The FDA Has Lost Its Soul

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While uncertainty occurs in every generation and with new policies, certain fundamental principles associated with our federal government's *independent* agencies should *always* remain the same. Public-health decisions, for one, should be made based on evidence and data, not catering to the political whims of whomever is in office.

Unfortunately, D.C. partisan politics are alive and well at the Food and Drug Administration (FDA). The "woke" politics of the Democratic Party have taken over the FDA. It doesn't help that the FDA is physically located just a few miles away from the Washington, D.C., "swamp." That inevitably has led to an infestation of the *politik liberale* in what historically was and should always be a 100-percent non-partisan, science-based, data-driven agency.

Below, I summarize FDA policies and actions (and complacency) over the past two years that ignore an abundance of published, peer-reviewed, hard scientific evidence.

FDA Personnel's Revolving Door With Big Pharma

Specific FDA senior leadership, such the new FDA Center for Drug Evaluation and Research director and ex-Pfizer executive Patrizia Cavazzoni, who magically "leap-frogged" to her senior executive position at the FDA to replace Janet Woodcock, recently approved multiple Alzheimer's drugs that clearly don't work. In addition, other FDA leadership has implemented a debased scientific standard for efficacy or safety of drug approvals in the name of catering to Biden's ideologies that seemed to serve no other purpose other than to benefit Big Pharma at the expense and detriment of American taxpayers.

Cavazzoni is not alone; FDA employees routinely zig-zag between Big Pharma and the FDA in order to obtain promotions, and therefore tend to avoid making draconian Big Pharma decisions that have the potential to prevent their future personal enrichment.

FDA Silent as White House Pays Pfizer 10.6 Billion for Ineffective Covid-19 Drug, Based on a *Pilot Study*

Back in November 2021, the White House paid drugmaker Pfizer nearly $5.3 billion for 10 million treatment courses of its experimental Covid-19 drug paxlovid. Paxlovid is an antiviral combination of *nirmatrelvir* and *ritonavir*. In addition to the $5.3 billion already committed, in January the Biden administration announced an additional "commitment" to order *an additional 10 million doses* (to the tune of an additional $5.3 billion, for a total of $10.6 billion). In December 2021, Pfizer claimed initial study findings showing that paxlovid cut the risk of hospitalization and death by nearly 90 percent in

people with mild to moderate coronavirus infections.

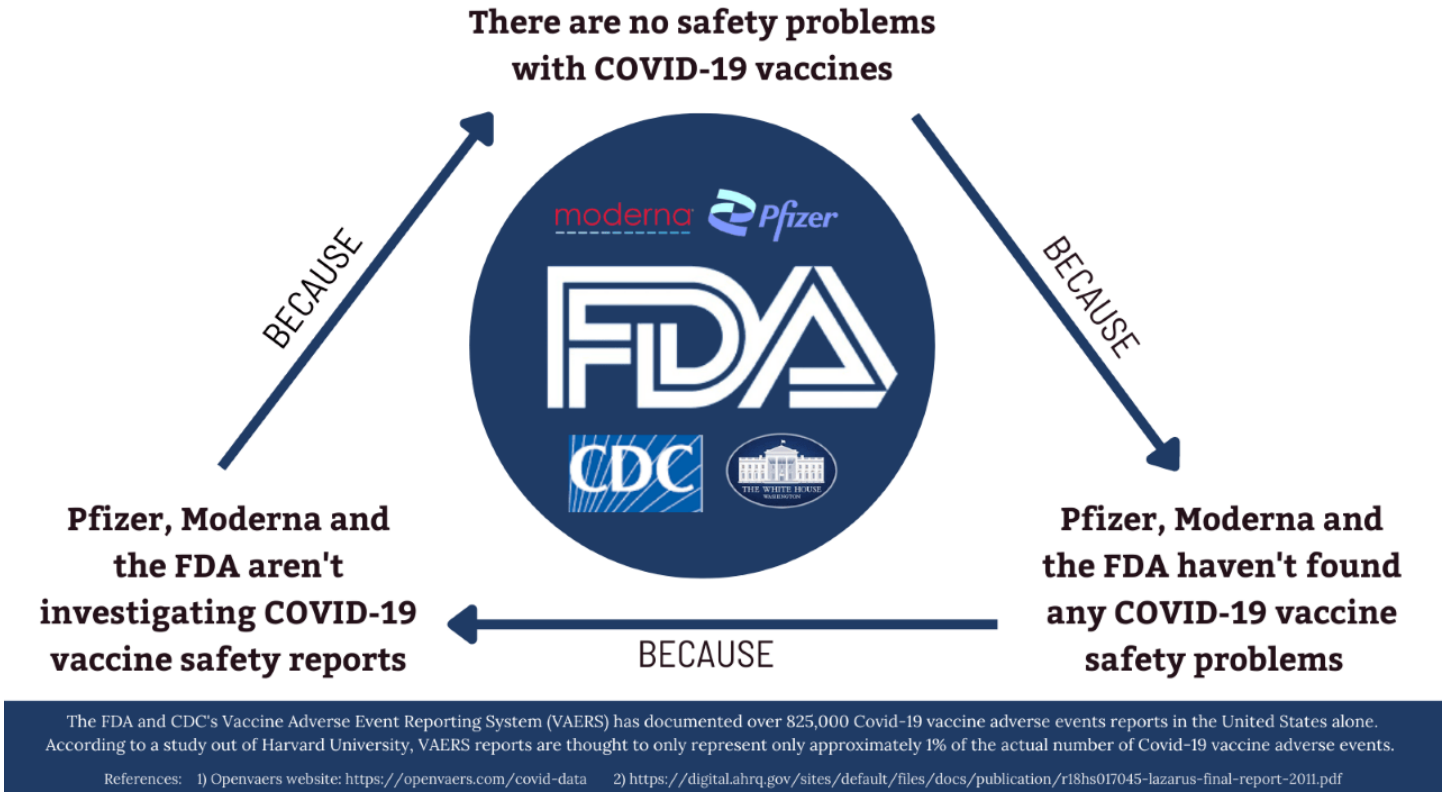
Later, According to Pfizer's official June 14, 2022 press release, results from the Phase 2/3 of the *amended* paxlovid protocol study showed that the drug was a failure, causing Pfizer to terminate its study early. Cavazzoni would have had to permit the last-minute protocol change, but neither Pfizer nor the FDA made any public mention of it, leaving taxpayers to foot the bill for this ineffective drug.

FDA's Dead Silence on Covid-19 Vaccine Safety

The FDA seems to be ignoring serious safety concerns related to the Covid-19 vaccines. There are no less than 1,291 different adverse events in almost 850,000 Americans alone. Since immunization commencement, worldwide there have been over 28,000 *deaths*, and 230,000 *serious* injuries verified to have been directly associated with vaccine administration. Fairly well-known, myocarditis and pericarditis are clear adverse events associated with mRNA Covid vaccine administration that can easily be diagnosed with echocardiograms and can sometimes be treated by inexpensive pharmacology and bedrest. But for that to happen, clinicians must be warned.

More recently, blood-clotting condition cerebral venous thrombosis (CVT), which can cause serious neurological incapacitations, was found to be *significantly* associated with mRNA Covid vaccination, according to a major study in published in the medical journal *Vaccines*.

The FDA (along with Pfizer and Moderna) have done *absolutely zero* to update official labeling or otherwise warn Americans of established risks. Indeed, the FDA's homepage is still actively promoting Covid-19 vaccines and boosters, even though they seem to do little to nothing to prevent infections or transmission from existing mutations of Covid-19, including "long haul" Covid. As a drug epidemiology expert, I beleive it is incumbent on the FDA to balance its promotion of vaccines with informing of the risks.



The FDA has failed to comment on very recent publications that have detailed the more serious

potential for existing mRNA vaccines to cause disease reoccurrence by reactivating otherwise latent conditions in one's immune system. While still hypothetical, the reasoning in the articles is sound and worthy of further examination by our erstwhile "non-political" drug experts at the FDA.

FDA Pushes Covid-19 Vaccines in Infants and Kids Based on Limited Efficacy and Well-established Risks

In May of 2022, the FDA approved a booster dose of the Pfizer Covid-19 shot for children five through 11 years of age. On top of that, in June 2022, America became the only country on the planet that allows and promotes Covid-19 mRNA vaccines for kids as young as six months old.

Much like Cavazzoni's Alzheimer's disease approval, vaccines for infants contradicts clear clinical findings as research shows that the shots provide no benefit to adults, and can, in fact, cause serious adverse effects, including death. To cater to the White House's "boosters for everyone" agenda, FDA is basing its decisions on a very small study that had a very low bar for effectiveness. (For more specifics on the shortcomings of boosters in children, see the initial summary by Dr. David Wiseman.) The low bar set by the FDA will likely be *even lower* in the real world because drug trials use an "enriched" (i.e., extremely healthy) population.

FDA Ignores Natural Immunity

The FDA has remained silent on the White House's mandates to vaccinate individuals who already have already acquired seropositive antigenic natural immunity from Covid-19 through a previous infection. The concept of acquired natural immunity following infection was established half a century ago. In April 2022, Moderna confirmed the same with its own 30,000 person study. Bottom line for almost all people: *If you have had Covid-19, you do not need vaccines or boosters due to rules of natural immunity.*

FDA's Lack of Transparency

The FDA refused to formally release vaccine-safety findings and all other public-health information surrounding mRNA decision making. It even defended the lack of transparency in court. Secrecy on public-health issues leads to a lack of trust by the public and opposition to future critical new initiatives.

FDA Commissioner Spreads Misinformation

FDA Commissioner Dr. Robert Califf attempted to misinform Americans about what the leading cause of death is in the United States, ironically spreading misinformation when he stated, "misinformation is now our leading cause of death" in the United States. He was promptly corrected by a fellow liberal CNN reporter with a *bachelor's degree in journalism*. On live television, Califf had to admit that no studies existed that could verify his claim. Yikes!

The FDA also purveyed misinformation to oppose hydroxychloroquine and ivermectin, which are legitimate treatments for Covid-19. For example, the FDA mocked Americans and physicians who had prescribed ivermectin simply because it was a recommendation made under President Trump's administration. The FDA even sent out a tweet implying that ivermectin is only used for animal deworming: "You are not a horse. You are not a cow. Seriously, y'all. Stop it" the agency said.

> You are not a horse. You are not a cow. Seriously, y'all. Stop it. https://t.co/TWb75xYEY4
>
> — U.S. FDA (@US_FDA) August 21, 2021

"Transgenderism"

In contrast to ivermectin and hydroxychloroquine, the FDA has been silent regarding the administration of puberty-blockers and cross-sex hormones that alter children's natural pituitary function, and the fact that unauthorized "off label" administration may render children permanently altered and infertile. How about an FDA webpage stating: "You are not a *female*, you are a *male*. Seriously, y'all … *Stop it*."

The FDA again was silent as Rachel Levine, the transgender assistant secretary for health at the Department of Health and Human Services, publically promoted, without evidence of their safety, off-label use of "gender transitioning" drugs for children, outrageously declaring, "There is no argument among medical professionals … about the value and the importance of gender-affirming care." Obviously, a comprehensive evidence-based, academic debate on using dangerous chemicals in an attempt to modify one's gender would very clearly show how absurd of an idea this is, but *not even one* of the FDA's approximately 20,000 employees could be bothered to speak out.

The FDA also remained *conspicuously* silent as the Department of Health and Human Services' Office of Population Affairs went on to circumvent the entire FDA and issued a standard of care "guidance document" called "*Gender Affirming Care in Young People*," raising many unanswered questions due to the lack of scientific basis supporting it.

FDA-caused Baby Formula Shortage

The FDA falsely accused baby-formula manufacturer Abbott of causing infections in infants. In a long series of tweets (which are worth reading), Abbott affirmed, "A comprehensive investigation by Abbott, FDA and CDC found no evidence that our formulas caused infant illnesses." Still, the FDA kept Abbott shut down even after they found no infected formula. After pointing fingers at everyone but themselves, the Biden administration was forced to purchase formula from other countries where it is unknown if FDA inspections have ever even occurred due to lack of FDA transparency. Along the same lines, the White House continues to distribute this formula to America's infants without performing any type of safety testing. In the meantime, the shortage has resulted in countless hospital admissions of starving infants.

The Golden Age of Public Heath Stupidity

In summation, the FDA's indifference to evidence-based science and medicine has thrust us into what I call the "golden age" of public health stupidity, which the FDA has contributed to with more than its fair share of silence, inaction, and scientifically indefensible decisions. Of course, it is worth noting that not all divisions or individuals at the FDA are making poor decisions, and not all employees in divisions who have made questionable decisions have agreed with unjustifiable decisions.

Unfortunately, it has come to the point that I hardly recognize the FDA today — the agency I was twice proud to work for throughout my career. Sadly, multiple, major divisions of FDA and its senior leadership team have become nothing more than partisan shills and bullies seeking only to enrich themselves while selectively ignoring public health and hard scientific findings for the purpose of blindly serving the Biden White House. In turn, they relegate Americans to a terrifying, science-defying agenda.

Under Biden, every single bad decision at the FDA has been addressed with spin, closed ranks, finger-pointing, excuses, obfuscation, withholding of documents, and accusing critics of race-based motives.

Has anyone at the FDA been held accountable for their actions? Answer: no. In fact, the Democrats,

unbelievably, recently voted to give FDA employees a collective $28 million salary raise!

Even worse, this is nowhere near the end of the "stupidity." I predict many, *many* more partisan, unjustifiable decision-making under the Biden White House, as the FDA remains unaccountable, and pushes forward with its blitzkrieg against medical science and public health.