

# America's Frontline Doctors White Paper On Experimental Vaccines For COVID-19

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## **Executive Summary**

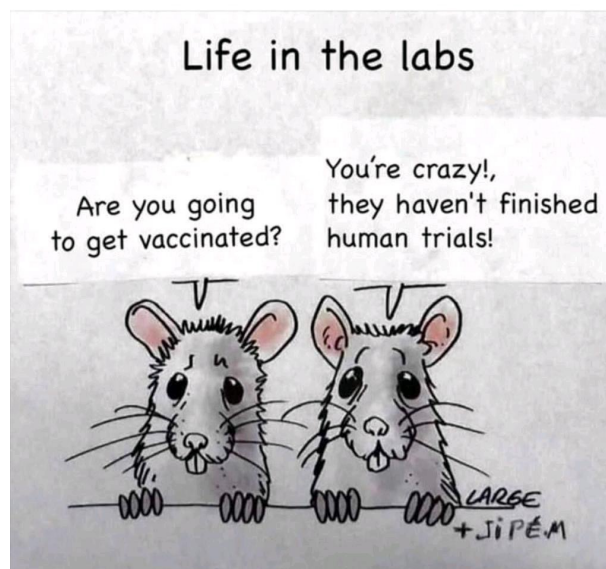
Simone Gold, MD, JD, James Todaro, MD, Lee Merritt, MD, Richard Urso, MD, Robin Armstrong, MD, Scott Barbour, MD, Jeff Barke, MD, Mark McDonald, MD, Teryn Clark, MD, Shelley Cole, MD, Geoff Mitchell, MD, JD

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  $\leq 69$ , 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.

## **I. COVID-19: Policy Myths**

COVID-19 was first identified in Wuhan China in December 2019. It spread from China to Europe and ultimately it swept the globe with the first non-travel cases in USA in late February. Since then COVID-19 has dominated every news story, every day, in every national and international conversation. Such omnipresent media attention is unprecedented for a pandemic. The American public heard about Zika, Ebola, Swine Flu, but nothing like this. Scientists know that there are pandemics every few years. In fact, this is the third respiratory virus that escaped from China in the past 25 years; first the bird flu, then SARS, then H7N9.

The most recent large pandemic to affect USA prior to COVID-19 was the Hong Kong Flu of 1968-69. As of mid-2020, it was similar size to COVID-19. (By CDC calculations, at this time COVID-19 has overtaken the Hong Kong Flu in deaths but the CDC numbers are widely accepted as inflated as deaths “with” COVID are counted alongside deaths “from” COVID.) As reported in the New York Times in 1968-69: “Hong Kong Flu Attacks Thousands Here Swiftly” and “Hong Kong Flu is Affecting Millions in Wide Areas Around the World.” 100,000 Americans died (equivalent to about 150-175k today with COVID due to higher population, obesity, and older age).

Despite the similar scope, the national response was completely different. American life continued entirely normally during the Hong Kong Flu, with no suggestion of locking down anything – in fact the Woodstock Festival took place in the midst of the Hong Kong Flu. We start with this to remind the reader that current information must be understood in the context of other events or the reader will be easily misled.

There has been massive disinformation from the beginning of the COVID-19 pandemic, starting with its name. Everyone recalls that its name was initially the Wuhan Virus. That is because epidemics have historically been named for the location from where they arise or are associated. Consider: Rocky Mountain Spotted Fever, Spanish Flu, Middle East Respiratory Syndrome, Lyme Disease, Zika, Ebola as some examples. The re-branding as COVID-19 took significant media effort and signaled a massive disinformation was coming. The Chinese Communist Party made it known that it did not want this to be called the Wuhan Virus, and that it should just be called “the coronavirus.” But this proved very confusing to doctors who already knew of six other coronaviruses. So it was renamed a third time, as COVID-19, which stands for Corona Virus Disease – 2019.

Following its re-branding as COVID-19, the disinformation regarding the pandemic continued in many other areas. Most notable was selling the lie to the American and European people that hydroxychloroquine is an unsafe medication. This incredibly safe medication, which halts SARS-Co-V-2, was rebranded as unsafe in 2020.

This disinformation campaign largely succeeded – until America’s Frontline Doctors came forward. We revealed four levels of censorship regarding HCQ safety: the scientists, the media, Big Tech, and the government itself.

### *The Scientists:*

The two most famous medical journals in the world were caught red-handed publishing fraud.<sup>1</sup> The sheer number and magnitude of the things that went wrong or missing in their studies were too enormous to attribute to mere incompetence. The data upon which these studies were based were so ridiculously erroneous that it only took two weeks for an eagle-eyed physician to publicly demand an explanation.<sup>2</sup> In pursuing a fraudulent headline maligning HCQ, the third most famous medical journal in the world, Journal of the American Medical Association (JAMA), literally printed evidence of a crime.<sup>3 4</sup>

*The Media & The Elite:* The media then took the fraudulent data and scared Americans and Europeans away from this safe, early treatment.

- USA Today: “Coronavirus Patients who took HCQ had higher risk of death, study shows.”<sup>5</sup>
- NY Times:<sup>6</sup>
  - “The FDA warned [HCQ] could cause serious heart problems.
  - “My concern would be that the public ... would believe that taking this drug ... is [safe]. In fact, there are serious hazards.
  - “What is irresponsible is the example he is setting.
  - “The President’s statement was “highly irresponsible”
- The World Health Organization ordered nations to stop using HCQ and CQ,<sup>7</sup> WHO Chief Tedros suspended trials being held in hundreds of hospitals across the world<sup>8</sup>
- The EU governments France, Italy, and Belgium banned HCQ for COVID-19 trials<sup>9</sup>

*Big Tech Censorship:* Physician writings that explained the safety of HCQ were disappeared from the internet without a trace.<sup>10</sup>

*Government Punishment of Doctors:* Many doctors have personally attested to the following four punishments Governors/State Medical Boards have taken/forced:<sup>11</sup>

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<sup>1</sup> <https://www.theguardian.com/commentisfree/2020/jun/05/lancet-had-to-do-one-of-the-biggest-retractions-in-modern-history-how-could-this-happen>

<sup>2</sup> [https://www.youtube.com/watch?v=4HYK5pL2Z\\_s](https://www.youtube.com/watch?v=4HYK5pL2Z_s)

<sup>3</sup> <https://jamanetwork.com/journals/jamacardiology/fullarticle/2765631>

<sup>4</sup> [https://www.americasfrontlinedoctors.com/custom\\_videos/brave-doctors-threatened-come-forth/](https://www.americasfrontlinedoctors.com/custom_videos/brave-doctors-threatened-come-forth/)

<sup>5</sup> <https://www.usatoday.com/story/news/health/2020/05/22/COVID-19-study-links-hydroxychloroquine-higher-risk-death/5244664002/>

<sup>6</sup> <https://www.nytimes.com/2020/05/18/us/politics/trump-hydroxychloroquine-COVID-coronavirus.html>

<sup>7</sup> <https://www.reuters.com/article/us-health-coronavirus-indonesia-chloroqu/exclusive-indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it-idUSKBN23227L>

<sup>8</sup> <https://medicalxpress.com/news/2020-05-trial-hydroxychloroquine-COVID-treatment.html>

<sup>9</sup> <https://www.reuters.com/article/health-coronavirus-hydroxychloroquine-fr/eu-governments-ban-malaria-drug-for-COVID-19-trial-paused-as-safety-fears-grow-idUSKBN2340A6>

<sup>10</sup> <https://docs.google.com/document/d/1HY50zIjuSIVKltTk5UegfgqdiHN9ehLxLqLES9nwDZ8/edit?ts=5f106ac5>

<sup>11</sup> <https://aapsonline.org/judicial/aaps-v-fda-hcq-6-2-2020.pdf>

- doctors have been sanctioned, disciplined, interrogated
- pharmacists have been empowered to over-ride physicians
- watching patients get sicker and die
- physicians self-censoring due to fear of retribution

At the same time Americans were being aggressively fed these four levels of lies, other countries were not.

On February 19, 2020, before a single case of non-travel COVID-19 was in the USA, the Chinese government mandated that this drug be used for COVID-19. “The drug [chloroquine] is recommended to be included in the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People’s Republic of China for the treatment of COVID-10 infection in larger populations in the future.”<sup>12</sup>

This was followed two weeks later by the printing of a successful trial of chloroquine in France, and another two weeks later by a report of 1450 patients successfully treated with only two deaths.<sup>13 14</sup> On March 22 the country of India had made it their national policy to recommend HCQ broadly to its population, a policy from which it has never deviated, and it continues to enjoy a death rate a fraction (~10%) of the USA even in the most densely populated slums.<sup>15</sup> (It is truly astonishing to read articles by authors desperately trying to credit everything *but* this HCQ policy. Some authors credit “gargle & spit”, testing, isolation in the slums and early detection.<sup>16</sup>

Since February through December there have been 195 HCQ studies worldwide. 100% of the studies that gave HCQ early, showed dramatic improvement, and 75% of those studies that gave HCQ late, also showed substantial improvement. The Senate Homeland Security & Governmental Affairs Committee held a hearing on November 19, 2020 on early treatment and heard testimony under oath from many physicians that if USA normalized its HCQ policy, deaths would plummet to a fraction of what they are.

The reasons for the lies exceed the scope of this paper, but it is impossible to discuss any COVID-19 medications without understanding that there would be no inter/national discussion on other treatments or vaccines, if all people hadn’t been massively lied to that a cheap, safe drug was unsafe.

HCQ derives from quinine, found in tree barks, and has been used many billions of times for decades across the world. It is considered one of the safest medications in the world, safer than Motrin or Tylenol, and is called “Sunday-Sunday” in much of Africa because

<sup>12</sup> [https://www.jstage.jst.go.jp/article/bst/14/1/14\\_2020.01047/\\_article](https://www.jstage.jst.go.jp/article/bst/14/1/14_2020.01047/_article)

<sup>13</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135139/>

<sup>14</sup> <https://academic.oup.com/aje/article/doi/10.1093/aje/kwaa093/5847586>

<sup>15</sup> <https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf>

<sup>16</sup> <https://blogs.bmj.com/bmj/2020/05/01/rolling-out-mass-hydroxychloroquine-prophylaxis-for-covid-19-in-indias-slums-risks-public-trust/>



people simply take the pill weekly – no different than an American who takes Tylenol. It is sold next to the vitamins in stores and it is on the WHO list of Essential Medications that all countries must have. For a detailed explanation of HCQ effectiveness, the reader is referred to [www.AFLDS.com](http://www.AFLDS.com) (hydroxychloroquine section) that includes many reference articles. We discuss its effectiveness here only to demonstrate the extent of the lies – first that it is not safe, second that it is not effective. All leaders must be aware of the following facts.

- Countries where HCQ is widely available, which are typically third world countries that have malaria or citizens who travel to malaria-endemic regions, have 1-10% of the death rates of first world nations where HCQ is severely restricted.
- HCQ availability correlates with COVID-19 death rates. We see this across the world and amongst USA states.
- A typical headline from the Washington Post April 6, 2020 was that Africa was going to be decimated by this virus. “Coronavirus presents a crisis for Africa” and per the UN: “Pandemic crisis may kill up to 3.3 million Africans.” (It is 1-2% of that.)
- Contrary to expert predictions and media headlines, the *lowest* death rates from COVID-19 are in the poorest countries with no masking, no social distancing, limited medical care, no ICUs ... but with easy access to hydroxychloroquine/chloroquine.

<https://www.washingtonpost.com/opinions/2020/04/06/coronavirus-presents-cr/>

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**Opinion**  
**Coronavirus presents a crisis for Africa. We have a duty to help.**



South African community activists gather with the help of police to enforce lockdown on Monday. (Lorenz Dreyer/AP)

**Opinion by Michael Gerson**  
Columnist

April 6, 2020 at 8:00 a.m. EDT

The first line of history's judgment on the Trump administration has already been written: For no days the president slept as the novel coronavirus spread.

President Trump's coronavirus response became a spectacular failure of competence. But it began as a failure of imagination. As the evidence of a dangerous virus mounted, Trump could not conceive of a problem immune to his peculiar brand of "leadership."

<https://www.aa.com.tr/en/africa/pandemic-crisis-may-kill-up-to-33m-africans-u/>

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**AFRICA, LATEST ON CORONAVIRUS OUTBREAK**

**Pandemic crisis may kill up to 3.3M Africans: UN body**

There are over 17,000 confirmed cases across continent

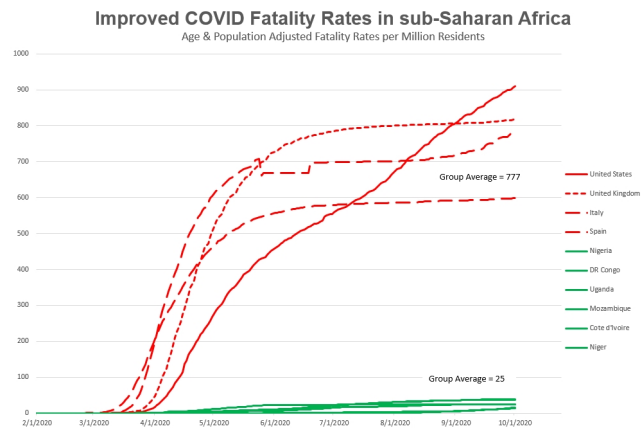
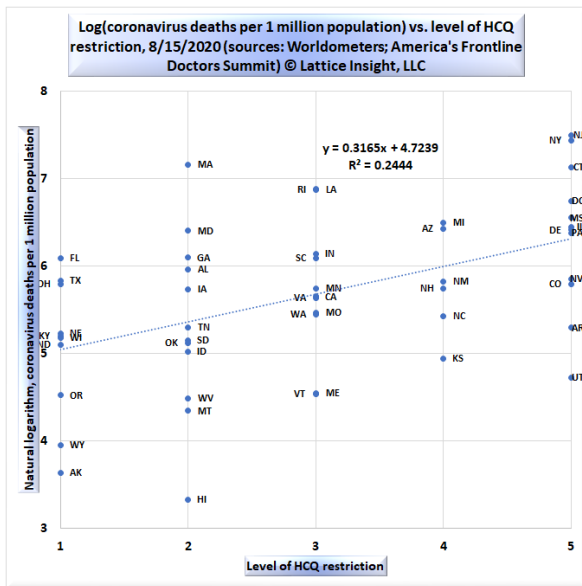
Felix Tih | 17.04.2020



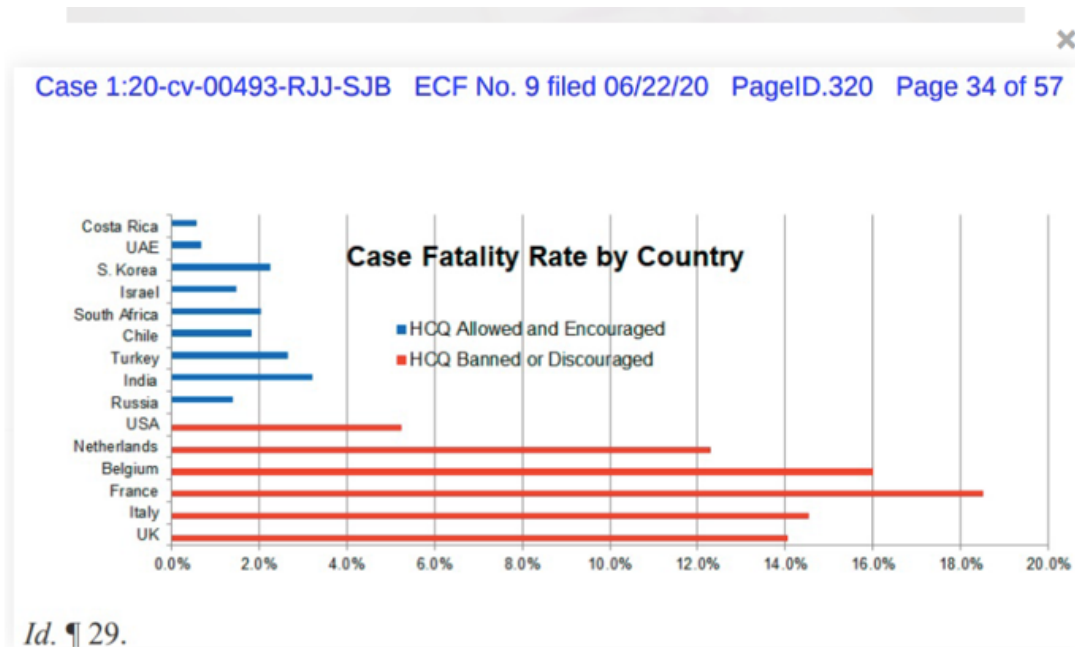
**ANKARA**

Without adequate intervention measures, estimates show that between 300,000 and 3.3 million African people could lose their lives due to coronavirus, the UN Economic Commission for Africa (ECA) said in a report on Friday.





Access to hydroxychloroquine compared to COVID-19 deaths across the USA, worldwide, and Europe vs. Africa. Everywhere HCQ is used, the death rates are *much* lower.



America's Frontline Doctors successfully challenged the narrative that HCQ was unsafe. In response to our efforts, many states were forced to revert back to the pre-COVID rules of no restriction on HCQ. We have also made it possible for any person to obtain HCQ legally by consulting with a telemedicine physician. We did this because Americans are dying and we felt an obligation to help, and also because we care deeply about our profession and watching the media and politicians lie to the American people that a drug was unsafe when it was not unsafe was unacceptable to us as practicing physicians.

We are here for the same reason today.

We did not think it bold to stand before the American people and declare that a drug that has been used hundreds of billions of times, by everyone from newborns to the extreme elderly by the healthy and the critically ill, all over the world for decades was safe. We thought it was self-evident.

Likewise, we do not think it is bold to stand before the American people and declare that an investigational biological agent that did not exist four months ago, that has only been given to a few thousand people, and not tested at all on the elderly, not tested at all in women who are or intend to become pregnant, should NOT be considered safe. We think this too is self-evident.

It is impossible to say that a drug with an extensively documented and strong safety record for fifty years<sup>17</sup> <sup>18</sup> is dangerous but a brand new medication is safe.

the database in 1968 through 2019 and into the beginning of 2020 shows 1,064 adverse event reports for HCQ, including 200 deaths for all of the cardiac causes that could be both specifically and broadly classified as rhythm-related. Of these, 57 events, including 10 deaths, were attributed to TdP tachycardia and long QT-interval syndrome combined. This concerns the entirety of HCQ use over more than 50 years of data—probably millions of uses and longer-term use than the 5 days recommended for COVID-19

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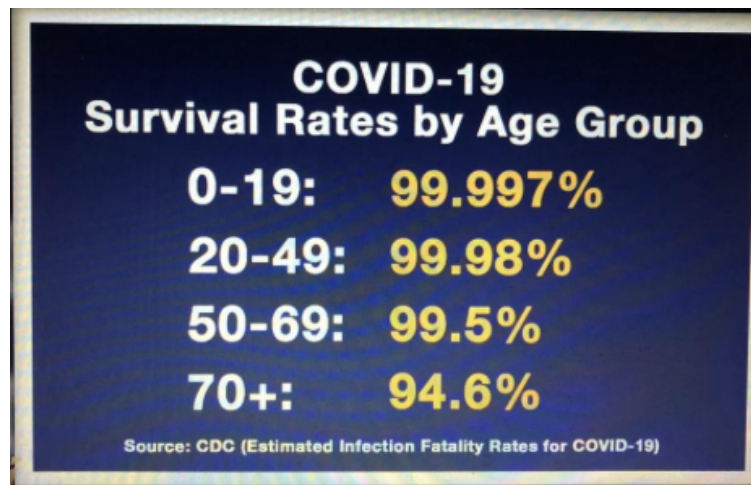
<sup>17</sup> US Food & Drug Administration. FDA Adverse Events Reporting System (FAERS) Public Dashboard. <https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis>

<sup>18</sup> <https://academic.oup.com/aje/article/189/11/1218/5847586>

## **II. COVID-19 Medical Myths: Low Infection Fatality Ratio (IFR)**

The most enduring myth regarding COVID-19 is that this is a highly lethal infection. It is not. The data is unequivocal:

- COVID-19 kills very rarely and is mostly limited to the medically fragile
- COVID-19 is less deadly than influenza in children
- COVID-19 is similar lethality in the middle adult years and treatable



When talking about the risk/benefit ratio of any treatment we must consider the Infection Fatality Ratio or IFR. The IFR for COVID-19 varies dramatically by age, from a low of 0.003% for Americans under age 19 to as high as 5.4% for those 70 years of age and above.<sup>19</sup> That is an 1800x risk difference based upon age! It is quite clear that young people are at a statistically insignificant risk of death from COVID-19. Nearly 80% of all coronavirus-related deaths in the US through November 28, 2020 have occurred in adults 65 years of age and older and only 6% of the deaths had COVID-19 as the only cause mentioned. On average, there were 2.6 additional conditions or causes per death.<sup>20</sup>

For most people under the age of 65, the study found, the risk of dying from COVID-19 isn't much higher than from getting in a car accident driving to work. In California and Florida, the fatality risk for the under-65 crowd is about equal to driving 16 to 17 miles per day. While higher in hot spots like New York (668 miles) and New Jersey (572 miles), the death risk is still lower than the public perceives. The risk climbs especially for those over age 80. According to the Foundation for Research on Equal Opportunity, Americans over 85 are about 2.75 times more likely to die from COVID-19 than those 75 to 84, seven times more likely than those 65 to 74 and 16.8 times more than those 55 to 64.<sup>21</sup>

For children COVID-19 is much less lethal than influenza. During the 2018-19 flu season, the CDC reported approximately 480 flu deaths among children ages 0-17. Comparably, 90 youths have died from coronavirus complications from the beginning of the pandemic

<sup>19</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>

<sup>20</sup> [https://www.cdc.gov/nchs/nvss/vsrr/COVID\\_weekly/index.htm#Comorbidities](https://www.cdc.gov/nchs/nvss/vsrr/COVID_weekly/index.htm#Comorbidities)

<sup>21</sup> <https://www.wsj.com/articles/the-COVID-age-penalty-11592003287>

through mid-August, according to the American Academy of Pediatrics. More than 46,000 children were hospitalized for flu in that 2018-19 period, with a hospitalization rate among children 5 to 17 of 39.2 children per 100,000 children. For COVID-19, that hospitalization rate is 6 per 100,000 children ages 5 to 17, according to the CDC. In a report detailing the differences between COVID-19 and the flu, the CDC states, "the risk of complications for healthy children is higher for flu compared to COVID-19."<sup>22</sup>

### **III. COVID-19 Experimental Vaccines Trials**

Vaccines against COVID-19 are now being approved for experimental use. This will be the shortest time scientists have ever been able to develop a new vaccination for a major disease. It not only typically takes years to create a new vaccination, but very often, despite the best efforts of scientists, a successful vaccine proves impossible. For example, scientists (including Dr. Fauci) tried to create an HIV vaccine for more than forty years.

The technology used for the first COVID-19 vaccinations being brought to market by Pfizer and Moderna uses an "mRNA" or "messenger RNA" technique. The COVID-19 virus is an RNA virus, meaning that the viral genetic code is carried in the virus' **ribonucleic acid** or RNA. The messenger RNA is the instruction manual that cells use to manufacture proteins. The mRNA *vaccine* instructs human cells to manufacture a specific COVID-like protein. This protein, once formed, then stimulates our immune system to produce an antibody to fight against this COVID-19-like protein. The hope is that the antibody would be ready to attack the real virus should it be encountered "in the wild."

This is the first time that an mRNA mechanism is being used in a vaccination. For the most part, mRNA technology is used in cancer therapy. It has had some success in producing various proteins to attack and disrupt certain cancer cells. Most of the commentary so far suggests that it may not be too much of a leap to use this approach in a vaccination therapy.

The AstraZeneca COVID-19 vaccination uses a different mechanism. It takes an adenovirus that has been modified to include genetic material from the SARS-CoV-2 virus so that it introduces the immune system to the spike protein of the COVID-19 virus. The immune system then produces antibodies against the spike protein. The good news is the AstraZeneca vaccine can be stored at normal refrigeration temperatures for up to 6 months. The bad news is it is only about 70 percent effective. This may become the preferred vaccination in third world countries because of the storage conditions.

The three SARS-CoV-2 vaccines nearest to FDA public distribution are two mRNA vaccines developed by Pfizer/BioNTech and Moderna, and one viral vector vaccine developed by AstraZeneca. All three companies recently released in November scant preliminary data reports on efficacy from Phase III trials in November. Only Pfizer's vaccine was recently published peer-reviewed papers on the findings.

Based on company press releases, all three Phase III trials include:

- 1:1 placebo controlled trial with saline injection

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<sup>22</sup> <https://amp.statesman.com/amp/113718780>

- Two doses administered approximately 21-28 days apart
- Efficacy was only measured beginning 28 days after the first dose (basically beginning at the time of the second dose)

#### Pfizer/BioNTech

- Trial launched on July 27, 2020
- 41% of participants between ages 56 and 85
- 43,931 participants enrolled (1:1 ratio) with 97% receiving a second dose of the vaccine or placebo
- The final efficacy analysis was conducted at 170 confirmed cases of COVID-19 with 162 in the placebo group and 8 in the vaccinated group
- 10 severe cases of COVID-19 in the placebo group and 1 in the vaccinated group
- 95% effective against COVID-19, fairly consistent across all ages
- Fatigue and headache were the most frequent Grade 3 adverse events at 3.8% and 2.0%, respectively, and mostly experienced in the younger age group

#### Moderna

- Trial launched on July 27, 2020
- 23% of participants over age 65
- 30,000 participants enrolled (1:1 ratio)
- The primary efficacy analysis was conducted at 196 confirmed cases of COVID-19 with 185 in the placebo group and 11 in the vaccinated group
- 30 severe cases of COVID-19 in the placebo group and zero in the vaccinated group. (Recently, a sudden death of a Philadelphia priest who participated in the trial and received his second dose on October 1st is under investigation.)
- 94.1% effective against COVID-19, fairly consistent across all ages
- Limited data on adverse events

#### AstraZeneca

- Trial launched on September 1, 2020
- Age distribution unknown
- 23,000 participants enrolled (1:1 ratio)
- A preliminary efficacy analysis was conducted at 131 confirmed cases of COVID-19 with about 77 in the placebo group and 54 in the vaccinated group
- No hospitalizations or severe cases of COVID-19 in the vaccinated group
- Data on adverse events not reported
- Reported to be 70% effective against COVID-19, fairly consistent across all ages. Notably, however, 2,741 participants mistakenly received a half dose of the vaccine initially followed by a full second dose as opposed to the protocol regimen of two full doses. In a subgroup analysis, the vaccine in this “mistake” group was found to be 90% effective compared to 62% effective in the group that received two full doses.

At first glance, all three trials appear very large with considerably higher enrollment than most Phase III trials, which typically range between 300 and 3,000 participants. Notably, however, there are actually very few participants who received the vaccine AND developed COVID-19. While this may (or may not) imply that the vaccine is effective, the much bigger problem is that it tells us almost nothing about how exposure to COVID-19 affects

people who receive the vaccine. For example, in the Pfizer/BioNTech and Moderna trials, only 8 and 11 vaccinated participants, respectively, developed COVID-19.

This is an alarmingly small number when taking into consideration the novelty of SARS-CoV-2 and the possibility of the adverse effect known as pathogenic priming, which has been seen repeatedly with prior coronavirus vaccines.

Pathogenic priming includes the deleterious effect of antibody-dependent enhancement (ADE) whereby a vaccine or reinfection could result in a **more severe** or lethal disease, should the person become infected with SARS-CoV-2 in the wild. This phenomenon has been well-documented with prior vaccines. The most recent terrible headlines related to this was a vaccine for Dengue for persons who received the vaccine and then encountered the virus in the wild suffered worse outcomes at an alarming rate. This is why the Dengue vaccine (“Dengvaxia”) was only approved for very restricted use by the FDA—despite years of active research and development. In the Philippines, the former head of the Dengue department of the Research Institute for Tropical Medicine (RITM) was indicted in 2019 by the Department of Justice for “reckless imprudence resulting [in] homicide,” because they “facilitated, with undue haste,” Dengvaxia’s approval and its rollout among Philippine schoolchildren.<sup>23</sup>

The antibody-dependent enhancement effect in the COVID-19 Experimental Vaccines will be further discussed in Section VI. But what is clear is that the Phase III trials from Pfizer, Moderna and AstraZeneca provide little to no insight into ADE and Vaccine-Associated Hypersensitivity (VAH). Not only is the sample size of vaccinated participants who developed COVID-19 very small, but, based on the information publicly available, it is unknown which strains of SARS-CoV-2 afflicted the participants in the trials.

#### **IV. COVID-19 Experimental Vaccines Controversies:**

Scientists have the same concerns for the experimental vaccines as for all drugs. Is the proposed treatment safe and is it effective.

##### **Safety Concerns Regarding the Experimental COVID-19 Vaccines**

###### **1. Brand New Technology.**

No vaccine based on messenger RNA has ever been approved for any disease, or even entered final-stage trials until now, so there’s no peer-reviewed published human data to compare how mRNA stacks up against older technologies.<sup>24</sup> How well mRNA vaccines will actually prevent COVID-19 remains unknown. This new technology is less stable than older technologies, for example, requiring deep freezing temperatures up to negative 70 degrees Celsius for Pfizer’s vaccine. This differs from other vaccines that are typically kept in ordinary refrigerators. Recently a vaccine candidate had to be halted because test

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<sup>23</sup> <https://www.sciencemag.org/news/2019/04/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines>

<sup>24</sup> <https://www.bloomberg.com/features/2020-moderna-biontech-COVID-shot/> August 11, 2020

subjects has ‘false positive’ HIV test results – in other words, unexpected things must be expected with brand new experimental technology.<sup>25</sup>

## 2. Failure of Previous Coronavirus Vaccines.

Despite trying for decades, scientists have never been able to create a successful coronavirus vaccine. Whenever they *think* they have, the experimental coronavirus vaccine has failed and animals who got the experimental vaccine died.<sup>26</sup>

## 3. No Independently Published Animal Studies.

Most other previous vaccines have performed and published results on animal studies prior to giving to humans. This is critical because deadly effects are often not seen until this step. Vaccines that have been given to humans prior to animal trials have *frequently* resulted in deaths that caused the governments to yank the vaccines. Most scientists believe that human death is inevitable if there are no prior peer-reviewed animal studies.<sup>27</sup>

## 4. Known Complications.

One of the known complications of vaccines is something called *immune enhancement*. One type of immune enhancement is known as Antibody Dependent Enhancement (ADE). This is a process where a virus leverages antibodies to aid infection. In short, the anti-COVID antibodies, stimulated by a vaccine, *amplify* the infection rather than prevent its damage. This paradoxical reaction has been seen repeatedly in other vaccines and animal development trials especially with *coronavirus* vaccine trials.<sup>28</sup>

Other known complications of vaccines include neurological diseases such as transverse myelitis, Bells’ Palsy multiple sclerosis, autism, and Guillain-Barre. For example, in 1976 the government attempted a mass vaccination of the population with a newly created Swine Flu vaccine. The vaccination program was aborted after about 450 people came down with Guillain-Barre. The extremely limited COVID-19 vaccine data already has at least two transverse myelitis cases<sup>29</sup> and four Bell’s Palsy cases that may be linked to vaccination..

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<sup>25</sup> <https://www.cnn.com/2020/12/10/australia/australia-vaccine-hiv-intl-hnk/index.html>

<sup>26</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/>

<sup>27</sup> <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-data-preclinical-studies-mrna> We learn about these studies only from the company itself.

<sup>28</sup> <https://academic.oup.com/jid/article/222/12/1946/5891764>

<sup>29</sup> <https://www.nature.com/articles/d41586-020-02706-6>

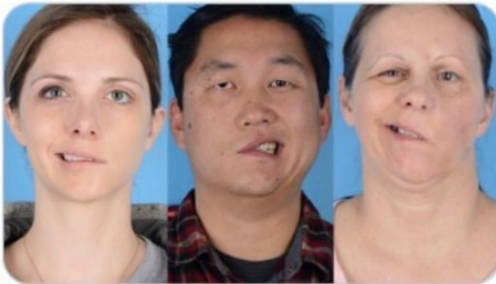


Four Pfizer vaccine volunteers develop Bell's palsy...

Bell's palsy is a condition that causes a weakness or paralysis of the muscles in the face...

The condition causes one side of your face to droop or become stiff.

[zeenews.india.com/world/covid-19...](https://zeenews.india.com/world/covid-19...)



NEWS • 25 SEPTEMBER 2020

## COVID-vaccine results are on the way – and scientists' concerns are growing

Researchers warn that vaccines could stumble on safety trials, be fast-tracked because of politics or fail to meet the public's expectations.

### 5. Unknown Complications.

There are entire populations for whom we don't know the data. For example, we have no knowledge of the immune response in vaccinated individuals who later contract the disease, and we also do not know the effects on disease course in vaccinated individuals with waning immunity. We do not know the effects on the elderly. We do not know the effect on the pregnant or soon to be pregnant. There is no actual data *at all* for an enormous percentage of the population, probably more than half.

Just by the mere fact that these trials were launched within the past six months, we cannot know of any long-term effects or interactions with other viruses such as influenza or the seasonal cold, especially considering that two of the vaccines nearest to public distribution take an entirely novel approach with mRNA.

The mechanism of action of the experimental mRNA vaccines includes a possible auto-immune rejection of the placenta. In layman's terms, the vaccine may permanently interfere with a woman's ability to maintain a pregnancy. The vaccine companies themselves acknowledge the possibility of ill effects on a pregnancy on the vaccine bottle, which says the following: "it is unknown whether COVID-19 mRNA VaccineBNT162b2 has an impact on fertility. And women of childbearing age are advised to avoid pregnancy for at least two months after their second dose."<sup>30</sup>

### 6. Pharmaceuticals are Immune from All Liability.

The same companies (and executives) that profit from this vaccine are immune from all liability. In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA). It provides immunity from liability to all vaccine manufacturing companies. With COVID-19 experimental vaccine, AstraZeneca goes even further in acknowledging that this is an emergency situation and requested no liability from the EU. "This is a unique situation

<sup>30</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/941452/Information\\_for\\_healthcare\\_professionals.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/941452/Information_for_healthcare_professionals.pdf)

where we as a company simply cannot take the risk if in ... four years the vaccine is showing side effects,” Ruud Dobber, a member of Astra’s senior executive team, told Reuters.<sup>31</sup>

## **7. An Experimental Vaccine Is Not Safer Than a Very Low IFR.**

The IFR was always known to be very low for the young and healthy middle aged, and it has now been shown to be extraordinarily low. We are getting better and better at *treating* COVID-19: the death *rate* in terms of population continues to fall, hospital stays for COVID-19 get shorter and hospital mortality from COVID-19 plummets.

### **Questions Regarding the Effectiveness of the COVID-19 Experimental Vaccines**

#### **1. No Proof the Vaccine Stops Transmission of the Virus.**

The trial data on the vaccinations released so far has not addressed the issue of *transmission* of the virus. That is, the efficacy data is primarily based on *symptoms*, not on transmission. Could the vaccine create asymptomatic carriers that can unknowingly transmit the virus? The scientists are very upfront about the fact that they don’t know if the vaccine even stops the spread of the virus!<sup>32</sup> Dr. Corey who oversees the vaccine trials for the NIH COVID-10 Prevention Network says: “the studies aren’t designed to assess transmission. They don’t ask that question and there’s really no information on this at this point in time.”

Scientists involved in oversight of the Operation Warp Speed COVID-19 vaccine trials are tempering excitement about efficacy, noting that **the studies haven't shown yet whether the products can prevent transmission** of the SARS-CoV-2 virus.

**"We don't know if people can become infected and thus also transmit even with vaccination,"** said former US Food and Drug Administration

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**Commissioner** Margaret Hamburg, MD, in a November 18 briefing on COVID-19 vaccines sponsored by the American Public Health Association (APHA) and the National Academy of Medicine (NAM).

**For that reason** and others — including if there isn't significant uptake of vaccine — **"people can expect to still be wearing masks, still be asked to follow non-pharmaceutical public health measures** that we've all come to know so well," she said.

#### **2. Unknown Mortality or Hospital Admission Benefit.**

Currently the pharmaceutical companies believe that their first COVID-19 vaccines are ~95% effective. Pharmaceutical companies typically believe their vaccinations are more effective than they actually are. For example, CDC data show that the influenza vaccine

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<sup>31</sup> <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN>

<sup>32</sup> <https://www.medscape.com/viewarticle/941388>

was 38% effective in 2017-18, 20% in 2018-19, and 39% in 2019-20 even though its efficacy was expected to be much higher when it was first introduced in 1938. Even if the COVID-19 vaccine is really 95% effective in the real world, the survival rate of those contracting the disease is already so much higher than that. If you are less than 70 years old you have a 99.5% chance of survival, if you are less than 50 years old you have a 99.98% chance of survival, and if you are less than 20 years old, you have a 99.997% chance of survival.

Notably, the vaccine trials had too few positive cases to assess with statistical significance any benefit in secondary outcomes such as decreased mortality or hospitalization. (ref: <https://www.bmj.com/content/371/bmj.m4037>)

### **3. The Vaccine Lasts Unknown Duration.**

We know very little about the longevity of the immunity acquired for COVID-19 from natural infections or from the vaccines. Will the vaccination give long lasting immunity or will another vaccination be needed next year? Recent studies have shown that the body's immune response to the virus, as measured in levels of antibodies and T-cells, tends to wane over time. "We don't know how long immunity lasts," said Akiko Iwasaki, professor of immunobiology at Yale University. We have no lasting immunity from influenza, for example, because the virus is constantly mutating, we are required to get a new shot each year. Pharmaceutical companies and researchers guess that the COVID-19 vaccine should be annual, but with little scientific basis for this timeline.

## **V. COVID-19 Experimental Vaccines**

Precise language is an important way to combat disinformation. There are no COVID-19 vaccines. The correct terminology is that there are experimental COVID-19 vaccines, also known as investigational COVID-19 vaccines. Multiple types of vaccines are being tried; here is an overview of the categories. The ones closest to mass distribution are the mRNA vaccines.<sup>33</sup>

One reason we must call this what it is, which is *experimental*, is because the American public has been primed to receive this biological agent simply because the word *experimental* has gone missing. Almost no normal person would volunteer to be the first to receive an experimental drug unless they were very sick and there were no alternatives. With COVID-19 the vast majority of people do not get very sick, and there are many alternative treatments. We must insist on using the correct language of *experimental vaccine*.

The other reason we must call this what it is, *experimental*, is because having an experimental status has important legal implications. These agents are being distributed under an EUA (emergency use authorization)<sup>34</sup> which determines how future harm to patients will be compensated.

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<sup>33</sup> <https://www.nature.com/articles/d41586-020-01221-y>

<sup>34</sup> [https://www.fda.gov/media/144245/download?utm\\_campaign=The%20DC%20Today&utm\\_medium=email&hsmi=102466647&hsenc=p2ANqtz--L3Cb8fl6aCL4ZBDWT3lZC\\_zZlxF7sEiXXY-](https://www.fda.gov/media/144245/download?utm_campaign=The%20DC%20Today&utm_medium=email&hsmi=102466647&hsenc=p2ANqtz--L3Cb8fl6aCL4ZBDWT3lZC_zZlxF7sEiXXY-)

Note the language the Pharmaceutical company uses in its December 10, 2020 Advisory Report to the FDA. We must use the same language but not all Americans know or understand the word “investigational.”

Pfizer-BioNTech COVID-19 Vaccine  
VRBPAC Briefing Document

### 1. Executive Summary

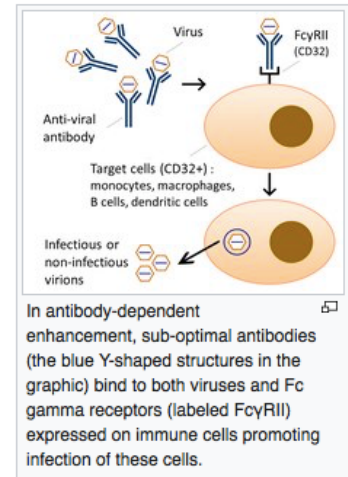
On November 20, 2020, Pfizer and BioNTech (the Sponsor) submitted an Emergency Use Authorization (EUA) request to FDA for **an investigational COVID-19 vaccine** (BNT162b2) intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The vaccine is based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNPs). The proposed use under an EUA is “for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.” The proposed dosing regimen is 2 doses, 30 µg each, administered 21 days apart.

## VI. COVID-19 Experimental Vaccines & Antibody-Dependent Enhancement

A well-documented and serious side effect of vaccines is known as pathogenic priming or antibody dependent or immune enhancement. It is difficult to prove, with doctors and scientists and the public tend to initially deny its existence by saying a person(s) has “a worse virus.” One way we learn that ADE is a real effect is by comparing vaccinated and unvaccinated populations. If entire populations are immediately vaccinated with these experimental vaccines, the true incidence of ADE will never be known, as many cases will just be falsely described as a “new strain” or “more severe strain.”

Although most readers have never heard of it, *antibody-dependent-enhancement* is so well known, it even has its own Wikipedia page: [https://en.wikipedia.org/wiki/Antibody-dependent\\_enhancement](https://en.wikipedia.org/wiki/Antibody-dependent_enhancement) screenshot date December 8, 2020. Note that coronaviruses are commonly implicated.

**Antibody-dependent enhancement (ADE)**, sometimes less precisely called **immune enhancement** or **disease enhancement**, is a phenomenon in which binding of a virus to suboptimal antibodies enhances its entry into host cells, followed by its replication.<sup>[1][2]</sup> Antiviral antibodies promote viral infection of target immune cells by exploiting the phagocytic FcγR or complement pathway.<sup>[3]</sup> After interaction with the virus the antibody binds Fc receptors (FcR) expressed on certain immune cells or some of the complement proteins. FcγR binds antibody via its fragment crystallizable region (Fc). This interaction facilitates uptake of the virus via phagocytosis of the virus-antibody complex by the immune cells. Consequently, FcR-bearing myeloid cells such as monocytes, macrophages, dendritic cells, and certain granulocytes are permissive to antibody-dependent enhancement infection, through phagocytic uptake of the immune complexes.<sup>[4]</sup> Usually the process of phagocytosis is accompanied by the virus degradation, however, if the virus is not neutralized (either due to low affinity binding or targeting to a non-neutralizing epitope), antibody binding might result in a virus escape and therefore, enhanced infection. Thus, phagocytosis can cause viral replication, with the subsequent death of immune cells. The virus “deceives” the process of phagocytosis of immune cells and uses the host's antibodies as a Trojan horse. ADE may occur due to the non-neutralizing characteristic of the antibody, which bind viral epitopes other than those involved in a host cell attachment and entry. ADE may also happen due to the presence of sub-neutralizing concentrations of antibodies (binding to viral epitopes below the threshold for neutralization).<sup>[4]</sup> In addition ADE can be induced when the strength of antibody-antigen interaction is below the certain threshold.<sup>[5][6]</sup> This phenomenon might lead to both increased virus infectivity and virulence. The viruses that can cause ADE frequently share some common features such as antigenic diversity, abilities to replicate and establish persistence in immune cells.<sup>[1]</sup> ADE can occur during the development of a primary or secondary viral infection, as well as after vaccination with a subsequent virus challenge.<sup>[1][7][8]</sup> It has been observed mainly with positive-strand RNA viruses. Among them are Flaviviruses such as Dengue virus,<sup>[9]</sup> Yellow fever virus, Zika virus,<sup>[10][11]</sup> Coronaviruses, including alpha- and betacoronaviruses,<sup>[12][13]</sup> Orthomyxoviruses such as influenza,<sup>[14]</sup> Retroviruses such as HIV,<sup>[15][16][17]</sup> and Orthopneumoviruses such as RSV.<sup>[18][19][20]</sup>



ADE is especially tricky because it is a delayed reaction. Initially all seems well. The person seems to have a great immune response but then becomes deadly when the person is exposed to the virus in the wild. It is well known that you must do animal testing first to try to rule out ADE. Strong vaccine advocates Dr. Offit and Dr. Hotez, who would be expected to be enthusiastic about these experimental vaccines, have not really endorsed these new experimental vaccines, because previous coronavirus vaccines have a long history of failure due to “antibody dependent enhancement.”

Antibody Dependent Enhancement (ADE), is when anti-COVID antibodies, created by a vaccine, instead of protecting the person, cause a more severe or lethal disease when the person is later exposed to SARS-CoV-2 in the wild. The vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world. This paradoxical reaction has been seen in other vaccines and animal trials. One well-documented example is with the Dengue fever vaccine, which resulted in avoidable deaths.<sup>35 36</sup>

Dengue fever has 100-400 million infections, 500,000 hospitalizations, and a 2.5% fatality rate annually worldwide. It is a leading cause of death in children in Asian and Latin American countries. Despite over 50 years of active research, a Dengue vaccine still has not gained widespread approval in large part due to ADE.<sup>37</sup> Sanofi Pharmaceutical spent 20

<sup>35</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642463/>

<sup>36</sup> <https://www.nature.com/scitable/topicpage/host-response-to-the-dengue-virus-22402106/>

<sup>37</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642463/>



years and nearly \$2 billion to develop the Dengue vaccine and published their results in the NEJM, which was quickly endorsed by the WHO. But there were scientists who clearly stated the danger, which the Philippines ignored, and they decided to give it to hundreds of thousands of children in 2016. Later when they were exposed in the wild, many got severely ill and 600 children died. Criminal charges were filed against the decision-makers.<sup>38</sup>

This same thing happened in the 1960's with Respiratory Syncytial Virus (RSV) – they also skipped the animal studies and gave the vaccine to 35 children and initially it looked like it worked well. But when those children were exposed to the wild virus, they got much sicker and then two of the kids died, which became a scandal. RSV typically is mild in children – whereas vaccinating children for it led to death.<sup>39</sup>

This has happened with other coronaviruses. SARS-CoV-1 had about 35 vaccine candidates, the best four were trialed in ferrets and it looked like it worked well. But when those ferrets were challenged in the wild they got very ill and died. Extremely concerning is that this antibody-dependent amplification, ADE, has long been known from experiments with corona vaccines in cats, for example. In the course of these studies all cats that initially tolerated the vaccination well died after catching the wild virus.<sup>40</sup>

The original SARS-CoV, a coronavirus 78% similar to the current SARS-CoV-2 causing COVID-19, caused an epidemic in 2003. Scientists attempted to create a vaccine. Initially it appeared promising, but ultimately it was abandoned because although the mice tolerated the vaccine and produced antibodies, when the mice were exposed to the actual virus in the wild, they died due to what we would think of as sudden severe cytokine storm.<sup>41</sup>

### Conclusions

These SARS-CoV vaccines all induced antibody and protection against infection with SARS-CoV. However, challenge of mice given any of the vaccines led to occurrence of Th2-type immunopathology suggesting hypersensitivity to SARS-CoV components was induced. Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated.

SARS-CoV-2, which can lead to COVID-19, was first documented less than one year ago with scant information on the disease course and interactions with immune systems from the various SARS-CoV-2 strains. We do know that SARS-CoV-2 is unique from other coronaviruses in that select individuals mount an aggressive immune response resulting in cytokine storm and death. It is still largely unknown why the immune response to SARS-

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<sup>38</sup> <https://childrenshealthdefense.org/news/COVID-19-robert-f-kennedy-jr-and-del-bigtree-talk-about-the-vaccine/>

<sup>39</sup> <https://www.reuters.com/article/us-rsv-shot/research-shows-why-1960s-rsv-shot-sickened-children-idUSTRE4BM4SH20081223>

<sup>40</sup> <https://2020news.de/en/dr-wodarg-and-dr-yeardon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygttnbNY>

<sup>41</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/>

CoV-2 varies so much from a large percentage of asymptomatic patients to rapid death in others.

Science, Nature, Journal of Infectious diseases and others, have already documented ADE, or vaccine-associated hypersensitivity (VAH) risks in relation to the development of experimental COVID-19 vaccines.<sup>42 43 44</sup>

The Phase III trials from Pfizer, Moderna and AstraZeneca provide little insight into ADE and VAH. Not only is the sample size of vaccinated participants who developed COVID-19 very small, but, based on the information publicly available, it is unknown which strains of SARS-CoV-2 afflicted the participants in the trials.

This ADE response is so concerning that many scientists already agree the risk is much too high to release these experimental vaccines to the public at large. On December 1, 2020, the ex-Pfizer head of respiratory research Dr. Michael Yeadon and the lung specialist and former head of the public health department Dr. Wolfgang Wodarg filed an application with the European Medicine Agency responsible for approving drugs in the European Union, for the immediate suspension of all SARS CoV 2 vaccine studies, in particular the BioNtech/Pfizer study on BNT162b.<sup>45 46</sup> One of the biggest reasons they cited was the formation of so-called “non-neutralizing antibodies” can lead to an exaggerated immune reaction, especially when the test person is confronted with the real, “wild” virus after vaccination. This so-called antibody-dependent amplification, ADE, has long been known from experiments with corona vaccines in cats, for example. In the course of these studies all cats that initially tolerated the vaccination well died after catching the wild virus.

If these experimental coronavirus vaccines cause an ADE reaction and millions and millions of Americans have taken this vaccine, instead of a 99.98% cure rate for COVID-19 we could face a 20-30% death rate when all these millions of Americans are exposed to COVID-19 in the wild.<sup>47</sup>

## **VII. COVID-19 Experimental Vaccines & Other Known Problems**

COVID-19 Experimental Vaccines should be expected to have similar problems as other vaccines, including neurologic disorders and possible racial disparities in vaccine responsiveness. Known complications of vaccines include neurological diseases such as transverse myelitis, multiple sclerosis, autism, and Guillain-Barre. For example, in 1976

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<sup>42</sup>[https://science.sciencemag.org/content/368/6494/945?fbclid=IwAR0BIDm74Kn3bbcX5MP5eLG\\_zn0kjkP23dSUB0SU-eNY7LKSyaloF7d6L-E](https://science.sciencemag.org/content/368/6494/945?fbclid=IwAR0BIDm74Kn3bbcX5MP5eLG_zn0kjkP23dSUB0SU-eNY7LKSyaloF7d6L-E)

<sup>43</sup> <https://www.nature.com/articles/s41564-020-00789-5>

<sup>44</sup> <https://academic.oup.com/jid/article/222/12/1946/5891764>

<sup>45</sup> <https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYdTxT3aK01NJDwHut3jWpygttnbNY>

<sup>46</sup> [https://2020news.de/wp-content/uploads/2020/12/Wodarg\\_Yeadon\\_EMA\\_Petition\\_Pfizer\\_Trial\\_FINAL\\_01DEC2020\\_EN\\_unsigned\\_with\\_Exhibits.pdf](https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf)

<sup>47</sup> This is speculation based upon the deaths of the ferrets in the prior SARS vaccine trials.



the government attempted a mass vaccination of the population with a newly created Swine Flu vaccine. The vaccination program was aborted after about 450 people came down with Guillain-Barre. The extremely limited experimental COVID-19 vaccine data already has revealed two transverse myelitis cases.<sup>48</sup>

There is already a large body of knowledge that ethnicity affects responsiveness to a vaccine, which is often underappreciated by scientists and the public.<sup>49</sup> A too strong immune reaction to a vaccine can result in inflammatory disease like transverse myelitis (inflammation and paralysis of the spinal cord). This raises grave concern about prioritizing African Americans to receive an experimental vaccine when so much available science shows that this demographic is already at a *higher* risk for adverse reactions to vaccines.

- i. Race and ethnicity were shown to affect antibody responses to the rubella vaccine, which elicited significantly higher titers in children of African ethnicity compared to those of European descent or Hispanic ethnicity [1].
- ii. A study conducted in the US found significantly higher seroprevalence rates of antibodies to measles virus in African Americans compared to Caucasians [2]
- iii. and antibody titers to the pertussis vaccine were strongly and consistently higher in African American children compared to Caucasian children [3].
- iv. A similar study conducted in Northern Canada showed that native Inuit and Innu infants developed higher antibody titers to a measles vaccine as compared to those of Caucasian descent [4].
- v. Disparities in serologic responses to vaccines were also observed between different ethnic groups for the *Haemophilus influenzae* type b-tetanus toxoid conjugate vaccine [5], or the *Haemophilus influenzae* type b polysaccharide-*Neisseria meningitidis* outer membrane protein conjugate vaccine [6].
- vi. A fifteen-year study of the hepatitis vaccine on babies found that “white boys were 64% less likely to have autism diagnosis relative to nonwhite boys.”<sup>50</sup>

Lastly, there are already known severe and unique problems with prior attempted coronavirus vaccines. The reason there are no upper respiratory coronavirus vaccines is because the risk/benefit ratio has never been overcome. The vaccine can cause pathogenic priming, increasing lethality whereas the virus itself is often transient and nonlethal. Dr. Hotez, strong vaccine advocate and scientist, testified at the House Science Committee Hearing that these type of vaccines caused worse outcomes including death in children.<sup>51</sup> One animal study of original SARS vaccine showed hypersensitivity to the SARS components “Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated.”<sup>52</sup> Previous coronavirus vaccine projects triggered immune responses so strong that the test animals died, and the vaccine trials were halted.<sup>53</sup>

<sup>48</sup> <https://www.nature.com/articles/d41586-020-02706-6>

<sup>49</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5325335/>

<sup>50</sup> <https://pubmed.ncbi.nlm.nih.gov/21058170/>

<sup>51</sup> Dr. Hotez, immunized and then paradoxical immune enhancement to respiratory virus vaccines –lab animals – same problem. proceed very slowly very cautiously  
<https://ican.wetransfer.com/downloads/17513d1218048533022b9bc163e9d64520201205190837/94d4f4540e3064b4bbbd42c7cecf67e920201205190837/e70343>

<sup>52</sup> <https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0035421&type=printable>

<sup>53</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/>

## **VIII. COVID-19 Experimental Vaccines & Other Unknown or New Problems**

Frontline physicians have a very healthy respect for what is unknown. With these new experimental vaccines more is unknown than known, so this section is by definition, incomplete. But we already have suggestions of where serious problems will arise, based upon early data and mechanism of action. There is evidence to support that the vaccine could cause permanent auto-immune rejection of the placenta.

Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. The way the experimental vaccines work, it is concerning that that deleterious effect on the placenta, which in the wild only lasts as long as the acute illness, would instead be lifelong.

There is a case report of a woman with a normally developing pregnancy who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with similar coronaviruses"<sup>54</sup> Thus far SARS-CoV-2 appears to be similar.<sup>55</sup> This issue has not been studied despite saying that "Additional studies of pregnant women with COVID-19 is warranted to determine if SARS-CoV-2 can cause similar adverse outcomes."

The purported mRNA vaccines may instigate a similar reaction as the virus. There is a component in the vaccine that could cause this same auto-immune rejection of the placenta but indefinitely. In layman's terms: getting COVID-19 has been associated with a high risk of mid-pregnancy miscarriage because the placenta fails – but the vaccine may do the exact same thing – but not for just the few weeks of being sick – but forever. Meaning repeated pregnancies would keep failing ~ mid-pregnancy. It is completely reckless to give this vaccine to millions of people who would otherwise all be expected to recover, until we know the answer to that question!

i. Here is the scientific theory/explanation for the effect on the placenta (and possibly on sperm): the spike protein of Sars-Cov-2, against which teams are competing to develop a vaccine, is highly homologous with a human HERV protein, syncytin-1. Syncytin-1, which is a HERV derived protein, causes fusion of cells in the trophoblast and has a role in placentation.<sup>56</sup> The vaccinations are expected to produce antibodies against spike proteins of SARS-CoV-2. However, spike proteins also contain syncytin-homologous proteins, which are essential for the formation of the placenta in mammals such as humans. It must be absolutely ruled out that a vaccine against SARS-CoV-2 could trigger an immune reaction against syncytin-1, as otherwise infertility of indefinite duration could result in vaccinated women.<sup>57 58</sup>

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<sup>54</sup> <https://jamanetwork.com/journals/jama/fullarticle/2765616>

<sup>55</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30311-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30311-1/fulltext)

<sup>56</sup> <https://bjgpilife.com/2020/05/21/of-hervs-and-COVID-19-questions-for-the-future/>

<sup>57</sup> <https://2020news.de/en/dr-wodarg-and-dr-yeardon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3y0j0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygtnnbNY>

Alignment of the endogenous elements Syn1 found on human chromosome 7, or Syn2 found on chromosome 6, or HERV-K expressed from chromosome 6, all show a number of sequence motifs with significant similarity to nCoV2019 spike protein.<sup>59</sup>

ii. As reported by Public Broadcasting Service, regarding placenta science: “The syncytiotrophoblast is the outermost layer of the placenta, the part that is pressed against the uterus. It’s literally a layer of cells that have fused together, forming a wall....This wall of cells keeps mom and baby working in harmony and not killing each other. There’s no other structure like this anywhere else in the body.”<sup>60</sup>

Many scientists already agree the risk is much too high to release these experimental vaccines to the public at large. On December 1, 2020, the ex-Pfizer head of respiratory research Dr. Michael Yeadon and the lung specialist and former head of the public health department Dr. Wolfgang Wodarg filed an application with the European Medicine Agency responsible for European approval, for the immediate suspension of all SARS CoV-2 vaccine studies, in particular the BioNTech/Pfizer study on BNT162b.<sup>61 62</sup> One of the biggest reasons they cited was the possibility of lifelong infertility as described above and copied here.

XI. Several vaccine candidates are expected to induce the formation of humoral antibodies against spike proteins of SARS-CoV-2. Syncytin-1 (see Gallaher, B., “Response to nCoV2019 Against Backdrop of Endogenous Retroviruses” - <http://virological.org/t/response-to-ncov2019-against-backdrop-of-endogenous-retroviruses/396>), which is derived from human endogenous retroviruses (HERV) and is responsible for the development of a placenta in mammals and humans and is therefore an essential prerequisite for a successful pregnancy, is also found in homologous form in the spike proteins of SARS viruses. There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, if this were to be the case this would then also prevent the formation of a placenta which would result in vaccinated women essentially becoming infertile. To my knowledge, Pfizer/BioNTech has yet to release any samples of written materials provided to patients, so it is unclear what, if any, information regarding (potential) fertility-specific risks caused by antibodies is included.

According to section 10.4.2 of the Pfizer/BioNTech trial protocol, a woman of childbearing potential (WOCBP) is eligible to participate if she is not pregnant or breastfeeding, and is using an acceptable contraceptive method as described in the trial protocol during the intervention period (for a minimum of 28 days after the last dose of study intervention).

This means that it could take a relatively long time before a noticeable number of cases of post-vaccination infertility could be observed.

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<sup>58</sup> [https://2020news.de/wp-content/uploads/2020/12/Wodarg\\_Yeadon\\_EMA\\_Petition\\_Pfizer\\_Trial\\_FINAL\\_01DEC2020\\_EN\\_unsigned\\_with\\_Exhibits.pdf](https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf)

<sup>59</sup> <https://virological.org/t/response-to-ncov2019-against-backdrop-of-endogenous-retroviruses/396>

<sup>60</sup> <https://whyy.org/segments/the-placenta-went-viral-and-protomammals-were-born/>

<sup>61</sup> <https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3y0j0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygttnbNY>

<sup>62</sup> [https://2020news.de/wp-content/uploads/2020/12/Wodarg\\_Yeadon\\_EMA\\_Petition\\_Pfizer\\_Trial\\_FINAL\\_01DEC2020\\_EN\\_unsigned\\_with\\_Exhibits.pdf](https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf)

## **IX. Pharmaceutical Companies Conflict of Interests**

When the worldwide government response to COVID-19 swept the globe, there was a rush to manufacture vaccines. What is mostly unknown is that pharmaceutical companies are shielded from paying anything to people who may be hurt by their vaccines. This is a unique carve-out and financial benefit that caused the pharmaceutical industry to explode to many times its former size in the 35 years since this deal was struck.

Since 1986, when pharmaceutical companies could no longer be sued when anything goes wrong with a vaccine, there has been a *huge* increase in vaccines and simultaneously much less caution than there should be when recommending a biological agent to millions of perfectly healthy people. “National Childhood Vaccine Injury Act” of 1986” said that nobody can sue pharmaceutical companies for any vaccine injury. 42 USC §300aa-11. So in 1986 there were 11 vaccines but fast forward to now there are 53 (1986: polio, DTP, MMR and that was it) and hundreds more planned. In that time the vaccine market went from \$1 billion to \$44 billion (that \$1B would be worth \$2.24B today) and it is obvious that pharmaceuticals are incentivized to make more and more vaccines.<sup>63</sup>

Pharmaceutical companies are now worth \$1.3 trillion.”<sup>64</sup> They are 2.5x Big Tobacco which is \$500 billion/year<sup>65</sup> and nearly 100x the NFL. Over the past twenty years, pharmaceutical companies have spent \$4 billion to lobby Congress which is more than aerospace, defense and oil/gas industries combined.<sup>66</sup>

While not alleging any negative purposeful intent, it is obvious that a company that does not *have* to be sure its products are safe will never be *as* careful as a company that cannot afford such mistakes. When there is a rush, as this unprecedented situation has revealed, all sorts of corners have been cut, including long-term studies and animal studies. And the very foundational question of even needing a vaccine has been pushed to the side, in large part due to the very exciting profit anticipated by the pharmaceutical companies. If things were not so rushed and financially incentivized, doctors and scientists would have noticed that a coronavirus vaccine is likely neither desirable nor safe and effective, given its low lethality, history of ADE and prior lethal result of coronavirus vaccines.

## **X. Experimental Vaccines & Legal Issues for Patients**

Once the FDA issues an EUA to permit any COVID-19 vaccine, a plaintiff’s options are limited pursuant to the PREP Act. Vaccine manufacturers lobbied for this legislation to

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<sup>63</sup> <https://www.bloomberg.com/features/2020-moderna-biontech-COVID-shot/> August 11, 2020. The possibility of a COVID-19 vaccine has led investors to more than triple the value of Moderna’s shares this year, giving the company a market capitalization of about \$28 billion, an astonishing number for a company with no products. BioNTech shares have more than doubled. A third company with an mRNA-based COVID-19 shot, CureVac AG, has said it’s considering an initial public offering. Both Stéphane Bancel, Moderna’s chief executive officer, and Ugur Sahin, his less flashy counterpart at BioNTech, have become multibillionaires.

<sup>64</sup> <https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/>

<sup>65</sup> <https://www.theguardian.com/business/2012/mar/22/tobacco-profits-deaths-6-million>

<sup>66</sup> <https://publicintegrity.org/health/opinion-big-pharmas-stranglehold-on-washington/>

preempt state vaccine safety laws in the case of an emergency declaration by the US Department of Health and Human Services (HHS).

“The PREP Act authorizes the Secretary of HHS to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of countermeasures to diseases, threats, and conditions determined by the Secretary to constitute a present, or credible risk of a future, public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability.”

On March 10, 2020, the Secretary of HHS made a public health emergency declaration for COVID-19, which makes the PREP Act’s protections applicable to the COVID-19 pandemic.

The PREP Act provides liability immunity to certain “covered persons” against any claim of loss cause by (or arising out of, relating to, or resulting from) the manufacture, distribution, administration, or use of medical countermeasures, which includes a COVID-19 vaccine. This Act shields the pharmaceutical companies from liability, making it difficult to hold them financially responsible. In other words, it is much more difficult than a regular products liability case. The pharmaceutical company can only be liable if there is “willful misconduct” as defined by the Act, which results in death or serious physical injury. AFLDS are putting the pharmaceutical companies on notice today, before the vaccine is distributed, administered, or used, that if they go forward now, with their intent to achieve a wrongful purpose and despite being informed of the serious potential risks as outlined herein, they are clearly engaging in willful misconduct and are, therefore, no longer protected under the PREP Act.

The PREP Act does *not* shield employers or businesses as “covered persons” and should they attempt to mandate vaccination, they may be liable for resulting harms.

Pursuant to an EUA, each person has a right to decline a medication/biologic that is not fully licensed. The subject needs to be told the risks/benefits and of the right to decline. An experimental treatment cannot be forced. So, for example, if a teachers’ union or an airline attempts to mandate a COVID-19 vaccine issued under an EUA, they may very well be liable for bad outcomes.

Many scientists already agree the risk is much too high to proceed with these experimental vaccines. On December 1, 2020, the ex-Pfizer head of respiratory research Dr. Michael Yeadon and the lung specialist and former head of the public health department Dr. Wolfgang Wodarg filed an application with the Medicine Agency responsible for EU-wide drug approval, for the immediate suspension of all SARS CoV 2 vaccine studies, in particular the BioNtech/Pfizer study on BNT162b (EudraCT number 2020-002641-42). Dr. Wodarg and Dr. Yeadon demand that the studies – for the protection of the life and health of the volunteers – should not be continued until a study design is available that is suitable to address the significant safety concerns expressed by an increasing number of renowned

scientists against the vaccine and the study design. Furthermore, they demand that it must be excluded, e.g. by means of animal experiments, that risks already known from previous studies, which partly originate from the nature of the coronaviruses, can be realized. The concerns are directed in particular to the following four points (the first two were stated earlier in this paper):

- The formation of so-called “non-neutralizing antibodies” can lead to an exaggerated immune reaction, especially when the test person is confronted with the real, “wild” virus after vaccination. This so-called antibody-dependent amplification, ADE, has long been known from experiments with corona vaccines in cats, for example. In the course of these studies all cats that initially tolerated the vaccination well died after catching the wild virus.
- The vaccinations are expected to produce antibodies against spike proteins of SARS-CoV-2. However, spike proteins also contain syncytin-homologous proteins, which are essential for the formation of the placenta in mammals such as humans. It must be absolutely ruled out that a vaccine against SARS-CoV-2 could trigger an immune reaction against syncytin-1, as otherwise infertility of indefinite duration could result in vaccinated women.
- The mRNA vaccines from BioNTech/Pfizer contain polyethylene glycol (PEG). 70% of people develop antibodies against this substance – this means that many people can develop allergic, potentially fatal reactions to the vaccination.
- The much too short duration of the study does not allow a realistic estimation of the late effects. As in the narcolepsy cases after the swine flu vaccination, millions of healthy people would be exposed to an unacceptable risk if an emergency approval were to be granted and the possibility of observing the late effects of the vaccination were to follow. Nevertheless, BioNTech/Pfizer apparently submitted an application for emergency approval on December 1, 2020.<sup>67 68</sup>

The reason it is so important that many scientists including the above, and including the undersigned have been so public with their concerns is that it is premature to plan for widespread release of a vaccine that is in experimental stages. It is willful misconduct to ignore the serious safety concerns.

## **XI. COVID-19 Experimental Vaccines & Unusual Processes**

### **a. Pharmaco-vigilance tracking system.**

The Department of Defense of the federal government has contracted with Google and Oracle to track vaccinated persons. In the document entitled “From the Factory to the Frontlines,” the Department of Health and Human Services (HHS) and the Department of Defense (DOD) stated that, because Warp Speed vaccine candidates use new unlicensed

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<sup>67</sup> <https://2020news.de/en/dr-wodarg-and-dr-yeardon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygttnbNY>

<sup>68</sup> [https://2020news.de/wp-content/uploads/2020/12/Wodarg\\_Yeardon\\_EMA\\_Petition\\_Pfizer\\_Trial\\_FINAL\\_01DEC2020\\_EN\\_unsigned\\_with\\_Exhibits.pdf](https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeardon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf)



vaccine production methods that “have limited previous data on safety in humans . . . the long-term safety of these vaccines will be carefully assessed using pharmacovigilance surveillance and Phase 4 (post-licensure) clinical trials.”<sup>69 70</sup> The vaccination effort itself (OWS) is being managed by the military with the DHS and NSA as opposed to what is usually done, which is civilian health agencies. Law enforcement and DHS officials are not to be prioritized and the CDC Advisory Committee on Immunization Practices has identified “critical populations” including ethnic minorities and the mentally challenged.

**b. Priming of Racial Minorities to Accept Experimental Vaccinations.**

There is scant evidence that race is an *independent* risk factor for severe COVID-19 disease and there is substantial evidence to suggest it is *irrelevant*. Individuals at much higher risk of dying are those with obesity, diabetes, hypertension, renal, heart disease and groups of people at higher risk are those who live in crowded areas and homes, use mass-transit, and work closely with the public (bus drivers, fast food.) So in Louisiana, blacks are 31% population but 70% infected, and this observation was sold to blacks as being a true racial difference. But while these individual and group risk factors are higher in blacks in the USA, in other countries, for example in the UK, it is not blacks but middle eastern and east Asian who are at higher risk.<sup>71</sup> And all ethnicities are affected worldwide but in Africa, COVID-19 deaths are exceedingly rare - 1% of western European nations.

**c. Racial Justice Via Experimental Vaccination?**

The CDC is telling the public at large that getting an experimental vaccine is a good thing, but it's *additionally* telling black people that getting the vaccine is “racial justice” and an advantage. Not only does phrase “racial justice” have no place in serious scientific inquiries, there is certainly no advantage to being first in line to get something experimental when the risk of the virus itself is so low.<sup>72</sup>

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<sup>69</sup> <https://www.thelastamericanvagabond.com/google-oracle-monitor-americans-who-get-warp-speeds-COVID-19-vaccine-for-two-years/> During an interview with the *Wall Street Journal* published last Friday, the “captain” of Operation Warp Speed, career Big Pharma executive Moncef Slaoui, confirmed that the millions of Americans who are set to receive the project’s COVID-19 vaccine will be monitored via “incredibly precise . . . tracking systems” that will “ensure that patients each get two doses of the same vaccine and to monitor them for adverse health effects.” Slaoui also noted that tech giants Google and Oracle have been contracted as part of this “tracking system” but did not specify their exact roles beyond helping to “collect and track vaccine data.”

<sup>70</sup> <https://www.thelastamericanvagabond.com/google-oracle-monitor-americans-who-get-warp-speeds-COVID-19-vaccine-for-two-years> “The key objective of pharmacovigilance is to determine each vaccine’s performance in real-life scenarios, to study efficacy, and to discover any infrequent and rare side effects not identified in clinical trials. OWS will also use pharmacovigilance analytics, which serves as one of the instruments for the continuous monitoring of pharmacovigilance data. Robust analytical tools will be used to leverage large amounts of data and the benefits of using such data across the value chain, including regulatory obligations.”

<sup>71</sup> <https://nypost.com/2020/07/16/the-lunatic-drive-for-racial-quotas-for-COVID-19-vaccines/>

<sup>72</sup> <https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-COVID-19-vaccine-allocation-and-distribution-in-the-us>



As a matter of justice, these disparities in COVID-19 risk and adverse outcomes across racial and ethnic groups should be addressed in our overall COVID-19 response.<sup>42</sup> The key questions here are whether these disparities should be addressed through a vaccine allocation plan, and, if so, how is that best achieved? For example, a question to consider is whether racial and ethnic groups should be prioritized directly. While this approach could potentially enable the greatest impact on reducing COVID-19 burden in these populations, awareness of historical or ongoing injustice in the medical system has led some Black individuals to lack confidence in the safety or efficacy of vaccines.<sup>43</sup> Directly prioritizing Black populations could further threaten the fragile trust that some have in the medical and public health system, particularly if there is the perception that there has been a lack of testing to assess vaccine safety and that they are the “guinea pigs.”<sup>43</sup> The implementation of directly prioritizing communities of color could also be challenging and divisive, as determining how to access specific populations and how to determine eligibility based on race or ethnicity includes many sensitive challenges.

#### d. Specific and Targeted Racial Profiling.

Is it “fairness” and “social justice” to be first to receive an experimental vaccine? “The ultimate safety of an approved vaccine is not knowable until it has been administered to millions of people. ... It is also possible that certain adverse effects may occur more frequently in certain population subgroups, which may not be apparent until millions are vaccinated. ... pharmaco-vigilance systems will provide critical information ... that may inform adjustments to the optimal allocation.”<sup>73</sup>

Previous coronavirus vaccine projects triggered immune responses so strong that the test animals died, and the vaccine studies were stopped. Claiming that vaccinating African Americans and other ethnic minorities first represents “fairness and justice” and would address “structural racism” contradicts the CDC admission that the safety of the COVID-19 vaccine is “not completely knowable” until millions have received it and that “certain adverse effects may occur more frequently in certain population subgroups.”

The most disenfranchised members of society are to be vaccinated first: “racial and ethnic minorities, tribal, incarcerated, rural, disabilities, underinsured, people who work in school settings, nurses.”<sup>74</sup> “Must prioritize blacks and Latinos to reflect fairness and justice.”<sup>75</sup>

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<sup>73</sup> <https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-COVID-19-vaccine-allocation-and-distribution-in-the-us>

<sup>74</sup> [https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf) page 15

<sup>75</sup> <https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-COVID-19-vaccine-allocation-and-distribution-in-the-us> page 12 It states that “a critical difference” between COVID-19 vaccine allocation and the “context envisioned in the 2018 guidance for pandemic influenza vaccine allocation” is the fact that the US is “currently in the midst of a national reckoning on racial injustice, prompted by cases of police brutality and murder.” It goes on to state that “although structural racism was as present in the 2018 and previous influenza epidemics as it is today, the general public acknowledgment of racial injustice was not.” It goes without saying that police brutality is decidedly unrelated to vaccine allocation as is increased national awareness of racial injustice as it relates to police brutality. This is further compounded by the police, in this document, being removed as a priority group for COVID-19 vaccine allocation, despite having been designated a priority group in all other government vaccine-allocation guidance since the 2001 anthrax attacks. Also odd is that it is only

e. **Specific and Targeted Racial Messaging.**

Relevant information (known and unknown risks) is being censored or minimized everywhere, but the censorship is particularly targeted in the black community. First note what The Johns Hopkins Center for Health Security, World Economic Forum, and Bill & Melinda Gates Foundation proposed in preparing for a pandemic (i) and then note what Operation Warp Speed actually implemented (ii).<sup>76</sup>

i. (all communities) Governments and the private sector should assign a greater priority to developing methods to combat mis- and disinformation prior to the next pandemic response. Governments will need to partner with traditional and social media companies to research and develop nimble approaches to countering misinformation. This will require **developing the ability to flood media with fast, accurate, and consistent information**. Public health authorities should work with private employers and trusted community leaders such as faith leaders, to promulgate factual information to employees and citizens. Trusted, influential private-sector employers should create the capacity to readily and reliably augment public messaging, **manage rumors and misinformation**, and amplify credible information to support emergency public communications. National public health agencies should work in close collaboration with WHO to create the capability to rapidly develop and release consistent health messages. For their part, **media companies should commit to ensuring that authoritative messages are prioritized and that false messages are suppressed including through the use of technology**.

ii. (minority communities):<sup>77</sup> “Further, work has begun with organizations representing minority populations and vulnerable communities, with consultation already occurring with more than 150 organizations dedicated to addressing health disparities. Faith-based and other trusted community organizations can also be critical in addressing vaccine hesitancy, and HHS’s Center for Faith and Opportunity Initiatives is working with minority-serving faith and community groups to enlist their help in educating Americans and encouraging participation in the vaccination program.

Strategic communications and public messaging are critical to ensure maximum acceptance of vaccines, requiring a saturation of messaging across the national media. An information campaign led by HHS’s public affairs department—developed using human-centered design, extensive public and stakeholder engagement, and research on message development and delivery—will focus on vaccine safety and efficacy, and target key populations and communities to ensure maximum vaccine acceptance.<sup>78 79</sup>



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increased access of minorities to the COVID-19 vaccine that is cited as a way to address “structural racism in health systems,” not other policies that would be more likely to address the problem.

<sup>76</sup> <https://www.centerforhealthsecurity.org/event201/recommendations.html>

<sup>77</sup> <https://www.hhs.gov/sites/default/files/strategy-for-distributing-COVID-19-vaccine.pdf>

<sup>78</sup> <https://www.hhs.gov/sites/default/files/strategy-for-distributing-COVID-19-vaccine.pdf>

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Obama, in an interview with SiriusXM host Joe Madison scheduled to air Thursday, said if Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases and the nation's top infectious disease expert, said a coronavirus vaccine is safe, he believes him.

"People like Anthony Fauci, who I know, and I've worked with, I trust completely," Obama said. "So, if Anthony Fauci tells me this vaccine is safe, and can vaccinate, you know, immunize you from getting Covid, absolutely, I'm going to take it."

"I promise you that when it's been made for people who are less at risk, I will be taking it," he said.

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During the interview, Obama appeared to acknowledge the unusual problem of vaccine

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<sup>79</sup> <https://cnnphilippines.com/world/2020/12/3/US-Barack-Obama-COVID-19-vaccine-television.html>

## **XII. AFLDS Recommendations Regarding COVID-19 Experimental Vaccines**

**Prohibited** for the young, **Discouraged** for the healthy middle-aged and **Optional** for the co-morbid and elderly. There is no evidence that vaccines should be racially prioritized.

- a. 0-20: **prohibited** (exceedingly low risk from COVID, unknown risk of auto-immune disease, unknown risk of pathogenic priming, risk of lifelong infertility)
- b. 20-50 healthy: **strongly discouraged** (exceedingly low risk from COVID, unknown risk of auto-immune disease, unknown risk of pathogenic priming, risk of lifelong infertility)
- c. 50-69 & healthy: **strongly discouraged** (low risk from COVID, unknown risk of auto-immune disease, unknown risk of pathogenic priming, unknown effect on placenta and spermatogenesis)
- d. 50-69 & co-morbid: **discouraged** (experimental vaccine is higher risk than early or prophylactic treatment with established medications)
- e. >70 & healthy: **personal risk assessment** (experimental vaccine is higher risk than early or prophylactic treatment with established medications)
- f. >70 & co-morbid: **personal risk assessment & advocacy access** (experimental vaccine early or prophylactic treatment with established medications)

In medicine, the guiding principle is “First, do no harm.” Widely distributing a COVID-19 experimental vaccine before adequately addressing and clinically evaluating the above concerns is reckless. This is especially true in adults under 50 years old who have an infection survival rate of about 99.98%, and even lower in those without high-risk comorbidities. While “first, do no harm” may not be a guiding principle for politicians or health authorities, it still resides in the forefront of the minds of frontline physicians.

The warp speed progress in vaccine development should be praised. This should not be confused, however, with readiness to distribute a vaccine to hundreds of millions persons globally. EUAs, for vaccines does not obviate the need to make good decisions for patients. Because the IFR (infection fatality ratio) is exceedingly low for younger persons and because the vaccine is experimental with so many known and unknown risks including neurologic disorders, auto-immune disorders, high concern for antibody-dependent enhancement and infertility concerns., America’s Frontline Doctors’ holds that it is unethical to advocate for the vaccine to persons under 50. The risk and safety evidence based upon trials cannot be justified in younger persons. It is therefore prohibited. If pharmaceutical companies, private businesses or the government mandate or coerce persons to comply with unethical policies for which there is substantial evidence of likely harm, and indeed a person is harmed, that person’s grievances must be adjudicated in light of the future defendant’s knowingly willful misconduct and AFLDS will do everything within its power to assist such plaintiffs. While we sincerely hope this will never be the case, and we are taking all measures to reduce that possibility, should that unfortunate situation come to pass, we expect to assist hundreds of thousands of patients in class action lawsuits.

Vaccination must always be an informed decision between a doctor and his/her patient that takes into consideration a plurality of risk factors including patient age, comorbidities and exposure risks. Every patient is unique both in mind and body. It is in the sacrosanct

relationship between a patient and doctor that these differences are explored, not by a politician or remote health authority that will never face a patient or grieving family member to report bad news from a medical intervention.

### **XIII. Call To Action**

1. Always use the correct language. COVID-19 **EXPERIMENTAL** Vaccines
2. Immediately make it know that you will refuse to consent with any attempt to mandate an experimental vaccine by an employer, school or business.

- sign and share the SMD PETITION

[www.SMDPetition.org](http://www.SMDPetition.org) and #StopMedicalDisc

- empower others by widely sharing the position paper, found at:

[www.StopMedicalDiscrimination.org](http://www.StopMedicalDiscrimination.org)

[www.SMDPetition.org](http://www.SMDPetition.org)

[www.AmericasFrontlineDoctors.com](http://www.AmericasFrontlineDoctors.com)

- write individual and group letters to your employer or school
- if you are part of a union, bring this concern to the union
- this is an apolitical, human rights issue

