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How Vaccine Trials Routinely Rig the Results: The FDA's "Future Framework" to Allow "Reformulated Covid Injections"

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The U.S. Food and Drug Administration has adopted a "Future Framework" scheme that will allow Pfizer and Moderna to reformulate and release updated COVID shots without conducting any additional clinical trials

This Framework will allow completely untested, reformulated COVID injections to be churned out; the elimination of clinical trial requirements may also, over time, be expanded to other vaccines and drugs

The "Future Framework" will almost certainly guarantee that future COVID shots be less effective and/or more dangerous, because adding more mRNA (to cover more variants) will result in higher adverse event rates, and less mRNA per variant will lower the effectiveness

Over the years, we've seen plenty of examples of how vaccine trials are being rigged, and that the "Future Framework" is an extreme expansion and formalization of that rigging

Not recording injuries, or recording them improperly, are a common tactic used to fudge results and make a vaccine appear safer than it is. Another common strategy is to exclude any parameter that turns out to be problematic, and that includes participants who are injured. Because this is such a common trick, the fact that 3,000 of the 4,526 children (aged 6 months through 4 years) enrolled in Pfizer's pediatric COVID trial were excluded is a huge red flag

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In a rather shocking turn of events, the U.S. Food and Drug Administration sneaked in a "Future Framework"[1] scheme that will allow Pfizer and Moderna to reformulate and release

updated COVID shots without conducting any additional human clinical trials, other than what's already been done.[2,3,4]

FDA Rewrites the Rules on the Fly

A vote on the Framework was scheduled to be taken June 28, 2022, by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), but while the VRBPAC approved (19-2) a bivalent COVID shot for fall 2022,[5] the expected voting on the Framework, specifically, didn't seem to take place — only it DID.

As it turns out, we've been bamboozled yet again by an agency that keeps rewriting the rules on the fly. Toby Rogers, Ph.D. — a political economist whose research focus is on regulatory capture and Big Pharma corruption[6] — explains how they sneaked this one by us:[7]

> "Yesterday [June 28], the FDA's Vaccines and Related Biological Products Advisory Committee approved a bivalent COVID-19 shot with the Wuhan strain and the Omicron variant …
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> At the meeting, the manufacturers (Moderna, Pfizer, and Novavax) were asked what their production timelines are… and they said out loud, 'So long as we don't have to provide any clinical data, we'll have them ready by fall.' No one had a problem with that …
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> Wait, hold up, I thought the FDA was voting on the Future Framework yesterday? The policy question was whether reformulated COVID-19 shots would be treated as new molecular entities (which they are) in which case they should be subject to formal review or whether reformulated shots would be treated as 'biologically similar' to existing Covid-19 shots and be allowed to skip clinical trials altogether.
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> Apparently the FDA did not have the votes to just pass this as a policy question. If you ask anyone whether reformulated mRNA represents a new molecular entity, well of course it is, so that would require formal regulatory review.
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> What the FDA did instead was to smuggle the policy question in disguised as a vote about reformulated 'boosters' for the fall.
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> In essence, the FDA just started doing the Future Framework (picking variants willy nilly, skipping clinical trials) and essentially dared the committee members to turn down a booster dose — knowing that all of the VRBPAC members are hand-picked because they've never met a vaccine they did not like.
>
> So of course only two people on the committee had the courage to turn down a booster dose — even though it was based on this preposterous process (that was never formally adopted) where there was literally no data at all … By stealth, the FDA replaced a system based on evidence with a system based entirely on belief."

Worst Idea in the History of Public Health

A decision to release reformulated mRNA shots without additional clinical trials is the worst

development yet, by far, and has the power to radically change medical science moving forward.

Not only will completely untested COVID injections be churned out, but this "framework" may also, over time, be widened to include other vaccines and drugs that drug makers may want to tinker with. Heck, it could even lower standards for drug trials in general, which historically have required at least 10 years of multi-phase testing.[8]

In a May 31, 2022, Substack article, Rogers explained the origin and purpose of this incredibly dangerous proposal:[9]

> "Pfizer and Moderna have a problem — their mRNA COVID-19 shots do not stop infection, transmission, hospitalization, nor death from the SARS-CoV-2 virus. Everyone knows this … Pfizer and Moderna are making about $50 billion a year on these shots and they want that to continue.
>
> So they need to reformulate the shots. Maybe target a new variant, maybe change some of the ingredients — who knows, these shots don't work so it's not clear what it will take to get them to work. This is a problem because reformulated shots mean new clinical trials and new regulatory review by the FDA.
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> There is a decent chance that any reformulated shot might fail a new clinical trial and the public is deeply skeptical of these shots so the scrutiny would be intense.
>
> So Pfizer and Moderna have figured out a way to use regulatory capture to get their reformulated COVID-19 shots approved WITHOUT further clinical trials. Their scheme is called the 'Future Framework' … The purpose of the 'Future Framework' is to rig the COVID-19 vaccine regulatory process in perpetuity in favor of the pharmaceutical industry.
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> If this 'Future Framework' is approved all future COVID-19 shots, regardless of the formulation, will automatically be deemed 'safe and effective' without additional clinical trials because they are considered 'biologically similar' to existing shots.
>
> This is literally the worst idea in the history of public health. If you change a single molecule of mRNA in these shots it will change health outcomes in ways that no one can anticipate. That necessarily requires new clinical trials — which is what the FDA is proposing to skip …
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> The FDA authorized COVID-19 shots for kids on June 14 and 15. So if the FDA approves the 'Future Framework' on June 28th, the shots that will be given to kids (and Americans of all ages) in the fall will be the reformulated shots that skipped clinical trials."

SARS-CoV-2 Is a Horrible Vaccine Candidate, and They Know It

Before we continue, let's review one important factor that tends to get lost. As explained by Rogers,[10] "Viruses that evolve rapidly are bad candidates for a vaccine," for the simple reason that they mutate faster than vaccine development can keep up with.

This is why we don't have a vaccine against the common cold. It's' also why all previous

attempts to develop a coronavirus vaccine failed. Those studies never made it past animal trials. The vaccines caused antibody-dependent enhancement, making the animals sicker than normal when exposed to the virus.

Most people are unaware that SARS-CoV-2 mutates at a rate that is two to 10 times faster than the influenza virus,[11,12] and these mutations can considerably reduce vaccine effectiveness. Indeed, we've seen this both with the seasonal flu vaccine and the COVID shots. When you vaccinate against a rapidly mutating virus you also run the risk of pressuring it into a more virulent and/or vaccine-resistant form. As noted by Rogers:

> "The FDA's 'expert advisory committee' (VRBPAC) met on April 6, 2022 to discuss the 'Future Framework' for the first time. All of the committee members agreed that COVID-19 shots are not working, that boosting multiple times a year was not feasible, and that the shots need to be reformulated.
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> They also unanimously agreed that there are no 'correlates of protection' that one can use to predict what antibody levels would be sufficient to prevent SARS-CoV-2 infection."

By now, the VRBPAC must know that the only way forward, really, is to withdraw the COVID shots and focus on therapeutics. But they're not doing that. Instead, they're doubling down on a failed strategy. On top of that, they're making the situation even worse by foregoing clinical trials. There's no doubt in my mind that this will pose grave risks to public health. I agree with Rogers, who said:[13]

> "Think about it. The more mRNA you put into a shot, the higher the adverse event rate (as the genetically modified mRNA hijacks the cell and starts cranking out spike proteins). So if Pfizer and Moderna put more mRNA into these shots (in order to cover multiple variants) adverse event rates will skyrocket.
>
> But if Pfizer and Moderna put less mRNA per variant into a shot (in order to keep the total amount of mRNA at 100 mcg for Moderna and 30 mcg for Pfizer) then the effectiveness against any one particular variant will be reduced. The Future Framework is 100% guaranteed to fail."

They're Fudging Effectiveness Too

The FDA also insists that, due to time constraints, evaluation of effectiveness must rely on "measures other than actual health outcomes."[14] In other words, whether the shots actually lower your risk of severe illness, hospitalization and death will have no bearing.

The only measure that will be taken into account is whether or not the jab triggers a rise in antibody levels, which has never been proven to offer significant protection. This also means that as long as antibody levels are through the roof, the death rate could be through the roof too, and the jabs will still be used, because that's not part of the equation.

The focus on antibody levels to the exclusion of everything else may actually be backfiring. Data from Moderna's trial suggest the shot actually makes you more prone to repeat infections due to the inhibition of antibodies against a particular portion of the virus.

A preprint study[15,16] posted on medRxiv April 19, 2022, found adult participants in Moderna's trial who got the real injection, and later got a breakthrough infection, did not generate antibodies against the nucleocapsid — a key component of the virus — as frequently as did those in the placebo arm.

Placebo recipients produced anti-nucleocapsid antibodies twice as often as those who got the Moderna shot, and their anti-nucleocapsid response was larger regardless of the viral load. As a result of their inhibited antibody response, those who got the jab may be more prone to repeated COVID infections.

These findings are further corroborated by data from the U.K. Health Security Agency. It publishes weekly COVID-19 vaccine surveillance data, including anti-nucleocapsid antibody levels. The report[17,18] for Week 13, issued March 31, 2022, shows that COVID-jabbed individuals with breakthrough infections indeed have lower levels of these antibodies.

There is a whole lot we do not know about this virus, these shots, and the interaction between them. So, allowing the vaccine makers to reformulate the shots without clinical trials is a recipe for disaster.

For clarity, antibodies thought to offer protection against COVID are the antibodies against the spike protein and the receptor binding domain (RBD).[19] But this study suggests antibodies against other parts of the virus may play an equally important role, and at least one of them is being inhibited rather than boosted, resulting in a situation where you can get reinfected time and again.

The moral of the story here is that there is a whole lot we do not know about this virus, these shots, and the interaction between them. So, allowing the vaccine makers to reformulate the shots without clinical trials is a recipe for disaster.

Vaccine Trials Are Routinely Rigged

Over the years, we've seen plenty of examples of how vaccine trials are being rigged, and what the FDA is now proposing is really just an extreme expansion and formalization of that rigging. For example, in 2017, an eight-month investigation by Slate magazine[20] revealed that HPV vaccine trials "weren't designed to properly assess safety."

In an internal report about Gardasil 9, obtained through a Freedom of Information Act (FOIA) request, the European Medicines Agency (EMA) had actually called attention to some of these problems, saying Merck's approach was "unconventional and suboptimal" and that it left "uncertainty" about Gardasil's safety. Yet nothing was done about it.

Then, in 2020, Dr. Peter Gøtzsche — a Danish physician-researcher, professor and cofounder of the Cochrane Collaboration and the Nordic Cochrane Centre — and two colleagues published a review and meta-analysis[21] of the data from 24 HPV vaccine trials. Slate magazine reported those findings as well.[22]

Again, the conclusion was that HPV trials had put safety on the back burner by failing to conduct proper safety testing. Still, to quote Slate magazine, "The findings don't affect official recommendations to get vaccinated." According to Gøtzsche and his coauthors:[23]

> "We judged all 24 studies to be at high risk of bias. Serious harms were incompletely reported for 72% of participants (68,610/95,670). Nearly all control participants received active comparators (48,289/48,595, 99%). No clinical study report included complete case report forms …
>
> At 4 years follow-up, the HPV vaccines decreased HPV-related cancer precursors and treatment procedures but increased serious nervous system disorders (exploratory analysis) and general harms.
>
> As the included trials were primarily designed to assess benefits and were not adequately designed to assess harms, the extent to which the HPV vaccines' benefits outweigh their harms is unclear."

Not recording injuries, or recording them improperly (such as listing an injury as a preexisting condition, for example), is a common tactic used to fudge results and make a vaccine appear safer than it is. Another common strategy is to exclude any parameter that turns out to be problematic, and that includes participants who are injured.

Because this is such a common trick, the fact that 3,000 of the 4,526 children (aged 6 months through 4 years) enrolled in Pfizer's pediatric COVID trial were excluded is a huge red flag.[24] Even more suspicious is the fact that Pfizer doesn't explain why two-thirds of the children were dropped.

World Health Organization Is Behind Idea to Toss Safety

The FDA did not invent the "Future Framework" idea all by itself, however. According to Rogers, the World Health Organization and other predictable names are the real masterminds:[25]

> "I did not understand until … I started to write this article, that this entire 'Future Framework' is actually coming from the WHO. The Bill & Melinda Gates Foundation is the biggest voluntary contributor to the WHO. So Gates is likely directing the play.
>
> Gates requires that WHO use the McKinsey consulting firm so this is probably a McKinsey operation (and McKinsey also works for Pharma so this is a huge conflict of interest). As Naomi Wolf points out, the involvement of the WHO also raises troubling questions about the influence of the Chinese Communist Party over this process.
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> As far back as January, the WHO/Gates/McKinsey junta realized that these shots were terrible and so they decided to use that as an opportunity to seize even more power and control.
>
> The WHO set up a Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) to implement these Orwellian 'Future Frameworks' across the developed world to lower manufacturing costs for Pharma and avoid bothersome health data that might hurt profits. All the messaging we have seen from the FDA and leaked to the press was initially developed and released by TAG-CO-VAC."

We Must Reject All Future mRNA Shots

This COVID debacle — from its fraudulent PCR test beginnings, to these devastatingly

dangerous COVID shots and the intentional negligence by vaccine makers and health authorities — is the most shocking example of a criminal enterprise I've ever seen. Nothing else even comes close.

And the proverbial cherry on top that proves none of it is accidental or caused by ignorance is this sneaky and underhanded erasure of the requirement of clinical trials for all future COVID shots in the name of expedience. COVID-19 is not a death sentence — far from it. So, there's no need for expedience. And since there's no need for expedience, there's also no need to accept collateral damage in the form of COVID jab-related injuries and deaths.

So, why are they doing this? That's the million-dollar question, and the most obvious answers are all disturbing in the extreme. At best, they don't care how many people, including children, suffer and die. At worst, the intention is to dramatically reduce the population through adverse effects on fertility, reduction of life span and near-term death.

To save ourselves, indeed, to save mankind, we must reject all mRNA shots, present and future. And not just the COVID shots but also any others that are in the pipeline, because if they're willing to skip the most basic of safety protocols once, you can be sure they'll do it again.

Skimping on safety assessment has been the secret norm for decades, and now they're attempting to formalize that process using stealth and subversion. The initial COVID shots haven't even completed their trials yet, and they want you to believe those incomplete trials are sufficient to "prove" all future reformulations are "safe and effective" too!

We've also seen how the U.S. Centers for Disease Control and Prevention came out saying they've seen no safety signals in the data, only to later discover that the reason they didn't find any was because they never actually looked.[26]

It's nothing short of insanity, and over the past two years, government agencies have proven they are not going to put a stop to the madness. No, they're going to take this experiment as far as it'll go, and that means, until people everywhere say "No more," and leave all their stockpiles to rot.

There's Help if You've Taken the Jab

In closing, if you've already taken one or more COVID jabs and now regret it, first, the most important step you can take is to not take any more shots, and that includes conventional vaccines and any other mRNA or gene-based injections as well.

Next, if you suspect your health may have been impacted, check out the Frontline COVID-19 Critical Care Alliance's (FLCCC) post-vaccine treatment protocol, I-RECOVER,[27] which you can download from covid19criticalcare.com in several different languages.

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Notes

[1] FDA Briefing Document June 28, 2022

[2, 14] The Defender June 27, 2022

[3] The Epoch Times June 28, 2022 (Archived)

[4] New York Times June 27, 2022 (Archived)

[5] The Defender June 29, 2022

[6] Brownstone Institute June 22, 2022, Author's Bio

[7] uTobian June 29, 2022

[8] Phrma.org Biopharmaceutical research and Development

[9, 10, 12, 13] uTobian Substack May 31, 2022

[11] VRBPAC Meeting Comments by Trevor Bedford, April 6, 2022

[15] medRxiv April 19, 2022 DOI: 10.1101/2022.04.18.22271936

[16, 18] The Defender May 4, 2022

[17] UK Health Security Agency COVID-19 Vaccine Surveillance Report Week 13

[19] CDC.gov MMWR December 10, 2021; 70(49): 1700-1705

[20] Slate December 17, 2017

[21, 23] BMC Systematic Reviews 2020; 9: article number 43

[22] Slate March 11, 2020

[24] Rumble June 17, 2022

[25] uTobian June 26, 2022

[26] Jackanapes Substack June 16, 2022

[27] FLCCC I-RECOVER Post-Vaccine Treatment Protocol (PDF)

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