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America's Frontline Doctors White Paper on Experimental Vaccines for COVID-19

By Frontline Doctors
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America's Frontline Doctors

Theme: Science and Medicine

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Below is the executive summary of an important study conducted by AMLD

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Executive Summary

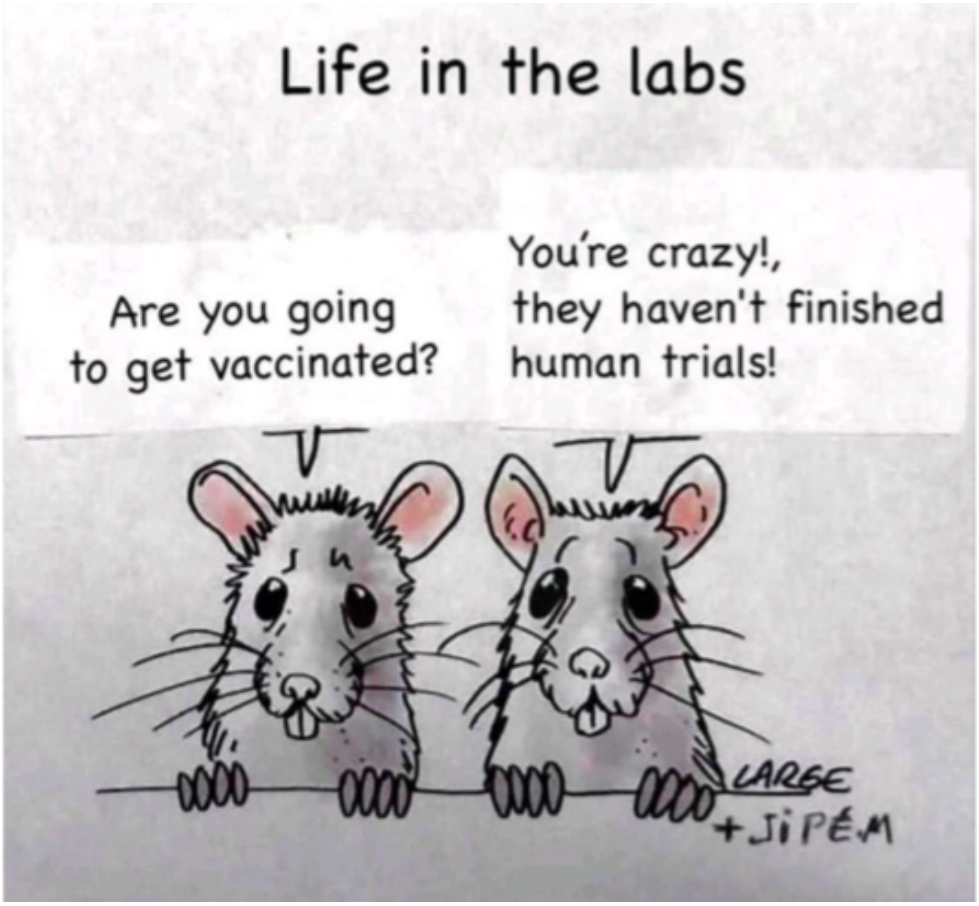
By Simone Gold, MD, JD, James Todaro, MD, Lee Merritt, MD, Richard Urso, MD, Robin Armstrong, MD, Scott Barbour, MD, Jeff Barke, MD, Mark McDonald, MD, Teryn Clark, MD, Shelley Cole, MD, Geoff Mitchell, MD, JD

This document represents the preliminary findings of an investigation conducted by the member-physicians of America's Frontline Doctors.

We are recommending caution for patients and policy makers and employers. Additional transparency and more research are needed before we ask Americans to embark on the largest experimental medical program in US history. The unknowns must be addressed through a scientifically rigorous process.

Mandates for experimental medical therapies are neither permissible nor advisable. Ordinary Americans should not be compelled to sign up for a "vaccine passport" or similar mandate just to travel on an airplane or see a concert with friends. The potential for third-party abuse of private health information and real medical risk to individuals remains much too high. Concentrations of private power pose a threat to privacy and other civil liberties and policy makers must proceed with caution.

We also ask our public health agencies to avoid prioritization of experimental biological agents based on race. Zero-pressure "opt-out" policies should be continued with the COVID-19 vaccine just as they have with previous inoculations. Furthermore, the CDC's tiers of prioritization place seniors not residing in long-term-care facilities last in line for immunization, even though patient experience and data tell us that 70 percent of US deaths have occurred among those 70 and older.



Frequently Asked Questions

Is America's Frontline Doctors (AFLDS) associated with any other group?

No. Our member-physicians are completely independent with no financial or corporate obligation to any related organization. We are associated with neither the pharmaceutical industry nor the so-called "anti-vaxxer" movement. We are not opposed to childhood inoculations, vaccination programs, or similar initiatives of public health. As practicing physicians, we have all been vaccinated. However, we oppose mandatory vaccination compelled by government or private interests, e.g., employers, airline carriers, concert venues, and so on, unless medically necessary based on mortality rates and other factors. This is of urgent concern since the current initiative uses an "investigational," or experimental, vaccine.

What does AFLDS mean by "experimental vaccine"?

According to the Food and Drug Administration, "An investigational drug can also be called an experimental drug and is being studied to see if your disease or medical condition improves while taking it." See pg. 15. The Pfizer and Moderna and AstraZeneca applications properly identify their new agents as "investigational," which is normal at this very early stage of development. All the vaccine candidates are categorized as experimental for the following four reasons:

- the pharmaceutical companies have applied for investigational use status
- adverse events will be settled under the legal standard for experimental medications
- recipients are enrolled as subjects in a medical trial to gather data on side effects.

- persons are enrolled in a pharmaco-vigilance tracking system for at least two years
- many groups of persons have not been studied at all, including: prior COVID-19 patients, pregnant women, youths, elderly
- no published animal studies data

Is the vaccine safe?

Vaccine safety requires proper animal trials and peer-reviewed data, neither of which has occurred during operation warp speed. This is especially concerning considering the fatal failure of prior coronavirus vaccine attempts such as SARS-CoV-1, the virus that is 78% identical to SARS-CoV-2 (COVID-19). Prior coronavirus (and other respiratory) vaccines have failed due to the scientific phenomena known as pathogenic priming that makes the vaccine recipient more likely to suffer a sudden fatal outcome due to massive cytokine storm when exposed to the wild virus. In addition to pathogenic priming there are three other potential safety issues that are being minimized. While we are hopeful that the vaccine is both effective and safe, hope is not science. Because these experimental vaccines have not been tested in accordance with the usual standards, we have serious concerns about safety.

Is AFLDS suggesting that the COVID vaccine is unsafe?

No. We are saying that by definition it is unsafe to widely distribute an experimental vaccine, because taking a vaccine is completely different than taking an ordinary medication. In contrast to taking a medication for an actual disease, the person who takes a vaccine is typically completely healthy and would continue to be healthy without the vaccine. As the first rule of the Hippocratic Oath is: do no harm, vaccine safety must be guaranteed. That has not yet happened. More studies of the vaccine's safety and efficacy should be conducted and published, and more transparency about possible risks provided to the public before Americans enter the largest experimental medication program in our history.

Is AFLDS arguing that the COVID vaccine is ineffective?

After it has been proved safe, the vaccine might be demonstrated to be effective in COVID-19 in certain categories, although we do not know that yet with a high degree of confidence. That is because the only group that really may benefit is the advanced elderly, and there is very limited data on efficacy and almost none on safety in this group. For healthy persons ≤ 69, it is impossible to state that a vaccine is effective simply because the lethality of the virus itself is virtually nonexistent. See pg. 13.

Why should Americans approach the vaccine's accelerated rollout with caution?

There are medical privacy and other civil liberties concerns surrounding the experimental vaccine that have not been properly addressed. In particular, granting third-party access (including technology platforms, governments, private enterprise) to patient data in the form of a proposed "vaccine passport" or other mechanism ought to receive additional scrutiny through legislative deliberation before airlines, concert venues and transit operators mandate its use. See pg. 30.

Why should experimental vaccine prioritization concern African Americans and

other ethnic minorities?

The Centers for Disease Control has three major phases for initial vaccination of the US population: 1a, 1b and 1c. We already know that Phase 1a will target healthcare workers and those living in long-term-care facilities. The remaining categories are less defined. For example, 1b consists of “essential workers” broadly categorized, but includes professional occupations in which black Americans are overrepresented. In addition, federal agency guidance has made early outreach to black and minority communities a top priority. AFLDS will never support prioritization of an experimental vaccine based on race. The only prioritization for a voluntary experimental medication must be based upon medical risk. Under this paradigm the prioritization should be to offer this first to SNF (and similar groups) patients on a voluntary basis See pg. 25.

Why is the FDA not prioritizing older persons?

Persons over 70 with co-morbid conditions should be offered (not mandated) access to this experimental medication first. That is person living in SNFs and similar groupings. The next priority is all persons over 70, and persons with co-morbid conditions, which are more common as Americans age, meaning persons over 60 with co-morbid conditions. Any other priority is inconsistent with the science.

Read the full report here.

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