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Del Bigtree
FOUNDER & CEO, ICAN
HOST, *The HighWire*

When we created the nonprofit Informed Consent Action Network (ICAN) and the voice for the legal work that ICAN would be doing, *The HighWire*, we discussed the idea that if a lawsuit wins in a forest and no one is there to talk about it, does it matter?

And so, we endeavored to build a media system that could amplify the lawsuits and legal actions we planned on bringing. This resulted in a proof of concept for "activist television," in which we invest almost half of the proceeds from donations to ICAN into fighting for the various causes that we report on. I don't know that anyone else has ever done this. It was always a part of the plan, and it has been successful.

The HighWire began with hundreds of viewers and quickly grew to thousands over the next 20 episodes. By the time COVID hit, we were in the millions of views across our platforms. Today, in the face of record censorship, 5 to 7 million viewers are watching every week. We've progressed faster than we had dreamed.

The vaccine issue has always been the tip of the authoritarian iceberg; if we don't control our bodies, then what freedom do we actually have? We thought we were embarking on a 10 to 15 year plan to really get the world talking about vaccines and today, it's the number one issue in the world, critical in elections of world leaders and presidents.

As we look ahead, we are bringing the same level of scrutiny and legal attention we have had on vaccines, and applying that template to other issues that affect humanity and where our freedom is under threat.

In the coming years, I believe we will be garnering viewers by the hundreds of millions—in large part due to the fact that the movement on the whole has grown, but I believe ICAN and *The HighWire* have been integral to that growth. I think we're on the verge of being the most important independent media/news sources of our kind in the world. Our brand represents the truth—and that is not defined by opinion—it is defined by facts and evidence.

We're going to continue to lead journalism back to what it was supposed to be.

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ICAN Informed Consent Action Network

YOUR PUBLIC HEALTH WATCHDOG

OUR MISSION:

Eradicate man-made disease

At the Informed Consent Action Network, you are the authority over your health choices and those of your children. In a medical world manipulated by advertising and financial interests, true information is hard to find and often harder to understand. Our goal is to put the power of scientifically researched health information in your hands and to be bold and transparent in doing so, thereby enabling your medical decisions to come from tangible understanding, not medical coercion.

THREE PILLARS OF OUR LEGAL WORK:

Watchdog over Public Health: The FDA, CDC and other 3-letter-institutions do not have a 'check' or watchdog over the medical products they are mandating and pushing to the public - that's where we have stepped in to fill the gap. Our legal team attends almost every FDA and CDC committee hearing, and sends pre and post-letters to ensure key individuals in these hearings have relevant facts, important perspectives, and are aware that we are watching their every move. **Over 30% of the FDA's FOIA docket are ICAN matters; we are a known force within the FDA and CDC.**

Safeguard Civil Rights: Ultimately, our legal efforts have led to the protection or restoration of civil rights for millions of Americans and their families. **We have restored over 2.9 million religious exemptions and protected over 700,000 members of the military from mandates.**

Influence Public Opinion: Judges and legislative bodies are often influenced by public opinion and cultural perceptions. We strive to influence public opinion by bringing evidence, science, and information to light. **Our legal work has been featured on Fox, Epoch Times, and other networks 12 times in 2023.**

We believe that by holding regulators accountable through our successful legal actions, individuals will become empowered to make truly informed decisions about their own health and the health of their families. 40% of every dollar donated goes toward these legal actions - making a lasting impact on the right to informed consent.

INTERNAL CDC PRESENTATION SHOWS IT KNEW FOR MONTHS THAT COVID-19 VACCINE EFFICACY WAS WANING AND KEPT IT A SECRET

WHAT YOU NEED TO KNOW:

- ICAN's attorneys obtained a 2021 presentation to FDA and NIH leadership indicating levels of waning immunity and breakthrough infection among the vaccinated.
- Fully vaccinated individuals made up an estimated 73% of COVID-19 cases and 63% of COVID-19 hospitalizations for 65+.
- There is evidence that the CDC kept this data from the FDA.

ICAN's attorneys have once again been successful at turning over rocks that the CDC and other federal health agencies would prefer to be left unturned.

Through FOIA requests, ICAN's attorneys have obtained a September 2021 presentation delivered to FDA and NIH higher-ups, including Anthony Fauci, Francis Collins, Peter Marks, and Janet Woodcock, which indicated shocking levels of waning immunity and breakthrough infection among the vaccinated as early as July 2021.

In fact, the data shows that for the final week of July, fully vaccinated individuals made up an estimated **73% of COVID-19 cases and 63% of COVID-19 hospitalizations** in the 65+ age group. The presentation goes on to show evidence of rapidly waning immunity, as infection rates 5-6 months post vaccination were **twice as high** as infection rates 3-4 months post vaccination.

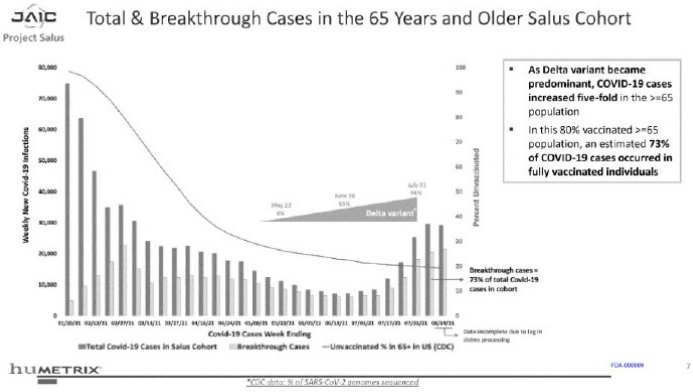
Despite having this data on hand—certainly by the date of the September 13, 2021 presentation, (but likely earlier, as a September 15, 2021 email states that the data had been "brought to the CDC three weeks ago") — public health officials, like Fauci, continued to double-down on the message that vaccines were the key to getting "control of the virus."

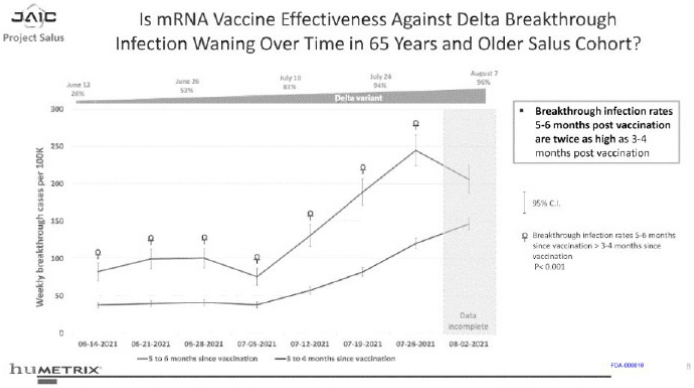
Meanwhile, on September 16, 2021, Collins noted about the data: "Interesting and pretty compelling evidence that VE [vaccine efficacy] is falling 5-6 months post vaccination **for both infection and hospitalization** for those over 65. Even for those 3-4 months out there is a trend toward worsening VE."

But the CDC didn't let the evidence get in the way of its messaging. As late as December 2021, the CDC kept up the outrageous façade that the vaccines offered "similar protection in real-world conditions as they have in clinical trial settings, reducing the risk of COVID-19, including severe illness by 90 percent or more among people who are fully vaccinated."

CDC apparently went as far as keeping the data from FDA, evidenced by the Director of CBER, Peter Marks', comment to Janet Woodcock, Acting Commissioner of FDA, that, it "might have been nice for CDC to share the data."

Rest assured that ICAN's legal team won't rest in its efforts to expose exactly what the government knew about these vaccines and when it knew it.





WHAT YOU NEED TO KNOW:

- Congress sent an urgent letter to VRBPAC (FDA's vaccine advisory committee) about child COVID-19 vaccine safety.
- June 7, 2022: 18 Congress members posed 19 questions on vaccine safety for infants and children.
- FOIA requests by ICAN's attorneys showed VRBPAC lead members didn't discuss or respond to the letter.
- Dr. Amanda Cohn and Dr. Ana El Sahly didn't communicate about the letter, ignoring Congress' questions.
- FOIA response indicated lack of attention to Congress' letters by FDA.
- ICAN has more pending requests for VRBPAC member communications and updates will follow.

You can read more about ICAN's citizen petitions at the links below:

ICAN's attorneys score another major win against FDA with Pfizer and Moderna COVID-19 Vaccine documents

ICAN's monumental Mississippi win

FDA assigned Pfizer's COVID Vaccine a license number months prior to actually licensing it

FDA's advisory committee ignores members conflict of interest and allows him to attend meetings and vote

FDA perpetuates failed strategy in latest VRBPAC meeting on flu shots

ICAN UNCOVERS FDA VACCINE ADVISORY COMMITTEE IGNORING POINTED QUESTIONS FROM CONGRESS

After members of Congress sent an urgent letter to VRBPAC, FDA's vaccine advisory committee, raising critical questions regarding the safety of COVID-19 vaccines for infants and children, ICAN's attorneys submitted FOIA requests which revealed that none of the lead members of VRBPAC bothered to even discuss the letter, let alone reply to Congress.

On June 7, 2022, 18 members of congress sent a 5-page letter to the FDA Commissioner and VRBPAC prior to its June 14, 2022 meeting where the committee was to discuss authorization of COVID-19 vaccines in infants and children. The letter posed 19 crucial questions, including:

"Why has the FDA recently lowered the efficacy bar for COVID vaccines for our youngest children?"

"If approved and widely used among children ... how many lives does the FDA estimate will be saved in this age group over the next year?"

"Given the injuries reported in the FDA's own VAERS, system, how will the FDA evaluate potential tradeoffs of serious vaccine injuries versus serious COVID outcomes?"

Given the serious nature of the letter and its authors, and that it's not often VRBPAC receives letters of this importance from Congress, ICAN's attorneys submitted FOIA requests to determine whether VRBPAC's Chairman and/or top committee members held any meetings, exchanged any emails, or had any discussions in response to this probing letter.

The response to the FOIA request was as disheartening as it was unsurprising. Neither Dr. Amanda Cohn, one of the lead members of VRBPAC, nor the Chairwomen herself, Dr. Ana El Sahly, exchanged any communications about the letter. Evidently, these VRBPAC members feel free to entirely disregard legitimate questions from another branch of government. So much for checks and balances.

While the response to the request for Dr. Sahly's communications stated simply, "No records were found responsive to your request," Dr. Cohn's emails indicated the only discussion of the letter was a message from an FDA management director to several higher-ups stating that, "FDA will use its standard process for responding to letters from Members of Congress" – which, we know from experience, means that little attention will be given to the letter as the FDA hopes it will "just go away."

ICAN still has numerous requests pending for the communications of other VRBPAC members, as well as Commissioner Califf, and we will be sure to bring you any updates.

LATEST BATCH OF PFIZER DOCUMENTS REVEALS EVEN MORE HIGHLY SUSPICIOUS DEATHS AND HOSPITALIZATIONS IN THE CLINICAL TRIAL

In July, ICAN uncovered highly concerning case report forms (CRFs) from individuals in Pfizer's clinical trial. ICAN's attorneys have once again obtained another trove of the Pfizer's COVID-19 vaccine documents and the August batch of documents contains even more cases of concern.

Twelve participants in particular experienced highly concerning health events. All the adverse events (AEs) listed below happened after receipt of the vaccine where the individuals were either in the original vaccine group or in the placebo group but vaccinated after the unblinding. And, yet again, all these events were determined to be "not related" to the trial vaccine by Pfizer.

- An approximately 65-year-old man **developed canker sores and oral mucositis** 8 days after his first dose. Oral mucositis is a "severely debilitating condition characterized by erythema, edema, and ulcerations of the oral mucosa" and it is almost always caused by chemotherapy. This man had no history of cancer but did have hypertension, high cholesterol and insomnia. The cause of the oral mucositis was listed as "topical irritant" and the toxicity grade for this adverse event was perplexingly listed as "1" – meaning not interfering with daily life. Four-and-a-half months later he was **hospitalized with a heart attack and coronary artery disease.**

- An approximately 87-year-old woman **died of gallbladder failure leading to septic shock** 3 months after her second dose. Despite no cause being given for the gallbladder failure, Pfizer still somehow determined it was "not related" to the study. Notably, this woman **was older than the cutoff age of 85 for the trial** and so it is unclear why she was permitted to participate. The clinical trial employees discuss this in her report, but still manage to get the math wrong, insisting that her birthdate was 1933 but that she was age 85 when she joined the trial in August 2020! Also, while Pfizer twice collected urine for a pregnancy test from this woman, she apparently was never tested for COVID-19 in the hospital, despite being hospitalized during a reported peak outbreak period in December 2020.

- An approximately 78-year-old man suffered **sepsis and gallbladder infection** less than 2 months after his second shot, which ultimately led to his **death** two months later. His cause of death simply listed the types of bacteria present and provided no explanation for what caused the infection to begin with. During this same illness period, he was also diagnosed with **rhabdomyolysis and acute kidney injury**, both attributed simply to "dehydration," as well as **atrial fibrillation** and **limb weakness.** Notably, this individual had also received both flu and pneumococcal vaccines two months earlier. And like other cases, it appears this man was in very poor health with type 2 diabetes, several toes amputated (presumably caused by diabetic neuropathy), a coronary bypass, hypertension, and congestive heart failure.

- An approximately 59-year-old man **died suddenly of cardiac arrest** nearly 4 months after his second dose. This individual had a history of coronary artery disease, hyperlipidemia, depression, anxiety, hyperglycemia, hypertension, and obesity. In fact, there was a comment in the report noting that his weight was "**outside of Normal Range... 50-300 lb**" but, nonetheless, Pfizer evidently felt he met the "healthy" criteria for trial inclusion.

- An approximately 76-year-old man **died suddenly of cardiac arrest** 1 month after his second dose. He had a congenital heart defect that was corrected with surgeries when he was a child, but otherwise appeared healthy and had no listed history of heart issues since then. Pfizer nonsensically listed the cause of the cardiac arrest as "cardiac related."

- An approximately 53-year-old man **died suddenly of cardiac arrest** less than 3 months after his second dose. This individual was also in apparently poor health with a history of COPD (chronic obstructive pulmonary disease), a previous heart attack in 2008, hypoglycemia, seasonal allergies, and on medication allergies.

- An approximately 63-year-old woman **died of worsening COPD** about 2 months after her second dose. This is another individual who had so many health conditions that it is **baffling how she was deemed eligible for the trial.** In addition to COPD, her extensive health history included two previous heart attacks, cervical cancer, type 2 diabetes, bilateral leg edema, depression, anxiety, GERD, hypertension, elevated cholesterol, irritable bowel syndrome, diabetic neuropathy, and a BMI of 40.1. Her cause of death was reported "per the family member who called in [that] the subject died under hospice care at home." The report indicates that her medical records included little detail on the specific circumstances surrounding her death, but Pfizer still determined it wasn't related to the vaccine.

- An approximately 70-year-old man was **hospitalized with ischemic myocardiopathy and an abdominal aortic aneurysm**, just 2 days after his first dose (after having received two placebo doses four months prior). Strangely, his file indicates he suffered an adverse event of "Severe Aortic Stenosis" 7 days prior to receiving his first COVID shot. This individual's health history included only high cholesterol, migraines, and resolved prostate cancer. The cause for all three adverse events was **simply listed as "unknown"** but Pfizer still confidently listed them as unrelated to the trial.

- An approximately 64-year-old woman was **hospitalized with spontaneous coronary artery dissection and myocardial ischemia** 11 days after her second dose. She did have a previous history of spontaneous coronary artery dissection in 2019. **She chose to withdraw from the study** because she "no longer wanted to participate after experiencing a spontaneous coronary artery dissection."

- An approximately 74-year-old man with a history of heart disease, type 2 diabetes, hypertension, and high cholesterol was **hospitalized with a heart attack** the day after his second dose. Yet again, Pfizer claims that he wasn't tested for COVID in the hospital, despite the event occurring in September of 2020.

- An approximately 73-year-old woman, whose only health history included osteoarthritis and seasonal allergies, was **hospitalized with a stroke (cerebral vascular accident) and expressive aphasia** (loss of ability to communicate) less than a month after her second dose. The cause for both was listed as "pending medical records." Despite not having these records, the events were determined to be not related.

- An approximately 78-year-old man with a health history that included cardiovascular issues and previous quadruple bypass surgery was **hospitalized with a heart attack** 15 days after his first dose. His outcome is unclear as there is no further information in his CRF and no note of death, although a withdraw form is dated 4 days earlier.

Pfizer's trial included over 43,000 people but, to date, FDA has only produced a small fraction of the case reports for these trial participants. If and when more are produced, ICAN will continue to update our supporters.

ICAN GETS TO THE BOTTOM OF THE CHANGE IN FAA PILOT HEART HEALTH PARAMETERS

WHAT YOU NEED TO KNOW:

- In October 2022, the FAA relaxed cardiology requirements for pilots.
- In February 2023, ICAN's attorneys sent a letter to the FAA, threatening legal action if a satisfactory explanation wasn't provided for changes in the Guide for Aviation Medical Examiners related to "first degree heart block" risk metrics.
- The FAA explained that the changes in the 2022 Guide were based on a conclusion reached in 2017, indicating that certain atrioventricular (AV) blocks within specific time ranges might not require further cardiac assessment and could be considered normal variants.
- ICAN investigated the FAA's response and verified, based on FAA archives, that these parameters were established as early as May 2016, pre-dating the COVID-19 vaccine rollout.

ICAN's mission to bring you **true** information demands that all information is shared, not just cherry-picked information. To that end, ICAN received what is hopefully a reassuring answer to a question raised back in February regarding the FAA's parameters for clearing pilots with potential heart conditions.

At that time, ICAN announced that its attorneys sent a letter to the Federal Aviation Administration (FAA) threatening suit if it failed to provide a sufficient explanation for the apparent change in its Guide for Aviation Medical Examiners which widened the acceptable metric that would indicate a risk for a "first degree heart block." The concern was whether this change was necessitated by issues caused by COVID-19 vaccination. The FAA recently sent a response.

The FAA disclosed that the change reflected in the 2022 Guide was based on a conclusion reached "in 2017 that first-degree atrioventricular (AV) blocks between 0.20 and 0.29 seconds ... may not require a cardiac workup and may be followed as a normal variant."

After looking into this claim, ICAN is pleased to confirm that, according to FAA archives, these parameters were indeed in place as early as May 2016 — well prior to the COVID-19 vaccine roll out. Thus, it appears that American travelers can breathe a small sigh of relief that the FAA, unlike so many other federal health agencies, at least in this instance, isn't sacrificing their safety at the altar of COVID-19 vaccines.

Continue for more instances where ICAN demanded answers from government agencies:

ICAN demands answers from the CDC about spike in RSV rates

ICAN demands answers about death discrepancies in Pfizer's clinical trial

ICAN demands VRBPAC decline to authorize Pfizer vaccine for babies

ICAN demands CDC authors withdraw rigged natural immunity study

Health department takes down false ad after ICAN legal demand

ICAN sues CDC to stop hiding V-Safe data from the public

ICAN demands evidence supporting Fauci and Walensky statements

ICAN confronts FDA and CDC about reproductive harms and COVID-19 vaccines

FDA director violates FDA's COVID Vaccine EUA

ICAN CONFRONTS FEDERAL HEALTH AGENCIES ABOUT THE DELETION OF OVER ONE THOUSAND VAERS REPORTS, MOST FROM J&J COVID VACCINE

After ICAN discovered that 1,102 reports were deleted from the Vaccine Adverse Event Reporting System (VAERS) on May 19, 2023 and May 25, 2023, ICAN's attorneys wrote letters to the CDC, FDA, and HHS demanding answers.

The deleted reports include serious adverse events reported after COVID vaccinations and included **225 deaths, 16 life-threatening events, 51 additional ER visits, and 108 hospitalizations.** An incredible 71% of the reports (784 out of 1,102 reports) were related to the J&J vaccine.

The timing is interesting as just a few weeks prior to the reports going missing, CDC announced all U.S. stock of the J&J vaccine was disposed of due to its expiration and, just a few days ago, FDA revoked J&J's COVID vaccine emergency use authorization. Of course, neither of these actions justifies the deletion of any VAERS report. As ICAN pointed out in the letter, removal of a vaccine from the market does not remove the harms it caused while authorized.

Many Americans continue to suffer debilitating injuries from the J&J vaccine while others continue to mourn their loved ones who died after receiving them. These missing reports only further damage VAERS' data integrity and further diminish the public's trust in federal health authorities.

Rest assured ICAN intends to get answers and will bring you any responses as we get them. In the meantime you can read ICAN's letters here, here, and here.

See below for some of ICAN's other letters demanding answers from federal health agencies:

CMS finally announces the end of the healthcare vaccine mandate after months of legal pressure

FDA lacks adequate safety testing of lipid nanoparticles (LNPs) in COVID-19 vaccines

ICAN demands answers from the CDC about spike in RSV rates

ICAN demands answers about death discrepancies in Pfizer's clinical trial

ICAN demands VRBPAC decline to authorize Pfizer vaccine for babies

ICAN demands CDC authors withdraw rigged natural immunity study

WHAT YOU NEED TO KNOW:

- ICAN discovered 1,102 deleted reports from Vaccine Adverse Event Reporting System (VAERS) on May 19 & May 25, 2023.
- ICAN's attorneys wrote to CDC, FDA, & HHS seeking explanations for the deletions.
- Deleted reports included adverse events post COVID vaccinations: 225 deaths, 16 life-threatening cases, 51 ER visits, & 108 hospitalizations.
- 71% of reports were linked to the J&J vaccine.
- CDC had recently disposed of J&J vaccine due to expiration; FDA revoked J&J's emergency use authorization.
- ICAN stressed that removing a vaccine from the market doesn't negate the harms it caused while authorized.

ICAN ATTORNEYS SECURE JUSTICE FOR TERMINATED FDNY INSPECTOR DENIED A RELIGIOUS EXEMPTION

WHAT YOU NEED TO KNOW:

- An FDNY Inspector was fired in July of 2022 after his request for a religious exemption for the COVID-19 vaccine was denied.
- In May 2023, a judge ruled that the denial of his religious exemption and termination were unlawful.
- The FDNY Inspector was awarded reinstatement and backpay from the date of his termination.

In May, ICAN's attorneys secured a legal victory for a New York Fire Department Inspector who was terminated after being denied a religious exemption to a COVID vaccine mandate. In agreeing that the denial and termination were unlawful, the judge awarded reinstatement and backpay from the date of his termination.

Back in October 2022, ICAN's attorneys filed a lawsuit and memorandum of law on behalf of an FDNY Inspector who, despite being called into work during the height of the pandemic, was fired in July 2022 after his request for a religious exemption from the NYC employee COVID vaccine mandate was denied in July 2022.

ICAN's attorneys argued that the City's religious exemption denial was arbitrary, capricious, an error of law, and an abuse of discretion. Specifically, they challenged the City's inability to justify its claim that accommodating the Inspector constituted an "undue hardship" given it was already accommodating him and had been for the 8 months prior to denying him!

ICAN's attorneys also thoroughly debunked the City's allegation that the Inspector posed a heightened risk to the public because he was unvaccinated.

ICAN is thrilled to announce that, on May 19, 2023, Judge Nicholas W. Moyne ruled in favor of the Inspector, ordered his reinstatement, and awarded him backpay from the date of his termination.

You can read Judge Moyne's Decision and Order here.

See below for more of ICAN's work of a similar nature:

ICAN funds its attorneys to depose and cross-examine the Godmother of Vaccines, Dr. Kathryn Edwards (and more!)

ICAN demands that the U.S. drop its COVID-19 vaccine mandate for non-citizens

NYC drops COVID vaccine mandate for student extracurricular activities

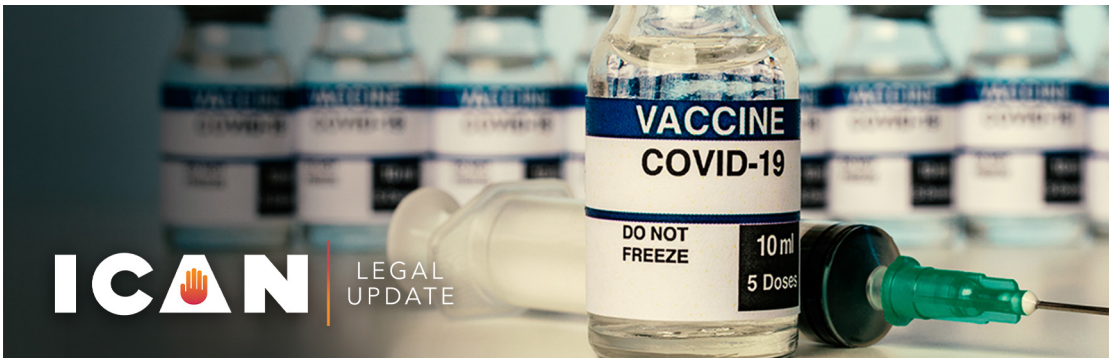
ICAN succeeds in pressing Newark school district to rescind its mask mandate

ICAN ensures that University of Miami's vaccine policies allow students to decline college vaccines

First, the government played doctor. Now it wants to play God!

ICAN lawsuit wins preliminary injunction in challenge to D.C.'S minor consent law!

WHY ARE MILLIONS OF AMERICANS SKIPPING THEIR SECOND COVID SHOT? ICAN PRESSES CDC TO ANSWER



As of February 2022, CDC data indicated that nearly 32 million Americans had received one dose of a COVID-19 mRNA shot but declined to complete the series with a second dose. Since vaccine supply was abundant during that time, it raises a serious concern that millions of people apparently changed their minds about being vaccinated halfway through the process.

ICAN, through its attorneys, therefore sent a letter to the CDC requesting an official explanation about this discrepancy and pointing out that a peer-reviewed study had indicated that some patients do not complete a multi-dose vaccine series due to an adverse reaction after one of the doses in the series.

When the CDC offered no response, ICAN's attorneys followed up with a second letter, this time pointing out the rate of adverse reactions reported to v-safe, VAERS, and other vaccine safety monitoring platforms for these shots, and again demanding that the CDC address why so many Americans had a sudden change of heart about receiving their second dose. By that time, the number of Americans who had skipped the second COVID-19 dose had grown even larger, exceeding 38 million.

Given that one of the CDC's primary responsibilities is to monitor vaccine safety through adverse event reporting, you would think that the CDC would be glad to address this so-called vaccine hesitancy and shed some light on the issue. Unfortunately, you would be wrong as the CDC has provided no explanation for this discrepancy.

In the meantime, the numbers only keep going up. The current number of Americans who received just one mRNA dose is approaching 40 million. Did 40 million people have a bad reaction to the first shot?

While the CDC's silence on the issue has been deafening, ICAN has absolutely no intention of letting it go. We fully intend to get to the bottom of why such a high number of Americans have skipped their second COVID-19 shot as well as our federal health agencies' apparent lack of explanation for it.

ICAN has consistently raised issues concerning the CDC's tracking of COVID-19 data (or lack thereof) and will continue to build this record.

You can read some of ICAN's prior work in this area below:

CDC cannot provide an instance of a single confirmed COVID-19 death in a child younger than 16

Report of toddler's death disappears from VAERS and CDC has no records as to why!

WHAT YOU NEED TO KNOW:

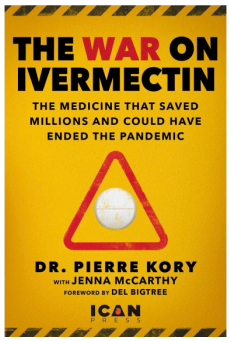
- Nearly 40 million people have only received one dose of a COVID-19 mRNA vaccine.
- ICAN sent two letters asking the CDC for an explanation about this discrepancy.
- There is a peer reviewed study indicating that some patients do not complete a multi-dose series due to an adverse reaction, but the CDC fails to address these concerns.

ICAN confronts FDA and CDC about reproductive harms and COVID-19 vaccines

CDC's V-Safe program did not bother to track a list of 15 conditions that the CDC's V-Safe protocol identified as "adverse events of special interest"

CDC admits once and for all it has no basis for its claim that COVID-19 vaccines do not cause variants

ICAN Press, the new publishing division of The Informed Consent Action Network, is partnering with dynamic writers, medical professionals and subject matter experts to bring you a captivating library of published works that seeks to inform, empower, and deliver you the truth, one publication at a time. You already receive *The Informant,* now take a look at what's coming up from ICAN Press.

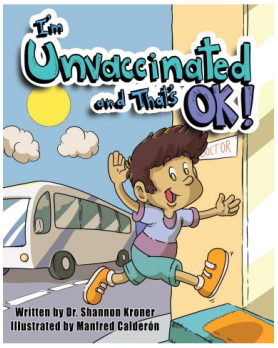


"Ivermectin is a dirty word in the media. It doesn't work. It's a deadly horse dewormer. Prescribe or promote it and you'll be called a right-wing quack, be banned from social media, or lose your license to practice medicine. And yet, entire countries wiped out the virus with it, and more than ninety-five studies now show it to be unequivocally effective in preventing and treating COVID-19. If it didn't work, why was there a coordinated global campaign to cancel it? What's the truth about this decades-old, Nobel Prize-winning medication?

The War on Ivermectin is the personal and professional narrative of Dr. Pierre Kory and his crusade to recommend a safe, inexpensive, generic medicine as the key to ending the pandemic.

Written with Jenna McCarthy, and foreword by Del Bigtree, Dr. Kory's story chronicles the personal attacks, professional setbacks, and nefarious efforts of the world's major health agencies and medical journals to dismiss and deny ivermectin's efficacy. Part personal narrative, part scathing expose, *The War on Ivermectin* highlights the catastrophic impacts of the mass media censorship and relentless propaganda that led to the greatest humanitarian crisis in history.

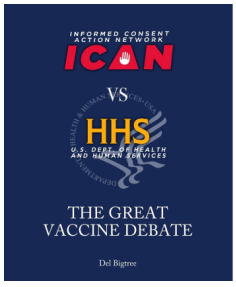
Although numerous studies and epidemiologic data have shown that millions of lives were saved globally with the systematic use of ivermectin, many more millions perished. This carnage was the direct result of what Dr. Kory eventually discovered to be the pharmaceutical industry's silent but deadly war on generic medicines and the corrupt, captured medical and media systems that allow it to continue. For anyone who thought COVID-19 was the enemy, Dr. Kory's book will leave no doubt that the true adversary in this war is a collective cabal of power-hungry elites who put profits over people and will stop at nothing in their quest for control."



"*I'm Unvaccinated and That's OK!* is the story of an unvaccinated child named Nicholas Novaks, who shares the many reasons why his parents have chosen not to vaccinate him. Nicholas explains his parents' personal concerns about vaccine injury, the importance of finding a doctor they can trust and openly speak with, the research they did before making this decision, and what life is like for an unvaccinated child who has an older, vaccine-injured sibling.

Inspired by the personal stories of vaccine-injured children, which have been shared with Dr. Shannon Kroner over many years of working with special needs families, Dr. Kroner aims to raise awareness of the importance of vaccine choice and the necessity of doing the research before making an important decision such as vaccination.

Join Nicholas as he shares what it means to be an unvaccinated child in today's world and why one's personal choice regarding vaccination must always be respected."



Over the course of one year the U.S. Department of Health and Human Services engaged in a written debate with The Informed Consent Action Network regarding the safety of vaccines. This book contains all of the unedited correspondence which represents the most thorough discussion on vaccine safety in history.

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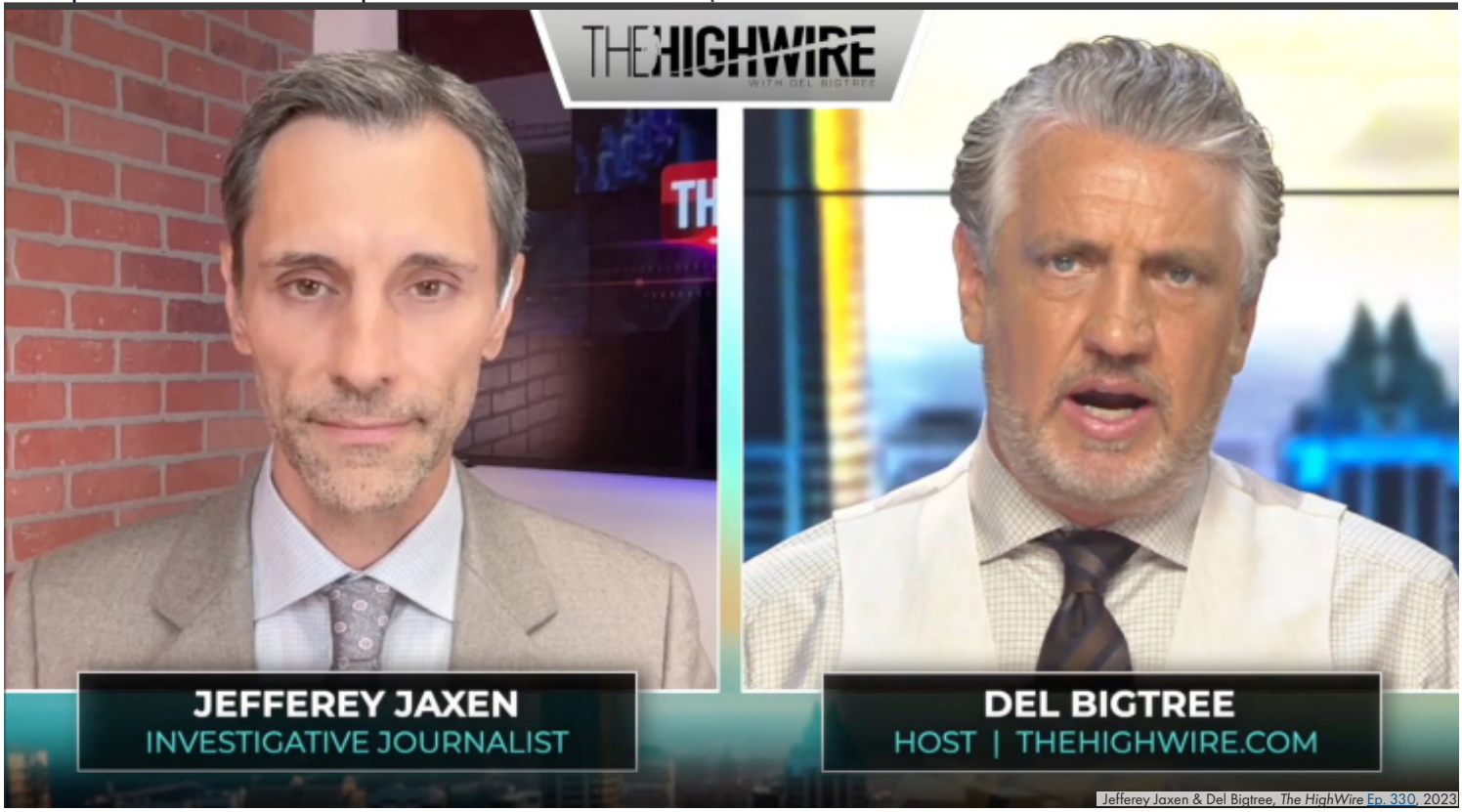


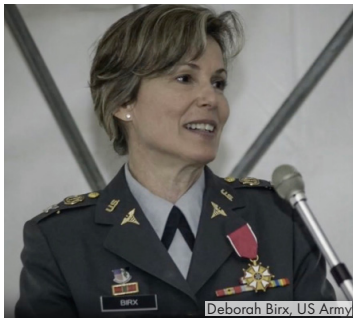
Jefferey Jaxen & Del Bigtree, *The HighWire* Ep. 330, 2023

JAXEN & SIRI TESTIFY IN MASSACHUSETTS

By Lea Lacey

On a recent episode of *The HighWire*, Jefferey Jaxen and Del Bigtree delve into the establishment of the White House Office of Pandemic Preparedness and Response (OPR), a body tasked with orchestrating the national response to potential pandemic threats. Their conversation centers on the evolving landscape surrounding COVID-19 and the emergence of what they term the "pandemic industrial complex." This complex is described as a distinct entity with its own marketing, products, and power structures.

The focus then shifts to Major General (ret) Paul Friedrichs, who has been appointed to lead the pandemic office. Jefferey voices concern about military involvement in the OPR, and draws parallels to the role of Dr. Deborah Birx during the COVID-19 response. Del agrees, noting how "she came from the military...the scarves threw us all off, but the truth is, she should have just been standing there in her epaulets because, in many ways, this was a 'national security,' 'Department of Defense,' 'military operation,' that was taking place on America. If we had seen her standing there in military garb saying things that she did, I think we would have realized that this was much more of a martial law state that was locking us down and not necessarily a fluffy, 'let's all stay in this together and be healthy'..."


Deborah Birx, US Army

Jefferey references a book by Dr. Scott Atlas, former Coronavirus Advisor to President Trump, specifically highlighting instances when Birx publicly countered the President's statements and would conduct state visits independently. This prompts Jefferey to question the current leadership of the pandemic office, noting Major General Friedrichs' background in the Pentagon and his role as a medical advisor to the Department of Defense's COVID-19 task force: "...and he was from the National Security Council—just the place that Deborah Birx was heading during the COVID response—and he has now been picked to come up to the office and run this thing. So this makes me think it's a closed system. When you have ex-military running it from the Pentagon, you're not going to get porous boundaries. You're not going to get a Scott Atlas floating in there and disrupting things. You're not going to get a Robert Redfield saying, 'we really need to investigate Wuhan, China.' This thing is closed—start to finish. They're going to work on the vaccine development from that space."

The conversation then shifts to the World Health Organization (WHO) and its ongoing efforts to establish a legally binding treaty for future pandemic responses. "...they have a 'target date of May 2024 for a legally binding agreement to be adopted by the UN Health Agency's 194 member countries.' And we have Tedros in there saying that this is a 'generational commitment.' That's the words he's using. So this is something they really want to make sure sticks and not go back to the old way. We have Jeremy Farrar going in there as the chief scientific officer of the WHO He, at the Wellcome Trust, co-founded Cepi. So there's a lot of players that are now moving into this space...We have to pay attention to this. We have to get in front of this."

Del reflects on the notion of a new war economy, specifically the "war on nature, on disease, on the pandemic." He underscores that this effort is being led by the military rather than doctors. "...think about all of those dystopian novels, especially 1984, that have some distant war that doesn't really make sense to anybody, but it keeps us all sort of locked in our own space trying to stay safe. This is just this ongoing, intangible, invisible war that we are pouring billions and billions of dollars into, and the pharmaceutical industry is pouring billions of dollars into our government officials and buying up our regulatory agencies that are refusing to do any proper safety trials. The whole thing is really, really a mess. These are dark times."

Del acknowledges that despite the current challenging times, there are opportunities for solutions. He highlights the role of independent voices, such as those in the podcasting world, in speaking truth to power and fostering positive change: "The beauty is the work that you're doing; that we're doing here on *The Highwire,* other podcasters, guys like Ice Cube, they're going to get out there and start speaking truth to power. This is a moment for the people to really step up and make a difference."

Del references a recent hearing in Massachusetts, where Jefferey testified against the removal of religious exemptions from vaccinations. Jefferey highlights the stories of parents whose children experienced vaccine injuries and emphasizes the need for transparency and public debate regarding vaccine safety:

"I sit here as a medical health journalist for nearly a decade telling the story of parents that you've heard here. This is a common story, telling the story of parents who had vaccine injuries. Their children had vaccine injuries after mandated vaccines. We hear a lot about the immunocompromised child in these bills trying to protect them. But there's another side of the story; there's vaccine injury. It is real and it's been paid out to a tune, as you heard, of over $4 billion by the vaccine injury compensation program. This is a liability-free product that market forces do not apply to it as it applies to the rest of the products out there. Unfortunately, these parents have been discriminated against and essentially neutralized by the media trying to tell their story and also by public health agencies. And as you've heard by the medical profession when they try to get their children the help they need. One of the things that we're left to do is to use legal actions and journalists that are outside the corporate media, if you will, that are influenced by big pharma as they take their money and the legal actions that have been pushed towards the public agencies like the CDC have found things like this, CDC and NIH unable to provide a single study to support the safety of injecting aluminum adjuvants, which are widespread in childhood vaccines. CDC concedes it's never conducted a vaccinated versus unvaccinated study. These are things that we need answers to. These are inconvenient facts that should have been debated publicly in the public space. And unfortunately, they haven't been. We've just finished a COVID response where the CDC has admitted it did a lot of wrong things that hurt public trust. I was expecting to see bills that would enshrine more public trust and civil liberties in these bills. And Unfortunately not seeing that."

ICAN's lead attorney, Aaron Siri, also testified during the hearing, stressing the hardships faced by families and the importance of preserving personal convictions. He references quotes from the CDC about certain vaccines' inability to prevent transmission, pointing out the disparity between public perception and factual information:

"Good afternoon. My name is Aaron Siri. I'm an attorney. My firm has over 30 professionals that engage

purely in vaccine-related work. We do not represent pharmaceutical companies. So we represent people who are injured by vaccines. We do vaccine policy work. We brought, for example, a lawsuit in Washington, DC, challenging a law that had permitted doctors to vaccinate minors without parental consent, and it got struck down. We also recently brought a lawsuit in Mississippi that challenged a lack of religious exemption there, and a federal court held that it violated the First Amendment right to free excersise *not* to have a religious exemption. The state of Mississippi has now re-instituted a religious exemption in that state. You've heard a lot of testimony today from parents—some of them very emotive. I really do want to stress these are real, real hardships. These families are going to suffer greatly if you remove the religious exemption. The folks don't always listen to what parents have to say, but when they're telling you this is their conviction, you should trust them. You should believe them—that's what this country was founded upon. It was letting people live out their convictions. And if I can't appeal to your emotion, maybe I can appeal to some of your logic. Let me read you some quotes. Here's a quote from the CDC about inactivated polio vaccine. The only vaccine for Polio used in the United States in last 20 years, quote, 'IPV inactivated polio vaccine does not contain live virus and cannot cause disease. It protects people from polio disease but does not stop transmission of the virus.' End quote. That's the CDC, because it creates a systemic immunity in the blood. It doesn't create any mucosal immunity where polio proliferates. The same is true of at least four of the six vaccines that you are talking about. They do not prevent transmission. Not my words. That's the government's words. There is what you're told about vaccines, and there's a reality. And when you litigate it, you have to actually look at the facts and proof. And I can tell you, what you're often told is not in accord with what the facts show. Thank you."

After the clip, Jefferey turns his attention to Massachusetts' current legislative efforts around vaccines, highlighting the shifting dynamics following the pandemic response and the consequent change in public trust towards vaccines. "The public trust is not a given right now. We have people questioning, we have RFK Jr. trying to push this debate. People now [think] we should have a big open debate about all vaccines. So this legislation is interesting because it's a little myopic in that it's picking up at the same pace it did before, as if the coronavirus response never happened."

He highlights the introduction of bills H2151 and S1458, which seek to lower the age of vaccine consent. He raises concerns about the wisdom of allowing young children to make vaccination decisions without adequately considering potential vaccine injuries. "In Washington, DC, they passed this bill of minor consent...at the age of 11. They said, 'we think that's reasonable.' And they were using these words: 'we're going to try to remove the parent barrier.'"

HOUSE DOCKET, NO. 2749 FILED ON: 1/19/2023

HOUSE . . . . . No. 2151

By Representative Donato of Medford, a petition (accompanied by bill, House, No. 2151) of Paul J. Donato and others relative to immunizations against infectious disease which give rise to a declared public health state of emergency. Public Health.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court (2023-2024)

An Act promoting community immunity.

Del brings up a critical point: Can an 11-year-old truly comprehend their medical history and potential risks? Jefferey adds another dimension, questioning whether children of this age possess the knowledge to recognize signs of vaccine-related injury and how parents can monitor potential harm when kept in the dark.
The implications of these bills extend beyond age of consent; they also grant schools, daycares, and colleges the authority to establish their own vaccine policies, potentially expanding the vaccine schedule even further.

Jefferey shifts focus to the COVID-19 vaccine, noting that it has been categorized as "recommended." However, he cites CDC Director Rochelle Walensky's admission that the decision to add it to the schedule was financially driven, not based on scientific grounds.

HOUSE DOCKET, NO. 1602 FILED ON: 1/18/2023

HOUSE . . . . . No. 582

The Commonwealth of Massachusetts

PRESENTED BY:

Michael J. Soter

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to the protection of medical exemptions for immunizations for school attendance.

HOUSE DOCKET, NO. 3251 FILED ON: 1/20/2023

HOUSE . . . . . No. 604

The Commonwealth of Massachusetts

PRESENTED BY:

Andres X. Vargas

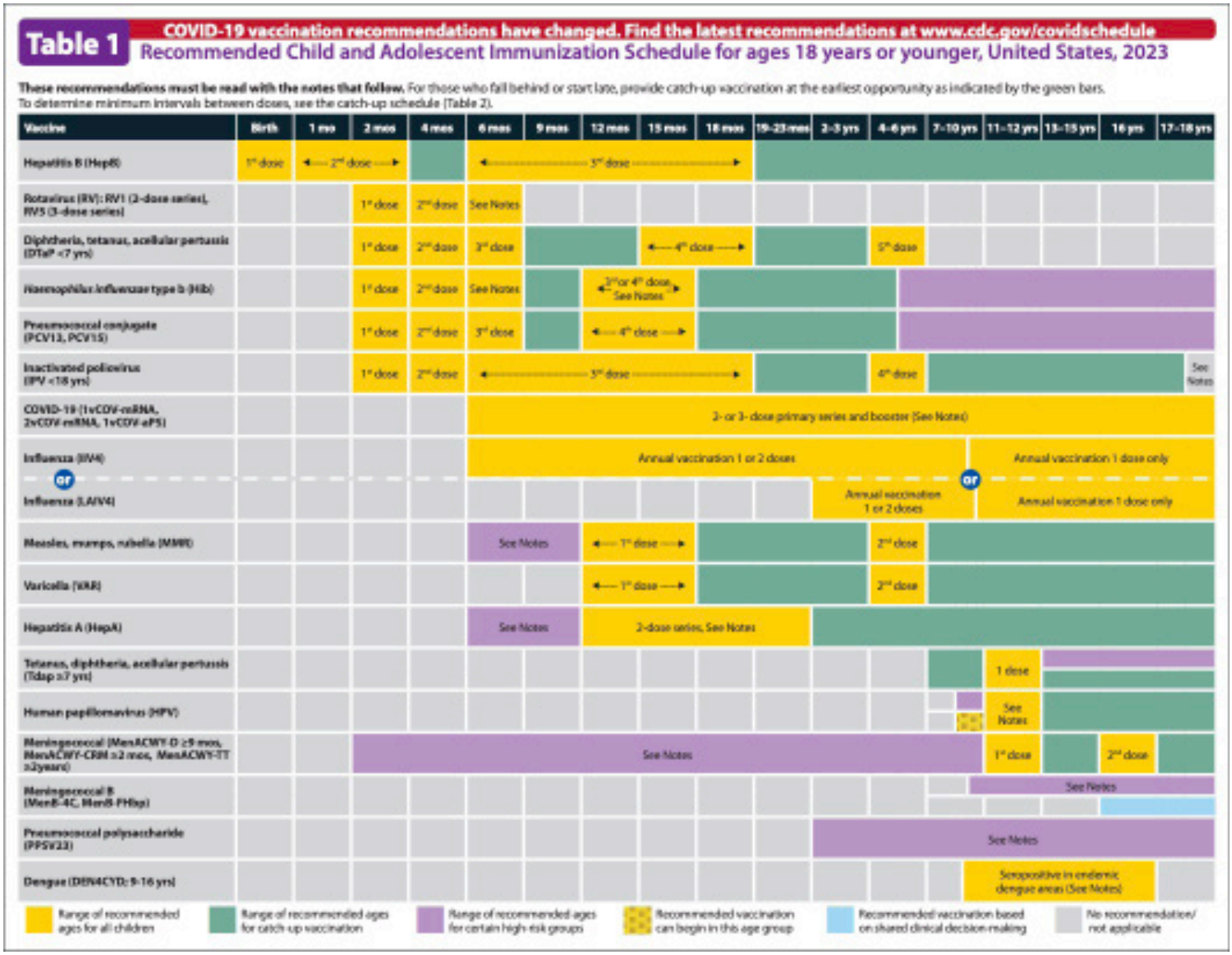
To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to routine childhood immunizations.

He highlights another bill, H.604, along with its companion bill S1391, which aims to eliminate religious exemptions. The final bill, H. 582, grants doctors and medical professionals broader leeway for medical exemptions, offering protection against repercussions similar to those experienced in California, where doctors frequently faced license revocations, even for speaking out during the COVID-19 response.

Jefferey emphasizes that Massachusetts is leading the charge in pushing these legislative changes, urging vigilance and caution in other states. He affirms ICAN's commitment to challenging these bills through legal action, while *The HighWire* will actively cover unfolding events. As always, there is a need for collective preparedness, courage, and the drive to speak truth to power in the face of such challenges.



THE NEXT COVID WAVE IS THE COVER UP

By Tracy Beanz

The COVID crisis is beginning to rear its head again in the legacy media and on television. For most of us in independent media, it hasn't ended. After a few years of desperately trying to educate the public about all of the things you didn't learn from your doctors, nurses, and the health establishment, to see this in the early stages of happening again is not only frustrating but highly concerning.

This entire debacle is a tapestry whose threads are so interwoven it is almost hopeless to untangle it all—even if there are snags all over the fabric.

They say two new variants are making the rounds, and for this, we must be on high alert. Are they more virulent? Do they cause more severe illness? They aren't telling us because they "do not know." But, what they do know, somehow, is that they are concerned. Scientists are racing to understand the mutations, and we need to keep an eye on them. Schools are postponing opening day due to an "increase" in COVID cases. As reported this week, the Biden Administration is beginning to stock up on supplies again. Colleges are reintroducing mask mandates "as a precaution." All of this, they say, because of SIX (yes, 6) cases with a new mutated strain of COVID.

The question is, why? If you watched Del Bigtree on a recent episode of *The Highwire*, you heard Geert Vanden Bossche explain what may be happening with this new variant—specifically when it comes to individuals who have been vaccinated and boosted, particularly when they were naive to natural infection. It isn't great. So, is it because all of these virologists and bureaucrats *know* that there is something we need to be concerned about in highly vaccinated populations, the United States being one of them?

I sit back and wonder if, by locking everyone down again, they hope to cover up the absolute failure of the "vaccine" they forcefully shoved at us for years. In the same episode of *The Highwire*, we saw a video compilation of countless young people experiencing cardiac issues, some sadly and tragically dying, and others needing heart transplants. What will happen to so many suffering the after-effects of this program? And how can we help those people if the very health establishment with a mandate to "protect" Americans refuses even to acknowledge that the shots are a problem in the first place?

When brave doctors initially attempted to inform the public about successful early treatment options, they were

censored. When they tried to prescribe the medicine that could save lives, they were shunned, maligned, and in some cases, had their medical licenses revoked. What incentive do doctors still practicing have to do, as Vanden Bossche says, and provide anti-virals in prophylaxis?

Unfortunately, it appears that those who have advocated for inoculating the population are engaged in yet another scheme. If we just lock down harder, if we just mask more forcefully, if we just follow directions better this time, we will be able to hide the absolute travesty we have created for a little bit longer.

They can't hide it forever. Participation to receive boosters is at an all-time low because people realized the shot doesn't do what was advertised. Additionally, due to the outcry from the public after many have realized adverse events are NOT rare, many people won't go near them again. The White House is set to recommend new boosters—step right up and get your COVID booster alongside your brand new Flu and RSV shots—however, the American public doesn't seem too keen. In Vanden Bossche's interview, he communicated that the brief immunity you may get from these boosters is obviously more harmful in the long run and wanes very, very quickly—a short and dangerous fix for a terrible long-term problem.

Is it possible that NO ONE in establishment government, academia, or science, knows this? Are they all this ill-informed, this unaware of the human immune system? Or, is it possible that they are just in too deep to be able to fix this, and so they are placing an ill-fitting and catastrophic band-aid over a global health atrocity the likes of which we haven't seen?

It is up to us to stand firm against this latest wave of impending tyranny. We know that the mitigation strategies they suggest don't work. Heck, we know more about pandemic mitigation strategies now than any of us ever wanted to know. We know that masking doesn't work. We know that social distancing doesn't work. We know that "vaccinating" doesn't work, and we certainly know that quarantining the healthy does not work.

We need to continue speaking with our neighbors. None of them are excited to go through this again. I would argue 99% of them don't want to go through this again. Take the opportunity to educate them with resources like the episode of *The Highwire* cited above. Let us take a step toward broader awareness and, more importantly, life-saving measures and help for the injured together.

You can not comply your way out of tyranny. Now it is time for us to drive home once and for all what is *really* happening here.

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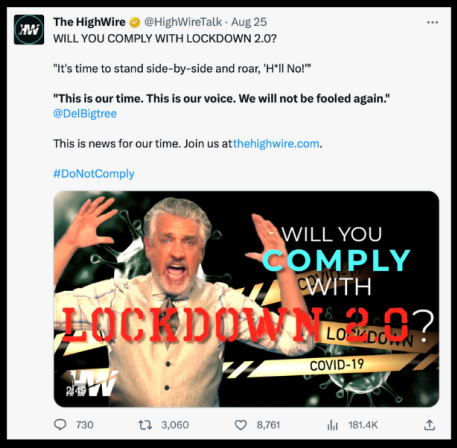

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Dr. McCullough, Dr. Vanden Bossche, Del Bigtree, *The HighWire* studio, 2023

DR. PETER MCCULLOUGH & DR. GEERT VANDEN BOSSCHE JOIN DEL ON *THE HIGHWIRE*

By Lea Lacey

On a recent episode of *The HighWire*, two of the most prolific doctors speaking out against the dangers of the COVID-19 vaccines, esteemed cardiologist Dr. Peter McCullough and Virologist Dr. Geert Vanden Bossche, join Del to discuss the failures of the mass vaccination, the dangers new variants pose for both the vaccinated and unvaccinated, as well as how to safeguard from future COVID outbreaks. Dr. McCullough discusses the increasing concern over COVID-19 Vaccine-related myocarditis and why so many healthy young people are suffering from heart issues and blood clots.

Del opens with a disclaimer acknowledging the government's tendency to amplify fear surrounding COVID and its variants, sharing his reluctance to aid in unnecessary fear. At the same time, he emphasizes the importance of remaining vigilant and informed if there is a genuine risk.

The conversation begins with Dr. Vanden Bossche delving into the interplay between vaccine-induced immunity, immune escape, and side effects. He explains that when individuals experience breakthrough infections after vaccination, their immune system shifts its focus to more conserved spike protein domains. These domains can resemble our own cells, potentially triggering autoimmune-like reactions. This immune refocusing not only poses the risk of autoimmune responses but also accelerates viral reproduction while reducing the effectiveness of neutralizing antibodies.

In simpler terms, when vaccinated individuals become infected, the virus can adapt in response to vaccine-induced immune pressure. This adaptation may give rise to new virus variants that are less controllable by the vaccine-induced immunity. The immune system can also become overly active, producing antibodies that attack the body's cells or tissues, potentially leading to autoimmune reactions. This cycle highlights some of the challenges and complexities associated with vaccine responses, especially in the context of rapidly evolving viruses like SARS-CoV-2.

Dr. Vanden Bossche suggests that individuals receiving multiple vaccine doses without prior infection could be at risk when their antibodies fail against future variants. He recommends antiviral treatments as a prophylactic measure for those at risk.

Del directs the conversation to Dr. McCullough and inquires about the rising awareness and concern regarding COVID vaccine-induced myocarditis. He notes that since the initial reports, there seems to be a lull in discussions about these conditions, however, in recent weeks, we have seen a resurgence of stories related to myocarditis and heart issues. He asks if there is a genuine increase in cases or just a shift in focus.

Dr. McCullough replie, "There certainly is great awareness, great concern. The entire country—the entire world is on edge, honestly, watching this."

He explains how the FDA acknowledged that myocarditis could result from COVID vaccines in October 2020 and that by June 2021, the FDA confirmed a link between the vaccines and heart inflammation, "thus paving the way for extensive research on vaccine-induced myocarditis, resulting in over 800 peer-reviewed papers on the topic."

Dr. McCullough references two studies conducted by Mansugyen and Burren/Mueller. These studies reveal that 2.5% of people who get their second and third COVID shots experience heart damage, which is a very concerning rate because it affects a significant number of people worldwide.

He explains that when this heart damage occurs, it disrupts the normal flow of electricity in the heart and can cause a small scar. This can set the stage for a random and unexpected occurrence, such as a rapid and abnormal heart rhythm, which can lead to serious health issues like cardiac arrest:

"Normally, the body relies on perfect depolarization and repolarization. The heart tissue is pristine. In fact, we do everything we can to avoid even the smallest heart attack because a heart attack could cause a small scar. But when a small scar occurs—which could be occurring in 2.3% of people who take these shots—they're set up for the stochastic event of a slow depolarization through the zone of scar or damage and then have it circle back up, and that's called reentry. Reentry ventricular tachycardia (VT) is a very fast heart rhythm; it typically lasts 15, 30 seconds to a minute or so. You can see it in the different montages, and then finally, when it degenerates to ventricular fibrillation, they go down like a rock. And that is the pathogenesis of what we're seeing, COVID-19 vaccine-induced cardiac arrest...we have now proof positive in autopsies in cases like this—100% of the time, it is fatal vaccine-induced myocarditis."

The conversation shifts to the lingering effects of myocarditis and Del raises the concern of myocarditis recurrence, asking about cases where children suddenly collapse. Dr. McCullough explains that "the vaccines don't work, so they get COVID anyway. And sometimes just the inflammation of COVID reignites some of the pathogenic processes, potentially myocarditis, but for sure blood clots. I have seen that in my practice over and over again. Vaccine, vaccine, vaccine, COVID, blood clots."

He illustrates this point with real-life cases, including those of weatherman Al Roker, ESPN announcer Kirk Herbstreit, and former Tampa Bay Buccaneers coach Bruce Arians, who required hospitalization due to myocarditis.

He discusses the highly concerning case of professional Dominican basketball player Óscar Cabrera Adames, who received two doses of the Pfizer COVID vaccine and suffered a cardiac arrest while playing basketball in 2021. McCullough explains, "Of these athlete cardiac arrests, roughly two-thirds are fatal; they're not resuscitable. A third are resuscitated. He's in the third; he gets resuscitated in 2021."

Oscar Cabrera Adames

Adames publicly shared on social media that he had vaccine-induced myocarditis: "I got a damn myocarditis from taking a...vaccine. (I got 2 doses of Pfizer) And I knew it! Many people warned me. But guess what? It was compulsory or I couldn't work. I am an international professional athlete and I am playing in Spain. I have no health problem, nothing, not hereditary, no asthma, NOTHING! I suddenly collapsed to the ground in the middle of a match and almost died. I'm still recovering and I've had 11 different cardiology tests done and guess? They find nothing."

When faced with the decision to get an implantable defibrillator, Adames declined. McCullough explains that the standard practice after a cardiac arrest is to recommend the implantation of a defibrillator due to a genuine risk of repeat cardiac arrest occurring in such individuals. As a result, most people in the United States who have suffered from different types of cardiac arrests typically have a defibrillator device implanted as a precautionary measure to address this risk.

He goes on to share that in June of 2023, Adames died while undergoing a stress test, emphasizing that it was during a medical treadmill test in a health center: "And he dies on this treadmill test. He dies. I'm a cardiologist, I have supervised treadmill tests for decades, I've never had a patient die on a treadmill. I've had cardiac arrests. But we have defibrillation, we have IV access, things we can do."

Dr. McCullough expresses significant concern about a documented case of cardiac arrest occurring more than two years after an individual received COVID-19 vaccines. This case suggests that the risk of cardiac arrest related to the vaccines can persist over an extended

period: "COVID is down, we're not hearing so much about acute myocarditis, but now we're hearing about this tale of cardiac arrests."

He discusses the results of two important studies—one from Yale (Barmada) and another from Hong Kong (Yu)—that have examined the heart health of young individuals who experienced myocarditis or heart inflammation, potentially related to COVID-19 vaccination. He points out that typically if there's minor inflammation or damage in the heart, serial MRIs can show a gradual return to normal heart function over time. In the case of these studies, the results are concerning. The Yale study found that even nine months after experiencing myocarditis, 80% of the MRIs showed that the hearts of affected individuals were still not back to normal. The Hong Kong study, conducted over a year, found that 58% of the MRIs still displayed abnormalities.

What Dr. McCullough finds particularly concerning is that some of the affected young individuals in the Hong Kong study had no symptoms or complaints related to their heart condition. This suggests that not all individuals with myocarditis can feel the ongoing damage or risks to their hearts. "So what I'm telling you is, not all the kids can feel it, there is a population of people at risk, and the biggest issue I'm facing in my practice, I'm having young people walk in, look me in the eye, and they say, *Dr. McCullough, am I going to have a cardiac arrest?*"

Dr. Vanden Bossche asks why cardiac problems, particularly myocarditis, are more pronounced in vaccine recipients. Dr. McCullough explains that the heart is highly sensitive to inflammation compared to other organs, leading to various heart-related complications.

He mentions that after receiving the vaccine, athletes engage in physical activities that raise their myocardial blood flow, potentially leading to increased deposition of vaccine-related material in the heart: "The heart uniquely receives this blood flow primarily in diastole, so the resting phase, so it's not systolically punching through...myocardial blood flow is dynamic. So at rest, our myocardial blood flow is at a baseline. When we exercise, we can have a two-, three-, four-fold increased risk of myocardial blood flow." He references a paper by Castri Yuda that demonstrates the circulation of the messenger RNA (mRNA) for at least a month after receiving the vaccine, "What do the athletes do? They take a shot, and they go exercise. They're working out, constantly juicing myocardial blood flow...more deposition of the vaccine material into the heart."

He references a paper from Massachusetts General Hospital, where kids hospitalized with myocarditis were measured for both spike protein in the blood and neutralizing antibodies. He said, "The kids with myocarditis had circulating spike protein, but the antibodies were not neutralizing the spike. The kids without myocarditis had spike, but the antibodies were correctly neutralizing it. So... the immune system now is missing the target, and some kids now are getting a prolonged exposure to the spike protein, more loading in the heart."

Referring to the theory put forth by Dr. Vanden Bossche, Del asks Dr. McCullough if he believes the use of a vaccine that was not fully effective at neutralizing may have contributed to an increase in the number of mutations we've observed. McCullough responds that it has been his observation that the vaccines have prolonged the duration of the virus. And that clinically, he is seeing both vaccinated and unvaccinated people get second and third infections.

Fortunately, he acknowledges the mild nature of these cases and emphasizes the efficacy of over-the-counter virucidal nasal washes and sprays, including diluted Povidone-iodine, xylitol-based products, and colloidal silver. However, he also shares a concerning observation from his clinical practice that individuals recovering from mild Omicron infections can still experience cardiovascular and thrombotic complications, such as blood clots, regardless of whether they have been vaccinated or not.

This engaging dialogue underscores the importance of providing a platform for in-depth discussions among brilliant minds. Dr. McCullough's Substack, *Courageous Discourse*, offers daily insights backed by scholarly references, fostering an environment where scientific discourse thrives. His newly founded *McCullough Foundation* promises to support investigative scholarship and promote change in legal, media, and governmental affairs.

Dr. Vanden Bossche's upcoming online course on epidemics and pandemics, in collaboration with IPAK EDU and Robert Frecarick's UK organization, signifies a dedication to sharing scientific knowledge.

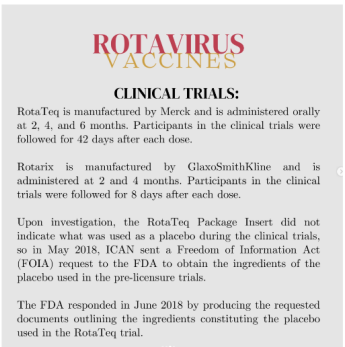
While some discussions may delve into complex territories, platforms like *The HighWire* play a vital role in facilitating these conversations.

AARON SIRI'S DEBATE WITH PAUL OFFIT

By Lea Lacey

In a recent exchange on *The Highwire*, guest host Dr. Jim Meehan and ICAN's lead attorney, Aaron Siri, discuss the critical importance of placebo-controlled clinical trials for childhood vaccines. Siri's appearance on the show centers around his Twitter exchange with Dr. Paul Offit, Director of the Vaccine Education Center at Children's Hospital of Pennsylvania and co-creator of the RotaTeq Vaccine.

Siri points out that numerous childhood vaccines, including Offit's own Rotateq, were not licensed by the US FDA based on placebo-controlled clinical trials. In the case of Rotateq, which was used as an example of a vaccine tested in a placebo-controlled trial, the control group received a mixture containing various substances present in the vaccine, leading to a lack of proper safety assessment.



ROTAVIRUS VACCINES

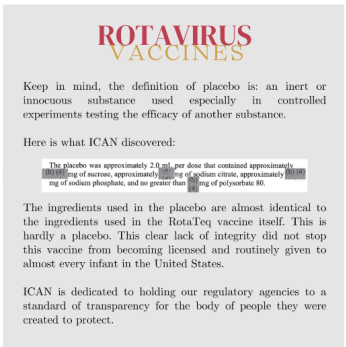
CLINICAL TRIALS:

RotaTeq is manufactured by Merck and is administered orally at 2, 4, and 6 months. Participants in the clinical trials were followed for 42 days after each dose.

Rotarix is manufactured by GlaxoSmithKline and is administered at 2 and 4 months. Participants in the clinical trials were followed for 8 days after each dose.

Upon investigation, the RotaTeq Package Insert did not indicate what was used as a placebo during the clinical trials, so in May 2018, ICAN sent a Freedom of Information Act (FOIA) request to the FDA to obtain the ingredients of the placebo used in the pre-licensure trials.

The FDA responded in June 2018 by producing the requested documents outlining the ingredients constituting the placebo used in the RotaTeq trial.



ROTAVIRUS VACCINES

Keep in mind, the definition of placebo is: an inert or innocuous substance used especially in controlled experiments testing the efficacy of another substance.

Here is what ICAN discovered:

The placebo was approximately 2.0 mL per dose that contained approximately [redacted] mg of sucrose, approximately [redacted] mg of sodium citrate, approximately [redacted] mg of sodium phosphate, and no greater than [redacted] mg of polysorbate 80.

The ingredients used in the placebo are almost identical to the ingredients used in the RotaTeq vaccine itself. This is hardly a placebo. This clear lack of integrity did not stop this vaccine from becoming licensed and routinely given to almost every infant in the United States.

ICAN is dedicated to holding our regulatory agencies to a standard of transparency for the body of people they were created to protect.

He also brings up the example of the Gardasil vaccine and the use of aluminum adjuvant in the control group, arguing that the use of such adjuvants can induce adverse reactions and, without a saline placebo, safety evaluations become skewed.

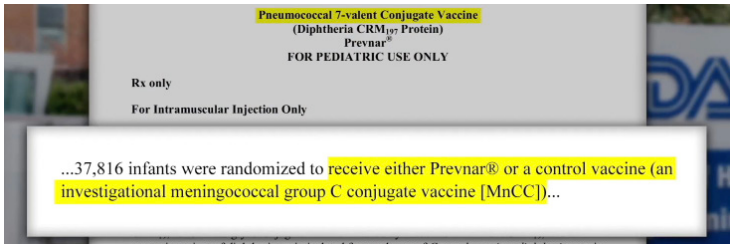
Siri further explains, "It's a critically deadly serious, important issue because if the baseline control that you're using in the clinical trial is not something inert, it's not something known to be safe, it can mask potential harms that the product can cause. So as an example, the initial Prevnar vaccine, Prevnar *7*, was clinically trialed against—and this sounds unbelievable, but it's on the FDA website—it was clinically trialed against another experimental vaccine. I mean, if I was going to make up something crazy about vaccines, I wouldn't have even dreamed of making that up. But there it is, right there in the FDA's own licensure documents. And it's for the world to see on the FDA website—you've just got to look."

Table 9: Summary of Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9412)
	n (%)	n (%)
Arthralgia/Arthritis/Arthropathy†	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism‡	27 (0.3)	21 (0.2)
Hypothyroidism§	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease¶	7 (0.1)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis#	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation Disorder**	4 (0.0)	3 (0.0)
Psoriasis††	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritis§§	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	3 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
All Conditions	245 (2.3)	218 (2.3)

Siri also points out a crucial consideration that once vaccines are licensed, it becomes ethically challenging to conduct proper placebo-controlled trials, as it would involve withholding potentially life-saving treatment from participants. Therefore, the critical step in ensuring vaccine safety is to conduct robust trials BEFORE licensure.

The conversation delves into the issue of conflicts of interest within the medical and pharmaceutical industries. Offit's vigorous defense of vaccines raises questions about his own potential bias and conflicts, given his involvement in vaccine development.



Pneumococcal 7-valent Conjugate Vaccine
(Diphtheria CRM_{197} Protein)
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For Intramuscular Injection Only

...37,816 infants were randomized to receive either Prevnar® or a control vaccine (an investigational meningococcal group C conjugate vaccine [MnCC])...

The following article entitled *What the "Casual Cruelty" of Dr. Paul Offit Reveals — Considered by many to be the world's leading expert on "vaccine safety"* is written by Aaron Siri and published to his Substack account:

In response to a Twitter exchange I had with Dr. Paul Offit, he penned an article titled *The Casual Cruelty of Placebo-Controlled Clinical Trials* that makes numerous categorically false claims to argue against proper clinical trials for products injected into babies.

His article is deeply concerning because he is viewed by many as the leading medical authority on vaccine safety who, among other things, sits on the FDA's vaccine committee that advises on whether to license childhood vaccines.

It is therefore worth reviewing every word of his article. But let's first review the exchange leading up to it.

On June 25, 2023, in response to Offit's claim that "all vaccines are tested in placebo-controlled trials before licensure," I tweeted the following, linking an article with the proof – FDA sources – for my claim:

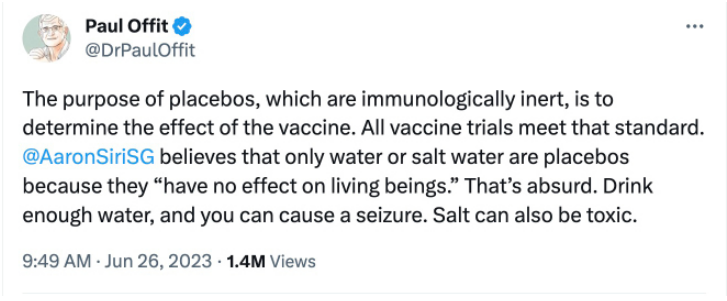
Aaron Siri ✓
@AaronSiriSG

Virtually all childhood vaccines on @CDCgov schedule, including RotaTeq, were not licensed by @US_FDA based on a placebo controlled clinical trial. @RobertKennedyJr is correct on that point. @nytimes @statnews @DrPaulOffit @PeterHotez are all dead wrong. aaron-siri.com/placebo-trials/

4:34 PM · Jun 25, 2023 · **1M** Views

1,867 Reposts **123** Quotes **5,124** Likes **375** Bookmarks

The next day, Offit responded with this:



Paul Offit ✓
@DrPaulOffit

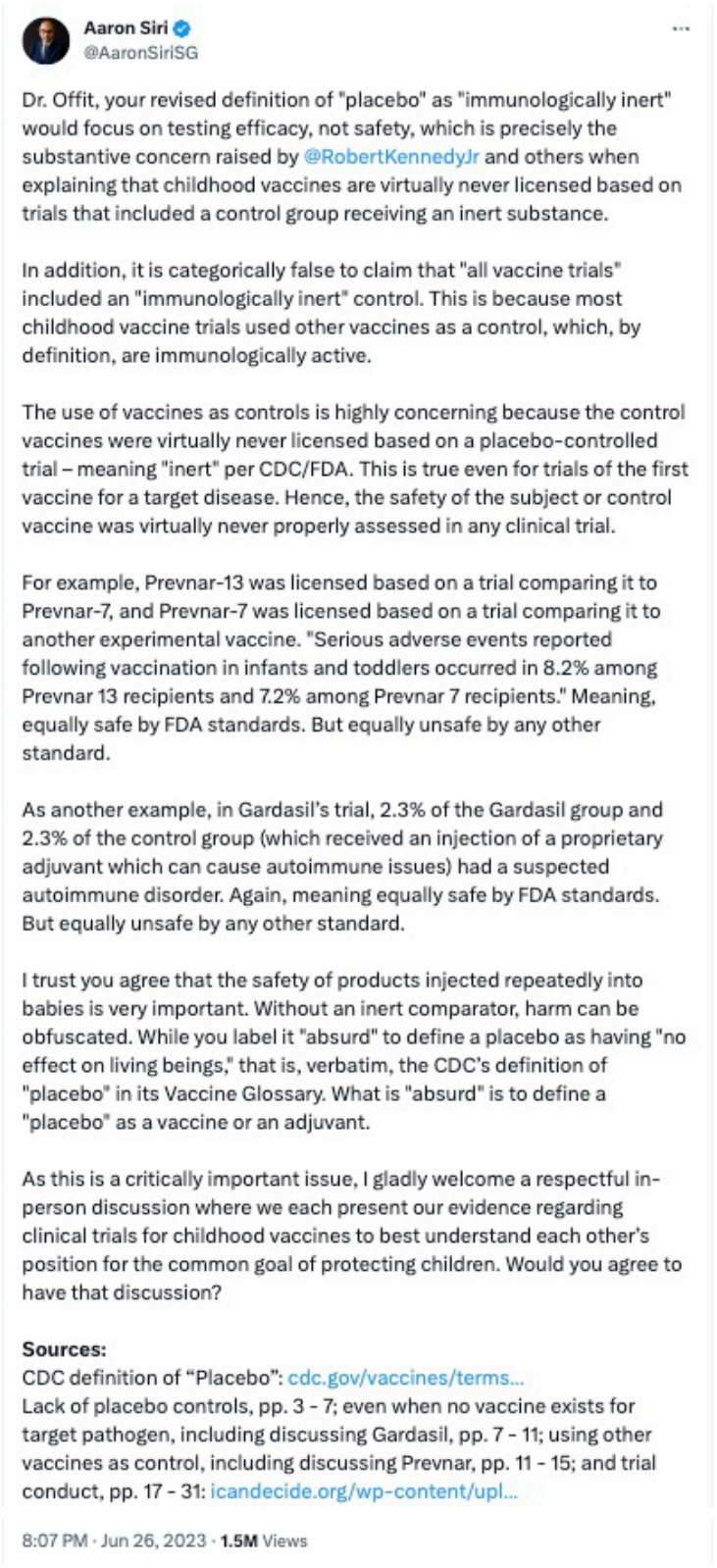
The purpose of placebos, which are immunologically inert, is to determine the effect of the vaccine. All vaccine trials meet that standard. @AaronSiriSG believes that only water or salt water are placebos because they "have no effect on living beings." That's absurd. Drink enough water, and you can cause a seizure. Salt can also be toxic.

9:49 AM · Jun 26, 2023 · **1.4M** Views

I tweeted back later that same day. (See right).

By the next day, Offit quietly updated his original claim from "**All** vaccines..." to "**Most** vaccines are tested in placebo-controlled trials before licensure." Offit's updated claim is still categorically false, but we will return to that below.

Offit also, on July 1, 2023, responded to the above Tweet in a Substack article which, as noted above, is titled *The Casual Cruelty of Placebo-Controlled Clinical Trials.* His entire article is in bolded text below (you don't want to miss a word) and, between paragraphs, I provide responses.



Aaron Siri ✓
@AaronSiriSG

Dr. Offit, your revised definition of "placebo" as "immunologically inert" would focus on testing efficacy, not safety, which is precisely the substantive concern raised by @RobertKennedyJr and others when explaining that childhood vaccines are virtually never licensed based on trials that included a control group receiving an inert substance.

In addition, it is categorically false to claim that "all vaccine trials" included an "immunologically inert" control. This is because most childhood vaccine trials used other vaccines as a control, which, by definition, are immunologically active.

The use of vaccines as controls is highly concerning because the control vaccines were virtually never licensed based on a placebo-controlled trial – meaning "inert" per CDC/FDA. This is true even for trials of the first vaccine for a target disease. Hence, the safety of the subject or control vaccine was virtually never properly assessed in any clinical trial.

For example, Prevnar-13 was licensed based on a trial comparing it to Prevnar-7, and Prevnar-7 was licensed based on a trial comparing it to another experimental vaccine. "Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients." Meaning, equally safe by FDA standards. But equally unsafe by any other standard.

As another example, in Gardasil's trial, 2.3% of the Gardasil group and 2.3% of the control group (which received an injection of a proprietary adjuvant which can cause autoimmune issues) had a suspected autoimmune disorder. Again, meaning equally safe by FDA standards. But equally unsafe by any other standard.

I trust you agree that the safety of products injected repeatedly into babies is very important. Without an inert comparator, harm can be obfuscated. While you label it "absurd" to define a placebo as having "no effect on living beings," that is, verbatim, the CDC's definition of "placebo" in its Vaccine Glossary. What is "absurd" is to define a "placebo" as a vaccine or an adjuvant.

As this is a critically important issue, I gladly welcome a respectful in-person discussion where we each present our evidence regarding clinical trials for childhood vaccines to best understand each other's position for the common goal of protecting children. Would you agree to have that discussion?

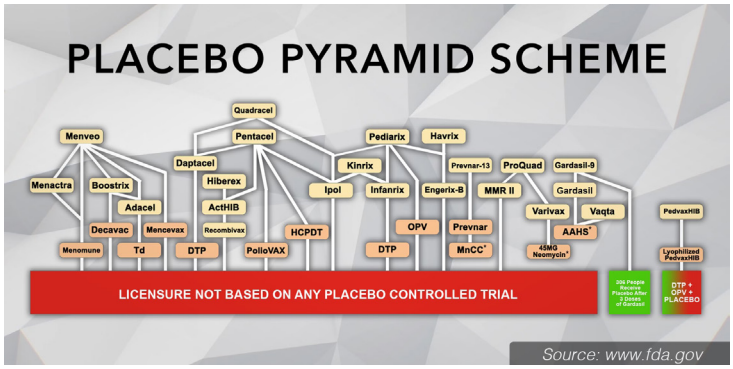
Sources:
CDC definition of "Placebo": cdc.gov/vaccines/terms...
Lack of placebo controls, pp. 3 - 7; even when no vaccine exists for target pathogen, including discussing Gardasil, pp. 7 - 11; using other vaccines as control, including discussing Prevnar, pp. 11 - 15; and trial conduct, pp. 17 - 31: icandecide.org/wp-content/upl...

8:07 PM · Jun 26, 2023 · **1.5M** Views

Offit's article opens with this:

> Anti-vaccine activists often tell the same story. Only the names of the vaccines, the materials in the vaccines, and the scientists who stand up for vaccines change. But the story remains the same. Government officials, pharmaceutical companies, public health agencies, scientists, and doctors are lying to you about vaccines. They are covering up safety problems. We, on the other hand, by pulling back the curtain on this conspiracy, will tell you the truth. Trust us. Not them.

An incredible opening. In our exchange, I made a statement about vaccines and then provided evidence to support that statement; I cited to FDA documentation for every routine childhood vaccine showing that virtually every single one lacked a placebo control. In response, Offit offers no proof to support his statement to the contrary or to refute my proof.



Instead, in a truly Machiavellian style, his opening paragraph tells you that if you don't trust him, then you believe in some sort of conspiracy through which everyone else is "lying to you." The lack of introspection is dumbfounding. When I and others, like Mr. Kennedy, raise concern about vaccine clinical trials we are not saying "trust us," we are saying precisely the opposite: we are saying look at the proof yourself, here it is!

Offit, on the other hand, is not only saying "trust me," while providing no evidence behind the supposed curtain he is pulling back, but he is also saying if you don't trust him, you are an anti-vaccine conspiracy theorist. Let's continue.

> A recent iteration of this story was told on an episode of Joe Rogan's podcast. RFK Jr. informed Rogan's listeners that pharmaceutical companies "never do placebo-controlled trials." Therefore, because what companies have called "placebos" during pre-licensure trials might have themselves been unsafe, we never really know whether vaccines are safe before licensure. This claim was recently supported by a lawyer [that's me] working for an anti-vaccine group ICAN, which stands for Informed Consent Action Network. As the word "Informed" implies, only ICAN will really inform you about vaccines.

Offit is apparently not letting the facts get in his way. The claim at issue is about the critical safety testing that is supposed to occur pre-licensure and pre-injection into millions of babies. The reality – the hard, clear reality – is that not a single routine childhood vaccine was licensed based on a long-term placebo-controlled trial.

And I won't name call you if you don't agree, nor do I want you or anyone else to take my word for it which is why I cited to the proof for every single vaccine (citations repeated in the chart below). ICAN, an incredible organization that is dedicated to the truth and to "informed consent," a phrase Offit seems unfamiliar with, does exactly the same by providing support for its assertions. Offit, still no proof. Just a "trust me."

> ICAN's lawyer wrote, "Robert F. Kennedy, Jr. is on record stating that almost all childhood vaccines were licensed based on clinical trials that did not include a placebo control. [Kennedy] is correct. A placebo is defined by the CDC as a 'substance or treatment that has no effect on living beings.' This means a saline injection or water drops in mouth."
>
> Let's take a closer look at the ICAN lawyer's claims. First, the CDC doesn't regulate vaccines; the FDA does. When researchers at pharmaceutical companies consider human testing, they immediately submit their plans to the FDA, which defines placebo as "inert," meaning immunologically inactive and harmless. The FDA would not allow any vaccine trials to proceed unless they deemed placebos to be true placebos. (There is one exception, which we'll get to later.) However, the ICAN lawyer's claim that vaccine trials didn't use a placebo control doesn't mean that vaccines are unsafe or that they don't work. Indeed, post-licensure studies comparing children who did or didn't get vaccinated have consistently shown that vaccines are safe and effective.

Still no proof from Offit. More "just trust me." Offit is now saying, without any proof and with his new definition of placebo, that (trust him) the FDA would never allow clinical trials for childhood vaccines without "true placebos." But that is in fact precisely what the FDA has allowed! The proof again is the FDA's own documentation – which I already cited to him and provide again below.

Amazingly, Offit then says that even if there were no placebo-controlled trials, there is no need to worry because "post-licensure studies comparing children who did or didn't get vaccinated have consistently shown that vaccines are safe and effective." But this claim is categorically false! Putting aside that Offit cites no studies for this claim, there is study after study after study finding that children without vaccines are healthier.

What makes Offit's casual disregard for placebo-controlled trials so cruel is that, as he is no doubt aware, proving causation between a claimed injury and a vaccine without such a trial is extremely difficult, if not often impossible. (See Section I(iv) of this letter.) This is why Offit and his kin, in response to a claim of vaccine injury (outside of a few narrow exceptions they trot out to assure you vaccines are otherwise safe), will almost always tell you "it's just correlation, not causation" or "it's just anecdotal." That is precisely why proper clinal trials are so important!

In fact, after licensure, pharma companies selling the vaccine (which cannot be sued for harms anyway) must, under federal law, disclose "only those adverse events for which there is some basis to believe there is a causal

relationship between the drug and the occurrence of the adverse event." Pursuant to this requirement, pharma companies have disclosed over 100 serious adverse harms they have a basis to assert are causally related to childhood vaccine products – see Appendix B. These are often the same harms parents complain of after vaccination! But without a clinical trial to prove causation, these parents (who, let's remember, vaccinated their child) are called anti-vaxxers and lectured that "correlation does not equal causation" – like a religious mantra.

And everyone should be terribly concerned about this state of affairs because the chronic health of American children has taken a nosedive since the 1980s, which happens to be when manufacturers were given immunity to liability for vaccine injuries and the vaccine schedule grew from 2 routine injected vaccines totaling 7 injections, to 13 routine injected vaccines totaling 54 injections. (See Sections I and VII of this letter).

> According to ICAN's lawyer, the only substances that have "no effect on living beings" are water and salt water. Which is incorrect. Any chemical on this planet (both water and salt are chemicals) if given at a high enough dose, can be harmful. Drink 3-4 liters of water at one time, and you can suffer fatal water intoxication. Eat massive amounts of salt, and you can suffer fatal salt intoxication. In the words of Paracelsus, a 16th century physician, "All things are poisons; for there is nothing without poisonous qualities. It is only the dose which makes a thing poison."

Hard to believe I need to explain this but when it comes to human beings, a saline injection is considered inert. Human beings are approximately 60% water and our blood is 0.9% salt by weight. Hence, saline solution (water with 0.9% salt) is used in clinical trials as a substance that has no effect on human beings. It also has a clearly defined safety profile and hence is often used as the control when conducting clinical trials of drugs (but not childhood vaccines).

While I prefer not to jest (given the seriousness of injecting babies with liability-free products), I guess I have to agree with Offit that, if someone tries to inject you with the full content of a syringe that is around three feet tall and half a foot wide (the size needed for 3-4 liters), sure, you should be concerned. It is telling that Offit needs to venture into the absurd to make his point. This is likely because, no doubt, Offit does not believe a saline injection used as a control would have an adverse effect on living beings.

> ICAN's lawyer argued that the only true placebos were water or saltwater, which isn't true. Indeed, a wide range of placebos have been used in vaccine trials. These placebos might contain buffers, stabilizing agents, emulsifying agents, or adjuvants, like aluminum salts. They might contain sodium citrate, sodium phosphate, sucrose, or polysorbate-80. At the level contained in vaccines, all these chemicals are safe, including aluminum salts. Therefore, all meet the FDA criteria for a placebo.

First, most clinical trials of childhood vaccines use another vaccine as a control – see chart below – which even Offit must agree cannot be considered a placebo (because Offit's own definition required that a "placebo," among other things, be "immunologically inactive").

Second, when something other than a vaccine is used as a control, it often includes, as Offit points out, numerous ingredients that are entirely unnecessary! This means they are not a placebo! An injection of saline solution is a placebo. An injection of aluminum salts, which is an adjuvant used for the very purpose of generating a strong immune response, is not a placebo under any definition of the term (again, including Offit's own definition). Below we will review the actual control used in the trials for each childhood vaccine – based on the actual evidence from the FDA – and you will see with your own eyes that virtually every single one fails to meet even Offit's definition.

> Not all vaccine trials, however, are placebo controlled. As noted by ICAN's lawyer: "Prevnar-13 was licensed based on a trial comparing it to Prevnar-7." Prevnar-7, which was licensed in the United States in 2000, was designed to prevent seven of the most common types of pneumococci that cause pneumonia, meningitis, and bloodstream infections (sepsis), collectively referred to as invasive pneumococcal disease. Prior to the availability of Prevnar-7, pneumococci caused about 17,000 cases of invasive disease, 700 cases of meningitis, and 200 deaths in children less than 5 years of age every year. Prevnar-7 worked, clearly reducing the incidence of invasive disease. To further broaden protection, researchers developed Prevnar-13, which protected against an additional six types. ICAN's lawyer apparently believes it would have been ethical to study Prevnar-13 pre-licensure with a water or saltwater placebo, knowing that a vaccine already existed that offered considerable protection against a severe and occasionally fatal bacterial infection. I can't imagine how this kind of trial would have been explained to parents. Not surprisingly, according to a World Health Organization Advisory Panel, the study proposed by ICAN's lawyer would have been unethical.

Offit does not address what I actually wrote about Prevnar. What I wrote was that "use of vaccines as controls is highly concerning because the control vaccines were virtually never licensed based on a placebo-controlled trial ... [and this] is true even for trials of the first vaccine for a target disease. ... For example, Prevnar-13 was licensed based on a trial comparing it to Prevnar-7, and *Prevnar-7 was licensed based on a trial comparing it to another experimental vaccine."* (emphasis added).

My point, as I clearly wrote, was that because Prevnar-7 was the first licensed vaccine of its kind in the United States, there was absolutely no excuse not to trial it against a placebo. Certainly, there was no excuse to trial it against another experimental vaccine! Offit has no response to that point because there is no excuse for such a morally and ethically bankrupt clinical trial.

Here is where it gets more than casually cruel. All one can say about Prevnar 7 is that it was at best shown to be equally as "safe" as another experimental vaccine.

Meaning both could be terribly unsafe. And to that point, as I pointed out to Offit, when Prevnar 7 was then used as the control in the clinical trial for Prevnar 13, here is what occurred: "Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients." Meaning, as I wrote in my tweet to him above, "these two vaccines were equally safe by FDA standards – but equally unsafe by any other standard." His response to that? None, because this finding is viciously cruel. Indeed, just take a look at the FDA's definition of "serious adverse event" – it means death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect, intervention to prevent permanent impairment or damage, or other serious medical event consistent with these. Meaning "serious adverse event" is something very serious! It is not normal for a group of healthy children to suffer this rate of serious adverse events every six months, absent something harming them! It is viciously cruel to ignore this data. Prevnar 7 was never properly assessed as safe in a clinical trial and, hence, using it as the baseline of safety for Prevnar 13 is morally and ethically bankrupt.

Instead of addressing this serious safety concern, Offit ignores it in his response. Instead, he sets up a false argument to bat down, and finally tries to focus on the efficacy of this product, meaning its ability to prevent disease. But even if the product is highly effective, unless you know the actual safety profile, you cannot know if you are causing more harm than good. It is also impossible to obtain informed consent and to allow parents and providers to make a good medical decision for each individual child.

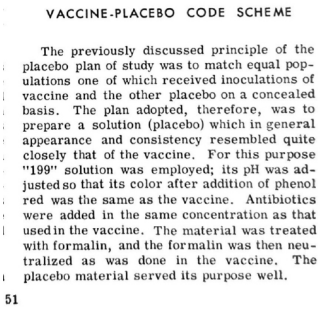
The CDC recommends injecting this product three times during the first six months of life to the over 4 million babies born in the United States each year. If this product causes a serious adverse event in just 1% of these infants (let alone 8.2% as occurred in the clinical trial), that would mean serious harm to over 40,000 babies a year from this product. This could certainly far exceed the claimed benefit. But this type of guesswork is no way to practice medicine – what is needed is a proper clinical trial so that the actual safety profile of this product is known.

And Offit's purported ethical concern is rich. Putting this into sharp focus, in the study that Offit cites regarding Prevnar 7 (in which it was trialed against another experimental vaccine), 15 children died after getting Prevnar 7, and 7 died after getting the other experimental vaccine (including sudden infant deaths, simply stopping to breathe, as well as accidents that could result from fainting or seizures caused by vaccination). But rest assured: the study says that none of the deaths were "judged [by Pfizer's paid researchers] to be associated with vaccine." This morally bankrupt study, comparing two experimental vaccines, relies upon the "judgment" of the company that stands to earn billions to make decisions on causality! It should simply be a valid statistical comparison of the rate of death between a group receiving Prevnar 7 and a group receiving a placebo. That didn't happen and will now never happen, and with Pfizer now making literally billions of dollars annually through sales of this product, good luck overcoming that juggernaut to get to the truth. But as Offit already told you – if you don't just trust him on this, you are a conspiracy theorist.

And here is how Offit's article ends.

> The casual cruelty expressed by ICAN's lawyer can also be found in an event that occurred almost 70 years ago. In 1954, 420,000 first and second graders in the United States were inoculated with Jonas Salk's inactivated polio vaccine; 200,000 were inoculated with salt water. It was one of the largest placebo-controlled trials of a medical product in history. Jonas Salk didn't want to do it. He couldn't conscience giving a saltwater shot to young children when as many as 50,000 were paralyzed by polio and 1,500 died every year. When the trial was over, the vaccine was declared "safe, effective, and potent." Church bells rang out; synagogues held special prayer meetings; department store patrons stopped to listen to the results of the trial over loudspeakers. How did we know that Jonas Salk's polio vaccine was effective? We knew because 16 children died from polio in that study—all in the placebo group. We knew because 34 of the 36 children paralyzed by polio in that study were in the placebo group. These are the gentle heroes we leave behind.
>
> I suspect that none of the parents who volunteered for Jonas Salk's polio vaccine trial were hoping their children were in the placebo group.

More false claims by Offit. First, it is categorically false to claim that "200,000 were inoculated with salt water." These children did not receive "salt water." The official final report from the Salk trial (Dr. Offit, I am happy to send you a copy), on page 51, describes precisely what these 200,000 children received as a control. It was an injection that included, among other things, the following ingredients: "199 solution" (a synthetic tissue culture medium and ethanol) "phenol red," "antibiotics," and "formalin." Don't take my word for it, see the official report for yourself. It is categorically false for Offit to claim "200,000 were inoculated with salt water."



VACCINE-PLACEBO CODE SCHEME

The previously discussed principle of the placebo plan of study was to match equal populations one of which received inoculations of vaccine and the other placebo on a concealed basis. The plan adopted, therefore, was to prepare a solution (placebo) which in general appearance and consistency resembled quite closely that of the vaccine. For this purpose "199" solution was employed; its pH was adjusted so that its color after addition of phenol red was the same as the vaccine. Antibiotics were added in the same concentration as that used in the vaccine. The material was treated with formalin, and the formalin was then neutralized as was done in the vaccine. The placebo material served its purpose well.

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And keep in mind, this is the one and only vaccine in his article he actually identified as being licensed based on a placebo control - a saline injection!

Offit then claims that "16 children died ... all in the placebo group" and that "34 of the 36 children paralyzed by polio in that study were in the placebo group." But the article he cites for this claim says, "There were four deaths among children who received placebo" and that "33 inoculated children receiving the complete vaccination series became paralyzed."

Offit also fails to mention the Salk vaccine ceased being used in the 1960s and does not disclose the many paradoxical and statistically improbable realities regarding the rise of polio and the claim that Salk's vaccine vanquished this disease. But again, that also misses the point. The point is that whatever the efficacy, the actual safety profile of each routine vaccine product on the CDC schedule needs to be determined in a valid clinical trial. Without that, you can never provide any parent proper informed consent.

Offit kindly calls children that died of polio during the Salk trial "gentle heroes." They are. Every child is precious. We should care about every child injured by an infectious disease. The issue is that when children are injured or killed by a vaccine, they are not called "gentle heroes." Instead, their parents are called pejoratives, gaslit, cast out of medical offices, and berated and demeaned in an attempt to ignore what they experienced.

If refusing them proper medical care and adding insult to injury were not enough, they are then attacked by their own government if they happen to learn about the Vaccine Injury Compensation Program (which most do not know about) and file a claim (most do not because they miss the time to file) because they must fight against an army at HHS (the department in which CDC and FDA are located) and DOJ attorneys in order to seek even minimal compensation to care for their injured children. This is a system that is rigged against the vaccine injured.

So, why is Offit's article incredible? It is incredible because he is literally the person the medical community and the FDA and CDC look to on the issue of vaccine safety. Offit is maybe the most renowned disciple of the godfather of vaccines, Dr. Stanley Plotkin, and one of the four editors of the medical textbook Plotkin's Vaccines and the author of the chapter "Vaccine Safety" in this textbook, hailed "the bible of vaccinology." He is also the Director of the Vaccine Education Center at CHOP which, I can tell you from deposing numerous pediatricians, is looked to as the pinnacle of truth regarding vaccine safety. He is even a current member of the FDA's vaccine advisory committee and a former member of the CDC's vaccine advisory committee.

Yet his article above shows not merely a casual disregard for proper clinical trials of childhood vaccines but in fact contempt for such trials – trials that would actually demonstrate the true safety profile of these products.

While Offit called me casually cruel for asking for placebo-controlled trials for vaccines where no vaccine exists for the target disease or when the control used was never validated through a prior placebo-controlled trial, what he was really doing was revealing more about himself; just as he sees the hero in children injured by infectious disease and expresses a deep caring for them, as we all should, he reveals a deep contempt for children injured by vaccines and, worse, for those seeking to identify and avoid such injuries in other children. That is more than casually cruel. And that is being generous.

If Offit can show that, in fact, all the routine vaccines on the childhood vaccine schedule were originally licensed based on a properly designed placebo-controlled trial (even using his narrow definition) then I will retract my assertion. I would in fact welcome being wrong. Like probably every other parent, there would be a lot of comfort in knowing that the products he pushes for injection into babies dozens of times in the first six months of life were licensed based on proper trials. Here is the chart with the proof that this is not, unfortunately, what occurs with childhood vaccines. I welcome receiving from you, Dr. Offit, proof to the contrary.

One final note: Offit wrote (regarding Mr. Kennedy) that, "You can't debate someone who knowingly manipulates or flat out lies about the facts to advance their claims." Our debate to date shows that Offit is incorrect. Many would submit that Offit's article reflects "someone who knowingly manipulates or flat out lies about the facts to advance their claims" but, yet, Offit and I have engaged in what many would consider a respectful debate based on evidence.

Proof Regarding The Clinical Trials Relied Upon By The FDA To License The Childhood Vaccines On The CDC Childhood Vaccine Schedule

HepB vaccine (Birth 1M 6M)

- Recombivax HB (Merck) licensed for babies based on trials with no placebo control & 5 days of safety monitoring after injection. See Package insert § 6.1
- Engerix B (GSK) licensed for babies based on trials with no placebo control & 4 days of safety monitoring after injection. See Package insert § 6.1

DTaP vaccine (2M 4M 6M 15M 4Y)

- Infanrix (GSK) licensed for babies based on trials with no placebo control (DTP vaccine used as a control) & up to 30 days of safety review after injection. See Package insert § 6.1 (Note that DTP was not licensed in a placebo-controlled trial and increases mortality)
- Daptacel (Sanofi) licensed for babies based on trials with no placebo control (DT or DTP vaccine used as control) & 2 months of safety review after injection except one trial which was 6 months with no control, 1,454 children and "[w]ithin 30 days following any dose of DAPTACEL, 3.9% subjects reported at least one serious adverse event." See Package insert § 6.1 (see note for Infanrix).

PCV vaccine (2M 4M 6M 12M)

- Prevnar 13, PCV-13 (Wyeth, part of Pfizer) licensed for babies based on trials with no placebo control (Prevnar 7 used as a control, and Prevnar 7 was licensed based on trial in which the control was another experimental vaccine) & 6 months of safety review after injection which found, "Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients." See Package insert § 6.1 (Note the package insert for Prevnar 7 states the control in its licensing trial was an "Investigational meningococcal group C conjugate vaccine"). Continue here.


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