The FDA's Proposed "Future Framework" is the Worst Idea in the History of Public Health

I. Pfizer and Moderna's Dilemma

Pfizer and Moderna have a problem – their Covid-19 shots do NOT work. Everyone knows this. The shots do not stop infection, transmission, hospitalization or death. Over half a billion doses of this product have been injected into Americans in the past 17 months and these shots have made NO discernible impact on the course of the pandemic. Far more Americans have died of coronavirus *since* the introduction of the shots than before they were introduced.

Pfizer and Moderna are making $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. 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" and it will be voted on by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on June 28.

II. Doubling down on a failed strategy

Viruses vary by region. At any given time, the influenza strain circulating in England is different than it is in South Africa which is different than in southeast Asia. However, pharmaceutical companies prefer to create one-size-fits-all vaccines in order to decrease manufacturing costs and thereby increase profits. So the W.H.O. and public health agencies around the world (including FDA and CDC) have created a vast "influenza surveillance network" that identifies the different influenza strains in circulation. Then they engage in an elaborate theatrical performance called the "flu strain selection process" where they select four influenza strains that will go into the one-size-fits-all flu vaccine used throughout the world that year.

This carefully choreographed process is a complete and total failure. This is not a surprise – using a one-vaccine-fits-all approach to prevent a rapidly evolving virus that varies by region is never going to work. Lisa Grohskopf from the CDC's Influenza Division reports that last year the flu shot was somewhere between 8% and 14% effective (based on data from

seven sites that participate in the U.S. Flu Vaccine Effectiveness Network).

Interim vaccine effectiveness against influenza A and A/H3N2 among patients aged 6 months and older, US Flu VE, 2021–22

	Influenza positive		Influenza negative		Vaccine Effectiveness			
					Unadjusted		Adjusted[1]	
Influenza A	N vaccinated /Total	(%)	N vaccinated /Total	(%)	VE %	95% CI	VE %	95% CI
Ages ≥6 mos	60/147	41	1253/2611	48	25	(-5 to 47)	8	(-31 to 36)
A/H3N2[2]								
Ages ≥6 mos	44/119	37	1110/2373	47	33	(2 to 54)	14	(-28 to 43)

But a case study of a flu outbreak at the University of Michigan between October and November 2021 found that the effectiveness of the flu vaccine was literally zero.

- Preliminary VE: 0% (CI: -25% to 20%)

Over the last thirty years, the federal government has paid out more compensation for adverse events in connection with the flu shot than any other vaccine – so we know that the shot comes with a high rate of harm. Given that the flu shot does not stop the flu, the harms thus outweigh the benefits.

In a sane world, the WHO, FDA, and CDC would admit that they made a strategic mistake and then change course to find better ways to support the human immune system. But we don't live in a sane world. Instead, the FDA is proposing to take the failed flu strain selection process and apply it to future Covid-19 shots.

The FDA knew that Covid-19 shots would fail but they proceeded

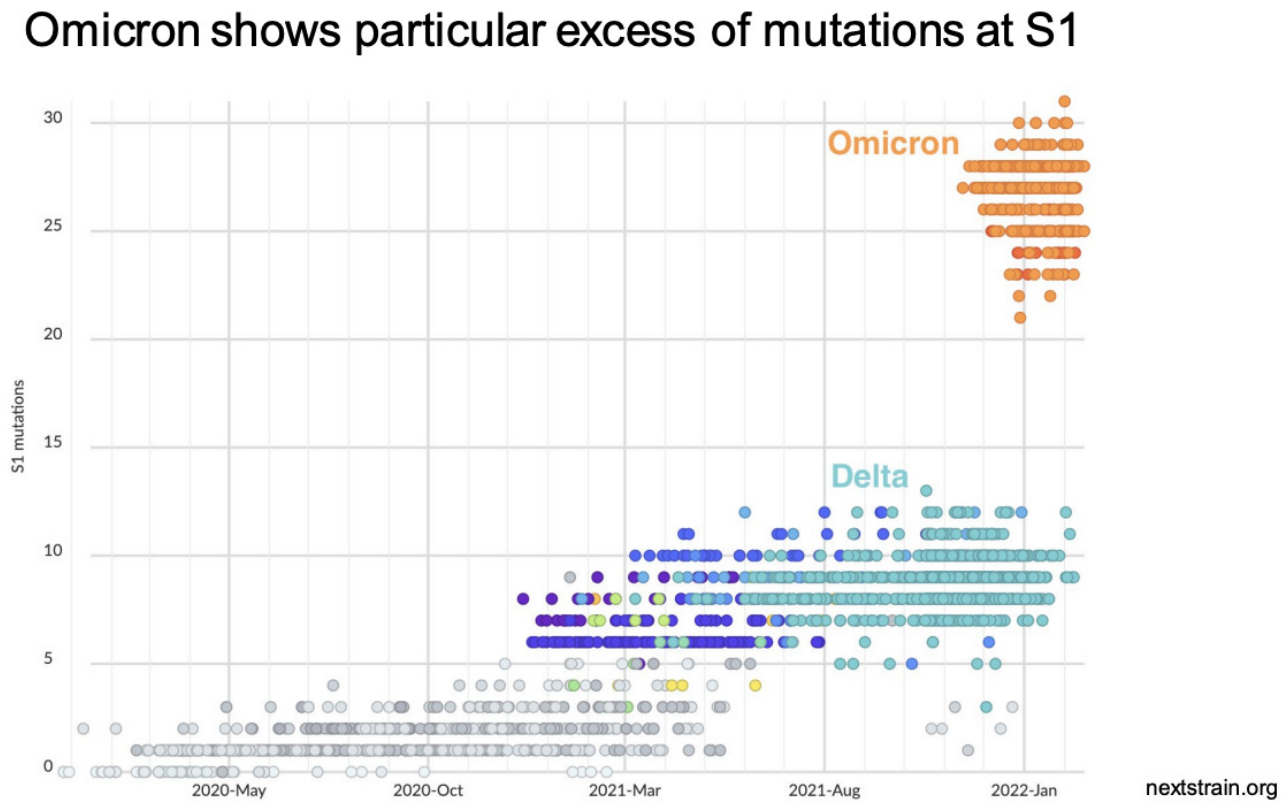
anyway

There are a quadrillion x quadrillion viruses in the world (literally more viruses on earth than stars in the known universe). Only a couple hundred of those seem to have the potential to impact human health. But some viruses make better candidates for a vaccine than others. Viruses that have been around a long time, that are very stable and evolve slowly are the best candidates for a vaccine.

Viruses that evolve rapidly are bad candidates for a vaccine. There is no vaccine for the common cold or HIV because these viruses evolve too quickly. The SARS-CoV-2 virus is a bad candidate for a vaccine which is why all previous attempts to develop a vaccine against coronaviruses have failed (they never made it out of animal trials because all of the animals died during challenge trials or were injured by the vaccine).

What are some of the bad things that can happen when you vaccinate against a rapidly evolving virus? Original antigenic sin, antibody-dependent enhancement, and the possibility of accelerating the evolution of the virus in ways that make it more virulent (and even more resistant to vaccination).

Trevor Bedford has his own lab at the Fred Hutchinson Cancer Center where he researches the evolution of Covid-19. He gave a fascinating presentation at the April 6 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee meeting where he explained that SARS-CoV-2 is evolving rapidly. He explained that SARS-CoV-2 evolves twice to ten times as fast as the flu virus and these mutations "substantially" reduce vaccine effectiveness. Following the introduction of Covid-19 vaccines, the evolution of the virus has accelerated.



Dr. Bedford's presentation rattled some of the smarter members of the VRBPAC because his data scream – "SARS-CoV-2 is a bad candidate for a vaccine!" But FDA officials just mumbled some platitudes and then continued on with the meeting.

The only way out of the pandemic is to withdraw these vaccines from the market and pivot to therapeutics. Instead, the FDA is proposing to just hide the data from the American people.

IV. The "Future Framework" = no more clinical trials for Covid-19 shots ever again

The purpose of the "Future Framework" is to rig the Covid-19 vaccine regulatory process in perpetuity in favor of the pharmaceutical industry. 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.

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. 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.

On June 28 the VRBPAC will meet once again to discuss the "Future Framework" and it will be presented as a done deal because manufacturers want a decision on vaccine strain selection by June in order to deliver shots for autumn vaccination appointments.

So if the FDA authorizes Covid-19 shots for kids on June 14 and 15 and then approves the "Future Framework" on June 28th, the shots that will be given to kids in the fall will be the reformulated shots that skipped clinical trials.

V. Monovalent Covid-19 shots failed, so maybe throwing two, three or four variants into a single shot will make it better?

When it comes to the flu shot, the FDA tries to hedge its bets by putting four strains of the virus into a single shot (so-called "quadrivalent" vaccines). As I explained above, this

strategy does not work. But these people are not very clever so that's exactly what they are planning to do with future Covid-19 shots.

Moderna is already signaling that they intend to manufacture a Covid-19 shot with the Alpha variant and then, to make it "new and improved (TM)", they will add genetically modified mRNA targeting the Beta variant. Here's the best part – Moderna claims that this formulation (Alpha + Beta) will somehow protect against *Omicron* variants – even though by the time these reformulated shots get to market, none of these variants will likely still be in widespread circulation.

There are reasons to believe that this approach will make future Covid-19 shots even less effective and more dangerous than the current failed Covid-19 shots.

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. If the "Future Framework" is approved, effectiveness of these shots will decrease, adverse events will increase, these shots will fuel the evolution of variants that evade the vaccines and there will be no clinical trial data before these reformulated Covid-19 shots are unleashed on the unsuspecting public.

VI. Summary

The FDA's Vaccines and Related Biological Products Advisory Committee will meet on June 28 to vote on a "Future Framework" for evaluating so-called "next generation" Covid-19 shots. The "Future Framework" is a plan to rig the Covid-19 vaccine regulatory process in perpetuity.

The "Future Framework" would take the "flu strain selection process" that fails every year and apply it to future (reformulated) Covid-19 shots. Federal bureaucrats, many of whom have financial conflicts of interests, would choose which SARS-CoV-2 variants to include in a yearly (or twice yearly) Covid-19 shot. In the process, all future Covid-19 shots will be deemed automatically "safe and effective" without further clinical trials because they are considered "biologically similar" to existing Covid-19 shots.

The "Future Framework" is the most reckless idea in the history of public health. It shows that the FDA has completely abandoned science and its statutory duty to protect the public. If the Republic is to survive, we must stop the "Future Framework" before June 28.

VII. Call to action

We have very little time and an enormous challenge in knocking this proposal down before the VRBPAC meets on June 28. So I am asking to you to contact your elected officials to tell them to reject this dangerous proposal.

Below are talking points that you can paste into an email, a script that you can use on the phone, and a tool for looking up your elected officials. I am only asking you to contact 8 officials – the President and Vice President; your two Senators and U.S. Representative; and your Governor, state House/Assembly member, and state Senator. Please be respectful

but make it clear that this plan must be stopped.

Talking points (to paste into an email, letter, or fax)

Subject line: NO "flu framework" for future Covid-19 shots

The FDA and CDC are developing a "Future Framework" to authorize future Covid-19 shots without requiring additional clinical trials. This would be a public health disaster. I am asking you to contact the FDA to tell them to stop all work on this "Future Framework" immediately. If the FDA proceeds with this "Future Framework" I am asking you to eliminate all funding for the FDA in this year's budget.

Phone script

> *Hi, my name is _____. I live at _____[address]. I'm calling because the FDA is proposing a "Future Framework" to authorize future Covid-19 shots without requiring additional clinical trials. This would be a public health disaster. I am asking you to contact the FDA to tell them to stop all work on this "Future Framework". If the FDA proceeds with this "Future Framework", I am asking you to eliminate all funding for the FDA in this year's budget.*

Whom to contact: 8 phone calls, letters, emails or faxes:

President Joseph R. Biden
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500
(202) 456-1111 (The White House comment line is open between the hours of 11 and 3 p.m. EST Tues.-Thurs.)
https://www.whitehouse.gov/contact/

https://twitter.com/POTUS

Vice President Kamala Harris
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500
(202) 456-1111 (between the hours of 11 and 3 p.m. EST Tues.-Thurs.)
https://www.whitehouse.gov/contact/
https://twitter.com/VP

You can look up contact info for your two **U.S. Senators** and **U.S. Representative** here:

https://www.govtrack.us/congress/members/map

The message for State elected officials is slightly different:

Hi, my name is _____. I live at _____[*address*]. I'm calling because the FDA is proposing a "Future Framework" to authorize future Covid-19 shots without requiring additional clinical trials. This would be a public health disaster. If the FDA proceeds with this "Future Framework" I am asking you to **nullify** the actions of the FDA and **reject** any Covid-19 shots that have not gone through proper clinical trials.

This is a great tool to look up contact info for your **Governor**, **state Senator**, and **state House/Assembly member**:

https://myreps.datamade.us/

That's it, just 8 people. We want to let them know that we are watching, that we understand what they are up to, and that this wretched plan must be stopped.

Extra credit:

Here are the email addresses for all of the public health political appointees, FDA staff and VRBPAC members who have a

say in connection with the “Future Framework”. Let’s contact them as well (proposed subject line and email text below).

Subject line: The “Future Framework” is the WORST idea in the history of public health. Please vote NO.

1. The FDA must revoke the authorizations for Moderna, Pfizer, and J&J Covid-19 shots and withdraw them from the market immediately. SARS-CoV-2 was never a good candidate for a vaccine. These shots do not stop infection, transmission, hospitalization, nor death. They appear to have negative efficacy and are driving the evolution of variants that evade vaccines. The pandemic will never stop as long as the FDA and CDC are promoting shots that lack sterilizing immunity.

2. The FDA and CDC must pivot to therapeutics. This was always the answer. About twenty off-the-shelf treatments are more effective than vaccines (if used for prophylaxis or early intervention). Get these safe and effective medicines to people who need them and let doctors be doctors again and treat patients based on their own best clinical judgment.

3. Any reformulated Covid-19 shots MUST go through proper clinical trials and FDA review.
That means:

- Large (50,000+ person) double-blind randomized controlled trials with inert saline placebos conducted by an independent third party;
- Safety and efficacy studies for two years prior to any application; the treatment and control groups must be followed for 20 years to monitor adverse events and all-cause mortality (no more wiping out the control group after 6 months to hide bad outcomes);
- Greater than 90% efficacy with less than 1% Grade 3 Adverse Events; and
- Proper monitoring for carcinogenesis, mutagenesis, and impairment of fertility.

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