Senate Health and Welfare

S.151

Thursday, February 22, 2024

Alison Despathy

THE FUNDAMENTAL QUESTION

Who is Responsible for the Safety of Children

The Broken System of Vaccine Safety

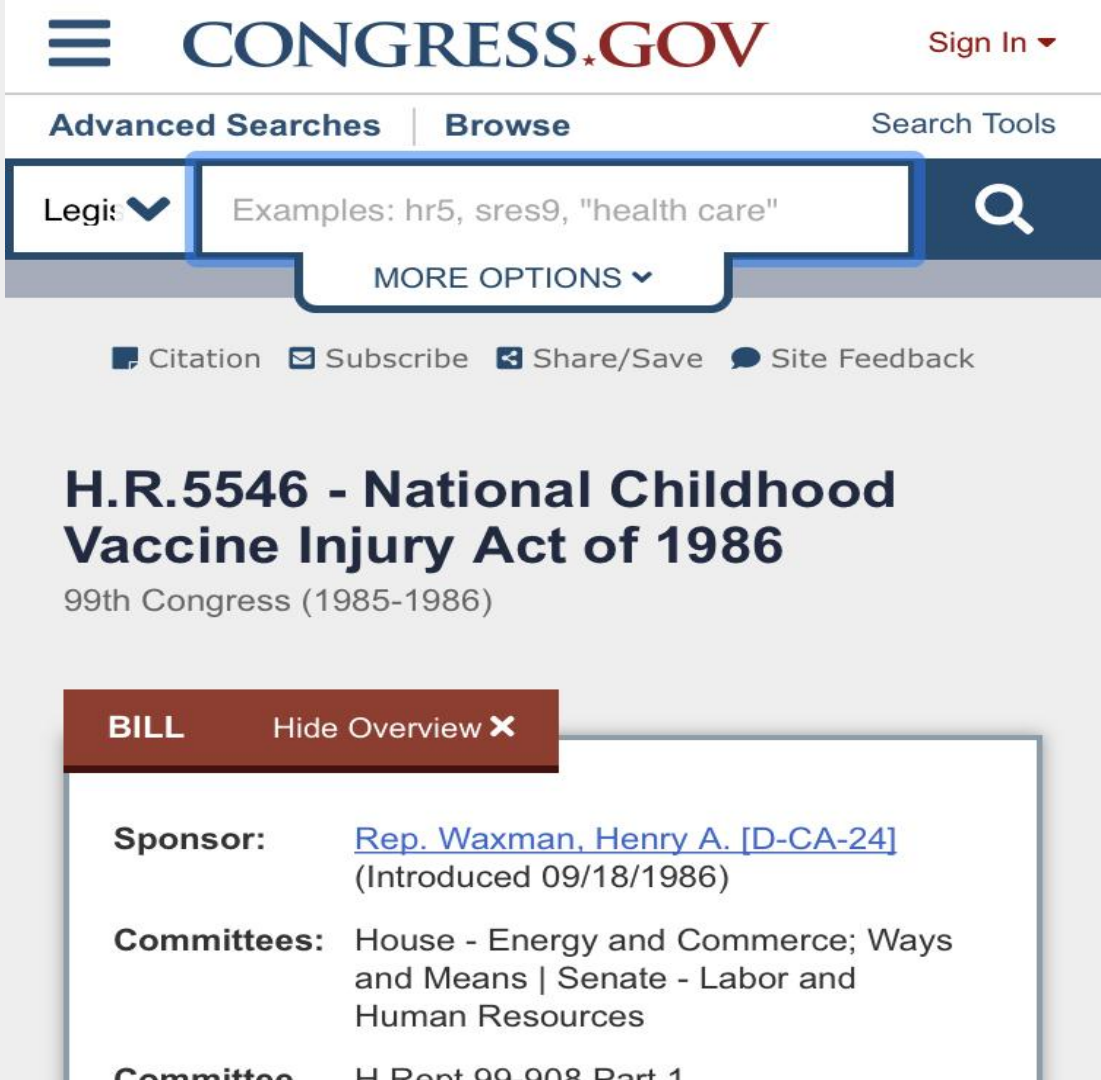
Product Safety is a function of-

1. Self-regulation- market forces demand
2. Regulatory Agencies

-Companies want to make money not lose money
-If they lose money or have liability issues they will stop making products.
-This incentivizes companies to ensure safety prior to market . because making money is the fundamental goal of a company, especially when they have shareholders invested in their company specifically for profit.

In 1986, President Reagan Signed the NCVIA

[H.R.5546 - 99th Congress (1985-1986): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress]



1986 National Childhood Vaccine Injury Act Broke Market Forces and Vaccine Safety

42 U.S.C. 300aa-11 –No person may bring a civil action for damages….against a vaccine administrator or manufacturer…for damages arising from a vaccine related injury or death associated with the administration of a vaccine.”

H.R.5546 - 99th Congress (1985-1986): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress

The Law removed a person's ability to sue a vaccine manufacture for damages or death effectively removing market forces and safety demands

- Americans lost their constitutionally protected right to trial by jury for vaccine damage or death
- Instead of vaccine manufacturers being directed to make safer products they were granted full immunity for their products.
- There is no other product or company that has full immunity and this has compromised their duty to ensure safety of their products. Manufacturers of Drugs, planes, cars are all responsible for product safety
- Vaccines are given to children and the manufacturers cannot be sued

How and Why Did This Happen

- 1985- US Senate Committee convened to deal with the lawsuits brought by parents whose children suffered brain injury and death from DPT vaccine
- Vaccine manufacturers were closing up shop because the amount of liability payments exceeded the revenues
- Average claims ranged from $10- 45.6 million in a decade and 200 lawsuits were filed.
- In 1985, Lederle was the only vaccine manufacture left

Vaccine Crisis: An Emerging Societal Problem - JSTOR
TV Report On Vaccine Stirs Bitter Controversy - The Washington Post

Pertussis acellular vs. whole

- Investigative Journalist Lea Thompson produced the documentary DPT vaccine roulette in 1982
- DPT- Vaccine Roulette

A comparison of whole-cell pertussis and acellular pertussis vaccines

https://pubmed.ncbi.nlm.nih.gov/15165669/

Acellular pertussis vaccines in Japan: past, present and future

Destructive Repercussions of the 1986 National Childhood Vaccine Injury Act

- Broke Market forces
- Significant Fundamental Flaw- at this time, there were 3 vaccines given to children -DTP, MMR and OPV. 1986 NCVIA granted immunity for any and all vaccines licensed for children in the future

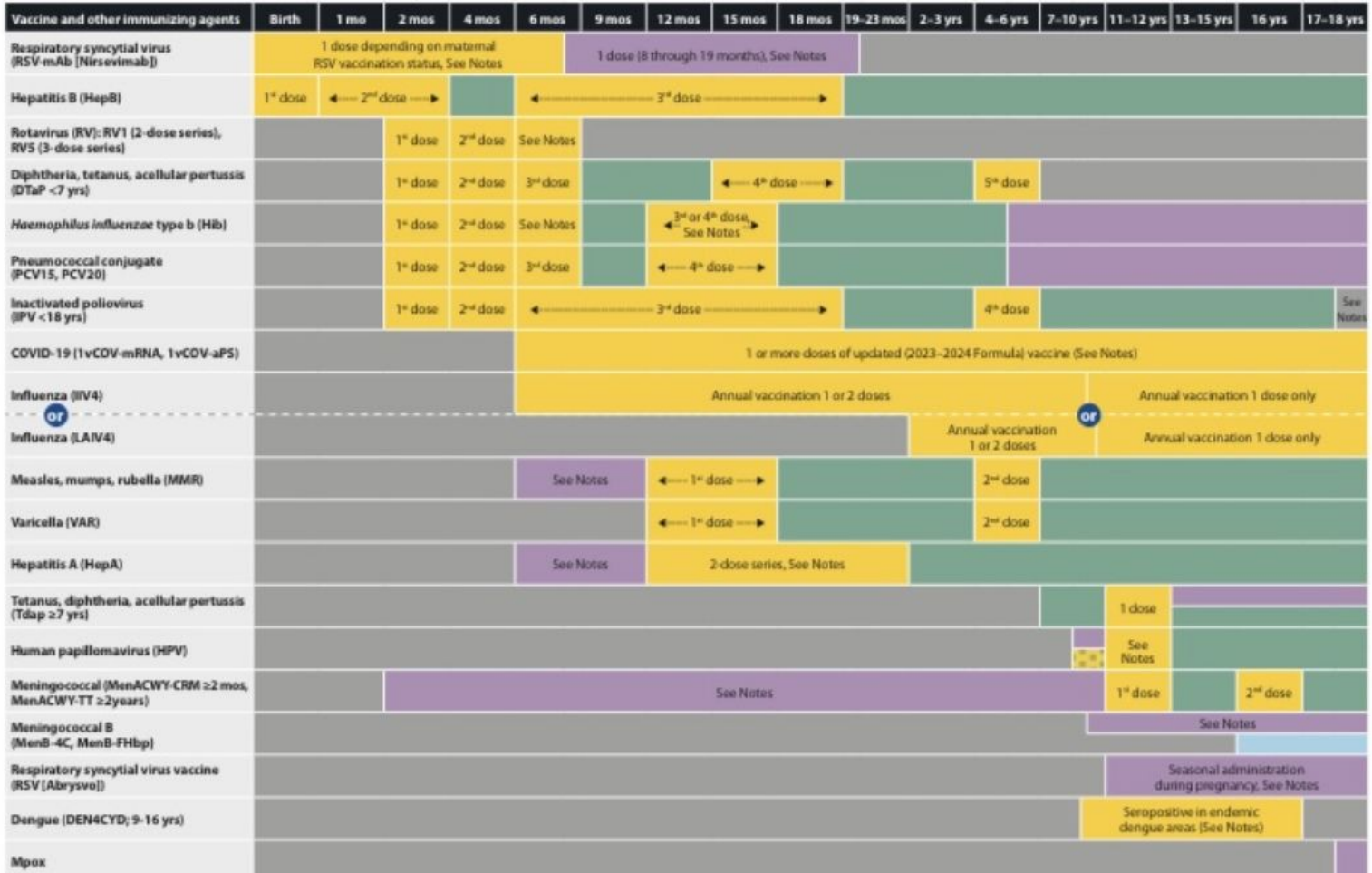
H.R.5546 - 99th Congress (1985-1986): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress
09-152.pdf (supremecourt.gov)

“Vaccines, especially childhood vaccines, are administered according to a schedule, which now comprises about seventy + doses covering about sixteen vaccines. The schedule-based combination effects of these seventy + vaccine doses have not been tested, and, therefore, adverse effects due to real-life vaccine synergies are unknown.”

Vaccine- and natural infection-induced mechanisms that could modulate vaccine safety - PMC (nih.gov)

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



MARKET FORCES ELIMINATED

Guaranteed Market + No Liability =

1986

DTP (2 months)
OPV (2 months)

DTP (4 months)
OPV (4 months)

DTP (6 months)

MMR (15 months)

DTP (18 months)
OPV (18 months)

DTP (4 years)
OPV (4 years)

T (14 years)

2023

Hepatitis B (one day)

Hepatitis B (one month)

DTaP (2 months)
IPV (2 months)
Hib (2 months)
PCV (2 months)
Rotavirus (2 months)

DTaP (4 months)
IPV (4 months)
Hib (4 months)
PCV (4 months)
Rotavirus (4 months)

DTaP (6 months)
IPV (6 months)
Hepatitis B (6 months)
Hib (6 months)
PCV (6 months)
Covid-19 (6 months)
Rotavirus (6 months)
Influenza (6 months)

Covid-19 (8 months)

MMR (12 months)
Varicella (12 months)
Hib (12 months)
Hepatitis A (12 months)
PCV (12 months)
Covid-19 (12 months)

DTaP (15 months)

Hepatitis A (18 months)
Influenza (18 months)

Influenza (2 years)

Influenza (3 years)

Influenza (4 years)
DTaP (4 years)
MMR (4 years)
IPV (4 years)
Varicella (4 years)

Influenza (5 years)

Influenza (6 years)

Influenza (7 years)

Influenza (8 years)

Influenza (9 years)

Influenza (10 years)

HPV (11 years)
Men ACWY (11 years)
Influenza (11 years)
Tdap (11 years)

HPV (11 ½ years)

Influenza (12 years)

Influenza (13 years)

Influenza (14 years)

Influenza (15 years)

Men ACWY (16 years)
Influenza (16 years)

Influenza (17 years)

1983 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
2023 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

SIMPSONWOOD- 2000

Government, Scientists, Pharmaceutical companies and public health officials gather in Georgia to discuss the fact that,

"Analysis to date raises some concerns of a possible dose-response effect of increasing levels of methylmercury in vaccines and certain neurologic diagnoses. Therefore, the purpose of this meeting is to have a careful scientific review of the data."

The-Simpsonwood-Documents.pdf (childrenshealthdefense.org)

Aluminum is neurotoxic. Its free ion, Al(3+) (aq), is highly biologically reactive and uniquely equipped to do damage to essential cellular (neuronal) biochemistry.

Recent studies have demonstrated that the brain may be considered as the target for Al toxicity (Exley, 2014), resulting in neurodegenerative (Exley, 2013; Shaw et al., 2014) and neurodevelopmental disorders (Blaylock, 2012). Recent detailed studies by Exley and the coauthors have highlighted the association between brain Al accumulation and neurological disorders including Alzheimer's disease, multiple sclerosis ....
Molecular mechanisms of aluminum neurotoxicity: Update on adverse effects and therapeutic strategies - PMC (nih.gov)

Aluminum is a ubiquitous neurotoxin highly enriched in our biosphere, and has been implicated in the etiology and pathology of multiple neurological diseases that involve inflammatory neural degeneration, behavioral impairment and cognitive decline.
Aluminum in neurological disease – a 36 year multicenter study - PMC (nih.gov)

What is the risk of aluminium as a neurotoxin? - PubMed (nih.gov)
The neurotoxicity of environmental aluminum is still an issue - PubMed (nih.gov)

MARKET FORCES ELIMINATED

Impact on Clinical Trials

Pfizer's Top 5 Selling Drugs of All Time*		
DRUG	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Enbrel (Pfizer)	6.6 years	Placebo
Eliquis (Pfizer)	7.4 years+	Placebo
PCV13 (Pfizer)	½ year	PCV7
Lyrica (Pfizer)	2 years+	Placebo
Lipitor (Pfizer)	4.9 years+	Placebo

Vaccines in First 6 Months of Life (3x Each)**		
VACCINE	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Hep-B (Merck)	5 days	None
IPV (Sanofi)	3 days	None
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
PCV13 (Pfizer)	6 months	PCV7

* https://moneyinc.com/the-five-highest-selling-pfizer-drugs-of-all-time/
** https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
Source for all data: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

Recombivax- Hepatitis B vaccine given to babies on the first day of life

download (fda.gov)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RECOMBIVAX HB safely and effectively. See full prescribing information for RECOMBIVAX HB.

RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant)
Suspension for intramuscular injection

6 ADVERSE REACTIONS

In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever (≥101°F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.

LONG TERM VACCINE EFFECTS

“It should be noted the biomedical literature is very sparse with studies on long-term vaccine effects, especially long-term adverse effects. Large numbers of people and long periods of time are required to identify such adverse events, and draw statistically-valid connections between vaccinations and disease. These efforts would be very resource-intensive, and there appears to be little motivation among the vaccine producers and regulators to make these resources available for such studies. Thus, the following examples reflect the extremely small tip of an extremely large iceberg of long-term adverse vaccine effects.”

Vaccine- and natural infection-induced mechanisms that could modulate vaccine safety - PMC (nih.gov)

VACCINES AND AUTOIMMUNE AND NEUROLOGICAL DISEASE

The two main categories of diseases reported in the biomedical literature triggered by vaccinations are:

- Autoimmune (e.g., Systemic Lupus Erythematosus, Psoriasis, Arthritis, Multiple Sclerosis, Hepatitis, Uveitis, Pseudolymphoma, Guillain-Barre Syndrome, Thrombocytopenic Purpura, etc.) and

- Neurological (e.g., Central Demyelinating Diseases, Developmental Disability, Febrile seizures, Narcolepsy, Encephalomyelitis, Autonomic Dysfunction, etc.).

- Others include Diabetes, Gastrointestinal, Joint-related, Necrobiotic Granuloma, Neutropenia, Pulmonary Fibrosis, etc

Vaccine- and natural infection-induced mechanisms that could modulate vaccine safety - PMC (nih.gov)

Vaccines and autoimmune diseases of the adult - PubMed (nih.gov)

VACCINES AND AUTOIMMUNE AND NEUROLOGICAL DISEASE

Toplak et al. reported the production of autoantibodies (such as antinuclear and antiphospholipid antibodies) in 92 healthy medical workers up to 6 months after influenza vaccination. **Other studies have demonstrated a latency period of years between HiB vaccination and diabetes mellitus, and between HBV vaccination and demyelinating events**. **In conclusion, latency periods can range from days to years** for postinfection and postvaccination autoimmunity

Adults receiving HBV had significantly increased odds ratios (OR) for

- ➔ multiple sclerosis (OR = 5.2, $p < 0.0003$, 95 % Confidence Interval (CI) = 1.9–20),
- ➔ optic neuritis (OR = 14, $p < 0.0002$, 95 % CI = 2.3–560),
- ➔ vasculitis (OR = 2.6, $p < 0.04$, 95 % CI = 1.03–8.7),
- ➔ arthritis (OR = 2.01, $p < 0.0003$, 95 % CI = 1.3–3.1),
- ➔ alopecia (OR = 7.2, $p < 0.0001$, 95 % CI = 3.2–20),
- ➔ lupus erythematosus (OR = 9.1, $p < 0.0001$, 95 % CI = 2.3–76),
- ➔ rheumatoid arthritis (OR = 18, $p < 0.0001$, 95 % CI = 3.1–740),
- ➔ thrombocytopenia (OR = 2.3, $p < 0.04$, 95 % CI = 1.02–6.2) in comparison to the TCV group.

Vaccine- and natural infection-induced mechanisms that could modulate vaccine safety - PMC (nih.gov)
Vaccines and autoimmunity - PubMed (nih.gov)
A case-control study of serious autoimmune adverse events following hepatitis B immunization - PubMed (nih.gov)

Vaccines and autoimmunity - PubMed (nih.gov)

VACCINES AND AUTOIMMUNE AND NEUROLOGICAL DISEASE

The rationale is that the sharing of peptides between SARS-CoV-2 and human proteins might trigger immune responses hitting not only the virus but also the human proteins, with consequent autoimmune pathologies in the human host. **Hence, the massive viral vs. human peptide commonalities described since 2000 clearly explain how the protective anti-viral antibody immune response can become a pathogenic autoimmune attack against the human organism,**

Peptide cross-reactivity: the original sin of vaccines - PubMed (nih.gov)
Computer-assisted analysis of molecular mimicry between human papillomavirus 16 E7 oncoprotein and human protein sequences - PubMed (nih.gov)
Massive peptide sharing between viral and human proteomes - PubMed (nih.gov)
Medical, Genomic, and Evolutionary Aspects of the Peptide Sharing between Pathogens, Primates, and Humans - PubMed (nih.gov)
"Self-nonself" peptides in the design of vaccines - PubMed (nih.gov)
Immunogenicity, Immunopathogenicity, and Immunotolerance in One Graph - PubMed (nih.gov)

Abstract

HBsAg and HPV L1 proteins - **the HBV and HPV antigens utilized in current vaccines - share amino acid sequences with human proteins** such as cardiomyopathy-associated protein 5, titin, protein-arginine deiminase, E3 ubiquitin-protein ligase RNF19A, bassoon, G-protein coupled receptor for fatty acids, insulin isoform 2, and mitogen-activated protein kinase kinase kinase 10, inter alia. Many shared peptides are also part of immunopositive epitopes.

The data

1) support the possibility of cross reactions between the two viral antigens and human proteins that, when altered, may associate with neuropsychiatric, cardiovascular and metabolic diseases such as multiple sclerosis, amyotrophic lateral sclerosis, diabetes, and sudden death;

2) confirm the concept that only vaccines based on sequences unique to pathogens might nullify potential crossreactivity risks in vaccination protocols.

From HBV to HPV: Designing vaccines for extensive and intensive vaccination campaigns worldwide - PubMed (nih.gov)

Exposure to HiB immunization is associated with an increased risk of IDDM.

Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM - PubMed (nih.gov)

- **“MMR Vaccine:** M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility. Animal reproduction studies have not been conducted with M-M-R II.;

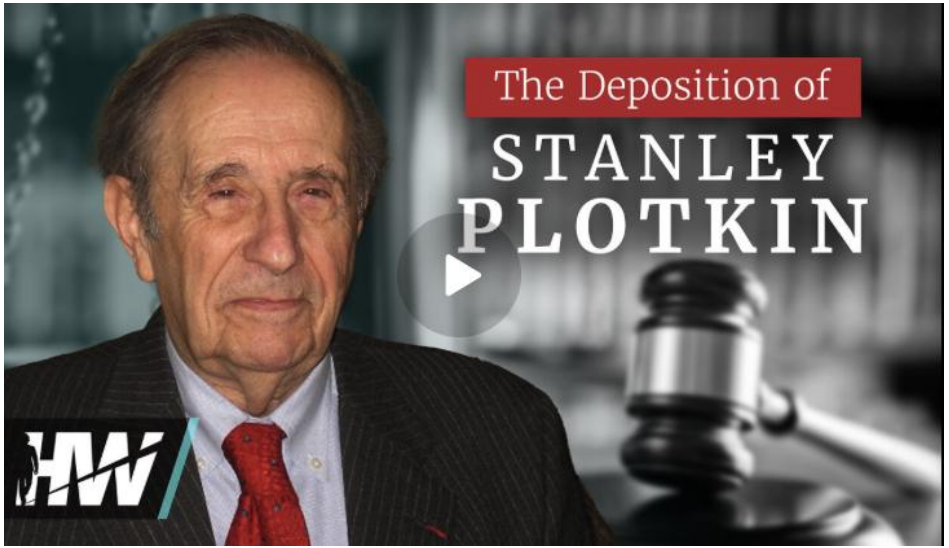
- **Influenza Vaccine FLUARIX QUADRIVALENT** has not been evaluated for carcinogenic or mutagenic potential or male infertility in animals.

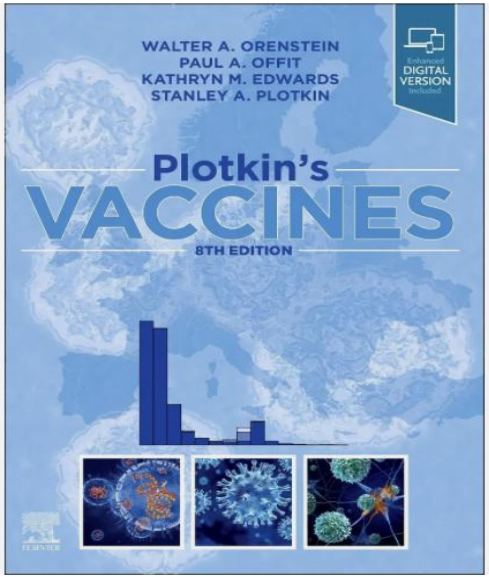
- **DTAP Vaccine INFANRIX** has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.

- **HPV Vaccine [137] GARDASIL 9** has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility.

- **Long-term safety studies of vaccines are rare. The typical vaccine study is aimed at efficacy. Such studies tend to be a few months long, and the main evaluation criterion is titers of antibody in the serum.”**

Vaccine- and natural infection-induced mechanisms that could modulate vaccine safety - PMC (nih.gov)





Vaccine hesitancy and Stanley Plotkin - conflicts of interest must be properly disclosed | The BMJ

THE DEPOSITION OF STANLEY PLOTKIN (rumble.com)

1986 Vaccine Injury Act

The vaccine manufacturers were offered immunity and protected from legal action. Because this created a massive vaccine safety gap, The NCVIA made the Secretary of Health and Human Services which is the Federal Health Authority composed of FDA, CDC, NIH responsible for vaccine safety.

§300aa–27. Mandate for safer childhood vaccines - NCVIA Text

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall-

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a). **TASK FORCE DISBANDED in 1988**

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period. **NO REPORTS EVER FILED**

42 USC 300aa-27: Mandate for safer childhood vaccines (house.gov)

ETHICS VIOLATIONS

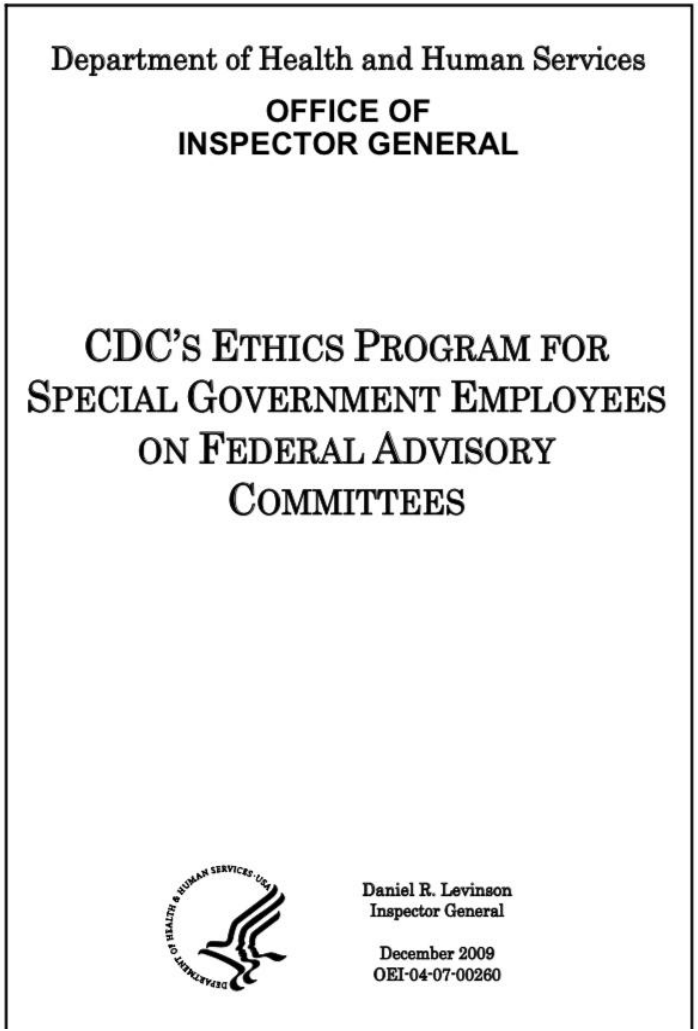
US House Report- (June, 2000)

“The overwhelming majority of member, both voting member and consultants, have substantial ties to the pharmaceutical industry.”

HHS Inspector General Report (December 2009)

CDC had a systemic lack of oversight of the ethics program including finding that 58% of (committee members) had potential conflicts of interest that CDC did not identify” and 32%.... Had potential conflicts of interest that CDC identified but did not resolve.”

oei-04-07-00260.pdf (hhs.gov)



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

CDC’S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES

Daniel R. Levinson
Inspector General

December 2009
OEI-04-07-00260

Senator Bernie Sanders on Revolving Door and Big Pharma Corruption

"At a time when the American people pay the highest prices in the world for prescription drugs and as drug companies continue to be the most powerful special interest in Washington, we need leadership at the FDA that is finally willing to stand up to the greed and power of the pharmaceutical industry. Not only have **the drug companies spent over $4.5 billion on lobbying and hundreds of millions of dollars in campaign contributions over the past 20 years, they also have created a revolving door between the FDA and the industry. Shockingly, nine out of the last ten FDA Commissioners went on to work for the pharmaceutical industry or to serve on a prescription drug company's board of directors.**

"**Unfortunately, Dr. Califf is not the exception to that rule. After leaving the FDA in 2017, he received consulting fees from Merck, Biogen and Eli Lilly. According to his financial disclosure form, he owns up to $8 million in the stocks of major drug companies. That is exactly the close relationship Big Pharma has exploited to regulate the FDA, instead of the FDA regulating them."**

Senator Bernie Sanders

NEWS: Sanders Opposes Califf for FDA Commissioner » Senator Bernie Sanders (senate.gov)

Senator Elizabeth Warren on Revolving Door and Big Pharma Corruption

“But this kind of revolving door influence-peddling smacks of corruption, and makes the American people rightly cynical and distrustful about whether high-level Trump administration officials are working for them, or for their future corporate employers." Senator Warren's Anti-Corruption and Public Integrity Act would prohibit companies like Pfizer from hiring senior government officials for at least four years after leaving government service. Gottlieb joined Pfizer's board just weeks after leaving government.

"This will certainly be a lucrative move for you -- according to Pfizer, board members in 2018 were paid $142,500 in cash retainers, plus received $192,500 worth of Pfizer stock," **wrote Senator Warren in her letter to Dr. Gottlieb.**

Senator Warren Calls on Former FDA Commissioner Scott Gottlieb to Resign from Pharmaceutical Giant Pfizer's Board of Directors | U.S. Senator Elizabeth Warren of Massachusetts (senate.gov)

FDA COMMISSIONERS and BIG PHARMA

Arthur Hayes- 1981- 1983 EM Pharmaceuticals, President
Frank Young- 1984- 1989 Braeburn Pharmaceuticals, VP
David Kessler- 1990-1997 None
Jane Henney- 1999- 2001- AmerisourceBergen Corp Board Member
Mark McClellan - 2002-2004 Johnson and Johnson Board Member
Lester Crawford -2005 Bexion Pharmaceuticals Board Member
Andrew Von Eschenbach-2006-2009- Bausch Health Board Member
Margaret Hamburg- 2009-2015- Alnylam Pharmaceuticals- Director
Robert Califf- 2016-2017- Verily Advisor, Merck, Biogen, Eli Lilly
Scott Gottlieb- 2017- 2019- Pfizer, Board Member

Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns | Science | AAAS

Alex Azar

Official portrait, 2019

Former Health and Human Services Secretary Alex Azar is the former President of Lilly, USA, the United States branch of the Eli Lilly pharmaceutical corporation.

Julie Gerberding speaking at the He... Details

WASHINGTON (Reuters) - Dr. Julie Gerberding, former director of the Centers for Disease Control and Prevention, was named president of Merck & Co Inc's vaccine division, the company said on Monday.

Fred Kummerow

At Long Last, a Trans Fat Ban: A Minute with Fred A. Kummerow

The New York Times

Fred A. Kummerow, an Early Opponent of Trans Fats, Dies at 102

[Fred A. Kummerow, an Early Opponent of Trans Fats, Dies at 102 - The New York Times (nytimes.com)]

[At Long Last, a Trans Fat Ban: A Minute with Fred A. Kummerow (youtube.com)]

“It appears that our mission is being influenced and shaped by outside parties and rogue interests… and Congressional intent for our agency is being circumvented by some of our leaders. What concerns us most, is that it is becoming the norm and not the rare exception,” the letter states. “These questionable and unethical practices threaten to undermine our credibility and reputation as a trusted leader in public health.”

CDC Scientists Preserving Integrity, Diligence and Ethics in Research

From the Huffington Post on October 17, 2016:

SPIDER Bites CDC

Some senior management officials at CDC are clearly aware and even condone these behaviors. Others see it and turn the other way….We have representatives from across the agency that witness this unacceptable behavior. It occurs at all levels and in all of our respective units.

— CDC Scientists Preserving Integrity, Diligence and Ethics in Research

https://www.huffpost.com/entry/spider-bites-cdc-ethics-c_b_12525012

The Experiences of New York City Foster children IN HIV/AIDS clinical trials.

Children from Incarnation Children's Center

"Codes of ethical research and Federal regulations for the protection of children were grossly violated; children suffered harm, many died".

THE EXPERIENCES OF NEW YORK CITY FOSTER CHILDREN IN HIV/AIDS CLINICAL TRIALS

THE EXPERIENCES OF NEW YORK CITY FOSTER CHILDREN IN ...

The research was conducted in at least seven states - Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas - and involved more than four dozen different studies. The foster children ranged from infants to late teens, according to interviews and government records.

https://natap.org/2005/HIV/050505_02.htm

2005 Associated Press reported that the Department Of Health and Human Services concluded that NIH and Columbia Presbyterian Hospital which ran the trial “acted unethically:and that “at least some AIDS drug experiment involving foster children violated federal rules to ensure vulnerable youths were protected from the risk of medical research”:

Later it was revealed that ,” Glaxosmithkline had used some of the children at ICC since 1995, “to test the safety and tolerance of AIDS medication, some of which have potentially dangerous side effects.” pg 164

Accountability Demanded – NYC Foster Children AIDS drug trials – Alliance for Human Research Protection (ahrp.org)

US Code of Federal Regulations prohibits the use of children who are wards of the state from being subjected to experiments involving “greater than minimal risk” and mandates that each child must have an advocate who fights for the best interest of the child. It was found that of 465 children in the NY City experiments, only 142 had an advocate.

Arthur Caplan, head of medical ethics at the University of Pennsylvania, said advocates should have been appointed for all foster children
"It is exactly that set of circumstances that made it absolutely mandatory to get those kids those advocates," Caplan said. "It is inexcusable that they wouldn't have an advocate for each one of those children.

"When you have the most vulnerable subjects imaginable - kids without parents - you really do have to come in with someone independent, who doesn't have a dog in this fight," he said. https://natap.org/2005/HIV/050505_02.htm

Vaccine Lawsuits

-Sue the Secretary Of HHS
Department of Justice represents the HHS
Not a typical lawsuit, pharmaceutical companies cannot be deposed, no discovery-

Over 5.1 billion paid in vaccine injury and death from the vaccine court

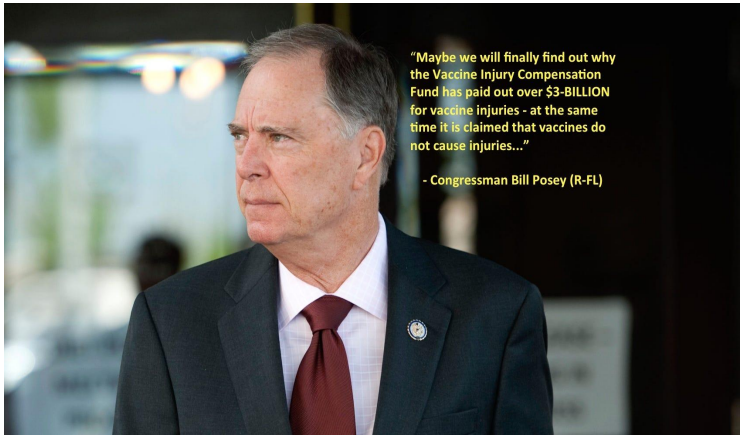
National Vaccine Injury Compensation Program
Monthly Statistics Report

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2020	733	$186,860,677.55	$20,165,188.43	114	$5,774,438.88	76	$5,090,482.24	$217,890,787.10
FY 2021	719	$208,258,401.31	$24,944,964.77	141	$6,998,787.07	53	$4,249,055.37	$244,451,208.52
FY 2022	927	$195,693,889.57	$22,992,062.07	102	$4,868,964.74	56	$6,329,886.09	$229,884,802.47
FY 2023	885	$123,810,693.81	$35,827,569.92	126	$6,760,733.64	61	$7,443,004.19	$173,842,001.56
FY 2024	361	$41,494,644.78	$9,353,614.80	43	$2,926,742.72	12	$1,011,564.54	$54,786,566.84
Total	**10,466**	**$4,640,419,600.43**	**$319,468,609.39**	**5,983**	**$112,791,129.67**	**745**	**$62,109,596.25**	**$5,134,788,935.74**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals.

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.



Congresswoman Carolyn Maloney
At a press conference Wednesday morning, U.S. Reps. Dave Weldon, M.D. (R-FL) and Carolyn Maloney (D-NY) introduced a bill that would give responsibility for the nation's vaccine safety to an independent agency within the Department of Health and Human Services, removing most vaccine safety research from the Centers for Disease Control (CDC). Currently, the CDC has responsibility for both vaccine safety and promotion, which is an inherent conflict of interest increasingly garnering public criticism.

10 REASONS CDC EMPLOYEES SHOULD BE CRYING IN THE ...

Congressman Dave Weldon, M.D.

“There’s an enormous inherent conflict of interest within the CDC and if we fail to move vaccine safety to a separate independent office, safety issues will remain a low priority and public confidence in vaccines will continue to erode,” said Weldon, noting that across the federal government similar conflicts of interests have been remedied, but with regard to mandatory childhood vaccines the conflict continues to persist unchecked. “This bill will provide the independence necessary to ensure that vaccine safety research is robust, unbiased, and broadly accepted by the public at large.”

BIG PHARMA are SERIAL FELONS

Pfizer has been convicted of illegal and corrupt marketing practices, bribery and suppression of adverse reactions in clinical trials, defective drugs, health care fraud, unapproved off label promotion and use of prescription medicines, foreign bribery in an attempt to gain business deals and on top of all this, they have accrued over 3 billion dollars in criminal convictions and at one point, they broke the record for the most significant fine ever paid in a fraudulent healthcare lawsuit which had been filed by the Department of Justice, in which Pfizer paid out 2.3 billion for illegal marketing claims. There are also many questions and lawsuits both past and present regarding some of their products such as Protonix, Prempro, Chantix, Depo-testosterone, Zoloft, and Effexor as examples

Tough on Crime? Pfizer and the CIHR - PMC (nih.gov)

Pfizer pleads guilty, but drug sales continue to soar - PMC (nih.gov)

Pfizer settles largest ever fraud suit for off-label promotion | Nature Biotechnology

In 2017, “a Yale School of Medicine study found that nearly one third of medication approved by the FDA between the years of 2001-2010 had major safety issues after the medications were made widely available to the patients. Seventy-one of the 222 drugs approved in the first decade of the millennium were withdrawn, required a“black box” warning on side effects or warranted a safety announcement about new risks,,,,,” This was reported in the Journal of the American Medical Association. Dr. Alexander, Co-Director of the John Hopkins Center for Drug Safety and Effectiveness, stated, “All too often, patients and clinicians mistakenly view FDA approval as (an) indication that a product is fully safe and effective, nothing could be further from the truth.” One-Third Of New Drugs Had Safety Problems After Approval : Shots - Health News : NPR

Vioxx | Treatment for Arthritis & Recall for Patient Deaths

What have we learnt from Vioxx? - PMC - NCBI

Merck to pay $5bn in rofecoxib claims - PMC - NCBI

Responding to widespread criticism of the government's handling of drug safety problems, the Food and Drug Administration announced Tuesday that it was creating a board to advise it on drug complications and to warn patients about unsafe drugs."

F.D.A. to Create Advisory Board on Drug Safety - The New York Times (nytimes.com)

Experimentation on children

Pfizer pays compensation to families of four children after 15-year legal battle over controversial drug trial in state of Kano- 2011

The families say Pfizer did not get their proper consent to test the antibiotic Trovan on 200 sick children during a meningitis outbreak in 1996.
Eleven children died and others were blinded, paralysed or brain-damaged. Pfizer denies all allegations.

Tough on Crime? Pfizer and the CIHR - PMC (nih.gov)
Pfizer pays out to Nigerian families of meningitis drug trial victims
Nigeria files criminal charges against Pfizer - PMC (nih.gov
Secret report surfaces showing that Pfizer was at fault in Nigerian drug tests - PMC (nih.gov)US Supreme Court rejects Pfizer Nigeria lawsuit appeal - BBC News

Experimentation on children

November 2017 - Philippines

Sanofi had found evidence that the vaccine increases the risk of hospitalization and cytoplasmic leakage syndrome in children who had no prior exposure to dengue, regardless of age.

"For individuals who have not been previously infected by dengue virus, vaccination should not be recommended,"

[How the World's First Dengue Vaccination Drive Ended in Disaster | Scientific American]

[A Vaccine For Dengue, Just Approved By The FDA, Has A Dark History : Goats and Soda : NPR]

[Estimating the proportion of vaccine-induced hospitalized dengue cases among Dengvaxia vaccinees in the Philippines - PMC (nih.gov)]

At a Feb. 21, 2018, Philippine Senate hearing in Manila on deaths linked to the dengue vaccine, families brought photos of children who had been vaccinated.

Noel Celis /AFP/Getty Images

Experimentation on children

“The Indian parliament's Standing Committee on Health, which, in April, 2010, began probing the use of HPV vaccines in two states after the reported deaths of seven girls, has concluded that “safety and rights of children were highly compromised and violated”. In view of the report's finding of violation of human rights and clinical trial rules, the committee has recommended legal action”

Pressure mounting on India to explain 'irregularities' in HPV vaccine trials (nature.com)
Rights violation found in HPV vaccine studies in India - The Lancet Oncology)

Donald W. Light, writing for the Center for Ethics at Harvard University found that new prescription drugs have a 1 in 5 chance of causing serious reactions after they have been approved. He stated, “That is why expert physicians recommend not taking new drugs for at least five years unless patients have first tried better-established options and have the need to do so.”

He found in his research that properly prescribed drugs alone, (not misprescribed, overdoses or self-prescribed drugs) cause approximately 1.9 million hospitalizations a year. In addition to this, 840,000 hospitalized patients are given medications that cause severe adverse reactions, thus the total for annual serious adverse drug reactions is 2.74 million. He further reported that 128,000 people die annually from drugs prescribed to them.

Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs by Donald W. Light, Joel Lexchin, Jonathan J. Darrow :: SSRN

Herpes vaccines- Warnings & Recalls

Herpes Zoster | New England Journal of Medicine

"A 36% increase in the rate of serious adverse events associated with the herpes zoster…"

Zostavax Shingles Vaccine Effectiveness 'Waned Substantially' After …

Effectiveness of the live zoster vaccine during the 10 years following …

FDA Requires a Warning about Guillain-Barré Syndrome (GBS) be Included in the Prescribing Information for Shingrix

FDA Requires a Warning about Guillain-Barré Syndrome (GBS) be ...

WHO and partners launch a new online resource to advance STI vaccine development

5 September 2022 | Departmental news
|Reading time: 1 min (364 words)

online resource to advance

Compromised Medical 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 of *The New England Journal of Medicine*" (Marcia Angell)

Richard Horton, editor of *The Lancet,* wrote that "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness"

Skeptical of medical science reports? - PMC (nih.gov)
Drug Companies & Doctors: A Story of Corruption | Marcia Angell | The New York Review of Books (nybooks.com)

mRNA-1608 Herpes Vaccine

To support these vaccine development efforts, the U.S. government announced on March 1, 2023, it is seeking applicants who can develop advanced vaccines that have limited candidates in the product development pipeline through the new request for applications Sexually Transmitted Infections Cooperative Research Centers Vaccine Development.

Sexually Transmitted Diseases - Precision Vaccinations

FDA to 'Fast Track' Review of Experimental Gonorrhea Vaccine

WebMD Subscribe

Adult Vaccines / News

FDA to ‘Fast Track’ Review of Experimental Gonorrhea Vaccine

Written by Damian McNamara, MA

2 min read

June 28, 2023 – The FDA announced on Tuesday that it will "fast track" review of a vaccine in development to prevent gonorrhea infections.

Sexually Transmitted Infection Vaccines -

Priorities for sexually transmitted infection vaccine research and development

Contents lists available at ScienceDirect

Vaccine: X

journal homepage: www.elsevier.com/locate/jvacx

Priorities for sexually transmitted infection vaccine research and development: Results from a survey of global leaders and representatives

Kara M. Plotnikoff [a,b], Robine Donken [a,b,c], Laurie Smith [b,d], Caroline Cameron [e,f], D. Scot
Julie A. Bettinger [b,c], Manish Sadarangani [c,i], Troy Grennan [j,k], C. Sarai Racey [a,b], Kevin H
Monika Naus [a,k], Amanda Monteiro [b,l], Gina S. Ogilvie [a,b,k,*]

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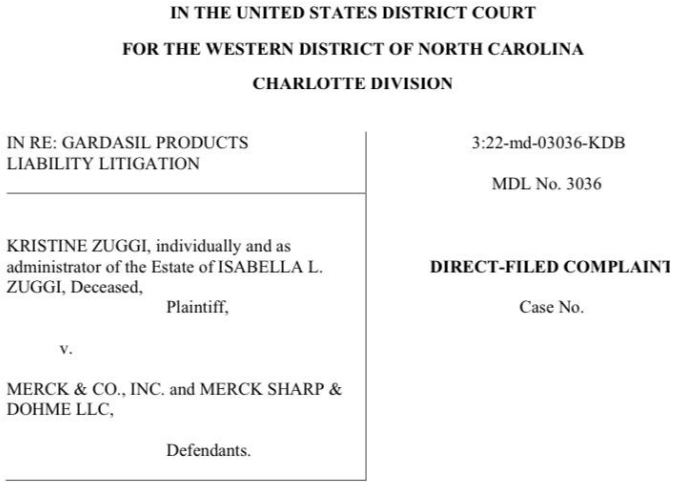
[k] British Columbia Centre for Disease Control, Vancouver, BC, Canada
[l] Faculty of Health Sciences, Simon Fraser University, Burnaby, BC, Canada

Merck Facing Two New Wrongful Death Suits From Mothers Of 10- And 14-Year Old Girls Who Died After Receiving Gardasil



IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CHARLOTTE DIVISION

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION

3:22-md-03036-KDB

MDL No. 3036

KRISTINE ZUGGI, individually and as administrator of the Estate of ISABELLA L. ZUGGI, Deceased,

Plaintiff,

v.

MERCK & CO., INC. and MERCK SHARP & DOHME LLC,

Defendants.

DIRECT-FILED COMPLAINT

Case No.

[Gardasil HPV Vaccine Lawsuit Update February 2024 - Wisner Baum]

[Mothers of 2 Girls Who Died After Gardasil HPV Vaccine Sue Merck]

So who is looking out for children??

Fred A. Kummerow, an Early Opponent of Trans Fats, Dies at 102 - The New York Times (nytimes.com)
At Long Last, a Trans Fat Ban: A Minute with Fred A. Kummerow (youtube.com)

AARON SIRI GIVES TESTIMONY TO THE ARIZONA STATE SENATE