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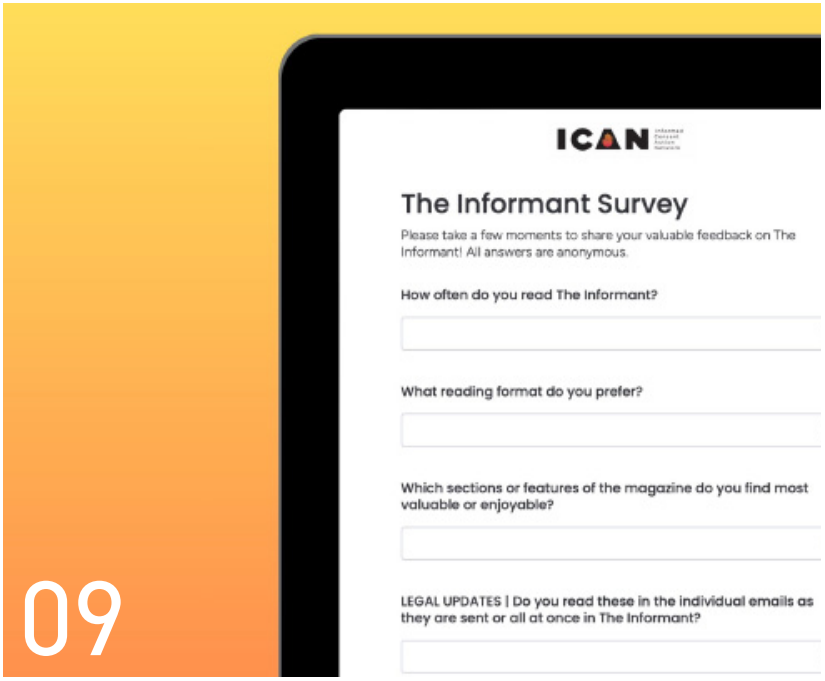
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Catharine Layton
COO, ICAN
Supervising Producer,
The HighWire

Welcome to *The Informant,* our new monthly magazine offering curated news and exclusive content to supporters of the Informed Consent Action Network. We really wanted to provide something more to those supporters who give something more. *The Informant* features exclusive interviews, articles, and a breakdown of our most impactful work over the past month.

When *The HighWire* premiered in 2017, we imagined a news program where we could report on the important news ICAN was making, but we hadn't considered at the time that there would be too much news for us to cover in our weekly show. During production meetings, we are often faced with the difficult decision of cutting important stories simply because there is not enough time to cover every breaking story, and every action ICAN is taking. *The Informant* provides a platform to bring you those important stories, highlight ICAN's most significant actions, and direct your eye to informative content you may have missed in the previous month.

ICAN's legal footprint is vast, spanning thousands of FOIA requests, numerous lawsuits & petitions to regulatory agencies, in-depth investigations of important health issues facing the public, publication of white papers, and more.

Also, expect to find behind-the-scenes interviews with our CEO, Del Bigtree, a breakdown of things we aren't able to cover extensively on *The HighWire,* and other articles only available here, for you.

Part of what I think makes ICAN unique is our relationship with our supporters, who make all that we do possible. Our team really has a passion for providing information directly to the public, so they can make truly informed decisions for themselves and their families. We have all been on a journey together since our founding in 2016, and *The Informant* is another exciting path along that journey. I hope that you find it insightful, interesting and informative.

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MUST-SEE MOMENTS

LEGAL UPDATES

FDA REFUSES TO ENFORCE EUA ADVERTISING RESTRICTION — BUT ALSO INSISTS IT MUST KEEP THE PROVISION!

WHAT YOU NEED TO KNOW:

- ICAN documented instances where state & federal public health entities falsely referred to COVID-19 vaccines under Emergency Use Authorization (EUA) as "approved" or "safe and effective," which directly violated federal law and EUA conditions
- ICAN's attorneys petitioned the FDA to enforce EUA conditions prohibiting advertisements with illegal language or to rescind the advertising

During the pandemic, ICAN witnessed many instances where state and federal public health entities falsely referred to COVID-19 vaccines released under Emergency Use Authorization (EUA) as "approved" or "safe and effective" in direct violation of federal law and the conditions of the vaccines' EUAs. ICAN's attorneys sent two petitions to the FDA demanding it either enforce the terms of its own EUAs that prohibit advertisements with this illegal language or rescind the advertising restrictions entirely. FDA chose to do neither.

The COVID-19 vaccine EUAs issued by the FDA includes an important advertising condition that states:

All descriptive printed matter, advertising, and promotional material relating to the use of the COVID-19 vaccines clearly and conspicuously shall state that: This product has not been approved or licensed by FDA.

However, in the early days of the COVID-19 vaccines, ICAN documented and took action on numerous instances where this provision being blatantly violated. For example, in January 2021, the New York State's COVID-19 website included a graphic for government officials, health care providers, and the public to use on social media that said, *"The COVID-19 vaccine went through the same rigorous approval process that all vaccines go through."* New York removed this claim after ICAN's attorneys wrote a letter pointing out they were violating federal law.

In March 2021, the Michigan Department of Health and Human Services posted a message on its Facebook page which stated, in part, "[E]ach COVID-19 vaccine had to pass through the same thresholds of research and testing as every other vaccine. And it's important to know that all three of the approved COVID-19 vaccines were proven to be safe and 100% effective..." Once again, Michigan promptly removed the information after ICAN's attorneys wrote to them demanding its removal.

But when it became clear that correcting this misinformation was becoming a game of whack-a-mole, ICAN's attorneys submitted a petition to the FDA demanding it take steps to enforce federal law and the conditions of the EUAs it issued by ensuring that the COVID-19 vaccines were not to be promoted as "approved."

When FDA failed to take any substantive action, ICAN's attorneys submitted a second petition on August 12, 2022, this time requesting that FDA, in light of the confusion caused by its refusal to enforce its own EUA conditions, remove the advertising condition from the COVID-19 vaccine EUAs entirely.

One of these two citizen petitions should have been granted—either enforce the condition of the FDA's own EUAs or remove the condition. So, what did FDA ultimately do? In a combined response to both petitions, it chose neither. To the first petition, it declared, *"The Agency makes decisions regarding whether to pursue enforcement actions on a case-by-case basis, considering all relevant facts and circumstances... At this time, we are not taking the actions you requested."* To the second petition, it stated, *"[T]he August 2022 Petition does not identify any legal requirement for FDA to remove this condition of authorization from any of the Authorized COVID-19 vaccines as requested. For these reasons, FDA denies this request."*

The FDA wants to have its cake and eat it too. It doesn't feel the need to enforce the provisions, but it also wants to give the appearance of caring about safety by keeping them in place—its response to ICAN's two petitions reveal this for exactly what it is: theater.

Rest assured that ICAN will continue to expose this kind of hypocrisy.

ICAN CHALLENGES FDA'S MOVE TO WEAKEN ITS ALREADY PALTRY CLINICAL TRIAL REQUIREMENTS FOR VACCINE APPROVAL

WHAT YOU NEED TO KNOW:

- Sept 2023 - an FDA advisory committee labeled the drug phenylephrine (Sudafed PE) as "ineffective," noting extremely small sample sizes, bias, & data integrity issues
- Just a day prior, the FDA issued guidance stating a manufacturer can show evidence of the effectiveness of a product with a single investigation in animals alone
- Dec 2023 - ICAN filed a formal comment in opposition to the draft guidance, reminding the FDA of its refusal to stick to its own standards

With public faith in FDA continuing to decline, the agency published draft guidance stating that a single animal study could be sufficient to demonstrate a vaccine's effectiveness. ICAN's attorneys submitted a comment in opposition to this draft guidance which comes shortly after FDA approved a COVID-19 booster based on trials performed solely in mice.

Back in 2007, an FDA advisory committee met to re-review the safety, effectiveness, and dosing of phenylephrine (Sudafed PE), which has been on the market for nearly 50 years. At the 2007 meeting, the committee considered its efficacy data "borderline" but nonetheless voted 11-1 in favor of its efficacy, although it did vote in favor of additional studies being done.

On September 12, 2023, the same FDA committee, *possibly attempting to bolster its image as a tough regulatory watchdog,* voted unanimously to label phenylephrine "ineffective" as a nasal decongestant. The committee noted "significant methodological and statistical issues with the design and conduct of the original studies submitted to and evaluated by the Panel...All but one evaluated extremely small sample sizes, none adequately controlled for bias...and none performed appropriate sample size calculations," and observed, "After a thorough review of all the available evidence, it is also possible that there may have been bias and/or data integrity issues at [at] least one study center...where five of the seven positive oral PE studies were conducted."

If FDA follows the panel's advice, the drug will be pulled from the market, despite the long-standing indications of its inefficacy, most of which were known in 2007. It's too bad the committee didn't perform this "thorough review" at any point prior to the last 50 years, before Americans wasted billions of dollars on an ineffective treatment (nearly $2 billion in 2022 alone) that apparently only exposed them to potential harm without benefit.

Ironically, on September 11, 2023, just one day before the committee met to clamp down on this "ineffective drug" with shoddy clinical trials, FDA issued draft guidance stating that, under certain circumstances, a manufacturer can show evidence of effectiveness for a biological product with a single clinical investigation conducted in animals, giving the example of "[w]hen the product is a preventive vaccine, and there is a well-established model of infection for a relevant infectious disease, and use of the vaccine in the animal model demonstrates prevention of disease." Notably, this occurred shortly after FDA authorized the newest Pfizer COVID-19 vaccines, which are as Dr. Paul Offit notes, "new product[s]," even though Pfizer tested this brand-new shot only in mice—not humans.

Thus, on December 18, 2023, ICAN, through its attorneys, filed a formal comment in opposition to the draft guidance.

Despite urging by ICAN in its November 2020 petition, FDA refused to amend the Phase III trials of the COVID-19 vaccines to ensure they met the required standard of "substantial evidence" of effectiveness. As a result, we now have generations of new vaccines being approved based on those original ineffective products.

Now, FDA is doubling down on its malfeasance by authorizing COVID-19 vaccines without human trials while simultaneously creating guidance to excuse its lack of oversight.

As ICAN's comment notes:

[I]t is apparent that FDA is tailoring guidance based on the vaccine manufacturers' clinical trials instead of requiring that these trials comply with what any reasonable licensing agency should and would require. FDA has seemingly forgotten that its function is to regulate the pharmaceutical industry, not rubber stamp it. The Draft Guidance does not provide oversight, and even worse lends illegitimacy to the FDA when there is clearly insufficient evidence to support authorization or licensure. This is especially troubling for products that will be injected into healthy humans—including babies, children, and pregnant women.

NEW CASE REPORTS RELEASED FOR PFIZER AGES 12-15 AND MODERNA AGES 18+ SHOW MYOCARDITIS, APPENDICITIS, INTESTINAL PERFORATION, AND MORE

WHAT YOU NEED TO KNOW:

- Jan 2024 - FDA released the final 180,000 pages of documents including case reports of individual clinical trial participants in the Pfizer COVID vaccine for ages 12-15
- Reports included four separate case reports of appendicitis & a case of teenage myopericarditis
- The vaccine efficacy of the 12-15 age group was assessed for only 7 days post-second dose

FDA released another 180,000 pages of COVID-19 vaccine documents in January, as required by court order. Many files in this production are case reports of individual clinical trial participants. According to FDA, this is the final batch of documents related to the authorization of the Pfizer vaccine for ages 12-15.

The January 2024 release of documents related to the Pfizer vaccine for ages 12-15 consisted of 67,924 pages. While FDA says this is the last batch for this age group, rest assured ICAN will be reviewing the documents to determine if anything critical is missing or was improperly redacted. Here are some areas of interest in this month's release:

There were 4 separate case reports of appendicitis, which was a prespecified adverse event of special interest. Appendicitis adverse events included an approximately 14-year-old boy (18 days after second placebo dose), an approximately 15-year-old boy (nearly 5 months after second vaccine dose), an approximately 16-year-old boy (nearly 6 months after second vaccine dose), and an approximately 13-year-old girl (3 days after second vaccine dose). The first 3 cases were deemed "unrelated" but on the final one there was disagreement: "In the opinion of the investigator, there was a reasonable possibility that the appendicitis was related to the study intervention... Pfizer did not concur..."

An approximately 16-year-old boy developed myopericarditis 2 days after his second dose of the vaccine (prior to that he had two placebo doses). Pfizer admitted that "there was a reasonable possibility that the myocarditis was related to the study intervention...." FDA also stated that "FDA agrees that this SAE [serious adverse event] was possibly related to vaccination."

A Pfizer Pharmacovigilance Plan reported the results of a myocarditis survey of approximately 360 individuals ages 12-29: "Thirteen (4%) patients reported readmission to the hospital, including 8 of 13 (62%) patients who were readmitted because of a concern with the heart. Seventy-one (20%) patients were prescribed medication for their heart as of their last appointment with the provider."

An sBLA Clinical Review Memorandum dated July 8, 2022, contained an FDA reviewer's praises of the vaccine efficacy of the 12-15 age group, which was assessed for only 7 days post-second dose: "Additionally, descriptive VE analyses, the VE after 7 days post Dose 2 was 100% (95% CI: 86.8; 100.0) in participants 12-15 years of age without prior evidence of SARS-CoV-2 infection and provided compelling direct evidence of clinical benefit in addition to the immunobridging results." She enthusiastically concluded her report with: "[C]urrently available data support a benefit-risk balance that is clearly favorable for approving Comirnaty for use in individuals 12-15 years of age."

The January release of documents related to Moderna's Spikevax consisted of 112,345 pages, including several case reports noting gastrointestinal adverse events. Notably, intestinal perforation has been linked to thrombosis and COVID-19 infection and, yet, in each of the following cases, the adverse event was deemed "unrelated" to the clinical trial:

A 60-year-old man with a health history that included IBS, high blood pressure, and testicular cancer was hospitalized with a "2 cm ulcer in the duodenal bulb [small intestine] with clot present" 22 days after his second vaccine dose.

A 73-year-old man whose pre-existing conditions included heartburn, hypertension, high cholesterol, hernias, and blood clots, had emergency surgery for a "closed loop bowel obstruction" 2 days after his second vaccine dose.

As always, we encourage those interested to download the productions and review the data.

ICAN OBTAINS FDA REPORT WHICH SHOWS SHOCKING CONDITIONS AT MODERNA VACCINE FACTORY

WHAT YOU NEED TO KNOW:

- ICAN's legal team sent FOIA requests to the FDA after learning about quality control lapses at a Moderna COVID-19 vaccine manufacturing facility
- The FDA inspected Moderna's Norwood, MA facility from Sept 11-21, 2023, and found numerous quality control lapses
- Issues include ignored air and temperature alarms, use of expired materials in the mRNA vaccines, failure to collect cleaning verification samples, and inadequate design and control of air handling equipment to reduce contamination risk

After hearing about quality control lapses at a Moderna COVID-19 vaccine manufacturing facility, ICAN's legal team immediately sent FOIA requests to FDA for more details. ICAN has now obtained FDA's inspection report, which includes detailed descriptions about the conditions at the plant.

On December 15, 2023, news broke that FDA found numerous quality control lapses during its September 11-21, 2023 inspection of Moderna's Norwood, Massachusetts facility, where it manufacturers its COVID-19 vaccine.

ICAN's attorneys immediately submitted several FOIA requests to get more details on the inspection's findings. In response, FDA recently produced this report to ICAN which has some stunning findings, including air and temperature **alarms that were ignored, use of expired materials in the mRNA vaccines**, failure to collect cleaning verification samples, and failure to design and control air handling equipment to reduce potential for contamination.

Incredibly, the report notes that Moderna "does not ensure that the equipment used for drug substance manufacturing are appropriately cleaned prior to the manufacturing of mRNA-1273 drug substance" and then proceeds to list the drug substance batch numbers that were manufactured using equipment utilized "without confirming the cleaning verifications test results for bioburden and endotoxin prior to the usage for subsequent batch manufacturing."

It also contains the following disturbing observations:

"Expired materials were found utilized beyond their expiration date and restricted materials were utilized in mRNA drug substance production. There are more than two thousand expired items stored in your GMP Warehouse and Cold Storage at time of inspection. These materials are currently stored at the same location with released or in-used materials. There was no clear demarcation between these items in the GMP Warehouse and cold storage."

"Equipment and Facilities are not designed to minimize potential for contamination. Specifically, the air handling systems were not adequately designed and controlled to assure appropriate air quality in the Grade C cleanroom in which mRNA drug substance is manufactured. The positive pressure was not consistently maintained between the grade C cleanrooms and grade D Airlocks. Monitoring data from [redacted] system showed frequent drops of Grade C Cleanroom pressure to negative values between January 2023 and September 2023. The negative DPs (differential pressure) were not assessed for potential impact."

"Your firm [Moderna] failed to respond and follow up on the alarm responses within the timeframe established per SOP-0416."

"Cleaning Validation studies of non-dedicated manufacturing equipment did not include challenges with actual conditions used in routine manufacturing processes."

"A cleaning procedure update was implemented based on the change control and a six-month effectiveness check through cleaning verification after each equipment usage (due date: 14Mar2023) was required after the implementation of change actions to review cleaning verification data to ensure automated method change was effective. However, the cleaning verification samples were not collected after 06Feb2023."

Given the deficiencies revealed in this report, ICAN's attorneys have already submitted additional FOIA requests to dig deeper and will keep you posted on the results.

EARLY V-SAFE FREE-TEXT ENTRIES SHOW REMARKABLE CONSISTENCY IN THE FREQUENCY OF MENTIONS OF ADVERSE EVENTS

WHAT YOU NEED TO KNOW:

- V-safe was the vaccine safety monitoring system rolled out for COVID-19 vaccines which included a free text field where users could type details of their post-vaccine symptoms
- It took an order from a federal judge for the American public to get access to the free text field entries
- ICAN received 780k of the 7.8 million entries in early 2024 including: ~3,200 mentions of "shortness of breath," 3,500 reports of "heart palpitations," & 2,000 reports of "ringing" of the ears, or tinnitus

In March, CDC released the second batch of V-safe free-text entries. V-safe was the vaccine safety monitoring system rolled out for COVID-19 vaccines. It took an order from a federal judge for the American public to get access to these entries, wherein users could type in up to 250 characters about anything they wanted, including details on the symptoms they were experiencing.

At first look, there's remarkable consistency between the 390,000 text entries received in February and the 390,000 text entries received in March (made by 523,150 unique V-safe users) in terms of the number of times certain symptoms were reported. For example, in both the February and March productions, roughly 3,200 entries mention the symptom of "shortness of breath." For the term "heart palpitations" there were about 1,900 reports in the February batch and 1,600 in the March batch. Concerningly, these are both symptoms of myocarditis. In addition, in each batch there were roughly 1,000 reports of "ringing" of the ears (tinnitus), which studies and news reports have linked to the COVID-19 vaccines, despite CDC's refusal to recognize it as an adverse event.

Here are a few examples of the sobering entries received and presumably ignored by CDC:

"My tinnitus is off the charts. It is EXTREMELY LOUD. Had I know [sic] the vaccination would make my tinnitus worse I would have NEVER gotten the vaccine. Put it this way, if I was suicidal I would be dead by now thats [sic] how bad it is."

"I had miscarriage after 2nd dose of Pfizer covid vaccine. I felt fine until I had the vaccine and within 48 hrs pregnancy symptoms ceased. I have no history of fertility issues or complications and had 2 healthy uneventful pregnancies prior to this."

"Today, I experienced heart palpitations accompanied by tachycardia, dizziness, and weakness. These symptoms lasted about 4 hours and my heart rate was between 135-145. I have never experienced any of these symptoms until today."

"Loss of consciousness and seizure immediately following injection. Went to ER by ambulance."

A full analysis of the data won't be possible until we have all 7.8 million entries.

In the meantime, we encourage those interested to download the data and review it yourselves.

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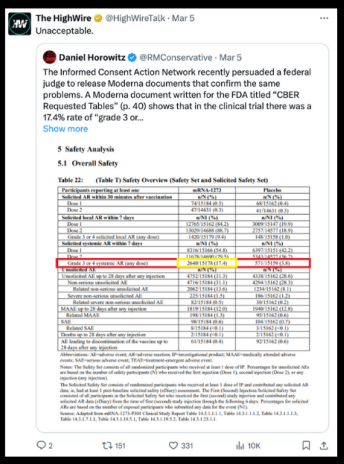

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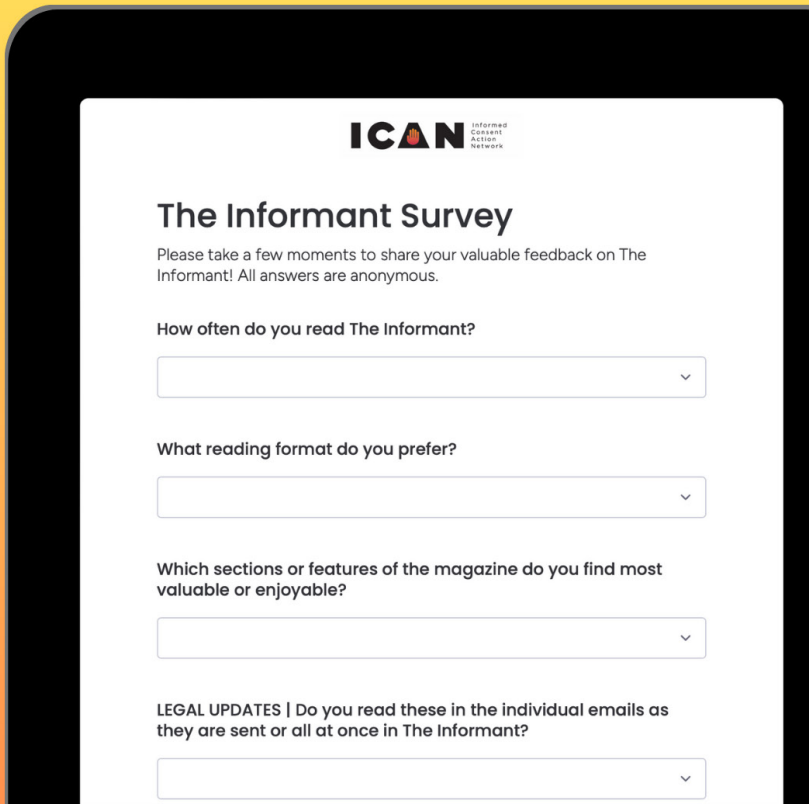

MUST-SEE MOMENTS

THE HIGHWIRE WITH DEL BIGTREE

SEN. RAND **PAUL** | EP 362

Sen. Rand Paul shares how his perspective as a physician and politician led to holding Fauci to the fire on his cover-up of gain-of-function research, push for draconian lockdowns, and his refusal to accept the strength of natural immunity against COVID.

WHAT TO KNOW

- Senator Rand Paul shares his new book, *Deception: The Great COVID Cover-Up,* as well as dysfunction within the US government and the inability of both parties to come together to seek solutions.
- While the Senator was initially against COVID lockdowns and draconian measures, he did not initially question the virus' origin.
- Senator Paul is focusing on a gain-of-function reform bill that would place a moratorium on all federal research grants involving risky gain-of-function research on potential pandemic pathogens.

CLICK TO WATCH

JILL **HINES** | EP 364

Jill Hines, co-director of Health Freedom Louisiana and plaintiff in the Murthy v. Missouri case, gives her first hand account of the oral arguments before the Supreme Court for this controversial free speech case, as well as the government censorship her organization received which led to her becoming a plaintiff.

WHAT TO KNOW

- Jill, a stay-at-home, homeschooling mom, is fervently committed to vaccine choice advocacy.
- Co-director of Health Freedom Louisiana, Hines spearheaded another grassroots initiative in April 2020 called Reopen Louisiana.
- Their account reached 1.4 million people on social media before facing severe censorship in October 2020.
- Louisiana's former attorney general, now governor, invited them to join a lawsuit against the Biden administration due to ongoing censorship concerns.

CLICK TO WATCH

MUST-SEE MOMENTS

THE HIGHWIRE WITH DEL BIGTREE

DR. SUZANNE **HUMPHRIES** | EP 365

Internist & Board-Certified Nephrologist, Suzanne Humphries, MD, shares details on the 10th Anniversary Edition of the groundbreaking book she Co-Authored, *Dissolving Illusions*, and how the vaccine safety space has changed in a post-COVID world where doctors are speaking out in droves over the controversial topic of vaccine injury.

WHAT TO KNOW

- Dr. Suzanne Humphries' book, *Dissolving Illusions*, originally published in 2013, was recently re-released with 200 additional pages.
- By providing historical insights, graphs, charts, and medical information, the book details the evolution of childhood illnesses now targeted by vaccines.
- She and Del dive into the financial challenges many doctors face, unable to leave the industry despite facing ugly truths encountered in their profession.
- Dr. Humphries concludes with an optimistic message, highlighting the growing awakening among physicians uniting to advocate for truth.

CLICK TO WATCH

CATHERINE AUSTIN **FITTS** | EP 365

Investment Banker & Economist, Catherine Austin Fitts, discusses the engineered financial coup that is squeezing the middle class through inflation and debt, and how families can protect themselves from what she calls "the great poisoning."

WHAT TO KNOW

- Fitts exposes the top-down engineering behind the current financial coup, aiming to centralize ownership and control of the financial system.
- Emphasizing the significance of cash usage and debt avoidance, Fitts advocates for preserving financial independence.
- Supporting local communities, Fitts recommends investing in community banks as an alternative to large financial institutions.
- Fitts discusses how immigration is being financed and orchestrated to potentially replace populations, contributing to the establishment of a control grid.

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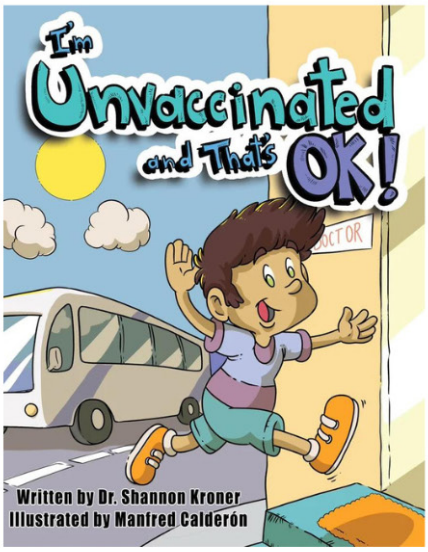

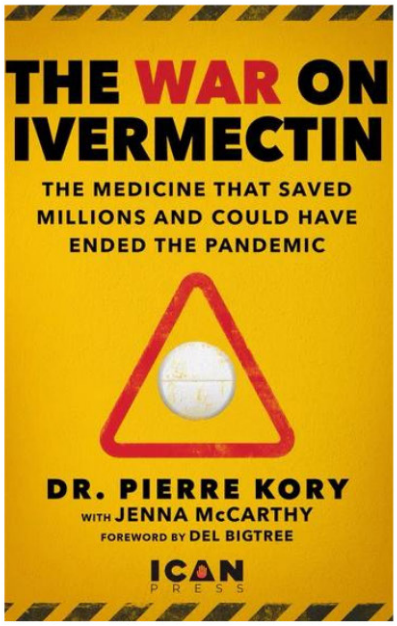

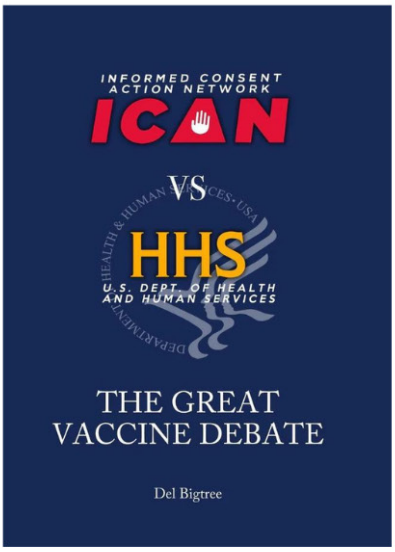

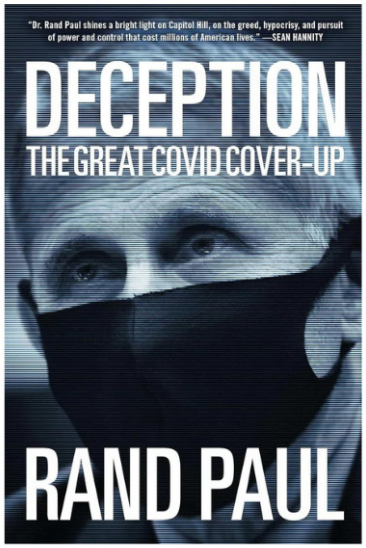

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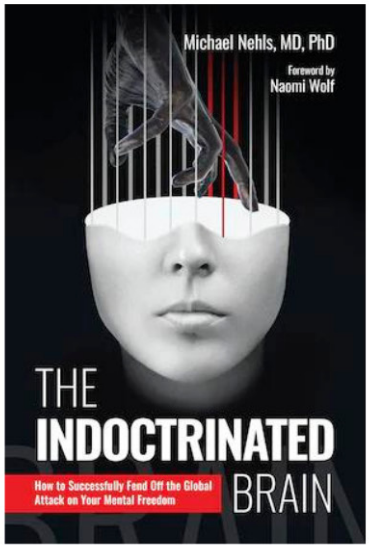

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