The FDA's War On America's Health

Why do so many innovative therapies never see the light of day

A HOMESTEIN-DOCTOR
APR 17, 2026

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Story at a Glance:

•The FDA was established in 1906 in response to public concern over unsafe food and drugs, such as spoiled food and counterfeit products. However, food industry lobbyists gradually gained influence, leading to the removal of the agency's original leader. As a result, numerous harmful food additives were granted "generally recognized as safe" (GRAS) status and continue to be used today.

•In 1962, the FDA was given broad powers to oversee drug safety following the thalidomide incident. Unfortunately, the new regulations created strict standards for drug efficacy that were often selectively enforced, benefiting the pharmaceutical industry. Unfortunately, the FDA increasingly targeted natural therapies, which led to many being erased from history.

•Despite numerous attempts to reform the agency, issues of inefficiency and bias within the FDA persist. This article examines these challenges and suggests potential reforms to improve the agency's role in safeguarding public health.

For most of my life, I've observed the FDA belligerently suppress natural treatments and any unorthodox therapy which threatens the medical monopoly while simultaneously railroading through a variety of unsafe and ineffective drugs regardless of how much public protest the agency meets. Consider this 2004 Senate testimony by the FDA scientist who got Vioxx banned that accurately described exactly what would come to pass with the COVID vaccines two decades later:

As such, I do not hold the FDA in a positive light, especially given that during COVID-19, I (like many others) spent hundreds of hours trying to get the agency to allow the limited use of off-patent therapeutics for COVID-19—all of which ultimately went nowhere due to the unjustifiable roadblocks the agency kept putting up.

Over the past year, especially since Trump's election, I've received many questions about FDA reform. To address the issue properly, I've carefully examined both sides.

In medicine, "sensitivity" refers to a test's ability to correctly identify those who have a condition (e.g., detecting an infection), while "specificity" measures how well the test avoids false positives (i.e., correctly identifying those who don't have the condition). The challenge is that improving one often reduces the other. For example, increasing the PCR cycle threshold in COVID tests made it more likely to detect infections (higher sensitivity), but also increased false positives (lower specificity). This trade-off leads to problems, like breast cancer screenings, where high sensitivity can result in false positives and unnecessary "treatments" for women who don't actually have cancer.

The FDA faces a similar challenge: it must prevent harmful foods and drugs from reaching the market while ensuring useful products aren't withheld. Though this seems straightforward, it's incredibly difficult, and the FDA has often failed at both, even with leadership dedicated to public health.

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Crime Against the Food Law

In the late 1800s, food producers were selling adulterated products, and pharmaceutical companies peddled medicines with secret ingredients like opium and alcohol. Public outrage grew, especially after exposés like Upton Sinclair's The Jungle, which helped spark the 1906 Pure Food and Drug Act. This law gave the Bureau of Chemistry the power to ensure accurate labeling and prevent harmful additives in food.

The director of the Bureau of Chemistry (and thus the first head of the FDA), Harvey Wiley conducted tests on food additives, proving they made healthy volunteers sick. While the public and many scientists supported his findings, the food industry fought back with powerful lobbyists and legal tactics.

Note: the additives Wiley scrutinized were boric acid and borax, salicylic acid (aspirin) and salicylates, benzoic acid and benzoates, sulfur dioxide and sulfites, formaldehyde, sulfate of copper (used to green produce), and saltpeter (nitrates).

Gradually, the food industry hijacked the presidency, and in 1912, Wiley resigned, realizing he could achieve more for America's health as a private citizen than within the government.

Wiley's book "The History of A Crime Against The Food Law" details much of the same abhorrent industry tactics we see happening now. For example, a series of investigative reports recently showed that the processed food industry's lobbyists worked fervently behind the scenes to block RFK's nomination and had there not been widespread public protest, would have stopped us from Make America Healthy Again.

Those tactics also highlight a key point Wiley made—**the only way to create change in this industry is to coax the public at large to demand it, as the moment you rely upon the members of the government to fix it, lobbyists will crush those efforts.**

Generally Recognized as "Safe"

Many food additives are "generally recognized as safe" (GRAS), meaning they're widely used without regulation. Wiley faced two major issues: food industry counterfeiting and harmful additives. The industry often faked products to cut costs, like selling grain alcohol as whiskey or using polluted waters to enlarge oysters.

Despite evidence of harm, the food industry claimed these additives were essential for production, even though competitors showed higher-quality (and ultimately more profitable) products could be made without them. Wiley also warned that chronic exposure to additives could cause long-term health issues, such as organ damage and aging.

Sadly, his concerns were ignored as industry influence grew and he was unable to ban them—rather they were eventually reclassified as "generally recognized as safe." As a result, these "safe" additives have contributed to widespread chronic illness in society.

*Note: these additives included sodium benzoate, sulfur dioxide, alum (potassium aluminum sulfate), sulfur dioxide, saccharin, modified corn sugar, saccharin, and nitrogen bleached flour —many of which were linked to cancer. Sadly, since 2000, **nearly 99 percent** of new food chemicals added to the food supply chain have exploited the GRAS loophole. I believe the widespread use of aluminum in processed foods is particularly detrimental (due to it greatly impairing the physiologic zeta potential and causing micro-clotting throughout the body), and provides a key explanation for why you often see certain rapid improvements in individuals once they stop eating processed foods and their additives.*

The Kefauver–Harris Amendment

In the years that followed Wiley's departure, the handicapping of the FDA continued. As such, the FDA agent assigned to the morning sickness drug thalidomide could only stall but not reject it—a tactic that prevented catastrophic birth defects across America. A 1962 amendment was then passed, giving the FDA the power to block unsafe drugs.

This law gave the FDA excessive power, slowing drug approval and causing mismanagement. It also required "well-controlled" trials for drug approval, which **the FDA defined** as expensive double-blind randomized controlled trials (RCTs). This:

- Elevated RCTs, making drug approval a "pay-to-play" system, with approval costs soaring to 0.98-4.54 billion.[1,2]
- Created bias, as RCTs cost so much they inevitably produce results in favor of their sponsor (which often outweigh any benefit of their expensive "controlled" design).
- Sidelined smaller, effective observational trials, which, being affordable, are feasible for investigators to conduct without pharmaceutical sponsorship and can yield the same results as large RCTs (**proven by a 2014 Cochrane Review**).
- Stifled innovative therapies, as unorthodox treatments lacking costly RCTs were dismissed. As a result, medical innovation in the U.S. slowed, with scientists financially pressured to avoid challenging existing paradigms, leading to fewer groundbreaking discoveries despite advancing technology.

Because the FDA had rapidly expanded in numerous directions it was not prepared for, it subsequently frequently failed to fulfill its primary responsibilities (e.g., taking something harmful off the market), and it simultaneously took things away Americans actually wanted. This in turn led to numerous committees investigating the FDA (e.g., Commissioner Lay's Kinslow report of his agency's serious shortcomings) and key officials with integrity like Lay being kicked out, all of which were encapsulated a series of scathing articles that were published by the New York Times in 1977.

In my eyes, the most important thing about this period of FDA reforms was that the FDA was the most complained about agency in the government. Congress made numerous attempts to fix it (as did ethical FDA officials)—**but nothing was ever solved.**

The DMSO Saga

Over the last seven months, I've begun exploring a remarkable forgotten side of medicine—DMSO. This simple and freely available natural chemical is incredibly effective at treating a variety of often "incurable" conditions, including many that are otherwise impossible to treat including:

- Strokes, paralysis, a wide range of neurological disorders and circulatory disorders.
- Chronic pain and a wide range of tissue injuries.
- Many autoimmune, protein and contractile disorders.
- Head conditions, such as tinnitus, vision loss, dental problems, and sinusitis.
- A wide range of internal organ diseases.
- Acute and chronic infections including shingles and herpes.
- Many skin conditions including acne, herpes, hair loss and varicose veins.
- Many aspects of cancer, and when used in combination with other therapies, directly treating challenging cancers.

Likewise, since publicizing this research, I've received over two thousand reports from readers who then took it and had almost unbelievable results **that precisely match what many reported in the 1960s and 1970s.**

This all raises a simple question. How is it that no one knows about DMSO or that an agent that could dramatically reduce the need for opioids or prevent millions with stroke and spinal cord injury from having a life of disability never saw the light of day?

That's because as DMSO rapidly spread across America in the 1960s, the FDA reversed its initial positive stance, declaring DMSO dangerous without evidence. This pivot was initially prompted by the FDA not wanting to have to process a flood of new drug applications, and then evolved into being done to protect the status quo and to justify the FDA's newfound police powers. Despite extensive safety studies showing DMSO posed no risk to humans and numerous Congressional hearing being held to legalize DMSO, for decades, the FDA continued to demonize it, claiming a lack of evidence for efficacy (as DMSO's characteristic effects make blinded trials with it impossible). Because of this, DMSO only became available decades later after the public got fed up with the FDA targeting natural medicines and the 1994 Dietary Supplement Health and Education Act was enacted (which removed the FDA's ability to regulate natural medicines and conduct police like raids on suppliers).

The FDA's War Against Natural Medicine

Shortly before the election, RFK Jr. gave what I considered to be one of the most important statements in the entire campaign:

This tweet touched upon the fact that for decades the American Medical Association has done everything it can to remove life-changing natural therapies from the market that compete with the medical monopoly (e.g., ultraviolet blood irradiation and alternative cancer cures) and the FDA has followed in their footsteps. For example:

GHB: In the 1990s, a life-changing natural sleep aid spread across America that safely cured insomnia—so the FDA banned it. In contrast, sleeping pills block restorative sleep (which is critical for health) and make you 2-5X more likely to die.

Psychedelic Therapy: MDMA-assisted psychotherapy is the only existing effective treatment for veterans with PTSD, but the FDA still blocked its approval despite

compelling "uncontrolled" clinical trials (as it's impossible to have blinded psychedelic sessions). Veterans hence often seek treatment abroad due to FDA restrictions.

Chelation Therapy: EDTA chelation therapy (especially a low doses) is effective for cardiovascular health, but the FDA has consistently targeted it despite the NIH reluctantly proving it worked.

Umbilical Cord Blood Stem Cells: FDA regulations under Biden and Peter Marks made it difficult to offer this life-changing therapy and shut down the companies who provided it.

Sunlight and Health: The dermatology industry has deceptively demonized sunlight as a cause of deadly skin cancers, overlooking its importance for overall health **and cancer prevention**, with studies showing those who avoid sunlight are 60-130% more likely to die.

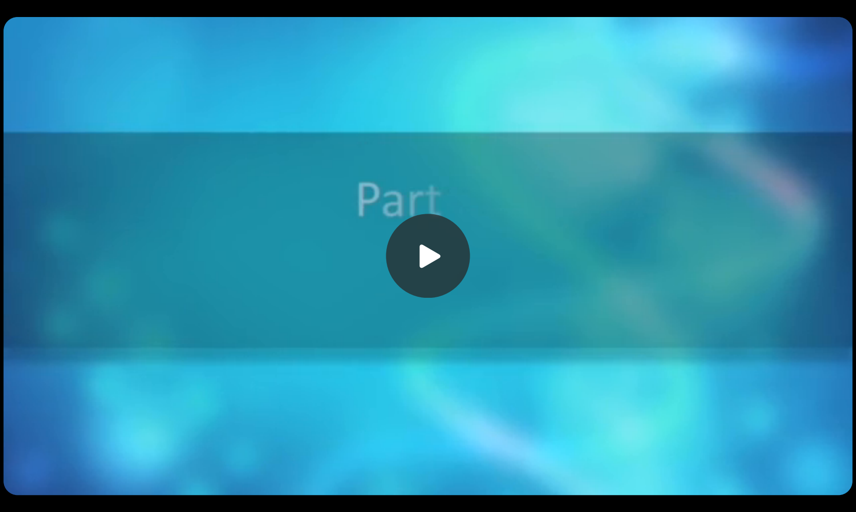
Raw Milk: The FDA has continually targeted raw milk sellers, despite widespread demand for it, no evidence linking it to an increased risk of microbial illness and growing evidence that pasteurization destroys critical nutrients and creates allergens (discussed further here).
Note: pasteurizing milk also makes it go from a zeta potential enhancing substance to one that impairs it (causing congestion throughout the body).

Infant Formula and Seed Oils: The Infant Formula Act of 1980 used outdated science from the 1960s to mandates infant formulas include problematic seed oils so the FDA targets manufacturers who do not include them. These ingredients contribute to childhood obesity, as they impair metabolism and promote rapid weight gain (which sadly has been normalized through the pediatric growth charts pediatricians use).

Vaccine Coverups

Many have been horrified to learn that the FDA and CDC systematically ignored every possible sign the COVID vaccines were dangerous as they pushed it on more and more people (e.g., recently leaked recordings show how stubbornly the head of FDA's vaccine division refused to acknowledge any of the evidence brought forward by a group of permanently injured vaccine recipients).

This severe betrayal of trust from our authorities thus made many ask, "How could this have happened?" In truth, this did not come out of nowhere. Rather it was simply the subsequent escalation of a longstanding tendency by the government to push vaccines they knew were unsafe and ineffective to market.



Vaccine Coverups and Failures by the FDA and CDC:

- **Historical Vaccine Disasters:** Many vaccine-related issues have been ignored or covered up by health authorities, including many deadly "hot lot" incidents.
- **Polio Vaccine Issues:** In the 1950s, defective rushed polio vaccine contained live polio viruses and caused cases of paralysis. Further, it was later discovered that the vaccine contained SV-40, a cancer-causing virus, which was also not disclosed to the public. Around 40-98 million Americans were exposed to SV-40, leading to a massive wave of cancer cases.

Note: to produce the emergency COVID vaccines at scale, a novel manufacturing process was used, which caused them to be contaminated with dangerous DNA-altering bacterial plasmids that contained part of the SV-40 virus.

- **Influenza Vaccine Failures:** In 1945, a government scientist discovered that early flu vaccines were ineffective and unsafe. Despite this, the scientist faced retaliation and the vaccines were released. This led to a 1972 Senate hearing that removed **32 dubious vaccines from the market.**
- **Swine Flu Vaccine Disaster (1976):** The swine flu vaccine, released despite evidence showing the flu posed no risk, caused hundreds of cases of Guillain–Barré syndrome, paralysis, and deaths. Like the Polio vaccines, the FDA was warned by its own scientists these vaccines were not safe but nonetheless pushed them to market. However it occurred in an era when 60 Minutes was willing to do a segment on the disaster (which has numerous remarkable parallels to what happened during COVID-19).

- **Gulf War Syndrome:** During the Gulf War, the FDA waived the protections soldiers had from experimental drugs and U.S. soldiers were given many, including a disastrous anthrax vaccine (which due to its rushed "emergency" production was contaminated). A wave of severe chronic illness (Gulf War Syndrome) followed, **affecting 250,000 veterans** (discussed further here). Despite this, the vaccine remained mandated for decades until a court overturned it in 2004.
- **HPV Vaccine Controversy:** The lucrative HPV vaccine, was approved by the FDA despite red flags throughout the clinical trials (e.g., high rates of autoimmunity, death, and it causing cervical cancer—discussed further here). Once it hit the market, a tsunami of injuries occurred, yet the FDA and CDC continued to relentlessly defend and promote the vaccine.

Other Disastrous Drug Approvals:

- **SSRI Antidepressants:** The FDA approved SSRIs like Prozac despite poor evidence for their effectiveness and known severe side effects including suicidal tendencies, emotional numbness, violent behavior and mass shootings. These risks were concealed from the public, despite extensive complaints and lawsuits later showing those dangers were detected in the trials.
- **Alzheimer's Drugs:** A new and misguided class of Alzheimer's drugs, despite failing to show efficacy and causing dangerous side effects like brain swelling and bleeding in 40% of participants, was approved by the FDA after bypassing an advisory committee's negative vote. The agency's manipulation of the approval process raised red flags, leading to widespread scrutiny.
- **Ozempic and Weight Loss Drugs:** The FDA also approved weight loss drugs like Ozempic without sufficient evidence, promoting them aggressively despite concerns over long-term safety and effectiveness. The drug's promotion has led to it being widely marketed, even for use in children.

In summary, the FDA has an established history of approving unsafe and ineffective vaccines and drugs, often suppressing evidence and protecting corporate interests over public safety.

Conclusion

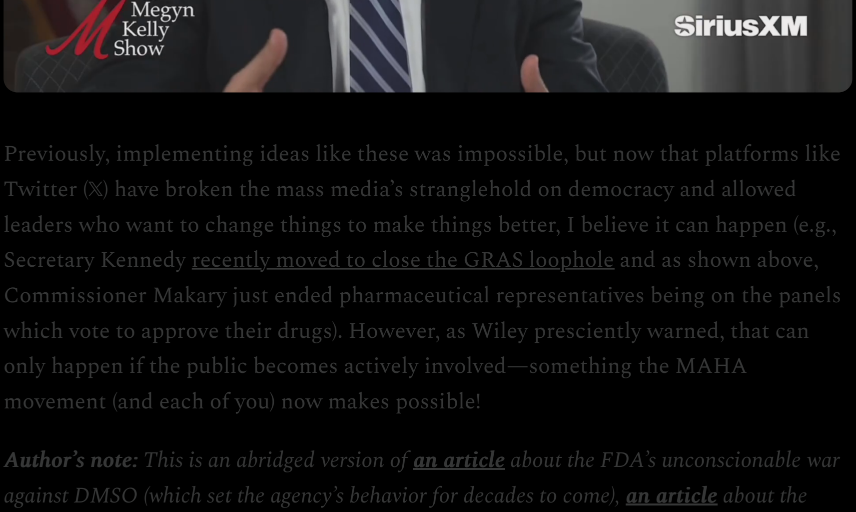
At this point, I've seen a variety of proposals put forward to fix the FDA, which alternate between reforming the agency and scrapping it entirely.

In my eyes, the core dilemmas are:

1. **Inadequate Resources:** Effectively regulating foods and drugs in America is a gargantuan task that exceeds the scope of what the FDA can do.
2. **Corruption and Conflicts of Interest:** The FDA often defers to pharmaceutical companies for drug safety evaluations, leading to a pay-to-play system where approval is influenced by financial contributions rather than scientific integrity.
3. **Lack of Accountability:** Once a drug is approved, the FDA rarely revokes approval, even when evidence of harm emerges.
4. **Selective Prosecution:** The FDA targets natural medicines because they lack the resources of fight back like pharmaceutical companies, creating a (risk-free) facade of protecting the public.

Proposed solutions for restructuring the FDA include:

1. **Conflict of Interest Laws:** Legislation that retroactively nullifies votes or decisions made by regulators or panel members with current or future financial ties to pharmaceutical companies.
2. **Separate Approval Tracks:** Create two approval systems: one for conventional drugs (focusing only on safety) and another for alternative therapies with proven safety but questionable efficacy.
3. **Market-Driven Efficacy:** Allow market demand to determine a drug's efficacy rather than relying solely on FDA approval, as consumers often have better insight into what works.
4. **Public Involvement:** Involve the public and AI systems in reviewing large (anonymized) patient datasets to help identify (frequently overlooked) red flags.
5. **Transparent Data Access:** Make drug trial data publicly available to expose fraudulent or incomplete data, (e.g., the COVID vaccine trials were rife with fraud).
6. **Revocation of Drug Approvals:** Implement mechanisms to revoke approval for unsafe drugs, including allowing state-level bans and empowering courts to remove harmful drugs from the market.



Previously, implementing ideas like these was impossible, but now that platforms like Twitter (X) have broken the mass media's stranglehold on democracy and allowed leaders who want to change things to make things better, I believe it can happen (e.g., Secretary Kennedy recently moved to close the GRAS loophole and as shown above, Commissioner Makary just ended pharmaceutical representatives being on the panels which vote to approve their drugs). However, as Wiley presciently warned, that can only happen if the public becomes actively involved—something the MAHA movement (and each of you) now makes possible!

Author's note: *This is an abridged version of* ***an article*** *about the FDA's unconscionable war against DMSO (which set the agency's behavior for decades to come),* ***an article*** *about the FDA's past vaccine disasters and* ***a longer article*** *which goes into greater detail on the points mentioned here along with other promising therapies the FDA has blacklisted (which can be read* ***here****).*

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Thomas A Braun RPh Apr 17 *Edited*

The bottom line is that the FDA has been captured by those who are supposed to be regulated by the FDA !

That is why we spend almost $5 trillion in medical cost per year, which is twice as much as most other industrialized countries . By addressing the root causes of our health issues in United States we can reduce that cost by $2 trillion and of course that is not acceptable to the status quo. I pray that RFK Jr. Can overcome the status quo that doesn't want the American public to be healthy again.!

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7 replies by A Midwestern Doctor and others

Lynn Fraley, RN, DrPH Lynn Fraley, RN, DrPH Apr 17

Liked by A Midwestern Doctor

Excellent article. This is a stark reminder about why we all need to eat real, unprocessed food and drink clean (not tap) water. Eating animals that have been vaccinated (practically all of them have been) is also important too. This is where free will comes in and accepting the reality that we choose what we eat and feed our families.. The system won't change fast enough to save us.

Looking for natural care options for health challenges is also critically important. Getting past the indoctrination we all grew up with. And not being bullied into conforming and going along with "usual" medical care we sense is not in our best interest.

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