# Letter Regarding COVID-19 Vaccines

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### Preface:

I believe that every individual should have enough information to make an informed decision. When deciding on any medical intervention, the risks need to be weighed against the benefits.

In the case of all the current COVID vaccines, there is little conclusive evidence about their effectiveness in the real world. And there is growing evidence that the vaccines carry significant risks of serious injury or even death. The information presented in this letter is, of course, current only to the date shown above.

I touch only briefly on the questions of the level of risk posed by COVID and on possible preventive treatments at the end of this letter.

### PART I: How COVID Vaccines Work

Understanding the biology behind these vaccines is important in order to understand why they are potentially dangerous. I include citations in the endnotes for the scientific papers. You can find most of the articles on the PubMed search engine: https://pubmed.ncbi.nlm.nih.gov/. There are two types of COVID vaccines: an mRNA vaccine (Pfizer, Moderna) and an adenovirus vector vaccine (Johnson and Johnson, AstraZeneca/Oxford, and CanSino).

Traditional vaccines, such as flu vaccines, use a weakened or inactivated strain of the pathogen in order to trigger our immune system to make antibodies.

Unlike traditional vaccines, the COVID vaccines don't involve the pathogen directly but rather "trick" our cells into making one of the COVID proteins. These vaccines inject DNA or RNA (packaged in different ways) into our bodies.

Pfizer and Moderna use a protective shell to deliver mRNA into our cells. Johnson and Johnson, AstraZeneca/Oxford, and CanSino use a common virus, the adenovirus, to transport COVID DNA. The adenovirus causes a range of illness such as the common cold, bronchitis, and pneumonia. The scientists remove some of the adenovirus genes that cause cold-like symptoms but leave behind the genes that allow the adenovirus to infect our cells. When the adenovirus gets into the cells, the DNA is turned into mRNA.

From there, all the vaccines work similarly. The mRNA directs the cells to make the COVID spike protein. The spike protein binds to the surface of our cells and is seen by our immune system, which responds by creating antibodies.

This letter focuses mainly on the Pfizer vaccine because Pfizer's report to the FDA offers the most detailed information publicly available on any of the vaccines. However, both the biological principles and the data that are available on the other vaccines suggest that the risks of those vaccines are likely to be similar to those of Pfizer's.

(All quotes from Pfizer, unless otherwise documented, come from their December 10, 2020 report to the FDA.)  $^{\rm 1}$ 

# PART II: Are the Vaccines Safe?

Before any medication is used, its safety has to be tested by the company. (There are questions as to whether this is a good system or if there should be an outside source testing the safety, but this is the current system used for medications.) Let's see what information is so far available on the safety of the COVID vaccines:

### A. Pfizer safety studies for a median of two months only

As of Pfizer's December 10, 2020 report, they had assessed the safety of the vaccine for a median of only two months. Even in that short time frame,

as discussed below, the report reflected some safety concerns. Yet that report is the basis of the current vaccine drive.

Moreover, some of the more serious possible consequences of the vaccine that will be discussed in PART III will only show up six months or longer after vaccination, and there are thus *no* data available to assess these risks. Research has shown that it often takes several years for scientists to definitively trace health problems to a specific vaccine. Pfizer's trial protocol calls for a total of 24 months of follow-up after the second vaccination in order to check on safety. In other words, everyone who takes the vaccine during the next two years is effectively taking part in an experiment.

# B. There are no safety data for children, immunocompromised individuals, and pregnant/nursing women

Pfizer reports that certain groups were specifically excluded when determining safety:

i. Pfizer reports that reactions to the vaccine for ages 12-15 in phase 2/3 were not included in the document because "the available data, including number of participants and follow-up duration, were insufficient to support a favorable benefit-risk determination at this time."

Please take a moment to appreciate this sentence: Pfizer admits that it excluded data *because they did not support a positive result for vaccine use*. This sentence can be construed in two ways: either the vaccine showed no clear benefits for ages 12-15, or the risks were too great for ages 12-15 to justify the use of the vaccine. Either way, there is no evidence that the vaccine is safe for children.

- **ii.** For slightly older children, ages 16-17, Pfizer reports that there are no safety data: "Solicited reactogenicity data in adolescents 16-17 years of age are not available for the reporting period."
- iii. Another important group was discarded for safety purposes: "HIVpositive individuals were included in the all-enrolled population, but not the phase 2/3 safety population because the number of participants enrolled by October 9, 2020 was small (n=120) and the median duration of safety follow-up was short."

Although the Pfizer study specifically checked HIV-positive individuals, this subgroup represents all immunocompromised individuals. Immunocompromised individuals include people undergoing chemotherapy, people suffering from lymphomas, people with auto-immune disorders who are taking immunosuppressant medications, and transplant recipients, among others.

iv. There are no data for pregnant or nursing women.

#### C. Side effects as reported by Pfizer

Over the two months that Pfizer evaluated the safety of the vaccine, "A higher proportion of vaccine recipients reported adverse events compared with placebo recipients." These adverse effects included pain, redness, swelling, fever, diarrhea, fatigue, headache, chills, vomiting, joint pain, muscle pain, and allergic reactions. The side effects lasted from hours to several days. Increased side effects were seen after the second dose than the first and were seen more in younger individuals rather than in the older group. These side effects lasted from a few hours to seven days. These side effects were seen in up to 80% of vaccine recipients and in a lower number of placebo recipients.

More serious side effects connected to the vaccine included lymphadenopathy and Bell's palsy. One of the most serious side effects that was confirmed to be related to the vaccine was ventricular arrhythmia (rapid, erratic heartbeat).

This covers the side effects Pfizer confirms are linked to the vaccine. But there is another set of side effects that may be linked to the vaccine but not necessarily to the experimental mRNA in the vaccine. What do I mean? Vaccines contain other components besides the pathogen (or, in this case, the mRNA that codes for the pathogen). In most vaccine studies, the placebo is made up of these other components. In other words, the manufacturers want to compare the effects of the injection with and without the pathogen.

That leaves open the possibility that nonpathogenic components of the vaccine can cause side effects. For example, Pfizer reports that about 6% of all the participants, both in the vaccine group and in the placebo group, dropped out after the first dose of the vaccine, many due to side effects after the first dose. Since dropouts occurred in about equal proportion in both the vaccine and placebo groups, a logical conclusion is that these side effects were caused by the nonpathogenic components of the vaccine.

More worrying than these nasty side effects that caused participants to drop out are Pfizer's reports of cardiac events and strokes. Pfizer reports that cardiac problems and strokes were two of the most frequent serious side effects seen after injections - in both the vaccine and placebo group. An important question is whether the cardiac events and strokes were triggered by the non-pathogen components that were present in both the vaccine and the placebo. Pfizer could have tried to determine whether the vaccine components were causing the problem by comparing the percentage of cardiac and stroke events to an equivalent non-injected population. The analysis would compare the same number of people of a similar age and health background as those in the study group. Pfizer does not provide any of that information in its report.

Alternatively, Pfizer could have included a group that got a placebo of just saline. Note that the Pfizer report doesn't say what the placebo group received, so there is a possibility that a saline injection was used, but it is unlikely. In most vaccine studies, the placebo contains all the ingredients except the actual pathogen.

While the risks to the people receiving the vaccine are the same whether the side effects are caused by the pathogen (mRNA in this case) or non-pathogenic ingredients, the distinction is important in future vaccine research. If the cause is only the pathogen, then the technology and other chemicals can still be used. If, however, the cause is related to the technology and other chemicals, one has to scrap the vaccine and start over.

### D. Serious side effects as reported by the CDC and FDA

Information about vaccine side effects is collected by the CDC in the Vaccine Adverse Event Reporting System (VAERS). VAERS records mild side effects as well as serious ones. It relies on individuals and health care professionals to submit reports voluntarily. Reports submitted to VAERS require further investigation before confirmation can be made that an adverse event was linked to a vaccine. It is estimated that only a small percentage of vaccine injuries are reported to the VAERS. Not only that, but the system crashed in January for at least two days because of an "unusually high volume of calls."<sup>2</sup>

Nonetheless, as of January 22, 2021, there were 9845 recorded adverse effects from the COVID vaccines, including 329 deaths. The average age of death was 76.  $^3$ 

Those side effects (seen in both the Pfizer and Moderna vaccines) include:  $^{\rm 4}$ 

- <u>Guillain-Barré syndrome:</u> auto-immune disorder affecting the nervous system which starts with muscle weakness and progresses to full body paralysis.
- <u>Acute disseminated encephalomyelitis:</u> inflammation of the brain and spinal cord that damages myelin.
- <u>Transverse myelitis:</u> inflammation of the spinal cord leading to damage of myelin and causing pain, muscle weakness, paralysis, sensory problems, or bladder and bowel dysfunction.

- <u>Encephalitis/myelitis/encephalomyelitis/</u> <u>meningoencephalitis/meningitis/encepholapathy:</u> inflammation of the brain and/or spinal cord.
- <u>Convulsions/seizures:</u> sudden change in the brain's normal electrical activity which temporarily affects behavior, movement, or sensation.
- <u>Stroke:</u> cessation of proper brain functioning due to either poor blood flow or internal bleeding.
- <u>Narcolepsy and cataplexy</u>: neurological disorder in which the normal sleep/wake cycle is confused; may be accompanied by extreme muscle weakness.
- <u>Anaphylaxis:</u> severe, potentially life-threatening allergic reaction.
- <u>Acute myocardial infarction:</u> heart attack.
- <u>Myocarditis/pericarditis:</u> inflammation of heart muscle or lining.
- <u>Autoimmune disease:</u> an attack of the immune system on the body.
- <u>Pregnancy and birth outcomes</u>, including spontaneous abortions and birth defects.
- <u>Other acute demyelinating diseases</u>, such as diseases which destroy the myelin covering on the nerves so that messages from the brain/spinal cord to the rest of the body are disrupted. This leads to deficiencies in sensation, movement, or cognition.
- <u>Non-anaphylactic allergic reactions:</u> non-fatal allergic reactions.
- <u>Thrombocytopenia:</u> low platelet count which might cause problems in clotting, possibly leading to internal bleeding.
- <u>Disseminated intravascular coagulation</u>: abnormal blood clotting, causing formation of small blood clots throughout the body. This may lead to bleeding, bruising, shortness of breath, confusion, and death.
- <u>Venous thromboembolism</u>: blood clot starting in a vein. This may just affect a leg or arm, or it may break off and travel to the lungs where it might block an artery.
- <u>Arthritis and arthralgia/joint pain:</u> swelling, stiffness and pain in the joints.
- <u>Kawasaki disease:</u> inflammation of blood vessels throughout the body. This may cause problems in the heart, lymph nodes, skin, mouth, nose, and throat.
- <u>Multisystem Inflammatory Syndrome in Children:</u> systemic illness involving high fever and extreme inflammation in the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs.
- <u>Vaccine enhanced disease (ADE)</u>: a syndrome in which having the antibodies to a disease actually makes you more susceptible to another form of the same disease (as described in PART III.)
- <u>Deaths:</u>self-explanatory

# E. Deaths

In addition to the 329 deaths reported by the CDC in the US, deaths have been reported in many countries following vaccination <sup>5, 6</sup>: Israel, Mexico, Denmark, Finland, Sweden, Portugal, Iceland, and Switzerland. Deaths connected to the vaccine have also been reported in Norway, <sup>7, 8</sup> Gilbralter, <sup>9</sup> and Germany. <sup>10</sup>

Unfortunately, the deaths from the vaccine are not unexpected when one looks at previous research. There are already several known physiological mechanisms which could account for the death toll. In the next section, I'll explain some of the mechanisms and describe the previous research.

# PART III: Serious Complications Any COVID Vaccine Might Cause

PART II described side effects that have already been observed following injection with COVID vaccines. However, the COVID vaccines have not been in use long enough for us to assess their full impact nor to know what long term side effects might occur. Research on the immunological effects of other vaccines, and the mRNA/DNA technologies being used in the COVID vaccines, however, have led scientists to warn of four possible serious complications of **any** COVID vaccine.

- i. <u>Antibody-dependent enhancement of the disease:</u> a condition where antibodies, such as those induced by the vaccine, can cause the person to suffer a more severe reaction to being exposed to COVID than if you didn't have the antibodies.
- ii. <u>Lung and heart disease caused by the vaccine itself</u>: the vaccines cause the body to manufacture a part of the COVID virus to induce an immune response. That part is the spike protein. The spike protein by itself, without any other part of the virus, can cause severe lung and heart problems.
- iii. <u>Chronic autoimmune disorders:</u> the COVID protein in the vaccines looks a lot like normal human proteins, leading the body's immune system to get confused and attack the proteins in the person's own body.
- **iv.** <u>Anaphylactic shock:</u> a deadly allergic reaction triggered by the components of the vaccine.

Let me describe the research behind each of these dangers more thoroughly.

#### A. Antibody-dependent enhancement of the disease (ADE)

Researchers have expressed great concern that COVID vaccines may lead to a complication known as ADE.<sup>11, 12</sup>

Pfizer/BioNTech, Moderna, and AstraZeneca concur that ADE is a potential risk. Pfizer writes: "The Sponsor identified vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease as an important potential risk."

ADE, pathogenic priming, and vaccine-associated enhanced disease are all terms that refer to very similar phenomena. In brief, these phenomena describe a situation in which having the antibodies to a disease actually makes us *more* susceptible to another form of the same disease, such as a wild strain or a slightly mutated strain.

Sounds paradoxical, right? We think of antibodies as good. We give vaccines in order to produce antibodies. *However, it turns out that antibodies to viruses sometimes make the infection worse.* In other words, rather than enhance our immunity against the infection, antibodies (whether naturally generated or induced by vaccines) actually enhance the virus' ability to enter and infect your cells, resulting in more severe disease than would have been the case had you not been vaccinated.

How does this happen? There are probably several different mechanisms, depending on the virus. One mechanism involving coronaviruses has been extensively studied. It turns out that virus-antibody complexes can interact with cell membranes and induce endocytosis (active transport into the cell), allowing the virus to enter the cell and replicate. <sup>13</sup> In fact, the antibody-virus complex can more effectively infect cells than the virus alone. <sup>14</sup> Once the virus enters the cell, it takes over and makes more viruses.

Vaccines against several coronaviruses have been shown to trigger this phenomenon:  $^{\mbox{\tiny 15}}$ 

- FIPV is a feline coronavirus. Researchers have shown that antibodies to the spike protein in FIPV enhances the uptake of the virus into feline cells.<sup>16</sup>
- In 2002, the coronavirus SARS was first seen in China. Two vaccines were created and tested in mice in 2006. The vaccines did a relatively good job in young mice, but were not as effective in older mice, for the strain of SARS that was circulating at that time. Then the researchers checked to see if the vaccinated mice would be protected against *other* strains of SARS. One vaccine seemed to offer good protection to

young vaccinated mice but only partial protection to the old mice. The other vaccine not only did *not* offer protection to any of the vaccinated mice exposed to the wild strain, but also seemed to cause a more robust infection of SARS in the vaccinated mice.<sup>17</sup> In a later study, four different SARS-CoV vaccines were evaluated in mice. All four vaccines produced antibodies against SACRS-CoV. However, when the mice were later exposed to SARS-CoV, vaccinated mice showed increased damage to lung cells as compared to unvaccinated mice, indicating that all the vaccines had led to more robust lung infections.<sup>18</sup>

 Middle East respiratory syndrome coronavirus (MERS-CoV) was first identified in Jordan and Saudi Arabia in 2012. Researchers have shown that mice vaccinated for Mers-CoVMERS-CoV show greater lung damage when challenged with the virus later. <sup>19</sup>

Because of the documented evidence that coronavirus vaccines have produced ADE, we can better understand the warnings of Pfizer and the WHO that the Pfizer vaccine is designed *merely to mitigate symptoms and does not necessarily prevent infection* (see part IV). The concern is that the vaccine will induce anti-COVID antibodies that will then make the vaccinated individual more susceptible to more severe reactions to COVID if he is exposed again.

ADE happens not just with vaccines against coronaviruses but also against other viruses, as well. <sup>20</sup> The following examples illustrate the seriousness of ADE:

- i. Respiratory syncytial virus (RSV) is a leading agent of serious pediatric respiratory tract disease. It is also is a significant cause of morbidity and mortality in the elderly. In the 1960's, children were given a RSV vaccine; up to 80% of vaccinated individuals were later hospitalized with RSV; two died. <sup>21, 22, 23</sup> The conclusion from that experience was clear: RSV lung disease was enhanced by the prior vaccination. <sup>24</sup>
- **ii.** The dengue virus has at least four subtypes. Exposure to one subtype generally causes mild illness. However, subsequent exposure to a second dengue subtype can result in more severe presentations that can lead to hemorrhagic fever, shock, and even death.

Sanofi Pasteur produced a vaccine against dengue called Dengvaxia. In 2012, researchers observed that the vaccine protected against only three of the four subtypes of dengue fever, and that the one subtype it did *not* protect against was actually the most common.<sup>25</sup> This means that when the vaccinated individual is exposed to the more common form, the virus may actually use the antibodies created by the

vaccine to spread the virus throughout the body, resulting in potentially deadly complications.<sup>26</sup>

Despite these warnings, Sanofi Pasteur conducted three clinical trials involving more than 35,000 children between the ages of 2 and 16 years in Asian–Pacific and Latin American countries. In 2015, the *New England Journal of Medicine* reported some of the results from one of those trials: "[A]mong participants younger than 9 years of age who were hospitalized for dengue, severe disease [...] occurred in 8 of 19 participants in the vaccine group and in none of 6 participants in the placebo group...."<sup>27</sup> Nonetheless, several countries continued to vaccinate their children with Dengvaxia.

By December 2017, when the Philippines Department of Health belatedly suspended Dengvaxia's use, nearly 734,000 children aged 9 and over had already received one dose of the vaccine. By April 2019, the deaths of 600 children were under investigation in the Philippines in connection with the vaccine. Government health officials in the Philippines are now being sued for "reckless imprudence resulting [in] homicide" because they "facilitated, with undue haste" Dengvaxia's approval and its rollout among Philippine schoolchildren.<sup>28</sup>

iii. Another famous case is that of the failed HIV vaccine. The human adenovirus vector technology (similar to that being used in the AstraZenaca and Johnsons and Johnson COVID vaccines) was used in several failed efforts to develop a vaccine against HIV. In 2007, two trials of Merck's HIV vaccine were cancelled. Rather than provide immunity, the vaccine actually increased the risk of HIV infections. In 2013, Nature reported, "Overall, people who had received the vaccine were significantly more likely to be infected than those who had received the placebo"<sup>29</sup> – by 41 percent!

#### B. Spike protein itself may cause lung and heart disease

There is evidence that has led to concern that the vaccines themselves may cause deadly lung and heart diseases.

All the COVID vaccines contain mRNA/DNA from the COVID spike protein. As you recall, the intention is that your body will produce the protein and then produce antibodies to it. The spike protein is critical to initiating the interactions between the virus and the surface receptor on the host cell, facilitating viral entry into the host cell. However, the spike protein itself, even without the rest of the virus, is dangerous. Recent research has shown that the COVID spike protein alone triggers cell-signaling events that may promote pulmonary vascular remodeling and pulmonary hypertension (PAH). Pulmonary hypertension results in heart failure and death; if untreated, patients diagnosed with pulmonary hypertension die within 2-3 years; even if treated, only 60-70% of patients survive for three years.

Researchers have studied the effects of COVID spike protein only on lung cells. Because of that, the researchers can only speculate that "this protein may also affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension, and stroke. In addition to cardiovascular cells, other cells that express ACE2 have the potential to be affected by the SARS-CoV-2 spike protein, which may cause adverse pathological events. Thus, it is important to consider the possibility that the SARS-CoV-2 spike protein produced by the new COVID-19 vaccines triggers cell signaling events that promote PAH, other cardiovascular complications, and/or complications in other tissues/organs in certain individuals." <sup>30</sup>

### C. Chronic autoimmune disorders

There is also concern that the vaccine may cause long-lasting, chronic auto-immune responses.

Auto-immune disorders occur when your immune system attacks your own cells. There are many theories about what might trigger an autoimmune response. One theory is molecular mimicry: the idea is that a part of a pathogen (an epitope) that triggers an antibody response looks a lot like part of a normal human protein. When the body is infected with a pathogen, it produces antibodies to fight it off. However, even after the pathogen has been vanquished, the body still sees similar epitopes in the body -- those epitopes belong to normal human proteins. But the immune system doesn't know that, so it attacks them anyway.

Again, the immune system doesn't realize that the epitopes are a normal part of the host's body. And since they are a normal part of the human body, the epitopes are present always, leading to a chronic immune-system attack on the body. Your body is fighting itself constantly.

Scientists now believe that molecular mimicry might have led to the narcolepsy seen in some patients after the H1N1 flu vaccine. <sup>31</sup> (Narcolepsy is a long-term sleep disorder, which can include excessive daytime sleepiness.) There are other cases, too, in which scientists have connected specific autoimmune diseases with specific vaccines. For example, a form of Guillain-Barre syndrome was associated with the 1976–77 vaccination campaign against swine influenza.<sup>32</sup> Another example of confirmed autoimmune adverse effects after vaccination is idiopathic thrombocytopenia, which might arise after administration of the measles-mumps-rubella vaccination.<sup>33</sup>

There is concern that the COVID vaccines, too, may trigger molecular mimicry. All the vaccines, (whether based on mRNA or adenovirus vector,) use the spike protein in COVID. The spike protein is similar to numerous human proteins. These proteins are found everywhere in the body, including in the brain, kidneys, B-cells, plasma cells, liver, GI tract, eye and lung. <sup>34</sup> This means that when the vaccine induces antibodies against the COVID spike protein, those same antibodies may attack normal human proteins. In the "best" case, these auto-immune responses will not be life-threatening; however, they may last for the rest of your life.

# D. Anaphylactic shock

An ingredient in the vaccines has been associated with extreme allergic responses that researchers believe could lead to death.

Moderna, Pfizer/BioNTech, and Arcturus Therapeutics COVID vaccines all utilize mRNA technology, an experimental approach designed to turn the body's cells into viral protein-making factories. Remember that the mRNA vaccines use a protective shell to deliver the mRNA to our cells. This protective shell is made up of lipid nanoparticles (LNPs). The LNPs encapsulate the mRNA to protect them from degradation and promote cellular uptake. The LNP formulations in the three COVID-19 mRNA vaccines are "PEGylated," meaning that the vaccine nanoparticles are coated with a synthetic and non-degradable polyethylene glycol (PEG). PEG is used also in a number of medications. PEGylation has well-documented adverse effects, including provoking an immune response to the PEG.<sup>35</sup> Furthermore, because of its use in popular medications, 72% of people already have anti-PEG antibodies. <sup>36</sup> Immunologists believe that some people who have high levels of PEG antibodies are at risk of an anaphylactic reaction to the vaccine. They are concerned that the PEGylation in the vaccine can trigger dangerous allergic reactions.

As of Jan 6, 2021, the CDC reported 21 cases of anaphylaxis out of the nearly 1.9 million people who received their first shot of Pfizer's COVID-19 vaccine in mid to late December, a ratio that is about 10 times higher than the ratio for the flu vaccine. <sup>37</sup> The U.S. National Institute of Allergy and Infectious Diseases (NIAID) was concerned enough to convene several meetings to discuss the allergic reactions with representatives of Pfizer, Moderna, and the FDA. <sup>38</sup>

On January 17, the California Department of Public Health halted injections of Moderna's COVID vaccines at one of its facilities due to "higher-than-usual number of adverse events," including several people who suffered from severe allergic reactions that required medical intervention.<sup>39</sup>

### PART IV: Is the Pfizer Vaccine Effective?

#### A. What is the purpose of the vaccine?

The purpose of the vaccine would seem obvious: to prevent COVID infections and reduce mortality.

But actually, according to Pfizer <sup>40</sup> and the WHO, there is not sufficient evidence that it does either.

- Pfizer admits that the vaccine has not yet been determined to protect against mortality: "A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality." <sup>41</sup>
- ii. Pfizer admits that the vaccine has not yet been determined to protect against asymptomatic infection: "Data are limited to assess the effect of the vaccine against asymptomatic infection." In other words, a vaccinated person might still get COVID but won't know it because he will not experience symptoms.
- iii. Pfizer admits that the vaccine has not been determined to prevent transmission of COVID: "Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination."

On December 28, 2020, the World Health Organization warned that there is no evidence that COVID-19 vaccines will prevent people from being infected with the SARS-CoV-2 virus and then transmitting it to other people: "I don't believe we have the evidence on any of the vaccines to be confident that it's going to prevent people from actually getting the infection and therefore being able to pass it on." <sup>42</sup> This is why the WHO advises people who have been vaccinated to still continue wearing masks and practice social distancing. In other words, after you receive the vaccines, you are not free to resume your normal pre-COVID way of life. The vaccines do not free you of restrictions because there is no evidence it prevents infection, transmission, or death.

So what do the COVID vaccines do?

According to Pfizer/BioNTech, Moderna, and AstraZeneca, their vaccines prevented more COVID *symptoms* in vaccinated participants as compared to unvaccinated people.

# B. Which groups have *not* been shown to benefit from the vaccine?

The efficacy of the vaccine cannot be determined for four important groups:

# • Group 1: Immunocompromised individuals

Pfizer: "The subset of certain groups such as immuno-compromised individuals (e.g. those with HIV/AIDS) is too small to evaluate efficacy outcomes."

Immunocompromised individuals also include people undergoing chemotherapy, people suffering from lymphomas, people with auto-immune disorders who are taking immunosuppressant medications, and transplant recipients, among others.

# • Group 2: Individuals who have had prior exposure to COVID

Pfizer: "Available data are *insufficient to make conclusions about the benefit in individuals with prior SARS-CoV-2 infections.*"

This may be a giant group since there is concern that many people who are infected are asymptomatic. Estimates vary greatly as to the number of asymptomatic COVID cases, as there seem to be large differences according to age. However, the most common estimate is that 50% of COVID cases are asymptomatic. <sup>43</sup> In October 2020, The WHO reported that it estimates that 10% of the world population has been infected with COVID <sup>44</sup> (and the number is expected to rise). The purpose of a vaccine is to generate antibodies against the disease in order to protect you; anybody who has been infected with COVID already has antibodies and has no need of the vaccine. In those cases, the vaccine provides no additional benefits but only possible risks.

# • Group 3: Children up to age 17

Pfizer: "The representation of pediatric participants in the study population is *too limited to adequately evaluate efficacy in pediatric age groups younger than 16 years*. No efficacy data are available from participants ages 15 years and younger. Although adolescents 16 to 17 years of age were included in the overall efficacy analysis, only one confirmed COVID-19 case was reported in this age group."

#### • Group 4: Elderly over 65 years old

In a summary of the Pfizer trials, the US Centers for Disease Control and Prevention (CDC) states: "In subgroup analysis in persons aged 65-74, there was 1 case of COVID-19 out of 3,255 participants in the vaccinated group and 14 cases out of 3,255 in the placebo group, with a vaccine efficacy of 92.9 (95% CI 53.2-99.8). In people 75 years of age or older there were 0 cases out of 805 participants in the vaccinated group and 5 cases out of 812 participants in the placebo group, with a vaccine efficacy of 100%, although this was not statistically significant (95% CI -12.1-100). Due to the small numbers in these subgroups, the results should be interpreted with caution."<sup>45</sup>

In other words, for people ages 65-74, there are not enough data to be confident of the results. In people over age 75, the data are not significant: in other words, there is little evidence that the vaccine benefits people over the age of 75.

On the other hand, there have been numerous reported deaths among the elderly after vaccination (see above, PART II/E.) Citing "insufficient data" over its efficacy for older people, Germany's vaccine committee has recommended that AstraZeneca's vaccine should only be given to people under 65. <sup>46</sup> This decision also follows reports of several deaths in the elderly following vaccination.

### C. Is the Pfizer vaccine actually effective in the real world?

In December 2020, Pfizer announced that their vaccine was 95% effective. This number was derived from clinical trials in mostly young, healthy individuals. Relatively few elderly were included in the trials. (From similarly conducted trials Moderna <sup>47</sup> reports comparable efficacy rates. AtraZeneca <sup>48</sup> and Johnson and Johnson <sup>49</sup> both report lower rates.)

How did Pfizer get that number?

Out of 20,033 vaccinated individuals, 8 got COVID. That means 0.04% of vaccinated individuals got COVID. Out of 20,243 in the placebo group, 162 people got COVID; that means 0.8% of placebo got COVID. The efficacy rate is (162-8)/162=95%.

Let's look at from whom the data points were collected. First, the company used mostly young, healthy individuals. Even then, before data were collected, 8.3% of the participants that had already received two doses of vaccine were excluded for not clearly defined reasons (such as "randomized but did not meet all eligibility requirements" whatever those are, or "had other important protocol deviations on or prior to 7/14 days after dose 2"). These are points that did not fit Pfizer's requirements but did represent real world effects. Second, there were few elderly in the trial though most of the danger of COVID deaths are in the elderly population.

Pfizer's results may be hugely significant in a carefully controlled clinical setting, but they are not necessarily relevant in the real world. They do not reflect the reality of who will get the vaccine. Pfizer preselected mostly healthy young adults with a strong immune system. In the real world, up to 50% of non-elderly Americans have a pre-existing medical condition while up to 86% of elderly Americans suffer from a pre-existing health condition. <sup>50</sup>

## D. For how long does the vaccine's benefit last?

Pfizer comments that they cannot state whether the limited benefit of the vaccine continues after 2 months: "As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period of longer than 2 months."

# E. The vaccine might not be effective on mutated strains of COVID

Pfizer admits that any mutations in the virus (as we see even now occurring) may make this vaccine useless: "The evolution of the pandemic characteristics, such as increased attack rates, increased exposure of subpopulations, as well as potential changes in the virus infectivity, antigenically significant mutations to the S protein, and/or the effect of coinfections may potentially limit the generalizability of the efficacy conclusions over time."

So far, thirty different mutant strains of COVID have been reported. <sup>51</sup> Two of these mutant strains, one originally isolated in England and the other in South Africa, have already spread across the world and scientists are worried that the current vaccines may not be effective against them.

# PART V: Are the Risks Worth the Benefits? And Are There Other, Less Risky Ways, to Deal With COVID?

Vaccines are irreversible, so it is important to weigh the risks of COVID vaccines, as discussed above, with the potential benefits, as well as the alternatives to vaccines.

There are two main risks associated with COVID. One is, of course, death.

According to the WHO's numbers, there have been about 2 million deaths worldwide involving COVID.<sup>52</sup> Compare the 2 million COVID dead with annual death rate of 8.9 million from ischaemic heart disease, over 6 million from stroke, over 3 million from chronic obstructive pulmonary disease, <sup>53</sup> and 1.6 million due to diabetes.<sup>54</sup>

Moreover, the real risk of dying from COVID is hard to determine since, according to the CDC, anyone who dies of anything but has ever tested positive for COVID is labeled as a COVID death. One of the most famous cases involved two people in Colorado who died of gunshot wounds but were labeled COVID deaths because they had tested positive. <sup>55</sup> In addition, the CDC also includes deaths labeled "presumed COVID without any lab verification that the patient had COVID." <sup>56</sup> The WHO defines COVID deaths as a death resulting from "a probable or confirmed COVID-19 case." <sup>57</sup> Several countries, such as Israel, <sup>58</sup> use these same criteria to calculate COVID deaths.

Simply put, one can die *from COVID*, one can die *with COVID* (but from something else), or one can die *from/with something that might be (presumably) COVID*. In every case, one is labeled as a COVID death.

Obviously, there is a real risk of dying from COVID, especially for the elderly. But the bottom line is that people who have died from other causes besides COVID have been labeled COVID deaths, so it is hard to define the real risk.

The second major risk from COVID is the long term effects of the disease, what is known in the media as "long-haulers." These are people who for weeks or months after recovering from COVID still experience symptoms. The most common symptoms are cough, low grade fever, and fatigue. A smaller percentage of people report shortness of breath, chest pain, headaches, heart palpitations, neurocognitive difficulties, muscle pains and weakness, gastrointestinal upset, rashes, and depression and other mental health conditions. Long haulers may be old or young. <sup>59</sup>

It is not yet known what leads to long haulers, but most researchers think it involves what is known as a cytokine storm, namely an overproduction of an immune system "messenger." The immune system contains many different components that help fight infections. These components need to communicate with each other; one of the main messengers for communication is a set of molecules known as cytokines. One of the effects of cytokines is to cause inflammation in the body. Cytokine storms can be caused by two possible scenarios: the first, if too many cytokines are released; the second, if the cytokine response is not "turned off" after the infection has passed. Cytokine storms have been implicated as one of the causes of death from COVID as well as a possible cause of long hauler symptoms.

Fortunately, since the start of the pandemic, doctors have learned a lot about treating the illness. One thing they have learned is that putting people on mechanical ventilators actually increases their chance of dying, unlike using other non-invasive oxygen treatments.<sup>60</sup> In addition, various medications have been shown to be effective, such as ivermectin and

quercetin or hydroxyquinine with zinc. <sup>61</sup> In countries which have adopted widespread use of these treatments, such as India, there has been a sharp decline in COVID cases and fatalities. <sup>62</sup>

In addition, several supplements and vitamins have shown to be protective and effective against COVID as well as mitigating the long-hauler effect. These supplements include vitamin C, vitamin D3 with K2, zinc, quercetin, and probiotics. The most researched supplement is vitamin D. Numerous research studies <sup>63</sup>,<sup>64</sup>,<sup>65, 66</sup> have shown that vitamin D can prevent COVID, reduce its severity, and calm cytokine storms, thus reducing COVID's morbidity effects as well as the long-haul phenomenon. Zinc is toxic to viruses <sup>67</sup> if it can get into the cells; quercetin (and the drug hydroxyquinine) helps zinc get into cells.

#### **Conclusion**

Not only do I not desire to make anyone's decisions for them, the bottom line is that there are not enough data to say many things absolutely.

What we do know is: (1) the vaccines have already been shown to have significant, serious side effects, and have been associated with hundreds of deaths, in the very short time that they have been administered; (2) research on past coronaviruses and related vaccines raises concerns that there could be yet more serious side effects that become apparent only six months to a year or more from now; (3) the vaccines' effectiveness in preventing death from, or transmission of, COVID has not been proven; and (4) the vaccine manufacturers have all been protected from liability for any harm caused by their vaccines.

Unfortunately, only a small fraction of the funding for vaccine production has gone into research on safe, effective ways to boost people's immune system to prevent COVID and reduce its effects. Even so, both research and the practical experience in countries such as India indicate that alternatives such as Vitamin D can slash the risk of COVID without carrying the risks of vaccination. <sup>1</sup> https://www.fda.gov/media/144246/download#page=55

<sup>2</sup> https://childrenshealthdefense.org/defender/329-deaths-9516-other-injuries-reported-following-covid-vaccine-cdc/

<sup>3</sup> https://childrenshealthdefense.org/defender/329-deaths-9516-other-injuries-reported-following-covid-vaccine-cdc/

<sup>4</sup> https://www.lifesitenews.com/news/fda-death-heart-attacks-stroke-blood-disorders-all-possible-side-effects-of-COVID-vaccine

<sup>5</sup> https://childrenshealthdefense.org/defender/death-by-coincidence/

<sup>6</sup> https://vaccinedeaths.com/2021-01-25-elderly-people-dead-after-coronavirus-vaccine.html

<sup>7</sup> https://norwaytoday.info/news/norwegian-medicines-agency-links-13-deaths-to-vaccine-side-effects-those-who-died-were-frail-and-old/

<sup>8</sup> https://www.bloomberg.com/news/articles/2021-01-18/norway-finds-no-direct-link-betweenelderly-deaths-and-vaccine?

<sup>9</sup> https://www.chronicle.gi/devastating-weekend-as-gibraltar-loses-13-people-in-two-days-tocovid-19/

<sup>10</sup> https://healthimpactnews.com/2021/10-dead-with-51-severe-side-effects-among-germanys-elderly-after-experimental-pfizer-covid-injections/

<sup>11</sup> Wen Shi Lee et. al. "Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies" Nat Microbiol. 2020 Oct; 5(10):1185-1191.

<sup>12</sup> Ann M Arvin et. al. "A perspective on potential antibody-dependent enhancement of SARS-CoV-2" Nature. 2020 Aug; 584(7821):353-363

<sup>13</sup> Ayato Takada, Yoshihiro Kawaoka. "Antibody-dependent enhancement of viral infection: molecular mechanisms and in vivo implications" Rev Med Virol. Nov-Dec 2003; 13(6):387-98.

<sup>14</sup> Sol M Cancel Tirado, Kyoung-Jin Yoon. "Antibody-dependent enhancement of virus infection and disease" Viral Immunology. 2003; 16(1):69-86.

<sup>15</sup> Y Wan et. al. "Molecular Mechanism for Antibody-Dependent Enhancement of Coronavirus Entry" J Virol. 2020 Feb 14; 94(5):e02015-19

<sup>16</sup> C W Olsen et. al. "Monoclonal antibodies to the spike protein of feline infectious peritonitis virus mediate antibody-dependent enhancement of infection of feline macrophages" J Virol. 1992 Feb; 66(2): 956–965.

<sup>17</sup> D. Deming, T. Sheahan, M. Heise. "Vaccine efficacy in senescent mice challenged with recombinant SARS-CoV bearing epidemic and zoonotic spike variants" PLoS Med. 3 (12) (2006) e525, 2006 Dec.

<sup>18</sup> Chien-Te Tseng et. al. "Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus" PLoS One. 2012. 7(4):e35421.

<sup>19</sup> Anurodh Shankar Agrawal et. al. "Immunization with inactivated Middle East Respiratory Syndrome coronavirus vaccine leads to lung immunopathology on challenge with live virus" Hum Vaccin Immunother. 2016 Sep; 12(9): 2351–2356.

<sup>20</sup> "Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data." Brighton Collaboration: The Task Force for Global Health https://brightoncollaboration.us/vaed/

<sup>21</sup> PL Collins, BS Graham. "Viral and host factors in human respiratory syncytial virus pathogenesis" J Virol. 2008; 82:2040–2055

<sup>22</sup> AZ Kapikian et. al. "An epidemiologic study of altered clinical reactivity to respiratory syncytial (RS) virus vaccine" Am J Epidemiol. 1969; 89:405–21

<sup>23</sup> HW Kim et al. "Respiratory syncytial virus disease in infants despite prior administration of antigenic inactivated vaccine" Am J Epidemiol. 1969; 89:422–34.

<sup>24</sup> "Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data." Brighton Collaboration: The Task Force for Global Health https://brightoncollaboration.us/vaed/

<sup>25</sup> https://www.sciencemag.org/news/2012/09/mixed-results-dengue-vaccine-trial

<sup>26</sup> Brian R Murphy and Stephen S Whitehead. "Immune response to dengue virus and prospects for a vaccine" Annu Rev Immunol. 2011; 29:587-619

<sup>27</sup> Sri Rezeki Hadinegoro et. al. "Efficacy and Long-Term Safety of a dengue Vaccine in Regions of Endemic Disease" N Engl J Med 2015; 373:1195-1206

<sup>28</sup> https://www.sciencemag.org/news/2019/04/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines

<sup>29</sup> https://www.nature.com/news/hiv-vaccine-raised-infection-risk-1.13971

<sup>30</sup> Yuichiro J. Suzuki and Sergiy G. Gychka. "SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines" *Vaccines* 2021, *9*(1), 36 ff.

<sup>31</sup> S.S. Ahmed, W. Volkmuth, J. Duca. "Antibodies to influenza nucleoprotein cross-react with human hypocretin receptor 2, Sci. Transl. Med. 7 (294) (2015 Jul 1)

<sup>32</sup> Alexander D Langmuir. "Guillain-Barre syndrome: the swine influenza virus vaccine incident in the United States of America, 1976-77: preliminary communication" Journal of the Royal Society of Medicine Volume 72 September 1979

<sup>33</sup> David C Wraith et. al. "Vaccination and autoimmune disease: what is the evidence?" The Lancet. June 3, 2003. http://image.thelancet.com/extras/02art9340web.pdf

<sup>34</sup> James Lyons-Weiler. "Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity" Journal of Translational Autoimmunity 2020 Volume 3

<sup>35</sup> Johan J.F. Verhoef and Thomas J. Anchordoquy. "Questioning the Use of PEGylation for Drug Delivery" Drug Deliv Transl Res. 2013 Dec; 3(6): 499–503.

<sup>36</sup> Qi Yang et. al. "Analysis of Pre-existing IgG and IgM Antibodies against Polyethylene Glycol (PEG) in the General Population" Anal Chem 2016 Dec 6; 88(23):11804-11812

<sup>37</sup> https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s\_cid=mm7002e1\_w

<sup>38</sup> https://www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-COVID-19-vaccine-trigger-rare-allergic-reactions

<sup>39</sup> https://investors.modernatx.com/news-releases/news-release-details/statement-californiadepartment-public-health-cdph-report and https://www.rt.com/usa/512825-moderna-californiavaccine-adverse-reactions/

<sup>40</sup> All quotes come from the Pfizer Dec 10, 2020 report to the FDA. The report can be downloaded at https://www.fda.gov/media/144245/download

<sup>41</sup> Pfizer December 10, 2020 report to the FDA. https://www.fda.gov/media/144245/download

<sup>42</sup> https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/pressbriefings

<sup>43</sup> https://www.uchealth.org/today/the-truth-about-asymptomatic-spread-of-COVID-19/

<sup>44</sup> https://www.dw.com/en/coronavirus-who-estimates-10-of-global-population-infected-with-COVID-19/a-55162783

<sup>45</sup> https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/Pfizer-BioNTech-COVID-19-Vaccine/

<sup>46</sup> https://www.bbc.com/news/world-europe-55839885

<sup>47</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html

<sup>48</sup> https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32623-4/fulltext

<sup>49</sup> Jerald Sadoff et. al. "Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine" N Engl J Med . 2021 Jan 13; NEJMoa2034201

<sup>50</sup> https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/preexisting

<sup>51</sup> https://www.foxnews.com/science/coronavirus-mutated-at-least-30-different-strains-study-finds

52 https://COVID19.who.int/

<sup>53</sup> https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

<sup>54</sup> https://www.who.int/news-room/fact-sheets/detail/diabetes

<sup>55</sup> https://www.bizpacreview.com/2020/12/18/colorado-coroner-expresses-shock-over-inflated-COVID-death-tallies-including-bodies-with-gunshots-1007116/

<sup>56</sup> https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm

<sup>57</sup> https://www.who.int/classifications/icd/Guidelines\_Cause\_of\_Death\_COVID-19.pdf

58 https://www.israelnationalnews.com/News/News.aspx/284837

<sup>59</sup> Trisha Greenhalgh et. al. "Management of post-acute covid-19 in primary care" BMJ 2020;

<sup>60</sup> See list of citations in: https://articles.mercola.com/sites/articles/archive/2020/07/14/ ventilators-deadly-for-covid-patients.aspx and https://www.chicagotribune.com/coronavirus/ctnw-coronavirus-ventilator-death-rate-20200408-gewfe64tu5c7rel6tsh5gov44m-story.html

<sup>61</sup> Peter A. McCullough, et. al. "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection" Am J Med. 2021 Jan 134(1):16-22.

<sup>62</sup> https://principia-scientific.com/indias-miraculous-ivermectin-covid-treatment-is-only-3-per-person/

<sup>63</sup> Yi Xu et. al. "The importance of vitamin d metabolism as a potential prophylactic, immunoregulatory and neuroprotective treatment for COVID-19" J Transl Med. 2020 Aug 26; 18(1):322.

<sup>64</sup> William B Grant et. al. "Evidence that Vitamin D Supplementation Could Reduce Risk of Influenza and COVID-19 Infections and Deaths Nutrients" 2020 Apr 2; 12(4):988

<sup>65</sup> Ali Daneshkhah et. al. "Evidence for possible association of vitamin D status with cytokine storm and unregulated inflammation in COVID-19 patients Aging Clin Exp Res" 2020 Oct 32(10):2141-2158

<sup>66</sup> Nurshad Ali. "Role of vitamin D in preventing of COVID-19 infection, progression and severity. J Infect Public Health" 2020 Oct; 13(10):1373-1380

<sup>67</sup> Aartjan J. W. te Velthuis et. al. "Zn<sup>2+</sup> Inhibits Coronavirus and Arterivirus RNA Polymerase Activity *In Vitro* and Zinc Ionophores Block the Replication of These Viruses in Cell Culture. PLOS Pathogens" November 4, 2010 https://doi.org/10.1371/journal.ppat.1001176