If You Had Covid, Do You Need the Vaccine?

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Vaccines have long been held the mainstay against maladies that previously in history have destroyed large swaths of the population. Polio, Mumps-Measles and Rubella (MMR), Chicken Pox and Pertussis come to mind among others. Vaccines have proven efficacy against certain transmissible infectious diseases. The majority of these successful vaccines have had a commonality in that they generally target infectious pathogens with a low rate of mutation. These mutations are due in part to selection pressures both from natural immunity and from the vaccinal component. It is a foregone conclusion that given time, viruses are mutable and thus all viruses will mutate and create "variant strains" to escape antibody-mediated immunity. This "escape" is more common in fast replicating viruses such as Influenza (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075021/) and other coronavirus illnesses. "A lot of the mutations are down to faults in the 'proof-reading' (https://www.dailymail.co.uk/debate/article-9053243/Viruses-mutate-time-writes-Professor-HUGH-PENNINGTON.html) operation when the DNA or RNA multiplies or replicates." It is estimated that "the SARS-CoV-2 (https://covexit.com/interview-with-adam-gaertner-part-2/) virus is known to accumulate…two single nucleotide mutations per genome month." In terms of pressure on

the pathogen, some even argue that the combination of containment strategies such as lockdowns, school closures, societal restrictions, and mass vaccinations also help drive the emergence of variants and this is to be clarified and validated further for this current pandemic.

This then brings us to some troubling issues that need to be reconciled. We are concerned about the future implications of the proposed and ongoing mass Covid-19 vaccination of the populace (and for our purposes here we define the 'vaccine' as any of the mRNA vaccines in use currently), its selection pressure effect, and indeed the potential for longer-term chronic effects (if any) on humans. We hope to show that there is an urgent need for debate on the issue of vaccinating people who have already recovered from Covid-19. We will be as clear as possible at the outset, that we believe it is not only potentially unsafe but we can argue it is unsafe, to indiscriminately vaccinate the recently or currently infected. We argue against this and are hoping that the US government and other governments and their regulators will reflect deeply and urgently on the issues. We reason below that these 'Emergency Use' Authorized vaccines do not meet the criteria for a fully Biologically licensed vaccine that takes years of efficacy and safety data. There are data that support that if you vaccinate persons who are infected or have been infected, there is evidence of potential adverse events/harms. Why are we not screening/testing persons for existing or prior infection prior to vaccination? Such screening should include PCR testing and Antibody testing at a minimum as a prelude to vaccinations. We believe that given the accumulated knowledge over the past year that indiscriminate application of mass vaccination is contrary to the Hippocratic dictum of "Primum Non Nocere." We raise these objections on the available scientific data and not on any emotional appeal. We consider this of utmost importance that the scientific community engage in a debate over the objections we raise and involve the policy makers to use real science as the benchmark for any further present and future decision-making.

We believe that the most appropriate and pressing need in society at the present time is to protect the vulnerable, the elderly with comorbid conditions and those in extended care, assisted-living facilities as well as elderly in private homes who have been infected with the SARS-CoV-2 virus. These individuals face the most risk from this virus. With respect to vaccination then, this is consistent with the notion that all vaccinations should be targeted and not delivered *en masse*. The disability and deaths in this group of individuals has been staggering when they are not protected, and we continue to fail to strongly protect the elderly in our nursing homes. We feel that the right decisions on preventing staff from bringing in infection have not been made and this remains the breach. Alike the move to vaccinate children and alike the continued failure to properly secure the elderly in congregated homes; these remain troubling and defy logic. That said, the tens of thousands of deaths in nursing homes continue to provide *prima facie* evidence for the need for focused protection. Hence, we are in agreement with the decision makers who are starting to focus vaccine delivery to this high-risk segment of the population. In support of this approach, evidence is now suggesting that the incidence in long-term care facilities (https://www.9news.com/article/news/local/covid-19-cases-long-term-care-facilities-declining-dallas-county-texas-united-states/287-2230f8ed-db61-4ea7-8463-b381dbb16058) of Covid-19 has dropped drastically following vaccination of these populations. This is very good news for very precious persons in our populations who must be protected. But we also point out that at this time, we have no way to predict the longer-term consequences of vaccination with the new mRNA vaccination platform given that vaccine safety has not been tested adequately. This issue of safety cannot be sidelined to efficacy or effectiveness. Fortunately, this issue is probably of less importance in the elderly due to issues of limited life expectancy to begin with.

We are researchers and scientists who wish to honor the system of verification and validation of available data well past the "fog of war" moments that occurred during the initial phases of the pandemic when information was murky and constantly in flux. At that time, some decisions were made which in retrospect were unsupported, but this could not have been known at the time. However, now that at least a year has passed since the beginning of the pandemic, the data have become more crystalized and nuanced and now reveal the true nature of SARS-CoV-2. Time has afforded

the affirmation of the term 'immunity' again. Sadly, this term has been misused by some to suit their narrative and who like to suggest that immunity is merely the equivalent to vaccination, which is decidedly not the case. But the fundamentals of immunology have not changed! The goal is 'immunity,' and not necessarily or solely 'vaccination.' Indeed, it is somewhat remarkable that we even have to point out immunity can be achieved either by natural infection and/or vaccination. We are appealing for a much-needed urgent discussion by government leaders, regulatory authorities, and the medical community as we move forward with the vaccination push. It must not be simply getting shots into the arms of people. This must have careful thought as the implications if mistakes are made can be lifelong and horrendous.

We argue that natural immunity provides for the type of durable, robust, full, comprehensive protection needed, and is much more robust than immunity induced by vaccination alone. Researchers have shown that the components of immune memory (https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19) (memory B cells, CD8+ T cells, and CD4+ T cells) in persons who had been exposed to SARS-CoV-2 persist (https://www.healthline.com/health-news/how-long-does-immunity-last-after-covid-19-what-we-know#How-natural-immunity-works-after-COVID-19-develops) for some time post-infection. Some have argued immunity may last for months (https://science.sciencemag.org/content/371/6529/eabf4063), years, decades, or even a lifetime. This important immunity research has emerged by Shane Crotty's lab in La Jolla California, Lauren Rodda's group (https://www.cell.com/cell/fulltext/S0092-8674(20)31565-8?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0092867420315658%3Fshowall%3Dtrue), as well as evidence in Iceland (https://www.nejm.org/doi/full/10.1056/NEJMoa2026116) and the US (https://www.cell.com/immunity/fulltext/S1074-7613(20)30445-3). For example, researchers found antibodies even in milder cases, and that there were antibodies with the capacity to neutralize the virus and antibodies specific to the spike protein. They also reported that the production of antibodies was greater in more severe disease. The NIH (https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19) reports that "This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them. All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19." This is indeed very good news and helps make our argument, our prognostication, on why persons recovered from infection are vaccine exempt.

We know that T-cell immunity specific to SARS-CoV-1 (https://pubmed.ncbi.nlm.nih.gov/32668444/) (SARS in 2003) has lasted for decades, at least 17 years. This T-cell longevity may well be the same for current SARS-CoV-2 infection. The body can 'remember' SARS-CoV-2 and besides T-cell (https://directorsblog.nih.gov/2020/07/28/immune-t-cells-may-offer-lasting-protection-against-covid-19/) memory, so-called memory B cells can also, on reexposure to the (previously seen) pathogen, ramp up to produce antibodies to fight it. Importantly, Alba Grifoni and Crotty (https://www.cell.com/cell/fulltext/S0092-8674(20)30610-3) at the La Jolla Institute for Immunology in California even detected SARS-CoV-2-reactive $CD4^+$ T cells ('helper cells') in approximately 40%–60% of 20 unexposed individuals, indicative of cross-reactive T-cell recognition (https://directorsblog.nih.gov/2020/07/28/immune-t-cells-may-offer-lasting-protection-against-covid-19/) between circulating "common cold" coronaviruses and SARS-CoV-2. Importantly also, is the issue of re-infections (https://www.dailymail.co.uk/news/article-9404915/Johns-Hopkins-professor-slams-Dr-Fauci-denying-approaching-herd-immunity.html) in patients who had Covid-19, and it appears (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30783-0/fulltext) to be very rare (https://theprint.in/opinion/covid-reinfections-are-real-but-heres-why-you-shouldnt-worry-about-that-just-yet/529305/), underscoring the idea that natural immunity is very real, persistent and potent.

Our concerns are raised out of an abundance of caution needed when marketing and promoting a vaccine product with very limited data (particularly safety data) observed over a very short period of time. The Hippocratic Oath states, "Above all do no harm" and we would like to apply the same tried and tested principle to the current therapeutics being used in this pandemic so that we can derive optimal decisions for the health and well-being of all the people. Therapeutics (https://www.cbsnews.com/news/gilead-coronavirus-treatment-remdesivir-private-insurance-cost/) and vaccines currently being employed have limited and actual absent safety testing. Although no definite conclusions either way can be drawn at this juncture due to limited scientific proof, we wish to urge caution in policy-making mandates nonetheless. The stakes are just too high, especially when it comes to our younger people and children. We have many of our populations, especially the poorer members of society e.g. minorities, African-Americans, women, least able to afford the devastating societal lockdown and restriction policies due to costly unsound government mandates, but alarmingly also, least able to afford catastrophic medical mistakes. These are our people who are often abused by the research and medical community in terms of the types of treatments afforded and given access to, and also disregarded in terms of the optimal safety precautions afforded to them in the first place. The fact is that after years of medical abuse and medical racism (https://www.psychologytoday.com/us/blog/the-color-wellness/202102/why-many-black-americans-don-t-trust-the-covid-19-vaccine), black Americans (https://www.washingtonpost.com/outlook/2020/12/15/years-medical-abuse-make-black-americans-less-likely-trust-covid-vaccine/) do not trust the vaccines, and rightly so. Much work in this regard must be done to earn their trust, especially with the many questions we and others have raised as to efficacy and safety.

As we refocus on the vaccine exemption issue, by forestalling and curbing viral infections, vaccines do indeed show promise when they have been studied extensively and their potential adverse effects have been collated and determined and this can only be accomplished with the use of appropriate sample populations and over a meaningful period of time (at least 2-3 years or often longer). Long-term safety of a vaccine or any medication cannot be inferred from data derived from even the largest of sample sizes without testing over time. And using this type of approach, the risk-reward ratios have been tallied and the overall benefits revealed. Polio, a crippling and deadly disease has been managed/prevented effectively by the polio vaccine. Yet this vaccine took almost 20 years (https://www.historyofvaccines.org/timeline/polio) to develop after much study and the performance of sometimes tedious work along with good scientific methodologies. There are also devastating consequences when mistakes are made e.g. the tainted polio vaccine in 1955 (https://www.washingtonpost.com/history/2020/04/14/cutter-polio-vaccine-paralyzed-children-coronavirus/) comes to mind and the catastrophe (https://globalnews.ca/news/7469951/coronavirus-vaccine-safety-polio-cutter-incident/) for children that ensued.

That said, on balance, creating the vaccines has been a remarkable feat of science. In terms of Covid-19, never before has such promise been delivered in such a short time and the prior administration deserves tremendous and full credit for bringing vaccines to fruition. Developed by some very capable and brilliant scientists, in tandem with the US military. But, this remarkable lightning-fast delivery is also the essence of our concern. The vaccines are only a few months old and let's face it, they have not gone through the routine and necessary full regulatory approval process (Biologics License Application (BLA) from the FDA. Consequently, the vaccines are being distributed and used under the umbrella of an 'emergency use authorization' (EUA). We understand the emergency and urgency, but the core argument remains that the optimal efficacy and safety tests have not been done or assessed by the FDA. Yet due to the urgency, a green light to "mass vaccinate" was given. However, now the CDC website VAERS (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html) details vaccine-related risks of adverse events including deaths from these vaccines. These events should raise concern for all in the field of medicine. Although in comparative terms, the numbers vaccinated far outweigh the number of deaths reported as a consequence of the vaccine itself, meaning that in the short term and presuming the post-vaccination enhancement of (herd)

immunity, it can be used safely. However, understanding the long-term effects, if any, will take time to unfold; something that cannot be substituted for by simply including massive numbers of subjects for vaccination over the short term.

Briefly, vaccines confer adaptive immunity and in conjunction with innate immunity (https://www.ncbi.nlm.nih.gov/books/NBK279396/) inherent in humans, the validity of using a conjoint effort of both is the hallmark against viral and other infectious illness. These two elements of immunity have been exploited to help support human life on this planet through the advent of modern medicine. Adaptive immunity occurs after exposure to an antigen either from a pathogen or a vaccination. The virus is the pathogen when it enters the body; it presents to the cell structure, its "calling card" also called an antigen. The cell is raised with the logic of defining "self" from "non-self." Any "non-self" is immediately frowned upon and dismantled by the immune cells. The immunity developed following actual infection is durable and recognizes the many antigenic elements (epitopes) on any given pathogen that conspire to evoke the immune response. An epitope is the region on an antigen that is recognized by the immune system (antibodies, B cells, T cells) and it is the part of the antigen that the antibodies bind to. For example, the many layers of the SARS CoV-2 virus (https://cen.acs.org/biological-chemistry/infectious-disease/know-novel-coronaviruss-29-proteins/98/web/2020/04) itself include at least four antigens such as: the (M) or membrane protein, the (E) or envelope protein, the (S) or spike protein and the (N) nucleocapsid protein.

When an individual is infected by the virus itself, all the antigenic elements (epitopes) are presented to the immune cells. These cells include the B-lymphocytes (white blood cells) present in the lymph nodes and elsewhere. These cells produce and release the antibodies against the infective agent into the bloodstream and because the B-lymphocytes have been presented with the several epitopes described above during a 'natural' exposure infection, they produce a wide array of active and effective antibodies. This is why natural exposure infection can be durable and broad.

Further to the above, and in relation to the argument that people who have had prior infection do not require vaccination, research conducted by the National Institute of Allergy and Infectious Diseases (https://www.nih.gov/news-events/news-releases/t-cells-recognize-recent-sars-cov-2-variants) (NIAID) provides support. In this study, blood cell samples from 30 people who had contracted and recovered from Covid-19 prior to the emergence of virus variants were analyzed for immune function. The research showed that previously infected persons retain robust immunity. The study asked if CD8+ T cells in the blood of patients who had recovered from the initial wild type form of SARS CoV-2 induced Covid-19, recognized three SARS-CoV-2 variants: B.1.1.7, which was first detected in the United Kingdom; B.1.351, originally found in the Republic of South Africa; and B.1.1.248, initially seen in Brazil. These variants have mutations in the spike protein region that could make it less recognizable to neutralizing antibodies and T-cells (these made by the immune system's B cells following infection or vaccination). The NIAID reported that the CD8+ T cell remained active against the virus. NIH (https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19) also reported similar research of the immune systems of more than 95% of people who recovered from Covid-19 had durable memories of the virus up to eight months after infection. Yet to reiterate, ongoing mutations of the virus have begun to render some of the vaccine-induced immunity less functional or nonfunctional with regard to some of the newer mutations (vaccine escape).

Additionally, these B cells cross-communicate with the T-cells that produce a cadre of helper and killer cells that target the infectious organism. The B cells have short-lived responses measured in months while the T-cells are long-lived and survive over decades. Thus, the *memory* of the infection lives within the body for any future attacks from similar infectious agents. The current crop of mRNA vaccines, however, confer very narrow immunity because they are focused on a single target; the spike (S) protein. The science is well-founded based on the fact that the "Spike" itself provides the means of entry into the human body cell via the ACE-2 receptor

(https://www.nature.com/articles/s41598-020-74715-4), and thus if such entry is prevented, infection will not ensue. The logic is correct and valid at its core. However, and here is what the past year and recent events have revealed; the virus has started to mutate given selection pressures it encountered, and the variants are more infectious and are more transmissible than the former (wild-type) parental self. The mutations have occurred in the spike protein itself, the very target of the vaccine. Although 677 mutations (https://www.forbes.com/sites/williamhaseltine/2021/02/19/what-are-the-677-mutations-new-covid-19-variants-found-in-the-us/?sh=14cbb90b54ae) have been observed in the United States alone, within the 30,000 nucleotides of the virus, most provide little value relating to transmission and virulence. These mutations are a direct result of the "selection pressure" exerted on the virus. Selection pressure is defined by the protective immunity encountered by the virus itself during its infectious raid on the human body. There is discussion that vaccinating a populace during a pandemic or when infection is elevated can drive the emergence of variants. This is the reason why influenza vaccine programs take place at the end of summer or early fall, and not during the peak influenza season.

Dr. J Lyons-Weiler (https://dryburgh.com/james-lyons-weiler-coronavirus-vaccine-safety-warning/) has weighed into this debate and stated that "all but one of the proteins in the SARS-CoV-2 virus have what we call unsafe epitopes, which are parts of proteins that are capable of causing immune conditions. Autoimmune conditions, and immune responses against proteins in our own body." Dr. Lyons-Weiler further outlines the condition of 'disease enhancement' as a result of pathogenic priming, which emerged in vaccinated animals as well as past vaccine safety studies for coronaviruses, whereby "vaccinated animals got more serious disease after being vaccinated, and then when they acquired an infection from the wild type vaccine, more animals got serious infections, serious conditions, and more animals died." The fact that the animals died when exposed to the wild type must not be disregarded, and we must reflect on this as it relates to the present vaccines. We await the full clear safety data that the vaccine developers must have collected thus far, and will collect. We are particularly interested in the animal study safety data used to make their decisions to move forward with Covid-19 vaccination at this time. Dr. Lyons-Welier also explained that "not a single, to my knowledge, not a single vaccine manufacturer took heed of my warning to remove those unsafe epitopes from the vaccines before they formulated their vaccines, in spite of being emailed my study with a plea to please consider taking out those unsafe epitopes."

The emergence of immune evasion is a virological response that has severe implications as to how we manage the pandemic going forward. We argue that the very narrow 'spike protein specific' vaccines will drive a narrowly configured form of immunity. Although, "The research (https://www.the-scientist.com/news-opinion/pfizer-vaccine-induces-immune-structures-key-to-lasting-immunity--68594?utm_campaign=TS_DAILY_NEWSLETTER_2021&utm_medium=email&_hsmi=117997647&_hsenc=p2ANqtz-9RVqFpApB_tHVaopuhaqU7kglP28nCgtBNezWg14vkB1665dHqX3nEqtHqbgimybyorgkTHUhYtMqWs7Gx2i5-Yc6EXA&utm_content=117997647&utm_source=hs_email) [on the Pfizer vaccine] provides reassurance that vaccinees will likely have long-lived antibody immunity to SARS-CoV-2." But does this mean that the lifelong presence of these antibodies will be those that target the spike protein epitope(s) only? This could be problematic in terms of reducing the effectiveness of these vaccines due to the emerging mutant variants that seem to be developing at an ever-quickening pace. Our concern and those of other researchers who have now weighed in on this issue relates to evolutionary selection pressure driving the mutations (variants) which has been stated as follows: "[t]he dynamics of natural or vaccinal collective immunity in the regions where these variants emerged might have placed substantial pressure on the viral ecosystem, facilitating the emergence of a variant with enhanced transmissibility (https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(21)00036-0/fulltext)." Perhaps unsurprisingly then, there is already a variant that is circulating the globe that evades the immunity conferred by the Oxford vaccine. Our concern remains that through repeated mutations a more lethal variant might 'potentially' emerge (though a theoretical risk and a low one at that) with both high transmissibility and virulence that might represent an escapee

from vaccine selection pressure. And as mentioned previously, other concerns related to the emerging evidence of harms from the vaccines (https://www.ukcolumn.org/article/why-are-we-still-giving-people-covid-19-vaccines) must be clarified and resolved. These emerging reported adverse reactions (https://healthimpactnews.com/2021/3964-dead-162610-injuries-european-database-of-adverse-drug-reactions-for-covid-19-vaccines/) e.g. reported (https://www.bloomberg.com/news/articles/2021-01-15/norway-warns-of-vaccination-risks-for-sick-patients-over-80) in Europe (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75123a-eng.php), reported in the CDC's (https://thevaccinereaction.org/2021/03/cdc-reports-1637-deaths-following-covid-19-vaccinations/) VAERS system, from the Covid vaccinations are troubling and should be also of concern to researchers.

However, we do believe that if a larger cohort of adaptive immunity is at hand associated with those (especially the young) who have borne the natural infection and recovered, when placed with those with the vaccinated crowd of the elderly, infirmed and vulnerable groups, the total immunity might help contain this virus by providing a hybrid form of herd immunity (vaccine-related plus post-natural infection). We again reiterate that natural exposure immunity, in our view, confers the robust and complete 'sterilizing' type immunity needed. We continue to think this while recognizing the utility of an 'optimally' developed 'safe' vaccine.

Similar to the problems related to pushing viral mutation by way of mass vaccination, we suggest also that lockdowns (https://www.aier.org/article/the-catastrophic-impact-of-covid-forced-societal-lockdowns/), school closures (https://www.aier.org/article/school-closure-a-careful-review-of-the-evidence/) etc (https://www.aier.org/article/lockdowns-do-not-control-the-coronavirus-the-evidence/). pressure the virus towards ongoing mutation as these measures merely extend the period of time that the pandemic will last. The increased time that the virus spends in the community allows it to mutate and adapt so as to spread itself more efficiently, when the lockdowns are relaxed. We can also argue that the delayed, patchy, piecemeal manner in which the vaccine rollout has occurred adds to the virus having room to adjust. Moreover, the longer the push to arrive at herd immunity, there is the risk that vaccine-induced immunity may wane and thus fall short of the herd threshold target. Remember, we are dealing with a virus that seeks to live with the host, us humans, in a stable symbiotic relationship, ideally to survive without causing harm to the host. It constantly seeks ways to mutate and fit the environment it finds itself in.

Any reasonable scientist and clinician must be concerned about the potential for harm if there is any. And we are concerned that we are engaging in this mass vaccination of people when naturally acquired herd immunity could have been established over time. And to reiterate, there is no question that naturally acquired immunity is far superior to that induced by a vaccine and in particular vaccines that are so laser-focused on a single protein (the spike).

We are already witnessing some worrying problems that we do not typically see with vaccines which include serious reactions and even deaths. Alain Townsend (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7382330/) explains the potential risks: "The interaction between ACE2 and the Receptor Binding Domain [RBD] of the Spike protein is high affinity (~10 nM), equivalent to many monoclonal antibodies. As such, the association of ACE2 with the Spike protein is likely to be long lived, and is expected to result in ACE2 entering antigen presenting cells associated with the Spike protein on viral particles or vaccines. This may be enhanced by Fc mediated uptake via Fc Receptors once an antibody response to the spike has occurred, and may set up conditions for intense presentation of ACE2 epitopes to T and B cells, aided by strong T-cell help from epitopes derived from the attached Spike or other viral proteins. This may be enough to break self-tolerance to ACE2. In principle, there may be protean downstream effects of an auto-immune response to ACE2. ACE2 expression in lung, heart and kidney would lead to inflammation at those sites. In addition, loss of local ACE2 activity may be associated with increased activity of angiotensin II through the AT2 type I receptors

in the lung, that are thought to be involved in initiating inflammation. Reduced ACE2 activity has been linked to increased thrombosis, and a thrombotic tendency has been described in severe Covid-19 disease. Autoantibodies to ACE2 have been described associated with vasculopathies including pulmonary hypertension."

Again, while we acknowledge that we are prognosticating and conjecturing, we do this to put other healthcare professionals on alert for the development of potential problems given the lack of vaccine safety testing and therefore the absolute lack of knowledge regarding long-term impacts of these vaccines. Our concern rests on two main pillars, safety and the implications of viral mutations as they reduce vaccine effectiveness. Looking further into the Emergency Trial data that is publicly available we note that according to the Federal Food, Drug, and Cosmetic Act (FD&CAct), unapproved drugs are allowed for emergency use but only if other viable treatments are unavailable. The fact that there were already viable and effective treatments and therapeutics for Covid-19, then this should have prevented EUAs for the vaccines. But regardless of this, these vaccines were approved for EUA based on data that spanned only 6-7 months, when the vaccine trials that have been approved prior have required a minimum of 6-7 years' (or longer) worth of investigation and data, both for efficacy and safety.

We also remind the reader that we have situations whereby children were administered vaccines in the past for other illnesses and they have died unnecessarily. This includes for example, the vaccine for Dengue fever (https://www.sciencemag.org/news/2019/04/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines). Administration resulted in severe illness and death. This alarmed some scientists, because the dengue virus is unusual: "A first infection is rarely fatal, but a second one with a different virus type can lead to much more serious disease, because of what is called antibody-dependent enhancement (ADE), in which the immune response to the first virus amplifies the effect of the second type. Scott Halstead, a retired dengue expert formerly at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, argued that dengue vaccines…should not be given to children never infected with dengue (https://www.npr.org/2019/05/02/719366831/dengue-vaccine-controversy-in-the-philippines)." We caution that similar 'pathogenic priming' could occur in children but of course we have no way of knowing one way or the other since the vaccine has not been tested for a long enough period of time and so true and reliable safety data are unavailable for both adults and children. We caution.

We support and always have supported strongly the use of vaccines, especially for children, to prevent *vaccine-preventable* disease including but not limited to such diseases as Measles, Mumps and Rubella. Vaccines are critically important insofar as public health is concerned. This said, no matter how much we hope and wish that the current vaccines for SARS-CoV-2 are going to be both safe *and* effective, we cannot ignore biologically plausible but unintended and negative outcomes.

One may ask, if you had prior infection with SARS-CoV-2 and you went through the infection and cleared it, and are immune to it, can you be reinfected again? Yes, there is always a potential but this is low because natural immunity is very robust and broad, and should protect you. We would argue that natural immunity via natural exposure can offer the type of sterilizing immunity with the optimal neutralizing antibodies to limit (blunt) infection, prevent you from getting sick or transmitting the virus. We argue that the narrow basis of the existing Covid vaccines indicates that they may not be as effective as reported in terms of offering a level of sterilizing immunity. Moreover, the variants (in which the mutations are emerging only on the 'spike epitopes') could potentially bypass vaccine-induced immunity but will likely be held off by the natural immunity which builds multiple types of antibodies and thus hits multiple protein targets on the virus. Vaccine-derived narrow immunity places us at much heightened risk of more severe illness. These vaccines are too narrowly focused, particularly for use in a mass vaccination campaign in the midst of a pandemic, and

we are arguing that the development of natural exposure immunity as a means to stave off the emerging variants should remain the most important goal, with vaccines prioritized only to the very high risk with underlying medical conditions.

While we are on the subject of the potential risks from the vaccines, we might as well look at the actual trial work performed to afford the release of the vaccines themselves. Specifically, Pfizer and BioNTech mRNA-based BNT162.b2 (BNT) and the Moderna vaccines. In the initial documents used for trialing the vaccine the following statements (https://off-guardian.org/2021/01/03/what-vaccine-trials/) were made that should cause alarm to clinicians: "It is important to note that some of the symptoms of COVID-19 overlap with solicited systemic ARs that are expected after vaccination with mRNA-1273 (e.g., myalgia, headache, fever, and chills). During the first 7 days after vaccination, when these solicited *(Adverse Reactions)* ARs are common, investigators should use their clinical judgement to decide if an NP swab should be collected." Further in the "exclusion criteria" for the trial, exclusion criteria included anyone with hypertension, asthma and diabetes, or those with a high BMI. Yet these are the very people for whom the vaccination should be used or who should be targeted! This means that data concerning safety and effectiveness of the vaccine are simply unknown for the population of people most at risk of dying from Covid-19! This makes the granting of an EUA even more inexplicable, though.

How Much Protection is Really Being Conferred?

If one is to make a compelling argument for administering this new mRNA vaccine in the first place and in particular to those who have already had and recovered from Covid-19, the protection offered by the vaccine must be examined very carefully and realistically. Both Pfizer and Moderna have said that their vaccines are highly effective. As an example, Pfizer has claimed that the efficacy of its vaccine, 95%, is based on the following (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine): according to their report, there were 8/18,310 (0.044%) cases of Covid in the vaccinated group *versus* 162/18,310 (0.88%) in the placebo group. We agree then that these data can be used to calculate a relative risk reduction of 100(1-(0.044/00.88) = RR 95%. This appears to be a very dramatic effect! However, the absolute risk reduction is only 0.88%-0.044% or 0.84%. A log difference in efficacy! Why would anyone, particularly someone who has already had Covid-19, rush to take any therapy that also has potentially severe adverse outcomes (including death), when the absolute reduction in risk from the disease is less than 1%? Why? The data is not being presented to the public in a manner to correctly inform the public for their optimal decision-making.

If we extrapolate the overall benefit of the vaccine in the broad population at risk of death, the Oxford Center (https://www.cebm.net/covid-19/the-declining-case-fatality-ratio-in-england/) estimated the Case Fatality Rate of 1.4%. Thus 1.4(0.88/100) =0.012%. In short, the absolute benefit to the population at large is a miniscule 0.012% or 12 per 1,000 individuals and not 95 per 100 as advertised in the mainstream media and their experts.

Given the data gathered above, we must caution about the broad application of this policy that might endanger people without the requisite available knowledge of the risks and benefits.

We are stating emphatically that the focus should be on high-risk elderly persons who might also have underlying medical conditions. We are arguing that the narrow focused 'spike protein specific' immunity (monolithic immunity) is placing us at a catastrophic disadvantage whereby vaccinated persons will not have immunity against the emerging variants. This is of particular importance should SARS-CoV-2 mutate into a more virulent pathogen, one that might actually be more lethal than the currently extant variants. We suggest that under the umbrella of targeted vaccination (not mass vaccination) that vaccine developers immediately construct mRNA's that induce the production of new iterations of the spike proteins that are concordant with the variants.

As opposed to the reliance upon mass vaccination and the hypothetical but not necessarily unlikely outcomes noted above, this means that vaccinations should only be given to high-risk patients who have never contracted Covid-19. We also agree with the notion that persons who interact frequently with high-risk persons for care such as front-line healthcare workers and nursing home staff etc. should be prioritized for vaccination. They're the ones who are most likely to pass the virus onto vulnerable people. There is a routine clarion call for more vaccines and shortages and thus why would we use vaccines on persons who have already been infected, cleared the virus, and have recovered? What about the potential risks we mentioned? We thus suggest that prior infected persons who have recovered will likely be well-protected with broad and robust natural immunity and are not candidates for vaccine. They must be exempt. Again, children, younger persons, and middle-aged persons with no medical conditions should *not* be candidates for vaccines. In our opinion this makes absolute sense given the naturally acquired immunity they can gain is far more safe than taking a vaccine that has no safety data. It should be stated emphatically that vaccines are only to be used in those who require vaccination based on sound biomedical principles as opposed to the mass vaccination that is currently taking place.

In closing, we conclude that persons with prior infection are not candidates for vaccine. Immunity caused by natural exposure remains the most robust and durable and successful manner to protect the population. Vaccines have a role in arriving at population-level herd immunity but most importantly when delivered in a targeted manner, along with natural exposure, but vaccines as they exist and are being delivered today are posing a potentially serious problem as briefly described above. We also reiterate, children are not to be vaccinated with these vaccines given their very low risks and the lack of safety data. However, the latter is not of concern given that we must never administer a drug, a medical device, or a vaccine if it is shown to be safe yet confers no benefit. These vaccines will confer no benefit for children. Are we missing something here? We seek common sense, and an optional, risk-based approach to vaccination based on Covid-19 susceptibility, and the risks and benefits of the product(s). We implore health care providers to explain the benefits and risks to their patients, *in full*, so that they can be fully informed in their decision-making. This can only happen if there is: 1) immediate suspension of coercive tactics, 2) physician supervision and orders for vaccination, 3) public information presented with fair balance as it would with any pharmaceutical or device product.

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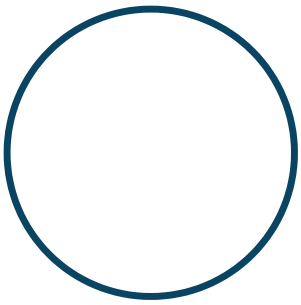

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