interest.shtml.

103 Advisory Committee on Immunization Practices: Work Groups. Standard operating procedures, August 2018. https://www.cdc.gov/vaccines/acip/committee/downloads/Work-Group-Guidance-508.pdf.

104 Hinman AR, Orenstein WA, Schuchat A, Centers for Disease Control and Prevention (CDC). "Vaccine-preventable diseases, immunizations, and MMWR—1961-2011." *MMWR Suppl* 2011;60(4):49-57.

105 Rosenthal, "The price of prevention."

106 "School and day care minimum immunization requirements." http://www.vdh.virginia.gov/immunization/requirements1/.

107 Children's Health Defense. "Upholding religious and conscience-based vaccine exemptions." Mar. 15, 2018. https://childrenshealthdefense.org/news/upholding-religious-and-conscience-based-vaccine-exemptions/.

108 Ingeno L. "Many state lawmakers want to loosen childhood vaccine requirements, but legal barriers persist." DrexelNow, Nov. 29, 2018.

109 Goldstein ND, Suder JS, Purtle J. "Trends and characteristics of proposed and enacted state legislation on childhood vaccination exemption, 2011-2017." *Am J Public Health* 2018 Nov 29:e1-e6.

110 "The development of the immunization schedule." https://www.historyofvaccines.org/content/articles/development-immunization-schedule.

111 "CDC recommended childhood vaccine schedule: 1983 vs 2017." https://www.nvic.org/cmstemplates/nvic/pdf/downloads/1983-2017-vaccine-schedules.pdf.

112 Hinman et al., "Vaccine-preventable diseases, immunizations, and MMWR—1961-2011."

113 Hinman et al., "Vaccine-preventable diseases, immunizations, and MMWR—1961-2011."

114 "Recommended immunization schedule for children and adolescents aged 18 years or younger, United States, 2018." https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.

115 Rosenthal, "The price of prevention."

116 "CDC vaccine price list." https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/.

117 Rosenthal, "The price of prevention."

118 Taylor G. Examining RFK Jr.'s claim that the CDC "owns over 20 vaccine patents." *GreenMedInfo*, Jan. 17, 2017. http://www.greenmedinfo.com/blog/examining-rfk-jrs-claim-cdc-owns-over-20-vaccine-patents.

119 Di Pasquale A, Bonanni P, Garcon N, Stanberry LR, El-Hodhod M, Tavares Da Silva F. "Vaccine safety evaluation: practical aspects in assessing benefits and risks." *Vaccine* 2016;34(52):6672-6680.

120 "Vaccine injury compensation data." https://www.hrsa.gov/vaccine-compensation/data/index.html.

121 Tomljenovic L, Colafrancesco S, Perricone C, Schoenfeld Y. "Postural orthostatic tachycardia with chronic fatigue after HPV vaccination as part of the 'Autoimmune/Auto-inflammatory Syndrome Induced by Adjuvants': case report and literature review." *J Investig Med High Impact Case Rep* 2014;2(1):2324709614527812.

122 Goldman GS, Miller NZ. "Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990-2010." *Hum Exp Toxicol* 2012;31(10):1012-1021.

123 Shimabukuro TT, Nguyen M, Martin D, DeStefano F. "Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)." *Vaccine* 2015;33(36):4398-4405.

124 "Search the VAERS database." http://www.medalerts.org/vaersdb/index.php.

125 Ross and Klompas, *Electronic Support for Public Health—Vaccine Adverse Event Reporting System (ESP:VAERS)*.

126 Shimabukuro et al., "Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)."

127 Di Pasquale et al., "Vaccine safety evaluation: practical aspects in assessing benefits and risks."

128 McNeil MM, Li R, Pickering S, Real TM, Smith PJ, Pemberton MR. "Who is unlikely to report adverse events after vaccinations to the Vaccine Adverse Event Reporting System (VAERS)?" *Vaccine* 2013;31(24):2673-2679.

129 Parrella A, Braunack-Mayer A, Gold M, Marshall H, Baghurst P. "Healthcare providers' knowledge, experience and challenges of reporting adverse events following immunisation: a qualitative study." *BMC Health Services Research* 2013;13:313.

130 "Regulatory capture." https://www.investopedia.com/terms/r/regulatory-capture.asp.

131 "FDA approval process." https://www.drugwatch.com/fda/approval-process/.

132 "Accelerated approval." https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm.

133 Lorenzetti L. "Drug companies are paying huge sums to fast-track FDA approval." *Fortune*, Oct. 20, 2015.

134 "FDA wants more money, claims they are a 'bargain.'" Mercola.com, May 1, 2013.

135 "HHS FY 2017 budget in brief—FDA." https://www.hhs.gov/about/budget/fy2017/budget-in-brief/fda/index.html.

136 Judicial Watch. "Examining the FDA's HPV vaccine records: detailing the approval process, side-effects, safety concerns and marketing practices of a large-scale public health experiment." Washington, DC: Judicial Watch, June 30, 2008.

137 Tyring SK. "Natural history of varicella zoster virus." *Semin Dermatol* 1992;11(3):211-217.

138 Clark HF, Marcello AE, Lawley D, Reilly M, DiNubile MJ. "Unexpectedly high burden of rotavirus gastroenteritis in very young infants." *BMC Pediatr* 2010;10:40.

139 Clark HF et al., "Unexpectedly high burden of rotavirus gastroenteritis in very young infants."

140 Brisson M, Gay NJ, Edmunds WJ, Andrews NJ. "Exposure to varicella boosts immunity to herpes-zoster: implications for mass vaccination against chickenpox." *Vaccine* 2002;20(19-20):2500-2507.

141 Children's Health Defense. "The varicella vaccine, skyrocketing shingles and CDC chicanery." May 9, 2018. https://childrenshealthdefense.org/news/the-varicella-vaccine-skyrocketing-shingles-and-cdc-chicanery/.

142 Betta M, Laurino M, Pugliese A, Guzzetta G, Landi A, Manfredi P. "Perspectives on optimal control of varicella and herpes zoster by mass routine varicella vaccination." *Proc Biol Sci* 2016;283(1826):20160054.

143 Schwartz JL. "The first rotavirus vaccine and the politics of acceptable risk." *Milbank Q* 2012;90(2):278-310.

144 Kassim P, Eslick GD. "Risk of intussusception following rotavirus vaccination: an evidence-based meta-analysis of cohort and case-control studies." *Vaccine* 2017;35(33):4276-4286.

145 "Porcine circoviruses and rotavirus vaccines." http://www.who.int/vaccine_safety/committee/topics/rotavirus/rotarix_and_rotateq/Jun_2010/en/.

146 Redwood L. "FDA acknowledged that vaccine technology outpacing ability to predict adverse events." Children's Health Defense, April 9, 2018. https://childrenshealthdefense.org/news/fda-acknowledged-that-vaccine-technology-outpacing-ability-to-predict-adverse-events/.

147 Lyons-Weiler J. "Dear FDA: Please reconsider 'safe' levels of aluminum, current levels based on outdated information, unwarranted assumptions, and errors." Apr. 11, 2018. https://www.linkedin.com/pulse/dear-fda-please-reconsider-safe-levels-aluminum-based-lyons-weiler/.

148 Poole RL, Pieroni KP, Gaskari S, Dixon T, Kerner JA. "Aluminum exposure in neonatal patients using the least contaminated parenteral nutrition solution products." *Nutrients* 2012;4(11):1566-1574.

149 Lyons-Weiler J, Ricketson R. "Reconsideration of the immunotherapeutic pediatric safe dose levels of aluminum." *J Trace Elem Med Biol* 2018;48:67-73.

150 Children's Health Defense. "Regulators remain indifferent to unsafe levels of aluminum in vaccines." Apr. 11, 2018. https://childrenshealthdefense.org/news/regulators-remain-indifferent-to-unsafe-levels-of-aluminum-in-vaccines/.

151 Bailey, "History of vaccination."

152 Wiedermann U, Garner-Spitzer E, Wagner A. "Primary vaccine failure to routine vaccines: why and what to do?" *Hum Vaccin Immunother* 2016;12(1):239-243.

153 Burdin N, Handy LK, Plotkin SA. "What is wrong with pertussis vaccine immunity? The problem of waning effectiveness of pertussis vaccines." *Cold Spring Harb Perspect Biol* 2017;9(12). pii:a029454.

154 McKinlay JB, McKinlay SM. "The questionable contribution of medical measures to the decline of mortality in the United States in the twentieth century." *Milbank Mem Fund Q Health Soc* 1977;55(3):405-428.

155 Sabbe M, Vandermeulen C. "The resurgence of mumps and pertussis." *Hum Vaccin Immunother* 2016;12(4):955-959.

156 Shilhavy B. "Whooping cough outbreaks continue nationwide due to failed pertussis vaccine." *The Vaccine Reaction*, June 11, 2018.

157 De Cellès MD, Magpantay FMG, King AA, Rohani P. "The impact of past vaccination coverage and immunity on pertussis resurgence." *Sci Transl Med* 2018;10(434):eaaj1748.

158 Schnirring L. "Researchers find first US evidence of vaccine-resistant pertussis." CIDRAP, Feb. 7, 2013.

159 Mogensen SW, Andersen A, Rodrigues A, Benn CS, Aaby P. "The introduction of diphtheria-tetanus-pertussis and oral polio vaccine among young infants in an urban African community: a natural experiment." *EBioMedicine* 2017;17:192-198.

160 Aaby P, Mogensen SW, Rodrigues A, Benn CS. "Evidence of increase in mortality after the introduction of diphtheria-tetanus-pertussis vaccine to children aged 6-35 months in Guinea-Bissau: a time for reflection?" *Front Public Health* 2018;6:79.

161 Heckenlively K. *Inoculated: How Science Lost its Soul in Autism*. Waterfront Press; 2016.

162 "Scientific review of Vaccine Safety Datalink information." Simpsonwood Retreat Center, Norcross, GA; June 7-8, 2000. Available at: https://childrenshealthdefense.org/wp-content/uploads/2016/10/The-Simpsonwood-Documents.pdf.

163 "Generation Zero: Thomas Verstraeten's first analyses of the link between vaccine mercury exposure and the risk of diagnosis of selected neuro-developmental disorders based on data from the Vaccine Safety Datalink: November-December 1999." SafeMinds, November 2004. https://childrenshealthdefense.org/wp-content/uploads/safeminds-generation-zero.pdf.

164 Verstraeten T, Davis RL, DeStefano F, et al. "Safety of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases." *Pediatrics* 2003;112(5):1039-1048.

165 Verstraeten T. "Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline." [Letter] *Pediatrics* 2004;113:932.

166 Stehr-Green P, Tull P, Stellfeld M, Mortenson PB, Simpson D. "Autism and thimerosal-containing vaccines: lack of consistent evidence for an association." *Am J Prev Med* 2003;25(2):101-106.

167 Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. "Association between thimerosal-containing vaccine and autism." *JAMA* 2003;290(13):1763-1766.

168 Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, et al. "Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data." *Pediatrics* 2003;112(3 Pt 1):604-606.

169 Andrews N, Miller E, Grant A, Stowe J, Osborne V, Taylor B. "Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not support a causal association." *Pediatrics* 2004;114(3):584-591.

170 Children's Health Defense. "Studies that the CDC claims exonerate thimerosal. . . and why they don't." Feb. 19, 2017. https://childrenshealthdefense.org/news/studies-that-the-cdc-claims-exonerate-thimerosal-and-why-they-dont/.

171 Children's Health Defense. "Don't fall for the CDC's outlandish lies about thimerosal." Nov. 1, 2018. https://childrenshealthdefense.org/news/dont-fall-for-the-cdcs-outlandish-lies-about-thimerosal/.

172 "Vaccine Safety Datalink." https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html.

173 Jackson ML, Yu O, Nelson JC, et al. "Safety of repeated doses of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine in adults and adolescents." *Pharmacoepidemiol Drug Saf* 2018;27(8):921-925.

174 America's Health Insurance Plans (AHIP). "The Vaccine Safety Datalink (VSD) Project: Annual Report for 2003." Washington, DC: AHIP; 2004. http://www.putchildrenfirst.org/media/4.15.pdf.

175 "Vaccine Safety Datalink." https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html.

176 Institute of Medicine. *Vaccine Safety Research, Data Access, and Public Trust*. Washington, DC: The National Academies Press; 2005.

177 Institute of Medicine. "Independent review of Vaccine Safety Datalink activities." Chapter 5 in *Vaccine Safety Research, Data Access, and Public Trust*. Washington, DC: The National Academies Press; 2005, pp. 96-103.

178 Geier MR, Geier DA. "Researcher experience with the Vaccine Safety Datalink (VSD) data sharing program." http://mercury-freedrugs.org/docs/Researchers'%20Experience%20with%20the%20VSD%20Data%20Sharing%20Program%20-%2023%20August%202004%20-%20IOM%20-%20Geiers%20PowerPoint%20Presentation.pdf.

179 Children's Health Defense. "CDC blocks testimony by vaccine whistleblower in medical malpractice case." Dec. 27, 2016. https://childrenshealthdefense.org/news/cdc-blocks-testimony-vaccine-whistleblower-medical-malpractice-case-2/.

180 DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C. "Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta." *Pediatrics* 2004;113(2):259-266.

181 Hooker BS. "Reanalysis of CDC data on autism incidence and time of first MMR vaccination." *Journal of American Physicians and Surgeons* 2018;23(4):105-109.

182 Ibid.

183 Children's Health Defense. "CDC blocks testimony by vaccine whistleblower in medical malpractice case."

184 McGreal C. "How big pharma's money—and its politicians—feed the US opioid crisis." *The Guardian*, Oct. 19, 2017.

185 "Fugitive profiles. OIG fugitive: Poul Thorsen." https://oig.hhs.gov/fraud/fugitives/profiles.asp.

186 "United States of America v. Poul Thorsen." Criminal indictment no. 1:11-CR-194. https://www.rescuepost.com/files/thorsen-indictment.pdf.

187 https://childrenshealthdefense.org/wp-content/uploads/bill-posey-letter-to-attorney-jeff-sessions-regarding-poul-thorsen-october-2-2017.pdf.

188 Grundvig JO. *Master Manipulator: The Explosive True Story of Fraud, Embezzlement, and Government Betrayal at the CDC*. New York, NY: Skyhorse Publishing; 2016.

189 Madsen KM, Hviid A, Vestergaard M, Schendel D, Wohlfahrt J, Thorsen P, et al. "A population-based study of measles, mumps, and rubella vaccination and autism." *N Engl J Med* 2002;347(19):1477-1482.

190 Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, et al. "Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data." *Pediatrics* 2003;112(3 Pt 1):604-606.

191 Clay B. "Poul Thorsen, fugitive researcher: Update August 2017." https://childrenshealthdefense.org/wp-content/uploads/world-mercury-project-report-on-poul-thorsen-9-7-17.pdf.

192 Children's Health Defense. "Criminal conduct—Poul Thorsen. Robert F. Kennedy, Jr. and Children's Health Defense issue report regarding new evidence of ongoing corruption and scientific misconduct at CDC." https://childrenshealthdefense.org/advocacy-policy/criminal-conduct-poul-thorsen/.

193 Hooker BS. "A matter of right and wrong: the CDC's troubling lack of research ethics." Children's Health Defense, Mar. 29, 2018. https://childrenshealthdefense.org/news/a-matter-of-right-and-wrong-the-cdcs-troubling-lack-of-research-ethics/.

194 "About us." http://nationalacademies.org/hmd/About-HMD.aspx.

195 "Institute of Medicine publications on vaccines." https://www.ncbi.nlm.nih.gov/books/NBK206941/.

196 National Academy of Medicine. "National Academy of Medicine elects 85 new members." Oct. 15, 2018. https://nam.edu/national-academy-of-medicine-elects-85-new-members/.

197 "Our study process." http://nationalacademies.org/hmd/About-HMD/Study-Process.aspx.

198 Institute of Medicine Immunization Safety Review Committee; Stratton K, Gable A, McCormick MC, editors. *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*. Washington, DC: The National Academies Press; 2001.

199 Institute of Medicine Immunization Safety Review Committee; Stratton K, Gable A, Shetty P, McCormick MC, editors. *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism*. Washington, DC: The National Academies Press; 2001.

200 "Organizational meeting of Immunization Safety Review Committee Closed Session," Jan. 12, 2001. Available at: https://childrenshealthdefense.org/wp-content/uploads/IOM.pdf.

201 "Chapter VI: 2004. IOM slams the door (quickly)." http://putchildrenfirst.org/chapter6.html.

202 Institute of Medicine. *Immunization Safety Review: Vaccines and Autism*. Washington, DC: The National Academies Press; 2004.

203 "IOM slams the door."

204 "Rep. Dave Weldon, MD before the Institute of Medicine, February 9, 2004." http://putchildrenfirst.org/media/6.2.pdf.

205 "IOM slams the door."

206 Conte, "Misconduct, mitochondria and the Omnibus Autism Proceedings."

207 Institute of Medicine, 2004.

208 Atkisson S. Family to receive $1.5M+ in first-ever vaccine-autism court award. *CBS News*, Sept. 10, 2010.

209 Wallis C. Case study. Autism and vaccines. *TIME*, Mar. 10, 2008.

210 Fugh-Berman A, Alladin K, Chow J. "Advertising in medical journals: should current practices change?" *PLoS Med* 2006;3(6):e130.

211 Ibid.

212 Ibid.

213 Pew Prescription Project. "Persuading the prescribers: pharmaceutical industry marketing and its influence on physicians and patients." Nov. 11, 2013.

214 Ibid.

215 Robbins R. "Drug makers now spend $5 billion a year on advertising. Here's what that buys." *STAT*, Mar. 9, 2016.

216 "How to advertise." https://www.nejm.org/about-nejm/how-to-advertise?query=footer.

217 Smith R. "Medical journals and pharmaceutical companies: uneasy bedfellows." *BMJ* 2003;326(7400):1202-1205.

218 Chopra SS. "Industry funding of clinical trials: benefit or bias?" *JAMA* 2003;290(1):113-114.

219 Jefferson T, Di Pietrantonj C, Debalini MG, Rivetti A, Demicheli V. "Relation of study quality, concordance, take home message, funding, and impact in studies of influenza vaccines: systematic review." *BMJ* 2009;338:b354.

220 Gulland A. Patients at risk as UK universities fail to disclose results of clinical trials. *The Telegraph News*, Jan. 24, 2019.

221 Gluud LL. "Bias in clinical intervention research." *Am J Epidemiol* 2006;163(6):493-501.

222 Chopra, "Industry funding of clinical trials."

223 Smith, "Medical journals and pharmaceutical companies."

224 Chopra, "Industry funding of clinical trials."

225 Tomljenovic et al., "Human papillomavirus (HPV) vaccines as an option for preventing cervical malignancies."

226 "Time for a flu vaccine? Fugetaboutit!" https://www.drbrownstein.com/time-for-a-flu-vaccine-fugetaboutit/.

227 Arbyn M, Xu L, Simoens C, Martin-Hirsch PP. "Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors." *Cochrane Database Syst Rev* 2018 May 9;5:CD009069.

228 Children's Health Defense. "Are Cochrane reviews truly 'independent and transparent'?" June 5, 2018. https://childrenshealthdefense.org/news/are-cochrane-reviews-truly-independent-and-transparent/.

229 Macrae F. "The 'false' pandemic: drug firms cashed in on scare over swine flu, claims Euro health chief." *Daily Mail*, Jan. 17, 2010.

230 Jorgensen L, Gotzsche PC, Jefferson T. "The Cochrane HPV vaccine review was incomplete and ignored important evidence of bias." *BMJ Evid Based Med* 2018;23(5):165-168.

231 Children's Health Defense. "Garbage in, garbage out: researchers dress down Cochrane for its flawed and biased review of HPV vaccines." Aug. 2, 2018. https://childrenshealthdefense.org/news/garbage-in-garbage-out-researchers-dress-down-cochrane-for-its-flawed-and-biased-review-of-hpv-vaccines/.

232 Hawkes N. "HPV vaccine safety: Cochrane launches urgent investigation into review after criticisms." *BMJ* 2018;362:k3472.

233 Children's Health Defense. "The house of cards is falling: the shake-up at Cochrane." Sept. 18, 2018. https://childrenshealthdefense.org/news/the-house-of-cards-is-falling-the-shake-up-at-cochrane/.

234 Gøtzsche P. "Why we're establishing an Institute for Scientific Freedom." *Mad in America*, Dec. 30, 2018.

235 Inbar R, Weiss R, Tomljenovic L, et al. "Behavioral abnormalities in young female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil." *Vaccine* 2016 Jan 9.

236 Kern JK, Geier DA, Deth RC, et al. "Systematic assessment of research on autism spectrum disorder and mercury reveals conflicts of interest and the need for transparency in autism research." *Sci Eng Ethics* 2017;23(6):1689-1690.

237 Fugh-Berman et al., "Advertising in medical journals."

238 Children's Health Defense. "How to suppress vaccine safety concerns and protect financial interests—Part Two." Dec. 21, 2017. https://childrenshealthdefense.org/news/suppress-vaccine-safety-concerns-protect-financial-interests-part-two/.

239 Doshi P. "The unofficial vaccine educators: are CDC funded non-profits sufficiently independent?" *BMJ* 2017;359:j5104.

240 Edwards KM, Hackell JM, Committee on Infectious Diseases; The Committee on Practice and Ambulatory Medicine. "Countering vaccine hesitancy." *Pediatrics* 2016;138(3).

241 Hough-Telford et al., "Vaccine delays, refusals, and patient dismissals."

242 Doshi, "The unofficial vaccine educators."

243 Handley JB. "'Every Child by Two' bites the hand that feeds them." Children's Health Defense, Mar. 21, 2018. https://childrenshealthdefense.org/news/every-child-by-two-bites-the-hand-that-feeds-them/.

244 Cáceres M. "What doctors learn in medical school about vaccines." *The Vaccine Reaction*, Jul. 27, 2018.

245 Children's Health Defense. "Incentivizing pediatricians to follow the CDC vaccine schedule." Mar. 8, 2018. https://childrenshealthdefense.org/news/incentivizing-pediatricians-to-be-vaccine-bullies/.

246 "Network deal OKs bonuses for pediatric performance." *Georgia Health News*, Dec. 8, 2015.

247 Blue Cross Blue Shield Blue Care Network of Michigan. "2016 Performance Recognition Program." Available at: http://whale.to/c/2016-BCN-BCBSM-Incentive-Program-Booklet.pdf.

248 "How much money do pediatricians really make from vaccines?" Wellness and Equality, June 20, 2016. https://wellnessandequality.com/2016/06/20/how-much-money-do-pediatricians-really-make-from-vaccines/.

249 Hough-Telford et al., "Vaccine delays, refusals, and patient dismissals."

250 Walker EP. "AAP: dismissing patients over refusal to vaccinate okay, doc says." *Medpage Today*, Oct. 21, 2009.

251 Gavagan TF, Du H, Saver BG, et al. "Effect of financial incentives on improvement in medical quality indicators for primary care." *J Am Board Fam Med* 2010;23(5):622-631.

252 Laff M. "Family physician salaries continue to rise at rapid clip." AAFP, June 17, 2016.

253 Rice S. "Physician quality pay not paying off." *Modern Healthcare*, May 30, 2015.

254 https://www.gsk.com/en-gb/about-us/vaccines/.

255 Ibid.

256 Guzman TA. "Big pharma and big profits: the multibillion dollar vaccine market." Global Research, Jan. 26, 2016. https://www.globalresearch.ca/big-pharma-and-big-profits-the-multibillion-dollar-vaccine-market/5503945.

257 Holland M. "Reconsidering compulsory childhood vaccination." Public Law & Legal Theory Research Paper Series, Working Paper No. 10-64, New York University School of Law.

258 Parpia R. "Biologics r vaccines: beware of 'informed consent.'" *The Vaccine Reaction*, Jan. 31, 2018.

259 Children's Health Defense. "Are doctors giving patients up-to-date vaccine safety information (or any safety information at all)?" Dec. 18, 2018. https://childrenshealthdefense.org/news/vaccine-safety/are-doctors-giving-patients-up-to-date-vaccine-safety-information-or-any-safety-information-at-all/.

260 DeLong G. "Is 'delitigation' associated with a change in product safety? The case of vaccines." *Review of Industrial Organization*. Issue 1/2018.

261 Boehm J. "Vaccine injury fund tops $3.5 billion, as patients fight for payment." *Cronkite News*, May 8, 2015.

262 Holland, "Reconsidering compulsory childhood vaccination."

263 Boehm J. "Critics say vaccine injury fund has strayed from original purpose." *Cronkite News*, May 8, 2015.

264 U.S. Government Accountability Office. "Vaccine injury compensation."

265 Boehm, "Vaccine injury fund tops $3.5 billion."

266 Hall DE, Prochazka AV, Fink AS. "Informed consent for clinical treatment." *CMAJ* 2012;184(5):533-540.

267 "State-by-state: vaccinations required for public school kindergarten." https://vaccines.procon.org/view.resource.php?resourceID=005979.

268 "Vaccination laws." https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html.

269 https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Recommendations/Vaccine-Recommendations-by-AOR.

270 "Vaccination requirements." https://www.uscis.gov/news/questions-and-answers/vaccination-requirements.

271 Haddad N, Allen RH, Szkwarko D, Forcier M, Paquette C. "Eliminating parental consent for adolescents receiving human papillomavirus vaccination." *R I Med J (2013)* 2018;101(7):12-14.

272 Agrawal S, Morain SR. "Who calls the shots? The ethics of adolescent self-consent for HPV vaccination." *J Med Ethics* 2018;44(8):531-535.

273 "Minors can now consent to HPV vaccine based on California law." https://www.christianpost.com/news/minors-can-now-consent-to-hpv-vaccine-based-on-california-law.html.

274 Children's Health Defense. "Vaccine vs. disease trade-offs: cheating children's immune systems." Dec. 13, 2018. https://childrenshealthdefense.org/news/vaccine-vs-disease-trade-offs-cheating-childrens-immune-systems/.

275 "Compulsory vaccination and rates of coverage immunisation in Europe." http://www.asset-scienceinsociety.eu/reports/page1.html.

276 Finnegan G. "Mandatory vaccination: does it work in Europe?" *Vaccines Today*, Nov. 27, 2017.

277 Gillam C. "The CDC is being influenced by corporate and political interests." *The Hill*, Oct. 17, 2016.

278 Children's Health Defense. "The U.S. needs an independent vaccine safety organization." May 23, 2018. https://childrenshealthdefense.org/news/the-u-s-needs-an-independent-vaccine-safety-organization/.

279 Salmon DA, Moulton LH, Halsey NA. "Enhancing public confidence in vaccines through independent oversight of postlicensure vaccine safety." *Am J Public Health* 2004;94(6):947-950.

280 Editorial. "Developing resistance." *Nature* 2006;439:1-2.

281 Children's Health Defense. "STAT News: An interview with Robert F. Kennedy, Jr. on vaccines, August 14, 2017." Aug. 21, 2017. https://childrenshealthdefense.org/news/interview-stat-news-august-14-2017/.

282 Children's health Defense. "Congress receives Vaccine Safety Project details including actions needed for sound science and transparency." Mar. 13, 2018. https://childrenshealthdefense.org/news/congress-gets-vaccine-safety-project-details-including-actions-needed-for-sound-science-and-transparency/.